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Borbála Tünde Dömötörfy:

Competition Law in the Pharma Sector:

Pay-for-delay settlements in the EU and in the US

PhD Thesis

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I. Introduction

The title of this thesis refers to the competition law analysis of pay-for-delay patent settlements. Pay-for-delay, or reverse payment settlements are a unique type of patent settlements, they seem to be special features of the pharmaceutical sector exclusively, as result of its unique characteristics.[1]

In the pharmaceutical sector, the supply side of the market is dominated by two types of companies: originators and generics. The originators are the R&D based companies that carry out research and develop pharmaceuticals from the laboratory up to the stage of marketing authorisation. Generics produce and sell pharmaceutical products which are bioequivalents of an originators' product after the originators' patents expire. Generic products contain the same active pharmaceutical ingredients (APIs) as branded medicines and can therefore be used for the same treatments.

Due to the very research-intensive and innovative nature of the sector, the special market structure, and the low marginal costs of production, the originators rely highly on patent protection, much more than any other high-tech sectors[2]. Intellectual property (IP) rights are therefore the real core assets in the sector.

Pay-for-delay, or reverse payment settlements raised antitrust scrutiny in the pharmaceutical sector first in the United States (US), and later also in the European Union (EU). While the US competition authorities, the Federal Trade Commission (FTC) and the Department of Justice (DoJ) have already had more than a decade experience in handling pay–for-delay settlements, the European Commission first identified such settlements as a problem in 2009. The European Commission started to monitor the settlements in the pharmaceutical sector in the framework of the Pharmaceutical Sector Inquiry.[3] Since then, the Commission has kept monitoring the sector and kept publishing its Monitoring Reports every year.

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[1] Herbert Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 14., C. Scott Hemphill: Collusive and Exclusive Settlements of Intellectual Property Litigation. Columbia Law School Working Paper No. 384. November 30, 2010. pp. 684-709. However, the opinion of the dissenting judges in Actavis differ in that point. (Roberts, C. J., dissenting 570 U. S.(2013) Ftc *v.* Actavis, Inc. Supreme Court of the United States No. 12-416 Chief Justice Roberts – Justice Scalia – Justice Thomas)

[2] Henry Grabowski, 'Patents, innovation and access to new pharmaceuticals' (2002) 5 Journal of International Economic Law 849, p 850.

[3] Sector inquiries generally are investigations carried out by the European Commission (or by national competition authorities) into sectors of the economy and into types of agreements across various sectors, when the Commission

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The US courts developed rich case law relating to reverse payment settlements, however, the "evolution" process has not always followed a straight line. Different courts applied diverse, sometimes even contradictory tests – from the per se illegality through the "scope of the patent test" to the rule of reason analysis.

In 2013, the Supreme Court set the standard to be followed by other courts in the Actavis case. In this cornerstone judgement, the Supreme Court ruled that pay-for-delay settlements are subject to rule of reason analysis, but this judgement did not mean the end of the dispute, even after Actavis, several questions are left open.

This debate goes deeper than the simple question of (il)legality of reverse payment settlements, and the classic intellectual property and competition law intersection serves as its basis.

The advocates of patent settlements emphasize the necessity of the strong protection of intellectual property rights: IP rights play an important role in encouraging innovation by ensuring a fair return on investment. Additionally, they also argue that peaceful settlements are more desirable than long and expensive litigations. On the other hand, antitrust/competition law enforcers express their concerns about the loss of short- and long-term consumer welfare, highlighting the anticompetitive nature of these settlements. They also recall the role of effective competition in enhancing innovation.

Pay-for-delay settlements require a careful analysis of not only competition law and IP law, but also the sector specific regulation of the pharmaceutical sector. In the US, reverse payment settlements are often called "Hatch-Waxman settlements", which is a reference to the Drug Price Competition and Patent Term Restoration Act, informally known as Hatch Waxman Act. Hatch-Waxman Act is a federal law from 1984 which had as its main goal encouraging generic competition. On the other hand, pay-for-delay settlements are not unique features of the US market, but they were identified in the EU as a common type of anti-competitive agreements by the Pharmaceutical Sector Inquiry, while it is not subject to any dispute that the EU has no similar regulation to the Hatch-Waxman Act. In order to address this discrepancy, and to answer the research questions, the thesis discusses in details the European and American relevant case law. Introducing the backgrounds of the main cases does not only help to address the regulation

(or the national competition authority) believes that a market is not working as well as it should, and breaches of the competition rules might contribute to this malfunctioning. For further details see the website of the Commission's Pharmaceutical Sector Inquiry. (Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/ Downloaded: 23 October 2018)

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related discrepancies, but also has relevance for the evaluation whether the EU cases and the US Actavis judgment indeed followed so different paths, or we are trying to compare an apple with a pear. Discussion of the relevant case law therefore has relevance for three research questions out of four. It should neither be forgotten that the assessment of pay-for-delay settlements has not always evolved in a straight line in the US. Reviewing the development process of the US case law helps to put into context the Supreme Courts Actavis judgment, and to highlight the center of these debates as essential part of the competition-IP intersection. After the European Commission's Lundbeck, Servier and Fentanyl, and Cephalon/Teva decisions the EU and US seem to follow different paths. The General Court and the ECJ until now confirmed the Commission's point of view. So, while in the US the Supreme Court in Actavis found that rule of reason analysis is necessary to rule on the legality of pay-for-delay settlement agreements, the European Commission and the European courts, the General Court and the European Court of Justice (ECJ) took the view that pay-for-delay settlements are anticompetitive by object. However, more careful analysis of this seemingly contradictory approach is necessary.

This thesis discusses European and American reverse payment patent settlements in three main parts: first, the regulatory questions are addressed, second, the US approaches and case law, third, the EU developments and case law. The three following chapters discusses the main research questions, and finally the conclusion summarizes the findings.

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I.1. Research Questions

The thesis seeks to answer the following research questions.

Q1) To what extent are pay-for-delay settlements the consequences of the sectoral regulation? In the US, reverse payment settlements are often called “Hatch-Waxman settlements” i.e. the Hatch-Waxman Act is ‘blamed’ as main cause of the pay-for-delay settlements. In the EU, the regulatory background is different, while pay-for-delay settlements were still identified as common types of agreements of the European pharmaceutical sector by the Pharmaceutical Sector Inquiry. It should also be examined whether there are important differences between the types of EU and US settlements.

Q2) Should competition law play a role in overcoming the discrepancies of patent laws? Recent EU and US developments suggest that antitrust/competition law should correct the shortcomings and problems of the patent systems and of the sectoral regulations in the pharmaceutical industry. This approach is based on the ECJ's AstraZeneca judgment, the statements of the monitoring reports, and the relevant US case law, especially the judgements which applied the "scope of the patent test". This approach suggests that competition law shall intervene if the patent – or marketing authorization – is the result of sham litigation or fraud on the relevant authority.

Q3) Is there room for two different legal standards analysing the legality of pay-for-delay agreements? The third research question seeks to compare the current US and EU approaches about the applicable standards. Understanding the exact meaning of the EU concepts “restriction by object or effect” and the similar US terms of “rule of reason and per se” infringements is crucial for this analysis.

Q4) What sort of pay for delay agreements are lawful? Both the US and the EU approaches agree that not all value transfers are illegal between the originator and the generic, even in the context of patent settlements. Generally, payments up to the amount of the (expectable) litigation costs are accepted in both jurisdictions. "[P]ayment for real service" is also accepted in both the EU and the US. But what is considered as genuine service and what price can be demanded accordingly? When is a reverse payment excessive and thus unjustified?

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II. Regulatory background – an overview

The right to health is a fundamental right of every human being according to the Preamble of the World Health Organization's Constitution[4]. Public health considerations are in the forefront of all modern states' public policy, and the pharmaceutical industry has a key importance in such public health considerations. As it is expressed by the first sentence of the Commission's Pharmaceutical Sector Inquiry: "[t]he pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines."[5] Additionally, in developed countries – like the EU Member States – prescription only medicines are generally– at least partially – supported by the social security, i.e. such social security costs increase the public expenses. Consequently, the aim of keeping public expenses at the lowest necessary level gives a key importance to the requirement for "affordable" medicines.

The pharmaceutical sector is traditionally subject to strict and rigorous regulation.

Given the highly research-intensive nature, and special characteristics of the manufacturing of medicines, intellectual property laws – especially patent laws – have also key significance in the sector. Not only IP laws, but also the procedural rules of IP, and especially patent enforcement are very important: the conditions of how patent rights are granted, opposed, and litigated can influence the outcome of a patent related dispute in a large extent.

The co-existence of patent laws and sectoral regulations, and the specialities of the industry gave birth to some "sector specific patent rules" in the pharmaceutical sector. These special rights generally provide additional protection to pharmaceutical products, when the originator cannot recover its R&D costs entirely due to a shorter patent protection period. The original protection period might be reduced in case of an innovative medicine as an effect of the requirement for marketing authorization. Supplementary protection certificate, (hereinafter also referred to as: SPC), provides additional protection in such cases. Figure 1.1 below provides a visual representation of the SPC system for the better understanding:

[4] "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition. The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States*" Preamble, 1. p. para 1, subparagraph 2-3.

[5] Final Report – Pharmaceutical Sector Inquiry Final (Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf , downloaded: 23 October 2018) p. 10. (1)

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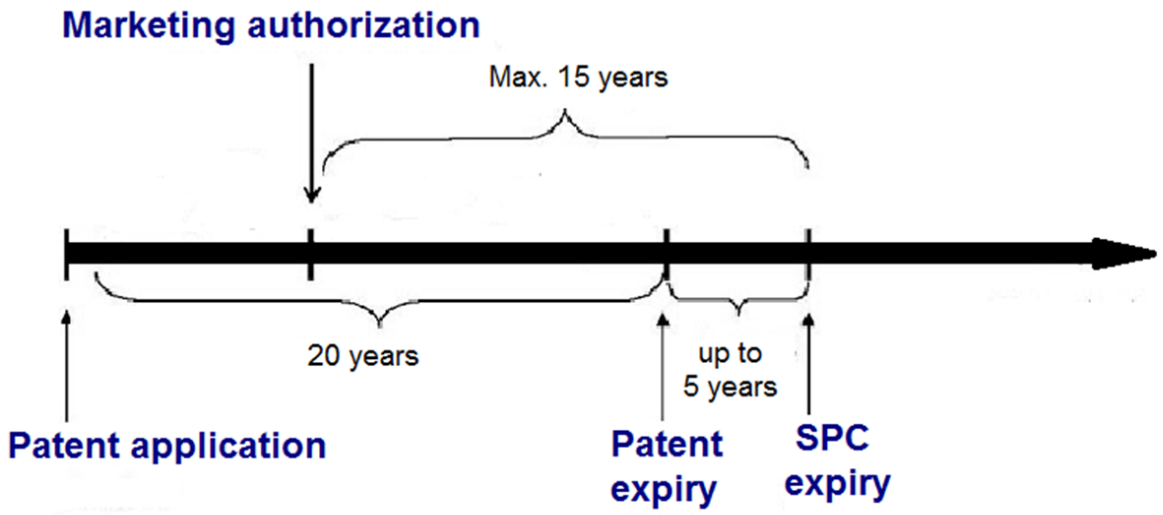

Another example of the sector specific patent rights is the half year additional protection for peadiatric experiments.[6]

The final relevant group of the applicable rules – and especially important for our research – is competition/antitrust law.

Before the detailed discussion of the regulatory background, I will provide a short insight into the structure of the pharmaceutical market.

II.1. Pharmaceutical market's structure

A viable European pharmaceutical industry is important for Europe's public health, economic growth, trade and science. The economic significance of the European pharmaceutical industry is shown by the following facts and figures: "the EU pharmaceutical sector produced an output of € 220 billion and employed approximately 800,000 people in 2012. It accounts for around 1.8% of the total manufacturing workforce and is one of the industries with the highest labour productivity. It is a major source of growth and economic performance as reflected by its average annual growth rate. The production index increase amounts to 2.5% (between 2006-2011) and the growth in labour productivity per person employed is 3.6% over the same period. The European pharmaceutical industry serves as a major contributor to the EU's trading power. The EU was the world's major trader in medicinal and pharmaceutical products

[6] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

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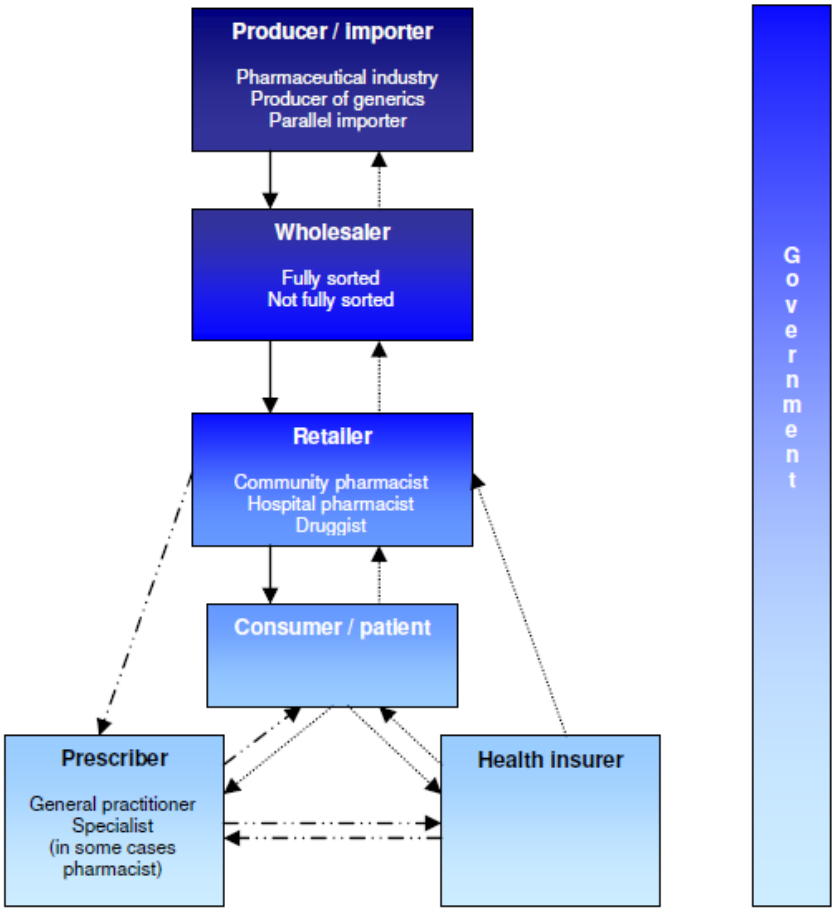
in 2013, with total trade amounting to € 156.9 billion (EU28) and the value of exports reaching more than € 107.4 billion".[7]

This strategic and economically viable market is a complex market characterized by a great variety of stakeholders, a significant involvement of the government and a high degree of regulation aimed at achieving diverse objectives.[8]

The complexity of the market is presented visually by Figure 1.2 below: The producer/importer level of Figure 1.2 – which is the most relevant for this research – consists of three different type of market players: originators, or with other words innovative companies, generic producers, and in the EU, parallel importers. Parallel importers are very special market players of this sector, enjoying an extraordinary situation in the EU: while parallel import is prohibited in almost the whole word[9], in the EU it is not only permitted



Source: Philipsen (2003).

[7] Pharmaceutical Industry: A strategic sector for the European economy. Commission Staff Working Document, SWD(2014) 216 final/2. p. 2.

[8] Ecorys: Competitiveness of the EU Market for Pharmaceuticals. Volume II. Markets, Innovation, Regulation. December 2009. Available at: http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_2_markets_innovation_regulation_en.pdf p. 11.

[9] Margaret K. Kyle: Parallel Trade in Pharmaceuticals: Firm Responses and Competition Policy. International Antitrust Law & Policy: Fordham Competition Law 2009, (edited by Barry HAWK) 339–358. Juris Publishing, New York, 2009. p. 341.

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but also encouraged, as a part of the move to a single market for pharmaceuticals.[10] Parallel importers do not produce medicines, they simply buy pharmaceuticals in one country, and – after repackaging – they distribute them in another country. Their existence is a result of geographical price discrimination[11] which stimulates arbitrage. So, parallel importers do not produce drugs, but they put additional competitive pressure on the producers. They are also suppliers selling drugs to the wholesalers, who will re-sell to retailers. The final consumers – the patients –buy these medicines through retailers, mostly pharmacist or hospitals in the case of prescription only drugs. In some EU Member States, general practitioners in remote areas are also allowed to dispense drugs, and in some Member States, druggists might sell some over-the-counter (OTC) drugs, too.[12]

Patients – in the case of prescription only drugs – are not free to choose their treatment, they are dependent on the decision of the prescriber/medical doctor. The financial consequences of the choice have limited effects on the end-users, due to the existence of the (obligatory) health insurance.

The pharmaceutical industry is characterized by i) information asymmetry, ii) availability of substitutes (and elasticity of demand), iii) special purchase methods and iv) autonomous market growth.[13] From the point of view of this research, information asymmetry and elasticity of demand have the most significant role.

Information asymmetry between consumers and pharmacists leads to the requirement of prescription of the drug by a specialist; the therapy cannot be chosen by the patient.[14] The consumer also lacks the required expertise to identify substitutes, there are few or no substitutes in his eyes for the prescribed medicine. In case of a long-term treatment, when the patient takes a certain medicine several years long, both the prescriber and the patient might find a change risky, even if the same active ingredient (INN) is available for a lower price due to patent

[10] Margaret K. Kyle: Strategic Responses to Parallel Trade. p.2.

[11] Dömötörfy Borbála Tünde: Árdiszkrimináció és párhuzamos kereskedelem a gyógyszeriparban: innovatív iparágak versenyjogi megítélése. Versenytükör, 2012/2. p. 9-17. p. 11-13.

[12] Ecorys: Study of regulatory restrictions in the field of pharmacies. 22 July 2007. SKH/AR13902finep1. Available at: http://ec.europa.eu/internal_market/services/docs/pharmacy/report_en.pdf p 12.

[13] Idem. p. 29-31.

[14] Idem. p. 29.

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expiry.[15] In addition, most of the costs are (re)covered by the health insurance. So, the demand is less price sensitive. An OECD study highlights that "where consumers are insured against the price of pharmaceuticals, they have no incentive to "buy the cheapest one"'.[16]

An Ecorys survey highlights that "[t]he demand side of the pharmaceutical sector is characterised by a complex interrelationship between patients, doctors, hospitals, insurance providers and reimbursement systems. For prescription medicines, the ultimate consumer (i.e. the patient) systematically differs from the decision maker (generally the prescribing doctor) and very often also from the bearer of the costs (generally the insurance companies or the health system)."[17] As a consequence of the substitution- and price elasticity characteristics, using the cheapest alternative medicine is not the interest of neither the ultimate consumer, nor the prescriber, while there is a very important public interest in lowering unnecessary public expenses. The following table shows the ratio of public expenses spent on different healthcare functions by the European – and some other – countries:

[15] Once confirmed as a successful treatment for a patient in an initial trial period, the patient typically takes the drug over many years and is unlikely to switch to an alternative, even when the purported alternative becomes available at significantly lower prices. (Case AT.39612 – Perindopril (Servier) para 91.)

[16] DAFFE/CLP(2000)29 – OECD: Competition and regulation issues in the pharmaceutical industry. February 2001. p.10. See also Servier para 91.

[17] Ecorys: Competitiveness of the EU Market for Pharmaceuticals. p. 12.

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	Services of curative and rehabilitative care	Services of long-term nursing care	Ancillary services to healthcare	Medical goods dispensed to outpatients	Prevention and public health services	Health administration and health insurance	Not specified by kind
Belgium	49.0	22.4	3.8	18.8	1.1	4.9	:
Bulgaria (')	48.9	0.1	3.2	41.4	3.8	2.0	0.6
Czech Republic	60.1	3.9	5.7	24.5	2.1	3.0	0.6
Denmark	*57.3*	*24.0*	*4.1*	*10.1*	*2.3*	*2.2*	:
Germany	54.5	12.6	4.8	19.4	3.3	5.4	:
Estonia	54.9	4.4	11.1	24.3	3.4	2.0	0.0
Ireland	:	:	:	:	:	:	:
Greece	64.4	0.7	4.5	27.2	1.2	2.0	0.1
Spain	58.9	10.9	5.4	19.6	2.1	3.2	0.0
France	54.6	11.4	5.1	20.8	2.0	6.1	:
Croatia	53.7	0.7	8.5	31.1	2.3	2.7	0.9
Italy	:	:	:	:	:	:	:
Cyprus	*64.8*	*2.8*	*10.7*	*18.9*	*1.3*	*1.3*	*0.3*
Latvia (²)	52.3	6.0	6.4	29.7	2.4	3.3	:
Lithuania	52.4	7.7	5.0	31.8	1.2	2.0	:
Luxembourg	56.5	22.5	5.8	11.6	1.9	1.7	0.1
Hungary	50.4	3.8	5.2	35.4	3.4	1.7	0.2
Malta	:	:	:	:	:	:	:
Netherlands	51.0	25.1	2.0	13.3	3.6	3.9	1.1
Austria	60.2	14.5	3.2	16.5	1.8	3.8	:
Poland	60.1	7.0	5.1	24.6	2.0	1.2	:
Portugal (')	*62.6*	*1.7*	*8.8*	*23.0*	*2.1*	*1.8*	:
Romania	46.2	11.5	3.9	29.9	6.8	1.7	0.2
Slovenia (')	56.5	8.9	3.4	23.8	4.0	3.5	:
Slovakia (')	46.9	0.3	8.5	38.0	2.8	3.5	0.0
Finland	62.4	9.4	3.6	16.7	6.2	1.7	:
Sweden	66.6	7.6	4.4	15.2	3.9	1.6	0.7
United Kingdom	:	:	:	:	:	:	:
Iceland	*59.3*	*18.6*	*1.7*	*17.0*	*1.3*	*2.2*	:
Norway	*50.1*	*28.9*	*7.2*	*10.6*	*2.5*	*0.6*	*0.0*
Switzerland	*58.9*	*20.1*	*3.4*	*11.0*	*2.1*	*4.4*	:
Australia (')	70.1	1.2	6.0	18.6	2.0	2.1	:
Canada (')	48.2	14.9	6.5	20.3	6.1	3.4	0.7
Japan (')	63.7	9.1	0.7	22.0	2.9	1.6	0.0
New Zealand (')	59.2	14.5	5.2	10.7	6.4	4.0	0.0
South Korea	56.0	12.7	1.0	22.5	3.1	4.8	:
United States	70.1	5.8	:	13.6	3.1	7.5	:

(') 2011.
(²) 2010.
Source: Eurostat (online data code: hlth_sha_hc)

Source: Eurostat[18]

In Hungary, 35,4% of the healthcare expenditure is spent on medical goods dispensed to outpatients, which is one of the highest ratio between the examined states. So, the market is very complex and the sector is highly R&D intensive.[19]

The two main types of producers are the originator companies and generic companies. Originator companies are involved in research, develop new pharmaceuticals from the laboratory to marketing authorisation and sell them on the market.[20]. Originators are the highest investors in R&D worldwide, and the second highest in the EU.[21] Their main activity is researching and inventing new treatments for medical needs, and bringing new medicines to

[18] Eurostat. (Available at: http://ec.europa.eu/eurostat/statistics-explained/images/9/9f/Healthcare_expenditure_by_function%2C_2012_%28%25_of_current_health_expenditure%29_YB15.png Downloaded: 30 November 2018)

[19] C. Matraves: Market Structure, R&D and Advertising in the Pharmaceutical Industry. *Discussion Paper FS IV 98 - 17*, Wissenschaftszentrum Berlin, 1998. p. 5.

[20] Ecorys: Competitiveness of the EU Market for Pharmaceuticals. p. 12.

[21] The 2013 EU Industrial R&D Investment Scoreboard. http://iri.jrc.ec.europa.eu/scoreboard13.html downloaded on 19 August 2014. p. 41-42.

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the market.[22] Most of the originator companies are big, multinational firms with worldwide presence, but there are also numerous SMEs in this segment. SMEs are mostly specialized in innovation in a well-defined and narrow area, or they are biopharmaceutical companies.[23] Biopharmaceutical companies are revolutionary creatures of the market, their presence seems to transform the structure of the industry. As an effect of their "revolution", new drugs increasingly originate from small firms. Their business model is based on out-licensing their innovative products to more experienced – and financially stronger – firms for later-stage drug development, regulatory review, and commercialization.[24]

Originator companies invest a large amount in R&D, and only a very low percentage of the experiments will result in a patented drug. New drugs are extremely expensive to develop, while the success rate of the experiments is very low. R&D costs can reach several hundred million USD[25], according to certain researches even 2,6 billion USD.[26] These estimates cover the price of failed experiments. Actually, big part of the costs is given by unsuccessful attempts: typically, less than 1 per cent of the molecules discovered in pre-clinical tests enter the clinical trial stage, and only 16 per cent of these molecules survive the process of human clinical trials and gain drug approval.[27]

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[22] European Commission: Final Report – Pharmaceutical Sector Inquiry. Staff Working Document. 8th July 2009 p. 23. (53)

[23] Pharmaceutical Sector Inquiry p. 23. (54)-(56)

[24] P. M. Danzon: Economics of the Pharmaceutical Industry. NBER Reporter Fall 2006. http://www.nber.org/reporter/fall06/danzon.html downloaded on 19 August 2014.

[25] Joseph A DiMasi, Roland W Hansen and Henry G Grabowski: The price of innovation: new estimates of drug development costs. Journal of Health Economics 22 (2003) p 151, see also Christopher P Adams and V. van Brantner, 'Estimating The Cost Of New Drug Development: Is It Really $802 Million?' Health Affairs Volume 25 Number 2 Available at: https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.2.420 p 420;

[26] Thomas Sullivan: A Tough Road: Cost To Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%. Available at: https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html) Downloaded: 23 October 2018 This new research indicates a sharp increase in the figures: in 2014, Gallash reported the highest estimate for a single drug was 1.8 billion USD. (See: Sven Gallash: The Anticompetitive Misuse of Intellectual Property Rights in the European Pharmaceutical Sector. PhD thesis. Available: https://ueaeprints.uea.ac.uk/50554/1/Sven_Gallasch_-_4170733_-_PhD_Thesis_-_The_anticompetitive_misuse_of_intellectual_property_rights_in_the_European_pharma~1.pdf p. 2, see also: : Steven M Paul .–Daniel S. Mytelka–Christopher T. Dunwiddie–Charles C. Persinger–Bernard H. Munos–Stacy R. Lindborg–Aaron L. Schacht: How to improve R&D productivity: the pharmaceutical industry's grand challenge. Nature Reviews Drug Discovery 9, 2010, pp 203-2014, p. 205

[27] Sven Gallash: The Anticompetitive Misuse of Intellectual Property Rights in the European Pharmaceutical Sector. See also: Steven M Paul .–Daniel S. Mytelka–Christopher T. Dunwiddie–Charles C. Persinger–Bernard H.

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Such companies often gain a very large ratio – up to 55% – of their total turnover from only one drug, called the "blockbuster".[28] Consequently, originator companies highly need and deserve the protection of intellectual property rights – especially patents –to recover their investments.

Generic companies in the European market tend to be significantly smaller than originator companies. Many of them are SMEs, producing medicines for their local market.[29] Generics develop bioequivalent – identical medicine – to a branded product, and enter the market after the expiry of the originator's patent[30]. Occasionally they enter the market earlier, e.g. when the generic believes that the originator's patent is invalid, or they have found a way not to infringe the patent.[31] Generic companies typically focus on the product which generates the highest revenue,[32] i.e., the 'blockbusters'. Generic entry significantly decreases the drug prices, so the early entry of the generics also serves the public interest, especially in countries where drugs are generously financed from public budget through the social security.

II.2. Sector specific regulation

In the EU, most stakeholders – including generic companies – stigmatised the shortcomings of the regulatory framework as a key factor leading to generic delay.[33] The situation is quite the same in the US, where pharmaceutical patent settlements are (almost) unanimously regarded as consequences of the regulatory framework, especially of the Hatch-Waxman Act.[34]

Munos–Stacy R. Lindborg–Aaron L. Schacht: How to improve R&D productivity: the pharmaceutical industry's grand challenge. Nature Reviews Drug Discovery 9, 2010, pp 203-2014, p. 205

[28] Final Report – Pharmaceutical Sector Inquiry 27. (67)

[29] Idem. p. 35 (88)

[30] Ecorys: Competitiveness of the EU Market for Pharmaceuticals. p. 12.

[31] It is typically the case, when the originator's patent on the INN expired, but it still holds one or more process patent, or formulation patent. After the INN patent expiry, originators are used to hold a bundle of so called "secondary patents" to prolong the patent protection – and earn monopoly profit – as long as possible.

[32] Final Report – Pharmaceutical Sector Inquiry p. 35 (89)

[33] Nicolas Petit: The outcome of the EC pharmaceutical sector inquiry – „Barka at the Moon*". Concurrences.* N. 3-2009. p. 11.

[34] Will be discussed later.

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The pharmaceutical sector is subject to strict regulation both in the EU and in the US [35], responding to health and other consumer law concerns. The path towards these strict regulations was catalysed by unfortunate events: in 1937 over 100 people died in the US as an effect of diethylene glycol poisoning following the use of a sulfanilamide elixir, which used the chemical as a solvent without any safety testing. In the US, this facilitated introduction of The Federal Food, Drug and Cosmetic Act with the premarket notification requirement for new drugs in 1938. The second catastrophe which influenced the development of pharmaceutical regulations worldwide more than anything else in history was the thalidomide disaster. Thalidomide was a sedative, introduced in 46 different countries worldwide between 1958 and 1960. [36] Thalidomide was very effective as a sedative and quickly discovered to also be an effective anti-emetic and it started to be used to treat morning sickness in pregnant women. [37] Thalidomide was believed to be safe for the babies without previous testing. As an effect, the estimated number of babies born with phocomelia and other deformities was over 10.000 worldwide.[38]

In the wake of the Thalidomide disaster, and European countries passed provisions in order to reshape the regulatory system[39] and granting the efficacy and quality of the medicines. For example in the UK, the Committee on Safety of Drugs was set up in 1963. Interesting to note that thalidomide has never been authorized in Hungary.[40] The first EEC directive came into

[35] See G. Wibaux: Un point de vue francais. *Concurrences* N. 3-2009. p.22. see also C. S. Hemphill: Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem. Columbia Law School 81. *New York University Law Review* 1553 (2006) Columbia Law and Economics Working Paper No. 306 pp. 101-167.

[36] Lembit Rägo – Budiono Santoso: Drug Regulation: History, Present and Future. Drug Regulation: History, Present and Future. In: VAN BOXTEL CJ, SANTOSO B, EDWARDS IR eds., *Drug Benefits and Risks: International Textbook of Clinical Pharmacology*, Revised 2nd Ed. (Chapter 6). IOS Press and Uppsala Monitoring Centre, 2008, pp.65

[37] Neil Vargesson: Thalidomide-induced teratogenesis: History and mechanisms. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4737249/ Downloaded : 24 January 2020.

[38] Lembit Rägo – Budiono Santoso: Drug Regulation: History, Present and Future. p.66

[39] Thalidomide has never been marketed in the US, since its Food and Drug Administration (FDA) refused to grant authorization because of inadequate evidence – despite the constant pressure from the company of this that time blockbuster. The officer who refused the approval, dr. Kelsey received several honours and awards for saving perhaps thousands from death or life-long incapacitation (Available: https://www.fda.gov/about-fda/virtual-exhibits-fda-history/frances-oldham-kelsey-medical-reviewer-famous-averting-public-health-tragedy Downloaded: 24 January 2020)

[40] MedicalOnline: Megfejtették a Contergan hatásának okát. Available: http://medicalonline.hu/tudomany/cikk/megfejtettek_a_contergan_hatasanak_okat Downloaded: 26 November 2020

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force in 1965 on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products. Primary purpose was to grant the safeguard of the public concerning distribution and marketing of the medicines and removing and eliminating differences among national legislations. Since then, the harmonization of pharmaceutical regulation continued. The WHO supports harmonization on national, regional, inter-regional and international levels, as it is believed that international consensus on quality, safety and efficacy standards can accelerate the introduction of new medicines and increase availability of generic medicines through fair competition, thereby lowering prices.[41]

The government also plays a significant role in the sector through the financing and reimbursement system. The industry's regulation pursues different objectives, which might vary significantly from country to country, general examples might be supporting innovation, ensuring a high degree of public health, and keeping public expenditure under control.[42]

The Pharmaceutical Sector Inquiry found that there are several differences between patent settlement practices in the EU and the US. These differences were alleged to be essentially consequences of the differences of the regulatory environments.[43]

II.2.1. Sectoral regulation in the EU

According to Article 168 of the TFEU, competence in public health matters is shared between the Union and the Member States. The Union's role in this strategic area is "complementary"[44], Article 168 provides that "Union action, […] shall complement national policies" which means that most part of the regulatory actions stay at Member States' level. Consequently, there are large differences between the Member States' regulations.

The pharmaceutical industry has a key importance for the European economy, it "is a major employer and it combines a large production value with high levels of innovation". Its political significance is also relevant. Consequently, three overlapping and sometimes competing

[41] Lembit Rägo – Budiono Santoso: Drug Regulation: History, Present and Future. p.66

[42] Final Report – Pharmaceutical Sector Inquiry. p. 19. (39)

[43] Idem. p. 286 (780)

[44] Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, p. 47–390 (TFEU) 168 (1)

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regulatory tasks might be identified: i) public health policy objectives, ii) healthcare policy objectives, including public expenditure, and iii) industrial policy objectives.[45]

The first two categories might seem somewhat overlapping. The wording to differentiate public health policy from health care policy is not a generally accepted consensus, but the referred study[46] follows this system. For the purposes of this research, differentiate public health policy from health care policy is fruitful, because it highlights the different objectives behind the regulation. Generally, both public health policy and health care policy are subsets of the broader category, health policy. Health policy is defined by WHO as a policy which refers to "decisions, plans, and actions that are undertaken to achieve specific health care goals within a society. An explicit health policy can achieve several things: it defines a vision for the future which in turn helps to establish targets and points of reference for the short and medium term. It outlines priorities and the expected roles of different groups; and it builds consensus and informs people."[47]

In this context, both public health policy and health care policy serves the goals of health policy; while health policy focuses rather on the fundamental right aspects, health care policy regulates the finances, marketing and prescription rules, etc., i.e. provides the detailed framework which is necessary to ensure that the healthcare system operates in a safe and secure manner.

The policy objectives of public health policy, industrial policy and healthcare policy are summarized by the following table.

[45] Ecorys: Competitiveness of the EU Market for Pharmaceuticals. p. 22.

[46] Idem. p. 22.

[47] https://www.who.int/topics/health_policy/en/ (Downloaded: 24 October 2018)

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Health care policy	Industrial policy	Public health policy
Cost containment and improving efficiency in health services and care	Promoting local research and development capacity	Innovative cures
Generic promotion and/or substitution	Generating and Protecting employment	Patient access to medicines
Regulating doctor and consumer behaviour vis-à-vis medicines	Supporting local scientific community	Efficacious treatments
Ensuring access to medicines	Intellectual property rights protection	High-quality preparations
Cost-effective medication	Promoting small and medium enterprise policies	Safe medicines
Improving prescribing	Contributing to positive trade balance	
	Sustaining the University research base	

Source: Ecorys[48]

The existence of these diverging, sometimes conflicting goals means that sectoral regulators have to make important policy choices which will have an impact on the competition between originators and generic producers. Also the Pharmaceutical Sector Inquiry recognized that "numerous regulatory features play an important role"[49] in how generic entry takes place.

National regulations may facilitate generic entry, if they follow some standards: (I) INN prescription[50] by doctors and mandatory generic substitution by pharmacists, (II) permitting relatively free pricing of medicines, (III) not imposing mandatory discounts or price gaps on generic products, (IV) keeping in mind that marketing authorization bottlenecks may lead to delayed entry, (V) national pricing and reimbursement systems should consider to grant automatic/immediate pricing and reimbursement status to generic products.[51] In the EU, significant differences were identified between Member States.

[48] Ecorys: Competitiveness of the EU Market for Pharmaceuticals. p. 22

[49] Final Report – Pharmaceutical Sector Inquiry. p. 190

[50] Active ingredient name prescription against of brand name prescription.

[51] James Killick – Anthony Dawes: The Elephant Uncovered. Concurrences N. 3-2009. p. 20

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From the point of view of this research, the marketing authorization process has an exceptionally high importance. This procedure – if not adequate – might delay generic entry either by hampering generic entry (e.g. a complicated, costly procedure, which does not provide enough incentives) or by facilitating 'evergreening' strategies of originator companies.[52] Furthermore, sectoral regulation might cause the same kind of discrepancies like patent system, if its level of harmonization is inadequate.

The European Commission's Pharmaceutical Sector Inquiry did not provide an in-depth analysis of the Union's regulatory framework and the rules on the authorization of generic medicines, but it reports that a new framework of marketing authorization was adopted in 2004.[53]

After the review of the marketing authorization framework[54] we can conclude that the European system offers three main routes for the authorisation of medicinal products:

- Centralised procedure[55] (CP) allows applicants to obtain a marketing authorisation that is valid throughout the EU. CP is compulsory for products derived from biotechnology, for orphan medicinal products and for medicinal products for human use which contain an active substance authorised in the Community after 20 May 2004,[56] and which are intended for the treatment of AIDS, cancer, neurodegenerative disorders or diabetes, etc. It is optional for any other products containing new active substances not authorised in the Community before 20 May 2004 or for products which constitute a significant therapeutic, scientific or technical innovation or for which a Union authorisation is in the interests of patients or animal health at EU level.[57] Applications for the centralised procedure are submitted directly to the European Medicines Agency (EMA) and lead to the granting of a European marketing authorisation by the Commission which is binding

[52] See Case C-457/10 P - AstraZeneca/Commisson. ECLI:EU:C:2012:770

[53] Final Report – Pharma Sector Inquiry para 1362

[54] Original package was adopted in January 1995

[55] Laid down by the Regulation (EC) No 726/2004

[56] The date of entry into force of Regulation (EC) No 726/2004

[57] Authorisation procedures - The centralised procedure: http://ec.europa.eu/health/authorisation-procedures-centralised_en.htm

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and valid in all Member States.[58] Products authorized through the CP may be marketed in all Member States after the marketing authorization is granted by EMA.

- The mutual recognition procedure (MRP) is applicable for the majority of conventional medicinal products. MRP is based on the principle of recognition of an already existing national marketing authorisation by one or more Member States.[59] To be eligible for MRP, a medicinal product must have already received a marketing authorisation in one Member State. Any national marketing authorisation granted by an EU Member State's national authority can be used to support an application for its mutual recognition by other Member States.[60]

- The decentralized procedure (DCP)[61] is also applicable for majority of conventional medicinal products. Through DCP an application for the marketing authorisation of a medicinal product is submitted simultaneously in several Member States, one of them being chosen as the "Reference Member State". At the end of the procedure, national marketing authorisations are granted in the reference and in the other concerned Member States.[62] . As the MRP, DCP is also based on the recognition by national authorities of a first assessment performed by one Member State. The difference lies in that it applies to medicinal products which have not received a marketing authorisation at the time of application.[63]

Additionally, purely national authorisations are still available for medicinal products to be marketed in one or some Member State only. Special rules exist for the authorisation of medicinal products for paediatric use, orphan drugs, traditional herbal medicinal products, vaccines and clinical trials.[64]

[58] http://ec.europa.eu/health/authorisation-procedures_en.htm

[59] http://ec.europa.eu/health/authorisation-procedures_en.htm Basic arrangements for implementing the mutual recognition procedure are laid down in Directive 2001/83/EC

[60] http://ec.europa.eu/health/authorisation-procedures-mutual-recognition_en.htm

[61] Introduced by Directive 2004/27/EC

[62] http://ec.europa.eu/health/authorisation-procedures_en.htm

[63] http://ec.europa.eu/health/authorisation-procedures-decentralised_en.htm

[64] http://ec.europa.eu/health/authorisation-procedures_en.htm

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Most stakeholders welcomed the current regulatory framework on marketing authorisations, stating that it provides a fair balance of interests[65], but individual companies, associations and other organisations have also identified delays in the assessment process due to shortcomings and backlogs in national approval systems,[66] or discrepancies in the national implementation of the EU regulatory framework[67]. Generic companies also raised concerns about the possibilities of originator companies to intervene in regulatory proceedings before marketing authorisation bodies and reported about diverging approaches to the disclosure of confidential information taken by different national authorities.[68]

Market players also call for further international harmonisation in the area of marketing authorisation, mostly between the EU and the US to reduce unnecessary regulatory divergences.[69] One generic company even recommended a more radical change in the current system, suggesting the introduction of a period of exclusivity for the first generic product entering the market prior to patent expiry, similar to the US Hatch-Waxman Act.[70] According to this company, establishing such exclusivity period could promote generic competition. It could also put pressure on originator companies to deliver more new medicines. Finally, patients and taxpayers would obtain lower prices on medicines due to earlier generic entry and more competition.[71]

The Pharmaceutical Sector Inquiry reported that the "[i]ndustry recognised that the existence of three different procedures, CP, DCP and MRP, and the 27 national agencies and the European medicine agency, provide a certain number of possibilities for marketing authorisation in comparison with the approach used in the USA. Nevertheless, some companies considered that the EU regulatory system was creating more complexity than necessary."[72]

From the point of view of generic-originator competition, another important issue is the pricing and reimbursement system. While pricing and reimbursement systems differ from Member

[65] Final Report on the Pharma Sector Inquiry, para 1362

[66] For further details see Chapter D.2.1 of the Final Report on the Pharma Sector Inquiry

[67] For further details see Chapter D.2.2. of the Final Report on the Pharma Sector Inquiry

[68] For further details see Chapter D.2.3. of the Final Report on the Pharma Sector Inquiry

[69] Final Report on the Pharma Sector Inquiry para 1363 and Idem. Chapter D.2.4.

[70] For further details see the next chapter.

[71] Final Report on the Pharma Sector Inquiry Footnote 669

[72] Idem. para 1377

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State to Member State, the Transparency Directive[73] at EU level aims speeding up the decision making at Member States' level. As a main rule, the Directive provides a short, 90-days-long deadline to the Member States to adopt and communicate the decision about the pricing of the pharmaceutical products to the applicant. If the information provided by the applicant is inadequate, the competent authorities shall request additional information and take their final decision within 90 days of receipt of this additional information. In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to market the product at the price proposed.[74] Member States shall ensure that the overall period of time taken by the two procedures does not exceed 180 days.[75]

In the current system, the same rules apply for generics and originators, and the companies complain that the deadlines of the Transparency Directive are not respected and they often face delays in pricing and reimbursement decisions.[76] However, the Commission reports that they "have considerably stepped up their efforts to ensure the implementation of the Transparency Directive".[77] Another factor creating delays is the trend towards fragmented decision making at a more regional/local, or even at hospital level.[78] However, the Commission highlighted that it is up to the Member States to decide how medicines are purchased.[79]

The patent linkage – the refusal by national bodies to grant pricing and reimbursement status to a generic product, unless the applicant can demonstrate that the product would not infringe valid patents – might be interesting also generic entry.[80] In that regard, the situation is also heterogeneous between the Member States.[81]

[73] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinaI products for human use and their inclusion in the scope of national health insurance systems ("Transparency Directive")

[74] 89/105/EEC Transparency Directive Article 2 (1)

[75] Transparency Directive Article 6 (1)

[76] Pharma Sector Inquiry para 1422.

[77] Idem. para 1430.

[78] Idem. para 1442.

[79] Idem. para 1443.

[80] Idem. para 1446

[81] Idem. para 1447

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In 2012, the European Commission adopted a new Directive Proposal to replace the old Transparency Directive. [82] This Proposal Directive – inter alia –aimed to reduce the duration of national decisions on pricing and reimbursement of medicines.

The Proposal highlighted that the conditions have fundamentally changed since the adaption of Directive 89/105/EEC, for instance with the emergence of generic medicines providing cheaper versions of existing products or the development of increasingly innovative – yet often expensive – research-based medicinal products.[83]

According to the Proposal, Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within 60 days of the receipt of an application submitted.[84] With respect to generic medicinal products, that time limit shall be 15 days, provided that the price of the reference medicinal product has been approved by the competent authorities.[85]

If the information is inadequate, the competent authorities shall notify the applicant and take their final decision within 60 days of receipt of this additional information. With respect to generic medicinal products, that time limit shall be in all events 15 days, provided that the price of the reference medicinal product has been approved by the competent authorities. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.[86]

To conclude, the Directive Proposal would not only reduce the deadlines, but also differentiates between applications made by originator and generic companies. Such a change would be very welcome from the point of view of generic entry, however, the Directive Proposal has never been accepted by the Council. The formal withdrawal of the Proposal was published on 7 March 2015 in the Official Journal. Pursuant to the official explanation, "[t]he withdrawal was justified by the fact that, after 16 meetings of the pharmaceuticals and medical devices council working

[82] COM(2012)0084 Transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. 2012/0035(COD)

[83] Idem. p. 3

[84] However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.

[85] COM(2012)0084 Transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. Art. 3 (3)

[86] Idem. Art. 3 (5)

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group, no agreement was foreseeable in the Council, where objections were made by a number of EU countries."[87]

II.2.2. Sectoral regulation in the US

In the US, the sectoral regulation has a key importance in any discussion of pay-for-delay settlements. One act, the Drug Price Competition and Patent Restoration Act (further on Hatch-Waxman Act) is known as the genesis of all pharmaceutical patent settlement issues.[88] Consumers have both a short-term interest in paying less for the medicines – which is ensured by a prompt generic entry – and a long term interest in promoting new drug discovery – which is ensured by patent rights. The Hatch-Waxman Act aimed to rebalance these interests[89] by "bring[ing] down the drug prices by providing incentives for generic entry and enhancing protections provided to intellectual property holders to sup innovation."[90]

The Hatch-Waxman Act represents a compromise between the generic and the brand name pharmaceutical industry[91] which aims to ensure the right balance between consumer's welfare – the right for the low-cost generic medicine – and the maintenance of the incentives to innovate, i.e. develop innovative pharmaceuticals.

The circumstances of the adoption of Hatch-Waxman Act might also be relevant. The US pharmaceutical industry faced a lot of problems during the 70's and 80's because of the Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetics Act in 1962. The Kefauver-Harris Amendments required even the generics to take the same health and safety

[87] https://ec.europa.eu/growth/sectors/healthcare/competitiveness/products-pricing-reimbursement/transparency-directive_en (Downloaded: 24 October 2018)

[88] Amanda P. Reeves: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis p. 9.

[89] K. M. Drake-M.A. Starr-T. McGuire: Do „Reverse Payment" Settlements of Brand-Generic Patent Disputes in Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay? NBER Working Paper No. 20292. July 2014. p. 3.

[90] Amanda P. Reeves: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis p. 9.

[91] Timothy A. Cook, Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice,17 MICH. TELECOMM. TECH. L. REV. 417 (2011), p. 425

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tests like the original applicant. Due to the high costs, generic applicants often opted to stay out of the market.[92]

The Hatch-Waxman Act extended the effective patent life and also made generic entry much easier by creating the Abbreviated New Drug Application (ANDA). In addition to expediting the market entry of generic drugs after patents expiry, Congress also intended the Act to encourage generic firms to challenge weak drug patents[93] and introduced the 180 days exclusivity period for the first filer generic.

In ANDA procedure, the generic company has to prove only that its product contains the same active ingredients like a listed drug, same dosage form, so that it is a bioequivalent of a listed drug.[94] The generic company is also obliged to send a certificate which proves that its product does not infringe the patent of the listed drug on which basis it aims to earn marketing authorization, or the original patent expired, or it is invalid or not infringed.[95] This is called Paragraph IV. Procedure, which plays an important role in reverse payment patent settlements.

The Hatch-Waxman Act also provides a 180 days long exclusivity for the first generic entrant company, during which period the FDA cannot approve another generic firm's ANDA.[96] By providing this exclusivity, the Act gives motivation to generic companies to be the first to enter the market. [97]

Through the 180 days exclusivity period, the Hatch-Waxman system gives a strong incentive to the generic to try to enter the market before the originator's patent expiry. Consequently, the generics often do not wait until the expiry date but try to enter before the originators patents expire. To do so, the generics would argue that the originator's patent is either invalid or it is not infringed (Paragraph IV. Procedure).

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[92] Timothy A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 425

[93] A. B. Mehl: The Hatch-Waxman Act and Market Exclusivity for Generic Manufacturers: An Entitlement or an Incentive. Chicago-Kent Law Review, Volume 81. Issue 2. Article 13. January 2006. p. 650.

[94] For further details see 21 U.S. Code §355 (j) 2A, (i)-(vi)

[95] For further details see 21 U.S. Code §355 (j) 2A, (i)-(vi) (I-IV)

[96] Hatch-Waxman Act 5 B (iv)

[97] C. Scott Hemphill–Bhave N. Sampat: When Do Generics Challenge Drug Patents? (Columbia Law and Econ. Working Paper No. 379, Aug. 2010) SSRN., See also C. Scott Hemphill: Collusive and Exclusive Settlements of Intellectual Property Litigation. Columbia Law School Working Paper No. 384. November 30, 2010. p. 702.

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Under the Hatch-Waxman Act, a typical generic challenge works as follows: before the patent's expiry, the generic files an ANDA and a Paragraph IV certification. The brand has up to forty-five days after the notice from the ANDA to file a patent infringement action. When the brand files suit, the FDA approval of the ANDA is stayed for thirty months unless the patent is ruled invalid, and such a stay can extend to several years. Taking into regard the pending patent litigation and the high economic stakes involved, the brand may settle with the generic challenger. [98]

However, against of the aims of the Hatch-Waxman Act, most often it is not the weakest patent which is challenged by the generics, but the one promising a high profit. In case of a blockbuster, a best-selling drug, even a prospect of one percent of success might justify the challenge for the generic. Not surprisingly, many of the best-selling drugs have attracted challenges.[99] This strategy may be followed especially when the relevant patent is not a basic patent on a novel active ingredient – which are generally considered as the strongest patents of the whole patent system – but a patent on an ancillary aspect, or "secondary" patent, such as an extended-release formulation. Similar to the US experiences, secondary patents are also more likely to be challenged in the EU.[100]

II.3. Patent system and patent enforcement system

After discussing the sectoral regulations in the EU and in the US respectively, in the case of the EU, another element of the regulatory background should be examined, as it was identified as key component of the regulatory background influencing pay-for-delay patent settlements by the European Commission, and also by the OECD. Since careful review of the US resources have not identified patent and patent enforcement system as part of the regulatory framework

[98] Xiang Yu– Anjan Chatterji : Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation p. 20-21.

[99] C. Scott Hemphill Regulatory Design Problem. Columbia Law School. 81 New York University Law Review 1553 (2006) Columbia Law and Economics Working Paper No. 306 Available at http://ssrn.com/abstract=925919

[100] The disputes in the cases didscussed in this thesis relate to secondary patents. Generally legal disputes – especially those which attract competition scrutiny – relate to secondary patents and anti-generic strategies. In an important abuse of dominance case, AstraZeneca was fined for misleading patent offices and courts in certain EU jurisdictions, and deregistering the marketing autorizations of original Losec capsules to introduce Losec MUPS tablets, which were a kind of extended release forms of original Losec, containing the same API, omeprazole. (See Case C-457/10 P – AstraZeneca AB and AstraZeneca plc v European Commission. ECLI:EU:C:2012:770, see also Case T-321/05 - AstraZeneca AB and AstraZeneca plc v European Commission. ECLI:EU:T:2010:266)

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behind patent settlements, the thesis only examines the relevant rules and their potentional developments in the EU.

II.3.1. IP regulation and enforcement system in the EU

According to the Commission's Pharmaceutical Sector Inquiry, the most relevant topics subject to pharmaceutical sectoral regulation are a) the marketing authorization system, b) the pricing and reimbursement system, and c) patent law and its enforcement system.[101]

An OECD study, "The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements" also identifies the discrepancies of the European patent regulation, which might affect companies' incentives to get involved in pay-for-delay settlements. [102]

The patent laws and enforcement systems in the examined jurisdictions therefore should be analysed to discover their potential role to play in incentivising pay-for-delay settlements.

Indeed, more than fifty years after the foundation of the European Economic Community[103], it is still not possible to obtain a patent that is valid and enforceable throughout the EU.[104] By the moment, patent applicants seeking for an EU-wide patent protection have two possibilities: filing at each national patent offices or filing a single patent application at the European Patent Office (EPO). Even in the second case, national validation of the European Patent is necessary in each Member States, where the applicant wants the existence of patent protection and enforceability of the patent. By the moment, the European Patent is a bundle of national patents. However, this situation seems to change soon, as the start of the new Unitary Patent System is currently expected for the beginning of 2022.[105] (Although the start date has been postponed several times during the last years.) The Unitary Patent System is going to be subject to further

[101] Final Report on the Pharma Sector Inquiry para 1289.

[102] DAF/COMP/WD(2014)75: "The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements"

[103] For the sake of completeness, it should be noted that in the EU, intellectual property laws are subject to harmonization requirements.
For example, Hungary had to re-regulate the whole IP system in order to be part of the EU. As a new jiner, it was also required that Hungary joins to the European Patent Convention. (For further details see: Tattay Levente: A szellemi alkotások teljeskörű újraszabályozása Magyarországon. Iustum Aequum Salutare, V. 2009/2. · 149–164.)

[104] Final Report on the Pharma Sector Inquiry para 1293.

[105] EPO: When will the Unitary Patent system start? (Available at: https://www.epo.org/law-practice/unitary/unitary-patent/start.html (Downloaded: 24 January. 2021))

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discussion later, but first here the old European patent system should be examined, since it contains the applicable rules which could be relevant for our research by influencing the incentives of the originators and generic companies to enter into pay-for-delay settlements.

Currently, there are two possibilities to enforce the European Patent: a) opposition procedure before the EPO on the basis of Part V. Chapter 1 of the European patent convention, or b) validity/infringement procedure before the courts of Member States.[106]

The Opposition Procedure before the EPO might be initiated within nine months of the publication of the grant of the European patent in the European Patent Bulletin,[107] and the opposition shall apply to the European Patent in all the Contracting States in which that patent has effect.[108] So, Opposition Procedure before the EPO has cross-border effects: if the patent is revoked, it is revoked in all Member States.[109] The opposition procedure before the EPO is the only cross-border tool, and limited to 9 month after the Publication of the patent.

The other way for patent enforcement – which is the only available tool after the expiry of the 9 months period – is litigation[110] before national courts. In the current system, every national court has jurisdiction for the national part of the European Patent only. The evaluation of patents by the national courts shows big differences between the EU Member States.[111]

This decentralised system also facilitates forum shopping. A good example to introduce the discrepancies of the current system is the so called "Italian torpedo". “Italian torpedo” was based on the rules of the Brussels Convention[112], and was known as a popular defence in European patent litigation. By using “Italian torpedo”, a company, under threat of infringement proceedings, filed a “torpedo suit” in Italy applying for a declaration of non-infringement in

[106] European Patent Convention Part V. Chapter 1.

[107] Idem. Art 99 (1)

[108] Idem. Art 99 (2)

[109] Member States of the European Patent Convention, or those where the patent was validated.

[110] Validity/Infringement/Declaratory action for non-infringement.

[111] For example, Article 69 (1) of the European Patent Convention is designed to solve as a bridge between the more "challanger-friendly" UK and the "patent holder friendly" German courts.

[112] 1968 Brussels Convention on jurisdiction and the enforcement of judgments in civil and commercial matters / Consolidated version CF 498Y0126(01) / Official Journal L 299 , 31/12/1972 P. 0032 – 0042 (Brussels Convention)

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respect of both the Italian and the foreign corresponding patents.[113] Article 5.3. of the Brussels Convention was the basis of the jurisdiction of Italian courts, which established that "a person domiciled in a Contracting State may, in another Contracting State, be sued … in matters relating to tort, delict or quasi-delict, in the courts for the place where the harmful event occurred".[114] Italian courts accepted these kinds of claims, and foreign courts – especially German courts – were willing to stay their own infringement proceedings if the alleged infringer had already launched a cross-border declaratory action for non-infringement action in Italy. [115] As result, once the alleged infringer had filed a torpedo suit in Italy, the patentee was prevented from enforcing its patent in other European jurisdictions.

The "Italian torpedo" seems to be a "never ending saga"[116]: Council Regulation 44/2001 (Brussels I Regulation) – which replaced the Brussels Convention – also served as a good basis for "torpedo" cases, and the new, revised regulation, Regulation 1215/2012 has exactly the same wording.[117] Therefore, it seems like neither the new regulation won't make an end to the use of "Italian torpedo" in patent disputes.

Furthermore, the current system is also very costly: cross-border litigations involve high legal costs.

II.3.1.1. The Unitary Patent System

There have been several attempts to introduce a patent with unitary effects throughout the EU Member States during the last decades. The first real proposal from 1975, "Convention for the European Patent for the common market"[118] has never entered into force, however, practitioners

[113] Gabriel Cuonzo: The "Italian torpedo" never ending saga. (Available at: http://kluwerpatentblog.com/2013/09/02/the-italian-torpedo-never-ending-saga/ Downloaded: 19 November 2018)

[114] Article 5.3. of the Brussels Convention.

[115] Article 21 of the Brussels Convention: "Where proceedings involving the same cause of action and between the same parties are brought in the courts of different Contracting States, anycourt other than the court first seised shall of its own motion stay its proceedings until such time as the jurisdiction of the court first seised is established. Where the jurisdiction of the court first seised is established, any court other than the court first seised shall decline jurisdiction in favour of that court."

[116] Gabriel Cuonzo: The "Italian torpedo" never ending saga.

[117] Regulation 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters. OJ L 351, 20.12.2012, p. 1–32. Article 7 (2)

[118] 76/76/EEC: Convention for the European patent for the common market (Community Patent Convention) Official Journal L 017 , 26/01/1976 P. 0001 - 0028

DOI: 10.15774/PPKE.JAK.2021.012

often used its rules as a guidance – given the lack of an applicable harmonized patent law.[119] In 1989, a new project was laid out under the name "Luxemburg Agreement relating to Community patents"[120], but it also failed.

As result of more than a decade long "negotiations and preparation", Member States and the European Parliament agreed on the “Unitary Patent Package” in 2012 – a legislative initiative consisting of two Regulations and an international agreement, the Agreement on a Unified Patent Court (UPC Agreement) laying the grounds for the creation of unitary patent protection in the EU. The patent package implements enhanced cooperation between 25 Member States – all Member States that time, except Italy and Spain.

The two Regulations were adopted in December 2012[121,] and the UPC Agreement, the third and last component of the “patent package” is under ratification. The EU regulations[122] establishing the Unitary Patent system entered into force on 20 January 2013, but they will only apply as from the date of entry into force of the UPC Agreement, on the first day of the fourth month following the deposit of the 13th instrument of ratification or accession (provided those of the three Member States in which the highest number of European patents had effect in the year preceding the signature of the Agreement, i.e. France, Germany and the United Kingdom, are included).[123] The contracting Member States agreed that they will proceed with the signature and ratification of the Agreement, and by the second half of 2018, 16 Member States have already ratified the UPC Agreement. [124] After 2018, no new ratification took place, and due to

[119] Presentation of Patricia Cappuyns, 2014, Liege. (Recognized IP law practitioner. Partner, Cape IP Law (Belgium), Lecturer, ULg.)

[120] 1989 Luxembourg Agreement relating to Community Patents (89/695/EEC) (Available at: http://www.patentim.com/eng/ipnewsinside.asp?Article=241 Downloaded: 19 November 2018)

[121] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection. OJ L 361, 31.12.2012, p. 1–8; Council regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements. OJ L 36131.12.2012, p. 89-92

[122] Idem. p. 89-92

[123] When will the Unitary Patent system start? (Available at: https://www.epo.org/law-practice/unitary/unitary-patent/start.html Downloaded: 19 November 2018)

[124] EPO: Unitary Patent. (Available at: https://www.epo.org/law-practice/unitary/unitary-patent.html Downloaded: 19 November 2018)

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the Brexit, the UK's withdrawal of ratification was received on, and effective as from 20 July 2020.[125]

Once the Agreement and the Regulations will enter into force, it will be possible to obtain a European patent with unitary effect – a legal title ensuring uniform protection for an invention across most Member States, providing huge cost advantages and reducing administrative burdens. Currently the start of the Unitary Patent system is expected for the first half of 2022.[126]

The EPO website highlights that Unitary Patents may not cover all participating Member States in the beginning, "as some of them may not yet have ratified the UPC Agreement when it enters into force. Outstanding ratifications are likely to take place successively, so there may be different generations of Unitary Patents with different territorial coverage. The coverage of a given generation of Unitary Patents will stay the same for their entire lifetime, irrespective of any subsequent ratifications of the UPC Agreement after the date of registration of unitary effect. In other words, there will be no extension of the territorial coverage of Unitary Patents to other Member States which ratify the UPC Agreement after the registration of unitary effect by the EPO."[127]

An OECD study highlights three problems of the current European patent regulation: (i) not all Member States provide effective preliminary injunction; (ii) full compensation for the suffered harm is not adequately ensured, and that (iii) the absence of a unified patent judiciary "create[s] a hold-up problem that incentivizes originator companies, especially the most risk averse, to make reverse payments to generics even if their patent position is strong".[128] Theoretically, the Unitary Patent System could solve certain problems, especially if all Member Sates become part of the System.

In the case of pay-for-delay settlements, the OECD study also identifies several shortcomings of the patent regulation system – i.e. limited availability of preliminary injunctions, insufficient

[125] https://www.consilium.europa.eu/en/documents-publications/treaties-agreements/agreement/?id=2013001

[126] When will the Unitary Patent system start? (Available at: https://www.epo.org/law-practice/unitary/unitary-patent/start.html. Downloaded: 25 October 2020)

[127] Idem.

[128] DAF/COMP/WD(2014)75: "The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements" p. 3.

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compensation for damages, lack of unified patent judiciary[129] – and also notes that the European Commission does not take this fact into consideration in its assessment of patent settlements.[130] However, it maintains that "settlement agreements must be examined under the antitrust laws against the background of the applicable patent system."[131]

II.4. Competition law in the EU and the US

The following chapters introduce the main rules and charactereistics of EU competition- and US antitrust laws in a nutshell. Although competition/antitrust law is the providing the viewpoint of the whole thesis, and definitely could not – and not even intended to – be introduced or compared here in its entirety, I found it necessary to highlight certain aspects of them. These subjectively selected features, in my view, have important implications for pay-for-delay settlements, and their evaluations in the respective antitrust systems.

II.4.1. Competition law in the US

The origins of US antitrust law can be traced back to the end of the 19th century, mainly as a reaction to the formation of trusts[132]. In the second half of the 19th century, the US experienced a number of events, which resulted in the transformation of manufacturing industries. Motta highlights that the most important events were the dramatic improvement in transportation and communication, which entailed the formation of a large single market, which in turn gave a powerful incentive to firms to exploit economies of scale and economies of scope. The economic situation at the end of the 19th century was characterized by price wars and market

[129] DAF/COMP/WD(2014)75: "The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements" p. 3-6

[130] Idem. p. 7

[131] Idem. p. 2

[132] "The 'trust' was originally a device by which several corporations engaged in the same general line of business might combine for their mutual advantage, in the direction of eliminating destructive competition, controlling the output of their commodity and regulating and maintaining its price, but at the same time preserving their separate individual existence, and without any consolidation or merger. This device was the erection of a central committee or board, composed, perhaps, of the presidents or general managers of the different corporations, and the transfer to them of a majority of the stock in each of the corporations, to be held in 'trust' for the several stockholders so assigning their holdings. These stockholders received in return 'trust certificates' showing that they were entitled to receive the dividends on their assigned stock, though the voting power of it had passed to the trustees. This last feature enabled the trustees or committee to elect all the directors of all the corporations, and through them the of ficers, and thereby to exercise an absolutely controlling influence over the policy and operations of each constituent company, to the end and with the purposes above mentioned " . (West Group, 1998.)

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instability. Firms often tried to respond by price agreements which enabled them to maintain high prices and profit margins.[133]

The emergence of large manufacturing conglomerates and the growth in their economic power lead to the adoption of the Sherman Act in 1890. Sections 1 and 2 of the Sherman Act prohibit cartels and monopolization at federal level. The Act outlawed "every contract, combination or conspiracy in restraint of trade" and "monopolization" and treated violations as crimes.[134]

The Sherman Act was followed by two additional antitrust laws in 1914, the Clayton Antitrust Act, and the Federal Trade Commission Act. The Federal Trade Commission Act outlaws "unfair methods of competition" and "unfair or deceptive acts or practices". The Clayton Act addresses specific practices that the Sherman Act does not clearly prohibit, such as mergers and interlocking directorates. [135] The Sherman Act, the Clayton Act and the Federal Trade Commission Act are considered as the "the three core federal antitrust laws" [136] of the US.

The US antitrust laws aimed at maintaining competition as the driving force of the US economy, and the driving force behind their creation was the opposition to the giant trusts that began to develop after the Civil War.[137]

[133] Massimo Motta: Competition Policy – Theory and Practice, Cabridge University Press, 2004, Cambridge, p. 1.

[134] William E. Kovacic – Carl Shapiro: Antitrust Policy: A Century of Economic and Legal Thinking. Journal of Economic Perspectives—Volume 14, Number 1—Winter 2000. Pages 43– 60

[135] The same person making business decisions for competing companies.

[136] FTC: The Antitrust Laws. (Available at: https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws Downloaded: 27 November 2018)

[137] Don Mayer – Daniel Warner – George Siedel – Jethro K. Lieberman : Government Regulation and the Legal Environment of Business. Section 16.1 (Available at : http://2012books.lardbucket.org/books/the-legal-environment-and-government-regulation-of-business/s19-01-history-and-basic-framework-of.html, Tóth Tihamér: Az Európai Unió versenyjoga, Complex, 2014. Budapest, p. 45.

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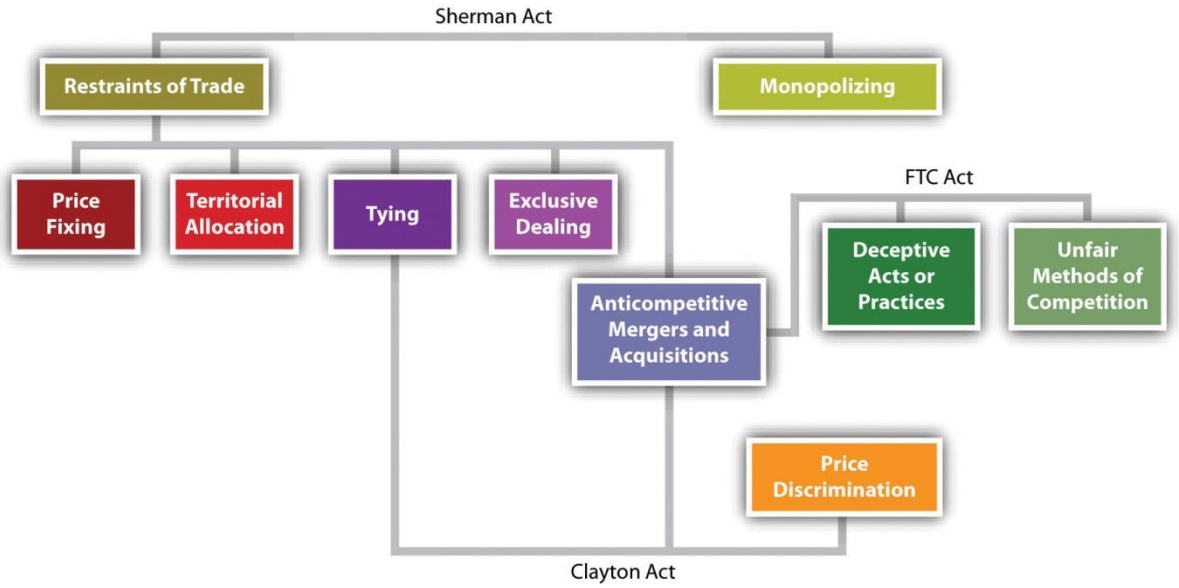

Source: Don Mayer – Daniel Warner – George Siedel – Jethro K. Lieberman : Government Regulation and the Legal Environment of Business[138]

The US enforcement system is based on four different means. First, the US Department of Justice may bring civil actions to enjoin violations of any section of the Sherman and Clayton Acts and may institute criminal prosecutions for violations of the Sherman Act. Second, the FTC hears cases under the Administrative Procedure Act, its decisions may be appealed to the US courts of appeals. Third, in the Antitrust Improvements Act of 1976, Congress authorized state attorneys general to file antitrust suits in federal court for damages on behalf of their citizens; such a suit is known as a parens patriae claim. Any citizen of the state who might have been injured by the defendant's actions may opt out of the suit and bring his or her own private action. Fourth, private individuals and companies may file suits for damages or injunctions individually or as a member of a class of plaintiffs, if they have been directly injured by a violation of the Sherman or Clayton Act.[139]

Generally, private enforcement and class actions have a very important role in US antitrust enforcement. Main part of the enforcement in the US happens at courts: even the FTC challenges companies' presumably anticompetitive conducts at courts.

[138] Don Mayer – Daniel Warner – George Siedel – Jethro K. Lieberman : Government Regulation and the Legal Environment of Business. Section 16.1 (Available at : http://2012books.lardbucket.org/books/the-legal-environment-and-government-regulation-of-business/s19-01-history-and-basic-framework-of.html

[139] Idem.

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II.4.2. Competition law in the EU

The first European competition rules were Articles 65 and 66 of the Treaty of Paris, which created the European Coal and Steel Community. The Rome Treaty, which established the European Economic Community in 1957, also contained competition rules. However, the real application of competition rules started after 1962, when Regulation 17[140] entered into force.

Competition law has been one of the most important Community (Union) competences since the creation of the European Communities. National competition rules exist in parallel and are highly harmonized. EU competition rules addressed to undertakings are based on two provisions, Article 101 and 102 of the Treaty on the Functioning of the European Union[141] (TFEU). Due to the European market characteristics, such as smaller firms and mainly national markets, there was no need for a merger regulation until 1989.[142] Article 101 prohibits anticompetitive agreements and concerted practices, Article 102 bans abuses of dominant position.

The different economic and political environment determines that the system and aims of EU competition law differ from US antitrust law to a large extent.

While US antitrust law was an answer to the creation of big trusts and their abuses, EU competition law has had the creation and protection of the common- and later internal market as one of its main aims since the very beginning. Some features of EU competition law – such as the rules applicable for some vertical restrains – are consequences of this background.

Since competition law was a new field of law for some Member States[143], its enforcement became centralised, based on the European Commission and on the Court of the European

[140] Regulation No. 17. (EEC): First Regulation implementing Articles 85 and 86 of the Treaty (at present Articles 81 and 82) [Official Journal No. 013, 21.02.1962]

[141] Consolidated version of the Treaty on the Functioning of the European Union OJ C 326, 26.10.2012, p. 47–390

[142] Council Regulation (EEC) 4064/89 (OJ 1989 L395/1, 30.12.1989), as amended by Council Regulation (EC) 1310/97 (OJ 1997 L180/1, 9.7.1997; corrigendum OJ 1998 L40/17, 13.2.1998)

[143] However, some early competition legislation might be found in Germany, UK and France at the end of the 19th century, focusing on the prohibition of cartels mainly. (Adrian Kuenzler – Laurent Warlouzet: National Traditions of Competition Law: A Belated Europeanization through Convergence? In: Kiran Klaus Patel – Heike Schweitzer: The Historical Foundations of EU competition Law. Oxford University Press, Oxford, 2013. p. 89.) Hungary had a pretty modern competition law, and enforcement system in the beginning of the 20th century. For further details see: Verseny – jog – történet. 85 éves a magyar kartellszabályozás. (Available at: http://www.gvh.hu//data/cms1032709/gvh25_jogtorteneti_kiadvany_2015.pdf Downloaded: 16 January 2016.)

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Union. Only after the EU legislators presumed that Member States' courts and national competition authorities (NCAs) have enough experience in applying competition rules could have decentralization start. In December 2002, Council Regulation No. 1/2003, the "Modernization Regulation"[144] was adopted, which largely decentralized competition law. After this regulation, the NCAs and the national courts have full jurisdiction in the application of EU competition rules, the European Commission has lost its exclusive jurisdiction in applying Article 101(3).

In the beginning of the 21st century – after the ECJ's judgements in cases Manfredi and Courage contra Crehan – European policy-making turned to private enforcement. The process of increasing the role of private enforcement is on-going, and the European Commission has made serious steps towards a unified European regime during the last few years. Nevertheless, the role of public enforcement is still more significant in the EU.

II.4.3. Innovation, and the goals of Competition and Antitrust Law

The goals of Competition/Antitrust Laws are subject to hot debate both in economic and legal literature, and also in the relevant case law. An in-depth examination and debate of this topic is not the aim of this research, and would certainly go beyond the limits of this thesis. The only goal of this subchapter is to introduce the main principles in a nutshell and highlight the main and very basic differences of US Antitrust law and EU Competition Law in that respect.

Antitrust/competition laws influence how undertakings compete,[145] and on thing is sure, their common goal is the protection of competition as a process.[146] All other goals are subject to dispute, and different studies highlight the importance of other elements of the goal set. The generally mentioned principal objectives of competition laws are to promote efficiency, and

[144] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty. OJ L 1, 4.1.2003, p. 1–25

[145] Dennis W. Carlton: Does Antitrust Need to be Modernized? http://papers.ssrn.com/sol3/papers.cfm?abstract_id=956930 EAG 07-3, January 2007. p. 3.

[146] Dr. Szilágyi Pál: Az összefonódások egyoldalú hatásainak megítélése az Európai Unió versenyjogában. Doktori értekezés. (Available: http://jak.ppke.hu/uploads/articles/12332/file/Szil%C3%A1gyi%20P%C3%A1l%20PhD.pdf Downloaded: 6th June 2021) p. 4

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total- or consumer welfare.[147] Over and above, "competition law exists to protect competition in a free market economy"[148].

The most commonly accepted goals of competition/antitrust laws are the following: consumer[149]- and economic welfare, efficiency, protection of competition, etc.[150] In the European Union, competition law has another objective, the creation and protection of the common, later internal market.[151] From the very beginning, EU competition rules have played a central role in the protection of common/internal market, the first competition law cases handled by the European Commission focused on parallel trade.[152]

Ezrachi[153] highlights that the various goals of competition law have not always been clearly outlined, and these values often overlap or reveal friction. Competition law is primarily concerned with consumer welfare i.e. competition law seeks to prevent harm to competition, and consumer welfare will be thereby maximised. Consumer and economic welfare is not only the primary goal of competitition laws, but also the less controversial. Ezrachi presents the not clearly outlined, somewhat overlapping, somewhat controversial goals of competition laws as follows:

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[147] Tóth Tihamér: Az Európai Unió versenyjoga. CompLex. Budapest, 2014. p. 59., see also Roger J. Van den Bergh – Peter D. Camesasca: European Competition Law and Economics: A Comparative Perspective, Sweet & Maxwell, 2006., London, p. 5. see also Richard Whish: Competition Law, Oxford University Press, 2009., Oxford, pp. 19-23., see also Massimo Motta: Competition Policy – Theory and Practice, Cabridge University Press, 2004, Cambridge, pp. 18-20

[148] Alison Jones – Brenda Sufrin: EU Competition Law. Text, cases, and materials, Fourth Edition, Oxford University Press, Oxford, 2011 p. 1

[149] Szilágyi Pál: A versenypolitika mozgástere a versenyképesség tükrében. In: Katona Klára (szerk.): Vállalati versenyképesség és az állam szerepe: Hitek és tévhitek. Szent István Társulat: Budapest, 2011. 153-162. p. 161.

[150] Tóth Tihamér: Az Európai Unió versenyjoga. Complex, Budapest, 2014. 3.3 fejezet, Ioannis Lianos: Some reflections on the question of the goals of EU Competition Law. (Available at: https://www.ucl.ac.uk/cles/research-paper-series/research-papers/cles-3-2013 Downloaded: 17th January 2016.)

[151] Tóth Tihamér: Az Európai Unió versenyjoga. 57., Ioannis Lianos: Some reflections on the question of the goals of EU Competition Law. Available at: https://www.ucl.ac.uk/cles/research-paper-series/research-papers/cles-3-2013 Downloaded: 17th January 2016. p. 13

[152] For example, Consten and Grundig. In the case of the pharmaceutical sector, the situation is the same: the first enforcement actions of the Commission were focused on parallel trade, and price discrimination (GSK cases), the commission started to deal with abuse of dominance (AstraZeneca) and agreements (Pharma Sector Inquiry, Lundbeck, J&J, servier) later.

[153] I am aware that the discussion and presentation used by Ezrachi might be debated. Without prejudice to the more commonly accepted, and potentially generally more relevant goals of the antitrust/competition laws, here I decided to use Ezrachi's presentation due to the innovative nature of the industry, and to highlight some important features related to innovation.

DOI: 10.15774/PPKE.JAK.2021.012

Source: Ariel Ezrachi: The Goals of EU Competition Law and the Digital Economy.[154]

The discussion of the goals of competition and antitrust laws has always been a hot topic of legal literature, for this research, one element of the above figure – probably the most controversial one – is important: innovation.

Whether the existence of competition serves the promotion of innovation is somewhat controversial topic, which leads us to the heart of IP/Competition intersection. Ezrachi highlights: "Innovation processes stimulate dynamic markets, enhance consumer welfare, and may help offset otherwise diminishing marginal returns. As a key driver of competition in, but also for markets, innovation should be safeguarded and promoted. Clearly, competition law has a role to play in fostering competition in innovation by supporting the free market system, and by creating conditions conducive to efficiency maximisation, market integrity, and competition on the merits." Pursuant to the general view competition as a dynamic force provides incentives to innovate – however, this view can be influenced in a large extend depending on whether we talk about competition on the market, or competition for the market. Furthermore, this view is

[154] Ariel Ezrachi: The Goals of EU Competition Law and the Digital Economy. BEUC Discussion Paper. Available at https://www.beuc.eu/publications/beuc-x-2018-071_goals_of_eu_competition_law_and_digital_economy.pdf Downloaded: 24 January 2020) p. 4)

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based on a model of "dynamic" competition opposed to "lazy" monopoly i.e. the model stating that monopoly enjoying monopoly profits without any competitive pressure lacks incentives to innovate. On the other hand, in the model of perfect competition, companies lack the sufficient resources to engage in costly and risky innovation.

At this point, without going deeper into the economists debate about competition and innovation, we accept that certain elements of competition (e.g. competitive pressure and dynamism) support innovation, while other features (e.g. economic strength, profit) might be controversial. It should also be highlighted that modern competition laws take into regard innovation, and if certain other circumstances meet, cooperations related to R&D and facilitating important innovations often are and/or might be exempted from general prohibition.

II.4.4. The main rules of EU Competition Law and US Antitrust Law

Both US Antitrust and EU Competition rules prohibit two main type of behaviours: (i) collusion between undertakings and (ii) unilateral actions of dominant undertakings.

Concerning collusion, Section 1 of the Sherman Act states that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."[155] Article 101 of the TFEU outrules "all 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 prevention, restriction or distortion of competition within the internal market".[156] Such "agreements or decisions […] shall be automatically void".[157] Unlike the Sherman Act, the TFEU contains also exceptions from the general prohibition[158]. As stated in Article 101 (3), the provisions of paragraph 1 may be declared inapplicable if the following four requirements meet: the agreement or decision (i) contributes to improving the production or distribution of goods or to promoting technical or economic progress, (ii) allows consumers a fair share of the resulting benefit, (iii) it does not impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives, and (iv) it does

[155] Sherman Act, para 1.

[156] Consolidated Version of the Treaty on the Functioning of the European Union, 2008 O.J. C 115/47 (TFEU) Art. 101 (1).

[157] TFEU Art. 101 (2)

[158] TFEU Art. 101 (3)

not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

From the point of view of this research, the main difference between the EU and US approach is that the TFEU contains Article 101 (3). If each of the the four conditions meet, the anti-competitive agreement will become lawful. The Sherman Act does not contain any statutory exception from the prohibition of Section 1. Judge made case law had to develop similar exceptions. The prohibition against "every" agreement in restraint of trade has been understood by the federal courts since the 1911 Standard Oil[159] decision, to forbid only "unreasonable restraints."[160]

Under Section 1, in determining whether an agreement unreasonably restrains competition, courts generally apply one of two analytical standards known as per se rule and rule of Reason. The applied standard depends on the nature of the restriction. The per se rule –which has limited applicability – is generally reserved for the narrow range of conduct that almost always causes harm to consumers and has little or no procompetitive benefit (i.e. price fixing or bid rigging). Under the per se rule, such restraints are deemed unlawful without any inquiry into asserted justifications or alleged reasonableness of the conduct.[161]

On the other hand, some agreements lead to improvement or benefits for the whole society while also being anticompetitive. In such cases, the prohibition of the agreement would lead to undesirable outcomes. These agreements cannot be handled the same way as a horizontal price cartel or other hardcore restrictions. This economic rationality was the basis of the rule of reason doctrine: while some – hardcore – agreements are per se illegal on the basis of the Sherman Act, other conducts require rule of reason consideration. According to Blair and Sokol, "[t]he rule of reason is aimed at determining the competitive effects of a business practice under review."[162] The doctrine was developed by 6th Circuit judge William Howard Taft in Addyston Pipe and

[159] Standard oil Co. v united States, 221 U.S. 1

[160] P. Areeda, The "Rule of Reason" in Antitrust Analysis: General Issues (Federal Judicial Center 1981) Available at: http://www.fjc.gov/public/pdf.nsf/lookup/antitrust.pdf/$file/antitrust.pdf Downloaded: 17th January 2016. p. 1

[161] Daniel C. Fundakowski: The Rule of Reason: From Balancing to Burden Shifting. ABA Perspectives in Antitrust, Volume 1. No. 2. 22 January 2013. (Available at: http://www.americanbar.org/content/dam/aba/publications/antitrust_law/at303000_ebulletin_20130122.authcheckdam.pdf Downloaded: 17th January 2016)

[162] Roger D. –Blair – D. Daniel Sokol: The Rule of Reason and the Goals of Antitrust: an Economic Approach. Antitrust Law Journal. 2012. Vol 78. p. 475

Steel Co. v. United States case[163], and in 1899, affirmed by the Supreme Court. In this case, Judge Taft made the distinction between naked and ancillary price fixing, by stating that courts should apply a per se rule where naked price fixing is concerned.[164] "It has been earnestly pressed upon us that the prices at which the cast-iron pipe was sold in pay territory were reasonable. [...]We do not think the issue an important one, because, as already stated, we do not think that at common law there is any question of reasonableness open to the courts with reference to such a contract. Its tendency was certainly to give to the defendants the power to charge unreasonable prices had they chosen to do so. But if it were important, we should unhesitatingly find that the prices charged in the instances which were in evidence were unreasonable. [...] The same thing was true all through pay territory to a greater or less degree, and especially at reserved cities.[...] The facts thus set forth show conclusively that the effect of the combination was to enhance prices beyond a sum which was reasonable, and therefore the first objection above set forth need not be further noticed."[165] How it has been already mentioned, rule of reason played also a major role in the famous 1911 Standard Oil Company of New Jearsey v. United States case.[166]

According to Bork, "[t]he main tradition of the Sherman Act's rule of reason-established by Justice Peckham, Judge Taft, and Chief Justice White in 1911- necessarily rests, whether phrased in such terms or not, upon the premise that the law's exclusive concern is with the maximization of wealth or consumer want satisfaction."[167]

Article 101 (3) TFEU and the American concept of the rule of reason seem to have the same goals. However, – due to the differences of the US and EU antitrust/competition regime – it leads to only one conclusion: both methods aim to differentiate between hardcore conduct which are presumed harmful, and those conducts which lead to benefits to the society as a whole.[168] US and EU law concepts, like by object and by effect restrictions and per se prohibition and rule of reason are however not equivalent. The relationship of such concepts

[163] U.S. v. Addyston Pipe & Steel [175 U.S. 211 (1899)]

[164] www.clt.astate.edu/crbrown/section1.ppt

[165] U.S. v. Addyston Pipe & Steel [175 U.S. 211 (1899)]

[166] Standard Oil Co. of N.J. v. United States, 221 U.S. 1, 60 (1911)

[167] Robert H. Bork: The Rule of Reason and the Per Se Concept: Price Fixing and Market Division, Part II. The Yale Law Journal, 1966. Vol 75:373. p. 375

[168] For further details on Rule of Reason and Antitrust goals see: Roger D. –Blair – D. Daniel Sokol: The Rule of Reason and the Goals of Antitrust: an Economic Approach. Antitrust Law Journal. 2012. Vol 78

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will be discussed in details later, here it seems enough to note that rule of reason is alegal concept which can be applied in different ways. In addition to the full rule of reason analysis there are abbreviated tests of reasonableness - so called “quick look” or “truncated” rule of reason.[169]

With regard to unilateral actions, Section 2 of the Sherman Act sanctions “[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations.”[170] Article 102 of the TFEU prohibits – as incompatible with the internal market – “[a]ny abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it […] in so far as it may affect trade between Member States.”[171]

In that regard, the main difference between EU and US rules is that the TFEU prohibits both exclusionary and exploitative practices, while Section 2 of the Sherman Act only prohibits exclusionary conducts: monopolization.

II.5. The pharmaceutical sector in the buffer zone of different regulations

In the EU, sector specific regulation and the pricing/reimbursement system differ from country to country. Given the R&D driven nature of the sector, intellectual property rights – which differ from country to country, too – play also a significant role in the sector. Additionally, as the third group of applicable rules, there is competition law, which is one of the most harmonized areas of law in the EU.

In such an innovative industry, IP rights are “core assets”[172]: innovator companies trust in their patents when expecting a fair return on their significant R&D investments. Taken into regard the detrimental role of IP rights in the industry – certain companies earn 55% of their profit on

[169] James A. Keyte: What It Is and How It Is Being Applied: The „Quick Look” Rule of Reason. http://heinonline.org/HOL/LandingPage?handle=hein.journals/antitruma11&div=36&id=&page= p. 21

[170] Sherman Act, Section 2

[171] TFEU, Art, 102

[172] L. G. Bryer: Corporate Strategies, Structures and Ownership of Intellectual Property Rights. In: Intellectual Property Strategies for the 21st century Corporation – A Shift in Strategic and Financial Managament. (Ed: L. G. Bryer – S. C. Lebson – M. D. Asbell) John Wiley & Sons, Inc., Hoboken, New Jersey. 2011. p. 2

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one, "blockbuster" product – creating IP strategies is a normal business behaviour. On the other hand, IP strategies have also key importance in the business strategy of generics.

The creation of IP-strategies is not unlawful, problems occur when a market conduct based on such strategies infringes competition law. After some disputes, the Final Report of the Pharmaceutical Sector Inquiry also states that such "tool-box", or patenting strategies would only give rise to an infringement in "exceptional circumstances."[173]

While there is an important public interest in supporting innovation and R&D figured out by originator companies – which protection is ensured by intellectual property law – there is another public interest related to the early market entry of generics, because generic competition decreases prices significantly. Generic competition decreases both the expenses of social security and consumers, so, it increases both total- and consumers' welfare, which are mentioned among the main goals of antitrust and competition laws. Hence, the interplay of intellectual property law and competition law attracts a high level of attention in the pharmaceutical industry. Both competition law and IP law have the enhancement and maintenance of innovation as their aim, however, in case of IP law, these are the ultimate goals, while these objectives are only one between the several aims of competition law.[174]

Furthermore, whilst both sector specific regulation and intellectual property law is fragmented by national borders in the EU, Competition Law is highly harmonized, and, as such, protects the Internal Market. It has a key importance with regard to the fact that between the problems of the current regulatory system, the fragmented nature of Member State's intellectual property regimes has been identified as a factor hindering generic entry.[175]

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[173] Final Report – Pharmaceutical Sector Inquiry (1568). See also; Case C-457/10 P, AstraZeneca v. Commission. ECR [2012] 00000. , Case T-111/96, ITT Promedia NV v. Commission. ECR [1998] p. II.-2937 Pfizer v Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato) and Others, Case 7467/2012, Regional Administrative Court for Latium, see also D. Hull: Proceed with caution across the IP/Competition intersection. p.15, see also David Hull: The Application of EU Competition Law in the Pharmaceutical Industry, Journal of European Competition Law & Practice. Oct2011, Vol. 2 Issue 5, p. 480-488

[174] Principal objectives of competition law are the efficiency, furthermore total- and consumer welfare.(R. J. Van den Bergh – P. D. Camesasca: European Competition Law and Economics: A Comparative Perspective. Sweet & Maxwell, 2006., London, p. 5. see also R. Whish: Competition Law. Oxford University Press, 2009., Oxford, pp. 19-23., see also M. Motta: Competition Policy – Theory and Practice. Cabridge University Press, 2004, Cambridge, pp. 18-20.) Over and above, "competition law exists to protect competition in a free market economy" (A. JONES – B. Sufrin: EU Competition Law. Text, cases, and materials. Fourth Edition, Oxford University Press, Oxford, 2011 p. 1), Tóth Tihamér: Az Európai Unió versenyjoga. CompLex, Budapest, 2014. 59

[175] D. Hull: Proceed with caution across the IP/Competition intersection. Concurrences N 3-2009. p. 14

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The Pharmaceutical Sector Inquiry highlights that patent settlements often occur after the originator or the generic won the litigation in one Member State, and after, on this basis, the parties decide to go into a settlement against of wasting money, time and other resources by finishing litigation in other Member States. Furthermore, the system – i.e. the differences in Member States IP laws and in their application – also enables a high level of forum shopping. The choice of the court might enormously influence the outcome of the case,[176] and consequently, the parties' envy to settle.

Consequently, the establishment of the Unitary Patent and the Unified Patent Court System could reduce the discrepancies about multiple patent filing, eliminate parallel litigation, and, by consequence, enhance legal certainty.[177] On the other hand, practitioners often note the possibility that pharmaceutical industry is likely to opt out of the Unitary Patent and Unified Patent Court System[178] due to the discrepancies and the risk of losing the patent all over the EU.

The Pharmaceutical Sector Inquiry states that the maintenance and enhancement of R&D activity and innovation in the sector is only adequately ensured through IP rights.[179] IP law creates exclusive rights to ensure a fair return for the investment, i.e. it functions as a reward for the benefit given by the inventor's effort to the community. By providing this protection, IP rights promote innovation.

Petit highlights the nonsense of that the "point is often made that in sectors where IP rights are granted ex ante, there should be the blanket ex post antitrust immunity".[180] Competition law also promotes innovation, but in a totally different way. The ultimate aim of competition law is promoting competition on the market, which might easily contradict with the exclusive rights protected by IP law.

Nevertheless, competition serves the promotion of innovation. Without the competitive pressure, undertakings might easily lose the incentive to innovate.

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[176] Final Report on the Pharmaceutical Sector Inquiry. p. 264 (727)

[177] D. Hull: Proceed with caution across the IP/Competition intersection. p. 14

[178] Alex Wilson–David Lancaster: Unitary patent and Unified Patent Court – opportunities for the pharmaceutical industry (Available at: http://www.internationallawoffice.com/newsletters/detail.aspx?g=f7c34916-804e-4cad-846c-cc3a679f1ac3 Downloaded: 27 November 2018)

[179] Final Report on the Pharmaceutical Sector Inquiry. 19 (39)

[180] Nicolas Petit: A quick look into the past, present and the future of competition enforcement in the pharmaceutical sector. (Available at http://orbi.ulg.ac.be/handle/2268/142782 Downloaded: 19 August 2014. p. 1)

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Additionally, there are arguments that "IP [law] is inherently pro-competitive as it ensures the protection of differentiated, intangible business assets."[181] Therefore, both competition law and IP law have at least, partially overlapping aims. However, IP law and competition law use different tools and approaches to motivate innovation, which might lead to contradiction easily. There are also other views stating that fostering dynamic efficiency means in itself innovation.[182]

Through the Magil[183], IMS Health[184] and Microsoft[185] cases, competition law started to "regulate" the exercise of IP rights, which extent has been widened further in recent cases in the pharmaceutical industry involving misuse of the patent system as an abuse of dominant position and reverse payment agreements as anticompetitive agreements.[186]

Since IP law and competition law have partially the same objectives, but their approaches to achieve these objectives often contradict, important question is that to what extent might and should competition law "regulate" the use of IP rights.

Compared to the US, the European legal system seems less favourable for quick generic entry. However, even the US system is subject to several criticism, especially from the point of view of patent litigation. While there is almost nothing to lose for the generics if they get involved in a patent lawsuit, the originators can lose everything.[187] Originator companies are more and more often SMEs, and their size might also be a very important factor in deciding whether to settle a patent related dispute or not.

The OECD study found that hold up is less likely a problem in the US than in Europe, and damages for the harm caused by infringing generic entry are generally higher there. It also

[181] WIPO: IP and Competition Policy (Available at: http://www.wipo.int/ip-competition/en/ Downloaded: 27 November 2018)

[182] Nicolas Petit: A quick look into the past, present and the future of competition enforcement in the pharmaceutical sector. p. 1

[183] Joined cases C-241-2/91 P Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities. ECR [1995] I-00743

[184] Case C-418/01. IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG. ECR [2004] I-05039

[185] Case T-201/04 Microsoft Corp. v Commission of the European Communities. ECR [2007] II-03601

[186] S. Anderman – H. Schmidt: EU Competition Law and Intellectual Property Rights (2d ed). Oxford University Press, Oxford. 2011.p. 4. 87, Case C 457/10 P, AstraZeneca v. Commission. ECR [2012] 00000

[187] Michael Clancy – Damien Geradin – Andrew Lazerow: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law. Pp. 3-4.

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highlights that in the "US an originator does not bear as high the risk of irreparable harm and may therefore more effectively rely on the patent court system to enforce its patent rights."[188]

On the other hand, the Actavis judgment has recently confirmed that lack of full compensation is a relevant factor that must be taken into account in the assessment of patent settlement agreements.[189]

In the US, the special environment created by the Hatch-Waxman Act is often blamed as the only cause of pay-for-delay settlements. In the EU, other factors – like a lack of harmonized substantive- and procedural laws – might be identified as a cause of settlements. However, in the EU the fragmented patent system seems even more problematic than the lack of sufficient harmonization of sector specific regulation.

II.6. The nature of the competition between generics and originators

Normally, competition between originators and generics begins on the day of the patent expiry, but it might also start before the end of the protection of the originator's patent, if the generic finds a way of entering into the market without infringing the patent, or the patent is not valid, or it is annulled before the formal patent's expiry date.[190]

Considering that the generic entry inevitably results in a significant decline of the price and the market share, originator companies may seek to protect their products by various means from strategic patenting to patent litigation and interventions before national regulatory authorities.[191]

Patenting strategies used by pharmaceutical companies were subject to a criticism by the European Commission during the Pharmaceutical Sector Inquiry, but the Final Report adopted a balanced and holistic approach about the "tool-box" of patent clusters, defensive patenting, secondary patents, etc. [192]

[188] DAF/COMP/WD(2014)75 p 7.

[189] Federal Trade Commission v. Actavis, judgment of June 17, 2013, 570 US 756 (2013), p.10.

[190] Final Report on the Pharmaceutical Sector Inquiry. p. 181. (464)

[191] Idem. p. 181. (465)

[192] D. Hull: Proceed with caution across the IP/Competition intersection 14.

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The advocates of patenting strategies highlight the positive outcomes, such as "[e]ffective, business-focused patent strategies can accelerate innovation, improve patent quality, simplify communication, facilitate executive participation, and reduce costs."[193]

A wide range of patent strategies have been identified from life cycle management to patent related disputes/litigation/opposition and settlements.[194]

While the strictly understood patenting strategies – i.e. filing strategies – are used by originators, the disputes, litigation and opposition procedures might be in the "tool-box" of both generics and originators. Originators may start lawsuits against their generic competitors for infringements. Generics may start declaratory actions for non-infringement or invalidity actions, might counterclaim for invalidity in the infringement action initiated by the originator, or simply might oppose the patent before the relevant patent authority.

Taken into regard that IP litigation – and the whole IP system – is fragmented currently in Europe, this situation might give rise for different litigation strategies, torpedoes, forum shopping, etc. Such situation makes it very hard to find the real "objectives" behind a patent settlement, because it is not necessarily the patent's weakness which can lead to a settlement, but it might be a well-chosen court by the competitor. Even in case of a strong patent, different national courts might have totally different conclusions regarding to its validity, or infringement.

The granting and opposition system before the European Patent Office, and the establishment of the single Unitary Patent, and the specialized, Unified Patent Court system could solve this problem in the extent which is strictly the shortcoming of the current regulatory framework.[195] However, practitioners say that especially in case of the pharmaceutical industry, opting out seems a very likely possibility.

II.6.1. Patent settlements between originators and generics, reverse payments and pay-for-delay

Patent settlement agreements are commercial agreements to settle patent-related disputes, e.g. patent infringement or patent validity. They are concluded in the context of patent disputes,

[193] M. S. Adler: Strategic Patent Management after the Boom. In: Intellectual Property Strategies for the 21st century Corporation – A Shift in Strategic and Financial Managament. (Ed: L. G. Bryer – S. C. Lebson – M. D. Asbell) John Wiley & Sons, Inc., Hoboken, New Jersey. 2011. p. 93.

[194] For further details see Final Report on the Pharmaceutical Sector Inquiry p. 182 (466)

[195] D. Hull: Proceed with caution across the IP/Competition intersection. p. 14.

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opposition procedures or litigation where no final adjudication has been handed down. Although the content of individual settlements will vary on the basis of the circumstances of the individual case, the common aim of a settlement is to end the disagreement.[196]

Settlements are generally considered as efficient means to avoid litigation, and, by doing so, save both public and private resources, and, by providing certainty, increase business investment.[197] Therefore, settlements are mutually accepted – and often encouraged – taken into regard the legitimate interest in finding a mutually acceptable compromise, and in saving costs, time, the efforts of administrative bodies and courts, etc.

However, some patent settlements – especially in the pharmaceutical sector – gave rise to antitrust scrutiny during the last decade.

According to the general principle, public policy favours settlements as a peaceful way to resolve a dispute. Why are settlements in the pharmaceutical industry so special from a competition law point of view? Do anticompetitive settlement cases exist in other industries?

First of all, patent litigation settlements are not generally prohibited – not even in the pharmaceutical sector. A detailed analysis will be provided later about the categorization of the settlements, because it differs in the EU and in the US. Now it should only be noted that generally the problem arises when a value transfer occurs from the originator to the generic company – i.e. the patent holder pays to the alleged infringer. That's why such settlement are called reverse payment settlements, because the value goes the different direction than usually it happens in patent infringement settlements, where the alleged infringer pays to the patent holder. However, not even all settlements are prohibited which contain a reverse value transfer. If the value transfer is paid for real services, or if it does not exceed the amount of the (expectable) litigation costs, the settlement does not seem to cause problems for competition law.[198]

[196] European Commission - 4th Report on the Monitoring of Patent Settlements (period: January-December 2012) Published on 9 December 2013. p. (2)-(3)

[197] A. F. Abbott – S. T. Michel: The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation. *IDEA – The Intellectual Property Review*. (2005) Volume 46 – Number 1. p. 3-4.

[198] Will be discussed later.

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However, when a huge lump sum transferred from the originator to the generic, and the payment has no other aim but paying off the competitor from the market, the contract deserves the highest level of antitrust scrutiny. These last kind of reverse payment settlements seem to be more likely to occur in the pharmaceutical sector. However, the ubiquity of pay for delay settlements has been a hot topic in the American legal literature, and the question was the basis of an important debate also between the majority and dissent opinion in Actavis.[199] In Actavis, the US Supreme Court has defined the inherent problem in reverse payment settlements as follows:

Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement. And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws."[200]

The majority of the Supreme Court held that "[i]t may well be that Hatch-Waxman's unique regulatory framework, including the special advantage that the 180-day exclusivity period gives to first filers, does much to explain why in this context, but not others, the patentee's ordinary incentives to resist paying off challengers (i.e., the fear of provoking myriad other challengers) appear to be more frequently overcome"[201], three dissenting judges came to a totally different opinion.

In their opinion, they expressed that "[l]ike most litigation, patent litigation is settled all the time, and such settlements—which can include agreements that clearly violate antitrust law, such as licenses that fix prices, or agreements among competitors to divide territory—do not ordinarily subject the litigants to antitrust liability."[202] For the dissenting judges, even pay for delay settlements are acceptable, if they do not exceed the scope of the patent – it gives and almost unrebuttable presumption to legality of such settlements, and it is not coherent with the goals of the Hatch-Waxman Act, which also aims challenging weak patents. The dissenting

[199] Herbert Hovencamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 13.

[200] 570 U.S. 2013. Actavis p. 1.

[201] Idem. p. 17.

[202] 570 U.S. 2013. Actavis dissent p. 3.

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judges express that the majority suggestion that “[a]pparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation” is not correct. In their view, the term “reverse payment agreement" creates the impression that such settlements are unique, but it "simply highlights the fact that the party suing ends up paying." But this is not a rare situation in intellectual property litigation. "Whatever one might call them, such settlements—paying an alleged infringer to drop its invalidity claim—are a well-known feature of intellectual property litigation, and reflect an intuitive way to settle such disputes.[203] To support their opinion, they cite a case: Metro-Goldwyn Mayer, Inc. v. 007 Safety Prods., Inc. To the extent there are not scores and scores of these settlements to point to, this is because such settlements—outside the context of Hatch-Waxman—are private agreements that for obvious reasons are generally not appealed, nor publicly available.

The majority suggests that reverse-payment agreements are distinct because “a party with no claim for damages walks away with money simply so it will stay away from the patentee’s market.” The dissenting judges note that "[w]hile the alleged infringer may not be suing for the patent holder’s money, it is suing for the right to use and market the (intellectual) property, which is worth money." [204]

Finally, dissenting judges state that "the right to settle generally accompanies the right to litigate in the first place; no one contends that drivers in an automobile accident may not settle their competing claims merely because no statute grants them that authority."[205]

With regard to the cases cited by Chief Justice Roberts and the other dissenting judges, Hovenkamp notes that none of them involved patents. These judgements dealt with trademarks, or copyrights. Hovenkamp and Hemphill[206] highlight that the only pay-for-delay case outside of the scope of Hatch-Waxman Act is the dispute between Microsoft and Lindows.com.[207] In the framework of this case, Microsoft paid $ 20 million to Lindows.com. Microsoft alleged that "Lindows" was confusingly similar to “Windows”. Microsoft was ready to pay $ 20 million–

[203] 570 U.S. 2013. Actavis dissent p. 9-10.

[204] 570 U.S. 2013. Actavis dissent p. 10.

[205] 570 U.S. 2013. Actavis dissent p. 10.

[206] Herbert Hovencamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 14. Hemphill

[207] Herbert Hovencamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 15.

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when it faced with the possibility of losing the Windows trademark because of "the genuine issue of material fact whether the name Windows was generic and thus could not have trademark protection".[208] In that case, Microsoft, the holder of Windows trademark sued Lindows Inc., developer of Linux-based operating system. The defendant built the defence on providing general expressions with the word “window” to prove it was general. In the preliminary injunction procedure, the court held that Microsoft failed to prove that “Windows is a non-generic name and thus eligible for the protections of federal trademark law is not a conclusive finding that the trademark is invalid”. [209] The conclusion of the Microsoft Corp. v. Lindows.com Inc. case from the point of view of this research is that reverse payments are more likely to happen if the rightholder – in Microsoft case, the trademark owner, in pharma cases, the patent holder – assumes a real chance of losing the case, and losing an important, special IP right.

So, in the US, the question whether pay-for-delay settlements are unique features of the Hatch-Waxman Context, or they are quite common in other industries[210] has not received a finite answer yet. Hovenkamp differentiates between reverse payment settlements and pay-for delay settlements, by noting that the term "pay-for-delay” is not appropriate here.[211] The concept of pay-for-delay is often used for reverse payment settlements, giving the idea what is the general incentive of the companies behind these settlements. However, pay-for-delay is a broader concept: providing value transfer for delaying market entry cannot only happen in a form of a patent dispute and settlement. One such example could be the Fentanyl[212] case handled by the European Commission. In Fentanyl case, the agreement was identified as a co-promotion agreement, where the generic provided little or no co-promotion activities, and agreed not to enter the market for "a part of [the] cake".[213]

[208] Herbert Hovencamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 16

[209] http://www.finnegan.com/publications/updatenewsletters/pubdetail.aspx?pub=ff528e15-dce4-4976-b768-e37acf906593 (Downloaded: 24 October 2017)

[210] Herbert Hovencamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 14.

[211] Herbert Hovencamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. Footnote 57.

[212] Case AT – 39685 Fentanyl

[213] Case AT – 39685 Fentanyl para 339-340

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With regard to reverse payment settlements, Hovenkamp concludes that they are predominantly – if not exclusively –features of the Hatch-Waxman Context. On the other hand, pay-for-delay settlements seem to be also common features of the European pharmaceutical industry, against of the different regulatory and economic background.

Against this backdrop, it seems reasonable to analyse whether the basis of the pay-for-delay settlements is found in the special legal environment, or more in the special characteristics of the pharmaceutical industry.

By examining this question, Hovenkamp's proposition – that the term pay-for-delay is not appropriate here – might be a good starting point. It has already been examined above, that pay-for-delay (i.e. paying for delayed entry) is not necessarily happening in the framework of a patent settlements. What else can be the main difference between the terms "reverse payment" and "pay-for-delay"? The answer seems pretty obvious from the wording: a "reverse payment" is not necessarily given for delayed market entry – unlike in case of the problematic settlements in the pharmaceutical industry. A very good example is the Microsoft Corp. v. Lindows.com Inc. case: Microsoft, as the holder of Windows trademark paid the alleged infringer, so the direction of the payment was reverse, while there was no delayed market entry at all.

In the pharmaceutical sector, the problematic settlements are generally concluded between generic and originator companies. Of course, patent settlements are also possible between originator companies.[214] However, according to the Pharmaceutical Sector Inquiry this "originator-originator" settlements seem to be less problematic. In contrast to originator-generic settlements, their aim is more limiting or avoiding litigation costs and possible damages than gaining market exclusivity.[215] The originator-originator settlements normally occur in an early stage of the product's life-cycle, normally during the development-phase,[216] and they might be poor settlement agreements with no payment, settlements with payment or settlements with licensing.[217] Even the category with payment seems to cover "agreements whereby parties mutually agree to abandon all existing and future claims and grant each other immunity from

[214] Final Report on the Pharmaceutical Sector Inquiry p. 418.

[215] Idem. p. 419 (1225)

[216] Idem. (1228)

[217] Idem. pp. 422-423.

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suit, but where one of the parties agrees to pay a specific amount as cost compensation and/or damages, in full satisfaction of all existing and potential claims by the other party."[218]

Thus, these are the generic-originator settlements which give raise to an antitrust scrutiny. With regard to all the above discussed issues, we can also conclude that the problem in the problematic settlement cases is not reverse payment itself, but the fact that the reverse payment is paid for delayed market entry.

The Final Report on the Pharmaceutical Sector Inquiry also suggests that competition concerns are likely to arise when an agreement is designed to keep generics – i.e. competitors – out of the market, especially if the agreement limiting the generic entry also includes a value transfer from the originator to the generic.[219] These are the real "pay-for-delay" settlements: where the value transfer from the originator to the generic occurs to keep the generic out of the market.

It is also consistent with the US Supreme Court's findings in Actavis: not all reverse payments are unlawful, only large lump sums paid for delayed market entry; reverse payments up to the litigation costs and payments for fair costs of real services are accepted.

In case of the pharma sector, its characteristics raise another question: why are pay-for-delay settlements good for the parties, and wrong for the consumers and the social security?

Generally, the prices for innovative drugs are high, because of the "legal monopoly"[220] created by patent protection. However, in case of medicines it is not only the lack of competition which ensures the high prices, but the national pricing and reimbursement authorities – where applicable – have the tendency to accept a higher price for an innovative medicine. While the originator's product is patent-protected, the prices stay high, and when generic entry occurs, the drug prices start to fall down quickly. Given the very important business interest for keeping patent protection the longest possible, originator companies are likely to engage different kind of "evergreening" strategies. After the expiry of the basic active ingredient patent, originators are likely to file bundle of process patents or patents on the crystalline form, etc. These so-called secondary patents are likely to be challenged by generic competitors. By contrast, the

[218] Idem. (1236)

[219] Idem. p. 524 (1573)

[220] Not necessarily a monopoly in competition law terms.

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patents on the active ingredients – the primary patents – are between the strongest patents in the patent system.

So, if the generic is ready to enter to the market, it can get involved in patent litigation with the originator. Against of taking the risk of entering the market – which might result in further generic entry, or in a court decision ordering damages– it might prefer to settle, especially when the originator is ready to pay the amount – or even higher amount – what the generic expected from the market entry. So, the generic receives the expected – or even higher – profit from the originator without the risks of a market entry, while the originator – thanks to the prices kept high – earns much more than it would earn if the generic entry occurs. Their surplus is paid by the consumers and the social security. Consumers in such cases – due to the information asymmetry and the low price-sensitivity of the medicines – are not likely to do any steps.

The value transfer from the originator to the generic might happen in different forms, not only as a payment. In case of the more sophisticated forms, an in-depth analysis of the facts is necessary to decide whether the value is paid for real services, or its only aim is to pay off the competitor from the market.[221]

According to Hovenkamp's definition, a pay-for-delay settlement is an agreement which preserves the exclusive right created by the patent but requires the patentee to share the profits with the first generic filer.[222] His definition focuses on the first filer, because of the characteristics of the US system: as a consequence of the 180 day exclusivity provided by the Hatch-Waxman Act, it is most often the first filer generic with whom the brand companies settle. In Europe, being the first is not really important. Originators prefer to settle with all the generic challengers, how it is proven by the analysed cases.[223]

Of course, pay-for-delay settlements should be evaluated on their merits.[224] In Actavis, the US Supreme Court held that not even the settlements involving a reverse payment are generally problematic under antitrust rules, even reverse payment may be based on entirely legitimate reasons. From another point of view, in many European countries the originator might lose

[221] Will be discussed in details later.

[222] H. Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. *Minn. J. L. SCI. & TECH.* [Vol. 15:1] 2014. (Available at: http://ssrn.com/abstract=2286255 Downloaded: 19 August 2014. p. 8)

[223] Case AT.39226 – Lundbeck, Case AT.39612 – Perindopril (Servier)

[224] D. Hull: Proceed with caution across the IP/Competition intersection. p. 16.

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financially even if it finally wins the litigation if it will not be able to recover all the damages from the generic company. Therefore, the originator may prefer to pay the generic to stay off the market, which might be the same even in case of a strong patent, so, it is not necessarily the fear of invalidity which leads to a pay-for-delay settlement.[225]

II.7. Economic theory behind patent settlements

Pay-for-delay settlements have become a hot topic not only in the legal, but also in economic literature. Taking a look at the different economic theories behind reverse payment patent settlements can also enable us to understand the origin of the problem better, and also can help us to find the right way of thinking about pay-for-delay settlements.

In the US, Shapiro has handled reverse payment settlement as a special kind of patent settlements already in 2003. In his article, he highlights the main antitrust/competition law related question of such settlements: "Are consumers better or worse off under the settlement than they would have been from ongoing litigation?"[226] He uses the following example to demonstrate that consumers necessarily have to be worse off after a settlement: he supposes that an originator holding a patent with four years to run has sued its sole challenger for patent infringement. This situation occurs in the US, so Hatch-Waxman exclusivity applies. The parties settle their dispute, the settlement involves a large value transfer from the patent holder to the challenger/alleged infringer. In exchange, the generic agrees not to enter the market for three years, so he can enter one year before the original date of the patent expiry. Consequently, under the settlement, consumers enjoy competition for 25 percent of the remaining patent term. Whether the consumers are better or worse off in such situation, depends on the strength of the patent. However, if the originator believes that he has 90% chance to win the litigation, and 10% of losing it, it is unlikely that the originator will settle under these terms. So, in such a case, "if we credit the patent holder's own assessment of its chances in litigation, consumers are worse off under the settlement".[227] However, Shapiro also highlights that "[t]he mere presence of some payment from the patent holder to the challenger as part of a more complex commercial

[225] D. Hull: Proceed with caution across the IP/Competition intersection. p. 16. Yu – A. Chaterji : Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation.

[226] Carl Shapiro: Antitrust Analysis of Patent Settlements between Rivals. (Available at: http://faculty.haas.berkeley.edu/shapiro/settle_am.pdf Downloaded: 27 November 2018) p. 72.

[227] Idem. p. 72.

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transaction is not sufficient" [228] to be determined as a signal of the patent's weakness and consumer's harm.

The assessment of reverse payment settlements provided by Shapiro in 2003 seems to be analogous to the Supreme Court's findings in Actavis. Both highlights that large lump sum paid by the originator to the generic in the framework of patent litigation settlement raises antitrust scrutiny, but the mere presence of some payment in the framework of complex transactions is acceptable. However, the views discussed above should be complemented by some important remarks: not only cheap drug prices, but also the invention of new, innovative medicines serves consumer's welfare. In that regard, ensuring sufficient patent protection and a fair return on investment is inevitable. On the other hand, only patents providing something new and innovative deserve the reward of patent protection. Therefore, challenging weak patents serves public interest – how creators of the Hatch-Waxman Act recognized it a long time ago.

The study of Xiang Yu and Anjan Chatterji supports the pro-patent and pro-settlement side. They accept that reverse payment settlements "may appear to be collusive market division", but in their opinion, this phenomenon cannot be viewed in isolation. The authors recommend to examine the pay-for-delay settlements in their context in the pharmaceutical industry and especially in the context of the Hatch-Waxman Act. The critical point to understand is the asymmetric litigation risk between the originator and the generic. This asymmetric litigation risk can lead to a strange outcome, where the brand might prefer to settle even if he strongly relies on the patent validity.[229] The main point of their argument is that "reverse payment is consistent with risk aversion and that no collusion is necessary for a brand to make a rational decision to pay the generic."[230] They also highlight that the (indirect) costs of the patent litigation should also be taken into account, because uncertainty about patent litigation can lead to similar inefficiencies.[231] In such an innovative industry, "the inefficient levels of non-price competition will decrease market output for approximately one year after generic entry […] and a short-run decline in output will create a consumer loss of approximately $400,000 per

[228] Carl Shapiro: Antitrust Analysis of Patent Settlements between Rivals. p. 72

[229] Xiang Yu – Anjan Chatterji: Why Brand Pharmaceutical Companies -choose to Pay Generics in Settling Patent Disputes: A systematic Evaluation of Asymmetric Risks in Litigation. Northwestern Journal of Technology and Intellectual Property. Volume 10, Number 2. (November 2011) p. 19.

[230] Idem. p. 20.

[231] Idem. p. 32.

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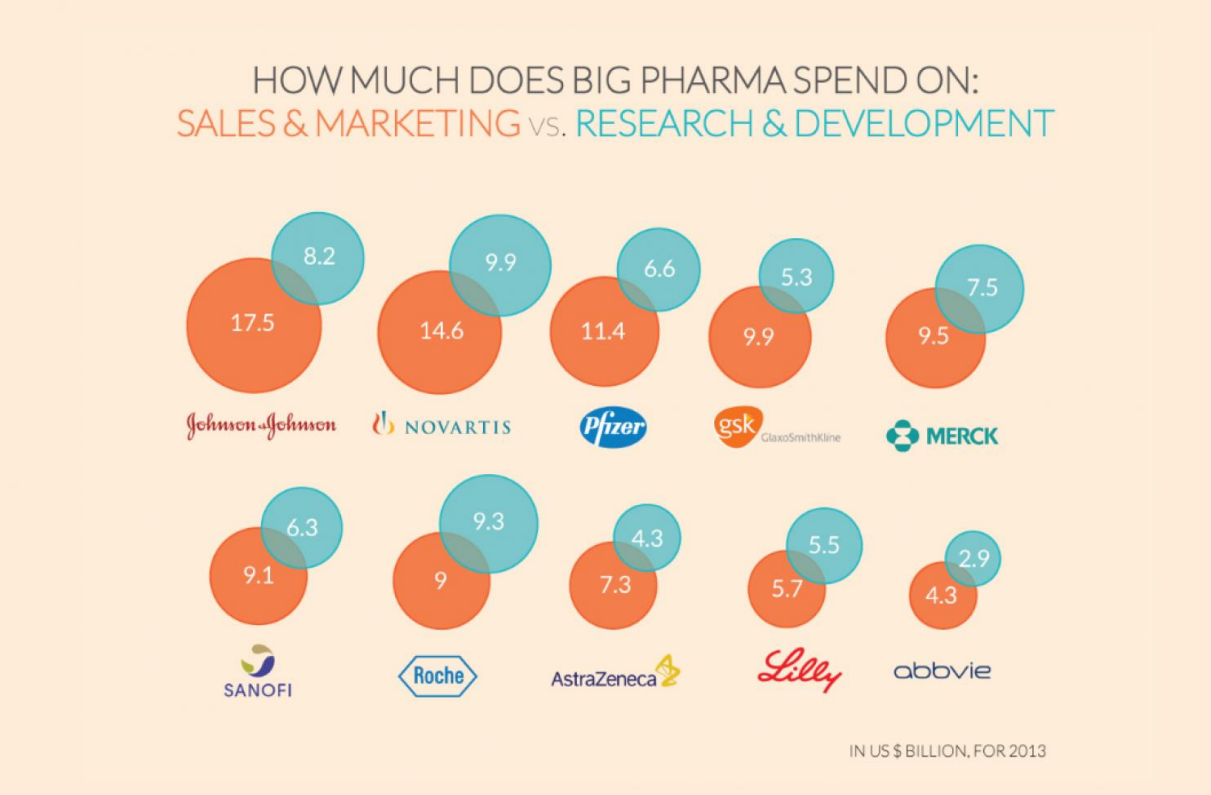
month for each drug facing generic entry"[232]. Consequently, they conclude that the FTC has incorrectly assessed that reverse payment settlements create negative consumer welfare effects in the short-run.[233]

In the recent past, big innovator companies have received criticism, because they spent more on marketing than on R&D. According to the most general complaints of the originators, early generic entry might have a detrimental effect on their incentive to innovate. Originators argue, as an effect of early generic entry, they cannot recover their investments, which might decrease innovation. The following figure provide us some interesting facts about marketing and R&D spending of the biggest innovative companies:



Source: Big Pharmaceutical Companies are Spending far more on Marketing than Research.[234]

Yu and Chatterji express their views that in the pharmaceutical industry non-price competition – particularly marketing – is indispensable to increase output and consumer welfare. An

[232]Xiang Yu – Anjan Chatterji: Impact of Reverse Exclusionary Settlements on Consumer Welfare: A Law and Economic Analysis. ABA Antitrust Health Care Chronicle. July, 2010. Vol. 23/No.4. p. 3.

[233] Idem. p. 10.

[234] Big Pharmaceutical Companies are Spending far more on Marketing than Research. (Available at: https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/ Downloaded: 22 February 2015)

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interesting point of their argument that pharmaceutical marketing increases awareness of commonly under-diagnosed diseases and promotes consumer consciousness for preventive care.[235]

Similarly to Shapiro, Elhauge and Krueger suppose that "[a] strong patent deters at-risk entry with certainty during litigation, even though there is a probability of patent loss. Therefore, for strong patents, the expected litigation exclusion period always exceeds the optimal patent exclusion period. In contrast, a weak patent produces at-risk entry with certainty during litigation, even though there is a probability of patent victory. Therefore, for weak patents, the optimal patent exclusion period always exceeds the expected litigation exclusion period."[236] Elhauge and Krueger created a mathematic model to prove that: "[i]f the reverse payment amount exceeds the patent holder's anticipated litigation costs, then we show that the settlement exclusion period necessarily exceeds the expected litigation exclusion period and the optimal patent exclusion period according to the patent holder's own estimate of the patent strength because otherwise the patent holder would be better off litigating. If the entrant's estimate of patent strength is below the patent holder's, then this settlement exclusion period must also exceed the entrant's estimate of the expected litigation exclusion period and optimal patent exclusion period. If the entrant's estimate of patent strength exceeds the patent holder's, then no reverse payment is necessary for settlement because without any reverse payment the parties could have agreed to a settlement exclusion period that is greater than the litigation exclusion period that the patent holder expects but less than what the entrant expects, which would make both better off than they have would been if they litigated." [237]

To determine whether a patent settlement is anticompetitive, they recommend two benchmarks: (i) ex post consumer welfare and (ii) optimal patent reward for ex ante innovation. Ex post consumer welfare is calculated assuming that the innovation has occurred.[238] The authors note that patent protection is often necessary to encourage innovation, but a well-designed patent

[235]Xiang Yu – Anjan Chatterji: Impact of Reverse Exclusionary Settlements on Consumer Welfare: A Law and Economic Analysis. ABA Antitrust Health Care Chronicle. July, 2010. Vol. 23/No.4. p. 2.

[236] Einer Elhauge – Alex Krueger: Solving the Patent Settlement Puzzle. Texas Law Review. Vol 91:283, 2012. p. 290.

[237] Idem. p. 291.

[238] Idem. p. 293.

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system "will maximize overall consumer welfare by giving patent holders the optimal fraction of ex post total surplus created by their innovations".[239]

The authors prove that both reducing the patent exclusion period below the optimal level and exceeding that optimal level will result in an inefficiently law amount of innovation.[240] Excessive patent period reduces the net reward for real innovation and leads to pseudo-innovation that leads to weaker patents.[241] Settlement with a reverse payment provide excessive exclusion periods,[242] therefore, they reduce optimal patent reward for ex ante innovation. In their views, a reverse payment settlement where the payment exceeds the patent holder's anticipated litigation costs, always harms both (i) ex post consumer welfare and (ii) ex ante innovation.

"The proof thus suggests that courts should presumptively condemn settlements when the reverse payment exceeds the patent holder's litigation costs, unless the defendants can rebut this presumption by showing either: (1) that the entrant would have entered at risk and is judgment proof to a sufficient effect to change the results or (2) that some other procompetitive justification exists and offsets the anticompetitive effect."

Wiliam Choi, Bruce Den Uyl and Mat Hughes start their analysis by pointing out the difference between typical settlements and the settlements between originators and generics: while in case of normal settlements, the alleged infringer pays to the patent holder, in case of pay-for delay settlements the value transfer happens in the reverse direction.[243] Both the innovative company and the generics are better off with reverse payment settlements, and consumers and the

[239] Einer Elhauge – Alex Krueger: Solving the Patent Settlement Puzzle. p. 293-294. See also Suzanne Scotchmer: Innovation and Incentives, 100–03 (2004); Partha Dasgupta – Joseph Stiglitz, Uncertainty, Industrial Structure, and the Speed of R&D, 11 BELL J. ECON. 1, 18 (1980); Pankaj Tandon, Rivalry and the Excessive Allocation of Resources to Research, 14 BELL J. ECON. 152, 152, 156–57 (1983). Such a system will also maximize overall *total* welfare because competing innovators will keep spending on *ex ante* investments until their investment costs equal their expected *ex post* profits, so that the profits to patent holders wash out *ex ante*.

[240] *"Exceeding the optimal patent exclusion period is likewise inefficient for several reasons. First, the economic literature shows that patent profits that exceed the optimal level result in excessive investments in innovation that reduce social welfare compared to the optimal investments in innovation.25 Second, excessive patent protection can produce a net reduction in innovation by precluding subsequent innovations by others.26 Third, settlements that overreward the patent holder with a longer exclusion period than it deserves reduce the net reward for true innovation by increasing the reward more for less-deserving patents than for more deserving patents."* Einer Elhauge – Alex Krueger: Solving the Patent Settlement Puzzle. p. 294.

[241] Einer Elhauge – Alex Krueger: Solving the Patent Settlement Puzzle. p. 294.

[242] Idem. p. 295.

[243] See also Hemphill.

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reimbursement systems pay the costs of the companies' shared "monopoly".[244] This argument is analogous to the Commission's findings in the major European pay-for-delay cases[245].

The authors have built an economic model to analyze the brand company's willingness to pay, and the generic's willingness to accept the payment. Their model explains well why the willingness to pay and delay entry falls down if the originator is more confident in winning the lawsuit. If "monopoly" profits were higher, more pessimistic the originator is, bigger the amount of the payment.[246]

The originator earns much higher "monopoly" profit without generic entry. Even if the generic entry occurs, the originator can enjoy a higher profit for a while, that's why the discounted profit of the originator is still much higher than the discounted profit of the generic.[247] The authors assume that the loser pays the other side's legal fees, unlike in the US where both party pay his own fees. So they calculate the worst outcome for the originator by reducing the litigation costs from the discounted monopoly profit of the originator.[248]

On the other hand, to understand the generic's willingness to accept the payment, the authors assume a much lower discounted profit on the generic's side – which is further decreased by the possibly lost litigation's costs. Actually, the settlement range – the gap between the reservation price of the brand and the price required by the generic – is generally very wide.[249]

Furthermore, in reality it can also happen that the generic earns more by a settlement than its expected profit from market entry might be. In that case, it is still not more than the reservation price of the brand.[250]

[244] Wiliam Choi–Bruce Den Uyl–Mat Hughes: Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and others. Journal of European Competition Law and Practice, 2014., Vol. 5, No. 1. p. 44.

[245] AT.39612 – Perindopril (Servier), AT.39226 – Lundbeck

[246] Wiliam Choi–Bruce Den Uyl–Mat Hughes: Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and others. p. 47.

[247] Idem. p. 47-48.

[248] Idem. 1. p. 47.

[249] Idem. p. 48.

[250] AT.39612 – Perindopril (Servier), AT.39226 – Lundbeck

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II.8. Pros and cons of patent settlements

In 2009, the OECD organized a Roundtable Proceeding[251] about the generic pharmaceuticals, which highlights the importance of finding the right balance between patent protection and competition policy: "consumers benefit not just when existing drugs sell at lower prices, but also when new and more effective drugs reach the market over time."[252]

To maximize consumer welfare, the most important is to find the optimal length of patent protection. If the patent protection is shorter than the optimal period, it does not ensure the fair return on investment, consequently, will result in an inefficiently poor innovation. If this period is too long, the originator will focus on protecting the "monopoly" profit i.e. engaging in patent strategies against of investing in R&D, the result is also a lower level of innovation.

The economic literature identifies three potential problems related to too long patent protection: "First, […] patent profits that exceed the optimal level result in excessive investments in innovation that reduce social welfare compared to the optimal investments in innovation. Second, excessive patent protection can produce a net reduction in innovation by precluding subsequent innovations by others. Third, settlements that overreward the patent holder with a longer exclusion period than it deserves reduce the net reward for true innovation by increasing the reward more for less-deserving patents than for more deserving patents".[253]

In an optimal case, the monopoly profit ensured by patents does not refer to market power, but to the high fixed cost of the R&D. The OECD Roundtable identifies reverse payments as one of the "most frequently used strategies to reduce competition on the pharmaceutical market"[254]

In order to examine the possible effects on consumer welfare, it seems reasonable to differentiate between two potential types of consumers' benefits. The categorization examines the question from the point of view of reverse payment patent settlement agreements: 1) ex post

[251] DAF/COMP(2009)39 OECD. Roundtable on Generic Pharmaceuticals.

[252] Idem. p. 9.

[253] Einer Elhauge & Alex Krueger: Solving the Patent Settlement Puzzle. p. 294.

[254] DAF/COMP(2009)39. p. 10.

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consumer welfare presupposes that the innovation has already occurred, 2) ex ante consumers' welfare examines the question from the point of view of future innovation.[255]

If patent settlements between generics and originators create a longer than optimal patent protection period, it harms both the ex ante and the ex post consumer welfare. In case of ex post consumer welfare, the problem is clear: without generic entry, the prices stay high. In case of ex ante consumer welfare, a too long patent protection undermines innovation.

Both in the US and in the EU, the problematic settlements concern the so called secondary patents, not the basic active ingredient patent. If we presume that the current patent protection system is well designed and works properly, patents shall ensure the fair return on investment by providing the optimal length of protection. This thesis does not aim to examine the underlying policy of the different relevant patent systems, so, here this presumption shall be accepted. In Europe, the specificities of the pharmaceutical sector are also taken into account by determining the length of the patent protection. In some cases, the marketing authorization arrives much later than the starting date of the patent protection. Supplementary protection certificate (SPC) is designed to give up to 5 years additional patent protection in such cases.[256] The companies can also gain half year additional protection by improving medicines for paediatric use.[257]

Nevertheless, the originator companies try to expand the patent protection in several ways – different "evergreening" strategies have been identified by the Pharmaceutical Sector Inquiry from the classic filing strategies through litigation to settlements. On the other hands, the generics try to enter to the market, and they also create their own business strategies, which is a completely normal market behaviour. In a competitive market, these concurring interests and efforts will lead to a balance, which is the desirable result also from the point of view of ex ante and ex post consumers' welfare.

In order to achieve this desirable outcome a well-designed legal environment is necessary, which will promote generic challenges. In the US, the main aim of Hatch-Waxman Act was to

[255] Einer Elhauge & Alex Krueger: Solving the Patent Settlement Puzzle. Texas Law Review [Vol. 91:283, 2012] p. 293.

[256] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products

[257] Regulation (EC) No 1901/2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

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rebalance the power play by incentivizing generic challenges. Generally, in the EU the legal environment seems less attractive for generic challengers than in the US.

The European Commission recommended in its Preliminary Report on the Pharmaceutical Sector Inquiry to delete secondary patent protection with regard to the high level of invalidation.[258] This approach received strong criticism, and finally the Commission expressed a more patient approach towards secondary patents in the Final Report. Even without taking into account the arguments of the advocates of secondary patents, it is not sure that the competition law enforcer expert body should make such a serious decision related to the patent system.

Branded drug makers argue that a relaxed approach to reverse payment settlements is desirable because higher profits promote R&D which leads to new drugs. In defence of settlements, it should be pointed out that often the branded firm wins, which results in generic entry at patent expiration.[259] Even some US District Court and Supreme Court judges stood up for the settlements, explaining their benefits and usual nature: settlements are usual and normal way to solve patent related disputes,[260] which are generally costly and time consuming procedures.

On the other hand, cheaper generic drugs have saved purchasers billions of dollars per year. In the US, according to an industry founded research the savings generated by generic drug use were more than $1.2 trillion during the 10-year period 2003 through 2012.[261]

In the EU, the Pharmaceutical Sector Inquiry found that in markets where generic medicines become available, average savings to the health system are almost 20% one year after the first generic entry, and about 25% after two years. However, this numbers describe the EU average, there are considerable differences, in the EU Member States and also across medicines.[262] This explains why regulators and agencies promote generic entry both in the US and in the EU.

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[258] Nicolas Petit: The outcome of the EC pharmaceutical sector inquiry – „Barka at the Moon". Concurrences. N. 3-2009.

[259] C. S. Hemphill – B. N. Sampat: When Do Generics Challenge Drug Patents? p 1386.

[260] Roberts, C. J., dissenting 570 U. S.(2013) Ftc *v.* Actavis, Inc. Supreme Court of the United States No. 12-416 Chief Justice Roberts, with whom Justice Scalia and Justice Thomas join, dissenting

[261] Generic Drug Saving sin the US. Fifth Annual Edition. 2013. (Available at: http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf Downloaded: 19 August 2014.)

[262] Final report on the Pharmaceutical Sector Inquiry. p. 9.

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In a typical "reverse payment" or "pay-for-delay settlement", an originator will pay to the potential generic entrant in exchange for delaying market entry. The term payment does not mean necessarily cash payment; the main element which makes it illegal is the harm caused to the consumers.[263] The harm is caused by the fact that in the absence of the agreement, the generic would be expected to enter the market earlier.

According to the OECD Roundtable "[t]he consumer and social welfare losses can be many multiples of the original payment from the branded firm to the generic firm. That is because there is a significant gap between what the branded firm will lose from generic competition and what the generic firm will gain, and therefore a relatively modest payment can preserve a very substantial profit margin."[264]

However, the phenomenon of reverse payments cannot be viewed in isolation. To understand the deeper legal and economic underpinnings of these settlements and associated reverse payments, it is important to examine the interaction between antitrust law and the regulatory environment in the particular context of the pharmaceutical industry.

In the US, a very special regulatory background is given by the Hatch-Waxman Act. In order to understand reverse payments, it is crucial to understand the asymmetric risks the brand and the generic face in patent litigation: while for the generic company there is almost nothing to lose, the originator can lose the patent on a blockbuster drug.[265] First instance court procedures and appeals might lead to totally different outcomes. These procedures are also lengthy. The originator might lose the patent – and so the "monopoly" profit – on a blockbuster in first instance, and the patent under appeal might be found valid. In such case, there is no real way to recover all the damages.

In the US, the asymmetric risk is strongly linked to the Hatch-Waxman Act. Under the Hatch-Waxman Act, a typical generic challenge works as follows: before the patent expiry, the generic files an ANDA and a Paragraph IV certification challenging the validity of the patent or

[263] Pallavi Guniganti: Wright: reverse payments need not be cash, but must harm consumers to be illegal. Available at: http://globalcompetitionreview.com/usa/article/37040/wright-reverse-payments-need-not-cash-harm-consumers-illegal/?utm_medium=email&utm_source=Law+Business+Research&utm_campaign=4845114_GCR+USA+Headlines&dm_i=1KSF,2VUII,9GQ3S4,AFW7S,1 Downloaded: 23 March 2015

[264] DAF/COMP(2009)39 OECD Roundtable on Generic Pharmaceuticals p. 10.

[265] X. Yu – A. Chatterji : Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation. p. 19.

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claiming non-infringement.[266] The patent holder has up to forty-five days from the date it receives notice from the ANDA filer to file a patent infringement action.[267] If he files suit, the FDA approval of the ANDA is stayed for thirty months unless the patent is ruled invalid,[268] and such a stay can extend to several years.[269] At the end of the 30 months stay, the FDA may grant the approval even if final judgment has not been reached. If it happens, the generic manufacturer may choose to launch at risk. In light of the pending patent litigation and the high economic stakes involved, the brand may settle with the generic challenger.[270] Sometimes the settlement provides payment or other form of value transfer from the originator to the generic, the alleged patent infringer, to delay the generic's entry into the market.

In the EU, the biggest problem seems to be the lack of unified, uniform patent litigation system, harmonized patent rules and better sectoral regulation. However, the Unitary Patent Package and the Unified Patent Court system could – at least partially – solve this problem, experts express their concerns that the pharmaceutical industry will potentially opt out from the system.[271] An EU wide judgement and so the possibility of losing the patent in all jurisdictions is very risky.

Currently, the lack of harmonisation – and the lack of transparency – creates excellent opportunities for forum shopping and different kind of patenting strategies, and the price is paid – indirectly – by the consumers. These together with the specificities of the pharmaceutical sector – the high fixed costs for R&D in the innovation phase and the very law marginal costs of further production might lead to market failures. Therefore, whether and to what extent do legislative enactments shape the scope of antitrust liability is not purely a matter of antitrust law. [272]

After analysing the two jurisdictions, two main common points might be identified: pharmaceutical patent settlements raise antitrust scrutiny only if (i) the settlement causes

[266] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[267] § 355(c)(3)(C).

[268] § 355(j)(5)(D)(i)(I)(BB)

[269] § 355(j)(5)(F)(ii). See generally C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553 (2006).

[270] X. Yu – A. Chatterji : Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation p. 21.

[271] Patricia Cappuyns

[272] C. S. Hemphill: Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem. p 103.

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generic delay, (ii) and there is an unjustified value transfer/compensation from the originator to the generic. Neither pay-for-delay settlements are not necessarily illegal. For example, paying the amount of the litigation expenses seems fully legal in both jurisdictions. There are other economic studies arguing that even a larger payment is legal, with regard to the asymmetric risks.[273]

Others argue against pay-for-delay settlements by referring to consumer welfare: "The size of the payment to the generic is an indeterminate rent. The arrangement is thus similar to a situation in which two firms cartelize their market but one of them shuts down its plant altogether while the other compensates it out of its monopoly profits. consumer welfare remains the same as it would be under continued monopoly production by a single firm". [274]

The main question behind pay-for-delay settlements seems refer to a policy choice: between patent policy and competition policy. Court cases might reach different outcomes depending on which policy is preferred and/or used by the judges as starting point. If the judges put an emphasis on innovation and on settling disputes in a friendly way, patent policy is favoured. If consumer welfare is considered, competition policy would be used as a starting point.

In Actavis, the Supreme Court unanimously agreed that "consumer welfare" rather than total welfare is the goal of antitrust enforcement.[275] However, the enhancement of innovation, and the importance of finding new treatments have at least the same importance for consumer welfare as low drug prices. Now pay-for-delay agreements are subject to a full rule of reason analysis in the US.

II.9. Attempts to regulate pay-for-delay settlements

In order to decide on the legality and usefulness of reverse payment patent settlement agreements a political choice between patent and antitrust policy is necessary. Consequently, some authors[276] recommend a legislative act as response to such settlements.

[273] X. Yu – A. Chatterji: Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation.

[274] Herbert Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision p. 8.

[275] Idem. p. 7. see also FTC v. Actavis. Tóth Tihamér: Az Európai Unió versenyjoga. p. 59.

[276] C. S. Hemphill: Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem and T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice.

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Dolin highlights that in the US the legislative branch has been particularly unhappy with reverse payment agreements and the judicial tolerance to thereof.[277] The first effort to regulate the issue occured in 2002 when the Senate unanimously passed the Drug Competition Act of 2001, which required such agreements to be disclosed to both the FTC and the DOJ.[278] A version of this bill was incorporated into the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

In the US Congress, there have already been hot debates about the topic, and several attempts to regulate pay-for-delay settlements have already been introduced which go much further.[279]

The first attempt was introduced on January 17, 2007, by Senator Kohl. It was titled the "Preserve Access to Affordable Generics Act". This Act would ban settlements which include a payment from the innovator to the generic to delay entry.[280] This bill never received a vote by the full Senate, Senator Kohl reintroduced it in substantially the same form on February 3, 2009.[281]

The other attempt was introduced by Representative Bobby Rush in the House of Representatives on March 25, 2009, titled the "Protecting Consumer Access to Generic Drugs Act.[282] It includes a per se prohibition of reverse payment settlements. This draft is considered to be influenced by FTC Chairman Leibowitz.[283] Also in the 110th Congress, Henry Waxman introduced a separate, nearly identical bill.[284]

None of the abovementioned attempts have succeeded. The drafts proposed either ban reverse payment settlements, or create the presumption of per se illegality, "leaving little room for a

[277] G. Dolin: Reverse Settlements as Patent Invalidity Signals. *Harvard Journal of Law & Technology* Volume 24, Number 2 Spring 2011. p. 305.

[278] Idem. p. 305

[279] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 441.

[280] Protecting Consumer Access to Generic Drugs Act, HR 1706 111th Cong. (2009) §316 2 (a)(11)

[281] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 442.

[282] Protecting Consumer Access to Generic Drugs Act, HR 1706 111th Cong. (2009)

[283] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 442.

[284] G. Dolin: Reverse Settlements as Patent Invalidity Signals. p. 307.

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case-by-case analysis of the economic reality of the transaction"[285] – which approach have been adopted by the Supreme Court in Actavis.

On September 9, 2015, US Senators reintroduced the "Preserve Access to Affordable Generic Act in the Senate. This was the first proposal offered post-Actavis, and "it surprised many in the pharmaceutical industry who had thought that legislative efforts would cease in light of the Supreme Court providing its Actavis "rule-of-reason" framework for antitrust analysis of patent settlements". The proposed legislation would modify the standard of review for FTC enforcement actions against pharmaceutical reverse payment patent settlements by presuming anti-competitive effects and "placing the burden of proof on defendants where the generic has received "anything of value" from the brand". This "presumption" is contrary to the Supreme Court's judgement in Actavis. The bill is presently pending in the Senate Judiciary Committee, its future remains unclear.[286] The Act – if accepted – would make pay-for-delay contracts illegal, including monetary payments and any form of benefit to generic manufacturers.[287]

In the EU, one of the major improvements has been that the new Technology Transfer Block Exception Regulation (TTBER)[288] and the accompanying Technology Transfer Guidelines[289] deal with patent settlements. Patent Settlements are subject to more detailed and specialised regulation in the new Guidelines comparing to the old one.[290] Furthermore, the TTBER and the Guidelines seem to be affected by the conclusions of the Pharmaceutical Sector Inquiry and of the Reports on the monitoring process. The main topics discussed by the Guidelines overlap with the typical issues identified by the Pharmaceutical Sector Inquiry. The Guidelines discuss the following potentially problematic points: cross-licensing, pay-for delay and non-challenge clauses.

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[285] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 442.

[286] https://www.wsgr.com/publications/PDFSearch/law360-1015-3.pdf

[287] https://www.pharmacytimes.com/publications/issue/2017/february2017/will-us-senate-address-payfordelay-agreements

[288] Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements Text with EEA relevance OJ L 93, 28.3.2014, p. 17–23.

[289] Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements OJ C 89, 28.3.2014, p. 3–50. (New Guidelines)

[290] New Guidelines 4.3, Commission Notice — Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (Text with EEA relevance) OJ C 101, 27.4.2004, p. 2–42. (Old Guidelines) 4.

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The Guidelines declare the general rule of legality of patent settlements which are "in principle a legitimate way to find a mutually acceptable compromise to a bona fide legal disagreement."[291]

Concerning licensing agreements – including cross licensing – the Guidelines declare that in the context of settlement agreements they are generally not as such restrictive of competition since it allows the parties to exploit their technologies after the agreement is concluded.[292] However, the individual terms and conditions of settlement agreements may be caught by Article 101(1).[293]

The Guidelines state that pay-for-delay agreements often do not involve the transfer of technology rights, but are based on a value transfer from one party in return for a limitation on the entry and/or expansion on the market of the other party and may be caught by Article 101(1) of the TFEU.[294]

If a settlement agreement also includes a licensing of the technology rights concerned by the underlying dispute, and that agreement leads to a delayed or otherwise limited ability for the licensee to launch the product on any of the markets concerned, the agreement may be caught by Article 101(1) and would then need to be assessed in particular in the light of Articles 4(1)(c) and 4(1)(d) of the TTBER. If the parties to such a settlement agreement are actual or potential competitors and there was a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation/market sharing.[295]

Considering the third potential problematic point, the non-challenge-clauses, the Guidelines expresses that they are generally considered to fall outside Article 101(1) of the Treaty. The Guidelines find it inherent in such agreements that the parties agree not to challenge ex post the intellectual property rights which were the centre of the dispute. It adds that "[i]ndeed, the very purpose of the agreement is to settle existing disputes and/or to avoid future disputes."[296] However, non-challenge clauses in settlement agreements can under specific circumstances be anti-competitive. For instance, it is the situation when the intellectual property right was granted

[291] New Guidelines 235.

[292] Idem. 236.

[293] Idem.237.

[294] Idem. 238.

[295] Idem. 239.

[296] Idem. 242.

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following the provision of incorrect or misleading information.[297] Scrutiny of such clauses may also be necessary if the licensor, besides licensing the technology rights, induces, financially or otherwise, the licensee to agree not to challenge the validity of the technology rights or if the technology rights are a necessary input for the licensee's production.[298]

In case of non-challenge clauses, the Guidelines express a strict approach if the underlying IP rights were granted on the basis of incorrect or misleading information. However, the Guidelines at that point seen to be affected by AstraZeneca[299], it might be a problematic issue in the future to define in which case IP rights were granted "following the provision of incorrect or misleading information". It should be highlighted that under the scope of the patent test in the US, it has also had a high importance if the patent was obtained by fraud or sham litigation.

The problem with the Guidelines is the lack of real guidance on the competition law analysis of various practices.

II.10. Findings related to the regulatory questions

The first two research questions I posed were the following: (i) to what extent does the regulatory environment influence reverse payment settlements, and (ii) what is the role of competition law in handling reverse payment settlements.

Different root causes have been found in the US and in the EU behind reverse payment settlement. The whole regulatory background of these two jurisdictions seem to be different. The features of the settlements are also different. While a sector specific regulation, the Hatch-Waxman Act has been identified as the background of reverse payment settlements in the US, in the EU pay-for-delay settlements seem to originate more from the shortcomings of the fragmented patent- and patent litigation system. The lack of sufficient harmonization in the sectoral regulation and the fragmented pricing and reimbursement system also affect the sector, and generics complain about the non-compliance with the Transparency Directive.

On the other hand, the patent system does not apply only to pharmaceuticals, neither creates such a special regulatory framework like Hatch-Waxman Act in the US. Nevertheless, pay for delay settlements are industry specific features also in the EU. However, the potential

[297] See also Case C-457/10 P, AstraZeneca v. Commission and US scope of the patent cases

[298] New Guidelines. 243.

[299] Case C-457/10 P, AstraZeneca v. Commission.

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cumulated effects of the sector specific regulation, of the special characteristics of the sector, and of the patent system should not be excluded.

It is not disputed that pay-for-delay settlements are – at least partially – the shortcomings of the regulatory framework, however, this fact does not mean that they would be beyond the scope of competition/antitrust law. I believe that regulatory problems shall be solved by adopting better regulation, and both in the US and in the EU we can find attempts to find a solution to this issue. However, the ECJ declared in AstraZeneca that competition law should solve the discrepancies created by the shortcomings of other regulations,[300] and the US courts which applied the scope of the patent test reached the same conclusion. On the other hand, there are arguments that „[i]f […] the system is inadequate, the better solution would seem to be to introduce improvements to that system, rather than have ad hoc intervention by competition authorities" [301]

However, the problem – and the market failure – in reverse payment cases is more a behavioural than a structural one, so, it cannot be handled by adopting better regulations only. Against of the totally different regulatory and economic background – more or less – the same kind of agreements developed both in the EU and in the US.

[300] Case C-457/10 P, AstraZeneca v. Commission

[301] David H. Hull: The Application of EU Competition Law in the Pharmaceutical Industry

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III. Patent settlements in the US

After reviewing the main characteristics of the oharmaceutical market and analysing the regulatory backgrounds, it is time to start to investigate real pharmaceutical patent settlements. The recent cases in the EU and in the US are going to be analysed intwo different chapters due to their specificities and volume. This chapter focuses on the US cases. The US is analysed first, because also chronologically, antitrust investigations of pay-for-delay settlements started there – that way referring to the US cases – as it has been done in certain EU cases – is more reasonable and understandable.

In the US, pay-for-delay agreements have been subject to hot debates not only in legal and economic literature but also at administrative, legislative, and judiciary level. Since reverse payment settlements appeared, they have been subject to an antitrust scrutiny.

Professor Hemphill highlights that the US settlements occurred in two distinct waves: the first wave occurred between 1993 and 2000. The FTC's antitrust activity reduced their number, but after 2005 – as an effect of court rulings adverse to antitrust liability – a new wave of settlements started.[302] Hemphill also presents that the settlements of the two waves are different: after the pretty straightforward and explicit settlements of the first wave, the settlements of the second wave are more complex and subtle.[303]

III.1. Types of reverse payment settlements in the US

Although US and EU patent settlements show many differences, similarities might also be discovered. First of all, similarly to Europe, brand-name and generic pharmaceutical companies sometimes prefer to settle their litigation before the final court decision. The FTC's Staff Study mentions as a typically lawful example when the generic might enter the market prior to the expiry of the originator's patent but later than it was seeking to enter throughout litigation.[304]

Also similarly to Europe, the most important question is whether the agreement causes delayed generic entry, and the generic is compensated by the originator for the delay. The FTC compare such agreements to general market sharing agreements: "The essence […] is that the [innovator]

[302] C. S. Hemphill: Drug Patent Settlements between rivals: A Survey. Working paper available at ssrn.com/abstract=969492 Downloaded: 19 August 2014. p 4.

[303] Idem. pp 1-49.

[304] FTC Staff Sudy January 2010: Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. p. 3.

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paid the generics not to compete for a period of time, which could be per se illegal in other contexts. Absent a legitimate business justification, naked agreements between competitors to allocate business by customers or geographic areas are routinely condemned out of hand."[305]

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), generic and innovator pharmaceutical companies who enter into a settlement have to file these agreements to the FTC and the Department of Justice no later than ten business days after the agreements' execution.[306]

As result of pharmaceutical Agreement Filings, a total of 218 agreements were filed to the FTC between 2004-2009. 152 of them did not include any compensation. 66 agreements included compensation from the brand-name company to the generic. Generally, they delayed generic entry 17 month longer than agreements without payment.[307]

Taken into regard the importance of the Hatch-Waxman rules – i.e. the 180 days marketing exclusivity of the first filer generic – the FTC also examined how many percent of the reverse payment settlement happened between the brand-name company and the first generic. The study found it was 77%, 51 agreements.[308]

The FTC highlights that the compensation for the generic not only means payment: a wide variety of techniques were identified.

Professor Hemphill divided these types of compensation into four broad categories as follows: i) cash and overpayment, ii) preserving exclusivity iii) underpricing and iv) additional channels.[309]

The first category does not need too much explanation, in case of overpayment, the generic provides some additional service to the innovator, who pays for both the settlement – delayed entry – and this service. The third type is its reverse: the innovator provides something of value

[305] Opinion of the Commission In the Matter of Schering-Plough Corporation, et al. Docket No. 9297. http://www.ftc.gov/sites/default/files/documents/cases/2003/12/031218commissionopinion.pdf p. 12.

[306] Medicare Prescription Drug, Improvement, and Modernization Act of 2003. PUBLIC LAW 108–173—DEC. 8, 2003. 117 STAT. 2066 108th Congress. See also Pharmaceutical Agreement Filing Requirements, available at http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/pharmaceutical_agreement_filing_requirements.pdf Downloaded: 19 August 2014.

[307] FTC Staff Sudy January 2010: Pay-for-Delay: How Drog Company Pay-Offs Cost Consumers Billions. p. 4.

[308] Idem. p. 4.

[309] C. S. Hemphill: Drug Patent Settlements Between Rivals: A Survey.

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– i.e. a licence to the generic. The fourth category can cover several of different agreements, i.e., even a settlement of an unrelated dispute between the parties.[310]

The third category – which is quite unlikely to happen in Europe – needs probably the most explication. This type is related to the Hatch-Waxman Act exclusivity: in many settlements, the generic retains eligibility for the 180 day exclusivity period, by agreeing to enter at a particular future date that is at least 180 days prior to patent expiry.[311] It also explains why most of the settlements in the US occur between the innovator and the first filer generic.

Another interesting type of settlements is identified by the FTC Staff Study: it is related to the so-called "authorized generic". The Hatch-Waxman Act, which gives a 180 days long exclusivity for the first generic does not protect from the competition of the "authorized generic". "Authorized generics" market brand-name pharmaceutical products as generic, i.e. they become the retailer of the innovators own drug – often the brand distribute the authorized generic product – creating a duopoly. By doing so, they share "duopoly profit" and undermine the generics' expected profit. According to the FTC Staff Study, about 25% of patent settlement agreements from the period 2004-2008 with first-filer generics involved an explicit agreement by the brand not to launch an authorized generic to compete against the first filer, combined with an agreement by the first-filer generic to defer entry.[312]

III.2. The approach of the FTC and the DOJ

Since their emergence, the FTC has closely monitored the legality of pay-for-delay settlement agreements.[313] An FTC Staff Study from January 2010 highlighted that FTC's investigations and enforcement actions against reverse payment agreements in the pharmaceutical sector deterred their use form April 1999 through 2004.[314] Court precedents before 2004 also helped the FTC: in 2003, an appellate court held that pay-for-delay agreements are per se illegal.[315]

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[310] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice.

[311] C. S. Hemphill: Drug Patent Settlements Between Rivals: A Survey. p 16.

[312] Authorized Generics: An Interim Report, Fed. Trade Comm'n at 3 (June 2009); available at http://emmanuelcombe.org/generic.pdf

[313] T. A. Cook, Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 437.

[314] FTC Staff Sudy January 2010: Pay-for-Delay: How Drog Company Pay-Offs Cost Consumers Billions. P. 1.

[315] In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003)

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The FTC Staff Study also highlights, that later, in 2005, a number of appellate court decisions[316] found that pay-for-delay agreements are not against antitrust law, and upheld them. Following these decisions, the number of reverse payment settlement agreements emerged again.[317]

According to the analysis of the FTC, patent settlement agreements including a reverse payment generally delay generic entry with 17 month comparing to such agreement without a payment. By doing so, pay-for-delay agreements cause a loss of $3,5 billion per year for the American consumers.[318]

In 2002, the FTC issued a study showing that generics prevailed in 73% of the patent litigation ultimately resolved by a court decision between 1992 and June 2002.[319]

The above discussed studies and the high number of proceedings initiated by the FTC show that the authority has always handled revers payment settlement agreements with suspicion. FTC's approach towards such settlements have always been on the stricter end of the scale, from per se illegality to "quick look" rule of reason analysis.

On the other hand, the other competition authority, the US Department of Justice (DOJ) did not always share the opinion of the FTC. In the beginning, the DOJ stood up against the per se invalidity of reverse payment settlements, taken into regard "the public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents".[320]

Moreover, similarly to most of the studies which identify Hatch-Waxman Act as the background or cause of pay-for-delay agreements, the DOJ shared this opinion, how it is

[316] See Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056 (11th Cir. 2005); see also In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006); In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008). But see Brief For the United States In Response To the Court's Invitation, In re Ciprofloxacin Hydrochloride Antitrust Litigation, No. 05-cv-2851(L) (2d Cir. July 6, 2009), available at http://www.justice.gov/atr/cases/f247700/247708.htm

[317] FTC Staff Sudy January 2010: Pay-for-Delay: How Drog Company Pay-Offs Cost Consumers Billions. p. 1

[318] Idem. p. 2.

[319] Generic Drug Entry Prior to Patent Expiration: An FTC Study. July 2002, available at http://www.law.fsu.edu/gpc2007/FTCGenericDrugStudy.pdf. Downloaded: 19 August 2014.

[320] Brief for the United States as Amicus Curiae No. 05-273. p. 10.

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obvious from its amicus curiae brief in Schering-Plough case – where the DOJ actually opposed the petition of the FTC.[321]

In its amicus curiae brief, the DOJ states: "the Hatch-Waxman Act may also create unique justifications for reverse payments, because the ability of prospective generic competitors in effect to force patent holders to initiate infringement litigation upon the filing of ANDAs, before any actual infringement has occurred, reduces the litigation risk for the generic manufacturers."[322]

However, later the DOJ changed the views about reverse payment settlements, and went closer to the FTC's position – after that the Obama White House has spoken out against pay-for delay settlements.[323]

III. 3. The jurisprudence of courts

Contrary to Europe, US courts have more than a decade long experience in assessing reverse payment settlements.[324] Despite this, US courts have not developed a consistent approach about pay-for-delay agreements. The US courts' approach towards pay-for-delay have been constantly evolving from the very beginnings until the quite recent past, when the Supreme Court delivered its landmark decision in Actavis case, ruling that pay-for-delay settlements shall b subject to a rule of reason analysis.

The long way from Cardizem CD to Actavis, which took ten years, and gave raise to different approaches from per se illegality through the scope of the patent test to rule of reason might be summarized around some main cases. In the next chapter, the development of case law will be introduced.

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[321] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 439.

[322] Brief for the United States as Amicus Curiae No. 05-273. p. 10.

[323] B. Hann: In Cipro, DOJ Aligns With FTC on Generic Drug "Reverse" Payments; FTC Continues To Seek Legislative Ban. Federal Civil Enforcement Committee Newsletter. July-August 2009. ABA Section of Antitrust. 1-4. see also T. A. Cook, Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice.

[324] S. de Margerie: 'Pay-for-Delay' Settlements: In Search of the Right Standard. *World Competition.* 36, No. 1. 2013. p. 88.

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In the following chapters, some selected US cases will be introduced. These cases were selected after careful literature review to highlight the most important tendencies.[325]

III.3.1. Review of selected U.S. cases

a) Cardizem

In the re Cardizem CD antitrust litigation case was the first case[326] where a reverse payment settlement was challenged under Section 1 of the Sherman Act.

The basis of the case was an agreement between Hoescht Marion Roussel (HMR) and Andrx Pharmaceuticals (Andrx). HMR manufactured and marketed Cardizem CD, a brand-name prescription drug used for the treatment of angina and hypertension and for the prevention of heart attack and stroke. HMR held a patent on diltiazem hydrochloride, the active ingredient of Cardizem CD. While HMR's patent on diltiazem hydrochloride expired before the settlement, HMR obtained a 'secondary' patent on the "dissolution profile" of Cardizem CD.[327]

Andrx was the first filer generic challenging the scope of HMR's patent, thus making Andrx eligible for the 180-day market-exclusivity period. HMR and Carderm – the holder of the 'secondary' patent on the „dissolution profile" of diltiazem hydrocloride, who licensed it o HMR – started a lawsuit against Andrx triggering the automatic thirty-month stay. On September 15, 1997, the FDA approved Andrx's ANDA, "indicating that it would be finally approved as soon as it was eligible, either upon expiration of the thirty-month waiting period […] or earlier if the court in the patent infringement action ruled that the […] patent was not infringed".[328]

Nine days later, just prior to the expiry of the stay, Andrx and HMR entered into an agreement providing that Andrx would not market a bioequivalent form of Cardizem CD in the US until the earliest of: "(1) Andrx obtaining a favorable, final and unappealable determination in the patent infringement case; (2) HMR and Andrx entering into a license agreement; or (3) HMR

[325] Of course, the total number of US cases is much higher.For further details see C. S. Hemphill: Drug Patent Settlements between rivals: A Survey.

[326] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 430.

[327] 332 F 3d 896 Opinion of the Court, United States Court of Appeals, Sixth Circuit. In re: Cardizem CD Antitrust Litigation. No. 00-2483. I. B.

[328] Idem. I. B.

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entering into a license agreement with a third party." Andrx also agreed to dismiss its antitrust and unfair competition counterclaims, and to not take any action to terminate its rights to the 180-day market-exclusivity period.[329]

In exchange, HMR agreed to make quarterly payments of $10 million to Andrx, beginning when Andrx received FDA approval to market Cardizem CD. HMR also agreed to pay Andrx $100 million annually to stay off the market once there was a final, unappealable determination that Andrx's product did not infringe the patent or once HMR dropped its patent-infringement suit.[330]

The Sixth Circuit judged that "[b]y delaying Andrx's entry into the market, the Agreement […] delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish or transfer. There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade."[331]

The Sixth Circuit based its analysis entirely on the antitrust aspect of the settlement. It judged it as a general market sharing agreement, it found that, regardless of the scope of the patent, the agreement contravened the Sherman Act.[332]

b) Valley Drug Co.

The next major case was Valley Drug Co. v. Geneva Pharmaceuticals, Inc., which represents the birth of the so called "scope of the patent test".

In Valley Drug Co. the Eleventh Circuit had to decide whether two settlement agreements between Abbott Laboratories'(Abott) and two generic manufacturers violated antitrust law.

[329] Idem. I. B.

[330] Idem. I. B.

[331] Idem. II. A. 2.

[332] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 431

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Both settlements concerned Abbott's blockbuster Hytrin. The chemical compound, terazosin hydrochloride, is used in the treatment of hypertension and benign prostatic hyperplasia.[333] The commercial success of Hytrin attracted the generic challengers, first Geneva Pharmaceuticals, Inc. (Geneva), later Zenith Goldline Pharmaceuticals ("Zenith") challenged the validity and scope of Abbott's related patents.[334]

Abbott ultimately entered into separate, confidential, settlement agreements with both Zenith and Geneva.[335]

Abbott and Zenith entered into an agreement whereby Zenith would acknowledge the validity of Abbott's patents and refrain from entering the terazosin hydrochloride market until either the patents expired or other generics entered the market. In exchange, Abbott agreed to pay Zenith $3 million up front, $3 million after three months, and $6 million every three months thereafter until March 1, 2000, or until the Agreement terminated by its own terms.[336]

According to the Geneva Agreement, Geneva agreed not to sell or distribute any pharmaceutical product containing any form of terazosin hydrochloride until either Abbott's patent expired, someone else introduced a generic terazosin hydrochloride drug, or an unappealable judgment of invalidity or non-infringement. In return, Abbott agreed to pay Geneva $4.5 million each month until either another generic entry or Abbott won a favourable decision in the district court on its infringement claim.[337]

When these agreements were challenged by a group of private plaintiffs the district court held that "the Agreements were per se violations of § 1 of the Sherman Act".[338] The Eleventh circuit reached another conclusion.

The Eleventh Circuit began by highlighting the inherent tension involved in these settlements: "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we would readily affirm the

[333] Valley Drug Company v. Geneva Pharmaceuticals Inc. 350 F3d 1181 (11th Cir. 2003) I. para 3.

[334] Idem. I. para 3-6.

[335] Idem. I. para 7. Valley Drug Company v. Geneva Pharmaceuticals Inc, 344 F3d. 1294. (11th Cir. 2003) para 2.

[336] The date of the settlement was 31 March 1998. 344 F3d. 1294. para 12.

[337] 344 F3d. 1294. para 13.

[338] Idem. para 16.

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district court's order. This is not such a case, however, because one of the parties owned a patent."[339]

Therefore, unlikely to In re Cardizem CD case, where the Sixth Circuit did not differentiate pay-for-delay settlements from simple market allocation cases, the Eleventh Circuit found that the existence – and the scope – of the patent are particularly important for the evaluation of the settlement.[340] Furthermore, the Court highlighted that the possibly problematic elements "are at the heart of the patent right and cannot trigger the per se label."[341]

The Eleventh Circuit declared that any provisions beyond the exclusionary effects of the patent may be subject to traditional antitrust analysis.[342] The Court found that the settlement could very well be within the scope of the patent.

c) Schering Plough

The Eleventh Circuit applied the scope of the patent test and also expanded it in the next, Schering- Plough Corp. v. FTC case two years later. It is an interesting case, which will be subject to more discussions later.

Schering manufactures and markets an extended-release microencapsulated potassium chloride product, K-Dur 20. The active ingredient in K-Dur 20, potassium chloride, is commonly used and unpatentable. Schering owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-Dur 20, until 2006. Upsher-Smith Laboratories ("Upsher"), a generic competitor of Schering applied for ANDA in 1995.[343]

On June 17, 1997 – the day before the patent trial was scheduled to begin – Schering and Upsher concluded a settlement. That agreement provided that Upsher do not concede the validity, infringement or enforceability of Schering's patent, it would refrain from marketing its generic potassium chloride supplement or any similar product until September 1, 2001. At this point Upsher would receive a non-royalty non-exclusive license to make and sell a generic form of Klor-Con. Additionally, Upsher granted Schering licenses to make and sell several

[339] 344 F3d. 1294. para 30.

[340] „To the extent that these or other effects of the Agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to per se antitrust condemnation." (344 F3d. 1294. para 51)

[341] 344 F3d. 1294. para 34.

[342] Idem. para 54.

[343] Schering-Plough Corporation v. Federal Trade Commission) 402 F.3d 1056. (11th Cir. 2005) I. A.

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pharmaceutical products Upsher had developed, including Niacor-SR, a sustained-release niacin product used to treat high cholesterol. In return, Schering promised to pay Upsher sixty million dollars over three years, plus additional smaller sums depending upon its sales of Niacor-SR in defined markets.[344]

The other settlement arose between Schering and ESI Lederle (ESI). ESI filed an ANDA in 1995, and in the fall of 1996, Schering and ESI reached a settlement. Schering granted ESI a royalty-free license of its patent beginning on January 1, 2004. In exchange, Schering would pay ESI $5 million up front and a varying sum depending on when ESI's ANDA was approved by the FDA. Specifically, Schering agreed to pay ESI an amount ranging from a maximum of $10 million if ESI's ANDA was approved before July 1999 down to a minimum of $625,000 if the ANDA was not approved until 2002. As part of the settlement, ESI also represented that it was not developing and had no plans to develop any other potassium chloride product.[345]

The Eleventh Circuit stated that: "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."[346]

The Court explained that this analysis ensured "a delicate balance . . . between the [patent and antitrust] regulatory schemes." The court also expressed that "[r]everse payments are a natural by-product of the Hatch-Waxman process." [347]

After the above mentioned two cases, the opinion of the Eleventh Circuit might be summarized as follows: "reverse-payment settlement fall within the scope of a party's patent rights, which rights were obtained in good faith and were valid at the time of the agreement, the agreement will not result in liability under the antitrust laws."[348]

[344] Opinion of the Court, United States Court of Appeals for the Third Circuit. In Re: K-Dur Antitrust Litigation No. 10-2077, No. 10-2078, No. 10-20799, and No. 10-4571. p. 11-12.

[345] Idem. p. 13.

[346] 402 F.3d 1056. IV

[347] Idem IV

[348] T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice. p. 435

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d) Tamoxifen Citrate

In Tamoxifen case, the Second Circuit applied also the scope of the patent test. The court was confronted with a settlement agreement between AstraZeneca Pharmaceuticals ("AstraZeneca"), the holder of a patent on tamoxifen citrate, a popular breast cancer drug, and Barr Laboratories ("Barr"), generic challenger. AstraZeneca agreed to pay Barr $21 million and grant it a non-exclusive license to sell—but not manufacture—tamoxifen in the United States under Barr own label. In exchange, Barr agreed to change its Paragraph IV (invalidity or non-infringement) certification to a Paragraph III (the patent will expire on a specified date and the ANDA filer will not market the dug until the expiry) certification and delay manufacture of its own tamoxifen until the patent's expiration.[349]

The court observed that reverse payment settlements were facially "suspicious, about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder." [350] Nevertheless, it stated that if "the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly". [351]

So, the court found that due to the presumption of patent validity, the settlement extended the valid patent monopoly legitimately. The court also determined that the agreement did not exceed the patent's scope.[352]

e) Ciprofloxacin Hidrocloride

In the next case, in re Ciprofloxacin Hydrochloride the Federal Circuit also applied the scope of the patent test and found no violation of Antitrust Law. The generic company, Barr filed an ANDA referencing Bayer's patent on ciprofloxacin hydrochloride, the compound that is the active ingredient of Bayer's brand-name drug Cipro. Bayer sued Barr for patent infringement.

[349] In Re: Tamoxifen Citrate Antitrust Litigation 466 F.3d 187 (2d Cir. 2006)

[350] Idem. para 61

[351] Idem.

[352] Idem.

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In 1996, Rugby (a subsidiary of HMR) and Barr entered into the "Litigation Funding Agreement," in which Rugby agreed to help Barr fund its litigation against Bayer in exchange for half of any profits realized from Barr's sale of ciprofloxacin. Also, in 1996, Bayer entered into settlement discussions with HMR and Barr.

Just before the trial, Bayer, Barr, HMR, and Rugby entered into separate agreements.

The first three agreements provided that Barr, HMR, Rugby, Apotex, and Bernard Sherman would not challenge the validity or enforceability of the patent. Pursuant to the Barr Settlement Agreement, Barr agreed to convert its Paragraph IV ANDA to a Paragraph III ANDA, In exchange, Bayer agreed to make a settlement payment to Barr of $49.1 million.

Under the Cipro Supply Agreement, Bayer agreed to either supply Barr with Cipro for resale or make quarterly payments to Barr until December 31, 2003. In return, Barr agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States. [353]

Beginning at least six months before the patent expired, Bayer agreed to allow Barr to sell a competing ciprofloxacin product. Barr affirmed the validity and enforceability of the patent and admitted infringement. [354]

The Federal Circuit affirmed the judgement of the district court. It began its analysis with a reminder of the general policy in the law favouring patent litigation settlements.[355] Applying the presumption of validity principle, the court reasoned that the patent confers a power to exclude others from profiting from the patented product. [356]

Finally, the court concluded that "the presence of a reverse payment, or the size of a reverse payment, alone is not enough to render an agreement violative of the antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent's protection". On the bases of Tamoxifen case, it reminded that "the validity of the patent need not be considered in the analysis of whether the settlement agreement violates the antitrust laws unless the infringement suit was objectively baseless." [357]

[353] In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008) I. A.

[354] Idem. I. A.

[355] Idem. III. B.

[356] Idem. III. B.

[357] Idem. III. C.

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f) K-Dur

After some years of hegemony, the scope of the patent test has been rejected by the Third Circuit in In re: K-Dur antitrust litigation case, which caused confusion.[358] The Third Circuit reviewed the same settlement agreement which was reviewed by the Eleventh Circuit in Schering-Plough[359] , and reached a different conclusion

Kutcher notes that the Third Circuit began its analysis by reminding the cost of reverse payment settlements to consumers, rather than highlighting the potential cost of not encouraging settlements. [360]

By examining the scope of the patent test, the Third Circuit highlights: "As a practical matter, the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny. As the antitrust defendants concede, no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial".[361] The court decided to not apply the scope of the patent test because it did not truly subject reverse payment settlements to antitrust scrutiny and ignored the policies underlying the Hatch-Waxman Act and Supreme Court precedents concerning patent litigation and competition.[362]

First, the court explained that the scope of the patent test created an "almost unrebuttable presumption of patent validity".[363] The court observed that when courts presume patent validity extends to the patent-holder's ability to exclude competitors from the market, the court forgets that the presumption of patent validity is a procedural device, rather than a substantive right to the patent holder.[364] More importantly, the Third Circuit highlighted the differences in burden of proof when the underlying suit concerns a patent infringement case, or patent validity. The

[358] S. de Margerie: 'Pay-for-Delay' Settlements: In Search of the Right Standard. *World Competition.* 36, No. 1. (2013) pp. 85-98.

[359] Opinion of the Court, United States Court of Appeals for the Third Circuit. In Re: K-Dur Antitrust Litigation No. 10-2077, No. 10-2078, No. 10-20799, and No. 10-4571. Point II. D. p.15.

[360] M. P. Kutcher: Waiting is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit's Analysis of Pay-for-Delay Settlement Agreements. *Loyola University Chicago Law Journal.* 2013. Vol. 44. p.1127.

[361] Opinion of the Court, United States Court of Appeals for the Third Circuit. In Re: K-Dur Antitrust Litigation No. 10-2077, No. 10-2078, No. 10-20799, and No. 10-4571. Point III. D. p.26.

[362] Idem. III. D. p.27.

[363] Idem. III. D. p.27.

[364] Idem. III. D. p.27. See also Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983.) (cited by the Court)

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key distinction is that in a patent infringement suit, the patent-holder bears the burden of demonstrating infringement and in a patent validity lawsuit, the challenger bears the burden of proof.[365]

Taken into account the fact that '[m]any patents issued by the PTO are later found to be invalid or not infringed"[366] the court offered empirical and legal support for the public interest in judicial testing and elimination of weak patents.[367]

The court found that allowing reverse payment settlements to occur does not reward patent-holders based on the strength of their patents, but rather, on the "strength of [their] wallets."[368] The court favoured freeing the competitive economy of narrow or invalid patents over the public interest supporting settlements because of the severe anticompetitive effects of reverse payment settlements.

Applying the Supreme Court's holding that antitrust analysis must pay particular attention to the "distinct economic and legal setting of the regulated industry to which it applies,"[369] the Third Circuit referred to the legislative intent behind Hatch-Waxman Act as evidence that the court should apply antitrust analysis to reverse payment settlements in the pharmaceutical industry.[370]

Considering that these settlements remove the most motivated challenger – because the first challenger has the potential to secure the 180-day marketing exclusivity period – the Third Circuit highlighted: "[The] goal [of Hatch-Waxman Act] is undermined by application of the scope of the patent test which entitles the patent holder to pay its potential generic competitors not to compete."[371]

Finally, the court articulated the test for the district court to follow, which is a quick look rule of reason analysis.[372] First, the court need not review the merits of the underlying patent

[365] Idem. III. D. p.27.

[366] Idem. Point III. D. p.27.

[367] Idem. Point III. D. p.29.

[368] Idem. Point III. D. p.31.

[369] Idem. Point III. D. p. 30.

[370] Idem. Point III. D. p.31.

[371] Idem. Point III. D. p.31.

[372] Idem. Point III. D. p. 32.

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infringement suit because "it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[373] The patent holder may then attempt to rebut plaintiff's prima facie case of an unreasonable restraint of trade by demonstrating that there was no reverse payment because the settlement amount was consideration for something other than a delay in market entry. As a second defence, the patent holder may argue that the reverse payment offers a competitive benefit that could not have been achieved without a reverse payment.[374]

Therefore, the scope of the patent test was rejected by the Third Circuit in K-Dur Antitrust Litigation.[375]

III.3.2. Actavis

In Actavis, two generic manufacturers—Watson Pharmaceuticals (later Actavis), Inc. and Paddock Laboratories, Inc.— filed two separate ANDA's in 2003, for Solvay's patented AndroGel, a topical gel that treats the symptoms of low testosterone in men. Solvay's patent was granted the same year. Both generic manufacturers made paragraph IV certifications, asserting that their product did not infringe Solvay's patent and/or Solvay's patent was invalid.

Solvay filed a patent infringement lawsuit, which triggered a 30-month stay of the FDA's approval. When the 30-month stay expired in 2006, all the parties settled the patent litigation.

Under the terms of the settlement Actavis agreed that it would not bring its generic drug to market until August 31, 2015, 65 months before Solvay's patent expired. Actavis also agreed to promote branded AndroGel to urologists. The other generics made "roughly similar promises". In return, Solvay agreed to pay Paddock $12 million total. 60 million in total to Par and an estimated 19 – $30 million amount annually for nine years to Actavis. The parties stated that the payment was a compensation for the services provided by the generics. FTC argued the payment was compensation for generic delay.[376]

[373] Idem. Point III. D. p.33.

[374] Idem. III. D. p.33.

[375] Idem. Point III. D. p. 32.

[376] FTC v. Actavis I. B. 1. p. 5-6.

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In their judgements, both the District Court and the Eleventh Circuit applied the scope of the patent test. [377]

The Supreme Court rejected to apply the scope of the patent test and declared that the patent may be valid or invalid, infringed or not infringed.[378] The Supreme Court reminded that "the public interest in granting patent monopolies" exists only to the extent that "the public is given a novel and useful invention" in "consideration for its grant."[379]

With regard to the general policy favouring patent settlements, the Supreme Court found it was not relevant here.[380]

The Supreme Court also rejected the FTC's approach advocating "quick look" analysis, stating that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries."[381]

The Supreme Court rejected both arguments, and found that reverse payment settlements are subject to the rule of reason analysis.

III.3.3. Legal tests

The above discussed cases might be classified into three groups based on the tests applied by the courts: i) the strict antitrust approaches[382], including in In re Cardizem CD and K-Dur; ii) the scope of the patent test, which was applied in Valley Drug Co., Schering Plough, In re Tamoxifen citrate and In re Ciprofloxacin Hydrocloride, and iii) the "rule of reason" approach, applied by the Supreme Court in Actavis.

The term "strict approaches", covers quite different tests from the per se illegality expressed in Cardizem CD to the quick look test applied in K-Dur. The K-Dur standard requires the patent

[377] Idem. I. B. 2. p. 6.

[378] Idem. II. A. p 8.

[379] Idem. II. A. p 10.

[380] Idem. II. B. p 14-19.

[381] Idem. III. p. 20

[382] S. de Margerie: 'Pay-for-Delay' Settlements: In Search of the Right Standard. p. 89.

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holder to demonstrate that there was no reverse payment because the settlement amount was consideration for something other than a delay in market entry or that the reverse payment offers a competitive benefit that could not have been achieved without a reverse payment.[383] The common feature of these approaches is that the courts give a preference to antitrust law at the expense of patent law, and to the underlying principles of Hatch-Waxman Act.[384] Furthermore, against the general interest in favouring settlements, the courts highlight the very importance of consumers' welfare. However, some authors discuss K-Dur case as a rule of reason example[385], with regard to the illegality presumption, this paper prefers to discuss it as part of the strict approaches. I associate myself with the views of another author, according to which K-Dur Antitrust Litigation applied a "quick look" rule of reason analysis, under which pay-for-delay agreements are presumed to be illegal.[386]

According to the scope of the patent test, reverse payments are permitted if (i) the exclusion does not exceed the patent's exclusionary scope; and the (ii) patent holder's claim was not objectively baseless or the patent was not procured by fraud on the patent office.[387] Courts applying this test generally also emphasize the general policy of the law in favour of the patent settlements against of costly litigation.

The third test was established in Actavis, where the Supreme Court held that reverse-payment settlement agreements should be reviewed under a rule of reason analysis. By doing so, it rejected both the scope of the patent test and the quick look approach supported by the FTC. Some authors state rule of reason is the "U.S. antitrust's equivalent of an effects analysis under EU competition law."[388] However, the situation is more complicated, none of the US antitrust tests – per se illegality, quick look or full rule of reason – have an exact equivalent in EU law. Even the opinions are not uniform about this test. For example, on the basis of Actavis, Hovenkamp notes that „the settlements must be evaluated under antitrust's rule of reason,

[383] M. P. Kutcher: Waiting is the Hardest Part: Why the Supreme Court Should Adopt the Third Circuit's Analysis of Pay-for-Delay Settlement Agreements. pp. 1094-1151.

[384] Opinion of the Court, United States Court of Appeals for the Third Circuit. In Re: K-Dur Antitrust Litigation No. 10-2077, No. 10-2078, No. 10-20799, and No. 10-4571.

[385] S. de Margerie: 'Pay-for-Delay' Settlements: In Search of the Right Standard. p. 90

[386] A. P. Reeves: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis p. 11.

[387] S. de Margerie: 'Pay-for-Delay' Settlements: In Search of the Right Standard. p. 88.

[388] P. Harrison – K. Nordlander : EU/US Patent Settlements: An overview of leading cases. *E-Competitions* N 58749. p. 4.

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although application need not require proof of everything that the long form rule of reason traditionally demands."[389]

Others highlight the other side of rejection of the "scope-of-the-patent" test: "that would have allowed courts to treat as per se illegal any patent settlement that went beyond the scope or duration of the restriction imposed by the patent at issue, and held that settlement agreements would not be immune from antitrust law to the extent that their anti-competitive effects fell "within the exclusionary potential of the patent""[390]

III.3.4. The importance and criticism of Actavis

Discussion about the critics of Actavis should be started by recalling Chief Justice Roberts' dissenting opinion. Three Supreme Court judges found the "novel approach" accepted by the majority "is without support in any statute, and will discourage the settlement of patent litigation."[391] The judges in their opinion – which supported the scope of the patent test – argued even the fact that pay-for-delay settlements are used only in the Hatch-Waxman context. They stated, that such agreements outside of the scope of Hatch-Waxman Act are "well known feature of intellectual property litigation", and they are "private agreements that for obvious reasons are generally not appealed, nor publicly available".[392]

They also argued the Court's assumption that "offering a "large" sum is reliable evidence that the patent holder has serious doubts about the patent." According to their view, the „patent holder may be 95% sure about the validity of its patent, but particularly risk averse or litigation averse" it may prefer to settle even if there is 5% chance of a finding of invalidity.[393]

With regard to the problem highlighted by the judgment, that a settlement in the Hatch-Waxman context removes the most motivated competitor, it argued that the "majority decision" will discourage generics from challenging patents, because of the time consuming, uncertain and costly nature of the litigation.[394]

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[389] H. Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. p 1.

[390] P. Harrison – K. Nordlander : EU/US Patent Settlements: An overview of leading cases. p 4

[391] *Roberts, C. J.*, dissenting 570 U. S.(2013) Ftc *v.* Actavis, Inc. Supreme Court of the United States No. 12-416 *Chief Justice Roberts*, with whom *Justice Scalia* and *Justice Thomas* join, dissenting. p 1.

[392] Idem. II. p.10

[393] Idem. III. p. 13

[394] Idem. IV. p. 17.

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In the legal literature, some authors argued that the decision "provides more question than answers".[395] According to this view, the Supreme Court only let us to know the followings: (i) the Hatch-Waxman settlements are subject to the rule of reason analysis, they are neither per se illegal, nor presumptively illegal (ii) large, bold payment from the innovator to the generic, which exceed the branded company's savings on litigation and cannot be tied to any other consideration than the generic delay are likely illegal (iii) agreements where the generic provides services for fair market value are likely defensible. [396]

With regard to other studies showing that a payment above the innovator's litigation costs might still be totally reasonable with regard to the very high and asymmetric risks of the litigation[397], these considerations might be problematic. It is indeed a very likely possibility that the branded company is willing to pay a high price to end the litigation in order to have security and stability – which are also the requirements of moving forward with research and development.[398] However, in its Actavis decision the Supreme Court seemed to consider this issue when it highlighted that the "owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment."[399]

The decision indeed might be criticized because of the lack of a clear guidance for the companies to minimize the risks of infringing antitrust rules. On the other hand – taken into consideration that the cases discussed above clearly show that the choice of test is a question of "preference" between antitrust or patent policy, so, by nature a political decision – it is not necessarily the judiciary power who has to take such a decision.[400]

[395] A. P. Reeves: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis. p. 9.

[396] Idem. p. 9.

[397] X. Yu – A. Chatterji : Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation

[398] A. P. Reeves: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis p. 12.

[399] FTC v. Actavis p. 19

[400] C. S. Hemphill: Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem and T. A. Cook: Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice.

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The total rule of reason analysis gives enough discretionary power to the judges to make decisions on the basis of a detailed analysis of the concrete case, however, it provides only a few guideline for the concerned companies.

III.3.5. Post Actavis cases

The hotly contested issue of the legality of reverse-payment settlements has not been resolved by the Supreme Court's decision in Actavis entirely. With Actavis, the Supreme Court answered the core question of what legal standard should apply to reverse payment settlements in favour of the rule of reason. Under this standard, the pharmaceutical patent settlements can potentially be anti-competitive when the originator makes a "large" and "unjustified" payment to a potential generic competitor. Practitioners were expecting that the lower courts would grapple with the question of what constitutes a "large" and "unjustified" payment, but they have instead struggled with a more basic question: What is a payment? [401] Or, in other term, is „reverse payment" limited to cash-only payments, or are other arrangements that somehow provide value to the generic manufacturer sufficient to satisfy these requirements? The courts reached different decisions in that regard.

It is impossible – and do not seem necessary – to discuss all the post-Actavis cases in detail, and providing an exhaustive list of them seems neither reasonable, nor possible. Here the eight cases most often discussed by legal literature[402] will be introduced in a nutshell, and a short highlight will be also given to some other, also often cited and relevant cases. The role of this subchapter is to introduce the most important post-Actavis challenges.

g) Lamictal

One of the first post-Actavis decision examining these issues came in January 2014. In the In re Lamictal Antitrust Litigation, the District Court of New Jersey examined whether Actavis applies to non-monetary reverse payments, especially whether no authorized generic agreements are reverse payments or not. The district court found that no authorized generic

[401] Maria Raptis: Post-Actavis Rulings Focus on What Constitutes a Payment in Reverse-Payment Settlements.(Available at: https://www.skadden.com/insights/post-iactavisi-rulings-focus-what-constitutes-payment-reverse-payment-settlements Downloaded: 12 February 2015)

[402] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow.

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agreements are not reverse payments, granted a motion to dismiss plaintiffs' challenge to a settlement on a drug treating epilepsy and bipolar disorder.[403]

In that case, GlaxoSmithKline, holder of US patent on lamotrigine, Lamictal's active ingredient (patent expired on July 22, 2008), settled with its first generic challenger, Teva – Teva first challenged the patent in April 2002, filing the first paragraph IV. ANDA – in 2005, granting a 37-month early entry to sell generic lamotrigine chewables, and a six-month early entry for generic lamotrigine tablets, which depended on whether a paediatric exclusivity period was granted.[404] GlaxoSmithKline also agreed not to launch its own generic versions of Lamictal products, i.e., it is the so-called a No-Authorized Generic agreement, which is in the centre of this case.

The court took a more limited view on what would qualify as a payment, holding that Actavis only applies to monetary reverse payments. In effect, this means the court held that No-Authorized Generic agreements are not payments subject to rule-of-reason scrutiny.

According to Carrier, the Court misused the five factors that the Actavis court had applied to justify more aggressive antitrust scrutiny to instead excuse its decision to employ "less vigorous scrutiny."[405]

In Lamictal, the District Court substituted the Actavis five step test by its own three step test as follows: For the first step, the court asked ''is there a reverse payment?" For the second step, the court asked ''is that reverse payment large and unjustified?" If the first two questions are answered in the affirmative, only then would the court apply the rule-of-reason analysis to the payments at issue. In this third step, the court asked ''whether the parties to an agreement creating a restraint of trade had market power and exercised it, whether the restraint had anticompetitive consequences and whether those consequences are otherwise justified.'' In this context, the district court suggested that Actavis's ''five sets of considerations'' which led the Supreme Court ''to conclude that the FTC should have been given the opportunity to prove its antitrust claim',' were laid out ''to guide district courts in applying the rule of reason . . .''

[403] In re Lamictal Antitrust Litigation (12-cv-995 (D.N.J.)

[404] In re Lamictal Antitrust Litigation (12-cv-995 (D.N.J.), In re Lamictal Antitrust Litigation 14-1243 (3rd Circuit) p. 17. See also: Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 4.

[405] Michael A. Carrier: How not to apply Actavis. Northwestern University Law Review. Vol. 109:103. (2015) p.113.

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Under this reading of Actavis, the Court found that the No-Authorized Generic agreement was not a reverse payment, and the case was dismissed. [406] Carrier states that the court „substituted its own armchair analysis for the burdens of proof articulated in Actavis"[407], which expresses well the general reactions to this judgement, as well.

Under appeal the Third Circuit dealt with the case. Multiple amicus curiae briefs have been filed, with amici including the FTC, the AARP, 28 states, and 53 law, economics, and business professors. [408]

In its amicus curiae brief, the FTC highlighted the trend about changing the practice of reverse payments by expressing that pharma companies moved on during the years from the initial „earliest" reverse payment agreements – where the brand compensated the generic in cash – towards more subtle forms of settlements, where the originator normally does not pay cash for the generic to stay away from the market, but uses other kind of incentives. A very typical form of such incentives is the No-Authorized Generic agreement, an agreement where the originator promises not to introduce its own generic version during the 180days Hatch-Waxman exclusivity. In the case under appeal, Teva itself stated that generic Lamictal tablet product generated "substantially increased" revenues because it did not face generic competition during the exclusivity period.[409]

Under appeal, the Third Circuit stated: „It seems to us that no-AG agreements are likely to present the same types of problems as reverse payments of cash. The no-AG agreement here may be of great monetary value to Teva as the first-filing generic. In Actavis, the Supreme Court recognized generally that the 180-day exclusivity period is "possibly 'worth several hundred million dollars,'" and may be where the bulk of the first-filer's profits lie."[410]

[406] In re Lamictal Antitrust Litigation (12-cv-995 (D.N.J.), Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 4.

[407] Michael A. Carrier: How not to apply Actavis. Northwestern University Law Review. Vol. 109:103. (2015) p.113.

[408] In re Lamictal Antitrust Litigation (12-cv-995 (D.N.J.), Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 4.

[409] Brief of Federal Trade Commission as Amicus Curiaein support of plaintiffs-appealants. (Available at: https://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140428lamictalbrief.pdf Downloaded: 19th January 2016) p. 11-13.

[410] In re Lamictal Antitrust Litigation 14-1243 (3rd Circuit) p 32.

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Absent a no-authorized generic promise, launching an authorized generic would seem to be economically rational for the brand. For this reason, the fact that the brand promises not to launch an authorized generic – thereby giving up considerable value to the settling generic – makes the settlement something more than just an agreed-upon early entry: it "may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."[411]

The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash – if not even more harmful. If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes – and along with it, the prospects of a more competitive market and higher level of consumer welfare. As with a reverse payment of cash, a brand agreeing not to produce an authorized generic may thereby have "avoid[ed] the risk of patent invalidation or a finding of noninfringement." [412]

Based on such reasoning, the Third Circuit did not accept the defendants arguments, and it overruled the judgement of the District Court of New Jersey stating that the District Court mistook the "five sets of considerations" that persuaded the Actavis[413] and that a no authorized generic agreement „may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified—whether as compensation for litigation expenses or services, or otherwise—is subject to antitrust scrutiny under the rule of reason."[414]

h) Loestrin

The ruling of the district court in In re Loestrin Antitrust Litigation received also several criticism.[415] In that case, District of Rhode Island examined – just like in Lamictal - whether No-Authorized Generic agreements should be considered as reverse payments, whether the provided payment was fair price for goods or services; and whether Actavis applies to

[411] In re Lamictal Antitrust Litigation 14-1243 (3rd Circuit) p 34.

[412] Idem. p 34.

[413] Idem. p. 47.

[414] Idem. p. 44.

[415] Michael A. Carrier: How not to apply Actavis. Northwestern University Law Review. Vol. 109:103. (2015) p.113-114.

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nonmonetary reverse payments. The District Court followed the later overruled logic used by the District of New Jersey in Lamictal, which lead to the same results.[416]

The active ingredients in Loestrin 24, norethindrone acetate and ethinyl estradiol, have been approved by the FDA as a means of oral contraception since 1973. [417] Warner Chilcott was the US patents fifth owner, after a predecessor acquired it in 2003. The patent expired in 2014.[418] In 2006, a potential generic competitor Watson (now Actavis) challenged the patent filing a paragraph IV. ANDA.[419] In January 2009, at approximately the same time that the 30-month stay would have expired, the parties filed a dismissal stipulation and entered into an Exclusion Payment Agreement. [420] Watson agreed to delay launching generic Loestrin 24 until January 2014, approximately six months prior to the expiration of the patent.[421] In return, 1) Warner Chilcott agreed to not launch an authorized generic during Watson's first 180 days of Loestrin 24 sales, 2) nor would it license a third party to do so, 3) gave Watson a worldwide license to Loestrin 24 beginning in January 2014., 4) paid Watson annual fees and royalties for promoting Warner Chilcott's Femring hormone therapy product and 5) the exclusive right to sell another branded oral contraceptive now named Generess Fe.[422]

Six months later, in June 2009, another potential generic competitor, Lupin filed a paragraph IV ANDA. Again, merely by filing suit, Warner Chilcott triggered a 30-month stay under the Hatch-Waxman Act. In October 2010, Warner Chilcott dismissed the suit and entered into an Exclusion Payment Agreement with Lupin. [423] Lupin agreed to delay marketing generic Loestrin 24 until the month that the patent at issue would expire. In return, Warner Chilcott granted Lupin a non-exclusive license to market Femcon Fe and Asacol 400 mg, supplied by Warner Chilcott, upon the entry of another generic version of each drug.[424] The district court dismissed the plaintiff's motion, because according to the court's view, „Actavis requires cash

[416] In re Loestrin Antitrust Litig., (13-md-2472 (D.R.I.)) Michael A. Carrier: How not to apply Actavis. Northwestern University Law Review. Vol. 109:103. (2015) p.113-114. Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p.

[417] In re Loestrin Antitrust Litig., (13-md-2472 (D.R.I.) p. 8

[418] Idem. p. 9

[419] Idem. p. 9-10

[420] Idem. p. 10

[421] Idem. p. 10

[422] Idem. p. 10-11.

[423] Idem. p. 11.

[424] Idem. p. 11-12.

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consideration in order to trigger rule of reason scrutiny, and because the Plaintiffs have not adequately alleged payment in the form of cash by Warner Chilcott in exchange for Watson and Lupin 's agreement to stay out of the market for Loestrin 24". [425]

By dismissing the motion, Chief Judge William E. Smith reflected to Chief Justice Roberts' dissent highlighting the struggles of district courts and appellate courts in the wake of Actavis.[426]

i) Lipitor

In In re Lipitor Antitrust Litigation the District Court of New Jersey examined whether Actavis applies to nonmonetary reverse payments; whether release of liability in unrelated litigation can be considered as a reverse payment; and whether granting rights in foreign markets can be a reverse payment.[427] Lipitor belongs to a class of drugs called statins, which lower cholesterol by inhibiting a liver enzyme.[428] Pfizer has obtained seven patents covering different aspects of the Lipitor product.[429] On August 19, 2002, Ranbaxy filed the first ANDA to market generic Lipitor. Other generic companies followed with ANDAs in 2005. [430] The parties got involved in litigation. On June 17, 2008, before the court could rule on Ranbaxy's motion to dismiss, Pfizer and Ranbaxy entered into a "settlement" agreement.[431] Ranbaxy agreed not to compete with Pfizer, to keep its generic product off the market until November 30, 2011, not to waive or relinquish its first-to-file 180 day marketing exclusivity, and to drop its challenge to the #995 reissuance proceeding.[432] In return, Pfizer agreed to release potential generic competitor Ranbaxy from liability in a separate suit, which allegedly could have represented hundreds of millions of dollars in value. In exchange for this release, Ranbaxy paid $1 million and Pfizer

[425] Idem. p 31.

[426] Idem. p. 31.

[427] In re Lipitor Antitrust Litig., 12-cv-2389 see also Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 2.

[428] In re Lipitor Antitrust Litig., 12-cv-2389 p. 1.

[429] Idem. p. 1.

[430] Idem. p. 4.

[431] Idem. p. 7.

[432] Idem. p. 7.

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was released from its $200 million injunction bond. Pfizer also granted Ranbaxy the exclusive right to sell Lipitor in 11 foreign markets, along with several licenses to Pfizer patents.[433]

Honourable Peter G. Sheridan in the District of New Jersey granted the direct purchaser class plaintiffs' motions partially: for ''reverse payment'' allegations, after dismissing related fraud, sham litigation, False Orange Book Listing and sham citizen petition claims.[434] Actavis was decided while motions to dismiss were pending, and after the parties briefed the court, the direct purchaser class plaintiffs moved to amend their complaints to clarify their ''reverse payment'' allegations.[435] The defendants argued that these amendments would be futile, ''because the amended allegations still fail to allege an actionable reverse payment under the Supreme Court's standard in Actavis, which Defendants say only applies to settlements involving large monetary payments from the brand name manufacturer to the generic.'' The court rejected this argument, holding ''that nothing in Actavis strictly requires that the payment be in the form of money, and so it declines to hold that the amendments would be futile on that basis. Nor does the Court agree that Plaintiffs have unduly delayed seeking leave to amend their complaints or that Defendants were prejudiced in any way."[436]

j) Effexor

In re Effexor antitrust litigation – another case decided by the Honourable Peter G. Sheridan in the District of New Jersey – examined whether a No-Authorized Generic agreement constitutes a reverse payment under Actavis. There is also some scheduling overlap between Effexor XR and Lipitor.[437] In that case, „the complaints allege that Wyeth unlawfully monopolized and unreasonably restrained competition in the market for extended release venlafaxine hydrochloride by, among other things, listing allegedly fraudulently procured patents in the Orange Book, asserting these patents in a number of infringement suits that plaintiff's claim were without basis, and allegedly conspiring with generic manufacturer Teva to extend Wyeth's

[433] In re Lipitor Antitrust Litig., 12-cv-2389 p. 7-8. Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 2.

[434] In re Lipitor Antitrust Litig., 12-cv-2389 p.13-20. Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 2.

[435] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 2.

[436] In re Lipitor Antitrust Litig., 12-cv-2389 p. 18.

[437] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 2.

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monopoly by entering into settlement agreements that plaintiffs alleged were improper reverse payment agreements."[438] In that regard, the case seems also quite similar to Lipitor.

The plaintiffs have argued that the no authorized generic agreement was in effect a payment worth $426 million to Teva. The defendants argue that this no authorized generic agreement is an early entry agreement and not a monetary reverse payment subject to review under Actavis. The FTC has filed an Amicus Curiae brief arguing that no authorized generic agreements are reverse payments.[439]

The court stayed the proceeding on the basis of the interest of judicial economy, stating that the „stay will allow for the potential simplification the issues in this case and promote judicial economy, as a Supreme Court decision may clarify the standard that, according to Plaintiffs, governs their reverse payment theories of recovery. Moreover, should the Supreme Court not grant the certiorari petition, the stay will be relatively short. Should the Court grant the petition, however, a lengthier stay is justified". [440]

k) Nexium (Esomeprazole)

In this case, direct and indirect purchasers of the drug Nexium sued AstraZeneca, the brand manufacturer of Nexium, and three generic manufacturers (Ranbaxy Inc., Teva Pharmaceuticals, and Dr. Reddy's Laboratories) for allegedly illegal reverse payment settlement.

The 2008 settlement between Ranbaxy – the first filer generic – and AstraZeneca agreed not to release an authorized generic during Ranbaxy's 180-day first-filer exclusivity period in exchange for a six-year delay in entry. Plaintiffs alleged that this no authorized generic clause was a pay-off for delay, allegedly worth hundreds of millions of dollars. Ranbaxy and AstraZeneca also entered into side agreements – manufacturing and distribution agreements – which plaintiffs alleged also constituted part of the alleged unlawful payment to Ranbaxy: these agreement "provided Ranbaxy a steady stream of profits in the millions of dollars" and that

[438] http://www.businesslitigationalert.com/files/2012/10/Effexor-order1.pdf p. 1 (Downloaded: 12 October 2014.)

[439] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 2.

[440] http://www.businesslitigationalert.com/files/2012/10/Effexor-order1.pdf p. 4 (Downloaded: 12 October 2014.)

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"Ranbaxy would not have received these agreements in the absence of the Nexium settlement."[441]

AstraZeneca's settlements with the other two, non-first filer generics, Teva and Dr. Reddy's granted licenses for the respective companies to sell generic Nexium starting in May 2014, assuming their products received FDA approval. Plaintiffs alleged that Teva and Dr. Reddy's also received payments through the simultaneous settlement of unrelated patent litigation. When resolving summary judgment motions, the Court determined that Dr. Reddy's had not received a reverse payment. The Court deemed triable the allegation that Teva received a payment, and those issues dominated the early portions of the trial.[442]

Nexium was the second case to issue a decision applying Actavis.[443] The court directly addressed the issue of whether reverse payments must be monetary, and held that using a broad interpretation of the word ''payment'' to include non-monetary consideration ''serves the purpose of aligning the law with modern-day realities.''[444]

l) Modafinil

In In re Modafinil Litigation, the Memorandum opinion of the Eastern District of Pennsylvania was issued on the 28 January 2015.

Cephalon was issued in April 1997 a patent covering specific formulations of modafinil, the active pharmaceutical ingredient ("API") in its drug Provigil. In 2002, Cephalon was granted a reissue patent on modafinil, which was scheduled to expire October 6, 2014. However, as a result of studying Provigil's effects on children, Cephalon also received an additional six months of paediatric exclusivity on Provigil, extending Cephalon's exclusivity period through April 6, 2015.The Generic Defendants each filed a separate Paragraph IV ANDA with the FDA on December 24, 2002, the first date on which ANDAs were able to be filed, seeking to market a generic version of Provigil. Because each of the generics filed ANDAs on the first possible

[441] Nexium p. 60

[442] Kevin McDonald–Jonathan Berman: Jury Finds for Drug Manufacturers in First Post-Actavis "Reverse Payment" Trial. (Available at: http://www.jonesday.com/antitrust-alert--jury-finds-for-drug-manufacturers-in-first-post-actavis-reverse-payment-trial-12-11-2014/ Downloaded: 12 December 2014)

[443] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 3.

[444] 8 In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 410 (D. Mass. Sept. 11, 2013) p. 19.

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day, all were eligible to share the 180 -day exclusivity of a first -filer. Cephalon filed suit against the Generic Defendants for patent infringement on March 28, 2003. [445]

Cephalon and the generics ultimately settled between December 2005 and February 2006. All of the settlement agreements included a provision where Cephalon granted the Generic a license to market their generic modafinil products on a "date certain" — the later of October 6, 2011, or, if Provigil obtained a paediatric extension, April 6, 2012. The settlement agreements also provided that the Generic Defendants could enter the market earlier than the date certain if: (1) Cephalon licensed any other generic manufacturer to market generic modafinil prior to that date; (2) another generic decided to launch "at risk"; or (3) if a judgment declared that generic modafinil may be sold without infringing the patent.[446]

With Teva, Cephalon also agreed to make royalty payments to Teva in exchange for a worldwide license to Teva's modafinil-related intellectual property. Total royalty payments reached a maximum of $125 million. Parties also entered into an API supply agreement, whereby Teva agreed to manufacture and supply Cephalon with 10,000 kg per year of modafinil API for a five -year period. Cephalon and Teva further agreed to settle pending patent litigation related to the modafinil patent in the United Kingdom in exchange for Cephalon paying Teva 2.1 million British pounds and 2.5 million Euros. Finally, Cephalon agreed to appoint Teva UK Limited as the exclusive distributor of Cephalon modafinil products in the United Kingdom for five years that Cephalon would provide Teva with modafinil at eighty percent of Teva's resale price, and Cephalon would pay Teva 2.5 million Euros. Pursuant to this settlement agreement, Cephalon has paid Teva in excess of $164 million.[447]

Concerning Ranbaxy, in addition to the license for date-certain entry, Cephalon made a one-time $2 million payment to Ranbaxy for avoided litigation costs, Cephalon was granted a non-exclusive worldwide license to Ranbaxy's IP involving formulations of modafinil in exchange for $1 million up front and certain milestone payments up to a maximum of $5 million, and parties also entered into an API supply agreement.[448]

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[445] Civil action Case No. 2:08-cv-2141 (Joined cases FTC and others v. Cephalon) (Available at:https://www.ftc.gov/system/files/documents/cases/150128cephalonopinion.pdf Downloaded: 25 October 2018) p 5.

[446] Idem. p. 6.

[447] Idem. p 6-7

[448] Idem. p. 7

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Altogether, Cephalon transfered to Ranbaxy an amount exceeding $25 million.[449]

The other two companies, Mylan and Barr were also compensated by the license for date-certain entry, made a one-time $2 million payment for avoided litigation costs, and other side agreements.[450]

The court examined whether the payment was fair price for goods or services; what preclusive effect do rulings from other trials have on antitrust liability; whether determining that a payment is ‘‘large and unjustified’’ is part of the rule-of-reason analysis or a preliminary requirement before reaching that analysis. [451]

In that regard the court found that the entirety of the reverse payment should be considered in determining whether the payment is large under Actavis, and in that case: „Plaintiffs have presented sufficient evidence to create a genuine dispute as to whether the reverse payments exceeded litigation costs and were large enough to induce the Generic Defendants to drop their patent challenge and stay off of the market. As Defendants have not challenged Plaintiffs' ability to demonstrate market power, Plaintiffs have presented sufficient evidence to meet their initial burden under the rule of reason.[452]”

The court also found that: „Plaintiffs have presented sufficient evidence to rebut Defendants' procompetitive justifications and raise a genuine factual dispute as to whether the payments were reasonably necessary to achieve the procompetitive benefits. A reasonable jury could conclude that the payments were aimed at delaying generic entry and that Defendants' justifications are pretextual.”

m) Androgel

This case is based on the same facts like Actavis. The most important issues examined by the court were the following: “Whether payment was fair price for goods or services; whether

[449] Case No. 2:08-cv-2141 p 8

[450] Idem. p. 8-10

[451] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 4.

[452] Case No. 2:08-cv-2141 p 25.

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determining that a payment is ‘‘large and unjustified’’ is part of the rule-of-reason analysis or a preliminary requirement before reaching that analysis”.[453]

With regard to the abovementioned facts, it seems interesting to look at the findings of the courts, due to the fact that it is based on the same fact, it might be called the ultimate real post-Actvis case.

So, the facts can be summarized as follows. Originator company Solvay reached a great success with its brand pharmaceutical, AndroGel, which became much more popular than other treatments for low level of testosterone in men. Around the 2000’s generic companies Par, Paddock and Watson filed Paragraph IV: ANDA. Around 2006, before the end of the relevant court proceedings, the parties settled.[454]

Under the settlements between Solvay, Paddock and Watson, Solvay agreed to voluntarily dismiss the infringement actions. I return, Watson agreed not to market generic AndroGel until the earlier of August 31, 2015 or the date another company marketed generic AndroGel. Paddock agreed not to market generic AndroGel until the earliest of August 31, 2015, but only if Watson did not assert its 180-day generic exclusivity period, or the date another company launched generic AndroGel, or February 28, 2016.[455]

On the same day, Solvay also entered into business promotion agreements with Watson, Par, and Paddock. Under the agreements, Solvay agreed to share profits of AndroGel with generics mostly in the form of promotion agreements. Watson agreed to promote AndroGel to urologists. Solvay estimated that its annual payments to Watson would be between $15 and $30 million. Par agreed to promote AndroGel to primary care physicians. Solvay estimated that its annual payments to Par would be about $6 million. Paddock agreed to serve as a backup supplier of AndroGel. Solvay estimated that its annual payments to Paddock would be about $2 million.[456]

[453] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 6.

[454] Civil Action IN RE: Androgel Antitrust Litigation (NO. II) FTC v. Actavis, NO. 1:09-CV-955-TWT http://cases.justia.com/federal/district-courts/georgia/gandce/1:2009cv00955/158248/419/0.pdf?ts=1451557593 (Downloaded: 25 October 2018) p. 2-3.

[455] Idem. p. 8.

[456] Idem. p 2-3.

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In 2014, the court denied a motion to dismiss based on Noerr-Pennington antitrust immunity.[457] Par, Paddock and Solvay argued that because their settlement agreements were memorialized by a court's consent agreement, they constituted legitimate petitioning for government action and thus protected by the Noerr- Pennington doctrine.[458] The court initially noted that "[c]ourts are largely uniform in their view that private settlement agreements entered into during the pendency of litigation that are neither presented to nor approved by the judge presiding over the dispute fall outside the ambit of Noerr-Pennington immunity." [459]

The court rejected to grant the motion because of three causes, the second and third of those were that "the Supreme Court's Noerr-Pennnington precedents, read in conjunction with Actavis, counsel against immunizing this reverse payment agreement. Third, consent judgments of this nature should generally not be entitled to Noerr-Pennington immunity." [460]

n) Niaspan

Eight actions were consolidated before the Honorable Jan E. Dubois in the Eastern District of Pennsylvania. The court had to examine especially whether payment was fair price for goods or services; and whether ''No Authorized Generic'' agreements are reverse payments.[461]

In this case, the plaintiffs aver that the brand-name manufacturer Kos entered into anticompetitive settlement agreements in March of 2005 with the generic manufacturer Barr.[462] According to the terms of the settlement, potential generic competitor Barr agreed to delay entry from 2005 until 2013.

[457] In re: Androgel Antitrust Litigation (NO. II) FTC v. Actavis, MDL DOCKET NO. 2084 ALL CASES 1:09-MD-2084-TWT CIVIL ACTION FILE NO. 1:09-CV-955-TWT (Available at: https://casetext.com/case/fed-trade-commn-v-actavis Downloaded 25 October 2018)

[458] Idem.

[459] Idem.

[460] Idem. para 14.

[461] In re: Niaspan Antitrust Litigation. NO. 13-MD-2460 (Available at: https://www.paed.uscourts.gov/documents/opinions/14D0744P.pdf Downloaded: 25 October 2018) see also Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 6.

[462] In re: Niaspan Antitrust Litigation. NO. 13-MD-2460 p. 1.

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Kos and Barr entered into three separate but interrelated contracts dated April 12, 2005: (1) a settlement and licensing agreement (2) a co-promotion agreement; and (3) a license and manufacturing agreement.[463]

The court decided to agree with with Judge Youngin Nexium that the term "reverse payment" is not limited to a cash payment. [464] The court stated that: " a reverse payment of cash by the brand-name manufacturer to the potential generic manufacturer is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree based solely on the estimated strength of its litigation position. In this respect, a no-AG provision works exactly as would a payment of cash. One can logically infer that, all else equal, with a no-AG provision, a generic would be willing to agree to a later entry date than it would otherwise agree to in order to settle a patent-infringement case."[465] Accordingly, the Court concluded "that plaintiffs have plausibly alleged the existence of a reverse payment for delayed entry with no legitimate procompetitive justification."[466]

o) Wellbutrin XL

In In re Wellbutrin XL Antitrust Litigation[467], Honorable Mary A. McLaughlin in the Eastern District of Pennsylvania examined whether a reverse payor's partner can be liable for making settlement possible; whether ''No Authorized Generic'' agreements are reverse payments. Wellbutrin XL was stayed awaiting resolution of Actavis.[468] There were also Noerr-Perrington and sham litigation issues. [469] The settlements at issue were originally between Biovail, GlaxoSmithKline, and four generic manufacturers.

The FTC attempted to file an amicus curiae brief explaining the background of ''No AG'' agreements and that they should be considered as reverse payments in the light of Actavis and

[463] Idem p. 8.

[464] Idem p 20.

[465] Idem. p. 21.

[466] Idem p. 24.

[467] In re Wellbutrin XL Antitrust Litigation., 08-cv-2431, 08-cv-2433 (E.D. Pa.) (Available at: https://www.paed.uscourts.gov/documents/opinions/12D0491P.pdf Downloaded 25 October 2018)

[468] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 6.

[469] In re Wellbutrin XL Antitrust Litigation., 08-cv-2431, 08-cv-2433 (E.D. Pa.)

that exclusive patent licences are not immune from antitrust law[470], but the brief was not accepted by the court. However, in the judgement issued on 23 September 2015. Honorable Mary A. McLaughlin found that "Wellbutrin Settlement does not present the same antitrust concerns that motivated the court in Actavis to subject the settlement to antitrust scrutiny", because the parties continued the underlying litigation.[471] However, the court analysed the settlement under rule of reason, in accordance with the Supreme Court's ruling in Actavis,[472] stating that: "The rule of reason asks three progressive questions of challenged agreements: (1) does the agreement have anticompetitive effects; (2) if so, are there procompetitive justifications for the agreement; and (3) can the plaintiffs present evidence that the challenged conduct is unnecessary to achieve those justifications."[473]

By examining the procompetitive justifications, the court stated that "[e]ven if the plaintiffs had demonstrated anticompetitive effects of the Wellbutrin Settlement, therefore, GSK has successfully presented sufficiently procompetitive justifications. The plaintiffs have not presented an actual factual dispute as to GSK's procompetitive justifications."[474]

According to legal literature, this case is also a good example which proves that Chief Justice Roberts was right in his dissent wishing good luck to the district courts.[475]

p) Further cases

In re Solodyn[476] was also a case involving reverse payment, where the District of Massachusetts examines whether ''No Authorized Generic'' agreements are reverse payments. The court, applying the rule of reason test, ruled that large and unjustified payments created a high risk of

[470] Amicus Curiae Brief in IN RE Wellbutrin XL Antitrust Litigation., 08-cv-2431, 08-cv-2433. Available at: https://www.ftc.gov/system/files/documents/amicus_briefs/wellbutrin-xl-antitrust-litigation-re/130926wellbutrinbrief.pdf Downloaded: 25 October 2018)

[471] In re: Wellbutrin XL Antitrust Litigation. *In re Wellbutrin XL Antitrust Litigation*, 133 F. Supp. 3d 734 (E.D. Pa. 2015) (Available at: https://casetext.com/case/in-re-wellbutrin-xl-antitrust-litig-4 para 41-42. Downloaded? 25 October 2018)

[472] Idem para 43.

[473] Idem para 44.

[474] Idem para 58

[475] Law 360: Where We Stand On Pharmaceutical Patent Settlements. (Available at: https://www.wsgr.com/publications/PDFSearch/law360-1015-3.pdf Downloaded: 25 October 2018)

[476] In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 14-md-2503 (D. Mass)

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anticompetetive harm, and once pled, the burden shifts to the defendants to justify the payments on 14th August 2015.

In In re Cipro Cases I & II[477] the court's decision was appealed to the Supreme Court of California, where it was stayed awaiting the resolution of Actavis. Weeks after Actavis was decided, brand manufacturer Bayer agreed to create a $74 million settlement fund and cooperate with the plaintiffs in their continued litigation against the generic defendants.[478] The plaintiffs, remaining generic defendants, and several amici have filed briefs before the court, where the issue remains as to whether California state antitrust claims may be brought to challenge reverse payments in pharmaceutical patent litigation.[479] The Supreme Court of California in its very recent judgement held about reverse payments – that "[u]nder federal antitrust law, these settlements are not immune from scrutiny, even if they limit competition no more than a valid patent would have. […] We conclude the same is true under state antitrust law."[480]

In re Aggrenox[481] the Judicial Panel on Multidistrict Litigation transferred 11 antitrust actions relating to Aggrenox to the Honorable Stefan R. Underhill in the District of Connecticut. [482] The issues examined are quite usual ones: whether ''No Authorized Generic'' agreements are reverse payments; whether payment was fair price for goods or services; whether settlement documents are protected work product. [483] By examining Actavis and several district court cases, and stated that "As of the date of this writing, at least one case applying Actavis has been argued before a federal Court of Appeals—In re Lamictal was argued at the Third Circuit in November 2014—but none of the circuits has yet issued an opinion interpreting it. There are some questions that arise in the application of Actavis that the district courts may answer in divergent ways—questions like what constitutes a reverse "payment," and what makes one "large" and

[477] In re Cipro Cases I & II, S198616 (Cal.)

[478] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 7.

[479] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 8.

[480] In re: Cipro Cases I & II. Available at: http://cases.justia.com/california/supreme-court/2015-s198616.pdf?ts=1431018029 Downloaded: 25 October 2018) p. 2

[481] In re Aggrenox Antitrust Litig., 14-md-2516 (D. Conn.)

[482] Brian Sodikoff – Thomas J. Maas – Patrick Abbott: Reverse Payments After Actavis: Fifteen Cases to Follow. p. 8.

[483] Idem.

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"unjustified." Some of those questions will surely end up in the Courts of Appeals, and perhaps eventually back again at the Supreme Court."[484]

Several other cases are or might be before the district courts or appellate courts. In this chapter, only a short introduction of a selection of some relevant cases could be given. By selecting the cases, my aim was introducing those which examine the most typical post-Actavis issues, and/or have a link with the former court cases, such as Androgel. The aim of this chapter was not to provide an exhaustive summary of the cases and introducing them in details, but to highlight some important points.

Against this backdrop, we can conclude that the most important questions after Actavis are the following: what constitutes a payment, especially whether No-authorized Generic agreements and side deals are considered as payments, or not, when is a reverse payment large and unjustified, what is a payment for real service or good, and what is a fair price of these goods or services. Most of the lower courts faced challenges by answering these questions, and it seems like Chief Justice Roberts and the dissenting Actavis judges were right by expressing their doubts about the applicability of Actavis principles by the district courts.

However, against of the first discrepancies, it seems that most courts agree in the basic principles, such as Actavis does not require cash payment, i.e. No-Authorized Generic agreements and side deals are meeting the requirements of the term payment used in "Actavis", because its central element is incentivizing the generic to postpone its market entry. On the other hand, there are still several questions to be answered, and there are some – such as when is a payment large and unjustified – which requires a case-by-case analysis by its very nature.

We can also ask the question, what can Europe learn from the US experience. First of all, the payment does not have to be only in the form of cash, any financial inducement for the generic from the originator might be regarded as payment. No-Authorized Generic Agreements are not relevant in Europe, but side-deals, licences, co-promotion agreements, etc. might be. About the size of the payment, we will look for further guidance in the next chapter. Concerning avoided litigation costs, we should keep in mind the different procedural rules, which can vary from country to country.

[484] In re: Aggrenox Antitrust Litigation No. 3:14-md-2516 (SRU) Available at: https://ecf.ctd.uscourts.gov/cgi-bin/show_public_doc?2014md2516-229 Downloaded: 25 October 2018) p. 9.

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III.3.6. US experiences related to lawful payment

The Supreme Court's Actavis judgement left several questions unanswered. Actavis pointed out that a large, bold payment from the innovator to the generic, which exceeds the branded company's savings on litigation and cannot be tied to any other consideration than the generic delay are likely to be anticompetitive, while agreements where the generic provides services for fair market value are likely defensible. [485]

These statements of Actavis raise several questions, such as: i) what constitutes a payment, ii) what amount of payment can be regarded as reasonable litigation costs, iii) what are the real services provided by the generic for fair market value. In the last chapter, we examined the relevant post-Actavis case developments at lower courts in order to answer these question.

With regard to the first question, the notion of payment, Carrier identifies four groups of value transfer generally applied in reverse payment settlements as follows: cash, poison pills, no-authorized-generic provision and brand forgiveness of damages. [486] It has never been questionable that cash is considered as a payment. The other three types of value transfer are however more problematic.[487] While the first reverse payment settlements were quite "easy" and straightforward, the later ones have become more subtle, more complex. Their analysis creates real challenge for the enforcers.

'Poison pill', or with other word, accelerator clause is a provision which ensures for the generic which has settled with the originator that it can expedite its entry when another generic enters the market at an earlier time.[488] Such clauses are not only offering the 180 days of exclusivity to the settling first filer, but also reduce the incentive for later filers to challenge the innovators patent.[489]

The no-authorized-generic provision has also a strong link to Hatch-Waxman exclusivity. With this clause, the originator obliges himself to not launch own generic product during the 180

[485] A. P. Reeves: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis p. 9.

[486] Michael A. Carrier: Payment After Actavis. Iowa Law Review, Vol. 100:7/2014. pp. 10-49.

[487] Damien Geradin – Douglas Ginsburg – Graham Safty: Reverse Payment Patent Settlements in the European Union and the –United States. p. 6.

[488] Michael A. Carrier: Payment After Actavis. p. 37.

[489] Idem. p. 38.

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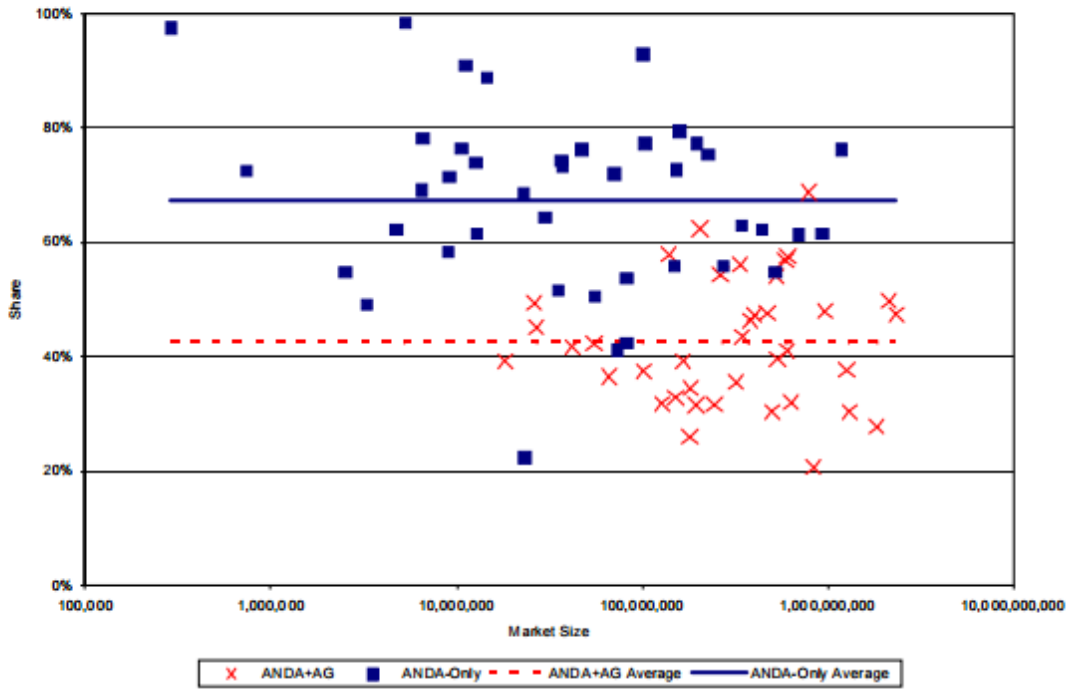
days exclusivity. Hatch Waxman Act provides 180 days exclusivity to the first filer generic against of other generics trying to enter the market. However, the brand will have the right to launch his own generic product – the so-called authorized generic – during this period, which can lower significantly the generic's profit. [490]

Figure 3-5: Revenue Share of ANDA Generic in Month Four of Exclusivity



Source: Authorized Generic Drugs: Short-Term Effects and Long-Term Impact[491]

The figure above shows the first filer generics revenue during the exclusivity period with authorised generics and without the entry of authorised generic. The FTC highlights that the market entry of the authorized generic reduces the revenues of the first filer generic by 45%, and it loses 25% of its market share.[492]

[490] Michael A. Carrier: Payment After Actavis. Iowa Law Review, Vol. 100:7/2014. pp. 10-49. p. 42.

[491] Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (Available at: https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf Downloaded 24 January 2020. 58.)

[492] https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf p. 57-58.

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On the other hand, launching an authorized generic – the originators own product with the same INN, but under a generic brand – is exactly in the interest of the originator, because it generally increases its profit by 6-21% during the 180 days exclusivity period,[493] and after.[494]

The fourth category, the brands forgiveness of damages is relevant in the scenario when the generic already entered the market, i.e. launched at risk. If later the court finds that the patent was valid and infringed, the generic will be responsible for the originator's substantial damages, which would exceed the generics profits won by the market entry.[495] In this scenario, they could settle the dispute and agree that the originator forgives some of these damages. This settlement can fall into the range of the potential expected litigation outcomes, so this type is a complicated case from an antitrust point of view.[496]

According to Carrier's estimation, a transfer of $5-10 million seems to be a rough approximation of litigation costs.[497]

Geradin at all. focus on side-deals.[498] According to Hemphill, "[t]oday, side deals take two complementary forms: overpayment by the brand-name firm for value contributed by the generic firm, and underpayment by the generic firm for value provided by the brand-name firm."[499] In case of side-deal, the generic and the originator settle, and they agree – for the first glance – in totally unrelated terms, e.g. a licence, or some service provided by the originator to the generic, settling unrelated litigations, etc. These agreements might seem ordinary business

[493] Federal Trade Commission: Authorized Generic Drugs: Short-Term Effects and Long-Term Impact. August 2011. (Availabe at: https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf Downloaded: 12 December 2014) p. 62.

[494] Idem. p. 96-100. See also Michael A. Carrier: Payment After Actavis. Iowa Law Review, Vol. 100:7/2014. pp. 10-49. p. 43.

[495] Michael A. Carrier: Payment After Actavis. Iowa Law Review, Vol. 100:7/2014. pp. 10-49. p. 44.

[496] Idem. p. 45.

[497] Idem. p. 21.

[498] Damien Geradin – Douglas Ginsburg – Graham Safty: Reverse Payment Patent Settlements in the European Union and the –United States. p.7.

[499] Scott C. Hemphill: An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition. Columbia Law Review, 2009. Vol (109:629) p. 663. Columbia Law and Economics Working Paper No. 347.

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agreements, and in the same time, they might be a subtle way of transferring value from the originator to the generic.[500]

Determining whether this agreements involve a value transfer or not is not an easy question, especially with regard to the findings of the Supreme Court in Actavis, that fair value for a real service should be found legal. Geradin at all highlight: "Even if the courts are able accurately to identify reverse-payment settlements that have an anti-competitive effect – a dubious proposition – the cost of doing so will be substantial, as companies devote resources to structuring complicated settlement agreements and then litigating whether those agreements are reasonable".[501]

The cases discussed above show well the difficulties of the courts determining especially what constitutes a payment. After Lamictal and Loestrin judgements and their criticism, it seems that courts are moving toward the approach that not only cash transfer might be considered as a payment. Taken into regard that the Supreme Court's Actavis judgement never put the requirement that the payment is expected to take the form of cash, this approach is welcome.

The balancing test the courts should apply is a difficult one, and they have to avoid both Type I. – they must not deter legitimate transactions – and Type II. – allowing restrictive and harmful settlements – errors.

Geradin at all., Hemphill and Carrier highlight that courts generally should be sceptical about agreements with a side-deal, especially because generics and originators rarely engage in these kind of deals without a patent settlement.[502]

[500] Damien Geradin – Douglas Ginsburg – Graham Safty: Reverse Payment Patent Settlements in the European Union and the –United States. p.7.

[501] Idem. p. 8. See also Bruce H . Kobayashi – Joshua D . Wright – Douglas H . Ginsburg – Joanna Tsai: Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly. Antitrust, Vol. 29, No. 2, Spring 2015. ABA.

[502] Damien Geradin – Douglas Ginsburg – Graham Safty: Reverse Payment Patent Settlements in the European Union and the –United States. p. 10, Michael A. Carrier: Payment After Actavis. Iowa Law Review, Vol. 100:7/2014. pp. 10-49. p. 22. Scott C. Hemphill: An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition. Columbia Law Review, 2009. Vol (109:629) p. 664. Columbia Law and Economics Working Paper No. 347.

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IV. Patent Settlements in the EU

In chapter II, I have already pointed out that the EU does not have a regulation similar to the US Hatch-Waxman Act. In the lack of such regulation, the fragmented European patent system seems to serve as the basis of reverse-payment settlements, by making the enforcement of patent rights difficult and expensive for originator companies. In this context, certain authors claim that the originators often prefer to settle, even when they have strong patent rights. [503]

In the EU, enforcers started to scrutinize pharmaceutical patent settlements later than in the US. When the 'first wave' of settlements in the US were over, in 2004, the Commission and the Danish Competition Authority, Konkurrence- og Forbrugerstyrelsen considered that the settlement concluded between originator company Lundbeck and the generics is in "a grey area" and found it doubtful whether those settlements are anticompetitive.[504] However, after the Pharmaceutical Sector Inquiry, the European Commission's attitude towards certain types of patent settlement changed significantly, and the Commission continued to monitor the patent settlements after 2009. Eight yearly reports were issued by the Commission, the closing date of the last one is December 2016.[505] The main findings of these monitoring reports will be presenteded later in this subchapter. At this point, it seems enough to highlight that the discrepancies identified in the sector lead to investigations by the European Commission.

After the first wave of cases handled by the European Commission, certain national authorities also started to show an interest towards pay-for-delay settlements. In 2016, the British competition authority, the CMA issued its first decision in a pay-for-delay case, and recent news suggest that further investigations related to reverse payment settlement cases are in progress in the UK.[506]

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[503] M. Clancy – D. Geradin – A. Lazerow: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law. p. 9.

[504] DCA, Press Release of January 28, 2004, R. Subiotto: Legal Assessment of Patent Settlement Agreements Containing "Reverse" Payments. (Available at http://fordhamipconference.com/wp-content/uploads/2013/04/2013.subiotto.pharma.pdf Downloaded: 19 August 2014)

[505] https://ec.europa.eu/competition/sectors/pharmaceuticals/archive/index.html

[506] Janith Aranze: CMA issues charges in second pay-for-delay case. (Available at: http://globalcompetitionreview.com/article/1129657/cma-issues-charges-in-second-pay-for-delay-case Downloaded: 4 December 2017) Although the CMA's GSK decision and the other ongoing national cases are going to be discussed shortly in this chapter, the chapter focuses primarily on the cases handled by the European Commission.

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The cases which ended up in front of the General Court or the ECJ – either as appeals or requests for preliminary ruling – also will be discussed in this subchapter.

Before examining the cases in details, it is necessary to discuss the European Commission's first attempts to monitor reverse payment settlements, and present the findings of the Pharmaceutical Sector Inquiry, due to the fact that the evaluation of pharmaceutical patent settlements is still based on the framework suggested by the Final Report of the Pharmaceutical Sector Inquiry.

IV.1. The Pharmaceutical Sector Inquiry and the Monitoring Reports

The first time when the European Commission expressed its concerns about patent settlements in the pharmaceutical sector was in 2009, in the framework of the Pharmaceutical Sector Inquiry.

The Final Report on the Pharmaceutical Sector Inquiry provides an in-depth analysis of patent settlements both in originator-originator and originator-generic context. The European Commission had been monitoring yearly the pharmaceutical sector between 2009-2016.

In the framework of the Pharmaceutical Sector Inquiry, the Commission reviewed 207 patent settlements.[507] Based on the experiences gained from this extensive review process, the European Commission set up a categorization system, which has been serving as a basis of each annual reports on the monitoring of patent settlements since then.

Eight annual reports have been published, showing a significant increase in the numbers of the settlements, with a peak in 2012. The numbers of settlements examined by the Commission are the following: 73 in 2009, 89 in 2010, 120 in 2011[508], and 183 in 2012[509]. Since 2012, the number of settlements has decreased, but it is still higher than the average number was in the 2000-2008 period:[510] The total number of patent settlement in 2015 was 125[511], in 2016 it was

[507] Final Report – Pharmaceutical Sector Inquiry.

[508] European Commission: 3rd Report on the Monitoring of Patent Settlements (period: January-December 2011) Published on 25 July 2012. p. 6. (20)

[509] European Commission - 4th Report on the Monitoring of Patent Settlements (period: January-December 2012) Published on 9 December 2013 p. 9. (26)

[510] European Commission: 6th Report on the Monitoring of Patent Settlements (period: January-December 2014) Published on 2 December 2015. p. 6. para 23.

[511] European Commission: 7th Report on the Monitoring of Patent Settlements (period: January-December 2015) Published on 13 December 2016. p. 6. para 23.

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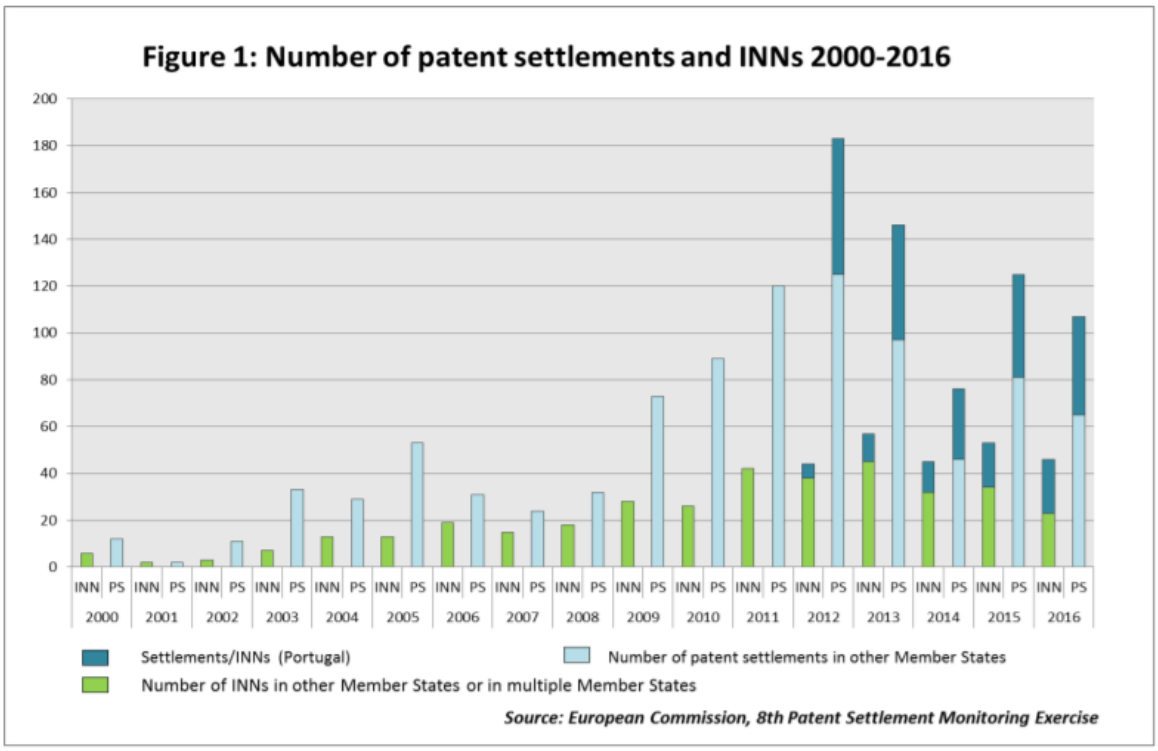
down to 107.[512] The chart below shows the numbers of patent settlements and INNs (international non-proprietary name for a pharmaceutical substance covered by patent settlements) between 2000-2016.



Source: European Commission: 8th Report on the Monitoring of Patent Settlements (period: January-December 2016) Published on 9 March 2018. p. 6.

The above Figure shows a sharp increase in the number of settlements in Portugal since 2012. The European Commission assumes that this tendency is likely explained by the implementation of Portuguese Law 62/2011 published on 12 December 2011.[513] This assumption of the Commission actually reinforces our conclusion that the regulatory background plays an important role behind patent settlements.

[512] European Commission: 8th Report on the Monitoring of Patent Settlements (period: January-December 2016) Published on 9 March 2018. p. 6. para 23.

[513] European Commission: 5th Report on the Monitoring of Patent Settlements (period: January-December 2014) Published on 5th December 2014. page 9. Para 27. The Commission explains: „This law essentially provides that an originator must initiate arbitration proceedings within 30 days of the publication of a marketing authorisation application by a generic company. If they do not comply with this provision, the originators then lose the ability to assert their IP rights. Hence, originators in Portugal are, since 2012, obliged to systematically bring arbitration proceedings against all generics applying for marketing authorisations. Many of these proceedings, where there is no issue on the validity of the underlying rights, are settled very rapidly with the generic agreeing to entry only after patent expiry" (footnote 14)

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IV.1.1. Categorization of patent settlements

In the framework of the Pharmaceutical Sector Inquiry, the European Commission identified three types of originator-generic patent settlement agreements.[514.] These three types are the following:

- Agreements that do not restrict the generic company's ability to market its own product are categorised as A-type,
- while those limiting generic entry are categorised as B-type agreements. B-type agreements are further divided into two subgroups:
    - B.I-type settlements which comprise those settlements where no value transfer from the originator to the generic company took place;
    - and B.II-type settlements which foresee a value transfer from the originator to the generic company.

Typically, category A settlements should be regarded as unproblematic from a competition law perspective. The same applies to category B.I settlements. Nonetheless, some settlement agreements in this category may attract competition law scrutiny. By contrast, category B.II settlements are likely to attract the highest degree of antitrust scrutiny since they limit access to the market and contain a value transfer from the originator to the generic. Nonetheless, this is not to suggest that agreements falling into this category would always be incompatible with EU competition law. This needs to be assessed on the basis of the circumstances of each individual case.

The main characteristics of these categories are going to be discussed below.

[514] See European Commission: Final Report – Pharmaceutical Sector Inquiry. 8th July 2009 pp. 269-270. See also: European Commission: 6th Report on the Monitoring of Patent Settlements (period: January-December 2014) Published on 2 December 2015. See also: European Commission: 5th Report on the Monitoring of Patent Settlements (period: January-December 2014) Published on 5th December 2014., See also European Commission - 4th Report on the Monitoring of Patent Settlements (period: January-December 2012) Published on 9 December 2013 p. 4. (14), see also European Commission: 3rd Report on the Monitoring of Patent Settlements (period: January-December 2011) p. 4. (11), see also 2nd Report on the Monitoring of Patent Settlements (period: January-December 2010) Published on 6 July 2011 p. 3. (11) see also 1st Report on the Monitoring of Patent Settlements (period: mid 2008 - end 2009) Published on 5 July 2010 p. 3. (11)

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IV.1.1. a) Type A agreements

Category A agreements do not put any limitation on the generic company. The generic is free to market its own generic product on the market without territorial, time, or any other limitation, under the conditions chosen by the generic itself.[515] A clear majority of category A settlements were concluded just about the time when the originator company lost its exclusivity[516], but it is not a necessary feature of all type A settlement agreements.

According to the Commission's view, type A agreements are most likely to occur when both parties believe that continuing the litigation would be a waste of time and other resources.[517] Similar to type B.II, Category A agreement might also contain a value transfer from the originator company to the generic company.[518] It might happen, for example, when preliminary injunction was granted by the court, and after the originator lost the lawsuit at first instance, or the patent was declared later invalid or non-infringed.[519]

Value transfers in the reverse direction, from the generic company to the originator are also possible. It may happen, when the patent was valid, but the generic entered the market on its own risk.[520] In these cases, the value transfer is used as a form of compensation for damages.[521]

IV.1.1. b) Type B.I agreements

In case of type B.I agreements, there is an explicit limitation of the market entry of the generic company.[522] These limitations might take various forms. The Pharma Sector Inquiry highlights that in almost all cases of type B.I settlements the validity of the originator company's patent, and/or, the infringement by the generic company was declared at least at first instance.[523] In these cases, the generic company had an interest in settling the case before the final decision,

[515] Final Report on the Pharmaceutical Sector Inquiry p. 271. (746)

[516] Idem. p. 272 (749)

[517] Idem. p. 272 (752)

[518] Idem. p. 273 (753)

[519] Idem. p. 273 (753-754)

[520] Idem. p. 273 (755)

[521] Idem. p. 274 (757)

[522] Idem. p. 275. (759)

[523] Idem. p. 275 (760)

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or the award of damages by the court. In such an agreement, the generic company might accept the decision of the first instance as final judgement, without appeal.[524]

IV.1.1.c) Type B.II agreements

Type B.II agreements are considered the most problematic type of patent settlements from a competition law perspective. Type B.II settlements limit the generic company's ability to market its own product and also include a value transfer from the originator company to the generic company.[525]

However, even according to the European Commission's categorization system, not all B.II agreements are by definition anti-competitive: The Final Report on the Pharmaceutical Sector Inquiry states that in-depth analysis of the individual agreement, taking into account the factual, economic and legal background is necessary to decide whether a certain B.II type settlement is compatible or incompatible with EU and/or national competition rules.[526]

The value transfer from the originator to the generic company can take different forms. The Pharmaceutical Sector Inquiry identified the following four groups:

i. direct payment,
ii. licence,
iii. distribution agreement, and
iv. side-deal.[527]

In the case of B.II type settlements, when the agreement included a payment, the generic company accepted not to enter the market (or to exit) until the patent of the originator company had expired.[528] The licencing agreements allow the generic to produce its product in a limited territory. The distribution agreements make the generic company distributor or sub-distributor of the product of the originator company in limited quantity in certain areas.[529] In the case of a

[524] Idem. p. 275 (760)

[525] Idem. p. 277 (762)

[526] Idem. p. 277 (763)

[527] Idem. p. 277 (765)

[528] Idem. p. 278 (767)

[529] Idem. p. 279 (767)

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side-deal, the parties agree to extend an existing clinical supply and development relationship.[530]

The background of B.II type agreements is explained as follows by the Commission. The existence of B.II type agreements „could mean that the originator undertaking has paid the generic undertaking to accept to give up, at least for the term of the agreement, its independent efforts to enter the market."[531] The direction of the payment is unusual, unexpected, that's why such payments are referred to as "reverse" payments in literature. The Commission elaborates that the „higher the originator estimates the chance of its patent being found invalid or not infringed, and the higher the damage to the originator undertaking resulting from successful generic entry, the more money it will be willing to pay the generic undertaking to avoid that risk."[532]

The economic rationality behind B.II type agreements brings us back to the classic economic problem with monopoly: without the thread of (potential) competition, the monopolist is able to charge higher price (monopoly price) for the good, and maximizes profit by selling lower quantity than in the case of (perfect) competition. If a competitor enters the market, price competition will bring down the prices: the new entrant won't be able to charge monopoly prices, it has to offer lower prices to get consumers. As an effect of the competition, neither the former monopolist will be able anymore to charge monopoly prices. This is the very basic model how competition drives down prices which enhances consumer welfare: consumer will pay less for the same good and also consumers who could not afford to by the product before will be able to purchase it.

The below figure represents the difference between monopoly and perfect competition:

[530] Idem. p. 283 (776)

[531] Lundbeck, para 640, Servier

[532] Lundbeck, para 640

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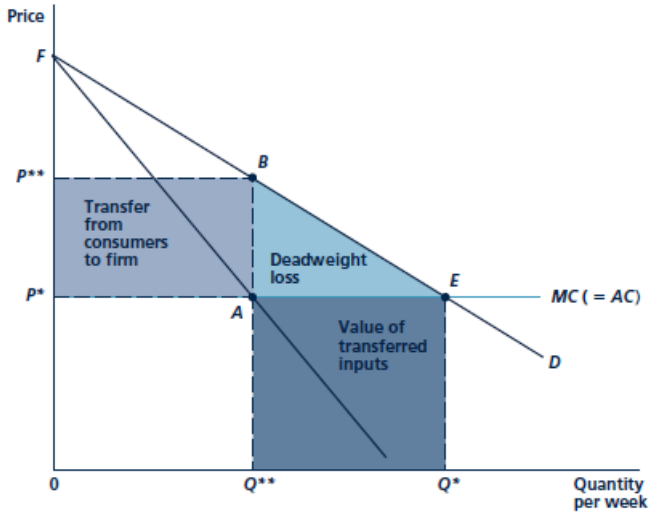

Source: Walter Nicholson – Christopher Synder: Intermediate Microeconomics and Its Application. Eleventh edition. p. 383

As – based on these basic differences between competition and monopoly – intuition suggests, both originators and generics can be better off at the same time by entering into anticompetitive settlements, as result of the characteristics of the market. The profit the generic undertaking could make from entering the market would be significantly lower than the amount the originator would lose as a consequence of the generic entry. Generic entrants will tend to price their product cheaper than the price of the brand product, price competition is the only important way for generics to compete with the originator's product and with other generics' products.[533] Consequently, it can easily happen that the sum paid by the originator to the generic in the framework of a type B.II settlement is higher than the amount what the generic could expect from a successful market entry. The originator might also be still better off by paying this amount to the generic because the generic entry would cause significantly higher deficit: as an effect of the generic entry and the price competition, the prices would drop significantly. The following figures explain the situation graphically:

Before generic entry, the originator earns "monopolprofit"[534]:

[533] Lundbeck para 644

[534] Please note that legal monopoly ensured by a patent or other intellectual property right does not mean necessarily monopoly in competition law terms, neither in the pharmaceutical sector. Here we refer to monopolprofit only to introduce the relationship between price drops, revenue loss, generic entry and reverse payment settlements. However, in certain cases, it can happen that an innovative product (especially a blockbuster) is so successful or innovative, that other products cannot even be considered as far substitutes.

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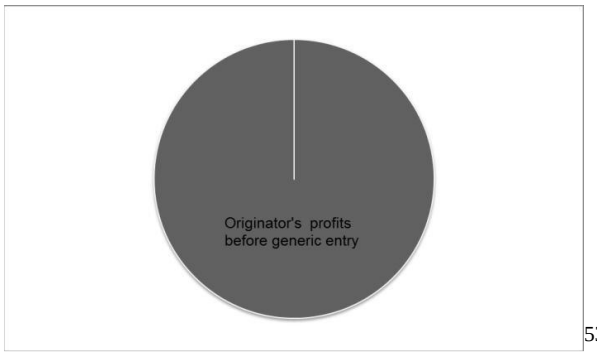
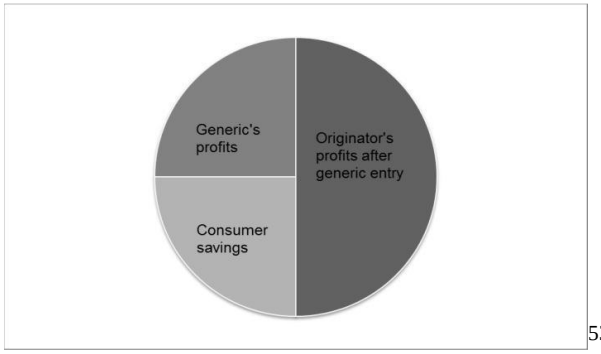


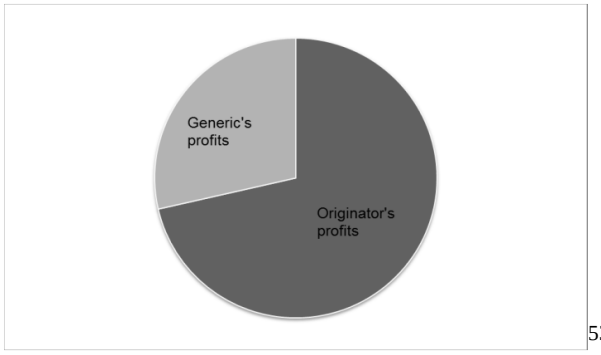
[535]

After generic entry, the profit is shared between the originator and the generic(s), and a "slice of the cake" is enjoyed by the consumers – or in certain cases by the social security – in the form of savings: the amount of the money saved by the consumers/social security as an effect of the price drop of the drug after generic entry is the consumers' surplus here.



[536]

If generic entry does not occur as result of a reverse payment settlement, the consumers' surplus is lost, the originator and the generic share the extra profit.



[537]

[535] Servier para 1152., Lundbeck para 646.

[536] Servier para 1152., Lundbeck para 646.

[537] Servier para 1152., Lundbeck para 646.

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So, while both originators and generics are better off with the settlement, consumers – even directly or as taxpayers through the social security – are likely to be considerably worse off in this situation, „as they fail to benefit, whether through their health insurance premium or the public health budget, from the prospect that a generic company might be able to lawfully enter the market"[538]

The originator and generic competitors could not reach the same outcome by litigation or by other legal tools. The Commission highlighted in its Lundbeck and Servier decisions that „while a patent holder has the right to oppose possible infringement of its patent, patent law does not provide for a right to pay actual or potential competitors to stay out of the market or to refrain from challenging a patent prior to entering the market […] even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they are likely to breach Article 101 of the Treaty when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself, but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market."[539]

The Commission emphasized that if the generic entry is not hindered through the strength of the patent, but through inducements from the originator to the generic, then a restriction of competition by object may exist.[540] The undertakings should not be entitled to enter into reverse payment settlement agreements which have the (partial) objective of blocking challenges to patents "perhaps wrongly granted" based on rent sharing. The patent systems of the EU offer no immunity against patent litigation and non-challenge clauses are not considered to fall within the scope of the patent.[541]

IV.2. Cases of European competition authorities

In this subchapter, four pay-for-delay cases of the European Commission, and an additional one, handled by the UK competition authority, CMA[542] will be discussed. The CMA has some other ongoing cases, as well, but due to the Brexit and the EU law focused nature of this research, I

[538] Lundbeck para 645

[539] Idem. para 641. See also Servier para 1153 for quite similar reasoning.

[540]Lundbeck para 659

[541] Servier para 1153

[542] Former Office of Fair Trading (OFT).

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found them less relevant. On the other hand, the Paroxetine case has important contribution not only to the field of pay-for-delay but also generally to the development of EU competition law. The ECJ's first judgment – a preliminary ruling – concerning pay-for-delay agreements was delivered in this case, therefore I found the discussion of the CMA's decision also necessary. The cases are going to be discussed in a chronological order, so our discussion is going to start with the first European pay-for-delay case, Lundbeck.

IV.2.1. Lundbeck

The first pay-for-delay case investigated and sanctioned by the European Commission was the Lundbeck case.[543] The European Commission imposed a fine of 93.8 million euros on the Danish pharmaceutical company, Lundbeck, and a total fine of 52.2 million euros on four generic producers. The fines were imposed on Lundbeck and on the generics for delaying the market entry of the generic version of Lundbeck's branded citalopram, a blockbuster antidepressant.

The Commission's Lundbeck decision concerns six agreements which operated in 2002 and 2003 between originator company Lundbeck on the one hand, and four generic pharmaceutical undertakings – Merck, Arrow, Alpharma, and Ranbaxy – on the other.[544]

The product concerned by each of the agreements was the anti-depressant citalopram, whether in the form of an active pharmaceutical ingredient (API) or in the form of a medicinal product.[545]

At the time the agreements were concluded, Lundbeck's patents and data protection on the citalopram compound and the two original production process patents had expired. Lundbeck still held a number of process patents ensuring exclusivity rights on certain, but not all new ways of producing citalopram. Since those process patents did not cover all potential ways of producing citalopram, Lundbeck no longer had complete blocking power against production and sales of citalopram by generic undertakings. [546]

[543] Case AT.39226 – Lundbeck

[544] Lundbeck para 1

[545] Idem. para 2

[546] Idem. para 3

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Citalopram, the API of Lundbeck's blockbuster drug is an antidepressant molecule which inhibits the reuptake of serotonin in the brain.[547] In the EEA, Lundbeck marketed citalopram as tablets of 10mg, 20mg and 40mg in packs of different tablets, liquid 40mg formulation, and for hospitals, an injection/infusion mode of delivery was also marketed. [548] In its decision, the Commission also considered that in principle, as long as an anti-depressant has been found to be sufficiently effective and well-tolerated, physicians are unlikely to switch to another treatment.[549]

Lundbeck's earliest citalopram patent, filed in 1977 in Denmark covered the pharmaceutical compound of citalopram and two processes to produce citalopram.[550] In Germany, due to the absence of an SPC, protection on the compound expired already in December 1994. Nevertheless, in this Member State the citalopram compound was still protected to the extent that it enjoyed data protection until 30 January 1999, and the expiry dates were different in almost all Member States. [551] By the mid-1980s, Lundbeck had developed and patented a new and more efficient process for purifying citalopram, these patents expired in 2005.[552] On 13 March 2000, two years before the expiry of the original compound and process patents, Lundbeck filed a priority patent application for the so-called crystallisation patent in Denmark.[553] This crystallisation patent and the process patents created considerable uncertainty for potential generic entrants and were at the heart of the generic companies' struggle for market entry. [554] In the 1980s, Lundbeck also started the development of a successor product to citalopram, escitalopram, which hold the patent expiry – including SPC – in most European countries in June 2014.[555]

Lundbeck could introduce citalopram, first patented in 1976, in the larger European markets only by the mid-1990s, so the available time for Lundbeck to fully exploit the product

[547] Idem. para 97

[548] Idem. para 98

[549] Idem. para 99

[550] Idem. para 109

[551] Idem. para 111

[552] Idem. para 112

[553] Idem. para 113

[554] Idem. para 114

[555] Idem. para 115

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commercially before patent expiry of the compound, by January 2002 was relatively short.[556] Soon after the launch it became a blockbuster. In 1997, Lundbeck assumed "that Citalopram generics will gain 40-70% of total substance volume in year five after introduction (at a 40% price discount to the original)".[557] The Commission's decision reports that in 1998, Lundbeck started to implement a complex generic strategy, which was reportedly successful in the next year.[558] One of the aims of the strategy was to reach agreements with generic manufacturers that will postpone or stop the manufacturing of generic citalopram in a short-run.[559]

As part of the generic strategy, Lundbeck purchased three patent applications filed a year before by the Italian generic citalopram producer Norpharma in October 1999. These manufacturing processes of citalopram differed from the ones patented by Lundbeck. Lundbeck has never used the processes, it only aimed to prevent generics from producing citalopram by using such processes.[560]

The second step of the above strategy was the purchase of VIS Farmaceutici S.p.A (VIS), an Italian generic citalopram API producer. VIS worked closely with Tiefenbacher to produce generic citalopram medicines. Tiefenbacher filed an application at the end of 1999 for a marketing authorisation based on VIS API, which was expected to be granted by the end of 2000. In October 2000, Lundbeck purchased VIS and "[i]mmediately following the purchase, VIS/Lundbeck withdrew the VIS Drug Master File from Tiefenbacher's marketing authorisation application in the Netherlands, claiming impurities in the VIS product."[561]

The Commission's decision found that CF Pharma, a small Hungarian API producer became the third target of Lundbeck's strategy. CF Pharma became a supplier to Lundbeck of intermediates after October 2002, when Lundbeck' increased its investment and shareholding in CF Pharma.[562]

Lundbeck was also closely monitoring API producers in India. First Lundbeck tried to eliminate Indian company Natco as a competitive threat. After Natco had developed an allegedly non-

[556] Idem. para 123

[557] Idem. para124

[558] Idem. para 125-126

[559] Idem. para 127

[560] Idem. para 174

[561] Idem. para 176

[562] Idem. para 178

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infringing method to produce generic citalopram, Lundbeck became "interested in initiating a commercial relationship with Natco". Natco rejected this proposal, and Lundbeck subsequently entered into negotiations with Merck (GUK), which had a 'preferred' right to purchase Natco's citalopram API for distribution in Europe. Through two agreements with Merck (GUK), one for the United Kingdom covering the period between 24 January 2002 and 1 November 2003 and one for the rest of the EEA, covering the period between 22 October 2002 and 22 October 2003, Lundbeck indirectly also aimed at preventing Natco from selling citalopram API to the EEA.[563]

In June 2002, Lundbeck made an agreement with a second Indian API producer, Ranbaxy. This agreement entailed that Ranbaxy would not sell citalopram API or citalopram medicines in the EEA. The agreement covered the period between 16 June 2002 and 31 December 2003.[564]

Finally, in February 2003, Lundbeck was reported in the press to have made an offer to the Indian API producer Matrix to acquire Matrix's process rights for the manufacture of citalopram. According to Tiefenbacher, this offer was made in October 2002.[565]

Lundbeck had been quite successful in eliminating the earliest competitive threat from Norpharma, VIS and CF Pharma, but its efforts in 2001 to persuade Indian API producers not to produce generic citalopram were less successful, both Natco and Matrix refused Lundbeck's offer. Indian companies Cipla and Sekhsaria also continued their preparations to produce generic citalopram.[566]

However, the first deals with Norpharma, VIS and CF Pharma – introduced as first elements of Lundbeck's anti-generic strategy were not covered by the Commission's decision, which concerned six agreements which Lundbeck concluded and operated in the period from January 2002 to December 2003 with Merck, Arrow, Alpharma and Ranbaxy.[567] All of the agreements covered by the Commission's decision had patent disputes as their backgrounds, but none of these settlements finally resolved a patent dispute. Rather, they postponed generic entry for a certain period of time.[568] Four of the agreements concerned the United Kingdom's market, so

[563] Idem. para 180-181

[564] Idem. para 182

[565] Idem. para 183

[566] Idem. para 184

[567] Idem. para 192

[568] Idem. para 194

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the Commission found it clear that Lundbeck focused its efforts to delay generic entry through agreements on the United Kingdom market.[569]

During the time the agreements were concluded, the UK was the most important market, and also – with its specialised and critical patent court – an important Member State for testing patent infringement and validity cases. Generic companies tend to select the United Kingdom as one of the first countries to try to enter the market with a new generic product. The United Kingdom market was also one of the markets most sensitive to generic penetration.[570] Two of the four agreements – with Alpharma and Ranbaxy – also covered all the other EEA countries.[571]

On 13 October 2003, Lundbeck also settled its only on-going infringement litigation with Lagap.[572] This settlement with Lagap basically put an end to Lundbeck's efforts to prevent generic citalopram from being distributed in the UK. The agreement with Alpharma had already ended by 30 June 2003. The agreements with Merck and Arrow were terminated following Lundbeck's settlement with Lagap. The agreement with Ranbaxy (EEA-wide) ended on 31 December 2003. Lundbeck's last legal action in the United Kingdom took place in January 2004, as it settled its infringement litigation with the generic supplier Neolab. This settlement included compensation paid to Neolab for the period December 2002 to October 2003 in which Neolab had not sold on the UK market because of the infringement proceedings Lundbeck had launched against it.[573] Following these events, the price of generic citalopram finally took on a strong downward trend.[574]

The decision highlights that the Commission found several internal documents and “smoking guns”.

At the time when Lundbeck and the generics concluded the agreements, Lundbeck's basic patent on the citalopram compound and the two original processes to produce the compound had expired – by January 2002 in most EEA Contracting Parties.[575] Lundbeck considered at the

[569] Idem. para 195

[570] Idem. para 196

[571] Idem. para 201

[572] Idem. para 207

[573] Idem. para 208

[574] Idem. para 209

[575] Idem. para 621

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time that "[g]eneric competition is foreseen on markets where the product patent has expired".[576]

„Patent litigation, which is very common when new generic products become available through expiry of exclusivity on originator medicines, is in fact an expression of the independent efforts of generic undertakings to enter the market and therefore a form of competition in the pharmaceutical sector. Likewise, patent litigation is also an expression of competition from the side of the originator undertaking, which in this way is trying to defend its market position against generic competition."[577] In the pharmaceutical sector, patent challenges are an essential part of the competitive process between generic companies seeking market entry.[578] Lundbeck itself confirmed to the Commission that its process patents were not capable of blocking all possible routes to the market, the production of citalopram that met European regulatory requirements was in principle possible without infringing any of Lundbeck's process patents.[579]

The Commission considered that Lundbeck's value transfer incentivised the generics to stay out of the market. The Commission explained: „Decisive for the legal assessment in this case is therefore not only whether certain limitations on the generic undertaking's behaviour were part of the agreements in question, but also, and particularly, whether those limitations were paid for by the originator undertaking. This applies as much to restrictions agreed in exchange for a payment that fall within the scope of the patent as to restrictions exceeding that scope. Payment for the limitations may have taken place either simply in the form of an outright cash payment or through a more covert transfer of value to the generic undertaking which cannot be adequately explained by, or which considerably exceeds, the value to the originator undertaking of any counter-performance of the generic undertaking. The specific facts and circumstances surrounding each agreement are obviously important in this respect."[580]

In Lundbeck, the Commission identified the following three step test which was also used after in Servier[581] to determine when a settlement infringes competition rules:

[576] Idem. para 622

[577] Idem. para 625

[578] Idem. para 626

[579] Idem. para 634

[580] Idem. para 660

[581] Servier, para 1154

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- First it should be examined whether the generic and the originator were at least potential competitors;
- After it should be determined whether the generic committed itself for the duration of the agreement to limit its independent efforts to enter one or more EEA; and
- Finally, the agreement was related to a transfer of value from the originator which substantially reduced the incentives of the generic to independently pursue its efforts to enter those markets.[582]

Besides the above test, in the Lundbeck case, the Commission also took into account the following facts:

(i) the value transferred by Lundbeck took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market;
(ii) Lundbeck could not have obtained the limitations on entry through enforcement of its process patents,
(iii) the obligations on the generic undertaking in the agreement going beyond the rights granted to holders of process patents; and
(iv) the agreement contained no commitment from Lundbeck to refrain from infringement proceedings if the generic undertaking entered the market with generic citalopram after expiry of the agreement.[583]

Finally, the Commission considered that the agreements went beyond the scope of the patent, therefore Lundbeck could not argue that it was merely enforcing its valid and infringed patents, „because the scope of the agreement was broader than the scope of the patent, and the commitments accepted by the generic in the agreement went beyond what a court enforcement of Lundbeck's process patents could have achieved”[584].

The quoted part of the decision is indeed interesting since the Commission seems to refer to the US scope of the patent test. Similarly, the legal literature also highlihts that the settlements between Lundbeck and the generics went beyond the scope of the patent.[585] If the agreement

[582] Lundbeck para 661

[583] Idem. para 662

[584] Idem. para 675

[585] P. Harrison – K. Nordlander : EU/US Patent Settlements: An overview of leading cases. p. 2. F. Carlin: Pay-for-delay settlements – EU Commission broadly aligns with the US Supreme Court. *EMEA Legal Insight Bulletin.* Summer 2013 p. 7-8.

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indeed went beyond the scope of the patent, it could be relevant for the case, even the less strict US test, the scope of the patent test would find a settlement anticompetitive which goes beyond the scope of the patent. However, during the appeal procedure before the General Court, Lundbeck stated that the settlement did not go beyond the scope of the patent. The General Court's view in that regard stayed unknown, the court refused to apply the scope of the patent test, simply reminding that it is a US test, and even in the US, the scope of the patent test is overruled. This cautious approach of the General Court is understandable towards application of the scope of the patent test in a European legal and economic system. It makes the Commission's above statement – regarding to the question whether Lundbeck's settlements went beyond the scope of the patent – even more surprising, and not only because of the foreign nature of the scope of the patent test as a US test, but because of the fact that the European Commission is a competition authority, not a patent court. It seems logical that a competition authority has neither jurisdiction nor expertise to decide what falls and what does not into the scope of the patent. Furthermore, even if we accept the Commission's jurisdiction in that respect, this courageous statement ought to have been proven sufficiently.

Alexander Italianer, Director General of DG Competition at the time when the Lundbeck decision was issued, summarized the main factors supporting DG Comp's view that the agreements restricted competition "by object" as follows:

(i) the generics had envisaged viable routes to market (i.e., they were potential competitors of Lundbeck),[586]

(ii) the agreements caused the generics to limit their independent efforts to enter the market;

(iii) the scale of the payments from Lundbeck to the generics substantially reduced the latter's incentives to enter; and

(iv) Lundbeck could not have achieved the limitations on entry by enforcing patents other than the patent that the Commission considered to be the "main molecule patent".[587] This statement is obviously based on the Lundbeck test discussed above.

[586] Data is available that one generic manufacturer has already entered the market int he time of the settlement (S. Kahmann – N. Baylis: The European Commission's first pay-for-delay anti-trust infringement decision. Available at: http://www.klgates.com/the-european-commissions-first-pay-for-delay-anti-trust-infringement-decision-07-09-2013/ Downloaded: 19 August 2014)

[587] P. Harrison – K. Nordlander: EU/US Patent Settlements: An overview of leading cases. p 3.

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> The last point mentioned by Italianer seems to slightly refer to the fact that the settlement went beyond the scope of the patent.

Lundbeck appealed against of the decision, the General Court's judgement and the very recent Opinion of the Advocate General in later the ECJ case will be discussed in a later subchapter.

IV.2.2. Fentanyl

In the Fentanyl case, the Commission imposed a fine of 10.8 million euro on the US pharmaceutical company Johnson & Johnson and of 5.5 million euros on the Swiss company Novartis for delaying the market entry of a cheaper generic version of the pain-killer fentanyl in the Netherlands. It was a co-promotion[588] agreement, not a patent settlement agreement; the relevant patents have already expired, neither litigation nor settlement took place between the parties. Therefore, it is not a reverse payment settlement case, but a pay-for-delay case in the sense that the originator paid for the generic to keep it away from the market. The payment occurred in the form of a co-promotion agreement.

In July 2005, Janssen-Cilag B.V. and Hexal B.V., the respective Dutch subsidiaries of Johnson & Johnson and Novartis/Sandoz concluded an agreement. According to the terms of the agreement, Novartis/Sandoz agreed to jointly promote, but not sell Johnson & Johnson's fentanyl matrix patches to pharmacists in the Netherlands. In return, Johnson & Johnson agreed to make monthly payments to Novartis/Sandoz. The agreement could be terminated immediately by Johnson & Johnson if Novartis/Sandoz launched its own generic product on the Dutch market.[589]

The legal environment in the Netherlands was also facilitated the conclusion of the agreement, because it put a general pressure on both the originator and the generic companies to considerably reduce the wholesale prices once a generic product entered the market.[590] It is important to note that in the Netherlands, if the prescription of the physician refers to the international non-proprietary name (INN) of a medicine, the pharmacist is free to choose the brand or the generic version of the medicine.[591]

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[588] Fentanyl para 1

[589] Idem. para 2

[590] Idem. para 43-48.

[591] Idem. para 53

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Fentanyl is the international non-proprietary name of a synthetic opioid which is 80 to 100 times stronger than morphine. It is used to treat chronic pain. Fentanyl was initially approved for cancer pain only, but after clinical studies, it was also approved for chronic intractable pain in many countries.[592] In many countries fentanyl is classified as a narcotic and as such, its distribution is subject to stricter rules than the distribution of ordinary prescription only medicines. In the Netherlands, the Opium Act categorized Fentanyl as hard drug.[593]

Fentanyl was introduced as an intravenous anaesthetic by Johnson & Johnson in the 1960's. The fentanyl compound patent expired already in 1982.[594] Fentanyl is used in the hospital sector and is also prescribed for personal use out of hospitals.[595] Fentanyl sales in the European Union in 2005 amounted to EUR 641 million and in the Netherlands to EUR 27 million. In 2006, fentanyl sales in the Union amounted to EUR 668 million and in the Netherlands to EUR 28 million.[596] Besides Johnson & Johnson and Novartis/Sandoz, there were other companies marketing fentanyl in the Netherlands in the period concerned or thereafter.[597]

Johnson & Johnson marketed fentanyl patches under the brand name Durogesic, and in the time of the Commission’s decision, it was still one of the most important blockbuster products in Johnson & Johnson's portfolio, accounting for USD 589 million worldwide revenues in 2011. In 2005, Johnson & Johnson's sales of Durogesic amounted to more than EUR 575 million in the Union and to USD 1.6 billion worldwide.[598] Depending on the Member State, data exclusivity expired either on 4 March 2000 or, as is the case for the Netherlands, on 4 March 2004. In the Netherlands it lost exclusivity on 4 March 2004.[599]

In 2004, Johnson & Johnson introduced the follow-on product, the matrix patch.[600] Following the introduction of the matrix patch, Johnson & Johnson stopped marketing the depot patch in most Member States and replaced it with its matrix patch. In the Netherlands, the matrix patches

[592] Idem. para 69

[593] Idem. para 73

[594] Idem. para 70

[595] Idem. para 71

[596] Idem. para 72

[597] Idem. para 63

[598] Idem. para 81

[599] Idem. para 83

[600] Idem. para 84

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were launched in August 2004 and, according to Johnson & Johnson, it sold the last batches of its reservoir patches in November 2004 which was followed by the product stocks at wholesaler, hospital and pharmacy level being depleted over time.[601]

In January 2007, when the permanent entry of an independent generic competitor, Ratiopharm became inevitable, Johnson & Johnson launched its own generic of the matrix patch in order to be able to run a "two-price strategy".[602]

After the loss of exclusivity of the fentanyl depot patch in the Netherlands in March 2004, any generic company could have entered the market. Johnson & Johnson was aware that Hexal B.V. was in an advanced stage of development and may be capable of launching its product in the foreseeable future. In June 2004 Janssen-Cilag B.V. prepared an internal note "Action list, Business Plan Presentations, 14-17 June 2004" which provided a "to do" list per molecule. For Durogesic it stated: "After the launch of matrix conduct market research among general practitioners and pharmacies concerning their willingness to still switch from matrix to generic reservoir. […] Work out a project on how to position the depot patch of Hexal as inferior. Research the possibility of cooperation with Hexal as a pre-emptive strategy for the arrival of the matrix generic."[603] Thus, Johnson & Johnson had a "comprehensive strategic response to the generic challenge".[604]

The effect of generic competition was estimated to amount to a loss of market share by 50% if Hexal B.V. launches its drug in March 2005 or by 40% if it would launch in July 2005. The estimated financial loss would be EUR 4.9 million or EUR 2.1 million, respectively. The price effect was anticipated to be even worse if the generic price was set at 40% of the brand price.[605]

Originally, Sandoz B.V. planned the launch of the Novartis/Sandoz's fentanyl patch in the Netherlands for the summer of 2005.[606] After the new proposal from Janssen-Cilag B.V. arrived – whereby Janssen-Cilag B.V. should keep the distribution/sales of Durogesic for itself and pay

[601] Idem. para 85

[602] Idem. para 88

[603] Idem. para 110

[604] Idem. para 112

[605] Idem. para 117

[606] Idem. para 127

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a royalty to Hexal B.V./Sandoz B.V. for promotion services only – Sandoz changed the plans.[607] The co-promotion agreement was concluded between Janssen-Cilag B.V. on the one hand and Hexal B.V. and Sandoz B.V. on the other hand.[608]

For the twelve month duration of the initial agreement, the total amount to be paid by Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. was EUR 3.7 million in monthly instalments. That amount corresponds to the profit Hexal B.V./Sandoz B.V. told Janssen-Cilag B.V. it could have made in the first year if it had launched its own fentanyl patch. The duration of the agreement was later extended and thereby the total amount paid by Janssen-Cilag B.V. also increased.

Novartis/Sandoz in fact did not launch its generic product in the Netherlands during the whole term of the co-promotion agreement, including the addendum which was in force until 15 December 2006.[609] It was another generic player, Ratiopharm, which launched the first generic fentanyl patch, a matrix patch, in the Netherlands on 1 February 2006,[610] however, its presence on the market was short-lived and it left the market on 15 March 2006 due to an interim injunction based on a complaint by Janssen-Cilag B.V.[611]

On 15 December 2006, the co-promotion agreement was terminated and replaced by the supply agreement.[612] The supply agreement entered into force on 1 January 2007 and had an initial duration of 2 years,[613] and it permitted Hexal B.V./Sandoz B.V. to introduce their generic versions once an independent generic player was present on the market. Given that Ratiopharm started a new marketing authorisation procedure for a generic matrix patch, Janssen-Cilag B.V. anticipated that Ratiopharm would enter the market either in December 2006 or in January 2007.[614]

[607] Idem. para 137

[608] Idem. para 153

[609] Idem. para 177

[610] Idem. para 178

[611] Idem. para 179

[612] Idem. para 193-194

[613] Idem. para 195

[614] Idem. para 198

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The total value transferred from Johnson & Johnson to Novartis/Sandoz in monthly instalments during the term of the Co-promotion agreement, including the addendum, was approximately EUR 5 million.[615]

The co-promotion activities actually performed by Hexal B.V./Sandoz B.V. during the term of the initial co-promotion agreement were limited. Only occasional contacts took place between the parties, the real co-promotion activities targeting pharmacists actually started only on 24 October 2005, so more than three months after the agreement entered into force. The monthly payments, however were also provided during that initial period.[616]

The only contemporaneous documents on co-promotion activities which the parties were able to provide for the Commission include three questionnaires containing replies of approximately 140 pharmacies to 13 multiple-choice questions and a one-page final evaluation report.[617]

The Commission evaluated the evidence of the co-promotion activities provided by Sandoz/Novartis as limited during the original period, and stated that „there is no available evidence at all that any specific promotion activities were performed by Hexal B.V./Sandoz B.V. during the period covered by the addendum." [618] The Commission added that „there is no available evidence showing that any specific promotion activities for the period covered by the addendum were even planned or discussed by the parties".[619] According to the Commission, this shows that the co-promotion agreement was unique and quite unusual, because, for other products Johnson & Johnson did not enter into co-promotion agreements.[620]

Termination clauses can be part of any agreement, but in this case Janssen- Cilag B.V. concluded the agreement with a close potential competitor which was on the verge of launching its own product. Moreover, the non-entry mechanism was designed in such a way that it made the potential market entry completely unattractive financially.[621]

[615] Idem. para 262

[616] Idem. para 266

[617] Idem. para 267

[618] Idem. para 276

[619] Idem. para 276

[620] Idem. para 287

[621] Idem. para 314

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According to the Commission's ex-post evaluation, Janssen-Cilag B.V. saved in total at least EUR 14.7 million for "a full year" by concluding the co-promotion agreement[622]

The Commission highlighted that the co-promotion agreement and the supply agreement were two distinct agreements based on self-standing, formally independent and separate legal contracts. The decision relates to the co-promotion agreement, not to the separate supply agreement which entered into force only after the co-promotion agreement was terminated.[623] The co-promotion agreement, delayed the entry of a cheaper generic medicine for seventeen months and kept prices for fentanyl in the Netherlands artificially high – to the detriment of patients and taxpayers who finance the Dutch health system.

The "part of [the] cake" provided by Johnson & Johnson to Sandoz was a co-promotion agreement,[624] the Commission found that the agreement was not designed to facilitate co-promotion, but to keep the price of fentanyl artificially high and to share the monopoly profits. The Commission has reached its decision on the basis that:

(i) no other co-promotion partners were considered;
(ii) Sandoz did not take part in any meaningful promotional activity; and
(iii) the payments received by Sandoz exceeded those which it might have expected to receive had it launched its own generic fentanyl. [625]

This case did not relate to intellectual property matters, the relevant patent expired earlier. Although strictly not a settlement agreement, but a pay-for-delay agreement; that time Commissioner Almunia stated that the logic was the same: "a company was paying its competitor to delay the entry on the market of the generic version of its drug".[626]

Absent any patent settlement agreement, the case appears to be a naked market-sharing arrangement. The parties did not appeal against the Commission's decision. The importance of

[622] Idem. para 325

[623] Idem. para 307

[624] J&J and Novartis mull appeal against €16 m EU Fine. (Available at: http://www.ft.com/cms/s/0/1dd1eb8e-6281-11e3-bba5-00144feabdc0.html Downloaded: 19 August 2014)

[625] Osman Zafar: Lundbeck, and Johnson & Johnson and Novartis: The European Commission's 2013 'pay-for-delay' decisions. Journal of European Competition Law & Practice, 2014. Available at: http://jeclap.oxfordjournals.org/content/early/2014/03/16/jeclap.lpu023.full.pdf?keytype=ref&ijkey=exwa7ZDYLckmBhc p. 1.

[626] SPEECH-13-1053_EN Joaquín Almunia: Fentanyl case

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presenting the Fentanyl case in detail is to highlight how pay-for-delay cases would be deemed naked restrictions on competition without the patent settlement elements. This point will lead us to two important conclusions:

- based on the fact that application of the scope of the patent test was rejected in Europe both by the Commission and by the General Court, and taking into regard that the European patent systems do not offer the possibility to protect patents against being challenge, it can be questionable in what extent the categorization of an agreement changes due to the existence of a (potentially invalid, or non-infringed) patent;
- a naked market-sharing agreement – ad one of the so-called hardcore restraints – would definitely meet the requirements of the narrow definition of by object restraints set out in the Cartes Bancaires case.

IV.2.3. Servier

In the third relevant case, the European Commission imposed a total fine of 427.7 million euros on French pharmaceutical company Servier and five generic companies for pay-for-delay agreements and other anticompetitive practices. This case was not a pure Article 101 case, the Commission also applied Article 102 of the TFEU. The Commission found that Servier engaged in a complex strategy aiming delaying generic entry. This strategy was partially based on reverse payment settlement agreements, and Servier also abused its dominant position by other, related conducts.

Servier and the generics concluded a series of deals protecting perindopril, a cardio-vascular medicine – the best-selling product of Servier – from price competition within the EU. Perindopril was Servier's "blockbuster" with annual global sales for the years 2006 and 2007 exceeding USD 1 billion, accounting for approximately 30% of Servier's total turnover.[627] The Commission found that "through a technology acquisition and a series of patent settlements with generic rivals, Servier implemented a strategy to exclude competitors and delay the entry of cheaper generic medicines to the detriment of public budgets and patients in breach of EU antitrust rules."[628]

[627] Servier para 2

[628] Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine European Commission - IP/14/799 09/07/2014

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Concerning Servier's incentives, the Commission highlighted that generic entry typically leads to two notable changes in the market:

(i) a significant decrease in prices and
(ii) substantial volume shifts from the originator company to the generic companies; Servier therefore had strong incentives to delay generic entry.[629]

In the framework of the assessment of Article 102 TFEU issues, the Commission found that Servier held dominance on the relevant market. As a consequence of the success of the perindopril molecule, no other medicines than the generic versions of perindopril were able to meaningfully compete.

The Commission's decision highlighted "[a] particularity of perindopril, like many other long term treatments, is that […] once confirmed as a successful treatment for a patient in an initial trial period, the patient typically takes the drug over many years and is unlikely to switch to an alternative, even when the purported alternative becomes available at significantly lower prices. In economic terms this corresponds to the low price-elasticity of demand. In the absence of a loss of efficacy, the occurrence of new side effects or the launch of a truly superior treatment (which was not the case during the period investigated), the patients will continue to take the same medicine, as doctors and patients are reluctant to go through a new trial period with an uncertain outcome. This was also confirmed by the extensive market survey carried out by the Commission."[1630]

When Servier's compound patent was about to expire, Servier started a complex anti-generic strategy.

First of all, the Commission found that Servier engaged in a patenting strategy aiming primarily blocking or delaying generic entry. The Commission also found "smoking guns" – i.e. internal documents discussing Servier's own evaluation regarding to certain secondary patents. In that regard, the Commission's decision notes: "[b]etween 2000 and 2005, Servier applied for and obtained a number of process and crystalline form patents, which Servier internally referred to

[629] Servier para 3

[630] Idem. para 91

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as “blocking patent” or “paper patent”. According to Servier's own assessment, some of them involved “zero inventive activity”.”[631]

Servier also followed the market very closely, when it learnt that an API producer claimed to have found an alternative – possibly non-infringing – way to produce perindopril, Servier acquired these technologies and removed them as a competitive source from the market. Servier bought two technologies, the latter with the explicit purpose to “strengthen the defense mechanism”.[632]

When Servier learnt about generic companies preparing for market entry, it tried to discourage them by sending warning letters, using litigation including injunction procedures, and Servier sought protection against generic entry by concluding five patent settlement agreements with the most advanced generic contenders: Niche/Unichem, Matrix, Teva, Krka and Lupin between 2005 and 2007. These settlements consisted of significant payments, or other inducements, from Servier to the generic companies, and the obligation for the generics not to challenge Servier's patents and not to enter the market – directly or indirectly – for a number of years. With one exception[633], the geographical scope of the settlements covered all EU Member States.[634]

As part of the anti-generic strategy, Servier also developed a second generation product, which was based on a new salt, arginine instead of erbumine, and for which Servier had obtained patent protection until 2023.[635]

The Commission’s decision deals with practices of patent acquisition and reverse payment settlements, which are considered to be violations of EU competition law. The reverse payment settlements amount to anti-competitive agreements pursuant to Article 101 of the TFEU, while the combination of the patent acquisition and the reverse payment settlements also amounts to an abuse of a dominant position by Servier pursuant to Article 102 of the TFEU.[636]

[631] Idem. para 5

[632] Idem. para 6

[633] The settlement with Teva concerned the UK only

[634] Servier para 7

[635] Idem. para 8

[636] Idem. para 9

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Actually, after the expiry of the compound patent Servier held dozens of "secondary" patents relating to processes and forms, but these patents – or patent cluster – was not enough to keep away the generics from such a profitable market. Producers of cheaper generic versions of perindopril were intensively preparing to enter the market.

Generic companies sought access to patent-free products or challenged Servier's patent. In 2004, Servier acquired the most advanced non-protected technology, forcing a number of generics to stop and delaying their entry. Servier never put to use the acquired technology. The acquisitions meant that these technologies were no longer available for generic operators seeking to enter the market with a form of perindopril that was not patent protected by Servier.[637]

Generic producers decided to challenge Servier's patents before courts and EPO[638]. Between 2003 and 2008, Servier engaged in a number of patent disputes with its generic competitors. [639] Between June 2004 and June 2009, in parallel to the EPO proceedings, Servier was party to twenty-five court cases involving perindopril.[640]

However, between 2005 and 2007, each time a generic company came close to entering the market, Servier and the generic settled. Servier concluded patent settlement agreements with five companies: Niche/Unichem, Matrix, Teva, Krka and Lupin. With the exception of Teva, the settlements covered the entire EU. The settlements essentially consisted, on the one hand, payment of significant amounts of money, or another type of significant value transfer, to the generic companies, and, on the other hand, the obligation for the generics to not enter the market and not to challenge the patents for a period of time determined by the agreements. Teva also entered into an agreement whereby it would distribute in the UK an authorised generic supplied by Servier.[641]

[637] Idem. para 139

[638] In 2004, ten generic companies filed opposition proceedings against the '947 patent at the EPO (Servier para 129) The view of many generic companies was that the '947 patent was not valid (Servier para 128) The European patent EP 1 296 947 (the abovementioned '947 patent) was granted by the EPO on 4 February 2004. It relates to the crystalline alpha form of perindopril and the process for its preparation. The '947 patent is one of Servier´s most controversial patents. In its annulment decision the Court of Appeal ruled the '947 patent "is invalid.(Servier para 124 and 127)

[639] Servier para 151

[640] Idem. para 157

[641] Idem. para 174

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The strategy of Servier included using authorised generics – referred to as by Servier as a "nuclear weapon"[642] –, the introduction of a second generation product[643], and it also concluded ten distribution agreements in total with the generic companies. All of the agreements concern the commercialisation of perindopril in the contractual territory with exclusive supply by Servier.[644]

With regard to the settlements, the Commission remined Irish beef and points out that: "the fact that an agreement may also have had other, entirely legitimate objectives does not bar the possibility of finding a restriction by object."[645]

The Commission recognizes that patent holders are free to rely on their patents to exclude competitors from practising the patented invention, and patent settlements may benefit both the parties to the dispute and the society, "by allowing for a more efficient allocation of resources than if all litigation were to be pursued to judgment".[646] However, intellectual property rights, including patent rights, are not immune from the application of competition law. [647] Preventing patent challenges – as Servier did - may therefore seriously impact the competitive process. The Commission also refers to the case law of the European Courts in that regard: in Windsurfing International, the Court of Justice confirmed that "it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error."[648]

The patent systems in the EU offers no immunity against patent litigation and the originator as the patent holder cannot buy certainty against the risks inherent in litigation as an expression of competition and still obtain immunity under competition law.[649]

The Commission highlighted that also other important factors have been taken into consideration: "First, the restrictions either lasted throughout the entire period of the patent term, or did not contain any commitment by Servier to refrain from infringement proceedings

[642] Idem. para 203

[643] Idem. para 218

[644] Idem. para 204

[645] Idem. para 1114

[646] Idem. para 1118

[647] Idem. para 1119

[648] Idem. para 1132

[649] Servier para 1153

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in case of independent entry with the relevant generic products after the expiry of the agreement. Second, the value Servier transferred to generics took into consideration the turnover or the profit the generic undertaking expected if it had successfully entered the market. Third, the obligations on certain generic undertaking in the respective agreements exceeded the scope of the underlying patent litigation/ dispute, in particular as the restrictions went beyond what Servier could have legally obtained through successful enforcement of its patents in the underlying disputes/litigation".[650] The list of these extra factors taken into regard by the Commission in its evaluation of the agreement reminds to the further important factors – not elements of the three step test – influencing the Commission's evaluation in Lundbeck. Both agreements went even beyond the scope of the patent – as concluded by the Commission, even though the scope of the patent test has never been applied in European cases and by the time of the decision, was outruled also in the US.

Also similarly to Lundbeck, the Commission found internal document which make clear the intent of generics and Servier in the settlements. Commissioner Almunia stated: "[P]atent settlements should not be misused. Engaging in an exclusionary strategy to foreclose important competing technologies and buying one close competitor after another is blatantly abusive."[651]

The decision is unique among the Commission's pay-for-delay cases as it is not solely based on Art. 101 TFEU, but also on Art. 102 TFEU. It adds "a new dimension to the Commission's enforcement agenda in relation to pay-for-delay settlements, as it not only focuses on the settlements themselves but also on broader unilateral conduct by the brand company".[652] By acquiring the remaining process patents, enforcing them, and inducing generic companies to enter into settlements, Servier was then able to delay generic entry.

Servier appealed against the decision, the General Court's judgment will be discussed in the appropriate subchapter.[653]

[650] Idem. para 1155

[651] SPEECH-14-541 – Joaquín Almunia – Decision in Servier case

[652] S. Gallash: The EU Commission Decision against Servier – a New Dimension to European Pharmaceutical Antitrust? Available at *http://competitionpolicy.wordpress.com/2014/07/11/the-eu-commission-decision-against-servier-a-new-dimension-to-european-pharmaceutical-antitrust/* Downloaded: 19 August 2014.

[653] Case T-691/14. Servier SAS and Others v Commission. ECLI:EU:T:2018:922

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IV.2.4. Cephalon

The fourth case handled by the Commission is Cephalon/Teva. In 2011, the European Commission opened a formal antitrust investigation to assess whether an agreement between Cephalon and generic company Teva may have had the object or effect of hindering the entry of generic modafinil in the European Economic Area (EEA). Modaphinil is used to cure certain types of sleeping disorders.

In December 2005, Cephalon and Teva settled patent infringement disputes in the United Kingdom and the United States concerning modafinil – INN of Cephalon's brand name drug Provigil. As part of the settlement agreement Teva undertook not to sell its generic modafinil products in the EEA markets before October 2012.[654] A series of side deals were included into the settlement agreement, which was also subject to antitrust litigation in the United States.

On 17 July 2017 the Commission sent Statement of Objection to Teva. The Commission informed Teva of its preliminary view that an agreement concluded with Cephalon was in breach of EU antitrust rules.

On 26 November 2020 the European Commission published a press release informing the public that fine of €60.5 million was imposed on Cephalon and Teva for agreeing to delay for several years the market entry of a cheaper generic version of Provigil. The agreement was concluded well before Cephalon became a subsidiary of Teva, therefore it is subject to antitrust rules even though later Teva acquired Cephalon[655].

The text of the decision is not available yet, press release informs us that Provigil accounted to 40% of Cephalons worldwide turnover for several years, and after the main compound patents protecting modafinil had expired in Europe by 2005, Cephalon still held secondary patents related to the pharmaceutical composition of modafinil aiming to securing additional patent protection. Cephalon induced Teva not to enter the market with its generic version of modafinil, in exchange for a package of commercial side-deals and some cash payments.[656] These side-

[654] IP/11/511 Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva

[655] Teva to acquire Cephalon in $6.8 billion transaction. (Available at: https://www.europeanpharmaceuticalreview.com/news/6990/teva-to-acquire-cephalon-in-6-8-billion-transaction/. Downloaded 29 November 2020)

[656] Antitrust: Commission fines Teva and Cephalon €60.5 million for delaying entry of cheaper generic medicine (available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2220, Downloaded: 28 November 2020)

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deals “included a distribution agreement, the acquisition of a licence on certain Teva modafinil patents by Cephalon, purchases of raw materials from Teva, and granting by Cephalon of access to clinical data that were highly valuable to Teva for a different medicine.” The Commission’s investigation found that none of these transactions would have been concluded in the absence of the patent settlement agreement, “either not at all or at least not at the terms that the companies agreed to.”[657] Unfortunately, no further information is provided about the side-deals and how they were beneficial to Teva by the moment, and the publication of the decision might take several months due to access to file and confidentiality issues. The nature of the inducements seems even more interesting taken into regard that based on the press release, it seems like – unlike in Lundbeck and Servier – Teva was more than a potential competitor: the generic held its own patents relating to modafinil's production process, was ready to enter the modafinil market with its own generic version in the EU, and it had even started selling its generic product in the UK, one of the most important EU markets – not only from business perspectives but also for patent lawsuits. Then, Teva agreed with Cephalon to stop its market entry and not to challenge Cephalon's patents, and this agreement cause harm to European consumers and healthcare systems by delaying cheap generic modaphinil becoming available to consumers for several years. The agreement delayed significant savings, since we also know that when Teva entered the UK market for a short period in 2005, it offered a 50% lower price than the price of Cephalon's Provigil.[658] The agreement lasted until Teva acquired Cephalon in October 2011, although pursuant to the original settlements Teva was supposed to enter the market with generic modaphinil as of October 2012, on the basis of a licence granted by Cephalon, in exchange for significant royalty payments to Cephalon. Even this limited entry under the licence eventually did not happen after the acquisition.

According to the further information known from the press release published by the Commission about the Statement of Objection, after the expiry of certain patents on the compound in the EEA Teva entered the UK market with generic Modaphinil for a short period of time. Cephalon initiated a lawsuit concerning an alleged infringement of Cephalon's process

[657] Idem.

[658] Idem.

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patents on modafinil. Following that Cephalon and Teva settled their litigation in the UK and the US with a world-wide agreement.[659]

Concerning this case, it is important to note that there were parallel issues related to Cephalon – Teva pay-for-delay agreement concerning modafinil in the US. However, the US procedure seems to differ from the European Cephalon/Teva case. In the US, the FTC initiated a lawsuit in 2008 against Cephalon. The FTC sued Cephalon for unlawfully protecting Provigil through a series of agreements with four generic drug manufacturers in late 2005 and early 2006. The FTC alleged that Cephalon sued the generics for patent infringement and later paid them over $300 million in total to drop their patent challenges and forgo marketing their products for six years, until April 2012. In May 2015 the FTC reached a settlement with Teva Pharmaceutical Industries, Ltd., which acquired Cephalon in 2012. According to the settlement, Teva will make a total of $1.2 billion available to compensate purchasers, including drug wholesalers, pharmacies, and insurers, who overpaid because of Cephalon's illegal conduct. [660]

IV.2.5. The Commission's tests applied in pay for delay cases

After introducing the Commission's pay-for-delay cases it is important to compare the applied legal tests. This will help us understand the essence of the problem with pay-for-delay cases.

For this purpose, the test applied by the Commission in Fentanyl case will be compared to the one applied in Lundbeck and Servier. It has already been discussed above that Fentanyl was not a patent settlement case, but a pure pay-for-delay case – or in other words, a genuine market sharing agreement.

The test applied by the Commission in Fentanyl case can be summarized as follows:

Firstly, the Commission considered that the parties at the time when the co-promotion agreement was concluded were at least close potential competitors. Entry was a plausible assumption, without the agreement, there would have been a strong likelihood that Hexal

[659] Antitrust: Commission sends Statement of Objections to Teva on 'pay for delay' pharma agreement (Available at: http://europa.eu/rapid/press-release_IP-17-2063_en.htm Downloaded: 30 November 2018)

[660] FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics (Available at: https://www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill Downloaded: 30 November 2018) See also: FTC Enters Global Settlement to Resolve Reverse-Payment Charges against Teva (Available at: https://www.ftc.gov/news-events/press-releases/2019/02/ftc-enters-global-settlement-resolve-reverse-payment-charges Downloaded: 28 November 2020)

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B.V./Sandoz B.V. would have entered the market.[661] Secondly, the co-promotion agreement included a non-entry mechanism.[662]Thirdly, as a consequence of the agreement, close potential generic competitor was excluded from the market at a time when the threat of its market entry was imminent.[663] Moreover, for the period concerned, the incumbent paid in total a large amount to the potential competitor in monthly instalments,[664] for very limited or non-existing co-promotion activities.

The Commission therefore concluded that the co-promotion agreement between the incumbent originator undertaking and its close potential competitor constitutes a restriction of competition by object.[665]

The Fentanyl test therefore is composed of the following elements:

- existence of potential competition
- non-entry mechanism
- generic excluded from the market
- value transfer form the originator to the generic (reverse payment).

This corresponds to the three step test applied by the Commission in Lundbeck, and also used in Servier,[666] just to remember:

- the generic and the originator were at least potential competitors;
- the generic undertaking committed itself in the agreement to limit its independent fforts to enter the market for the duration of the agreement with generic product; and
- value transfer from the originator to the generic which substantially reduced the later's incentives to independently enter the market with generic product.[667]

Furthermore, in Fentanyl, the decision also noted that the objective elements of the analysis were confirmed by the intentions of the parties as they showed that both parties acted in the full

[661] Fentanyl para 361

[662] Idem. para 362

[663] Idem. para 363

[664] Idem. para 364

[665] Idem. para 366

[666] Servier para 1154

[667] Lundbeck para 661

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knowledge of the anticompetitive objective of the Agreement.[668] The Commission also took into consideration the intention of the parties in Lundbeck and Servier, and both decisions referred to so called "smoking guns" as it was discussed above.

IV.2.6. The UK cases

The British competition authority has been handling several pharma sector related cases in the recent past. Some of them concerns pay-for-delay agreements.[669] In Fluocortisne case, the infringement decision was issued on the 9 July 2020, while the two other cases are on-going. Since the thesis focuses on EU (and US) law, and the UK is not an EU Member State anymore, detailed discussion of these cases is out of the scope of this thesis. On the other hand, one UK case has a vital importance for this research, and consequently, should be subject to detailed examination. The infringement decision in this case was delivered while the UK was still a Member State of the EU, and the first judgment of the ECJ – preliminary ruling – concerning pay-for-delay agreements was delivered in this case. Until the very recent past, it was also the only judgment of the ECJ dealing with pay-for-delay agreements. However, this situation changed this March when Lundbeck was published, but discussion of Paroxetine case is still important for the research.

IV.2.6.1. GlaxoSmithKline (GSK, or Paroxetine)

The fifth European pay-for-delay competition law case to be discussed was delivered by the UK competition authority – initiated by the Office of Fair Trading (OFT), now the Competition and Markets Authority (CMA). In its statement of objections,[670] the OFT alleged that GlaxoSmithKline (GSK) had concluded agreements which infringed competition law with four generic companies – Alpharma Limited (Alpharma), Generics (UK) Limited (GUK) and Norton Healthcare Limited (IVAX) – over the supply of paroxetine in the UK. The OFT also alleged GSK's conduct amounted also to an abuse of dominant position.

[668] Fentanyl para 365

[669] Case 50455 Fluocortisone, Case 50277-2 Hydrocortisone (Concordia-Actavis UK), Case 50277-3 Hydrocortisone (Auden Mckenzie-Waymade)

[670] Press release: OFT issues statement of objections to certain pharmaceutical companies. (Available at: http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www.oft.gov.uk/news-and-updates/press/2013/36-13 Downloaded: 30 November 2018)

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The generic companies were each attempting to supply a generic paroxetine product in competition to GSK's branded paroxetine product, Seroxat. However, in each case, GSK challenged the generic companies with allegations that their products would infringe GSK's patents. To resolve these disputes, each of the generic companies concluded one or more agreements with GSK. In the statement of objections, the OFT's provisional view was that these agreements included substantial payments from GSK to the generic companies in return for their commitment to delay their plans to supply paroxetine independently. [671] On 21 October 2014 the CMA – OFT's successor – issued a supplementary statement of objections,[672] and the decision was delivered on 12 February 2016.[673]

In its 700 pages long decision, the CMA found that between 2001 and 2004[674] GSK agreed to make payments and other value transfers totalling over £50 million to suppliers of generic versions of paroxetine. The CMA has found that these payments and other value transfers were aimed at delaying the potential entry of generic competitors into the UK market for paroxetine.

Seroxat was launched by GSK in the UK in 1991. It is an antidepressant medicine that became a 'blockbuster' with UK sales of £91 million in 2001. GSK's primary patent on the paroxetine molecule itself expired in January 1999, although certain other patents, so-called secondary patents remained for particular forms of paroxetine and for certain production processes.[675]

Between 1997 and 2002 generic companies Norton Healthcare Limited (which traded as IVAX Pharmaceuticals UK), GUK and Alpharma took steps to enter the UK paroxetine market. Each generics considered that there was a real prospect to enter the market with generic paroxetine that would withstand any legal challenge from GSK under patent law. The generics also supposed that the relevant GSK patent claims may be found invalid and/or not infringed by the courts. [676]

[671] Press releases 2013 – OFT issues statement of objections to certain pharmaceutical companies. 36/13 19 April 2013. Available at: http://oft.gov.uk/news-and-updates/press/2013/36-13 Downloaded: 19 August 2014.

[672] https://www.gov.uk/government/news/cma-takes-further-procedural-step-in-paroxetine-investigation

[673] Paroxetine – Case CE - 9531/11. (Available at: https://assets.publishing.service.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=HxtPHsAmxLeaNW8GCjIUyfQMOHiK7QoGNUDLGdxKhi4,&dl Downloaded: 30 November 2018)

[674] Idem. p. 9. para 1.3.

[675] Idem. p. 9. para 1.4.

[676] Idem. p. 9. para 1.5.

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Patent disputes arose, and were not resolved by the courts – GSK instead entered into agreements with each generics, "providing for the distribution by those Generic Companies of restricted quantities of GSK's product"[677] as value transfer. (i.e. the generics became authorized generics)

The CMA found that these agreements were anticompetitive by object, and as such, fall under the prohibition of Chapter I. of the Competition Act 1998 and Article 101. TFEU. In its decision – similarly to the Commission's respective decisions – the CMA emphasized:

While settlements of litigation are generally desirable, they may not be concluded on terms that infringe competition rules. It is particularly important to prevent patentees (the incumbents) and their generic challengers from entering into anti-competitive settlement agreements in the pharmaceutical sector, because patent challenges, most often by generics, are important means to test the validity of a 'legal monopoly' in this crucial sector. Due to the sector's characteristics discussed in chapter I, patent challenges in this field can in themselves be viewed as an important – or the only – aspect of the competitive process. Settlement agreements that result in patent challenges being 'bought off', on the basis that the challengers will share in the continued 'monopoly' profits made by the patentee, are apt therefore seriously to harm competition and the interests of consumers".[678]

The CMA found that GSK paid the generics to desist, during the term of the agreements, from continuing their efforts to enter the UK paroxetine market independently of GSK, and thereby from offering independent generic competition against GSK. The CMA declared that in the present case, it is clear that the substantial value transfers made by GSK to the generics cannot be explained by any legitimate objective, the only plausible basis was to induce the generics to delay their efforts to challenge GSK's position and enter the UK paroxetine market independently.[679]

The CMA also found that GSK committed an abuse of dominant position according to Chapter II of the Competition Act 1998 and Article 102 of the TFEU, and failed to objectively justify this abuse.[680]

[677] Idem. p. 9. para 1.6.

[678] Idem. p. 9. para 1.10

[679] Idem. p. 9. para 1.11

[680] Idem. p. 418. para 8.75

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An interesting element of the case is that the CMA cited extensively the ECJ's judgement in Cartes Bancaires[681] by examining the object of the agreements. The CMA's GSK decision was issued after both the Commission's Lundbeck and Servier decisions and also after the ECJ's landmark judgment in Cartes Bancaires, but before the General Court's judgment in Lundbeck. Considering the hot disputes about Cartes Bancaires's potential effect on the Lundbeck case preceding the General Court's judgment, it seems interesting that the CMA found it important to refer to the ECJ's reasoning in Cartes Bancaires and provided an argument in support of its views that even after Cartes Bancaires, GSK's conduct infringes competition rules by object, i.e. to prove that the ECJ's reasoning in Cartes Bancaires does not affect the outcome pay-for-delay cases as expected by the opponents of the by object evaluation.

The following points of the decision obviously refer to the ECJ's reasoning in Cartes Bancaires: "certain types of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition. The [E]CJ characterised as the essential legal criterion for a finding of anti-competitive object that the coordination between undertakings reveals in itself 'a sufficient degree of harm to competition' that there is no need to examine its effects"[682]. By noting the most relevant sentence of Cartes Bancaires, the CMA clearly expressed its views that the concerned agreement meets the Cartes Bancaires requirement. Considering the timeline of the EU courts' case law, I find it important to highlight that in the middle of the debate about the evaluation of pay-for-delay triggered by Cartes Bancaires, the CMA used this reference.

"The notion of restrictions of competition by object cannot be reduced to an exhaustive list. In order to determine whether an agreement may be considered to have the object of restricting competition, regard must be had to the content of its provisions, its objectives, and its legal and economic context. In assessing the context, it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market(s) in question. Although the parties' intention is not a necessary factor in determining whether an agreement is restrictive, there is nothing prohibiting that factor from also being taken into account."[683] This reference to the context and the intent in pay-for-delay cases is crucial. Thinking about the harm caused by such agreements, and the generally found

[681] Case C-67/13. Groupement des Cartes Bancaires c. Commission, EU:C:2014:2204

[682] Idem. p. 247 para 6.12

[683] Idem. p. 247 para 6.13.

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"smoking guns" in the European cases, the CMA supported its evaluation by using this reference from Cartes Bancaires.

Although the CMA's decision came out half year before General Court's judgement in Lundbeck, it seems that the UK competition authority came to the same conclusion like the General Court in Lundbeck case:

„In a case where it is contended that an agreement has the object of restricting competition from a potential new entrant, one must have regard to 'the structure of the market and the economic and legal context within which it functions', to ascertain whether there are 'real concrete possibilities … for a new competitor to enter the relevant market and compete with established undertakings'. This is not a hurdle requiring proof of likely effects, since otherwise the distinction between cases where an agreement has a restrictive object and cases where an agreement has - at least potentially - restrictive effects, would be eliminated. The underlying idea behind paying regard to the economic and legal context is that 'purely theoretical and abstract considerations' should not amount to infringements."[684]

The CMA also reached the same conclusion as the General Court in Lundbeck concerning subjective evaluation of potential competition by the parties:

„The perception of the market incumbent(s) on the relevant market that there is a threat, and the response of the market incumbent(s), is relevant to the assessment whether there is a sufficiently serious threat to amount to potential competition. The GC stated in Visa that: '… the essential factor is the need for the potential entry to take place with sufficient speed to form a constraint on market participants.'"[685]

„The very existence of an agreement under which a party undertakes to a market incumbent not to enter a market is in itself a clear indication that the market incumbent faces potential competition from that other party"[686]

The pharma companies appealed the decision of the CMA, and in 8 March 2017 the Competition Appeal Tribunal gave an initial judgment, and referred questions to the ECJ for a preliminary ruling "concerning the interpretation of Art 101, as regards potential competitors,

[684] Idem. p. 247 para 6.15.

[685] Idem. p. 247 para 6.16.

[686] Idem. p. 247 para 6.17.

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the object of the GUK and Alpharma Agreements, and the effect of the GUK and Alpharma Agreements; and specific questions concerning the interpretation of Art 102 as regards the definition of the market in the context of the abuse here alleged and as regards the question of abuse including the relevance of the benefit to the NHS resulting from the IVAX Agreement."[687] The ECJ's recent preliminary ruling judgment will be discussed in details later.

IV.2.7. Critical analysis of the cases handled by the European Commission and the CMA

Four cases handled by the European Commission, and one other case of the CMA have been introduced in the previous subchapter. The Commission adopted its decision very recently in Cephalon/Teva, therefore, the text of this decision is not available yet. The exact facts of the cases and the assessment of the authorities are unknown at this stage, so, commenting on them seems too early.

The Fentanyl case is a unique one, due to the fact that neither patent infringements, nor patent settlements were involved. This case is going to be used only for the sake of comparison, while this analysis is going to focus on Servier, Lundbeck, and GSK cases.

We should start with the Lundbeck test, which was applied also in the Servier case. The three-prong test elaborated and applied in Lundbeck by the Commission remains at the heart of the Commission's assessment. However, the test has been subject to criticism.[688] Killick at all. criticize the test for being very loose, and not differentiating "between patent disputes where the possible outcome is 50/50 and one where it is 10/90 or 90/10 or even 1/99 or 99/1."[689] While this argument might be valid, it should also be noted that the European Commission is not

[687] Case Nos: 1251-1255/1/12/16. Competition Appeal Tribunal. (Available at: http://www.catribunal.org.uk/files/1.1251-1255_Paroxetine_Judgment_CAT_4_080318.pdf Downloaded: 30 November 2018) para 453.

[688] Cartes Bancaires para 89. See also: Killick and P. Berghe, Applying a by object test to patent settlements is very different from the rule of reason. Concurrences N° 2-2014, pp. 21-24. See also James Killick – Jérémie Jourdan – Jerome Dickinson: The Commission's Lundbeck decision: A critical review of the Commission's test for patent settlement agreements. CPI, 24 February 2015. (Available at: https://www.competitionpolicyinternational.com/the-commissions-lundbeck-decision-a-critical-review-of-the-commissions-test-for-patent-settlement-agreements/ Downloaded: 17 December 2017)

[689] James Killick – Jérémie Jourdan – Jerome Dickinson: The Commission's Lundbeck decision: A critical review of the Commission's test for patent settlement agreements. CPI, 24 February 2015. (Available at: https://www.competitionpolicyinternational.com/the-commissions-lundbeck-decision-a-critical-review-of-the-commissions-test-for-patent-settlement-agreements/ Downloaded: 17 December 2017)

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competent to decide about the strength of patents, neither able to predict the potential outcome of a – potential – patent dispute.

The test applied by the Commission was also criticized for the very broad concept of potential competition, stating that such a test will not allow for any distinction between a generic company ready to enter the market and one that has serious hurdles to overcome.[690] In that regard, the judgment of the General Court in the Lundbeck case – which will be discussed in the next subchapter – clarified that the generics should have real, concrete possibilities to enter the market within a short period of time, in order to be considered as potential competitors. This requirement complies with the ECJ's findings in the Visa case.[691]

The Commission also listed the possibilities of the generics to enter the market in the Lundbeck case, which can be relevant in cases which have the same background as Lundbeck. In Lundbeck, the compound and the two original production processes were no longer patent-protected; while Lundbeck still had a number of process patents covering several, but not all possible ways to produce marketable citalopram medicine. So, in Lundbeck the Commission listed the following potential routes of generics to enter the market:

a) launching at risk;
b) making efforts to "clear the way" with the originator undertaking first before entering the market;
c) action for declaration of non-infringement;
d) invalidity actions at national courts,
e) changing the way of production to eliminate risk, or changing the API supplier (e.g producing citalopram in a non-infringing way).[692]

Killick at all. also highlight that "the existence of a limitation of the generic's freedom to independently market its product is an inevitable consequence of most settlements, which will often include a non-challenge and a non-infringement clause" and "the presence of a value transfer to the benefit of the generic company cannot be enough to infer the existence of a restriction by object. […] Any settlement requires mutual concessions, so it must be expected

[690] Idem.

[691] Case T-461/07, Visa Europe Ltd and Visa International Service v Commission, judgment of the General Court of 14 April 2011, EU:T:2011:181, § 68 and 166.

[692] Lundbeck para 635.

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for a settlement to include some form of transfer from the originator to the generic company. And there is a fundamental difference between one competitor paying another not to compete and the typical scenario of patent litigation: the difference is the patent, which grants one competitor a monopoly. The patent is the elephant in the room, which despite its size and importance seems often to be downplayed or forgotten."[693]

This point of the argument is indeed interesting. It suggests that value transfer from the originator to the generic – i.e. – reverse payment is a necessary element of a settlement in the pharmaceutical sector. While it is obvious that even in the sector there are several settlements without such value transfer, it cannot be excluded that in certain cases the generic – bearing a significantly lower risk in the patent dispute – expects to be incentivised by the originator to settle. Besides the lower risk on the side of the generic, the information asymmetry also supports the generics' position, and – at least theoretically – could enable it even to bluff on the originator. In that regard, it should be noted, even the Commission found that not all reverse payment settlements are by object restriction, the assessment is subject to a case-by-case analysis. The Commission also declared in Lundbeck that not all payments are problematic. Neolab settlement serves as an example of non-problematic settlements: if the generic refrained from entering the market due to the originator's actions and threats, and at a later stage of the litigation the parties came to the conclusion that it is likely that the patent is invalid or not infringed. The potential danger of reverse payments is highlighted by the Commission as follows: in the light of the specific circumstances of the case, the reverse payment may actually constitute "exclusion" payments, that is to say payments by the originator to the generic in exchange for the acceptance of commercial limitations which it would not, based purely on its assessment of the likelihood of infringing a patent and of invalidating any such patent, have the same incentives to accept in the absence of the payment.[694]

From the comparison of the Fentanyl and Lundbeck tests, it is visible that the two tests are very similar. Obviously, the Commission did not differentiate between paying for delay in the presence or absence of patents. The Commission provided the following reasoning: even if the limitations in the agreement on the generic undertaking's autonomy do not go beyond the material scope of the patent, they are likely to breach Article 101 of the TFEU "when those

[693] James Killick – Jérémie Jourdan – Jerome Dickinson: The Commission's Lundbeck decision: A critical review of the Commission's test for patent settlement agreements.

[694] Lundbeck para 639-640.

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limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself, but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market. However, such restrictions are all the more likely to be illegal when the restrictions agreed do go beyond the substantive scope of the patent, in the sense that the same restrictions could not have been obtained by the patentee's right to oppose possible infringement before the court."[695] This reasoning might be criticized for blurring what the Commission understands under the scope of the patent, and even the fact that the Commission refers to the scope of the patent test, which as a US test was rejected by the Commission in the same decisions, is kind of questionable. Interesting to note that the reference was used before Actavis, when the scope of the patent test was not overruled, but the general standard applied in the US. While the Lundbeck test summarizes the main criteria applied by the Commission to assess patent settlement agreements and can seem well suited for the purposes of the assessment at first sight, the test – and its application – leaves several questions unanswered. While the main elements of the Lundbeck case can be summarized as generic entry restriction, significant value transfer and potential competition and the aggravating criteria, the Commission did provide sufficient guidance for drafting lawful settlements in the future. We know that additional elements, smoking guns and the intent was taken into regard in the European cases – but we do not know in what extent this influenced the decisions.

The same test was applied by the competition authorities in Servier and in the UK GSK cases. These later cases however have a further interesting element to be discussed: the application of Article 102.

In Servier, the Commission found that Servier was dominant and followed a generic strategy to delay generic entry: "Servier put in place and rigorously pursued a comprehensive strategy using all complementary means to protect perindopril. This broader strategy relied on the creation of a "maze of patents", and influencing regulatory standards so that they would, for example, "lead to the use of [Servier's] protected processes" and thus influenced the parameters for viable market entry by generic perindopril. Within that broader context, Servier pursued a targeted exclusionary strategy, […] to remove, before market entry, all close sources of competitive threats on the up- and down-stream markets for perindopril with the potential to

[695] Idem. para 641-642.

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overcome notably the patent and regulatory barriers. By and large, these threats were not ousted from competition based on the merit of Servier's patent portfolio, its superior efficiency, or better quality of its products, but by a string of technology acquisitions (Azad in 2004, Sandoz (failed) in 2008) and rent sharing in the form of a series of reverse payment patent settlements with generic companies (Niche/Unichem and Matrix in 2005, Teva and Krka in 2006, Lupin in 2007)."[696]

So, in Servier, not only the patent settlement, but a whole anti-generic strategy is assessed in its entirety. In GSK the CMA followed this approach, and also the Concordia case is opened on the basis of Article 101 and 102 and of their british equivalents.

While it is not directly related to pay-for-delay settlements, these cases lead to the "misuse of patent" doctrine originating from AstraZeneca case. In Servier, the Commission highlighted that Servier misused otherwise legitimate tools such as the patent settlements and process patents, by shutting out a competing technology and buying out several competitors that had developed cheaper medicines.[697] In AstraZeneca, it was found by the Commission and the European Courts that AstraZeneca misused the regulations and procedures – i.e. otherwise legitimate tools – inter alia by providing misleading information to patent authorities, and by deregistering marketing authorisation of its old product, Losec.[698]

AstraZeneca was not a pay-for delay-case but is nevertheless relevant for this research because it shows that the Commission and also the European Courts seem to be willing to correct the inefficiencies and problems of other regulations by applying competition law.

IV.3. The expected effects of Cartes Bancaires, and the evolution of by object

The ECJ's Cartes Bancaires judgement is not related to the pharmaceutical sector. It becomes interesting and important for this research by its approach towards by object restrictions. Before the General Court's judgment in Lundbeck, the potential effect of the ECJ's reasoning in Cartes Bancaires on the European Commission's pay-for-delay cases was subject to hot debates, it was

[696] Servier para 2793.

[697] Press release IP-14-799 - Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine. (Available at: http://europa.eu/rapid/press-release_IP-14-799_en.htm Downloaded: 30 November 2018)

[698] Case C-457/10 P AstraZeneca AB and AstraZeneca plc v European Commission, ECLI:EU:C:2012:770.

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expectable that Cartes Bancaires will strongly affect the judicial reviews of Lundbeck and Servier. This vital importance of Cartes Bancaires lays in the fact that after a long time, the ECJ interpreted the notion of by object restrictions narrowly.

Critical voices towards the Commission's Lundbeck (and Servier) decisions were expecting that the General Court's evaluation related to the classification of the infringement as a by object infringement will be affected by this case, and consequently, the General Court will reject the Commission's classification. After the General Court's judgement in Lundbeck became available it is well known that the General Court did not do so. The case is exactly the same with Servier. Since March 2021, it is also known that the ECJ confirmed the Commission's decision in Lundbeck, but Servier is under appeal. Since the ECJ did not provide a detailed guidance on the evaluation of pay-for-delay cases, rather it expressed that they are subject to case-by-case analysis, the recent practice of the EU courts regarding to the object/effect dispute is still important for tis research. Although object/effect dichotomy is important for the sake of this research, the extent and volume of the related more than a half century long debate does not make it possible to discuss its developments in its entirety. Therefore, here in this chapter I will discuss certain, subjectively selected cases and their effects in the evaluation of the object/effect debate. Due to the topic of this research, these cases will be selected on the basis of their impact on the evolution process of by object doctrine, which finally lead to condemning Lundbeck's conduct as by object restraint. I am aware that certain other elements, e.g. the role of intent in the assessment of competion cases could also be relevant for the assessment of pay-for-delay cases, but after careful review, I found that such approach would over-expand the framework of this research.

IV.3.1. Object-effect dichotomy

The object-effect dichotomy has been in the centre of interest of both practice and theory since the very beginnings of EU competition law. Given that the exact wording of Article 101 TFEU in 2020 is essentially unchanged since the Treaty of Rome of 1957[699], it seems indeed interesting that after more than six decades of experiences the interpretation of this provision is still unclear, and consequently, cases are regularly referred to the ECJ for preliminary ruling.[700]

[699] Tóth Tihamér: A 60 éves Római Szerződés versenyjogi rendelkezései: Ami változott, ami nem, s ami kimaradt. Iustum Aequum Salutare, XIV. évf., 2018/2. szám, 60.; Szilágyi Pál: A közösségi versenypolitika (antitröszt jog) ötven éve. Iustum Aequum Salutare, II. évf., 2007/4. szám, 146-147.

[700] Interesting to note, that Advocate Genera Bobek refers to this 'paradox' in his opinion given in the Hungarian MIF case (Case-C-228/18. Budapest Bank at all. v. GVH. ECLI:EU:C:2019:678) as follows: "From the early days

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As Advocate General Bobek highlights in his Opinion in the Budapest Bank case the distinction between anticompetitive object and effect is relatively easy to make in theory, but in practice, it is more complex. Bobek also admits that the case-law of the EU Courts has not always been crystal clear on the subject and refers to the fact that a number of decisions given by the EU Courts have been criticised in legal scholarship for blurring the distinction between the two concepts. [701]

Besides the fact that the case law of the ECJ on object effect dichotomy was indeed not crystal clear, its development neither has not followed a straight line during the decades. Until Cartes Bancaires, , the EU courts had the tendency to widen the notion – and application - of by object restrictions by including crisis cartels, complex anti-competitive arrangements, information exchange, cases in this category.[702] This practice of course, triggered criticism.[703] So, the ECJ's judgment in Cartes Bancaires[704], giving a narrower interpretation to the by object category was welcomed as a unique new approach in a context characterized by almost unlimited use of the by object category.

Before going into the details of this revolutionary approach, however, it is necessary to introduce in a nutshell the context – i.e. the "state of the art" settled case law of the European courts by the time Cartes Bancaires was delivered. This necessity is fuelled by the fact that

of EU competition law, much ink has been spilled on the dichotomy between restriction of competition by object and restriction by effect. (2) It may thus come as a surprise that this distinction, stemming from the very wording of the prohibition in (what is now) Article 101 TFEU, still requires interpretation by the Court."

[701] Opinion of Advocate General Bobek, Case-C-228/18. Budapest Bank at all. v. GVH. ECLI:EU:C:2019:678. para 2. For a Hungarian example, see: Csongor István Nagy: The Distinction between Anti-competitive Object and Effect after Allianz:The End of Coherence in Competition Analysis? World Competition 36, no. 4 (2013): 541–564.

[702] Case C-56/65. Société Technique Minière (L.T.M.) k. Maschinenbau Ulm GmbH, EU:C:1966:38, ("STM"), See also: BIDS case, See also: Case C-8/08 T-Mobile Netherlands BV and Others v. Raad van bestuur van de Nederlandse Mededingingsautoriteit, ECLI:EU:C:2009:343; ("Dutch T-Mobile"), See also: Case C-439/09. Pierre Fabre v. Dermo-Cosmétique SAS v Président de l'Autorité de la concurrence and Ministre de l'Économie, de l'Industrie et de l'Emploi. ECLI:EU:C:2011:649. See also: Alliance Hungária, See also: CPI: Cartes Bancaires: A Revolution Or A Reminder of Old Principles We Should Never Have Forgotten? (Available at: https://www.competitionpolicyinternational.com/cartes-bancaires-a-revolution-or-a-reminder-of-old-principles-we-should-never-have-forgotten/ Downloaded: 20 January 2017)

[703] For a pay-for-delay related example, see for example Peter Alexiadis – Pablo Figueroa: Mixed Messages in the "By Object" vs "By Effects" Saga: The Enigma of Lundbeck. Competition Policy International, February 2018. Available at: https://www.competitionpolicyinternational.com/mixed-messages-in-the-by-object-vs-by-effects-saga-the-enigma-of-lundbeck/#_ftn4 (Downloaded: 20 October 2018)

[704] C-67/13 P Cartes Bancaires case

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nothing can be revolutionary, unique, or paradigm-changing in itself – only compared to something else, the earlier paradigm.

This never-ending saga of the ECJ with the object/effect dichotomy started soon after the Treaty of Rome, in the LTM case, when the ECJ determined that anticompetitive object and effect are alternative, not cumulative requirements, therefore, if the anticompetitive object is proven, it is not necessary to examine the effects of an agreement.[705] Since LTM, the establishment of anticompetitive effects therefore was not required if an agreement had already been found to be restrictive by object, because in such cases anticompetitive effects would be obvious, and the agreement would qualify as prima facie anticompetitive.[706] Consequently, 'establishing the object of an agreement is an exercise that differs from the evaluation of its impact on competition'.[707]

An exhaustive introduction of the post-LTM case law is not the aim of this thesis, here it seems enough to highlight some interesting examples, kind of cornerstones to present the approach which was broadening – for a period, seemingly without limits – the by object category in the past.

The so-called 'object-box'[708] contains the types of certain collusive behaviour, "such as that leading to horizontal price-fixing by cartels, [which] may be considered by their nature as likely to have negative effects, in particular on the price, quantity or quality of the goods and services, so that it may be considered redundant, for the purposes of applying Article 101(1) TFEU, to prove that they have actual effects on the market"[709] Based on the case law of the European courts in the last decades, the following conducts fall into the object box:

[705] Case C-56/65. Société Technique Minière (L.T.M.) k. Maschinenbau Ulm GmbH, EU:C:1966:38, 249.

[706] Ibáñez Colomo, Pablo: Legal Tests in EU Competition Law: Taxonomy and Operation. Journal of European Competition Law & Practice, Vol. 10. No. 7. pp. 424–438, p. 427. (Available at : https://doi.org/10.1093/jeclap/lpz045, downloaded: 15 January 2020)

[707] Ibáñez-Colombo, Pablo–Lamadrid, Alfonso: On the notion of restriction of competition: what we know and what we don't know we know. p. 16 (Available at : https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2849831, downloaded: 15 January 2020). See also: Dömötörfy Borbála Tünde–Kiss Barnabás Sándor–Firniksz Judit: Látszólagos dichotómia? Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre. In: Verseny és Szabályozás, 2019. Available at: https://www.mtakti.hu/wp-content/uploads/2020/03/02_DomotorfyBT-KissBS-FirnikszJ.pdf Downloaded: 29th September 2020)

[708] Richard Whish–David Bailey: Competition Law. Ninth edition. Oxford University Press, 2018, 131.

[709] Case C-345/14, Maxima Latvija k. Konkurences padome, EU:C:2015:784, para 19; see also case C-123/83. Bureau national interprofessionnel du cognac v Guy Clair ECLI:EU:C:1985:33, para 22.

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- horizontal price fixing[710],
- market sharing[711],
- export restrictions between member states[712],
- agreements to reduce production capacity [713],
- horizontal information sharing[714],
- vertical price fixing[715]
- vertical agreements containing absolute territorial protection.[716]

For the first sight, these classic categories seem obvious examples of by object restraints, however, certain aspects of some of them worth to be examined. Furthermore, the content of the object box cannot be determined exactly, and it is rather dynamic, then static: the changes and improvements of the market also influence it.

In the above list, the reference to the output restricting category refers to a very important judgment, the BIDS-case[717], also widely cited by the European Commission in its pay-for-delay decisions, and also mentioned as highlighted example of the category by the European Commission's Guidance on restrictions of competition "by object" for the purpose of defining which agreements may benefit from the De Minimis Notice.[718] In BIDS, the 10 principal beef and veal processors in Ireland agreed in a reduction of processing capacity by 25%. The stayers compensated – i.e. provided financial inducement to – the leavers.[719] In fact, based on this information, the BIDS agreements seem to be naked hardcore by object restraints for the first sight. However, the High Court ruled that the agreements do not fall under the prohibition of

[710] C-345/14 Maxima Latvija para 19; Case C-67/13 Groupement des Cartes Bancaires k. European Commission, EU:C:2014:2204, para 51, Case T-374/94 European Night Services and others k. European Commission ECLI:EU:T:1998:198 para 136.

[711] T-374/94 *European Night Services para* 136

[712] Idem

[713] C-209/07 BIDS

[714] C-8/08 *T-Mobile Netherlands*

[715] Case C-243/83 *SA Binon & Cie v SA Agence et messageries de la presse* ECLI:EU:C:1985:284

[716] Joined cases 56 and 58-64. Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community. ECLI:EU:C:1966:41

[717] C-209/07 BIDS

[718] Guidance on restrictions of competition "by object" for the purpose of defining which agreements may benefit from the De Minimis Notice. SWD(2014) 198 final. 2.3.1

[719] C-209/07 BIDS para 8

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(the current) Article 101 (1), but satisfy the requirements for exemption laid down in Article 101 (3).[720] BIDS was not a simple naked restraint, but a so-called crises cartel: its aim was to solve a sectoral crises in the Irish Beef industry, what the main producers found to be solved the easiest through a cartel agreement reducing overcapacity. In that respect, the ECJ found that "even supposing it to be established that the parties to an agreement acted without any subjective intention of restricting competition, but with the object of remedying the effects of a crisis in their sector, such considerations are irrelevant for the purposes of applying that provision. Indeed, an agreement may be regarded as having a restrictive object even if it does not have the restriction of competition as its sole aim but also pursues other legitimate objectives".[721] Therefore, the evaluation of a naked output / capacity restriction as by object infringement was not influenced by the fact that the agreement aimed to solve a sectoral crisis. The Commission – and the European courts – reached the same conclusion in pay-for-dealay cases: the fact that the subjective intent of the parties was to settle a dispute, does not change the evaluation of the agreements – although smoking guns and complex anticompetitive strategy was found both in Lundbeck and in Servier, and the relevant decisions and judgments suggest clearly that these elements were even taken into account.

T-Mobile Netherlands represents an important step towards the broadening of the by object category, as well: the ECJ found that certain type of information exchange between competitors can constitute a by object infringement. In this case, the ECJ found that "for a concerted practice to be regarded as having an anti-competitive object, it is sufficient that it has the potential to have a negative impact on competition" [722], and that if "the undertaking participating in the concerted action remains active on the market in question, there is a presumption of a causal connection between the concerted practice and the conduct of the undertaking on that market, even if the concerted action is the result of a meeting held by the participating undertakings on a single occasion".[723] Therefore, even participating one meeting where information exchange occurs, will be considered as a by object infringement.[724] Although the results of this case are

[720] Idem. para 12

[721] Idem. para 21.

[722] Idem. para 31

[723] Idem. para 55

[724] For further details see: Szilágyi Pál: A holland T-Mobile-ügy: a versenytársak közötti találkozók tilalma: C-8/08. JeMa, 2. évf. 1. sz. / 2011. p. 66-70

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less relevant for pay-for-delay cases, since they are not information exchange cases, I find important to shortly discuss this case due to its representative role in pre-Cartes Bancaires case law evolution: this represents perfectly how the courts were (over)-broadening the use of by object concept before Cartes Bancaires.

Considering the market partitioning category, the GSK case[725] is a good example how a complex dual pricing scheme in the pharmaceutical sector hindering parallel trade can classify as by object restraints, even without " requiring proof that the agreement entails disadvantages for final consumers as a prerequisite for a finding of anti-competitive object."[726]

Here it is not the aim to introduce all interesting, not naked[727] restraint cases which have ever been condemned as by object infringements by the ECJ, the aim of presenting these cases is to set up the context in which Cartes Bancaires judgment was evaluated as unique and revolutionary due to its ruling that object category should be interpreted narrowly.

IV.3.2. Cartes Bancaires

In Cartes Bancaires, the background to the dispute and the essential elements of the decision can be summarized as follows.

The appellant was an economic interest grouping governed by French law, created in 1984 by the main French banking institutions in order to achieve the interoperability of the systems for payment and withdrawal by bank cards issued by its members.[728]

The Commission found that Cartes Bancaires had infringed Article 101 of the TFEU, and the conduct under examination was by object anticompetitive. The Commission stated that the by object anticompetitive nature is evident: "That anti-competitive object reflects the genuine objectives of those measures, stated by the main members in the course of their preparation, namely the intention to (i) impede competition of new entrants and to penalise them, (ii) to safeguard the main members' revenue and (iii) to limit the price reduction for bank cards".[729]

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[725] Joined Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, GlaxoSmithKline Services Unlimited, formerly Glaxo Wellcome plc Commission of the European Communities. ECLI:EU:C:2009:610

[726] Idem. para 64

[727] Agreements are naked restraints if they seek to restrict competition without any objective countervailing benefits. (Sufrin-Jones, p. 211, footnote 113.

[728] C-67/13 P Cartes Bancaires para 3

[729] C Idem. para 8

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Cartes Bancaires appealed against the Commission decision, but the General Court dismissed the action in its entirety. Cartes Bancaires turned to the ECJ. In the plea, Cartes Bancaires referred to the interpretation of BIDS, is important element of the case, taken into regard that in all pay-for-delay decisions the Commission referred to the BIDS judgment as important support of its reasoning, i.e. to confirm that pay-for-delay settlements are by object restrictions.[730]

In BIDS and the ECJ stated: "In the context of competition, the undertakings which signed the BIDS arrangements would have, without such arrangements, no means of improving their profitability other than by intensifying their commercial rivalry or resorting to concentrations. With the BIDS arrangements it would be possible for them to avoid such a process and to share a large part of the costs involved in increasing the degree of market concentration."[731]

In the Cartes Bancaires judgement, the ECJ started by highlighting that „it is apparent from the Court's case-law that certain types of coordination between undertakings reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects."[732] The ECJ also noted, where the coordination between undertakings does not reveal a sufficient degree of harm to competition, the effects should be considered and necessary to find factors showing that competition has in fact been prevented, restricted or distorted to an appreciable extent.[733]

In Cartes Bancaires, first the ECJ found that when the General Court defined the concept of the restriction 'by object, it did not refer to the settled case-law of the ECJ[734] thereby failing to have regard to the fact that the essential legal criterion for ascertaining whether coordination between undertakings involves such a restriction of competition 'by object' is the finding that such coordination reveals in itself a sufficient degree of harm to competition.[735] Secondly, the General Court erred in finding that the concept of restriction by 'object' must not be interpreted 'restrictively'. The Court expressed that „[t]he concept of restriction of competition 'by object'

[730] See Servier, Lundbeck, Fentanyl

[731] C-209/07 BIDS para 33-34. See also Servier 1139.

[732] C-67/13 P Cartes Bancaires para 49, See also LTM, 56/65, EU:C:1966:38,paragraphs 359-360, See also, BIDS, paragraph 15, See also C-32/11 Allianz Hungária Biztosító and Others, EU:C:2013:160, paragraph 34

[733] Cartes Bancaires para 52, Allianz Hungária para 34

[734] Case 56/65 LTM para 359-360; See also C-209/07 BIDS, para 15, See also C-32/11 Allianz Hungária para 34 See also C-67/13 P Cartes Bancaires para 49-52

[735] C/67/13 P Cartes Bancaires para 57

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can be applied only to certain 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, otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which are in no way established to be, by their very nature, harmful to the proper functioning of normal competition. The fact that the types of agreements covered by Article 81(1) EC [Article 101 TFEU] do not constitute an exhaustive list of prohibited collusion is, in that regard, irrelevant."[736]

The ECJ criticised the General Court for failing to explain in what respect the restriction of competition in the case under consideration reveals a sufficient degree of harm in order to be characterised as a restriction 'by object' within the meaning of Article 101 (1), given that no analysis have been given of that point in the judgment under appeal.[737]

„In order to assess whether coordination between undertakings is by nature harmful to the proper functioning of normal competition, it is necessary, in accordance with the case-law […] to take into consideration all relevant aspects – having regard, in particular, to the nature of the services at issue, as well as the real conditions of the functioning and structure of the markets – of the economic or legal context in which that coordination takes place, it being immaterial whether or not such an aspect relates to the relevant market."[738]

The ECJ found that in the case of Cartes Bancaires, the General Court erred in finding that the measures at issue could be regarded as being analogous to those examined by the ECJ in the BIDS judgment, in which the ECJ held that the arrangements concluded between the then principal beef and veal processors in Ireland had as their object the restriction of competition within the meaning of Article 101 TFEU.[739]

In Cartes Bancaires, the General Court did not find or argue that the measures at issue – unlike in case of the BIDS arrangements – were intended to change appreciably the structure of the market concerned through a mechanism intended to encourage the withdrawal of competitors

[736] Idem. para 58

[737] Idem. para 69

[738] Idem. para 78

[739] Idem. para 83

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and, accordingly, that those measures revealed a degree of harm such as that of the BIDS arrangements.[740]

IV.3.3. Post-Cartes Bancaires developments

Although this comparison with the BIDS judgment is interesting, and highlights that sometimes conducts which seem similar for the first sight are not so similar if a deeper analysis is figured out, the most important point of Cartes Bancaires for our research is the point determining that the by object category should be interpreted restrictively.[741] This statement has affected several later judgments of the EU courts[742], including the appeals in Lundbeck and Servier.

However, it should be noted that even after Cartes Bancaires, the restrictive interpretation of the by object category cannot be taken as secure: in the Hoffmann-La Roche and Novartis case[743] the ECJ found that the respective companies were licensees of the same pharmaceutical distributor on the EU market. The pharmaceutical products – Lucentis and Avastin – were based on the same technology, but hold marketing authorization for different purposes: oncology and ophthalmology.

The licensees engaged in an anticompetitive agreement to undermine confidence in the off-label use of Avastin for ophthalmic conditions by spreading misleading information about its harmful effects. The ECJ found that "arrangement put in place between the parties to a licensing agreement regarding the exploitation of a medicinal product which, in order to reduce competitive pressure on the use of that product for the treatment of given diseases, is designed to restrict the conduct of third parties promoting the use of another medicinal product for the treatment of those diseases, does not fall outside the application of that provision on the ground that the arrangement is ancillary to that agreement".[744] Furthermore, "an arrangement put in place between two undertakings marketing two competing products, which concerns the dissemination, in a context of scientific uncertainty, to the EMA, healthcare professionals and

[740] Idem. para 85

[741] Idem. para 58

[742] Case C-373/14 P Toshiba Corporation k European Commission, EU:C:2016:26, para 30-31, see also Case C-345/14, Maxima Latvija k. Konkurences padome, EU:C:2015:784, see also Case C-228/18, Budapest Bank at all k. Gazdasági Versenyhivatal ECLI:EU:C:2020:265

[743] Case C-179/16 F. Hoffmann-La Roche Ltd at all k. Autorità Garante della Concorrenza e del Mercato, EU:C:2018:25

[744] C-179/16. F. Hoffmann-La Roche para 75

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the general public of misleading information relating to adverse reactions resulting from the use of one of those products for the treatment of diseases not covered by the MA for that product, with a view to reducing the competitive pressure resulting from such use on the use of the other medicinal product, constitutes a restriction of competition 'by object' for the purposes of that provision."[745] This post-Cartes Bancaires judgment surprisingly seems to broaden the definition of by object restraints[746] and have been subject to criticism.[747]

Two other prominent examples of the post-Cartes Bancaires era are Maxima Latvija[748] and Toshiba.

Maxima Latvija is a Latvian supermarket chain that leases areas from shopping malls. The case is about an obligation included in an agreement between the 'anchor tenant' of a shopping mall and the lessor. In the course of a preliminary ruling procedure, the ECJ had to answer whether lease agreements that reserve the right to Maxima Latvija as the 'anchor tenant' the right to give consent to the lessor letting to third parties commercial premises not let to Maxima Latvija, can qualify as a by object infringement of competition. This restraint would work as an exclusivity obligation, in the sense that the 'anchor tenant' is given the right to oppose the letting of premises to competing supermarket chains. Following the appreciation of available documents and the economic context of the case, the ECJ concluded that the lease agreements containing the above clause do not show a degree of harm with regard to competition sufficient for them to be considered to constitute a restriction of competition by object. Even though this contractual obligation is capable of having an anticompetitive effect, this fact alone is insufficient to establish that it is restrictive by its very nature. [749] In other words, a restriction

[745] Idem. para 95

[746] Dömötörfy Borbála Tünde – Kiss Barnabás Sándor - Firniksz Judit : Látszólagos dichotómia? – Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre. Verseny és Szabályozás, 2019.

[747] Nagy Csongor István: Anticompetitive object/effect: An overview of EU and national case law. e-Competitions Bulletin Anticompetitive object/effect, Art. N° 91905, 2019. p 6-8

[748] Case C-345/14, Maxima Latvija k. Konkurences padome

[749] Idem. para 15–24.

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by object does not exist merely because an agreement can be presumed to have anticompetitive effects.[750]

In the Toshiba case, on the other hand, which was related to the power transformers market, the ECJ was satisfied with less extensive object analysis. In its appeal, Toshiba asserted that the General Court erred in law in characterising the 'gentlemen's agreement' between market-sharing European and Japanese cartel members as a by object infringement because it did not examine if an entry to the EEA market represented an economically viable strategy for Japanese producers. Toshiba argued that the General Court did not take into account the insurmountable barriers to entry to the European markets, which ruled out any potential competition between Japanese and European producers.[751] The ECJ was reluctant to provide detailed requirements on the acceptable extent of economic analysis. It found it sufficient to state that '[i]n respect of such agreements, the analysis of the economic and legal context of which the practice forms part may thus be limited to what is strictly necessary in order to establish the existence of a restriction of competition by object.'[752] The ECJ thus found the existence of the gentlemen's agreement to be sufficient to provide a strong indication that competition existed between the European and the Japanese producers.[753]

IV.3.4. Budapest Bank

The aim of the above discussed exemples is to highlight the controversy around the standard of proof and the notion of by object restraints in the recent past, the list of the cases is not exhaustive. Although Budapest Bank[754] is certainly an (important) element of the post-Cartes Bancaires evolution, due to its importance for the whole field, I find it important to discuss this case separately, just as I did with Cartes Bancaire.

[750] Pablo Ibanez Colomo: What the Court said, and did not say, in Maxima Latvija. Available at: https://chillingcompetition.com/2015/12/10/what-the-court-said-and-did-not-say-in-maxima-latvija/ downloaded: 11 June 2021

[751] Case C-373/14 P, *Toshiba Corporation v Commission*, EU:C:2016:26, para 30-31. See also: Dömötörfy Borbála Tünde – Kiss Barnabás Sándor - Firniksz Judit : Látszólagos dichotómia? – Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre.

[752] Idem. para. 29.

[753] Idem. para. 33.

[754] Case C-228/18, Budapest Bank at all k. Gazdasági Versenyhivatal

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In Budapest Bank, the Opinion of Advocate General Bobek have already suggested his aim to finally put an end to the by object discrepancy:

"From the early days of EU competition law, much ink has been spilled on the dichotomy between restriction of competition by object and restriction by effect. It may thus come as a surprise that this distinction, stemming from the very wording of the prohibition in (what is now) Article 101 TFEU, still requires interpretation by the Court. The distinction is relatively easy to make in theory. Its practical operation is nonetheless somewhat more complex. It is also fair to say that the case-law of the EU Courts has not always been crystal clear on the subject. Indeed, a number of decisions given by the EU Courts have been criticised in legal scholarship for blurring the distinction between the two concepts."[755]

Just as we can expect after such a remarkable start, Bobek in his Opinion attempts to clarify the interpretation of EU case law on the object analysis. For the sake of clarity, he divided the object analysis into two steps:

i. Analysis of the content of the provisions of the agreement and its objectives;
ii. Analysis of the economic and legal context of the agreement.

The first step is an examination of the agreement and its contents, its aim is 'to ascertain whether the agreement in question falls within a category of agreements whose harmful nature is, in the light of experience, commonly accepted and easily identifiable.' [756]

The Opinion – referring to former case law, especially the opinion of Advocate General Wahl in Cartes Bancaires[757] – emphasizes the role of experience in this step, which is defined as what can traditionally be seen to follow from economic analysis, as confirmed by the competition

[755] Case C-228/18, Budapest Bank at all. V. Gazdasági Versenyhivatal. Opinion of Advocate General Bobek. ECLI:EU:C:2019:678

[756] Idem. para 42. See also: Dömötörfy Borbála Tünde – Kiss Barnabás Sándor - Firniksz Judit : Látszólagos dichotómia? – Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre. p. 12.

[757] C-67/13 P, Groupement des Cartes Bancaires v. Commission. Opinion of Advocate General Wahl. EU:C:2014:1958.

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authorities and supported by case law.[758] The first step therefore has the purpose of examining whether the agreement's anticompetitive object stems obviously from the agreement itself.

In the course of step two, 'the authority is required to verify that the presumed anticompetitive nature of the agreement, determined on the basis of a merely formal assessment of it, is not called into question by considerations relating to the legal and economic context in which the agreement was implemented. To that end, it is necessary to take into account the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the markets in question. In addition, although the parties' intention is not a necessary factor in determining whether an agreement between undertakings is restrictive, that factor may be taken into account where relevant.'[759]

The Opinion acknowledges that the extent and depth of this second step is unclear, as it does not answer where the object analysis ends and the effects test begins. At the same time, Bobek affirms that the second step – however, to a different extent – is inevitable and mandatory for competition authorities, which serves as a legal and economic justification for prohibiting an anticompetitive agreement. Bobek points out that even in cases dealing with hardcore restraints – such as price fixing, market sharing or export bans – which are generally accepted to be particularly harmful to competition, the economic and legal context cannot be totally ignored.[760]

The opinion also addresses the discrepancies caused by Toshiba*:* [the limited examination of economic and legal context to the absolutely necessary elements of the case] "means that the competition authority […] must […] check that there are no specific circumstances that may cast doubt on the presumed harmful nature of the agreement in question." If experience tells us that the agreement belongs to the hardcore anticompetitive category, a detailed analysis of the impact is unnecessary. In such a case, the competition authority is only required "to verify that the relevant market(s) and the agreement in question do not have any special features which might indicate that the case at hand could constitute an exception to the experience-based

[758] Opinion, para. 42. See also: Dömötörfy Borbála Tünde – Kiss Barnabás Sándor - Firniksz Judit : Látszólagos dichotómia? – Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre.

[759] Ibid. para. 43.

[760] Ibid. paras. 44–45.

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rule.'[761] This second step is called "a basic reality check" by Bobek. It requires the competition authority to check whether there are any legal or factual circumstances that preclude the agreement or practice concerned from restricting competition. Bobek admits "[t]here is no standard type of analysis or set level of depth and meticulousness that an authority has to adopt to carry out that verification. The complexity of the analysis required of the authority to find an agreement anticompetitive 'by object' depends on all of the relevant circumstances of the case. It is impossible to (or at least I am unable to) draw, in abstract terms, a bright line between (the second step of) an object analysis and an effects analysis." The distinction between the two tests is 'more one of degree than of kind.'[762]

Bobek chooses to use the following – albeit admittedly extreme – metaphor to demonstrate the above: 'if it looks like a fish and it smells like a fish, one can assume that it is fish. Unless, at the first sight, there is something rather odd about this particular fish, such as that it has no fins, it floats in the air, or it smells like a lily, no detailed dissection of that fish is necessary in order to qualify it as such. If, however, there is something out of the ordinary about the fish in question, it may still be classified as a fish, but only after a detailed examination of the creature in question."[763]

The Opinion does not try to re-interpret existing case law, instead it attempts to put the pieces of the preceding case law in their right, coherent place. It does not state anything new, and it does not attempt to resolve the blurred lines between object analysis and effects test. It even acknowledges that impossible to give a general, abstract determination of such a line, therefore it is always subject to case-by-case anylysis. Therefore, the Opinion seems to admit that the line blurred by Allianz Hungaria is not even going to be clarified – at least not in a one size fits all way – in the future. After this 'confession' with my colleagues, we concluded that even the EU systems seem to leave behind the strict dichotomy approach: we set in contrast the Opinion of Advocate General Bobek with the US antitrust law, and found that "by object/*per se*/quick look restrictions and by effect/rule of reason restrictions do not represent a dichotomy but a continuum, where – as AG Bobek states – the difference between the types of economic analysis is more of degree than of kind. *Hovenkamp* [2018] highlights the difference in the burden of

[761] Ibid. para. 48.

[762] Ibid. paras. 49–50.

[763] Ibid. para. 51.

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proof: in the case of simpler factual circumstances, the burden of proof should be greater for the defendant undertakings, while in a more complicated case the authority should bear a greater obligation. Both systems might be interpreted in a way that places emphasis on the depth of demonstration and the allocation of the burden of proof, and from this viewpoint both the EU and the US regime appears to be more like a multicolored scale than a structure of clear-cut categories. European competition law commentators have previously raised the continuum-like approach of legal tests (see *Ibáñez Colomo* [2019] pp. 3–4.), and the Opinion, in our view, appears to point toward the same direction".[764]

I discussed the Opinion of Advocate General Bobek in the Budapest Bank case in details because in my view, it provides excellent answers to several post-Allianz and post-Cartes Bancaires cases, what cannot be found in the ECJ's judgment[765]. Also, it has important implications for the interpretation of the ECJ's judgment. The judgment follows the two-step structure recommended by the Opinion in order to decide whether the examined agreemets meet the Cartes Bancaires standard and therefore infringe competition by object.

As first step – as stipulated by AG BObek – the ECJ examined the content and objectives of the MIF agreement. In this respect the ECJ did not find that the content of the MIF agreement, or the objectives pursued by the agreement does not "necessarily point to a restriction 'by object', in the absence of proven harmfulness of the provisions of that agreement to competition"[766]. Referring to the Opinion, the judgment highlights the importance of "sufficiently reliable and robust experience […] that [an] agreement is, by its very nature, harmful to the proper functioning of competition".[767]

As second step, as recommended by Bobek, the ECJ assessed whether the coordination is by nature harmful to the proper functioning of competition, taking into consideration all relevant aspects — in particular, the nature of the services, as well as the real conditions of the

[764] Dömötörfy Borbála Tünde – Kiss Barnabás Sándor - Firniksz Judit : Látszólagos dichotómia? – Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre. p. 21.

[765] Case C-228/18, Budapest Bank at all. v. Gazdasági Versenyhivatal. ECLI:EU:C:2020:265

[766] Idem para 65-66

[767] Idem para 76

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functioning and structure of the markets — of the economic or legal context.[768] ECJ then carefully examined the context of the agreement and turned to the counterfactual analysis, and finally concluded that in-depth examination of the effects is necessary.[769]

IV. 4. Judgements of the EU Courts in pay-for-delay cases

After this short introduction about the non-linear development of object-effect dichotomy, the currently available judgments of the EU courts should be analyzed. By the moment, the General Courts judgment is available both in Lundbeck and Servier, so these judgments will be discussed in this subchapter. Servier is pending at the ECJ, but in Lundbeck, the Advocate General's opinion was published in the summer of 2020. It was followed by the ECJ's judgment in March 2021.

The first judgment of the ECJ dealing with pay-for-delay however was not Lundbeck, it was delivered in January 2020 in the Paroxetine preliminary ruling case. Consequently, this preliminary ruling will be also subject to discussion in this subchapter.

Although generally I find chronological order important for this thesis, to represent the development of the assessment in pay-for-delay cases, these mentioned cases will not be discussed in a chronological order: to ensure higher level of clarity, the General Court's judgment in Lundbeck will be followed by the Opinion, and by the ECJ's judgment. After Servier, and finally the Paroxetine preliminary ruling will be introduced.

IV.4.1. The judgement of the General Court in Lundbeck

The General Court adopted its judgment in Lundbeck on 8 September 2016. The judgement rejected all appeals of Lundbeck and confirmed the Commission decision entirely. The applicants referred to ten arguments in their appeal, the most important issues of the judgement are those related to the potential competition and to the categorization of reverse payment settlements as by object restriction. This sub-chapter is going to discuss the most important elements of the judgment divided into three groups: i) potential competition; ii) categorization of the agreement as by object restriction; iii) other questions.

[768] Idem para 67

[769] Idem para 83

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IV.4.1.1. Potential competition

The existence of potential competition plays a decisive role in the assessment of pay-for-delay agreements as by object restrictions: if – at least – potential competition does not exist between the parties, the agreement cannot be categorized either as a by object or by effect restriction. In pay-for-delay cases it is a crucial question whether the generic company can be regarded as a potential competitor of the generic producer.

In its judgment, the General Court started the assessment of potential competition by reminding that to determine that potential competition exists, "real concrete possibilities" for market entry by the generic are necessary. Merely hypotetical demonstration of the existence of potential competition is not sufficient, it must be supported by factual evidence or an analysis of the structures of the relevant market. Market entry also must be an economically viable strategy for the generic. [770]

According to the court's argument, even the mere fact of the existence of an undertaking outside the market may give rise to competitive pressure on the incumbent undertakings, a pressure represented by the likelihood that a new competitor enters if the market becomes more attractive. [771] The General Court also found that the likelihood of collusion between the undertakings can be regarded as a signal of the existence of potential competition.[772]

Concerning intellectual property rights, the General Court stated that the existence of rights recognised under the industrial property legislation of a Member State is not affected by Article 101(1) TFEU, the conditions under which those rights may be exercised may nevertheless fall within the prohibitions set out in that article.[773] However, although the Commission is not competent to determine the scope of a patent, it may not refrain from all action when the scope of the patent is relevant for the purposes of determining whether there has been an infringement of Articles 101 TFEU and/or 102 TFEU.[774] Whilst patents are presumed valid until they are revoked or invalidated by a competent authority or court, that presumption of validity cannot

[770] T-472/13 Lundbeck para 100. Case T-360/09, E.ON Ruhrgas and E.ON k. Commission. EU:T:2012:332., para 86

[771] Case T-472/13 Lundbeck para 102, Case T-461/07, Visa Europe and Visa International Service k. Commission., EU:T:2011:181, para 169

[772] Case T-472/13 Lundbeck para 103, Case T-112/07, Hitachi at all. k. Commission, EU:T:2011:342, para 226, Case T-519/09, Toshiba k. Commission, EU:T:2014:263, para 231.

[773] T-472/13 Lundbeck para 118. pont. Case 15/74, Centrafarm and de Peijper, EU:C:1974:114 para 39-40.

[774] Case 193/83, Windsurfing International k. Commission, EU:C:1986:75, para 26. (Windsurfing)

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be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent. At risk entry is not illegal.[775]

In order to establish the existence of potential competition, it must be examined whether, given the structure of the market and the economic and legal context within which it functions, there are real and concrete possibilities for the undertakings to compete among themselves or for a new competitor to enter the relevant market. [776] By examining the "real concrete possibilities" of generics to enter to the market in Lundbec case, the General Court concluded that the generic undertakings had several routes to enter the market,[777] and it should also be taken into account that the original patents of Lundbeck expired.[778]

The General Court expressed that the Commission did not take the view that the mere possibility of challenging the validity of a patent before a court or the competent authorities suffices to establish the existence of potential competition. Rather, the Commission took several factors into consideration, such as the significant investments and efforts already made by the generic undertakings in order to prepare their entry to the market, the fact that they had already obtained marketing authorizations or had taken the necessary steps to obtain one within a reasonable period, the fact that Lundbeck had acknowledged that there were a certain number of processes available to produce citalopram without infringing their remaining patents, the fact that, at the time the agreements at issue were concluded, no court had found the generic products to be infringing and the fact that there was a non-negligible possibility that some of Lundbeck's process patents might be declared invalid. In addition, one undertaking, Merck (GUK), even succeeded in entering the market before and during the term of the agreements. Lastly, the General Court found that the fact that Lundbeck decided to pay significant amounts to the generic undertakings in order to keep them out of the market during the period of the agreements, also shows that those generic undertakings were potential competitors, since they were perceived by Lundbeck as a threat exerting competitive pressure on Lundbeck's market position.[779]

[775] T-472/13 Lundbeck para 121-122

[776] T-472/13 Lundbeck para.123., See also Lundbeck decision para 610-611

[777] T-472/13 Lundbeck para 128, See also Lundbeck para 635

[778] T-472/13 Lundbeck para 129

[779] Idem. para 157

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Nevertheless, the purely theoretical possibility of market entry is not sufficient to establish the existence of potential competition and the Commission must demonstrate, that the market entry could have taken place sufficiently quickly for the threat of a potential entry to influence the conduct of the market players, on the basis of costs which would have been economically viable. [780] In this case, the entry of the generic undertakings to the citalopram market was not a mere theoretical possibility, but the generics had real concrete possibilities in that respect. The General Court highlighted, it would be surprising if an undertaking as experienced as Lundbeck would have decided to pay several million euros to the generics in exchange for their commitment not to enter the market during a certain period if the possibility that those generic undertakings could enter the market was purely theoretical.[781]

In order to establish the existence of potential competition, case-law requires only that the entry to the market takes place within a reasonable period, without fixing a specific limit in that respect. The Commission does not need to demonstrate with certainty that the entry of the generic undertakings to the market would have taken place before the expiry of the agreements in order to be able to establish the existence of potential competition in the present case, particularly since the ECJ had held in the AstraZeneca judgment that potential competition may be exerted long before the expiry of a patent.[782] In that regard, it is irrelevant that the SPCs in AstraZeneca case had been obtained fraudulently or irregularly. [783]

The General Court stated that potential competition includes the activities of generic undertakings seeking to obtain the necessary marketing authorizations, as well as all the administrative and commercial steps required to prepare for entry to the market. If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product and which have made significant investments to that end, to cease or merely slow that process, effective competition would never take place, or would suffer significant delays, at the expense of consumers, in the present case, patients or national health insurance schemes.[784]

[780] Idem. para 160

[781] Idem. para 161

[782] T-472/13 Lundbeck para 163, See also Case C-457/10 P. AstraZeneca k. Commission, EU:C:2012:770, para 108

[783] T-472/13 Lundbeck para 164

[784] Idem para 171

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The General Court also took into account that Lundbeck itself declared to the Commission that the generics could produce non-infringing citalopram,[785] if they find a way which is outside of the scope of Lundbeck's process patents.[786]

Even if the generic products had infringed one of Lundbeck's patents, which was not established at the time of the conclusion of the agreements, the generic undertakings would also have been able to challenge the validity of those patents before the competent courts.[787] The fact that Lundbeck concluded agreements with the generics constitutes an important indication that Lundbeck perceived the generics as a potential threat, exerting a competitive pressure on its position on the market.[788]

IV.4.1.2. The categorization of the agreement as by object restriction

The other important question of the Lundbeck case was whether the agreements constitute by object restriction on competition, or their effects should be examined. In its decision, the Commission found that the agreements between Lundbeck and the generics infringed competition by object and did not examine the effects of the agreements. The categorization of the agreements at issue as by object restriction gave place to hot debates since the Commission imposed the sanctions on the undertakings, but the criticism has grown significantly since the ECJ's judgement in Cartes Bancaires case was published. After the Cartes Bancaires judgement, where the ECJ expressed its view that the notion of by object restriction should not be interpreted broadly, several practicing professionals were expecting that the General Court will reject the categorization of pay-for-delay cases as by object restriction. However, the General Court did not do so.

In its judgement the General Court highlighted that the existence of reverse payment played a crucial role in the legal assessment of the agreements.[789] The General Court also reinforced that reverse payments are not always problematic, only if the requirements of the Lundbeck test set out by the Commission in its decision are met.[790] The generic entry in the Lundbeck case was not hindered by the strength of the patents but by the amount paid by Lundbeck. Practically,

[785] Idem. para 190

[786] Idem. para 191

[787] Idem. para 202

[788] Idem. para 205

[789] Idem. para 349

[790] Idem. para 350

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Lundbeck bought-off competition from the market.[791] By referring to the Actavis judgement[792] of the US Supreme Court, the General Court stated that the size of the reverse payment may signal the parties assessment related to the strength of the patents.[793] In the Lundbeck case, the fact that the amounts of reverse payments seemed to correspond at least to the profit anticipated by the generic undertakings if they had entered the market led also to the by object categorization of the restrictions.[794] The very existence of reverse payments and the disproportionate nature of those payments were relevant factors in establishing whether the agreements at issue constituted restrictions of competition 'by object' for the purpose of Article 101 TFEU.[795] However, the General Court did elaborate on what the appropriate amount of reverse payments should be. It obviously seems like an amount corresponding to the profit expected by generics is not acceptable.

The General Court highlighted that the applicants intended to use 'a large pile of [USD]' to exclude generics from the market whereas they doubted the validity of their patents and their chances of succeeding in a proceeding before a court.[796] In that regard, the General Court noted: "[t]he Commission was not required to demonstrate irrefutably that the applicants doubted the validity of their patents in order to establish the existence of an infringement by object in the present case, since the evidence set out in the contested decision shows that the generic undertakings were confident of their chances of being able to enter the market within a sufficiently short period, either by overcoming the applicants' infringement allegations, or by challenging the validity of their patents, in the event of a dispute. […] What matters, therefore, is that there was uncertainty, at the time the agreements at issue were concluded, as to the possibility, for the generic undertakings, of entering the market without being subject to injunctions or infringement actions, or of successfully challenging the validity of the applicants' patents, and that those agreements had replaced that uncertainty, by means of significant reverse

[791] Idem. para 352

[792] Judgment of the Supreme Court of the United States of 17 June 2013 in Federal Trade Commission v. Actavis, 570 U.S. (2013)

[793] T-472/13 Lundbeck para 353

[794] Idem. para 354

[795] Idem. para 355

[796] Idem. para 368

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payments, with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue".[797]

The General Court expressed that – against the indeed asymmetric risks between the generics and the originator company – the fact that the adoption of anticompetitive behaviour may be the most cost-effective or least risky course of action for an undertaking in no way excludes the application of Article 101 TFEU, especially, if that behaviour consists in paying actual or potential competitors not to enter the market and sharing with those competitors the profits resulting from the absence of generic medicinal products on that market, to the detriment of consumers.[798]

Referring to the applicant's arguments stating that the asymmetry of risks allowed the generic undertakings to 'bluff' Lundbeck in order to obtain significant amounts of money, by pretending that they were preparing to enter the market with non-infringing products,[799] the General Court found that it strengthens the Commission's assessment towards the possible outcome of a patent litigation.[800] Furthermore, the fact that a reverse payments may constitute the only means of reaching an agreement by 'bridging the gap' between the parties to that agreement, does not mean that such a payment constitutes a legitimate means of reaching such an agreement or that that agreement is exempt from the application of competition law, especially not in the case if the four requirements of the Lundeck test meet.[801] This point is somewhat controversial, since the General Court seems to accept that in certain cases, due to asymmetry of risk, reverse payment is the only way to reach a settlement between the parties. Although the General Court explains it as a signal of patent strength, in my view, it is not necessarily the case, and the patent litigation system currently is not so predictable as it could be assumed from this part of the judgment.

According to the applicants' argument, an irreversible price fall would occur upon the generic entry, which could not have been avoided even if they had been successful in infringement actions brought before the national courts. They could therefore, by concluding reverse payment agreements, maintain higher prices for their products, to the detriment of consumers and the

[797] Idem. para 369

[798] Idem. para 380

[799] Idem. para 381

[800] Idem. para 382

[801] Idem. para 383

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healthcare budgets of Member States, even though such an outcome could not have been obtained even if the national courts had confirmed the validity of their patents and the products of the generic undertakings had been held to be infringing. Such an outcome would be manifestly contrary to the objectives of the competition rules, which are intended inter alia to protect consumers from unjustified price increases resulting from collusion between competitors. There is no reason to suppose that such collusion would be lawful, when the defence of the process patents before the national courts could not, even in the most favourable scenario for the applicants, have led to the same negative consequences for competition and, in particular, for consumers.[802] It is unacceptable for undertakings to attempt to mitigate the adverse effects of legal rules which they consider excessively unfavourable.[803]

There are ways of resolving a dispute amicably, which are acceptable from a competition law perspective, other than delaying the market entry of potential competitors through reverse payments. According to the jurisprudence of the Court [804], the specific subject matter of the patent cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity, which may arise where a patent was granted in error. Although the applicants were entitled to enter into settlements with the generic undertakings in order to avoid the costs of potential litigation, they could not, on that ground, substitute their own assessment of the validity of their patents and the infringing nature of the generic undertakings' products for that of an independent judge while paying the generic undertakings to comply with that assessment and refrain from entering the market for a certain period.[805]

The General Court also confirmed the analogy between Lundbeck and BIDS:[806] in both cases the undertakings bought off competition from the market by offering money to their (potential) competitor to stay away from the market.[807]

[802] Idem. para 386

[803] Idem. para 387, Joined Cases T-49/02 - T-51/02, Brasserie nationale at all. k. Commission, EU:T:2005:298, para 81.

[804] 193/83. Windsurfing para 92

[805] T-472/13 Lundbeck para 390

[806] Idem. para 423

[807] Idem. para 424

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According to the General Court, in Cartes Bancaires judgement the ECJ did not call into question the basic principles concerning the concept of a restriction 'by object' set out in the previous case-law. The ECJ rejected the General Court's analysis according to which the concept of restriction of competition 'by object' should not be interpreted in a restrictive manner. The Court of Justice noted that the concept of restriction of competition 'by object' could be applied only to certain types of coordination between undertakings which revealed a sufficient degree of harm to competition that it could be found that there was no need to examine their effects. Otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which were in no way established to be, by their very nature, harmful to the proper functioning of normal competition.[808]

In the case the General Court argued that the agreements at issue were comparable to market exclusion agreements which are among the most serious restrictions of competition, constituting an extreme form of market sharing and of limitation of production. The Commission took into account Lundbeck's process patents, but took the view that, even if those patents were presumed to be valid, they did not allow the exclusion of all competition in relation to the citalopram API. In addition, the Commission also took into account the fact that there was uncertainty regarding the validity of those patents, and that no court in the EEA had ruled on that issue at the time the agreements were concluded.[809] After considering all the above discussed facts and case law, the General Court found that the Commission reached the right conclusion when it found that the agreements are by object restrictions.[810] Accordingly, the Commission was not required to examine the specific effects of the agreements on competition and, in particular, whether, in the absence of those agreements, the generic undertakings would have entered the market without infringing one of Lundbeck's patents, in order to be able to establish the existence of a restriction of competition by object, within the meaning of Article 101(1) TFEU, since those generic undertakings had real concrete possibilities in that respect and were potential competitors of Lundbeck at the time the agreements were concluded.[811]

Moreover, as the General Court declared, contrary to what is claimed by the applicants, it is not necessary that the same type of agreement have already been censured by the Commission in

[808] Idem. para 434

[809] Idem. para 435

[810] Idem. para 436

[811] Idem. para 437

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order to constitute a restriction of competition by object. The role of experience, mentioned by the Court of Justice in the Cartes Bancaires judgement does not concern the specific category of an agreement in a particular sector, but rather refers to the fact that it is established that certain forms of collusion are, in general and in view of the experience gained, so likely to have negative effects on competition that it is not necessary to demonstrate that they had such effects in the particular case at hand. The fact that the Commission has not, in the past, considered that a certain type of agreement was, by its very object, restrictive of competition is therefore not, in itself, such as to prevent it from doing so in the future following an individual and detailed examination of the measures in question having regard to their content, purpose and context.[812]

With regard to the objectively necessary nature of the restrictions, the General Court found that the applicants did not prove it in the case under examination, because there are numerous ways of settling a patent dispute without agreeing to restrictions on the market entry of generic undertakings, by means of reverse payments corresponding approximately to the profits expected by those undertakings if they had entered the market.[813]

The General Court also highlighted that the examination of a hypothetical counterfactual scenario — besides being impracticable since it requires the Commission to reconstruct the events that would have occurred in the absence of the agreements, whereas the very purpose of those agreements was to delay the market entry of the generic undertakings — is more an examination of the effects of agreements at issue on the market than an objective examination of whether they are sufficiently harmful to competition. Such an examination of effects is not required in the context of an analysis based on the existence of a restriction of competition by object.[814]

Accordingly, the Commission rightly considered that the agreements at issue were akin to market exclusion agreements between competitors and that they were liable to have negative effects on competition, without it being necessary, for the purpose of Article 101(1) TFEU, to demonstrate that they had had such effects.[815]

[812] T- Idem. para 438, C-67/13 P Cartes Bancaires para 51

[813] T-472/13 Lundbeck para 458, 461

[814] Idem. para 473

[815] Idem. para 476

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IV.4.1.3. Other relevant questions

Concerning the scope of the patent test, which was referred by the applicants, the Court highlighted that whilst the specific subject matter of the industrial property is, to guarantee that the inventor will be rewarded for the creative effort, this exclusive right cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error.[816] The General Court argued that test is problematic from a competition law perspective in several respects. First, it leads to a presumption that a generic medicinal product infringes the originator undertaking's patent and thus allows the generic medicinal product to be excluded on that basis, when the question whether it infringes any patents is an unresolved issue. Secondly, it is based on the premiss that any patent invoked in the context of a settlement agreement will be held valid if its validity is challenged, although there is no basis in law or in practice for that outcome. The 'scope of the patent' test is therefore based on a subjective assessment, by the applicants, of the scope of their patents and of their validity, whereas a national court or competent authority may have taken a different view.[817] The General Court reminded that the test was also rejected by the Supreme Court of the US in its Actavis judgement.[818]

With regard to the complex anti-generic strategy applied by Lundbeck in the time when the agreements were reached, the Court concluded that the Commission was fully entitled to take into account the applicants' intention.[819] However, the strategy itself[820] was not illegal, the Commission's decision did not establish that such actions were unlawful. The Commission solely took into account the factors that allowed the agreements at issue to be placed in their wider context and demonstrated that Lundbeck sought to delay the market entry of generics in order to find a suitable window for the launch of escitalopram by all possible means, whether

[816] Idem. para 487

[817] Idem. para 491

[818] Idem. para 492, Actavis judgment

[819] T-472/13 Lundbeck para 523

[820] Intervention in the generics' marketing authorization procedure, development of escitalopram, obtaining secondary patents.

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lawful or unlawful.[821] This was found to be relevant from the point of view if the existence of potential competition.[822]

The General Court also rejected the applicants' arguments relating to the sanctions, breach of the rights of the defence, and the assessment of efficiency gains.

IV.4.1.4. The importance of the Lundbeck judgement

The Lundbeck judgement – as the first pay-for-delay judgement of the EU courts – was long-awaited by legal professionals.

From a competition law point of view, its main elements are related to potential competition, and to the definition of by object restriction. The Cartes Bancaires standard requires a sufficient degree of harm associated with certain types of agreements to categorize agreements as by object restrictions. According to the General Court's judgement, the reverse payment settlement in Lundbeck was similar to market exclusion agreements, which are among the most serious restrictions of competition, constituting an extreme form of market sharing and of limitation of production.

The problem with reverse payment settlements has already been discussed: if the generic entry does not occur as an effect of a pay-for-delay agreement, the generic and the originator will share the profit, and the consumers do not enjoy the benefits of competition. It can also happen that the generic will earn more than its expected profit from market entry. Even if the payment is a bit lower that the expected profit, the generic might choose to conclude the agreement to avoid the risks.

The key question of the Lundbeck case therefore was whether potential competition existed between Lundbeck and the generics on the relevant market – a positive answer in itself determines the evaluation of the agreements as a by object restriction. If there was potential competition between the originator and the generics when the agreements were concluded, the originator bought out its most efficient (potential) competitors from the market. By the very nature of such agreements, this only can be evaluated as by object restriction on competition.[823]

[821] T-472/13 Lundbeck para 524

[822] Idem. para 527

[823] Pablo Ibanez Colomo: GC Judgment in Case T-472/13, Lundbeck v Commission: on patents and Schrödinger's cat. (Available at: https://chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat/ Downloaded: 30 November 2018)

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On the other hand, without potential competition, the same outcome is not possible. If neither actual nor potential competition exists between the parties of an agreement, competition cannot be distorted, and consequently, the provisions of competition law cannot be infringed. Therefore, the existence or non-existence of potential competition actually decided whether the agreement between Lundbeck and generics constitutes by object restriction, or it does not infringe competition law at all. It should be noted that Lundbeck is definitely not the first case where the outcome of the judgment was influenced by the existence or non-existence of potential competition, and the General Court – in this earlier case, confirmed by the ECJ – found that the mere existence of a market-sharing agreement suggests that the parties considered themselves to be at least potential competitors.[824] Interestingly, the parties' considerations about potential competition received less attention from the Commission in a recent merger prohibition case,[825] but they certainly seem to play a role in the evaluation of antitrust cases.

In Lundbeck, the General Court found that potential competition took place between Lundbeck and the generics. This finding was based on the special circumstances of the case. Considering the existence of potential competition in that case, both the Commission and the General Court took into account the special characteristics of the pharmaceutical sector i.e. the patent system, the patent enforcement system, and the regulatory background, which have been discussed in details in the first subchapter. In that regard, the General Court's judgment became subject to disputes.

According to some authors, the reasoning of both the General Court's judgment and of the Commission's decision were accurate and correct in that respect, and only criticize the General Court for failing "to provide more general guidance as to how pharmaceutical undertakings can safely draft their settlement agreements".[826]

[824] C-373/14 P Toshiba para 47

[825] Case M.8677 - SIEMENS/ALSTOM

[826] Konstantinos Sidiropoulos:Lundbeck: Remedying IP overprotection through competition law enforcement in the pharma sector. European Law Blog, 22 November 2016. (Available at: https://europeanlawblog.eu/2016/11/22/lundbeck-remedying-ip-overprotection-through-competition-law-enforcement-in-the-pharma-sector/ Downloaded: 13 December 2017)

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Other authors, on the other hand, highlight the contradictory nature of the General Court's reasoning.[827] Ibanez Colomo finds the relevant parts of the judgment contradictory, because it suggests that a generic producer is a potential competitor even if it is uncertain (i) that the generics would necessarily have infringed the patent(s); (ii) that the patent(s) holder would have brought an action for infringement and (iii) that the patent(s) would have been found to be valid. Ibanez Colomo argues in that respect that generic producers may not see the prospect of an injunction as realistic, either because they believe they would be successful in the event of a challenge or because they do not believe that the patent holder would bring an action in the first place.

Ibanez Colomo also criticizes the General Court's judgment for three other reasons:

i) while the General Court accepts that patents are valid, it also emphasizes that patents can be declared invalid, which two statements cannot be reconciled;
ii) General Court seems to conflate ex ante and ex post considerations, while the judgment suggests that the generic producer is a potential competitor because it may appear, ex post, "which considerations seem to ignore that the very point of a genuine pay-for-delay agreement is to deal with ex ante uncertainty;"
iii) the General Court did not take into consideration the ECJ's relevant case law[828]. On the basis of the referred case law, Ibanez Colomo argues "that potential competition does not exist where market entry depends on the infringement of an intellectual property right. The fact that the right in question may be declared invalid at a subsequent stage is not a relevant consideration under this case law".

Ibanez Colomo also disputes the statement of the General Court that the analysis of counterfactuals is only relevant in by effect cases by stating "it is impossible to determine whether an agreement restricts competition by object without considering the counterfactual",

[827] Pablo Ibanez Colomo: GC Judgment in Case T-472/13, Lundbeck v Commission: on patents and Schrödinger's cat. (Available at: https://chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat/ Downloaded: 30 November 2018)

[828] Case 35/83, BAT Cigaretten-Fabriken GmbH v. Commission ECLI:EU:C:1985:32, Case 258/78 Nungesser and Kurt Eisele v. Commission ECLI:EU:C:1982:211, Case 262/81 Coditel v. Ciné-Vog Films ECLI:EU:C:1982:334, Case 27/87 Erauw-Jacquery v. La Hesbignonne SC. ECLI:EU:C:1988:183, Case 9/IHT Internationale Heiztechnik GmbH and Uwe Danzinger v Ideal-Standard GmbH and Wabco Standard GmbH ECLI:EU:C:1994:261

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and he also expresses his hopes that the ECJ should confirm the existence-exercise dichotomy.[829]

Other authors highlight that while the Lundbeck judgment seems indeed contradictory with the ECJ's orthodox interpretation of potential competition and of by object restriction, and especially, with Cartes Bancaires, "in Lundbeck, the legal and economic context served, in effect, to confirm the likelihood that these potentially restrictive arrangements would in fact harm competition. Relevant factors included the significant opportunities for market entry and thus upheaval created by expiry of the API patent, the comparative weakness of Lundbeck's process patent, and the likely impact of any attempted new entry on regulated drug prices at national level. Moreover, although the subjective intention of the contracting parties is not determinative, the fact that Lundbeck sought deliberately to ensure that potential competition would not translate into actual competition served to reinforce the conclusion that these agreements were inherently harmful to competition, even if the precise harm anticipated remained somewhat contingent or remote. The Commission could thus validly conclude that the impugned settlements were comparable to market exclusion agreements.[830]

On the basis of the above arguments, it can be seen that the General Court's Lundbeck judgment is subject to hot disputes. Concerning Ibanez Colomo's views, I have to agree in certain aspects: the judgment indeed has a contradictory nature in respect of ex ante/ex post competition issues and by discussing the discrepancies related to the presumption of patent's validity. The confirmation of the long-standing principle of the existence-exercise dichotomy would be welcome. With regard to the ECJ's Cartes Bancaires judgment, it can also be argued that a counterfactual analysis can be necessary in by object cases, although it further blurres the line between object/effect analysis. Concerning the case law referred by Ibanez Colomo, one important fact should be highlighted however: these cases are not related to the pharmaceutical industry, in which sector competition has a special nature, as it is discussed in the first chapter of this thesis. With regard to this special nature – e.g. taking into consideration the existence and aim of the Bolar exemption, etc. – generics preparing for market entry – if certain

[829] Pablo Ibanez Colomo: GC Judgment in Case T-472/13, Lundbeck v Commission: on patents and Schrödinger's cat. (Available at: https://chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat/ Downloaded: 30 November 2018)

[830] Niamh Dunne: Why Protect Potential Competition? In: Sandra Marco Colino – Niamh Dunne – Knut Fournier – Sofia Oliveira Pais – Derek Ritczmann: The Lundbeck case and Potential Competition. Concurrences Review, No. 2-2017, June 2017. p. 19.

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circumstances also examined by the General Court met – cannot be considered as potential competitors. On the other hand, the Lundbeck judgment fails to provide guidance to companies for future settlement agreements, and it is not even clear whether any reverse payment settlement agreements, which restrict competition would be considered as a by object restriction. The circumstances of the Lundbeck case were special, it is questionable what would happen without the case specific factors – e.g.'smoking guns' – considered by the General Court.

IV.4.1.5. The ECJ's judgment in Lundbeck

In Lundbeck, the opinion of the Advocate General[831] (AG Opinion) was made available on 4th June 2020. It was followed by the long avaited judgment of the ECJ on 25 March 2021. The judgment dismissed all the appeals against the European Commission's decision and is largely based on the reasoning given in the Paroxetine judgment, as it could be expected after the AG Opinion. It follows the same path like the General Court's judgment concerning potential competition and the evaluation of by object, therefore I don't find it necessary to repeat the discussion in details here. I find it better to highlight a few important findings.

Concerning potential competition, the ECJ confirmed that in order to assess whether an undertaking not present in a market is a potential competitor of another undertaking already present in that market, it must be determined whether there are real and concrete possibilities of market entry for the former. When certain agreements are assumed to have the effect of temporarily keeping undertakings outside a market, it must be determined, having regard to the structure of the market and the economic and legal context within which it operates, whether in the absence of those agreements would have existed, real and concrete possibilities for market entry. In the context of the pharmaceutical sector, it is necessary to examine in that respect whether the generic manufacturer actually has a clear intention and ability to enter the market and does not meet barriers to entry that are insurmountable. The existence of a patent is not in itself such an insurmountable obstacle if a generic who actually has a clear intention to enter the market also has the ability to do so, and through its actions, appears to be ready to challenge the validity of the patent and accept the risk of an infringement action. The ECJ also confirmed that it is not the competition authority's task to carry out a review of the strength of the patent

[831] Case C-591/16 P Lundbeck v Commission, Opinion of Advocate General Kokott. ECLI:EU:C:2020:428. para 36

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or in the case of a dispute, of the probability of finding that the patent is valid and has been infringed.[832]

The Court also confirmed that taking into account the subjective factors in order to establish the existence of potential competition cannot be excluded provided that that competition is not established exclusively or principally on the basis of those factors. This applies in particular to the originator's perception about the risk delivered by a generic to its commercial interests if that perception affects the originator's market conduct.[833]

Concerning by object restraints, the judgment confirms: the notion of by object restraint must be interpreted strictly, as it is required by Cartes Bancaires and the following jurisprudence, and pay-for-delay agreements cannot be considered to be 'restrictions by object' in all cases for the purpose of Article 101(1) TFEU. However, the "characterisation as a 'restriction by object' must be adopted when it is plain from the examination of the settlement agreement concerned that the transfers of value provided for by it cannot have any explanation other than the commercial interest of both the holder of the patent at issue and the party allegedly infringing the patent not to engage in competition on the merits, since agreements whereby competitors deliberately substitute practical cooperation between them for the risks of competition can clearly be characterised as 'restrictions by object'".[834]

In my view, the judgment's main contribution relates to the object effect dichotomy, the long-lasting debate reopened by Allianz Hungária and Cartes Bancaires and clarified by Budapest Bank and Paroxetine. First, it perfectly follows the structure of assessment determined by the later judgments, and also explains when counterfactual analysis is not necessary in the case of by object analysis.

Shortly:

- In each case, it must be assessed whether the net gain of value transfers made by the originator to the generic was sufficiently significant incentivise the generic to refrain

[832] C-591/16 P Lundbeck v European Commission, ECLI:EU:C:2021:243, para 54-60

[833] Idem. para 75-76

[834] Idem. para 112-114

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from entering the market and not to compete on the merits (the net gain does not need to be greater than the profits expected by the generic from market entry)[835]

- For the purposes of classifying an agreement as "restrictive by object", only the specific characteristics of the agreement are relevant, on the basis of which "any particular harmfulness of that agreement for competition can be inferred, where necessary as a result of a detailed analysis of that agreement, its objectives and the economic and legal context of which it forms part".[836]
- The fact that the agreements did not contain any no-challenge clauses, (unlike in Paroxetine) is not relevant for their assessment, because the generics had no incentive to challenge Lundbeck's new process patents after concluding the agreements, since the reverse payments broadly corresponded to the profits they expected from market entry or to the damages which could have been paid to them if they had succeeded in litigation against Lundbeck. Even if the reverse payments were less than the expected profits, they nevertheless constituted a certain and immediate profit, without the risks that market entry would have entailed.[837]
- Absence of pro-competitive effects of the agreements: furthermore, the agreemnets do not meet the standard of proof required by paragraph 107 of the Paroxetine judgment to rebut characterisation as 'restrictions by object' on the basis of reasonable doubts as to whether they caused a sufficient degree of harm to competition[838]. (or, to quote Advocate General Bobek's Opinion[839], the fish appears to be fish)

Concerning counterfactual analysis, the judgmnent found that it "allows the effects of a concerted practice with regard to Article 101 TFEU to be assessed when the analysis of that practice does not reveal a sufficient degree of harm to competition to enable it to be

[835] Idem. para 115

[836] Idem. para 131

[837] Idem. para 133-135

[838] Idem. para 136-137

[839] Opinion of AG Bobek in case C-228/18 Gyzdasági Versenyhivatal v. Budapest Bank at all. ECLI:EU:C:2019:678, para 51 "if it looks like a fish and it smells like a fish, one can assume that it is fish. Unless, at the first sight, there is something rather odd about this particular fish, such as that it has no fins, it floats in the air, or it smells like a lily, no detailed dissection of that fish is necessary in order to qualify it as such. If, however, there is something out of the ordinary about the fish in question, it may still be classified as a fish, but only after a detailed examination of the creature in question."

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characterised as a 'restriction by object'". Consequently, "an examination of the 'counterfactual scenario', the purpose of which is to make apparent the effects of a given concerted practice, cannot be required in order to characterise a concerted practice as a 'restriction by object'"[840] Although, in the case of an agreement which has the effect of temporarily keeping an undertaking outside a market, "it must be determined whether there would have existed, in the absence of that agreement, real and concrete possibilities for that undertaking to enter that market, it should be noted that that specific clarification concerned the assessment of the existence of a potential competitive relationship between the parties to an agreement such as those at issue in the case which gave rise to that judgment and not the characterisation of those agreements as a 'restriction by object'"[841]

IV.4.2. The General Court's judgment in Servier

The judgment of the General Court was issued on 18 December 2018. The decision is interesting in itself, however its most interesting parts – overruling the Commission's market definition and consequently the findings related to Servier's abuse of its dominant position – fall out of the scope of our research. With regard to the Article 101 part of the judgment, the General Court annulled the Commission decision for the part relating to settlement between Servier and Krka, reduced the fine imposed on Servier for the Matrix settlement by 30%, otherwise – related to the Niche/Unichem, Teva, and Lupin settlements – maintained the Commission's decision.

Since certain elements of the judgment have already been discussed in details related to the General Court's Lundbeck judgment, it seems reasonable to not repeat them here. My analysis is going to focus on the following points:

a) short discussion of the Lundbeck criteria (to determine whether patent settlements constitute restrictions of competition by object) upheld by the General Court;
b) potential competition vis-à-vis the presumption of patent validity
c) reverse payments and costs inherent to patent settlements
d) side deals concealing value transfers vs. the Krka licensing and assignment agreements

[840] C-591/16 P Lundbeck v European Commission para. 139-140

[841] Idem. para 143

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The General Court's Lundbeck judgment discussed above set up the following three criteria to determine whether patent settlements between originators and generics constitute a by object restriction of competition law:

- the originators and the generics are at least potential competitors;
- settlements contained non-challenge and non-commercialisation clauses;
- such clauses were obtained by the originator in return for a value transfer (reverse payment).

The General Court reviewed the Commission's decision based on that structure and found that the Lundbeck criteria was fulfilled by the Commission's examination in that respect.[842] The General Court also rejected the appellant's claims related to the ancillary restraint nature of the non-challenge and non-commercialisation clauses.

With regard to the amount of the value transfer, the General Court's analysis is somewhat different from those figured out in Lundbeck: "in order to establish whether or not the transfer of value from the originator company to the generic company constituted an inducement to accept non-marketing and non-challenge clauses, the Commission rightly examined whether the value transfer corresponded to the specific costs of the settlement for the generic company. The relevant criterion […] in the identification of the costs borne by the generic company that are inherent in that settlement and not in any asymmetry of information existing between the parties or in their respective commercial interests."[843]

Concerning the inducive nature of the value transfere in four agreements, the General Court confirmed that a value transfer in itself is not problematic, only inducive value transfers are, which are defined by the judgment as follows: "In order to establish whether or not a reverse payment […] constitutes an inducement to accept nonmarketing and non-challenge clauses, it is necessary to examine, taking into account its nature and its justification, whether the transfer of value covers costs inherent in the settlement of the dispute […] If a reverse payment provided for in a settlement agreement containing clauses restrictive of competition is aimed at compensating costs borne by the generic company that are inherent in that settlement, that payment cannot in principle be regarded as an inducement. Nevertheless, a finding of an

[842] Case T-691/14 Servier and others k European Commission. ECLI:EU:T:2018:922 para 391, para 406, para 418

[843] T-691/14 Servier para 416

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inducement and of a restriction of competition by object is not ruled out in such a case. It means however that the Commission must prove that the amounts corresponding to those costs inherent in the settlement, even if they are established and precisely quantified by the parties to that settlement, are excessive."[844]

The General Court expressed clearly that "specific costs of the settlement", or "costs inherent to the settlement" are generally accepted, and if the amount of the reverse payment corresponds to the amount of such costs, the burden of proof switches to the Commisssion, and it has to prove that such a reverse payment has incucive nature, and therefore, is anticompetitive. As a typical example of costs inherent to the settlement, the General Court refers to litigation costs[845]. By contrast, the General Court does not consider as inherent costs certain categories, but "too extraneous to the dispute and to its settlement to be regarded as inherent in the settlement of a patent dispute." Such costs include, pursuant to the wording of the judgment: "for example, the costs of manufacturing the infringing products, corresponding to the value of the stock of those products, and research and development expenses incurred in developing those products. The same is true of sums which must be paid by the generic undertaking to third parties as a result of contractual commitments which were not undertaken in the context of the dispute (for example supply contracts)." However, it seems the General Court does not want to outrule such costs entirely, but places the burden of proof on the parties to the agreement, "if they do not wish the payment of those costs to be regarded as an inducement, and indicative of a restriction of competition by object, [they need to] demonstrate that those costs are inherent in the dispute or in its settlement, and then to justify the amount. They could also, to the same end, invoke the insignificant amount of the repayment of those costs which are a priori not inherent in the settlement of the dispute," showing that that amount is insufficient to constitute a significant inducement to accept the clauses restricting competition stipulated in the settlement agreement .[846] After detailed discussion of different type of costs of the agreements at issue, the General Court found that value transfers in the Niche, Matrix, Teva and Lupin agreements had an inducive nature.[847]

[844] Idem.para 527-529

[845] Idem. para 530, para 682

[846] Idem. para 531, para 683, para 828

[847] Idem. para 532

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With regard to the existence of potential competition, Servier confirms Lundbeck's – and Cartes Bancaires's – findings referring to the necessity of real concrete possibilities to enter the market[848]. Lundbeck is also confirmed in the respect that the existence of market barriers such as patents and the obligation to obtain a marketing authorisation does not call into question the generics intention, nor their ability to enter the marker, therefore, they do not call into question the existence of real concrete possibilities to enter.[849]

Interesting elements of the judgment are the findings related to the incumbent's perception: "the criterion of the incumbent operator's perception is a relevant, but not sufficient, criterion for assessing the existence of potential competition. […G]iven its subjective, and thus variable nature — which depends on the operators in question, their knowledge of the market and their contacts with their possible competitors — the perception of these operators, even experienced ones, cannot by itself lead to the conclusion that another operator is one of their potential competitors. However, that perception may support the conclusion that an operator has the ability to enter a market and, accordingly, may contribute to its classification as a potential competitor"[850] This statement is welcome, the General Court seems to accept – at least to an extent – the reality of the markets: information asymmetry in several cases rules out rational judgments on the perceived competitor's position or intent, and therefore, enables it even to bluff the incumbent.

A very important part of the reasoning of the General Court relates to the presumption of patent validity. In that respect, in my view, Servier goes farther and clarifies certain points of Lundbeck: the Court not only clarifies that the existence of potential competition does not question the presumption of patent validity – and therefore cannot be considered as presumption of invalidity – but specifies the case in which the existence of potential competition is excluded: "a court has confirmed the validity of the patent and a court has ruled that the valid patent was infringed."[851] Moreover, the court later adds, that "a judgment on the merits finding the existence of an infringement is itself provisional as long as the possible remedies have not been exhausted."[852] Therefore, the judgment ruling the patent valid and infringed is required to be

[848] Idem. para 318-320

[849] Idem. para 321

[850] Idem. para 347

[851] Idem. para 360

[852] Idem. para 368

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final and binding – otherwise generics can still contest patent's validity and infringement, therefore, potential competition exists.

The judgment also sophisticates certain requirements relating to the generics intentions to enter the market: on a supplementary basis, they are relevant in the assessment of the existence of potential competition: "while the intention to enter the market is neither necessary in order to find that there is potential competition on that market […] nor capable of calling that finding into question, nevertheless, when such an intention is established, it may support the conclusion that a given operator has the ability to enter the market and thus contribute to its classification as a potential competitor."[853]

Otherwise the judgment confirms Lundbeck related to the issues of potential competition, finding the existence of viable strategies and that it was sufficient for the Commission to establish the existence of a marketing authorization application and of the active participation of the generics in the application procedure. To question the existence of potential competition, the burden of proof would shift to the undertakings to show that there were problems which objectively prevented the grant of a marketing authorisations.[854]

Concerning side-deals – as it was already introduced in the part discussing the Commission's decision, the conduct of Servier included a complex system of side- deals, e.g. licensing, distribution and acquisition agreements – and the Krka agreement the General Court highlights that the presence of a 'side deal' "may constitute, as regards the settlement of a patent dispute, a strong indication of the existence of an inducement and, consequently, of a restriction of competition by object".[855] The General Court's judgment determines the definition of side deal as "a normal commercial agreement linked to a settlement agreement which contains clauses which are by themselves restrictive. Such a link exists, in particular, where the two agreements are concluded on the same day, where they are legally linked, the binding nature of one of the agreements being conditional upon the conclusion of the other agreement, or where, in the light of the context in which they are concluded, the Commission is able to establish that they are

[853] Idem. para 382

[854] Idem. para 478-479

[855] Idem. para 797

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indissociable. It may be added that, the shorter the time between the conclusion of each agreement, the easier it will be for the Commission to establish that indissociable nature."[856]

The General Court adds that "the fact that a commercial agreement, which does not normally have the settlement of a dispute as its subject matter […] and which serves as a vehicle for a transfer of value from the originator company to the generic company, is […] linked with a settlement agreement containing competition-restricting clauses is a strong indication of the existence of a reverse payment"[857]

Important that restrictive side-deals discussed above are clearly separated form lawful agreements by the judgment stipulating that "the linking of a normal commercial agreement to a settlement agreement containing non-challenge and non-marketing clauses no longer constitutes a strong indication of a reverse payment where the commercial agreement in question is a licence agreement concerning the patent in dispute."[858] With respect to the Krka agreement, the General Court acknowledged that licence agreements are appropriate means of resolving a dispute, and "[l]inking a licence agreement to a settlement agreement is all the more justified since the presence, in a settlement agreement, of non-marketing and non-challenge clauses is legitimate only where that agreement is based on the parties' recognition of the validity of the patent." The conclusion of a licence agreement makes sense only if the licence is actually used and based on a valid patent. Therefore, the licence agreement supports the legitimacy of the settlement agreement, which fully justifies the linking of the two.[859]

The judgment also determines certain requirement for the future cases of the Commission: "It is therefore for the Commission to rely on indicia other than the mere linking of the licence agreement and the settlement agreement for the purpose of establishing that the licence agreement was not concluded at arm's length and that it actually masks a reverse payment inducing the generic company to accept the non-marketing and non-challenge clauses.[860]

Since in Krka the Commission did not prove that the royalty for the license was abnormally low, and therefore the value transfer was not proven, it cannot be concluded that it was intended

[856] Idem. para 798

[857] Idem. para 803

[858] Idem. para 943

[859] Idem. para 946-947

[860] Idem. para 949

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to compensate for the costs inherent in the settlement and constitutes an inducement. Consequently, the Krka agreement did not reveal a sufficient degree of harm to be classified as by object restriction.[861] The General Court also found that the allaged potential effects were based on hypothetical circumstances which were not objectively foreseeable at the time of the conclusion of the agreement.[862] Therefore, the part of the Commission's decision relating to Krka was annulled.

IV.4.3. The ECJ judgment in Paroxetine case

The UK Paroxetine case, a similar case to Servier, was referred for preliminary ruling to the ECJ by the Competition Appeal Tribunal (CAT). The questions related to the definition of potential competition, by object/by effect restraint and authorized generics. Since questions 7-10 related to Article 102, the parts of the judgment referring to them are not going to be discussed here, they fall out of the scope of our research.

By discussing the first two questions relating to potential competition, the ECJ highlighted – similarly to the former case law - that to decide whether an agreement has the effect of temporarily keeping an undertaking outside a market, it must be determined whether there would have existed, in the absence of that agreement, real and concrete possibilities for that undertaking to enter that market and compete with the incumbent. A merely hypothetical possibility of such entry or the mere wish or desire of the generic to enter the market is not sufficient. Conversely, neither it is required to be demonstrated with certainty that the generic will in fact enter the market concerned and, that it will be capable of retaining its place there".[863] Important part of the judgment is that the ECJ determines a real step plan to be followed by such analysis:

- The assessment must be carried out having regard to the structure of the market and the economic and legal context.[864] In that respect, the ECJ emphasizes that in the case of medicines currently entering the public domain, "due account must be taken of the

[861] Idem. para 982-985.

[862] Idem. para 990

[863] Case C-307/18 GUK and others k. CMA (Paroxetine) para 37-38

[864] Idem. para 39

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regulatory constraints that are characteristic of the medicine sector", especially rules regulating marketing authorizations.[865]

- As second step, "full account must be taken of the intellectual property rights and, in particular, the patents held by the manufacturers of originator medicines relating to one or more processes of manufacturing an active ingredient that is in the public domain"[866]
- Furthermore, "the perception of the established operator is a factor that is relevant to the assessment of the existence of a competitive relationship between that party and an undertaking outside the market since, if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market." To determine whether the originator and the generics are potential competitors, it is necessary to first determine, whether at the time when that agreement was concluded, the generic had taken sufficient preparatory steps "to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicines."[867] Therefore, subjective considerations of the parties are taken into account. In that respect, the ECJ stipulates that legal and administrative steps taken by generics to enter the market "permit the conclusion" that the generic "has a firm intention and an inherent ability to enter the market […] even when there are process patents held by the manufacturer of originator medicines."[868] Interesting to note that the ECJ also requires that "the referring court must determine that the market entry of such a manufacturer of generic medicines does not meet barriers to entry that are insurmountable."[869] It seems like process patents held by the originator are not considered as barriers to entry by the ECJ on the pharmaceutical market, if the generic challenges them or starts the marketing authorization proceeding.[870]

Since this statement raises certain questions from the point of view of the presumption of patent validity, the ECJ emphasized that this presumption is an automatic consequence of the registration of the patent, and does not determine any way the outcome of any dispute related

[865] Idem. para 40

[866] Idem. para 41

[867] Idem. para 42-43

[868] Idem. para 44

[869] Idem. para 45

[870] Idem. para 46

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to the patent.[871] If the presumption of validity of a process patent would be regarded as it precludes the holder of that patent from being in a relationship of potential competition with any party that is allegedly infringing that patent on the market of the medicine containing that active ingredient (the compound, which could be created by other, non-infringing processes), "that would have the consequence […] that Article 101 TFEU would be deprived of all meaning and that would be liable, thereby, to frustrate EU competition law".[872]

According to the ECJ's reasoning, this does not mean that the competition authority must disregard any question relating to patent law that might influence the existence of a competitive relationship. Patents should be taken into account as part of the economic and legal context. However, the assessment of the competition authority must not consist of a review of the strength of the patent or of the probability of the outcome of the dispute between the originator and the generic. That assessment must rather concern whether the generic has real and concrete possibilities of entering the market at the relevant time.[873] In that respect the ECJ determines that "account must be taken of, inter alia, the following: that the uncertainty as to the validity of patents covering medicines is a fundamental characteristic of the pharmaceutical sector; that the presumption of validity of a patent for an originator medicine does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal; that a patent does not guarantee protection against actions seeking to contest its validity; that such actions, and, in particular, the 'at risk' launch of a generic medicine, and the consequent court proceedings, commonly take place in the period before or immediately after the market entry of such a generic medicine; that, to obtain an [marketing authorization] for generic medicine, there is no requirement to prove that that marketing does not infringe any originator medicine patent rights; and that, in the pharmaceutical sector, potential competition may be exerted before the expiry of a compound patent protecting an originator medicine, since the manufacturers of generic medicines want to be ready to enter the market as soon as that patent expires."[874]

[871] Idem. para 48

[872] Idem.para 49

[873] Idem. para 50

[874] Idem. para 51

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Patent disputes between the originator and the generic are rather considered as evidence of the existence of a potential competitive relationship between them by the ECJ.[875] In the next point, the ECJ goes even further by stating "that interim measures in no way prejudge the merits of an infringement action brought by the patent holder, a fortiori when, as in the main proceedings, such an injunction is granted in return for a cross-undertaking in damages, given by that patent holder."[876] The judgment also highlights further factors supporting the lack of barriers to entry, as follows: the existence of horizontal agreement with parties which are not present on the market concerned[877], and value transfer from the originator to the generic for the later entry[878].

With regard to the nature of the restriction by object, the ECJ confirmed interpretations given in Maxima Latvija and Cartes Bancaires, i.e strict approach shall be followed by classifying agreement as by object restraint.[879]

In that respect, the ECJ highlights that the background to the examined agreements "is a genuine dispute relating to a process patent, that dispute being the subject of proceedings before a national court. Accordingly, those agreements cannot be regarded as agreements bringing to an end entirely fictitious disputes, or as designed with the sole aim of disguising a marketsharing agreement or a market-exclusion agreement. […] it is necessary to assess, […] whether those agreements may, nonetheless, be treated as equivalent to such market-sharing or market-exclusion agreements."[880] In that respect the ECJ stipulates that settlement whereby a generic recognises, at least temporarily, the validity of the originator's patent and gives up challenging that patent and its independent efforts to enter the market "are liable to have effects that restrict competition […] since challenges to the validity and scope of a patent are part of normal competition in the sectors where there exist exclusive rights in relation to technology."[881]

The ECJ also admits that it is indeed possible that a generic manufacturer, after assessing its chances of success in the court proceedings may decide to abandon entry and conclude a settlement agreement with the originator an agreement to put an end to the proceedings. Such

[875] Idem. para 52

[876] Idem. para 53

[877] Idem. para 55 and Toshiba para 33-34

[878] C-307/18 Paroxetine para 56

[879] Idem. para 67-68

[880] Idem. para 76-77

[881] Idem. para 81

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an agreement cannot be considered in all cases as a 'restriction by object'. Even the fact that it involves transfers of value, either pecuniary or non-pecuniary, made by the e originator to the generic is not sufficient ground to classify it as a 'restriction by object', since those transfers of value may prove to be justified.[882] The ECJ explains that this is the case especially "where [the reverse payment] correspond[s] in fact to compensation for the costs of or disruption caused by the litigation between them, or that correspond to remuneration for the actual supply, immediate or subsequent, of goods or services to the manufacturer of the originator medicines. […] particularly financial, given by the patent holder to him, such as a cross-undertaking in damages"[883]

However, "characterisation as a 'restriction by object' must be adopted when […] the transfers of value […] cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits."[884]

A very important point of the judgment declares that paying for delay – or give up – market entry has never been a patent protected conduct: "the conclusion of an agreement under which a competitor of the patent holder undertakes not to enter the market and to cease its challenge to the patent in exchange for payment of a substantial sum, the sole consideration for which is that undertaking, amounts precisely to ensuring protection for that patent holder against actions seeking the revocation of its patent and to establishing a presumption that the products which may be put on the market by its competitor are unlawful. Therefore, it cannot be maintained that entering into such an agreement falls within the exercise, by the patent holder, of its prerogatives stemming from the object of the patent. That is all the more the case when it is for public authorities and not private undertakings to ensure compliance with statutory requirements. Accordingly, it cannot be asserted that the conclusion of such an agreement represents, on the part of the manufacturers of generic medicines, no more than their recognition of patent rights, presumed to be valid […] If the patent holder makes, in their favour, a significant transfer of value, the sole consideration for which is their undertaking not to enter the market and no longer to challenge the patent, that indicates, in the absence of any other plausible explanation, that it is not their perception of the patent's strength, but the prospect of

[882] Idem. para 84-85

[883] Idem. para 86

[884] Idem. para 87

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that transfer of value which has induced them to refrain from entering the market and challenging the patent." In order to assess whether the value transfer can have no other explanation than the commercial interest of the parties to that agreement not to engage in competition on the merits, it is important to take into consideration all the transfers of value made between the parties, whether those were pecuniary or non-pecuniary. Indirect transfers e.g. ensuring profits to be obtained by the generic from a distribution contract enabling it to sell a possibly defined quota of generic medicines manufactured by the originator should typically be taken into account.[885]

The net gain arising from the value transfer may be justified "by the existence of any quid pro quo or waivers by the manufacturer of generic medicines that are proven and legitimate."[886] If justification is not successful, it has to be determined whether that net gain is sufficiently large to act as an incentive to the generic to refrain from entering the market.[887]

In that regard, there is no requirement that the value transferred should be greater than the profits expected by the generic from market entry. "All that matters is that those transfers of value are shown to be sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits with the manufacturer of originator medicines concerned."[888] If it is the case, the agreement falls into the by object category. [889]

The ECJ rejected the scope of the patent doctrine again, that patent does not permit its holder to enter into anticompetitive agreements.[890] The ECJ explains, that it is exactly the uncertainty as to the outcome of the proceedings in relation to the patent held by the originator is valid and whether the generic version infringes that patent which contributes, for as long as it lasts, to the existence of a situation of at least potential competition between the parties.[891]

With regard to the pro-competitive effects, the ECJ highlights, that they must "be duly taken into account […] as they are capable of calling into question [the] sufficient degree of harm to

[885] Idem. para 90-91

[886] Idem. para 92

[887] Idem. para 93

[888] Idem. para 94

[889] Idem. para 95

[890] Idem. para 96-97

[891] Idem. para 100

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competition and, consequently, of whether it should be characterised as a 'restriction by object'." [892] The mere existence of pro-competitive effects cannot however preclude characterisation as a 'restriction by object'.[893] Such effects should be "relevant and specifically related to the agreement, […] sufficiently significant" to justify a reasonable doubt as to whether the settlement agreement caused a sufficient degree of harm to competition."[894]

Concerning the questions relating to the anticompetitive effects, the most notable parts of the judgment relate to the counter-factuals.

In that respect the ECJ notes that the establishment of the counter-factual does not involve any definitive finding in relation to the chances of success of the generic in the patent proceedings or to the probability of the conclusion of a less restrictive agreement. The sole purpose of the counter-factual is "to establish the realistic possibilities with respect to that manufacturer's conduct in the absence of the agreement at issue. Accordingly, while that counterfactual cannot be unaffected by the chances of success of the manufacturer of generic medicines in the patent proceedings or again in relation to the probability of conclusion of a less restrictive agreement, those factors constitute, however, only some factors among many to be taken into consideration in order to determine how the market will probably operate and be structured if the agreement concerned is not concluded."[895] The problem with this conclusion is that it only explains what is not required to be examined by the court, without giving guidance on what should be examined in the framework of a counterfactual analysis.

V. The applicable standard and the amount of payment

Subchapter I.1 posed four research questions: the first and second were addressed by subchapter II.10 at the end of the chapter dealing with regulatory background. The aim of the three subchapters of this fifth chapter is to address the other research questions, namely those related to the evaluation of pay-for-delay settlements as by object restraint, the differences of legal standards applied in the EU and in the US, and the lawful payment.

[892] Idem. para 103

[893] Idem. para 106

[894] Idem. para 107

[895] Idem. para 119-120

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V.1. The place of pay-for-delay agreements in the object/effect dichotomy

The dichotomy of anticompetitive object and effect has been a hot topic of competition law for a long time both for practitioners and for the legal literature.

At the time when the Commission's Lundbeck decision was issued, the legal atmosphere was friendly to classify a restriction of competition as by object restriction. In the period between 2000 and 2011 the Commission issued, excluding cartels, 18 infringement decisions, 17 out of which involved by object restrictions and only one case was classified as by effect restriction. At the level of the ECJ, it was barely possible to find an Article 101 judgment which did not conclude that the practice at hand was a by object restriction.[896] It was a general approach by the time that the courts broadened the concept of „by object" infringements.[897] The ECJ's judgment in Allianz Hungária somewhat complicated the picture by stating that "[i]n order to determine whether an agreement involves a restriction of competition 'by object', regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms a part[…]. When determining that context, it is also appropriate to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question".[898]

The Allianz judgment created an atmosphere where it was unsure where by object analyses ends and by effect standards start. Some authors even criticized the judgment for requiring an effect based analysis to qualify an agreement as a by object restriction, thus blurring the distinction between the two.[899] In the post-Allianz world, Cartes Bancaires seemed to change the approach

[896] Gerard, "The Effects-Based Approach Under Article 101 TFEU and its Paradoxes: Modernisation at War with Itself?" in BOURGEOIS and WAELBROECK (eds.), Ten Years of Effects-Based Approach in EU Competition Law, Bruylant, 2012, p 17- 41. p 38.

[897] Frank Montag – Marcel Meinhardt: Restriction of competition by object or effect. 23rd St. Gallen International Competition Law Forum ICF. (Electronic copy available at: http://ssrn.com/abstract=2780009 Downloaded: 30 November 2018)

[898] C-32/11 Allianz Hungária 36

[899] See G. Cosmo, "Methods for Determining whether an Agreement Restricts Competition: Comment on Allianz Hungária," European Law Review 2013, pp.542-551; D. Harrison, "The Allianz Hungária case – The ECJ's judgment could have ugly consequences," Competition Law Insight, (2013) 12(6), pp.10-12; Csongor István Nagy, "The Distinction between Anti-competitive Object and Effect in Allianz: The End of Coherence in Competition Analysis?," World Competition, (2013) 36(4), pp.542-564; for a more general reference see Opinion of AG Wahl in Case C-67/13 P, Cartes Bancaires, EU:C:2014:1958, §52.

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towards by object restriction significantly: Cartes Bancaires was a "landmark ruling insofar as it limited the broad application of the notion "by object" restriction".[900]

Other authors also highlight that in the first ten years after the entry into force of regulation No. 1/2003, the European Commission and national competition authorities have made a broad and unprecedented use of the notion of 'restriction by object' in the application of Article 101(1) TFEU. For competition authorities, if an agreement can be qualified as by object restriction, applying the prohibition of Article 101(1) TFEU and national equivalents becomes easier since there is no need to prove that the agreement has either an actual or a potential anticompetitive impact on the market. In this respect, the notion of by object restriction is an important tool for effective enforcement.[901] Since Cartes Bancaires seemed to be a real turning point of this practice, it lead several experts to the conclusion that this judgement will affect the evaluation of pay-for-delay cases.[902]

After the judgements discussed in the above chapters, it seems like that the European Courts found – if certain circumstances are present – that pay-for-delay agreements meet the Cartes Bancaires requirements in order to be classified as by object restrictions.

Often the advocates of IP rights argue against the Commission's evaluation – as it happened in all the above discussed cases – by referring to the exclusive rights protected by the patent. In that respect, the Commission – and now also the European courts, similarly to the US Supreme Court's judgment in Actavis – made it clear that paying out a competitor from the market has never been considered as a patent-protected conduct; no patent protection can legalize such behaviour.

Indeed, patents are granted to ensure a fair return on an investment. That way, legal monopoly is provided for the inventor for giving something new, industrially applicable, based on an inventive step to the public. If the patent is not valid, or because of the lack of any necessary

[900] Frank Montag – Marcel Meinhardt: Restriction of competition by object or effect.

[901] Ginevra Bruzzone – Sara Capozzi: Restriction by Object in the Case Law of the Court of Justice: in Search os a Systematic Approach. p. 1. (Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2753521 Downloaded: 30 November 2018)

[902] Clancy–Geradin–Lazerow (Lj. 4), Choi–Den Uyl–Hughes (Lj. 4.) Zafar (Lj. 4) Killick–Jourdan–Dickinson (Lj. 4), Ginevra Bruzzone – Sara Capozzi: Restriction by Object in the Case Law of the Court of Justice: in Search os a Systematic Approach. p. 1. (Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2753521 Downloaded: 30 November 2018), Ginevra Bruzzone – Sara Capozzi: The procompetitive and anticompetitive impact of patent settlements, in: G. Muscolo – G. Pitruzzella (eds.) 'The Pharmaceutical Sector between Patent Law and Competition Law: an International Perspective".

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criteria of patentability it should not have been granted, there is a public interest in challenging such patents at the EPO, national patent offices, or national courts. Cases where the originator pays significant sums of money to the generic not to compete, or offers other compensation are not and cannot be foreseen by the patent system.

The Commission highlighted in Servier: „While a patent holder has the right to oppose possible infringement of its patent, patent law does not provide for a right to pay actual or potential competitors to stay out of the market or to refrain from challenging a patent prior to entering the market." Therefore, such cases „constitute a breach of Article 101 of the Treaty when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market."[903]

As reverse payments are declared to be outside of the scope of the patent – i.e. it is declared by the Commission that patents do not ensure the right to originators to protect themselves against generic challenges by transferring value to the generics –the evaluation of potential competition has a very important role in classifying a specific pay-for-delay case as a by object restriction. If generics were potential competitors of the originator, paying off competitors from the market shall be considered as a by object restriction, due to its rather harmful nature. Since the conduct is not patent protected, we end up in the same situation like in Fentanyl– a naked market sharing agreement. Therefore, the real question seems to be whether the generic is a potential competitor, or not.

This problem can be clearly addressed by using the ancillary restraint theory as discussed by Nagy: even patent settlements including with reverse payments are not by definition by object restraints. If market sharing is an effect of settling a real patent dispute between the parties, i.e. market partition is an ancillary consequence of an otherwise legitimate settlement, the agreement is not considered as by object restraint.[904] Referring to Paroxetine, Nagy also highlights, that a reverse payment settlement between generic and originator companies where the parties settle one or more patent disputes constitute a by object restraints only if the net gain from the value transfers from the originator to the generic "can have no other explanation than

[903] Servier decision para 1137

[904] Nagy Csongor István: A kartelljog dogmatikai rendszere. HVG Orac, Budapest, 2021. p. 191

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the commercial interest of the parties to the agreement not to engage in competition on the merits". [905] Even in such a case, exemption is possible if the settlement concerned is "accompanied by proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition"[906] – which is a real difference compared to US antitrust's per se or quick look test. On the other hand, the European cases discussed above really do not seem to have ancillary nature, each agreements are rather part of a complex a well designed antigeneric strategy, which is even stated in the Commission's decisions.

V.2. „Rule of reason" vs. by object restrictions

After the Commission's decision in the Lundbeck case and the US Supreme Court's judgement in Actavis, several scholars and practitioners argued about the similarity and/or contradictory nature of the American and European approaches towards pay-for-delay settlements.[907] Geradin at all. conclude that while the US Supreme Court rejected the FTC's desired "presumptively illegal" standard for the assessment of reverse-payment patent settlement agreements, the European Commission applied the "presumptively illegal" ("restriction by object") standard. Geradin at all. assume that the key issue is that this European approach has not yet been tested in front of the EU Courts, [908] but since then, the judgments generally reinforced the Commisssion's approach in the relevant cases.

Killick – who has been the legal representative of Servier, so cannot be considered as an independent scholar – shares this view by stating that "[i]n the United States, the Supreme Court rejected the Federal Trade Commission's view (similar to the Commission's views) in the Actavis case. It found that there was no reason to apply a per se or quick look rule finding patent settlements with a payment to the generic company presumptively illegal. It instead concluded that the rule of reason should be applied to determine whether an agreement had anticompetitive

[905] Idem. p. 142-143, see also C-307/18 Paroxetine para 111.

[906] C-307/18 Paroxetine para 111.

[907] Michael Clancy – Damien Geradin – Andrew Lazerow: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law, Patrick Harrison – Kristina Nordlander: EU/US Patent Settlements : An overview of leading cases. e-Competitions | N° 58749, www.concurrences.com

[908] Michael Clancy – Damien Geradin – Andrew Lazerow: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law. p. 16

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effects. The Supreme Court thus held that the parties can justify the payment and demonstrate pro-competitive effects as well as present arguments that the agreement did not bring about anticompetitive effects." According to Killick, the Commission should follow the same logic and apply an effects-based test to patent settlements in Europe.[909]

Alexander Italianer, at that time director general of DG Competition, so again, not an independent scholar, gave, on the other hand, a speech on this topic where he tried to bridge the gap between the EU-US approaches.[910] Harrison and Nordlander refer to his speech in their article, and argue that despite some similarities, it appears that "the FTC will be held to a tougher standard than the standard suggested by DG Comp when looking to assert that patent settlement agreements breach applicable antitrust/competition laws […] a marginal difference in the applicable legal test, may nonetheless lead to a huge gulf in enforcement activity". Harrison and Nordlander also highlight that other "differences between U.S. antitrust and EU competition enforcement procedures seem set to exacerbate the discrepancies in the applicable legal tests. DG Comp needs only make out its cases to its own satisfaction and then defend them on judicial review (i.e., a limited legality check) before the EU's General Court or Court of Justice. The FTC, on the other hand, must prove its cases to the satisfaction of the ordinary courts."[911]

After this introduction, we can conclude that the examination of the similarities and dissimilarities of the EU and US approaches is a complex task. Before continuing to discuss the above dispute, the EU and US concepts shall be shortly discussed, and their main features should be compared. Both the European object-effect dichotomy and the US rule of reason are subject to discussions in several studies and cases. Providing a complex assessment is not the aim of this thesis, hereby the discussion simply focuses on the role played by these concepts in the evaluation of reverse payment settlements. The main features of these concepts should be highlighted in order to understand whether the EU and the US reached different conclusion in pay-for-delay cases, especially in Actavis and in Lundbeck.

[909] James Killick: Patent settlements as by object restrictions: a European approach, but is it the right one? (Available at: https://awards.concurrences.com/IMG/pdf/patent_settlements_as_by_object_restrictions_-_2015.pdf Downloaded 19 December 2017) p. 16.

[910] Italianer http://ec.europa.eu/competition/speeches/text/sp2013_07_en.pdf

[911] Patrick Harrison – Kristina Nordlander: EU/US Patent Settlements: An overview of leading cases. e-Competitions | N° 58749, www.concurrences.com P. 5.

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This discussion builds on Chapter I. of this thesis, where the basic features of EU and US competition law were introduced.

V.2.1. The US system

According to Section 1 of Sherman Act "every contract, combination in the form of a trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal". This rule prohibits every contract or conspiracy, in any form, no justification is provided by the text of the provision.

Nevertheless, US courts applied a less literal approach to prohibit only unreasonable restraints. In order to determine the reasonableness or the lack of reasonableness of a restraint, antitrust law adopted the "rule of reason' test, the application of which requires the weighing of pro- and anticompetitive effects of the restraint in question. Under the rule of reason, specific information about the relevant business and the restraint's history, nature and effect are taken into account as substantial factors by the court in order to distinguish between a) restraints with anticompetitive effect, detrimental to consumers and b) restraints stimulating competition for the benefit of consumers.[912]

So, first of all, the US antitrust system applies two main concepts to address infringements:

a) per se illegality applies in case of naked restraints, when a conduct is explicitly illegal, e.g. a horizontal price fixing, while
b) rule of reason applies to cases where the anti-competitive nature of a conduct is not obvious.

The test of "reasonableness" examines whether the clause, contract, conspiracy in any form unreasonably restrict competition on the relevant market. The rule of reason balances pro-competitive and anticompetitive effects.[913] However, it can seem like for the first sight, but the per se-rule of reason concepts cannot be considered as a dichotomy. A leading US antitrust scholar, Hovenkamp explains the difference of rule of reason and per se illegality as follows: "In a per se case the question is typically whether an anticompetitive agreement such as price fixing exists, the defendants are strongly motivated to keep such agreements secret. […] By

[912] Wikis der Freie Universität Berlin. (Available at: http://wikis.fu-berlin.de/pages/viewpage.action?pageId=410157604 Downloded: 31 July 2017)

[913] Antitrust Rule of Reason and Per Se Illegality. (Available at: http://thebusinessprofessor.com/knowledge-base/antitrust-rule-of-reason-and-per-se-illegality/ Downloded: 31 July 2017)

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contrast, in the typical rule of reason case the existence of the agreement is not in dispute, but only whether it is anticompetitive under the circumstances."[914] He also highlights that „a full blown rule of reason inquiry is significantly more costly than analysis under the per se rule. Applying the rule of reason typically requires expert testimony identifying a relevant market or alternative mechanisms for estimating market power, as well as some evidence that purports to measure actual anticompetitive effects. By contrast, the per se rule requires only proof that a particular type of conduct has occurred. The rule of reason is thus justified only to the extent that it provides superior outcomes." [915]

The rule of reason is, however, not a uniform concept, it is not always applied in its total form. 'Quick look', or 'truncated' analysis refers to a framework under which a plaintiff can establish a violation of the rules set out in Section 1 of the Sherman Act without having to prove all elements that would be required under a full rule of reason analysis. Generally, if a plaintiff can establish that a particular restraint is "inherently suspect" because it is of a type that always or almost always tends to harm competition, a truncated analysis permits the plaintiff to satisfy its initial burden without presenting evidence that the defendant's conduct caused or is likely to cause actual harm to competition. The burden of proof then shifts to the defendant. It may rebut the plaintiff's showing by demonstrating that the restraint has a plausible procompetitive justification. If the defendant does so, a full rule of reason analysis must be undertaken.[916]

Waller explains that „Justice Stevens explained the continuum of the rule of reason in two key footnotes. In footnote 26, he stated: "Indeed, there is often no bright line separating per se from rule of reason analysis. Per se rules may require considerable inquiry into market conditions before the evidence justifies a presumption of anticompetitive conduct." At the other end of the spectrum of the rule of reason continuum, he also noted that the rule of reason can sometimes be applied in "the twinkling of an eye" when the anticompetitive harm is obvious."[917]

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[914] Herbert J. Hovenkamp: The Rule of Reason. *Faculty Scholarship*. 1778. (Available at: http://scholarship.law.upenn.edu/faculty_scholarship/1778 Downloaded: 30 November 2018) p. 7.

[915] Herbert J. Hovenkamp: The Rule of Reason. *Faculty Scholarship*. 1778. http://scholarship.law.upenn.edu/faculty_scholarship/1778 p 13.

[916] Geofrey D. Oliver: Of Tenors, Real Estate Brokers And Golf Clubs: A Quick Look at Truncated Rule of Reason Analysis

[917] Spencer Weber Waller: Justice Stevens and the Rule of Reason. SMU Law Review, 2009. Vol. 62. 693-724., p. 705-706.

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Concerning the different "shades" of rule of reason, one important characteristic of the above discussed concepts should be highlighted: the US antitrust doctrine should be considered as "less a dichotomy than a continuum".[918]

However, the nature of the continuum – or different "shades", or sliding scale[919] – of rule of reason are subject to disputes in the US: "in practice, however, the "continuum" description has proven less than accurate. The application of the quick look test, rather than the full rule of reason analysis, has generally been a death sentence for the activity in question, as defendants have been limited to only facially plausible competitive justifications in attempting to surmount the court's presumption of economic harm. Unlike under the traditional rule of reason, defendants have been unable to use the in-depth factual inquiry to provide myriad business justifications for their decisions to engage in questionable activity. As a result, instead of creating an antitrust doctrine to reflect the legal shades of grey that exist in the business world, the quick look has functioned as another tool that allowed courts to strike down any difficult agreement without expanding the harsh per se category. […] Between the rule of reason and per se legal conduct on this new branch of Professor Areeda's continuum is the American Needle nonfatal quick look rule of reason.".[920]

Even if we think about rule of reason as a "many faces" fenomenon or a continuum[921], something in-between quick look and full rule of reason might be relevant for pay-for-delay cases, as it is highlighted by Professor Hovenkamp:

"In general, analysis of a contractual restraint under the rule of reason requires a showing of (1) power sufficient to warrant a conclusion of plausible competitive harm; (2) a restraint that

[918] American Needle, Inc. v. National Football League. Harvard Law Review. Vol. 124:179. pp. 400-410. p. 407. (Available at: https://harvardlawreview.org/wp-content/uploads/pdfs/vol_12401american_needle_inc_v_national_football_league.pdf), See also Phillip E. Areeda: Antitrust Law p 408 (1986). See also: Herbert J. Hovenkamp: The Rule of Reason. Penn Law: Legal Scholarship Repository. 7-2017. P. 32. (Available at: http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2780&context=faculty_scholarship. Downloaded: 19 December 2017)

[919] Herbert J. Hovenkamp: The Rule of Reason. Florida Law Review, Vol. 70. 123–124. o. Available at: http://www.floridalawreview.com/wp-content/uploads/3-Hovenkamp.pdf Downloaded: 19 November 2019)

[920] American Needle, Inc. v. National Football League. Harvard Law Review. Vol. 124:179. pp. 400-410. p. 408. (Available at: https://harvardlawreview.org/wp-content/uploads/pdfs/vol_12401american_needle_inc_v_national_football_league.pdf)

[921] Herbert J. Hovenkamp: The Rule of Reason. Penn Law: Legal Scholarship Repository. 7-2017. Available at: (http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2780&context=faculty_scholarship. Downloaded: 19 December 2017)

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threatens to reduce output or increase price and that (3) is not justified by efficiencies or some other redeeming virtue. Without departing from any of these principles, the majority's opinion in Actavis permitted trial courts to "structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed." This approach is consistent with the Supreme Court's historical reluctance to adopt any kind of bipolar distinction between a full "rule of reason" on one hand and a drastically abbreviated "quick look" on the other".[922]

Hovenkamp also highlights that "[l]ower courts, the FTC, and commentators have often suggested that antitrust analysis in fact occupies three silos: the rule of reason, per se illegality, and an intermediate "quick look," which has been described in different ways by different courts. These intermediate quick look cases are said to bear some of the characteristics of per se unlawful restraints, but there may be an additional complicating factor that deserves additional examination. In some cases the restraint is sufficiently unique that judges lack sufficient judicial experience with it. In that situation further examination is required, although perhaps not a full blown rule of reason inquiry." Hovenkamp obviously uses this "tripartite" explanation, and its "alternative view", the continuum theory for the same phenomenon while he explains that the "entire debate about antitrust "modes of analysis" is at bottom about presumptions, burdens of proof, and appropriate judicial responses to concerns about plausibility and location of the evidence."[923]

According to Hovenkamp, in Actavis the Supreme Court "simultaneously said that the rule of reason rather than any "quick look" should apply, but then went on to indicate that sufficient market power and anticompetitive effects could be inferred from the size of an exclusion payment", just as the Supreme Court did in California Dental.[924] This later case might be important for this analysis, because the Supreme Court declared that:

"As the circumstances here demonstrate, there is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect

[922] Herbert Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minnesota Journal of Law, Science and Technology. Vol 15, Issue 1. Pp. 3-30. P. 23.

[923] Herbert J. Hovenkamp: The Rule of Reason. Penn Law: Legal Scholarship Repository. 7-2017. P. 31-32. Available at: (http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=2780&context=faculty_scholarship. Downloaded: 19 December 2017)

[924] Idem. p. 33.

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and those that call for more detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint. The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one. And of course what we see may vary over time, if rule-of-reason analysis in case after case reach identical conclusions. For now, at least, a less quick look was required for the initial assessment of the tendency of these professional advertising restrictions."[925]

The discussion of rule of reason could be, of course continued to reach complex understanding of even its historical improvements.[926] However, for the purposes of the analysis of pay-for-delay agreements, and especially for the comparison of the EU and US approaches towards such agreements, here the "Antitrust Guidelines for Collaborations Among Competitors" seems reasonable to be quoted. First, the Guidelines states that "Agreements of a type that always or almost always tends to raise price or to reduce output are per se illegal." After per se illegality, rule of reason is discussed, as follows: under rule of reason "analysis begins with an examination of the nature of the relevant agreement. As part of this examination, the Agencies ask about the business purpose of the agreement and examine whether the agreement, if already in operation, has caused anticompetitive harm. In some cases, the nature of the agreement and the absence of market power together may demonstrate the absence of anticompetitive harm. In such cases, the Agencies do not challenge the agreement. Alternatively, where the likelihood of anticompetitive harm is evident from the nature of the agreement, or anticompetitive harm has resulted from an agreement already in operation, then, absent overriding benefits that could offset the anticompetitive harm, the Agencies challenge such agreements without a detailed market analysis. If the initial examination of the nature of the agreement indicates possible competitive concerns, but the agreement is not one that would be challenged without a detailed market analysis, the Agencies analyze the agreement in greater depth. The Agencies typically define relevant markets and calculate market shares and concentration as an initial step in assessing whether the agreement may create or increase market power or facilitate its exercise. The Agencies examine the extent to which the participants and the collaboration have the ability

[925] 8Cal. Dental, 526 U.S. at 780–81 (1999)

[926] Andrew I. Gavil: Moving beyond caricature and characterization: The Modern Rule of Reason in Practice. Southern California Law Review, Vol. 85:733. 2012. (Available at: http://www.antitrustinstitute.org/sites/default/files/1100CLE.pdf Downloaded: 19 December 2017)

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and incentive to compete independently. The Agencies also evaluate other market circumstances, e.g. entry, that may foster or prevent anticompetitive harms."[927]

One part of this paragraphs should be highlighted, before the discussion of the EU legal system takes place: "where the likelihood of anticompetitive harm is evident from the nature of the agreement […] absent overriding benefits that could offset the anticompetitive harm", then the relevant authorities challenge the agreement without a detailed analysis. We can conclude this explanation is very similar to the reasoning of the General Court in Lundbeck and of the ECJ in Cartes Bancaires.

Since per se illegality and rule of reason should not be seen as a dichotomy, or the two sides of a coin, handling rule of reason as a continuum, or sliding scale seems to be a reasonable idea. The comparison of Actavis and Lundbeck therefore will focus on the burden of proof, the standard of proof of the relevant authorities and other relevant factors – as it appears to be the only way to compare a point of a continuum to the European concept, the object-effect dichotomy.

V.2.*2.* The EU system

In the EU, Article 101 (1) and 101 (2) of the TFEU prohibits and declares void anticompetitive agreements. In the EU, the by object-by effect dichotomy comes from the wording of Article 101 (1) of the TFEU which outrules, "all agreements […] which have as their object or effect the prevention, restriction or distortion of competition within the internal market". Article 101 (3) TFEU provides a general exemption: any agreement which restricts competition, whether by its effect or by its object, may in principle benefit from this exemption if the cumulative conditions are satisfied. Article 101 (3) provides a structural framework for assessing the economic benefits generated by restrictive agreements and balancing them against anticompetitive effects, considering the efficiency gains that may result from this agreement.

Taking into regard the exemption provided by Article 101 (3), it can be concluded that per se rules do not exist in the application of Art. 101. However, certain authors refer to the fact that

[927] Federal Trade Commission and the U. S. Department of Justice: Antitrust Guidelines for Collaborations Among Competitors. (Available at: https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf Downloaded: 30 November 2018)

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Advocate General Kokott "went further […] and actually used the term "per se prohibition,""[928] due to the fact that in Lundbeck the General Court applied the Cartes Bancaires standard, which is close to the standard applied in BIDS, referred to as by the author as other end point of the scale – "certain forms of collusion between undertakings can be regarded, by their very nature, as being injurious to the proper functioning of normal competition"[929] – here the nonexistence of per se rule in EU competition law will be handled as accepted. This approach is also supported by the fact that legal disputes about Lundbeck and Actavis are focusing on the quick look/rule of reason and by object/by effect dichotomy.

This by object/by effect dichotomy is also subject to hot debates in the EU. There are certain views – especially after the opinion of Advocate General, and the judgment in the Hungarian MIF case[930] Hereby without getting involved in these disputes, only a generally accepted notion of by object and by effect restrictions will be provided just for the purpose of being comparable to the US concepts.

First of all, it should be noted that they are not cumulative but alternative requirements.[931] Jones and Sufrin introduce this dichotomy as follows: "EU law thus draws a distinction between agreements which are so likely to harm the objectives pursued by the competition rules that they are presumed to restrict competition (they are restrictive by object), and those which can be held to be restrictive only after their actual or likely effect on competition has been examined. […] Whether or not an agreement falls within the object or effect category has a critical impact on the case and the burden of proof. Where it is shown that the object of an agreement is to restrict competition […] [and the other requirements meet] a violation of Article 101 is proved unless it can be demonstrated that the agreement satisfies the Article 101 (3) criteria. Where the

[928] Caleb Vesey: *Per se* Rules in U.S. and EU Antitrust/Competition Law. (Available at: http://www.eucomplaw.com/comparing-eu-and-us-competition-law/per-se-rules/ Downloaded: 19 December 2017) See also Case C-8/08 T-Mobile Netherlands BV and Others v. Raad van bestuur van de Nederlandse Mededingingsautoriteit [2009] ECR I-04529, AG Opinion, paragraph 43.

[929] Case C-209/07 Beef Industry Development Society and Barry Brothers [2008] ECR I-0000 ('BIDS'), paragraph 16.

[930] Case C-228/18. Budapest Bank at all. c. Gazdasági Versenyhivatal. See also: Dömötörfy Borbála Tünde–Kiss Barnabás Sándor–Firniksz Judit: Látszólagos dichotómia? Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre. In: Verseny és Szabályozás, 2019. Available at: https://www.mtakti.hu/wp-content/uploads/2020/03/02_DomotorfyBT-KissBS-FirnikszJ.pdf Downloaded: 29th September 2020)

[931] Case 56/65, Société La Technique Miniere v. Maschinebau Ulm GmbH [1966] ECR 234. para 249. See also Case C-234/89, Delimists v. Henninger Bräu [1991] ECR-I-935. para 13. and Cases T374, +75, 384 and 388/94, EuropBrenda ean Night Services v. Commission [1998] ECR-II-3141, para 136.

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object of an agreement is not found to restrict competition, however, the burden of proving that this is its effect is on the person alleging the breach. Only where this is established does the burden shifts onto the parties to defend it under Article 101 (3).”[932]

The Commission’s Guidelines on the Application of Article 81 (3) [now Article 101 (3)] of the Treaty explains the dichotomy as follows:

“Restrictions of competition by object are those that by their very nature have the potential of restricting competition. These are restrictions which in light of the objectives pursued by the Community competition rules have such a high potential of negative effects on competition that it is unnecessary for the purposes of applying Article 81(1) to demonstrate any actual effects on the market. This presumption is based on the serious nature of the restriction and on experience showing that restrictions of competition by object are likely to produce negative effects on the market and to jeopardise the objectives pursued by the Community competition rules. Restrictions by object such as price fixing and market sharing reduce output and raise prices, leading to a misallocation of resources, because goods and services demanded by customers are not produced. They also lead to a reduction in consumer welfare, because consumers have to pay higher prices for the goods and services in question.”[933]

Even in the European dichotomy, the borders between object and effect “boxes” are not always clear, the topic is subject to hot debates. After Allianz Hungária, the Court was blamed for blurring this “border” between the object and effect boxes. The evolution of the object/effect dichotomy – as it was presented in subchapter IV.3. – did not always followed a straight line. After the Opinion of Advocate General Bobek in the Budapest Bank case, in my view, this blurred nature of the object/effect borders is acknowledged. Tóth also highlights that some real-life competition restraints cannot easily be placed into by object and by effect boxes.[934] Consequesntly, I somewhat question whether the by object, by effect categories of European competition law should be still considered as a dichotomy, in my view, probably with Allianz Hungária as a starting point, the EU started to move closer to the US continuum, or sliding scale

[932] Alison Jones – Brenda Sufrin: EU Competition Law. Texts, cases and materials. Oxford University Press, Oxford, 2011. Fourth Edition. P. 202.

[933] Guidelines on the application of Article 81(3) of the Treaty. Official Journal C 101/97. para 21.

[934] Tihamér Tóth: Az Európai Unió versenyjoga. 2014.

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approach. Of course, as compared to the US, the EU system has more of a dichotomic nature still.

V.*2*.3. Comparison of the EU and US concepts

After discussing the main features of the EU and the US conceptual systems, we can conclude – for the first sight – that EU and US tests are not identical. While EU law applies the object/effect dichotomy, i.e. focuses on two poles – a conduct might restrict competition by its object or by its effect – the US system seems to be more complex. Although there are two main categories here as well, per se illegality and rule of reason, however the rule of reason box has more "shades", or it may even be considered as a continuum, from truncated or "quick look" analysis to full rule of reason. These shades, or continuum of rule of reason are relevant from the point of view of the burden of proof, which has important relevance for the outcome of the case.

Identifying per se restrictions with by object restrictions, and "rule of reason" with by effect restrictions seem an excessive simplification. Identifying "quick look" with by object restrictions and full rule of reason with by effect restrictions is even more problematic therefore theoretically.

The strictest US category is per se illegality. Per se illegality differs from European by object restriction in an important feature: in Europe, even if an agreement infringes competition law by object, exemption under Article 101 (3), at least theoretically, is possible. If in the US a conduct is per se illegal, exemption is not possible, neither theoretically.

The concepts of per se illegality and rule of reason – especially its different levels, or shades – are subject to disputes even in the US. In the US, the trends show that per se restrictions are rarely applied in the recent days.[935]

So, by object restrictions are not the European alternatives of US per se illegality. First, in the US, an exemption considering the positive economic effects of the agreement is not possible if a per se restriction of competition is determined. On the other hand, in the EU, the by object restrictions – at least theoretically – might be exempted on the basis of Article 101(3) TFEU.

[935] Spencer Weber Waller: Justice Stevens and the Rule of Reason. SMU Law Review, 2009. Vol. 62. 693-724., Michael A. Carrier: The Rule of Reason: An Empirical Update for the 21st Century. Geo. Mason Law Review, 2009. Vol. 16:4. 827-834., Alison Jones: Analysis of agreements under U.S. and EC antitrust law–convergence or divergence? The Antitrust Bulletin. Vol 51. No. 4./Winter 2006. 691-811. 806.

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Second, the reach of the European by object concept is broader in the sense that in the US, hardcore vertical restrictions are not treated as per se illegal.[936] The strict approach taken by EU law towards vertical restraints originates from different goals pursued by EU competition rules – since the beginning, competition rules have served as main protector of the Common, later Internal Market.

Examining rule of reason from this point of view is more complicated, taken into account that even in the US, it is subject to disputes whether rule of reason is considered as a continuum, or as a dichotomy of quick look and full analysis, or it has different, but certainly more than two shades. Even if there are questions about whether the dichotomy is indeed a dichotomy in EU competition law,[937] for the purposes of this thesis it seems more reasonable to discuss it as such, for the sake of simplicity, and also with regard to the fact that the relevant judgment and opinion in Budapest Bank was delivered later, than the pay-for-delay judgments of the General Court.

It seems reasonable to consider rule of reason from the point of view of the burden of proof. The first category, the so-called full rule of reason passes the burden of proof totally on the plaintiff.[938]. On the other hand, the so-called "quick look," or truncated, rule of reason – which was advocated in Actavis by the FTC (the FTC is likely to differentiate between quick look and full rule of reason) – is a rebuttable presumption of unreasonableness unless the defendant comes with a pro-competitive justification.[939]

Additionally, the rule of reason has an in-between category for the cases where the restrictive consequences on competition are less obvious, but the total analysis of full rule of reason is not necessary. In this case, the analysis proceeds in several distinct steps. First, the FTC, focusing on the nature of the restraint and not its market effects, determines whether it is obvious from the nature of the challenged conduct that it will likely harm consumers, i.e., whether the restraint is 'inherently suspect'. 'If the restraint is not inherently suspect, then the traditional rule of reason, with attendant issues of market definition and power, must be employed.' Second,

[936] Alison Jones: Analysis of agreements under U.S. and EC antitrust law–convergence or divergence? The Antitrust Bulletin. Vol 51. No. 4./Winter 2006.761. Footnote. 299.

[937] Dömötörfy Borbála Tünde–Kiss Barnabás Sándor–Firniksz Judit: Látszólagos dichotómia? Versenykorlátozó cél és hatás vizsgálata az uniós versenyjogban, különös tekintettel a Budapest Bank ügyre. In: Verseny és Szabályozás, 2019. Available at: https://www.mtakti.hu/wp-content/uploads/2020/03/02_DomotorfyBT-KissBS-FirnikszJ.pdf Downloaded: 29th September 2020)

[938] Alison Jones: Analysis of agreements under U.S. and EC antitrust law–convergence or divergence? 702-705.

[939] Spencer Weber Waller: Justice Stevens and the Rule of Reason. SMU Law Review, 2009. Vol. 62. 701.

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where the restraint is inherently suspect, the defendant must come forward with a legally cognizable and plausible efficiency justification to avoid summary condemnation (e.g., that the agreement will reduce the costs of producing or marketing the product, create a new product, or improve the operation of the market). Third, if the defendant raises legally cognizable and plausible efficiency justifications, the FTC must show that the restraints are likely to harm competition (using an inquiry 'meet for the case').[940]

In the Actavis case, the Supreme Court supported this middleshaded test, not the full rule of reason.[941]

In Actavis, the Supreme Court ruled as follows, referring to Areeda:

"As a leading antitrust scholar has pointed out, "[t]here is always something of a sliding scale in appraising reasonableness," and as such "the quality of proof required should vary with the circumstances.'" […] As in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences. […] We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation. We reverse the judgment of the Eleventh Circuit. And we remand the case for further proceedings consistent with this opinion."[942]

From the above, it can be seen that rule of reason cannot be considered as a dichotomy. Especially, in Actavis, the Supreme Court followed the continuum theory, and expressis verbis stated that neither the quick look end of the scale, not the full rule of reason is applicable in pay-for-delay cases. The fact that the extent of the applicable standard is left by the Supreme Court for lower courts, might be criticised. However, it might have a reasonable explication: the extent required can differ case by case.

There are opinions stating that EU and US approaches are contradictory – while EU declared pay-for-delay settlements are by object anticompetitive, while the US rejected the quick look

[940] Alison Jones: Analysis of agreements under U.S. and EC antitrust law–convergence or divergence? The Antitrust Bulletin. Vol 51. No. 4./Winter 2006. 712.

[941] Herbert Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014 p. 23-27

[942] Actavis p. 21

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analysis, the "similar" US concept, while making a by effect equivalent applicable[943], however as it has been shown above, there is no total equivalence between the two systems.

The main question here is the burden of proof. As Jones explains:

"As the courts have moved away from widespread reliance on the traditional per se rule, they have also recognized the inherent uncertainties and difficulties involved in plenary rule of reason analysis. They have, therefore, looked for shortcuts to avoid, where feasible, the need for a full and costly plenary market examination. Where obvious restraints are incorporated within the agreement, anticompetitive effects may be actually identified or assumed (following a quick (or quickish) look), leaving the defendant to justify the agreement or to expect summary judgment against him. In other cases, an absence of anticompetitive effects may be assumed, and summary judgment for the defendant awarded, where the defendant lacks market power. Only where these situations do not arise, will the plaintiff be required to demonstrate actual anticompetitive effects or that such effects are likely. Presumptions and burden shifting are, therefore, relied upon in addition to full market analysis. The complex analysis involved in establishing the relevant market and the existence of market power means that, absent actual, obvious, or severe restraints, an extremely onerous burden is imposed upon the plaintiff. The courts have, therefore, moved away from a dichotomous approach (or even a 'trichotomous' one) to a situation in which the analysis is more flexible, and structured to take account of the circumstance, details, and logic of the case before it."[944] Jones – after analysing the two legal systems in details – even finds that the greatest similarity in approach in the two systems is with regard to agreements that are per se illegal in the US and those that have as their object the restriction of competition in the EU.

By comparing the EU and the US tests, two more characteristics should be taken into account.

In case of Actavis, the judgment of the US Supreme Court is analysed. The US Supreme Court does not only decide concrete cases but creates precedents for lower courts, as it was highlighted by Clancy and Geradin earlier.[945] However, when their article was published, only the

[943] James Killick: Patent settlements as by object restrictions: a European approach, but is it the right one? (Available at: https://awards.concurrences.com/IMG/pdf/patent_settlements_as_by_object_restrictions_-_2015.pdf Downloaded 19 December 2017) p. 16

[944] Alison Jones: Analysis of agreements under U.S. and EC antitrust law–convergence or divergence? The Antitrust Bulletin. Vol 51. No. 4./Winter 2006. p. 739.

[945] Michael Clancy – Damien Geradin – Andrew Lazerow: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law.

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Commission's decisions and the General Court's Lundbeck judgment were out, and the ECJ's approach was totally unknown in pay-for-delay cases. After the General Court's judgment in Servier, and the ECJ's judgments in Lundbeck and in Paroxetine, we are aware that the EU courts' approach does not differ so much from the Commission's point of view. Even though, while the Supreme Court provided precedent to the lower courts, the General Court highlighted that pay-for-delay settlements should be examined on a case-by-case basis – and the ECJ confirmed it in Lundbeck and reached the same conclusion in Paroxetine. For me, this does not really seem like a real guidance to the European courts and competition authorities in handling pay-for-delay cases. We also know that in Lundbeck and Servier complex antigeneric strategy existed, and the courts – and the Commission – took into account the intents, and the "smoking guns" found during the dawn raids. After detailed comparison of the US and EU cases, in my view, we can conclude that – at least the more recent US cases – are more subtle, the respective market conducts do not seem to correspond to the European counterparts.

There are also interesting views supposing that the Commission has only faced with so called "easy" cases until now, pretty straightforward restrictions, while the FTC litigated more complicated cases in the US.[946] After analysing several pre- and post-Actavis judgments[947], and also the European cases, these views can also have relevance. This views also seem to be confirmed by the Krka related part of the General Court's Servier judgment.

Other authors find very special similarities between Lundbeck and Actavis: "the approach followed in Actavis also takes into account the probabilistic patent rights theory, and the results achieved are not very different from those obtained in the EU context. In fact, in spite of the different regulatory context, the solution proposed by the GC in Lundbeck is consistent with the one followed by the Supreme Court: both considered that patent settlements with a high

[946] Fabrizio Esposito–Francesco Montanaro: A Fistful of Euros: EU Competition Policy and Reverse Payments in the Pharmaceutical Industry. European Competition Journal, Volume 10, Number 3, December 2014. 499-52.

[947] 332 F.3d 896, No. 10-2077, No. 10-2078, No. 10-20799, és No. 10-4571., 344 F3d. 1294, 350 F3d 1181 (11th Cir. 2003), 402 F.3d 1056., 466 F.3d 187, 544 F.3d 1323, 570 US 756 (2013), In re Lipitor Antitrust Litig., 12-cv-2389, Sept. 5, 2013. In re Effexor XR Antitrust Litig., 11-cv-5479, In re Nexium (Esomeprazole) Antitrust Litig.,12-md-2409 (D. Mass.), In re Lamictal Direct Purchaser Antitrust Litig., 12-cv-995 (D.N.J.), 14-1243 (3d Cir.), In re Modafinil Litigation, 06-cv-1797, 06-cv-1833, 06-cv-2768, 08-cv-2141 (E.D. Pa.), In re Wellbutrin XL Antitrust Litig., 08-cv-2431, 08-cv-2433 (E.D. Pa.), In re Androgel Antitrust Litig. (No. II), 09-cv-955 (N.D. Ga.), In re Loestrin 24 Antitrust Litig., 13-md-2472 (D.R.I.), In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 14-md-2503 (D. Mass), In re Cipro Cases I & II, S198616 (Cal.), In re Aggrenox Antitrust Litig., 14-md-2516 (D. Conn.), In re Adderall XR Antitrust Litig.,12-cv-3711 (S.D.N.Y.), 13-1232 (2d Cir.), In re Niaspan Antitrust Litig., 13-md-2460 (E.D. Pa.), In re Skelaxin (Metaxalone) Antitrust Litig., 12-md-2343 (E.D. Tenn.), In re Opana ER (Oxymorphone Hydrochloride) Antitrust Litig.,14-cv-2630 (N.D. Cal.), 14-cv-3185, 14-cv-3190 (E.D. Pa.)

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level of value transfer should be subject to antitrust scrutiny, setting aside the scope of the patent test, and both insisted on the uncertainties of this type of IP rights and the specificities of the pharmaceutical sector, calling into the equation the probabilistic patent rights theory.[948]

V.3. Lawful payment

Another important question in pay-for-delay cases is, what is the amount of payment which is still lawful? Neither in the EU, nor in the US are all (reverse) payments illegal.

Concerning Europe, in Lundbeck, the General Court confirmed that "a large reverse payment could be an indication that the originator undertaking had paid the generic undertakings to stay out of the market." It also confirmed that "whether the agreement can be justified […] depends, among other things, on the size of the payment: if "the payment only covers the costs that can be expected if the case is taken to court, then the agreement might fall out of the scope of Articles [101 TFEU] and [102 TFEU]". However, if the payment is more substantial it can be seen as a way of paying competitors to stay out of the market, which constitutes an infringement of Article 101 TFEU or 102 TFEU. In Lundbeck, the fact that the reverse payments "were substantial and corresponded roughly to the profits expected by the generic undertakings in the event of market entry, and not the cost of potential litigation which had been avoided", was a key factor in identifying the conduct as an infringement of Article 101(1) TFEU.[949]

In the same case, the General Court also highlighted that: "The size of a reverse payment may constitute an indicator of the strength or weakness of a patent". Interesting to note, the General Court at that point referred to the US Supreme Court stating that it "has also held that the presence of a significant reverse payment in a patent settlement agreement can provide a workable surrogate for the weakness of a patent". The General Court – as general rule – concluded: "the higher the originator undertaking estimates the chances of its patent being found invalid or not infringed, and the higher the damage to the originator undertaking resulting from successful generic entry, the more money it will be willing to pay the generic undertakings to avoid that risk". In Lundbeck, the Commission found that the disproportionate nature of the reverse payments, combined with several other factors —i.e. the fact that the amounts seemed to correspond at least to the profit anticipated by the generic in the case of market entry, the

[948] Sandra Marco Colino – Niamh Dunne – Knut Fournier – Sofia Oliveira Pais – Derek Ritczmann: The Lundbeck case and Potential Competition. Concurrences Review, No. 2-2017, June 2017. p. 9., see also Sofia Oliveira Pais: The Lundbeck Case through the Lens of Probabilistic Patents?

[949] GC Lundbeck judgment para 751.

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absence of provisions allowing the generic undertakings to launch their product on the market upon the expiry of the agreement without having to fear infringement actions brought by Lundbeck, or the presence of restrictions going beyond the scope of Lundbeck's patents in the agreements — led to the conclusion that the agreements at issue had as their object the restriction of competition, within the meaning of Article 101(1) TFEU.[950]

It is also known from the Commission's cases that payment for real services are acceptable:

In Servier, the Commission acknowledged that patent settlements may include other provisions or be related to other parallel transactions which deal with provision of services, transfer of assets, or behavioral constraints. In the case of such settlements, the assessment of the contractual limitations and of the inducement must take these into account: various parts of the settlement, including the inducement, should not be assessed in isolation, but as a part of the overall settlement balance. In such cases, the payment can be considered as a "necessity inherent in the agreement" – as conditio sine qua non for the conclusion of the investigated settlements". However, in the decision, the Commission left the question unanswered, what is, and how is decided, whether the value of a service is considered proportionate.[951]

In European case law, certain examples were found obviously disproportionate. In Lundbeck, the Commission did not accept that the value transfer provided by Lundbeck to Merck (GUK) was the price of services provided by Merck (GUK) to Lundbeck. Pursuant to the Commission decision, "the level of guaranteed profits Lundbeck paid to Merck (GUK) under the exclusive distribution agreement was based not on any value to Lundbeck of Merck (GUK)'s distribution services but rather on the value to Lundbeck of Merck (GUK) not selling Natco citalopram"[952]

An even more illustrative example of unlawful payments is presented by the Fentanyl case, where the Commission took into account that "services to be provided by Hexal B.V./Sandoz B.V. were described only very briefly and in a very general manner"[953] and "[neithet t]he description of the services to be provided [n]or the elements for calculation of the amount to be paid for those services were therefore not defined in the final version of the Co-promotion

[950] GC Lundbeck judgment para 353-354.

[951] Servier para 1185.

[952] Lundbeck para 793.

[953] Fentanyl para 148.

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agreement".[954] Furthermore, the Commission noted, that "Janssen-Cilag paid approximately EUR 1.3 million to Hexal B.V./Sandoz B.V. and there is no evidence of any promotion services being provided in return in that period at all", so the Commission concluded that "such payments were computed in a way to remunerate Hexal B.V./Sandoz B.V. for staying out of the market rather than for any co-promotion services. "[955] The Commission in that case did not accept that the service provided by Hexal B.V/Sandoz B.V was worth to the price paid by Janssen-Cilag.[956]

In Servier, the judgment of the Genral Court urged to clarify certain aspects of side-deals. Pursuant to the judgment "a side deal is a normal commercial agreement linked to a settlement agreement which contains clauses which are by themselves restrictive […]. Such a link exists, in particular, where the two agreements are concluded on the same day, where they are legally linked, the binding nature of one of the agreements being conditional upon the conclusion of the other agreement, or where, in the light of the context in which they are concluded, the Commission is able to establish that they are indissociable. […] [T]he shorter the time between the conclusion of each agreement, the easier it will be for the Commission to establish that indissociable nature."[957]

The fact that the settlement agreement and the side deal were „concluded on the same day or that there is a contractual link between them" is therefore seen as an indication that those agreements form part of a single contractual framework. If this is not the case, but one of the parties would grant the other party everything it wants „without any certainty of ultimately obtaining the expected quid pro quo" is also seen as an indication „that they were negotiated together" by the General Court.[958]

The General Court highlights however that „side deal is a normal commercial agreement that could exist independently without the settlement of a dispute being at issue. The conclusion of a settlement agreement does not require the concurrent conclusion of a commercial agreement. „Thus, the two agreements do not need to be linked. Moreover, that linkage cannot be justified

[954] Idem. para 151, see also para 264.

[955] Idem. 310 and 316.

[956] Idem. para 267.

[957] T-691/14 Servier para 798

[958] T-691/14 Servier para 799

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by the settlement of a dispute, because the purpose of the side deal is not to reach such a settlement but rather to carry out a commercial transaction." [959]
If however the side-deal involves value transfers, of a financial or non-financial nature, from the patent holder to the generic , there is a risk that the linking of a commercial agreement with a settlement agreement containing non-marketing and non-challenge clauses, „which are, by themselves, restrictive of is actually intended — under the guise of a commercial transaction, taking the form, as the case may be, of a complex contractual arrangement — to induce the generic company to accept those clauses, through a value transfer provided for in the side deal."[960]

The General Court concluded that the „fact that a commercial agreement, which does not normally have the settlement of a dispute as its subject matter […], and which serves as a vehicle for a transfer of value from the originator company to the generic company, is, […] linked with a settlement agreement containing competition-restricting clauses is a strong indication of the existence of a reverse payment."

However, even such a „strong indication" is not considered sufficient by the General Court and „the Commission must therefore support it with other consistent evidence justifying the conclusion that there is a reverse payment. Such a payment, in the specific context of side deals, corresponds to the part of the payment made by the originator company which exceeds the 'normal' value of the asset traded (or, as the case may be, to the part of the 'normal' value of the asset traded which exceeds the payment made by the generic company)."[961]

Buttgieg and Piffault, analysing Servier, conclude that in order to identify by object restraint, the "Commission must show that the payments are, unquestionably, incentives for generic companies to stop competing; it must examine the nature of the payment, its justification and whether the payment covered costs that were 'inherent' to patent settlements, such as litigation costs. Payments that are inherent to the patent settlements can only constitute an 'incentive' if the Commission can show that they are excessive and disproportionate to the cost. Usefully, the Court gives various examples of cost that it deems not to be inherent to the settlement, being too removed from the litigation, such as the production and R&D cost of the counterfeit goods

[959] Idem. para 800

[960] Idem. para 802

[961] T-691/14 Servier para 803

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or the money that the generic company has to pay third parties for terminating supply agreements. Payment to cover such costs would be deemed an 'incentive' unless the parties can show that these costs are inherent to the dispute and its settlement and can justify the amount. They could also show that though the costs are not inherent to the settlement, the portion of costs reimbursed is too insignificant to constitute an incentive. […] In order to determine whether an agreement is restrictive by object, an individual and concrete examination must be carried out of the content of its provisions, its objectives, and the economic and legal context of which it forms a part."[962]

In my view, based on the above, it seems that in Europe, payment for real services, which is proportionate, not exceeding the litigation costs, and not corresponding to the value expected by the generic from market entry might be lawful, however, all circumstances should be taken into account, therefore, cases are subject to a case-by-case analysis. On the other hand, the exact meaning and assessment methods to be applied to assess the above circumstances is unclear, which is not a desirable situation from the point of view of legal certainty. This approach seems to be confirmed also by the General Court's judgment in Servier, as well.

In the US, the Supreme Court in Actavis reached a quite similar conclusion, providing little guidance for the district courts. According to the Supreme Court, district courts should look at the size of the payment: "its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[963] In that respect, the Supreme Court explained: "There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."[964]

In Actavis, the Supreme Court also indicated that the reasonableness of a particular settlement may be assessed "without litigating the validity of the patent," as a "large, unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court

[962] Eugene Buttigieg – Henri Piffault: The EU General Court's Servier judgment. ournal of Antitrust Enforcement, Volume 7, Issue 2, July 2019, Pages 279–302, https://doi.org/10.1093/jaenfo/jnz015. p 286. (Downloaded 23 November 2020)

[963] Actavis p. 20.

[964] Idem. p. 17.

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to conduct a detailed exploration of the patent's validity."[965] Geradin at all. conclude that the existence of an "unexplained large reverse payment" could suggest an anticompetitive motive.[966] Fialkoff highlights that "the [Supreme] Court in Actavis suggested that the FTC could satisfy this burden by focusing on the reverse payment amount, rather than the underlying patent validity."[967] Fialkoff also highlights another important issue: in Actavis, the majority rejected the suggestion that any patent settlement in which the alleged infringer settles for less than the full amount requested by the patent holder involves an implicit reverse payment: the party with a claim for damages may agree to settle its case for less than the full amount of damages requested. On the other hand, the majority distinguished pay-for-delay arrangements on the ground that in a typical pay-for-delay arrangement, a party with no claim for damages (the generic manufacturer) receives money to drop its patent challenge.[968]

It can be therefore seen that with regard to the amount of the payment, there are certain similarities between the US and EU approaches. On the other hand, both the US Supreme Court, and the European Commission and the General Court can be – and also have been – criticized for not providing enough guidance for companies how to draft settlements safely and legally, and when is a payment large and unjustified, or, when does it make the settlement subject to antitrust scrutiny. It is obvious from Lundbeck and Servier that paying an amount which corresponds to the earnings expected by the generic from market entry is not acceptable. An excellent eample would be if internal documents proved that the originator took into account the profit expected by the generic from market entry.

Both EU and US cases help us conclude that an amount equivalent to the litigation costs, and the value of real services is likely to be legal. Actavis shows that the originator can accept smaller amount than that first claimed in the framework of a settlement, which is welcome taken into consideration that settlements are generally based on a compromise. The current state of affairs, however, raises more questions than provides answers, only provides high-level guidance, which creates unsecure situation for practice.

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[965] Idem. p. 19.

[966] Michael Clancy – Damien Geradin – Andrew Lazerow: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law. p. 8 (Available at: http://awa2015.concurrences.com/IMG/pdf/rever.pdf Downloaded: 30 November 2018)

[967] Michael L. Fialkoff: Pay-For-Delay Settlements in the Wake of Actavis. Michigan Telecommunications and Technology Law Review, Volume 20, Issue 2. Pp. 523-546. P. 537-538.

[968] Idem. p. 535. See also Actavis p. 13.

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VI. Conclusion

At the beginning of my thesis, I posed four research questions: (i) To what extent are pay-for-delay settlements the consequences of the regulatory background? (ii) What is the role of competition law? (iii) Is there room for two different standards for pay for delay agreements? (iv) Under what conditions are pay for delay agreements lawful?

In order to address these questions, first the market structure of the pharmaceutical industry its different types of market players, and the relationships between those players were introduced. The role of this introductory part was to emphasize the complexity of the market, the diversity of the market players on that market, and to highlight the very complex nature of the potential and typical business transactions. Although this section is integrated into the chapter discussing the regulatory background, it rather serves as a basis of the whole thesis, since a deep understanding of the market is not only necessary to discuss the role played by regulations in pay-for-delay settlements, but also to discuss the further questions discussed later.

After that the three regulatory fields affecting pay-for-delay agreements were introduced: sectoral regulation, patent rules, and competition law, each of them play an important role in shaping the regulatory background in which reverse payment settlements take place both in the US and in the EU. In that respect, the pricing and reimbursement system was considered as part of the regulatory background, and procedural rules relating to patent litigation as part of the patent system. Being aware that other areas are also important and relevant in regulating how new drugs are researched, authorized, marketed, etc. (e.g. fundamental rights, distribution laws, criminal rules relating to counterfeighting, etc.) it should be highlighted that the three fields introduced in the thesis refer to pay-for-delay settlements only. Both in the EU and in the US, and even in certain national cases sectoral regulation, IP and competition law were identified as playing a role in shaping the field in the background of pay-for-delay settlements.

The introductory part plays also an important role in addressing the question why pay-for-delay settlements only occur – and raise competition law concerns – in the pharmaceutical sector. Most scholars agree that such patent settlements only occur in the pharmaceutical sector, although others – including the dissenting judges of Actavis[969] – refer to relevant cases in another sectors. Since these judgements indeed dealt with trademarks, or copyrights, as As

[969] 570 U.S. 2013. Actavis dissent p. 10.

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Hovenkamp and Hemphill[970] highlight, the fact that reverse payment settlements are special features of patent settlements in the pharma industry seems not to be questioned, so the pharma related specificities of the relevant patent systems should be discussed.

The relevant regulations differ in large extent in the examined jurisdictions, in the EU and in the US, even though reverse payment patent settlements are present in both, which fact raises two questions: whether EU and US settlement are similar, and what serves as their background.

As far as the regulatory background is concerned, different factors were identified with a potential to encourage companies to participate in pay-for-delay settlements, on both sides of the Atlantic. Due to these differences, the features of settlements differ in these two jurisdictions. While I found that an Act embedded in the sector specific regulation, the Hatch-Waxman Act is mainly behind reverse payment agreements in the US, in the EU, it seems to be the fragmented patent and patent litigation system – taking also into regard certain shortcomings of the sector specific regulations – which might be identified as at least facilitator of pay-for-delay settlements. The patent system does not relate only to pharmaceuticals, it does not create such a unique regulatory environment, like Hatch-Waxman Act does in the US. Nevertheless, pay-for-delay settlements are industry specific features also in the EU. The cumulated effects of the sector specific regulation, the special characteristics of the pharma industry, and the patent system may be the cause of this.

Although these backgrounds seem totally different, their effect – and consequently their role in settlements -seem to be quite similar in creating uncertainties and asymmetric risks in patent litigation.

It is not disputed that reverse payment settlements are – at least partially – the consequences of the shortcomings of the regulation – both in the EU and in the US. However, this fact does not mean that they would be out of the scope of competition/antitrust law. The General Court kept this view in Lundbeck and in Servier, and the ECJ did so in Paroxetine and. On the basis of AstraZeneca and the pay-for-delay cases, it can be concluded that the Commission – supported by the European courts – is of the view that competition law should not refrain from correcting the discrepancies of other regulations. Although from a competition and consumer welfare point

[970] Herbert Hovencamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 14.

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of view this attitude can be justified, it would be more favourable to correct the discrepancies of certain regulations by amending those regulations, not (only) by applying competition law.

In Europe, the introduction of the Unitary Patent and the Unified Patent Court system might have important results in the future, although the start date has been permanently postponed now for years. Obviously, the EU has been facing unprecedented challenges recently, taking into consideration the two largest ones, the Brexit and the COVID 19 crisis, it seems understandable that there are other priorities. Until then, competition law plays its role in correcting discrepancies, as it is presented by the discussed cases and AstraZeneca. On the other hand, the existence of certain "hardcore" cases discussed in the third part underline the need for a competition law intervention, whatever the result of a regulatory reform will be.

Therefore, after the discussion of the market under examination, the nature of originator-generic competition, the relevant regulations and the economic background behind them, it seems like – while the role played by the regulatory background in pay-for-delay settlements cannot be questioned – the market failure element of the problematic settlements cannot be eliminated only by amending regulations (i.e. even under the current patent rules paying a competitor out the market and eliminating patent challenges by doing so was not in the scope of the patent according to the relevant judgment and by the state-of-the art literature). Therefore, competition law has, and most probably even in the future will have its role to play in correcting discrepancies of sectoral and patent rules.

After the regulatory part, the thesis discusses in different chapters the main US and European cases. These discussions are necessary to address the further research questions, since without solid knowledge of these cases and the factual background of the disputes the applicable legal standard cannot be decided, and the drops of information relating to the lawful level – and type – of payment is also embedded in the relevant judgments.

It is important to note that this thesis is not a comparative research, its aim was not to compare the US and EU systems completely, rather to introduce some of the relevant similarities and differences. The thesis focuses on European law, and on European patent settlements, the discussion of the US parts rather refers to the need for an example. Since the US had long-term experiences in handling reverse payment patent settlements when the EU started to scrutinize them, knowledge of the US cases was unavoidable for the European enforcers, lawyers and scholars, as it is presented by the fact that the EU cases always contain references to the US cases and state-of-the-art literature.

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Therefore, the role of discussion of the US rules, cases and literature was to introduce it in the necessary depth to find important conclusions for the EU. Although certain parts of the thesis compare EU and US approaches, this fact does not make the thesis a comparative research. The EU law focused nature of the thesis also explains why the European cases are discussed in more details, although it is not the only cause: the published European judgments and administrative decisions simply let us know more details of the cases compared to the US ones.

The US part of the thesis discusses certain important cases, especially the cases preceding Actavis and the Supreme Court's Actavis judgment. Since the US has a large amount of pay-for-delay cases, providing a taxative list of the cases is not goal of this thesis, only the most relevant ones playing a role in shaping the applicable US legal standards are discussed, and the selection is by nature subjective. The cases discussed in this part are divided into three groups representing the timeline and also evolution of the US evaluation standard: i) stricter approaches; ii) scope of the patent test; iii) rule of reason. The most prominent example of the latest is of course, Actavis. The detailed discussion of Actavis – and of the dissenting judges opinion – also builds on the preceding cases, and the discussion of them is also necessary to understand certain references in the EU cases (e.g. both Lundbeck and Servier judgments contain references to the scope of the patent test). Certain post-Actavis cases are also introduced shortly. The purpose of this is to highlight that important questions are still unanswered, and to introduce the nuances of rule of reason and the sophisticated nature of value transfers. Therefore, it has a relevance for the third and fourth research questions, as well.

Since the focus of the thesis is the evaluation of European jurisprudence, the detailed discussion of the EU cases is necessary. The background which led to these cases – including the Pharmaceutical Sector Inquiry and its main conclusions towards originator-generic settlements – needs to be presented first. After discussing the main pay-for-delay cases, the time has come to address the question whether pay-for-delay agreements should be categorized as by object restrictions. As the main European cases, Lundbeck and Servier pointed out, the assessment of potential competition is relevant here. The European courts found that if the generics are considered as potential competitors of the originators, concluding a reverse payment agreement would raise antitrust issues. The originators' willingness to pay a large amount can be assessed as indicator of potential competition, how the General Court found in Lundbeck and Servier, and the US Supreme Court in Actavis. The General Court interpretation in Lundbeck – confirmed by Servier – of what constitutes potential competition can be criticized as contradictory, and not providing sufficient guidance to companies for self-assessment.

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Competition law and IP law advocates certainly will be on different opinions. Yet, one thing is sure: courts and authorities should take into account the specialities of the pharmaceutical sector in order to ensure that the "antitrust doctrine [will be] supple enough, and its commitment to economic rationality strong enough" [971] to handle the challenges posed by pay-for-delay agreements. However, this requirement seems to be fulfilled by the fact that competition law analysis always have to take into account the economic and legal context behind the examined agreements.

In Lundbeck –later confirmed by the ECJ and also followed in Servier – the General Court found that the market conduct at issue was harmful enough to meet the Cartes Bancaires test, the examined market conduct caused a harm reaching the sufficient degree to European consumers and healthcare systems, to identify the conduct as by object restraint. In Fentanyl, where no patent dispute was involved, the infringement was assessed as a pure market sharing agreement. In Lundbeck, Servier, and the other discussed European cases the main difference compared to Fentanyl is the existence of (boundle of) patents, i.e. while roughly the same type of conduct takes place, it seems to be covered by a patent for the first sight. If the incumbent provides value transfer to a competitor to stay out of the market, it is market sharing. If, however the incumbent is a patent holder, who provides incentive to a generic company, the question is more complex, even though the European courts pointed out now several times that paying a (potential) competitor to stay out of the market – in which market the patent holder anyway has a patent protected position – has never been a patent protected right. The ancillary restraint theory discussed by Nagy addresses this problem in an clear and probably more understandable way: If market sharing is an effect of settling a real patent dispute between the parties, i.e. market partition is an ancillary consequence of an otherwise legitimate settlement, the agreement is not considered as by object restraint.[972] Paying the potential competitor out the market eliminates the incentives to challenge weak patents, which is not beneficial for public welfare. If we examine this by keeping in mind that patents are exclusive rights provided to the inventor in return for delivering something new and valuable to the public, and their role is to ensure a fair return for an investment which provides something valuable to the public, it makes

[971] R. A. Posner: Antitrust in the new economy. John M. Olin Program in Law and Economics Working Paper No. 106, 2000. Available at: https://chicagounbound.uchicago.edu/law_and_economics/58/ Downloaded: 27 November 2018) p. 2.

[972] Nagy Csongor István: A kartelljog dogmatikai rendszere. p. 191

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sense that eliminating weak patents is important, not only for social welfare but also to enhance other players possibilities and incentives to innovate.

However, especially in the pharma sector – due to the authorization system and sectoral regulations – it cannot be doubted that originator companies often cannot use a sufficient part of the patent protection to recover their investments due to the long gap between the granting of the patent and of obtaining the marketing authorization. Partially as a consequence, evergreening strategies are common. Partially, because it is highly questionable that e.g. starting the patent protection time only from the date the originator started to sell the drug would make an end to evergreening strategies. Nevertheless, such strategies are not illegal – but competition rules should be respected.

The same is true in the case of reverse payment settlements, which are not generally considered as infringement on competition law, especially not are identified automatically as a by object restraint. The cases raising competition scrutiny are subject to a case-by-case analysis, as it might be concluded after Lundbeck and Servier. Although some guidelines are provided to assess cases similar to the already examined ones, pay-for-delay settlements surely stay a challenging area both for enforcers and compliance experts. At the end of the day, it can be concluded that both the US and EU judgments can be criticized for not providing sufficient guidance for companies to draft lawful settlements, and especially for not elaborating what is the lawful amount of a payment. However, due to the diversity and nuances of the settlements, and the evolving nature of the industry – and of the business practices – it is probably impossible.

In order to properly understand the different approaches in the US and in the EU, and to answer the third research question, I compared the similar legal concepts of per se illegality/rule of reason and by object/effect infringements. This is of great relevance as to the standard of proof rules. With regard to Actavis, it was found that the Supreme Court accepted the continuum theory, and did not suggest either a quick look, or a full rule of reason approach to assess pay-for-delay settlements, but something in-between. It was discussed that per se illegality and rule of reason are not considered as a dichotomy, but rather as a sliding scale. Actavis is somewhere in-between its endpoints.

The European pay-for-delay cases were discussed keeping in mind the main developments of the evolution of object/effect dichotomy. Although while discussing Budapest Bank case, and especially the Opinion of Advocate General Bobek in that case, I questioned the strictly dichotomic nature of the European concepts, for the sake of clarity – and keeping in mind the

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disputable nature of my suggestion – I returned to the dichotomy for the sake of discussion of the European cases. In my view, whatever the nature of the European evaluation system, dichotomy or continuum, is less relevant for cases such straitforward as Lundbeck and Servier. I pointed out, that compared to the US, the European Commission – and in Paroxetine, the CMA – faced with more hardcore cases. In my view, this fact influences the judgments, and might somewhat explain the continuous emphasis on the necessity of case-by-case analysis by the European Courts.

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