

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 sectors². 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.

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

(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)

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 discuss the main research questions, and finally the conclusion summarizes the findings.

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 Constitution⁴. 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.

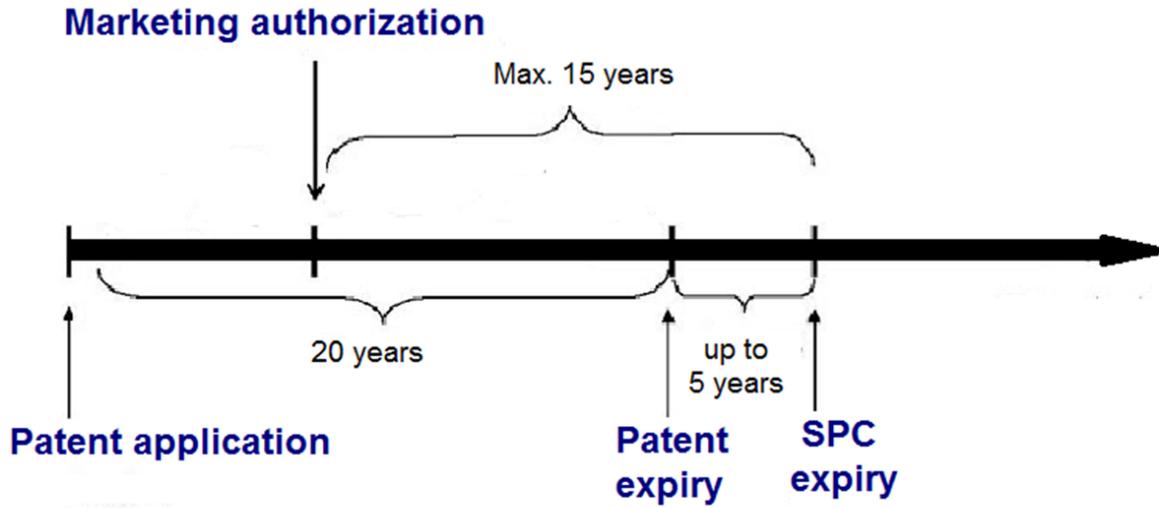
The pharmaceutical sector is traditionally subject to strict and rigorous regulation.

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)

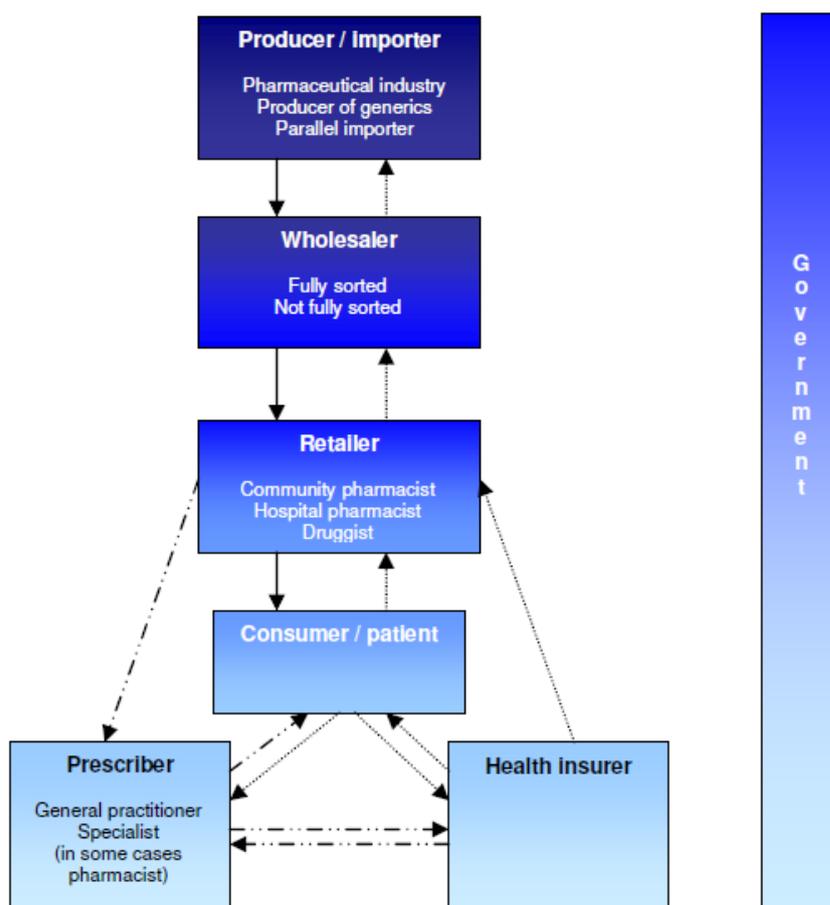


⁶ Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

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



Source: Philipsen (2003).

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 world⁹, in the EU it is not only permitted

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.

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.

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 DAFPE/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.

	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 (*)	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.

(*) 2010.

Source: Eurostat (online data code: hlth_sha_hc)

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. Mataves: 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.

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 USD²⁵, 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

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.

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.

The pharmaceutical sector is subject to strict regulation both in the EU and in the US³⁵, 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 system³⁹ 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 français. *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

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)

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 study⁴⁶ 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)

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	

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

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 framework⁵⁴ we can conclude that the European system offers three main routes for the authorisation of medicinal products:

Centralised procedure⁵⁵ (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/Commission. 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

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

Most stakeholders welcomed the current regulatory framework on marketing authorisations, stating that it provides a fair balance of interests⁶⁵, 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 framework⁶⁷. 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

⁷³ Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal 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

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)

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

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 patents⁹³ 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).

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.

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 discussed 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 authorizations 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)

behind patent settlements, the thesis only examines the relevant rules and their potential 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 Community¹⁰³, 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))

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 "challenger-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)

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, any court 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

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 361 31.12.2012, 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)

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 States 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.

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 officers, 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.)

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

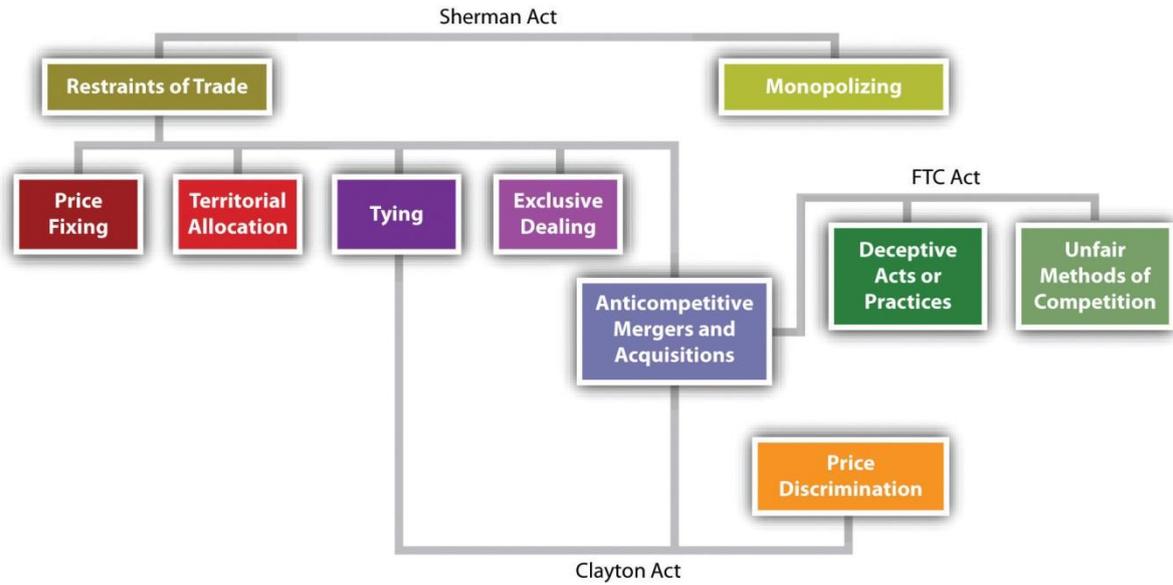
¹³³ Massimo Motta: Competition Policy – Theory and Practice, Cambridge University Press, 2004, Cambridge, p. 1.

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.



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.

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 17¹⁴⁰ 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 Union¹⁴¹ (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 States¹⁴³, 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 Warloutzet: 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.)

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

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: consumer¹⁴⁹ - 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

Ezrachi¹⁵³ 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 competition laws, but also the less controversial. Ezrachi presents the not clearly outlined, somewhat overlapping, somewhat controversial goals of competition laws as follows:

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*, Cambridge 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 mozgásterét 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.



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)

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 prohibition¹⁵⁸. 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)

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](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 case¹⁶³, 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 Jersey 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

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 Management. (Ed: L. G. Bryer – S. C. Lebson – M. D. Asbell) John Wiley & Sons, Inc., Hoboken, New Jersey. 2011. p. 2

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

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. Cambridge 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

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)

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 Magil¹⁸³, IMS Health¹⁸⁴ and Microsoft¹⁸⁵ 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.

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.

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 Management. (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.

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.

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 un rebuttable 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.

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.

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 industries²¹⁰ 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 Fentanyl²¹² 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 Hovenkamp: 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 Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision. Minn. J. L. Sci & Tech. Vol. 15:1 2014. p. 14.

²¹¹ Herbert Hovenkamp: 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

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

²¹⁵ *Idem.* p. 419 (1225)

²¹⁶ *Idem.* (1228)

²¹⁷ *Idem.* pp. 422-423.

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.

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.

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.

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

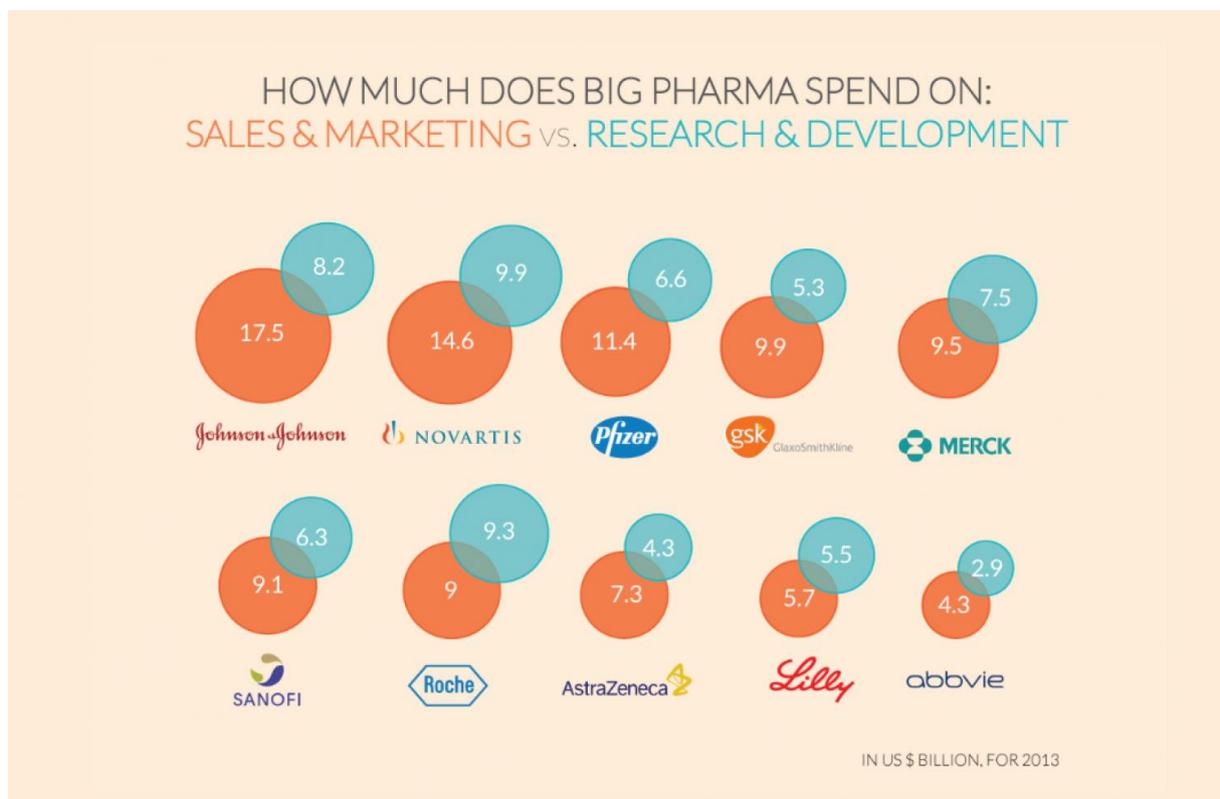
²²⁹ Xiang Yu – Anjan Chatterji: Why Brand Pharmaceutical Companies -choose to Pay Generics in Settling Patent Disputes: A systematic Evaluation of Asymmetric Risks in Litigation. *Northwestern Journal of Technology and Intellectual Property*. Volume 10, Number 2. (November 2011) p. 19.

²³⁰ *Idem.* p. 20.

²³¹ *Idem.* p. 32.

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

²³²Xiang 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)

²³⁵Xiang 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.

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 low 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."

William 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.

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

II.8. Pros and cons of patent settlements

In 2009, the OECD organized a Roundtable Proceeding²⁵¹ 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.

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

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.

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.

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.

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 low 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.

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.

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 occurred 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 Invalidation 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 Invalidation Signals. p. 307.

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

²⁸⁶ <https://www.wsg.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.

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.

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.

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

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 Study January 2010: Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. p. 3.

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 Study January 2010: Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. p. 4.

³⁰⁸ Idem. p. 4.

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

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 Study January 2010: Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. P. 1.

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

The FTC Staff Study also highlights, that later, in 2005, a number of appellate court decisions³¹⁶ 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 reverse 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 Study January 2010: Pay-for-Delay: How Drug 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.

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.

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 case³²⁶ 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 hydrochloride, 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.

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

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.

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.

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

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 drug 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 Hydrochloride

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.

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.

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 un rebuttable 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)

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.

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.*

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.

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 example³⁸⁵, 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.

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.

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 litigation³⁹⁷, 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.

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.

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.

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 Curiae in support of plaintiffs-appellants. (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.

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 Actavis⁴¹³ 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.

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.

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.

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.

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.)

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.

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

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

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.

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-Actavis 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. In 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.

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.

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 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.)

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.wsg.com/publications/PDFSearch/law360-1015-3.pdf> Downloaded: 25 October 2018)

⁴⁷⁶ In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 14-md-2503 (D. Mass)

anticompetitive 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*.

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.

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

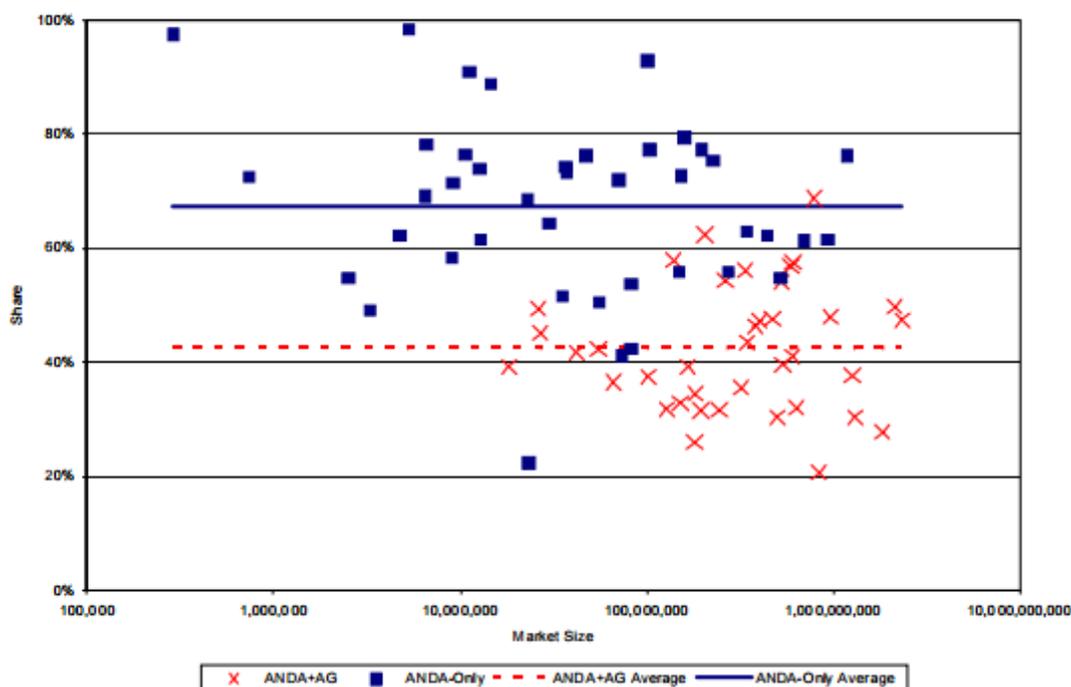
⁴⁸⁵ A. P. Reeves: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis p. 9.

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.

Figure 3-5: Revenue Share of ANDA Generic in Month Four of Exclusivity

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.

On the other hand, launching an authorized generic – the originator's 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 brand's 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 generic's 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 et al. 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. (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: 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*.

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.

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 presented 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

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.

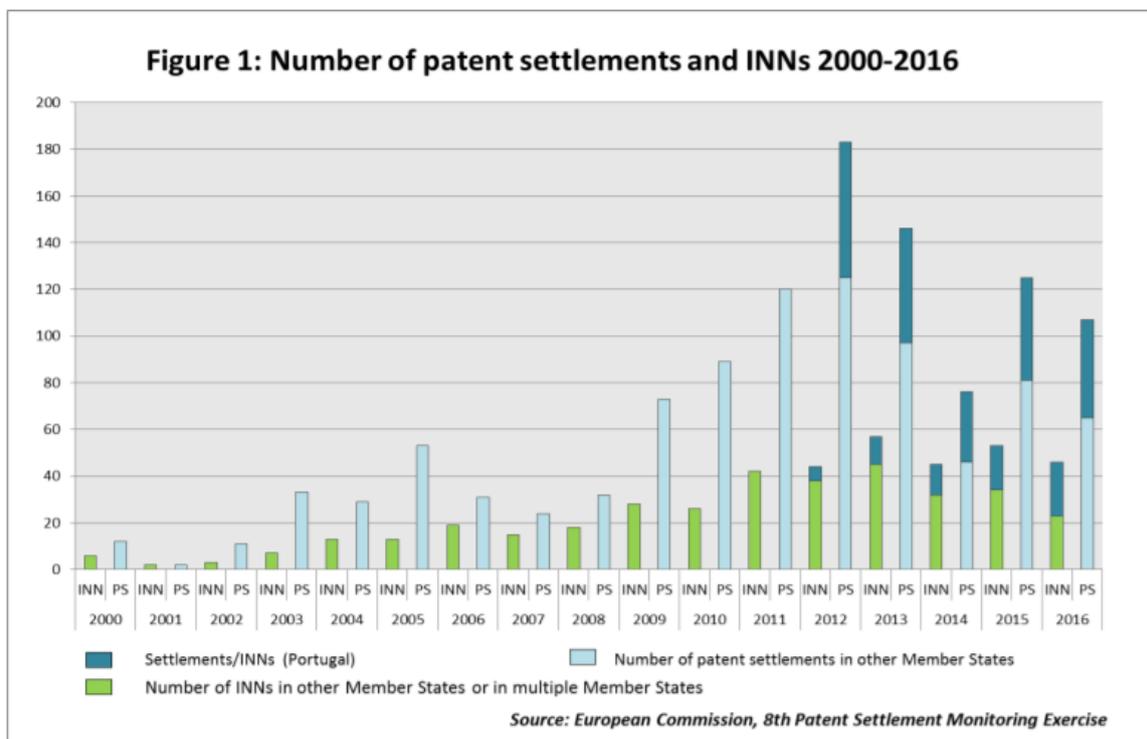
⁵⁰⁷ Final Report – Pharmaceutical Sector Inquiry.

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.



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)

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)

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)

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)

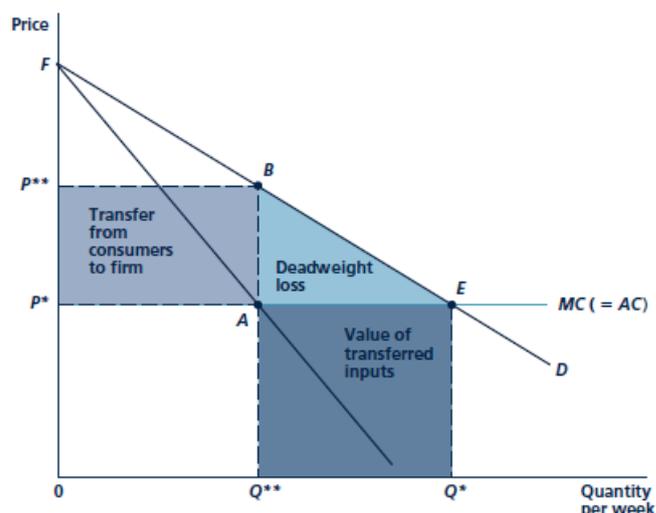
⁵²⁸ *Idem.* p. 278 (767)

⁵²⁹ *Idem.* p. 279 (767)

⁵³⁰ *Idem.* p. 283 (776)

⁵³¹ Lundbeck, para 640, Servier

⁵³² Lundbeck, para 640



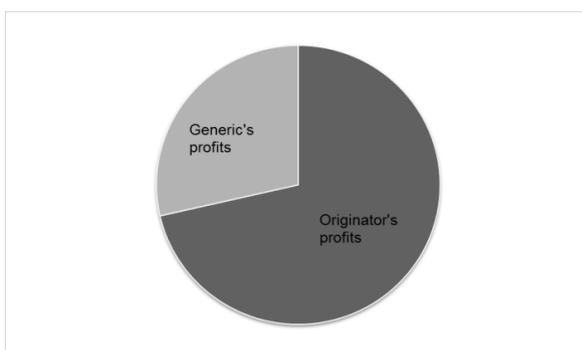
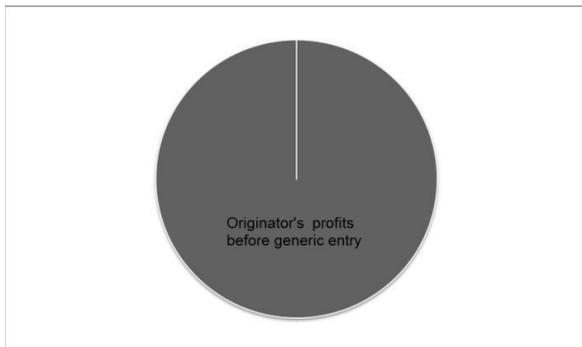
Source: Walter Nicholson – Christopher Synder: *Intermediate Microeconomics and Its Application*. Eleventh edition. p. 383

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.



⁵³⁵ Servier para 1152., Lundbeck para 646.

⁵³⁶ Servier para 1152., Lundbeck para 646.

⁵³⁷ Servier para 1152., Lundbeck para 646.

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, CMA⁵⁴² 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).

⁵⁴³ Case AT.39226 – Lundbeck

⁵⁴⁴ Lundbeck para 1

⁵⁴⁵ Idem. para 2

⁵⁴⁶ Idem. para 3

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

⁵⁵⁶ Idem. para 123

⁵⁵⁷ Idem. para 124

⁵⁵⁸ Idem. para 125-126

⁵⁵⁹ Idem. para 127

⁵⁶⁰ Idem. para 174

⁵⁶¹ Idem. para 176

⁵⁶² Idem. para 178

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

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

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 Servier⁵⁸¹ 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

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.

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

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 in the 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.

⁵⁸⁸ Fentanyl para 1

⁵⁸⁹ Idem. para 2

⁵⁹⁰ Idem. para 43-48.

⁵⁹¹ Idem. para 53

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

⁶⁰¹ Idem. para 85

⁶⁰² Idem. para 88

⁶⁰³ Idem. para 110

⁶⁰⁴ Idem. para 112

⁶⁰⁵ Idem. para 117

⁶⁰⁶ Idem. para 127

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

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

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 agreement⁶²²

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=exwa7ZDY_LckmBhc p. 1.

⁶²⁶ SPEECH-13-1053_EN Joaquín Almunia: Fentanyl case

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

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

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

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 EPO⁶³⁸. 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

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

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

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)

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.

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)

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 from 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 efforts 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

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.offt.gov.uk/news-and-updates/press/2013/36-13> Downloaded: 30 November 2018)

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 2004⁶⁷⁴ 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 Alparma 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.

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

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. *Groupeement des Cartes Bancaires c. Commission*, EU:C:2014:2204

⁶⁸² *Idem*. p. 247 para 6.12

⁶⁸³ *Idem*. p. 247 para 6.13.

⁶⁸⁴ Idem. p. 247 para 6.15.

⁶⁸⁵ Idem. p. 247 para 6.16.

⁶⁸⁶ Idem. p. 247 para 6.17.

the object of the GUK and Alparma Agreements, and the effect of the GUK and Alparma 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)

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.

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.

⁶⁹⁵ Idem. para 641-642.

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.

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 General 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

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

⁷⁰⁵ Case C-56/65. Soci t  Technique Mini re (L.T.M.) k. Maschinenbau Ulm GmbH, EU:C:1966:38, 249.

⁷⁰⁶ Ib n ez 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 Ib n ez-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: D m t rfy Borb la T nde–Kiss Barnab s S ndor–Firnicsz Judit: L tsz lagos dichot mia? Versenykorl toz  c l  s hatás vizsgálata az uni s versenyjogban, k l n s tekintettel a Budapest Bank  gyre. In: *Verseny  s Szab lyoz s*, 2019. Available at: https://www.mtakti.hu/wp-content/uploads/2020/03/02_DomotorfyBT-KissBS-FirnicszJ.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.

- horizontal price fixing⁷¹⁰,
- market sharing⁷¹¹,
- export restrictions between member states⁷¹²,
- agreements to reduce production capacity⁷¹³,
- horizontal information sharing⁷¹⁴,
- vertical price fixing⁷¹⁵
- 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-case⁷¹⁷, 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

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

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 case⁷²⁵ 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 naked⁷²⁷ 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

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. (Suftrin-Jones, p. 211, footnote 113.

⁷²⁸ C-67/13 P Cartes Bancaires para 3

⁷²⁹ C *Idem.* para 8

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

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

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

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 restraints⁷⁴⁶ 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.

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

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 - Firmiksz 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.

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.

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 analysis. 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.

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

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

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)

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

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

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

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

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 Lundbeck 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

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

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

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

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 itself⁸²⁰ 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.

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)

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)

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

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 blurs 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 Ritzmann: *The Lundbeck case and Potential Competition*. *Concurrences Review*, No. 2-2017, June 2017. p. 19.

⁸³¹ Case C-591/16 P Lundbeck v Commission, Opinion of Advocate General Kokott. ECLI:EU:C:2020:428. para 36

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 to 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

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 *Gydasági 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.”

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

⁸⁴² Case T-691/14 Servier and others v European Commission. ECLI:EU:T:2018:922 para 391, para 406, para 418

⁸⁴³ T-691/14 Servier para 416

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 Commission, and it has to prove that such a reverse payment has an inductive nature, and therefore, is anticompetitive. As a typical example of costs inherent to the settlement, the General Court refers to litigation costs⁸⁴⁵. 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 types of costs of the agreements at issue, the General Court found that value transfers in the Niche, Matrix, Teva and Lupin agreements had an inductive 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

⁸⁴⁸ Idem. para 318-320

⁸⁴⁹ Idem. para 321

⁸⁵⁰ Idem. para 347

⁸⁵¹ Idem. para 360

⁸⁵² Idem. para 368

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

⁸⁵⁶ Idem. para 798

⁸⁵⁷ Idem. para 803

⁸⁵⁸ Idem. para 943

⁸⁵⁹ Idem. para 946-947

⁸⁶⁰ Idem. para 949

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 alleged 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

³⁶⁵ Idem. para 40

³⁶⁶ Idem. para 41

³⁶⁷ Idem. para 42-43

³⁶⁸ Idem. para 44

³⁶⁹ Idem. para 45

³⁷⁰ Idem. para 46

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

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

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 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

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

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

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.

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’.

⁹⁰³ Servier decision para 1137

⁹⁰⁴ Nagy Csongor István: A kartelljog dogmatikai rendszere. HVG Orac, Budapest, 2021. p. 191

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 Commission’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

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.

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 Freien Universität Berlin. (Available at: <http://wikis.fu-berlin.de/pages/viewpage.action?pageId=410157604> Downloaded: 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/> Downloaded: 31 July 2017)

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 Geoffrey 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.

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 scale⁹¹⁹ – 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” phenomenon or a continuum⁹²¹, 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)

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.

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)

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)

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 case⁹³⁰ 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–Firnicsz 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.mtaki.hu/wp-content/uploads/2020/03/02_DomotorfyBT-KissBS-FirnicszJ.pdf Downloaded: 29th September 2020)

⁹³¹ Case 56/65, Société La Technique Minière v. Maschinenbau Ulm GmbH [1966] ECR 234. para 249. See also Case C-234/89, Delimitis 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.

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.

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.

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–Firnicsz 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.mtaki.hu/wp-content/uploads/2020/03/02_DomotorfyBT-KissBS-FirnicszJ.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.

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, nor 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

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.

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 antigereneric 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 judgments⁹⁴⁷, 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 F.3d. 1294, 350 F.3d 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.)

⁹⁴⁸ Sandra Marco Colino – Niamh Dunne – Knut Fournier – Sofia Oliveira Pais – Derek Ritzmann: 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.

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 "[neither 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.

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

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

⁹⁶² Eugene Buttigieg – Henri Piffault: The EU General Court’s Servier judgment. *Journal 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.

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 example 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.

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.

⁹⁶⁹ 570 U.S. 2013. Actavis dissent p. 10.

Hovenkamp and Hemphill⁹⁷⁰ 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 Hovenkamp: Anticompetitive Patent Settlements and the Supreme Court's *Actavis* Decision. *Minn. J. L. Sci & Tech.* Vol. 15:1 2014. p. 14.

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.

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

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

Bibliography

Abbott, F. – Michel, S. T.: 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.

Abel–Imray: The Unitary Patent Package is back on the table. (Available: <https://www.abelimray.com/downloads/newsletters/The-Unitary-Patent-Package-is-back-on-the-table.pdf> Downloaded: 27 November 2018)

Adams, Christopher P. –van Brantner, V.: ‘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> Downloaded: 30 November 2018);

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

Alexiadis, Peter –Figuerola, Pablo: 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)

American Needle, Inc. v. National Football League. Harvard Law Review. Vol. 124:179. pp. 400-410. (Available at: https://harvardlawreview.org/wp-content/uploads/pdfs/vol_12401american_needle_inc_v_national_football_league.pdf),

Anderman, S. – Schmidt, H.: 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.

Aranze, Janith: 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)

Areeda, P.: 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](http://www.fjc.gov/public/pdf.nsf/lookup/antitrust.pdf/$file/antitrust.pdf) Downloaded: 17th January 2016.)

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

Bork, Robert H.: 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.

Bruzzo, Ginevra – Capozzi, Sara: Restriction by Object in the Case Law of the Court of Justice: in Search of a Systematic Approach. p. 1. (Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2753521 Downloaded: 30 November 2018)

Bruzzo, Ginevra – Capozzi, Sara: 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’.

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

Buttigieg, Eugene – Piffault, Henri: The EU General Court’s Servier judgment. *Journal 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)

Cappuyns, Patricia: presentations, Liege, Ulg, 2013-2014.

Carlin, F.: Pay-for-delay settlements – EU Commission broadly aligns with the US Supreme Court. *EMEA Legal Insight Bulletin*. Summer 2013 p. 7-8.

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

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

Carrier, Michael A.: How not to apply Actavis. *Northwestern University Law Review*. Vol. 109:103. (2015)

Carrier, Michael A.: Payment After Actavis. *Iowa Law Review*, Vol. 100:7/2014. pp. 10-49.

Carrier, Michael A.: The Rule of Reason: An Empirical Update for the 21st Century. *Geo. Mason Law Review*, 2009. Vol. 16:4. 827-834.,

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

Clancy, M. – Geradin, D. –Lazerow, A.: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law

Clancy, Michael –Geradin, Damien –Lazerow, Andrew: Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law

Cook, T. A.: *Pharmaceutical Patent Litigation Settlements:Balancing Patent & Antitrust Policy Through Institutional Choice.*

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

Cosmo, G.: “Methods for Determining whether an Agreement Restricts Competition: Comment on Allianz Hungária,” *European Law Review* 2013,

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)

Cuonzo, Gabriel: The “Italian torpedo” never ending saga. (Available at: <http://kluwerpatentblog.com/2013/09/02/the-italian-torpedo-never-ending-saga/> Downloaded: 19 November 2018)

Danzon, P. M.: *Economics of the Pharmaceutical Industry.* NBER Reporter Fall 2006. (Available at: <http://www.nber.org/reporter/fall06/danzon.html> downloaded on 19 August 2014.)

Dasgupta, Partha –Stiglitz, Joseph: Uncertainty, Industrial Structure, and the Speed of R&D, 11 *BELL J. ECON.* 1, 18 (1980)

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

DiMasi, Joseph A. – Hansen, Roland W. – Grabowski, Henry G.: The price of innovation: new estimates of drug development costs. *Journal of Health Economics* 22 (2003)

Dolin, G.: Reverse Settlements as Patent Invalidation Signals. *Harvard Journal of Law & Technology* Volume 24, Number 2 Spring 2011

Dömötörfy Borbála Tünde: Árdiszkrimináció és párhuzamos kereskedelem a gyógyszeriparban: innovatív iparágak versenyjogi megítélése. *Versenytükrök*, 2012/2. p. 9-17

Drake, K. M. –Starr, M.A. – McGuire, T.: 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.

Dunne, Niamh: Why Protect Potential Competition? In: Sandra Marco Colino – Niamh Dunne – Knut Fournier – Sofia Oliveira Pais – Derek Ritzmann: The Lundbeck case and Potential Competition. *Concurrences Review*, No. 2-2017, June 2017

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

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

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

Esposito, Fabrizio – Montanaro, Francesco: 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.

Fundakowski, Daniel C.: 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.)

Gallash, Svan: 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.

Gallash, Sven: 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

Gavil, Andrew I.: 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)

Geradin, Damien – Ginsburg, Douglas – Safty, Graham: Reverse Payment Patent Settlements in the European Union and the –United States.

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,

Grabowski, Henry: ‘Patents, innovation and access to new pharmaceuticals’ (2002) 5 Journal of International Economic Law 849, p 850.

Guniganti, Pallavi: 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

Hann, B.: 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

Harrison, D.: “The Allianz Hungária case – The ECJ’s judgment could have ugly consequences,” Competition Law Insight, (2013) 12(6),

Harrison, P. – Nordlander, K.: EU/US Patent Settlements: An overview of leading cases. E-Competitions N 58749.

Harrison, Patrick – Nordlander, Kristina: EU/US Patent Settlements : An overview of leading cases. e-Competitions | N° 58749, www.concurrences.com

Hemphill, C. Scott – Sampat, Bhav N.: When Do Generics Challenge Drug Patents? Columbia Law and Econ. Working Paper No. 379, Aug. 2010,

Hemphill, C. Scott: Collusive and Exclusive Settlements of Intellectual Property Litigation. Columbia Law School Working Paper No. 384. November 30, 2010.

Hemphill, C. Scott: Drug Patent Settlements between rivals: A Survey. Working paper available at ssrn.com/abstract=969492 Downloaded: 19 August 2014

Hemphill, C. Scott: 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

Hemphill, C. Scott: Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem. p 103.

Hemphill, C. Scott: 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>

Hemphill, Scott C.: 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.

Hemphill, Scott: Collusive and Exclusive Settlements of Intellectual Property Litigation. Columbia Law School Working Paper No. 384. November 30, 2010.

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

Hovencamp, H. J.: The Rule of Reason. Florida Law Review, Vol. 70. 123–124. o. <http://www.floralawreview.com/wp-content/uploads/3-Hovencamp.pdf>.

Hovenkamp, Herbert J.: The Rule of Reason. Faculty Scholarship. 1778. (Available at: http://scholarship.law.upenn.edu/faculty_scholarship/1778 Downloaded: 30 November 2018)

Hull, David: Proceed with caution across the IP/Competition intersection. p.15.,

Hull, David: The Application of EU Competition Law in the Pharmaceutical Industry, Journal of European Competition Law & Practice. Oct2011, Vol. 2 Issue 5, p. 480-488.

Ibanez Colomo, Pablo: 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)

Ibanez Colomo, Pablo: 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)

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)

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)

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)

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

Jones, Alison: Analysis of agreements under U.S. and EC antitrust law–convergence or divergence? The Antitrust Bulletin. Vol 51. No. 4./Winter 2006. 691-811.

Kahmann, S. – Baylis, N.: 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)

Keyte, James A.: What It Is and How It Is Being Applied: The „Quick Look” Rule of Reason. [http://heinonline.org/HOL/LandingPage?handle=hein.journals/antitrumal1&div=36&id=&page=](http://heinonline.org/HOL/LandingPage?handle=hein.journals/antitrumal1&div=36&id=&page= p. 21.) p. 21.

Killick, James – Berghe, P.: Applying a by object test to patent settlements is very different from the rule of reason. *Concurrences* N° 2-2014, pp. 21-24

Killick, James – Jourdan, Jérémie – Dickinson, Jerome: 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)

Killick, James – Dawes, Anthony: The Elephant Uncovered. *Concurrences* N. 3-2009.

Killick, James: 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)

Kobayashi, Bruce H. – Wright, Joshua D. – Ginsburg, Douglas H. – Tsai, Joanna: Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly. *Antitrust*, Vol. 29, No. 2, Spring 2015. ABA.

Kovacic, William E. – Shapiro, Carl: Antitrust Policy: A Century of Economic and Legal Thinking. *Journal of Economic Perspectives*—Volume 14, Number 1—Winter 2000

Kuenzler, Adrian – Warlouzet, Laurent: 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.

Kutcher, M. P.: 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.

Kyle, Margaret K.: 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

Kyle, Margaret K.: Strategic Responses to Parallel Trade. 2007. NBER Working Paper Series. Available at: http://www.nber.org/papers/w12968.pdf?new_window=1 (Downloaded: 18th May 2015.)

Law 360: Where We Stand On Pharmaceutical Patent Settlements. (Available at: <https://www.wsg.com/publications/PDFSearch/law360-1015-3.pdf> Downloaded: 25 October 2018)

Lianos, Ioannis: 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.)

Marco Colino, Sandra –Dunne, Niamh –Fournier, Knut –Oliveira Pais, Sofia – Ritzmann, Derek: The Lundbeck case and Potential Competition. *Concurrences Review*, No. 2-2017, June 2017.

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

Mayer, Don – Warner, Daniel – Siedel, George – Lieberman, Jethro K.: 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>

McDonald, Kevin –Berman, Jonathan: 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)

Mehl, B.: 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

Montag, Frank – Meinhardt, Marcel: 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)

Motta, Massimo: *Competition Policy – Theory and Practice*, Cambridge University Press, 2004, Cambridge

Motta, Massimo: *Competition Policy – Theory and Practice*, Cambridge University Press, 2004, Cambridge, pp. 18-20.,

Nagy Csongor István: “The Distinction between Anti-competitive Object and Effect in Allianz: The End of Coherence in Competition Analysis?,” *World Competition*, (2013) 36(4

Nagy Csongor István: A kartelljog dogmatikai rendszere. HVG Orac, Budapest, 2021.

Nagy Csongor István: 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.

Nagy Csongor István: Anticompetitive object/effect: An overview of EU and national case law. *e-Competitions Bulletin Anticompetitive object/effect*, Art. N° 91905, 2019.

Nicholson, Walter –Synder, Christopher: *Intermediate Microeconomics and Its Application*. Eleventh edition. p. 383

Oliver, Geoffrey D.: Of Tenors, Real Estate Brokers And Golf Clubs: A Quick Look at Truncated Rule of Reason Analysis

Paul, Steven M. – Mytelka, Daniel S. – Dunwiddie, Christopher T. – Persinger, Charles C. – Munos, Bernard H. – Lindborg, Stacy R. – Schacht, Aaron L.: How to improve R&D productivity: the pharmaceutical industry's grand challenge. *Nature Reviews Drug Discovery* 9, 2010, pp 203-2014,

Petit, Nicolas: 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.)

Petit, Nicolas: The outcome of the EC pharmaceutical sector inquiry – „Barka at the Moon”. *Concurrences*. N. 3-2009.

Posner, R. A.: 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)

Rägo, Lembit –Santoso, Budiono: 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

Raptis, Maria: 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)

Reeves, Amanda P.: Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis

Scotchmer, Suzanne: Innovation and Incentives, 100–03 (2004)

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

Sidiropoulos, Konstantinos: Lundbeck: Remediating 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-remediating-ip-overprotection-through-competition-law-enforcement-in-the-pharma-sector/> Downloaded: 13 December 2017)

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

Subiotto, R.: 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)

Sullivan, Thomas: 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)

Szilágyi Pál: A közösségi versenypolitika (antitröszt jog) ötven éve. Iustum Aequum Salutare, II. évf., 2007/4. szám, 146-147.

Szilágyi Pál: A versenypolitika mozgásteret a versenyképesség tükrében. In: Katona Klára (szerk.): Vállalati versenyképesség és az állam szerepe: Hitek és tévhitek. Szent István Társulat: Budapest, 2011

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)

Tandon, Pankaj: Rivalry and the Excessive Allocation of Resources to Research, 14 BELL J. ECON. 152, 152, 156–57 (1983)

Tóth Tihamér: A 60 éves Római Szerződés versenyjogi rendelkezései: Ami változott, ami nem, s ami kimaradt. *Iustum Aequum Salutare*, XIV. évf., 2018/2. szám,

Tóth Tihamér: *Az Európai Unió versenyjoga*. CompLex. Budapest, 2014

Van den Bergh, Roger J. – Camesasca, Peter D.: *European Competition Law and Economics: A Comparative Perspective*, Sweet & Maxwell, 2006., London

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

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.)

Vesey, Caleb: 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)

Weber Waller, Spencer: Justice Stevens and the Rule of Reason. *SMU Law Review*, 2009. Vol. 62. 693-724.,

Whish, Richard –Bailey, David: *Competition Law*. Ninth edition. Oxford University Press, 2018, 131.

Whish, Richard: *Competition Law*, Oxford University Press, 2009., Oxford

Whish, Richard: *Competition Law*, Oxford University Press, 2009., Oxford, pp. 19-23

Wibaux, G.: Un point de vue francais. *Concurrences* N. 3-2009.

Wibaux, G.: Un point de vue francais. *Concurrences* N. 3-2009.

Wikis der Freie Universität Berlin. (Available at: <http://wikis.fu-berlin.de/pages/viewpage.action?pageId=410157604> Downloaded: 31 July 2017)

Wilson, Alex –Lancaster, David: 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)

Yu, Xiang – Chatterji, Anjan: Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation

Zafar, Osman: 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.

US cases

Niaspan Antitrust Litigation. NO. 13-MD-2460 (Available at: <https://www.paed.uscourts.gov/documents/opinions/14D0744P.pdf> Downloaded: 25 October 2018)

Judgment of the Supreme Court of the United States of 17 June 2013 in Federal Trade Commission v. Actavis, 570 U.S. (2013).

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)

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)

Wellbutrin XL Antitrust Litigation. In re Wellbutrin XL Antitrust Litigation, 133 F. Supp. 3d 734 (E.D. Pa. 2015)

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

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

8Cal. Dental, 526 U.S. at 780–81 (1999)

Aggrenox Antitrust Litig., 14-md-2516 (D. Conn.)

Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003)

Cipro Cases I & II, S198616 (Cal.)

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

Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008)

Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (Fed. Cir. 2008)

Lamictal Antitrust Litigation (12-cv-995 (D.N.J.)

Lamictal Antitrust Litigation 14-1243 (3rd Circuit)

Lipitor Antitrust Litig., 12-cv-2389

Loestrin Antitrust Litig., (13-md-2472 (D.R.I.))

Solodyn (Minocycline Hydrochloride) Antitrust Litig., 14-md-2503 (D. Mass)

Wellbutrin XL Antitrust Litigation., 08-cv-2431, 08-cv-2433 (E.D. Pa.)

Tamoxifen Citrate Antitrust Litigation 466 F.3d 187 (2d Cir. 2006)

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

Valley Drug Company v. Geneva Pharmaceuticals Inc. 350 F3d 1181 (11th Cir. 2003)

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983.) (cited by the Court)

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

Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056 (11th Cir. 2005)

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

Brief for the United States as Amicus Curiae No. 05-273

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>

Brief of Federal Trade Commission as Amicus Curiae in support of plaintiffs-appellants. (Available at: https://www.ftc.gov/system/files/documents/amicus_briefs/re-lamictal-direct-purchaser-antitrust-litigation/140.428lamictalbrief.pdf Downloaded: 19th January 2016)

Chief Justice Roberts – Justice Scalia – Justice Thomas dissenting 570 U. S.(2013)
Ftc v. Actavis, Inc. Supreme Court of the United States No. 12-416

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>

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.

EU cases

C-32/11 Allianz Hungária Biztosító and Others, EU:C:2013:160

Case 193/83, Windsurfing International k. Commission, EU:C:1986:75 (Windsurfing judgment)

Case 35/83, BAT v. Commission, ECLI:EU:C:1985:32

Case 258/78 Nungesser v. Commission, ECLI:EU:C:1982:211

Case 262/81 Coditel v. Commission, ECLI:EU:C:1982:334

Case 27/87 Erauw-Jacquery v. Commission, ECLI:EU:C:1988:183

Case 9/93 Ideal Standard at all v. Commission ECLI:EU:C:1994:261

Case 56/65 LTM, EU:C:1966:38

Case 56/65, Société La Technique Minière v. Maschinenbau Ulm GmbH [1966] ECR 234.

Case 9/93 Ideal Standard at all v. Commission

Case AT – 39685 Fentanyl

Case AT.39226 – Lundbeck,

Case AT.39612 – Perindopril (Servier)

Case C-209/07 Beef Industry Development Society and Barry Brothers [2008] ECR I-0000 ('BIDS'), paragraph 16

Case C-234/89, Delimists v. Henninger Bräu [1991] ECR-I-935.

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

Case C-457/10 P. AstraZeneca k. Commission, EU:C:2012:770

Case C-591/16 P., Lundbeck v Commission, EU:C:2021:243

Case C-8/08 T-Mobile Netherlands BV and Others v. Raad van bestuur van de Nederlandse Mededingingsautoriteit [2009] ECR I-04529, AG Opinion

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)

Case T-111/96, ITT Promedia NV v. Commission. ECR [1998] p. II.-2937

Case T-112/07, Hitachi at all. k. Commission, EU:T:2011:342,

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

Case T-360/09, E.ON Ruhrgas and E.ON k. Commission. EU:T:2012:332.

Case T-461/07, Visa Europe Ltd and Visa International Service v Commission EU:T:2011:181

Case T-472/13 Lundbeck

Case T-519/09, Toshiba k. Commission, EU:T:2014:263

Case T-691/14. Servier SAS and Others v Commission ECLI:EU:T:2018:922

Joined Cases T-374, 375, 384 and 388/94, EuropBrenda ean Night Services v. Commission [1998] ECR-II-3141

Case 15/74 Centrafarm and de Peijper, EU:C:1974:114

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

Joined Cases T-49/02 - T-51/02, Brasserie nationale at all. k. Commission, EU:T:2005:298

Opinion of AG Wahl in Case C-67/13 P, Cartes Bancaires, EU:C:2014:1958

Paroxetine – Case CE - 9531/11. (Available at: <https://assets.publishing.service.gov.uk/mwg-internal/de5fs23hu73ds/progress?id=HxtPHsAmxLeaNW8GCjIUyfQMOHiK7QoGNULDGdxKhi4,&dl> Downloaded: 30 November 2018)

Case C-345/14, Maxima Latvija k. Konkurences padome, EU:C:2015:784,

Case C-123/83. Bureau national interprofessionnel du cognac v Guy Clair ECLI:EU:C:1985:33, para 22.

Case C-67/13. Groupement des Cartes Bancaires v Commission, EU:C:2014:2204

Case T-374/94. European Night Services v Commission [1998] EBHT II-03141,

Case C-209/07. Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd. [2008] EBHT I-08637.

C-8/08. sz. ügy, T-Mobile Netherlands és mások kontra Raad van bestuur van de Nederlandse Mededingingsautoriteit [2009] EBHT I-04529.

C-243/83. sz. ügy, SA Binon & Cie v SA Agence et messageries de la presse [1985] EBHT 02015.

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

C-209/07. sz. ügy, Competition Authority kontra Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd. [2008] EBHT I-08637.

Case C-56/65. Société Technique Minière (L.T.M.) k. Maschinenbau Ulm GmbH, EU:C:1966:38, 249.

Opinion of Advocate General Bobek, Case-C-228/18. Budapest Bank at all. v. GVH. ECLI:EU:C:2019:678.

Case-C-228/18. Budapest Bank at all. v. GVH. ECLI:EU:C:2019:678

Case C-56/65. Société Technique Minière (L.T.M.) k. Maschinenbau Ulm GmbH, EU:C:1966:38, (“STM”),

Case C-8/08 T-Mobile Netherlands BV and Others v. Raad van bestuur van de Nederlandse Mededingingsautoriteit, ECLI:EU:C:2009:343;

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.

Case M.8677 - SIEMENS/ALSTOM

Policy documents, websites and other resources

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

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)

Authorized Generics: An Interim Report, Fed. Trade Comm’n at 3 (June 2009); available at <http://emmanuelcombe.org/generic.pdf>

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

DAF/COMP/WD(2014)75: “The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements”

DAFFE/CLP(2000)29 – OECD: Competition and regulation issues in the pharmaceutical industry. February 2001

<https://www.gov.uk/government/news/cma-alleges-anti-competitive-agreements-for-hydrocortisone-tablets> (Downloaded 4 December 2017)

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

EPO: When will the Unitary Patent system start? (Available at: <https://www.epo.org/law-practice/unitary/unitary-patent/start.html> (Downloaded: 24 Sep. 2018))

Eurostat. 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

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)

Federal Trade Commission: Authorized Generic Drugs: Short-Term Effects and Long-Term Impact. August 2011. (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: 12 December 2014) p. 62.

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)

FTC Staff Study January 2010: Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. p. 3.

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

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.

Generic Drug Savings in 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.)

Guidelines on the application of Article 81(3) of the Treaty. Official Journal C 101/97.

IP/11/511 Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva

Italianer http://ec.europa.eu/competition/speeches/text/sp2013_07_en.pdf

Medicare Prescription Drug, Improvement, and Modernization Act of 2003. PUBLIC LAW 108–173—DEC. 8, 2003. 117 STAT. 2066 108th Congress.

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.

Pfizer v Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato) and Others, Case 7467/2012, Regional Administrative Court for Latium,

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

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)

CMA alleges anti-competitive agreements for hydrocortisone tablets. (Available at: <https://www.gov.uk/government/news/cma-alleges-anti-competitive-agreements-for-hydrocortisone-tablets> Downloaded: 30 November 2018)

OFT issues statement of objections to certain pharmaceutical companies. (Available at: <http://webarchive.nationalarchives.gov.uk/20140402142426/http://www.offt.gov.uk/news-and-updates/press/2013/36-13> Downloaded: 30 November 2018)

SPEECH-13-1053_EN Joaquín Almunia: Fentanyl case

SPEECH-14-541 – Joaquín Almunia – Decision in Servier case

The 2013 EU Industrial R&D Investment Scoreboard. <http://iri.jrc.ec.europa.eu/scoreboard13.html> downloaded on 19 August 2014.

The Brussels Convention

Website of the Commission's Pharmaceutical Sector Inquiry. (Available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/> Downloaded: 23 October 2018)

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

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

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

CMA alleges anti-competitive agreements for hydrocortisone tablets. (Available at:
<https://www.gov.uk/government/news/cma-alleges-anti-competitive-agreements-for-hydrocortisone-tablets> Downloaded: 30 November 2018)

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)

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)

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)

Websites:

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

http://ec.europa.eu/health/authorisation-procedures-centralised_en.htm

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

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

<http://thebusinessprofessor.com/knowledge-base/antitrust-rule-of-reason-and-per-se-illegality/>

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

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

https://ec.europa.eu/growth/sectors/healthcare/competitiveness/products-pricing-reimbursement/transparency-directive_en

https://ecf.ctd.uscourts.gov/cgi-bin/show_public_doc?2014md2516-229

<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>

<https://www.gov.uk/government/news/cma-takes-further-procedural-step-in-paroxetine-investigation>

<https://www.pharmacytimes.com/publications/issue/2017/february2017/will-us-senate-address-payfordelay-agreements>

www.clt.astate.edu/crbrown/section1.ppt