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Paying for Delay or Something Else?

The Potential Anticompetitive Effect of Reverse Payment Patent Settlements in the Pharmaceutical Industry under article 101 TFEU

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Summary

This thesis discusses the recent hot topic in the intersection of IP law and competition law; “pay-for-delay” agreements in the pharmaceutical industry. Such agreements arise in patent disputes where originator manufacturers (‘Originators’) claim patent infringement by the generic manufactures (‘Generics’). However, patent infringing defendants end up paying the plaintiff large sums of money, accompanied with the generic’s agreement to delay or refrain from challenging the patent and launching generic drugs. Due to the fact that the parties may have agreed to not compete by sharing monopoly profits, pay-for-delay deals could lead to an artificially higher market price which detriments consumer welfare. Whether all suspicious pay-for-delay deals are anti-competitive has been controversial in the academic field and the courts in the US. As the EU has only recently started its study and investigations into the issue, it is worthwhile to study: whether such deals are anti-competitive in themselves, to what extent they could be anti-competitive under the EU competition law and how should they be examined to reach the optimum result for competition law implementation.

Section 1 of this thesis will firstly give a general picture of the history of pay-for-delay deals in EU and US. Section 2 will further offer the legal context and the industry features that fertilize the emergence of pay-for-delay deals. Section 2.5 summarizes the change of attitude of US courts and the investigations in Europe. Through studies into the judgement/decisions of these cases, Section 3 proposes a system of classification for pay-for-delay, which puts pay-for-delay deals into high-risk, medium-risk and low-risk categories. The rationale and method of such classification will also be included. The thesis ends with the conclusion that not all the agreements that meet the superficial criteria of pay-for-delay agreements (restriction on generic entry and reverse value transfer) are of anti-competitive effect. Some may be the reasonable result of a genuine patent dispute and will not leave anti-competitive impacts on the market. It is thus necessary to classify these agreements by their level of anti-competitive risk and that they should be scrutinized differently in accordance with the classification they fall into.

Preface

I started the research of this master thesis with my general interest in the intersection of IP law and competition law. Pay-for-delay seems to be a perfect topic, as it is one of the hot topics in the field.

However, it is a rather new issue in the EU, not much has been said by the CJEU. The process of producing the thesis has been filled with both moments of inspiration and those of confusion. However, I am pleased that my interest in the field was strengthened during this process. The dynamic nature in EU competition law calls for nuanced approaches ensure the most effective result of competition law. This thesis reflects my attempt to develop my thoughts into plausible tests to solve the pay-for-delay issue.

A big thank you goes to my supervisor Björn Lundqvist, who suggested the topic and led me with inspiring questions and encouragement during my research. I am grateful for my parents' support and Lund University's generosity in granting me the Lund Global Scholarship, without which I will not be able to start my journey at Lund in the first place. Here, I learned from lecturers and colleges from all over the world. And here, I made great friends, who has been and will always be great infulence to me. A special thank you to Ian for reading and commenting on my thesis, and for all your support and sharing over the past stressful yet exciting year.

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Abbreviations

ANDA	Abbreviated New Drug Applications
CFI	The Court of First Instance
CJEU	The Court of Justice of the European Union
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FTC	The Federal Trade Commission
R&D	Research and Development
SPC	Supplementary Protection Certificate
TFEU	The Treaty on the Functioning of the European Union
US	United States of America
WHA	Hatch-Waxman Act

1 Introduction

1.1 History Background of pay-for-delay

The pharmaceutical industry is one of the most innovative sectors in the EU[1], which attracts a high volume of investment[2]. Businesses of the drug manufacturers and investors, health and lives of patients and quality of state welfare are all at stake in this industry.

For the pharmaceutical companies, the massive investment and long research processes lead to the formation of a heavily patented industry. Companies obtain patents to ensure protection of their intellectual work and to recoup previous investment. This is especially true for the originator companies, who invest heavily in initial R&D, and the marketing of new innovative medicines[3]. Patents are also essential for the generic companies. Generics develop and market drugs that bear the same active ingredient and are comparable to an authorized originator's drug (the '*reference medicine*') in terms of dose and usage. Although such processes are normally much easier than what the originators have gone through, investment into R&D is still notable, especially for the medium and small size generics. Both originators and generics wish to make the previous R&D worthwhile through product profits, which could lead to aggressive business strategies with potentially anti-competitive effects.

For states, huge amount of public funds are invested to provide high standard healthcare across the EU. Any waste of public funds due to anti-competitive behaviours of private firms is surely frowned upon. Thus, behaviours of pharmaceutical companies, especially their use of patent should be regulated for the benefits of health welfare.

This conflict of interests has given rise to various new patent strategies adopted by the pharmaceutical companies, which often bring new tasks and issues for the national authorities.

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[1] Commission, ' Executive Summary of the Pharmaceutical Sector Inquiry Report', COM (2009) 0351 (Executive Summary)
[2] Commission, '*The 2013 EU Industrial R&D Investment Scoreboard*', (Publications Office of the European Union 2013), p 11
[3] Commission, 'Pharmaceutical Sector Inquiry-Preliminary Report, Fact Sheet, Originator-Originator competition', COM (2009) 0351

The patent strategies used by the originators are mainly aimed to prolong the life period of patents and products, or to defer the generics from entering the specific market. An example of the first type of strategy could be that originators file new patents on an already patented product. Instead of protecting a new drug, such new patents often protect delivery profiles, packaging, dosing and other production processes of the patented drug[4] (so-called '*evergreen patents*'). Some originators also change the name of an earlier version of product prior to the expiry of patents. By re-marketing this "new" drug to previous consumers and doctors, originators try to secure consumer loyalty so that fewer consumers will switch to the future generic drugs. Typical strategies to actively delay or exclude entry of generics may involve withdrawing the first generation of a drug before its patent expiry and meanwhile launching a new product with a secondary patent (similar effect as product name-changing). Another tactic that originators often use is to file unnecessary patents, sometimes in the hundreds, on the same product to confuse the generics that wish to apply for market authorization ('*patent clusters*')[5] since the generics need to either wait for the legal protection on a reference drug to collapse or to innovate around the technologies patented.

In the recent decades, a new type of strategy has emerged and caught the attention of the competition authorities. In some patent disputes where the originator initiated the procedure against certain generics, the originator ended up paying to the alleged infringer, resulting in the generics' delaying or giving up launch of generic drugs. This behaviour has been named "*pay-for-delay*" or "*reverse payment*".

Attention from the US competition authority on pay-for-delay deals has existed for years. Pay-for-delay has been deemed as an agreement between originators and generics to avoid competition by the US Federal Trade Commission ("FTC")[6].

One of the early high-profile reverse payment cases emerged in 1995, where two generic manufacturers submitted requests to the FDA for permission to launch generic versions of Schering Plough's K-Dur tablets. The generics claimed the generic

[4] Inderjit Singh Bansal, et al, 'Ever greening- A Controversial Issue in Pharma Milieu', [2009] 14 Journal of Intellectual Property Rights 299

[5] Nicoleta Tuominen, 'Patenting Strategies of the EU Pharmaceutical Industry: Regular Business Practice or Abuse of Dominance' [2012] 35(1) World Competition <https://www.kluwerlawonline.com/abstract.php?area=Journals&id=WOCO2012003> accessed 16 March 2014

[6] FTC, ' Pay-for-delay: when drug companies agree not to compete', <http://www.ftc.gov/news-events/media-resources/mergers-and-competition/pay-delay>, accessed 16 March 2014

drug would not infringe Schering's patent due to different chemical composition. However, after a settlement agreement, Schering Plough paid the generics respectively 60 and 30 million USD, leading to one of the generics postponing the marketing for five years (but prior to Schering's patent exclusivity); another generic agreed to license Schering the marketing of its generic drug. Initially the administrative court ruled that both agreements were legal and the settlements were not illegal per se. But on appeal, the 11th Circuit held that although the settlement was not per se illegal by including ancillary license agreement, it was necessary to adopt a scope of patent test[7]. It meant as long as the restrictions in the settlements was within the scope of Schering Plough's patent, the settlement was not problematic to competition law. This judgement reconfirmed the potential anti-competitive effect a pay-for-delay settlement may bring about.

After several debated cases, the US Supreme Court finally ruled on the Actavis case in 2013[8] and ruled in favour of the "rule-of-reason" test over FTC's "per-se illegal" rule, the detail of which will be expanded below. In Europe, the Commission has started its sector inquiry into the pay-for-delay settlements since 2008. Several statements of objections on pay-for-delay have been sent since then. Akin to the US Supreme Court's ruling, the EU Commission fined 93 million euro on Danish originator Lundbeck[9] and 52 million euro on other generics involved ("*Lundbeck case*"). With more pay-for-delay investigations appearing in Europe, various predictions have been discussed on how the Commission and CJEU will judge this type of deal.

The Commission's opinion released in *Lundbeck* and its earlier sector inquiry report gave rise to discussions between lawyers, economics and corporate representatives. In the academic field, some have argued that forbidding pay-for-delay in settlements reduces the scope of settlements, making it harder for parties to solve disputes. They argue that the parties in a patent dispute have completely reasonable economic drives to reach pay-for-delay deals due to risk aversion instead of an intention to form cartels[10]. Others try to stress that not all pay-for-delay deals are detrimental to

[7] *Schering-Plough Corp. v. FTC*, 402 F. 3d 1056 (11th Cir. 2005)
[8] *FTC v. Actavis, Inc.*, 570 U.S. __ (2013)
[9] Commission, 'Antitrust: Commission Fines Lundbeck and Other Pharma Companies for Delaying Market Entry of Generic Medicines' [2013] IP/13/563 (Lundbeck Press Release)
[10] William Choi, Bruce Den Uyl, and Mat Hughes, 'Pay-For-Delay Practices in the Pharmaceutical Sector: Lundbeck, Actavis, and Others' [2014] 5(1) Journal of European Compean Competition Law & Practice 44

competition. Sometimes penetration of generics and their effect of lowering prices could be limited or even raised. This could happen when the originator has the confidence in its brand and focus on brand-sensitive consumers[11]. Therefore there might not exist any anti-competitive effects. Corporations involved in the recent investigations also raised some objections to the Commission's views. The generics from the Lundbeck decision have already appealed to the CJEU against the decision and fining[12]. Representatives of Lundbeck also stressed that the Commission has misinterpreted the competitor relationship between the parties to the settlement as well as the content of those agreements itself[13].

In brief, pay-for-delay in the pharmaceutical sector seems to be a new way of abusing patents for competition authorities, yet whether all of them are anti-competitive and to what extent should they be regulated and prosecuted are complex questions.

1.2 Purpose

By looking into how the pay-for-delay cases have been dealt with in the US and the EU, this thesis will attempt to define and differentiate various scenarios of pay-for delay deals and analyse their respective potential anti-competitive effects under EU competition law.

The thesis will then suggest an assessment approach based on the characteristics of these different scenarios. It will demonstrate that different scenarios are of different competition law risk and call for different level of investigation. Proposals on how to implement such approach and to mitigate potential anti-competitive effects will also be elaborated.

[11] Herbert Hovenkamp, 'Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision' [2013] Minnesota Journal of Law, Science & Technology, Forthcoming; University lowa Legal Studies Research Paper No 13-35 < http://ssrn.com/abstract=2286255 >accessed 16 May 2014, p 5

[12] Case T-469/13 *Generics (UK) v. Commission* [2013] ; Case T-460/13 *Ranbaxy Laboratories and Ranbaxy (UK) v. Commission* [2013], T-467/13 *Arrow Group and Arrow Generics v. Commission*[2013], T-470/13 *Merck v. Commission* [2013], T-471/13 *Xellia Pharmaceuticals and Zoetis Products v. Commission* [2013], T-472/13 *Lundbeck v. Commission* [2013]

[13] Commission, 'Action Brought on 30 August 2013—H. Lundbeck and Lundbeck v. Commission' [2013] OJ C 325/76

1.3 Methology and Materials

This thesis will mainly adopt the legal dogmatic method, the historical method, and the comparative method.

The legal dogmatic method will be mainly used for analysing the legislation and related cases on both sides of the Atlantic; EU treaties, regulations and directives, the decisions of the Commission, press release on these decisions, guidelines released by Union bodies, and study papers and reports released by the Commission; US legislations related to the topic of the case, US case law, and US competition authority's study report on pay-for-delay.The historical method will be used to illustrate the development of courts' changing attitudes on pay-for-delay deals in US from beginning of the century till now, the EU Commission's rising attention and investigations into the issue since its pharmaceutical sector inquiry.The comparative legal method will be used to compare the legislation frames in pharmaceutical industry between EU and US; to contrast the elaborated discussions on pay-for-delay among US courts and academics with the vague and general remarks from the Commission.

Certain law and economics views will be presented to illustrate the economic motivation of pharmaceutical companies to settle patent disputes with reverse payments. These views will show the anti-competitive effects of certain pay-for-delay deals.

1.4 Delimitations

This thesis will focus on the pay-for-delay behaviour in the EU, with those of US as a comparison as only limited amount of cases have been decided in EU.

Even though pay-for-delay could potentially violate both article 101 and article 102 TFEU, this thesis will mainly focus on the anti-competitive effect under the context of article 101.

Also, the incorporation of US pay-for-delay cases is for the illustration of different views on the potential anti-competitive effects of pay-for-delay and potential approaches to assess them. This thesis will not conduct in-depth discussion into the legislations in the US pharmaceutical industry and US antitrust law.

2 Arising of Pay-for-delay issue in the EU and the US

2.1 Background and Regulations of the EU Pharmaceutical Market

2.1.1 Originators and Generics

Pay-for-delay deals happen between an originator and one or several generics. The difference between originators and generics is an important factor that stimulates them to reach pay-for-delay deals. The main difference is seen in their R&D investment.

Originators invest more heavily than most generics. According to the Commission's final report for its Pharma Sector Inquiry ('Sector Inquiry'), between 2000-2007, the respondent originators spent around 17% of its global turnover on R&D into improving or innovating prescription medicines, which are the main profit generators for the originators. On the other hand, generics spend 7% on R&D and focus more on manufacturing and marketing[14], which normally make generic drugs much cheaper than the corresponding originator's drug. Therefore, regulators around the world set up separate market authorization process and protection for the two types of companies. Legislations are required to take into consideration both the benefits for originators and those for generics to strike the balance between recouping large R&D investment and long-term innovation benefits brought about by generic drugs.

[14] Commission, 'Pharmaceutical Sector Inquiry Final Report' [2009] Staff Working Paper <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed 22 March 2014, p 32

2.1.2 Legislation support for generic companies

In the EU, one of the main protections for the generics is the so-called Bolar provision in the Data Exclusive Directive[15]. In order to fulfil a market authorization, most generics would need to conduct certain tests and clinical trials in relation to the patented originator's drug. Such tests and trials prior to the expiry of an originator's patent were previously not regulated at EU level. Most Member States deemed such tests as potential infringements of the originator's patent. The Bolar provision enables the generics to conduct tests and trials that are strictly necessary to obtain market authorization before the expiry of patent without risk of infringing the patent.

Besides the Bolar provision, generics are also offered a more expedite procedure of market authorization application. According to the amended article 10 of Data Exclusive Directive, the generics are refrained from providing results of pre-clinical tests and trials if they can demonstrate similarity of the generic drug to an already market authorized originator's drug. The authorities will rely on the data of tests and trials already submitted by the originator. The abridged application and Bolar provision simplify the market authorization process for generics, no matter what route of procedure they choose. Both the research activity and filing of abridged application are only allowed after period of data exclusivity, the concept of which will be explained below.

2.1.3 Legislation support for Originators

Originators enjoy a period of data exclusivity in relation to abridged applications from the generics. The convenience provided for the generics is not unlimited. According to the amended Data Exclusive Directive, for eight years after an originator's obtaining of market authorization, generic applicants may not refer to the information and data relating to pre-clinical testing of the original drug. Also generics may not bring to market generic drugs by filing an abridged application until an originator's has obtained market authorisation for 10 years. This provides the

[15] Council Directive (EC) 01/83 of November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67 art. 10(6)

originators with a less disturbed period to explore its profits and to recover the massive R&D investments.

And to make up for the period that market authorization applicants spend on tests and trials, the EU has created a Supplemental Protection Certificate (hereinafter "SPC")[16] scheme. The idea is that for medicines, patent protection of 20 years is strongly lessened by its long and complex market authorization process. Holders should at least enjoy an effective period of protection for 15 years, meaning the years of patent protection deducted by years applying for market authorization should at least be 15 years. If the effective period is less than 15 years, an SPC will be granted, allowing an extra period of patent protection with a maximum of five years.

2.2 US regulations on pharmaceutical market

In the US, the process of market authorization for drugs is overseen by the US Food and Drug Administration (FDA) and regulated by the Federal Food, Drug and Cosmetic Act (FFDCA). The main legislation balancing the benefits between originators and generics is the Hatch-Waxman Act ('WHA').

Similar to the situation in the EU, the FDA offers data exclusivity protection for the originators, the protection of which is between 5 to 7 years[17]. During this period, the generics may not rely on data of an originator's drug for its own generic drugs.

For the generic manufacturers, they may apply for an Abbreviated New Drug Application ("ANDA"), equivalent to the EU abridged application. The generic may either wait for the patent on the originator's drug to elapse or actively challenge the validity of the patent. If such a challenge succeeds, the WHA grants the first generic challenger a 180-day marketing exclusive period, where other generics are not allowed to compete with the first mover. As the generics' profits depend largely on peer competition, the 180 days are highly valuable for the generics. Prices of a generic drug

[16] Council Regulation (EC) 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L182

[17] FDA, 'Frequently Asked Questions on patents and exclusivity', <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#How long is exclusivity granted for?>, accessed on 29 March 2014

are said to drop substantially once another authorized generic enters the market [18]. It also means substantial monopoly and profit loss from the originators to the generics. In the EU case *Lundbeck*, the price of the originator's drug Citalopram is said to have dropped on average by 90% in the UK with the entry of a corresponding generic drug[19].

This arrangement is aimed at encouraging the generics to file ANDA and challenge patents of originators' drugs, leading to a more dynamic competition between the generics and originators. The originator can counter this process by alleging patent infringement from the generics that refer to its drug. If this is the case, the FDA is obliged to suspend the process of approving the generic's ANDA for 30 months. During this period the parties may litigate or settle prior to a court judgment[20].

2.3 Incentives to enter into pay-for-delay deals in settlements

The various legislation arrangements explained in Section 2.1 aim at balancing the benefits of both the generics and the originators and facilitating their business, but competition law does bear other social functions. Such functions could be: ensuring freedom of actions of individuals, innovation in a society, structure of a market, or consumer welfare[21]. In terms of pay-for-delay deals, the ultimate intention of legislators is to maintain a large amount of innovative drugs as well as reasonable drug price. While for the companies, it is always profits that are more inducing. As with many other patent strategies, pay-for-delay settlements originated in the context of conflicts of interests between the public and private sector. Drug companies maximize their own profits through settlement agreements in order to avoid the intervening of competition law.

[18] FTC, 'Authorized Generics: An interim Report, Federal Trade Commission Report' [2009] <http://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authorizedgenericsreport.pdf>, accessed on 02 April 2014
[19] Alexander Italianer, 'Competitor agreements under EU competition law' (40th Annual Conference on International Antitrust Law and Policy, New York, September 2013)
[20] United States Congress, Drug Price Competition and Patent Term Restoration Act of 1984, p.L. 98-417
[21] Vladimir Bastidas Venegas, 'A legal and Economic Analysis of the Application of Article 101 TFEU to Patent Technology Transfer Agreements' (PhD thesis, Stockholm University 2011)

2.3.1 Incentives for originators

Because the entry of generic drugs normally would substantially affect the originator's profit, most originators may not want to run the risk of losing the market monopoly and the profit because of court decisions. Nor do the big originators wish to see lost of reputations due to patent litigations.

Even though many competition law practitioners argue that the risk aversion attitude of originators is a sign for weak patent, many originators counter-argue that patent disputes are highly complicated and unpredictable in the European Union. It is rather common that patent right holders are not perfectly confident in this situation[22]. Originators' risk-aversion attitude is thus exacerbated by such uncertainty and the importance of the patents, in spite of their confidence in the disputed patent.

2.3.2 Incentives for generics

For generics, limited market profit and financial constraints are major factors for participating in pay-for-delay deals. Market prices of an originator's drug are said to be 25% lower once generics enter the market[23]. Therefore, the profit that generics are able to generate during their own monopoly period might be limited due to relatively low price of generic drugs. Prices of generic drugs would drop further after other generics are allowed on the market. At this point, the prices of generic drugs are on average 40% lower than the previous originator's monopoly price[24]. The estimated profit for the generics may thus be lower than originators' profit loss due to the lowered price, the scale of the generic firm and its marketing capacity. The originators will have enough profit to share to a competing generic, which also prefers to avoid the hassle of market competition. A lump sum payment or periodical payments may become an ideal settlement solution for small generics with limited cash flow[25]. Side deals such as licensing and marketing agreements with the originator could be a more sustainable and

[22] Pat Treacy and Sophie Lawrance, 'Intellectual Property Rights and Out of Courts Settlements' in Steven D. Anderman and Ariel Ezrachi, *Intellectual Property and Competition Law : New Frontiers* (Oxford ; New York: Oxford University Press, 2011).
[23] Executive Summary (n 1) p 9.
[24] Executive Summary (n 1) p 10.
[25] Commission, 'Antitrust: Commission fines Johnson & Johnson and Novartis 16 million for delaying market entry of generic pain-killer fentanyl', IP 13/1233 [2013] (J&J Press Release)

secure way of gaining profits. This is especially true for those firms sharing other similar or related products.

The worries of losing patent disputes impose more influence on the smaller generics. Preparation of patent disputes is often costly, yet the litigation time limit is sometimes not enough for the generics to present all its proofs. It is reported in the Executive Summary of Pharmaceutical Sector Inquiry[26] that it takes more than two years to obtain about 80% of final decisions from the EPO regarding patent disputes, making it hard for generics to elaborate details of patents to secure a favourable decision. This intensifies the risk aversion attitude of the generic firms. Building up a business relationship is of often preferred to the risk of losing the patent litigation[27].

2.3.3 Uncertainty from the patent system

Another factor affecting originators and generics is the uncertainty of patent dispute resolution offered by the patent offices across the Europe.

According to the Commission's sector inquiry, due to lack of a union patent, the same patent dispute in different Member states may sometimes receive conflicting results[28]. It is clear that drug manufacturers who have heavily invested into their patents do not want to risk profits in a messy patent system. As some have said, the more inefficiencies a patent system brings, the greater the risk of expansive competition law intervention due to large amount of private agreements[29].

2.4 Pay-for-delay defined by competition authorities

What is a pay-for-delay settlement? This section will first introduce the notion of pay-for-delay settlements in the competition authorities' eyes.

The notion of pay-for-delay agreements in the EU came from the said Sector Inquiry in 2009, during which the Commission noticed delays in the entry of generic medicines and decline in innovation[30]. However, there is no official definition of what is

[26] Executive Summary (n 1) p 12.
[27] J&J Press Release (n 22) p 278
[28] Pharmaceutical Inquiry Final Report (n 14)
[29] Nicoleta Tuominen (n 5)
[30] Executive Summary (n 1), p3.

an anti-competitive pay-for-delay agreement, as the legal concerns on pay-for-delay agreements have not been elaborated extensively, nor has the Commission published any decision. Yet according to the Commission, there are two key elements that make a settlement agreement between generics and originators suspicious to competition authorities. The First element is the limitation imposed on the generic company's ability to launch its own drugs and second is an agreed value transfer from the originator to the generic company[31]. Only those agreements that limit the market entry of generics are likely to attract competition law scrutiny (defined as 'B type agreements' according to the Commission Sector Inquiry). And those B type agreements that bear value transfers ('B.II. agreements') are more likely to be scrutinized by the Commission than those without value transfers ('B.I. agreements'). Yet the Commission has acknowledged that not all B.II. agreements are anti-competitive by nature, each case should be reviewed individually[32]. This is because value transfers in the agreements have different bases, some of which may be justifiable.

In the US, the FTC has described the pay-for-delay agreements in a similar fashion. Agreements restricting generic entry with compensation from the brand (US notion of originators, "originators" hereafter) to the generic are deemed problematic[33].

Knowing the two key elements help us to understand that various types of pay-for-delay agreements exist. In practice, limitation to generic entry may take different forms, giving the originator different level of control and resulting in different degrees of delay. The most straightforward form of limitation would be that the generics agree not to launch their own drug. Such limitation could be imposed until the expiry of the disputed patent, after the expiry of the patent, or even until further notice from the originator. The originator could also require the generic to refrain from challenging the patent in dispute forever ("non-challenge clause"). License agreements from the originator to the generic with limitations on: quantities, composition, pricing or other marketing conditions are also deemed as limitations since they control the freedom of the generic to launch its own products whenever it becomes possible. Other agreements,

[31] Commission, '4th report on the Monitoring of Patent Settlements (period: January-December 2012)' <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf> accessed 10 Apr 2014, p3. (4th Monitoring Report)
[32] Executive Summary (n 1), p 5.
[33] FTC, 'Pay-for-delay: How drug Company Pay-offs Cost Consumer Billions' (2010) < http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf > p2., accessed 17 April 2014.

such as distribution agreements that involve exclusive sourcing from the originator are also deemed as limitations to generic entry[34].

As to value transfer, the most straightforward form is monetary payment from the originator to the generic. Such value transfers could either be consideration for the generic's undertaking of delaying the launch of its product or for the originator's purchase of the generic's stock (disable the possibility of further preparation of launching of generic drugs). Another kind of value transfer is what the Commission called side deals, which are agreements offering the generic some commercial benefits. Some side deals grant the generics limited market entry (either in another market other than the disputed one, or with another product of the originator), others grant the generic some license agreements to enable market entry within the originator's control. Overall, the side deals trade some profit benefits of the originator for limitations on the generic's freedom to launch its own product, which is more valuable to the originator than the side deal.

In conclusion, there seems no official definition on what conditions ensure an anti-competitive pay-for-delay deal. Instead, both competition authorities in the EU and in the US propose criteria to spot potentially anti-competitive pay-for-delay deals; those with reverse payment and restriction on generic entry.

Out of these suspicious agreements, one type is considered especially harmful[35]. When the parties end a settlement, not because of the merit of the originator's patent, but because of the inducement from the originator, they reached an agreement not to compete by sharing the monopoly profit. Consumers lose the chance to benefit from a lowered drug price. Such arrangement between firms is of a cartel nature.

Article 101(1) forbids competing firms to engage in cartels such as market sharing and controlling. Such arrangements are normally regarded as anti-competitive by object because firms divide up markets mainly to protect themselves from competition pressure, costing the consumers more for less competitive products[36]. In the past cases, typical ways to avoid market competition and market division include price-

[34] Fourth Monitoring Report (n 31) 3
[35] Lundbeck Press Release (n 9) para 2; FTC, 'pay-for-delay: How Drug Company Pay-off Cost Consumers Billions' [2010} <http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf >accessed 18 May 2014
[36] Commission, 'Competition-Making Markets Work Better' [2013] <http://europa.eu/pol/pdf/flipbook/en/competition_en.pdf > accessed 18 May 2014

fixing[37], market sharing[38], bid rigging[39], etc. The Commission and the Court have consistently fined such behaviors heavily. Although undertakings may escape article 101 according to article 103 TFEU, true cartels like these have little chance of being exempted. Even for the technology transfer agreements, which are generally regarded as pro-competitive, the limitation of output and allocation of markets are not exempted by Block Exemption[40].

Should a suspicious pay-for-delay settlement bear similar effects to market division and avoiding competition, despite its novel appearance, it should be seen as a cartel in nature. However, in practice, the competition authorities need to answer: how can one differentiate this type of cartel pay-for-delay from others; and whether other types of pay-for-delay deals may bring anti-competitive effect.

2.5 Pay-for-delay cases in EU and US

This section will review the landmark cases in the EU and the US in order to demonstrate the common structure of a pay-for-delay deal in recent cases. From studying the change of view of the competition authorities, this section aims to analyse what makes a pay-for-delay deal anti-competitive from the current competition authorities' view and how the competition authorities and courts have tried to investigate such deals. Such analysis will facilitate the understanding of features of different pay-for-delay deals and how we should treat the different types of deal.

Table A. Summary of recent pay-for-delay cases in EU and US

Case Name	**Restriction on the generic's market**	**Form of value transfer**
Lundbeck[41] (EU)	➢ Delay market entry for the duration of the agreement, no guaranteed entry time. ➢ Main substance patent has already	➢ Monetary: Significant lump sum; Direct payment for buying stocks. ➢ Distribution agreement with

[37] *Calcium Carbide* (Case COMP/39.396) Commission Decision [2009] OJ C301/18
[38] *Power Transformers* (Case COMP/39.129) Commission Decision [2009] OJ C 301/18; *Prestressing Steel* (Case COMP/38.344) Commission Decision [2010] OJ C 339/7
[39] *Marine hoses* (COMP/39.406) Commission Decision [2009]
[40] Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements [2014] C 89/3 (Block Exemption Guideline)
[41] Case T-469/13 *Generics (UK) Ltd v. European Commission* [2013] OJ C325; *Lundbeck* (Case COMP/39226) Commission Decision [2013] no public version available yet

	expired. ➢ Process patent in dispute.	guaranteed profits.
J&J with Novartis [42] (EU)	➢ Delay market entry until a third party launches generic drug ➢ Main substance patent has already expired. ➢ No patent dispute.	➢ Monetary: monthly payments (exceeding the generic's expected profits accordingly). ➢ "co-promotion agreement".
Actavis[43] (US)	➢ Delay market entry until 65 months prior to patent expiry unless third party launches generic drug. ➢ FDA has already approved Actavis' generic drug. ➢ Main substance patent expired. ➢ Disputed main patent itself was a formulation patent[44].	➢ Monetary: yearly payment. ➢ Agreement enabling the generic to promote the originator's drug to doctors.
Cipro[45] (US)	➢ Delay market entry until the patent expires. ➢ Acknowledge patent infringement. ➢ Disputed main patent itself was a structural change to increase chemical potency.	➢ Monetary: lump sum payment.
Schering-Plough Corp[46] (US)	➢ Delay market entry for five years but before patent expiry. ➢ Disputed main patent itself was a formulation patent on unpatented substance[47].	➢ Monetary: payment as upfront loyalties and milestone payments. ➢ License agreement enabling the originator to market some of the generic's products.

Table A is a summary of the high-profile pay-for-delay cases appeared in EU and US, representing the previous and current views on such deals from the competition authorities.

[42] J&J Press Release (n 22)
[43] *Actavis* (n 8)
[44] *FTC and the State of California v. Watson Pharmaceuticals; et al*, [2009] para 39
[45] *Ciprofloxacin Hydrochloride Antitrust Litig*, 363 F. Supp. 2d 514 (E.D.N.Y 2005)
[46] *Schering-Plough Corp* (n 7)
[47] *Schering-Plough Corp* (n 7) 3

2.5.1 Pay-for-delay cases and their developments in the EU

The two recently decided cases in Europe are the *Lundbeck* case and the *J&J* case. Lundbeck was the inventor and manufacturer of a blockbuster antidepressant medicine Citalopram, the main substance patent of which has expired. The generic firms thus have fewer worries on infringing Lundbeck's main substance patent rights. However in 2002, Lundbeck agreed with each of these generic companies to delay the market entry of cheaper generic versions of Citalopram for the duration of the agreements without giving the generic producers any guarantee of market entry. In return, Lundbeck paid the generic firms with significant lump sums and bought out stocks of the generics involved. Lundbeck also offered the generic firms with distributor agreements with guaranteed profits. In 2013, the Commission imposed a fine of 93.8 million euros on Lundbeck and 52.2 million on the various generic firms involved. Although the public version of the Commission decision has not yet been published we can tell from the press release that the Commission holds that the parties have violated article 101 TFEU by agreeing not to compete, benefiting each other at the sacrifice of social health welfare and consumers[48].

Following *Lundbeck*, originator Johnson and Johnson was fined 10.7 million euros and Novartis as the generic involved was fined 5.9 million euros. In 2005, J&J's patent protection on the fentanyl depot patch expired in the Netherlands and generic firm Sandoz started preparing for launch of a generic version of the drug. Yet later the parties concluded an agreement to delay the market entry of the generic drug. In return Sandoz received monthly payments, which were said to be higher than its expected profits from its sales of the generic drug. The parties also signed a "co-operation agreement" where Novartis undertook to co-promote J&J's other products. According to the Commission's press release, no date of allowed market entry was noted. The agreement was terminated in 2006 when another generic firm brought their product to the market. The Commission concluded that the agreement(s) was anti-competitive and infringed article 101 TFEU because the parties, instead of competing, cooperated to avoid launching a generic of Fentayl, sharing the monopoly profits and bringing harm to consumers. The Commission pointed out that such intention of conspiracy was obvious

[48] Commission, 'Antitrust: Commission Sends Statement of Objections to Lundbeck and Others for Preventing Market Entry of Generic Antidepressant Medicine' [2012] IP/12/834

from the fact that J&J's subsidiary didn't consider other competitors but Sandoz for the "co-promotion agreement" and that Sandoz had only engaged in very limited co-promotion activities[49]. The Commission views the co-promotion more like a sham to cover the reverse payment and share of profits rather than a genuine agreement.

A third pay-for-delay case in EU is the *Servier* case[50] (currently pending). According to the press release on opening of formal proceedings, the French originator firm Servier invited generics to conclude settlement agreements, which could be aimed at delaying or preventing the market entry of generic versions of Perindopril. The action was a kind of "restrictive business practice" in violation of article 101 TFEU. As Servier is also a dominant firm in the relevant market, its purchase of key technologies of producing perindopril could be abuse of dominance and thus in violation of article 102 TFEU.

So far the cases objected by the Commission are not all straightforward cartel cases. In terms of restrictions on generic entry, both *Lundbeck* and *J&J case* imposed delay of generic product launching after expiry of the originator's main substance patent on the drug. In terms of value transfer, both cases included direct monetary payment together with other kinds of commercial agreements ("side agreements"). The payments were mostly considerations of these other kinds of agreements. According to the Commission's press releases, such deals are restrictive business activities in nature due to several conclusions:

1) The payments were aimed to bribe the generics, inducing the generic to refrain from competing on the market at the sacrifice of higher market price.
2) The side agreements were shams designed to cover the intention of the monetary payment. The amount of payments was excessive compared to the terms of side agreements.
3) The huge reverse payments show the originator's weak confidence in the disputed patent. The Commission thus had reasonable doubt on the validity of the disputed patents.

However, parties of both cases planned future appeals and claimed that the Commission misinterpreted the agreements. The key controversy is on the interpretation of the purpose of value transfer and the validity of the disputed patents. Lundbeck has

[49] J&J Press Release (n 22)
[50] Commission, 'Antitrust: Commission sends Statement of Objections on perindopril to Servier and others' [2012] IP/12/835

declared in its own press release[51] in response to the Commission's fine that the validity of its process patents on Citalopram was solid and never an issue. It claimed that the generics had acknowledged infringement on these patents in their internal documents. The reverse payment was legitimate consideration for the side agreement, which is just an additional outcome of a give-and-take settlement agreement. It is reasonable that firms with similar products are more likely to reach settlements and trade goods instead of go into litigations to make one party lose.

While details of facts have not been offered for in-depth discussion, two questions are prominent. The first is; whether the kind of deal explained by the drug manufacturers is acceptable under EU competition law. If yes, where is the line between an acceptable settlement and an anti-competitive pay-for-delay. The second is, how can we differentiate them from a competition authority's point of view?

2.5.2 Pay-for-delay cases and their developments in the US

In the US the debate on pay-for-delay cases starts from FTC's strong stance on the per-se illegal view in many cases. After some disagreements between the district courts, the US Supreme court finally made a ruling in the recent case *FTC v. Actavis*[52], which established that the proper approach towards pay-for-delay deals should be rule-of-reason.

2.5.2.1 Per se illegal or scope of patent

One of the early US cases on pay-for-delay was *Schering-Plough Corp . v. FTC* (*Schering-Plough*).[53] Schering, the originator company, paid generic companies Upsher with 60 million USD and EDI with 30 million USD. Upsher agreed to postpone their entry of a generic drug five years later but before patent entry. Meanwhile Schering was licensed to market various Upsher's products as a value transfer.

Initially the administrative judge held that both agreements are legal and reverse payment did not make the settlement anticompetitive per se. Later on appeal, the 11th Circuit amended the administrative judge's view, holding that reverse payment, as a part

[51] Lundbeck, 'Lundbeck Intends to Appeal the Decision from the European Commission' [2013] <http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=772307 >Accessed 16 April 2014
[52] *Actavis* (n 8)
[53] *Schering-Plough Corp* (n 7)

of the ancillary license agreement, did not make the settlement per se illegal. However, the court required the examination of the scope of the exclusionary zone of the patent; the extent to which the agreements exceed the scope and whether it results in actual competitive results. This ruling was named as "scope of patent" approach. The foundation is that patent itself is a monopoly power. Law permits such monopoly, so that researchers can gain financial reward to their work. But law also limit patents in a "zone of exclusion", so that after inventors have recouped their R&D investments, the knowledge can be shared for future development in the public domain. The Circuit court thus concluded that use of patent rights within that zone of exclusion is not an antitrust issue.

2.5.2.2 Further application of Scope of Patent

The *Schering-Plough* case was later followed by the *Cipro* case[54]. In *Cipro*, Bayer held a patent on the anti-biotic drug Cipro. In 1991, Barr applied for generic versions referring to Bayer's patent on Cipro. Bayer sued Barr but settled with 49 million of reverse payment. Barr undertook not to market the generic until the patent expired, and acknowledged that Barr had infringed a valid patent. The Federal Circuit court followed *Schering* case, holding that to establish the settlement agreement is illegal, and that the FTC should adopt the scope of patent test. Without additional anticompetitive restraints, reverse payment settlements of a genuine patent dispute are "within the exclusionary zone of the patent". And as patents shall be presumed valid until proven otherwise, this issue cannot be "redressed by federal antitrust law"[55].The Federal court also responded to the possibility that the patent dispute itself was a sham litigation. Even though the court recognized this as a potential issue, it stressed that the plaintiff mush show the lawsuit to be "objectively baseless", meaning no reasonable litigant could realistically expect success on the merits, and that the litigant's "subjective motivation" for bringing the action was a sham to conceal antitrust behaviours[56].

[54] *Ciprofloxacin Hydrochloride Antitrust Litig* (n 45)
[55] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 08-1097 (Fed. Cir. Oct. 15, 2008)
[56] Ibid, p 38.

This decision of the Federal court was consistent with views of the 2nd and 11th Circuits in various cases[57]. Yet the 6th Circuit court ruled on one pay-for-delay *Cardizem*[58] by using per-se illegal approach. The Federal Court responded in *Cipro* that the 6th Circuit reached this conclusion due to specific facts in Cardizem. In *Cardizem*, the restriction on the generic firm was clearly out of the scope of patent rights because there was not an issue of patent infringement from the generic firm. The generic firm promised not to market a non-infringing drug in that case. Till that point, the scope of patent test seemed to be widely applied by US courts.

2.5.2.3 The "quick look" rule-of-reason test

,Not all Circuit courts endorsed the scope of patent test. In a later private antitrust lawsuit in relation to *Schering-Plough*'s pay-for-delay deal[59], the 3rd Circuit court rejected the scope of patent test and applied a "quick look" rule of reason test.

The judge of the 3rd Circuit court noted that on history, the scope of patent test has never subjected a pay-for-delay case under antitrust law. Yet pay-for-delay agreements do have the potential effect of stifling competition. The court also challenged the previous presumption of the validity of patents in patent scope tests, stating that patent is not a substantive right of the patentee, but rather a procedural device. Thus the court applied a "quick look" rule of reason, which it deemed more appropriate. The test would subject patent settlements with reverse payment under antitrust law yet meanwhile comply with the public policy favouring settlements. The 3rd Circuit Court instructed that reverse payment in patent settlements should be deemed as a prima facie unreasonable restraint of trade, unless it could be proven that the reverse payment was for a purpose other than delaying market entry of generic drugs, or that the agreements offer pro-competitive benefits.

The decision of the 3rd Circuit court highlighted the potential anti-competitive effect of pay-for-delay deals and the flaw of scope of patent approaches in examining such potential. The split between circuit courts lead to anticipation on the US Supreme Court to review the pay-for-delay issue.

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[57] *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006); *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005); Valley Drug Co. v. Geneva Pharms. Inc., 344 F.3d 1294 (11th Cir. 2003).
[58] *re Cardizem CD Antitrust Litig.* 6th Cir 2003 332 F. 3d896
[59] *In re KDur Antitrust Litigation* 214, 686 F.3d 197 (3d Cir. 16 Jul. e2012)

2.5.2.4 *Actavis* and rule-of-reason test

In 2013, finally the *FTC v. Actavis* case[60] was appealed to the Supreme Court. Originator Solvay Pharmaceuticals holds the patent for its drug Androgel. Two generic firms Actavis and Paddock applied ANDA for the marketing of generic equivalents of AndroGel. Solvay then sued Actavis for patent infringement according to the Hatch-Waxman Act. The dispute lasted for three years. As the FDA is entitled to grant market permission after 30 months of patent settlement, Actavis obtained the market permission from the FDA during its patent dispute with Solvay. However, instead of launching the generic product with the market permit, Solvay and Actavis reached a settlement agreement where Actavis and other generics were restricted not to bring their generic drugs on the market until 65 months prior to the patent expiry, unless a third party launched the generic drug earlier. In return, the value transfer from Solvay included direct monetary payments and a license agreement enabling the generics to market and promote AndroGel to doctors.

The FTC then filed suit against all the parties involved, claiming that the parties violated antitrust law by refraining from competing and sharing monopoly profits. The 11th Circuit Court applied the scope of patent test and concluded that in absence of sham litigation or fraud in obtaining the patent, the restrictions imposed did not go beyond the scope of patents.

As with lots of other circuit courts, the 11th Circuit Court stressed the public policy support for settlements in general and noted that the parties should not be forced to finalize a patent litigation for the purpose of antitrust procedure. However the Supreme Court neither endorsed the 11th Circuits scope of patent test, nor FTC's per-se illegal rule, nor the quick look rule of reason test. The Court developed its own rule-of-reason test by a narrow margin between the majority and the dissenters.

Firstly, Supreme Court's opinions on *Actavis* reaffirmed that patent settlements should be weighted against antitrust law as well as patent law. Because the patents in dispute were ended by a settlement, it is unreasonable to answer the antitrust question by presuming the validity of the patent.

Furthermore, the Supreme Court pointed out the potential "genuine adverse effects on competition" that the restraints in pay-for-delay cases might cause, namely

[60] *Actavis* (n 8)

when a drug company pays off its competitor to be out of the market and divide the monopoly profit it might otherwise lose during the patent litigation[61]. While some of these restrictions in a settlement agreement might be justified, some are not. In cases where the restrictions are unjustified and brings anticompetitive harm, the size of the reverse payment is a strong indication of the patentee's power to realise these harms.

Thirdly, the Supreme Court stressed that the public policy in favour of settlements cannot immunise patent settlements from antitrust scrutiny. It is possible and common in patent settlements that reverse payment happens, for instance for the litigation expenses saved by the settlement or fair consideration for services provided by the originator. Those cases, according to the Supreme Court, may not intend to or have the consequence of antitrust effect[62]. But large amounts of reverse payment are still indicative of antitrust behaviour. The amount of the reverse payment shows the originator's financial power to charge high prices after the generic leaves the market, harming consumer welfare.

The court also suggested that the parties could settle in other ways to avoid sacrificing consumer welfare. If the originator offers generics entry into the market earlier than patent expiration, the generics are compensated with market profits, meanwhile competition and lower price is brought about.

Finally, the court explained its refusal to apply the quick look approach. The quick look approach should only be favored over the rule of reason when the arrangement in question is blatantly anticompetitive for people with limited economic knowledge. The court concluded this was not the case at hand. The likelihood of a reverse payment of anti-competitive effect is a complex issue, where the size of reverse payment should be compared to the anticipated future litigation costs, its independence from the other services provided by the generics and other possible justifications.

Without giving out detailed instructions on structure of a rule-of-reason test, the court leaves it for the future trial courts to carry out a fair and efficient assessment. Such uncertainty created by *Actavis* would possibly make it harder for the originators and the generics to settle disputes in the future[63].

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[61] *Actavis* (n 8) 15.
[62] *Actavis* (n 8)17
[63] 'PhRMA Statement on Supreme Court Ruling in Patent Settlement Case'[2013] < http://www.phrma.org/phrma-statement-on-supreme-court-ruling-in-patent-settlement-case> accessed 17 May 2014

2.5.2.5 Post *Actavis*

The years after the *Actavis* case still saw a rising amount of pay-for-delay deals[64]. Till now, the drug manufacturers are still carrying on reaching pay-for-delay deals. Boehringer Ingelheim, GlaxoSmithKline ("GSK"), Teva and lots of other top drug companies are involved in pending or recent pay-for-delay deals[65].

In January 2014, the district court of New Jersey dismissed a pay-for-delay case[66], which was later remanded by the 3rd Circuit court in light of Supreme court's opinion on *Actavis*. The district court nevertheless affirmed its dismissal, the reasoning of which is inspiring for the pay-for-delay debate.

Originator GSK and the generic Teva were sued by a third party for agreeing to delay marketing of generic drug of Lamictal ("*Lamictal*"). In return, GSK undertook not to launch an authorized generic version of Lamictal after Teva's entry to market. ("No-AG agreement") This means Teva will face less competition and therefore gain higher future profits. The plaintiff and the FTC deemed this as a reverse payment. However, the trial court pointed out that *Actavis* should only apply to patent settlement agreements that involve monetary reverse payment without justifiable reasons[67]. The Supreme Court especially noted that parties could settle in other ways than reverse payment, such as allowing earlier market entry for the generics. It should be respected that every settlement agreement would contain considerations and benefits to both sides, which is a fact that Actavis didn't change. Noting that no monetary sum was paid in *Lamictal*, and that the settlement agreements are all directly related to the Lamictal patents, the district court accepted the originator's No-AG agreement as a normal settlement condition.

In addition, the trial court judge also stressed that from *Actavis* it is clear that not all monetary reverse payments will lead to antitrust scrutiny since the Supreme Court rejected the per-se illegal approach and the quick look rule-of-reason. Instead, the "potential for genuine adverse effects on competition", depends on "the size of the

[64] FTC, 'FTC Study: In FU 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-delay Settlements to Keep Generic Competitors off the Market' <http://www.ftc.gov/news-events/press-releases/2013/01/ftc-study-fy-2012-branded-drug-firms-significantly-increased>, accessed 12 April 2014

[65] U.S PIRG, 'Top Twenty Pay-for-delay Drugs: How drug industry payoffs delay generics, inflate prices and hurt consumers' [2013] < http://www.communitycatalyst.org/doc-store/publications/top-20-pay-for-delay-drugs.pdf > accessed 1 April 2014

[66] *In re Lamictal Direct Purchaser Antitrust Litigation* (United States District Court of New Jersey 2014)

[67] Ibid 8.

payment, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification"[68]. After these considerations, it is up for the court to observe whether the parties to the agreements had market power and exercised it, whether the agreements brought anti-competitive consequences and whether reasonable justification exists to show the settlement was not intended to maintain supra-competitive prices or serve as a workable surrogate for a patent's weakness.

For the purpose of discussion, the court carried out the rule-of-reason test on to *Lamictal* in spite of its decision to dismiss the case. The court thus found that the No-AG agreement is not likely to bring anti-competitive effect due to its lack of large monetary payment and short period (six months in *Lamictal*). The court also found the payment could be justified. GSK, according to the court, saved litigation cost, took away the uncertainty of a patent dispute and gained benefits from Teva's licensed sales of its drug. The value of the No-AG agreement reflects the value of the aforementioned consideration fairly.

Its not surprising that Judge Walls' opinion remains controversial; it is criticized for being too formalistic on illustration of 'payment' and thus overlooks the economic effects. And some think that Judge Walls should not look for the intention of parties to retain supra-competitive prices but rather examine the effect that the No-AG agreement will bring about[69].

Despite all the criticism, it was clear from Walls' judgment that the court attempts to strike the balance between respecting the scope of settlements and prevent anti-competition harms. Also, the discussion on the scope of implementation of *Actavis* itself shows that the court doesn't regard all agreements containing delay of entry and value transfer anti-competitive per-se. The court carried out its own analysis to differentiate the *Lamictal* from *Actavis*.

The *Lamictal* judgment also mentioned two other decisions released post Actavis, *re Liptor*[70] and *re Nexium*[71]. Both decisions of the cases supported a wider

[68] *Actavis* (n 8)
[69] Carrier, Michael A., 'A US Court Issues Formalistic Ruling on Reverse-Payment Settlements After 'Actavis' (GlaxoSmithKline/Teva Pharmaceuticals/Louisiana Wholesale Drug Company/King Drug Company)' [2014] No. 63588, e-Competitions Bulletin, <http://ssrn.com/abstract=2395629> accessed 21 April 2014
[70] *In re Lipitor Antitrust Litigation*, No. 12-cv-2389 (D.N.J. 5 Sept 2013)
[71] *In re Nexium (Esomeprazole) Antitrust Litigation*, No. 12-md-02409 (11 Sept 2013)

interpretation of 'payment', claiming nothing in *Actavis* indicates the payment is confined to money. It could be expected that debates on implementations of Actavis in terms of 'payment' will carry on. This thesis will cover this main issue of Lamictal in the analysis of pay-for-delay deals.

2.5.2.6 Summary of US antitrust scrutinies on pay-for-delay deals

The antitrust scrutiny against pay-for-delay deals in US reflects the changing views on pay-for-delay deals' anti-competitive effect.

The FTC and district courts were originally on two ends of the debate. The FTC strongly accused pay-for-delay as being per-se anti-competitive. Yet the district courts mostly held that pay-for-delay was an issue arising from patent disputes. Since patents are legal monopoly rights, they are exempted from antitrust law, as long as the patent settlements are within the scope of patent granted by patent law.

From the 3rd Circuit's "quick look" rule of reason, where pay-for-delay agreements are presumed anti-competitive unless proven otherwise, some US courts started to recognize that even when a settlement seems within the scope of patent, they may have anti-competitive effects. Indeed, the patent offices may manage the patents prior and during patent issuance, but once a patent issues, it should be deemed the same as any other business property, which could be subject to harmful use[72].

The split between the circuits finally lead to the Supreme Court's judgment on *Actavis*, which rejected all the approaches previously used by the lower courts. As the author understands, *Actavis* established several crucial rules in dealing with pay-for-delay deals. Firstly, *Actavis* showed that not all settlement agreements involving limitations on generic entry and reverse payment are anti-competitive. It is the behavior of sharing monopoly profits to avoid losing monopoly power that is most anti-competitive. Secondly, some reverse payment may have fair reasons to exist as a natural outcome of a genuine patent settlement, for instance litigation cost or fair consideration for legal services. Both the per-se illegal rule and the quick look test would trigger too much unnecessary and strict antitrust scrutiny on those genuine settlement agreements. Furthermore, the *Actavis* judgment aims to analyse the real purpose of a reverse payment rather than investigating the validity of the disputed patent. By excluding fair

[72] Herbert Hovenkamp,(n 11)

consideration for saved litigation cost and service exchange in good faith, the unjustified reverse payments are read as a sign of confidence in the patent involved.

The unsolved problem is, in cases where value transfer from the originator is not straightforward cash payment but other benefits, to what extent may they be acceptable? To what extent may those value transfers become anti-competitive? The following sections will try to answer the questions.

3 Classifying and analysis of pay-for-delay settlements

3.1 Necessity of differing and classifying pay-for-delay settlements

Section 3 will further examine the anti-competitive effect of different types of pay-for-delay deals. First of all, this subsection will explain the necessity to classify pay-for-delay settlements, the several difficulties and considerations, and how the new method of assessing and classifying will serve the coming analysis.

It is obvious from the history of anti-competition scrutinises against pay-for-delay settlements in EU and US that such deals have complex variations and not all of them may be anti-competitive. Over-enforcement of competition law in pay-for-delay cases may eventually lead to higher amount of weak or invalid patents. Both originators and generics fear potential patent litigation. If prospect of reaching a settlement agreement is unreasonably challenged by competition law and potential fines, firms may simply refrain from entering the market in question. A new invention may be possible in this situation, yet at the cost of extra research time and possible failure of small firms. A classification and assessment approach is necessary to focus competition law scrutinise on the most dangerous pay-for-delay deals avoid such over-implementation.

The phrase "pay-for-delay" indicates that the value transfer is for the purpose of delaying generic market entry. However the realistic value transfers in such cases may serve some other or several different purposes. The amount of the value transfer may also bring about different effects to the market. These differences could be hard to tell because parties may try to disguise the deal into a superficially fair and genuine settlement agreement. Apparently according to the EU Commission, lots of the side-deal agreements are artificial only for the purpose of providing a reason for monetary payment[73]. Proper classification of pay-for-delay deals by their superficial features that

[73] 'Action brought on 30 August 2013—H. Lundbeck and Lundbeck v. Commission'(n 13)

reflect their level of potential anti-competition effect would make the investigations easier.

3.2 Consideration on classification of pay-for-delay

The classification of the pay-for-delay deals must take it into consideration that the anti-competitive issues of such deals are overlapped with scope of patent law and settlements, which competition law should give due respect to.

Neither absolute distrust nor reliance on patent system helps to solve the issue. It is not competition authorities' speciality to judge on the merit of an originator or a generic's patent, which is normally even highly complicated for the experts at the patent offices. In pay-for-delay deals, because the parties settled without a court decision is made on the patent dispute, there's no obvious proof showing that the originator's patent is weak or invalid nor that the side deal is designed to disguise the weak patent. If competition authorities delegate the examination of patent validity to patent office for the purpose of competition law, it will add extra time and financial burdens to the drug manufacturers expecting to recoup their sum costs. It will also deprive the parties' willingness to save litigation costs and exchange goods and services via settlements, causing extra transaction costs. However, as past cases prove, it is also improper to simply presume that a patent is valid before proven otherwise. Although the scope of patent forms the zone within which the right holder could exclude others from profiting from the patented invention, such monopoly is inherently restricted by law. Patent law not only need to ensure the economy recoup of inventors, but also a sufficiently abundant public domain for future inventions. It has been recognized that over protection of patents (through protection period or through protecting weak inventions) would burden the competitors with cost of asking for licensing or innovate around.[74] Overly respecting a granted patent may thus also harm innovation. In pay-for-delay situations, the merit of the patent is not proven before a court. And even when a patent itself is valid according to patent office, the use of it might still be anti-competitive

[74] Christopher R. Leslie, 'Antitrust and Patent Law as Component Parts of Innovation Policy' (2009) 34 The Journal of Corporation Law, 1259; 1262

according to previous cases. (for instance United states v. Singer Manufacturing Co.[75]) Patents cannot be exempted from competition law scrutiny.

Also, private settlements could be very different from court litigations. In a court, a decision is made on who wins the case and gets compensation. Similar situations may happen where the originator holds an undoubtedly valid patent and surely infringed by the generic. No value transfer is needed from the originator in this case and the generic should simply compensate and discontinue the infringement. However, it has been noticed that IP settlements often result in other forms, such as a license agreement[76], in which the licensor is acknowledged as the rightful proprietor of the patent. The licensor grants the licensee the right to produce and/or marketing. Good faith IP settlements as such are encouraged under various IP systems. Such value transfer facilitates launching of more products and will eventually stimulate dynamic competition. What competition law cares are those payments not genuinely for exchanging benefits but to induce competitors to delay market entry. However, due to the existence of large amount of good faith settlements, competition law cannot simply rule out and frustrate all the other good faith settlements.

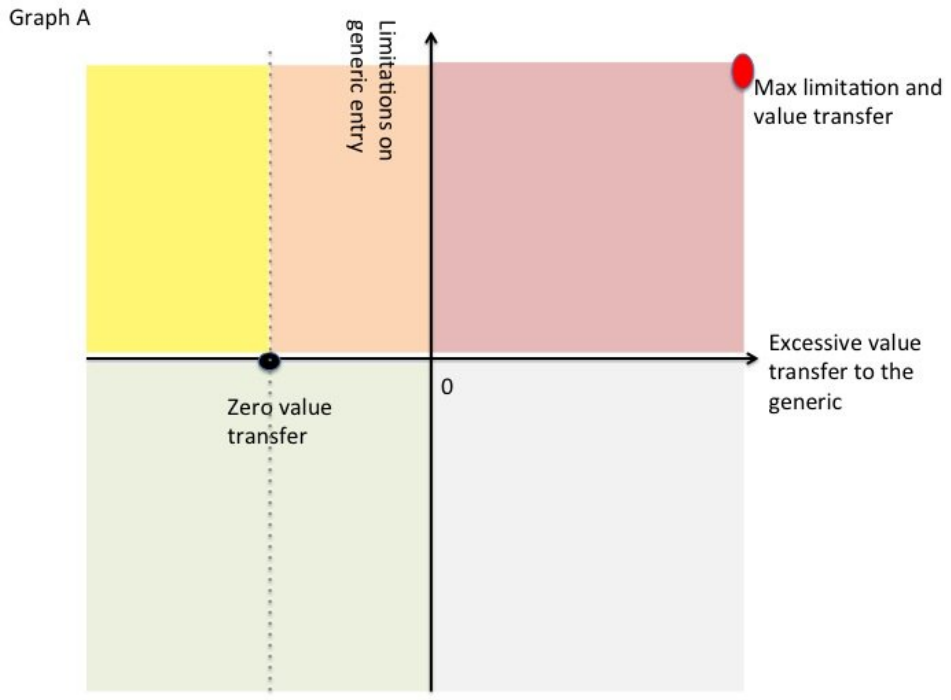
The new classifications thus will focus on analyzing the characteristics of a pay-for-delay deal rather than presuming the merit of the patent or that of the settlement.

3.3 Introduction of new classification method

This section introduces Graph A as the starting point of the classification. Graph A is based on the two factors mentioned by the competition authorities. It sets value transfer as the horizontal axis and limitations on generic entry as the vertical axis. Agreements with existing value transfer as well as limitations are in the red and orange areas, representing B.II. agreements as defined by the Commission. Agreements with limitations yet zero/negative value transfer to the generics fall into the yellow area, representing B.I. agreements. The same logic applies to the third and fourth quadrant of Graph A.

[75] *United States v. Singer Mfg. Co.,* 374 U.S. 174 (1963). In this case three firms settled their patent disagreements by assigning the broadest patent claims to the firm best able to enforce the patent against other competitors. Although the patent is valid by its merit, the using of the patent should be subject to US antitrust law. A simple scope of patent test would have overlooked such anti-competition effects.

[76] Herbert Hovenkamp, 'Antitrust and Patent Law analysis of pharmaceutical reverse payment settlements' [2011] <http://ssrn.com/abstract=1741162> assessed 22 April, 2014



Graph A is designed to facilitate understanding of different variations of pay-for-delay agreements. Agreements in each color block bear their own features and competition law concerns.

The simplest case of a pay-for-delay agreement would be the red point in the Graph ("Max limitation and Value Transfer"), where the generic is banned from launching its own version of the reference drug and the value transfer reaches the maximum price that the originator would reasonably be willing to pay (the amount of total profits that the originator would have gained without the market entry of the generic). For the purpose of analysis in this thesis, such cases are defined as '*Perfect pay-for-delay* scenarios'. Such an extreme case could illustrate the anti-competitive element of a pay-for-delay deal. (See Section 3.4.1)

3.4 Anti-competition risks of variations of pay-for-delay settlements

3.4.1 An extreme case: *perfect pay-for-delay*

Section 2.4 noted that pay-for-delay deals of cartel nature are anti-competitive

by object. Cartel agreements involving market sharing enable competitors to remain their respective highest profit by refrain from natural competition, leading to higher prices and harm consumer benefits.

A perfect pay-for-delay is such a case. Should the parties settle with genuine belief in the validity of the originator's patent, there wouldn't be a reason for huge amount of cash payment from the originator. Some sharing of litigation cost might occur, but only of a relatively small amount. The only logical reason of the payment is that it is an inducement for the generic to drop the challenge and refrain from competing with the originator. The parties here reached an agreement on profit and market allocating/output limitation[77], committing a cartel.

However, as it is shown in Table A, in practice, companies would hardly reach such a settlement. It simply seems too obvious for the competition authorities and too fragile to defend from. The following subsections will demonstrate why Graph A is a useful device for analysing pay-for-delay cases and what are the possible anti-competitive effects of other various kinds of pay-for-delay cases.

3.4.2 An Economic presumption on reverse payment – based on the amount of reverse payment

In the Orange and Red fields of Graph A, a pay-for-delay deal includes both restrictions on generic entry and reverse value transfer. As said, the key would be analysing the relationship between the two features; whether the generic's decision of not entering the market was a willingness decision based on the merit of its patents and the risk of losing a patent litigation, or on the inducement from the reverse payment.

Economists have suggested that the range of an originator's willingness to induce a potential generic competitor to stay out of the market is driven by the cost of losing its monopoly. We can imagine a situation where the originator is considering paying off a generic firm who challenged his patent. If M=total monopoly profit that an originator is expecting to gain based on the monopoly price prior to settlement; C= total profit gain if a generic succeed in challenging patent and entered the market; L = litigation cost; P^w=originator's estimated probability of winning; P^L=originator's estimated probability of losing

[77] Nicoleta Tuominen (n 5)

Then the originator's capacity to pay the generic to settle the case would be

$$X = M - P^{w} \times M + P^{L} \times (C-L)$$[78].

The two key driving elements in this equation are the value of *P* (either for winning or losing the case) and the value of (*M-C*). The more an originator is confident in wining a patent dispute (high P^{w}), the smaller is the value of X, meaning the originator has less to offer to the generic. Similarly, the smaller the price difference between M and C, the less will the originator have to offer.

So if other conditions remain the same, if an originator is willing to pay off a generic with excessively large amount of money, it means either the confidence in winning litigation is low (need to take the risk-aversion attitude into consideration too) or that the monopoly profit gain is too high to lose. Or both are true. Therefore, large amounts of reverse payment shows an originator's strong doubt on its disputed patent and motivation to form a cartel.

It is thus reasonable for the competition authorities to challenge a pay-for-delay deal with large reverse payments, which do raise a suspicion on one's intention to pay a generic challenger. But since the equation is based on the presumption that an originator aims to pay off the generic firm, we should look into the possibility that the presumption is not true. The large payment could be for other purposes. This is where the horizontal axis in Graph A comes into play.

3.4.3 Red or Orange area: high-risk and medium-risk pay-for-delay deals

3.4.3.1 Horizontal Axis

The horizontal axis will help the competition authorities to access the level of excessiveness of the payment and make a judgment on its association with the vertical axis (restrictions on generic entry). Five steps need to be taken to ensure a through examination.

Step 1. Understanding reasons for reverse payment

The first key question is what should the reverse payment be compared to. The author believes that the amount of the reverse payment should first be broken down into

[78] William Choi (n10)

the reasons behind the payments, the various services or agreements they claimed to be paid for.

Step 2.Examine the reasons for reverse payment

Secondly, a superficial examination on whether such services or agreements themselves are anti-competitive should be carried out. For instance, payment for settlement cost saved is rather common and normal for settlement agreements. Parties may or may not share such costs the same way a court would order them to do. Also, as said, settlements are different from court judgments; some value transfer between the parties is common and acceptable for the purpose of settling uncertainties. When neither party is actually fully confident in their patents, mutual benefit is the best way to avoid court litigation and potential patent infringement. Such agreements with redeeming virtues[79] may take the form of cash payments or some commercial agreements, the value of which could be a bit more than litigation cost. This should be recognized as the scope of settlement rather than anti-competitive by itself, their potential anti-competitiveness should be examined in the following steps.

Step 3. Examine effect of reverse payment

One should then evaluate the value of the causes of the reverse payment to see whether they are excessive to what is needed for each cause. For cost of the settlement, it will be relatively easy to estimate based on the patent and the drugs involved in the dispute. For any commercial side agreements, if the value of the services to be provided by a generic according to the agreements is disproportionately lower than the payment made, then the suspicion of pay-for-delay inducing strengthens due to the excessive payment.

The hardest issue is how much freedom should be left to the parties in order to agree terms of a settlement? To what extent are the parties allowed to benefit each other in a settlement?

In settlements certain restrictions and value transfers are an inherent result of the dispute resolution. For instance, non-challenge clauses in settlements impose restrictions on one party, but they are regarded necessary to resolve current disputes and avoid future disputes[80]. And license agreements, especially cross-licensing, are

[79] *Actavis* (n 8) 2236 and 2237
[80] Frank L. Fine, *The EC Competition Law on Technology Licensing* (Sweet & Maxwell 2005) 216

recognized as legitimate and common approaches to resolve patent disputes[81]. Thus the coexistence of value transfer together with restriction on a patent challenger is possible to be totally natural and without anti-competitive object. But the fact that such arrangements are a natural result of settlements doesn't protect them from competition law scrutiny.

When the mutual/reverse benefits go beyond what is necessary to settle a dispute, such arrangements put unreasonable restraints on one party. For example, the new Technology Transfer Block Exemption Regulation Guidelines[82] proposes that non-challenge clauses may be caught by Article 101 when the patentee knows the patent was granted with incorrect or misleading information or the when there's financial inducement from the patentee. The Commission and CJEU have also held in some intellectual dispute cases that agreements that simply aim for market partitioning or go beyond the necessity of avoiding confusion and would infringe article 81 (1) (Now article 101(1))[83]. Similarly, in a technology transfer context, while the licensor is allowed to discontinue the license once a licensee challenge the patent[84], such behavior could be subject to article 101 when the license is very valuable to the licensee. The right to discontinue differs from a contractual obligation or an inducement on the licensee to not challenge the validity of the patent.

So for the value transfers claimed to be within settlement scope (mostly, to avoid future uncertainty of the dispute, end current dispute, boost mutual benefits), they also need to be assessed on their power to impose obligation or inducement on the generics, and the actual restrictions imposed on the generic. It was even clear from the Commission's Monitoring report that some reverse payment maybe too small to cause further investigation[85].

As said in the beginning of the section, the more confident an originator feels about its patent, the less profit margin does it feel necessary to pay to the generic for no

[81] Herbert Hovenkamp,(n 11)
[82] Block Exemption Guideline (n 40)133
[83] Case C-35/83 *BAT Cigaretten-Fabriken GmbH v. Commission* [1985] OJ C 43/07
[84] Commission Regulation, No 316/2014 On the application of Article 101 (3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements [2014] OJ L 93/17, article 5
[85] Commission, *2nd Report on the Monitoring of Patent Settlements (period: January-December 2010)* [2011]<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report2.pdf> accessed 01 April 2014, para 35; Commission,3rd *Report on the Monitoring of Patent Settlements (period: January-December 2011)*
[2012]<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf> accessed 20 March 2014, para 33

reason. Originators could be requested to prove that the value transfers here would not be large enough to act as a disincentive to the generics from launching their own generic drug if they could. Thus any reverse payment that is larger than the estimated profits of the generic would have a hard time escaping competition law scrutiny.

Step 4. Examine implementation of side-deals

Considering that the parties may forge side agreements where the generic offers services of high value, it is also meaningful to investigated how much of the services on paper are actually carried out.

In J&J's press release[86], the Commission has mentioned that Sandoz actually carried out very little of the co-promotion activities according to their agreements, a sign of the reverse payment outbalancing the value of serviced provided. If investigation shows that actual businesses has been carried out as considerations for the payment during the term of the contract, the Commission could maintain supervision of the service provided to ensure that the agreement with the reverse payment is not a sham.

Step 5. Examine value of side-deals

After passing the afore-mentioned steps, would the net profit of the service agreement be so big that it may be regarded as a cash inducement? Is that going to be anti-competitive as well? The author believes that it is much less likely so. As said, lots of the reverse payments are larger than the estimated profit gain of the generic firms, which caught the Commission's attention. A well-performed good-faith contract, however, is much less likely to bring that amount of profit margin and serve the purpose of a inducement. Besides, the content of the service provided may bring certain pro-competition effects. Investigation should balance between the pro- and anti-competition effect of the whole deal. Side deals that are fully carried out and with fair considerations do not need to be further scrutinized as the excessive ones.

Finally, a new issue has risen from the new post *Actavis* cases. When there's no existence of side deals but only non-monetary value transfer from the originator, isn't it possible that non-monetary benefit have exactly the same effect as naked reverse payment? The judgment cannot be so rushed since we are in the context of settlement. If the value of the non-monetary profits is minimal and the generic acknowledge the patent validity of the originator, the non-monetary benefit might just be a substitute for litigation cost. However, as concluded in *Step 3*, if the value of the non-monetary value

[86]J&J Press Release (n 25)

transfer is large enough to become a suspicious inducement for the generic to leave the market, the parties should bear the burden of proof to object to that suspicion.

Conclusion

After the examination of the 5 steps above, if a reverse payment turned out to be excessive, such a pay-for-delay should fall into the red-area of Graph A ("the high-risk pay-for-delay"). This type of pay-for-delay is most likely to have been designed by the generic and the originator to share monopoly profits, as the large amount of reverse payment is found groundless or hugely disproportionate to side agreements. And the size of the reverse payment implies the power of the originator to buy off a generic, and its power to keep monopoly price for consumers.

If the reverse payment is not excessive, such pay-for-delay deals fall into the orange-area of Graph A, the medium-risk pay-for-delay, for which further investigation and analysis should be followed according to the next section.

3.4.3.2 Application of Vertical Axis

After an extensive examination on the value of the horizontal axis, now comes the vertical axis. What constitutes restriction in pay-for-delay deals has been introduced in section 2.4. The author suggests that all those mentioned forms of restriction, either explicit promise of market delay or non-challenge or other restrictions in agreements, should all be put above zero on the vertical axis. Restrictions imposed through agreements should be deemed less restrictive than non-challenges and explicit delay, as some of the restrictions may be inherent in commercial agreements and may bring about pro-competitive effects.

Similar with value transfer, the higher value of restriction that is imposed, the more should it be scrutinized by competition authorities.

When reverse payment is excessive based on aforementioned examination, the level of restriction shouldn't affect the initiation of competition law scrutiny. This is because, even if a clear restriction of market delay seems a much more dangerous sign than an acknowledgement of the originators patent, the latter could still be a false claimant, where the parties aim to design a pay-for-delay deal into an undisputedly clear patent settlement. Therefore where reverse value transfer is deemed excessive, the level of restriction showed on agreements is not the primary element for pay-for-delay investigation. They do, supplement or illustrate the conclusions drawn from the

horizontal axis analysis.

For the medium-risk pay-for-delay deals, the reverse payment could be the natural result of a genuine patent settlement. Thus the level of restrictions on generic entry should be further reviewed in detail to ensure the restriction is necessary and proportionate for the purpose of settling patent dispute and future certainty. For instance, clauses that simply acknowledge an originator's patent is probably the result of a genuine patent dispute. But to further restrict a generic in terms of its future product launching would be obviously beyond necessity. The generic is even restricted from launching non-infringing products in the future.

Extra restrictions outside the zone of intellectual property protection that do not have a real connection with the original IP dispute are also unlawful[87]. Such reasoning is also seen in the EU pay-for-delay cases. In the *J&J* case, the Commission stressed that the delay of generic entry and the co-operation agreement had nothing to do with any intellectual property matters[88]. Similarly, in Lundbeck, the Commission pointed out that besides the suspicious monetary value transfer, the restrictions on the generic firm were also unreasonably beyond the scope of the patent. Lundbeck didn't confirm whether the generic might enter the market without obstacles caused by Lundbeck. The anti-competitive effect of such cases should be assessed case by case in relation to the market power of the parties.

3.4.3.3 Conclusion on High-risk and Medium-risk pay-for-delay

In conclusion, by conducting a 5-step assessment, this thesis defines high-risk pay-for-delay deals as those agreements with excessive and unjustifiable reverse payment. On the contrary, Medium-risk pay-for-delay deals are those of non-excessive reverse payment, but potential anti-competition effects.

High-risk pay-for-delay (Red)

Where the reverse value transfer is excessive and unjustifiable, it is more likely that the value transfer was an inducement to the generic for purpose of late market entry. This is a sign of the parties' arrangement of market and/or production allocation with competitors, which is a cartel in nature. It is important that assessment on the excessiveness of the reverse payment should not only focus on the amount. Detailed

[87] Pat Treacy and Sophie Lawrance (n 22) 300
[88] J&J Press Release (n 25)

examination should be conducted on the basis of the reverse payments, the amount and excessiveness of such payments, and the performance of the side agreements.

Medium-risk pay-for-delay (Orange)

For those pay-for-delay deals without excessive reverse value transfer, they are much less likely to be of a cartel nature. The restrictions imposed on the generic are more likely to be necessary methods to exercise valid patent rights.

However, if the restriction is unnecessary and/or disproportionate for the purpose of settling patent dispute, medium-risk pay-for-delay deals may still have anti-competitive effect. The same rules should apply to medium-risk pay-for-delay deals with restrictions that do not have connection to the dispute.

3.4.4 Yellow area: low-risk pay-for-delay deals

Settlements involving restrictions on generic entry but without reverse value transfer fall into the yellow area in Graph A ("low-risk pay-for-delay deals"). Although these cases are not by definition pay-for-delay case, they were under discussion in the Commission's Monitor Report and may in very limited cases catch the attention of competition authorities.

Due to lack of reverse value transfer, pay-for-delay deals in this area are even less possible to become inducement cases compared to those in the orange area. The restrictions on the generic is most likely to be the result of a patent dispute where the generic indeed infringed the originator's patent and ended up acknowledging that fact. It was observable from the Commission's 4th Monitoring Report that in countries where pre-litigation settlements are requested by law, the number of settlement agreements of this kind is much higher than other member states.[89]

Such settlement agreements may be anti-competitive in the cases where the restrictions on the generics are beyond the scope of patent. This could either be the situation that the patent was valid but the restriction is beyond the scope of protection and the time period of the patent (See also Section 3.4.3.2), or that the originator knows or should know that the obtaining of the patent was a fraud due to misleading, incorrect or incomplete information during the application process (See also Section 3.4.4.1).

3.4.4.1 Blacklist: Sham litigation, Fraud in patent obtaining and naked

[89] 4th Monitoring Report (n 31) 4

pay-for-delay

Previous sections introduced a proposal to assess the suspicious pay-for-delay deals. In some cases, however, the pay-for-delay may include certain elements that make them anti-competitive by nature.

One underlying principle from cases in both the US and the EU is that sham litigations or naked pay-for-delay cases are anti-competitive in themselves. So are restrictions on competitors in the context of a patent granted through fraud. In all of the three situations, there's either no legitimate basis for restrictions on a competitor or the seemingly legitimate basis is forged or a fraud. And in lack of a solid reason to justify the restriction on competitors, the combination of reverse value transfer and delayed generic market entry become obvious sign of market allocation.

The term sham litigation was frequently mentioned in US pay-for-delay cases and consistently regarded as anti-competitive[90]. In the US, sham litigation is generally defined as cases where the right being asserted is so weak that no reasonable litigant would have brought the action and where such baseless litigation is used to 'conceal an attempt to interfere directly with the business relationships of a competitor'[91]. Thus the parties filed the action only to create a situation where the parties are invited to negotiate and settle. In the EU, sham licensing agreements aiming at concealing cartel behaviours are carved out from any safe harbours provided for by technology transfer agreement[92]. In the *ITT Promedia*[93] *case*, the Commission established two requirements to establish the existence of potential sham litigation; first, the action could not reasonably be considered as an attempt to establish the rights of the undertaking concerned and thus can only serve to harass the opposite party. Secondly, the action is conceived in the framework of a plan whose goal is to eliminate competition. Meanwhile, as undertakings should not be demotivated from claiming for their rights to be heard in court, the key is not whether the rights of the undertaking concerned were eventually found or not, but whether the undertaking could reasonably perceive such

[90] *In re Androgel Antitrust Litgation* (NO. II) 687 F Supp. 2d 1371, 1319 (ND Ga. 2010)
[91] *Professional Real Estate Investors, Inc. V. Columbia Pictures Industries, Inc.*, 508 US 49, 60-61 (1993)
[92] Van Bael & Bellis, 'Competition law of the European Community' in Van Bael & Bellis (ed), *Competition Law of the European Community* (Kluwer Law International 2009) 569
[93] Case T-111/96 *ITT Promedia NV v. Commission* [1998] ECR II-2937 para 55

rights at the time of initiating a litigation[94]. As long as a sham is proven, any other justification for the pay-for-delay behaviour would virtually become impossible.

If an undertaking obtained a patent through fraud, by giving misleading, incomplete or incorrect information, the exclusionary power of a patent monopoly becomes unlawful. Any restriction on a competitor based on such fraudulent patent is unreasonable and anti-competitive. And for the originators that are dominant, provision of fraudulent information to patent offices for the purpose of excluding competitors constitutes abuse of dominance. A notorious example is the *AstraZeneca* case. Originator AstraZeneca was found providing misleading information to patent offices in several countries to prolong the exclusivity period for their patent (SPC). As the fraud was later interpreted in light of AstraZeneca's other abusive behaviors, the Court concluded that the fraud aimed at delaying or preventing market entry[95], a new way of abusing dominant position.

In some cases, the parties don't even bother to fake a justification for the pay-for-delay deals. In the US, such naked pay-for-delay cases have been consistently ruled as anti-competitive by object.[96] In *FTCv. Warner Chilcott*[97], the drug of the originator Warner Chilcott was not patented. The generic Barr Laboratories later obtained market entry but didn't launch the generic drug. Instead, the parties reached a pay-for-delay agreement in 2004, in which Warner Chilcott paid Barr 1 million USD and made it their supplier. In return Barr agreed to delay market entry for five years. Without the exclusionary effect of valid patents and the potential safe harbour of scope of settlement, such pay-for-delay are no doubt intended to induce competitors into monopoly sharing of profits..

All the aforementioned three situations would put a pay-for-delay deal into anti-competitive category. However, investigation of the sham litigation and fraud in patent application are relatively hard to proceed. It is in the public's interest to encourage undertakings to claim their own rights even though they might fail. Technology firms who already bear the burden of providing patent application documents should not be punished for unintentional mistakes during the process.

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[94] Ibid para 73.
[95] Case C -457/10 P *AstraZeneca v. European Commission* [2010] OJ C 501/18
[96] Silvio Cappellari, "reverse payment settlement in the EU- Finding the right dosage" (2011) 7 Competition Law international 27
[97] *FTC v. Warner Chilcott Holdings CO. III, Ltd*., No. 05-2179 (D.D.C. Nov. 7, 2005))

3.4.4.2 Burden-of-proof

The burden of proof sets the general rule of who carries the proving process, but the standard of proof decides the real burden put on a party. Regulation 1/2003[98] stipulates that the burden of proving an infringement of article 101 rests on the party or the authority alleging the infringement. And the burden of proving that the conditions of article 101(3) are fulfilled rests on the party claiming the benefit. However, the regulation does not elaborate the standard of proof that the Commission needs to present. Generally, the standard of proof should be 'beyond reasonable doubt'[99].

Following from previous classification of pay-for-delay, the burden put on parties should vary for each type of pay-for-delay deal. It is the logical conclusion that when the pay-for-delay deal is of a less potentially harmful type, the Commission should put forward more factual evidence to establish the infringement.

This means it would be sufficient for the Commission to provide factual evidence to establish a prima facie blacklisted pay-for-delay or high-risk pay-for-delay. And it would be the undertaking's task to offer factual evidence to deny such infringement. If the undertaking fails to put forward such evidence, it should generally not benefit from article 101(3) TFEU.

For the medium-risk pay-for-delay deals, as such cases are less likely to be objectively anti-competitive, the Commission should offer more factual evidences and analysis to establish the anti-competitive effect beyond reasonable doubt. When an undertaking wishes to benefit from article 101(3) TFEU, it should be sufficient to prove the existence of pro-competitive factors. It would then be the Commission's task to conduct market analysis on whether such pro-competitive effect outweighs the anti-competitive effects. This however, does not mean the burden of proof on article 101(3) is shifted back to the Commission[100].

Such an arrangement is based on the logic that the more obvious that a case is anti-competitive, the less is needed for the Commission to illustrate the infringement. On the other hand, when the Commission cannot establish a blacklisted or high-risk pay-for-delay, the threshold of evidence providing shall be raised. This is avoids putting

[98] Council Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the EC Treaty [2003] OJ L 1/1

[99] Ioannis Lianos, Damien Geradin, 'Handbook on European Competition Law: Enforcement and Procedure' (Edward Elgar Publishing 2013) 500

[100] Case C 501/06P *GlaxoSmithKline Services v. Commission* [2009] para 100

too much burden on the undertakings so that they would not fear reaching a genuine settlement agreement.

3.4.5 Other factors influencing assessment of pay-for-delay

3.4.5.1 **The patent in dispute: substance or follow-on**

As it is introduced in Section 1.1, most originators try to protect their product with patent clusters. The substance patent protecting the active substance of a drug is generally well examined and solid. The originators would, however, file follow-on patents on the formulation, the concentration in dosage, forms and other features of the product. As these patents are often harder for patent officers to examine due to lack of relevant published information, not all of these patents could stand undoubtedly valid when challenged by generics. And as these follow-on patents are closely linked to the production of a product, they generally have very narrow scope, making it easier for potential competitors to circumvent.

Therefore the fact that the disputed patent is a follow-on patent does cast certain doubt on the validity on the disputed patent and the intention of the settlement. On the other hand, if the main substance patent on an originator's drug is in dispute, it is more likely that the dispute was genuine and the restrictions imposed on generic firm were not totally unreasonable. However, this factor could not be a starting point of an investigation because the competition authorities are not competent to judge the merit of the patents in dispute. Secondly, this factor should not become an absolute defence for the generics because the exercise of the patent right may still be anti-competitive, especially for those follow-on patents.

If a follow-on patent of an originator was indeed valid and a generic did infringe the patent, the parties are still possible to enter pay-for-delay agreements. Because the originator may fear that the infringing generic will have the resource and technology to invent around the narrow follow-on patent. Lundbeck stressed on its appeal that the generics has infringed the process patent and therefore the generics are not potential competitors. This defence, however, will not remove the potential anti-competitive effect when the pay-for-delay falls into blacklisted or high-risk category. The parties are potential competitors in this case since the originator feels the necessity and urge to

induce the generic to leave the market. If the pay-for-delay is of medium-risk and the originator claim that the follow-on patent was infringed, then the originator should only restrict the generic's use of the infringed patent. If the restrictions went beyond the patent at issue, the court should continue examine the effect of anti-competitive effect.

It is also possible that an originator had strong confidence in its follow-on patent upon the initiation of the settlement. As the discovery carried on, such confidence decreased, which motivates the originator to considering entering pay-for-delay agreements. The generic may defend itself by claiming it did genuinely fear that it had infringed the patent and therefore entered the settlement. While this could be a valid defense, the court needs to look at other evidences. If the pay-for-delay is of high risk, it is doubtful why the generic as the infringing party accepts the offer without anti-competitive objective. If the pay-for-delay is of medium risk, meaning the reverse payment is not excessive, and that the generic is able to prove its genuine belief in its patent infringement, then the pay-for-delay may not be caught by article 101 TFEU due to lack of mutual agreement. The originator may, however, be subject to article 102 TFEU if it suffices requirement of dominant firm.

To sum up, the validity of a follow-on patent may become a valid defense. It should nevertheless be assessed on a case-by-case basis.

3.4.5.2 Possibility of earlier market entry

Those who riposte to the Commission's strict stance towards pay-for-delay argue it is unknown in a pay-for-delay deal whether the generic entry could have been reached earlier. Because it is unclear whether the generic in question has the technology resources to enter the market to become a potential competitor, even in the absence of the financial inducement. Besides this uncertainty, cash payment may be the only acceptable option for the parties to settle[101]. Therefore pay-for-delay should be allowed when the generic doesn't show real ability to compete with the originator.

However, while it is true that competition law should not go too far into the scope of settlement, it doesn't mean that settlement agreements could be totally exempted from competition law. Not even when the reverse payment settlement is only one option.

[101] Sean-Paul Brankin, 'Patent Settlements and competition law: where is European Commission going?' [2010) 5(1) Journal of Intellectual Property Law & Practice 23

The fact that a generic may or may not become a competitor does indicate pay-for-delay deals should not be judged as per-se illegal. But uncertainty of the patent dispute does not take the doubt of cartel behaviour away. Instead, the more an originator gives a generic challenger excessive value transfer, the more serious does the originator take the generic as a potential competitor. Therefore, the uncertainty of the generic entry should not play too important a role in the analysis.

3.5 Proposals

The emergence of pay-for-delay behaviours is caused by mixed reasons, the regulatory framework supervising the pharmaceutical sector, the technology-intensive nature of the industry, certain flaws of the current EU patent system, etc.

The EU policy seems to mainly put the emphasis on using competition law to eliminate weak patents in the current system, correcting IP by competition law[102]. The aim of competition law however, should focus on preventing and altering the anti-competitive effect of such deals instead of fixing all the problems caused in other areas, such as the weak validity of a patent in itself. Because all firms should have the right to benefit from a granted patent[103], even if they may or may not be perfectly confident about gaining the patent upon filing. If a patent was wrongfully granted without the applicant's intentional fraud, the applicant shouldn't bear the fault of the patent office nor for its future legitimate exercise of that patent.

On the other hand, competition law should care about those firms knowing the patent was likely to be invalid and still exercise this right to exclude third parties (and sham litigation), or those committing fraud during application, or those who have made an excuse out of the patent right to pay off/restrict a competitor[104]. Competition law should act only in response to certain exercises of patent rights in suspicious situations. In unsuspicious situations, the battlefield of enhancing innovation and patent quality should be left for patent system, which protects the quality of patents through invalidity defence and declaratory judgment actions[105]. Otherwise, overly scrutinizing by

[102] Katarzyn Czapracka, *Intellectual Property and the Limits of Antitrust--a comparative study of US and EU Approaches* (Edward Elgar Publications, 2010) 36-91
[103] Kjolbye, Lars, 'Article 82 EC as remedy to Patent System Imperfections: Fighting Fire with Fire?' (2009) 32 World Competition 182
[104] Christopher R. Leslie (n 74) 1259
[105] Christopher R. Leslie (n 74) 1272

competition law authorities into patent rights may cause firms to lose trust in the patent system and patent dispute institutions.

Thus the starting point of solving the anti-competitive effect is to set up a monitoring system as well as a transparent, well-reasoned investigation process, rather than simply "intensify competition scrutiny [106] ". A monitoring system prior to competition scrutiny on settlement agreements between originators and generics should focus on the content and amount of the reverse value transfer (likely to be an excessive payment or not), the restriction imposed on the generic, and the status of the disputed patent (main substance patent or process patent). For the monitoring, parties could be requested to disclose certain relevant information after a settlement is reached. For the investigation and assessing process, any formalist approach may demotivate innovation or overlook anti-competitive behaviours. So an approach similar to the US "rule-of-reason" is more proper.

The improvement on quality of patents should be solved by the patent system. First, consistency among patent offices in different member states is important for boosting pharmaceutical firms confidence in the patent dispute system. Many have called for a single Community patent and an ad-hoc litigation system. The EPO has also started to "raise the bar" for patent applicants. Secondly, the procedure of patent dispute resolution should be more convenient to parties to avoid parties turning into settlements. One of the reasons that parties turn to settlements is that a court injunction might take long time and requires certain level of proofs.

The Executive Summary of the Sector Inquiry also mentioned a few other methods to ease the administration burden on originator firms so that they feel more secure about the profit gains from the launching of drugs. Such proposals included streamlining the marketing authorisation process and improving pricing and reimbursement provisions.

[106] Executive Summary (n 1) p 21

3.6 Summary

Some practitioners pointed out that objective anti-competitive restrictions should be restrictive by their very nature, which is either a conclusion based on past experience or through thorough analysis[107]. Pay-for-delay is not such a case.

The complex nature of these different situations decides that it is too strict and unreasonable to adopt a "per-se illegal"/"by object anti-competitive" views to all pay-for-delay deals. The different levels of competition law scrutiny they should receive are as follows. Pay-for-delay deals with the blacklisted features are most anti-competitive. Pay-for-delay deals accompanied with sham litigation, fraud in patent or naked pay-for-delay should be deemed anti-competitive by object. If no such blacklisted situations were found, a five-step examination would examine the excessiveness of the reverse payment and then divide high-risk pay-for-delay from medium-risk and low-risk ones. A pay-for-delay deal with excessive reverse payment means that the payment and the whole restriction to the generic had no legitimate ground to be "ancillary"[108] to the settlement. Among the medium-risk and low-risk deals, the examination of the restrictions on the generic firms and their necessity would help one to judge whether there existed unreasonable constraints to a competitor. Market power and the scope of the agreements should be taken into consideration to decide the anti-competitive effect of such agreements. Such a division of the pay-for-delay deals help to pick out those ones which are obviously outside the scope of settlements and intended to share monopoly profit (high-risk) from those within the scope of settlements but could be potentially restrictive to competition (medium-risk).

The author also objects to the Commission's remarks on the function of competition law to eliminate weak patents. Even though it is a problem of the patent system, it is better for competition law to remain passive until reasonable doubt of anti-competitive activities arises.

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[107] Romanno Subiotto, 'Legal Assessment of Patent Sttlement Agreements Containing "Reverse Payments"' (Fordham IP Conference, New York, 2013) <http://fordhamipconference.com/wp-content/uploads/2013/04/2013.subiotto.pharma.pdf> accessed 1 April 2014

[108] Herbert Hovenkamp (n 76)

4 Conclusion

In conclusion, those “pay-for-delay” deals that are anticompetitive are surely influential to its relevant market and stakeholders and competition authorities should take necessary steps to punish such behaviour. However, the issue of “pay-for-delay” is in the very heart of a conflict between the patent system, competition law authorities and the public policy of settlements. To avoid negative impact brought by over-implementing competition law, it is necessary to be aware of the nature and the scope of patent law and settlements.

The review of pay-for-delay cases in the US shows the modifications that US courts have strived for. The courts rejected the FTC’s per-se illegal rule and replaced with the “scope of patent” test, which overlooks the fact that such scope is not certain as the patent is in dispute. After a new “quick-look rule-of-reason” approach is introduced, which presumes a pay-for-delay to be anti-competitive with certain justification grounds, a split between the circuits arose. The landmark *Actavis* case symbolize the US Supreme Court’s realization that all the simplistic approaches brought up earlier are not sufficient for balancing the competition law concern and companies’ freedom to settle.

However, the *Actavis* judgement remains general, leaving it for the district court to conduct its own test. The author believes, as Europe has just started its competition law scrutiny into pay-for-delay, it is beneficial to learn from its US counterpart. This thesis agrees that a rule-of-reason approach would be appropriate and suggests a classification system based on the level of anti-competition risk of a pay-for-delay deal. The proposed classification system gives due respect to the scope of settlements and tries not to order the competition authority to intrude into the detailed contents of patents. Only the blacklisted and high-risk pay-for-delay deals should be able to be considered anti-competitive by object. Medium- and low-risk pay-for-delay could be subject to monitoring when necessary.

Finally, to offer a robust and innovative environment for the pharmaceutical industry requires not only competition law effort but also improvement of the consistency of patent system, the convenience of court process, and efficiency of national reimbursement systems to support the drug manufacturers.

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