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Contribution

By

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Activating Actavis in Europe – The Proposal of a
“Structured Effects-based” Analysis for Pay for Delay
Settlements

Activating Actavis in Europe - The Proposal of a “Structured Effects-based” Analysis for Pay for Delay Settlements

KEYWORDS: Pharmaceutical antitrust; pay for delay settlements; object/effect;
Europe

BACKGROUND

- Pay for delay settlements are at the centre of the European Commission’s enforcement agenda for the pharmaceutical sector.
- The European Commission found a restriction by object in its first pay for delay decision against Lundbeck
- The paper criticises this “object approach” and proposes instead a “structured effects-based approach” inspired by the FTC v Actavis judgment of the US Supreme Court.

METHODOLOGY

- A detailed comparative analysis highlights the differences between the US and EU regulatory regimes for pharmaceuticals and shows a decreased potential for anticompetitive effects in Europe.
- A doctrinal analysis of pay for delay settlements under Art. 101 rejects the use of an “object approach” that does not have to show anticompetitive effects and advocates for an “effects-based approach”.
- Based on a detailed legal analysis of the FTC v Actavis judgment of the US Supreme Court, the paper develops a novel “structured effects-based approach” to EU pay for delay settlements.

KEY FINDINGS

- The anticompetitive potential of EU pay for delay settlements is likely to be significantly reduced compared to their US counterparts.
- Pay for delay settlements should not be regarded as a restriction by object.
- It is possible to adopt the underlying rationale of the US Supreme Court judgment to the European framework.

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POLICY ISSUES

- This paper criticises the European Commission finding that a pay for delay settlement in the EU constitutes a “restriction” by object in general.
- Competition authorities should not apply a stricter test than is applied in the United States, if the anticompetitive potential of pay for delay settlements is decreased in comparison.
- Novel infringements of competition law should not be regarded as a restriction by object in order to avoid the punishment of benign or procompetitive conduct (false positives) – especially in the pharmaceutical sector.
- The proposed “structured effects-based” approach strikes the right balance between procompetitive nature of patent settlements and the anticompetitive potential of pay for delay settlements in Europe.
- The proposed test enhances the competition authorities’ procedural economy while avoiding over-enforcement.

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Activating *Actavis* in Europe – the Proposal of a “Structured Effects Based” Analysis for Pay for Delay Settlements

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Abstract

Striking the right balance between protection competition law and intellectual property rights is of utmost importance, especially in the pharmaceutical sector; affordable generic drugs are as important as new innovative drugs. Pay for delay settlements take place at exactly this intersection. They end patent infringement litigation but, at the same time, delay entry of generic drugs by means of a substantial payment from the brand company to the generic. Whereas, the US Supreme Court opted for a rule of reason approach which requires an analysis of the potential anticompetitive effects, the European Commission regarded such settlements as restriction by object, finding an infringement without the need for an effects-based analysis. This approach is criticised and a novel “structured effects-based” approach is proposed allowing the authority to effectively scrutinise such settlements while striking the right balance in order to protect the innovative process and the exercise of intellectual property rights.

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ACTIVATING ACTAVIS IN EUROPE – THE PROPOSAL OF A “STRUCTURED EFFECTS BASED” ANALYSIS FOR PAY FOR DELAY SETTLEMENTS

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Striking the right balance between protection competition law and intellectual property rights is of utmost importance, especially in the pharmaceutical sector; affordable generic drugs are as important as new innovative drugs. Pay for delay settlements take place at exactly this intersection. They end patent infringement litigation but, at the same time, delay entry of generic drugs by means of a substantial payment from the brand company to the generic. Whereas, the US Supreme Court opted for a rule of reason approach which requires an analysis of the potential anticompetitive effects, the European Commission regarded such settlements as restriction by object, finding an infringement without the need for an effects-based analysis. This approach is criticised and a novel “structured effects-based” approach is proposed allowing the authority to effectively scrutinise such settlements while striking the right balance in order to protect the innovative process and the exercise of intellectual property rights.

Introduction

Pay for delay settlements in the pharmaceutical sector are currently at the centre of attention of European competition law and policy. A pay for delay settlement is an arrangement between an innovating pharmaceutical company (brand company) and a generic pharmaceutical company (generic company), whereby the generic company agrees not to enter the market in return for a substantial payment from the brand company. This is often exceeds the profits the generic company would have made by entering the market. In other words, the brand company pays the generic company to stay off the market. On the one hand, this delay of entry based on the substantial payment from the brand company to the generic company is a major concern with regard to competition law and policy, as the conduct has the potential to foreclose the market for a certain drug and cause significant consumer harm. Originating from the United States, these settlements have therefore received extensive antitrust scrutiny. The Federal Trade Commission has in fact estimated that pay for delay settlements have delayed generic entry by an average of 17 months at a cost to the consumer of savings totalling US\$ 3.5 billion for the period of 2004 to 2009;¹ also affecting the affordability of potentially life-saving drugs.

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¹ Federal Trade Commission, *Pay-for-Delay: How drug company pay-offs cost consumers billions*. An FTC staff study (2010).

On the other hand, one has to remember that pay for delay settlements are patent settlements and that such settlements are generally regarded as a legitimate means to end patent infringement litigation. The brand company has obtained 20 years of patent protection as a reward for its innovation and patent policy permits the brand company to actively exclude other companies from using its innovation, which naturally includes defending its patents against infringement. Unduly intervention and ultimately restriction of the granted intellectual property right might stifle innovation which might lead to fewer innovative drugs in the long-run.

Although the existence of the intellectual property right should generally not get affected by competition law, its exercise and the exploitation of the intellectual property right in question that can be subject to competition law scrutiny.² Keeping both policy consideration in mind it is paramount to strike the right balance between the aims of competition policy in the pharmaceutical sector and brand company's right to defend its patents by means of patent infringement litigation and patent settlement. The aim has to be to ensure the maximum generic competition possible to ensure the affordability of drugs without jeopardising the innovative process leading to new drugs.

In the United States, following long and extensive scrutiny of pay for delay settlements by the US Federal Trade Commission (FTC), the US Supreme Court has finally addressed this balance its judgement in *FTC v. Actavis* on 17 June 2013.³ In this judgment the US Court adopted a "rule of reason" approach requiring to show the anticompetitive effects of a pay for delay settlement.

Just two days later, the European Commission handed down its very first decision to a pay for delay arrangement, imposing a fine on a brand company, Lundbeck, and a number of generic companies for delaying the market entry of a cheaper generic version of citalopram, an antidepressant drug, finding this conduct to be an anticompetitive agreement and thus an infringement of Art. 101 TFEU.⁴ The total of the fine imposed was in excess of €152 million. In subsequent decisions, the Commission imposed a fine of €16 million on Johnson & Johnson

² Luc Peeperkorn, 'IP Licences and Competition Rules: Striking the Right Balance' (2003) 26 World Competition 527, 531.

³ *FTC v. Actavis* 133 S.Ct. 2223 (2013).

⁴ European Commission, *Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines* (2013).

and Novartis for the delay of a generic pain-killer based on *Fentanyl*⁵, and a fine in excess of €427 million on Servier and five generic companies in relation to the delay of generic version of the blood pressure drug *Perindopril* in July 2014.⁶ In the case of *Lundbeck*, the parties have since appealed the decision to the General Court.⁷ Since these appeals, it has become evident that the European Commission has found the pay for delay settlement in *Lundbeck* to be a *restriction by object*, meaning that it treats the arrangement as an infringement, regardless of whether it actually has an anticompetitive effect. This is a lot less onerous on the authority than treating the arrangements as restrictions by effect, which requires it to establish actual anticompetitive effects. The European Commission therefore seems to have struck the balance between the competition policy and protection of the brand company's right to defend its patent far more in favour of competition law intervention than the US Supreme Court in *FTC v Actavis*.

This approach by the European Commission is criticised by this article. Yet, at the same time, this article also offers a solution to the problem, adjusting the balance without impairing the European Commission in its enforcement efforts in relation to pay for delay settlements that have anticompetitive effects.

Contrary to the belief in the lead up to the decision that the European Commission is only likely to be successful in its enforcement efforts when relying on a restriction by object,⁸ this article not just rejects this approach but proposes a novel "structured effects-based" test for an investigation of pay for delay settlements, which is inspired by the recent US Supreme Court judgment in *FTC v Actavis*.⁹ Following a cautious analysis of the rationale behind the US Supreme Court's judgment – taking into consideration the regulatory differences between the US and Europe – a novel structured effects-based analysis is proposed. The analysis of the *FTC v. Actavis* judgment and adapting it to the European framework is not just motivated by

⁵ European Commission, *Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl* (2013).

⁶ European Commission, *Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine* (2014).

⁷ *Case T-460/13 Ranbaxy Laboratories and Ranbaxy (UK) v Commission* [28 August 2013] OJ C 325/71; *Case T-472/13 H. Lundbeck and Lundbeck v Commission* [28 August 2013] OJ C 325/76; *Case T-470/13 Merk v. Commission* [30 August 2013] OJ C 325/74; *Case T-471/13 Xellia Pharmaceuticals and Zoetis Products v Commission* [30 August 2013] OJ C 325/75.

⁸ Pat Treacy and Sophie Lawrance, 'Intellectual property rights and out of court settlements' in Steven D Anderman and Ariel Ezrachi (eds), *Intellectual property and competition law: New frontiers* (Oxford University Press, Oxford ;, New York 2011).

⁹ *FTC v. Actavis* n (3).

the fact that it is a judgment of the highest judicial authority in the United States regarding pay for delay settlements. Furthermore, Alexander Italianer, Director General for Competition in the European Commission, has made the following statement in relation to the *Lundbeck* decision during a conference at the Fordham Competition Law Institute in New York City.

*'Incidentally, to those of you who are familiar with the Supreme Court's Actavis opinion, the factors taken into consideration by the Commission will sound familiar. Indeed, the Supreme Court looked at the same factors, in particular the size of the payment including as compared to the expected profits of the generic producer, and the lack of any other convincing justification.'*¹⁰

It should thus not be too far-fetched to consider the rationale behind the US Supreme Court's judgment in *Actavis* for the analysis of pay for delay settlements in the European context. This not only ensures that the approach of the European Commission is not overly restrictive, but also strikes the right balance with regard to the protection of the innovative process and the exercise of intellectual property rights.

This article is structured as follows. First, the regulatory differences between the US and the European pharmaceutical sector which need to be considered for the adaption of the US *Actavis* judgment to the European regulatory framework. It then examines the possible prevention or distortion of competition through pay for delay settlements. The notion that such settlements should be scrutinised as restrictions by object is rejected. The effects-based analysis then discusses and considers the US Supreme Court's judgment in *Actavis*, including the FTC's amicus curiae brief in *Effexor XR*, as possible sources of guidance. Following this discussion, a novel "structured effects-based" approach to pay for delay settlements is developed, which acknowledges the general need for patent settlements and, as such, is not considered to be over-inclusive. Finally, the article concludes providing policy recommendations for future investigations.

Regulatory differences between the US and Europe

¹⁰ Alexander Italianer, *Competitor agreements under EU competition law: 40th Annual Conference on International Antitrust Law and Policy, Fordham Competition Law Institute* (New York 2013) http://ec.europa.eu/competition/speeches/index_speeches_by_the_dg.html.

Although the above described pay for delay scenario should already raise concern, the potential for anticompetitive foreclosure by means of pay for delay settlements is heavily dependent on the pharmaceutical regulatory framework in place. It is therefore necessary to examine the differences between the US and European pharmaceutical regulations, before one can determine to what extent the rationale behind the US Supreme Court's approach to pay for delay settlements can be adopted in Europe.

The United States and the Hatch Waxman Act

In the United States the pharmaceutical sector is regulated by the so-called Hatch Waxman Act.¹¹ The purpose of this act is to incentivise generic companies to enter the market for a given drug prior to the brand company's patent expiry by challenging the validity of the brand company's patent. In theory this should ensure that only brand drugs based on valid patents benefit from the maximum patent protection. This challenge of brand patents by a generic company that intends to enter the market generally triggers patent infringement litigation between the two parties. In the context of this patent infringement litigation most of the pay for delay settlements take place.

According to the regulatory framework of the Hatch Waxman Act, the generic applicant can apply to the US Food and Drug Administration (FDA) for drug approval prior to the expiry of the brand company's patents but must notify the brand company whose drug it wants to market as a generic version about the application. The so-called 'Paragraph IV certification' has to mention every related patent that has been previously filed by the brand company in the FDA's so-called Orange Book, a register of all patents in relation to every brand drug that is registered with the FDA . This gives the brand company the ability to challenge the generic application on grounds of patent infringement.¹² The requirement for the FDA to consider the listed patents in the Orange Book therefore creates a so-called patent linkage. If the brand company decides to challenge the generic application, the FDA's decision on the generic approval is postponed by 30 months to enable the parties to resolve their patent dispute in court. Following this postponement, the FDA approval of the generic drug will be effective from the date on which: (1) the patent expires, (2) the court reaches a

¹¹ [XXX]

¹² C. S Hemphill and Mark A Lemley, 'Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act' (2011) 77 ANTITRUST LAW JOURNAL 947. 952.

decision on the non-infringement or patent invalidity in the patent litigation, or (3) the 30 months from the date of notification have expired,¹³ whichever comes first.¹⁴ Under normal circumstances, the court's judgment should have either declared the patent invalid, enabling generic applicants to enter the market because they no longer have to obey this patent, or declared that the patent had not been infringed by the generic applicant leading to the start a period of 180 days of generic exclusivity. This exclusivity period was introduced by the Hatch Waxman Act with the intention to provide the first generic applicant with an incentive to incur the risk of patent infringement litigation and the costs that are associated with it.¹⁵ During this period of generic exclusivity, the FDA is not allowed to grant any further generic drug applications. After this period, as many generic companies as are willing to enter the market may do so simultaneously.

Pay for delay settlements are, however, able to skew these incentives in favour of the parties to the settlement and to the disadvantage of the final consumer. As mentioned above, the 30-month stay triggered by the FDA's approval decision of the generic application for market authorisation should allow the parties to litigate the patent infringement. Instead, the parties settle their patent infringement dispute. The generic company is nonetheless granted the 180 days of generic exclusivity, as the generic exclusivity is linked to the filing of the first generic drug approval application with the FDA and *not* to successful litigation.¹⁶

Because the initial patent infringement lawsuit has not been concluded by means of a judgment, but rather by means of settlement, the start of the 180 day exclusivity period is set to the date of actual generic entry, which has been stipulated by the parties in the settlement agreement. In doing so, the parties can control and delay subsequent generic entry, as the FDA is not allowed to grant further generic drug approvals until the 180 generic exclusivity has elapsed. If the generic applicant agreed not to enter the market until 180 days prior to patent expiry, the brand company's patent monopoly is effectively unchallengeable for the entire duration of the patent life, as the generic exclusivity functions as a regulatory

¹³ Federal Trade Commission, *Generic drug entry prior to patent expiration: A FTC study* (2002). 41.

¹⁴ Phillip E Areeda and Herbert Hovenkamp, *Antitrust law: : an analysis of antitrust principles and their application* (2. ed. Aspen Law & Business, New York, NY 2013). ¶2046c1

¹⁵ Elizabeth S Weiswasser and Danzis Scott D. 'The Hatch-Waxman Act: History, Structure, and Legacy' (2003) 71 ANTITRUST LAW JOURNAL 585. 603.

¹⁶ Herbert J Hovenkamp, Mark D Janis and Mark A Lemley, 'Anticompetitive Settlement of Intellectual Property Disputes' [2003] 87 Minnesota Law Review 1754.

bottleneck.¹⁷ In return for this delayed entry of the first-filing generic company, the brand company typically compensates the generic applicant with a payment that is ideally larger than the estimated profits of the generic company.

In terms of patent law, this effect could be described as turning the rebuttable presumption of validity into effectively a non-rebuttable presumption, allowing the brand company to obtain a guaranteed legal patent monopoly. However, receiving a patent is not equivalent to an entitlement to exclude every competitor. The patent holder can only try to exclude its competitors and the probability of success is based on the strength of the patent itself.¹⁸

In 2003 forfeiture rules were introduced to the Hatch Waxman Act which now allow subsequent generic competitors to overcome this bottleneck, yet the process is still very lengthy, causing considerable delays. This forfeiture forces the first generic applicant to start using its generic exclusivity or risk losing it, if a later-filing generic applicant wins its own patent lawsuit. However, the lawsuit has to be won in front of an appellate court.¹⁹ If this is the case, the first generic applicant has to start using its generic exclusivity within 75 days.²⁰ So, in order to overcome this regulatory bottleneck the generic company would have to file an ANDA application, win a patent lawsuit, win the appeal of this patent lawsuit, wait 75 days for the first-filing generic company to start using its generic exclusivity and then wait another 180 days until it can enter the market. This process can easily endure for several years and therefore can delay subsequent generic by a significant amount.

In conclusion, a brand company can use a pay for delay settlement to foreclose the market itself until the generic exclusivity of the generic company that has entered into the agreement has expired. It also shields its patents from being challenged by any potential competitor, thereby guaranteeing a legal monopoly. This outcome that might be within the technical boundaries of patent rights but, at the same time, contradicts fundamental patent policy. The patent settlement itself is not based on the validity of the patent and the probability of success of getting the validity confirmed by a court's judgment. Rather, it is

¹⁷ Hemphill and Lemley (n 13) 963.

¹⁸ Carl Shapiro, 'Antitrust limits and patent settlements' (2003) 34 *Rand J. Econ.* 391. 395.

¹⁹ Michael A Carrier, 'Unsettling drug patent settlements: A framework for presumptive illegality' (2009) 108 *Michigan Law Review* 37, 48.

²⁰ *ibid.*

based on a payment by the brand company to the generic company which reflects, at least the estimated profit of the generic company if it were to have entered the market.

Europe

In contrast to the US regulatory framework of the Hatch Waxman Act, the European regulatory framework lacks most of the “US factors” that facilitate market foreclosure. Firstly, the European drug safety regulators that approve brand and generic drugs and grant market authorisations do not take economic factors into consideration, such as patent rights of the brand company. Under EU law, such a patent linkage is not permitted. The relevant EU Regulation states that

*‘In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, **to the exclusion of economic and other considerations.**’(emphasis added)²¹*

This approach to pharmaceutical regulation in Europe is not only reflected in further secondary legislation²² but also in the European Commission’s pharmaceutical sector inquiry where it was found that no other criteria apart from those regarding public health - such as the safety, the quality, and the efficacy of the relevant drug - should be taken into consideration when deciding upon the application for a market authorisation.²³ If it should be the case, that a market authorisation for a generic version of a drug interferes with the patent status of the originator drug, the issue should be resolved by means of private patent litigation in front of competent courts. The patent protection for a drug is an important issue for the pharmaceutical company, but is dealt with separately from the safety and efficacy of the drug.

Secondly, the European regulation does not provide a framework similar to the Hatch Waxman Act. Similar to the US, the generic applicant does not have to pursue the same

²¹ Regulation (EC) No. 726/2004 of the European parliament and of the council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (2004). Recital 13.

²² *ibid.* Art. 81; Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (2001) OJ L 311 Art. 126.

²³ European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009) 130.

lengthy application procedure as the brand company but can rely on an abbreviated application procedure.²⁴ However, there is no difference between the first filing applicant and any subsequent generic company that decides to enter the market prior to patent expiry. Due to the missing patent linkage, the European framework has not created a bottleneck similar to the FDA. The relevant agency is not prevented from approving several generic drugs prior to patent expiry. Yet every generic entrant runs the same risk of being sued for patent infringement by the brand company which might occur separately to the approval process. For this reason, it is also not necessary to incentivise the first filing generic applicant with a period of generic exclusivity, as this applicant is not the only party that can challenge the validity of the brand company's patents that cover the drug in question. As a result the European drug approval regulation does not automatically create a type of temporary duopoly without potential for further entry within the market for a specific drug simply by granting the first market authorisation.

As a consequence, it is only possible for the brand company to secure duopoly profits for a certain period of time, in return for payment to the first generic entrant, if the number of possible generic entrants is very limited. For example, if only one of the potential generic entrants has the necessary financial power to take the risk of being sued for patent infringement, it would be a viable option to pay off this competitor.

However, if several potential competitors are equally strong or equally willing to take the risk of possible patent infringement litigation, the viable options for the brand company to achieve market foreclosure become more complex. Although it has been suggested that paying off multiple entrants at the same time might even be cheaper than paying off just one competitor due to the price development of the drug in question after the market entry of multiple generic versions of the drug,²⁵ generic companies should have an incentive to disguise their intent to enter to the last minute and therefore enter sequentially instead of simultaneous. This would force the brand company to enter into agreements with each of the generic entrants in turn, which would increase the brand company's cost for market foreclosure significantly.

²⁴ *Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use*, Art. 10 (1).

²⁵ Michael Kades, 'Whistling Past the Graveyard: The Problem with the Per Se Legality Treatment of Pay-for-Delay Settlements' (2009) 5 *Competition Policy International* 142, 158.

The incentive for the brand company is to retain its monopoly for a certain drug, despite sharing the profits with the first generic entrant who has agreed not to enter the market. A subsequent generic entrant is therefore still likely to have the same incentive to enter the market as the first generic entrant – to gain its share of the monopoly. However, every paid of potential generic entrant brings the brand company one step closer to market foreclosure. Thus the brand company's payment to the generic competitor to achieve foreclosure should increase with every further generic company being paid off, with the last potential generic entrant being the most expensive to be paid off.

However, a pay for delay settlement could be a viable option to foreclose the market, if the market in question is less diverse than anticipated. If this should be the case, the actual structure of the relevant pharmaceutical market could prove an influential factor when deciding whether or not to enter into a pay for delay settlement, in addition to factors relating to market value and the national pharmaceutical regulations of the Member State in question.

Fundamentally, the fewer generic companies are able to enter the market, the more likely foreclosure of the market by the incumbent becomes. If only a few generic companies are capable of entering "at their own risk" prior to patent expiry despite a large number of generic companies being present in the pharmaceutical sector as a whole. In fact, this might be the case in the European Commission's proceedings against the French pharmaceutical company Servier and its recent decision against Lundbeck.²⁶ The Commission has sent a statement of objections to Servier and a number of generic companies taking the view that 'patent settlement agreements between Servier and the generic companies were aimed at delaying or preventing the market entry of cheap generic versions of perindopril'.²⁷ In *Lundbeck* the European Commission has imposed a €152 Million fine on Lundbeck and a small number of generic companies because of the delay of generic entry of citalopram.²⁸

Keeping these important differences between the two regulatory frameworks and their impact of the potential for anticompetitive foreclosure in mind, this article turns now to

²⁶ European Commission (n 5).

²⁷ European Commission, *Antitrust: Commission sends Statement of Objections on perindopril to Servier and others* (2012).

²⁸ European Commission (n 5).

the discussion whether European pay for delay settlements should be regarded as restrictions by object or rather effect.

Pay for delay as restriction by object

Under European competition law, Art. 101(1) TFEU is only infringed if the agreement has as its 'object or effect the prevention, restriction or distortion of competition within the internal market'. Indeed, the question of whether a pay for delay settlement is to be regarded as an infringement by object or by effect is one of the core issues to determine. These two are alternative requirements and should be read disjunctively.²⁹ The answer to this question determines the level of proof that the European Commission needs to satisfy in order to find an infringement. Agreements that are a restriction by object always fall within the scope of Art. 101(1) TFEU without the need for the European Commission to take into account the actual anticompetitive effects of the agreement. Restrictions *by object* are those that, by their very nature, have the potential to restrict competition within the meaning of Article 101(1).³⁰

*'These are restrictions which in light of the objectives pursued by the Community competition rules have such a high potential of negative effects on competition that it is unnecessary for the purposes of applying Article [101(1)] to demonstrate any actual effects on the market. This presumption is based on the serious nature of the restriction and on experience showing that restrictions of competition by object are likely to produce negative effects on the market and to jeopardise the objectives pursued by the Community competition rules.'*³¹

Although an agreement can be restrictive by object, even if its object is not solely anticompetitive but also serves legitimate aims,³² it is according to the Court of Justice now settled case law that '*regard must be had inter alia to the content of its provisions, the*

²⁹ Case 56/65 *Société Technique Minière v Maschinenbau Ulm GmbH* [1966] ECR 337. p.249

³⁰ C-209/07 *Competition Authority v Beef Industry Development Society Ltd* [2008] ECR I-8637. para.17.

³¹ *Guidelines on the application of Article 81(3) of the Treaty* (OJ [2004] C 101/97). para. 21.

³² C-551/03 *General Motors BV v Commission* [2006] ECR I-3173. para. 64.

objectives it seeks to attain and the economic and legal context of which it forms a part'.³³ If these factors are considered, it is sufficient to show that the conduct in question is merely capable of resulting in the prevention, restriction, or distortion of competition within the relevant market.³⁴ Furthermore, there is no requirement to consider whether the potential negative effect on competition will deprive the final consumer of competitive advantages in terms of supply and price.³⁵

Where an agreement is found not to be a restriction by object, the European Commission has to conduct an extensive analysis of the restrictions by effect on the market, which is a much more onerous task.³⁶ The effects need to be established in the context of factual and legal circumstances which cause it to prevent, restrict or distort competition.³⁷

With regard to pay for delay settlements, it has been argued that such settlements should be regarded as restrictions by effect and not by object, as they are by their very nature settlements of patent litigation.³⁸ It is generally accepted that settlements are a legitimate means by which to end disputes, especially in patent litigation which is costly and time-consuming.³⁹ Further consideration has been given to the fact that the settlements concern patents which constitute exclusive rights that entitle the holder to exclude infringing products. It would therefore be difficult to categorise such settlements as restrictions by object.⁴⁰ Furthermore, a large number of settlements identified in the pharmaceutical sector inquiry were found not to restrict generic entry into the market; some even had procompetitive features,⁴¹ and only a minority gave rise to competition concerns.⁴² It seems that these considerations led the European Commission to state in its final report that,

³³ *C-501/06, C-513/06, C-515/06 and C-519/06 GlaxoSmithKline Services and Others v Commission and Others* [2009] ECR-I 9291. para.58 citing *Joined Cases C-96/82 to C-102/82, C-104/82, C-105/82, C-108/82 and C-110/82 IAZ International Belgium and Others v Commission* [1983] ECR-I 3369. para.25 and *C-209/07 Competition Authority v Beef Industry Development Society Ltd* [2008] ECR I-8637. para. 16 and 21.

³⁴ *Case C-8/08 T-Mobile Netherlands and Others* [2009] ECR I-4529. para. 31

³⁵ *Case C-501/06 P, GlaxoSmithKline Services and Others v Commission and Others* [2009] ECR I-9291.

³⁶ Richard Whish, *Competition law* (7th edn Oxford University Press, Oxford 2012). 120

³⁷ *Case 23/67 Brasserie De Haecht v Wilkin* [1967] ECR 407. p. 415; *Case C-234/89, Delimitis v Henninger Bräu* [1991] ECR I-935. para.14

³⁸ Mark van der Woude, 'Patent Settlements and Reverse Payments Under EU Law' (2009) 5 *Competition Policy International* 182.

³⁹ European Commission (n 24) para 707.

⁴⁰ Treacy and Lawrance (n 9) 293.

⁴¹ European Commission (n 24) para 750, 751.

⁴² *ibid.* para 743.

'any assessment of whether a certain settlement could be deemed compatible or incompatible with EC competition law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background'.⁴³

However, in spite of the abovementioned consideration and the European Commission's quoted statement from its final report of the pharmaceutical sector inquiry - suggesting the application of an effects-based analysis - does not guarantee that the Commission is not opting for a "by object" analysis after all. Despite having proclaimed the more effects-based approach to Art. 101 TFEU for more than a decade in its regulations and guidelines,⁴⁴ the European Commission has framed 17 out of 18 infringement decisions since January 2000 in "object" terms.⁴⁵ The underlying reason for this kind of approach is likely to be based on strategic considerations, as it is a lot easier to bring a successful case when there is no requirement to show the anticompetitive effects of an agreement. The European Commission regularly justifies this approach by stating that an "object" restriction should not be seen as a "per se" style infringement as in the United States. Even an "object" restriction would allow for justifications which make the presumption a rebuttable one. Yet it has been correctly stated that such an argument is only valid if a rebuttal is a *'reality rather than a theoretical possibility'*.⁴⁶ Although the European Court of Justice has previously considered that object restrictions should be theoretically open to justification, it has *'never in recent memory overturned a finding that they were not'*.⁴⁷

⁴³ *ibid.* para 1530.

⁴⁴ *Commission Regulation 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements ; Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements ; (n 32); Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements ; Commission notice - Guidelines on Vertical Restraints ; Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices ; Commission Regulation 2659/2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements ; Commission Regulation 2658/2000 on the application of Article 81(3) of the Treaty to categories of specialisation agreements ..*

⁴⁵ Damien M Gerard, 'The Effects-Based Approach Under Article 101 TFEU and its Paradoxes: Modernisation at War with Itself?' in Jacques Bourgeois (ed), *Ten years of effects-based approach in EU competition law: State of play and perspectives* (Bruylant, Bruxelles op. 2013). 38..

⁴⁶ Alison Jones, 'Left behind by modernisation? Restrictions by object under Art. 101 (1)' (2010) 6 *European Competition Journal* 649. 663.

⁴⁷ Gerard (n 46). 40.

In fact, the European Commission did revert to this modus operandi in its *Lundbeck* decision – the first European decision in relation to pay for delay settlements. This became apparent on 9 November 2013, when a number of generic companies and Lundbeck itself appealed the decision to the General Court, arguing that the European Commission had committed a manifest error of assessment by finding that the pay for delay settlement constituted a restriction of competition ‘by object’.⁴⁸

Earlier this year, the European Commission then published its *Lundbeck* decision. With regard to its finding of a restriction by object the European Commission started by citing extensively the recent *Allianz Hungaria* judgment including the reference to the *T-mobile* judgment where the Court held that

*‘in order for the agreement to be regarded as having an anti-competitive object, it is sufficient that it has the potential to have a negative impact on competition’.*⁴⁹

This finding arguably set a lower standard for restriction by object as it no longer referred to the ‘sufficient’ harm to competition but the mere potential to have a negative effect and has already lead at the time of the decision to the criticism and anxiety concerning the creation a too broad category of restriction by object. In addition, the European Commission also relied on the General Court’s judgment in *Groupement des Cartes Bancaires* where it was held that the restriction to competition must be serious yet not obvious.⁵⁰ Although the statement referred to the legal and economic context that needs to be considered in the analysis, it arguably broadens the scope of restrictions by object. Interestingly, the European Commission did not, at least explicitly in the decision, put forward the argument that Lundbeck’s conduct was outside the scope of competition on the merits by using the settlements as a means to game the regulatory system

⁴⁸ *Case T-460/13 Ranbaxy Laboratories and Ranbaxy (UK) v Commission* [28 August 2013] OJ C 325/71; *Case T-472/13 H. Lundbeck and Lundbeck v Commission* [28 August 2013] OJ C 325/76; *Case T-470/13 Merk v. Commission* [30 August 2013] OJ C 325/74; *Case T-471/13 Xellia Pharmaceuticals and Zoetis Products v Commission* [30 August 2013] OJ C 325/75. The European Commission also found a restriction by object in another pay for delay case against Johnson & Johnson and Novartis, however this decision has not been appealed. European Commission (n 6).

⁴⁹ *Case C-32/11 Allianz Hungária Biztosító and Others, judgment of 14 March 2013*. para 38 citing *Case C-8/08 T-Mobile Netherlands and Others* [2009] ECR I-4529. para 31 (emphasis added).

⁵⁰ *Commission Decision of 19 July 2013 (Case AT.39226 - Lundbeck)* OJ C (2013) 3803 final. para 651 citing *Case T-491/07 Groupement des cartes bancaires v Commission, judgment of 29 November 2012*. para 146 "With respect, firstly, to the argument of the applicant that the measures in question do not contain any obvious restriction of competition, it needs to be recalled that Article 81, paragraph 1, does not refer to the notion of obvious restriction."

akin to its findings in AstraZeneca. In fact, the term “competition on the merits” is not mentioned once in the entire decision.

Yet, with the European Court of Justice’s judgment in *Groupement des Cartes Bancaires*, the European Commission’s task to defend their reasoning that pay for delay settlements constitute a restriction by object has become a lot more difficult if not insurmountable.⁵¹ First and foremost, the Court set aside the General Court’s judgment in its entirety due to the erroneous assessment of the law raising the bar for the finding of a restriction by object – arguably reinstating old principles initially established by the Court.⁵² The Court held that that the notion of restriction by object should be interpreted narrowly, requiring the display of evidence for a “sufficient degree of harm” to competition so that the agreement in question “can be regarded by [its] very nature as being harmful”.⁵³ Furthermore, the Court made reference to the *experience* with regard to the anticompetitive effects of price fixing; echoing Advocate General Wahl’s opinion where he proposed that

‘only conduct whose harmful nature is proven and easily identifiable, in the light of experience and economics, should therefore be regarded as a restriction of competition by object, and not agreements which, having regard to their context, have ambivalent effects on the market or which produce ancillary restrictive effects necessary for the pursuit of a main objective which does not restrict competition.’⁵⁴

In light of the aforementioned, the European Commission should generally resist the temptation to regard pay for delay settlements as restrictions by object. The European Commission does not yet have successfully defended a number of pay for delay settlements based on similar economic reasoning which could count towards the “experience” with

⁵¹ Case C-67/13 P *Groupement des cartes bancaires v Commission*, judgment of 11 September 2014 ..

⁵² James Killick and Jeremie Jourdan, ‘Cartes Bancaires: A Revolution or a Reminder of Old Principles We Should Never Have Forgotten?’ [2014] Competition Policy International p 6. The Court not just cited [at para 49, 50] the established case law of STM and BIDS in support for the “sufficient degree of harm” and the “very nature of the agreement being harmful” but at the same time omitted any direct citation to the more recent judgment in C-8/08 *T-mobile* and C-439/09 *Pierre Fabre* which arguably set a lower standard in relation to the finding of a restriction by object.

⁵³ Case C-67/13 P *Groupement des cartes bancaires v Commission*, judgment of 11 September 2014 . para 50.

⁵⁴ Case C-67/13 P. *Opinion of Advocate General Wahl in Groupement des cartes bancaires v European Commission* [. 27 March 2014]. para 56.

regard to the anticompetitive effects of such settlements. Even if one would interpret *experience* widely, taking into consideration the experience of the US authorities, one has to keep in mind that the anticompetitive potential of pay for delay settlements in Europe is likely to be reduced when compared to the United States. As has been mentioned earlier, there does not exist in Europe a regulatory bottleneck akin to the Hatch Waxman Act, which facilitates market foreclosure. Despite this increased anticompetitive potential in the United States, the US Supreme Court has nonetheless dismissed the FTC's proposition to apply a "quick look" analysis, by which pay for delay settlements would have been regarded as presumptively illegal. The quick look approach was regarded as inappropriate because of the complex nature of the conduct and the possibility of convincing justifications. Instead the US Supreme Court opted for a rule of reason approach, acknowledging the ambivalent nature of pay for delay settlements. The European Commission should thus opt for a similar approach; so far it has not yet successfully defended its pay for delay decisions on appeal which could count towards experience, nor are the anticompetitive effects of pay for delay settlements obvious and uncontested.⁵⁵

This leads to an additional factor that needs careful consideration. Regarding pay for delay settlements in Europe as restrictions by object also increases the potential for Type I errors and over-enforcement, due to the novel nature of the competition law infringement. Depending on the actual definition of pay for delay settlements, patent settlements with a value transfer from the brand company to the generic company which are followed by the exit of the generic company from the market could fall foul of Art 101(1) TFEU. Such a payment could, however, be perfectly reasonable. It might settle litigation costs or may constitute a payment for services rendered by the generic company.⁵⁶ An indicator for anticompetitive conduct could be the level of the payment. However, such an evaluation cannot take place for object restrictions. The different factors that need to be taken into account are too manifold to regard such conduct as a restriction by object without any experience. Based on the novelty of the infringement and the associated inexperience one should also reject a potential countervailing argument that the level of analysis in the object category has been raised by the ECJ in recent judgments, suggesting a market structure

⁵⁵ [XXX]

⁵⁶ [XXX]

inquiry in the context of object cases.⁵⁷ Such an analysis of market structure would assist in determining the actual anticompetitive potential of the pay for delay settlement, as mentioned above, but it would not account for any potential justification of the value transfer from the brand company to the generic, failing to deal with the propensity to over-enforcement and the creation of false positives. This issue and more generally the capacity building of enforcement experience in the area can only be achieved through an effects-based analysis.

Two exceptions to this general rule could nonetheless be considered. One is the case when the agreement clearly exceeds the scope of the patent; for example, when the agreement prevents the generic company from entering the market after the protection of the relevant patent has elapsed. This type of conduct has also been accepted as being anticompetitive by the US jurisprudence prior to the US Supreme Court's decision in *Actavis*.⁵⁸ The second exception could be a situation in which the parties are aware of facts that would remove the uncertainty regarding the outcome of patent litigation to the point at which the European Commission would no longer have to second-guess the validity of the patent at issue. One possibility could be the discovery of internal documents that provide evidence that the patentee was aware of patent's invalidity.⁵⁹ In such a scenario would not have to rely on any past experience in relation to the anticompetitive effects, as the anticompetitive purpose and the very nature of the agreement becomes apparent, which justifies the finding of a restriction by object. Apart from these noted exceptions, pay for delay settlements should not be subjected to a "restriction by object" analysis.

Pay for delay as restriction by effect

In light of this finding, this section therefore analyses pay for delay settlements by employing an effects-based approach. After having set out the basic principles of such an analysis based

⁵⁷ When determining [the] context [in which a restriction by object is considered] , it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question *Case C-67/13 P Groupement des cartes bancaires v Commission, judgment of 11 September 2014* para 53 citing *Case C-32/11 Allianz Hungária Biztosító and Others, judgment of 14 March 2013* para 36.

⁵⁸ *FTC v. Actavis* n (3).

⁵⁹ Bill Batchelor, 'EC tones down its final report into the pharma sector, but ramps up enforcement activity' (2010) 31 *European Competition Law Review* 16; Treacy and Lawrance (n 9) 293.

on the European Commission's relevant guidance papers and the relevant case law, the section addresses what has so far been regarded as the major legal issue of an effects-based analysis of pay for delay settlements; namely, the need to evaluate the validity of the underlying patent. Acknowledging this legal issue, it will be established whether the US Supreme Court's judgment in *Actavis* can be used as guidance to overcome this hurdle in the European context, as the Supreme Court addressed the very same issue – the antitrust scrutiny of pay for delay settlements without an inquiry into the validity of the underlying patent. Following a detailed description of the US judgment, the remainder of this section develops a novel structured effects-based analysis inspired by the rationale of the US Supreme Court's judgment in *Actavis* that circumvents this issue of patent validity, without being over-inclusive with regard to patent settlements that lack a value transfer from the brand company to the generic company.

Determining whether an agreement amounts to a restriction by effect requires proof of the likely negative impact of the agreement on inter- or intra-brand competition. According to the European Commission's Guidelines, the agreement:

'must affect actual or potential competition to such an extent that on the relevant market negative effects on prices, output, innovation or the variety or quality of goods and services can be expected with a reasonable degree of probability'.⁶⁰

In order to find that an agreement has an actual or potential anticompetitive effect, the European Commission must determine whether the parties to the agreement have a degree of market power and whether the agreement contributes to the strengthening or maintenance of this market power.⁶¹ This requires the consideration of the economic and legal context in which the agreement takes place.⁶² In addition, the Guidelines also provide

⁶⁰ (n 32). para. 24.

⁶¹ *ibid.* para. 25.

⁶² *Cases T-374/75, 384, 388/94 European Night Services v Commission* [1998] ECR II-3141. para. 136; *T-328/03, O2 (Germany) GmBH & Co OHG v Commission* [2006] ECR II-1231. para. 66

for a counterfactual analysis, questioning whether the restriction to competition would not have existed without the agreement.⁶³

This counterfactual analysis has so far posed the question of what the outcome would have been without the settlement agreement. Treacy and Lawrance argue that this would require the assessment of the probable outcome of the settled patent litigation and, thus, an estimation of the strength of the litigated patent.⁶⁴ Such an inquiry by the European Commission would not only pre-judge the finding of specialist patent courts,⁶⁵ but would also be inherently difficult. The European Commission would only be able to infer generic entry but for the pay for delay, if the disputed patent is weak. The definition of “weakness” also raises difficulties as the European Commission would have to decide at which probability of success the companies would have to refrain from settling.⁶⁶

These considerations and arguments are not unique to the European context. The very same issues had to be addressed by the US Supreme Court in its *Actavis* judgment. The following subsection therefore discusses the US judgment itself in order to establish whether inspiration can be drawn from Supreme Court’s analysis.

FTC v Actavis and the FTC’s amicus curiae brief in Effexor XR

This section discusses the recent US Supreme Court decision in *Actavis* and the Federal Trade Commission’s (FTC) amicus curiae brief in *Effexor XR*, in which the FTC argues that the *Actavis* rule should be extended to non-cash payments as a form of value transfer. Drawing conclusions from the judgment and the amicus curiae brief might help to develop a European approach to pay for delay settlements.

In *Actavis*, the US Supreme Court for the first time examined the legality of pay for delay settlements. The FTC had applied for writ of certiorari, the petition for judicial review by the US Supreme Court, in earlier pay for delay settlement cases but the US Supreme Court

⁶³ (n 32). para. 18; *Case C-234/89, Delimitis v Henninger Bräu* [1991] ECR I-935. para. 23; *T-328/03, O2 (Germany) GmbH & Co OHG v Commission* [2006] ECR II-1231. para. 68

⁶⁴ Treacy and Lawrance (n 9) 295.

⁶⁵ *ibid.*

⁶⁶ *ibid.* 298.

had refused to grant it until the present case.⁶⁷ The reason for the Supreme Court's change of heart was the fact that the Federal Trade Commission managed to create a so-called "split circuit". This refers to a situation where several circuit courts come to different decisions on the same issue. In the case of pay for delay settlements, the split was achieved between, on the one side, the Second Circuit,⁶⁸ Eleventh Circuit⁶⁹ and Federal Circuit⁷⁰ who essentially applied the so-called "scope of the patent" test and, on the other side, the Third Circuit⁷¹ who treated pay for delay settlements as "presumptively unlawful". According to the "scope of the patent" test,

*'absent sham litigation or fraud in obtaining the patent, a pay for delay settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.'*⁷²

The finding that pay for delay settlements should be immune from antitrust liability was based on the assumption that such liability would undermine the patent incentive and would stifle innovation.⁷³ Additionally, the courts stressed the general importance of the settlements, especially in patent infringement litigation.⁷⁴ The only noted exception under which the court has to consider the patent's validity in an antitrust analysis is in the case of fraud in front of the patent office or in the case of sham litigation. In the event of such conduct, the agreement's restrictive effect on competition would be regarded as beyond the exclusionary scope of the patent.⁷⁵

⁶⁷ *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008), cert. denied, 129 S.Ct. 2828 (2009).

⁶⁸ *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005).

⁶⁹ *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008).

⁷⁰ *Federal Trade Commission v. Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012).

⁷¹ *In re K-Dur Antitrust Litigation* 686 F. 3d 197 (3d Cir. 2012).

⁷² *Federal Trade Commission v. Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012). 1312.

⁷³ *Valley Drug Co. v. Geneva Pharmaceuticals, Inc* 344 F.3d 1294, (11th Cir. 2003). 1311 & n.2, affirmed in *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005). 1065-66.

⁷⁴ *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005). 1072-73; *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008). 1333.

⁷⁵ *In re Ciprofloxacin Hydrochloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008). 1336; *Valley Drug Co. v. Geneva Pharmaceuticals, Inc* 344 F.3d 1294, (11th Cir. 2003). 1308 & n.21; *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005). 213; *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005). 1068.

The Third Circuit expressly rejected the “scope of the patent” test, holding pay for delay settlements to be a *prima facie* unreasonable restraint of trade. The Court based this finding on a number of reasons. First of all, it rejected the notion that the statutory presumption of validity in patent law is a substantive right of the patent holder; rather, it constitutes a procedural device that puts the burden of proof on the party that is challenging patent validity.⁷⁶ Furthermore, pay for delay settlement cases do not concern patent validity but rather patent infringement, in which case the burden of proof is on the patent holder – hence, the argument based on the presumption of validity is misguided.⁷⁷ Secondly, the Court emphasises that

*“the public interest [...] is dominant in the patent system and [...] the right to challenge [a patent] is not only a private right to the individual, but it is founded on public policy.”*⁷⁸

This public policy consideration on which not only vital for a efficient patent system but also with regard to the Hatch Waxman Act, which is aimed at providing incentives to increase competition in the pharmaceutical sector through patent challenges by generic companies. The Court directly quoted congressional statements made in relation to the Bill which underlines the intention of Congress to provide consumers with cheaper generics by encouraging generic companies to challenge patents that they regard as weak or invalid.⁷⁹ This public policy consideration is undermined by the “scope of the patent” test.⁸⁰ Following these considerations, the Court remanded the case and directed the District Court to:

*‘apply a quick look rule of reason analysis based on the economic realities of the pay for delay settlement [regarding a reverse payment] as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.’*⁸¹

⁷⁶ *In re K-Dur Antitrust Litigation* 686 F. 3d 197 (3d Cir. 2012). 214.

⁷⁷ *Ibid.*

⁷⁸ *Ibid* 216.

⁷⁹ *Ibid* 217.

⁸⁰ *Ibid.*

⁸¹ *Ibid* 218.

The US Supreme Court's majority decision written by Justice Breyer, however, rejected both propositions, the scope of the patent test and the quick look rule of reason approach and instead struck the middle-ground, ruling that a full rule of reason analysis would be appropriate in the case of pay for delay settlements.

The decision strongly dismissed the "scope of the patent" test. First of all the Court accepted the 11th Circuit's finding that the agreement's 'anticompetitive effects fall within the scope of the exclusionary potential of the patent',⁸² but it disagreed with the suggestion that this fact could also 'immunize the agreement from antitrust attack'.⁸³ It further indicated that patent and antitrust policy are both relevant in determining the "scope of the patent monopoly" – and consequently antitrust immunity – that is conferred by a patent.⁸⁴ Yet, with regard to pay for delay settlements which according to the FTC tend to have significant adverse effects on competition, the "scope of the patent" test simply refers to what the holder of a valid patent can do and does not answer the antitrust question. The Court therefore found that:

*'it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy rather than by measuring them against procompetitive antitrust policies as well.'*⁸⁵

At the same time, the Court rejected a "quick look" analysis proposed by the FTC which would have been based on a presumption of illegality. The Court cited its decision in *California Dental* and held:

*'that abandonment of the "rule of reason" in favour of presumptive rules (or a "quick look" approach) is appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on consumers and markets.'*⁸⁶

⁸² *Federal Trade Commission v. Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012) 1312.

⁸³ *FTC v. Actavis* n (3) 2230.

⁸⁴ *Ibid* 2231.

⁸⁵ *Ibid* 2230-31.

⁸⁶ *Ibid* 2242; quoting *California Dental Ass'n v. FTC* 526 U.S. 756 (1999). 770.

Applying these findings to the case at hand, the Court decided that the criteria for a “quick look” analysis of pay for delay settlements had not been met, as the likelihood of anticompetitive effects arising from pay for delay settlements depends on a number of factors such as ‘[the] size [of the payment], its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.’⁸⁷ The Court opted for a full rule of reason analysis because of this complexity.

A full-scale rule of reason analysis traditionally requires definition of a relevant market, proof of market power and the existence of anticompetitive effects, meaning the existence of a restraint that threatens to reduce output or increase prices without being justified by efficiencies or some other redeeming virtue.⁸⁸ The burden of proof in a rule of reason analysis is on the plaintiff. However, the Court determined at length the level of evidence the plaintiff would have to provide in order to satisfy the burden of proof.⁸⁹ It found that because of the circumstances surrounding pay for delay settlements the plaintiff would only be required to provide more abbreviated proof than normally required by a rule of reason analysis⁹⁰ – thereby also addressing the question of how to evaluate the antitrust concern without having to rule on the relevant patent’s validity. The Court found that this kind of abbreviated proof was sufficient in relation to market power as well as the anticompetitive effect of pay for delay settlements.

Addressing the market power issue the Court found that the

*‘size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator for power – namely the power to charge prices higher than the competitive level’.*⁹¹

⁸⁷ Ibid 2242.

⁸⁸ Herbert J Hovenkamp, ‘Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision’ (2014) 15 Minnesota Journal of Law, Science and Technology 3, 6.

⁸⁹ *FTC v. Actavis* n (3) 2234-7.

⁹⁰ Ibid 2238.

⁹¹ Ibid 2236.

A firm without such power would not be likely to pay ‘large sums to induce others to stay of the market’.⁹² This finding is based on the rationale that, in a competitive market, the incentive of keeping a competitor out of the market should be close to zero. In a highly competitive market, price-cost margins are very low and this situation cannot be improved by keeping competitors out of the market.⁹³ However, this incentive rises with the increase in price-cost margins. A firm with market power typically enjoys high profit margins and therefore has an incentive to defend these by excluding competitors from the market.⁹⁴ In the case of a time-limited monopoly, such as patents, the rational patentee would pay no more than the anticipated monopoly return over the remaining period of patent protection.⁹⁵ Thus the level of market power is a function of the size of the payment made to the generic - The bigger the size of the payment, the higher the market power.

Furthermore, the Court also noted that the size of the payment can also be an indicator for the anticompetitive harm caused by the pay for delay settlement and can act as *‘a workable surrogate for a patent’s weakness’*.⁹⁶ According to the Court, it was therefore also unnecessary to evaluate the validity of the patent itself as part of the rule of reason analysis. It agreed with the FTC that the rationale behind a payment of this size cannot in every case be traditional settlement considerations.⁹⁷ It should rather be seen as evidence that the patentee is not confident in the strength of the patent in question and seriously doubts that it would prevail in patent litigation.⁹⁸ According to the Court, a settlement in such a situation reduces the extent or likelihood of competition. The Court also indicated that a small reduction of likely competition is sufficient by stating that:

*‘the owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.’*⁹⁹

⁹² Ibid.

⁹³ Aaron Edlin and others, ‘Activating Actavis’ (2013) 38 Antitrust Health Care Chronicle 16.

⁹⁴ Ibid.

⁹⁵ Hovenkamp (n 89). 24

⁹⁶ *FTC v. Actavis* n (3) 2236.

⁹⁷ Ibid 2233.

⁹⁸ Ibid 2236.

⁹⁹ Ibid.

Nonetheless, the Court conceded that payments might reflect legitimate settlement considerations, such as avoiding litigation costs or attaining fair value for services provided. Yet this possibility should not prevent the FTC from scrutinising the settlement. Ultimately, a district court should be able to examine the size of the payment, its likely anticompetitive effects and its potential justifications in the future.¹⁰⁰

Judging by these considerations, it is possible to set out the following test to determine whether a pay for delay settlement restricts competition:¹⁰¹

- (1) The plaintiff has to prove that the relevant payment to the generic company is large by:
 - a. Valuing the consideration flowing from the patentee to the alleged infringer, and
 - b. Deducting the avoided litigation costs for the patentee.

If this net payment is positive it may be understood as a *prima facie* restriction of competition by means of delaying entry.

- (2) The defendant then has the burden of proof for showing that this net payment can be explained as payment for services or goods rendered by the alleged infringer to the patentee as part of the same transaction.

In the wake of the US Supreme Court's judgment in *Actavis*, the Federal Trade Commission has now sought to extend the *Actavis* rule to non-cash payments. In recent months, the FTC has filed two amicus curiae briefs; one in the District Court for the district of New Jersey,¹⁰² and one in the District Court for the eastern district of Pennsylvania.¹⁰³ Both cases concern patent settlements between a brand company and a first-filing generic company that do not involve pay for delays in monetary terms but rather in terms of non-cash contributions for the generic company. The respective brand companies agreed as part of the settlement not to launch an authorised generic version of the brand drug during the period of generic

¹⁰⁰ Ibid.

¹⁰¹ Edlin and others (n 94). 17, 18

¹⁰² Lead case no.: 3:11-cv-05479. *Federal Trade Commission brief as amicus curiae in re: EFFEXOR XR ANTITRUST LITIGATION* [14 August 2013].

¹⁰³ Case no.: 2:08-cv-2431, 2433. *Federal Trade Commission brief as amicus curiae in re: WELLBUTRIN XL ANTITRUST LITIGATION* [26 September 2013].

exclusivity granted by the Hatch Waxman Act. Authorised generics do not need separate drug approval from the FDA, as they are identical to the brand drug. Thus brand companies can therefore compete with the first-filing generic company even during the period of generic exclusivity. In the case of *Effexor XR*, a “no-authorized-generic commitment” by Wyeth Pharmaceuticals induced TEVA, a generic manufacturer, to abandon its patent challenge and refrain from selling its generic version of Effexor XR for a two-year period.¹⁰⁴ According to the FTC, this type of authorised generic competition during the generic exclusivity period can lead to reduction of the first-filing generic company’s profits by approximately 60 per cent.¹⁰⁵ In another case it was estimated that an authorised generic reduced the generic company’s revenues by approximately \$400 million.¹⁰⁶ The FTC therefore argues that the Supreme Court in *Actavis* did not limit the applicability of the *Actavis* rule to monetary payment and claims that:

‘accepting the defendants’ claim of immunity whenever patentees use vehicles other than cash to share the profits from an agreement to avoid competition elevates form over substance, and it would allow drug companies to easily circumvent the ruling in Actavis, at great cost to consumers.’¹⁰⁷

In the light of this argument the FTC proposes in its briefs as amicus curiae to extend the *Actavis* rule to non-cash payment by asking:

- (1) Whether the alleged payment is something that a generic challenger could not have obtained had it won the litigation, and
- (2) Whether the parties are sharing monopoly profits preserved by avoiding competition.¹⁰⁸

A “no-authorized-generic commitment” is a benefit that a generic company could not obtain by prevailing in patent litigation. Even if the generic company were to win the patent litigation, the brand company would nonetheless have the right to compete against the generic

¹⁰⁴ *Amicus curiae in re: EFFEXOR XR ANTITRUST LITIGATION* n (102) 1.

¹⁰⁵ FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* [at 81].

¹⁰⁶ *Amicus curiae in re: EFFEXOR XR ANTITRUST LITIGATION* n (102) 12.

¹⁰⁷ *Ibid* 2.

¹⁰⁸ *Ibid* 8; Case no.: 2:08-cv-2431, 2433. *amicus curiae in re: WELLBUTRIN XL ANTITRUST LITIGATION* n (103) 6.

company by entering the market with an authorised generic, as patent invalidity or non-infringement does not affect the right to market an FDA-approved drug.¹⁰⁹

This extension of the judgment in *Actavis* seems to be sensible. Although, in the months following the judgment a number of District Courts have unfortunately limited the *Actavis* judgment to “cash payments”,¹¹⁰ the Supreme Court of California has recently developed a detailed test for the pay for delay scenario based on the Supreme Court’s *Actavis* decision, akin to the test proposed by Edlin et al above, finding that the settlement may ‘include cash or [an] equivalent financial consideration flowing from the brand to the generic challenger.’¹¹¹ Although this judgment only refers to state antitrust law it is likely to have a signalling effect for the federal circuit and “nudge” federal district court in a similar direction.

Application of the rationale in FTC v Actavis in the European context

Following the discussion of the majority opinion of the US Supreme Court, the question is whether the issues surrounding patent validity, including the pre-judging of patent courts, could also be avoided in the European context by applying the rationale of the US Court. As set out above, the Supreme Court infers not only market power but also the anticompetitive effect from the size of the payment that is directed from the brand company to the generic company and, therefore, it avoids an assessment of the validity of the patent in question.

Taking the same approach with regard to market power in the European context should not be problematic. Market power as a concept is defined as the ability to profitably raise prices to a supra-competitive level, to profitably maintain output in terms of product quantities, product quality and variety, or to innovate below competitive levels for a period of time.¹¹² Similarly to the situation in the United States, the brand company should only be willing to make a payment to the generic company that exceeds litigation costs and costs for services rendered, if the brand company’s intention is to protect its high price-cost margins. However, such high price-cost margins are only likely to occur in markets that are not

¹⁰⁹ *Amicus curiae in re: EFFEXOR XR ANTITRUST LITIGATION* n (102) 15; *Amicus curiae in re: WELLBUTRIN XL ANTITRUST LITIGATION* n (103) 12.

¹¹⁰ *In re Lamictal direct purchasers antitrust litigation (District of New Jersey) No. 12-cv-995 (WHW)* [24.01.2014]; *In re Loestrin antitrust litigation (District of Rhode Island) No. 1:13-md-2472-S-PAS* [09.04.2014].

¹¹¹ *In re Cipro Cases I & II, Cal. S. Ct. JCCP 4154/4220* [2015].

¹¹² European Commission, *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements* (2011) para. 39.

competitive. It should therefore be possible, by implication, to infer market power through the willingness to defend high price-cost margins by way of assessing the size of the payment.

However, inferring anticompetitive effects from the size of the payment is more problematic in the European context and must therefore be discussed in detail. It is important to consider the regulatory context in which pay for delay settlements take place on both sides of the Atlantic and factor in the regulatory differences. In the United States, the relevant market can be effectively foreclosed by a *single* pay for delay settlement. The brand company induces the first generic entrant by means of a substantial payment not to market its generic drug for a certain amount of time, thereby postponing the period of generic exclusivity which is, in turn, the trigger for subsequent generic applications to the FDA. In light of this regulatory bottleneck, it is acceptable to infer anticompetitive effects from the size of the payment, due to the causal link between the size of the payment from the brand company to the generic company and the delay of generic entry which leads to the foreclosure of the market.

However, such a regulatory bottleneck does not exist in the European context. Pharmaceutical regulators in Europe base their decision of generic approval solely on health and safety considerations and do take economic factors such as patents into account. The regulator is not limited in the number of generic drug approvals it can issue for the same brand drug prior to patent expiry, as long as all applications are compliant with the relevant health and safety regulations. Paying off a single generic company does not therefore guarantee that the brand company will be protected from competition for the duration of that agreement. Other generic companies are not prevented from entering the market, although they run the risk of being sued for patent infringement by the brand company. Ultimately, this also means that one cannot presume that an anticompetitive foreclosing effect results from the agreement between the brand company and a single generic company that agrees not to enter the market or to delay its entry. It is therefore also not appropriate to infer an anticompetitive effect solely on the basis of the size of the payment within this agreement, just as in the United States.

That said, this should also not lead to the conclusion that the anticompetitive effects of pay for delay settlements in Europe can only be shown by means of examining the validity of the patent. The assessment of the regulatory framework in Europe does not suggest that it is impossible for a single pay for delay settlement to result in anticompetitive foreclosure effects. The lack of a regulatory bottleneck similar to the Hatch Waxman Act should not be

equated with a lack of potential for anticompetitive foreclosure in Europe. The manifestation of such an effect is, rather, dependent on the actual market structure and the competitive environment in the relevant market. Imagine a scenario where a number of generic companies are present in a given market, but only one of these companies has the financial and technical means to realise the economies of scale that are necessary to profitably market the generic version of a branded drug. In this case, the remaining generic companies would not be able to enter the market to exert competitive pressure on the brand company despite the lack of any legal or regulatory absolute barriers to entry and the ability to apply for market authorisation. In effect, this scenario would lead to at least the same level of anticompetitive effects witnessed in the United States. Indeed, the situation could be even more detrimental to competition due to the lack of potential competitors which are foreclosed by the agreement.

It should therefore be possible to infer anticompetitive foreclosure effects from the size of the payment *in addition to* an assessment of the competitive environment within the relevant market (ie the number of potential generic competitors).

Such an analysis would not be dissimilar to the ECJ's judgment in *Delimitis v Henninger Bräu*,¹¹³ which epitomises the EU Court's approach to restrictions by effect. In this case, the Court had to assess whether exclusive beer supply agreements between a brewery and public houses amounted to a restriction by effect because of their potential to foreclose the market. Having highlighted the general pro-competitive features of such beer supply agreements,¹¹⁴ the Court set out a test to establish whether the beer supply agreement in question led to an anticompetitive foreclosure of the relevant market. In order to establish the potential foreclosure, the Court deemed it necessary to define the relevant market. The Court then went on to examine whether it was difficult for competitors to gain access to the market in the light of the economic and legal context of the agreement at issue.¹¹⁵ The market in *Delimitis v Henninger Bräu* was comprised of a multitude of similar beer supply agreements, which led the Court to find that these agreements could have a cumulative effect on

¹¹³ Case C-234/89, *Delimitis v Henninger Bräu* [1991] ECR I-935.

¹¹⁴ *Ibid.* para. 10,11.

¹¹⁵ *Ibid.* para. 27.

competition. Because of this cumulative effect on competition, it was therefore necessary to assess whether the agreement in question had made a significant contribution to the foreclosure of the market brought about by the totality of those agreements in their legal and economic context. In general terms, the judgment in *Delimitis v Henninger Bräu* has thereby established that even vertical agreements with pro-competitive features can potentially give rise to significant anticompetitive effects when considered in their legal and economic context in the relevant market.

The Court's judgment in *Delimitis v Henninger Bräu* therefore shows that it is possible to have a "structured approach" to an effects-based analysis under Art. 101(1) TFEU. In addition, it has been suggested that it should generally be possible to have a truncated analysis in "restriction by effect" cases, in which the actual anticompetitive effects are not measures but inferred by an evaluation of circumstantial evidence.¹¹⁶ The Court of Justice, for example, has accepted that the evidence for actual anticompetitive effects might not be required, if a careful evaluation of circumstantial evidence in relation to information exchange between competitors can be provided.¹¹⁷

The structured analysis in *Delimitis v Henninger Bräu* and the fact that the EU courts are familiar with the possibility of employing a truncated analysis lend themselves well to the situation of pay for delay settlements in Europe. The discussion of the theory of harm of pay for delay settlements above has shown that a single pay for delay settlement in a European market that includes a number of potential generic competitors is likely to have a significantly lower anticompetitive potential than the same scenario in the United States. A viable option would be for the brand company to pay-off all possible generic entrants so that they do not enter the market at the same time, thereby foreclosing the market. Yet this scenario might change in light of the actual competitive environment of the relevant market.

This article therefore proposes to extend the *Actavis* test by an additional criterion to accommodate the regulatory differences in the European setting. Additionally, it would also appear sensible to follow the FTC's approach in its amicus curiae briefs regarding the extension of pay for delay settlements to non-cash payments. Due to the increased scrutiny

¹¹⁶ See Andreas P Reindl, 'Resale price maintenance and article 101: Developing a more sensible analytical approach' (2011) 33 Fordham International Law Journal 1300, 1309-1313.

¹¹⁷ *Case 7/59 John Deere, Ltd. v. Commission* [1998] ECR I-3111. para 78, 90.

of the pharmaceutical sector and the attention that pay for delay settlements receive in Europe, it is likely that the companies will try to hide or disguise the value transfer. Monetary payments are likely to decrease, whereas the focus will shift to other types of value transfers such as

*'distribution agreements or a "side-deal" in which the originator company grants a commercial benefit to the generic company, for example by allowing it to enter the market before patent expiry in another geographical area or by allowing market entry with another product marketed by the originator company.'*¹¹⁸

The European Commission also confirms that the list of possible value transfers is non-exhaustive,¹¹⁹ which is understandable. A set list of possible value transfers would only provide the opportunity to circumvent such a transfer. For the same reason, it is sensible to broaden the proposed test to non-monetary value transfers from the brand company to the generic company.

The proposed test is the following:

- (1) The European Commission has to define the relevant market and examine the competitive environment within the market.
- (2) The European Commission must also prove that the relevant value transfer to the generic company is large either:
 - (a) In the case of a monetary payment by –
 - (a) Valuing the consideration flowing from the patentee to the alleged infringer,
and
 - (b) Deducting the avoided litigation costs for the patentee,
 - OR*
 - (b) In the case of a non-monetary value transfer by –

¹¹⁸ European 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 01 February 2014 recital 9.

¹¹⁹ *ibid.*

- a. Valuing the consideration flowing from the patentee to the alleged infringer, and
 - b. Determining whether this value transfer could have been achieved by successful patent litigation.
- (3) There is to be a presumption of a *prima facie* restriction of competition by means of delaying entry, if:
- (a) this net payment is positive *or* the value transfer could not have been achieved by means of patent litigation, and
 - (b) the agreement at issue has made a significant contribution to the actual or potential foreclosure of the market based on the economic and legal context.
- (4) The investigated companies then have the burden of proof to show that this net payment or the value transfer can be justified as a payment for goods/services rendered by the alleged infringer to the patentee as part of the same transaction.

This test is not over-inclusive; it takes into consideration the efficiency considerations of patent settlements and the actual conditions on the relevant market. It does not disincentivise patent settlements and does not condemn settlements that have no appreciable anticompetitive effect on the market. Even if the two parties enter into a pay for delay settlement that included a positive net payment, the agreement is not likely to produce anticompetitive effects if a number of equally efficient generic competitors are able to enter the market – hence the need to cumulatively satisfy the criteria under (2)(a) in order to infer anticompetitive effects from the positive net payment. The test is also not over-burdening the parties involved as it is assumed that the parties have the best knowledge of the competitive environment within the relevant market and are therefore well-equipped to determine whether the agreement in question is likely to have a foreclosing effect on the market. Furthermore, the test can also be applied to a situation where the brand company enters into pay for delay settlements with a number of generic companies in order to foreclose the market.

It is not suggested that the proposed test, and more precisely the evidentiary burden of the European Commission to quantify the value considerations from the brand company to the generic company, is straightforward to satisfy. Quantifying the cost of litigation is only

one aspect. Although it might sound more challenging to put a “price tag” on an exclusive licence that is granted as part of a side deal for other services rendered in relation to drug distribution or the provision of back-up manufacturing capacity, its complexity has been downplayed given that these services are routinely sold in a broad market.¹²⁰ The European Commission should therefore have a number of reference points in the market. The alternative to the quantification of the value transfer would be an investigation into the validity of the underlying patent, which is not only more onerous but also more problematic for the European Commission. This is due to the fact that the assessment of patent validity by a competition authority leads to the “second-guessing” of patent authorities and the potential judgment of a patent court. Such a judgment is not, however, a quantitative exercise but rather a subjective value judgment with regard to the relevant prior art of the patent and its “non-obviousness” or “inventive step”. Judges in one jurisdiction might hand down a judgment that contradicts judgments regarding the same patent in another jurisdiction. Thus, it is regarded as a lot more sensible and much less onerous for the competition authority to undertake the quantitative exercise to evaluate the consideration flowing from the brand company to the generic company than delving into the subjective assessment of patent validity.

Conclusion

A number of conclusions can be drawn from the discussion in this article. First, the European Commission should generally refrain from regarding pay for delay settlements as restrictions by object, as their anticompetitive potential is less evident than in the United States, where a *per se* approach has been rejected. Secondly, the European Commission should not shy away from an effects-based approach. Similar to the guidance provided for the lower courts by the US Supreme Court in *FTC v Actavis*, the “structured effects based” test proposed by this article avoids an examination of the validity of the underlying patent without dis-incentivising general patent settlements in the pharmaceutical sector. In addition, the proposed test takes into consideration the described regulatory differences and only regards pay for delay settlements as anticompetitive if, based on the market structure, they have the actual potential to cause anticompetitive foreclosure. In more general policy terms, and even more

¹²⁰ Hovenkamp (n 89). 27, 28.

importantly, this approach adjusts the balance between the aims of competition policy and exercise of intellectual property rights for the European pharmaceutical sector. Pharmaceutical innovation is of utmost importance and should not be jeopardised by an over-interventionist application of competition law. Yet, at the same time, competition law and policy needs to ensure that the pharmaceutical market is competitive to make drugs affordable for as many patients as possible.

Furthermore the proposed test enhances legal certainty and does not require any legislative change. Legal certainty is enhanced as the test circumvents the most contentious and problematic issue – the probabilistic nature of patents and the need to determine their validity as part of the antitrust inquiry. Instead, the proposed test is a cost-based analysis into the economic gains received by the generic company as part of the pay for delay settlement. This test is beneficial for the competition authority, who should be comfortable in administering a cost-based analysis, as well as for the brand and generic company, because the test offers a brighter line than a potential inquiry into the validity of the underlying patent, whose outcome is often difficult to predict.

The applicability of the proposed test is also provided under the current European competition law regime. The EU courts' effects-based approach in *Delimitis* can be regarded as a structured inquiry into anticompetitive effects. The proposed test is therefore to be seen as an extension to the rationale of *Delimitis*. The EU courts have also previously recognised, in relation to information exchange in RPM cases, that certain proxies might be used as evidence of effects. A truncated effects-based analysis is therefore not unheard of. The proposed test combines these two features. The European Commission should thus be able to issue guidelines for the pharmaceutical sector that set out the approach to pay for delay settlements and outline the facts considered in such an analysis.