

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 the protection of 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 that 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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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 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 USA, 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

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totalling US\$3.5 billion for the period from 2004 to 2009;¹ also affecting the affordability of potentially life-saving drugs.

One 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. Undue 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 can be subject to competition law scrutiny.² Keeping both policy considerations in mind, it is paramount to strike the right balance between the aims of competition policy in the pharmaceutical sector and the 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 USA, 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 judgment 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 (EC) handed down its very first decision for 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 fine imposed was in excess of €152 million. In subsequent decisions, the Commission imposed a fine of €16 million on Johnson & Johnson and Novartis for the delay of a generic painkiller 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,

1. Federal Trade Commission 'Pay-for-delay: how drug company pay-offs cost consumers billions', FTC staff study (2010).

2. L Peepkorn 'IP licences and competition rules: striking the right balance' (2003) 26 World Competition 527 at 531.

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

4. EC 'Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines', press release (2013).

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

6. EC 'Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine', press release (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.

it has become evident that the EC 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 EC therefore seems to have struck a balance between the competition policy and protection of the brand company's right to defend its patent that is far more in favour of competition law intervention than the US Supreme Court in *FTC v Actavis*.

This approach by the EC is criticised in this paper. Yet, at the same time, this paper also offers a solution to the problem, adjusting the balance without impairing the EC 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 EC is only likely to be successful in its enforcement efforts when relying on a restriction by object,⁸ this paper not only 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 USA and Europe – a novel structured effects-based analysis is proposed. The analysis of the *FTC v Actavis* judgment and its adaptation to the European framework are not just motivated by the fact that it is a judgment of the highest judicial authority in the USA regarding pay-for-delay settlements. Furthermore, Alexander Italianer, Director General for Competition in the EC, alluded to the similarity between the US *Actavis* decision and the European *Lundbeck* decision during a conference at the Fordham Competition Law Institute in New York City.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 EC 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 paper is structured as follows. First, it considers the regulatory differences between the US and the European pharmaceutical sector, which need to be considered for the adaptation 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

8. P Treacy and S Lawrance 'Intellectual property rights and out of court settlements' in SD Anderman and A Ezrachi (eds) *Intellectual Property and Competition Law: New Frontiers* (Oxford: Oxford University Press, 2011).

9. *FTC v Actavis*, above n 3.

10. A Italianer 'Competitor agreements under EU competition law', 40th Annual Conference on International Antitrust Law and Policy, Fordham Competition Law Institute (New York, 2013); available at http://ec.europa.eu/competition/speeches/index_speeches_by_the_dg.html (accessed 1 December 2015): '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.'

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 paper concludes by providing policy recommendations for future investigations.

REGULATORY DIFFERENCES BETWEEN THE USA AND EUROPE

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 key difference between the two frameworks – namely the so-called patent linkage – and its impact on pay-for-delay settlements, 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 USA and the Hatch–Waxman Act

Under the US framework of the so-called Hatch–Waxman Act,¹¹ 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. In doing so, the generic applicant has to notify the brand company about its intention by filing a so-called 'Paragraph IV notification', which 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. The creation of such a 'patent linkage' not only allows the brand company to challenge the generic application on grounds of patent infringement,¹² but also stays the FDA's approval of the generic drug by 30 months in order to enable the parties to resolve their patent dispute in court.¹³

In return for this patent challenge, the first generic applicant receives 180 days of generic exclusivity once the FDA application is approved and the market is entered.¹⁴ 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.

11. Drug Price Competition and Patent Term Restoration Act 1984 (Public Law 98-417): Hatch–Waxman Act. 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.

12. CS Hemphill and MA Lemley 'Earning exclusivity: generic drug incentives and the Hatch–Waxman Act' (2011) 77 *Antitrust L J* 947 at 952.

13. The FDA's approval of the generic drug will be effective from the date on which: (1) the patent expires, (2) the court reaches a decision on the non-infringement or patent invalidity in the patent litigation, or (3) the 30 months from the date of notification have expired. Federal Trade Commission *Generic Drug Entry Prior to Patent Expiration: A FTC Study* (Washington, DC: FTC, 2002) p 41.

14. This exclusivity period was introduced by the Hatch–Waxman Act with the intention of providing the first generic applicant with an incentive to incur the risk of patent infringement litigation and the costs that are associated with it. See ES Weiswasser and SD Danzis 'The Hatch–Waxman Act: history, structure, and legacy' (2003) 71 *Antitrust L J* 585 at 603.

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. Instead of using the 30 months stay to resolve the patent dispute in court, the parties settle their 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.¹⁵

The parties can therefore stipulate the actual start date of the generic exclusivity as part of their settlement agreement, thereby delaying subsequent generic entry, as the FDA is not allowed to grant further generic drug approvals until the generic exclusivity has elapsed. This regulatory bottleneck¹⁶ renders the brand company's patent monopoly effectively unchallengeable for the entire duration of the patent life, directly contradicting general patent policy.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.

Ultimately, the patent settlement can shield the patents from any challenge without itself being based on patent validity and the probability of success of getting the validity confirmed by a court's judgment. Rather, it is based on a payment by the brand company to the generic company that reflects, at least, the estimated profit of the generic company if it had entered the market.

Europe

Under the European regulatory framework, the relevant drug safety regulators approve brand and generic drugs and grant market authorisations without taking economic factors such as the patent rights of the brand company into consideration. In fact, a patent linkage is not permitted.¹⁸

15. HJ Hovenkamp, MD Janis and MA Lemley 'Anticompetitive settlement of intellectual property disputes' (2003) 87 *Minn L Rev* 1754.

16. Hemphill and Lemley, above n 12, at 963. In order to mitigate this regulatory bottleneck, forfeiture rules have been introduced in 2003 that provide subsequent generic entrants with the possibility to overcome this hurdle, yet the process has been described as still very lengthy – in fact, taking several years – which causes considerable delays. See MA Carrier 'Unsettling drug patent settlements: a framework for presumptive illegality' (2009) 108 *Mich L Rev* 37 at 48.

17. This effect could be described as effectively turning the rebuttable presumption of validity into 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. See C Shapiro 'Antitrust limits and patent settlements' (2003) 34 *Rand J Econ* 391 at 395.

18. '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' – *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; also *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*, Art 126. To the same extent, see *EC Pharmaceutical Sector Inquiry: Final Report* (2009) p 130, finding 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.

Any interference caused by the generic application for marketing authorisation with the patent status of the originator drug is thus dealt with and resolved by means of private patent litigation in front of competent courts.

The European framework thus provides for a similar abbreviated application procedure,¹⁹ without creating a bottleneck similar to that of the FDA, due to the missing patent linkage. The relevant agency can in fact approve several generic versions of the same brand drug prior to patent expiry. 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.

Achieving market foreclosure becomes therefore more complex, as soon as several potential competitors are equally strong or equally willing to take the risk of possible patent infringement litigation. 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.

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; for example, 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 such a situation, 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.

In fact, this might be the case in the EC's proceedings against the French pharmaceutical company Servier and its recent decision against Lundbeck.²⁰ 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'.²¹ In *Lundbeck*, the EC has imposed a €152 million fine on Lundbeck and a small number of generic companies because of the delay of generic entry of citalopram.²²

Keeping these important differences between the two regulatory frameworks and their impact of the potential for anticompetitive foreclosure in mind, this paper now turns to the discussion of whether European pay-for-delay settlements should be regarded as restrictions by object or rather by 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

19. *Directive 2001/83/EC*, above n 18, Art 10(1).

20. EC, above n 4.

21. EC 'Antitrust: Commission sends Statement of Objections on perindopril to Servier and others', press release (2012).

22. EC, above n 4.

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.²³ Restriction *by object* constitutes the most serious infringements of competition law of Art 101(1).²⁴ The EC therefore does not need to take into account their actual anticompetitive effects.²⁵ Having taken into consideration the economic and legal context in which the agreement takes place,²⁶ 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.²⁷ The assumption of anticompetitive effects is based on the nature of the restriction and experience showing they are very likely to produce negative effects. The finding of a restriction by object is also not contradicted by additional legitimate aims that might be served by the agreement.²⁸

Finding a restriction by object is a less onerous task, compared to finding a restriction by effect.²⁹

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.³⁰ 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.³¹ 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.³² 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 pro-competitive features³³ and only a minority gave rise to competition concerns.³⁴ It seems that these considerations led the EC to state, in its final report, that

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.³⁵

23. These two are alternative requirements and they should be read disjunctively. See *Case 56/65 Société Technique Minière v Maschinenbau Ulm GmbH* [1966] ECR 337 at 249.

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

25. There is also 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. See *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.

26. *Ibid*, 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 paras 16, 21: 'regard must be had inter alia to the content of its provisions, the objectives it seeks to attain and the economic and legal context of which it forms a part'.

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

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

29. R Whish *Competition Law* (Oxford: Oxford University Press, 8th edn, 2015) p 120.

30. M van der Woude 'Patent settlements and reverse payments under EU law' (2009) 5 *Competition Pol'y Int'l* 182.

31. EC, above n 18, para 707.

32. Treacy and Lawrance, above n 8, p 293.

33. EC, above n 18, paras 750, 751.

34. *Ibid*, para 743.

35. *Ibid*, para 1530.

However, in spite of the above-mentioned consideration and the EC's quoted statement from its final report of the pharmaceutical sector inquiry – suggesting the application of an effects-based analysis – this 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,³⁶ the EC has framed 17 out of 18 infringement decisions since January 2000 in 'object' terms.³⁷ 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 EC regularly justifies this approach by stating that an 'object' restriction should not be seen as a 'per se' style infringement as in the USA by virtue of Art 101 (3) TFEU. Even an 'object' restriction would allow for justifications that 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'.³⁸ Although the European Court of Justice (ECJ) 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'.³⁹

In fact, the EC 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 EC had committed a manifest error of assessment by finding that the pay-for-delay settlement constituted a restriction of competition 'by object'.⁴⁰

In July 2013, the EC then published its *Lundbeck* decision. With regard to its finding of a restriction by object, the EC started by citing extensively the recent *Allianz Hungária* judgment, including the reference to the *T-mobile* judgment, where the Court held that

36. 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; Guidelines on the application of Article 81(3) of the Treaty (above n 24); 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.

37. DM Gerard 'The effects-based approach under Article 101 TFEU and its paradoxes: modernisation at war with itself?' in J Bourgeois and D Waelbroeck (eds) *Ten Years of Effects-Based Approach in EU Competition Law: State of Play and Perspectives* (Brussels: Bruylant, 2013) p 38.

38. A Jones 'Left behind by modernisation? Restrictions by object under Article 101(1)' (2010) 6 Eur Competition J 649 at 663.

39. Gerard, above n 37, p 40.

40. *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; *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 EC also found a restriction by object in another pay for delay case against Johnson & Johnson and Novartis; however, this decision has not been appealed. EC, above n 5.

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.⁴¹

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 it had already led at the time of the decision to criticism and anxiety concerning the creation of too broad a category of restriction by object. In addition, the EC 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.⁴² 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 EC 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 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 ECJ’s judgment in *Cartes Bancaires*, the EC’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.⁴³ 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.⁴⁴ The Court held 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’.⁴⁵ 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.⁴⁶

41. *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).

42. *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.’

43. *Case C-67/13 P Groupement des Cartes Bancaires v Commission, judgment of 11 September 2014*.

44. J Killick and J Jourdan ‘Cartes Bancaires: a revolution or a reminder of old principles we should never have forgotten?’ [2014] Competition Pol’y Int’l 6; available at <https://www.competitionpolicyinternational.com/cartes-bancaires-a-revolution-or-a-reminder-of-old-principles-we-should-never-have-forgotten> (accessed 1 December 2015). 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.

45. *Case C-67/13 P Groupement des Cartes Bancaires*, above n 43, para 50.

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

In light of the aforementioned, the EC should generally resist the temptation to regard pay-for-delay settlements as restrictions by object.⁴⁷ As yet, the EC has not successfully defended a sufficient number of pay for delay settlements based on similar economic reasoning for them to count towards ‘experience’ with regard to the anticompetitive effects of such settlements. Even if one can 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 USA. 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 USA, 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 EC 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.⁴⁸

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 ‘false positives’ and over-enforcement, due to the novel nature of the infringement of the competition law. Depending on the actual definition of pay-for-delay settlements, patent settlements with a value transfer from the brand company to the generic company that 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 it might constitute a payment for services rendered by the generic company.⁴⁹ An indicator for anticompetitive conduct could be the level of

47. Two notable exceptions to this general rule can be envisaged. (1) The case when the agreement clearly exceeds the scope of the patent; eg 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: FTC v Actavis*, above n 3, at 2223. (2) The case when evidence suggests that the patentee was aware of the patent’s invalidity. In such a scenario, one 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 would become apparent, which would justify the finding of a restriction by object. B Batchelor ‘EC tones down its final report into the pharma sector, but ramps up enforcement activity’ (2010) 31 *Eur Competition L Rev* 16; Treacy and Lawrance, above n 8, p 293.

48. RD Willig and JP Bigelow ‘Antitrust policy toward agreements that settle patent litigation’ (2004) 49 *Antitrust Bull* 655, arguing that pay for delay settlements might be welfare enhancing; see also B Dickey, J Orszag and L Tyson ‘An economic assessment of patent settlements in the pharmaceutical industry’ (2010) 19 *Ann Health L* 367; B Dickey and DL Rubinfeld ‘Would the per se illegal treatment of reverse payment settlements inhibit generic drug investment?’ (2012) 8 *J Competition L & Econ* 615; V Meunier and AJ Padilla ‘Should reverse payment patent settlements be prohibited per se?’ (2015) http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2604071 (accessed 15 October 2015), arguing that such settlements can spur new drug development and patent challenges.

49. HJ Hovenkamp ‘Anticompetitive patent settlements and the Supreme Court’s *Actavis* decision’ (2014) 15 *Minn J L, Sci & Tech* 3 at 27.

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 lack of experience, 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 inquiry in the context of object cases.⁵⁰ 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 for 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.

PAY-FOR-DELAY AS RESTRICTION BY EFFECT

In light of this finding, this section sets out and analyses a possible effects-based approach to pay-for-delay settlements. Drawing on the EC's relevant guidance papers and the relevant case-law, the section addresses 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. It will consider 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. This section goes on to develop a novel structured effects-based analysis inspired by the reasoning in *Actavis*, which avoids this issue of patent validity without being over-inclusive of patent settlements that lack a value transfer from the brand 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 EC'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.⁵¹

In order to find that an agreement has an actual or potential anticompetitive effect, the EC must determine whether the parties to the agreement have a degree of market power and whether the agreement contributes to the strengthening or maintaining of this market power.⁵² This requires the consideration of the economic and legal context in which the agreement takes place.⁵³ In addition, the Guidelines also provide

50. '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*, above n 43, para 53, citing *Case C-32/11 Allianz Hungária*, above n 41, para 36.

51. *Guidelines on the application of Article 81(3)*, above n 24, para 24.

52. *Ibid.*, para 25.

53. *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.⁵⁴

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.⁵⁵ Such an inquiry by the EC would not only pre-judge the finding of specialist patent courts,⁵⁶ but would also be inherently difficult. The EC would only be able to infer generic entry, but for the pay-for-delay, were the disputed patent weak. The definition of 'weakness' also raises difficulties, as the EC would have to decide at which probability of success the companies would have to refrain from settling.⁵⁷

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 question is therefore whether one can draw inspiration from the Supreme Court's analysis for the competition law scrutiny of such settlements in Europe.

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

In order to answer this question and to develop a meaningful approach to EU pay-for-delay settlements, it is necessary to analyse in detail the US Supreme Court decision in *Actavis* and the Federal Trade Commission's (FTC) *amicus curiae* brief in *Effexor XR*, which argues that the *Actavis* rule should be extended to non-cash payments as a form of value transfer.

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 had refused to grant it until the present case.⁵⁸ The reason for the Supreme Court's change of heart was the fact that the Federal Trade Commission managed to create a so-called 'circuit split'.⁵⁹

A number of circuit courts⁶⁰ favoured the so-called 'scope of the patent' test, holding that

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.⁶¹

54. *Guidelines on the application of Article 81(3)*, above n 24, 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.

55. Treacy and Lawrance, above n 8, p 295.

56. *Ibid.*

57. *Ibid.*, p 298.

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

59. This refers to a situation in which several circuit courts come to different decisions on the same issue.

60. *Federal Trade Commission v Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012); *In re Ciprofloxacin*, above n 58; *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005).

61. *Federal Trade Commission v Watson*, above n 60, at 1312.

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.⁶² Additionally, the courts stressed the general importance of the settlements, especially in patent infringement litigation.⁶³ 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.⁶⁴

However, 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,⁶⁵ creating the circuit split. 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.⁶⁶ 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.⁶⁷ Lastly, the court stressed that the 'scope of the patent test' would contradict public policy considerations of the Hatch–Waxman Act.⁶⁸

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.⁶⁹

The US Supreme Court's majority decision written by Justice Breyer, however, rejected both propositions 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. Despite accepting that the agreement's 'anticompetitive effects fall within the scope of the exclusionary potential of the patent',⁷⁰ the Court disagreed with the suggestion that this fact could

62. *Valley Drug Co. v Geneva Pharmaceuticals, Inc.* 344 F.3d 1294 (11th Cir. 2003) at 1311 & n 2, affirmed in *Schering-Plough Corp. v FTC* 402 F.3d 1056 (11th Cir. 2005) at 1065–1066.

63. *Schering-Plough Corp. v FTC*, above n 62, at 1072–1073; *In re Ciprofloxacin*, above n 68, at 1333.

64. *In re Ciprofloxacin*, above n 58, at 1336; *Valley Drug Co. v Geneva Pharmaceuticals, Inc.* 344 F.3d 1294 (11th Cir. 2003) at 1308 & n 21; *In re Tamoxifen*, above n 60, at 213; *Schering-Plough Corp. v FTC*, above n 62, at 1068.

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

66. *Ibid.*, at 214.

67. *Ibid.*

68. 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 and further emphasised 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'. *Ibid.*, at 216.

69. *In re K-Dur Antitrust Litigation*, above n 65, at 218.

70. *Federal Trade Commission v Watson Pharmaceuticals Inc.*, above n 60, at 1312.

also ‘immunize the agreement from antitrust attack’.⁷¹ Indeed, 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.⁷² Yet, with regard to pay-for-delay settlements that, according to the FTC, tend to have significant adverse effects on competition, the ‘scope of the patent’ test 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.⁷³

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’.⁷⁴

According to the Court, these criteria had not been met with regard to pay-for-delay settlements, 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’.⁷⁵

The Court opted for a full rule of reason analysis, which traditionally requires the 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.⁷⁶ The burden of proof in a rule of reason analysis is on the plaintiff.

However, having determined at length the level of evidence the plaintiff would have to provide in order to satisfy the burden of proof⁷⁷ and the circumstances surrounding pay-for-delay settlements, the Court found that the plaintiff would only be required to provide more abbreviated proof than normally required by a rule of reason analysis⁷⁸ – thereby also addressing the question of how to evaluate the antitrust concern without having to rule on the relevant patent’s validity.

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.⁷⁹

71. *FTC v Actavis*, above n 3, at 2230.

72. *Ibid*, at 2231.

73. *Ibid*, at 2230–2231.

74. *Ibid*, at 2242, quoting *California Dental Ass’n v FTC* 526 US 756 (1999) at 770.

75. *FTC v Actavis*, above n 3, at 2242.

76. Hovenkamp, above n 49, at 6.

77. *FTC v Actavis*, above n 3, at 2234–2237.

78. *Ibid*, at 2238.

79. *Ibid*, at 2236.

A firm without such power would not be likely to pay ‘large sums to induce others to stay of the market’.⁸⁰ 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.⁸¹ 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.⁸² 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.⁸³ 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.

The Court also noted that the size of the payment can 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’.⁸⁴ It was therefore also unnecessary to evaluate the validity of the patent itself as part of the rule of reason analysis. The Court agreed with the FTC that the rationale behind a payment of this size cannot in every case be traditional settlement considerations.⁸⁵ Rather, it should 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.⁸⁶ 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.⁸⁷

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.⁸⁸

Judging by these considerations, it is possible to set out the following test to determine whether a pay-for-delay settlement restricts competition:⁸⁹

- (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

80. Ibid.

81. A Edlin et al ‘Activating *Actavis*’ (2013) 38 Antitrust Health Care Chronicle 16.

82. Ibid.

83. Hovenkamp, above n 49, at 24.

84. *FTC v Actavis*, above n 3, at 2236.

85. Ibid, at 2233.

86. Ibid, at 2236.

87. Ibid.

88. Ibid.

89. Edlin et al, above n 81, at 17, 18; similar arguments have been put forward by E Elhauge and A Krueger ‘Solving the patent settlement puzzle’ (2012) 91 Texas L Rev 283.

- 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.

The so-called ‘Actavis Inference’ has since been criticised by a number of academics.⁹⁰ Yet these criticisms have been convincingly rebutted by the proponents of the ‘Actavis Inference’ in a sequence of articles. The criticism regarding the condemnation of pro-competitive or welfare-enhancing settlements buttresses on economic models that describe potentially feasible yet hypothetical settlements instead of ‘desirable settlements that would actually be chosen in equilibrium’ that would be prevented by the proclaimed approach.⁹¹ The ‘Actavis Inference’ should not be rejected because of the theoretical possibility of a false positive based on an economic model using particular assumptions.⁹² Instead, Edlin et al take a practical approach that not only closely follows the majority opinion of the US Supreme Court in *Actavis* but is also correct from a policy perspective. Fundamentally, the ‘Actavis Inference’ reduces potential false negatives significantly by providing the plaintiff with the practical means to infer the anticompetitive effect of a pay-for-delay settlement at the expense of a small number of false positives that can only occur on very specific assumptions that would not be chosen by the parties to a settlement in the absence of the ‘Actavis Inference’.⁹³

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.⁹⁴ Instead of direct monetary payment, 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 exclusivity granted by the Hatch–Waxman Act. In such a scenario, the brand companies can compete with the first-filing generic company even during the period of generic exclusivity, as authorised generics do not need separate drug approval from the FDA.⁹⁵ According to the FTC, this type of authorised generic

90. BC Harris et al ‘Activating *Actavis*: a more complete story’ (2014) 28 *Antitrust Health Care Chronicle* 83 assert (1) that the ‘Actavis Inference’ is in conflict with rejection of the ‘quick look’ approach by the Supreme Court in *Actavis* and (2) that the inference condemns pro-competitive agreements. BH Kobayashi et al ‘*Actavis* and multiple ANDA entrants: beyond the temporary duopoly’ (2015) 29 *Antitrust Health Care Chronicle* 89 assert, similar to the previous article, that the ‘Actavis Inference’ (1) will not allow welfare-increasing settlements, (2) that it will encourage litigants to use inefficient means of settlement such as non-cash payments and (3) that it will increase the cost of Type I errors.

91. A Edlin et al ‘The Actavis Inference: theory and practice’ (2015) 67 *Rutgers U L Rev* 585; available at <http://chicagoip.com/hemphill.pdf> (accessed 16 October 2015).

92. A Edlin et al ‘*Actavis* and error costs: a reply to critics’ (2014) *Antitrust Source* 1 at 7.

93. *Ibid.*, at 8.

94. The FTC has filed two *amicus curiae* briefs, in Lead case no.: 3:11-cv-05479. *Federal Trade Commission brief as amicus curiae in re: EFFEXOR XR ANTITRUST LITIGATION* [14 August 2013] and Case no.: 2:08-cv-2431, 2433 *Federal Trade Commission brief as amicus curiae in re: WELLBUTRIN XL ANTITRUST LITIGATION* [26 September 2013].

95. Eg 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. *In re: EFFEXOR XR ANTITRUST LITIGATION*, above n 94, at 1.

competition during the generic exclusivity period can lead to reduction of the first-filing generic company's profits by approximately 60%.⁹⁶ In another case, it was estimated that an authorised generic reduced the generic company's revenues by approximately \$400 million.⁹⁷

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.⁹⁸

In the light of this argument, the FTC proposes in its briefs as *amicus curiae* to extend the 'Actavis Inference' 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.⁹⁹

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 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.¹⁰⁰

This extension of the judgment in *Actavis* is sensible and in the author's opinion necessary to avoid an easy means to circumvent the ruling in *Actavis*.¹⁰¹ Although, in the months following the judgment, a number of district courts have unfortunately limited the *Actavis* judgment to 'cash payments',¹⁰² 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'.¹⁰³ Although this judgment only refers to state antitrust law, it has possibly had a

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

97. *In re: EFFEXOR XR ANTITRUST LITIGATION*, above n 94, at 12.

98. *Ibid*, at 2.

99. *Ibid*, at 8; *In re: WELLBUTRIN XL*, above n 94, at 6.

100. *In re: EFFEXOR XR ANTITRUST LITIGATION*, above n 94, at 15; *In re: WELLBUTRIN XL*, above n 94, at 12.

101. The extension to non-cash payment also rebuts one of the above-mentioned criticisms that the 'Actavis Inference' would lead to inefficient types of settlements. Kobayashi et al, above n 90, at 95. The extension of *Actavis* to all forms of consideration discourages parties to use more 'inefficient types' of pay for delay settlements. Edlin et al, above n 91, at 23.

102. *In re Lamictal direct purchasers antitrust litigation (District of New Jersey) No. 12-cv-995 (WHW)* [24 January 2014]; *In re Loestrin antitrust litigation (District of Rhode Island) No. 1:13-md-2472-S-PAS* [9 April 2014].

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

signalling effect for the federal circuit and ‘nudged’ the federal district court in a similar direction.¹⁰⁴

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.¹⁰⁵ Similarly to the situation in the USA, 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 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 USA, 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. This regulatory bottleneck makes it 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. In the light of these considerations, the majority opinion also rejected the argument put forward by Chief Justice Roberts in his dissenting opinion that a pay-for-delay settlement including a large reverse payment would induce further generic challenges.¹⁰⁶

104. *King Drug Co. v SmithKline Beecham*, 791 F.3d 388 (3d Cir. 2015) quoting *FTC v Actavis*, the Court held ‘that [non-cash] agreements are likely to present the same types of problems as reverse payments of cash; ‘the prevention of that risk of competition – eliminating the risk of patent invalidation or a finding of noninfringement by paying the challenger to stay out of the market [...] constitutes the relevant anticompetitive harm,’ [at 404]; see also *American Sales Co. v City of Providence* (1st Cir. 22 February 2016), where the court disagreed with the ‘with the district court’s limited reading of *Actavis*’ [at 7].

105. *EC 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.

106. See *FTC v Actavis*, above n 3, at 2235, 2236 (for majority opinion) and at 2246 (for dissenting opinion).

In the European context, such a regulatory bottleneck does not exist. 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 USA.

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 regulatory differences should have no impact on the focal point of the antitrust inquiry – the *ex ante* assessment of the settlement. It is the risk of competition due to the potential loss of the patent dispute that causes the antitrust violation and this risk needs to be assessed at the time of the settlement, not once the patent dispute is resolved.¹⁰⁷ The regulatory differences should also not necessarily lead to the conclusion that pharmaceutical companies in Europe would have a lesser incentive to enter into pay-for-delay settlements. Edlin et al have argued that the threat of multiple generic entry as opposed to the entry of a single generic competitor in the USA further increases the brand company's incentive to enter into a pay-for-delay settlement, in order to preserve its market share by creating a duopoly with the first-filing generic entrant¹⁰⁸ This finding is supported by empirical evidence showing that multiple generic entrants erode the brand company's profit faster than a single generic entrant.¹⁰⁹

Although Europe lacks a regulatory bottleneck similar to the Hatch–Waxman Act on which Edlin's findings are based, it is nonetheless the case that multiple generic entrants erode brand companies' profits faster. Brand companies in Europe should therefore not have a lesser incentive to enter into pay-for-delay settlements. The only difference is that the manifestation of anticompetitive foreclosure is dependent on the actual market structure and the competitive environment in the relevant market, as opposed to the existence of a regulatory bottleneck. The same holds true for potential future generic challenges induced by a large reverse payment. 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

107. Edlin et al, above n 91, at 24; this finding is substantiated by a counterfactual analysis showing that an *ex post* antitrust analysis of patent licences would lead to a potential finding of antitrust violations in every license of a patent that would later be found to be invalid [at 25].

108. Ibid, at 16.

109. Hemphill and Lemley, above n 12.

lead to at least the same level of anticompetitive effects witnessed in the USA. Indeed, the situation could be even more detrimental to competition due to the lack of potential competitors that are foreclosed by the agreement.

Based on these considerations, 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*,¹¹⁰ 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,¹¹¹ 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.¹¹² 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 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 measured but inferred by an evaluation of circumstantial evidence.¹¹³ 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.¹¹⁴

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 above discussion of the theory of harm of pay-for-delay settlements 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 USA. A viable option would be for the brand company to pay off all possible

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

111. *Ibid*, paras 10, 11.

112. *Ibid*, para 27.

113. See A Reindl 'Resale price maintenance and Article 101: developing a more sensible analytical approach' (2011) 33 *Fordham Int'l LJ* 1300 at 1309–1313.

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

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.

PROPOSAL OF NOVEL TEST

This paper therefore proposes a novel test for pay-for-delay settlements under EU competition law. Based on the detailed discussion of the ‘Actavis Inference’ and its extension to non-cash payments,¹¹⁵ the proposed test takes account of the regulatory differences in the European setting by requiring the definition of the relevant market as an additional criterion.

The proposed test is as follows:

- (1) The European Commission (EC) has to define the relevant market and examine the competitive environment within the market.
- (2) The EC must also prove that the relevant value transfer to the generic company constitutes a positive net payment 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 –
 - 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 dis-incentivise patent settlements and it 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 includes a positive net payment, the agreement is not

115. The extension to non-cash payments in Europe becomes necessary as the EC has already recognised a 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.’ EC *3rd Report on the Monitoring of Patent Settlements (period: January–December 2011)* (2012) Recital 9; available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report3_en.pdf (accessed 1 December 2015).

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 EC 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.¹¹⁶ The EC 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 EC. 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 judgement 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.

Although the EC has addressed in its *Lundbeck* decision some of the relevant factors of the proposed test, such as the nature of the value transfers and their direction of flow,¹¹⁷ it did not embrace a structured effects-based approach and it especially failed to sufficiently consider the competitive environment of the market¹¹⁸ – a factor that, based on the provided analysis, is crucial to determine the anticompetitive effects of pay-for-delay settlements in Europe. Even if it were to be argued that the EC’s decision has led to the correct outcome in the *Lundbeck* case, one should not forget that, for the reasons set out in this paper, an effects-based test is necessary to ensure that Art 101 TFEU does not wrongly punish behaviour that may be beneficial. An object approach might be less onerous for the EC, but the legal and factual issues highlighted in this

116. Hovenkamp, above n 49, at 27, 28.

117. *Lundbeck*, above n 42, at 824: ‘the transferred value corresponded roughly to the profits Merck (GUK) expected if it had successfully entered the market; Lundbeck could not have obtained those limitations on entry through enforcement of its process patents, the obligations on Merck (GUK) in the agreement going beyond the rights granted to holders of process patents’; the EC briefly dismissed a number of potential justifications for such payments [ie at 801].

118. The EC merely assessed whether the parties to the respective pay for delay settlements were actual or potential competitors, including their actual threat of market entry. See *Lundbeck*, above n 42, at 738, 827 (for Merck (GUK)), 877, 965 (for Arrow), 1016 (for Alpharma) and 1090 (for Ranbaxy).

paper do not lend themselves to general per se prohibitions such as the finding of an infringement of Art 101 TFEU by object.

CONCLUSION

A number of conclusions can be drawn from the discussion in this paper. First, the EC should generally refrain from regarding pay-for-delay settlements as restrictions by object, as their anticompetitive potential is less evident than in the USA, where a per se approach has been rejected. Secondly, the EC 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 in this paper avoids an examination of the validity of the underlying patent without disincentivising 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 importantly, this approach adjusts the balance between the aims of competition policy and the exercise of intellectual property rights for the European pharmaceutical sector. Pharmaceutical innovation is of the utmost importance and should not be jeopardised by an over-interventionist application of competition law. Yet, at the same time, competition law and policy need 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 avoids 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, which 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 EC 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.