

Adding a New Dimension to EU Pharmaceutical Antitrust - Pay for Delay Settlements as Part of a Unilateral Strategy such as Product Hopping

Sven Gallasch
Centre for Competition Policy
UEA Law School
University of East Anglia

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Abstract

Pay for delay settlements are currently at the centre of the European Commission's enforcement activities in the pharmaceutical sector. The focus in these investigations is on the collusive nature of the agreements between a brand company and generic companies and the associated anticompetitive potential. This paper advocates the broadening of the antitrust scrutiny of pay for delay settlements to unilateral conduct. It argues that pay for delay settlements could be used as a "facilitator" for broader unilateral conduct by the brand company such as product hopping. The developed theory of harm is based on the fact that pay for delay settlements in Europe are less likely to foreclose the market for generics than they do in the United States, but they 'only' delay generic entry in most cases. This delay could however 'buy' the brand company enough time to achieve a broader unilateral strategy. As part of the overall analysis, highlighting a more general issue of European competition law, the paper takes issue with the concept of 'competition on the merits' suggesting that there could be merit in considering the concept in the context of the actual facts of the individual case at hand and not in isolation.

Contact Details:

Sven Gallasch

s.gallasch@uea.ac.uk

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1. Introduction

Agreements in the pharmaceutical sector by which the brand pharmaceutical company pays the generic entrant to stay off the market as part of a patent settlement, so-called pay for delay settlements, are currently at the centre of attention of the European Commission at the moment, with decisions against *Lundbeck*¹ and *Johnson & Johnson*² and *Servier*³. Predominately, the European Commission's current enforcement efforts so far rest on Art. 101 TFEU, similar to the longstanding enforcement against these types of agreements in the United States. The antitrust scrutiny in the United States is based on the fact that a pay for delay settlement between a brand company and a *single* generic company can foreclose the entire market concerned. In Europe, however, actual market foreclosure based on the pay for delay settlement *itself* is only possible in a small number of cases and only with very limited anticompetitive potential compared to the situation in the United States. This reduced anticompetitive potential arises from the differences in the European regulatory framework, which does not block subsequent generic entrants despite the conclusion of a pay for delay settlement in the market.

However, it would be misleading to think that pay for delay settlements have no anticompetitive potential in Europe. This article rather argues that the brand company can

¹European Commission, *Commission Decision of 19 July 2013 (Case AT.39226 - Lundbeck)* OJ C (2013) 3803 final.

²European Commission, *Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl* (2013).

³European Commission, *Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine* (2014).

cause significant consumer harm by using pay for delay settlements as a means to achieve broader unilateral anticompetitive conduct, such as product hopping, akin to the second abuse in the *AstraZeneca* judgment. It is recognised in the literature that the brand company can evade the threat of cheaper generic competition which would decrease its profits significantly and at the same time would benefit the consumers greatly, by establishing a “new” version of the brand drug on the market prior to generic competition.⁴ Pay for delay settlements have the potential to “buy” the brand company sufficient time to safely switch to a new version of its drug at the latest possible time without having to fear generic competition that would impede such conduct.

This paper thus aims to extend the common understanding of the anticompetitive nature of pay for delay settlements in Europe by adding a new dimension – the facilitation of anticompetitive unilateral conduct through pay for delay settlements.

This article first addresses the reduced anticompetitive potential of ‘stand-alone’ pay for delay settlements in Europe when compared to the United States and suggests to broaden the scrutiny of these kind of settlements as part of a unilateral strategy of the brand company. Product hopping is used as an example to showcase the anticompetitive potential of unilateral conduct by the brand company facilitated by a pay for delay settlement. The paper therefore defines product hopping, before it critically assesses the second abuse in *AstraZeneca*, which was the first opportunity for the EU Courts to address product hopping in general under the European framework. The article then sets out the proposed theory of harm and establishes that the finding of an abuse of a dominant position would be consistent with the European case law. As part of this analysis the article also takes issue with and assesses the concept of competition on the merits in the pharmaceutical sector. Finally it concludes by making a number of policy suggestions.

⁴ Alan Devlin, ‘Exclusionary Strategies in the Hatch-Waxman Context’ (2007) Mich. St. L. Rev. 632. 658; Steve D Shadowen, Keith B Leffler and Joseph T Lukens, ‘Anticompetitive product changes in the pharmaceutical industry’ (2009) 41 Rutgers L.J. 51; Bengt Domeij, ‘Anticompetitive marketing in the context of product switching’ in Hans H Lidgard (ed), *Nordic Perspectives on Competition in Innovation markets* (Maria Magle Publishing, Lund 2013). 132; also European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009). para 1010;

2. EU pay for delay settlement in a broader unilateral context

Competition law scrutiny of pay for delay settlements focuses predominantly on the anticompetitive nature of the agreement between the parties and the possible infringement of Art. 101 TFEU. A possible theory of harm regarding the use of pay for delay settlements in a broader unilateral context based on Art. 102 TFEU seems not yet to be considered by the European Commission or national competition authorities. Although an inclination to competition law scrutiny under Art. 101 TFEU is understandable following the longstanding enforcement practice and experience in the United States as well as recent US Supreme Court judgment in *Actavis*⁵, a viable theory of harm for unilateral conduct by the brand company should not be easily dismissed; especially, considering the fundamental differences between the pharmaceutical regulations in the United States and Europe. In order to develop a unilateral theory of harm based on pay for delay settlements, this section first introduces and briefly discusses the differences between the two respective regimes, which in turn has a significant impact on the anticompetitive potential that can arise from pay for delay settlements individually.

It is widely accepted in the academic literature and amongst policy makers that pay for delay settlements are used as a vehicle to foreclose a relevant market by paying off potential generic entrants.⁶ In return for a certain value transfer from the brand company to

⁵ *FTC v. Actavis* 133 S.Ct. 2223 (2013).

⁶ Among others Kevin D McDonald, 'Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea' (2002) 15 *Antitrust Health Care Chronicle* 2; Marc G Schildkraut, 'Patent-splitting settlements and the reverse payment fallacy' (2003) 71 *Antitrust Law Journal* 1033; Herbert J Hovenkamp, Mark D Janis and Mark A Lemley, 'Anticompetitive Settlement of Intellectual Property Disputes' [2003] 87 *Minnesota Law Review* <http://ssrn.com/paper=380841>; Thomas F Cotter, 'Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley' (2003) 87 *Minnesota Law Review* 1789; Carl Shapiro, 'Antitrust limits and patent settlements' (2003) 34 *Rand J. Econ.* 391; Anne-Marie C Yvon, 'Settlements between brand and generic pharmaceutical companies: A reasonable antitrust analysis of reverse payments' (2006) 75 *Fordham L. Rev.* 1883; C. S Hemphill, 'Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem' [2006] 81 *New York University Law Review*, Vol. 81, p. 1553, 2006 <http://ssrn.com/paper=925919>; Mark W Murphy, 'Red flag or red herring? Reverse payments and the settlement of pharmaceutical patent litigation' (2008) 4 *European Competition Journal* 541; 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; C. S Hemphill, 'An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition' (2009) 109 *Colum. L. Rev.*; Michael A Carrier, 'Unsettling drug patent settlements: A framework for presumptive illegality' (2009) 108 *Michigan Law Review* 37; Michael A Carrier, 'Solving the Drug Settlement Problem: The Legislative Approach' (2009) 41 *Rutgers L.J.* 83; Michael A Carrier, 'A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping' (2010) 62 *Florida Law Review*, Vol. 62 1009; Phillip E Areeda and

the potential generic entrant, the generic entrant agrees not to enter the market before a certain date that has been stipulated in the settlement agreement.⁷ It is argued that the generic exclusion from the market is caused by value transfer rather than by the exclusionary nature of a valid patent.⁸ A value transfer from the brand company to the generic entrant would normally only be expected, if the parties to the settlement regard the patent in question as invalid. Consequently one would expect generic entry and the potential payment of damages and litigation cost by the brand company. However, following a pay for delay settlement, the potential generic entrant asserts the validity of the patent. Nonetheless, the generic company receives payment from the brand company. Assuming the patent would be valid and enforceable, a value transfer from the brand company to the potential generic entrant would not be necessary to achieve the exclusion. The payment thus arguably goes in the “wrong direction”.⁹

The anticompetitive potential of this conduct does not arise from the settlement itself but rather the regulatory environment in which it takes place. In the United States, the regulatory framework is based on the so-called Hatch Waxman Act.¹⁰ According to this framework, a generic company can apply for FDA drug approval prior to the expiry of the brand company’s patent as long as the generic company notifies the brand company about its intended entry. This notification is achieved through a so-called “Paragraph IV certification” which needs to list all related patents that have been filed by brand company with the FDA in its “Orange Book”.¹¹ This Orange Book requirement creates a patent linkage between the FDA’s consideration of the drug’s safety and efficacy and the related economic considerations stemming from patent protection.¹² The ‘Paragraph IV certification’ also

Herbert Hovenkamp, *Antitrust law: : an analysis of antitrust principles and their application* (2. ed. Aspen Law & Business, New York, NY 2013) ¶2046; Aaron Edlin and others, ‘Activating Actavis’ (2013) 38 *Antitrust Health Care Chronicle* 16; Herbert J Hovenkamp, ‘Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision’ (2014) 15 *Minnesota Journal of Law, Science and Technology* 3; Federal Trade Commission, *Pay-for-Delay: How drug company pay-offs cost consumers billions*. An FTC staff study (2010).

⁷ Areeda and Hovenkamp (n 6). 2046c

⁸ [XXX]

⁹ Mark A Lemley and Carl Shapiro, ‘Probabilistic Patents’ (2005) 19 *The Journal of Economic Perspectives* 92.

¹⁰ The purpose of the Hatch Waxman Act is to incentivise generic companies to enter the market for a given drug prior to the expiry of the brand company’s patent by challenging the validity of the patent.

¹¹ The Orange Book is the FDA’s register of all patents in relation to every brand drug that is registered with the FDA.

¹² *The pharmaceutical company ‘shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with*

allows the brand company to challenge the generic application on grounds of patent infringement, as the generic application constitutes an act of patent infringement.¹³ Should the brand company decide to do so, the FDA decision on the generic application is postponed by 30 months in order to allow the parties to resolve their patent dispute in court.¹⁴ If the generic company would be successful in its patent challenge, the FDA would grant the generic applicant a period of 180 day generic exclusivity, as a reward for the incurred risk of patent infringement litigation and the associated litigation cost.¹⁵ During this period of generic exclusivity, the FDA is not allowed to grant any further generic applications for the same drug. It is this situation that is exploited by pay for delay settlements as *'the Hatch-Waxman Act has been interpreted to give 180 days of generic exclusivity to the first generic company to file for FDA approval, whether or not that company succeeds in invalidating the patent or finding a way to avoid infringement'*.¹⁶ The brand company can therefore "pay-off" the generic entrant for not entering the market. In fact, the situation is even worse, as the start date of the generic exclusivity period can be stipulated in the settlement. One has to remember that no other generic application can be approved by the FDA during this period, leading ultimately to the foreclosure of the market for as long as the period of generic exclusivity has not expired.

The situation in Europe is different. Unlike in the United States, where a pay for delay settlement with a *single* generic company can foreclose the entire relevant market, the relevant European market generally cannot be foreclosed by paying off a single generic entrant. Most importantly, the European drug safety regulators that approve brand and generic drugs and grant market authorisations do not take economic factors, such as patent rights of the brand company, into consideration. Under EU law, such a patent linkage is not

respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. 21 CFR §314.53 (b).

¹³ C. S. Hemphill and Mark A Lemley, 'Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act' (2011) 77 Antitrust Law Journal 947. 952.

¹⁴ *ibid.* 952.

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

¹⁶ Hemphill and Lemley (n 13). 948.

permitted.¹⁷ Following European secondary legislation,¹⁸ 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.¹⁹ The European authorities are thus not constrained by a regulatory bottleneck akin to the Hatch Waxman Act, in particular the Orange Book requirement. Even if the brand company enters with the first generic applicant into a pay for delay settlement, subsequent generic companies are not prevented from entry, as long as they can satisfy the relevant safety and efficacy requirements. Although they might or are even likely to face patent infringement litigation, subsequent generic entrants are not barred from entry based on the regulatory regime. It is therefore also not necessary to incentivise the first generic applicant with a period of generic exclusivity to reward him for the patent challenge, as multiple generic companies can simultaneously challenge the same patent. Ultimately, a pay for delay settlement with a single generic entrant is at least very unlikely to cause anticompetitive market foreclosure based on the regulatory environment alone. As I have argued elsewhere anticompetitive foreclosure would only be possible in very limited cases where the brand company manages to pay off *all* viable generic entrants at the same time.²⁰ This situation is highly dependent on the competitive nature of the market and is not facilitated by the European regulatory regime for drug approval.

However, it is far more likely that a pay for delay settlement in Europe would only cause a delay in generic entry. A generic delay is also difficult to sustain as a stand-alone strategy for the brand company due to likelihood of multiple subsequent generic entrants challenging the relevant patent. One should therefore consider, whether it is possible for the brand company to use pay for delay settlements in a broader unilateral type of conduct, in which the settlement can facilitate anticompetitive foreclosure. One such scenario in which it can be envisaged that a pay for delay settlements is used in a broader unilateral type of

¹⁷ *'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) 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.

¹⁸ *ibid.* Art. 81; Directive 2001/83/EC Art. 126.

¹⁹ European Commission (n 4). 130.

²⁰ [XXX]

conduct as part of the brand company's "product lifecycle management"²¹ strategy. Scrutinising such unilateral conduct under Art. 102 TFEU would also have a further strategic advantage. In an investigation against a brand company regarding the alleged abuse of its dominant position, the European Commission is more likely to receive cooperation from the generic company that entered into the pay for delay settlement, as only the brand company is subject of the investigation. This is also not likely to be an undue prioritisation of the enforcement, as the investigated conduct is based on unilateral conduct that has been facilitated by the agreement between the brand company and the generic company. The predominant anticompetitive potential is therefore likely to stem from the brand company's unilateral conduct. Due to the different focal point, an investigation of a brand company's abuse of dominance should therefore be seen as an alternative enforcement strategy against pay for delay settlements rather than a complementary approach to the analysis of pay for delay settlements under Art. 101 TFEU.

An example for such broader unilateral conduct by the brand company that goes beyond the competitive practice of "product lifecycle management" is the "second" abuse in *AstraZeneca*, concerning the deregistration of a market authorisation in order to avoid generic entry and to facilitate AstraZeneca's product switch to a second generation version of its brand drug Losec. This type of conduct has also been referred to as 'product hopping'. In the remainder of this article it is argued that an adapted version of this conduct, in which the deregistration of the marketing authorisation is replaced by a pay for delay settlement can lead to the similar anticompetitive result and therefore should be regarded as an abuse of the brand company's dominant position. Before this article turns to the discussion of whether product hopping could be facilitated by a pay for delay settlement, constituting an infringement of Art. 102 TFEU, it first explains the phenomenon of product hopping and critically analyses the European Courts' approach to this phenomenon in the 'second' abuse of the *AstraZeneca* judgment, in particular with reference to the use of the concept of competition on the merits.

²¹ Product lifecycle management is the business activity of managing a company's products across their lifecycle, from the very first idea of a product all the way through until it's retired and disposed of. The main objectives are the increase of product revenue, the reduction of product related costs, and the maximisation of the product portfolio's value for customers and shareholders. John Stark, *Product lifecycle management: 21st century paradigm for product realisation* (Decision engineering, 2nd Springer, London, New York 2011) 1.

a. What is product hopping?

Product hopping is an exclusionary strategy involving the brand company's reformulation of its brand drug.²² These reformulations can take place in different ways. The brand company might decide to change the form of the drug, switching from a capsule to a tablet or injectable.²³ Another possibility is to slightly change the chemical composition of the drug, while keeping the actual active ingredient the same.²⁴ Alternatively, the brand company might also combine two or more pharmaceutical compositions in a single drug that used to be marketed separately.²⁵ Although brand companies always claim that these 'second generation' drugs are an improvement to the original drug, the clinical benefit of these improvements is sometimes at least questionable. In the EU pharmaceutical sector inquiry generic companies have indeed claimed that there are no improved therapeutic effects and that some of the second generation drugs show little if any innovation and limited if any additional benefits.²⁶

The timing of the product hop is crucial in order to develop the full anticompetitive potential. The strategy is more successful for the brand company if it can switch the market before generic entry.²⁷ For the United States, Carrier nicely highlights the importance of timing by a number of case studies about the brand drugs Provigil and Androgel.²⁸ The fact that the European pharmaceutical sector is not immune to the same considerations by brand companies is showcased by quotes from internal documents that came to light during the pharmaceutical sector inquiry.

"The launch of [our second generation product] is a challenge, not experienced until now, as generics firms, [...] press onto the market with all force and as we have to fear the loss of our patent [...]. This means each patient that is not switched quickly enough to [our second generation product] is forever lost to the generics. Once the patient is switched to [our second

²² Carrier (n 6). 8.

²³ Shadowen, Leffler and Lukens (n 4) 24.

²⁴ *ibid.* 24.

²⁵ *ibid.* 25.

²⁶ European Commission (n 4) para. 994

²⁷ Carrier (n 6). 11.

²⁸ *ibid.* 13, 19.

generation product] the physician does not have to, cannot and will not switch him to a generic, and what is more important: the pharmacist cannot substitute!! ²⁹

The generic entrant is faced with a number of problems, if the brand company brings the second generation drug to the market before a generic version of the original brand drug. The generic drug can be market, if it has already been approved, but it cannot be substituted for the second generation brand drug, as it lacks in bioequivalence.³⁰ If the original brand drug would be withdrawn from the market, the generic company might have to forgo entering the market, as it would no longer be considered as a substitute for the second generation drug.³¹ Alternatively, the generic company could consider to reapply for generic approval of the second generation drug.³² However, such a re-application might be prevented by the data and marketing exclusivity period which has been granted to the second generation drug, if the brand company has obtained additional patents. Even if the original brand drug is not withdrawn from the market, the negative impact on the generic entrant's revenue as well as on consumer welfare is likely to be significant. The brand company will try to switch as many consumers as possible to the new second generation drug that is still patent protected, as it will incur considerable value losses both in terms of smaller volumes and reduced prices, if cheaper, generic versions of the first product come on the market before or simultaneously with the switch to the follow-on product.³³ Physicians or pharmacists would not be allowed to provide already switched patients with the generic substitute for the original brand drug.

Competition law scrutiny of this product hopping strategy should thus focus not necessarily on the product switch itself but rather on the brand company's behaviour that ensures the successful switch by facilitating the timing of the switch prior to generic entry or by exploiting pharmaceutical regulation to deter generic substitution. The product switch itself should rather be seen as trigger for increased competition law vigilance, if the switch

²⁹ European Commission (n 4) para. 1028

³⁰ This means that the generic company must establish that the generic product is composed of the same substances – in qualitative and quantitative terms – and has the same pharmaceutical form as the originator product which has already been granted marketing authorisation. *ibid.* para. 860.

³¹ Devlin (n 4) 657.

³² *ibid.* 657.

³³ European Commission (n 4) para. 1010.

takes place a few years prior to patent expiry. One of such types of conduct was the deregistration of marketing authorisations in AstraZeneca.

b. The second AstraZeneca abuse – deregistration of marketing authorisations

The European Commission's finding of abuse in relation to the selective deregistration of market authorisations for AstraZeneca's brand drug Losec was based on AstraZeneca's so-called "Losec-Post-Patent-Strategy" which consisted of three elements: (1) the extension of the Losec product line by Losec MUPS, which is Losec in a tablet form instead of a capsule³⁴; (2) the raising of technical and legal barriers to entry designed to delay generic entry which was accomplished through the deregistration of the marketing authorisations for Losec capsules in several Member States; and (3) the introduction of a new generation product called esomeprazole, which was supposed to have significant clinical benefits compared to omeprazole, the active pharmaceutical ingredient in Losec.³⁵

In order to switch as many patients as possible from Losec to Losec MUPS before generic entry, AstraZeneca thus raised barrier to entry by means of creating regulatory obstacles that prevented generic companies from obtaining marketing authorisations for generic versions of Losec. The regulatory obstacle was created by the selective deregistration of AstraZeneca's marketing authorisation for Losec. According to the legal framework at the time, an abridged drug application for generic drug by which the generic company could rely on the clinical trials and the necessary scientific literature was only available if the marketing authorisation for the brand drug is in force on the date on which the generic abridged drug application is filed.

³⁶ With the withdrawal of the marketing authorisation AstraZeneca had prevented generic companies from using the abridged application procedure and therefore delayed generic

³⁴ It needs to be kept in mind that the extension of the product line by itself does not constitute an abuse as '*an undertaking, even in a dominant position, [can employ] a strategy whose object it is to minimise erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process*' Case T-321/05. *Case T-321/05 AstraZeneca v European Commission* [2010] ECR 00 para. 804.

³⁵ For the purpose of the finding of abuse only the first two points are relevant. *Ibid.* para. 803.

³⁶ *Ibid.* para. 828.

entry and increased the generic companies' costs to overcome this barrier to market entry.³⁷ Based on this conduct the European Commission found that

*'the requests for deregistration of capsules in [...] combination with the tablet/capsule switch (i.e. the launch of Losec MUPS tablets and the withdrawal from the market of Losec capsules), as part of its LPPS Strategy with a view to preventing, or at least delaying, generic market entry [resulted in an abuse of AstraZeneca's dominant position]*³⁸

The abuse is therefore not to be found in the extension of the product line and the product switching itself, but in the delay of generic competition into the market which allowed the brand company to introduce a follow-on brand drug to the same market and attempt to switch as many patients as possible to the new follow-on brand drug without having to fear generic competition. In the view of the Court of Justice, a dominant undertaking, having the special responsibility not to distort competition

*'cannot therefore use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.'*³⁹

In relation to AstraZeneca's conduct it was found that the deregistration of the relevant marketing authorisation created a regulatory obstacle to generic market entry.⁴⁰ Doing so, the brand company was able to switch patients to its new and still patent protected follow-on version of the brand drug. Where successful the brand drug would not face significant

³⁷ Ibid. para. 829. Generic companies could still enter the market but were unable to rely on AstraZeneca's clinical data.

³⁸ Case COMP/A. 37.507/F3 AstraZeneca [2005] (European Commission) para. 860. This finding was upheld by the General Court Case T-321/05. Case T-321/05 AstraZeneca v European Commission (n 34) para. 671-696 and by the ECJ Case C-457/10 P AstraZeneca v European Commission [6 December 2012] [not yet reported]. para. 129-141 holding that *'the deregistration of [Losec's marketing authorisation] [...] by which AstraZeneca intended [...] to hinder the introduction of generic products [...] does not come within the scope of competition on the merits.'* at [130].

³⁹ Case C-457/10 P AstraZeneca v European Commission (n 38) para 134.

⁴⁰ Joseph Drexler, 'AstraZeneca and the EU sector inquiry: When do patent filings violate competition law?' Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02. 10.

competitive pressure from generic entrants as these could only enter with generic version for the brand drug but not for the follow-on brand drug, which is effectively replacing the brand drug on the same market.

AstraZeneca's plea that it was entitled to withdraw its marketing authorisation was rejected by the Court of Justice. First of all, it was held in general terms that no relationship exists between the lawfulness and compliance of a certain type of conduct under one body of law and potential immunity from competition law scrutiny.⁴¹ The availability of a deregistration request and its legality under Directive 65/65 did not bar the Court from finding an abuse of Art. 102 TFEU. Secondly, the Court of Justice rejected for a number of reasons AstraZeneca's argument that the Commission failed to apply the IMS Health criteria which only afford competition law intervention in 'exceptional circumstances'.⁴² AstraZeneca's conduct in question was not regarded as comparable to the conduct in IMS Health which concerned a compulsory licence for the use of the copyright protected "brick structure" by a competitor.⁴³ The possibility to request the deregistration of a marketing authorisation was also not deemed to be an equivalent to an exclusive property whose exercise could be justified as a means of 'effective expropriation'.⁴⁴ The Court held that after the expiry of the relevant period of data exclusivity, the clinical data is regarded to be in the public domain, allowing generic applicants for the same drug to rely on this data for marketing authorisation purposes.⁴⁵ In fact, AstraZeneca's conduct rendered the abridged application procedure for generic applicants unavailable solely for the purpose to create barriers to entry for generic applicants and to delay such entry, thus constituting an abuse of AstraZeneca's dominant position.

⁴¹ *Case C-457/10 P AstraZeneca v European Commission* (n 38) para 132.

⁴² *Ibid.* para 142.

⁴³ *Ibid.* para 148.

⁴⁴ *Ibid.* para 149.

⁴⁵ According to Advocate General Mazak *'the primary purpose of Directive 65/65 is to safeguard public health while eliminating disparities between certain national provisions which hinder trade in medicinal products within the Union, and it therefore does not, as claimed by the appellants, pursue the same objectives as Article 82 EC in such a way that the application of the latter is no longer required for the purposes of ensuring effective and undistorted competition within the internal market'*. *Ibid.* para 133.

Finally it needs to be noted that this kind of abuse, based on the deregistration of market authorisations is not likely to be replicated in the future due to the change in secondary legislation. Council Directive 65/65/EEC has been since repealed by Council Directive 2001/83/EEC and further amended by Directive 2004/27/EEC. According to Art. 10 of Council Directive 2004/27/EEC the deregistration of a marketing authorisation can no longer prevent generic applicant from relying on the necessary clinical trial data of the brand company. It is now sufficient that the brand drug has received marketing authorisation for its drug at some point in the past, so that the authorisation does no longer have to be active at the time of the generic application.

Nonetheless, it has been argued that the Court of Justice has opened the field, allowing competition law to intervene in the exercise of intellectual property rights and stop the abuse of such rights, if the relevant authority is not able to remedy the relevant distortion of competition.⁴⁶ From a competition law perspective this not surprising, that the rules of the market should apply in these cases; after all, intellectual property rights shape to a certain extent the markets.⁴⁷

c. Decisions in the wake of AstraZeneca

Indeed, it can be argued that a number of national competition authorities received a stimulus from this judgment and have not only increased their competition law scrutiny of certain types of conduct⁴⁸ in the pharmaceutical sector but also employed a rather interventionist approach which has been heavily criticised by some. Geradin, for example, heavily criticised the Italian competition authority (ICA) for its decision in *Pfizer* that was largely based on the rationale established by the Court of Justice in *AstraZeneca*.⁴⁹

⁴⁶ Rupperecht Podszun, 'Can competition law repair patent law and administrative procedures? AstraZeneca' (2014) 51 Common Market Law Review 281, 290.

⁴⁷ *ibid.*

⁴⁸ [XXX]

⁴⁹ Damien Geradin, 'The Uncertainties Created by Relying on the Vague 'Competition on the Merits' Standard in the Pharmaceutical Sector: The Italian Pfizer/Pharmacia Case' (2014) 5 Journal of European Competition Law & Practice 344.

The factual background to this decision was as follows; Pfizer acquired Pharmacia and hereby became proprietary owner of the drug Xalatan. Pharmacia had initially applied for patent extensions in the form of supplementary protection certificates⁵⁰ in a number of Member States, which led to the expiry for the main patent for the active ingredient in Xalatan in 2011.⁵¹ For some reason, Pharmacia had not applied for the same lawful type of patent extension in Italy and a number of other Member States, which would have led to a patent expiry in these Member States in 2009. Following the acquisition of Pharmacia, Pfizer then filed a divisional patent for Xalatan. This allowed Pfizer to apply for a SPC in Italy, which brought the patent expiry for the drug in line with the other Member States.⁵²

The ICA has found this conduct to be a restriction of competition and an abuse of Pfizer's dominant position. The authority set aside the fact that it is lawful under patent law and pharmaceutical regulation to apply for divisional patents as well as SPCs and regarded this conduct as outside the scope of competition on the merits.⁵³ This finding was largely based on the fact that divisional patent was challenged and prior to the decision by the ICA revoked by the competent patent authority. However, one has to note that after the ICA's decision was handed down, the divisional patent was held to be valid on appeal.⁵⁴ Geradin not only criticised the hasty nature of this decision and the fact Pfizer's conduct is perfectly legal under patent law and pharmaceutical regulation⁵⁵ but also because of the very vague nature of the concept of 'competition on the merits' and the associated lack of legal certainty.⁵⁶

Another decision in the wake of AstraZeneca was the Office of Fair Trading's (OFT) decision against Reckitt Benckiser.⁵⁷ The brand company had successfully marketed the acid reflux drug Gaviscon for years and had also introduced a second generation version of the drug, called Gaviscon Advance. In order to facilitate the prescription of the follow-on drug,

⁵⁰ Supplementary protection certificates were introduced in 1982 by Council Directive [XXX] in order to mitigate the significant reduction of period of patent protection for the brand companies due to the very lengthy approval process for novel drugs.

⁵¹ Geradin (n 50) 348.

⁵² *ibid.* 348

⁵³ *ibid.* 349

⁵⁴ *ibid.* 351

⁵⁵ *ibid.* 351.

⁵⁶ *ibid.* 352.

⁵⁷ *Decision of the Office of Fair Trading: Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc Decision No. CA98/02/2011 [2011] (Office of Fair Trading).*

Reckitt Bankiser delisted the original drug Gaviscon from the NHS sales channels – again, conduct that the company was entitled to under the law.⁵⁸ Following the withdrawal, physicians were only provided with the choice of ‘Gaviscon Advance’ when using the system and thus prescribed the follow-on drug that was still under patent protection.⁵⁹ The OFT regarded the deletion of Gaviscon from the NHS prescription list as conduct outside the scope of competition on the merits and thus a restriction of competition – directly referring to the AstraZeneca decision.⁶⁰ This finding was supported by contemporaneous internal documents, which showed that Reckitt Benckiser intentional withdrew Gaviscon Original from the NHS list, preventing physicians from being able to prescribe generic versions of Gaviscon and instead having to prescribe the still patent protected follow-on version Gaviscon Advance.⁶¹

Ultimately, both decision found restrictions of competition based on conduct outside competition on the merits that delayed generic entry. However, Geradin’s criticism of the AstraZeneca judgment in the light of the Italian Pfizer decision should not be seen as universally applicable to any decision that relies on the concept of competition on the merits as stipulated in AstraZeneca. One should consider the concept of competition on the merits in the context of the facts of the relevant case.

Pfizer concerned an original brand drug that was still under patent protection in most Member States. The filed divisional patent and the associated SPC extended Pfizer’s patent protection for Xalatan in line with other Member States and was achieved by a means originally introduced to mitigate the inequality in patent protection in the pharmaceutical sector that is caused by the lengthy drug approval procedure. Reckitt Benckiser, on the other hand, concerned a follow-on drug to an original brand drug whose patent protection was already expired or was about to expire. From a societal point of view and from an investment/reward perspective both cases are fundamentally different.

Whereas the drug concerned in Pfizer can be regarded as an example for breakthrough innovation, Gaviscon Advance is an example for incremental innovation. Whereas breakthrough innovation requires a significant amount of investment in R&D,

⁵⁸ *ibid.* para. 2.127

⁵⁹ *ibid.* para. 6.16

⁶⁰ *ibid.* para. 3.42

⁶¹ See *ibid.* para. 6.19

incremental innovation is to a certain extent based on the original R&D that was required for the original brand drug. As mentioned above, the clinical benefit of these incremental innovations is sometimes questionable and one could potentially argue for a reallocation of resources, favouring breakthrough innovation over incremental innovation that only leads to a product line extension. From a societal point of view, innovation is essential; this is evidenced by the bargain with society, which is inherent in intellectual property policy. The innovating pharmaceutical company is rewarded for its investment in R&D with patent protection for its drug. The SPC regulation can be seen as an extension to this bargain with society to ensure that the innovating company is adequately rewarded for its investment. If this premise is accepted one has to agree with Geradin's criticism of the ICA's decision in Pfizer and one needs to question whether Pfizer's conduct should really be regarded as conduct outside the scope of competition on the merits.

However, the situation in Reckitt Benckiser is different. The pharmaceutical company has already been rewarded for its innovation in Gaviscon and society can expect to be provided with cheaper generic versions of this drug once the patent protection has expired. Also in this case, the brand company effectively tried to 'extend the patent protection'. The company did not actually extend the protection for the original drug, but rather forced through its conduct the patients to use the patent protected follow-on drug instead of providing them with the choice to either take a cheaper generic version of the original drug or the still patent protected 'new' follow-on drug. Reckitt Benckiser thus effectively tried to reap additional rewards by creating a situation akin to breakthrough innovation through less R&D intensive and potentially less beneficial incremental innovation.

In this situation it should therefore be acceptable to regard this conduct as outside of the scope of competition on the merits and one should be less hostile towards the concept itself. Reckitt Benckiser would have had the alternative to bring Gaviscon Advance to the market in addition to the original drug and let the prescribing doctors and the patients itself decide which one to take, based on the potential therapeutic benefit of the follow-on drug. In addition to this fact, it is also worth remembering the incrementing internal documents.

Based on the discussion of these two cases one should consider the concept of 'competition on the merits' always in context of the relevant case. Neither every delay of

generic entry should be per se outside the scope of competition on the merits, nor should the concept be dismissed in general.

d. Product hopping facilitated by pay for delay settlements

This section sets out the unilateral theory of harm based on pay for delay settlements as a means to achieve ‘anticompetitive’ product hopping. It then discusses whether this theory of harm is in line with the Court of Justice’s approach in *AstraZeneca*; in particular attempting to determine whether the conduct in question falls outside the scope of competition on the merits and whether it could be objectively justified.

i. Theory of harm

It is vital for the brand company to introduce the follow-on brand drug on the market before generic competition for the original brand drug arises.⁶² The introduction of a follow-on brand drug also does not constitute an abuse itself. After all, the drug could constitute an improvement from the original brand drug and should be seen as part of the normal competitive process to mitigate the erosion of sales.⁶³ If the follow-on drug would be a real improvement over the original drug, consumers would switch to the follow-on drug despite a generic presence in the market. This would be a good indicator to measure the level of improvement of the follow-on drug over the original⁶⁴ and is a reason for why the product switch itself should not be an abuse. It allows the consumer “to vote with their feet” by choosing the drug that is most beneficial to them.

It would be a legitimate attempt to switch patients to the follow-on drug by introducing the follow-on brand drug to market after the brand company’s data exclusivity has lapsed but before the 2-year period of market exclusivity has expired.⁶⁵ Although the

⁶² European Commission (n 4). 360.

⁶³ *Case T-321/05 AstraZeneca v European Commission* (n 34) para. 804.

⁶⁴ Devlin (n 4). 666.

⁶⁵ Every brand drug that has been approved after 30 October 2005 receives 8 years of data exclusivity, 2 years of market exclusivity with a possible extension of a further year (so-called 8+2+1 formula). For more details see Appendix section 2.3.

brand company might argue that this could lead to the cannibalisation of profits⁶⁶ from the original brand drug that is still patent protected, one should always take into consideration that the follow-on brand drug is likely to be still under data exclusivity and is thus shielded from generic competition for a longer period.

However, a pay for delay settlement could replace the closed loophole of deregistration in the product switching scenario in AstraZeneca and push the generally legitimate conduct of product switching outside the scope of competition on the merits. As it has been discussed above pay for delay settlements in the European context do not necessarily provide the brand company with the opportunity to foreclose the market by paying off a single generic competitor. The foreclosure of the relevant market depends heavily on the competitive structure of the market and the number of generic company that are capable of entering in the market and of posing a viable threat to the brand company's monopoly profits.

Nonetheless, the brand company could attempt to delay the most viable and imminent entrant by a pay for delay settlement in order to gain sufficient time to introduce the follow-on brand drug on the same market as the brand drug. The settlement could ensure that the brand company can introduce the follow-on brand drug on the marketing without the fear of generic competition and can attempt to switch as many patients to from the original brand drug to the new follow-on brand drug at a later stage than under the normal competitive process, even after the expiry of the marketing exclusivity period.

In contrast to the legitimate business practice, the brand company delays generic entry by paying off the generic company to a point in time after the expiry of market exclusivity. This means that under normal circumstances the paid-off generic company could have potentially entered the market and the consumer could have made their drug choice based on the therapeutic benefit. The generic delay could also lead to the minimisation of the aforementioned profit cannibalisation and to a successful product switch at a point in time when the generic company could have already exerted competitive pressure on the original brand drug, which would directly benefit consumers. With generic competition in the market, the switch of patients would be less likely to be successful on a large scale or would be required prior to the expiry of the marketing exclusivity period, as patients' would be more

⁶⁶ Shadowen, Leffler and Lukens (n 4). 45.

likely to be switched to the generic version of the original brand drug than to the follow-on brand drug due to the significant price erosion that is associated with generic entry. Consumers would have been likely to switch to the cheaper generic version of the original brand drug than to the follow-on brand drug.

A pay for delay settlement could therefore be used by a brand company in a similar manner as the deregistration of marketing authorisations in *AstraZeneca*. The conduct should be regarded as outside the scope of competition on the merits in the pharmaceutical sector, as it allows the brand company to switch consumers to a follow-on drug due to the intentional delay of generic alternatives and is not based on an actual improvement of the follow-on drug.⁶⁷

ii. Is the theory of harm in line with *AstraZeneca*?

In order to determine whether the proposed theory of harm would be in line with the Court of Justice's approach in *AstraZeneca*, it is helpful to reiterate that the Court found in general that product switching

*'as a strategy whose object it is to minimise the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.'*⁶⁸

In *AstraZeneca* it was held that the deregistration of marketing authorisations was held to be outside the scope of competition on the merits, as the conduct created barriers to entry for generic companies without being justified, such as the need to protect an intellectual property rights or its effective expropriation in order to legitimately protect an investment.

Despite the fact, that the potential anticompetitive effect from the proposed theory of harm would be generally very similar to the one in *AstraZeneca*, one has to consider the differences in the means by which the anticompetitive effect is achieved. In *AstraZeneca* the product switching was facilitated by an abuse of the regulatory procedure to deregister a marketing

⁶⁷ See *C-457/10 P AstraZeneca v European Commission* (n 38) para. 130.

⁶⁸ *Ibid.* para 129.

authorisation that was deemed to be outside the scope of competition on the merits. In the proposed theory of harm, the product switch is facilitated pay for delay settlements which could also be regarded as a patent settlement between the brand company as intellectual property proprietor and a generic company that intends to enter the market prior to patent expiry. The settlement could thus be regarded as a justified means by the brand company to protect its intellectual property right and investment as well as to ensure its effective expropriation. After all, the generic company wants to gain market entry prior to patent expiry.

Yet for once, the strong argument has to be kept in mind that the settlement is not based on the validity of the patent but rather on the value transfer from the brand company to the potential generic entrant. It would not be necessary for the brand company to make a substantial value transfer to the generic entrant, if its patent would be strong and valid. In this case, the generic entrant should be deterred from entry by the patent itself. Even if one would accept that the proprietor can enforce its patent in any way as long as the patent is not yet expired one has to consider the underlying nature of the intellectual property right. Intellectual property policy does not confer an unfettered “right to exclude” but rather the right to “try to exclude”.⁶⁹ Intellectual property rights should be by no means unchallengeable from an intellectual property perspective and should not be immune from competition law scrutiny. In fact the US Supreme Court has held in its *Actavis* judgment that a pay for delay settlements falls outside the scope of a patent should be scrutinised by the US antitrust laws.⁷⁰ At the same time, the European Commission has found a pay for delay settlement to be a restriction by object in *Lundbeck*.⁷¹ A pay for delay settlements is thus unlikely to be within the scope of competition on the merits.

In addition, one also needs to take a step back and remember that the pay for delay settlement in this scenario is only part of a broader unilateral conduct. The anticompetitive effect is not achieved following the conclusion of the settlement with the potential generic entrant. It is rather achieved by the product switching to an incremental follow-on drug combined with a “facilitator” that enables the switch without having to fear any generic

⁶⁹ Shapiro (n 6). 395.

⁷⁰ *FTC v. Actavis* 133 S.Ct. 2223 (2013).

⁷¹ *Lundbeck* (n 1).

competition at a period of time at which generic competition is possible from a pharmaceutical regulation perspective, i.e. after the expiry of marketing exclusivity. Whereas in AstraZeneca, the “facilitator” was the abuse of the deregistration procedure, in this scenario the pay for delay settlement is the “facilitator” that makes the product switching fall outside the scope of competition on the merits.

What remains to be discussed is whether the brand company could argue that the product hopping facilitated by the pay for delay settlement is objectively justified. As already alluded to earlier, the brand company should not be able to rely on the exclusionary nature of the patent, arguing that it should be allowed to defend its patent by means of patent infringement litigation, also when the litigation is concluded by a settlement. A similar argument was brought forward in *Microsoft*.⁷² However, Microsoft’s plea that it would be allowed to refuse to grant access to its technology to third parties based on the fact that the technology was patent protected was rejected by the General Court. The Court held that this would lead to the conclusion that refusal to licence an intellectual property right could never constitute an abuse, which would contradict the ECJ’s judgments in *Magill* and *IMS Health*.⁷³ In the similar vein it could be argued that it should not be allowed to shield any patent enforcement from competition law scrutiny because of the exclusionary nature of the patent.⁷⁴

Furthermore, the conduct should also not be objectively justifiable by arguing that incentives to innovate would be reduced. Contrary to Microsoft which dealt with the refusal to licence an intellectual property right, the brand company is not curtailed in putting an innovative product to the market or is forced to provide a generic company with a licence. Instead, the company is prevented from shielding the market from generic competition, which allows the brand company to make the transition from an original brand drug to a follow-on brand drug without any competitive constraint from generic companies. The brand

⁷² *Case T-201/04 Microsoft v. Commission* [2007] ECR II-3601.

⁷³ *Ibid.* para.690 In *Magill* and *IMS Health* the ECJ stated that refusal to licence can constitute an abuse of a dominant position.

⁷⁴ This would circumvent antitrust scrutiny of potential anticompetitive conduct such as vexatious patent litigation such as the European Commission’s investigation against Rambus for their “patent ambush” strategy which has been concluded by a commitment decision *Case COMP/38.636 RAMBUS Commitments decision* [2010] OJ C30/17., or the recent investigations against Samsung in relation to standard-essential patents European Commission, *Antitrust: Commission sends Statement of Objections to Samsung on potential misuse of mobile phone standard-essential patents IP/12/1448* (2012).

company should also not be able to argue that the pay for delay settlement which facilitates the product switch would realise efficiencies to the benefit of the consumers, as the main purpose of a pay for delay settlement is to keep cheaper generic alternatives to the original brand drug of the market.

3. Conclusion

A new dimension has indeed to be added to European pharmaceutical antitrust. Pay for delay settlement should not only trigger competition law scrutiny with a focus on collusive conduct between the brand company and the generic company or companies. Following these remarks it can be concluded that pay for delay settlements could be used as a means to an end for the brand company to succeed with a broader unilateral conduct, which would justify an investigation under Art. 102 TFEU. In fact, a pay for delay settlement could turn the general legitimate attempt of the brand company to switch consumers to a new follow-on drug into an anticompetitive conduct that falls outside competition on the merits. In more general terms, this article has shed some light on the concept of ‘competition on the merits’ in the pharmaceutical sector and has argued that the concept should neither be outright dismissed nor generally accepted as the sole basis of the finding of an infringement. It is important to take into consideration the context of each individual case. Finally, from an enforcement perspective, one can derive a “plus factor” for competition law scrutiny in the pharmaceutical sector from this article. Stand-alone pay for delay settlements are likely to have limited anticompetitive potential compared to their US counterparts. However, competition authorities should raise increased concern, if a pay for delay settlement takes place in connection or proximity to a brand company’s product switch.