

A New Dimension to EU Pharma Antitrust  
Product Hopping and Unilateral Pay for Delay

Dr Sven Gallasch

University of East Anglia Law School

Norwich Research Park

Norwich, NR4 7TJ

01603 597623

s.gallasch@uea.ac.uk

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### Product Hopping and Unilateral Pay for Delay

Pay for delay settlements are currently high on the competition law enforcement agenda 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. However, this article moves the discussion away from the commonly recognized collusive anticompetitive potential, advocating for the expansion of antitrust scrutiny of pay for delay settlements to unilateral conduct. It argues that pay for delay settlements could be used as a “facilitator” for a broader unilateral strategy by the brand company such as product hopping – the intentional or even coercive switch of patients to a reformulated version of the original brand drug in anticipation of generic drug competition. The proposed theory of harm is not only in line with the European approach to related conduct in AstraZeneca and the CMA’s decision in Reckitt Benckiser, but also finds support in the US Second Circuit’s judgment in *State of New York v. Actavis* from May 2015.

Keywords: Pharmaceutical antitrust, product hopping, pay for delay settlement, unilateral conduct, theory of harm.

#### 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 in Europe. On a European level decisions against *Lundbeck*<sup>1</sup> and *Johnson & Johnson*<sup>2</sup> and *Servier*<sup>3</sup> have been issued in 2013 and 2014. On 8 September 2016, the General Court upheld the European Commission’s decision in *Lundbeck* in its entirety, finding pay for delay settlements to be a restriction by object.<sup>4</sup> On a national level, the Competition and Markets Authority has issued its first pay for delay infringement decision against GlaxoSmithKline and a number of generic companies in

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<sup>1</sup> Commission Decision of 19 July 2013 (Case AT.39226 - Lundbeck) OJ C (2013) 3803 final.

<sup>2</sup> European Commission Press Release, IP/13/1233, 10 December 2013, *Antitrust: Commission fines Johnson & Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl*, [http://europa.eu/rapid/press-release\\_IP-13-1233\\_en.htm](http://europa.eu/rapid/press-release_IP-13-1233_en.htm) (accessed 17 July 2016).

<sup>3</sup> European Commission Press Release, IP/14/799, 9 July 2014, *Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine*, [http://europa.eu/rapid/press-release\\_IP-14-799\\_en.htm](http://europa.eu/rapid/press-release_IP-14-799_en.htm) (accessed 17 July 2016).

<sup>4</sup> Case T-472/13 *Lundbeck v European Commission* [8 September 2016] (not yet reported)

February 2016.<sup>5</sup> Predominately, the competition authorities' current enforcement efforts rest on Art. 101 TFEU, challenging the anticompetitive harm caused by the collusive behaviour between a brand company and one or more generic companies that are paid off by the brand company in order to stay out of the market. This notion that pay for delay settlements facilitate collusion is in line with the longstanding enforcement against these types of agreements in the United States and is also widely recognized in the academic literature. In fact, a considerable amount of ink has been spilled over this kind of collusive behaviour by academics from around the world.<sup>6</sup> However, recently it has been argued that European pay for delay settlements have a reduced anticompetitive potential compared to United States, if the inquiry is based on the collusive behaviour of the parties involved; or at least require a detailed albeit structured effects-based analysis.<sup>7</sup> Such a different approach is required due to the regulatory differences in the respective pharmaceutical sectors. Whereas, a brand company in the United States can foreclose the entire market concerned by paying off a *single* generic company, achieving market foreclosure in Europe is more difficult or at least highly dependent on the actual market structure. Compared to the United States, the European regulatory framework, does not block subsequent generic entrants despite the conclusion of a pay for delay settlement in the market.

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<sup>5</sup> Competition and Markets Authority Press Release, 12 February 2016, *CMA fines pharma companies £45 million*, <https://www.gov.uk/government/news/cma-fines-pharma-companies-45-million> (accessed 17 July 2016).

<sup>6</sup> Among others Kevin D McDonald, *Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea* 15 *Antitrust Health Care Chronicle* 2 (2002); Marc G Schildkraut, *Patent-splitting settlements and the reverse payment fallacy* 71 *Antitrust Law Journal* 1033 (2003); Herbert J Hovenkamp, Mark D Janis and Mark A Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 *Minnesota Law Review* 1719 (2003); Thomas F Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley* 87 *Minnesota Law Review* 1789 (2003); Carl Shapiro, *Antitrust limits and patent settlements* 34 *Rand J. Econ.* 391 (2003); Anne-Marie C Yvon, *Settlements between brand and generic pharmaceutical companies: A reasonable antitrust analysis of reverse payments* 75 *Fordham L. Rev.* 1883 (2006); C. S Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 *New York University Law Review* 1553 (2006); Mark W Murphy, *Red flag or red herring? Reverse payments and the settlement of pharmaceutical patent litigation*, 4 *European Competition Journal* 541 (2008); Michael Kades, *Whistling Past the Graveyard: The Problem with the Per Se Legality Treatment of Pay-for-Delay Settlements*, 5 *Competition Policy International* 142 (2009); C. S Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 *Colum. L. Rev.* 629 (2009); Michael A Carrier, *Unsettling drug patent settlements: A framework for presumptive illegality*, 108 *Michigan Law Review* 37 (2009); Michael A Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 *Rutgers L.J.* 83 (2009); Michael A Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product-Hopping*, 62 *Florida Law Review* 1009 (2010); Phillip E Areeda and Herbert Hovenkamp, *Antitrust law: an analysis of antitrust principles and their application* (2. ed. Aspen Law & Business, New York, NY 2013) ¶2046; Aaron Edlin and others, *Activating Actavis*, 38 *Antitrust Health Care Chronicle* 16 (2013); Herbert J Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 *Minnesota Journal of Law, Science and Technology* 3 (2014).

<sup>7</sup> Sven Gallasch, 'Activating Actavis in Europe – the Proposal of a "Structured Effects Based" Analysis for Pay for Delay Settlements' *Legal Studies* (2016) forthcoming.

Foreclosure purely based on the pay for delay settlement's collusive nature is only possible in concentrated markets where the brand company is able to pay off all viable generic entrants.

Therefore, this article moves away from the common understanding that the anticompetitive harm of pay for delay settlements can only be caused by collusive behaviour and argues that these kind of agreements can also facilitate unilateral anticompetitive conduct by the brand company, such as product hopping.

It is recognized 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.<sup>8</sup> In the past, this kind of product hopping was facilitated by regulatory peculiarities that were exploited by the undertakings, as in AstraZeneca<sup>9</sup> or in the CMA's Reckitt Benckiser decision.<sup>10</sup> Using a pay for delay settlement as a facilitator for unilateral conduct such as product hopping instead, provides the brand company with a lot more 'flexibility' as it is no longer reliant on regulatory loopholes that can be closed by means of legislative reform. In essence, a pay for delay settlement provides the brand company with the potential to "buy" 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. The topicality of this issue can be highlighted by internal Lundbeck documents that have been discovered during the European Commission's investigation against the company in relation to pay for delay settlements.<sup>11</sup>

Before the article sets out the proposed theory of harm and establishes that the finding of an abuse of a dominant position would be consistent with the previous product hopping cases, it is setting the scene. It first addresses the reduced anticompetitive potential of *collusive* pay for

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<sup>8</sup> Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, Mich. St. L. Rev. 632, 658 (2007); Steve D Shadowen, Keith B Leffler and Joseph T Lukens, *Anticompetitive product changes in the pharmaceutical industry*, 41 Rutgers L.J. 51 (2009); 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.

<sup>9</sup> AstraZeneca (Case COMP/A. 37.507/F3) (2005) upheld by Case T-321/05 AstraZeneca v European Commission [2010] ECR 00 and Case C-457/10 P AstraZeneca v European Commission [6 December 2012] (not yet reported).

<sup>10</sup> *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).

<sup>11</sup> *Commission Decision of 19 July 2013 (Case AT.39226 - Lundbeck)* (n 1) para 808. "The immediate goal after launch [of escitalopram] will be to switch loyal Citalopram prescribers into loyal escitalopram prescribers".

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. Secondly, the article defines product hopping before it critically assesses two prominent European product hopping cases; the second abuse in *AstraZeneca*, and the UK CMA's decision in *Reckitt Benckiser*. Having done so, the article then turns to the discussion of pay for delay settlements as facilitator for unilateral conduct by brand companies; developing the theory of harm and arguing that that such conduct should not be able to be justified by the fact that the product hop is facilitated by a patent settlement, allegedly reducing litigation cost and increasing legal certainty.

## 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*<sup>12</sup>, 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.<sup>13</sup> In return for a certain value transfer from the brand company to the potential generic entrant, the generic entrant agrees not to enter the market before a certain date that has

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<sup>12</sup> *FTC v. Actavis* 133 S.Ct. 2223 (2013).

<sup>13</sup> See fn 6

been stipulated in the settlement agreement.<sup>14</sup> It can therefore be argued that the generic exclusion from the market is caused by value transfer rather than by the exclusionary nature of a valid patent. 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”.<sup>15</sup>

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.<sup>16</sup> According to this framework, a generic company can apply for drug approval with the Food and Drug Administration (FDA) 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 the brand company with the FDA in its “Orange Book”.<sup>17</sup> 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.<sup>18</sup> The ‘Paragraph IV certification’ also allows the brand company to challenge the generic application on grounds of patent infringement, as the generic application constitutes an act of patent infringement.<sup>19</sup> 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

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<sup>14</sup> Areeda and Hovenkamp (n 6) ¶2046c.

<sup>15</sup> Mark A Lemley and Carl Shapiro, *Probabilistic Patents*, 19 *The Journal of Economic Perspectives* 92 (2005).

<sup>16</sup> 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.

<sup>17</sup> The Orange Book is the FDA’s register of all patents in relation to every brand drug that is registered with the FDA.

<sup>18</sup> *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 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).

<sup>19</sup> C. S Hemphill and Mark A Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, (2011) 77 *Antitrust Law Journal* 947, 952.

dispute in court.<sup>20</sup> 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.<sup>21</sup> 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*’.<sup>22</sup> 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 authorizations do not take economic factors, such as patent rights of the brand company, into consideration. Under EU law, such a patent linkage is not permitted.<sup>23</sup> Following European secondary legislation,<sup>24</sup> 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 authorization.<sup>25</sup> The European authorities are thus not constraint 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

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<sup>20</sup> *ibid.* 952.

<sup>21</sup> Elizabeth S Weiswasser and Danzis Scott D. ‘The Hatch-Waxman Act: History, Structure, and Legacy’ (2003) 71 *Antitrust Law Journal* 585, 603.

<sup>22</sup> Hemphill and Lemley (n 19) 948.

<sup>23</sup> ‘*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.

<sup>24</sup> *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, OJ L 311 (2001) Art. 126.

<sup>25</sup> European Commission (n 8) 130.

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 incentive 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. Anticompetitive foreclosure would therefore only be possible in very limited cases where the brand company manages to pay off *all* viable generic entrants at the same time.<sup>26</sup> 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 strategy, potentially referred to as part of the brand company's "product lifecycle management"<sup>27</sup>, in which the settlement can facilitate anticompetitive foreclosure. Scrutinizing 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. In fact, the European Commission could initiate proceedings under Art 101 TFEU as well as under Art. 102 TFEU and could use its discretion to drop the Art. 101 TFEU proceedings against the generic company in return for their cooperation.<sup>29</sup> This is also not likely to be an undue

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<sup>26</sup> Gallasch (n 7) 10.

<sup>27</sup> 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.

<sup>29</sup> The European Commission not only has the discretion to decide how to conduct its investigation but also can decide only focus in its infringement decision only on a part of the case, so only on the unilateral of the brand company instead of the collusive behaviour. See Wouter Wils, *Discretion and Prioritisation in Public Antitrust Enforcement, in Particular EU Antitrust*, (2011) 34(3) World Competition 353, 364.

Enforcement



prioritization of the enforcement, as the investigated conduct is based on unilateral strategy that has been facilitated by the agreement between the brand company and the generic company. For example, assume that the pay for delay and product hop take place one year prior to the expiry of the patent. In this scenario the European Commission would have the choice to investigate all parties to the pay for delay settlement under Art. 101 TFEU with the potential anticompetitive harm being the delay of generic competition for one year; or it could investigate the brand company for unilateral product hopping which was facilitated by the pay for delay settlement with the potential anticompetitive harm being the delay of generic competition for several years due to the “renewed“ brand exclusivity of the follow-on drug. This example nicely illustrates that the predominant anticompetitive potential stems from the brand company’s unilateral conduct and not the pay for delay settlement itself. 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 conduct that rely on 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 authorization 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 authorization 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 as well as the CMA’s decision in *Reckitt Benckiser*.

### 3. Product hopping defined and explained

Product hopping is an exclusionary strategy involving the brand company's reformulation of its brand drug.<sup>30</sup> 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.<sup>31</sup> Another possibility is to slightly change the chemical composition of the drug, while keeping the actual active ingredient the same.<sup>32</sup> Alternatively, the brand company might also combine two or more pharmaceutical compositions in a single drug that used to be marketed separately.<sup>33</sup> 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.<sup>34</sup>

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 the switch takes place before generic entry.<sup>35</sup> For the United States, Carrier nicely highlights the importance of timing by a number of case studies about the brand drugs Provigil and Androgel.<sup>36</sup> 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 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!! "<sup>37</sup>*

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

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<sup>30</sup> Carrier (n 6) 8.

<sup>31</sup> Shadowen, Leffler and Lukens (n 8) 24.

<sup>32</sup> *ibid.* 24.

<sup>33</sup> *ibid.* 25.

<sup>34</sup> European Commission (n 8) para. 994.

<sup>35</sup> Carrier (n 6) 11.

<sup>36</sup> *ibid.* 13, 19.

<sup>37</sup> European Commission (n 8) para. 1028.

drug can be marketed, if it has already been approved, but it cannot be substituted for the second generation brand drug, as it lacks in bioequivalence.<sup>38</sup> 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.<sup>39</sup> Alternatively, the generic company could consider to reapply for generic approval of the second generation drug.<sup>40</sup> However, such a re-application might be prevented by the data and marketing exclusivity period which has been granted to the second generation drug, in case the brand company has obtained additional patents. 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.<sup>41</sup> Physicians or pharmacists would not be allowed to provide already switched patients with the generic substitute for the original brand drug. So, even if the original brand drug is not withdrawn from the market, the negative impact is likely to be significant for the generic entrant's revenue but also more importantly for consumer welfare, as consumers are deprived of cheaper generic choices.

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 takes place a few years prior to patent expiry. Examples of such conduct are the deregistration of marketing authorizations in *AstraZeneca* and the withdrawal of Gaviscon Original from the NHS sales channels in *Reckitt Benckiser*.

#### 4. Product hopping facilitated by regulatory gaming

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<sup>38</sup> 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.

<sup>39</sup> Devlin (n 8) 657.

<sup>40</sup> *ibid.* 657.

<sup>41</sup> European Commission (n 8) para. 1010.

Having defined product hopping and explained the underlying intuition of its anticompetitive potential, the article now discusses the rationale behind the abuse in *AstraZeneca* and in *Reckitt Benckiser*.

In *AstraZeneca*, the product hopping was achieved by the selective deregistration of marketing authorizations for AstraZeneca's brand drug Losec. The European Commission's finding of abuse 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 capsule<sup>42</sup>; (2) the raising of technical and legal barriers to entry designed to delay generic entry which was accomplished through the deregistration of the marketing authorizations 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.<sup>43</sup>

In order to switch as many patients as possible from Losec to Losec MUPS before generic entry, AstraZeneca raised barrier to entry by the selective deregistration of AstraZeneca's marketing authorization for Losec. According to the legal framework at the time, an abridged drug application for generic drugs by which the generic company could rely on the clinical trials and the necessary scientific literature was only available if the marketing authorization for the brand drug was in force on the date on which the generic abridged drug application was filed.<sup>44</sup> With the withdrawal of the marketing authorization AstraZeneca had created a regulatory obstacle,<sup>45</sup> preventing generic companies from using the abridged application procedure and therefore delayed generic entry and increased the generic companies' costs to overcome this barrier to market entry.<sup>46</sup> Based on this conduct the European Commission found that

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<sup>42</sup> 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 AstraZeneca v European Commission* (n 9) para. 804.

<sup>43</sup> For the purpose of the finding of abuse only the first two points are relevant. *ibid.* para. 803.

<sup>44</sup> *ibid.* para. 828.

<sup>45</sup> Joesph Drexl, *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, [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2009276](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2009276) (accessed 17 July 2016).

<sup>46</sup> *Case T-321/05 AstraZeneca v European Commission* (n 9) para. 829. Generic companies could still enter the market but were unable to rely on AstraZeneca's clinical data.

*'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]*<sup>47</sup>

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.<sup>48</sup> This delay allowed the brand company to introduce a follow-on brand drug and attempt to switch as many patients as possible to the new follow-on brand drug. Where successful the brand drug would not face significant 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. 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.'*<sup>49</sup>

AstraZeneca's plea that it was entitled to withdraw its marketing authorization 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.<sup>50</sup> 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

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<sup>47</sup> Case COMP/A. 37.507/F3 AstraZeneca (n 9) para. 860. This finding was upheld by the General Court Case T-321/05 AstraZeneca v European Commission (n 9) para. 671-696 and by the ECJ Case C-457/10 P AstraZeneca v European Commission (n 9). para. 129-141 holding that *'the deregistration of [Losec's marketing authorization] [...] by which AstraZeneca intended [...] to hinder the introduction of generic products [...] does not come within the scope of competition on the merits.'* at [130].

<sup>48</sup> In fact the product switching as such is expressly permitted by the Court; *'as a strategy whose object it is to minimize 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.'* *ibid.* para 129.

<sup>49</sup> *ibid.* para 134.

<sup>50</sup> *ibid.* para 132.

the Commission failed to apply the IMS Health criteria which only afford competition law intervention in ‘exceptional circumstances’.<sup>51</sup> 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.<sup>52</sup> The possibility to request the deregistration of a marketing authorization was also not deemed to be an equivalent to an exclusive property whose exercise could be justified as a means of ‘effective expropriation’.<sup>53</sup> 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 authorization purposes.<sup>54</sup> 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.

In *Reckitt Benckiser*, 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, Reckitt Benckiser delisted the original drug Gaviscon from the NHS sales channels – again, conduct that the company was entitled to under the law.<sup>55</sup> However the withdrawal led to the situation that physicians no longer had the choice between prescribing Gaviscon and Gaviscon Advance using their IT system. Even more importantly, prescribing physicians could no longer successfully search for generic alternatives for Gaviscon by hitting “Ctrl +G”. If a generic version is found, the physician can issue an open prescription using the generic name. This allows the pharmacists to either prescribe the original brand drug or the usually cheaper yet

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<sup>51</sup> *ibid.* para 142.

<sup>52</sup> *ibid.* para 148.

<sup>53</sup> *ibid.* para 149.

<sup>54</sup> 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.

<sup>55</sup> *Reckitt Benckiser Group plc Decision No. CA98/02/2011* (n 10) para. 2.127; Under the Best Practice Guide agreed between the Department of Health and the Association of the British Pharmaceutical Industry, a manufacturer may wish to withdraw a product from the market for a number of reasons such as changes in medical practice, commercial decisions or problems in obtaining active ingredients.

equivalent generic version. Gaviscon Advance, however, was still under patent protection and did not have any generic alternatives yet.<sup>56</sup>

Internal documentation referring to project “White Tiger” further highlighted Reckitt Benckiser’s intention to strategically use the withdrawal of Gaviscon to pre-empt ‘the publication of a generic name corresponding to Gaviscon, and to ensure that the NHS Gaviscon portfolio was not exposed to the full generic competition associated with the widespread issuing of open prescriptions;’<sup>57</sup> meaning prescriptions using the generic drug name which allow the pharmacist choose the cheapest generic version available.

As in the case of AstraZeneca, timing was of the essence. The withdrawal of Gaviscon needed to be completed before a generic name for Gaviscon was granted. The importance of this timing and the associate risk can again be illustrated by internal documentation referring to Project White Tiger stating that,

*‘If we do not act Peptac will be in a position to take control of the UK Alginates market and our entire Gaviscon NHS franchise will be under threat. It is imperative that we maintain control of our own destiny and do not allow the competition to dictate the future of one of RB’s power brands.’*<sup>58</sup>

Similar to AstraZeneca, Reckitt Benckiser was running a two stage strategy, (1) the introduction of a follow-on drug and (2) the timely withdrawal of the original drug which which was aimed at doing ‘everything possible to encourage [physicians] and pharmacists to upgrade patients to Gaviscon Advance instead’.<sup>59</sup>

The CMA 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.<sup>60</sup> The authority rejected Reckitt Benckiser’s argument that it has always intended to convert sales from Gaviscon to Gaviscon Advance as part of its normal “life cycle management strategy”.<sup>61</sup> In fact, the conversion of sales is not by itself anticompetitive or “outside” normal competition. It is rather the combination of the switch and

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<sup>56</sup> *ibid.* para. 6.16.

<sup>57</sup> *ibid.* para. 6.18.

<sup>58</sup> *ibid.* para. 2.180.

<sup>59</sup> *ibid.* para. 2.169.

<sup>60</sup> *ibid.* para. 3.42.

<sup>61</sup> *ibid.* para. 6.136.

the timing of the withdrawal, which was at the time a loss-making decision and therefore irrational absent the ulterior motive of hindering the ascendancy of generic competition.<sup>62</sup>

What both cases have in common, is the fact that the anticompetitive conduct is not the product switch as such but rather the combination of the product switch with the exploitation of the regulatory framework that facilitated the switch. However, at the same time, the necessity of having to rely on highly specific regulatory loopholes is also the “downside” of this kind of conduct. The very abuse might work once, but the loophole is likely to be closed swiftly by means of legislative reform, as in *AstraZeneca*.<sup>63</sup>

#### 5. Product hopping facilitated by pay for delay settlements

However, relying on a pay for delay settlement in order to facilitate product hopping instead of having to rely on pharmaceutical regulation and a specific regulatory loophole, allows brand companies to achieve the same goal. Furthermore, the use of pay for delay settlements makes the ‘anticompetitive’ product hopping strategy a lot more flexible for the brand company. Increased flexibility for potential anticompetitive conduct should generally lead to increased competition law scrutiny.

##### a. Theory of harm

The theory of harm centres on the brand company’s delay of generic competition that allows it to switch patients from a soon-out-of-patent-protection drug to a patent protected follow-on drug without the need for any notable therapeutic improvement as it does not have to fear any

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<sup>62</sup> *ibid.* para. 6.136.

<sup>63</sup> 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.



competitive pressure. Ultimately, consumers are deprived of the choice between the branded follow-on drug and the generic version of the original brand drug.

It is known to be vital for the brand company to introduce the follow-on brand drug on the market before generic competition for the original brand drug arises.<sup>64</sup> The introduction of a follow-on brand drug 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.<sup>65</sup> 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 can be regarded as a good indicator to measure the level of improvement of the follow-on drug over the original<sup>66</sup> 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.<sup>67</sup>

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.<sup>68</sup> During this period, the brand company does not have to fear generic competition, as generic companies are allowed to develop and produce the generic version, however, cannot market it yet. Although the brand company might argue that this could lead to the cannibalization of profits<sup>69</sup> 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.

The combination of a product switch with a pay for delay settlement could however turn the generally ‘procompetitive product switch’ into an ‘anticompetitive product hop’. Drawing an analogy with AstraZeneca, a pay for delay settlement could replace the closed loophole of deregistration in the product switching scenario in AstraZeneca.

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<sup>64</sup> European Commission (n 8) 360.

<sup>65</sup> *Case T-321/05 AstraZeneca v European Commission* (n 9) para. 804.

<sup>66</sup> Devlin (n 8) 666.

<sup>67</sup> For a similar argument see *Walgreen v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146 (D.D.C. 2008) ‘Courts and juries are not tasked with determining which product among several is superior. *Those determinations are left to the marketplace.*’ (emphasis added)

<sup>68</sup> 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).

<sup>69</sup> Shadowen, Leffler and Lukens (n 8) 45.

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 companies that are capable of entering in the market and of posing a viable threat to the brand company's monopoly profits.

The brand company could, nonetheless, 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 market 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 procompetitive product switch, the brand company delays generic entry by paying off the generic company to a point in time after the expiry of market exclusivity. This has a number of implications. (1) Under normal circumstances the paid-off generic company could have potentially entered the market providing consumers with a drug choice based on the therapeutic benefit. With generic competition in the market, the switch of patients would be less likely to be successful on a large scale or would have to be undertaken prior to the expiry of the marketing exclusivity period. This is the case as patients would be more 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, assuming the follow-on drug is of limited therapeutic benefit. (2) The product hop is also based on the intentional delay of generic alternatives rather than the actual improvement of the follow-on drug.<sup>70</sup> In fact, meaningful therapeutic improvement is not required due to the lack of generic alternatives. (3) Furthermore, the generic delay could also lead to the minimization of the aforementioned profit cannibalization as the successful product switch takes place 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. The brand company could thus switch consumers to the follow-on drug not only safely, but also at the latest point in time possible; close to the end of the patent life instead of the end of the marketing exclusivity period. In essence, the brand

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<sup>70</sup> See *Case C-457/10 P AstraZeneca v European Commission* (n 9) para. 130.

company gains the ‘best of both worlds’; near optimal profits from for the original brand drug and the safe consumer switch to the still patent protected follow-on drug.

This theory of harm finds support in the recent Second Circuit decision in *People of the State of New York vs. Actavis*.<sup>71</sup> In this decision the court upheld a preliminary injunction sought by the New York Attorney General against Actavis and its subsidiary Forest Laboratories in relation to the product hop from Namenda IR, an Alzheimer drug, to Namenda XR, the extended release version that only needs to be taken once a day instead of twice. The court distinguished between a “soft switch” and a “hard switch”. Where as “soft switch” concerns the introduction of a second-generation drug followed by the attempt to persuade patients to switch, the “hard switch” describes the scenario in which the new drug is introduced and patients are *coerced* into the switch due to the withdrawal of the original drug. Importantly, the court held that

*“neither product withdrawal nor product improvement alone is anticompetitive, [however] when a monopolist combines product withdrawal with some other conduct the overall effect of which is to coerce consumers rather than persuade them on the merits and to impede competition [then the conduct would be anticompetitive].”*<sup>72</sup>

The court also convincingly rejected a number of arguments brought forward by Actavis, attempting to justify conduct, such as: the relevant patents bar antitrust liability;<sup>73</sup> the superior nature of the drug justifies the withdrawal of the older drug;<sup>74</sup> the conduct prevents “free-

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<sup>71</sup> *People of the State of New York v. Actavis* Case No. 14-4624 (2d Cir. May 28, 2015).

<sup>72</sup> *ibid.* 35 citing *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979).

<sup>73</sup> quoting the US Supreme Court’s decision in *FTC v Actavis* 133 S.Ct. 2223, 2231 (2013) that “patent and antitrust policies are both relevant in determining the scope of the patent monopoly—and consequently antitrust law immunity—that is conferred by a patent,” the court held that the introduction of the new drug in combination with the withdrawal of the old drug in the context of the state’s drug substitution law goes beyond the scope of the patent protection conferred by the individual patents for Namenda IR and Namenda XR. *ibid.* 53.

<sup>74</sup> The court held that the alleged superior nature of the new drug would not be significant in this case, as the anticompetitive conduct in question originates from the coercive nature of the conduct of forcing patients to switch by withdrawing the original drug. *ibid.* 34. This finding is also in line with the reasoning in *Walgreen v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146 (D.D.C. 2008) where it has held that ‘Courts and juries are not tasked with determining which product among several is superior.’

riding” of competitors;<sup>75</sup> and finally that the application of antitrust laws to product hopping would deter innovation.

The last point is especially noteworthy from a more general policy perspective. Here the court suggested that

*“immunizing product hopping from antitrust scrutiny may [in fact] deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations.”(emphasis added)*<sup>76</sup>

In doing so, the court seems to have taken into careful consideration concerns voiced by a number of academics in relation to a potential antitrust inquiry into the degree or even necessity of the product innovation that led to the drug improvement of the follow-on drug.<sup>77</sup> Moreover, the court’s judgment suggests that the brand company is not forced to keep producing the original drug, indefinitely, alongside the follow-on drug, putting an additional burden on the company. This can be inferred from the fact that the court upheld the injunction, which required Actavis to produce the original brand drug for a mere 30 days post generic.<sup>78</sup>

It can be derived from this discussion that the court’s reasoning is in line with the general premise of the decisions by the ECJ and the CMA,<sup>79</sup> providing robustness to the proposed theory of harm.

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<sup>75</sup> The court rejected the “free-riding” argument as this kind of conduct in the context of the pharmaceutical sector was expressly granted by law; in fact accepting the argument would have contradicted the purpose of the Hatch Waxman Act, which allows generic competitors to rely on the brand company’s clinical data in an abbreviated drug application. *ibid.* 45.

<sup>76</sup> *ibid.* 50.

<sup>77</sup> According to Dogan and Lemley ‘*product hopping antitrust suits [could] require courts to inquire into product design choices, something antitrust judges take pains to avoid; they also raise concerns about courts second-guessing judgments by agencies and legislators about how best to balance competition and innovation in regulated markets.*’ Stacey L Dogan and Mark A Lemley, ‘Antitrust law and regulatory gaming’ (2009) 87 *Texas Law Review*. 4; see also Cheng which regards product hopping to raise minimal market antitrust concerns, ‘*as launching new product formulations and engaging in successful advertising campaigns are consistent with the unfettered market competition that antitrust law promotes.*’ Jessie Cheng, ‘An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry, 1512’ 108 *Colum. L. Rev.* 1471. 1510.

<sup>78</sup> *State of New York v. Actavis* (n 71) 24.

<sup>79</sup> *Supra* p. 15.

b. Pay for delay has the same effect as regulatory gaming

Although the potential anticompetitive effect from the proposed theory of harm would be generally very similar to the ones discussed above, one has to consider the differences in the means by which the anticompetitive effect is achieved. Whereas the product switching in the previous cases was facilitated by an abuse of the regulatory procedure that was deemed to be outside the scope of competition on the merits, the product switch in the proposed theory of harm is facilitated by 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. It could also be argued that the settlement generally lowers risk and increases certainty, thereby increasing investment.

Yet, it has to be kept in mind that pay for delay settlements are no ordinary patent settlements.<sup>80</sup> 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”.<sup>81</sup> 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 scrutinized by the US antitrust laws.<sup>82</sup> In a similar vein, the General Court found that

*‘even if the restrictions contained in the agreements at issue potentially fell within the scope of Lundbeck’s patents, in that they could also have been obtained through litigation, the contested decision rightly finds that this was merely a possibility at the time the agreements at issue were*

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<sup>80</sup> Sven Gallasch, ‘Debunking the pay for delay myth: pay for delay settlements are no ordinary patent settlements’ (2016) 15 Competition Law Journal 89.

<sup>81</sup> Shapiro (n 6) 395.

<sup>82</sup> *FTC v. Actavis* (n 12).

*concluded. Replacing that uncertainty in relation to whether or not the generic undertakings were infringing and to the validity of the applicants' patents with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue constitutes, as such, a restriction on competition by object in the present case, since that result was obtained through a reverse payment*<sup>84</sup>

A pay for delay settlement is thus not part of the normal competitive process and infringes competition law.

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 strategy. The anticompetitive effect is not caused by the conclusion of the settlement with the potential generic entrant. It is rather achieved by the product switching to an incremental follow-on drug facilitated by a “plus factor” that enables the switch without having to fear any generic 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 “plus factor” was the abuse of the deregistration procedure, and in Reckitt Benckiser the withdrawal of the drug from NHS sales channel, the “plus factor” in this theory of harm is the pay for delay settlement that makes the product switching fall outside the scope of competition on the merits. Even if one would assume that a pay for delay settlement would not infringe Art 101 TFEU – a situation that is unlikely following the General Court’s decision in Lundbeck – it should not be forgotten that the lawfulness of certain behaviour under one body of law has no impact on the determination of abusive behaviour under competition law.<sup>85</sup> *In the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.*<sup>86</sup>

Attempts to justify the conduct based the need to protect an intellectual property right or its effective expropriation in order to legitimately protect an investment should be rebutted.

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.<sup>87</sup> A similar

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<sup>84</sup> Case T-472/13 Lundbeck v European Commission (n 4) para. 401.

<sup>85</sup> Case C-457/10 P AstraZeneca v European Commission (n 9) para 132.

<sup>86</sup> Ibid.

<sup>87</sup> See Case T-472/13 Lundbeck v European Commission (n 4) para. 390 ‘*Although the applicants were entitled to enter into settlements with the generic undertakings in order to avoid the costs of potential litigation, they could not, on that ground, substitute their own assessment of the validity of their patents and the infringing*

argument was brought forward in *Microsoft*.<sup>88</sup> 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*.<sup>89</sup> 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.<sup>90</sup>

Furthermore, arguments that the conduct would reduce the incentive to innovate should be rejected. 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 company should also not be able to argue that the pay for delay settlement which facilitates the product switch would realize 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 off the market.

## 6. Conclusion

This paper has argued that pay for delay deals can bring rise to unilateral, as well as bilateral anticompetitive outcomes and that scrutiny of pharmaceutical antitrust should be widened accordingly. 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. Instead, pay for delay settlements could be used as a means to an end for the brand company

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*nature of the generic undertakings' products for that of an independent judge while paying the generic undertakings to comply with that assessment and refrain from entering the market for a certain period.'*

<sup>88</sup> *Case T-201/04 Microsoft v. Commission* [2007] ECR II-3601.

<sup>89</sup> *ibid.* para.690 In *Magill* and *IMS Health* the ECJ stated that refusal to licence can constitute an abuse of a dominant position.

<sup>90</sup> 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 *RAMBUS (Case COMP/38.636 Commitments decision)* OJ C30/17 (2010), or the investigations against Samsung in relation to standard-essential patents European Commission Press Release, IP/12/1448, 21 December 2012, *Antitrust: Commission sends Statement of Objections to Samsung on potential misuse of mobile phone standard-essential patents*, [http://europa.eu/rapid/press-release\\_IP-12-1448\\_en.htm](http://europa.eu/rapid/press-release_IP-12-1448_en.htm) (accessed 17 July 2016).

to succeed with a broader unilateral strategy, which would justify an investigation under Art. 102 TFEU. 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. It seems that the European Commission has alluded to this possibility in its Lundbeck decision when it was stated that

*‘The avoidance of generic sales of citalopram in the United Kingdom before the launch of escitalopram, and gaining a year and four months to establish escitalopram in the market before widespread generic entry took place in the United Kingdom was [...] very important to Lundbeck.’<sup>91</sup>*

In the author’s opinion such conduct warrants increased scrutiny, as product hopping facilitated by a pay for delay settlement is not constrained by the need to exploit a regulatory loophole, which makes the implementation of such conduct more flexible for the brand company. Yet, from an enforcement perspective, there is also good news. The detection rate of such conduct should be high. Competition authorities should start investigating, if they observe a product switch towards the end of a patent life in combination with a potential pay for delay settlement.

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<sup>91</sup> Lundbeck (n 1) para 808.