DRAFT SUMMARY

On 12 February 2016 the Competition and Markets Authority (CMA) issued its first infringement decision concerning so-called pay for delay settlements in the UK pharmaceutical market, imposing a fine of £44.99 million on the branded pharmaceutical company GlaxoSmithKline plc and a number of generic pharmaceutical companies. This article considers the CMA's decision and seeks to debunk arguments that pay for delay agreements are patent settlements that reduce litigation costs, create legal certainty and are also pro-competitive as they allow for early generic entry. It argues that pay for delay agreements are not "normal" patent settlements whose exclusionary power is derived from the validity of the underlying patent and should therefore never be immune from competition law scrutiny.

Debunking the Pay for Delay Myth: Pay for Delay Settlements Are No Ordinary Patent Settlements

Sven Gallasch[*]

1. Introduction

On 12 February 2016 the Competition and Markets Authority (CMA) issued its first infringement decision concerning so-called pay for delay settlements in the UK pharmaceutical market, imposing a fine of £44.99 million on the branded pharmaceutical company (brand company) GlaxoSmithKline plc (GSK) and a number of generic pharmaceutical companies (generic company) including Generics (UK) Limited and Alpharma Limited.[1] Notably, the CMA's decision is not only based on an infringement of Chapter I of the Competition Act 1998[2], but also on Chapter II of the Act with the CMA finding an abuse of GSK's dominant position in relevant market between 2001 and 2003.[3] However, the

[*] Lecturer in Law, University of East Anglia Law School, and faculty member, Centre for Competition Policy. The normal disclaimers apply.

[1] CMA Press release, '*CMA fines pharma companies £45 million'* (12 February 2016) https://www.gov.uk/government/news/cma-fines-pharma-companies-45-million (accessed 24 March 2016)

[2] In relation to the agreement with Generics (UK) Limited the CMA found an infringement of the Chapter I prohibition and/or Article 101 of the Treaty on the Functioning of the European Union.

[3] ibid. note 9 '*GSK infringed the Chapter II prohibition by making cash payments and other value transfers to induce three potential competitors (GUK, Alpharma and IVAX) to delay their potential*

article only focuses on the Chapter I assessment of the pay for delay settlement between GSK and its generic competitors.[4]

It did not take long for GSK to react to this decision. The company took to the big news outlets claiming that

"GSK and the generics companies entered into these agreements at the time in order to settle costly, complex and uncertain patent disputes. The agreements allowed the generics companies to enter the market early with a paroxetine product and ultimately enabled a saving of over £15m to the NHS."[5]

This statement seems to suggest that pay for delay settlements are in essence patent settlements that reduce litigation costs, create legal certainty and are also pro-competitive as they allow for early generic entry. This article debunks these arguments. It is argued that pay for delay settlements are not "normal" patent settlements whose exclusionary power is derived from the validity of the underlying patent and should therefore never be immune from competition law scrutiny.[6] These settlements are also not as pro-competitive as GSK claims. In fact, GSK provides the answer to the wrong question. The question should not be "How much has the NHS saved because of the agreement?" but rather "How much could have been saved in the absence of the agreement?"

2. Why pay for delay settlements are so contentious

Pay for delay settlements allow the brand company to delay generic entry into the relevant pharmaceutical market by paying off generic companies whose entry is imminent. In the case of GSK, the company entered into pay for delay settlement with the generic companies in relation to its blockbuster drug Seroxat (paroxetine), an anti-depressant drug in 2001.

From a competition law perspective the described conduct should seem rather straightforward; a company with significant market power pays a potential competitor a

---

independent entry to the UK paroxetine market. The CMA has concluded that the infringing conduct lasted from 3 October 2001 until 30 November 2003.'

[4] The CMA's infringement decision has yet to be published and therefore this article is based on the CMA's press release (note 1).

[5] The Guardian, '*Glaxo fined £37.6m for 'illegal behaviour' over Seroxat deals'* (16 February 2016) http://www.theguardian.com/business/2016/feb/12/glaxosmithkline-fined-anti-competitive-behaviour-seroxat (accessed 24 March 2016).

[6] As I have argued elsewhere, this does not mean that every pay for delay settlement should be regarded as per se anticompetitive. For a detailed discussion of the anticompetitive potential of pay for delay settlements see Sven Gallasch, *'Activating Actavis in Europe – The Proposal of a "Structured Effects-based" Analysis for Pay for Delay Settlements'* Legal Studies (forthcoming)

considerable amount of money to stay off the market. Doing so, the brand company can not only retain its supra-competitive or potentially even monopoly profits, but also inhibits product choice and undermines the general competitive process on the relevant market. The anticompetitive potential of this type of conduct is thus apparent.

However, this is only one side of the story. In fact, these mentioned value transfers from the brand company to the generic company are part of a patent settlement between the two parties. This raises at least indirectly the question whether a potential competition law intervention would strike the right balance between the protection of static consumer welfare compared to the brand company's incentive to innovate.

Indeed, legal counsels for the defending parties in such cases generally stress the importance of innovation in the pharmaceutical sector and put forward a myriad of arguments in support of their position, including the following:

(1) The brand company as patent holder is entitled to exclude competitors from the market until the patent has expired.
(2) The generic entry constitutes a patent infringement and the brand company is entitled to defend its patents by means of patent infringement litigation.
(3) Patent settlements are part of the patent enforcement toolbox and are simply ending patent infringement litigation early, reducing the cost and length of litigation, also creating legal certainty.
(4) Pay for delay settlements should be regarded as pro-competitive as they often allow for generic entry prior to the expiry of the patent(s) that cover the original brand drug.

Although all of these arguments seem to be convincing, one should not forget that they are based on a number of assumptions; chief amongst them that the patent(s) protecting the original brand drug are *valid* and not challengeable through patent infringement. The remainder of this article will show that these basic yet very strong assumptions are not necessarily true and are very much an over-simplification of reality.

3. The brand company has not the unfettered right to exclude competitors

It is often argued that brand companies entering into a pay for delay settlement with a generic competitor generally act within the scope of the patent; meaning that the settlement is covered by the exclusionary potential of the patent. Indeed, this position was

previously held by a number of courts in the United States, finding that any conduct including pay for delay settlements would be immune from competition law scrutiny as long as it takes place within the scope of the respective patent.[7] The same argument has been put forward by Xellia Pharmaceuticals and Zoetis Products in their appeal against the European Commission's pay for delay decision in *Lundbeck*,[8] stating that

'*the Settlement Agreement solely reflected the exclusionary scope of Lundbeck's patents, which, as a matter of law, must be presumed to be valid.*' [9]

This quote nicely highlights the cornerstone on which the argument is based – the presumed validity of the patent. Relying on this presumption however evades an important underlying question: *How likely is the respective patent to be found valid?* For the United States, for example, empirical evidence suggests that in only half of the litigated patents are deemed to be valid.[10] This empirical evidence supports the suggestion that the presumption of validity should therefore not be regarded as a substantive right as advocated by Xellia Pharmaceuticals and Zoetis Products in the Lundbeck appeal, but rather as a procedural tool that shifts the burden of proof on the party that calls the validity of a patent into question.[11] A patent should thus be considered as probabilistic right:[12] '*The actual scope of a patent right, and even whether the right will withstand litigation at all, are uncertain and contingent questions, at least until the patent is actually enforced in court.'*[13] A patent therefore does not provide its holder with an unfettered right to exclude competitors but rather the right to *try to exclude* its competitors.[14] The brand company is thus obviously entitled to enforce its patents against competitors that are infringing its patents. However, putting such a strong emphasis on the validity and the scope of the patent, especially in relation to a settlement as

---

[7] *Federal Trade Commission v. Watson Pharmaceuticals Inc.* 677 F.3d 1298 (11th Cir. 2012); *In re Ciprofloxacin Hydrocloride Antitrust litigation* 544 f.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litigation* 466 F.3d 187 (2nd Cir. 2005); *Valley Drug Co. v. Geneva Pharmaceuticals, Inc* 344 F.3d 1294, (11th Cir. 2003). 1311 & n.2, affirmed in *Schering-Plough Corp. v. FTC* 402 F.3d 1056, (11th Cir. 2005). 1065-66.

[8] Commission Decision of 19 July 2013 (Case AT.39226 - Lundbeck) OJ C (2013) 3803 final.

[9] *Case T-471/13 Xellia Pharmaceuticals and Zoetis Products v Commission* [30 August 2013] OJ C 325/75.

[10] John R Allison and Mark A Lemley, 'Empirical evidence on the validity of litigated patents' (1998) 26 AIPLA Q.J. 185, finding that only 54% of all validity decisions by US district or Federal Circuit courts were found to be in favour of the patent holder between 1989 and 1996. For similar results see also James Bessen and Michael J Meurer, 'Lessons for patent policy from empirical research on patent litigation' (2005) 9 Lewis & Clark Law Review 1

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

[12] Mark A Lemley and Carl Shapiro, 'Probabilistic Patents' [2005] 19 The Journal of Economic Perspectives.

[13] ibid. 32.

[14] Carl Shapiro, 'Antitrust limits and patent settlements' (2003) 34 Rand J. Econ. 391, 395.

suggested above, would lead to a situation in which the patent holder is always better of settling the lawsuit than fully litigating it. Such an outcome would go fundamentally against the probabilistic nature of patents.

4. A pay for delay settlement is not a normal patent settlement

In the pay for delay scenario, the brand company and the generic competitor indeed do not fully litigate the potential patent infringement, ending with a court's judgment deciding whether the brand company's patent is invalid or whether the generic competitor actually infringed the relevant patent. Instead, the parties settle their dispute. A patent settlement is generally regarded as beneficial, as it reduces significantly the length and the cost of the patent infringement dispute, thereby also creating legal certainty for the parties.[15] This is again not disputed. Yet, the main question is whether a pay for delay settlement truly constitutes a patent settlement that leads to the early resolution of the patent infringement lawsuit. A patent settlement should determine whether the patent is valid and ultimately infringed by the generic competitor or whether the patent is invalid and thus not infringed by the generic competitor.

Generally, one should expect two potential outcomes for patent settlements that include a payment from one party to the other. Either the parties to the settlement regard the patent as valid and infringed, leading to a payment of damages from the infringing party to the patent holder; or the parties deem the patent to be invalid or not infringed, leading to a potential payment of damages from the patent holder to the allegedly infringing party. In a pay for delay settlement these two scenarios are somewhat combined. The generic competitor that intended to enter and therefore infringed the relevant brand company patent accepts the validity of the patent and stays off the market. Nonetheless, the brand company makes a considerable payment to the generic competitor, normally exceeding the profits that the generic competitor could have gained following its market entry. The payment thus arguably not only goes in the "wrong direction"[16] but also exceeds the gains that could have been achieved by the generic competitor, should it have decided to litigate the patent infringement lawsuit to the end.

In the case of GSK, the CMA states that the UK market for Seroxat exceeded £90 million in 2001 and the payments to the generic competitors that decided to stay off the market were

[15] European Commission, *Pharmaceutical Sector Inquiry: Final Report* (2009) para 707.
[16] Lemley and Shapiro (n 10). 92.

totalled £50 million over the period of 2001 to 2004.[17] These payments are significantly higher than the profits that could have been expected upon entry.[18]

Under normal circumstances such a payment should not be required, if the generic company accepts the validity of the patent. The exclusionary power of the patent should be sufficient to prevent the generic competitor from entering the market. It can be therefore argued by implication that the exclusionary power of the pay for delay settlement does not stem from the validity of the patent but rather from the payment itself. It is exactly this conclusion that has led the US Supreme Court in its seminal *Actavis* judgment to infer market power as well as anticompetitive harm from the size of the payment.[19] The majority opinion written by Justice Breyer expressly states that size of the payment can act as '*a workable surrogate for a patent's weakness*'.[20] A pay for delay settlement is thus not really ending patent infringement litigation; it is rather evading it.

5. A pay for delay settlement blocks future patent challenges

Apart from evading patent infringement litigation between the parties to the settlement, a pay for delay settlement also leads to the effective foreclosure of patent challenges by subsequent generic entrants. Admittedly, this effect is more prevalent in the United States than in the UK/EU, yet should not be entirely dismissed for in the European context.

In the United States, a single pay for delay settlement can foreclose the market entirely until the expiry of the underlying patent, due to the regulatory regime that is in place. Following the Hatch Waxman Act, no subsequent generic entrant can even challenge the respective patent. A patent challenge can only be achieved by means of patent

[17] CMA Press Release (n 1). '*Generics (UK) Limited (GUK) and Alpharma accepted value transfers from GSK as compensation for their agreement to delay their efforts to enter the market independently of GSK. Those value transfers included cash payments, and the effective transfer from GSK of profit margins by means of agreements permitting the supply of limited volumes of product to the market in place of GSK. The appointment of GUK and Alpharma as distributors of GSK's paroxetine provided a means of transferring value from GSK to these companies, with no meaningful increase in the level of competition facing GSK.*' [at note 10].

[18] According to the CMA's press release, the sales volume of £90 million was based on 4.2 million prescriptions for Seroxat leading to a price per prescription to roughly £21.40. Following the generic entry in 2003 the average price dropped by 70% within two years, leading to a price of roughly £6.40 per prescription. Even if we assume an instant generic market share of 50% by a single generic company (which is highly unlikely), the generic company could have expected a sales volume of roughly £12.8 million. See ibid.

[19] *FTC v. Actavis* 133 S.Ct. 2223 (2013).

[20] Ibid 2236.

infringement, which is only possible once the US Food and Drug Administration (FDA) has granted the subsequent generic entrant a marketing authorisation. The FDA however is barred from granting a subsequent generic marketing authorisation, until the first-filing generic applicant, who is the generic party to the pay for delay settlement in question, has entered the market for a period of 180 days. This regulatory bottleneck provides the parties to a pay for delay settlement with the possibility to stipulate the date on which the FDA is allowed to grant further marketing authorisations. The brand company can effectively prevent its patent from being challenged at all, if it is stipulated that the first-filing generic competitor is able to enter the market 180 days prior to patent expiry.[21] This leads to the result that a patent is rendered unchallengeable for the entirety of the patent life due to a pay for delay settlement whose exclusionary power is based on the payment to the generic company instead of the validity of the patent. This contradicts patent law policy, as no patent should be unchallengeable; remember a patent only confers the right to *try to exclude*.

It is true that such foreclosure and prevention of patent challenges is more difficult to achieve under the European framework yet not impossible, as no such regulatory bottleneck exists. As I have previously argued elsewhere, market foreclosure is highly dependent on the actual market structure and the competitive environment.[22] In order to achieve a similar anticompetitive outcome in Europe as compared to the United States, a brand company would have to pay off all generic companies that have the capabilities of becoming a viable competitor and whose entry is imminent – ideally at the same time.[23] Imagine a scenario in which three generic companies could produce a generic version of the brand drug, yet only two of the companies are already preparing for market entry with the third company being one year away from market entry. In this case, it is sufficient for the brand company to pay off the two imminent entrants for now in order to evade a patent challenge for the time being and effectively buying itself another year of monopoly profits.

In fact, this appears likely to have been the situation in the case against GSK as well as in the European Commission's case against Lundbeck. GSK paid off Generics (UK) Limited

[21] For a general discussion of the intricacies of the Hatch Waxman Act and its impact on pay for delay settlements see amongst others 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) 2046c; C. S Hemphill and Mark A Lemley, 'Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act' (2011) 77 Antitrust Law Journal 947.
[22] Gallasch (n 4)
[23] Ibid

and Alpharma in 2001 with independent generic entry only taking place at the end of 2003.[24] This suggests that all generic companies that posed a viable threat of competition have been paid off at the time. In the case of Lundbeck, the brand company paid off Alpharma, Generics (UK), Arrow and Ranbaxy.[25] The simultaneous conclusion of pay for delay settlements with a number of generic competitors again suggests that all viable entrants at the time have been paid off at once.

Ultimately, a pay for delay settlement should not be equated with a normal patent settlement and should not be considered as part of the brand company's patent enforcement toolbox.

6. Allowing early generic entry does not eradicate the anticompetitive harm

According to GSK's press release '*the agreements allowed the generics companies to enter the market early with a paroxetine product and ultimately enabled a saving of over £15m to the NHS.'*

This statement is again based on a number of assumptions: that the underlying patent is valid and infringed; and that one can determine an actual date on which the drug comes off patent allowing generic entry.

We have already seen above that a pay for delay settlement is at the very least not a very good indicator for patent validity. The brand company has rather induced its competitors not to challenge the patent's validity by means of a value transfer; ultimately safeguarding the patent from any challenges. However, we have so far only partly addressed the first assumption, namely the validity of the patent. The second part of the assumption is that the generic competitor has not infringed the brand company's patent. Yet, this is not as self-evident as it may seem. The validity of the patent does not necessarily lead to patent infringement by a potential generic competitor. The alleged infringer might not have used the valid patent in the first place, which begs another very important question: What kind of patent is at the heart of the pay for delay settlement?

If the patent in question covers the actual active ingredient of the drug itself, the generic company is likely to infringe the patent while producing a generic version of the drug prior to patent expiry. However, the situation is different when the patent does not cover the

[24] CMA Press Release (n 1).
[25] European Commission (n 6).

active ingredient itself but rather the process by which the ingredient is produced. In this scenario, the generic company might be able to develop its own non-infringing process to produce the drug. Patent validity would then no longer be an issue as the generic competitor has found a way around the brand company's process patent. For example, this has been the case in European Commission's pay for delay decision against Lundbeck. Lundbeck had argued that Matrix Laboratories Limited infringed one of its process patents for the production of generic citalopram, yet had to concede later that Matrix was using a non-infringing process.[26] The European Commission thus correctly found that *'Lundbeck could not - and cannot now - claim as an objective fact that an infringement existed and that Lundbeck therefore had the right to exclude its generic challengers from the market.'*[27]

It is important to keep these differences between product and process patents in mind, when determining the "date" on which the brand drug comes off patent or rather the date on which the generic competitor risks market entry. In reality, these patents do not expiry simultaneously but rather sequentially over time. Brand companies often file process patents years after the patent covering the active ingredient. This sequential process has a direct impact on the generic competitors' decision over market entry. Again, these decisions by generic competitors are likely to vary, as some generic competitors might be more capable than others in inventing around the brand company's process patents. Based on this premise, it is possible to derive a number of conclusions. Firstly, a real universal date on which a drug comes off patent does not exist; it is rather an individual date based on the generic competitors' drug production capabilities. Second, when generic entry does happen, it is likely that the brand company has decided to cease defending its process patents.

In the case of paroxetine, independent generic entry occurred in late 2003, which is still prior to patent expiry, meaning that GSK decided to no longer challenge generic entry.[28] It is therefore reasonable to assume that generic entry could have already occurred in 2001, at a point in time when the generic parties to the pay for delay settlements with GSK were taking steps to market entry.[29] In terms of GSK's statement concerning the savings for the NHS it can thus be concluded that these savings only constitute those "granted" by GSK and

---

[26] See *Commission Decision of 19 July 2013 (Case AT.39226 - Lundbeck)* OJ C (2013) 3803 final, para 674: *"Lundbeck and [an independent expert on whose views Lundbeck had relied] now had to admit, having examined the process in operation in India, that their firm and unshakeable confidence that it was impossible for Lagap and its suppliers to be operating a non-infringing process was unfounded. The process that they had seen was indeed a non-infringing process and did produce a product which appeared to be Lagap's product [a generic version of citalopram]."*

[27] Ibid.

[28] CMA Press Release (n 1).

[29] ibid.

not the ones that could have been achieved through the normal competitive process since 2001. The pay for delay settlement effectively deprived the NHS from additional savings between 2001 and 2003 that would have emerged following generic entry.

7. Conclusion

Pay for delay settlements should not be equated with ordinary patent settlements. Their exclusionary power is not derived from the validity of the patent but from the size of the payment flowing from the brand company to the generic competitor. As such, they should not be seen as within the scope of the relevant patent and should never be immune from competition law scrutiny.

Pay for delay settlements are entered into by brand companies and their generic competitors because they constitute a win-win situation for the parties. Both parties achieve more than they could have achieved under the normal competitive process. The brand company protects its patents against generic challenges, retains its market share and avoids a significant drop in sales prices due to generic entry. The generic company gains more profit than it could have achieved following market entry; even better it does not even have to produce any products, it simply receives a share of the brand company's profits. The only party that is losing out is the consumer – or in the case of GSK's deal with its competitors, the National Health Service.