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Reverse Payment Patent Settlements in the European Union and the United States

Damien Geradin, Douglas Ginsburg & Graham Safty^(*)

ABSTRACT

In recent years, reverse patent settlement agreements — whereby a patent holder pays or gives other forms of value to an infringer in order to avoid or to settle patent litigation — have raised considerable debate in the pharmaceutical field in both the United States and the European Union, with the antitrust authorities and courts reaching different conclusions as to their compatibility with competition rules. In the United States, the Supreme Court addressed this matter in the *Actavis* case, in which it determined that reverse patent settlements should be assessed under the “rule of reason.” In contrast, the European Commission in its *Lundbeck* decision considered that reverse patent settlements were per object restrictions of EU competition law and therefore the effects of such agreements did not need to be analyzed. This decision is, however, being appealed before the General Court of the EU. In its more recent *Servier* decision, the Commission has modified its approach as, while it declared that the reverse patent settlements in question were per object restrictions, it also demonstrated that these agreements had anticompetitive effects. Against this background, we contrast the approaches taken in the US and the EU with respect to reverse patent agreements, and assess which approach makes the most sense. We also address a number of important questions, which are being looked at by lower courts in the US and may also be relevant in the EU.

Keywords: Patent settlements, pharmaceuticals, Actavis, antitrust, competition, drugs

JEL: H51, I11, K21, K41, L40

I. INTRODUCTION

In the pharmaceutical industry, originator companies researching and developing new medicines will typically obtain a range of patents to protect these medicines against generic competition. On the other side, generic suppliers seeking to enter the market will often challenge

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the validity of these patents or may simply launch their product, forcing the originator to bring litigation to enforce its patent and prevent the generic's entry. In the resulting litigation, the originator and the generic supplier often decide to enter into a settlement.

The settlement terms vary from case to case, but many of settlements have involved a payment made by the patent holder (the originator) to the accused infringer (the generic supplier) in order to settle the dispute. These settlements are known as "reverse-payment patent settlements" because they involve the plaintiff paying the defendant rather than the defendant paying the plaintiff to settle a case. Although settlements are ordinarily encouraged by courts because they save the resources of both the parties and the court itself, the lawfulness of settlements involving a reverse-payment is the subject of a heated debate in both Europe and the United States. Competition authorities on both sides of the Atlantic are concerned that such settlements may unduly delay market entry of generic drugs to the detriment of consumers and of governments' health care budgets.

II. UNITED STATES

We begin by addressing the legality of reverse-payment patent settlements under the U.S. antitrust laws. Section A describes the statutory framework that governs challenges to the validity of pharmaceutical patents. Section B examines the Supreme Court's decision in *Federal Trade Commission v. Actavis*,¹ which holds that a reverse-payment patent settlement "can sometimes unreasonably diminish competition in violation of the antitrust laws." Section C identifies several important questions that pharmaceutical companies, regulators, and courts must now confront in evaluating the legality of a reverse-payment settlement agreement.

A. Statutory Framework

A company that wishes to sell a drug in the United States must submit a New Drug Application (NDA) to the Food and Drug Administration (FDA), which evaluates the safety and effectiveness of the drug. The applicant must disclose, among other things, any patents covering the formulation of the drug or the method of using it.²

The FDA's process for approving a new drug is notoriously long and expensive, but a shortcut is available to a company that wishes to sell a bioequivalent generic version of a drug that has already been approved by the FDA. Under the Hatch-Waxman Act of 1982, an applicant may request permission to sell a generic by filing an Abbreviated New Drug

¹ 133 S. Ct. 2223 (2013)

² 21 U.S.C. § 355(b)(1).

Application (ANDA).³ The applicant must certify that any patent covering the brand version of the drug has expired or, as is more relevant here, that the patent is “invalid or will not be infringed by” the sale of the generic,⁴ perhaps because the invention was obvious or the patent was procured by fraud. The brand may defend the validity of its patent by filing suit against the generic within 45 days.⁵ The brand ordinarily does sue because the FDA must then refrain from approving the generic’s ANDA for 30 months in order to give the parties time to litigate the validity of the patent.⁶

The Hatch-Waxman Act provides an additional incentive to manufacturers of generic drugs to challenge patents they believe are invalid. The first applicant to file an ANDA with a paragraph IV certification receives a 180-day period of exclusivity during which no other manufacturer may sell a generic version of the drug.⁷ During those 180 days, the generic applicant need only compete with the branded drug and with the “authorized generic” should the brand manufacturer decide to produce one, but not with the numerous other generics that may enter the market soon after a patent expires or is invalidated.

Of course, both the brand and the generic companies have an important incentive to prevail in the patent infringement suit. The brand can preserve its patent monopoly by proving the patent is valid, and the generic, if it proves the patent is invalid, can enter the market with the advantage of the 180-day exclusivity period. Both parties, however, also have a compelling reason to settle the patent infringement suit, in addition to avoiding the cost of prolonged litigation: By reaching a settlement agreement before the court might invalidate the patent, the patent continues to generate monopoly profits that the brand and the generic can divide between them.

A hypothetical example illustrates this powerful incentive to settle. Assume the brand version of a drug is protected by a patent that expires in seven years. The brand will face no competition from generics during that period and is therefore able to sell the drug for the profit maximizing monopoly price of \$10 per unit. A generic manufacturer, believing the patent is weak, files an ANDA with a paragraph IV certification and the brand manufacturer sues it for patent infringement. If the generic successfully defends the suit by proving the patent is invalid, then the generic will enjoy a 180-day exclusivity period, free from competition from other generics. During the exclusivity period the generic and the brand have a duopoly and therefore

³ *Id.* § 355(j).

⁴ *Id.* § 355(j)(2)(A)(vii)(IV),

⁵ 21 U.S.C. § 355(j)(5)(B)(iii).

⁶ *Id.*

⁷ *Id.* § 355(j)(5)(B)(iv).

each can sell the drug for, say, \$6 per unit. After the expiration of the 180-day exclusivity period, several other generics enter the market and the price drops to the competitive price of \$2 per unit.

Defeating the patent and entering the market with a brief period of exclusivity might be a profitable outcome for the generic, but settling the patent litigation with the brand might prove much more profitable. If the brand manufacturer withdraws the patent infringement suit, then the brand will maintain its monopoly until the patent expires in seven years and will continue to sell the drug for \$10 per unit during that period. The generic might agree to dismiss the suit, even though it believes the patent is vulnerable, if the brand agrees to pay the generic more than the generic would have earned by invalidating the patent. Continuing the example above, the brand might agree to pay the generic \$5 for every unit it sells — still at the monopoly price of \$10 — until the patent expires in seven years. That might well prove more profitable than earning \$6 per unit during the 180-day exclusivity period followed by only \$2 per unit thereafter, when both the brand and the generic would be subject to competition from other generics. In short, both the brand and the generic might be better off settling the patent litigation, leaving the brand's monopoly in place, and dividing the resulting profits. They will be benefitting, however, at the expense of consumers who must continue to pay \$10 per unit for the same drug they could have purchased for \$2 if the generic had successfully invalidated the patent.⁸

For this reason, the Federal Trade Commission (FTC) and drug purchasers have argued that at least some reverse-payment settlement agreements are unlawful “restraints of trade” in violation of the antitrust laws. Indeed, in a series of cases spanning more than a decade, the FTC argued that reverse-payments are *per se* violations of the Sherman Act. The federal courts of appeals divided over that claim and in 2013 the Supreme Court finally evaluated a reverse-payment settlement agreement in *Federal Trade Commission v. Actavis*.

B. The Actavis decision

Prior to the Supreme Court's decision, one court of appeals had held that reverse-payment agreements are indeed *per se* illegal under the antitrust laws.⁹ Another concluded they are presumptively illegal, but offered the brand and the generic an opportunity to rebut that

⁸ After the generic and the brand enter a settlement agreement, other manufacturers of generics are unlikely to sue to attempt to invalidate the patent because only the first generic to file an ANDA with a paragraph IV certification is eligible for the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(D)(iii). Without that window of exclusivity, there is little reward for a generic that invalidates a patent because it must immediately compete with every other manufacturer that enters the market. A trade association that represents manufacturers of generic pharmaceuticals has noted that the “vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.” *Actavis*, 133 S. Ct. 2223 (2013).

⁹ *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

presumption.¹⁰ Yet another court of appeals evaluated the strength of the patent, reasoning that the agreement between the brand and the generic to settle the litigation was more likely to be anticompetitive if the generic had a good chance of invalidating the patent had it continued to litigate.¹¹ Still other courts held that a reverse-payment settlement agreement is lawful so long as its terms fall within the “scope of the patent,” i.e., do not extend beyond the expiration date of the patent or restrict competition in the market for a drug other than the one protected by the patent.¹²

In *Actavis* three Justices of the Supreme Court would have adopted the scope of the patent test, but the majority disagreed and held a reverse-payment settlement agreement “can sometimes unreasonably diminish competition in violation of the antitrust laws.” Specifically, the Court explained, a “large and unjustified” reverse-payment “can bring with it the risk of significant anticompetitive effects.” It nevertheless rejected the proposition, advanced by the FTC, that a reverse-payment settlement agreement should be deemed “presumptively unlawful.” Instead, it held that, like most other agreements subject to antitrust scrutiny, a reverse-payment settlement must be evaluated under the “rule of reason.” In other words, a reverse-payment settlement is neither inherently nor presumptively lawful nor unlawful. A court must evaluate each agreement individually and determine whether it is reasonable by considering its anticompetitive effects and its legitimate objectives.

The *Actavis* Court did not instruct the lower courts how to structure their rule of reason analysis. Nor did it specify the factors a court should consider in determining whether an agreement is unlawful beyond noting that

“the likelihood of a reverse-payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”

In sum, we now know that reverse-payment settlement agreements are “sometimes” unlawful and that a court must apply some variation of the rule of reason in assessing their legality, but the Supreme Court left unresolved a number of important questions about how to determine whether a reverse-payment settlement is unlawful.

¹⁰ *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012).

¹¹ *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

¹² *In re Ciprofloxacin Hydrochloride Antitrust Litig. (Cipro)*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005).

C. Important Questions after Actavis

In this section we discuss four questions that must be addressed in post-*Actavis* litigation involving reverse-payment settlements. Some of these issues have already divided the trial courts and led to inconsistent results in cases with billions of dollars at stake.

1. What is a reverse-payment?

We begin with what seems like a question with an obvious answer — what, exactly, is a reverse-payment? In the first section we offered a simple hypothetical in which the brand promised to pay to the generic a portion of its revenues from future sales of the patented drug. Settlement agreements are often more complicated, however, and may not even involve the brand making a direct payment to the generic.

In several instances the brand has compensated the generic for delaying its entry into the market simply by agreeing not to produce its own generic, known as an “authorized generic,” during the 180 days in which the first generic is protected from entry by another generic manufacturer. That exclusivity does not preclude the brand from producing its own generic — which is nothing but the branded drug sold under a different name and at a lower price. The brand manufacturer prolongs its time as a monopolist and the generic, when it later enters, might be able to earn hundreds of millions of dollars during the 180-day exclusivity period that it would have otherwise lost to the brand’s authorized generic product.¹³ In essence, both producers delaying their entry into the generic market confers substantial value to the generic without requiring the brand to make any payment to the generic.

Two trial courts held this type of agreement is not subject to scrutiny under the criteria specified in *Actavis*, and is therefore not subject to the antitrust rule of reason, because the Supreme Court addressed itself only to “payments.”¹⁴ In 2015 the Third Circuit court of appeals rightly, in our view, rejected this distinction and explained that a reverse-payment may entail any kind of consideration given in return for the generic’s agreement to delay its entry into the market.¹⁵ We expect the other circuits will agree. Indeed it would be absurd for them to do otherwise, as it would allow parties to avoid scrutiny under the antitrust laws simply by agreeing upon a non-cash form of compensation in lieu of an equivalent sum of cash.¹⁶

¹³ *King Drug Co. of Florence v. Smithkline Beecham Corp. (Lamictal)*, 791 F.3d 388 (3d Cir. 2015).

¹⁴ *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560 (D. N.J. 2014); *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180 (D. R.I. 2014).

¹⁵ *Lamictal*, 791 F.3d 388 (3d Cir. 2015).

¹⁶ Michael A. Carrier, *Eight Reasons Why “No-Authorized-Generic” Promises Constitute Payment*, 67 RUTGERS U. L. REV. 697 (2015).

Still, it will not always be easy for a court to identify a reverse-payment; at the very least, the non-cash compensation going to the generic manufacturer must exceed any reasonable estimate of the litigation cost the brand is avoiding by settling the case. Some reverse-payment settlement agreements are quite complex, however, and it can be difficult to value the various forms of consideration flowing back and forth between the brand and the generic.¹⁷ Consider, for example, the settlement agreement between Cephalon, a brand manufacturer, and the generic manufacturer, Teva, regarding the eugeroic drug modafinil.¹⁸ In addition to resolving the parties' patent suit, the agreement provided that Cephalon would purchase modafinil from Teva at a fixed price and make royalty payments to Teva in exchange for a license to use certain "modafinil-related intellectual property."¹⁹ Did Cephalon make a reverse-payment to Teva? These agreements might be ordinary business arrangements that both parties believed to be in their best interest, or they might be a method for covertly transferring value from Cephalon to Teva without arousing suspicion. The FTC and purchasers of modafinil argued the settlement agreement involved a reverse-payment because Cephalon paid far in excess of market value for the goods and services it received from Teva. For example, the agreement provided Cephalon would purchase modafinil from Teva for approximately \$500/kg even though it already had contracts to purchase it from other suppliers for \$200/kg, and Cephalon paid \$131 million for modafinil-related intellectual property that the plaintiffs alleged was of little value to Cephalon.

As another example, consider the settlement agreement between AstraZeneca and Teva involving Nexium. In addition to dismissing the suit related to the patents protecting Nexium, a popular brand medication for acid reflux, the parties agreed that Teva would pay \$9 million to AstraZeneca in order to settle an unrelated litigation involving Prilosec, another AstraZeneca drug for the same condition.²⁰ Did AstraZeneca make a reverse-payment to Teva? At first glance the agreement appears to provide for precisely the opposite because it requires the generic (Teva) to pay \$9 million to the brand (AstraZeneca). The plaintiffs argued the payment from Teva to AstraZeneca was in fact a cleverly disguised reverse-payment from AstraZeneca to Teva. At the time the parties entered this agreement, a trial court had determined that Teva had infringed AstraZeneca's patents related to Prilosec and a court of appeals had affirmed the judgment against Teva and remanded the case to the trial court to calculate damages. According to the plaintiffs, Teva would have been liable for far more than \$9 million if the trial court had

¹⁷ Aaron Edlin et al., *The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585 (2015).

¹⁸ In the next section we discuss the European Commission's investigation of the same settlement agreement.

¹⁹ *King Drug Co. of Florence, Inc. v. Cephalon, Inc. (Modafinil)*, Nos. 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2:08-cv-2141, 2015 WL 356913 (E.D. Pa. Jan. 28, 2015).

²⁰ *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367 (D. Mass. 2013).

imposed damages. AstraZeneca therefore conferred upon Teva a substantial benefit by agreeing to settle the Prilosec litigation for only \$9 million.

Determining whether this kind of arrangement involves a reverse-payment is no easy task. As expected, the plaintiffs presented an expert who said the \$9 million settlement agreement was extraordinarily favorable to AstraZeneca and the defendants countered with an expert who opined that the agreement was fair.²¹ A jury was left to decide whether the settlement agreement in the Prilosec litigation was unreasonable so that it could determine whether the settlement agreement in the Nexium litigation was unreasonable. Not surprisingly, the trial was long and expensive.

The Court's decision in *Actavis* encourages pharmaceutical companies to construct these elaborate settlement agreements in order to disguise a reverse-payment. The scope of the patent test favored by the dissenting justices would have avoided this problem by exempting most reverse-payment settlement agreements from antitrust scrutiny. Even if the courts are able accurately to identify reverse-payment settlements that have an anti-competitive effect – a dubious proposition – the cost of doing so will be substantial, as companies devote resources to structuring complicated settlement agreements and then litigating whether those agreements are reasonable.²²

Not surprisingly, courts have adopted inconsistent approaches to identifying reverse-payment agreements. Some courts have insisted that the plaintiff quantify in its complaint the value of the consideration flowing from the brand to the generic. Consider, for example, the settlement agreement between Wyeth and Teva related to the patents covering the antidepressant Effexor. As part of the settlement agreement, Wyeth promised not to sell an authorized generic version of Effexor during Teva's 180-day exclusivity period.²³ The plaintiffs alleged the no-authorized-generic agreement was a reverse-payment from Wyeth to Teva of approximately \$500 million. To support this estimate, the plaintiffs compared Effexor to Paxil, a similar drug that generated comparable revenue. The first generic manufacturer to produce Paxil had told the FDA "that the presence of an authorized generic for Paxil cost the company \$400 million in sales during its 180-day exclusivity period." The court nevertheless dismissed the plaintiffs' complaint, explaining that "[w]hile this comparison is useful for purposes of showing that a no-authorized generic agreement has value, it does not specifically value the monetary amount of

²¹ *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231 (D. Mass. 2014).

²² Bruce H. Kobayashi et al., *Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly*, 29 ANTITRUST 89 (2015).

²³ *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 WL 4988410 (D. N.J. Oct. 6, 2014)

the no-authorized generic agreement in this case.” The court advised that the plaintiff’s valuation of the no-authorized-generic agreement must account for the “difference in market expectations with and without an authorized generic,” which includes consideration of

“the share of the market that converts from the brand to the generic, the retail price of the generic during the 180-day exclusivity period with and without an authorized generic, and the share of the generic market that would have been retained by the authorized generic if there had been one.”

It is important to note that the court required that this analysis appear in the plaintiffs’ complaint, and that it dismissed the suit before allowing the plaintiffs to conduct discovery in order to substantiate their estimate of the value of the no-authorized generic agreement.

Compare the trial court’s reasoning in *Effexor* with the decision of the court of appeals in *Lamictal*, which held that the plaintiff’s complaint adequately alleged that a no-authorized-generic agreement was a valuable reverse-payment.²⁴ The *Lamictal* court relied upon the same type of evidence deemed inadequate in *Effexor*, explaining that “by using sales of the drug Paxil as a yardstick” it could infer that the no-authorized-generic agreement “would have been worth hundreds of millions of dollars.”²⁵

In litigation involving Aggrenox a trial court similarly allowed the plaintiff to rely upon general allegations estimating the value of the settlement agreement rather than requiring it to offer a reliable basis for quantifying the alleged reverse-payment.²⁶ The defendants pointed out that “the plaintiffs ha[d] not attempted to assign dollar values with significant precision or very obvious methodological justification to the various provisions of the settlement.”²⁷ The court acknowledged the “importance of the court’s ability to calculate the value of any nonmonetary payments,” but it reasoned that “these issues are sufficiently factual to require discovery” and therefore refused to dismiss the complaint.²⁸

These courts are performing a difficult balancing act. On the one hand, they must identify provisions in a settlement agreement that resemble ordinary business transactions but are

²⁴ *Lamictal*, 791 F.3d 388 (3d Cir. 2015).

²⁵ The plaintiffs in *Effexor* have appealed the district court’s decision to the Court of Appeals for the Third Circuit, where they are likely to prevail because that is the appellate court that decided *Lamictal*.

²⁶ *In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516, 2015 WL 1311352 (D. Conn. March 23, 2015).

²⁷ *Id.*

²⁸ *Id.*

in fact “cloaked reverse-payments” from the brand to the generic.²⁹ On the other hand, the courts must not deter legitimate transactions by allowing plaintiffs free reign to engage in invasive and costly discovery whenever a brand and a generic enter an intricate settlement agreement.

Commentators have suggested at least two reasons why courts should generally be skeptical about a settlement agreement that includes certain types of business arrangements, such as a promise by the generic to supply the brand with drugs or to market the brand’s products to physicians. First, there is evidence that brands and generics rarely engage in these kinds of deals unless they are settling a patent infringement suit.³⁰ Because these agreements are unusual, a court might infer they are “cloaked reverse-payments” rather than ordinary business arrangements. Second, commentators have argued there is no reason why brands and generics cannot enter legitimate business transactions separate from their agreements to settle a patent litigation.³¹ The parties’ decision to group together a business transaction and a settlement agreement arguably raises the inference that the business transaction is in fact a reverse-payment to the generic. On the other hand, the occasion of the settlement negotiations may bring to light other potential gains from trade. Nothing would be gained by insisting that the parties enter into two agreements, one to settle their litigation and one incorporating other business transactions, nor would a court be any more satisfied that the formal separation of the agreements negates the possibility of a reverse-payment.

2. When is a reverse-payment “large and unjustified?”

Recall that not all reverse-payments are inherently, or even presumptively, unlawful. In *Actavis* the Supreme Court explained that a reverse-payment “can bring with it the risk of significant anticompetitive effects” when the payment is “large and unjustified.”³² The lower courts are now tasked with deciding when a reverse-payment is “large and unjustified” and therefore possibly unlawful.

The nub of the problem is that, because the parties decided to settle, no one knows how the underlying patent litigation would have turned out. Perhaps the generic would likely have succeeded in invalidating the patent but nevertheless agreed to settle because the brand offered to pay it more than it expected to earn selling the drug – discounted, of course, by the probability

²⁹ *In re Niaspan Antitrust Litig.*, 42 F. Supp. 2d 735 (E.D. Pa. 2014).

³⁰ Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7 (2014); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009).

³¹ Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16 (2013).

³² *Actavis*, 133 S. Ct. 2223 (2013).

that it might lose the case. Under these circumstances, the settlement agreement might have an adverse effect upon consumers because it prolongs the brand's monopoly based upon what would have proved to be an invalid patent. Perhaps, however, as the litigation progressed the generic realized it was not so likely to prevail and that victory, again discounted by the probability of losing, would be worth more than the amount for which it could settle the case. Under these circumstances, the settlement agreement might be innocuous or, as discussed below, it might be beneficial to consumers. Although some courts before *Actavis* had attempted to evaluate the strength of the patent in order to determine whether the settlement agreement would likely have an anticompetitive effect, the Supreme Court foreclosed that approach. The Court instead used the size of the payment — i.e., whether it is “large and unjustified” — as a proxy for determining why the plaintiff settled. The assumption implicit in its decision is that a generic would demand a “large” payment if it had a strong case, but would settle for a small payment if it was unlikely to prove the patent is invalid. A large payment therefore indicates a greater likelihood the generic would have prevailed and thereby made the market more competitive had it not settled the litigation. The size of the payment clearly matters under *Actavis*, but the difficult question left unanswered by the Court is “the size of the payment relative to what?”³³

One possibility, and the most parsimonious, is that a payment to the generic from the brand is “large and unjustified” merely because it exceeds the expected cost of litigating the patent suit.³⁴ A payment in excess of that amount arguably raises the inference of an anticompetitive effect because it indicates the parties thought there was at least some chance the patent would be deemed invalid.

As other commentators have pointed out, however, this approach fails to account for the possibility that a brand might be risk averse and therefore decide to settle the patent litigation even if it is confident the patent is valid.³⁵ Some companies are heavily reliant upon a few “blockbuster” drugs that bring in billions of dollars per year. The vagaries of litigation make it impossible for a patentee's counsel to say there is no possibility of losing. And, because the patent is so important to the company, a brand might be willing to pay a substantial sum to avoid even a small possibility that a patent protecting a blockbuster drug will be declared invalid. Indeed it might be reasonable for the brand to pay a hefty ransom to the generic even if the generic's claims are quite weak. A company is ordinarily wary of overpaying to settle a weak case lest it encourage others to file nuisance suits. That is less likely to occur in the case of challenges to pharmaceutical patents because, as noted, only the first generic to file an ANDA

³³ Joshua D. Wright, *Antitrust Analysis of Reverse-payment Settlements After Actavis: Three Questions and Proposed Answers*, 2014 WL 5302766 (Oct. 10, 2014).

³⁴ Edlin et al., *Activating Actavis*, *supra*.

³⁵ Barry C. Harris et al., *Activating Actavis: A More Complete Story*, 28 ANTITRUST 83 (2014).

with a paragraph IV certification is eligible for the 180-day exclusivity period. Because other generics are not eligible for this valuable reward, they are less likely to challenge the validity of the patent, even if the first generic to file an ANDA extracts a large settlement from the brand.³⁶

The trial court presiding over the modafinil litigation offered a different test for determining whether a reverse-payment is “large and unjustified” that might prove more sensible. The court posited that “a reverse-payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim.”³⁷ It further reasoned that a payment is large enough to “induce a generic challenger to abandon its patent claim” if the value received by the generic “comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation.” As we read this passage, a discount for the probability of losing the patent litigation is embedded in the phrase “expected profits to be earned from prevailing.” If the generic challenger successfully invalidates the patent, then it will compete with the brand’s authorized generic for 180 days, after which it will also have to compete with any other generic entrants. The court might compare the profits the generic would be expected to earn under that scenario with the value of the reverse-payment. If the value of the reverse-payment exceeds the generic’s expected profits, then the court can infer that the generic would have accepted the settlement agreement even if it was confident that it would have invalidated the patent.

Although a reverse-payment provision that satisfies this test might be deemed “large and unjustified,” that does not necessarily mean the agreement as a whole harmed consumers. As discussed in the next section, the court must also account for the procompetitive effects of the settlement agreement.

3. How will courts evaluate the procompetitive effects of a reverse-payment settlement agreement?

In *Actavis* the Supreme Court instructed the lower courts, in keeping with the rule of reason, to consider the procompetitive as well as the anticompetitive effects of a reverse-payment settlement agreement: “[I]t would be incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.”

Courts applying the rule of reason generally have followed a three-step process. First, the plaintiff must demonstrate the defendants’ agreement produced an anticompetitive effect. In a

³⁶ *Actavis*, 133 S. Ct. 2223 (2013).

³⁷ *Modafinil*, 2015 WL 356913 (E.D. Pa. 2015).

case involving a reverse-payment settlement agreement, the plaintiff likely satisfies this burden by showing that the payment is “large and unjustified.”³⁸ If the plaintiff makes this showing, then the burden shifts to the defendants to justify the agreement by demonstrating that it had a greater pro- than anti-competitive effect.³⁹ Finally, the plaintiff may rebut the defendants’ justification and show the agreement was not necessary to achieve the procompetitive effect invoked by the defendants.

A typical reverse-payment agreement has several possible procompetitive effects. First, the parties often agree to allow the generic challenger to sell the drug at issue well before the patent on it expires. For example, Teva challenged the validity of AbbVie’s patent on the testosterone drug AndroGel by filing an ANDA with a paragraph IV certification in 2011, and the parties settled the patent litigation later that year. The agreement provided that Teva could sell a generic version of AndroGel starting in 2014 even though it was protected by a patent that will not expire until 2020.⁴⁰ If the case had not been settled, then after 30 months or more of patent litigation, Teva might have proved the patent was invalid and opened the market to competition after its 180-day exclusivity period. Relative to that outcome, the settlement agreement reduced competition. It is also possible, however, that the court would have concluded the patent was valid, thereby preserving AbbVie’s monopoly until the patent expired in 2020. Relative to that outcome, the settlement agreement increased competition. Even if other provisions of the settlement agreement were anticompetitive, the net effect of the agreement still might have been procompetitive relative to the alternative of having the court decide the validity of the patent.

Second, some settlement agreements have a so-called “out of market” procompetitive effect.⁴¹ The agreement between AbbVie and Teva is again illustrative. In addition to resolving

³⁸ One first instance court in the Third Circuit held a plaintiff must show the reverse-payment was “large and unjustified” as a “preliminary” matter before analyzing the agreement under the rule of reason. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560 (D. N.J. 2014). Another first instance court expressly rejected the view that a plaintiff has a separate “threshold burden” to show the reverse-payment was “large and unjustified” before proving it had an anti-competitive effect under the rule of reason. *Modafinil*, 2015 WL 356913 (E.D. Pa. 2015). That court instead adopted the FTC’s position that a plaintiff need establish only that the payment was large and unjustified in order to meet its burden “under the first step of the rule of reason analysis.” The Third Circuit Court of Appeals agreed with the latter approach and instructed the district court in the former case “to proceed with the litigation under the traditional rule of reason.” *Lamictal*, 791 F.3d 388 (3d Cir. 2015). Other courts will likely follow the lead of the Third Circuit because the *Actavis* Court seemed to say an anticompetitive effect could be inferred from the presence of a large and unjustified reverse-payment. Also, it is unlikely the Court would have instructed the lower courts unqualifiedly to apply the rule of reason if it had intended to create a novel threshold burden.

³⁹ *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001).

⁴⁰ *FTC v. AbbVie Inc. (AndroGel)*, No. 14-5151, 2015 WL 2114380 (E.D. Pa. May 6, 2015).

⁴¹ Jan M. Rybnicek & Joshua D. Wright, *Outside In or Inside Out? Counting Merger Efficiencies Inside and Out of the Relevant Market*, in 2 WILLIAM E. KOVACIC: AN ANTITRUST TRIBUTE — *LIBER AMICORUM* (2014).

their litigation related to AndroGel, the parties' settlement agreement provided that AbbVie would supply Teva with an authorized generic version of the anti-cholesterol drug TriCor. In exchange, Teva agreed to pay AbbVie a fixed price for each unit of TriCor it purchased and a royalty on the profits it earned from the sale of TriCor. The FTC asserted there was a reverse-payment embedded in the agreement because the royalty Teva agreed to pay to AbbVie on the profits it earned from selling TriCor was smaller than is customary in the industry. In dismissing the complaint, the court explained "what the FTC does not seem to recognize is that the benefit flowing to Teva is also a benefit flowing to consumers who will now be able to purchase the generic form of TriCor at a reduced price."

In assessing the settlement agreement involving AndroGel, the court rightly considered the effect of the agreement on the separate market for TriCor. There is reason to fear, however, that other courts, perhaps following the lead of the FTC, might not do the same.⁴² In *Lamictal*, GlaxoSmithKline sold the branded drug as a tablet and a chewable. 791 F.3d 388 (3d Cir. 2015). Its settlement agreement with Teva authorized Teva to sell a generic version the tablet six months before the patent expired and a generic version of the chewable more than three years before the tablet expired. An industry group supporting the plaintiffs attempted to downplay the effect of Teva's early entry into the market for the chewable version of the drug by arguing that "procompetitive effects in one market cannot justify anticompetitive effects in a separate market (i.e., the [Lamictal] tablet market)." The court of appeals refrained from deciding this argument, but it will likely arise again in the future because settlement agreements often involve more than one market. As one trial court succinctly explained, the courts "must look at the Settlement Agreement as a whole and cannot extricate individual provisions."⁴³ The question, after all, is whether the agreement is anticompetitive, not whether a particular provision within the agreement is anticompetitive.

Finally, an obvious but perhaps overlooked procompetitive benefit of a reverse-payment settlement agreement is simply that it settles the patent litigation. Pharmaceutical patent litigation is exceptionally expensive and, like all appellate litigation worth the cost to the parties, irreducibly somewhat uncertain; if patent litigation must be pursued to judgment because it cannot safely be settled for more than the litigation cost saving, then the risks attendant to litigation will reduce the incentive of brand manufacturers to invest in new drugs, to the detriment of consumers with potentially treatable medical conditions.

4. What is the role of the FTC in regulating reverse-payment settlement agreements?

⁴² In the *AndroGel* litigation, the FTC argued "courts may not properly balance the procompetitive effects in one market against the anticompetitive effects in [a] different market." Plaintiff Federal Trade Commission's Memorandum in Opposition to Defendants' Motion to Dismiss, *AndroGel*, 2015 WL 2114380 (E.D. Pa. 2014).

⁴³ *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D. N.J. 2014).

Having addressed several of the most important issues that will be resolved by the courts in the coming years, we comment briefly upon the role of the FTC in shaping the law regarding reverse-payment settlement agreements. The FTC affects the development of the law by deciding when to bring a case — and when to refrain from doing so — and by submitting amicus briefs in suits filed by private parties.

The first case filed by the FTC after the Supreme Court decided *Actavis* is *AndroGel*, in which, as we have seen, the trial court swiftly dismissed the complaint against AbbVie and Teva. In three other district court cases, the FTC has argued in amicus briefs that a no-authorized-generic agreement may be a reverse-payment even though it does not involve the direct transfer of cash to the generic from the brand. The first court of appeals to decide the issue agreed with the FTC’s position, and the other courts will likely do the same.⁴⁴ Whether any particular no-authorized-generic agreement is “large and unjustified,” is of course a separate question.

The FTC’s most important victories, however, might come not in the cases it wins but in the cases it settles. In 2015 the FTC reached a settlement agreement with Teva and Cephalon in the modafinil litigation.⁴⁵ The agreement requires the defendants to create a \$1.2 billion fund to compensate purchasers of modafinil. Cephalon also agreed to relinquish the profits it earned from selling modafinil between the date the patent litigation was settled in 2006 and the date generics entered the market in 2011. More important, the agreement prohibits Teva and its subsidiaries for a period of ten years, absent advance written approval from the FTC, from entering into any reverse-payment settlement agreement in which a brand promises to transfer value in excess of avoided litigation costs to a generic if that promise is contingent upon the settlement of a patent suit against the brand or occurs within 30 days of the settlement of a patent suit. This provision has the potential to decrease substantially the number of reverse-payment settlements that occur in the future; Teva is, after all, the largest generic manufacturer in the world and has frequently received reverse-payments.

By entering similar settlement agreements with other major generic manufacturers, the FTC could effectively bring an end to reverse-payment settlement agreements in the United States even though such agreements are not inherently or even presumptively unlawful under the antitrust laws as interpreted by the Supreme Court in *Actavis*. Were that to happen, the net effect upon consumer welfare, taking account of both the pro- and anti-competitive effects of diverse

⁴⁴ *Lamictal*, 791 F.3d 388 (3d Cir. 2015).

⁴⁵ *King Drug Co. of Florence, Inc. v. Cephalon, Inc. (Modafinil)*, No. 2:08-cv-2141, 2015 WL 4931442 (E.D. Pa. June 17, 2015).

settlement terms and the disincentive effect upon investment in drug innovation, could well be negative.

III. EUROPEAN UNION

In this section we discuss the assessment of reverse-payment patent settlements under EU competition law.⁴⁶ In section A we discuss the EU regulatory framework and we explain the evolution of the assessment under EU competition law in section B, including the pharmaceutical sector inquiry, the annual monitoring reports and the Commission's Draft Technology Transfer Guidelines. We then discuss the Commission decision in the *Lundbeck*, *J&J/Novartis* and *Servier* cases in section C, and other on-going investigations in section D.

A. Regulatory context

Unlike the US, the EU does not have a regulation similar to the Hatch-Waxman Act, which provides a single framework for resolving patent disputes between originators and generics. In the EU, patents are issued by national patent offices or by the European Patent Office. However, a European patent is effectively a bundled of national patents that have to be enforced in each Member State. Thus, an originator seeking to enforce its patents and prevent a generic from entering the market must bring litigation in the courts of each (relevant) EU Member State. It is difficult and expensive for originators to effectively enforce their patents to prevent generic entry. Further, in the EU, any entry by a generic company can have serious adverse effects on the pricing of the originator's products, as generic entry can trigger automatic price reductions and requirements for pharmacies to dispense generic products. Additionally, any price reduction in one country, such as the UK, can trigger follow-on price reductions in other countries.

Due to the cumbersome system for enforcing patents in the EU and the automatic price reductions triggered by the entry of a generic supplier, originator companies have strong incentives to settle, even in cases where they hold strong patent rights.⁴⁷ These higher risks faced by the originator are often cited as the reason for the inclusion in the settlement of payments going the "wrong" direction. In the negotiations leading up to a settlement agreement,

⁴⁶ This section draws partly on Damien Geradin, Michael Clancy & Andrew Lazerow, *Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An analysis of US antitrust law and EU competition law*, (2014) Antitrust Bulletin 59.

⁴⁷ See Romano Subiotto, *The Implications of the Imperfect European Patent Enforcement System on the Assessment of Reverse Payment Settlements*, Expert Paper, OECD, 17 June 2014, DAF/COMP/WD(2014)75.

it is only logical that generic suppliers would seek to exploit the higher risk faced by originators to extract a payment.

B. Evolution of the assessment of patent settlements in the EU

Prior to 2008-2009, no guidance or case-law was available on the legality of reverse-payment patent settlements under EU competition law. In January 2008, however, the Commission launched a pharmaceutical sector inquiry, focusing on the competitive relationship between originator and generic companies, and particularly into practices that may affect or delay generic entry, including settlement agreements. The corresponding detailed the results of its investigation, identifying a so-called “tool box” of instruments including settlement agreements, allegedly used by originator companies to prevent or delay generic entry.⁴⁸

In the Commission’s Sector Inquiry Report and the subsequent reports from the annual monitoring process,⁴⁹ the Commission has provided limited guidance on the legality of patent settlement agreements, which it categorizes as follows:

- **Category A: No limitation on generic entry** – The patent settlement agreement enables the generic company to enter the market and compete freely or does not require the generic company to leave the market.
- **Category B: Limitation on generic entry** – The generic company cannot enter freely the market with its own product. Entry restrictions can vary from a total entry ban to limited entry controlled (e.g., through a license terms) by the originator.

Category B is then subdivided into two categories:

- **Category B.1: No value transfer from the originator company:** In this case, the patent settlement agreement limits generic entry but contains no value transfer from the originator to the generic company.

⁴⁸ Commission Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report (July 8, 2009), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf; Commission Staff Working Document, Technical Annex to the Commission Communication Part 1 (July 8, 2009), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

⁴⁹ As a continuation of the Sector Inquiry, the Commission launched an annual monitoring exercise of patent settlements, for the purpose of better understanding how settlement agreements are used in practice and identifying settlement agreements that delay generic entry in violation of EU competition law. As part of this exercise, pharmaceutical companies are required to report settlement agreements relevant to the EU market each year.

- **Category B.2: Value transfer from the originator company:** The patent settlement agreement limits generic entry and contains value transfer from the originator to the generic company.

The Commission considers that settlement agreements in categories A and B.I are generally unlikely to violate EU competition law, either because they do not restrict entry by the generic suppliers or because there is no value transfer to the generic supplier. The Commission however considers that that settlement agreements in category B.II are more likely to be problematic, particularly if the generic agrees to limit its entry onto the market in exchange for a value transfer from the originator company. Importantly, the Commission takes a broad view on what constitutes a “limitation on entry” and a “value transfer”:

“1. Limitations on Entry of a Generic Supplier

The generic company’s entry can be limited in several ways. The clearest limitation of generic entry is when the settlement agreement contains a clause explicitly stating that the generic company recognises the validity of the originator company’s patent(s) and refrains from entering the market until the patent(s) have expired. If the parties to a patent settlement agreed that the originator company should grant a license to certain patent rights to the generic company, thereby allowing it to enter the market, the agreement was still categorised as limiting generic entry. The reason for this is that the generic company cannot enter the market with its own product unless it has an agreement with the originator company. Accordingly, the generic company’s entry is partly or wholly controlled by the originator company through the terms of the concluded licence agreement ... The same is true for patent settlement agreements in which the parties agree that the generic company can become a distributor of a product of the originator company or if the generic company will source its supplies of the active ingredient from the originator company.

2. Value Transfer to a Generic Supplier

Value transfer to the generic company in patent settlement agreements can take different forms. The most clear-cut value transfer is a direct monetary transfer ... from the originator company to the generic company. Monetary transfer can also take the form of compensation for the generic company’s legal cost(s) in the patent dispute or can be classified as the purchase of an asset ... Other types of value transfer include distribution agreements in which the generic company becomes a distributor of a product of the originator company or a “side-deal” in which the originator company grants a commercial benefit to the generic company ... Furthermore, value transfer could consist in granting a patent licence to the generic company. A patent licence enables the generic company to enter a market with a product but, as explained above, the commercial

freedom of the generic company is limited by the terms of the licence agreement ... The terms of the license agreement determine the level of the value transfer to the generic company.”

In light of these broad definitions, a large number of settlement agreements fall into the potentially problematic category B.II. For example, any settlement agreement with a corresponding license agreement will fall into the potentially problematic category, unless the license agreement is royalty-free and allows immediate entry by the generic supplier.

Irrespective of the category, the Commission has also indicated that the following settlement agreements are potentially problematic: (1) settlement agreements restricting entry by generic suppliers, where the restrictions imposed on the generic suppliers exceed the scope of the relevant patents; and (2) settlement agreements restricting entry by generic suppliers, where the patent holder knows that the underlying patent does not meet the patentability criteria, for example, where the patent was granted following the provision of incorrect, misleading, or incomplete information.⁵⁰

Finally, in 2014, the Commission provided additional guidance on patent settlements involving a license in the context of its Technology Transfer Guidelines. In the Guidelines, the Commission states the following:

“non-challenge clauses in settlement agreements can under specific circumstances be anti-competitive and may be caught by Article 101(1) of the Treaty. The restriction of the freedom to challenge an intellectual property right is not part of the specific subject-matter of an intellectual property right and may restrict competition. For instance, a non-challenge clause may infringe Article 101(1) where an intellectual property right was granted following the provision of incorrect or misleading information. Scrutiny of such clauses may also be necessary if the licensor, besides licensing the technology rights, induces, financially or otherwise, the licensee to agree not to challenge the validity of the technology rights or if the technology rights are a necessary input for the licensee's production.”⁵¹

This statement indicates that settlement agreements involving licenses are potentially problematic if the originator offers a value transfer in exchange for the generic’s agreement to license terms that are more restrictive than would have been agreed absent the value transfer.

⁵⁰ Commission, 4th Report on the Monitoring of Patent Settlements (period: January-December 2012), (Dec. 9, 2013), §4, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>

⁵¹ Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, O.J. 2014, C 89/3.

C. The decisions from the Commission

Since the end of the pharmaceutical inquiry, the Commission has adopted three infringement decisions against reverse-payment settlements.

In June 2013, the Commission ruled that settlements concluded between Lundbeck and several generic manufacturers regarding citalopram, a best-selling antidepressant drug, violated Article 101 TFEU and imposed a €3.8 million fine on Lundbeck and a total fine of €52.2 million on the generic companies.⁵² Since the early 2000s, Lundbeck was the manufacturer of citalopram, sold under the brand names Celexa and Cipramil. Lundbeck held patents covering both the citalopram molecule and the process by which the molecule was manufactured. As the 2002 patent expiry date for the citalopram molecule approached, several companies were preparing to enter the market with generic versions of the drug. Lundbeck initiated patent infringement actions against the generic companies, alleging they would infringe Lundbeck's manufacturing process patents. The parties ultimately settled the disputes in 2002 on terms that included payments by Lundbeck to the generic companies. Lundbeck also agreed to purchase the generic companies' stocks of the drug (with the purpose of destroying them) and offered the generics guaranteed profits in a distribution agreement. In return, the generics agreed not to enter the market with the allegedly infringing generic citalopram.

In its decision, the Commission considered that “[w]hen in a patent dispute a settlement is reached without inducement on the basis of each party's assessment of the probability of a patent being held valid and infringed by a court, such a patent settlement will normally not infringe Article 101(1) of the Treaty if the agreed limitations on the behaviour of the generic undertaking do not go beyond the rights granted by patent law.” By contrast, “when an agreement is concluded in which the generic undertaking accepts to exit or not to enter the market for a certain period of time ... but instead the originator undertaking pays a considerable sum of money to the generic undertaking, then such an agreement, whether referred to as a patent settlement or not, merits the full scrutiny of competition law.”

An important aspect of the decision is that, unlike the US Supreme Court in *Actavis*,⁵³ the Commission considered that the settlements between Lundbeck and the generic companies were presumptively illegal (anticompetitive “by object”), and thus did not assess whether the agreements had any anticompetitive effects. The Commission based its conclusion principally

⁵² COMP/AT 39226, *Commission decision of 19 June 2013 (Lundbeck)*.

⁵³ By contrast, like the US Supreme Court in *Actavis*, the Commission rejected the “within the scope of the patent” test as it stated that “even if the limitations in the agreement on the generic undertaking's commercial autonomy do not go beyond the material scope of the patent, they are likely to breach Article 101 of the Treaty when those limitations cannot be justified and do not result from the parties' assessment of the merits of the exclusive right itself, but in particular from a transfer of value overshadowing this assessment and inducing the generic undertaking not to pursue its independent efforts to enter the market.”

on the following findings: (i) Lundbeck and the generics were at least potential competitors at the moment when the agreements were concluded; (ii) the generics committed themselves in the agreements to limit, for the duration of the agreement, their independent efforts to enter one or several markets with their generic products; and (iii) the agreements provided for a transfer of value from Lundbeck, which substantially reduced the incentives of the generics to independently pursue their efforts to enter the market.

Following the decision, Lundbeck and all of the generic suppliers appealed the Commission's decision to the EU General Court. Substantive issues raised on appeal include: (i) whether Lundbeck and the generic parties were potential competitors, particularly in light of Lundbeck's patent rights; (ii) whether reverse-payment patent settlements constitute a restriction of competition by object or whether the Commission needed to demonstrate their anticompetitive effects; (iii) whether the settlement agreements restricted competition in the market beyond the scope of Lundbeck's patent rights; and (iv) whether the Commission is correct that patents have exclusionary powers only once they have been confirmed in litigation and that a duty existed for the applicant to litigate or exhaust all other options before concluding the settlement agreements. The judgment of the EU General Court is pending.

The next decision of the Commission came in December 2013 when the Commission considered that a co-promotion agreement concluded between Janssen-Cilag, a Johnson & Johnson (J&J) subsidiary and its generic competitor Sandoz, a Novartis subsidiary, breached Article 101 TFEU.⁵⁴ The Commission condemned Johnson & Johnson and Janssen-Cilag to a €10.798 million fine and Sandoz and Novartis to a €5.493 million fine. The companies decided not to appeal the Commission decision.

The Agreement in question concerned the Dutch market for fentanyl, a strong pain-killer, in the form of transdermal patches. In July 2005, Janssen-Cilag B.V. entered into the co-promotion agreement with Hexal B.V./Sandoz B.V. which was amongst the most advanced generic competitors of J&J in the Netherlands. According to the agreement, Novartis/Sandoz agreed to jointly promote J&J's fentanyl matrix patches to pharmacists in the Netherlands. In return, J&J agreed to make monthly payments to Novartis/Sandoz. The Agreement could be terminated immediately by J&J if Novartis/Sandoz launched its own generic transdermal fentanyl patch on the Dutch market.

As in *Lundbeck*, the Commission considered the co-promotion agreement had the "object" of restricting competition in that "it contained a transfer of considerable value from the originator J&J to a close potential generic competitor, Novartis/Sandoz, with the objective that the latter would not enter the Dutch market with generic fentanyl patches during the

⁵⁴ COMP/AT 39685, *Commission decision of 12 October 2013 (Fentanyl)*.

duration of the agreement.” The Commission observed that the amount paid to Sandoz considerably exceeded what Sandoz expected to make at the time of the conclusion of the agreement if it had launched its own fentanyl patches in the Netherlands. Moreover, Sandoz’s co-promotional activities pursuant to the agreement were poorly defined and not meaningful. Therefore, the co-promotion agreement was thus a fig-leaf for a “pay for delay” arrangement.

Finally, in July 2014, the Commission imposed fines totaling €427.7 million on French originator Servier and five producers of generic medicines for concluding a series of agreements all aimed at protecting Servier’s bestselling blood pressure medicine, perindopril, from generic competition in the EU.⁵⁵ The Commission found that through a technology acquisition and a series of patent settlements with generic rivals, Servier implemented a strategy to exclude competitors and delay the entry of cheaper generic medicines. The decision has been appealed to the General Court of the EU. The case is still pending.

In its decision, the Commission found that Servier held significant market power in the market for perindopril as no medicines other than the generic versions of perindopril were able to meaningfully constrain Servier’s sales and prices. Servier’s patents for the perindopril molecule essentially expired in 2003. Generic competitors continued to face a number of “secondary” patents relating to processes and form, but these provided a more limited protection to perindopril. Thus, producers of cheaper, generic versions of perindopril were preparing their market entry. There were a limited number of technologies for the production of perindopril that were not covered by Servier’s patents, but, in 2004, Servier acquired the most advanced one, forcing a number of generic projects to stop and therefore delaying their entry.

Generic producers decided to challenge Servier’s “secondary” patents before courts. However, the Commission found that between 2005 and 2007, each time a generic company came close to entering the market, Servier and the company in question settled the challenge. The generic companies agreed to abstain from competing in exchange for large cash payments from Servier. Servier thus gained the certainty that the generic producers would stay out of the national markets and refrain from legal challenges for the duration of the agreements

Following the approach already adopted in *Lundbeck and Fentanyl*, the Commission found that the patent settlements in question were restrictions by “object.” However, the Commission’s analysis contains two novelties. First, although the Commission observes that according to the case-law there is no need to take into account the concrete effects of an agreement when it is established that it has as its object to restrict competition, it nevertheless, for the “sake of completeness,” examines the likely restrictive “effects” of the agreements on competition. This new approach is not entirely surprising considering that one of the main

⁵⁵ COMP/AT 39612, *Commission decision of 9 July 2014 (Perindopril (Servier))*.

criticisms made against the *Lundbeck* decision was that the “by object” restriction approach pursued by the Commission was inappropriate considering the complex nature of reverse-payment patent settlements. Unlike price-fixing cartels – whose negative effects on competition are clear and cannot be redeemed by efficiencies – the effects of reverse-payment patent settlements, which can vary a lot in scope and nature, are unlikely to be so clear cut and thus should be proven. In addition, in its *Cartes Bancaires* judgment adopted in September 2014, the Court of Justice of the EU ruled that the concept of restriction of competition “by object” (the equivalent of *per se* illegality under Article 101 TFEU) must be interpreted “restrictively” and “can be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects, otherwise the Commission would be exempted from the obligation to prove the actual effects on the market of agreements which are in no way established to be, by their very nature, harmful to the proper functioning of normal competition.”⁵⁶ Thus, by showing the effects of reverse-payment patent settlements the Commission placed itself on safer grounds.

Second, the Commission also decided that Servier, the maker of the originator product, had abused its dominant position on the perindropil market in breach of Article 102 TFEU. According to the Commission, Servier’s unilateral conduct consisted in the inducement of generic companies to accept various restrictions of competition in a series of reverse-payment patent settlements. The Commission argues that, pursuant to case-law of the EU courts, Article 102 TFEU may apply to an agreement between undertakings concurrently with Article 101 TFEU, provided that there is “an additional element.” In this case, the series of patent settlements concluded by Servier with its generic competitors “had also a distinct unilateral aspect, based on the fact that Servier used its market power in order to induce a number of closed generic threats to withdraw from competition with Servier with their respective generic products.”

D. Ongoing investigations

The Commission has opened an investigation into a patent settlement between Teva and Cephalon in relation to modafinil, a medicine used for the treatment of sleeping disorders.⁵⁷ According to the Commission, as part of the settlement agreement, Teva committed not to sell its generic modafinil products in the EEA markets before October 2012, and the parties entered into a series of side deals. The investigation is still pending.

In addition to the European Commission, the UK Office of Fair Trading, now the Competition and Markets Authority (CMA) is currently investigating GlaxoSmithKline and three

⁵⁶ Case C-67/13 *P Groupement des cartes bancaires (“CB”) v. European Comm’n*, 11 September 2014.

⁵⁷ Press Release, Commission Opens Investigation against Pharmaceutical Companies Cephalon and Teva (April 28, 2011), available at http://europa.eu/rapid/press-release_IP-11-511_en.htm?locale=fr.

generic companies in relation to a reverse-payment patent settlement for the antidepressant drug paroxetine.⁵⁸ It is understood that the CMA has completed its investigation and will issue a decision during the fall of 2015.

III. Conclusion

Reverse-payment patent settlements have drawn a great degree of attention on both sides of the Atlantic. The main concern expressed by the FTC and the European Commission was that originators could use such settlements to buy-off their generic competitors by sharing the monopoly rents they make on the sale of the originator product. In the United States, the Supreme Court in *Actavis* rejected both the FTC's view that reverse-payment patent settlements should be seen as presumptively illegal and the industry's view that these agreements should be presumptively legal when the agreement remained within the scope of the patent. Instead, the Supreme Court considered that reverse-payment patent settlements should be analyzed under a rule of reason without, however, saying much about the way it should be structured. As a result, there is a great deal of ongoing litigation dealing in particular with the issue of what should be considered as a transfer of value from the originator to the generics.

In the EU, the European Commission also rejected the "within the scope of the patent" test. It ruled in *Lundbeck* and *Fentanyl* that reverse-payment patent settlements should be considered as restrictions "by object" and that therefore their effects did not need to be demonstrated. However, in *Perindopril (Servier)*, the Commission seems to have modified its position. It continued to argue that reverse-payment patent settlements were restrictions by object, but it also decided to show that these settlements produced anticompetitive effects. The Commission also considered that Servier's unilateral conduct consisting in inducing generic companies not to launch their products in return for substantial payments also breached Article 102 TFEU. Both the *Lundbeck* and *Perindopril (Servier)* decisions have been appealed to the General Court of the Union and the appeals are still pending.

Of the US and EU approaches, we believe that the rule-of-reason analysis supported by the US Supreme Court in *Actavis* makes more sense in that it requires the courts fully to analyze and to balance the pro- and anti-competitive effects of the reverse-patent settlement in question. This approach is not, however, without difficulties as seen with the large amount of litigation that has taken place since the *Actavis* decision.

⁵⁸ Press Release, UK Office of Fair Trading, OFT Issues Statement of Objections to Certain Pharmaceutical Companies (April 19, 2013) available at <http://www.offt.gov.uk/news-and-updates/press/2013/36-13#.Um0Gp3BWym4>.