Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law

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In the pharmaceutical industry, originator companies researching and developing new medicines 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 the validity of these patents or may simply launch their products, forcing the originators to bring litigation to enforce their patents and prevent the generics' entry. In the context of the corresponding litigation, the originators and generic suppliers often decide to enter into a settlement. While the settlement terms will vary from case to case, a number of settlements have involved a payment made from the patent holder (the originator) to the accused infringer (the generic supplier) in order to settle the dispute ("reverse-payment patent settlements"). Against this background, this paper seeks to analyze the compatibility of such settlements under US antitrust law and EU competition law drawing on recent cases.

KEY WORDS: *reverse-payment patent settlements; originators; generics; Actavis; Lundbeck; antitrust*

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 the validity of these patents or may simply launch their products, forcing the originators to bring litigation to enforce their patents and prevent the generics' entry. In the context of the corresponding litigation, the originators and generic suppliers often decide to enter into a settlement.

While the settlement terms vary from case to case, a number 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." The legality of such settlements is the subject of a heated debate, both in Europe and in 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 governments' health care budgets.

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In June 2013, both the US Supreme Court and the European Commission (Commission) addressed the legality of reverse-payment patent settlements between originator and generic drug companies, reaching rather different conclusions. In order to explain the causes and consequences of this divergence, this article discusses first, in part II, the relevant Hatch-Waxman Act provisions and explores the evolution of the US case law with regard to patent settlements. In part III, we analyze the European Union (EU) regulatory context and current investigation activity of the Commission and the national competition authorities. Finally, in part IV, we compare the US approach to reverse-payment patent settlements, as highlighted by the recent *Actavis* ruling, to the approach endorsed by the Commission in the *Lundbeck* decision. Part V concludes.

II. UNITED STATES

In part II.A, we analyze the regulatory context under which patent settlements have been concluded between originator and generic companies. In part II.B, we review the evolution of the assessment of patent settlements in the United States, and in part III.C we analyze the recent decision of the Supreme Court in *Actavis*.

A. Regulatory context: The Hatch-Waxman Act

Known as the "grand bargain" between the competing interests of the innovator industry and the generic industry, the Hatch-Waxman Act, enacted in 1984, allows generic manufacturers to shorten the lengthy process required to approve a drug. A company wishing to market a new drug that has not previously been approved by the US Food and Drug Administration (FDA) must file a New Drug Application (NDA) with the FDA, demonstrating that the drug is safe and effective for its intended use.[1] However, a company wishing to market a generic version of a drug that previously has been approved by the FDA may follow a truncated approval process by filing an Abbreviated New Drug Application (ANDA). In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy with the pioneering drug.[2] Unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. Instead, the ANDA applicant is permitted to rely on the approval of the NDA applicant's drug—in essence, piggybacking on the NDA application and safety and effectiveness conclusions.[3]

When an originator company files its NDA for a new drug, it must submit patents that cover the drug substance (active ingredient), drug product (composition or formulation), or

[1] Hatch-Waxman Act, 21 U.S.C. § 355(b) (2013).

[2] *Id.* § 355(j)(2)(A)(iv).

[3] *Id.* § 355(j).

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methods of using the drug. These patents are then listed in FDA's *Approved Drugs with Therapeutic Equivalence Evaluations*, known as the Orange Book. When filing its ANDA, the generic manufacturer must make a certification to each patent listed in the Orange Book for the reference drug.[4] The generic manufacturer has four options for this certification:

> (I) that such patent information has not been filed,
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> (II) that such patent has expired,
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> (III) [by certifying] the date on which such patent will expire, or
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> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.[5]

The Hatch-Waxman Act encourages challenges to drug patents by holding out a lucrative incentive to the first generic manufacturer that files an ANDA with paragraph IV certification. This first filer receives a 180-day exclusivity period, during which the FDA will not approve subsequent ANDA applications.

The filing of an ANDA with a paragraph IV certification is seen as an "artificial act" of patent infringement and provides the jurisdictional basis for the patent litigation.[6] The Hatch-Waxman Act requires filers of a paragraph IV certification to provide notice to each owner of the patent(s) subject to the certification, as well as to the holder of the NDA for the reference listed drug.[7] Under the Act, if the patent holder files an infringement suit within forty-five days after receiving notice of the paragraph IV certification, the FDA must stay the approval of the generic manufacturer's ANDA until the earlier of (1) thirty months or (2) a court decision that the patent is invalid or not infringed.[8]

The Hatch-Waxman Act thus creates a unique incentive structure. The ANDA filer faces little financial risk, because the thirty-month stay allows the parties to litigate before the generic drug goes to market. This means that, regardless of the outcome of the patent litigation, the generic will not be subject to damages (relief is declaratory and injunctive). Thus, the potential monetary upside for the generic company of continuing with the litigation may be substantial, even if the chance of success is low.

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[4] *Id.* § 355(j)(2)(A)(vii).

[5] *Id.*

[6] *See* 35 U.S.C. § 271(e)(2)(A) (2013).

[7] Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(B)(iii).

[8] *Id.* § 355(j)(5)(B)(iii).

The originator company, by contrast, may face enormous consequences. If its suit is successful, the originator has lost little financially. However, if the generic wins, the originator immediately loses a large part of the market. Many states have automatic substitution laws based on the Orange Book, meaning a patient will automatically receive a generic version of the drug once it is available (unless a doctor explicitly requires otherwise). The consequences of losing a Hatch-Waxman action may cause originator companies to be extremely risk averse, especially if the originator is a small company with few products, regardless of the strength of its patent(s).

As a result of this shift in the usual balance of litigation risks, a number of Hatch-Waxman settlements involve some consideration flowing from the originator to the generic (the potential patent infringer). These reverse-settlements have included cash payments, as well as other things of value, such as manufacturing or marketing assistance. Until the Supreme Court's June 2013 opinion in *FTC v. Actavis, Inc.*,[9] the courts were divided on the question of whether such settlements are permitted by the antitrust laws.

B. Evolution of the assessment of patent settlements in the United States

Following a series of early appeal decisions against the settling parties,[10] several circuits addressing settlements of Hatch-Waxman ANDA litigation opted for an approach that came to be known as the "scope of the patent" test. According to this test, reverse-payment settlements could be upheld and not considered as being in breach of antitrust rules if the terms of the settlement are within the exclusionary scope of the patent, the patent was not procured through fraud on the US Patent and Trademark Office, and the patent litigation itself was not a sham.

The Eleventh Circuit developed and refined this standard in three decisions, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,[11] *Schering-Plough Corp. v. FTC,*[12] and *FTC v. Watson Pharmaceuticals, Inc.*[13]

Valley Drug concerned the settlement of patent infringement suits launched by the brand manufacturer Abbott against generic manufacturers Geneva and Zenith.[14] In these suits, the generic manufacturers admitted to having infringed one of Abbott's patents. However, the generics argued that the patent was invalid and indeed the same patent was subsequently

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[9] 133 S. Ct. 2223 (2013).

[10] *In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 902 (6th Cir. 2003), Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 811 (D.C. Cir. 2001).

[11] 344 F.3d 1294 (11th Cir. 2003).

[12] 402 F.3d 1056 (11th Cir. 2005).

[13] 677 F.3d 1298 (11th Cir. 2012).

[14] 344 F.3d at 1299–301.

declared invalid in a different litigation.[15] In the two settlements, Abbott agreed to pay substantial compensation in exchange for the generics' abstention from entering the market until the date of expiry of Abbott's patent.[16]

Reversing the ruling of the district court holding the settlements per se illegal, the Eleventh Circuit held that:

> "[b]ecause the district court failed to consider the exclusionary power of Abbott's patent in its antitrust analysis, its rationale was flawed and its conclusion that these [settlements] constitute per se violations of the antitrust laws must be reversed."[17]

The court considered that the lawfulness of the agreement had to be judged at the time it was entered into, when the patent was still valid. Adopting the contrary approach would disincentivize patent settlements and as a consequence "impair the incentives for disclosure and innovation."[18] Moreover, the court emphasized that Abbott's payments to the generics did not have an exclusionary effect that would go beyond that of the patent itself.[19] The court referred the case with instructions to the district court to consider "the scope of the exclusionary potential of the patent, the extent to which these provisions of the [settlements] exceed that scope," and whether any provisions that exceed the scope were illegal according to "traditional antitrust analysis."[20]

The Eleventh Circuit applied the test developed in *Valley Drug* in *Schering-Plough*, an appeal of a FTC administrative decision condemning agreements between brand manufacturer Schering-Plough and ANDA-filers Upsher-Smith and ESI. The court reaffirmed that the only adequate antitrust analysis of Hatch-Waxman settlements takes the following elements into account:

(1) the scope of the exclusionary potential of the patent;

(2) the extent to which the agreements exceed that scope; and

(3) the resulting anticompetitive effects.[21]

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[15] *Id.* at 1304–06.

[16] *Id*. at 1300.

[17] *Id.* at 1306.

[18] *Id.* at 1308.

[19] *Id*. at 1309.

[20] *Id.* at 1312.

[21] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005).

The court rejected the FTC's conclusion that Schering-Plough's payment to Upsher-Smith had a purpose other than payment for the licenses it obtained. Therefore, it concluded that the settlement with Upsher-Smith did not violate the antitrust laws.[22] With regard to the ESI settlement, the court found "the terms of the settlement to be within the patent's exclusionary power" and therefore a " 'reasonable implementation' of the protections afforded by patent law."[23]

The development of the law on Hatch-Waxman settlements described above took a surprising turn in 2012 when the Third Circuit in *In re K-Dur Antitrust Litigation*[24] overturned the scope of the patent test and ruled that settlements involving a payment from the patent holder to the alleged patent infringer were presumptively illegal as in breach of antitrust law.

K-Dur involved an antitrust challenge by private plaintiffs to the exact same settlement agreements that the Eleventh Circuit had already found to be legal in *Schering-Plough Corp. v. FTC*. However, instead of following the Eleventh Circuit's "scope of the patent" test, the court labeled that standard an "almost unrebuttable presumption of patent validity" and stated that the presumption according to which a patentee has the right to exclude competitors would be "particularly misguided." [25] The court considered that this was especially true where the underlying suit concerned patent infringement as opposed to patent validity challenges, because the patent holder would bear the burden of proving infringement.[26] The court further concluded that, by endorsing settlements that protect weak patents, the scope of the patent test would undermine the objectives of the Hatch-Waxman Act to increase the supply of affordable drugs through generic challenges.[27] Lastly, with respect to the argument that the scope of the patent test promotes settlements, the court objected by stating that:

> "the judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress's determination . . . that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers."[28]

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[22] *Id.* at 1069–71.

[23] *Id*. at 1072 (quoting *Valley Drug*, 344 F.3d at 1312).

[24] 686 F.3d 197 (3rd Cir. 2012).

[25] *Id.* at 214.

[26] *Id.* at 214.

[27] *Id.* at 217.

[28] *Id.*

The Third Circuit then went on to instruct the district court to apply a "quick look rule of reason analysis" in which the court would have to

> "treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."[29]

Similar to the FTC, the Third Circuit stressed that its decision would not prevent parties from concluding settlements consisting only of a deferred market entry date for the generic products.[30] The court also considered that this approach does not mandate an investigation into the actual strength of the patent because:

> "[a]bsent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[31]

C. The Actavis *case*

By mid-2012, a split existed in the US circuit courts (including a split of circuits with respect to the same settlements in *Schering-Plough and K-Dur*). The Eleventh, Second, and Federal Circuits upheld reverse payment settlements as lawful unless (1) the settlement exceeded the exclusionary scope of the patent, (2) the patent at issue had been obtained by fraud on the US Patent and Trademark Office or (3) the infringement lawsuit was objectively baseless. However, the Third Circuit found reverse payment settlements to be presumptively illegal and subject to a quick-look analysis, which required courts to treat any "payment" from an innovator to a generic as "prima facie evidence of an unreasonable restraint on trade."[32]

In its June 2013 decision in *Actavis*, the Supreme Court rejected both analyses, determining that such settlements "can sometimes violate the antitrust laws" and therefore must be judged under rule of reason analysis.[33] In *Actavis*, Watson Pharmaceuticals and Paddock Laboratories had both filed ANDAs to market a generic version of Solvay's testosterone gel product AndroGel, and both included a paragraph IV certification. Generic Par Pharmaceutical

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[29] *Id.* at 218.

[30] *Id.* at 217–18.

[31] *Id*. at 218 (quoting *In re* Schering-Plough Corp., Final Order, 136 F.T.C. 956, 988 (2003)).

[32] *Id.*

[33] *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

agreed to share litigation costs with Paddock, in exchange for a share of Paddock's profits if Paddock obtained FDA approval for its proposed drug.

Solvay sued both Watson (now known as Actavis) and Paddock for patent infringement, but both cases ultimately settled. Under the terms of the settlement, Actavis agreed it would not bring its generic product to market until August 31, 2015 (sixty-five months before patent expiry). Actavis also entered into a copromotion agreement with Solvay, agreeing to promote AndroGel to urologists. Paddock and Par entered into similar agreements. Solvay also agreed to pay $12 million to Paddock, $60 million to Par, and $19–$30 million annually, for nine years, to Actavis. Solvay stated it was paying the generics for services the generics agreed to perform, such as copromotion. The FTC argued that these payments were disguised compensation for the generics' agreements to stay off the market until 2015.

While the FTC urged the Supreme Court to "hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason', " the Supreme Court considered that given the complexities raised by such agreement the FTC should prove its case as in other rule of reason cases.[34] In reaching this conclusion, the Court offered the following guidance to district courts evaluating such settlements. According to the Court, district courts should look at the size of the payment, "its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."[35] An "unexplained large reverse payment" could suggest an anticompetitive motive. While the Court did not indicate what constitutes a "large" payment, it did provide that

> "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement."[36]

Finally, the Court indicated that the reasonableness of a particular settlement may be assessed "without litigating the validity of the patent," as a "large, unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the patent's validity."[37]

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[34] *Id.* at 2237.

[35] *Id.*

[36] *Id.* at 2236.

[37] *Id.* at 2236–37.

As a practical matter, the impact of *Actavis* is likely to be considerable. The decision will increase uncertainty for parties contemplating reverse-payment settlements. As courts struggle to balance the procompetitive justifications of these agreements against any anticompetitive effects, parties will be faced with higher litigation costs. *Actavis* signals equally that patent holders will no longer be able to rely only on scope of the patent arguments to shelter reverse-payment settlements from antitrust analysis. As a result, companies considering such settlements will need to evaluate very carefully the procompetitive justifications supporting the terms of their settlement.

III. EUROPEAN UNION

In this section we discuss the assessment of reverse-payment patent settlements under EU competition law. In particular, in section A we discuss the EU regulatory framework and 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's recent decision in the *Lundbeck* case 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. Instead, in the EU (1) patents are issued by each individual EU Member State and (2) 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. In this context, it is very difficult and expensive for originator companies to effectively enforce their patents to prevent generic entry.

Further, in the EU, any entry by a generic competitor 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 very strong incentives to settle, even in cases where they hold strong patent rights. These higher risks faced by the originator are also often cited as the reason for the inclusion in the settlement of payments going the "wrong way". Indeed, in the negotiations leading up to a settlement agreement, 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. For example, in 2003 the Danish competition authority ("DCA") and the European Commission reviewed settlement agreements between Lundbeck and a number of generic suppliers involving reverse-payments. According to a January 2004 DCA press release,[38] the DCA and the Commission considered that the settlement agreements fell into a "legal grey zone", and the Commission would "initiate a general analysis of these types of cases, which shall result in the development of a general standard for how they should be handled".

Subsequently, in January 2008 the Commission launched its 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 Report[39] 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.[40]

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.

In the Commission's Sector Inquiry Report and the subsequent reports from the annual monitoring process, the Commission has provided limited guidance on the legality of patent settlement agreements, which it categorizes as follows[41]:

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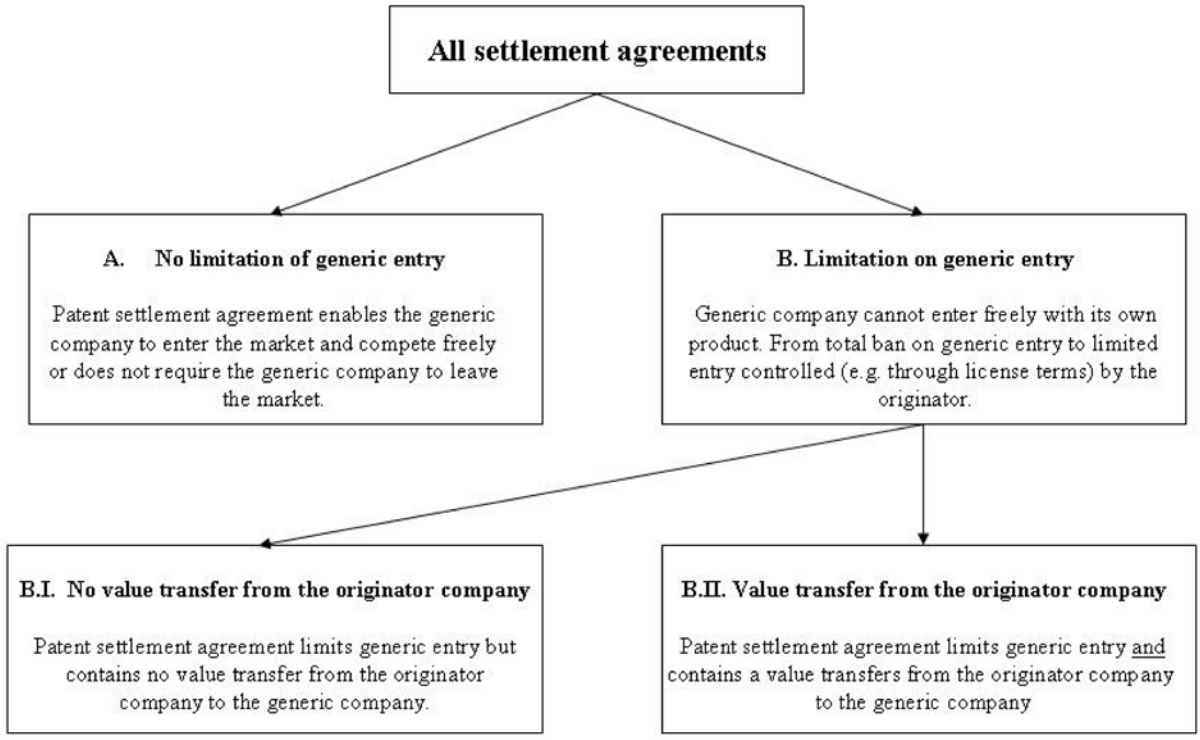
[38] *See* Danish Competition Authority, Press Release, Investigation of Lundbeck, Council Meeting, 28 January 2004.

[39] *See* 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 [hereinafter TECHNICAL ANNEX PART 1]; and COMMISSION STAFF WORKING DOCUMENT, TECHNICAL ANNEX TO THE COMMISSION COMMUNICATION PART 2 (July 8, 2009), *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part2.pdf.

[40] TECHNICAL ANNEX PART 1, *supra* note 39, § 24.

[41] *Id.* fig. 106.



Concerning settlement agreements in categories A and B.I, the Commission has indicated that these categories are generally unlikely to violate EU competition law, either because they do not restrict entry by the generic suppliers (category A) or because there is no value transfer to the generic supplier (category B.I).

Concerning settlement agreements in category B.II, the Commission has indicated that these 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
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> 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."[42]

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

[42] *Id.* at 269.

example, where the patent was granted following the provision of incorrect, misleading, or incomplete information.[43]

Finally, in January 2013, the Commission provided additional guidance on patent settlements involving a license in the context of its public consultation on the revision of its Technology Transfer Guidelines. In the draft Guidelines, the Commission states the following:

> "Settlement agreements between competitors which include a licence for the technology and market concerned by the litigation but which lead to a delayed or otherwise limited ability for the licensee to launch the product on this market may under certain circumstances be caught by Article 101(1). Scrutiny is necessary in particular if the licensor provides an inducement, financially or otherwise, for the licensee to accept more restrictive settlement terms than would otherwise have been accepted based on the merits of the licensor's technology."[44]

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.

C. The Lundbeck *decision*

In June 2013, the Commission issued its first decision on reverse-payment settlements, holding that settlements relating to Lundbeck's drug citalopram violated EU competition law.

In the early 2000s, Lundbeck was the manufacturer of citalopram, a "blockbuster" antidepressant medicine 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. As a consequence, Lundbeck initiated patent disputes 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

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[43] *See* EUROPEAN COMM'N, 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/.

[44] EUROPEAN COMM'N, DRAFT COMMUNICATION, GUIDELINES ON THE APPLICATION OF ARTICLE 101 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION TO TECHNOLOGY TRANSFER AGREEMENTS § 223 (Feb. 20, 2013), *available at* http://ec.europa.eu/competition/consultations/2013_technology_transfer/guidelines_en.pdf.`

return, the Commission alleges that the generics agreed not to enter the market with the allegedly infringing generic citalopram.

In its 2013 decision, the Commission determined 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 on the following allegations:

- that Lundbeck and the generics were at least potential competitors at the moment when the agreements were concluded;
- that Lundeck transferred significant value to the generics manufacturers through the agreements; and
- the existence of a link between the value transfer and the generics' commitments not to compete with Lundbeck in the EEA for a certain period.

It is worth noting that the agreements at issue in this case are the same agreements that the Danish competition authority and Commission reviewed ten years earlier in 2003 (see Section B). However, in 2013, after the Commission clarified its legal position on reverse-payment patent settlement agreements, it held that the agreements violated EU competition law, and imposed a €93.8 million fine on Lundbeck and a total fine of €52.2 million on four generic pharmaceutical companies.

Following the decision, Lundbeck and all of the generic suppliers have appealed the Commission's decision to the EU General Court.[45] Substantive issues raised on appeal include:

- Whether Lundbeck and the generic parties were potential competitors, particularly in light of Lundbeck's patent rights.
- Whether reverse-payment patent settlements constitute a restriction of competition *by object* (meaning the Commission does not have to demonstrate anticompetitive effects).
- Whether the settlement agreements restricted competition in the market beyond the scope of Lundbeck's patent rights.
- 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.

[45] Case No. T-460/13, Ranbaxy Labs. & Ranbaxy (UK) v. Comm'n 2013 O.J. (C 325) 71; Case No. T-467/13, Arrow Group & Arrow Generics v. Comm'n, 2013 O.J. (C 313) 62; Case No. T-469/13, Generics (UK) v. Comm'n, 2013 O.J. (C 325) 73; Case T-470/13, Merck v. Comm'n, 2013 O.J. (C325) 74; Case No. T-471/13, Xellia Pharm. & Zoetis Prods. v. Comm'n, 2013 O.J. (C 325) 47; Case No. T-472/13, Lundbeck v. Comm'n, 2013 O.J. (C 325) 76.

The judgment of the EU General Court is pending. Based upon the average duration of competition cases before the EU General Court, a judgment is not anticipated until late 2017.

D. Ongoing investigations

The Commission is currently investigating two additional patent settlements. First, the Commission has issued a statement of objections to Servier and several generic companies, alleging that the parties' patent settlement agreements were aimed at delaying or preventing market entry of generic versions of Perindopril.[46] The Commission also accuses Servier of acquiring scarce competing technologies to produce the drug.

Second, 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.[47] 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.

In addition to the European Commission, the UK Office of Fair Trading is currently investigating GlaxoSmithKline and three generic companies in relation to a reverse-payment patent settlement for the antidepressant drug paroxetine.[48]

IV. COMPARISON BETWEEN THE RULING IN *ACTAVIS* AND THE COMMISSION DECISION IN *LUNDBECK*

While the analysis of the legality of reverse-payment patent settlement agreements under US antitrust law and EU competition law is highly complex, and in part depends upon the differing regulatory framework in each region, the approach of the regulators in both the US and the EU has been broadly similar. In particular, both the European Commission and the US FTC have essentially the same position that reverse-payment patent settlement agreements should be presumptively illegal.

The key difference, however, lies in the fact that the legal position of the European Commission has not been tested by the EU Courts. As discussed in Section II, above, in the

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[46] Press Release, European Comm'n, Commission Sends Statement of Objections on Perindopril to Servier and Others (July 30, 2012), *available at* http://europa.eu/rapid/press-release_IP-12-835_en.htm?locale=en.

[47] Press Release, European Comm'n, 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.

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

Actavis case, the US Supreme Court rejected the FTC's desired "presumptively illegal" standard for the assessment of reverse-payment patent settlement agreements, and instead adopted a "rule-of-reason" approach, meaning that the FTC or private plaintiffs must prove their case that the settlement agreement harms competition.

Of course, significant uncertainty remains in the US concerning how lower courts will apply the *Actavis* decision. In particular, it remains unclear whether, in arguing that the payment was justified, the parties must in fact litigate the validity of the patent(s) and the existence of infringement by the generics. Put another way, this would lead to litigation of the questions that the parties agreed to settle years before—all to be decided by jury (not a judge, as would have been the case in the patent litigation) with the stakes increased exponentially given the availability of treble damages to prevailing antitrust plaintiffs. While the Court indicated that reverse-payment settlements would be analyzed "without litigating the validity of the patent," it remains to be seen how lower courts will interpret this guidance. And, of course, regardless of whether the liability element of an antitrust claim will require an examination of the patent merits, the causation element will require it because there can be no liability if the settlement permitted entry earlier than would have been the case had the parties litigated the patent case to conclusion, with the innovator prevailing and being permitted to exclude the infringing generic until expiration of the patent.

Unlike in the US, in the EU the European Commission's "presumptively illegal" ("restriction by object") standard has not yet been tested in front of the EU Courts. While the EU Courts are generally more deferential to the European Commission than the US Courts to the US authorities, it remains possible that the EU Courts will ultimately reject the Commission's legal position. If this occurs, the European Commission will likely have to struggle with many of the complex issues faced by the FTC and private plaintiffs in the US following the *Actavis* decision. However, pending the results of the ongoing appeals in the *Lundbeck* decision, and the assessment by the EU Courts of whether the European Commission's "presumptively illegal" standard is correct, companies may wish to avoid reverse-payment patent settlements in the European Union.

V. CONCLUSION

Patent settlements are a complex and hotly contested area at the intersection of patent law, competition law, and health care policy. In *Actavis*, the Supreme Court made a choice in favor of a rule of reason analysis, thus confirming that reverse-payment patent settlements cannot be considered per se illegal. The Commission, in its first decision involving this type of agreement, decided to consider the settlement in question as presumptively illegal (anticompetitive by object), hence exempting the Commission from an analysis of its effects. This approach is significantly less favorable to originator companies than the rule-of-reason

approach selected by the Supreme Court in *Actavis*. However, the Commission's position remains subject to appeal to the EU courts, which will clarify the extent to which companies are able to plead efficiencies or objective justifications for reverse-payment patent settlements.