FTC V. ACTAVIS : ARE REVERSE PAYMENT SETTLEMENTS ANTITRUST IMMUNE?

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Introduction

A 2010 study by the Federal Trade Commission (FTC) demonstrates that average savings for consumers from a mature generic market are increased by 77% as

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opposed to pre-generic entry savings.[2] In order to encourage the challenge of weak patents, facilitate generic entry and decrease drug prices, the U.S. legislator enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.[3] Under the Hatch-Waxman Act, the first generic manufacturer to file a paragraph IV certification[4] for approval of its generic version with the Food and Drug Administration (FDA), before the expiration of the patent(s) covering the respective brand-name drug, is entitled to a 180-day period of generic exclusivity once it enters the market. During this exclusivity period other generic manufacturers cannot enter the generic market; only the patent holder is entitled to launch an authorised generic drug under the same FDA approval as the branded drug. The Hatch-Waxman system backfired and has been abused by brand-name and generic pharmaceutical companies using reverse payment settlements to delay generic entry. These settlements have been the subject of a heated academic debate and contradictory jurisprudence. On June 17, 2013 the U.S. Supreme Court ruled on reverse payment settlements for the first time in *FTC v. Actavis*,[5] shedding antitrust light on these controversial settlements.

The purpose of this article is to analyse the Supreme Court's decision in *FTC v. Actavis* and to provide an overview of the legal debate on reverse payment settlements. First, the facts and the holdings of the District and the Appellate Court on the *Actavis* settlement will be presented. Second, an analysis of the "scope of the patent" test, the "presumptive illegality" approach and the *Actavis* rule of reason will follow. Third, the issues arising from the Supreme Court's decision in *Actavis* will be discussed. Finally, the European Commission's initiatives on reverse payment settlements and the *Lundbeck* case will be briefly presented, aiming to stress the need for the European Union to benefit from the troubled U.S. experience on reverse payment settlements.

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2 FTC Staff Study, Pay-for-Delay, p. 8. Available at: http://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff (Last accessed on January 31, 2014). See also CONGRESSIONAL BUDGET OFFICE Study, pp. 8-9 (stating that retail prices of generics are on average 75% cheaper than the prices of branded pharmaceuticals). Available at: http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf (Last accessed on January 31, 2014).

3 Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). In 2003 this scheme was amended by the Congress in Title XI of the Medicare Prescription Drug, Improvement, and Modernisation Act of 2003, Pub. L. No. 108-173, tit. XI, subtits. A-B, 177 Stat. 2066, 2448-64, codified at 21 U.S.C. § 355 (2006).

4 Paragraph IV certification on the basis of 21 U.S.C § 355(j)(2)(A)(vii)(IV).

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

I. FTC v. Actavis

1. The facts of Actavis

Solvay Pharmaceuticals filed a New Drug Application (NDA) for the brand-name drug AndroGel in 1999, which was approved by the FDA a year later. In 2003, Solvay was granted a patent for the gel formulation used in AndroGel, since the patent covering the active ingredient of the drug (synthetic testosterone) had expired decades earlier.[6] Subsequently, in 2003, two generic companies, first Actavis, Inc. (then known as Watson Pharmaceuticals) and then Paddock Laboratories each filed an Abbreviated New Drug Application (ANDA) with paragraph IV certifications based on both patent invalidity and non-infringement for their own generic versions of AndroGel.[7] Paddock joined Par Pharmaceuticals in order to share the litigation's costs and risks, agreeing in return to share part of its potential profits with Par. Taking the paragraph IV route automatically amounts to patent infringement and Solvay filed a patent infringement lawsuit against Actavis and Paddock. After the 30-month automatic stay expired,[8] the FDA approved Actavis' first-to-file generic product in January 2006, but the litigating parties settled.

By means of several settlement agreements, the generic companies undertook the obligation to promote Solvay's branded AndroGel while agreeing not to enter the market with their generic versions until August 31, 2015, unless another manufacturer launched a generic version of AndroGel before that date. The most striking elements of these agreements are the huge amounts Solvay paid the generic manufacturers in order to settle, even though the latter had no claim for damages against Solvay. Concretely, Solvay paid $60 million to Par and $12 million to Paddock while it agreed to share some of the AndroGel monopoly profits with Actavis for 9 years (through September 2015), estimating that those payments would be between $19 and $30 million per year. In 2009, the FTC filed an antitrust lawsuit against all settling parties, alleging that the settlement agreements were unlawful agreements not to compete, in violation of Section 5(a) of the Federal Trade Commission Act.[9] The FTC contended that the aim of these settlements was to illegitimately maintain Solvay's monopoly by postponing

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6 Besins Healthcare S.A. (the company that developed AndroGel) and Solvay were granted Patent Number 6,503,894 ("the '894 patent") which expires in August 2020.

7 Paragraph IV certification on the basis of 21 U.S.C § 355(j)(2)(A)(vii)(IV).

8 21 U.S.C. § 355(j)(5)(B)(iii) provides for a 30-month automatic stay of FDA approval in case the patent holder files a patent infringement suit against the generic filer, within 45 days from the paragraph IV certification of the latter.

9 15 U.S.C. § 45(a)(1), (banning "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce").

generic entry and to share the profits between the parties at the expense of consumers.[10]

2. The decisions of the District Court and the Appellate Court

The District Court applied the "scope of the patent" test and concluded that since the FTC did not allege that the scope of Solvay's patent was exceeded by the settlements, it was not material whether the defendants settled their disputes with reverse payments.[11] Courts applying the "scope of the patent" test were required to examine the scope of the "exclusionary potential" of the patent (defined by the patent application's claims, the duration of the patent's term, etc.) and determine the extent to which the agreements at issue exceeded that scope.[12] When the scope was not exceeded, the agreement would not be considered problematic from an antitrust perspective. In the District Court's opinion, the settlements among Solvay and the generic manufacturers did not constitute an antitrust violation since they only: 1) excluded generic AndroGel from the market and not any other product; 2) provided for 5 years less exclusion than the patent term (the patent was to expire in August 2020), and; 3) only prevented the three settling generic companies from entering the market and not other companies as well.[13] The FTC appealed the District Court's decision alleging that it had sufficiently pleaded an antitrust claim by asserting that the parties had entered into the reverse settlements even though Solvay was not likely to prevail in its patent infringement claim.[14]

The Court of Appeals for the 11th Circuit upheld the decision of the District Court also applying the "scope of the patent" test: "absent sham litigation or fraud in obtaining a patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the exclusionary scope of the

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10 FTC Second Amended Complaint for Injunctive and Other Equitable Relief in *FTC v. Watson Pharmaceuticals, Inc., et al.*, no. 1:09-CV-00955-TWT, filed on May 28, 2009, (analysing how these settlements harm competition and consumer welfare), pp. 35-38. Available at: http://www.ftc.gov/sites/default/files/documents/cases/2009/05/090528androgelfinalcmpt.pdf (Last accessed on January 31, 2014).

11 *In re: AndroGel Antitrust Litigation (No. II)*, 687 F. Supp. 2d 1371, 1377-1379 (ND Ga. 2010).

12 See further *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), ("These arguments require consideration of the scope of the exclusionary potential of the patent, the extent to which these provisions of the Agreements exceed that scope, and the anticompetitive effects thereof").

13 *In re: AndroGel Antitrust Litigation (No. II)*, 687 F. Supp. 2d 1371, 1377 (ND Ga. 2010).

14 FTC Brief as Plaintiff-Appellant in *FTC v. Watson Pharmaceuticals, Inc., et al.*, no. 10-12729-DD, filed on June 26, 2010, pp. 22-32. Available at: http://www.ftc.gov/sites/default/files/documents/cases/2010/07/100726androgelbrief.pdf (Last accessed on January 31, 2014).

patent".[15] The 11th Circuit reaffirmed its previous rulings that patent holders have a "lawful right to exclude others from the market", that "a patent confers the right to cripple competition" and finally emphasised that public policy favours the settlement of disputes and courts could not require parties to continue to litigate.[16] Therefore, the 11th Circuit found that the FTC did not sufficiently state an antitrust claim since, in the Court's opinion: 1) the FTC equated the likely failure of the infringement claim with an actual result; 2) the FTC's approach required a precarious after-the-fact calculation of the possibility for the patent holder to prevail in the lawsuit; 3) such an approach would impose heavy burdens on parties and courts, depriving them of the benefits of settlement; 4) non-specialised Circuit Courts were ill-equipped to adjudicate the merits of a patent infringement claim, and; 5) it would be difficult for a patent holder to escape competition merely by paying the first generic challenger since many other challengers would follow.[17]

3. The Supreme Court reverses the appellate decision

In June 2013, the Supreme Court found that the 11th Circuit erred in affirming dismissal of the FTC complaint and reversed this decision in *FTC v. Actavis*.[18] The Court emphasised that patent and antitrust policies are *both* relevant in determining the "scope of patent monopoly" and consequently the scope of antitrust law immunity conferred by a patent, since referring to what the holder of a valid patent would do does not provide a valid answer to the antitrust question.[19] The Court also held that traditional antitrust factors, such as likely anticompetitive effects, redeeming virtues, market power and potentially offsetting legal considerations should be considered to determine whether the restraint at issue exceeded the limits of the patent monopoly.[20] The Supreme Court noted that, based on its precedents, "patent-related settlement agreements can sometimes violate antitrust laws", while overly restrictive patent licensing agreements (*e.g.*

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15 *FTC v. Watson Pharmaceuticals, Inc*., 677 F.3d 1298, 1312 (11th Cir. 2012). The 11th Circuit referred to its case law applying the "scope of the patent" test in: *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005); *Andrx Pharmaceuticals, Inc. v. Elan Corp.,* 421 F.3d 1227, 1235 (11th Cir. 2005).

16 *FTC v. Watson Pharmaceuticals, Inc*., 677 F.3d 1298, 1314, (supporting the argument that if the FTC's position were adopted, the benefit of settling litigation would be lost and settlements would be discouraged). The 11th Circuit referred to *Valley Drug*, 344 F.3d 1294, 1306, (on the lawful right to exclude others from the market) and to *Schering-Plough*, 402 F.3d 1056, 1065-1066 (on the right to cripple competition).

17 *FTC v. Watson Pharmaceuticals, Inc*., 677 F.3d 1298, 1312-1315.

18 *FTC v. Actavis, Inc*., 133 S.Ct. 2223 (2013).

19 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2230-2231.

20 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2231.

multiple patentee agreements fixing retail prices) have also been struck down.[21] Even though the Court recognised the general policy favouring the settlement of disputes, it nevertheless stated that the true underlying concern of the 11th Circuit was that antitrust scrutiny of reverse settlements would result in lengthy, complex and expensive patent litigation.[22]

II. Three different tests for reverse settlements

U.S. Courts ruling on reverse payment settlements have applied two diametrically opposed tests: the "scope of the patent" test and the "presumptive illegality" approach. This section discusses these tests and presents the rule of reason analysis the Supreme Court outlined in *Actavis*.

1. The "scope of the patent" test

a) Granting antitrust immunity

The "scope of the patent" test allows for antitrust immunity to reverse settlements so long as courts deem that the anticompetitive restraints imposed by a reverse settlement do not exceed the "potential exclusionary scope" of the patent. This test has been criticised by certain academic commentators who disapproved of courts assuming patent validity and allowing the patent holder to pay huge amounts in order to shield its patent from being challenged and to keep generic competitors off the market.[23] Decisions applying this test, such as that of the Appellate Court

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21 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2232. The Supreme Court referred to the following cases: *United States v. Singer Mfg. Co*., 83 S.Ct.1773 (1963), (where the agreements at issue violated antitrust laws, despite settling patent disputes); *United States v. Line Material Co*., 68 S.Ct. 550 (1948), (holding that antitrust laws forbid multiple cross-licensing agreements fixing retail prices); *United States v. New Wrinkle, Inc*., 72 S.Ct. 350 (1952), (refusing antitrust immunity on the basis of the existence of a patent); *Standard Oil Co.(Indiana) v. United States*, 51 S.Ct. 421 (1931), (upholding the cross-licensing agreements at hand but stressing that such agreements would have violated the Sherman Act had the patent holders dominated the industry and limited the manufacture and supply of a patented product).

22 *FTC v. Actavis*, *Inc*., 133 S.Ct. 2223, 2234.

23 See the 118 Law, Economics, and Business Professors and the American Antitrust Institute Brief as *Amici Curiae* in *FTC v. Watson Pharmaceuticals, Inc. et al.,* no. 12-416, 2013 WL 391001 (U.S.), filed on January, 29, 2013, (hereinafter 118 Professors *Amici* Brief), pp. 30-31, criticising the "scope of the patent" test. See also HEMPHILL, Paying for Delay, pp. 1600-1604, and; COTTER, Antitrust Implications, pp. 1090-1093, (advocating in favour of the presumptive illegality approach for reverse payment settlements).

for the 11th Circuit in *Actavis*, were criticised for misunderstanding patent policy and for avoiding the adjudication of the anticompetitive concerns created by the reverse payment at issue, conveniently "pushing them under the patent scope rug" with disastrous effects on competition.[24] Since the "scope of the patent" test was adopted for the adjudication of reverse payment settlements, there has been an increase of settlements which may have involved pay-for-delay payments from 3 (in 2005) to 40 (in 2012).[25] It is worth mentioning that the 2nd and the Federal Circuits adopted similar approaches, declining to impose antitrust liability for such settlements.[26]

Not all courts welcomed the "scope of the patent" test; in *K-Dur Antitrust Litigation*, the Court of Appeals for the 3rd Circuit renounced the test for not subjecting reverse payments to *any* antitrust scrutiny and noted that "no court applying the 'scope of the patent' test has ever permitted a reverse payment antitrust case to go to trial".[27] In the same decision, the 3rd Circuit emphasised that the presumption of patent validity is merely a procedural device for allocating the burden of proof and not a substantive right of the patent holder.[28] According to CARRIER, the three main problems posed by the "scope of the patent" test are that it: 1) twists the initial concept of the test towards granting automatic legality; 2) assumes the validity of the patent at issue, and; 3) ignores the issue of patent infringement.[29] Following the same line of reasoning, a number of academics have argued that under the "scope of the patent" test, the rebuttable presumption of patent validity becomes an irrebuttable one: by ruling that a reverse payment agreement was within the "scope of the patent", courts automatically accepted that the patent at issue was valid and had been infringed.[30] This irrebuttable

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24 118 Professors *Amici* Brief, pp. 13-14, 32.

25 FTC Report, "Agreements Filed with the Federal Trade Commission under the Medicare, Prescription Drug, Improvement and Modernization Act of 2003: Overview of Agreements Filed in FY 2012", (January 2013). Available at: http://www.ftc.gov/os/2013/01/130117mmareport.pdf (Last accessed on January 31, 2014).

26 See for instance *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 212-213 (2nd Cir. 2006); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1332-1337 (Fed. Cir. 2008). See also *King Drug Co. of Florence, Inc., et al. v. Cephalon, Inc., et al.,* 702 F. Supp. 2d 514, 528-29, 533 (E.D. Pa. 2010).

27 *In Re: K-Dur Antitrust Litigation*, 686 F.3d 197, 214 (3rd Cir. 2012). See also *Upsher-Smith Labs., Inc. v. Louisiana Wholesale Drug Co., Inc.,* 133 S. Ct. 2849 (2013), (where the Supreme Court vacated the *K-Dur* judgment and remanded the case to the United States Court of Appeals for the 3rd Circuit for further consideration in the light of *FTC v. Actavis, Inc*).

28 *In Re: K-Dur Antitrust Litigation*, 686 F.3d 197, 214; citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983), ("The presumption, like all legal presumptions, is a procedural device, not substantive law").

29 CARRIER, Scope of the Patent, pp. 5-8.

30 118 Professors *Amici* Brief, pp. 21-22. See also HOVENKAMP, Reverse Payment Settlements, pp. 16-17, (arguing that courts putting emphasis on the presumption of patent validity seem to ignore the question of whether the patent at issue is infringed by the generic manufacturer's product; if it is not, the agreement resembles a naked market division agreement).

presumption of patent validity failed to take into consideration the empirical studies demonstrating that generic challengers have prevailed in 48% of paragraph IV challenges that have been litigated in court, where the respective patents were found to be invalid or not infringed.[31]

b) The Supreme Court rejects the "scope of the patent" test

Representative Henry A. Waxman, one of the two principal sponsors of the Hatch-Waxman Act, filed a brief as *amicus curiae* in the *Actavis* case, advocating that the "scope of the patent" test immunised reverse payment settlements from antitrust scrutiny and "turned on its head" the legislative policy of lowering pharmaceutical prices by enhancing competition.[32] In its decision in *Actavis*, the Supreme Court made extensive reference to the provisions of the Hatch-Waxman Act and highlighted the fact that reverse patent settlements delaying competition were condemned by the sponsors of the Act themselves.[33] The Court further emphasised that the "scope of the patent" finds no support in the Hatch-Waxman Act which is a statute of "general precompetitive thrust", aiming to facilitate generic challenges to weak patents and requiring parties to a paragraph IV dispute to report the terms of their settlement to federal antitrust regulators.[34]

Rejecting the "scope of the patent" test, the Supreme Court ruled that even if it were to accept that the anticompetitive effects of a reverse payment settlement could fall within the exclusionary scope of the patent, such a characterisation would not immunise the agreement from antitrust attack: a traditional antitrust analysis should be applied instead.[35] As the Court noted, "[w]hether a particular restraint lies beyond the limits of patent monopoly, is a conclusion that flows from

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31 RBC Capital Markets, p. 4. See also FTC Study, Generic Drug Entry, p.13, (demonstrating that generic challengers prevailed in 73% of paragraph IV challenges that were litigated before the court between 1992 and 2002). Available at: http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (Last accessed on January 31, 2014).

32 Representative Henry A. Waxman Brief as *Amicus Curiae* in support of Petitioner for a Writ of *Certiorari* in *FTC v. Watson Pharmaceuticals, Inc., et al.*, no. 12-416, 2013 WL 417736 (U.S.), filed on January 29, 2013, p. 25, ("The policy chosen by the Eleventh Circuit, however much it may benefit brand-name manufacturers who wish to preserve their monopoly profits is a bad policy from the perspective of the consumer, precisely the constituency Congress was seeking to protect"), quoting *In Re K-Dur Antitrust Litigation*, 686 F.3d 197, 217 (internal quotation marks omitted).

33 *FTC v. Actavis*, *Inc*., 133 S.Ct. 2223, 2234. The Supreme Court cited Senator Orrin Hatch, 148 Cong. Rec. 14437 (2002), ("it was and it is very clear that the [Hatch-Waxman Act] was not designed to allow deals between brand and generic companies to delay competition") and Representative Henry A. Waxman 146 Cong. Rec. 18774 (2000), (introducing the Drug Competition Act of 2000 with the aim of deterring companies from "strik[ing] collusive agreements to trade multimillion dollar pay-offs by the brand company for delays in the introduction of lower cost, generic alternatives").

34 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2234.

35 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2230-2231.

that analysis and not its starting point".[36] The Supreme Court concluded that if a reverse payment is "large and unjustified" it could have significant anticompetitive effects which should be assessed by examining, on the one hand, the size of the payment and, on the other hand, the potential justifications invoked, without litigating the validity of the patent.[37]

The 11th Circuit and other courts that adopted the "scope of the patent" test heavily relied on the argument that such an approach serves the public interest by encouraging the settlement of disputes instead of costly and complex litigation.[38] In response to this public interest consideration, certain scholars have pointed out that settlements which have adverse effects on consumers are not desirable, while the settlement of patent infringement suits does not necessarily require a reverse payment settlement; other means could be employed, which do not limit competition.[39] The Supreme Court agreed with the latter position and stressed that the relevant antitrust question focuses on the reasons for which parties prefer settlements including reverse payments: if the underlying reason for such a payment is the extension and share of patent monopoly profits, the settlement may be in breach of antitrust laws.[40]

2. The "presumptive illegality" approach

Numerous scholars of antitrust law supported the adoption of a "quick-look" analysis arguing that reverse settlements should be deemed presumptively unlawful, unless parties can invoke procompetitive justifications and rebut this presumption.[41] The "quick-look" approach is reserved for highly suspicious restraints, almost to the point of deserving *per se* condemnation, but for which at least some consideration of defences or justifications is required due to the lack of

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36 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2231-2232.

37 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2236-2237. The Supreme Court stressed that "the size of the unexplained payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself".

38 *FTC v. Watson Pharmaceuticals, Inc*., 677 F.3d 1298, 1314 (11th Cir. 2012); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072, 1075 (2005). The 2nd Circuit also supported the view that courts should encourage settlements in its decision *In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d, 187, 202 (2nd Cir. 2006).

39 118 Professors *Amici* Brief, pp. 26-30; CARRIER, Drug Patent Settlements, pp. 60-61, (arguing that the Hatch-Waxman Act's specific framework has displaced any general preference for settlements). See also *In Re K-Dur Antitrust Litigation,* 686 F.3d 197, 217-218, (noting the Congress's determination that patent challenges necessary for consumer protection should not be set aside in the name of judicial preference for settlement).

40 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2237.

41 KUTCHER, pp. 1141-1145; ELHAUGE/KRUEGER, pp. 323-329; HEMPHILL, Aggregate Approach, pp. 668-670; HOVENKAMP/JANIS/LEMLEY, pp. 1759-1766; 118 Professors *Amici* Brief, pp. 30-35.

judicial experience.[42] Under this approach, once the plaintiff shows that the restraint exists, the anticompetitive effect is presumptively established and the burden of proof shifts to the defendant; the latter must then provide procompetitive justifications for the restraint which outweigh the anticompetitive effects.[43]

Three different Circuits rejected the "scope of the patent" test, either adopting such a "presumptive illegality" approach or going even further, treating similar agreements as *per se* illegal restraints of trade.[44] Thirty-one U.S. States joined forces and filed a brief as *amici curiae* in *FTC v. Actavis*, arguing that drug patents that are challenged under the Hatch-Waxman provisions are usually weak and thus represent "aggressive claims of rights to exclude competition that are legally tenuous".[45] It was also submitted that in the event that the patent at issue is either invalid or not infringed, pay-for-delay agreements should be seen as a form of market division, whereby settling parties, rather than allocating geographic markets, allocate time in between them.[46] 118 Law, Economics, and Business Professors who filed a brief as *amici curiae* in *FTC v. Actavis* argued that even if market division could ever be justified, it should never be tolerated when it concerns pay-for-delay agreements in the pharmaceutical industry, burdening patients with billions of extra dollars a year and resulting in limited access to prescription medications.[47]

The Supreme Court rejected the view that reverse payment settlements are presumptively unlawful. Citing its decision in *California Dental*, the Court argued that such a "presumptive illegality" approach would only be suitable in cases

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42 HOVENKAMP, Federal Antitrust Policy, pp. 285-286, (explaining that the only acceptable justifications in a "quick-look" inquiry are those showing that the restraint tends to increase output and therefore decrease price).

43 See further, *idem*, pp. 287-289, (arguing that the burden of proof should lie with the party whose claim is hardest to believe).

44 *In Re: K-Dur Antitrust Litigation*, 686 F.3d 197, 214 (3rd Cir. 2012), (adopting the presumptive illegality approach); *In re: Cardizem CD Antitrust Litigation, et al.*, 332 F.3d 896, 908 (6th Cir. 2003), (ruling that the agreement at issue was a *per se* illegal restraint of trade); *Andrx Pharmaceuticals., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 815 (D.C. Cir. 2001), (where the court found that the extension of the exclusivity period granted under the Hatch-Waxman Act is an unlawful objective, potentially causing an antitrust injury).

45 The States of New York, Arizona, Arkansas et al. Brief as *Amici Curiae* in support of Petitioner for a Writ of *Certiorari* in *FTC v. Watson Pharmaceuticals, Inc., et al.*, no. 12-416, 2012 WL 5424728 (U.S.), filed on November, 5, 2012, p. 21. See also HEMPHILL/SAMPAT, pp. 327-339, (demonstrating that weak patents are disproportionately targeted by paragraph IV challenges).

46 *Supra* fn. 39, CARRIER, Drug Patent Settlements, pp. 71-73.

47 118 Professors *Amici* Brief, p. 32. See *idem* pp. 13, 23 (arguing that reverse payment settlements pose dangers analogous to territorial market allocation and that paying the generic manufacturer to stay out of the market amounts to market division if the patent is invalid). See also *supra* fn. 2, FTC Staff Study, Pay-for-Delay, p. 10, (estimating the annual purchaser savings to be gained by the elimination of pay-for-delay agreements at $ 3,5 billion per year).

where the anticompetitive effect of such an agreement on customers and markets would be obvious even to an observer with an elementary understanding of economics; this criterion was not satisfied in the Court's opinion.[48] The refusal of the Supreme Court to adopt the "presumptive illegality" approach is not astonishing given the great disparities in the jurisprudence of lower courts on reverse payment settlements.

3. The Actavis "rule of reason"

In *Actavis*, the Supreme Court employed five considerations against the decision of the 11th Circuit which applied the "scope of the patent" test. First, the restraint at issue had the potential for genuine effects on competition: the price of AndroGel was kept at patentee-set levels, the monopoly benefits were divided between the settling parties, while the first paragraph IV filer which would have introduced competition quickly was removed from consideration. Second, even though the Court accepted that there may be justifications for reverse payment settlements, it affirmed that the anticompetitive consequences they give rise to will sometimes prove to be unjustified. Third, the size of the payment was acknowledged to be a strong indicator of the patentee's power to bring about anticompetitive harm in practice. Fourth, the Court stated that it is normally not necessary for courts to litigate patent validity in order to answer the antitrust question, since the size of an unjustified reverse payment is a strong indicator of the patent's weakness. Finally, the Court considered that litigating parties would not be prevented from settling their lawsuits if large unjustified reverse payments were subject to antitrust scrutiny and liability; on the contrary, parties should seek other means of settlement that do not restrict competition, such as, for example, allowing the generic manufacturer to enter the market before the patent's expiration, without paying it to stay out of the market prior to that point.[49]

Having rejected both the "scope of the patent" test and the "presumptive illegality" approach, the Supreme Court ruled that a rule of reason analysis should be adopted in scrutinising reverse payment settlements.[50] As AREEDA and HOVENKAMP note, in a rule of reason case the plaintiff bears the burden of proving that the challenged restraint is of "a type reasonably calculated to have anticompetitive effects" which can be measured by reduced output in a defined market; once this requirement is satisfied, the burden shifts to the defendant, who is then required to show that the restraint at issue serves a legitimate objective.[51] The analysis of a contractual restraint under the rule of reason normally requires

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48 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2237, citing *California Dental Assn. v. FTC*, 119 S. Ct. 1604, 1612 (1999).

49 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2234-2237.

50 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2236-2237.

51 AREEDA/HOVENKAMP, § 15.02, p. 15-7.

demonstrating: 1) sufficient power to warrant a conclusion of plausible anticompetitive harm; 2) a restraint liable to reduce output or increase price, and; 3) that the restraint cannot be justified by efficiencies or another redeeming virtue.[52]

The Supreme Court ruled in *Actavis* that the likelihood of a reverse settlement creating anticompetitive effects depends on: 1) the payment's size; 2) the payment's scale *vis-à-vis* the anticipated litigation costs; 3) the payment's independence from other services provided to the patent holder, and; 4) the lack of any other convincing justification.[53] The Court clarified that even a payment aiming to prevent a small risk of patent invalidity in essence seeks to prevent the risk of competition and that consequence "constitutes the relevant anticompetitive harm".[54] Additionally, it was stressed that "the quality of proof required should vary with the circumstances" and that lower courts should structure their own rule of reason antitrust analysis, finding the golden section between using abbreviated antitrust theories that would not allow a proper analysis on the one hand and considering every potential fact of theory of minimal importance on the other hand.[55]

It was argued that the rule of reason analysis that the Supreme Court has opted for in *Actavis* is not substantially different from the "quick-look" approach the FTC supported.[56] The Supreme Court's observation that the size of a payment is a strong indicator of market power[57] has been interpreted by one of the leading commentators as implying that there is no need to define the relevant market and to compute the respective market share, if there is a large unjustified reverse payment.[58] It was also sustained that the anticompetitive effect of higher prices paid by consumers could be inferred by a large payment.[59] Despite the above-mentioned interpretations of the *Actavis* decision the questions of: 1) when and to what extend the validity of the patent will need to be examined by lower courts as part of the rule of reason analysis, and of; 2) whether market definition will play a meaningful role to the rule of reason analysis, are two of the many questions that are considered to be still open.[60]

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52 HOVENKAMP, Anticompetitive Patent Settlements, p. 22.
53 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2237.
54 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2236.
55 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2237-2238.
56 COTTER, FTC v. Actavis, (arguing that the majority opinion in *Actavis* adopted a *de facto* presumptive illegality approach, even if it suggests that it did not, due to political reasons).
57 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2236.
58 HOVENKAMP, Innovation and Competition, p. 100.
59 *Idem*.
60 See further, Remarks of Joshua D. Wright, Commissioner, FTC, "*FTC v. Actavis* and the Future of Reverse Payment Cases", (September 26, 2013), p. 8. Available at: http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis_0.pdf (Last accessed on January 31, 2014).

The *Actavis* decision has been described as a historic one, since had the dissenting judges prevailed and upheld the "scope of the patent" test, this would be the end of antitrust scrutiny for the vast majority of reverse payment settlements,[61] amounting to huge losses for consumers and public health schemes. What the Supreme Court made clear in *Actavis* is that unjustified reverse payments, aiming to keep competitors off the market, preserve prices at patentee-set levels and divide the benefit between the settling parties, are harmful to consumers and cannot be considered antitrust-immune.[62]

III. Reverse payment settlements after Actavis

1. Which settlements are permissible?

The ruling of the Supreme Court in *FTC v. Actavis* does not provide a clear-cut, black-or-white answer on which settlements are unlawful from an antitrust perspective. Opting for a rule of reason analysis, the Court ruled that "large and unjustified payments" *may* have anticompetitive effects and that parties who make such payments *may* be unable to justify them.[63] Nonetheless, the Supreme Court provided examples of lawful settlements, stating that it is normally permissible: 1) to make a payment which reflects traditional settlement considerations and does not exceed the litigation costs saved by means of the settlement, or to pay the fair value for services the generic has promised to perform,[64] and; 2) to conclude a settlement that allows generic entry prior to the patent's expiration without any payment to the generic challenger.[65] On the contrary, an unexplained large reverse payment normally reflects the serious doubts the patent holder has concerning the validity of its patent and suggests that the objective of the payment is to prolong monopoly profits and divide them among settling parties; the maintenance of prices at patentee-set levels and the exclusion of competition constitute the anticompetitive consequence of such a payment.[66]

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61 CARRIER, Arguments After Actavis, pp. 1-3.

62 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2226 ("Payment for staying out of the market keeps prices at patentee-set levels and divides the benefit between the patentee and the challenger, while the consumer loses").

63 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2237.

64 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2236.

65 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2234, 2237. The Court stated that such a settlement without payment "would also bring about competition, again to the consumer's benefit". The reasoning of the Court is supported by the relevant FTC study, demonstrating that agreements including payment on average prohibit generic entry for 17 months longer than agreements without payments. See further *supra* fn. 2, FTC Staff Study, Pay-for-Delay, p. 4.

66 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2236-2237.

2. When is a payment "large and unjustified"?

The size of the payment is a key element in determining whether an agreement between a patent holder and a generic challenger is a "pay-for-delay" agreement or a potentially justifiable reverse settlement. The Supreme Court did not expressly quantify what should be considered a large payment; it merely stated that the size of the payment should be examined *vis-à-vis* the following parameters: 1) the anticipated litigation costs, if the infringement lawsuit were litigated; 2) the independence of the payment from other services provided to the patent holder by the generic challenger, and; 3) the lack of any other "convincing justification".[67] The lack of a concrete definition of what constitutes a "large payment" gave rise to a debate among academics, who failed to reach a common conclusion. It was argued that it is nearly impossible to determine the scale of a payment with respect to the gross revenues of the settling pharmaceutical companies, since products, sales and profit ratios of companies vary to such an extent that it is impossible to find an "one size fits all" solution.[68] It was further maintained that a payment lower than $5 to $10 million could be considered to be a refund for the avoidance of litigation costs, whereas payments over these amounts should be justified.[69]

The second thorny question arising from the Supreme Court's decision is what should be considered a valid justification for a reverse payment settlement. The Court merely stated that "[t]here may be other justifications" for reverse payments, without however providing any examples of such justifications.[70] The rejection of the "scope of the patent" test has been interpreted by some scholars as implying that the Court did not acknowledge the existence of a valid patent as a valid defence for an unjustified large payment,[71] even though this was not explicitly stated in the *Actavis* decision. Will common sense be sufficient for fact-finders to determine if the aim of a payment is to delay generic entry or if the payment simply represents fair consideration for provided services, as one commentator has argued?[72] In any case, providing a valid justification for a large reverse payment, exceeding the anticipated litigation costs plus the value of any

67 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2237.

68 MORRISON. See also BERNARD, p. 3 (arguing that the payment of $1 million may or may not be large, depending on the product concerned).

69 CARRIER, Unjustified Payments.

70 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2236.

71 EDLIN/HEMPHILL/HOVENKAMP/SHAPIRO, p. 21 ("You may not consider the validity of the patent as a defense"); *supra* fn. 58, HOVENKAMP, Innovation and Competition, p. 101 ("Note that the one defense that the Court did not acknowledge was that the patent was valid").

72 *Supra* fn. 69, CARRIER, Unjustified Payments.

other services delivered to the patent holder, does not seem to be a simple task for the settling parties.[73]

3. The consumer welfare approach

The *Actavis* decision was described by the FTC as a "significant victory for American consumers, American tax-payers and competition".[74] The Supreme Court made explicit in its decision that a payment in return for staying out of the market keeps prices at patentee-set levels and has as a result that "the patentee and the challenger gain; the consumer loses".[75] Even though the *Actavis* decision was not unanimous, both the majority and the dissenting judges agreed that consumer welfare is the ultimate objective of antitrust law.[76] The Supreme Court's emphasis on consumer welfare rather than on total welfare was highlighted by one of the leading authorities on antitrust, noting that consumer welfare generally focuses only on the welfare of consumers and does not offset producer benefits against consumer harms. [77] On the contrary, total welfare "refers to the aggregate value an economy produces, without regard for the way that gains or losses are distributed".[78] Such a focus on consumer welfare is not novel, since horizontal agreements reducing market output, leading to price increases or reduced innovation have never been approved by courts on the grounds that producers' surplus compensated consumer losses.[79]

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73 *Supra* fn. 71, EDLIN/HEMPHILL/HOVENKAMP/SHAPIRO, p. 19 (arguing that in order to defend a payment to reduce competition, defendants in a reverse payment settlement case shall show that competition is enhanced or at least not delayed by the settlement).

74 Statement of FTC's Chairwoman Edith Ramirez before the U.S. Senate, Washington DC, of July 23, 2013, p. 2. Available at: http://www.ftc.gov/sites/default/files/documents/public_statements/statement-chairwoman-edith-ramirez-pay-delay-settlements/130923pfdopening statement_0.pdf (Last accessed on January 31, 2014).

75 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2234-2235.

76 *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 2238, Chief Justice Roberts dissenting, ("The point of antitrust law is to encourage competitive markets to promote consumer welfare").

77 *Supra* fn. 52, HOVENKAMP, Anticompetitive Patent Settlements, p. 7.

78 See further HOVENKAMP, Welfare Goals, p. 2471.

79 *Supra* fn. 71, EDLIN/HEMPHILL/HOVENKAMP/SHAPIRO, p. 17. See also HOVENKAMP, Welfare Goals, p. 2477, (stressing that antitrust policy in the U.S. follows a consumer welfare approach and condemns restraints harming consumers, irrespectively of the existence of "offsetting efficiencies" and regardless of their size).

4. The *Effexor* case

An interesting question is whether the *Actavis* rule of reason analysis should be applied to the *Effexor XR Antitrust Litigation* case.[80] In *Effexor* there was not a straightforward reverse payment settlement. Wyeth Pharmaceuticals held a patent on the compound of the blockbuster drug Effexor XR (venlafaxine hydrochloride) which expired on June 13, 2008 and three patents related to "extended release" Effexor XR, expiring on March 20, 2017.[81] Teva Pharmaceuticals was the first generic manufacturer to file an ANDA on December 10, 2002, seeking approval for its generic version of Effexor XR before the compound's patent expired. Wyeth and Teva settled on November 2, 2005.

The settlement did not include an explicit transfer of value from Wyeth to Teva. The plaintiffs allege that Teva agreed to delay its generic entry into the market of "extended release" Effexor until July 2010 (more than two years after the patent covering the compound of the drug had expired) and Wyeth in return committed not to launch its own authorised generic drug, providing Teva with 11 months of exclusivity on the generic market by means of an exclusive license to sell a generic version of Effexor.[82] An authorised generic drug is a generic drug that is produced by the patent holder, under the same New Drug Application (NDA) as the branded drug. Notably, even if all subsequent generic filers are excluded from entering the market during the 180-day exclusivity period, the patentee is allowed to enter the generic market and compete with the first generic entrant, by launching an authorised generic drug.[83] The competition - in essence the duopoly - between the generic manufacturer and the patentee during the exclusivity period deprives the first generic filer of a substantial part of its profits.[84]

The main argument of Teva and Wyeth as defendants is that their settlement did not include a reverse monetary payment from Wyeth to Teva and therefore is not

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80 *In re: Effexor XR Antitrust Litigation*, Lead case no.: 3:11-cv-05479, pending before the U.S. District Court of New Jersey. This article briefly discusses Wyeth's "no-authorised generic commitment" and does not address the remaining legal questions raised by the *Effexor* case.

81 See further, Indirect Purchaser Class Plaintiffs' Consolidated Class Action Complaint and Jury Demand, *In re: Effexor XR Antitrust Litigation*, no. 11-5590(JAP)(LHG), filed on January 9, 2012, paras 89-92, (the plaintiffs allege that Wyeth's patents on "extended release" Effexor have been fraudulently obtained).

82 *Idem*, paras 276-294, (alleging that Wyeth also agreed not to sell an authorised generic of the "instant release" Effexor XR and granted Teva an exclusive license amounting to at least a year and a half of generic exclusivity before the compound's patent expired).

83 *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005), ("We hold § 355(j)(5)(B)(iv) of the [Federal Food, Drug & Cosmetic] Act clearly does not prohibit the holder of an approved NDA from marketing, during the 180-day exclusivity period, its own brand-generic version of its drug") (internal quotation marks omitted).

84 FTC Report, "Authorised Generic Drugs: Short-Term Effects and Long-Term Impact", (August 2011). Available at: http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf (Last accessed on January 31, 2014).

subject to antitrust scrutiny under *Actavis* as a matter of law.[85] From the defendants' point of view their settlement does not fall under the definition of reverse payment settlements and consequently does not risk antitrust liability.[86] Moreover, the defendants sustain that the *Actavis* decision should be interpreted as suggesting that early-entry agreements need not to be analysed under the rule of reason.[87]

On August 14, 2013, the FTC filed a brief as *amicus curiae* in the *Effexor* case, arguing that a "no-authorised generic commitment" raises the same antitrust concern as the reverse payment settlements that the Supreme Court considered in *Actavis*.[88] In its brief on the *Effexor* case, the FTC presents its interpretation of *Actavis*, arguing that the Supreme Court's decision reflects the following "two-part framework" to assess whether a settlement agreement contains a potentially suspicious reverse payment: 1) is the alleged payment something that the generic challenger could have obtained had it prevailed in the litigation? and; 2) are the parties sharing monopoly profits obtained by avoiding competition?[89] The FTC also insists that the *Actavis* decision should not be interpreted so as to apply only to cash payments, since such a limitation would allow settling parties to avoid potential antitrust challenges merely by opting for alternative types of consideration.[90] According to the FTC's Report on Authorised Generic Drugs, when an authorised generic is marketed, the first paragraph IV filer's revenues during the 180-day exclusivity period are reduced by 40-52%, a reduction which may amount to several millions of dollars.[91] On this basis, the FTC supports the position that a "no-authorised generic commitment" can serve as a vehicle to convince the generic first filer to abandon its patent challenge and share the monopoly profits incurred with the patent holder. Such an agreement should be scrutinised under the *Actavis* rule of reason since it serves the same function as a reverse payment settlement, irrespectively of whether it is labelled as one.[92]

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85 Supplemental Memorandum in Support of Teva Defendants' Motions to Dismiss, *In re: Effexor XR Antitrust Litigation*, no. 11-5479 (PGS)(LHG), filed on August 7, 2013, pp. 3-6; Supplemental Memorandum in Further Support of Wyeth's Defendants' Motions to Dismiss All Complaints, *In re: Effexor XR Antitrust Litigation*, no. 11-05479, Doc. No. 231, filed on August 7, 2013, pp. 2-5.

86 Supplemental Memorandum in Support of Teva Defendants' Motions to Dismiss, *In re: Effexor XR Antitrust Litigation*, no. 11-5479 (PGS)(LHG), filed on August 7, 2013, p. 8.

87 *Idem*, p. 5.

88 FTC Brief as *amicus curiae*, *In re: Effexor XR Antitrust Litigation*, no.: 3:11-cv-05479, filed on August 14, 2013, p. 15. Available at: http://www.ftc.gov/sites/default/files/documents/amicus_briefs/re-effexor-xr-antitrust-litigation/130816effexoramicusbrief.pdf (Last accessed on January 31, 2014).

89 *Idem*, pp. 7-8.

90 *Idem*, p. 6.

91 *Supra* fn. 84, FTC Report, "Authorised Generic Drugs: Short-Term Effects and Long-Term Impact", p. 33.

92 *Supra* fn. 88, FTC Brief as *amicus curiae, In re: Effexor XR Antitrust Litigation*, pp. 9, 16.

Did the FTC overstretch the *Actavis* ruling with its two-part framework, arguing that the rule of reason analysis should not be limited to monetary reverse payment settlements?[93] Or do "no-authorised generic commitments" substitute one form of consideration paid to the generic filer for another and may have anticompetitive effects similar to those of monetary reverse payment settlements, passing on to consumers part of the costs of the settlement?[94] Is the decision of a patentee not to market an authorised generic "a source of payment to induce delay",[95] or is it simply a legitimate form of consideration, part of a negotiated early-entry agreement that has been explicitly approved by the Supreme Court in *Actavis*?[96] These admittedly difficult questions will need to be addressed by the U.S. District Court of New Jersey in the *Effexor* case.

IV. The European perspective

Reverse payment settlements are not limited to the U.S. territory and have been attracting increasing attention in the European Union. The European Commission has been closely monitoring patent settlements, investigating agreements potentially delaying generic entry. This section briefly discusses the Commission's relevant initiatives and the *Lundbeck* case, the first reverse payment settlement to reach the General Court of the European Union.

1. Monitoring patent settlements

Patent settlements among patent holders and generic drug manufacturers have been in the spotlight in the European Union ever since 2008, when the European Commission launched the first pharmaceutical sector inquiry.[97] Between 2010 and

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93 See further, *supra* fn. 68, BERNARD, p. 5 (arguing that the two-part framework of the FTC overstretches the *Actavis* decision, reversing it to a presumptive illegality test).

94 KERR/TYLER, pp. 34-35.

95 *Supra* fn. 41, HEMPHILL, Aggregate Approach, p. 684, (noting that a patent holder can increase the generic entrant's profits by agreeing not to launch an authorised generic product; this decision is described as "costly", since the patent holder forgoes extra profits it would have obtained by marketing its own authorised generic competitor).

96 Supplemental Memorandum in Further Support of Wyeth's Defendants' Motions to Dismiss All Complaints, *In re: Effexor XR Antitrust Litigation*, no. 11-05479, Doc. No. 231, filed on August 7, 2013, pp. 3-7.

97 European Commission Press Release, "Antitrust: Commission Launches Sector Inquiry into Pharmaceuticals with Unannounced Inspections", IP/08/49, January 16, 2008. Available at: http://europa.eu/rapid/press-release_IP-08-49_en.htm?locale=en (Last accessed on January 31, 2014).

2013, four reports on the monitoring of patent settlements were published by the Commission, covering the period from mid-2008 to December 2012.[98] Following the Commission's enforcement actions against settlements delaying generic entry, there has been a decrease in the number of agreements limiting access to the market and containing a value transfer from the patent holder to the generic manufacturer (codified by the Commission as "B.II agreements") from an average of 22% in 2000-2008, to 7% in 2012.[99] Despite this decrease, the Commission maintains its firm stance against settlements imposing undue delays to generic entry and has been investigating Servier and other pharmaceutical companies for practices resulting in potential delays in the entry of generic Perindopril.[100] Moreover, the Commission is investigating on an agreement between Cephalon and Teva which may have hindered the entry of the generic version of Modafinil.[101]

On December 10, 2013 the Commission imposed fines of approximately € 16 million on the U.S. company Johnson & Johnson and on the Swiss enterprise Novartis for the agreements concluded by their Dutch subsidiaries which were found to delay the entry of generic versions of the pain-killer Fentanyl.[102] Nevertheless, this was neither the only nor the highest fine imposed for an anticompetitive agreement delaying generic entry. On June 19, 2013, only two days after the *FTC v. Actavis* was decided by the U.S. Supreme Court, the Commission imposed a fine of € 93.8 million on Lundbeck, a Danish pharmaceutical company, and fines of € 52.2 million on generic manufacturers who have agreed to delay the entry of their generic versions of Citalopram, Lundbeck's blockbuster branded antidepressant.

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98 European Commission Reports on Monitoring of Patent Settlements in the Pharmaceuticals Sector (2010-2013). Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/ (Last accessed on January 31, 2014).

99 European Commission, 4th Report on the Monitoring of Patent Settlements (period January-December 2012), December 9, 2013, p. 11. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report4_en.pdf (Last accessed on January 31, 2014).

100 European Commission Press Release, "Antitrust: Commission sends Statement of Objections on perindopril to Servier and Others", IP/12/835, July 30, 2012. Available at: http://europa.eu/rapid/press-release_IP-12-835_en.htm (Last accessed on January 31, 2014).

101 European Commission Press Release, "Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva", IP/11/511, April 28, 2011. Available at: http://europa.eu/rapid/press-release_IP-11-511_en.htm?locale=en (Last accessed on January 31, 2014).

102 It should be noted that the parties' co-promotion agreements did not relate to intellectual property matters. See further European Commission Press Release, "Antitrust: Commission fines Johnson and Johnson and Novartis € 16 million for delaying market entry of generic pain-killer fentanyl", IP/13/1233, December 10, 2013. Available at: http://europa.eu/rapid/press-release_IP-13-1233_en.htm (Last accessed on January 31, 2014).

2. The Lundbeck case

The Commission found that Lundbeck's agreements with Alpharma, Merck KGaA/Generics UK, Arrow and Ranbaxy[103] intended to delay generic entry and constituted restrictions by object, violating Article 101 TFEU.[104] First, Citalopram is a blockbuster antidepressant and was Lundbeck's best selling product at the time the fines were imposed; losing monopoly because of generic entry would amount to losses of millions for the patent holder. Second, Lundbeck's basic patent for the Citalopram molecule had expired, and the company held a number of related process patents providing a more limited protection. Third, this was a sophisticated bundle of agreements: Lundbeck paid significant lump-sums, purchased generic manufacturers' stock of generic drug versions with the sole purpose of destroying it and offered to the settling generic manufacturers guaranteed profits in a distribution agreement, thereby avoiding the obligation to make one single cash payment. Fourth, these settlements offered Lundbeck the certainty that generics would not enter the market for the duration of the agreements, prolonging and shielding Lundbeck's monopoly. The settling companies allegedly had the intention to divide among them the resulting profits, since internal communications refer to the formation of a "club" and "a pile of $$$" to be shared among the participants.[105]

Restrictions by object are restrictions that are by their very nature harmful to the proper functioning of normal competition; once the anticompetitive object of an agreement is established, it is unnecessary to examine its effects on competition.[106] Importantly, as the Director-General for Competition has stressed, a finding by the Commission of a restriction by object is not the equivalent of a *per se* offence under Section 1 of the Sherman Act; such an agreement could still fall under the exception of Article 101(3) TFEU if the conditions of said provision are met.[107]

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[103] By June 2013 when the fines were imposed, Alpharma was part of Zoetis, Generics UK part of Mylan, and Arrow part of Actavis.

[104] Press Release of the European Commission, "Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines", IP/13/563, June 19, 2013. Available at: http://europa.eu/rapid/press-release_IP-13-563_en.htm (Last accessed on January 31, 2014).

[105] See also the Statement by Vice-President of the European Commission Joaquín Almunia, "Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines", SPEECH/13/553, June 19, 2013, (arguing that Lundbeck did not prevent generic entry by successfully enforcing its patent rights but simply paid other companies not to compete). Available at: http://europa.eu/rapid/press-release_SPEECH-13-553_en.htm (Last accessed on January 31, 2014).

[106] Case C-32/11, *Allianz Hungária Biztosító and Others*, March 14, 2013, [2013] OJ C 141/3, paras 34-35; Case C-226/11, *Expedia*, December 13, 2012, [2013] OJ C 38/6, paras 35-36; Case C-209/07, *Beef Industry Development Society and Barry Brothers*, November 20, 2008, [2008] ECR I-8637, para. 17.

[107] Speech of Alexander Italianer, Director-General for Competition, European Commission, "Competitor agreements under EU competition law", September 26, 2013, New York,

The Commission's decision imposing the fines is not yet final, since not only Lundbeck but also the settling generic manufacturers have brought actions against it, which are currently pending before the General Court of the European Union.[108] In its action, Lundbeck argues that the European Commission erred in dismissing the "scope of the patent" test as the relevant standard for the competition law assessment of patent settlements under Article 101(1) TFEU.[109] Raising a nearly identical argument, all settling parties allege that the agreements did not exceed the scope of Lundbeck's patent rights.[110] Moreover, one of the applicants contends that the Commission erred in law by finding that the settlements at issue constitute a restriction by object, since it failed to take into consideration the existence of "validly issued patents" and considered the inclusion of a payment to a settlement as sufficient to establish the existence of a restriction by object.[111]

This is the first time the General Court is faced with settlement agreements that the Commission alleges are illegitimate "pay-for-delay" settlements. Judging from the actions of the applicants, the General Court will be addressing issues similar to those the Supreme Court ruled upon in *Actavis*. What is the potential role of patent validity in determining the anticompetitive effects of a settlement agreement? Can parties to a settlement invoke the existence of a presumptively valid patent in order to shield themselves from antitrust liability? Do reverse payment settlements constitute restrictions by object as the Commission argues? And most importantly, is the "scope of the patent" test the relevant standard for the assessment of patent settlements under Article 101 TFEU? The General Court should benefit from the turbulent U.S. experience on reverse payment settlements in providing the answers to these crucial questions.

U.S.A., Fordham Competition Law Institute, pp. 7-8. Available at: http://ec.europa.eu/competition/speeches/text/sp2013_07_en.pdf (Last accessed on January 31, 2014).

108 Case T-472/13, *H. Lundbeck and Lundbeck v Commission*, Action brought on August 30, 2013, [2013] OJ C 325/47; Case T-460/13, *Ranbaxy Laboratories and Ranbaxy (UK) v Commission*, Action brought on August 28, 2013, [2013] OJ C 325/43; Case T-469/13, *Generics (UK) v Commission*, Action brought on August 30, 2013, [2013] OJ C 325/45; Case T-470/13, *Merck v Commission*, Action brought on August 30, 2013, [2013] OJ C 325/46; Case T-471/13, *Xellia Pharmaceuticals and Zoetis Products v Commission*, Action brought on August 30, 2013, [2013] OJ C 325/47.

109 Case T-472/13, Action by Lundbeck, plea 4.

110 Case T-472/13, Action by Lundbeck, plea 6; Case T-460/13 Action by Ranbaxy Laboratories and Ranbaxy (UK), plea 3; Case T-469/13, Action by Generics (UK), plea 1; Case T-470/13, Action by Merck, plea 5; Case T-471/13, Action by Xellia Pharmaceuticals and Zoetis Products, pleas 1, 4.

111 Case T-469/13, Action by Generics (UK), pleas 2 and 3. It should be noted that all applicants argue that the Commission erred in its finding of a restriction by object.

Conclusion

In reply to the question of whether reverse payment settlements are permissible or illegal under antitrust law, the Supreme Court in *Actavis* gave the answer all lawyers adore: it depends. A payment from a patent holder to a generic challenger is likely to be found permissible if it reflects a rough approximation of the avoided litigation costs or the fair value for goods or services the generic manufacturer delivered to the patent holder; on the flipside, a large unjustified payment runs a high risk of engendering antitrust liability.

Rejecting both the "scope of the patent" test and the "presumptive illegality" approach, the Supreme Court ruled that reverse payment settlements should be scrutinised under a rule of reason analysis, which lower courts are to structure based on the individual circumstances of each case. There are a number of questions the *Actavis* decision left unanswered, such as the exact role of patent validity when applying the rule of reason test or the possibility of considering as payment other forms of consideration. These questions will need to be addressed by lower courts in cases like *Effexor XR Antitrust Litigation*.

In the European Union, patent settlements are closely monitored by the European Commission which has been imposing high fines for alleged antitrust violations. The decision of the General Court in the *Lundbeck* case will be the first to set the standard for the review of reverse payment settlements under European competition law.

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