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Status of Reverse Payment Cases against Pharmaceutical Companies

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Summary of antitrust issues

Reverse payment cases arise in the context of settlement agreements between brand-drug pharmaceutical companies and generic-drug manufacturers to resolve patent litigation under the Hatch-Waxman Act[1] (Hatch-Waxman or the Act).[2] Patent litigation under Hatch-Waxman is the product of the Act's effort to encourage new drug innovation by brand-drug pharmaceutical companies and other innovators while expediting the entry of generic drugs into the market.

Under the Act, no prescription drug can be marketed in the United States without approval from the US Food and Drug Administration (FDA).[3] Generic-drug manufacturers looking to enter the market seek FDA approval of their generic drug through an abbreviated new drug application (ANDA), through which the applicant must demonstrate that the generic drug contains the same active ingredients as, and is bioequivalent to, a brand drug listed in the Approved Drug Products with Therapeutic

1 Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355). Passed in 1984, and amended since, Hatch-Waxman amends the Federal Food, Drug, and Cosmetic Act.

2 *FTC v. Actavis, Inc.*, 570 U.S. 136, 141 (2013) ('[M]ost if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a patent owned by an already-approved brand-name drug owner.').

3 21 U.S.C. § 355(a).

Equivalence Evaluations (commonly known as the Orange Book).[4] An ANDA also must include one of four certifications for each patent listed for the brand drug by the patent holder in the Orange Book.

A Paragraph IV certification requires the applicant to certify that the brand manufacturer's patent listed in the Orange Book is invalid or will not be infringed by the generic drug (or both). The filing of a Paragraph IV certification constitutes a statutory act of infringement, enabling the brand manufacturer, who holds the Orange Book patent, to file a patent infringement case against the Paragraph IV filer without waiting for the generic manufacturer to make or sell the generic equivalent drug.[5] Once the patent holder files a patent infringement action against the Paragraph IV filer, a statutorily imposed 30-month stay is triggered, preventing the FDA from granting the ANDA final approval – the last regulatory approval needed by the generic manufacturer to launch its product – until the stay has lapsed.[6]

It is within this regulatory framework that patent litigants often settle in lieu of pursuing a final court determination in favor of either the brand or the generic manufacturer. Although settlement normally is a favored form of dispute resolution – providing litigants with outcome certainty and legal cost savings, and lessening the burden on the judiciary – a particular form of Hatch-Waxman settlement has drawn significant antitrust scrutiny in the past two decades. In some of these settlements, the agreements allegedly include a payment from the patent holder to the Paragraph IV applicant in return for an agreement by the Paragraph IV applicant to delay its entry into the market until a negotiated date up to the date of expiry of the patent. Settlement agreements allegedly containing such terms have been challenged by the Federal Trade Commission (FTC)[7] and private and class litigants as anticompetitive under certain circumstances, based on the theory that the patent holder is paying the

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4 *Id.* §§ 355(b)(1), (c)(2). For each drug, the Orange Book lists the number and expiry date of any patents that claim the drug substance (active ingredient), drug product (formulation and composition), and methods of use of the drug, *id.* § 355(b)(1), providing notice of the patents to generic companies. Jennifer E Sturiale, 'Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition', 69 *Ala. L. Rev.* 59, 68 (2017).

5 35 U.S.C. §§ 271(e)(2)(A), (e)(4), (e)(5).

6 21 U.S.C. § 355(j)(5)(B)(iii).

7 The Medicare Prescription Drug Improvement and Modernization Act of 2003 [MMA] requires that patent settlements involving Paragraph IV certifications be filed with the Antitrust Division of the Department of Justice and the Federal Trade Commission [FTC] for the purpose of providing the antitrust agencies with notice of settlement agreements that may require further investigation. Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003) (codified at 21 U.S.C. § 355 note).

generic firm to stay out of the market longer than the patents at issue would otherwise allow, and, thus, the patent holder may maintain its price above a competitive level.[8] On the other hand, patent holders are entitled to settle litigation involving their patents, and many settlements permit generic firms to enter the market earlier than expiry of the claimed patents.[9]

Challenges to these patent litigation settlements by the FTC and private and class litigants are brought under sections 1 and 2 of the Sherman Act,[10] section 5 of the FTC Act,[11] and various state antitrust laws. In October 2019, California became the first state to enact a law specifically aimed at reverse payment settlements.[12] Generally, Sherman Act section 1 claims are based on allegations that brand-drug and generic-drug companies are competitors or potential competitors, and any settlement in which the generic company receives money in exchange for staying out of the market is an agreement to allocate the market. Section 2 claims typically are based on the theory that the brand-drug company, by inducing generic firms through payment to stay out of the market, is illegally extending its monopoly power in the relevant drug market.

Agencies' and courts' original approach to reverse payments

Early challenges of purported reverse payment settlements were met with inconsistent treatment by the federal courts.[13] Although some courts held that such agreements were presumptively legal, immune from antitrust scrutiny absent generic exclusion

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8 E.g., FTC, Press Release, 'FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market' (Jan. 17, 2013), available at https://www.ftc.gov/news-events/press-releases/2013/01/ftc-study-fy-2012-branded-drug-firms-significantly-increased; Christopher M Holman, 'Do Reverse Payment Settlements Violate the Antitrust Laws?,' 23 *Santa Clara Computer & High Tech. L.J.* 489, 494 (2007).

9 E.g., *Impax Labs., Inc. v. FTC*, No. 19-60394, 2021 WL 1376984, at *6 (5th Cir. Apr. 13, 2021).

10 15 U.S.C. §§ 1, 2.

11 *Id.* § 45.

12 Preserving Access to Affordable Drugs Act of 2005, which took effect January 2020, codifies as presumptively illegal any transfer of value from a brand-drug firm to a generic-drug firm settling patent infringement litigation coupled with a delay of the generic drug's entry into the market. 2019 Cal. Legis. Serv. Ch. 531 (A.B. 824), Cal. Health and Safety Code §§ 134000-02.

13 See, e.g., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1340 (Fed. Cir. 2008), overruled by *Actavis*, 570 U.S. 136 (holding that 'the [settlement] Agreements were not violative of section 1 of the Sherman Act since all anticompetitive effects were within the exclusionary power of the [ ] patent.'); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005) ('Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law. This alone underscores

beyond the scope of the asserted patents,[14] other courts viewed the agreements as presumptively illegal or, at least, sufficiently anticompetitive as to justify a 'quick look' approach.[15] In 2013, the US Supreme Court resolved this circuit split in *FTC v Actavis, Inc*,[16] by holding that neither presumption applied. Instead, the Court ruled that reverse payment settlements are subject to the rule of reason.

The facts underlying the Court's decision in *Actavis* involved settlement agreements between the brand-drug company Solvay Pharmaceuticals and Paragraph IV applicants Actavis, Paddock, and Par, in resolution of Solvay's infringement action against the generic-drug firms over Solvay's testosterone-replacement drug AndroGel.[17] The FTC challenged the agreements under section 5 of the FTC Act,[18] asserting that the companies unlawfully agreed 'to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.'[19] The US District Court for the Northern District of Georgia rejected the FTC's claims,[20] and, on appeal, the US Court of Appeals for the Eleventh Circuit affirmed, ruling that 'absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack

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the need to evaluate the strength of the patent.'); *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 525 (E.D. Pa. 2010), overruled by *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) ('In 2003, the Sixth Circuit Court of Appeals found a reverse payment settlement to be a per se illegal restraint of trade in violation of the Sherman Act. Subsequently, however, the Second, Eleventh, and Federal Circuits have taken a different approach and have adopted what is referred to as the "scope of the patent test."').

14 *Ciprofloxacin Hydrochloride*, 544 F.3d 1323; *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206–07 (2d Cir. 2006), overruled by *Actavis*, 570 U.S. 136; *Schering-Plough*, 402 F.3d 1056; *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1073–74 (11th Cir. 2003).

15 *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 212 (3d Cir. 2012); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907 (6th Cir. 2003).

16 570 U.S. 136.

17 Under the settlement agreements, Solvay agreed to pay $12 million in total to Paddock, $60 million in total to Par, and an estimated $19 million to $30 million annually, for nine years, to Actavis. *Id.* at 145. Actavis, the first to file a Paragraph IV certification for generic AndroGel, agreed not to launch its generic until 65 months before the expiry of Solvay's asserted patent (unless someone else marketed a generic sooner). *Id.* Actavis also agreed to promote AndroGel to urologists. *Id.*

18 The Court did not limit its holding to claims bought under section 5 of the FTC Act, and courts have consistently applied the holding to claims brought under section 1 or 2 of the Sherman Act. *In re Cipro Cases I & II*, 348 P.3d 845, 858–59 (Cal. 2015).

19 570 U.S. at 145.

20 *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.'[21] The Supreme Court reversed the judgment of the Eleventh Circuit and remanded.[22]

Although the Supreme Court accepted that the anticompetitive effects of the settlement agreements fell within the scope of the claimed patent, it rejected the argument that this fact alone immunized the agreements from antitrust scrutiny.[23] The Court reasoned that although the holder of a valid patent may be exempt from antitrust liability based on a legitimate patent right to exclude and collect monopoly profits, the issue in reverse payment cases is whether the patent holder has such a right.[24] Accordingly, if a generic-drug firm is successful in demonstrating that a claimed patent is invalid or not infringed, the patent holder would not enjoy the right to exclude the proposed generic product from the marketplace. The Court concluded, therefore, that the agreements at issue had the potential to have 'significant adverse effects on competition,' reasoning that 'it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.'[25]

The Court, however, also rejected the proposition that the settlement agreements' potential for anticompetitive effects justified per se or quick-look treatment in light of the strong judicial policy favoring the settlement of disputes and 'because the likelihood of reverse payment bringing about anticompetitive effects depends on its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.'[26]

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21 *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

22 570 U.S. at 160. Trial was scheduled to begin in the district court in March 2019; however, the last remaining defendant in the matter settled with the FTC in February 2019. FTC, Press Release, 'Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments"' (Feb. 28, 2019), available at https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme.

23 570 U.S. at 158.

24 *Id.* at 147.

25 *Id.* at 148.

26 *Id.* at 159.

Accordingly, the Court ruled that reverse payment settlements are to be evaluated case by case under the rule of reason.[27] In doing so, the Court rejected the argument that such scrutiny would lead to 'time-consuming, complex, and expensive litigation,' as procompetitive justifications could be examined as part of the rule of reason assessment and evaluation of the underlying patent claim normally would not necessitate that the parties 'litigate patent validity to answer the antitrust question.'[28] Instead, 'the size of the reverse payment [could] serve as a proxy for the patent's weakness without forcing a court to conduct a "detailed exploration of the validity of the patent itself."'[29] The Court also held that the size of the reverse payment could serve as a proxy for market power if larger than the patent holder's anticipated litigation costs.[30]

Applying the rule of reason to reverse payment cases, lower courts have looked to five 'considerations' outlined by the *Actavis* court:

- whether there was a 'large and unjustified' reverse payment so as to create a 'potential for genuine adverse effects on competition';
- whether the one who made such a payment is able to justify it, for example, as 'avoid[ing] litigation costs or fair value services';
- whether the reverse payment 'threat[ens] to work unjustified anticompetitive harm';
- whether an antitrust action was administratively feasible; and
- the parties' reasons for 'prefer[ring] settlements that include reverse payments.'[31]

Following *Actavis*, lower courts were left to grapple with whether and how to apply these considerations to challenged settlement agreements.

One of the primary issues lower courts confronted following the *Actavis* decision was how to define 'payment' as contemplated by the Supreme Court, or more specifically, whether and what type of alleged non-monetary forms of consideration fall within the scope of the term, and whether such a payment was, in fact, 'large and unjustified' so as to create the potential for anticompetitive effects (or demonstrate market power). Although the district courts had diverged on whether 'payments'

27 *Id.*
28 *Id.* at 153.
29 *Id.* at 137, 157–58.
30 *Id.* at 157.
31 *Id.* at 153–58.

included non-cash consideration,[32] circuit courts that have considered the issue have ruled that a payment under *Actavis* is not just limited to cash, but, rather, includes other forms of consideration as well.[33] The US Court of Appeals for the Third Circuit, in *King Drug Co v SmithKline Beecham Corp*,[34] held that an agreement by the patent holder not to launch an authorized generic (AG) drug during a first filer's 180-day exclusivity period,[35] known as a 'no-AG' clause,[36] was a 'payment' within the scope of *Actavis*.[37] The US Court of Appeals for the First Circuit and other federal courts have reached the same conclusion.[38] In *In re Niaspan Antitrust Litigation*,[39] the district court

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32 *Compare In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 192 (D.R.I. 2014) (holding that payments under *Actavis* did not include non-cash consideration), vacated and remanded, 814 F.3d 538 (1st Cir. 2016), *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2014 WL 10435333 (E.D. Pa. Jan. 17, 2014) ('The Court is not prepared at this point to accept [the] argument that only a large cash payment . . . is subject to antitrust analysis under *Actavis*.'), and *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ('Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction . . . to constitute a reverse payment.'), with *In re Actos End Payor Antitrust Litig.*, No. 13–CV–9244(RA), 2015 WL 5610752, at *13 (S.D.N.Y. Sep. 22, 2015) (holding that *Actavis* was not limited to payments made in cash), *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224 (D. Conn. 2015) (same), *United Food & Com. Workers Loc. 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069–70 (N.D. Cal. 2014) (same), and *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (same).

33 *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016); *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

34 791 F.3d 388.

35 Hatch-Waxman awards the first to file an abbreviated new drug application [ANDA] with a Paragraph IV certification with a 180-day exclusivity period in which the US Food and Drug Administration [FDA] cannot approve any subsequent Paragraph IV ANDA applicant with a certification on the same drug. 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period may be forfeited if the first filer fails to market the drug by the later of either (1) the earlier of 75 days after the date that approval of the first applicant's application is effective or 30 months after the ANDA submission date, or (2) 75 days after the patent for each listed drug is found invalid or not infringed in a final decision, the court signs a settlement order that includes a finding that the patent is invalid or not infringed, or the ANDA holder removes the patent from the Orange Book. *Id.* § 355(j)(5)(D).

36 An AG is 'a generic version of a drug, authorized by a branded drug maker under its own FDA approval.' *In re Intuniv Antitrust Litig.*, No. 1:16-CV-12396-ADB, 2020 WL 5995984, at *8 (D. Mass. Oct. 9, 2020) (internal quotation marks omitted). AGs are not bound by the 180-day exclusivity period faced by subsequent Paragraph IV applicants. See footnote 35, above.

37 791 F.3d 388 (3d Cir. 2015).

38 *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704 (N.D. Ill. 2016); *United Food*, 74 F. Supp. 3d 1052.

39 42 F. Supp. 3d 735 (E.D. Pa. Sep. 5, 2014).

denied a motion to dismiss an action based on payments in the form of agreements on other drugs. The district court in *In re Solodyn Antitrust Litigation*[40] similarly held that a settlement and license agreement with upfront and milestone payments may constitute a payment. In contrast, the district court in *In re Actos End Payor Antitrust Litigation*[41] dismissed the plaintiffs' antitrust claims on the basis that the plaintiffs failed to establish that the acceleration clauses in the brand-drug company's settlements with the generic-drug companies constituted payments under *Actavis*. Courts have also accepted agreements separate from, but contemporaneous to, the settlement as 'payments.'[42]

Starting in 2005, in its annual report on pharmaceutical patent settlements filed under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA Report), the FTC began to track no-AG clauses, exclusive licenses, and exclusive supply arrangements as 'compensation' because such 'value transfers could compensate generics for agreeing to abandon their patent challenges for a share of the brand's monopoly profits.'[43] In the 2011 report titled 'Authorized Generic Drugs: Short-Term Effects and Long-Term Impact,' the FTC publicized its position that 'some brand-name companies have used agreements not to launch an authorized generic as a way to compensate an independent generic in exchange for the generic's agreement to delay its entry.'[44] Beginning in 2013, the FTC also began tracking as 'possible compensation' terms that do not 'explicitly compensate the generic company, but might operate as compensation' owing to 'the increasing complexity of some pharmaceutical settlement agreements and need for facts beyond the face of the agreements to assess their true nature and likely effects.'[45]

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40 No. 14-MD-2503-DJC, 2015 WL 5458570 (D. Mass. Sep. 15, 2015).

41 No. 1:13-cv-09244(RA), 2015 WL 5610752 (S.D.N.Y. Sep. 22, 2015).

42 E.g., *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 253–62 (3d Cir. 2017); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016).

43 Brad Albert, Armine Black and Jamie Towey, Bureau of Competition, 'MMA Reports: No tricks or treats – just facts,' FTC (Oct. 27, 2020), https://www.ftc.gov/news-events/blogs/competition-matters/2020/10/mma-reports-no-tricks-or-treats-just-facts.

44 FTC, 'Authorized Generic Drugs: Short-Term Effects and Long-Term Impact,' vii (Aug. 2011), available at https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

45 Albert, Black and Towey (footnote 43, above). The FTC identifies such terms as 'possible compensation' because 'it is not clear from the face of each agreement whether certain provisions act as compensation to the generic patent challenger.' *Id.*

When non-monetary reverse payments are alleged, as with traditional cash payments, courts have held that plaintiffs must establish that the payment is 'large' by providing sufficient facts to demonstrate a reliable value of the payment.[46] Courts have rejected attempts to apply a heightened standard for demonstrating the value of non-cash reverse payments at the pleading stage.[47] The *Actavis* court did not provide a bright-line threshold as to what makes a payment 'large.' Some lower courts, as well as the FTC, have defined a large payment as one that is greater than the expected litigation costs plus the fair value for services received pursuant to the agreement.[48] In its MMA Report for fiscal year 2015, the FTC endorsed a $7 million threshold: '[R]ecent stipulated orders for permanent injunction entered by the Commission in reverse payment cases have not prohibited settlements that restrict a generic's entry and include a cash payment of US$7 million or less in litigation fees.'[49]

Outside the contours of *Actavis*, another issue over which courts, litigants, and commentators have spilled much ink concerns how, and the standard under which, a private plaintiff must show that but for the reverse payment agreement, generic entry would have happened earlier (i.e., that the illegal agreement caused a remediable injury). Generally, plaintiffs assert one or more of the following theories of causation: absent the violating agreement, the generic firm would have entered the market

46 *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016); *In re Actos*, 2015 WL 5610752; *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D.N.J. 2014).

47 *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 253–62 (3d Cir. 2017); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016).

48 *Impax Labs., Inc. v. FTC*, No. 19-60394, 2021 WL 1376984, at *7 (5th Cir. Apr. 13, 2021); *In re Effexor XR Antitrust Litig.*, No. CIV.A. 11-5479 PGS, 2014 WL 4988410, at *23 (D.N.J. Oct. 6, 2014), rev'd and remanded sub nom. *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017).

49 Bureau of Competition, 'Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2015' at 1 (Nov. 2017), available at https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview_of_fy_2015_mma_agreements_0.pdf.

(1) after having won the patent litigation, (2) at risk, following expiry of the statutory 30-month stay,[50] and (3) at a date earlier than the date in the settlement agreement. The theory of causation bears on the manner and standard of proof.[51]

Latest trends in how agencies and courts approach reverse payments

Nearly eight years after *Actavis*, reverse payment cases continue to focus on the question of what constitutes a large and unjustified reverse payment, and according to the FTC's latest MMA Report, settlements have eschewed cash payments but have included non-monetary terms that have elicited the interest of the FTC[52] and, at times, private litigants. These settlements include, for example, what the FTC terms 'side deals' between the parties. The FTC categorizes the following as examples of side deals: (1) global patent settlements; (2) supply, development, co-promotion, or manufacturing agreements; and (3) other non-cash terms, such as 'a commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time,' a royalty payment structure whereby a generic company's royalty payment obligation to the brand declines if the brand either launches an AG or enters a later settlement agreement that permits subsequent Paragraph IV ANDA filers to sell an AG during the exclusivity period.[53]

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50 Under Hatch-Waxman, at the end of the 30-month stay triggered by the brand-drug manufacturer's filing of an infringement action against the Paragraph IV ANDA applicant, if the patent litigation has not concluded, FDA approval of the ANDA is made effective, 21 U.S.C. § 355(j)(5)(B)(iii), and if the ANDA applicant was the first to file, it may launch its generic while the patent litigation is still ongoing, in what is known as an 'at-risk' launch.

51 See, e.g., *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2018 WL 2984873, at *13–8 (N.D. Ga. Jun. 14, 2018); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-MD-02503, 2018 WL 563144, at *25–6 (D. Mass. Jan. 25, 2018); *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1160–64 (N.D. Cal. 2017); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 757-69 (E.D. Pa. 2015), aff'd *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017).

52 Bureau of Competition, 'Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2017' at 2 (Dec. 2020), available at https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf.

53 *Id.*

In the past year, courts have weighed whether these types of settlements are large and unjustified reverse payments under *Actavis*, serving up both wins and losses to reverse payment challengers seeking to establish anticompetitive effects on the basis of these settlements. For example, in *In re Intuniv Antitrust Litigation*,[54] the US District Court for the District of Massachusetts considered how to treat an alleged payment from the brand-drug company in the form of an agreement not to launch an AG where no such agreement was found in the express terms of the settlement agreement. Instead, the agreement at issue provided for the generic's early entry and a royalty payment to be paid to the brand company by the generic company for the generic's first 180 days on the market (provided the generic was the only generic on the market), during which time (as explicitly stated in the agreement) the brand could launch and market an AG itself or through an affiliate, but not through a third party.[55]

In holding that a triable issue of fact existed concerning whether the agreement constituted a reverse payment, the court rejected the defendants' argument that because the agreement expressly preserved the brand's ability to launch an AG, there was no implicit agreement that it would not do so.[56] The court ruled that '[a] contract that purports to prohibit an unlawful agreement is insufficient to establish the lack of such an agreement, however, if the plaintiff puts forth sufficient evidence to suggest that the contract was merely used as a cover to mask an unlawful intent.'[57] The court looked to the terms of the agreement, the parties' course of dealing, expert testimony, and the credibility of exculpatory conduct in determining that the purchaser plaintiffs put forth sufficient evidence to overcome summary judgment on whether the defendants agreed the brand-drug company would not launch an AG.[58]

In the context of its market power analysis, the court also rejected the defendants' argument that no payment was made on the bases that (1) it was more profitable for the brand to collect royalties than launch an AG and, thus, the brand did not sacrifice anything by not launching, and (2) by preserving its right to launch an AG on its own, the brand did not sacrifice any profit.[59] With respect to the first argument, the court reasoned that the question was 'not whether, after engaging in a potentially unlawful agreement, [the brand] made more money than it would have otherwise and thus

54 No. 1:16-CV-12396-ADB, 2020 WL 5995984 (D. Mass. Oct. 9, 2020).
55 *Id.* at *5.
56 *Id.* at *17.
57 *Id.*
58 *Id.* at *17–20.
59 *Id.* at *12.

did not sacrifice profits' but rather 'whether, by declining to launch its own AG, [the brand] sacrificed profits that it otherwise would have had by not launching its own generic or by not taking a larger percentage of royalties.'[60] As to the defendants' second argument, the court cited the plaintiffs' assertion that the brand 'had no intention of launching, and did not have the capacity to launch, an AG on its own' and thus, the court concluded that a triable issue of fact existed 'concerning whether [the brand] sacrificed potential profits by limiting its ability to launch an AG with a third party.'[61]

The *Intuniv* court also considered motions on the relevant market, state law, and causation issues – namely, whether the brand and generic firms were ready and able to launch a generic and whether the generic was likely to succeed in the underlying patent litigation. Aside from the firms' ability to launch generics and the state law motions, the court ruled in favor of allowing all the other issues to go to trial.[62]

In June 2020, the US District Court for the Northern District of Illinois, in *In re Humira (Adalimumab) Antitrust Litigation*,[63] dismissed a reverse payment claim alleging that AbbVie, Inc (AbbVie), paid biosimilar manufacturers in the form of separate agreements that allowed the biosimilars to enter the European market early while agreeing to 'AbbVie-friendly' generic entry dates in the United States.[64] The plaintiffs alleged, inter alia, that payment existed in the form of package deals that 'conferred large European revenue streams (hundreds of millions of dollars) onto the biosimilar companies, while buying AbbVie even more lucrative monopoly time in the United States (worth billions of dollars in revenue for AbbVie).'[65] The US District Court for the Northern District of Illinois disagreed, concluding that the packaged global patent settlements 'were not an *Actavis*-like unlawful reverse-payment,' as the settlements allowed early entry without a transfer of value.[66] The Court found that 'the hallmarks of an unjustified and otherwise inexplicable payment' were absent because the settlement package 'either increased competition or preserved an anticompetitive status quo.'[67] The court also noted that, unlike agreements in which a brand agrees not

60 *Id.*
61 *Id.*
62 *Id.* at *1, *29.
63 465 F. Supp. 3d 811, 835 (N.D. Ill. 2020).
64 *Id.* at 840.
65 *Id.* (citations omitted).
66 *Id.*
67 *Id.* at 840–41.

to compete by launching its own AG, the agreements at issue increased competition in the US and European markets.[68] The plaintiffs are appealing this decision to the US Court of Appeals for the Seventh Circuit.[69]

In contrast, in *FTC v AbbVie Inc*,[70] the Third Circuit held that the district court erred in dismissing the FTC's reverse payment case against AbbVie, Abbott Laboratories (Abbott), Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc – the owners of the patent for AndroGel, a testosterone replacement therapy – and alleged infringer Teva Pharmaceuticals USA, Inc (Teva).[71] The Third Circuit began by providing a detailed overview of its pay-for-delay precedent. Thereafter, it concluded that the FTC plausibly alleged a large and unjustified reverse payment from Abbott to Teva. The FTC alleged that on the same day that Abbott and Teva settled an allegedly sham patent litigation asserted by Abbott against Teva, the two companies also made a deal involving another blockbuster drug, named TriCor, whereby Teva paid Abbott to supply an AG version of TriCor at a price based on Abbott's cost, plus a royalty on Teva's profits.[72] The Third Circuit found that the payment was both large – as TriCor was 'extremely valuable' to Teva as first filer on the product – and unjustified – as the TriCor deal (1) could not be 'explained as an independent business deal from Abbott's perspective,' (2) was counter to AbbVie's incentives regarding another of its blockbuster products, (3) was uncommon to other industry norms, and (4) contained royalty terms that were 'significantly worse for [AbbVie]' than is usual in AG agreements, including other contemporaneous agreements that AbbVie entered.[73]

On 13 April 2021, in *Impax Laboratories, Inc v FTC*,[74] the US Court of Appeals for the Fifth Circuit affirmed a unanimous decision by the FTC a year earlier that a settlement agreement between Endo Pharmaceuticals, Inc (Endo), and Impax Laboratories, Inc (Impax), constituted a reverse payment in violation of section 5 of the FTC Act. The case was the first FTC proceeding to consider a reverse payment challenge since *Actavis*.

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68 *Id.* at 841.

69 *UFCW Local 1500 Welfare Fund v. AbbVie, Inc.*, No. 20-2402 (7th Cir. argued Feb. 25, 2021).

70 976 F.3d 327, 351 (3d Cir. 2020).

71 *Id.* at 356.

72 *Id.*

73 *Id.* at 357.

74 No. 19-60394, 2021 WL 1376984 (5th Cir. Apr. 13, 2021).

The underlying patent litigation concerned the branded extended-release opioid pain reliever Opana ER. Endo sued Impax in 2008 after Impax was the first to file a Paragraph IV ANDA for the drug. At that time, Endo had planned to introduce a new crush-resistant formulation of Opana ER and, according to the FTC, Endo wanted to delay Impax's generic entry until after the new formulation had launched, after which Endo would stop marketing the original formulation, thus destroying the largest market for Impax's generic version of the original formulation.[75] On the eve of the patent trial, in June 2010, the parties settled the litigation. Impax agreed not to enter the Opana ER market until January 2013. Endo agreed not to launch an AG during the first 180 days after Impax's launch, to pay Impax a portion of sales for the original Opana ER if sales dropped below a certain volume, and to grant Impax a license to Endo's current and future patents on Opana ER, coupled with a covenant not to sue for infringement of those patents. The parties also entered into a collaboration agreement for a new Parkinson's treatment, pursuant to which Endo paid Impax $10 million at the time of signing and up to $30 million more based on certain milestones. Following the settlement, Endo introduced its new formulation and paid Impax $102 million in credits based on the decline in sales of the original Opana ER, as the parties had agreed.[76] The administrative law judge who first heard the case concluded that although the agreement restricted competition, it was lawful nonetheless because its procompetitive benefits outweighed its anticompetitive effects.[77] Reviewing the decision *de novo*, the FTC disagreed, finding that Impax failed to establish any procompetitive benefits and, alternatively, that any purported benefits could have been achieved through less restrictive means.[78]

Though the question of whether there was a large payment that induced delayed generic entry was not in dispute, Impax challenged the premise that such a payment alone was enough to establish anticompetitive effects.[79] Instead, Impax argued that the FTC needed to 'evaluate the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation.'[80] The Fifth Circuit disagreed with

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75 Prescriptions are written for the brand-name drug. In most states, the pharmacy fulfilling a prescription is required to substitute a generic formulation where available, unless the prescriber specifically requires the brand.

76 Endo later withdrew its new formulation because of safety concerns.

77 *Impax Laboratories, Inc. v. FTC*, No. 19-60394, 2021 WL 1376984 (5th Cir. Apr. 13, 2021), at *4.

78 *Id.*

79 *Id.* at *5–7.

80 2021 WL 1376984, at *7 (internal quotation marks omitted).

Impax's argument, reasoning that the *Actavis* decision stood squarely for the opposite, allowing an unexplained reverse payment to serve as a surrogate for a full patent inquiry.[81] The Fifth Circuit also rejected Impax's attempt to rely on *ex post* evidence as to the agreement's competitiveness, ruling that an agreement is to be evaluated at the time entered.[82]

Having concluded that 'substantial evidence support[ed] the FTC's finding that the reverse payment settlement threatened competition,' the Fifth Circuit considered the Commission's application of the remaining factors of the rule of reason analysis.[83] The court declined to resolve the much-debated issue concerning whether there were procompetitive effects arising from the agreement, assuming *arguendo* the existence of procompetitive benefits.[84] Instead, the Fifth Circuit upheld the FTC's alternative ruling that there were also less restrictive means to achieve procompetitive effects.[85] In reaching its conclusion, the Fifth Circuit relied on 'industry practice, economic analysis, expert testimony, and adverse credibility findings discounting the testimony of Impax's lead settlement negotiator.'[86] Notably, the Fifth Circuit gave great deference to the FTC's factual findings on these factors.[87]

There were several decisions during the past year concerning class certification in reverse payment cases, with courts weighing in on representative evidence, numerosity, typicality, and adequacy of representation, among other issues.

On 22 April 2020, the Third Circuit vacated an order certifying a class of direct purchasers in *In re Lamictal Direct Purchaser Antitrust Litigation*,[88] reaffirming that Federal Rule of Civil Procedure 23(a) requires a 'rigorous analysis' under which factual determinations are to be resolved by a preponderance of the evidence.[89] Before the Third Circuit was the question of whether direct purchasers could 'establish, through common proof at trial, facts supporting an antitrust injury.'[90] The direct purchasers argued that general pricing information and an expert model providing 'average

81 *Id.* (citing *Actavis*, 570 U.S. at 158).
82 *Id.*
83 *Id.*
84 *Id.* at *9–10.
85 *Id.* at *10–1.
86 *Id.* at *10.
87 *Id.* at *10–1.
88 957 F.3d 184 (3d Cir. 2020).
89 *Id.* at 191–92.
90 *Id.* at 192.

hypothetical price' demonstrated that the entire putative class[91] suffered injury.[92] Although the district court accepted the evidence in certifying the class, the Third Circuit held that the district court abused its discretion in assuming that 'absent a rigorous analysis . . . averages [were] acceptable' in light of the parties' dueling expert reports and concern that averages might 'mask individualized injury.'[93] The Third Circuit remanded for the district court to consider this competing evidence.[94]

Two months later, in *In re Niaspan Antitrust Litigation*,[95] the US District Court for the Eastern District of Pennsylvania relied, in part, on the Third Circuit's *Lamictal* decision in denying a motion by end-payor purchasers for class certification for failure to show, inter alia, predominance.[96] The court concluded that the averages in the purchasers' proposed 'yardstick model' did not 'purport to show that all class members were injured' and 'hid[] several groups of uninjured class members who cannot be easily identified.'[97]

The direct purchasers in *In re Intuniv Antitrust Litigation*[98] faced decertification in July 2020, based on a class representative's post-certification bankruptcy filing, which the District of Massachusetts concluded barred the plaintiff from serving as a class representative where the defendants themselves are included among the plaintiff's creditors.[99] The issue marked one of first impression in the First Circuit, but the court was careful to note that its decision did not constitute 'a blanket rule that a debtor-in-possession could never be an adequate class representative.'[100] Although the court ruled that the plaintiff was an inadequate representative, given the conflict of interest that had arisen, the court declined to decertify the class at that time, instead allowing the parties to file motions to provide a substitute class representative.[101]

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91 The proposed class consisted of purchasers who purchased the brand drug directly from the brand manufacturer or the generic drug directly from the generic manufacturer. *Id.* at 189.

92 *Id.* at 193.

93 *Id.* at 194.

94 *Id.*

95 464 F. Supp. 3d 678 (E.D. Pa. 2020).

96 *Id.* at 713–14.

97 *Id.* at 714.

98 No. 1:16-CV-12653-ADB, 2020 WL 3840901 (D. Mass. Jul. 8, 2020).

99 *Id.* at *2.

100 *Id.* at *3, *7.

101 *Id.* at *7.

Conversely, the purchasers' bids for class certification were successful in *In re Zetia (Ezetimibe) Antitrust Litigation*[102] and *In re Glumetza Antitrust Litigation*.[103] In *Zetia*, the purchasers defeated attacks that the size of their 35-member class was insufficient to meet Rule 23(a)(1)'s numerosity requirement.[104] In *Glumetza*, the court rejected, inter alia, the defendants' argument that the named plaintiffs – who were assignees of other purchasers – are atypical of the class.[105] The *Glumetza* court concluded that the assignees had the same rights as their assignors and that calculating the assignees' interests posed no greater difficulty than could already be expected in 'ensur[ing] that all damages are no more than 'just and reasonable estimate[s]' of the actual harm to each putative class member.'[106]

102 481 F. Supp. 3d 571 (E.D. Va. 2020).
103 336 F.R.D. 468 (N.D. Cal. 2020).
104 481 F. Supp. 3d at 575–77.
105 336 F.R.D. at 481–82.
106 *Id.* at 482 (quoting *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264–66 (1946)).

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