The Antitrust Review of the Americas 2019

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The Antitrust Review of the Americas 2019

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Global Competition Review is delighted to publish the 2019 edition of *The Antitrust Review of the Americas*, one of a series of three special reports that deliver specialist intelligence and research designed to help subscribers – general counsel, government agencies and private practice lawyers – successfully navigate the world's increasingly complex competition regimes. Read in conjunction with *The European, Middle Eastern and African Antitrust Review* and *The Asia-Pacific Antitrust Review*, subscribers have unparalleled annual updates on the development of the world's competition regimes.

In preparing this report, *Global Competition Review* has worked exclusively with leading competition practitioners. It is their wealth of experience and knowledge – enabling them not only to explain law and policy, but also to put them into context – which makes the report of particular value to all those doing business in the Americas today.

Although every effort has been made to ensure that all matters of concern to readers are covered, competition law is a complex and fast-changing field of practice, and therefore specific legal advice should always be sought. Subscribers to *Global Competition Review* will receive regular updates on any changes to relevant laws over the coming year.

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United States: Private Antitrust Litigation

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The Hatch-Waxman Act effectively encourages private litigation between the makers of branded and generic pharmaceutical products, and these cases usually settle given the stakes at risk. But instead of ending litigation, these settlements themselves may in turn be challenged as anticompetitive 'reverse payment' or 'pay for delay' schemes. With these settlement challenges becoming increasingly prevalent – and an ongoing focus of the Federal Trade Commission (FTC) – private litigants should consider the evolving approach by the FTC and courts for assessing the potential for antitrust challenges of private settlements.

In fiscal year 2012, for example, the FTC informed Congress that there were 40 potentially anticompetitive pharmaceutical patent settlements covering drugs with combined annual sales of over US$8.3 billion, and that '[a] single anticompetitive agreement can easily increase prescription drug costs by many millions of dollars'.[1] But despite classifying such settlements as an antitrust violation – and therefore an 'unfair method of competition' under section 5 of the FTC Act – since 1998, it was only in June 2013 that the FTC finally procured a favourable US Supreme Court precedent in *FTC v Actavis, Inc*.[2]

This article examines how the FTC has tried to use, expand or clarify the *Actavis* decision over the past five years and the potential implications for private parties in or considering patent litigation. Though the FTC's post-*Actavis* record as a litigant has been mixed, answers to at least a few of the questions left open by the Supreme Court's *Actavis* opinion have begun taking shape in the lower federal courts, driven in part by the FTC's consistent advocacy.

The legislative and regulatory framework for branded and generic drugs: an invitation to collusion

To understand the FTC's post-*Actavis* enforcement efforts and their lessons for private litigants, it is helpful to review the legislative and regulatory factors in the United States that can create incentives for branded and generic pharmaceutical companies to engage in private antitrust litigation. Initially, the maker of a brand-name drug, which usually holds any relevant patents, will be the only producer in the market for that drug. The branded drug will have gone through a long and costly vetting by the Food and Drug Administration (FDA) before reaching the market, and as part of the FDA approval process, the manufacturer must publicly disclose the number and expiration date of any relevant patents.[3] Until a generic manufacturer may enter that specific market, the brand-name manufacturer lawfully maintains its monopoly by virtue of its presumptively valid patent.

Congress passed the Hatch-Waxman Act[4] in 1984 to encourage generic manufacturers to benefit consumers by entering drug markets at the earliest possible time with lower-priced generic versions of branded drugs. In particular, Hatch-Waxman gives generic manufacturers access to an abbreviated FDA approval process. As part of that process, however, the generic manufacturer must explain in its application why its generic drug will not infringe the branded manufacturer's disclosed patents. One way a generic manufacturer can do so is to certify that any patent listed on the branded manufacturer's original FDA application 'is invalid or will not be infringed by the manufacture, use or sale' of the generic – a 'paragraph IV' certification.[5] By statute, submitting a paragraph IV certification to the FDA is an act of patent infringement that entitles the branded manufacturer to sue.[6] Through that legal fiction, Congress provided a private litigation mechanism for the accelerated weeding-out of invalid or weak pharmaceutical patents.[7]

In this way, Hatch-Waxman rewards generic manufacturers for identifying and eliminating drug patents that are unlikely to withstand scrutiny. Of course, if a drug patent withstands a generic maker's challenge – that is, if the branded manufacturer successfully sues the generic maker for patent infringement following the generic's paragraph IV certification – then the branded manufacturer's lawful monopoly is undisturbed, and generic manufacturers must await the expiration of the patent before introducing generic versions of the branded drug. But if the generic challenger defeats the brand-name manufacturer's patent, it will obtain 180 days of generic exclusivity, during which its only direct competitor will be the brand-name manufacturer. After the 180-day exclusivity period ends, the market for that drug is open to any other generic manufacturer that wishes to enter.[8]

Because Hatch-Waxman can threaten a branded drug maker's patent-based monopoly profits, it can create incentives for potentially anticompetitive collusion when the branded drug maker recognises a risk that its patent may be invalidated by a generic challenger. The branded manufacturer may prefer to avoid that risk by:

- sharing its monopoly profits with a first-filing generic manufacturer that has submitted a paragraph IV certification to the FDA;
- securing the generic manufacturer's agreement to delay its market entry for some period of time; and
- settling its patent infringement litigation with that first-filing generic manufacturer on that basis.

This dynamic can lead to 'reverse payment' settlements – instead of the alleged infringer making a payment to settle the branded manufacturer's claim, the party claiming infringement makes a payment to the alleged infringer. The branded manufacturer preserves some of its patent-based monopoly profits, the first-filing generic shares in those profits, and both parties eliminate their respective risks of losing the patent infringement litigation. Other potential generic manufacturers lose out, the FTC has argued, because they are excluded from that drug market during the remaining life of the patent, instead of potentially being able to enter after a successful first-filing generic challenger's 180-day exclusivity period ends. But the biggest losers, in the view of the FTC and the plaintiffs' bar, are purchasers of the branded drug, who must pay higher prices because the relevant producers have essentially agreed not to compete.

The Actavis decision: the rule of reason applies to reverse-payment patent-litigation settlements

Actavis clarified the legal standard for analysing potentially anticompetitive reverse-payment settlements in 2013. Prior to *Actavis*, several federal courts of appeals had adopted the 'scope of the patent' test, which tended to insulate reverse-payment settlements from antitrust scrutiny by holding that a patent holder's preservation of its lawful monopoly for its authorised term of existence – including by entering into a reverse-payment settlement with a challenger – is presumptively legal even if it has some anticompetitive effect. In 2012, however, the Third Circuit Court of Appeals rejected that test and instead held that reverse-payment settlements between branded and generic pharmaceutical companies should be subjected to 'quick look' antitrust analysis, with any payment by a patent holder to a generic challenger deemed to be prima facie (but rebuttable) evidence of an unreasonable restraint of trade.[9] The resulting circuit split led the Supreme Court to take up the issue in *Actavis*. Although the FTC urged the Supreme Court to adopt the Third Circuit's 'quick look' analysis, the majority held that reverse-payment settlements are not obviously or intrinsically anticompetitive and that the FTC (or a private plaintiff) must prove its case under the standard rule-of-reason antitrust analysis.[10] In other words, a litigant must prove that a challenged reverse-payment settlement harms competition and that its anticompetitive effects are not outweighed by pro-competitive justifications. In particular, the Supreme Court noted that a 'large, unjustified' reverse payment could signal an unlawful agreement to restrain competition, absent countervailing pro-competitive benefits.[11]

Given *Actavis*'s holding and the fact-sensitive nature of the rule-of-reason standard, the decision unsurprisingly provided only a general outline of the analysis to be applied in litigation, leaving it to the lower courts to work out its application in specific cases. In 2014, then-Commissioner Joshua Wright identified three open questions that the FTC and the courts would need to resolve.

- Given that the 'reverse payment' at issue in *Actavis* was in cash, does the Supreme Court's reasoning apply to non-cash transfers of value?
- What makes a reverse payment 'large' and 'unjustified', and is a settlement payment necessarily 'large or unjustified' if it is greater than the branded manufacturer's avoided litigation costs?
- Which pro-competitive benefits is a defendant entitled to balance against anticompetitive harms for purposes of the rule-of-reason analysis?[12]

The FTC has advocated aggressively for its preferred answers to those key questions and others in the five years since *Actavis*. It has attempted to shape the continued development of the law in two ways: as a plaintiff in its own right and as amicus curiae in cases brought by private plaintiffs. Much of this litigation activity has occurred in federal courts in the Third Circuit, covering Pennsylvania, New Jersey and Delaware, which features a high concentration of pharmaceutical companies and a large amount of patent litigation. While the FTC has had mixed success in persuading the lower courts to adopt its preferred answers to the questions left open by the Supreme Court, the FTC's arguments and outcomes still provide valuable guidance for private litigants assessing Hatch-Waxman-related litigation settlements.

The FTC as a plaintiff since Actavis

FTC v Cephalon

The FTC's biggest reverse-payment victory to date ironically came in a case that had been pending since 2008, long before *Actavis* was decided. *FTC v Cephalon, Inc* involved allegations of a reverse-payment settlement involving the sleep-disorder drug Provigil. The US District Court for the Eastern District of Pennsylvania resolved two key motions against the defendant in 2014 and 2015. First, because the court had already decided in related litigation that the relevant patent was invalid, it held that the defendant was precluded from arguing the strength of the patent or relying on patent-litigation uncertainty to justify the reverse-payment settlement.[13] Second, at the summary judgment stage, the court rejected the defendant's argument that the FTC had to meet a 'threshold burden' of proving the existence of a 'large and unjustified' reverse payment before the court could undertake a rule-of-reason analysis of the settlement as a whole. The court held instead that evidence of a large, unjustified reverse payment was simply part and parcel of the FTC's burden of demonstrating anticompetitive harm under the rule of reason. Because the court found that the FTC presented sufficient evidence of a large reverse payment and that there was a genuine dispute as to whether the defendant's proffered pro-competitive justifications were pretextual, it denied summary judgment.[14] A few months later, the defendant entered into a settlement with the FTC in which it stipulated to the payment of US$1.2 billion in equitable monetary relief, among other relief, representing, in the FTC's view, disgorgement of unlawful profits.[15]

FTC v AbbVie

Around the same time the FTC triumphantly settled *Cephalon*, it suffered a reverse-payment defeat before another judge of the Eastern District of Pennsylvania in *FTC v AbbVie Inc*. That case involved the testosterone replacement therapy AndroGel, the same drug at issue in *Actavis* itself. The FTC alleged two kinds of anticompetitive conduct, sham patent-infringement litigation and a reverse-payment settlement of that litigation, premised on the brand-name maker entering into two agreements. One agreement allowed the generic maker to enter the AndroGel market nearly six years before the expiration of the relevant patent and did not involve any payment from the brand-name maker to the generic maker. The other agreement, signed the same day as the first, licensed the generic maker to sell an authorised generic version of an entirely different drug, the cholesterol medication TriCor, on terms highly favourable term to the generic maker. The FTC alleged that the TriCor agreement was a payment to induce the generic maker to enter into the AndroGel agreement – that is, to settle for market entry six years before the AndroGel patent expiration, rather than continue attempting to invalidate the patent and enter the AndroGel market sooner with a 180-day generic exclusivity period.

On a motion to dismiss, the court rejected the FTC's attempt to link the two agreements, holding that each agreement, considered alone, was pro-competitive and that neither involved a 'payment' by the brand-name maker to the generic maker. In the court's view, the AndroGel agreement was pro-competitive because it allowed market entry by the generic maker prior to expiration of the patent – thus benefiting consumers – and did not involve any payment. And the TriCor agreement created generic competition in that drug market that would not have existed but for the licence granted by the agreement – also benefiting consumers. These characteristics, the court found, distinguished the challenged agreements from the reverse-payment agreement in *Actavis*, which involved an exchange of cash for delayed generic entry.[16] After dismissing the FTC's reverse-payment claims, the court denied reconsideration and also denied the FTC's request to take an immediate appeal of the decision.[17] Instead, the court proceeded to adjudicate the

FTC's remaining claims alleging anticompetitive sham litigation. Through a combination of summary judgment and findings made after a bench trial, the court on 29 June 2018 granted judgment in the FTC's favour on those claims and awarded disgorgement in the amount of US$448 million.[18] It remains to be seen whether the FTC, having prevailed on its sham-litigation claims and obtained equitable monetary relief in AbbVie, will now appeal the dismissal of its reverse-payment claims to the Third Circuit.

FTC v Actavis on remand

The AndroGel-related claims in *Actavis* returned to the US District Court for the Northern District of Georgia on remand from the Supreme Court and continue to be actively litigated. After discovery, the defendants sought summary judgment the FTC's alleged antitrust conspiracy or anticompetitive effects. The court denied summary judgment on 14 June 2018 and will allow the FTC's claims to proceed to a future trial.

As to the conspiracy issue, the court held that the reverse-payment settlement agreements themselves are clear and direct evidence of a conspiracy, provided that the arrangement embodied in them is in fact an illegal restraint of trade. As to the FTC's burden of proof with respect to anticompetitive effects, the court made several rulings that will be strategically favourable for the FTC if followed by other courts. First, the court held that the FTC does not need to prove that a challenged settlement actually caused a delay in generic market entry. Instead, the FTC need only prove that the settlement was a vehicle for the branded manufacturer to avoid 'even the possibility of competition'. The FTC can satisfy that burden by showing that the reverse payment is larger than 'what could reasonably be expected to cover such traditional settlement concerns as future litigation costs or the value of services rendered' by the generic manufacturer, such as marketing or other services. Further, to avoid summary judgment, the FTC does not have to quantify precisely the value of any 'services rendered' by the generic manufacturer – rather, it is sufficient for the FTC to point to evidence from which a jury could reasonably conclude any ancillary agreements for the provision of services 'were merely post-hoc justifications when the true purpose of the settlement was to avoid the risk of competition'. The court also concluded that, at a future trial, the defendants will have the burden of justifying the challenged patent-litigation settlement as pro-competitive by showing that the relevant patents were both valid and infringed, and that the settlement therefore allowed generic manufacturers to enter the market earlier than would otherwise have been lawful. However, the court declared that it will not allow the defendants to conduct a 'trial within a trial' on the issue of patent validity. Instead, each defendant will be limited to offering evidence of what it 'thought at the time [of the settlement] about the strength of its patents'.[19]

In the Matter of Impax Laboratories

After initially filing in two different federal courts, the FTC recently brought challenges to reverse-payment settlements involving two otherwise unrelated pain medications, Lidoderm and Opana ER, in a Part III administrative litigation before the FTC's chief administrative law judge.[20] After proceeding through discovery and a lengthy trial before the administrative law judge (ALJ), on 11 May 2018, the ALJ's initial decision handed the FTC a stinging defeat, finding in favor of the defendants and dismissing the FTC's complaint.

The ALJ synthesised post-*Actavis* case law from a number of courts to formulate a four-step framework for the required rule-of-reason analysis as applied to reverse-payment settlements.

- First, the FTC must prove that the challenged settlement provided a payment to prevent the risk of competition. As part of that showing, and consistent with *Actavis*, the FTC must prove that any payment was 'large and unjustified'.
- Second, evidence of any pro-competitive effects arising from the challenged settlement must be evaluated. For purposes of that inquiry, the ALJ rejected the FTC's contention that 'the only relevant pro-competitive justifications are those that justify the reverse payment' itself, holding instead that any pro-competitive benefits arising from the settlement, whether or not directly connected to the reverse payment, are properly part of a rule-of-reason analysis.
- Third, the court must determine whether the demonstrated pro-competitive benefits could have been achieved with a less restrictive agreement.
- Fourth, the court weighs the settlement's anticompetitive effects against its pro-competitive effects to determine whether, on balance, the agreement is anticompetitive.[21]

Applying this framework to the record before him, the ALJ found that the FTC had shown the existence of a reverse payment that was both 'large' and, in part, 'unjustified' in exchange for an agreement not to launch a generic version of Opana ER until January 2013.[22] However, the ALJ also found that any anticompetitive effects of the challenged settlement were largely 'theoretical', because the evidence indicated that earlier market entry by the generic would have been unlikely even without the settlement agreement.[23] Further, the challenged settlement had significant pro-competitive benefits because it licensed the generic manufacturer to enter the market in January 2013, whereas other generic manufacturers have continued to be excluded from that market by ongoing patent infringement litigation brought by the brand-name manufacturer.[24] Briefly noting that the FTC did not meet its burden of proving those pro-competitive effects could have been achieved by a less restrictive agreement, the ALJ concluded that the significant pro-competitive aspects of the challenged settlement outweighed its merely 'theoretical' anticompetitive effects, mandating dismissal of the FTC's complaint.[25]

The FTC has appealed the ALJ's initial decision to the full commission. Because the appeal will be decided by the new slate of commissioners recently appointed by President Trump, their decision in the Opana ER litigation will be a window into the reconstituted FTC's thinking about how the *Actavis* rule-of-reason analysis should be applied in reverse-payments cases where there is some record evidence of both anticompetitive and pro-competitive effects.

The FTC as amicus curiae since Actavis

So far, the FTC also has shaped post-*Actavis* legal developments through strategically filing friend-of-the-court briefs in private litigation. Appearing as amicus curiae allows the FTC to advocate for its desired legal rules in a specific factual context but without taking a position on the merits of a case. The FTC has filed at least eight such briefs on reverse-payment issues in the five years since *Actavis*, mostly in the Third Circuit, and where the courts have reached the questions briefed by the agency, they have tended to adopt the FTC's preferred answers at the appellate level.[26]

The issue briefed most aggressively by the FTC in the two years following *Actavis* was the first of the questions posed by then-Commissioner Wright back in 2014: are non-cash transfers of value 'reverse payments' for purposes of the *Actavis* analysis? In briefs filed with two district courts in the Third Circuit and with the First and Third Circuit Courts of Appeals, the FTC consistently argued

that the answer to this question must be 'yes'.[27] In particular, these cases involved 'no-authorised generic' (no-AG) agreements between branded and generic manufacturers. Under the Hatch-Waxman Act, although a first-filing generic obtains 180 days of exclusivity as to other generic manufacturers, it must still compete with the branded manufacturer. Because the lower-priced generic product will typically take a large share of the higher-priced branded product's sales during the 180-day exclusivity period, the branded manufacturer often tries to recapture some of those sales by introducing its own 'authorised' generic product to compete with the generic manufacturer. By agreeing not to do this, the branded manufacturer can permit the generic manufacturer to extract maximum profit from the 180-day exclusivity period. The courts of appeals, reversing district courts that reached the opposite conclusion, have agreed with the FTC that such an arrangement is merely a non-cash reverse payment that should be analysed under the rule of reason in the same way as a cash payment.[28]

In other friend-of-the-court filings, the FTC has successfully fended off procedural defences that, if successful, could have hampered the agency's – or private plaintiffs' – ability to reach the rule-of-reason analysis in some reverse-payments cases. By statute, pharmaceutical patent litigation settlements must be filed with the FTC and the US Department of Justice, though the agencies are not required to take any particular action with respect to such filings.[29] A reverse-payment defendant argued that the FTC's lack of action in response to a submitted settlement agreement showed that the agreement was not anticompetitive. In similar vein, a reverse-payment defendant argued that because a challenged settlement agreement had been presented for approval to, and actually approved by, a federal district court, the agreement was effectively protected from antitrust review by the First Amendment of the United States Constitution as a form of petitioning the government. The FTC filed amicus briefs opposing both of these arguments.[30] The Third Circuit reversed the district court on both points, effectively adopting the FTC's position.[31]

Conclusion: prospects for Actavis under new commissioners and considerations for litigants

The current US administration has secured confirmations of new commissioners for all five seats on the FTC. Four of the new commissioners were seated by May 2018, and the fifth will be seated no later than September or October 2018. Questioning by senators in connection with the confirmation hearings did not elicit any testimony that revealed the new commissioners' thinking about reverse-payment settlements or the FTC's future efforts to develop the *Actavis* framework. The new FTC chairman, Joseph Simons, briefly touted the 'landmark' 2015 US$1.2 billion settlement in *Cephalon* when he presented the agency's fiscal year 2019 appropriations request to the Senate,[32] but that reference cannot necessarily be interpreted as a commitment that the agency will continue to seek monetary disgorgement in reverse-payment lawsuits brought in federal court. On the numerous still-unresolved questions raised by *Actavis*, the new FTC is largely an unknown quantity. Only through their litigation decisions over the next few years will the current FTC incrementally make known its policy and legal positions on how the rule of reason should be applied to potentially anticompetitive reverse-payment settlements.

As the law in this area continues to develop, private litigants settling Hatch-Waxman patent-infringement litigation should be attentive to the following considerations that have emerged from the FTC's enforcement agenda to date.

- Though only two of the US Courts of Appeals have weighed in on non-cash reverse payments, it would be prudent to assume that the courts will treat any transfer of value by a brand-name manufacturer to a generic manufacturer as a 'reverse payment' for rule-of-reason purposes.
- To the extent that a settlement payment exceeds the branded manufacturer's expected litigation costs, there should be a clear pro-competitive (or at least competition-neutral) explanation for the excess, such as the value of marketing or other services to be rendered by the generic manufacturer. And the provision of such services should make sense in terms of the parties' relationship, to avoid an inference that they are merely pretextual.
- The courts appear unreceptive to permitting a branded manufacturer to, in effect, litigate the settled patent case within the antitrust case to prove that the settlement was not anticompetitive because the branded manufacturer was not truly avoiding the risk of competition. Rather, the branded manufacturer will likely be limited to presenting evidence of its subjective belief about the strength of its patent at the time of settlement (as in *Actavis* on remand) or – if the patent has meanwhile been held invalid in some other, ancillary proceeding – precluded altogether from arguing the strength of the patent (as in *Cephalon*).
- If any factors other than the challenged patent would have precluded generic market entry even absent the Hatch-Waxman litigation settlement, those factors should be carefully documented, as they may demonstrate (as in *Impax*) that any anticompetitive effects are more theoretical than real.
- If the settlement arguably occurs in coordination with other agreements affecting other drug markets (as in *AbbVie*), care should be taken to ensure that each agreement, standing alone, confers discernible pro-competitive benefits.

Notes

1 23 July 2013 Prepared Statement of the FTC before the United States Senate, Committee on the Judiciary, Subcommittee on Antitrust, Competition Policy, and Consumer Rights, at 4, 12.
2 570 US 136.
3 Id at 142–43.
4 Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417.
5 21 USC Section 355(j)(2)(A)(vii).
6 35 USC Section 271(e)(2)(A).
7 Hatch-Waxman also incentivises a generic manufacturer to be the first "paragraph IV" challenger in a given market by conferring a (potentially highly profitable) 180-day exclusivity period during which no other generic manufacturer can enter that market. 21 USC Section 355(j)(5)(B)(iv).
8 See *Actavis*, 570 US at 141–44.
9 *In re K-Dur Antitrust Litig.*, 686 F3d 197 (3d Cir. 2012) (Sloviter, J), cert. granted and judgment vacated, 570 US 913 (2013).
10 570 US at 158–59. *Actavis* was a 5–3 decision. Justice Breyer wrote the majority opinion, joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan. Chief Justice Roberts dissented, joined by Justices Scalia and Thomas. Justice Alito did not participate in the decision.
11 Id at 157–58.
12 See 'Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers', Remarks of Commissioner Joshua D Wright at the Antitrust Masters Course VII, 10 October 2014. As discussed below, the FTC has so far managed to obtain a firm judicial answer to only the first of these questions.
13 No. 2:08-cv-02141-MSG (ED Pa.), Docket No. 322 (29 July 2014).

14 No. 2:08-cv-02141-MSG (ED Pa.), Docket No. 343 (28 January 2015).
15 28 May 2015 FTC press release ('FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished'); No. 2:08-cv-02141-MSG (ED Pa.), Docket No. 405 (17 June 2015).
16 No. 2:14-cv-05151-HB (ED Pa.), Docket No. 81 (6 May 2015).
17 No. 2:14-cv-05151-HB (ED Pa.), Docket Nos. 118 (25 August 2015) and 120 (26 August 2015).
18 No. 2:14-cv-05151-HB (ED Pa.), Docket No. 439 (29 June 2018).
19 No. 1:09-cv-955-TWT (ND Ga.), Docket No. 698 (14 June 2018).
20 FTC File No. 141-0004, FTC Docket No. 9373; administrative complaint filed 23 January 2017.
21 FTC Docket No. 9373, 11 May 2018 Initial Decision at 98–100.
22 Id at 6–7, 138–39.
23 Id at 7.
24 Id at 141, 146.
25 Id at 146–47, 156–58.
26 In addition to the filings discussed below, the FTC has filed two appellate amicus briefs highlighting the difference between what a private antitrust plaintiff must prove and what the FTC must prove in a reverse-payments case, and raising rule-of-reason issues that the courts did not squarely reach in rendering their decisions. Compare 12 February 2016 Brief of Amicus Curiae FTC, No. 15-2005 et al (1st Cir.) with *In re: Nexium (Esomeprazole) Antitrust Litig*, 842 F3d 34 (1st Cir. 2016); compare 11 March 2016 Brief of FTC as Amicus Curiae, No. 15-3559 et al (3d Cir.) with *In re: Wellbutrin XL Antitrust Litig*, 868 F3d 132 (3d Cir. 2017). These outcomes demonstrate one pitfall of the amicus curiae strategy for shaping development of the law: a relative lack of control over how legal issues are prioritised on appeal.
27 14 August 2013 FTC Brief as Amicus Curiae in No. 3:11-cv-05479 (DNJ), Docket No. 236-2; 26 September 2013 FTC's Brief as Amicus Curiae, Nos. 2:08-cv-2431 and 2433 (ED Pa.), Docket No. 510-2; 28 April 2014 Brief of FTC as Amicus Curiae, No. 14-1243 (3d Cir.); 16 June 2015 Brief of FTC as Amicus Curiae, Nos. 14–2071 and 15–1250 (consolidated) (1st Cir.).
28 *King Drug Co of Florence, Inc v Smithkline Beecham Corp*, 791 F3d 388 (3d Cir. 2015), cert. denied, 137 S Ct 446 (2016); *In re Loestrin 24 Fe Antitrust Litig*, 814 F3d 538 (1st Cir. 2016).
29 Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub L No. 108–173, Section 1111-17.
30 17 November 2015 Brief for Amicus Curiae FTC, No. 15-1184 et al (3d Cir.); 17 March 2016 Supplemental Brief of Amicus Curiae FTC, No. 15-1184 et al (3d Cir.).
31 *In re: Lipitor Antitrust Litig / In re: Effexor XR Antitrust Litig*, 868 F3d 231 (3d Cir. 2017), cert. denied, 138 S Ct. 983-84 (2018).
32 17 May 2018 Prepared Statement of the FTC Before the Committee on Appropriations, Subcommittee on Financial Services and General Government, United States Senate.

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Mr Hittinger is a frequent author and speaker on antitrust topics. He organised and led a day-long seminar on section 5 of the Federal Trade Commission Act that featured high-level representatives from all three branches of government.

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Danyll W Foix, a partner in BakerHostetler's Washington, DC office, regularly advices clients on a wide range of antitrust subjects, from questions that arise during day-to-day business operations to marketing strategies and pricing regimes. He also represents clients in commercial disputes, particularly antitrust litigation. Throughout his career, Mr Foix has provided vigorous representation of large companies defending antitrust claims. He likewise helps clients bring antitrust claims as plaintiffs, with these cases, recovering over US$400 million for clients in recent years.

Dan is the editor of BakerHostetler's Antitrust Advocate blog and he also publishes and presents on best practices and developments in the antitrust and class action sectors. His antitrust experience and client representation have been recognised by leading attorney directories, including being 'recommended' for antitrust-civil litigation/class actions by *The Legal 500* (2017) and being selected as a 'top rated antitrust litigation lawyer' by *Super Lawyers* (2017).

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Jeffry W Duffy, partner in BakerHostetler's litigation group, uses his experience as a litigator and diplomat to advise clients on all aspects of dispute resolution. He concentrates his practice on representing both plaintiffs and defendants in antitrust and unfair competition matters, business disputes, insurance and reinsurance coverage disputes, and civil rights litigation. He has also successfully argued appeals in state and federal courts. Mr Duffy's varied experience, including US government service in Japan, Singapore and Haiti, translates into effective persuasion on behalf of clients in many different settings. He holds a diploma in economics from the London School of Economics and Political Science. Mr Duffy is resident in the firm's Philadelphia office.

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M Mitchell Oates, an associate in BakerHostetler's litigation group and resident in the firm's Philadelphia office, is an experienced litigator who focuses his practice on complex commercial litigation, including antitrust and intellectual property matters. Mr Oates has represented diverse corporate clients in various industries as both plaintiffs and defendants, including representation of pharmaceutical companies in patent infringement litigation under the Hatch-Waxman Act. Before pursuing a career in law, Mr Oates was a behavioural neuroscience researcher and completed a master's degree in neuroscience from the University of California, San Diego. Because of his broad scientific background, he has often been called upon in connection with litigation and pre-litigation matters involving technical subject matter. Mr Oates served as a law clerk to US District Judge Richard J Holwell of the Southern District of New York and Judge Wilfred Feinberg of the US Court of Appeals for the Second Circuit.

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