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I. INTRODUCTION

For both plaintiffs and defendants in reverse-payments cases, 2015 was the best of times, and it was the worst of times.[2] In *In re Modafinil Antitrust Litigation*,[3] the U.S. Federal Trade Commission ("FTC") obtained a U.S. $1.2 billion settlement prior to trial, marking the largest settlement or judgment obtained by plaintiffs in a reverse-payments litigation. *In re Nexium (Esomeprazole) Antitrust Litigation*[4] went to trial, and the plaintiffs lost. Addressing the scope of *FTC v. Actavis*[5] for the first time, a U.S. Court of Appeals held that agreements by brand-name drug manufacturers not to market authorized generics fell within *Actavis*'s rule against reverse-payment settlements. But the plaintiffs lost both challenges to no-authorized-generic agreements that were adjudicated this year.

If there is a lesson to be learned from 2015, it is that reverse-payments cases are alive and well, but great care must be taken in choosing which cases to bring and to defend through trial. The legal and factual complexities of these cases, involving regulatory and patent issues in addition to antitrust issues, must be rigorously analyzed for pitfalls which can make the difference between winning and losing, or make a difference of hundreds of millions of dollars in damages.

II. MODAFINIL

In May 2015, the FTC settled its suit against Cephalon for allegedly delaying generic competition to its blockbuster sleep-disorder drug Provigil® (modafinil). Teva Pharmaceutical Industries Ltd. ("Teva"), which acquired Cephalon in 2012, agreed to pay $1.2 billion into an equitable fund to compensate purchasers—including drug wholesalers, pharmacies, and insurers—for overcharges during the period that generic drug competition was allegedly delayed. Payments made to purchasers who had previously settled their litigation with Teva would be credited against the fund, with any remainder paid to the U.S. Treasury.

In addition to monetary relief, Teva agreed to refrain from entering into the kinds of reverse-payment settlements Cephalon entered into with four generic-drug manufacturers in late

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[2] A reverse-payment agreement settles a patent-infringement suit between a pharmaceutical patent-holder and a would-be generic-drug competitor, with the generic agreeing not to launch its allegedly infringing product for some period of time before patent expiration in exchange for some payment by the patent holder (instead of the allegedly infringing generic paying the patentee for damages, hence the term "reverse payment"). In *FTC v. Actavis*, 133 S. Ct. 2223 (2013), the Supreme Court declared that reverse-payment settlements may be anticompetitive and are subject to antitrust scrutiny.

[3] No. 2:06-cv-01797-MSG (E.D. Pa. Apr. 27, 2006). The authors assisted Lloyd Constantine as an independent consultant to the court in *Modafinil*.

[4] 12-md-02409-WGY (D. Mass. Dec. 7, 2012).

[5] 133 S. Ct. 2223 (2013).

2005 and early 2006. In total, Cephalon had paid the generics upwards of $300 million for dropping their patent challenges and not entering the market for six years, until April 2012. The settlement also bars Teva from entering into a business deal with a competitor within 30 days of a patent-litigation settlement that prevents that generic's market entry.

III. NEXIUM

Nexium was brought by groups of direct purchasers, end payors (health plans and consumers), and individual retailers against AstraZeneca, Teva, Dr. Reddy's Laboratories Ltd., and Ranbaxy, Inc. The plaintiffs alleged anticompetitive reverse-payment settlements of patent litigation between AstraZeneca and each of the generics, as well as an overarching conspiracy among all the defendants, to delay the launch of generic competition to AstraZeneca's super-blockbuster acid-reflux drug Nexium®.

Trial began before a jury on October 21, 2014, and concluded with a jury verdict for the defendants on December 5, 2014.[6] On July 30, 2015, the court denied the plaintiffs' motions for a new trial.[7] The trial largely concerned AstraZeneca's agreement not to launch its own authorized generic (non-branded) product during Ranbaxy's 180-day generic-exclusivity period—the period during which the Food and Drug Administration ("FDA") is statutorily prohibited from approving new generic drugs to compete with the first generic to file an Abbreviate New Drug Application ("ANDA") for that generic drug—allegedly as an inducement for delayed generic competition from Ranbaxy. This no-authorized-generic agreement ("no-AG agreement") allegedly protected Ranbaxy's loss of hundreds of millions of dollars from competition from AstraZeneca's authorized generic during Ranbaxy's 180 days of FDA exclusivity.[8]

The pitfall in the case was that, because of manufacturing irregularities, Ranbaxy had failed to receive FDA approval to enter the market prior to May 27, 2014, the date when AstraZeneca's reverse-payment agreements allowed generic entry. The court had previously ruled, on summary judgment, that the AstraZeneca/Ranbaxy settlement therefore by itself could not have caused the plaintiffs' injury, as a matter of law, because Ranbaxy could not have entered the market earlier anyway.[9] And because the FDA statutorily could not approve any other generic until Ranbaxy's 180-day exclusivity period had run, Ranbaxy's manufacturing difficulties also foreclosed other generics' earlier entry.

The plaintiffs therefore resorted to trying to prove that, absent the no-AG agreement, Ranbaxy would have done a deal with one of the other generic manufacturers under which another generic would manufacture the product in exchange for some of Ranbaxy's substantial profits during its 180 days of exclusivity.[10] The plaintiffs failed to do so, and thereby failed to prove that

[6] *In re Nexium (Esomeprazole) Antitrust Litigation*, 2015 U.S. Dist. LEXIS 102115, at *40 (D. Mass. Jul. 30, 2015).

[7] *Id.*

[8] *See id.* at *70-71.

[9] *See Nexium*, 2014 WL 4370333, at *36 (D. Mass. Sept. 4, 2014).

[10] *Nexium*, 2015 U.S. Dist. LEXIS 102115, at *77.

the no-AG agreement, as opposed to Ranbaxy's manufacturing problems, caused the delay in generic entry.[11] The court held:

> the jury verdict—amply supported by the evidence—put paid to the Plaintiffs' largely speculative claims of antitrust injury. Tested against the common sense of actual jurors, the Plaintiffs' evidence fell short. Far short. The message is clear— the plaintiffs' bar will need far more detailed evidence of events in the "but-for" world before a jury will find actual antitrust damages.[12]

But the jury also indicated on the verdict form that the no-AG agreement was "unreasonably anticompetitive."[13] The court emphasized the importance of the jury's finding:

> Most important, here the jury has **found as fact** that the "no-AG" clause central to the AstraZeneca-Ranbaxy Settlement Agreement was a large and unjustified reverse payment with anticompetitive effects outweighing any procompetitive justifications. This real-world **finding** is of surpassing importance. It is as much "a development in the law" as it would be were I to have made this same finding in the context of a jury-waived proceeding, for
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> > [j]urors are as much constitutional officers as are [judges], U.S. Const., art. III, § 2, cl. 3 (criminal cases), id., Amend. VII (civil cases). Indeed, when applying the law to the facts they have found, jurors are supreme. Their verdicts are an even more important indicia of legal development as they come from the people themselves, a transparent expression of direct democracy.
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> *S.E.C. v. EagleEye Asset Mgmt.*, 975 F. Supp. 2d 151, 161 n.12 (D. Mass. 2013). No longer can the pharmaceutical industry simply assume that no antitrust liability can attach to the use of no-AG clauses simply because the FTC cannot, or has not, barred them. Why? An American jury has said so.[14]

Thus, despite the plaintiffs' loss in *Nexium*, the case was a victory for the plaintiffs' bar in challenging no-AG agreements.

IV. LAMICTAL

In a case involving Lamictal, GlaxoSmithKline's ("GSK") epilepsy and bipolar disorder drug, the U.S. Court of Appeals for the Third Circuit held that reverse-payment agreements need not involve cash transfers from the brand to the generic.[15] The court further held that no-AG agreements can constitute an "unusual, unexplained reverse transfer of considerable value" subject to scrutiny under *FTC v. Actavis*.

Teva was the first to file an ANDA to market generic lamotrigine tablets and chewables containing the active ingredient in Lamictal. After the main claim in the lamotrigine patent had been declared invalid, Teva and GSK settled their suit before the judge ruled on the validity of the

[11] *See id.* at *77-79, 127-131.

[12] *See id.* at *145.

[13] *See id.* at *77-79.

[14] *See id.* at *145-46.

[15] *King Drug Co. of Florence Inc. v. SmithKlineBeecham Corp. d/b/a GlaxoSmithKline*, No. 14-1243 (3d Cir. June 26, 2015) ("*Lamictal*").

patent's remaining claims.[16] Teva agreed to delay launching its generic while GSK agreed not to market an authorized generic during Teva's 180-day marketing exclusivity period—"where the bulk of the first-filer's profits lie."[17] A direct-purchaser class later sued Teva and GSK, alleging, among other things, that the no-AG agreement was effectively a "reverse payment" from GSK to Teva in violation of Section 1 of the Sherman Act.[18]

The district court dismissed the complaint on the ground that "only cash payments constitute actionable 'reverse payments.'"[19] The Third Circuit stayed the plaintiffs' appeal pending the Supreme Court's decision in *Actavis*. After *Actavis*, the Circuit remanded for further consideration, and the district court again dismissed, holding that *Actavis* applied only in patent settlements involving "'an exchange of money' rather than some other type of valuable consideration."[20]

On appeal, the Third Circuit rejected the district court's narrow reading of *Actavis* and declined to "draw such a formal line" with regard to what constitutes "payment."[21] The Third Circuit reasoned that no-AG agreements may be as anticompetitive as agreements involving cash, and are value transfers.

V. WELLBUTRIN XL

In *In re Wellbutrin XL Antitrust Litigation*,[22] the district court granted summary judgment to the defendant GSK notwithstanding GSK's agreement not to market an authorized generic during the first 180 days of generic exclusivity. As in *Nexium*, the plaintiffs' case faltered on causation.

In addition to GSK's no-AG agreement, the Wellbutrin Settlement:

- allowed the underlying patent-infringement litigation to continue, and "provided for entry of generic Wellbutrin XL immediately upon a finding of non-infringement or patent invalidity, and in any case no later than May 30, 2008, 10 years before the expiration of the patent;"
- "granted the generic manufacturers sublicenses to patents (which expired in 2022) at issue in a separate patent lawsuit," which patents had also been preventing generic entry; and
- "provided a guaranteed generic supply of Wellbutrin XL."[23]

It was thus clear that, despite the no-AG agreement and far from causing a delay in generic entry, the Wellbutrin Settlement **created** generic entry.

[16] *Id.* slip op., at 17.
[17] *Id.* at 33.
[18] *Id.* at 19.
[19] *Id.*
[20] *Id.*
[21] *Id.* at 36.
[22] Civil Action No. 08-2431, 2015 U.S. Dist. LEXIS 127373 (E.D. Pa. Sep. 23, 2015).
[23] *Id.* at *6-7.

The court further held that the plaintiffs had failed to adduce proof of alternate causes of anticompetitive harm: "either that an alternate settlement would have been reached absent a no authorized generic agreement, or that continued litigation would have resulted in earlier generic entry" at risk of patent infringement.[24] Regarding at-risk entry earlier than May 30, 2008, the court held that the patents at issue in the separate lawsuit remained "an independent bar to market entry."[25]

VI. CONCLUSION

Plaintiffs in reverse-payment cases had some success in 2015 by establishing, both in the Court of Appeals and at trial, the unlawfulness of no-AG agreements. But perhaps the bigger takeaway from this year is that causation of antitrust injury remains a major potential pitfall in these cases.

[24] *Id.* at *9.
[25] *Id.* at *10.