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I. INTRODUCTION

As the first reverse-payment antitrust case to go to a jury since the watershed U.S. Supreme Court case, *FTC v. Actavis*[2]—indeed, the first such case to be tried, ever— *In re Nexium (Esomeprazole) Antitrust Litigation*[3] promises to help map the U.S. legal landscape left largely unexplored by the Supreme Court in *Actavis* concerning the antitrust analysis of reverse-payment settlements. 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").

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

On September 4, 2014, U.S. District Judge William G. Young issued an opinion explaining his earlier granting in part and denying in part Defendants' 11 motions for summary judgment. Trial began on October 20.

II. THE *NEXIUM* OPINION

The court's 155-page opinion held:

1. **Contingent-launch clauses with generic rivals may support an inference of an overarching conspiracy among all manufacturers to delay generic competition**. All three of AstraZeneca's patent-litigation settlement agreements with the generic defendants contained "virtually identical" contingent-launch clauses allowing market entry by each generic if any of the other generics entered the market before the agreed-upon launch date, May 27, 2014. Judge Young held that, because these launch provisions were contingent on the actions of other generics, no generic engaged in a "genuinely independent concession" to AstraZeneca and each "acted in concert with its

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[2] 133 S. Ct. 2223 (2013).

[3] 12-md-02409-WGY (D. Mass. 2012).

competitors."[4] That, Judge Young held, supported an inference of an overarching conspiracy among all defendants.[5]

2. **Forgiveness of a debt may constitute a reverse payment**. AstraZeneca allegedly forgave (or discounted) over $22 million in damages that Teva allegedly owed AstraZeneca from a patent infringement suit over AstraZeneca's other blockbuster heartburn drug, Prilosec, in exchange for Teva's delayed entry into the generic Nexium market.[6]

3. **Profitable side deals may constitute reverse payments**. Ranbaxy allegedly received lucrative manufacturing, distribution, and marketing deals from AstraZeneca in connection with the patent settlement which it would not otherwise have received but-for the settlement.[7]

4. **An agreement by the brand to refrain from launching an authorized generic may be a payment.** AstraZeneca agreed not to launch its own authorized generic (non-branded) Nexium during Ranbaxy's 180-day exclusivity period—the period during which the Food and Drug Administration ("FDA") is statutorily prohibited from approving new generic drugs—allegedly as an inducement for delayed generic competition from Ranbaxy. This agreement allegedly protected Ranbaxy's loss of hundreds of millions of dollars from competition from AstraZeneca's authorized generic during the 180 days the FDA would be prohibited by statute from approving new generic drugs like Teva's or Dr. Reddy's.[8]

5. **Plaintiffs bear the burden of proving causation, *i.e.*, that the reverse-payment settlement in fact caused delay in generic entry that otherwise would have occurred, through evidence that the generic would have obtained FDA approval to market its product and would have launched that product "at risk" of patent infringement.** Because Ranbaxy was the first new-generic applicant, the FDA statutorily could not approve any other generic versions of Nexium until Ranbaxy's 180-day exclusivity period had started and run. However, Ranbaxy failed (and, indeed, has yet) to receive FDA approval, because of manufacturing irregularities. Judge Young ruled that the AstraZeneca/Ranbaxy settlement therefore by itself could not have caused Plaintiffs' injury, as a matter of law, because Ranbaxy could not have entered the market anyway.[9] And because the FDA statutorily could not approve any other generic until Ranbaxy's 180-day exclusivity period had run, Ranbaxy's inability to enter the market poses a significant hurdle for Plaintiffs to clear at trial in proving that generic competition would have entered prior to May 27, 2014, the patent settlements' agreed-upon launch date. In his preliminary charge to the jury, Judge Young instructed the jury that Plaintiffs would have to show, by a preponderance of the evidence, that generic competition would have

[4] *Nexium*, No. 12-md-02409-WGY, 2014 WL 4370333, at *15 (D. Mass. Sept. 4, 2014).

[5] *Id. But see In re Modafinil Antitrust Litig.*, 2:06-cv-1797, 2014 WL 2813312, at *13 (E.D. Pa. June 23, 2014) (rejecting overarching conspiracy among brand and generics because agreements with identical contingent-launch clauses were "in line with [generics'] economic self-interests").

[6] *See Nexium*, 2014 WL 4370333, at *46.

[7] *See id.* at **21-22.

[8] *See id.* at **25-26.

[9] *See id.* at *36.

entered prior to May 27, 2014, notwithstanding Ranbaxy's inability to enter. For example, Plaintiffs could show that the Nexium patents would have been invalidated in the patent litigation, which would trigger the start of Ranbaxy's 180 days of exclusivity notwithstanding its inability to enter, or that Teva or Dr. Reddy's and Ranbaxy would have entered into a business arrangement that would have solved the manufacturing problem.

III. THE NO-AUTHORIZED-GENERIC DEAL

Like the *Nexium* court, Commissioner Joshua Wright of the U.S. Federal Trade Commission ("FTC"), one of the FTC's two Republican members, recently expressed his view, which the FTC shares, that a potentially anticompetitive reverse payment could be pretty much anything of value that the patent-holder gives to the generic manufacturer, and that *Actavis* is not confined to monetary or cash reverse payments.[10] He further stated that no-authorized-generic ("no-AG") deals may be anticompetitive and should be subject to a "full-blown rule of reason analysis." While acknowledging that valuing no-AG settlement components may be complicated, Commissioner Wright was critical of judicial trepidation in valuing non-cash components of reverse-payment settlements, which "mistakenly" have resulted in dismissal. He postulated that mistaken dismissal of suits involving no-AG deals may encourage "clever parties" to structure settlements and avoid cash payments in order to avoid antitrust liability.

Also of note is the recent dismissal of a direct-purchaser claim in *In re Effexor XR Antitrust Litigation*.[11] The *Effexor* plaintiffs alleged that Wyeth agreed not to launch an authorized generic in exchange for Teva discontinuing its patent invalidity suit and delaying generic entry until 2010.[12] The court ruled that, while *Actavis* should not be limited to cash payments, the Supreme Court and its analysis nevertheless "emphasized cash payments" and therefore a "non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors."[13] The court dismissed the *Effexor* direct-purchaser action for failure to "specifically value the monetary amount" of the no-AG deal.[14]

IV. PROGRESS MADE, BUT STILL A LONG ROAD

Though slow to build, courts are beginning to develop approaches to the antitrust analysis of reverse-payment settlements. The majority of district courts to have addressed reverse payments post-*Actavis* have held that *Actavis* is not limited to cash payments, although some have held that antitrust plaintiffs in these cases must provide a valuation of non-cash consideration—and one that survives the pleading standards of *Bell Atlantic Corp. v. Twombly*[15]— in order to satisfy the limited guidance provided by the Supreme Court. The federal courts of appeals, however, have yet to address the issue. The debates over such valuations, and

[10] Remarks at the Antitrust Masters Course VII: Antitrust Analysis of Reverse Payment Settlements After *Actavis*: Three Questions and Proposed Answers (Oct. 10, 2014).

[11] 3:11-05479 (PGS) (LHG) (D. N.J. 2011).

[12] *See* 3:11-05479 (PGS) (LHG), 2014 WL 4988410, at **10-11 (D.N.J. Oct. 6, 2014).

[13] *Id.* at *20.

[14] *Id.* at *21.

[15] 550 U.S. 544 (2007).

over causation, promise to be significant battlefronts in these cases and particularly in *Nexium*. And unless the *Nexium* defendants settle before a verdict, a jury will decide these key issues for the first time.