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Antitrust

Reverse Payments After *Actavis*



By Brian Sodikoff, James Calder and Thomas J. Maas

On June 17, 2013, the Supreme Court held in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 570 U.S. 756 (2013), that reverse payment settlements in patent infringement litigation are not immune from antitrust attack, and that the anticompetitive effects of such ''pay-for-delay'' agreements may be found unlawful under the Sherman Act. The court explained reverse settlements as: ''Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars.'' *Actavis*, 133 S. Ct. at 2227. The court ruled that reverse payment antitrust claims must be evaluated under a fact-intensive rule-of-reason analysis, partly ''because the likelihood of a reverse payment bringing about anticompetitive effects depends upon 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.'' Cases applying the rule-of-reason analysis to antitrust violations often cite Justice Brandeis' formulation of the rule: ''The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.'' *Chicago Board of Trade v. United States*, 246 U.S. 231, 238 (1918).

To root out these unjustified anticompetitive consequences, the court noted, ''trial courts can structure antitrust litigation so as to avoid, on one hand, the use of antitrust theories too abbreviated to permit proper analysis, and on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question.'' In his dissent, Chief

Brian Sodikoff, James Calder, and Thomas J. Maas are attorneys at Katten Muchin Rosenman LLP. Any opinions expressed herein are those of the authors. All information relied upon for this survey of ongoing cases comes from publicly available sources. The authors of this article represent plaintiff Apotex in the In re Modafinil Litigation discussed herein. All information discussed there is drawn from publicly available sources and presented without opinion or argument. For more information about any of the authors, please visit http://www.kattenlaw.com.

Justice Roberts offered a few words for the district courts to help assess these settlements under the ''unruly'' rule of reason: ''Good luck . . . .''

It has been over three years since the lower courts, surely buoyed by Justice Roberts' support, have endeavored to put some meat on the skeletal bones of *Actavis*. To date, there has been only one reverse payment case to go to a full jury trial—*In re Nexium*, which was affirmed on appeal. But the facts in that case were somewhat unique, by his own admission the judge may not have tried an optimal case, and the verdict was mixed.

The lack of a concrete blueprint for evaluating whether potential reverse payments violate the antitrust laws, coupled with minimal case law addressing causation and damages, makes counseling in this area difficult in the extreme. Accordingly, in these cases more than most, practitioners and pharmaceutical companies are well advised to keep close tabs on the numerous cases moving through the courts. Although antitrust attacks on reverse payment settlements have been brought for roughly 20 years, the law is still developing—and is doing so at a frustratingly slow pace. Below, we provide a starting point for assessing the development of the law post-*Actavis*. While the case law is still developing, the cases suggest that:

1. The *Noerr-Pennington* doctrine will not provide a post-*Actavis* defense to reverse payment challenges (*In re Androgel; In re Nexium*). Under the *Noerr-Pennington* doctrine, private entities are immune from antitrust law liability for attempting to influence the government's passage or enforcement of laws, even if such laws would have anticompetitive effects. The doctrine is grounded in the First Amendment guarantee of freedom of speech, of assembly, and to petition the government for a redress of grievances;

2. If the brand loses a trial on patent validity, infringement, and/or inequitable conduct, it can have serious and dramatic repercussions in the subsequent resolution of the antitrust challenge to the reverse payment settlement (*In re Modafinil*);

3. Non-cash consideration can be considered a reverse payment under the *Actavis* test. This includes (at least at the motion to dismiss stage) the brand's agreement (a ''No-AG'' provision) not to launch an authorized generic product during the first-filer's exclusivity period (*In re Lidoderm*; *In re Opana*; *In re Nexium*; *In re Lamictal*; *In re Loestrin 24*; *but see In re Lipitor*; *In re Effexor* (requiring that plaintiffs plead some form of conversion of the non-monetary consideration to a monetary measure in order to apply *Actavis*); *In re Wellbutrin* (holding certain non-monetary settlements fell outside *Actavis*));

4. Despite a private plaintiff's ability to prove that a reverse payment is anticompetitive under *Actavis*, proving causation of damages is a ''fighting issue'' both at the pleading stage and at trial. This may impose on the plaintiff the burden of alleging and proving certain facts in a ''but for world'' scenario, such as generic launch, regulatory approval, or other factors (*In re Nexium*; *In re Actos*; *In re Asacol*); and

5. Injunctive relief prohibiting individual companies from entering into future pay-for-delay agreements appears to be an enforcement priority for the FTC (*In re Modafinil; In re Opana*).

For the most part, we group cases by generic drug. For many, there are, or were, multiple private actions pending for the same drug, which have either been MDL'd, consolidated, or coordinated (or likely will be soon). In these circumstances, we did not endeavor to list every case, but rather highlight one of the cases as for the most part representative of the group. We begin with cases where the FTC is/was a party.

In re Androgel Antitrust Litig. (No. II), 09-cv-955 (N.D. Ga.)

Notable Rulings/Issues: *FTC v. Actavis* standard-setting case; consent settlements of underlying patent litigation are not protected by *Noerr-Pennington* immunity.

Including *FTC v. Actavis*, these cases are back before the Honorable Thomas W. Thrash, Jr., in the Northern District of Georgia after being vacated and remanded by the Supreme Court. The alleged reverse payments at issue here are:

1. Solvay, the patentee, agreed to share Androgel® profits with Par, Paddock, and Watson, the alleged infringers; while

2. Par agreed to promote Androgel® to primary care physicians and delay entry until 2015;

3. Paddock agreed to serve as an Androgel® backup supplier and delay entry until 2015; and

4. Watson agreed to promote Androgel® to urologists and delay entry until 2015.

The defendants characterize these payments as legitimate compensation for services, while the plaintiffs argue that the payments were compensation for delayed competition. The court denied a motion to dismiss based on *Noerr-Pennington* antitrust immunity. Par, Paddock, and Solvay argued that because their settlement agreements were memorialized by a court's consent agreement, they constituted legitimate petitioning for government action and thus were protected by the *Noerr-Pennington* doctrine. The court rejected this argument because the consent agreement did not contain the full scope of the agreements between the parties and because ''the full agreement between Par/Paddock and Solvay is precisely the sort of agreement the Supreme Court directed district courts to review with the rule of reason.'' The court has since denied Par and Paddock's request for interlocutory appeal on the matter.

The FTC has moved to dismiss its claims against Endo subsidiaries Paddock and Par from this action as part of the Opana ER/Lidoderm settlement.

Current Status: On December 1, 2016, the FTC filed an opposition to Actavis's motion for summary judgment. On December 9, 2016, Actavis filed its reply brief in response to the FTC's opposition.

In re Modafinil Litigation, 06-cv-1797, 06-cv-1833, 06-cv-2768, 08-cv-2141 (E.D. Pa.); 153475 (3d Cir.)

Notable Rulings/Issues: In applying the rule of reason under *Actavis*, it is plaintiff's burden to show a large re-

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verse payment and defendant's burden to justify that payment; the interplay between patent rulings and application of *Actavis*; FTC entitlement to seek disgorgement of brand's profits as an equitable remedy; whether direct purchasers and end-payors can be certified in classes; causation.

Modafinil demonstrates just how expensive these cases can be. To date, the settlements have cost three defendants $1.2 *billion*. The claims of the remaining plaintiffs against the remaining defendants are yet to be tried.

In *Modafinil*, the FTC, direct purchasers, end-payors, and Apotex (a competing drug manufacturer) each alleged that anticompetitive reverse payments were made by Cephalon to four generic first-filers. The cases are before the Honorable Mitchell S. Goldberg in the Eastern District of Pennsylvania. There are also allegations of *Walker Process* fraud, sham litigation, and formation of an illegal bottleneck. The *Walker Process* doctrine allows a patent infringement defendant to show that a wrongfully brought infringement action based on a patent that was acquired by fraud or other inequitable conduct constitutes unlawful monopolization or an unlawful attempt to monopolize. The doctrine is grounded in the principle that while the First Amendment grants the right to sue (i.e., ''petition the government for redress of grievances''), the right does not extend to baseless litigation. The alleged reverse payments at issue are:

1. Cephalon allegedly entered into licenses to intellectual property held by Teva, Ranbaxy, and Barr-Chemagis at prices that plaintiffs claim are higher than fair value.

2. Cephalon allegedly purchased active pharmaceutical product (''API'') from Teva, Ranbaxy, and Barr-Chemagis at prices plaintiffs claim are higher than fair value.

3. Cephalon allegedly entered into product development deals with Mylan and Barr-Chemagis that the plaintiffs claim were reverse payments.

Before *Actavis* was decided, the district court denied motions to dismiss, allowing discovery to proceed to near completion. After *Actavis*, the court made a number of findings in summary judgment, *Daubert*, and class certification rulings.

Unique to this case are earlier court determinations holding the patent at issue invalid, unenforceable, and not infringed by Apotex. The Federal Circuit affirmed the judgments of invalidity and inequitable conduct in a *per curiam* opinion. After the appeal, in the private actions the district court granted summary judgment for plaintiffs on the materiality element of the *Walker Process* fraud claim based on collateral estoppel. However, the court denied summary judgment on the intent element of that claim, because the court found that Cephalon was entitled to have that issue resolved by a jury under the Seventh Amendment to the Constitution.

The private plaintiffs in this action alleged four individual agreements in restraint of trade (Cephalon and each generic, respectively) as well as an overall conspiracy between Cephalon and all four generics. The court denied all of defendants' motions for summary judgment, except for one attacking plaintiffs' overall conspiracy claim. The court also ruled on a number of *Daubert* challenges.

The court granted the FTC's motion for a bench trial in the spring of 2015 solely on the FTC's claims. In the lead up to that trial, the court held in a *Daubert* ruling that its prior finding of Cephalon's intent to deceive the U.S. Patent and Trademark Office (''PTO'') in the Apotex matter *would* preclude Cephalon from asserting the possibility of the patent being valid as a pro-competitive benefit of settlements in the FTC action. The court was able to make this ruling despite its earlier finding of no collateral estoppel on Cephalon's intent to deceive because the *FTC v. Cephalon* action was going to be a bench trial, and so Cephalon's Seventh Amendment rights to a jury determination were inapplicable. Defendants wished to argue that there was a pro-competitive benefit in that the generics were allowed to enter three years before patent expiry under the terms of the underlying patent settlements. In other rulings, the court held that the FTC was not precluded from seeking the equitable remedy of disgorgement from Cephalon of its ''ill-gotten gains'' from the reverse payment under Section 13(b) of the Federal Trade Commission Act. Just before trial, the FTC settled with Cephalon and Teva (who had acquired Cephalon) for $1.2 *billion*, which was placed in a settlement fund and made available to other injured parties. The FTC settlement also prohibited Teva from entering into pay-for-delay settlements for 10 years. Attorneys general for 47 states and the District of Columbia also settled their related claims for $125 million, which was facilitated at least in part by the FTC settlement fund. The court denied certification of the end-payor class and found that end-payor plaintiffs failed to meet their burden to show ascertainability, predominance, and superiority. In language that might suggest an advantage to forum-shopping for aspiring end-payor class plaintiffs, the court highlighted the differences between the evidence required to show ascertainability in the Third Circuit as opposed to the First Circuit (which certified an end-payor class in *In re Nexium*). The court also found similarities between the *In re Modafinil* case and two other decisions denying certification of end-payor classes in pharmaceutical cases: (1) *In re Skelaxin* when considering ascertainability; and (2) and *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC* when considering predominance. However, notwithstanding denial of the end-payors' class certification motion, public filings indicate that counsel purporting to represent 46 different health plans have negotiated a global settlement with Cephalon, Teva, and Barr under a confidential memorandum of understanding. This settlement is already the subject of litigation, including a sealed motion to enforce the settlement agreement filed before Judge Goldberg and a separate case filed under seal. One health plan has also filed suit individually in federal court in Minnesota.

The court certified a direct purchaser class to proceed to trial. Cephalon, Barr, and Teva settled with that class for $512 million, and also reached separate, confidential settlements with Apotex and the direct purchaser opt-out plaintiffs. Each of these settlements was eligible to be discounted against the $1.2 billion FTC settlement fund, under the terms of the order establishing the fund. The case was set for a combined trial on liability of the plaintiffs' remaining claims against Mylan and Ranbaxy for February 2016, which was stayed after Mylan and Ranbaxy appealed the order certifying a class of direct purchasers under Rule 23(f).

On appeal, a majority of the Third Circuit panel reversed and remanded the order certifying the direct purchaser class, holding that the district court erred in its analysis of the numerosity requirement. The Third Circuit acknowledged that it had ''never even identified the factors that a district court should consider in its numerosity analysis,'' and dubbed its rulings on judicial economy ''a matter of first impression'' for any court of appeals. The Third Circuit held that the district court abused its discretion in analyzing numerosity by: (1) considering the late stage of the litigation as relevant to the judicial economy factor; and (2) failing to properly consider the ability and motivation of the plaintiffs to proceed as joined, as opposed to individual, parties.

The Third Circuit rejected, however, defendants' arguments on predominance, including the argument that *Comcast Corp. v. Behrend* required a new damages model after dismissal of the overall conspiracy claims. The court found that direct purchasers' ''theory of liability is that each individual agreement contributed to the market-wide harm, and that all five original defendants are jointly and severally liable . . . as concurrent tortfeasors.'' Thus, this theory of liability matched the direct purchasers' damages theory. Similarly, in light of this market-wide harm that prevented a generic market from forming at all, the Third Circuit held that ''[t]here is no need to pursue an individualized inquiry into the harm caused by each agreement.'' Accordingly, common questions of act or law predominated.

After the appeal, Mylan settled with the direct purchaser class plaintiffs for $96,525,000, which is still pending court approval.

Current Status: All parties have settled with or settled in principle with Cephalon, Barr, and Teva, except for the litigation regarding the end-payor settlement. On December 12, 2016, the District Court lifted the stay that was entered for the interlocutory appeal regarding class certification. Trial is set for June 2017 for Apotex and several large retailers that were assigned claims by certain direct purchasers, as the direct purchaser class plaintiffs brief class certification on remand.

FTC v. Endo et al., 16-cv-1440 (E.D. Pa.); *In re Lidoderm Antitrust Litig.*, 14-md-2521 (N.D. Cal.); *FTC v. Allergan et al.*, 17-cv-00312 (N.D. Cal.)

Notable Rulings/Issues: Whether No-AG clauses, in which the patentee/branded drug manufacturer promises not to market its own authorized generic in competition with the generic manufacturer during its period of exclusivity, can constitute a large reverse payment. Post-*Actavis*, this is a key issue in the developing antitrust law concerning what constitutes a reverse payment for delayed generic entry.

As part of its continuing post-*Actavis* enforcement program, the FTC filed a combined action against Endo and other defendants alleging delays in the entry of generic competitors for Endo's Opana ER and Lidoderm products based on reverse payments. The FTC later withdrew that suit after the court severed the claims, and refiled the action in the Northern District of California.

In addition, there are a number of private cases before the Honorable William H. Orrick in the Northern District of California involving antitrust claims related to Lidoderm (lidocaine patch 5%). The alleged pay-for-delay agreements in the Lidoderm case include:

1. Endo, Teikoku, and Watson allegedly agreed to end ongoing abbreviated new drug application (ANDA) litigation, with Watson agreeing to delay launching generic Lidoderm for about 13 months.

2. Endo and Teikoku also allegedly agreed to deliver $96 million of brand Lidoderm product to Watson's wholesaler affiliate free of charge for Watson to resell at noncompetitive pricing.

3. Endo allegedly agreed to delay launching its own authorized generic until seven and a half months after Watson's delayed generic entry. Endo was allegedly entitled to 25% of Watson's gross profits on sales during the ''No-AG'' window. This ''No-AG'' agreement allegedly amounted to a $170 million payment from Endo and Teikoku to Watson.

On November 17, 2014, the district court ruled on motions to dismiss. The defendants argued that neither agreements allowing for early entry nor non-cash payments are ''payments'' under *Actavis*. The court rejected the first argument, stating that the ''Defendants' argument mistakenly distinguishes between early-entry settlements, where the value to the generic manufacturer comes *solely* from the ability to enter the market with a competing product, and a reverse payment term, where the value to the generic manufacturer comes from compensation from the patentee.'' The court acknowledged that ''[e]ven though some terms that allow early entry are pro-competitive and not subject to antitrust scrutiny as a matter of law. . . here plaintiffs plausibly allege that the provision of brand-name product was not procompetitive because it did not 'increase output, reduce price, or increase consumer choice.' '' The court also held that plaintiffs had alleged that using brand product as payment for delay was plausibly a ''payment'' under *Actavis*.

In regards to whether *Actavis* contemplated non-cash payments, the court held that ''in order to determine if a term is a large and unjustified payment, as *Actavis* requires, courts must be able to calculate its value. However, not all non-monetary payments are impossible to value. There are many plausible methods by which plaintiffs may calculate the value of non-monetary terms.'' The court went on to ''agree with the bulk of the recent decisions holding that courts need not restrict the definition of 'payments' under *Actavis* to cash.'' Accordingly, the court found that the plaintiffs plausibly alleged that the terms of the agreement amounted to large and unjustified reverse payments. However, the court rejected the plaintiffs' argument that the ''No-AG'' clause was a *per se* illegal under Section 1 of the Sherman Act.

The court also dismissed plaintiffs' claims under Section 2 of the Sherman Act for failing to plead which single entity possessed monopoly power. While holding that ''a monopolization or attempted monopolization claim cannot stand against both Endo and Teikoku,'' the court offered plausible allegations that would cure this defect and granted the dismissal with leave to amend. The court also granted in part and denied in part certain state law claims.

Plaintiffs have amended their complaints, with direct purchaser plaintiffs filing claims only under the Sher-

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man Act and end-payor plaintiffs and government employees' health association filing claims only under state antitrust and unfair competition statutes. Defendants filed motions to dismiss related to certain state claims, and the court granted the motions in part and denied the motions in part.

Current status: A pretrial conference is set for November 6, 2017, and a jury trial is set for December 4, 2017.

FTC v. Endo et al., 16-cv-1440 (E.D. Pa.); *In re Opana ER (Oxymorphone Hydrochloride) Antitrust Litig.*, MDL No. 2580, Case No. 14-cv-10150 (N.D. Ill) (including *Value Drug Co. v. Endo Health Solutions Inc.*, 14-cv-2630 (N.D. Cal.); *Rochester Drug Co-operative, Inc. v. Endo Health Solutions Inc.*, 14-cv-3185 (E.D. Pa.); and *Fraternal Order of Police v. Endo Health Solutions Inc.*, 14-cv-3190 (E.D. Pa.))

Notable Issues: Whether ''No-AG'' agreements are reverse payments; what is sufficient to allege causation for private plaintiffs.

The alleged reverse payments include:

1. Endo ended litigation with Impax, the first-filer for five Opana® ER dosages, in exchange for a future lump sum payment of over $100 million based on sales the quarter immediately prior to the delayed launch.

2. Endo and Impax entered into a ''No-AG'' agreement preventing Endo from competing with Impax during its 180-day first-filer exclusivity period.

3. Endo paid Impax $10 million up front, with a $30 million obligation to follow under a copromotion agreement for an unapproved Parkinson's disease medication.

4. Endo ended litigation against Actavis, Barr, Sandoz, Watson, and Roxane (all of which are not named defendants) in exchange for early entry, the dates of which were allegedly rendered illusory in light of the regulatory bottleneck created by the Endo-Impax agreements.

One novel element of the alleged reverse payment was that the payee purportedly anticipated the payor's eventual product switch, and structured the agreement to insulate against this possibility. Impax's future cash payment was based on brand sales the quarter before generic entry and was triggered by brand sales falling below a certain threshold in case Endo switched brand formulations to preclude Impax's AB-rating, and therefore, automatic generic substitution.

The cases were transferred to the Northern District of Illinois under an MDL. Judge Leinenweber denied motions to dismiss, holding that the 180-day exclusivity period could have ''great monetary value.'' The court also rejected the defendants' argument that there was no allegation of antitrust injury because there was no allegation defendants would have won the underlying patent case.

The FTC recently announced a settlement with Endo, which would prohibit Endo and its subsidiaries from entering into pay-for-delay and No-AG agreements. This settlement also releases Endo from liability in the AndroGel case.

Current Status: Discovery.

In re Lipitor Antitrust Litig., 12-cv-2389 (D.N.J.)

Notable Issues: Whether *Actavis* applies to non-monetary reverse payments; whether release of liability in unrelated litigation can be a reverse payment; whether granting rights in foreign markets can be a reverse payment.

Lipitor was the first post-*Actavis* decision of note. On September 5, 2013, the Honorable Peter G. Sheridan in the District of New Jersey granted the direct purchaser class plaintiffs' motions for leave to amend their complaints to focus solely on ''reverse payment'' allegations, after dismissing related *Walker Process* fraud, sham litigation, and sham citizen petition claims.

Actavis was decided while motions to dismiss were pending, and after the parties briefed the court, the direct purchaser class plaintiffs moved to amend their complaints to clarify their ''reverse payment'' allegations. The defendants argued that these amendments would be futile, ''because the amended allegations still fail to allege an actionable reverse payment under the Supreme Court's standard in *Actavis*, which Defendants say only applies to settlements involving large *monetary* payments from the brand name manufacturer to the generic.'' The court rejected this argument, noting ''that nothing in *Actavis* strictly requires that the payment be in the form of money,'' and thus amendments would not be futile on that basis.

The plaintiffs' amended complaints alleged that Pfizer made various anticompetitive reverse payments to Ranbaxy in order to delay generic competition on Lipitor®, including:

1. Pfizer agreed to release Ranbaxy from liability in a separate suit, which allegedly could have represented hundreds of millions of dollars in value. In exchange for this release from liability, Ranbaxy paid Pfizer $1 million and Pfizer was released from its $200 million injunction bond.

2. Pfizer granted Ranbaxy the exclusive right to sell Lipitor® in 11 foreign markets, along with several licenses to Pfizer patents.

3. Ranbaxy agreed not to compete directly or indirectly with Pfizer prior to the agreed-upon entry date (November 30, 2011). Plaintiffs alleged that this is an agreement not to relinquish or waive Ranbaxy's first-to-file 180-day marketing exclusivity, creating a bottleneck that prevents other generic competitors from obtaining regulatory approval.

Defendants moved to dismiss the newly amended complaints. On September 12, 2014, the court granted the defendants' motion to dismiss with prejudice. The court held that while *Actavis* did not necessarily require cash payments, the Supreme Court ''emphasized cash payments,'' and thus a ''non-monetary payment must be converted to a reliable estimate of its monetary value

so that it may be analyzed'' against other factors. Furthermore, non-monetary payments required more ''factual explication'' at the pleading stage under the flexible pleading benchmark for antitrust cases established by *Twombly* and *Iqbal*. Specifically, the pleadings required ''a reliable foundation used within the industry to convert the non-monetary payment to monetary value.''

Having differentiated pleading standards for monetary and non-monetary reverse payments, the court found that the plaintiffs ''failed to delineate any type of methodology to connect the claim to its monetary value. To meet [the pleading standard for non-monetary reverse payments], Plaintiffs must stand in the shoes of the underlying parties at the time of the settlement, and determine an estimate of the monetary value of the settlement at the time.'' Plaintiffs have appealed the court's decision. Plaintiffs also requested leave to amend their complaints based on the court's ''new, heightened pleading standard.'' On March 16, 2015, the court denied the request to amend, explaining that there was nothing novel in the decision as it ''principally relied upon the cases of *Actavis*, *Twombly*, and *Iqbal*'' and ''simply applies the precedent.''

Current Status: Multiple appeals have been consolidated with the *In re Effexor XR Antitrust Litigation* appeals in the Third Circuit.

In re Effexor XR Antitrust Litig., 11-cv-5479 (D.N.J.)

Notable Issues: Pleading standards for alleged non-monetary reverse payment.

Effexor XR is also before the Honorable Peter G. Sheridan in the District of New Jersey, and thus there was some scheduling overlap between it and *Lipitor*. In addition to claims of *Walker Process* fraud and sham litigation, plaintiffs alleged Wyeth paid Teva for delay by agreeing not to release its own authorized generic Lipitor, pursuant to a ''No-AG'' agreement. The plaintiffs argued that the ''No-AG'' agreement was in effect a payment worth $426 million to Teva. While not alleging an anticompetitive bottleneck outright, plaintiffs argued during oral argument that a change in royalty rates after the six-month first-filer exclusivity was indicative of bottlenecking. The defendants argued that the settlement agreement allowed for early entry, and a No-AG provision did not qualify as a monetary reverse payment subject to review under *Actavis*.

On October 6, 2014, the court granted in part and denied in part defendants' motion to dismiss. Similar to the ruling in *Lipitor*, the court held that when applying *Actavis*, ''the nonmonetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors.'' While the court demonstrated that the value of a ''No-AG'' provision could be calculated based upon the different market expectations with and without an authorized generic, the court found that the plaintiffs failed to set forth a reliable foundation for their claims. Without the proper foundation for the value of the settlement, the plaintiffs' claims that the payment was reverse and large enough to trigger an *Actavis* review were found to be similarly insufficient. While these deficiencies led the court to dismiss the plaintiffs' reverse payment antitrust claims under *Actavis* and under the *Twombly* and *Iqbal* flexible pleading standards, the plaintiffs' *Walker Process* claims against the patentee survived because they sufficiently pleaded plausible facts that, if proven true, would demonstrate the defendant's fraud upon the USPTO.

Current Status: Multiple appeals have been consolidated with *In re Lipitor Antitrust Litigation* appeals in the Third Circuit.

In re Nexium (Esomeprazole) Antitrust Litig., 12-md-2409 (D. Mass.); 15-2005, 15-2006, 15-2007 (1st Cir.)

Notable Issues: Framing of jury instructions; factual basis for causation of antitrust injury.

Nexium was the second case to issue a decision applying *Actavis*. On September 11, 2013, the District of Massachusetts ruled on a number of motions to dismiss. In finding that the direct purchaser plaintiffs pleaded facts sufficient to establish antitrust violations, the Honorable William G. Young outlined the application of the rule of reason for reverse payment antitrust analysis. The court found that the plaintiffs sufficiently alleged: (1) market power in the relevant market; (2) anticompetitive consequences; and (3) that the economic detriments of the agreement outweighed economic benefits, relying on the rule-of-reason test under *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 61 (1st Cir. 2004).

The court directly addressed the issue of whether reverse payments must be monetary, and held that using a broad interpretation of the word ''payment'' to include non-monetary consideration ''serves the purpose of aligning the law with modern-day realities.'' The alleged non-monetary reverse payments included:

1. AstraZeneca agreed to a No-AG provision during Ranbaxy's solely-held 180-day first-filer exclusivity period in exchange for a six-year delay in entry. Ranbaxy also agreed to be a Nexium® supplier as well as a distributor of two other AstraZeneca drugs. This agreement purportedly created a ''bottleneck'' preventing non-first-filers from challenging the patents at issue.

2. Both Teva and Dr. Reddy's (non-first-filers) attempted to ''uncork the FDA approval bottleneck'' by filing declaratory judgment actions against AstraZeneca. Before final judgments were reached in these actions, AstraZeneca settled litigation with Teva and Dr. Reddy's involving infringement of unrelated patents.

The court held that the consent agreement entered by the District of New Jersey memorializing these settlement agreements did not grant the defendants *Noerr-Pennington* antitrust immunity.

On September 4, 2014, the district court ruled on various summary judgment motions after outlining the case's ''extensive and tortuous procedural history.'' The court denied defendants' summary judgment motion on overall conspiracy, finding that a reasonable fact-finder could draw an inference of conspiracy based on the fact that the ''settlement agreements were not in the Generic Defendant's self-interest unless their agreements contained provisions aligning their behavior . . . .''

When analyzing the settlement agreements under the standards set forth in *Actavis*, the court reiterated that unlawful reverse payments were not limited to mon-

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etary payments. It further explained that the illegality of a reverse payment was determined with a burden-shifting analysis, beginning with the plaintiffs' evidence that the payments exceeded expected litigation costs and the costs of other services, and lacked ''any other convincing justification.'' If this showing is made, the defendants must show that the payment was justified by some pro-competitive advantage, after which the plaintiffs may show that the settlement is ''nevertheless anticompetitive on balance.'' At the summary judgment stage in the First Circuit, this requires a showing of ''harm to competition, either directly or by reasonable inference.'' Under this standard, the court found that, based on the information in the record, a reasonable jury could determine that unlawful reverse payments were made from AstraZeneca to Teva or Ranbaxy. The court found that the alleged reverse payment to Dr. Reddy's, namely AstraZeneca's voluntary dismissal of an appeal to unrelated litigation that Dr. Reddy's had won, did not provide a factual basis for a jury to properly engage in a rule-of-reason analysis, thus warranting summary judgment in Dr. Reddy's favor on that point.

The court then found that there was not enough evidence to support that the alleged reverse payments to Ranbaxy or Dr. Reddy's were material causes of antitrust injury. The court held that the anticompetitive payment did not need to be the sole cause, but a proximate cause, such that the antitrust injury cannot be fully attributed to a separate independent cause. In disputes involving the market entry of generic pharmaceuticals ''an injury can have multiple independent causes—some stemming from, as alleged in this case, FDA regulatory actions, some from manufacturing problems, and some from anticompetitive behaviors.'' For Ranbaxy and Dr. Reddy's, antitrust causation turned on whether these companies had a ''will'' and a ''way'' to overcome regulatory and manufacturing hurdles to actually launch a generic product within the period of alleged antitrust injury. While the plaintiffs provided scenarios where these defendants could possibly launch generics within the period of alleged antitrust injury, the court found the plaintiffs' evidence insufficient to survive summary judgment. On the other hand, the court found that the plaintiffs' evidence and legal arguments insofar as Teva's ability and willingness to launch generic product were ''far more crystallized and grounded'' than as to the other generic defendants. Accordingly, defendants' motions for summary judgment on the issue of antitrust causation related to settlement agreements between AstraZeneca and Teva were denied.

The court held a six-week jury trial between October 20 and December 5, 2014. Dr. Reddy's settled with the plaintiffs on the eve of trial, and Teva settled with the plaintiffs near the end of trial. Ultimately, the jury found that AstraZeneca exercised market power within the relevant market, that the AstraZeneca-Ranbaxy settlement included a large and unjustified reverse payment, and that that settlement was unreasonably anticompetitive. However, the jury answered ''no'' to Question 4 on antitrust causation, which read: ''Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?''

The plaintiffs moved for a new trial based on, *inter alia*, the framing of this jury question and new disclosures regarding Ranbaxy's forfeiture of first-filer exclusivity. Judge Young issued a surprisingly candid and academic denial of these motions, beginning with: ''I did not try this case very well. I did try it fairly.'' Judge Young's Memorandum outlines and debriefs the course of the six-week trial, highlights certain steps and missteps of the parties and the court, and offers insight into at least one federal judge's concerns with modern jurisprudence.

Defendants had also filed an interlocutory appeal from the class certification. After briefing, oral argument, and submission of the case, the proceedings in the district court concluded and the defendants voluntarily moved to dismiss their appeal, which the plaintiffs agreed with if awarded costs. The First Circuit, however, denied the motion to dismiss, citing the time the panel had invested in the case already and that the defendants should not be able to strategically dismiss an appeal to ''manipulate the formation of precedent'' by later raising the issue ''again before a different panel in an appeal after final judgment.'' It then issued a separate opinion affirming the lower court's end-payor class certification, holding that certification is permissible ''even if the class includes a de minimis number of uninjured parties'' so long as a mechanism exists for sorting injured and uninjured parties at some stage of the litigation. Costs on appeal were awarded to the plaintiffs.

After the district court denied the plaintiffs' motion for a new trial on July 30, 2015, the plaintiffs appealed to the First Circuit. Plaintiffs argued that the district court erred in its partial grant of summary judgment, the exclusion of certain evidence at trial, the district court's special verdict form and jury instructions, and the grant of judgment as a matter of law on the claim of overarching conspiracy.

The First Circuit concluded that the exclusion of certain economic expert testimony at trial regarding the likely but-for generic entry date did not constitute an abuse of discretion, because this testimony did not fit the conclusions for which it was offered under *Daubert* and/or was cumulative of other testimony. The First Circuit found that the exclusion of other economic testimony regarding the side deals and their exact value was harmless, in light of the jury's finding that AstraZeneca made a large and unjustified payment to Ranbaxy. Exclusion of other evidence was upheld based on its cumulativeness, plaintiffs' failure to preserve their objections on appeal, and the judge's discretion to determine both witnesses' qualifications and the scope of permissible rebuttal evidence.

The plaintiffs also argued that the district court erroneously granted judgment as a matter of law on the overarching conspiracy claim between the brand manufacturer and all of the generic manufacturers (as opposed to multiple conspiracies, each between the brand and one generic manufacturer). Plaintiffs argued that they had proved the existence of contingent launch provisions in the defendants' settlement agreements and this evidence was sufficient to survive summary judgment and defeat judgment as a matter of law. The First Circuit, in contrast, focused on plaintiffs' failure to present any evidence that Ranbaxy and Teva agreed with each other to engage in anticompetitive conduct beyond Ranbaxy and Teva's individual, parallel contingent

launch provisions with AstraZeneca. The Court found that given ''the dearth of additional evidence,'' the district court correctly found that was not sufficient evidence that ''Ranbaxy and Teva conspired together, that they acted otherwise than in their own individual best interest.''

The First Circuit noted serious waiver concerns about plaintiffs' objections on appeal to the jury verdict form questions. However, in response to FTC's request via *amicus* brief for greater clarity on antitrust injury versus violation, the First Circuit reached the merits of Question 4 of the verdict form. This question asked whether AstraZeneca and Ranbaxy would have agreed to permit Ranbaxy to launch an earlier generic version of Nexium, if not for the anticompetitive settlement?

In analyzing this question, the Court highlighted a key distinction between the FTC and private plaintiffs seeking damages: private plaintiffs must prove actual damages ''by reason of'' the antitrust violation. The First Circuit found no error in Question 4, holding that it properly asked whether plaintiffs ''suffered an injury of the type the antitrust laws were intended to prevent.'' Likewise, the Court found that the jury's ''no'' answer to this question ''confirms the jury's finding that notwithstanding the existence of an antitrust violation, the plaintiffs failed to establish an antitrust injury that entitled them to monetary relief.'' The Court also rejected other challenges to the wording of Question 4 in the context of the verdict form and jury instructions as a whole, and in light of plaintiffs' failure to preserve their objections to these issues at trial.

Finally, addressing what it described as the ''core of the plaintiffs' appeal,'' the Court found that any error in granting summary judgment regarding four causation theories was harmless in light of the jury verdict, later trial proceedings on patent invalidity, and evidence presented to the jury in support of other theories.

For example, the Court highlighted the district court's finding that there was no adequate evidence of invalidity of the Nexium patents. Relying on *In re Wellbutrin XL*, the First Circuit held that this lack of evidence mooted any error in excluding plaintiffs' two causation theories based on: (1) an earlier at-risk launch; or (2) Teva winning its paragraph IV challenge regarding these patents. Absent evidence of invalidity or noninfringement, the Court saw no evidence to show that the reverse payments—instead of the patents—barred or delayed generic launch. The Court repeatedly pointed to plaintiffs' strategic decision not to attempt to prove patent invalidity as a factor in the Court's decision. The Court also noted plaintiffs' freedom to argue that the mere *risk* of litigation provided incentives to violate antitrust laws, regardless of whether the patent was actually valid or invalid.

Plaintiffs also argued that the district court improperly excluded other causation theories; namely, that Ranbaxy could have negotiated an earlier license date with AstraZeneca to: (1) allow Ranbaxy to launch its generic product; or (2) allow Teva or another manufacturer to launch. According to the First Circuit, the jury's answer to Question 4 rendered any such error harmless, because that answer reflected a finding that AstraZeneca would not have agreed to generic entry earlier than the relevant patent expiration date. The Court also noted that the jury must have understood the threat Ranbaxy posed to AstraZeneca, because the jury found that AstraZeneca was willing to offer a large and unjustified payment to Ranbaxy. Plaintiffs failed to point to sufficient evidence unique to Question 4 that was impermissibly excluded, other than the ''recycle[d] grievances'' about evidence the First Circuit already upheld as properly excluded.

In sum, the Court repeatedly pointed to plaintiffs' ''tactical decisions'' at trial regarding what evidence to present and what objections to preserve. The First Circuit's decision keenly focused on the failure to find antitrust injury despite the jury's finding of an antitrust violation, and the Court emphasized plaintiffs' many missed opportunities to show that injury over a lengthy trial. In conclusion, the Court rejected what it characterized as plaintiffs' search for ''a do-over.''

Current Status: On November 21, 2016, the First Circuit affirmed the judgment of the district court.

In re Lamictal Direct Purchaser Antitrust Litig., 12-cv-995 (D.N.J.)

Notable Issues: Whether *Actavis* applies to nonmonetary reverse payments; whether ''No-AG'' agreements are reverse payments; whether determining that a payment is ''large and unjustified'' is part of the rule-of-reason analysis or a preliminary requirement before reaching that analysis.

On January 24, 2014, the Honorable William H. Walls of the District of New Jersey again granted a motion to dismiss. The court's earlier grant of a motion to dismiss had been remanded for re-consideration in light of *Actavis*. The alleged reverse payments at issue included:

1. GlaxoSmithKline granted Teva a 37-month early entry to sell generic lamotrigine chewables, while supplying the chewable tablets to allow entry before the FDA approved Teva's ANDA.

2. GlaxoSmithKline granted Teva a six-month early entry for generic lamotrigine tablets, which depended on whether a pediatric exclusivity period was granted.

3. GlaxoSmithKline agreed to a ''No-AG'' provision, under which it would not launch its own generic versions of Lamictal® products.

The district court's interpretation of *Actavis* required a three-part test that differed from the test in *Nexium* in two major areas. First, the court established a threshold inquiry, asking, ''Is there a reverse payment?'' The court took a more limited view on what would qualify as a payment, holding that *Actavis* only applies to monetary reverse payments. In effect, this means ''No-AG'' agreements are not payments subject to rule-of-reason scrutiny. In doing so, the court directly addressed contrary holdings from *Lipitor* and *Nexium*, and found that they are ''unsupported by the words of *Actavis* or are inapposite.''

For the second step, the court asked, ''Is that reverse payment large and unjustified?'' The third step in applying the rule of reason requires asking ''whether the parties to an agreement creating a restraint of trade had market power and exercised it, whether the restraint had anticompetitive consequences and whether those consequences are otherwise justified.'' In this context, the district court suggested that *Actavis*'s ''five sets of considerations,'' which led the Supreme Court ''to conclude that the FTC should have been given the opportu-

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nity to prove its antitrust claim,'' were laid out ''to guide district courts in applying the rule of reason. . . .''

The district court acknowledged that there is ''some overlap in the [three] steps'' but held that deciding whether the settlement was a reverse payment and whether it was large and unjustified were preliminary steps and necessary precursors to rule-of-reason analysis. Under this reading of *Actavis*, the alleged reverse payments did not qualify and the case was dismissed.

On June 26, 2015, the Third Circuit vacated and remanded the District Court's Opinion. The Third Circuit held that the ''no-AG agreement falls under *Actavis*'s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.''

Current Status: Petition for *certiorari* to Supreme Court denied on November 7, 2016.

In re Wellbutrin XL Antitrust Litig., Nos. 2:08-cv-2431, 2:08-cv-2433 (E.D. Pa.)

Notable Issues: Whether a reverse payor's partner can be liable for making settlement possible; whether ''No-AG'' agreements are reverse payments.

Wellbutrin XL was stayed awaiting resolution of *Actavis*, and is now back before the Honorable Mary A. McLaughlin in the Eastern District of Pennsylvania. The settlements at issue were originally between Biovail, GlaxoSmithKline, and four generic manufacturers not named as defendants. But on November 11, 2012, the court approved Biovail's settlement with the plaintiff class, leaving GlaxoSmithKline as the only defendant. The remaining alleged reverse settlements at issue are that:

GlaxoSmithKline waived its right to sell generic 150mg Wellbutrin® as Biovail's authorized generic during Anchen's 180-day first-to-file exclusivity period. Anchen had transferred this exclusivity to Teva two months before Biovail and Teva settled the Wellbutrin dispute. Plaintiffs argue that this allowed Biovail to secure a ''No-AG'' agreement preventing the generic manufacturers from launching.

Upon reopening the case, the court requested briefing on the application of *Actavis* before discovery. The FTC attempted to file an *amicus curiae* brief to support the notion that *Actavis* applies to non-monetary ''No-AG'' reverse payments, but the brief was not accepted by the court. After moving forward with briefing on the applicability of *Actavis* from both sides, the court found it was not yet prepared to accept that *Actavis* only applied to cash payments from the patentee to the generic, calling it ''a close question.'' Still, the district court dismissed the complaint.

Current Status: Case is on appeal at the Third Circuit.

In re Loestrin 24 Antitrust Litig., 13-md-2472 (D.R.I.)

Notable Issues: Whether ''No-AG'' agreements are reverse payments; whether payment was fair price for goods or services; whether *Actavis* applies to non-monetary reverse payments.

Loestrin 24 was filed October 3, 2013, before the Honorable William E. Smith in the District of Rhode Island. The alleged reverse payments at issue are:

1. Watson (now Actavis) agreed to delay launching generic Loestrin® 24 until the earliest of three years after the settlement, 180 days before a third party's approved generic entry, or the very date another generic version actually entered the market;

2. Warner Chilcott agreed to not launch an authorized generic for Watson's first 180 days of Loestrin® 24 sales, nor would it license a third party to do so;

3. Warner Chilcott gave Watson a worldwide license to Loestrin® 24 beginning in 2014;

4. Warner Chilcott paid Watson annual fees and royalties for promoting Warner Chilcott's Femring® hormone therapy product and the exclusive right to earn brand sales on another oral contraceptive now named Generess® Fe;

5. Lupin agreed to delay marketing generic Loestrin® 24 until the month that the patent at issue would expire; and

6. Warner Chilcott granted Lupin a non-exclusive license to market Femcon® Fe and Asacol® 400mg, supplied by Warner Chilcott, upon the entry of another generic version of each drug.

In addition to their reverse payments claims, plaintiffs also argued that defendants maintained an illegal bottleneck. Motions to dismiss were filed, with the plaintiffs arguing that these settlements were large and unjustified payments, and the defendants urged the court to follow *Lamictal* and hold that *Actavis* only applies to monetary reverse payments. On September 4, 2014, the district court granted the defendants' motion to dismiss, in what it described as ''a close call, involving a challenging interpretation of a very recent and confusing Supreme Court case, complicated by principles of law that seem at cross purposes.'' Following the guidance of *In re Lamictal Direct Purchaser Antitrust Litig.*, discussed supra, the court held that *Actavis* imposes a three-part inquiry, asking: 1) was there a reverse payment; 2) was that reverse payment large and unjustified; and then 3) applying the rule of reason. As in *In re Lamictal*, the court here used the five considerations that the Supreme Court used to show that ''the FTC should have been given the opportunity to prove its antitrust claim'' to ''guide the inquiry as to whether a settlement payment satisfies the rule of reason.'' Applying the five considerations to a particular alleged reverse payment required ''an ability to assess or calculate the true value of the payment.'' In light of this analysis and other factors, the court held that ''the narrowness of the Supreme Court's language and the cash-focused guidance for applying the rule of reason to permit no other conclusion'' that *Actavis* applies ''solely to monetary settlements'' ''until and unless the Supreme Court expands its holding.'' Because the plaintiffs had ''not adequately alleged payment in the form of cash by Warner Chilcott in exchange for Watson and Lupin's agreement to stay out of the market for Loestrin 24,'' the court held they failed to state a claim upon which relief could be granted, and granted the defendants' motion to dismiss. Plaintiffs appealed the district court's decision.

On appeal, the First Circuit reversed. The court stressed looking to substance over form, holding that *Actavis* could be applied to payments that were non-cash. However, the panel also suggested that in cases of non-cash payments, the plaintiffs should allege enough facts to estimate the value of the deal to the generics company.

Current Status: On remand, the plaintiffs added additional allegations, including product hopping. Defendants again moved to dismiss the claims, and the District of Rhode Island heard arguments on January 13, 2017. The Court is taking the matter under advisement and will issue a ruling at a later date.

In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 14-md-2503 (D. Mass)

Notable Issues: Whether ''No-AG'' agreements are reverse payments; how sequential periods of generic exclusivity affect damages or liability.

At least 12 antitrust actions involving Medicis's flagship Solodyn® product were consolidated by the Judicial Panel on Multidistrict Litigation to the Honorable Denise J. Casper in the District of Massachusetts. The anticompetitive conduct alleged by the plaintiffs include:

1. Medicis allegedly committed inequitable conduct in obtaining patent protection for Solodyn® and filed allegedly sham litigation to protect it from generic competition.

2. Medicis allegedly paid Impax at least $55 million to delay marketing generic Solodyn® for three years under the guise of a joint development agreement.

3. Medicis allegedly granted Impax the ability to sell an authorized generic version of 65mg and 115mg Solodyn® should a generic competitor launch at those strengths.

4. Medicis allegedly agreed to pay Sandoz to delay marketing generic Soldyn for over two years under the guise of an asset purchase agreement for ''virtually worthless'' products or services.

5. Medicis allegedly product-hopped to new dosage strengths to prevent generic competition.

6. Medicis allegedly paid Teva to drop its first-filer challenge to 65mg and 115mg Solodyn®, creating a bottleneck that it then allegedly paid Ranbaxy, Mylan, and Lupin to not challenge.

7. Medicis allegedly paid Lupin at least $20 million to delay launching generic Solodyn® under the guise of a joint development agreement.

Defendants filed motions to dismiss all of the claims. In August, Judge Casper ruled that the plaintiffs' pay-for-delay claims could move forward. She required plaintiffs to show a large and unjustified payment, and then shifted the burden to show that the settlement had a sufficient pro-competitive objective to prevent it from being anticompetitive. She found the plaintiffs had sufficiently alleged a large reverse payment not obviously explained by a pro-competitive reason, i.e. one other than to delay generic competition. Judge Casper did dismiss the monopolization claims against Medicis based on sham litigation.

Current Status: In discovery.

In re Cipro Cases I & II, S198616 (Cal.)

Notable Issues: *Actavis*'s impact on state antitrust claims.

The *Cipro I & II* cases involve state law claims of contested reverse payments that were later ruled not in violation of the Sherman Act in Federal Court under the pre-*Actavis* scope-of-the-patent test. The plaintiffs alleged that the reverse payment settlements are in violation of California's Cartwright Act, Unfair Competition Law, and common law monopolization. The Court of Appeal in the Fourth District of California held that, ''unless a patent was procured by fraud, or a suit for its enforcement was objectively baseless, a settlement of the enforcement suit does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent.'' The alleged settlement agreements at issue involved:

1. Barr agreed to amend its Paragraph IV certification into a Paragraph III certification, precluding Barr from obtaining FDA approval until the patent covering ciprofloxacin expired in exchange for an immediate payment of $49.1 million from Bayer.

2. In a ''supply agreement'' with Bayer, Barr and HMR agreed to not manufacture ciprofloxacin, giving Bayer the option of either supplying ciprofloxacin to Barr and HMR to distribute in the U.S. or making quarterly payments until the patent expired. Bayer chose to make the quarterly payments, and total cash payments (including the $49.1 million initial payment) equaled about $398 million.

The Court of Appeal's decision was appealed to the Supreme Court of California, where it was stayed awaiting the resolution of *Actavis*. Weeks after *Actavis* was decided, Bayer agreed to create a $74 million settlement fund and cooperate with the plaintiffs. The plaintiffs, remaining defendants, and several *amici* filed briefs before the court.

The Supreme Court of California, similar to the federal courts, held that analysis of reverse payments should be under the rule of reason where the ''inquiry is limited to whether the challenged conduct promotes or suppresses competition.'' Facts to be considered include the business at issue, the nature of the restraint, and the reason for the adoption of the restraint.

Under California law, to make out its *prima facie* case, a plaintiff must show four elements: (1) the settlement includes a limit on the settling generic challenger's entry into the market; (2) the settlement includes cash or equivalent financial consideration flowing from the brand to the generic challenger; and the consideration exceeds both (3) the value of goods and services other than any delay in market entry provided by the generic challenger to the brand; and (4) the brand's expected remaining litigation costs absent settlement. The ''payment'' in this context is not limited to cash transfers, but may include side deals involving difficult-to-value assets.

Once the plaintiff establishes a reverse payment and the resulting delay, the burden of going forward with evidence shifts to the defendants who must then prove

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that the payment was justified. If defendants fail to do so, the plaintiff ''has satisfied its burden on these points.'' If defendants meet their burden of production, then plaintiff carries the ultimate burden of persuasion of showing a large, unexplained payment.

Current Status: A motion for preliminary approval of settlement with Barr is currently pending, which would bring the class action plaintiffs' total recovery to $399 million.

In re Aggrenox Antitrust Litig., 14-md-2516 (D. Conn.), No. 12-5393 (D.C. Cir.)

Notable Issues: Whether ''No-AG'' agreements are reverse payments; whether payment was fair price for goods or services; whether reverse settlement documents are protected work product.

The Judicial Panel on Multidistrict Litigation transferred 11 antitrust actions relating to Aggrenox® to the Honorable Stefan R. Underhill in the District of Connecticut. The alleged reverse payments at issue appear to be:

1. Boehringer and Barr entered a ''co-promotion'' agreement including up to $120 million in upfront and continuing yearly royalty payments to Barr; and

2. Boehringer agreed not to launch its own authorized generic Aggrenox product once Barr launched generic Aggrenox in 2015.

The FTC sued Boehringer in the U.S. District Court of the District of Columbia to enforce a subpoena duces tecum requiring it to produce documents relating to the settlements at issue. Boehringer succeeded in convincing the lower court that these documents were protected work product, a ruling that was upheld in part and vacated in part by the D.C. Circuit.

On March 23, 2015, the court ruled on four motions to dismiss, and in doing so offered a detailed overview of the history and present state of pay-for-delay case law. In August 2016, the court also ruled on other motions to dismiss, and entered an early order regarding market power and the relevant market.

Current Status: Discovery.

In re Adderall XR Antitrust Litig., 12-cv-3711 (S.D.N.Y.), 13-1232 (2d Cir.)

Notable Issues: Antitrust implications when a reverse payor does not perform contractual obligations under a generic reverse payment settlement; patentee's unilateral refusal to deal.

This case involves both reverse payments and a ''patentee's unilateral refusal to deal in its patented product.'' Two related class action suits were consolidated before the Honorable Victor Marrero in the Southern District of New York. The alleged reverse payment at issue had the following terms:

1. Teva and Impax agreed to delay launching their generic Adderall XR® products for about three years.

2. Shire granted Teva and Impax patent licenses after that period and further agreed to supply all of their Adderall XR® supply needs under separate requirement contracts.

The plaintiffs alleged that Shire, as sole manufacturer of Adderall XR® products, purposefully underperformed on these requirement contracts to keep supplies artificially low and prices artificially high. The district court dismissed the plaintiffs' claims because the original agreements did not exceed the scope of the patents in question. The plaintiffs appealed to the Second Circuit. Defendant-Appellees argued that *Actavis* is inapposite because it applies to ''the extent to which the antitrust laws should apply to settlements of patent litigation and not to a patentee's unilateral refusal to deal.'' Plaintiff-Appellants argued back that the district court's opinion relied on *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), and was fatally undermined by *Actavis*'s abrogation of that case.

On June 9, 2014, the Second Circuit Court of Appeals affirmed the lower court's dismissal for failure to state a claim. The court found that the plaintiffs expressly limited their argument to an antitrust ''duty to deal'' analysis and failed on that issue. In doing so, it fully avoided ''the complexities that attend cases at the intersection of antitrust and patent law.'' The court did not assess ''the potentially anticompetitive effects, if any, of [the alleged reverse settlements] against 'patent law policy [and] procompetitive antitrust policies.' ''

Current Status: Dismissal for failure to state a claim affirmed on appeal, June 9, 2014.

In re Niaspan Antitrust Litig., 13-md-2460 (E.D. Pa.)

Notable Issues: Whether payment was fair price for goods or services; whether ''No-AG'' agreements are reverse payments.

Eight actions were consolidated before the Honorable Jan E. Dubois in the Eastern District of Pennsylvania. The alleged reverse payments at issue are:

1. Barr agreed to delay entry from 2005 until 2013.

2. Barr agreed to develop an FDA-approved manufacturing process and stand as a back-up supplier for Niaspan®, for which brand-name manufacturer Kos Pharmaceuticals, Inc. (''Kos'') would provide a start-up payment and quarterly stand-by payments.

3. Barr would co-promote Niaspan® and Advicor® (another Kos product) to doctors specializing in women's health.

4. Kos agreed to pay Barr cash as a percentage of overall Niaspan® sales, license its patents to Barr, and not launch authorized generic versions of Niaspan® and Advicor®.

Because Barr retained its 180-day first-filer exclusivity, plaintiffs have alleged a bottleneck preventing other generics from entering the market. On September 5, 2014, the district court granted in part and denied in part the defendants' motions to dismiss.

Current Status: Discovery.

In re Skelaxin (Metaxalone) Antitrust Litig., 12-md-2343 (E.D. Tenn.)

Notable Issues: Effect of reverse-bifurcated damages trial on settlement and future litigation; comparison of

estimated damages to awarded damages; class certification.

Both federal and state antitrust claims are at issue here before the Honorable Curtis L. Collier in the Eastern District of Tennessee. Sherman Act violations were pleaded against King Pharmaceuticals, Inc., and Mutual Pharmaceutical Co., Inc., while additional state law claims were pleaded against these and other defendants. The alleged reverse payments at issue are:

1. King agreed to pay Mutual $35 million and at least 10% of branded Skelaxin® sales in exchange for intellectual property licenses on recently performed metabolism studies while Mutual agreed to not sell generic metaxalone.

2. Mutual and King allegedly stayed instead of settling their litigation to delay its resolution beyond the statutory 30-month stay of final FDA approval by filing multiple citizen petitions, amounting to an extended bottleneck.

3. In exchange for a four-year delay in entry, King granted CorePharma the right to enter the market as an authorized generic version of Skelaxin and supply CorePharma with API.

In what appears to be a coincidence, on the very same day *Actavis* was decided, the court in *Skelaxin* scheduled a damages-only trial to avoid expending ''time, money, and energy on issues such as the conspiracy allegations . . . the sham FDA petitions . . . or the Orange Book and sham patent litigation issues in the complaint.'' The court has since denied class certification for the end-payor and indirect purchaser plaintiffs.

A damages-only jury trial for individual plaintiffs concluded on June 12, 2014, although the court granted a motion to seal the verdict form.

Current Status: Settled.

In re Actos End Payor Antitrust Litig., 13-cv-9244 (S.D.N.Y.), 15-3364 (2nd Cir.)

Over a dozen end-payor cases were consolidated before Judge Ronnie Abrams in the Southern District of New York involving antitrust claims related to ACTOS (pioglitazone HCl) and ACTO*plus* Met (pioglitazone and metformin HCl). The alleged anticompetitive conduct included:

1. Takeda allegedly falsely listed two patents in the FDA Orange Book for ACTOS that purportedly only covered ACTO*plus* Met; and

2. Takeda allegedly entered into settlement agreements with Teva, Mylan, Actavis, and Ranbaxy to delay their launches of generic ACTOS and ACTO*plus* Met products that included: (a) acceleration clauses to deter other generics from undermining the settlement agreements; (b) ''sweetheart deals'' on ACTO*plus* Met; (c) a ''No-AG'' clause; and/or (d) a guarantee not to grant additional generic licenses.

The settlement agreements allegedly created an anticompetitive bottleneck preventing other generic competitors from entering the market until after the 180-day exclusivity period, which plaintiffs complained would not have occurred but for Takeda's false patent listing.

Defendants filed motions to dismiss, claiming that the alleged reverse payments are nothing more than pro-competitive early-entry licenses. The defendants also attempted to differentiate the ''No-AG'' agreements here, which were offered to multiple generic companies who might compete on price at some point in the future, from ''No-AG'' agreements with only one brand product and one generic product.

The district court granted the motion to dismiss. While agreeing with the ''majority'' view that *Actavis* was not limited to cash payments, the court required the plaintiffs to set forth sufficient factual allegations to conclude that the payment was large and unjustified. Judge Abrams ultimately found the complaint in this case had not alleged sufficient facts. With respect to causation, he found that, *inter alia*, plaintiffs failed to identify a viable regulatory route for generic drug approval that would have hastened generic entry despite the 180-day bottleneck and/or delay associated with Takeda's patent infringement suits.

On February 8, 2017, the Second Circuit affirmed in part, vacated in part, and remanded to the district court. The Second Circuit distinguished plaintiffs' two causal theories: one applying to generic applicants who submitted Paragraph IV certifications and one applying to Teva, who instead relied on ''section viii'' carve outs.

The Second Circuit affirmed the dismissal of the plaintiffs' claims relating to the first group of generic applicants, who submitted Paragraph IV certifications. Plaintiffs had argued that but for Takeda's false submissions describing their patents as drug product patents, these applicants would not have needed to make Paragraph IV certifications. Thus, plaintiffs reasoned, there would be no 180-day exclusivity to cause a bottleneck, and generics would have entered the market earlier. The Second Circuit found this theory implausible, because it rested on a necessary premise not supported by well-pleaded factual allegations. The court focused on the ''causal chain,'' reasoning that ''because plaintiffs claim that the generic manufacturers filed their Paragraph IV certifications under duress, their theory presupposes that the generic manufacturers *knew* that Takeda had described them as drug product patents when they filed their ANDAs.'' If the generic applicants did not even know of Takeda's false descriptions, they would necessarily have filed their Paragraph IV certifications for other reasons *not* related to these descriptions. This would break the causal chain at the first link: if the false patent descriptions did not cause the generic firms to submit Paragraph IV certifications, these descriptions could not have caused the resultant 180-day exclusivity period and the related delay of generic competition. Accordingly, because plaintiffs' complaint lacked any allegations that the generic manufacturers knew of Takeda's allegedly false patent descriptions when they filed their ANDAs, the Second Circuit found that this entire theory of causation could not be sustained.

The allegations regarding Teva, however, were slightly different. Instead of submitting a Paragraph IV certification with respect to the listed patents like the other generic applicants, Teva submitted ''section viii'' carve outs. These statements carve out the patented uses from the generic product's label, and state that the ANDA does not seek approval for any indications

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claimed by those patents. Thus, no Paragraph IV certification is required. If Teva's ANDA had been approved, it would not have been subject to the other generic applicants' 180-day exclusivity period, and Teva could have begun marketing its product for non-patented uses much earlier.

Takeda ultimately stymied Teva's attempt to get earlier regulatory approval, by re-affirming to the FDA the same, allegedly false patent description it had previously made: that Takeda's patents covered actual drug products, and not just a method of use. This description by Takeda precluded earlier approval of Teva's application, because: (1) the FDA automatically credits the brand firm's statements on patent scope without review; and (2) drug product claims cannot be skirted with a section viii carve out.

However, when it came to plaintiffs' causation theories, Teva's different approach to regulatory approval proved conclusive for the Second Circuit. The court held that plaintiffs' theory regarding Teva did not require any knowledge of the false patent descriptions, because the FDA relied directly on Takeda's allegedly false patent descriptions in rejecting Teva's bid for earlier approval. This was a different causal chain between the allegedly false patent descriptions and any delay in generic entry, and the court held that it was sufficiently clear and supported by the pleadings. The Second Circuit reversed dismissal of these claims, and remanded to the district court. In doing so, the court: (1) rejected Takeda's argument that plaintiffs should have to rule out other possible causes of Teva's delayed market entry at the pleading stage; and (2) noted that even on summary judgment, the burden to address alternative potential causes may actually shift to defendants.

Current Status: Remanded to district court.

In re Asacol Antitrust Litigation, 1:15-cv-12730 (D. Mass)

In this case, direct purchasers and end-payors alleged anticompetitive conduct in connection with Warner Chilcott's Asacol franchise (Asacol, Asacol HD, and Delzicol). Plaintiffs alleged a combination of product hopping, sham litigation, and reverse payments. The defendants filed motions to transfer venue to the District of Massachusetts pursuant to 28 U.S.C. § 1404(a), the plaintiffs consented, and the court granted the motions on August 19, 2016.

The court granted a motion to dismiss direct purchasers' complaint in part, and denied it in part. It held that plaintiffs sufficiently pleaded a large and unjustified payment to Zydus in the form of the ability to serve as Warner Chilcott's exclusive authorized generic manufacturer, which effectively ensured an estimated $101 million in net profits to Zydus. The court refused to consider Warner Chilcott's justifications for this alleged payment on a motion to dismiss, analogizing such justifications to affirmative defenses under the rule of reason burden-shifting framework. It noted that such issues cannot be resolved on a motion to dismiss, unless the facts establishing the defense are clear on the face of plaintiffs' complaint.

The court had previously dismissed allegations by the end-payors, finding that they did not have standing because of inability to show causation. The defendants argued that the agreement with Zydus was not a but-for cause of any delay before the licensed generic entry date in November 2015, because Zydus did not even obtain FDA approval to sell its own product by that time. The direct purchasers' amended complaint included additional allegations that the settlement agreement created financial incentives for Zydus to forego FDA approval of its own product, and instead simply manufacture defendants' authorized generic product. The court found that even these amended allegations were insufficient to show causation and convey standing with respect to a separate reverse payment claim, but that these allegations may still support a claim as to an overall monopolization scheme.

Finally, although the court made clear that ''illegal product hopping'' is anticompetitive, it distinguished the ''hard switch to Delzicol'' from the ''allegations of a soft switch through marketing efforts'' that occurred when Asacol and Asacol HD were both on the market at the same time. The court highlighted the importance of an actual product withdrawal in pleading illegal product hopping, as opposed to marketing efforts that still ''left consumer choice intact.'' Although this line of reasons led to dismissal of one of direct purchaser's claims, direct purchasers were still permitted to allege this behavior in the context of their larger monopolization claim.

Current Status: Discovery.

Conclusion

In *Actavis*, the Supreme Court declined to apply a bright line scope-of-the-patent test to patent litigation settlement agreements. Instead, it called for traditional, antitrust rule-of-reason analysis, leaving it to the lower courts to determine, under the specific facts of each case, what reverse payment devices are lawful and what devices are not. Not surprisingly, given the factual complexity of the cases and limited guidance from the Supreme Court, the lower courts have struggled to interpret and apply *Actavis* and their rulings have frequently been inconsistent. Here are what we see as trends (especially in more recent decisions), as well as some of the battlefront issues that are currently hotly contested.

Trends. The defendant has some form of burden to justify a large payment.

The large reverse payment need not be cash, at least in most courts.

There may be a need to allege or provide evidence regarding the size of the payment, but, especially early in a case, it need not be especially precise.

Because of the burden allocations, cases with plausible allegations of large reverse payments are mostly surviving motions to dismiss, either in the first instance or on appeal. Like any case, it may be more difficult to sustain those charges on summary judgment or at trial.

The FTC will likely seek long-term injunctive relief prohibiting future reverse payments in settlement of these cases.

Battlefields. The types of non-cash consideration that can qualify as a reverse payment, including No-AG clauses, settlement of other litigation, types of product-hopping efforts, and foreign rights.

The role of pro-competitive benefits in other markets in the rule-of-reason analysis.

Causation for private plaintiffs.

Class certification for direct purchasers and end-payors.

Damages and their links to causation theories.

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