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Antitrust

Plaintiffs' Antitrust Claims May Proceed Under *Actavis*'s Rule of Reason Approach

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The maker of the brand-name heartburn treatment Nexium and several potential generic competitors that allegedly agreed to stay out of the generic Nexium market must defend Sherman Act claims brought by direct purchasers and end-payers of the drug, a federal judge ruled Sept. 11 (*In re Nexium (Esomeprazole) Antitrust Litigation*, D. Mass., No. 1:12-md-02409-WGY, 9/11/13).

Judge William G. Young of the U.S. District Court for the District of Massachusetts denied the drugmakers' motions to dismiss the direct purchasers and end-payers' claims challenging a patent litigation settlement agreement between Nexium maker AstraZeneca and several generic drug companies.

Young found that the purchasers had sufficiently pleaded their antitrust claims.

AstraZeneca Disagrees. In a Sept. 13 email, Michele L. Meixell, director of corporate communications at AstraZeneca, told Bloomberg BNA that ''the company disagrees with the Court's decision.''

''We are confident that our agreements are lawful and will be found lawful under application of the correct legal standard and law,'' she said, but she did not address what the company's next steps would be.

In the current case, AstraZeneca is alleged to have agreed to enter into a no-authorized generic agreement with generic companies Ranbaxy Pharmaceuticals Inc., Ranbaxy Inc., and Ranbaxy Laboratories Ltd. (collectively ''Ranbaxy''), and to pay it over $1 billion. In addition, under the settlement of the Nexium litigation, Astra is alleged to have forgiven certain contingent liabilities owed by Teva Pharmaceutical Industries Ltd., Teva USA Inc. (collectively ''Teva''), and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. (collectively ''Dr. Reddy's''), tied to Teva and Dr. Reddy's alleged past infringement of AstraZeneca's patents related to two other drugs.

Supreme Court's Ruling. In *FTC v. Actavis Inc.*, U.S., 133 S.Ct. 2223 (2013), the U.S. Supreme Court in June ruled that reverse payments, which generally involve payments from branded drug companies to generic drug companies in exchange for the generic staying off the market, may not escape antitrust scrutiny (11 PLIR 771, 6/21/13).

Interpreting *Actavis*, Young said that even though the generic defendants in the Nexium case did not receive any kind of direct monetary payment from AstraZeneca in return for staying off the market with their generic versions of Nexium, *Actavis* does not require reverse payments to be so narrowly defined.

''Nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment,'' Young said.

''This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone,'' he wrote. ''Adopting a broader interpretation of the word 'payment,' on the other hand, serves the purpose of aligning the law with modern-day realities.''

In addition, Young said the drugmaker defendants failed to ''put forward a shred of affirmative evidence tending to show that the agreements into which they allegedly entered produced any countervailing procompetitive benefits whatsoever.'' Young also rejected the defendants' argument that the direct Purchasers failed to allege a plausible relevant market, finding that the direct purchasers' complaint ''alleges more than enough facts to enable a reasonable jury to find that the Defendants exercise market power.''

He also rejected the defendants' arguments that all of the agreements between AstraZeneca and the generic defendants were immune from antitrust scrutiny under the *Noerr- Pennington* doctrine.

Under the *Noerr- Pennington* doctrine, which takes its name from two U.S. Supreme Court cases, a party that exercises its First Amendment right to petition the government for redress generally is immune from antitrust liability. But the judge said the consent agreements at issue were not eligible for such protection.

''The ways in which parties maneuver to transform a settlement agreement into a judicially approved consent judgment,'' he said, ''cannot be fairly characterized as direct 'petitioning' '' immunized by *Noerr- Pennington*.

Accordingly, the court said the purchasers sufficiently pleaded violations of Sherman Act Sections 1 and 2 of the Sherman Act under *Actavis*'s rule of reason approach and said they could proceed with their claims challenging continuing harms flowing from the Nexium patent litigation settlement.

Young did grant the drugmakers' motions to dismiss some of the purchasers' state antitrust and consumer protection claims on statute of limitations grounds.

Antitrust Attoneys Weigh In. Meanwhile, antitrust attorneys tell Bloomberg BNA that the district court's decision in the *Nexium* case, which interprets and applies

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the high court's rule of reason approach adopted in *Actavis*, may be a guide to how district courts will approach such reverse payment cases post-*Actavis*.

Attorney James M. Burns, an antitrust partner in the Washington office of Dickinson Wright, told Bloomberg BNA Sept. 13 that Young's decision may indicate that it may be harder for drug companies to get reverse payment cases dismissed in the early stages of the litigation.

''The Court's decision is precisely what the pharmaceutical industry feared would be the result of the Supreme Court's unwillingness to adopt a 'bright line' rule on reverse payments,'' he said. ''The decision demonstrates that no such settlement is likely to be immune from challenge, and a defendant's ability to have such cases dismissed at an early stage of the proceeding will be difficult in almost all cases.''

And attorney C. Scott Hemphill, professor of law at Columbia Law School in New York, told Bloomberg BNA Sept. 12 that Young's ''decision recognizes that a payment to the generic firm can take many forms, not just cash.''

''For example,'' Hemphill said, ''if the branded firm agrees to forgive a debt owed by the generic firm, or to provide something else that the generic firm values, the analysis is unchanged. Either way, if the competitor agrees to delay entry in exchange for value received, that exchange is of antitrust concern.''

Indeed, Burns said, ''the *Nexium* decision demonstrates, quite clearly, that virtually all reverse payment settlements will face careful scrutiny by the courts, and that dismissals of such cases at an early stage of the litigation are likely to be rare,'' Burns said.

And Burns said, the Federal Trade Commission ''is likely silently cheering the Court's ruling in Nexium, as it confirms that the Supreme Court's ruling in *Actavis*, despite its measured tones, was a broad victory for the FTC's position.''

Burns also said that ''the court's ruling on the *Noerr-Pennington* issue was both predictable and probably necessary because any contrary ruling would likely have had a significant chilling effect on the willingness of district courts to accommodate party requests for consent judgments.''

Challenged Conduct. In the case at bar, two groups consisting of wholesale drug distributors (direct purchasers) and health and welfare benefit funds (end-payers) brought suit separately against AstraZeneca, Ranbaxy, Teva and Dr. Reddy's, contending that AstraZeneca had entered into illegal reverse payment agreements with the generic defendants to delay generic versions of Nexium from entering the market. The lawsuits were subsequently consolidated.

In their motions to dismiss, the defendants argued that the direct purchasers' claims must fail because the alleged conduct falls within the scope of AstraZeneca's Nexium-related patents and because, even if they could be liable under federal antitrust law for such conduct, the underlying agreements would be immunized by the *Noerr-Pennington* doctrine, and the claims would be barred by the federal statute of limitations.

The defendants also contended that the end-payers' claims must fail under certain states' statutes of limitations and that the end-payers lack standing under both Article III and Federal Rule of Civil Procedure 23. They further challenged the end-payers' claims under the antitrust laws of eight states and the consumer protection laws of two other states for various reasons.

April Motions Hearing. At a motions hearing in April, the court denied the motions and requested further briefing on two issues—namely, the end-payers' standing under Rule 23 and their claims under Illinois antitrust law.

Explaining that the court ''may have acted hastily on some of the matters presented'' at the motions hearing, Young explained that the court was ''tak[ing] the time here to revisit some of its earlier conclusions,'' especially in light of the Supreme Court's intervening decision in *Actavis*.

The *Actavis* court resolved a split among the circuits regarding how reverse payments, such as those at issue here, should be evaluated under the law, with some courts relying on a scope-of-the-patent test and others applying a rule of reason analysis. The Supreme Court adopted the rule of reason approach, ''the contours of which'' it ''left to the lower courts to etch.''

Applying the *Actavis* rule of reason approach, Young started out by looking at whether the plaintiffs had adequately alleged that the defendants exercised market power in the relevant market, which the direct purchasers had defined as ''brand Nexium and generic equivalents that also share its active ingredient, esomeprazole magnesium.'' The defendants argued that this definition was improperly narrow because it ''excludes other products that are either similar in chemical composition or used to treat comparable medical conditions.''

Issue Best Left to Jury. But Young found the defendants' arguments to ''ring hollow upon review of the case law,'' as the relevant inquiry is instead the cross-elasticity of demand for the product at issue. As the direct purchasers expressly alleged that such elasticity is not present in the market for branded and generic Nexium, the court concluded that the fact that other medications may be used to treat heartburn is irrelevant and that any further factual inquiry into its reasonable interchangeability with other products ''is better left for resolution by a jury.''

As the direct purchasers presented sufficient direct evidence of the defendants' market power in that market to survive dismissal, Young turned to whether they have also demonstrated that the defendants' exercise of that power ''generated anticompetitive consequences,'' as clarified by the Supreme Court in *Actavis*.

In that case, he explained, the Court instructed that ''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.''

It is irrelevant, it continued, that there is no allegation that the generic defendants ''receive[d] any kind of *monetary* payment from AstraZeneca in exchange for their alleged commitment to stay out of the market,'' he said.

Although the court conceded that the Supreme Court ''spoke only to the merits of cash payouts as a quid pro quo for promises of delayed generic market entry,'' because the underlying facts of *Actavis* involved allegations of large cash payments, ''the Supreme Court's confined analysis hardly seems surprising.''

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Noerr-Pennington **Doesn't Apply.** Young next addressed the defendants' argument that, even if their conduct was anticompetitive, the underlying agreements are immune from antitrust liability under the *Noerr-Pennington* doctrine, having each been sanctioned by consent judgments entered by the U.S. District Court for the District of New Jersey.

While Young instructed that courts generally agree that private settlement agreements generally fall outside the realm of *Noerr-Pennington*, he said there is little guidance in which a judge has entered a consent judgment, as here. It thus invoked a 13-year-old law review article that sets forth ''a sensible analytical approach whose adoption proves useful in determining whether the consent judgments at issue ought be covered under *Noerr-Pennington*.

In the article, ''Antitrust Immunity, the First Amendment and Settlements: Defining the Boundaries of the Right to Petition,'' 33 Ind. L. Rev. 385 (2000), Raymond Ku set forth a ''bidimensional framework'' that essentially boiled down to a single question—namely: ''Is the private conduct a valid effort to influence the government?''

In this case, it is clear that the underlying consent judgments ''are not eligible candidates for *Noerr-Pennington* coverage,'' the court concluded, because the conduct surrounding the formation of the settlement agreements and their subsequent ''transform[ation]'' into consent judgments cannot be considered ''petitioning''—''at least not as that word is commonly understood in the context of the political process.''

Here, Young explained:

> Nothing prohibited AstraZeneca and the Generic Defendants from simply stipulating to a dismissal of the patent infringement actions. A decision of a court that serves merely to memorialize a bargained-for agreement that could have otherwise been resolved without judicial intervention ought not benefit from the exemption allowed by *Noerr-Pennington* [citation omitted].

The court thus declined to extend *Noerr-Pennington* immunity to the underlying agreements.

It also summarily declined to dismiss the claims based on the federal statute of limitations, to the extent that they rely on a theory of continuing harm, as the direct purchasers suffered a cognizable injury each time they purchased branded Nexium at a supracompetitive price resulting from the alleged misconduct. However, the court ruled, they may not challenge the AstraZeneca/Ranbaxy reverse payment agreement itself because that agreement was entered into more than four years prior to the filing of the suit.

Benefit Funds' Claims. Proceeding to the motions to dismiss with regard to the end-payers' claims, the court reiterated its conclusions regarding the applicable statutes of limitations and limiting the end-payers' ability to challenge the AstraZeneca/Ranbaxy agreement, but permitted them to proceed on a theory of continuing harm in those states with a four-year statute of limitations. It allowed them to pursue all claims, however, in those three states with a six-year limitations period—namely, Maine, Vermont and Wisconsin.

Young also rejected the defendants' arguments that the end-payers lacked standing. Instead, he found that the end-payers possessed Article III standing to pursue their claims because they suffered a monetary injury in the form of reimbursements paid at supracompetitive prices. Even if the court were to hold otherwise, he determined that the end-payers would nonetheless be able to proceed under an exception to the strict standing analysis set forth in *Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762 (1st Cir. 2011).

In that case, the U.S. Court of Appeals for the First Circuit held that, ''in those unusual circumstances presented in class action disputes where the interests of the named plaintiffs, in bringing claims for which they do have Article III standing, are sufficiently aligned with the interests of the putative class over which they do not have Article III standing,'' the plaintiffs may proceed. Here, the court concluded, ''the requisite 'identity of issues' and 'alignment of incentives' is present amongst'' end-payers and thus ''[a]ll members of the putative class have a common interest in litigating claims arising from the Defendants' allegedly anticompetitive collusion designed to cause the End-Payors to pay supracompetitive prices across the several states.''

Young next addressed the end-payers' claims arising under the Illinois antitrust law, which expressly states that all indirect purchaser suits must be brought by the state attorney general. Although the end-payers attempted to argue that the law is preempted by Rule 23 ''where it purports to govern the procedural mechanism by which litigants can bring suit in federal courts,'' Young was not convinced and dismissed their claims.

He also dismissed their claims arising under Puerto Rico law, as its antitrust law is to be interpreted in accordance with federal law and thus indirect purchasers are barred from bringing suit, and under Utah law, as the end-payers failed to satisfy its statutory citizenship or residency requirement.

Liaison counsel for the proposed end-payer class was the law firm of Berman DeValerio in Boston; interim co-lead counsel for the proposed end-payer class included Wexler Wallace LLP, Chicago; Shepherd Finkelman Miller & Shah LLP in Weston, Fla.; Hilliard & Shadowen LLC, Mechanicsburg, Pa.; and Cohen Milstein Sellers & Toll PLLC in New York.

The law firms of Hagens Berman Sobol Shapiro LLP, in Cambridge, Mass.; Garwin Gerstein & Fisher LLP, in New York; and Berger & Montague PC in Philadelphia, are co-lead counsel for the proposed direct purchaser class.

The law firms of Covington & Burling LLP, Washington; Williams & Connolly, LLP, Washington, and McCarter & English, LLP, Wilmington, Del. and Boston, were counsel for AstraZeneca defendants.

The law firms of Venable LLP in Washington; and Minerva Law, P.C. in Andover, Mass, were counsel for Ranbaxy defendants.

The law firms of Jones Day in Washington; Budd Larner PC in Short Hills, N.J.; and Hamilton Brook Smith & Reynolds, P.C. in Concord, Mass., were counsel for the Dr. Reddy's defendants.

The law firms of Kirkland & Ellis LLP, Washington, and Mintz, Levin, Cohn, Ferris, Glovsky & Popeo PC, in Boston, represent the Teva defendants.

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Text of the court's decision is at http://www.bloomberglaw.com/public/document/In_Re_Nexium_Esomeprazole_Antitrust_Litigation_Docket_No_112md024.

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