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Indirect Purchaser Plavix Class Actions Tossed for Lack of Antitrust Standing

On January 31, 2011, the District Court for Southern District of Ohio granted defendants' Rule 12(b)(6) motion, dismissing indirect purchaser class actions that challenged proposed reverse payment agreements as anticompetitive under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2. Plaintiffs alleged those agreements prevented the defendants from entering into an alternative competitive agreement that would have permitted the cheaper generic version of Plavix to enter the market sooner. *In re Plavix Indirect Purchaser Antitrust Litig.* ("*Plavix*"), Slip Op., No. 1:06-cv-226, 2011 WL 335034 (S.D. Ohio Jan. 31, 2011).

Background – Kroger Co. v. Sanofi-Avantis, 701 F.Supp.2d 938 (S.D. Ohio 2010)

In an earlier opinion, which was incorporated by reference into the January 31 decision, the court dismissed the direct purchaser actions based on the same allegations. Accordingly, a brief description of the background of the case and the court's prior decision is helpful in understanding the context of the court's ruling dismissing the indirect purchaser claims.

The defendants in both sets of actions were Sanofi Aventis and Sanofi-Synthelabo, Inc., Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (collectively "Sanofi") and Apotex Corporation ("Apotex"). Sanofi manufactures a patented clopidogrel bisulfate drug, known as Plavix, which is used to treat patients with a risk of heart attacks and strokes. Apotex was the first generic applicant to seek FDA approval to market a generic version of Plavix in the United States, alleging that Sanofi's patent was invalid (called a Paragraph IV certification). Sanofi then initiated a patent infringement suit against Apotex. *Kroger*, 701 F.Supp.2d at 942.

The FDA grants the first generic applicant to file a Paragraph IV certification with a six-month exclusivity period during which the generic drug manufacturer may sell the drug free of competition from any other generic manufacturer. However, the filing of a patent infringement suit stays the FDA approval process for the generic drug for up to 30 months. 21 U.S.C. § 355(j)(5)(B)(iii); *Kroger*, 701 F.Supp.2d at 942.

The automatic 30-month stay that was triggered by Sanofi's infringement suit pursuant to section 355(j)(5)(B)(iii) expired in May 2005, and the trial of the infringement action was scheduled for April 2006. Apotex received FDA approval in January 2006, which started the 6-month exclusivity period running before the patent issues were resolved. Apotex was, therefore, faced with either losing the lucrative 6-month exclusivity rights or launching its generic drug "at risk," thus exposing itself to infringement damages if Sanofi's patent was upheld. Apotex began preparing for an at risk launch based on a belief that it had a strong invalidity case. Meanwhile, Aventis had obtained independent professional advice that called into question the validity of the patent at issue. *Kroger*, 701 F.Supp.2d at 944.

Given the risks on both sides, negotiations ensued resulting in two sets of proposed settlement agreements, both of which required government approval to take effect. The first called for a series of "reverse payments" by Sanofi to Apotex, also guaranteeing that neither Apotex nor Sanofi would launch a generic during Apotex's exclusivity period. When this agreement failed to gain government approval, the parties entered into a second proposed agreement that capped Apotex's damages if the patent litigation was resolved in Sanofi's favor and

under which Sanofi would not be prohibited from launching its own generic during Apotex's exclusivity period. Moreover, the effective date of the agreement was moved forward to June 1, 2011 from September 17, 2011. However, this agreement also failed to gain the required government approval. A later government investigation into the proposed settlement resulted in criminal charges against, and a guilty plea by, Bristol Meyers for making false statements to government officials in connection with the proposed settlement. *Kroger*, 701 F.Supp.2d at 945-46.

In August 2006, while the patent litigation was ongoing, Apotex launched its generic version of Plavix at risk and sold it a few weeks before Sanofi obtained an injunction against Apotex and halted the sale of the generic drug. *Id.* at 946. The infringement action was later resolved against Apotex and the patent was held valid and infringed. Apotex litigated the issue through the Federal Circuit which upheld the findings below. *Id.* at 962-63.

Plaintiffs, both direct and indirect purchasers, alleged that, but for the two proposed settlement agreements, defendants would have entered into another, procompetitive agreement either (1) licensing Apotex to market its generic brand, or (2) shortening the life of Sanofi's patent rights in return for Apotex's delayed entry into the generic market. They claimed that such alternative hypothetical agreement would have avoided the unsuccessful patent trial and would have resulted in plaintiffs receiving the benefits of lower-priced generic competition sooner. Id. at 946. They also raised a Section 2 claim premised on a *Walker Process* theory of monopolization through enforcement of a fraudulently-obtained patent based on misrepresentations made to the Patent and Trademark Office ("PTO"). *Id.* at 949.

The district court dismissed the direct purchasers' Section 1 claims for lack of antitrust injury. The court concluded, "Plaintiffs' allegations, taken as true and construed in their favor, preclude the possibility that their injury flowed from the anticompetitive effects of the [proposed] agreements 'which make [D]efendants' acts unlawful.'" *Id.* at 954 (internal citation omitted). The court distinguished the case from *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906 (6th Cir. 2003) which similarly involved a reverse payment agreement, noting that the agreement involved in that case in fact kept the generic drug from entering the market.

In contrast, Apotex launched the generic drug at risk and sold it on the market for a few weeks before its sales were halted by valid injunctions. Accordingly, the injunctions, not the proposed agreements, caused plaintiffs' alleged injury and were "impenetrable legal impediments to the sale of generic" Plavix. The court held, such "alleged injury, although related to an antitrust violation, nevertheless will not qualify as 'antitrust injury.'" *Kroger, 701* F.Supp.2d at 954. (internal quotation marks and citation omitted).

The court also rejected direct purchaser plaintiffs' Section 2 *Walker Process* theory of monopolization. The court noted that such claims are typically brought as counterclaims in patent infringement suits, and that outside this context, "a patent's validity can be challenged only by a party (1) producing or preparing to produce the patented product, and (2) being threatened or reasonably likely to be threatened with an infringement suit." *Id.* at 960. Because the direct purchasers did not fall into either category, they could not directly challenge the validity of Sanofi's patents. However, the court found that whether purchasers could nonetheless assert a *Walker Process* claim like plaintiffs' was not a settled question.

Relying on *In re DDAVP Direct Purchaser Antitrust Litigation*, 585 F.3d 677 (2d Cir. 2009), the court opted for a narrow application of such a claim. In *DDAVP*, the Second Circuit held "that purchaser plaintiffs have standing to raise Walker Process claims for patents that are *already* unenforceable due to inequitable conduct." 585 F.3d at 691-92 (emphasis added); *Kroger*, 701 F.Supp.2d at 961-62.

The court found *DDAVP* inapplicable, however, because Apotex litigated the validity of the patent at issue through the Federal Circuit and lost, thereby failing to establish "by clear and convincing evidence that Sanofi engaged in inequitable conduct" before the PTO. *Kroger,* 701 F.Supp.2d at 963. Accordingly, the court dismissed the direct purchasers' claims.

The Indirect Purchaser Actions

At the outset, and with the foregoing rulings in mind, the court noted that "a complaint's '[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all of the complaint's allegations are true.'" *Plavix*, 2011 WL 335034, at *2 (quoting *Bell Atl. Corop. v. Twombly*, 550 U.S. 544, 555-56 (2007)). The court also stressed that "something beyond the mere possibility of [relief] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an in terrorem increment of the settlement value." *Id.* (internal quotation marks and citation omitted).

The court first turned to indirect purchaser plaintiffs' injunctive relief claim under Section 16 the Clayton Act, 15 U.S.C. § 26. The court noted that plaintiffs sought to enjoin not just any future reverse payment agreements related to Plavix, but went "so far as to request to enjoin Defendants from the *possibility* of entering into a yet-to-be-determined reverse payment agreement on some yet unidentified drug." *Plavix,* 2011 WL 335034, at *4 (emphasis added). In other words, indirect purchasers sought "an injunction preventing the practice of entering into reverse payment agreements." *Id.* at *3 (emphasis in original). The court rejected the claim as "too speculative a basis for injunctive relief," as plaintiffs "provide[d] no factual basis for their claims that there is any kind of threatened violation on the part of Defendants" and "merely speculate[d] that Defendants' previous behavior and their status as the 'world's leading' pharmaceutical or generic drug makers leads to the assumption that Defendants will engage in future collusive agreements." *Id.* at *4.

The court next turned to the indirect purchasers' claims under various states' antitrust and consumer protection laws and rejected those claims based on the absence of antitrust injury as found in *Kroger. See id.* at *5 (indirect purchaser plaintiffs' "alleged injury - paying 'artificially inflated prices for Plavix' - derives from the lack of access to a generic substitute caused by the court-ordered injunctions" and "is not of the type the antitrust laws were intended to prevent"). In reaching the same result as in *Kroger*, the court noted that indirect purchaser plaintiffs conceded that state courts are guided by federal decisions in interpreting similar state antitrust and consumer protection statutes. *Id.* The court also relied on a number of cases dismissing state law claims when similar federal claims based on the same allegations were dismissed. *See, e.g., id.* (citing and quoting, among others, *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F.Supp.2d 986, 996 (N.D.III.2003) for proposition that "the state antitrust charge falls for the same reasons as the federal, since there is no difference material to this case between the state and federal statutes").

Finally, the court also dismissed indirect purchasers' unjust enrichment and restitution claims. Noting that an unjust enrichment claim "hinges on, inter alia, a benefit conferred by a plaintiff upon a defendant," the court held that "[a]ny payment by Indirect Purchasers for Plavix was not a 'benefit conferred' but instead consideration for the patented drug." *Id.* at *6.

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