

K-Dur: The Rejection Of 'Scope Of The Patent' Test

Law360, New York (July 24, 2012, 1:11 PM ET) -- On July 16, 2012, the Third Circuit in *In re K-Dur Antitrust Litigation* rejected the “scope of the patent” test that has been almost uniformly adopted by other courts of appeals and reversed a lower court’s judgment dismissing a pay-for-delay case against Schering-Plough Corporation involving the potassium supplement K-Dur. Nos. 10-2077, 10-2078, 10-2079, 10-4571 (3d Cir. July 16, 2012).

Parting ways with the majority of its sister circuits, the Third Circuit held that reverse payment settlement agreements must be reviewed under a quick look rule of reason test, under which the reverse payment constitutes prima facie evidence of an unreasonable restraint of trade, and a defendant can only rebut the presumption of illegality by showing that the agreement has a purpose other than delaying entry or that the agreement has some pro-competitive benefit.

Pay-for-delay settlements — sometimes also referred to as reverse payment settlements — have been a topic of great controversy for many years, and more recently, the Federal Trade Commission has made them a top enforcement priority. Such payments have generally been deemed lawful by the courts, however. Courts have recognized that, ultimately, any settlement agreement involves some sort of consideration to the defendant — whether in the form of monetary payment or other benefit. Without such consideration, the defendant would have no reason to settle.

And generally, public policy favors and encourages settlement. The Third Circuit’s decision in *K-Dur* is contrary to these principles. It not only makes settling patent disputes more difficult, but also introduces a great deal of uncertainty by deepening a circuit split regarding the standard that governs the legality of such settlements.

Pay-for-Delay Litigation and the “Scope of the Patent” Test

Pay-for-delay cases are those arising out of settlements between brand-name drug manufacturers and their generic rivals. A pay-for-delay settlement resolves a patent infringement suit initiated by a brand-name drug manufacturer against a generic drug-manufacturer for the latter’s attempt to market a competing version of the brand-name product. Pay-for-delay settlements — like all settlements — involve risk assessment and business judgment.

By choosing to settle, a brand-name drug manufacturer makes a calculated decision not to take a chance that the generic firm might convince the court that the underlying patent is invalid or is not infringed by the proposed generic. Instead, the brand-name drug manufacturer pays or bestows some other benefit upon the generic firm to convince it to abandon its challenge and, in some cases, to delay entry.

The U.S. Supreme Court has not addressed the legality of reverse payment settlements. Prior to the Third Circuit's decision in *K-Dur*, however, the weight of appellate authority — and all of the more recent appellate authority — has adopted one form or another of the “scope of the patent test.” Under that test, reverse payments are permitted as long as (1) the exclusion does not exceed the patent's scope, (2) the patent holder's claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud on the U.S. Patent and Trademark Office.

The Second, Eleventh and Federal Circuits have adopted this test, rejecting challenges to pay-for-delay settlements where the restrictions in the settlement agreement fell within the scope of the patent with respect to duration and the products covered. See, e.g., *Ark. Carpenters H. & Welfare Fund v. Bayer AG*, 604 F.3d 98, 106 (2d Cir. 2010) (Cipro); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335-36 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213-15 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005). In fact, the Eleventh Circuit's decision in *Schering-Plough* arose out of the same set of facts as the Third Circuit's decision in *K-Dur*.

Under the “scope of the patent” test, a plaintiff can still prove a settlement exceeded a patent's scope by showing that the patent was obtained by fraud (e.g., *Walker-Process* or inequitable conduct allegations) or that the underlying patent infringement litigation was objectively baseless (i.e., a sham). See, e.g., *In re Cipro*, 544 F.3d at 1336 (“In addition, we agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”); *In re Tamoxifen*, 466 F.3d at 208 (“[S]o long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”).

Unlike the Second, Eleventh and Federal Circuits, the Sixth Circuit has upheld the grant of summary judgment to plaintiffs in a pay-for-delay case, holding that a reverse payment settlement agreement was per se unlawful. *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003). *Cardizem*, however, was the first appellate decision in a “pay for delay” case, and was largely disregarded by subsequent appellate courts. For example, in *Tamoxifen*, the court distinguished *Cardizem*, noting that the settlement agreement was an “interim settlement” of a motion for a preliminary injunction, so it did not fully resolve the case. See *In re Tamoxifen*, 466 F.3d at 197 (discussing district court opinion).

History of the K-Dur Litigation

K-Dur arose out of two patent disputes involving Schering's brand-name drug K-Dur 20 (K-Dur) — one between Schering and Upsher-Smith Laboratories and another between Schering and ESI Lederle. Upsher and ESI each sought approval to produce generic versions of K-Dur, and Schering filed a patent infringement lawsuit against each generic alleging patent infringement. Both suits were resolved by settlement agreements, which involved some form of payment from Schering to the generic drug manufacturer in exchange for the generic's promise to delay entry into the market.

Various private parties attacked the Schering-Upsher and Schering-ESI settlements, arguing that they were unlawful under the Sherman Act; those suits were consolidated in the District of New Jersey by the judicial panel on multidistrict litigation. The FTC filed its own complaint against Schering, Upsher and ESI, which was ultimately rejected by the Eleventh Circuit. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (adopting the "scope of the patent" test).

In the private action, a special master certified a class of plaintiffs consisting of 44 wholesalers and retailers who purchased K-Dur directly from Schering. The district court adopted that decision. The special master then issued a report and recommendation granting defendants' motions for summary judgment and denying plaintiffs' motion for partial summary judgment. In that decision, the special master applied the "scope of the patent" test, holding that Schering's patent was presumptively valid and that it gave Schering the right to exclude infringing products until the patent's expiration unless the settlements (1) exceeded the scope of the patent or (2) the underlying patent infringement suits were objectively baseless. The special master determined that neither of these conditions applied. The district court adopted the report and recommendation in its entirety.

The Third Circuit's Decision

On appeal, the Third Circuit reversed and rejected the "scope of the patent" test. The court concluded that the test "does not subject reverse payment agreements to any antitrust scrutiny." *Id.* at 26 ("As the antitrust defendants concede, no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial.").

The court criticized the "scope of the patent" test's "almost un rebuttable presumption of patent validity," noting that the "presumption that a patent holder is entitled to exclude competitors is particularly misguided with respect to agreements — like those here — where the underlying suit concerned patent infringement rather than patent invalidity: In infringement cases, it is the patent holder who bears the burden of showing infringement." *Id.* at 27. The court also observed that "[m]any patents issued by the PTO are later found to be invalid or not infringed," *id.*, and criticized other courts' assumption "that subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger," *id.* at 28.

In addressing public policy interests, the court stressed that those interests “support[] judicial testing and elimination of weak patents,” *id.* at 29-30, and that the Hatch-Waxman Act’s goal is to increase the availability of low cost generic drugs, *id.* at 31. Concluding that the “scope of the patent” test undermines those objectives, the court rejected that test as misguided. *Id.* at 32. The court recognized that its decision undermined a conflicting public policy goal — settlement — but determined that while the judicial preference for settlement is “generally laudable, [it] should not displace countervailing public policy objectives or, in this case, Congress’ determination ... that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.” *Id.*

Ultimately, the court held that reverse payment settlements should be scrutinized under the quick look rule of reason analysis. *Id.* at 32. Under this analysis, the payment from the branded company to the generic must be viewed as *prima facie* evidence that the settlement is an unreasonable restraint of trade. *Id.* at 33. This presumption can be rebutted by “showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.” *Id.* The court noted that the second possible defense will rarely be effective.

Notably, the *K-Dur* decision does not affect the analysis of settlements that merely allow the generic to enter at some point before patent expiration, but do not involve payment from the branded company to the generic. *Id.* at 32 (emphasizing that its decision does not “limit[] the ability of the parties to reach settlements based on a negotiated entry date for marketing of the generic drug: the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger.”).

The Third Circuit’s decision reflects the position long sought by the FTC, and is the first court of appeals decision that has fully embraced the view advocated by the commission. The FTC filed an amicus brief last year urging the Third Circuit to reverse the district court’s decision, arguing that it conflicts with basic antitrust principles, patent law and the policies behind the Hatch-Waxman Act. Following the Third Circuit’s opinion, Chairman Jon Leibowitz stated that the court “seems to have gotten it just right: These sweetheart deals are presumptively anticompetitive.” Although the FTC is not a party to the *K-Dur* case, the decision is therefore a major victory for the agency.

Implications of the K-Dur Decision

The effect of the Third Circuit’s decision in *K-Dur* will be felt in situations where parties might have entered into side deals (such as supply agreements, co-promotion arrangements and the like) in addition to simply settling the litigation. The decision does not necessarily forbid such side deals in settlements but it increases the associated risks.

At the very least, the Third Circuit’s decision increases the importance of making sure that any payments in such deals are consistent with the market value of the services or products being provided by the generic, or vice versa. Otherwise, they will be easier to characterize as involving a premium which is really a payment for delayed entry. Plaintiffs are now likely to bring cases involving such side deals in the Third Circuit to avoid application of the “scope of the patent” test. The Third Circuit’s decision makes it much easier for plaintiffs to survive an early motion to dismiss. The FTC will also continue applying the *K-Dur* approach.

Because the K-Dur decision has deepened a circuit split with respect to the validity of reverse payments, this issue is ripe for Supreme Court review. Not only have three circuits embraced the “scope of the patent” test that the Third Circuit rejected, but also the Eleventh Circuit dismissed the FTC’s own challenge concerning the very same set of facts as those involved in K-Dur. The legality of Schering’s settlements has therefore been decided differently by two courts of appeals and, unless the Supreme Court weighs in, the outcome of future cases will similarly depend on where one gets sued.

Key Points

- The U.S. Third Circuit in *In re K-Dur Antitrust Litigation* rejected the “scope of the patent” test that has been almost uniformly adopted by other courts of appeals, deepening the circuit split and making this issue ripe for Supreme Court review.
- The Third Circuit held that reverse payment settlement agreements must be reviewed under a quick look rule of reason test, under which the reverse payment constitutes prima facie evidence of an unreasonable restraint of trade, and a defendant can only rebut the presumption of illegality by showing that the agreement has a purpose other than delaying entry or that the agreement has some pro-competitive benefit.
- The K-Dur decision makes it more difficult for parties to settle their patent disputes in circumstances where the settlement involves some form of payment from the brand-name manufacturer to the generic challenger. The decision does not affect the analysis of settlements that merely allow the generic to enter at some point before patent expiration.

--By George Gordon and Steven Bradbury, Dechert LLP

George Gordon is a partner in Dechert's Philadelphia office, where he co-chairs the firm's antitrust group and life sciences practice. Steven Bradbury is a partner in the firm's Washington, D.C., office.

Irene Ayzenberg-Lyman, an associate in the firm's Philadelphia office, assisted in the preparation of this article.

The opinions expressed are those of the authors and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

All Content © 2003-2012, Portfolio Media, Inc.