Third Circuit Provides Friendly Environment for FTC and Plaintiffs Challenging Certain Patent Litigation Settlements

Summary

On July 16, 2012, the U.S. Court of Appeals for the Third Circuit announced its decision in *In re K-Dur Antitrust Litigation* , a case involving so-called "reverse payment" or "pay-for-delay" settlements. A pay-for-delay settlement resolves a patent infringement suit initiated by a brand-name drug manufacturer against a generic drug manufacturer – a lawsuit that centers on the latter company's attempt to market a competing version of the established brand-name product. In the settlement, the brand pays a (substantial) sum of money to the generic not to market its product upon FDA approval, but instead delay until some time prior to patent expiration. The brand-name drug manufacturer settles because it does not want to risk a verdict rendering its patent invalid or non-infringed by the generic product, and the generic settles because it's gaining a positive result without the need to incur further, substantial litigation expenses. A 2010 analysis by the FTC found that reverse payment settlements cost consumers $3.5 billion annually. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), *available at* http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf.

The Third Circuit starkly departed from the analysis employed in such cases by its sister circuits. The Second, Eleventh and Federal Circuits have all approved such agreements under some variation of the so-called "scope of the patent" test. That test relies on the principle that patents issued by the PTO are entitled to a presumption of validity until proven otherwise. Given the fact that a patent is a right to exclude others, these circuits held that pay-for-delay agreements are valid so long as (i) the exclusion agreed to in the settlement does not exceed the scope of the patent, (ii) the patent holder's claim of infringement was not objectively baseless, and (iii) there was no fraud on the PTO in procuring the patent. Any other rule, these courts reason, would require the district court to hold mini-patent trials to determine the likelihood that the generic would have won. As the Eleventh Circuit put it: "[W]hat the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that, we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task."

The Third Circuit disagreed with the underlying premise of the scope-of-the-patent test. Not only is the fact that a patent is presumed legal irrelevant to cases in which the claim is non-infringement, but many patents issued by the PTO are later found to be invalid or not infringed. Thus, overreliance on the presumption would unduly protect otherwise anticompetitive conduct. Furthermore, the court stressed the public policy in testing and eliminating weak patents, holding that the policy favoring settlements should not "displace countervailing public policy objectives" or Congressional intent that patent challenges root out weak patents that confer "unjustified monopolies" on brand companies. Accordingly, the court held that that such settlements are illegal unless the parties could show the payment was either for something other than the delayed entry or related to some procompetitive benefit.

Background

Under the 1984 Hatch-Waxman Act, when a drug manufacturer wishes to make a generic drug, it must file what is called an Abbreviated New Drug Application. Generic drugs can piggyback off of the clinical studies performed by the branded drug product so long as the generic manufacturer demonstrates that its product is bioequivalent to it. Along with the ANDA, the generic manufacturer is also required to file a certification that its proposed product does not infringe any patent listed with the FDA as covering the patented drug. One way it may do so is by certifying that the brand's patent is invalid or that the generic product will not infringe the brand's patent. By statute, such a certification constitutes a technical act of patent infringement. Also by statute, if the patent holder files an infringement action within 45 days, it is entitled to an automatic stay that prevents the FDA from approving the generic drug for either 30 months or until a judicial declaration that the patent is invalid or not infringed,

whichever is earlier.

Schering-Plough Corporation held a patent on K-Dur, a brand name drug used to treat potassium deficiencies, which was set to expire on September 5, 2006. Two generic companies – Upsher-Smith Laboratories and ESI Lederle – filed separate ANDAs with the requisite certifications, each stating that its respective product did not infringe Schering's patent. Schering timely filed suit against them both.

A little under two years after filing suit, and just before trial, both Upsher and ESI independently settled with Schering. While the precise terms of the settlements differed, both generic makers were paid a large sum of money, in return for which they promised not to market their generic products until 2001 and 2004, respectively. Assuming the defendants would have prevailed in the infringement, the settlements represented a generic entry delay of approximately four to six years, though the entry date was five years before patent expiry.

The FTC filed an administrative action alleging that the settlement violated Section 5 of the Federal Trade Commission Act. While the ALJ ruled for the defendants, a unanimous FTC overruled the ALJ and found a violation. Schering appealed to the 11th Circuit, which reversed the FTC decision. Private plaintiffs also filed suit and the actions were consolidated in the District of New Jersey. The district court granted summary judgment for defendants, which gave rise to the Third Circuit appeal.

Other Circuits' Analysis

Five other circuits have previously considered the issue of reverse payment settlements. The first two circuits to consider the matter, the D.C. and Sixth Circuits, both held that such agreements were illegal. However, because of the peculiarities of the Hatch-Waxman Act, the settlements involved in those cases caused a bottleneck to occur such that no other generic manufacturer was able to market its product. Thus, not only did the generic makers involved in the settlements at issue there agree not to enter until some point in the future, but no other company was able to either. As a result, those cases are generally considered distinguishable.

The next three circuits to rule on reverse payments all held that such agreements pass antitrust muster. These circuits – the Eleventh, Second and Federal – adopted some form of the "scope of the patent test." Relying on the presumption of validity to which a patent issued by the U.S. Patent and Trademark Office is entitled, these circuits held that such settlements are legal so long as (1) the exclusion does not exceed the scope of the patent, (2) the patent holder's claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud.

Third Circuit's Opinion

The Third Circuit, in *K-Dur,* flatly rejected the "scope of the patent" test because the test "does not subject reverse payment agreements to any antitrust scrutiny." Instead, the Third Circuit held that these settlements should be judged by a "quick look" rule of reason. The court took strong issue with the scope of the patent test's "almost unrebuttable presumption of patent validity" because it "assumes away the question being litigated in the underlying patent suit." The court explained that the presumption was really only a procedural litigation device to shift the burden to the party challenging the patent but was not intended as a substantive right of the patent holder. Elevating such a procedural device was particularly inappropriate in a case where the parties challenge infringement, not patent validity; in infringement cases, it is the patent holder who bears the burden of showing infringement. Relying too heavily on the presumption was also inappropriate, the court held, because many issued patents are later held to be invalid or non-infringed. In support of the latter point, the court cited a 2002 FTC study that concluded that the generic drug maker prevailed 73% of the time in Hatch-Waxman cases. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002), *available at* http://www.ftc.gov/os/2002/07/

Moreover, the court held that public policy weighs in favor of scrutinizing these settlements. While settlement is a laudable public policy goal, the court noted that that there are countervailing policy goals, including judicial testing of weak patents and increasing the availability of low-cost generic drugs.

The court also addressed one of the major criticisms of the FTC's position – namely, that the court would have to hold a mini-patent trial to determine what would have been the outcome of the underlying suit had it been fully litigated, and that only if, in

retrospect, the patent would have been deemed to be invalid or infringed would the settlement be considered illegal. Rather, the Third Circuit stated that "it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." Accordingly, the comparison is not between a reverse payment settlement and a valid patent, but a reverse payment settlement and a settlement without payment to the generic company, which presumably would have allowed the generic to enter even earlier and provide consumers with the low-cost product that much longer.

The Third Circuit, therefore, held that any payment by a patent holder to a generic challenger for delaying entry of the generic product will be considered as *prima facie* evidence of an antitrust violation, which can be rebutted by demonstrating that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.

Implications of the Decision

While the opinion is interesting in and of itself, the decision will have several near-term, and some longer-term, effects.

First, the decision certainly sets the stage for Supreme Court review. There is now a direct and obvious conflict between the Third Circuit and at least three other circuits. Indeed, one of the Eleventh Circuit cases that enunciated the scope of the patent test came in the FTC case brought against the very same Schering/Upsher-ESI settlement, and another Eleventh Circuit decision approving reverse payment settlements was handed down just this past April. While it is folly to predict with certainty whether the Supreme Court would accept certiorari, all the ingredients supporting review are there.

Second, the FTC and plaintiffs now have a friendly environment in which to pursue these cases. The fact that it is the Third Circuit that advocates a tougher antitrust stance is particularly significant because the Third Circuit covers Pennsylvania, Delaware and New Jersey, where many pharmaceutical companies have their headquarters.

Third, and related to the point above, the decision will likely lead to increased FTC enforcement. The FTC has been waging a war against these settlements for years, even though it continued to lose. Nevertheless, it stands to reason that given its track record, as a matter of prosecutorial discretion, and being ever mindful of the bottom line, the FTC did not investigate or bring cases that were not clear cut. Indeed, parties to settlements had all the leverage on their side and had no incentive to settle.

With the Third Circuit now providing a friendly venue, the FTC might now choose to investigate and bring the more "marginal" case. Thus, one might expect to see not only more cases brought, but also cases that may not have been brought in recent years in which the anticompetitive effect of the agreement is not as clear, such as instances in which the parties have entered into side deals (e.g., supply agreements, co-promotion arrangements, etc.) in addition to simply settling the litigation. Parties must now be mindful that any and all consideration flowing from the brand to the generic must equal, or nearly equal, the services the generic is providing to the brand. Importantly, the cost of litigation has now gone up as defendants cannot simply rely on dismissing such actions on a motion to dismiss.

Finally, it will be interesting to see the effect the Third Circuit's decision has on the ongoing debate concerning the proper balance between patent and antitrust law. While the court stated explicitly that its decision "is limited to reverse payments between patent holders and would-be generic competitors in the pharmaceutical industry," the opinion nevertheless resolved the public policy issues in favor of antitrust enforcement. The fact that the Third Circuit did not appear to give much weight to the presumption of validity, calling it a mere "procedural device," could have more far reaching implications.

Additionally, the bottom line is that the court held that a patent holder who isn't seeking to exclude another beyond the scope of the patent can nevertheless be held liable under the antitrust laws. . That may well resonate in other arenas. For example, the antitrust agencies have been speaking loudly and often about the potential evils of granting injunctions for standard essential patents (SEP), which are patents that were incorporated into standards applicable to all industry participants. Allowing holders of such patents to exclude competitors from using the patents necessarily excludes the competitors from the standard and ultimately from competing in the market. While the patent-antitrust issues implicated in the reverse-payment and SEP contexts differ, the fact that the exclusionary force of a patent was not dispositive in the former (as held by the Third Circuit) could affect the analysis in the latter, and in other situations where patent law and antitrust law clash.

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Jay Levine is a partner in the firm's Washington, D.C. litigation department. His practice is concentrated in complex litigation, particularly antitrust and consumer protection matters.

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