

# AntitrustConnect Blog

## Third Circuit Rejects Scope-of-Patent Test in Antitrust Challenge to K-Dur Patent Settlement

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Reverse payments settlements between patent holders and would-be generic competitors in the pharmaceutical industry should be reviewed under a “quick look” rule of reason analysis based on the economic realities of the reverse payment settlement, the U.S. Court of Appeals in Philadelphia ruled today.

The appellate court decided that wholesalers and retailers who purchased a brand-name sustained-release potassium chloride supplement (K-Dur) used to treat high blood pressure could proceed with an antitrust challenge to patent infringement litigation settlement agreements between Schering-Plough Corporation — the manufacturer of K-Dur — and generic drug companies. The purchasers alleged that the settlements included payments from Schering to the generic drug makers and resulted in the delayed entry of a generic alternative to K-Dur. A March 24, 2010, order of the federal district court in New Jersey granting summary judgment in favor of the drug companies was reversed.

On remand, the federal district court was instructed to apply quick look or “truncated rule of reason” analysis. Under that test, the finder of fact would be required to treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.

In adopting a quick look standard, the Third Circuit rejected the scope-of-the-patent test adopted by the lower court and other federal appellate courts, including the Eleventh Circuit, which earlier rejected an FTC challenge to the same settlement agreement. In a friend-of-the-court brief supporting the complaining purchasers, the FTC had urged the Third Circuit to hold what it calls “pay-for-delay settlements” to be presumptively illegal and condemn them unless the drug companies can show that their agreements do not harm competition.

Under the scope-of-the-patent approach for reviewing reverse payment agreements, as long as the settlements restrained competition only within the scope of the underlying patent, and the underlying patent lawsuits were not objectively baseless, the defendants were entitled to summary judgment on the antitrust claims.

The appellate court concluded that the scope-of-the-patent test “improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of

Supreme Court precedent on patent litigation and competition.” The test created an almost un rebuttable presumption of patent validity, even though many patents issued by the Patent and Trademark Office were later found to be invalid or not infringed. Moreover, the court questioned an assumption supporting the presumption of legality that subsequent challenges by other generic manufacturers would suffice to eliminate weak patents preserved through a reverse payment to the initial challenger.

### **Class Action Certification**

The court also affirmed certification of a class of 44 wholesalers and retailers who purchased K-Dur directly from Schering between November 20, 1998 and September 1, 2001 and subsequently purchased a generic version of K-Dur. The court rejected the defendants’ contention that the plaintiffs were required to show lost profits in order to demonstrate antitrust injury. Also rejected was the defendants’ argument that insurmountable conflicts prevented the named plaintiffs from adequately representing the members of the class.

The July 16, 2012, opinion in *In Re: K-Dur Antitrust Litigation*, No. 10-2077, is available [here](#).

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