

“Reverse Payments” Pass Another Test: Federal Circuit Adopts Rule of Reason

By Thomas Carey

The *Hatch-Waxman Act* rewards a generic drug manufacturer for going through the trouble of challenging the patents of a pioneer drug company: 180 days of exclusive marketing rights, if the patent challenge succeeds. This incentive has been sufficient to motivate numerous generic drug companies to challenge patents listed in the Orange Book, and many have done so successfully.

Increasingly, pioneer drug companies are settling such patent litigations on terms that call for so-called reverse payments, that is, substantial compensation to the generic drug company that is linked to the challenger's agreement to refrain from selling its generic drug. The facts of these cases are complex, and the settlement agreements steer clear of stating baldly that payment is made to keep a potential competitor off the market. Nonetheless, that is exactly how they are perceived.

The Sixth Circuit was the first appeals court to consider the propriety of this type of settlement, and found it a per se violation of the antitrust laws. See *In re Cardizem Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003). The FTC warmed to the task of pursuing pioneer drug companies that settled patent litigation on such terms, but encountered rough sledding at the Eleventh and Second Circuits. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); and *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006).

Both of those courts applied a “rule of reason” and found no antitrust violation in the making of reverse payments to the potential infringer. These courts

reasoned that a patent is after all a legal grant of exclusivity, and that as long as the pioneer drug company did not try actually to *expand* the scope of its patent through the settlement process, the agreement would be immune from antitrust scrutiny.

On October 15, 2008, the Federal Circuit lined up with the Eleventh and Second Circuits, applying the same rule of reason and finding the settlement agreement before it to pass antitrust muster. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, Fed. Cir. (October 15, 2008).

This opinion, like those of the Eleventh and Second Circuits, does not formally disagree with the Sixth Circuit's ruling in *Cardizem*, but instead distinguishes that case because it involved a generic drug maker who not only agreed to stay out of the market, but who agreed (using a statutory idiosyncrasy since corrected¹) to block all other generic makers from proceeding with their own patent challenges under the Hatch-Waxman Act.

Meanwhile, the FTC continues to publish annual reports on the frequency of reverse-payment settlements using data that the parties to such settlements are required to submit. On the next page is a chart showing, in red, the number of reverse payments settlements since 2004.

As this chart demonstrates, the FTC's enforcement activities suppressed reverse payments entirely until the Eleventh Circuit's ruling in *Schering Plough*. The floodgates have since opened, however, and the Federal Circuit's ruling in October has stretched them even wider.

¹ At the time of the *Cardizem* litigation, the 180-day exclusivity period deprived the FDA of the power to approve a second Abbreviated New Drug Application (ANDA) filing until 180 days after the first filer's initiation of commercial marketing or a court determination of invalidity or non-infringement in the litigation between the first ANDA filer and the pioneer drug manufacturer. Thus, a settlement between the first ANDA filer and the pioneer drug company created a bottleneck because it removed the opportunity for either commercial marketing or the requisite court determination.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, removed this bottleneck for filings made after December 2003. Under this law, once the pioneer drug manufacturer and the first ANDA challenger have had 30 months to resolve the infringement question in court, if a later ANDA filer wins a favorable court decision of non-infringement or enters into a court-approved settlement agreement with the pioneer drug maker, that decision or settlement triggers a forfeiture of the first ANDA filer's 180-day exclusivity period after a 75-day waiting period. The second ANDA challenger does not get the benefit of a 180-day exclusivity period.

Congressional response to this situation has been muted. While at least one proposed bill would outlaw reverse payments, it has languished in committee and does not appear to be gathering momentum.


The moral: A carefully crafted reverse-payment settlement agreement with a generic drug maker is likely to pass muster under the antitrust laws, at least outside the Sixth Circuit. 

Figure IV
Breakdown of Final Settlements with First-Filers by Restriction and Compensation

