Again, the FTC Talks Tough on Protecting Introduction of Generic Drugs

Reverse payments are denounced but rarely litigated

By Thomas Carey, Partner

In a report issued May 21, 2008, the Federal Trade Commission has documented – and sternly criticized – payments made by pharmaceutical companies to induce generic-drug makers to stay off the market. It has done little, however, to back up its rhetoric with action.

Under the Hatch-Waxman Act, a generic-drug maker may submit an abbreviated new drug applications (ANDA) that avoids the lengthy drug trials that the pioneer drug maker (whose products have patent protection) must conduct.

But the generic maker faces risk: If the pioneer's patents remain in effect, it can sue for infringement before the generic drug is actually made or sold. As an incentive to induce generic-drug makers to run this gauntlet of patent infringement litigation, the first generic maker to file an ANDA for a particular drug is eligible, if it succeeds in the patent litigation, for a 180-day period of marketing exclusivity.

ANDA litigation is often settled on terms that call for payments to the generic-drug maker and a delay in the introduction of the generic drug. These "reverse payment" settlements are often accompanied by pious rationales that try to overcome the suspicion that the generic drug maker has been paid off to keep out of the market.

No matter how the arrangement is dressed up, the FTC and some federal courts find this practice repugnant to the antitrust laws. See Cardizem, 332 F.3d 896 (6th Circuit 2003) (*per se* antitrust violation found). More recent cases have not agreed with this position, however. See Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005) (not every payment from patent-holder is a sham to delay generic entry). This has left the FTC with a spotty litigation record and an apparent unwillingness to launch more challenges to these settlements. Its recent complaint against Cephalon Inc. is the sole such suit filed in recent years.

Under a 2003 reform to the federal Food, Drug and Cosmetic Act, drug companies must submit copies of their ANDA settlement agreements to the FTC. The agency prepares an annual report summarizing the settlements. In its latest report, issued on May 21, the FTC cites 45 settlements in FY 2007, of which 33 were final settlements. Of the 33 final settlements, 16 were with "first filers," generic makers who were in line for the 180-day period of exclusivity.

The FTC report is noteworthy for the industry trends that it spotlights. The FTC's Figure IV (reprinted below), shows that:

- For the first time since the FTC began issuing these reports, **all settlements** with ANDA first filers **restricted the entry of the generic product**
- **Compensation to generics** continues to be a common feature of these settlements
- Pioneer drug companies increasingly aim to **delay generic introduction** while not compensating the generic maker at all
- Generic makers who are not the first to file are **much less likely to receive any compensation.**

The FTC report indicates that, in 9 of the 11 cases involving compensation to first-filers, the compensation took the form of the pioneer agreeing not to launch an "authorized generic" for a period of time.

In the accompanying press release, FTC commissioners lambasted these settlements. Commissioner Jon Leibowitz said, "As our report today sadly demonstrates, pay-for-delay settlements continue to proliferate. That's good news for the pharmaceutical industry, which will make windfall profits on these deals. But it's bad news for consumers, who will be left footing the bill." FTC Chairman William E. Kovacic said: "The Commission remains committed to ensuring that brand and generic companies do not use such settlements as a way to deny consumers the benefits of competition."

How committed the FTC really is remains to be seen. Reverse payment settlements (the red bar in Figure IV below) have shown hardy growth, but **the FTC has pursued only one pioneer drug company of the 22 that seem to have strayed over the bright line that the FTC has drawn.**