Antitrust

FTC, California Say Companies Delayed Generic Competition of AndroGel Drug

Two generic drug manufacturers colluded with a branded drugmaker, which paid both firms to delay generic competition to the testosterone-replacement drug AndroGel (testosterone gel 1 percent), according to a complaint filed by the Federal Trade Commission and the California attorney general Jan. 27 (FTC v. Watson Pharmaceuticals Inc., C.D. Cal., No. CV-09-00598, 1/27/09).

Watson Pharmaceuticals Inc. and Par Pharmaceutical Companies Inc., through its partner Paddock Laboratories, sought regulatory approval from the Food and Drug Administration to market generic versions of AndroGel. In their FDA filings, both companies certified that their products did not infringe the only patent that Solvay Pharmaceuticals Inc. had relating to AndroGel, which generates revenues in excess of $400 million, and that the patent was invalid.

FTC and California charged that the brand-name drug company, Solvay, violated FTC Act § 5, Sherman Act § 2, the Cartwright Act, and the California Unfair Competition Act by agreeing to pay the generic companies to abandon their patent challenges and to refrain from bringing a generic AndroGel product to market until 2015. The FTC and the state filed their complaint in U.S. District Court for the Central District of California. FTC announced the filing Feb. 2.

The governments seek injunctive relief to promote competition between Solvay and the generic drug makers that had sought to introduce generic versions of AndroGel, which is a prescription drug. AndroGel, Solvay’s second-highest-selling pharmaceutical product, is a pharmaceutical gel containing synthetic testosterone. It is approved for testosterone replacement therapy in men with low testosterone levels, which often are associated with advancing age, certain cancers, and HIV/AIDS.

Manufacturers Say Settlement Facilitated Competition. In a statement issued Feb. 2 Solvay said it was “disappointed but not discouraged by [the decision to file the complaint] and intends to use all necessary means to defend the validity of these settlements.” The company asserted that its AndroGel patent was valid, and that the settlements with the generic companies “were completely lawful, facilitated both wider distribution of AndroGel and earlier generic competition for AndroGel than if the company had enforced its patent rights fully, and brought an end to expensive and burdensome patent litigation.”

In a press release issued the same day, Watson said the agreement with Solvay fully complied with “the spirit and letter of the antitrust and consumer protection laws” and conferred benefits on consumers by providing for the entry of a generic version of AndroGel five years prior to the expiration of patents on the drug. Par said in a press release also issued on Feb. 2 that the patent settlement agreement was approved by the U.S. District Court for the Northern District of Georgia in 2006.

Headed for Supreme Court Review? FTC’s challenge to the AndroGel reverse-payment patent litigation settlement may be its latest attempt to draw Supreme Court review of the issue, antitrust law attorneys told BNA.

Joel M. Cohen, a partner in Davis Polk & Wardwell’s New York office, told BNA Feb. 4, “There may have been perfectly sensible reasons for bringing the AndroGel case in California [with the California attorney general] rather than in Georgia, where the underlying patent case is pending, but it certainly would not be surprising if the FTC is seeking to find a more favorable forum than the Eleventh Circuit for this case and is looking to create a Circuit split that would increase the likelihood of Supreme Court review.”
Georgia is part of the U.S. Court of Appeals for the Eleventh Circuit, where the appeals court has upheld the legality of such drug patent settlement agreements in Valley Drug Co. v. Geneva Pharmaceuticals Inc., 344 F.3d 1294 (11th Cir. 2003) and Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005). In the Schering-Plough case, the FTC itself lost its argument that Schering-Plough Corp. and Upshersmith Laboratories Inc.’s patent litigation settlement involving the drug K-Dur 20 was anticompetitive (3 PLIR 243 3/11/05).

The FTC has been actively seeking to bring a case in district court to resolve the split in the circuits on reverse payments (6 PLIR 1199 10/24/08). California is in the Ninth Circuit.

Cohen successfully represented AstraZeneca in another reverse payments case, In re Tamoxifen Citrate Antitrust Litigation, in which plaintiffs asserted that the settlement of a patent infringement suit involving a generic drug manufacturer violated federal and state antitrust laws (3 PLIR 1169 11/11/05). Cohen argued the case successfully in the district court and in the U.S. Court of Appeals for the Second Circuit.

James M. Burns, an antitrust partner with the Washington office of Williams Mullen, told BNA, “It can certainly . . . be suggested that the decision to avoid the 11th Circuit, where the FTC failed on a similar claim in the Schering-Plough litigation, was intentional.”

Reverse payment settlements, which often include payments from brand-name drug manufacturers to generic drug manufacturers in an effort to delay competition from generic drugs, have been challenged as anticompetitive by FTC and by drug payers, such as employers or benefit funds, in the courts. Courts—including appeals courts in the Second, Eleventh, and Federal Circuits—generally have upheld such agreements.

“They [the FTC] have made it clear that they disagree with those decisions, and presumably also disagree with the Federal Circuit’s recent decision in Cipro [In re Ciprofloxacin Hydrochloride Antitrust Litigation 6 PLIR 1199 10/24/08]. So . . . I do think that they will continue to test the waters,” Cohen said.

The change in administration may have given added impetus to the FTC’s action, Burns said.

FTC’s challenge to the AndroGel settlement “is not surprising, given that, on the campaign trail, presidential candidate Obama specifically criticized the Bush Administration for failing to bring monopolization claims.” Burns said. “Only weeks into his administration, this case provides an opportunity to achieve that result and he has taken it.”

“Moreover,” Burns said, “candidate Obama also specifically indicated that he would challenge pharmaceutical company patent settlements, so this case is almost a ‘perfect storm’ of opportunity for President Obama to fulfill some campaign promises.”

**FTC Enforcement History.** FTC’s latest enforcement action follows a similar complaint the commission filed against Cephalon Inc. in 2008 (6 PLIR 201, 2/22/08). In February 2008, FTC charged Cephalon with anticompetitive conduct over agreements it entered into with four generic drug companies that would block the sale of lower-cost generic versions of its popular narcolepsy treatment, Provigil (modafinil), until at least 2012.

Moreover, the FTC has made clear that it believes reverse payments are a continuing problem. In May 2008, the FTC’s Bureau of Competition issued a report on drug patent litigation settlement agreements in which it concluded that brand-name drug manufacturers are continuing to pay generic drug manufacturers in an effort to delay competition from generic drugs.

The report found that nearly half of all drug patent litigation settlement agreements filed with the agency in fiscal year 2007 (ending Sept. 30, 2007) involved payment from brand-name drug companies to generic firms (6 PLIR 629, 5/30/08).

**Hatch-Waxman Law.** In 1984, Congress passed the Hatch-Waxman Act to encourage generic manufacturers to challenge patents that either are invalid or narrow enough to be designed around. Studies have shown that generic manufacturers have prevailed in the majority of patent challenges, the FTC said in announcing the action against Solvay and others. The resulting generic entry, which often occurs well before patent expiration, leads to significantly lower prices and huge savings for patients and the health care system, the commission said.

In May 2003, Watson and Paddock, which partnered with Par, each filed applications for FDA approval to market generic versions of AndroGel. Solvay’s patent on Androgel had been issued in January 2003, with an expiration date of August 2020. By early 2006, Watson had received final approval to market its generic product. According to the complaint, it was well-known that if Watson or Par were to enter with cheaper generic versions of AndroGel, Solvay’s AndroGel sales would plummet, and consumers would benefit from the lower prices.

The complaint alleges that Solvay, realizing the devastating effect generic entry would have on sales of AndroGel, acted unlawfully to eliminate this threat. Solvay paid Watson and Par a share of its AndroGel profits to abandon their patent challenges and agree to delay generic entry until 2015. As a result, the complaint contends, the defendants now are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing. The defendants’ agreements to eliminate generic AndroGel competition constitute unfair methods of competition violative of FTC Act § 5, according to the complaint.

The FTC seeks a declaratory judgment that Solvay’s agreements with Watson and with Par and Paddock violate Section 5, and asks for injunctive relief to restore competitive conditions and a prohibition on the defendants engaging in similar or related conduct in the future.

David P. Wales, acting director of the FTC’s Bureau of Competition, said in a statement, “At a time of escalating health care costs, these unlawful agreements deprive patients the benefit of competition between branded and generic pharmaceuticals and ultimately cost consumers hundreds of millions of dollars a year.”

This case, he emphasized, “reaffirms the commission’s commitment to protect American consumers from artificially high prescription drug prices that result when branded and generic pharmaceutical companies decide to collude rather than compete.” Wales predicted that the evidence “will show that Watson and Par agreed to defer their generic entry for nine years, not out of respect for Solvay’s patent, but due to the size of Solvay’s payments to them.”
The commission vote authorizing its staff to file the complaint was 4-0, with Commissioner Jon Leibowitz issuing a separate concurring statement.

Leibowitz asserted: “This is yet another example of pharmaceutical companies turning competition on its head.”

**California AG Statement.** California Attorney General Edmund G. Brown Jr. (D) characterized the defendants’ conduct as a conspiracy to monopolize the sale of the testosterone supplement.

“The companies plotted to keep cheap generic drugs off the market, costing consumers millions,” Brown said in a Feb. 2 statement. “This was a predatory move pure and simple, increasing drug company profits at the expense of critically ill patients.”

Deputy Attorney General Cheryl Johnson described the complaint as a joint action by federal and California regulators.

The complaint initially was lodged under seal Jan. 20 with portions redacted from the publicly filed version in order to comply with federal regulations, Johnson explained.

In a related development, Sens. Herb Kohl (D-Wis.) and Chuck Grassley (R-Iowa) introduced a bill Feb. 3 (S. 369) to prohibit brand-name drug manufacturers from paying generic companies to keep generic versions of their drugs off the market (see related item in the Federal News section).