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FTC Loses Suit against Drug Maker over 2006 Acquisition

Jeffrey May (Wolters Kluwer) · Friday, September 17th, 2010

The Federal Trade Commission recently suffered a significant setback in its merger enforcement efforts when the federal district court in Minneapolis rejected an action brought by the agency along with the State of Minnesota against global pharmaceutical company Lundbeck, Inc.

In December 2008, the FTC and Minnesota filed a complaint against Ovation Pharmaceuticals, Inc., which was later acquired by Lundbeck. The suit challenged the company's 2006 acquisition of the rights to market NeoProfen (injectable ibuprofen)—a drug used to treat premature infants with a heart condition known as patent ductus arteriosus (PDA).

The FTC alleged violations of the FTC Act and Sec. 7 of the Clayton Act and sought equitable relief, including divestiture and disgorgement of unlawfully obtained profits from the sales of Indocin and NeoProfen. The state alleged violations of the Sherman Act, the Minnesota Antitrust Law of 1971, and the Clayton Act.

When Ovation acquired NeoProfen, it already held the rights to Indocin IV (injectable indomethacin)—the only drug available to treat PDA in the United States. NeoProfen had not yet been approved by the Food and Drug Administration to treat PDA but was used in Europe to treat the disease.

According to the FTC, Ovation preserved its U.S. monopoly in drugs used to treat PDA by acquiring NeoProfen. In its press release announcing the action, the agency pointed to Ovation's pricing practices following the acquisition. The FTC said: "Ovation promptly raised the price of Indocin to nearly $500 per vial, and when it introduced NeoProfen, set the price at virtually the same level . . . Nearly three years later, Ovation continues to charge artificially high prices for both Indocin and NeoProfen."

Minnesota Attorney General Lori Swanson made similar assertions when announcing the state's claims. "Ovation acquired a monopoly over the only two drugs that treat this particular heart problem in premature babies, then it unfairly increased the cost by nearly 1,300%," Swanson said.

"Superficially Appealing" Claims

In finding for Lundbeck, the court said: "Although the FTC's and Minnesota's cases are superficially appealing—Lundbeck bought the rights to NeoProfen, Indocin IV's price went up, therefore Lundbeck must have done wrong—a considered evaluation of the evidence reveals that Lundbeck did not engage in the alleged statutory violations."

Relevant Product Market

The court rejected the claims based on the plaintiffs' failure to define a relevant product market that included both Indocin and NeoProfen. In its findings of fact, the court noted that Indocin IV and NeoProfen were not bioequivalent compounds and their FDA approved labels were not identical. Moreover, their side effects differed.

The court found that, although hospitals primarily purchased the drugs, neonatologists were the relevant consumers. It was neonatologists who ultimately decided which drug, if any, to use to treat PDA. The neonatologists testified that a price differential would not lead them to switch from one drug to the other for treating PDA.

An economist retained by the FTC testified that Indocin IV and NeoProfen were in the same market based on the functional suitability of the drugs, data regarding hospitals' purchases of the drugs, and the drug maker's documents referring to a market that consisted of the drugs. However, the economist's testimony was not persuasive, according to the court. The economist did not offer any opinion as to the cross-elasticity of demand between Indocin IV and NeoProfen and discounted testimony from the neonatologists and pharmacists regarding their reasons for choosing between the two drugs, it was noted. The drug maker's economist, on the other hand, testified that the cross-elasticity of demand between Indocin IV and NeoProfen was very low.

Monopoly Power

Having failed to demonstrate that the market was FDA-approved drugs to treat PDA in the United States, the FTC and Minnesota did not establish that Lundbeck possessed monopoly power in such a market and willfully acquired or maintained monopoly power that market. Thus, monopoly claims under the FTC Act, the Sherman Act, and Minnesota state law failed. For the same reason, the Clayton Act claims also had to fail.

The court's decision follows a bench trial in December 2009. The parties made closing arguments in March 2010. The matter went to trial after the court denied Lundbeck's motions for summary judgment in July 2009 ((CCH) 2009-2 Trade Cases ¶76,682). At that time, the court—viewing the record in the light most favorable to the FTC and Minnesota—held that a reasonable finder of fact could conclude that Lundbeck violated state and federal antitrust law.

The court's findings of fact, conclusions of law, and order dismissing the complaint were filed under seal on August 31. Last week, the parties consented to the court's public filing of the documents.

The decision in *FTC v Lundbeck, Inc.*, Civil No. 08-6379, will appear at **(CCH) 2010-2 Trade Cases ¶77,160**.

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