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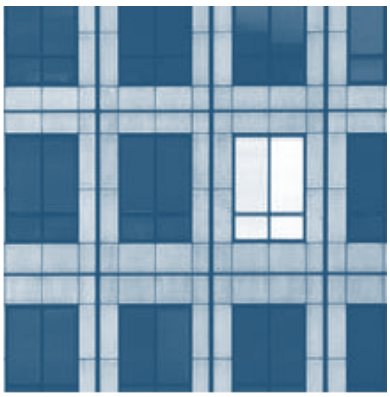
On the Subject



Antitrust & Competition

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The Federal District Court in Minnesota recently decided Ovation Pharmaceutical did not violate federal or state antitrust laws when it acquired Indocin IV and NeoProfen, the only two drugs approved for treatment of a specific heart condition that primarily affects premature babies, because the challengers failed to establish that the drugs were in the same product market. The decision raises significant issues to consider when evaluating antitrust risks in future transactions.

Market Definition Spurs District Court's Decision Denying Product Ownership Challenge

The U.S. District Court of the Federal District in Minnesota held that Ovation Pharmaceutical Inc. did not violate federal or state antitrust laws when it acquired Indocin IV and NeoProfen, the only two drugs approved for treatment of patent ductus arteriosus (PDA), a specific heart condition that primarily affects low-birth-weight, customarily premature babies (*FTC v. Lundbeck, Inc*., No. 08-6379 and *Minnesota v. Lundbeck, Inc*., No. 08-6381 [D. Minn. August 31, 2010]). The U.S. Federal Trade Commission (FTC) and Minnesota lost their challenges because they failed to establish that NeoProfen and Indocin are in the same product market. The district court concluded NeoProfen and Indocin are not in the same product market because there is low cross-elasticity of demand between the two drugs. The opinion, while interesting, is likely to be appealed and the U.S. Court of Appeals of the Eighth Circuit can revisit the controversial findings of the district court.

Background

Approved by the U.S. Food and Drug Administration (FDA), Indocin and NeoProfen are pediatric heart drugs used to treat PDA, a potentially fatal neonatal heart condition in which the blood vessel that connects the aorta and pulmonary artery fails to close on its own. Surgery or pharmaceutical drugs are both treatment options for PDA, however, neonatologists prefer to use drugs as a first-line treatment due to the health risks and costs associated with surgery.

Ovation acquired the exclusive rights to Indocin from Merck & Co. in 2005. At the time Indocin was the only drug approved by the FDA to treat PDA. Less than a year later, Ovation acquired the rights to NeoProfen from Abbott Laboratories Inc. in a transaction that fell below Hart-Scott-Rodino reporting thresholds, thus escaping pre-closing review by the antitrust agencies. The FDA approved NeoProfen as a treatment for PDA in 2006. Shortly after acquiring NeoProfen, Ovation increased the prices charged to hospitals for Indocin and NeoProfen by as much as 1300 percent.

In December 2008 the FTC and the State of Minnesota filed a complaint against Ovation Pharmaceuticals (now Lundbeck Inc., the successor in interest to Ovation Pharmaceuticals) alleging the company violated antitrust laws by acquiring the rights to NeoProfen in violation of FTC Act Section 5, completed an acquisition that substantially lessened competition in violation of Clayton Act Section 7 and willfully maintained its monopoly power in violation of Sherman Act Section 2. The FTC asked the district court to compel the divestiture of NeoProfen and disgorge all excessive profits for Ovation.

FTC v. Lundbeck Decision

The FTC and Minnesota offered strong evidence indicating that NeoProfen and Indocin were, at the time, the only two FDA-approved drugs to treat PDA. The district court accepted as fact the following:

- The FDA labels for NeoProfen and Indocin both state that the drugs are approved to close significant PDA in premature infants.
- Clinical studies reveal that the active ingredients for NeoProfen and Indocin are "equally efficacious."
- Ovation anticipated that NeoProfen would capture significant market share at the expense of Indocin. Ovation's internal documents predicted the acquisition of NeoProfen would

enable Ovation to "cannibalize our Indocin IV sales in a controlled manner, retain sales for both products and continue to grow total company sales in the PDA market with an exclusivity protected product."

- Many doctors switched from Indocin to NeoProfen, once it became available, to treat PDA in part because Ovation took steps to convert accounts from Indocin (which faced generic entry) to NeoProfen.

- NeoProfen was priced competitively with Indocin.

Despite this evidence, Judge Joan N. Erikson credited the testimony of physicians and Ovation's expert witness as more compelling. Judge Erikson found that neonatologists—not the hospitals that actually purchase the drugs—are the relevant consumers of Indocin and NeoProfen because they ultimately determine which drug is purchased and used to treat PDA. Neonatologists testified that their selection between Indocin or NeoProfen is contingent on the presence or lack of long-term clinical studies, side effect differences or safety perceptions, but, notably, not on price differences. Neonatologists prescribe the drug they perceive is best for the patient without regard to the respective drug costs. Ovation's expert economic witness testified that the cross-price elasticity between NeoProfen and Indocin is very low. The FTC's expert witness was unable to rebut this testimony with any cross-elasticity analysis. Judge Erikson concluded that because there is a low cross-elasticity of demand between NeoProfen and Indocin, the two drugs are not in the same product market.

The district court cited several other factors to help bolster its decision. Indocin and NeoProfen are not bioequivalent compounds and their FDA-approved labels are not identical. Judge Erikson de-emphasized the 1300-percent Indocin price increases because Ovation's internal documents showed Merck had priced Indocin well below a reasonable commercial price for the product. Ovation's chief commercial officer proposed, and Ovation planned, substantial price increases for Indocin prior to any knowledge of a potential NeoProfen acquisition, so the price increase resulted not from a merger to monopoly, as the same price would have been charged had Ovation not acquired Indocin.

The court dismissed the FTC's case after concluding it had not met its burden of proving the two drugs were in the same relevant market. The FTC has not yet announced whether it will appeal the decision.

Significance

The district court's opinion raises some significant issues parties may want to consider when evaluating antitrust risks in future transactions. First, on the issue of how to define a relevant market, the court apparently found dispositive the low cross-elasticity of demand, based largely on the physician testimony that a change in price would not affect their decision to prescribe either of the drugs, as well as expert economic testimony. This was so even though the drugs were approved for and could treat the same condition. This opinion may be used in support of arguments that products that appear very similar may, in fact, not compete significantly against each other. Economic or econometric analysis may demonstrate that facially similar products are in separate markets.

Second, the district court's decision was announced just after the U.S. Department of Justice and FTC released the revised Horizontal Merger Guidelines on August 19, 2010, which explain that market definition is not essential to evaluating a merger's competitive effects. The revised Horizontal Merger Guidelines state: "The Agencies' analysis need not start with market definition." This position represents a departure from the antitrust agencies' prior guidelines and also departs from judicial precedent that has placed significant weight on market definition in merger challenges. *FTC v Lundbeck* demonstrates that despite the new guidelines courts likely will continue to insist that the government satisfy its burden of defining the relevant market to prevail on a merger challenge.

Third, this case is another indication that merger analysis is fact-specific, and the determination whether any particular transaction may violate federal or state antitrust laws will depend upon the facts and economics specific to the products and markets relevant to the transaction

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