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News from our Antitrust & Trade Regulation Group

FTC Loses Lundbeck Appeal, Opening Door for More Aggressive Pharmaceutical Merger & Acquisition Activity

In the first-ever appellate antitrust decision dealing with a pharmaceutical industry merger, *Federal Trade Commission v. Lundbeck, Inc.*, the Eighth Circuit recently affirmed a finding that the Federal Trade Commission ("FTC") failed to prove that two drugs were in the same relevant market, reasoning that doctors prescribe the drugs based on their effectiveness and side-effect profile and pay no attention to price.

The decision—in the face of evidence that Lundbeck raised the price of one drug thirteen-fold after the acquisition—may open the door to companies doing deals that would previously have been sure to draw an FTC challenge.

It is rare that mergers are challenged in court by the FTC or Department of Justice and even rarer for those challenges to make it to a court of appeals. Most agency challenges are resolved through consent decrees or by the companies abandoning their proposed transaction. That makes the *Lundbeck* decision, not long after the FTC lost its court challenge to LabCorp's acquisition of Westcliff Laboratories (involving clinical labs), particularly significant for future mergers.

The issues in *FTC v. Lundbeck*

The FTC, together with the Minnesota Attorney General, sued Ovation Pharmaceuticals, Inc. (now Lundbeck, Inc.) in federal court in Minnesota in December 2008, challenging the company's January 2006 acquisition of the drug NeoProfen from Abbott Laboratories. The FTC asserted that NeoProfen was the only competitor to Ovation's Indocin IV, used for the treatment of patent ductus arteriosus ("PDA"), a serious and potentially deadly congenital heart defect affecting babies born prematurely.

Ovation had acquired the rights to Indocin IV in August 2005 from Merck & Co., and, according to the FTC, expected that NeoProfen, which was then awaiting regulatory approval, would take a substantial portion of sales from Indocin IV. Merck had been charging $77.77 per treatment, Ovation immediately raised the price, and after acquiring the rights to NeoProfen, raised the price thirteen-fold. By 2008, the price of Indocin IV was $1614.44 and the price of NeoProfen was $1522.50 per treatment.

The FTC seemed to think that the magnitude of price increases involving two drugs capable of treating the same condition was sufficient for it to prevail in court. When the FTC filed suit, then-Commissioner (now Chairman) Leibowitz wrote: "Ovation's profiteering on the backs of critically ill premature babies is not only immoral, it is illegal. Ovation's behavior is a stark reminder of why America desperately needs health care reform and why vigorous antitrust enforcement is [still] relevant today."

The FTC alleged a relevant market of drugs approved to treat PDA, asserting that the two drugs (i) were intravenous formulations of non-prescription drugs; (ii) both utilized the same mechanism of action; and (iii) some physicians and hospitals considered the two drugs reasonable substitutes, using one of the two exclusively.

In August 2010, after a bench trial, the district court dismissed the FTC's case. The court relied on the testimony of neonatologists, who said that they based treatment decisions solely on perceived clinical advantages of the two drugs "without regard to price," and pharmacists who testified that the final decision as to which drug was prescribed was that of the neonatologist and not the hospital. The court concluded that there was low cross-elasticity of demand between the two drugs, and thus they are not in the same market.

While the agencies' new *Horizontal Merger Guidelines* downplay market definition, suggesting a price increase is sufficient alone to establish anticompetitive effects, the relevant market was the key issue on appeal.

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The Eighth Circuit noted that determining the relevant market is an issue for the trier of fact and used a deferential "clearly erroneous" standard to review the district court's decision. In doing so, the Eighth Circuit rejected the FTC's argument that the district court made an error of law by applying the incorrect legal standard by failing to examine all the pertinent factors to determining a relevant market.

The Eighth Circuit emphasized that "the outer boundaries of a product market can be identified by the reasonable interchangeability, or cross-elasticity of demand, between the product and possible substitutes," and that determining a market "requires identifying the choices available to consumers, focusing on 'whether consumers will shift from one product to the other in response to changes in their relative cost.'"

On appeal, the FTC attacked the district court for relying on the consumer preferences expressed by physicians. The FTC argued that the hospitals are the consumers and would switch based on price differences. The FTC also argued that the district court ignored the fact that the two drugs were practicable alternatives, emphasizing that the drugs were functionally similar products. The Eighth Circuit, however, noted that similar products may be in separate product markets, depending on the facts of the case, and deferred to the trial court's reliance on the doctors' testimony as indicating there was low cross-elasticity. The FTC also attacked the district court for failing to credit Lundbeck's internal documents, which the FTC believed showed that Lundbeck considered the two drugs competitors. The Eighth Circuit, though, found that those documents could be interpreted in more than one way, and that the district court's view was not unreasonable.

A concurring judge suggested that the trial court's reliance on the physicians seemed odd, since "there [was] no real dispute that (1) both drugs are effective when used to treat the illness about which the doctors testified and (2) internal records from the defendant raise an odor of predation." Still, the judge concluded that "the standard of review carries the day" and deferred to the district court.

Implications

The Federal Trade Commission has closely scrutinized mergers in the pharmaceutical industry for the last 20 years. It has entered consent decrees requiring divestitures and licenses in more than 40 matters, while a couple of transactions have been abandoned in the face of threatened challenges.

FTC v. Lundbeck is the first merger challenge in the industry in which the agency has gone to court. The outcome is a significant loss for the government.

Several points should be noted.

First, despite the new, more flexible merger analysis set forth in the government's *Horizontal Merger Guidelines* released last August, the courts are continuing to focus on defining relevant markets and measuring market shares. The agencies may believe that concentration is only "one useful indicator" of likely competitive effects but they are unlikely to prevail in court if they cannot offer evidence to support an alleged market definition.

Second, the case highlights the fact that despite inroads of managed care, purchase decisions in the pharmaceutical industry are still often made without considering price. Thirty five years ago, one court recognized that "[p]erhaps in the long run there will be some massive receptivity" to cost-conscious drug therapy that will dramatically alter the prescribing habits of physicians. However, in the interim, courts must define the market on the basis of consumer-physician practices, "whether their practices are rational, irrational, or unnecessarily costly."

Third, the decision highlights several issues critical to market definition in the pharmaceutical industry:

- one must consider approved indications, mechanisms of action, chemical formulations, dosage forms, and strength and frequency of dosage, but each case is fact specific; there is no simple formula to defining markets;
- one must consider the role of patients, physicians, pharmacists, hospitals, managed care providers, and insurers—all of which may play some role in purchase decisions—in defining relevant markets.

Fourth, the case highlights the tendency of the FTC to focus on company documents, while courts often find other evidence persuasive, and recognize that documents may have multiple interpretations.

Though the FTC will no doubt continue to carefully review mergers in the pharmaceutical, biotech, and medical device industries, moving forward, parties to mergers may be able to point to *Lundbeck* to pave the way for transactions that the FTC would otherwise have challenged.