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FTC loses Lundbeck drug acquisition challenge

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Author

Robert F Leibenluft

In November 2010 the Federal Trade Commission (FTC) appealed to the Eighth Circuit Court of Appeals a decision of the US District Court for the District of Minnesota to dismiss a challenge brought by the FTC and the state of Minnesota to the acquisition by Lundbeck, Inc (previously known as Ovation Pharmaceuticals) from Abbott Laboratories of the US rights in NeoProfen. The court had ruled that the acquisition did not violate the Clayton Act because NeoProfen and Lundbeck's Indocin IV were not in the same product market, even though both drugs are approved by the Food and Drug Administration to treat patent ductus arteriosus (PDA), a heart condition affecting premature babies.

In August 2005 Lundbeck acquired from Merck the exclusive worldwide rights to Indocin IV, and soon thereafter raised its price from $78 to $1,500 for each three-vial course of treatment. Lundbeck acquired NeoProfen from Abbott in January 2006, and when the drug was approved by the Food and Drug Administration for PDA in July 2006, Lundbeck set its price at $1,450 for a three-vial package, about three times the price that Abbott had forecast. When the FTC challenged the NeoProfen acquisition in December 2008, it highlighted the large price increases for a treatment used for such critically ill patients. FTC Chairman Jon Leibowitz stated that "Ovation's profiteering on the backs of critically ill premature babies is not only immoral, it is illegal". The matter drew particular attention because FTC Commissioner Tom Rosch (joined by Leibowitz) suggested that Lundbeck's initial acquisition of Indocin IV was actionable under the Clayton Act — even though at that time Lundbeck did not own a competing product. Their theory was that Merck had not raised prices of Indocin IV out of concern that it would harm its reputation and the sale of other Merck products, and that because Lundbeck lacked such concerns, its acquisition of Indocin IV enabled it to charge monopoly prices, and thus could be subject to challenge.

Ultimately, however, the FTC and the Minnesota attorney general challenged the NeoProfen acquisition only under a more conventional theory that Lundbeck, having already acquired NeoProfen, was eliminating its principal competitor in the sale of Food and Drug Administration-approved drugs to treat PDA. The FTC sought not only divestiture, but also disgorgement of unlawful profits. The complaint pointed to the large price increase for Indocin IV and NeoProfen as evidence of competitive effects.

Defendants in merger cases often assert that the relevant product market is much broader than the plaintiffs allege, and therefore post-merger they will continue to face many other competitors. In this case, Lundbeck took the opposite position, and argued that notwithstanding the fact that both Indocin and NeoProfen are used to treat PDA, there is little real-world competition between the two products, and they are not in the same product market. The district court judge agreed. At the heart of her conclusion was her finding that the key decision makers as to which drug is purchased are not the hospitals that buy the drugs, but rather the physicians who prescribe them. The judge found that neonatologists pick Indocin IV or NeoProfen based on perceived differences in the drugs' safety, side effects or the presence or lack of long-term studies. Because these physicians would not switch their prescription from one drug to another in response to changes in relative costs, she concluded that the two products were not in the same product market. In reaching this conclusion the judge noted, but ultimately rejected, the FTC's economist testimony that relied on Lundbeck's documents and the role of hospital formulary committees in making purchasing decisions.

Recent revisions to the Horizontal Merger Guidelines downplay the role of market definition and highlight the importance of competitive effects evidence (for further details please see "New merger guidelines emphasise flexibility"). However, this decision demonstrates that market definition still plays a crucial role in merger litigation. The case is particularly important for the pharmaceutical industry since it highlights the importance of properly identifying the 'customers' when considering market definition,

and in healthcare this enquiry can be complicated because patients, doctors, hospitals and health plans may all have a role in the purchasing decision. This will be an important case to watch as the appeal is heard in the Eighth Circuit.

For further information on this topic please contact Robert F Leibenluft at Hogan Lovells US LLP by telephone (+1 202 637 5600), fax (+1 202 637 5910) or email (robert.leibenluft@hoganlovells.com).