



## Federal Trade Commission Protecting America's Consumers

December 16, 2008

### FTC Sues Ovation Pharmaceuticals for Illegally Acquiring Drug Used to Treat Premature Babies with Life-Threatening Heart Condition

#### Unlawful Acquisition Resulted in Nearly 1,300 Percent Price Hike; Agency Asks Court to Require Company to Give Up Unlawful Profits

The Federal Trade Commission today filed a complaint in federal district court challenging Ovation Pharmaceuticals, Inc.'s January 2006 acquisition of the drug NeoProfen, which eliminated its only competitor for the treatment of a serious and potentially deadly congenital heart defect affecting more than 30,000 babies born prematurely each year in the United States. When it acquired NeoProfen, Ovation already held the rights to Indocin I.V., the only other drug used to treat this serious condition. After ensuring that it would not face competition from NeoProfen, Ovation promptly raised the price of Indocin nearly 1,300 percent, from \$36 to nearly \$500 a vial. When it launched NeoProfen in July 2006, Ovation set a similarly inflated price.

"By acquiring its only competitor in the treatment of a serious heart condition affecting premature babies, Ovation has been able to charge dramatically higher prices for its drugs," said Acting FTC Bureau of Competition Director David P. Wales. "While Ovation is profiting from its illegal acquisition, hospitals and ultimately consumers and American taxpayers are forced to pay millions of dollars a year more for these life-saving medications. The action taken today is intended to restore the lost competition and require Ovation to give up its unlawful profits."

The FTC filed its complaint in the U.S. District Court for the District of Minnesota.

Indocin and NeoProfen are the only two pharmaceutical treatments sold in the U.S. for a condition known as patent ductus arteriosus, a disorder that primarily affects very low birth-weight premature infants. In babies with this condition, the blood vessel connecting two major arteries of the heart fails to close on its own soon after birth. Patent ductus arteriosus can be fatal if not treated. The only treatment other than drug therapy is surgery, which carries the risk of serious complications and costs far more than treatment with either Indocin or NeoProfen.

Ovation, a privately owned corporation based in Deerfield, Illinois, sells pharmaceuticals in more than 85 countries, including the United States. In August 2005, Ovation purchased the rights to Indocin from Merck. At that time, NeoProfen was awaiting regulatory approval by the Food and Drug Administration. According to the FTC's complaint, Ovation expected that NeoProfen, once approved, would take a substantial portion of sales from Indocin. To eliminate the threat that NeoProfen posed, the Commission charges, Ovation acquired the U.S. rights to NeoProfen from Abbott Laboratories in January 2006. The NeoProfen transaction fell below the regulatory threshold for reporting acquisitions to the federal antitrust authorities.

By acquiring NeoProfen, the complaint alleges, Ovation preserved its U.S. monopoly in drugs used to treat patent ductus arteriosus in premature babies. Following the acquisition, 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. Merck supplied Indocin to Ovation for a small fraction of the price Ovation charges. Nearly three years later, Ovation continues to charge artificially high prices for both Indocin and NeoProfen. The FDA approved a generic version of Indocin in July 2008, but to date it has not entered the market.

Because there are no other drugs available to treat patent ductus arteriosus, hospitals treating babies with this critical condition have no choice but to pay Ovation's monopoly price. And ultimately, the artificially high prices paid by hospitals are passed on to families, government programs such as Medicaid, and other public and private purchasers.

The Commission's complaint charges that Ovation's acquisition of NeoProfen substantially reduced competition in violation of Section 7 of the Clayton Act, and illegally maintained the company's monopoly of drug treatments for patent ductus arteriosus in violation of Section 5(a) of the FTC Act. The Commission is seeking equitable relief, including divestiture and disgorgement of unlawfully obtained profits from Ovation's sales of Indocin and NeoProfen.

The Commission vote approving the complaint was 4-0, with Commissioners Jon Leibowitz and J. Thomas Rosch issuing separate concurring statements. In his statement Commissioner 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 as relevant today as it was when the agency was created almost one hundred years ago in 1914."

Commissioner Rosch's concurring statement explains that like Commissioner Leibowitz, he would have also voted to challenge Ovation's earlier acquisition of Indocin. Commissioner Rosch wrote ". . . there is reason to believe that Merck's sale of Indocin to Ovation had the effect of enabling Ovation to exercise monopoly power in its pricing of Indocin . . . [and] had the effect of substituting Ovation, a firm that had an incentive to protect its ability to engage in monopoly pricing, for Merck, which lacked the same incentive." Commissioner Rosch added, ". . . it is hard to imagine a more compelling case for application of this legal theory."

**NOTE:** The Commission authorizes the filing of a complaint when it has "reason to believe" that the law has or is being violated, and it appears to the Commission that a proceeding is in the public interest. A complaint is not a finding or ruling that the defendants have actually violated the law.

**Copies** of the Commission's complaint will be available soon from the FTC's Web site at <http://www.ftc.gov> and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to [antitrust@ftc.gov](mailto:antitrust@ftc.gov), or write to the

Office of Policy and Coordination, Room 383, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave, N.W., Washington, DC 20580. To learn more about the Bureau of Competition, read "Competition Counts" at <http://www.ftc.gov/competitioncounts>.

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**Related Items:****[Federal Trade Commission, Plaintiff, v. Ovation Pharmaceuticals, Inc., Defendant](#)**

(United States District Court for the District of Minnesota)

FTC File No. 0810156

- [Concurring Statement](#) of Commissioner Leibowitz
- [Concurring Statement](#) of Commissioner Rosch

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