IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

FEDERAL TRADE COMMISSION 600 Pennsylvania Avenue, N.W. Washington, D.C. 20580 Plaintiff, v. LUNDBECK INC., Four Parkway North, Suite 200, Deerfield, IL 60015 Defendant.	08-cv-6379 (JNE/JJG)

AMENDED COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF, INCLUDING DISGORGEMENT OF UNLAWFUL MONOPOLY PROFITS

Plaintiff, the Federal Trade Commission (FTC), by its designated attorneys, petitions this Court, pursuant to Section 13(b)(2) of the Federal Trade Commission Act, 15 U.S.C. § 53(b)(2), for a permanent injunction and ancillary equitable relief against defendant, Lundbeck Inc., for Lundbeck's unlawful asset acquisition and exercise of monopoly power in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

NATURE OF THE CASE

1. This action challenges an anticompetitive acquisition that is forcing hospitals to pay monopoly prices for drugs used to treat premature babies born with a potentially life-threatening congenital heart defect known as patent ductus arteriosus

(PDA). Indocin and NeoProfen are the only two pharmaceutical treatments for PDA sold in the United States. Lundbeck – which was then named Ovation Pharmaceuticals, Inc. (Ovation) – purchased rights to Indocin in August 2005 and then acquired the U.S. rights to NeoProfen in January 2006.

2. At the time Ovation (now Lundbeck, and hereafter called Lundbeck) purchased the rights to Indocin, NeoProfen was awaiting approval by the Food and Drug Administration (FDA). Lundbeck expected that NeoProfen would take a substantial portion of sales from Indocin. To eliminate this competitive threat, Lundbeck acquired NeoProfen.

3. Once it acquired NeoProfen, Lundbeck immediately raised the price it charged for Indocin nearly 1,300 percent, from $36 to approximately $500 per vial. When Lundbeck launched NeoProfen in July 2006, it set a price of approximately $483 per vial, essentially matching Indocin's price. Lundbeck has maintained prices for the two PDA drugs at or above this level for more than two years.

4. The only alternative treatment for PDA is surgery, which carries a risk of serious complications and costs far more than treatment with drugs. As a result, hospitals have little choice but to pay Lundbeck's monopoly price for PDA drug therapy. The artificially high prices that hospitals are forced to pay ultimately raise costs for families, tax-supported programs such as Medicaid, and other public and private purchasers.

5. Lundbeck's acquisition of NeoProfen substantially reduced competition and illegally maintained Lundbeck's monopoly in drug treatments for PDA, depriving

consumers of the benefits of competition and the lower prices such competition would bring. As a result of its unlawful acquisition, Lundbeck has obtained and continues to obtain substantial ill-gotten gains.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

7. This Court has personal jurisdiction over Lundbeck pursuant to 15 U.S.C. § 53(b) in that Ovation has the requisite minimum constitutional contacts with the United States of America and the State of Minnesota.

8. Venue in this district is proper under Section 13(b)(2) of the FTC Act, 15 U.S.C. § 53(b)(2), and 28 U.S.C. § 1391(b), (c), and (d) because Lundbeck resides or transacts business in the District of Minnesota.

THE PARTIES

9. Plaintiff, the Federal Trade Commission, is an administrative agency of the United States, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 *et seq*., with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC has authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, which prohibits unfair methods of competition, and Section 7 of the Clayton Act, which prohibits acquisitions that may substantially lessen competition or tend to create a monopoly. The FTC is authorized under Section 13(b) of the FTC Act, 15

U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces.

10. Defendant, Lundbeck, successor in interest to Ovation, is a privately owned, for-profit Illinois corporation with its headquarters at Four Parkway North, Deerfield, Illinois, 60015. Lundbeck was established on or about March 19, 2009, as a result of the acquisition of Ovation by H. Lundbeck A/S, based in Denmark. Lundbeck sells pharmaceuticals in more than 85 countries, including the United States.

11. Lundbeck is, and at all relevant times has been, engaged in "commerce" as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12. Lundbeck's general business practices, its NeoProfen acquisition, and the unfair methods of competition alleged herein are acts "in or affecting commerce" within the meaning of Sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44 and 45.

12. Lundbeck is, and at all times relevant has been, a "corporation" within the meaning of Section 4 of the FTC Act, 15. U.S.C. § 44.

BACKGROUND

13. PDA is 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, the aorta and the pulmonary artery, fails to close on its own soon after birth. PDA can lead to fatal complications if not treated.

14. The preferred treatment for PDA is drug therapy. Surgery presents a risk of serious complications as well as much higher costs.

15. Hospitals purchase PDA drugs for use in neonatal intensive care units.

16. An estimated 30,000 cases of PDA are treated with drugs in the United States each year.

17. Indocin (indomethacin for injection) was approved by the FDA to treat PDA in infants in 1985. There are no unexpired patents on the product. Until April 2006, Indocin was the only FDA-approved drug for treatment of PDA.

18. In August 2005, Lundbeck purchased rights to Indocin from Merck & Co. Merck agreed to manufacture Indocin and supply it to Lundbeck.

19. Upon acquiring Indocin from Merck, Lundbeck raised the price of Indocin from approximately $26 to $36 per vial.

LUNDBECK ELIMINATES THE COMPETITIVE THREAT POSED BY NEOPROFEN

20. When it acquired Indocin, Lundbeck became the only seller of PDA drug treatment in the United States. But Lundbeck knew that it faced the threat of imminent entry from a new drug to treat PDA that was awaiting approval by the FDA, NeoProfen (ibuprofen lysine injectable). Lundbeck expected NeoProfen to take substantial sales from Indocin. Acquiring NeoProfen would eliminate this threat.

21. In January 2006, Lundbeck purchased the U.S. rights to NeoProfen from Abbott Laboratories, Inc. The size of the NeoProfen transaction fell below the regulatory threshold for reporting acquisitions to the federal antitrust agencies. The FDA approved NeoProfen for treatment of PDA in premature infants in April 2006.

LUNDBECK EXPLOITS ITS MONOPOLY POWER

22. Once Lundbeck acquired rights to NeoProfen in January 2006, thereby eliminating NeoProfen as a competitive threat, it promptly raised the price of Indocin nearly 1,300 percent, from approximately $36 to approximately $500 per vial.

23. The price at which Merck supplied Indocin to Lundbeck was a small fraction of the $36 per vial that Lundbeck had previously charged for Indocin.

24. When Lundbeck launched NeoProfen as its second PDA drug in July 2006, it set the price of NeoProfen at slightly below the price of Indocin.

25. Lundbeck has continued to charge prices for Indocin and NeoProfen at or above the level it set for those drugs in 2006.

THE MONOPOLIZED MARKET

26. The relevant line of commerce, or product market, in which to analyze the effects of Lundbeck's acquisition of NeoProfen is the sale of drugs approved by the FDA to treat PDA.

27. Indocin and NeoProfen are the only two FDA-approved PDA drugs available in the United States. Both products are intravenous formulations of non-prescription drugs (indomethacin and ibuprofen, respectively) and both work to close a patent ductus arteriosus through inhibition of prostaglandin synthesis. Some physicians and hospitals consider Indocin and NeoProfen to be substitutes and exclusively use one product or the other for treating infants with PDA. Many other physicians and hospitals

consider Indocin and NeoProfen to be reasonable substitutes for the vast majority of PDA patients.

28. The relevant section of the country, or geographic market, in which to analyze the effects of Lundbeck's acquisition of NeoProfen is the United States.

29. At all times relevant to the complaint, Lundbeck has possessed a 100 percent share of the relevant market.

30. Direct evidence of Lundbeck's monopoly power in the relevant market includes Lundbeck's ability to raise the price of Indocin nearly 1,300 percent and to maintain prices for both Indocin and NeoProfen at or above this level for over two years.

ENTRY BARRIERS

31. Lundbeck has charged a monopoly price for its PDA drugs for more than two years and during that time no competing PDA drug has entered the market.

32. Developing a new drug and obtaining FDA approval to market it in the United States is a costly and time consuming process that takes substantially more than two years. Entry by a generic version of an existing drug product requires a manufacturer to develop and obtain FDA approval for the generic product. Once a company submits an application, FDA approval of a generic drug takes an average of about 18 months and the approval process can take two years or more.

33. Characteristics of the market for PDA drugs also make entry difficult. With an estimated patient population of 30,000, the PDA drug therapy market is small relative to numerous other pharmaceutical product markets, which limits sales opportunities for

any potential new entrant. In addition, the patient population is exceedingly fragile, and any new entrant must convince physicians who treat premature infants with PDA to forgo use of an existing product with a well-established track record in favor of one that lacks such a history and may present a risk of unanticipated side effects.

34. One company – Bedford Laboratories, Inc. – has FDA approval to sell a generic version of Indocin, but to date it has not entered the market. Bedford received FDA approval for generic Indocin in July 2008.

35. The earliest the FDA could approve a generic version of NeoProfen is 2013, because until then NeoProfen enjoys market exclusivity under the Orphan Drug Act, 21 U.S.C. §§ 360aa-360dd. In addition, two patents claim NeoProfen, the latter of which expires in 2021.

ANTICOMPETITIVE EFFECTS

36. The effects of Lundbeck's acquisition of NeoProfen include, among other things:

a. eliminating the expected actual, direct, and substantial competition between Indocin and NeoProfen;

b. maintaining Lundbeck's monopoly in the sale of drugs to treat PDA in the United States;

c. enabling Lundbeck to exercise monopoly power in the relevant market;

d. eliminating the competitive constraint that the independent introduction of NeoProfen in 2006 would have placed upon the price of Lundbeck's first PDA drug, Indocin;

e. dramatically increasing the price of PDA drug treatment;

f. raising the cost that hospitals and other purchasers, including federal and state agencies, pay for drugs to treat PDA; and

g. depriving consumers of the benefits of competition from entry of NeoProfen as an independent competitor in the market for sale of drugs for PDA in the United States.

37. By acquiring NeoProfen, dramatically increasing the price of Indocin, and pricing NeoProfen to virtually match the Indocin price, Lundbeck has unlawfully maintained its monopoly and unlawfully profited from its ability to extract monopoly price increases.

38. Had Lundbeck not acquired NeoProfen, an independent competitor likely would have entered the market, and prices for both Indocin and NeoProfen would have been substantially below the monopoly prices Lundbeck has charged since January 2006.

VIOLATIONS

COUNT I – UNLAWFUL ACQUISITION IN VIOLATION OF CLAYTON ACT § 7 AND FTC ACT § 5

39. Paragraphs 1-38 above are realleged as if fully set forth.

40. Lundbeck's acquisition of rights to NeoProfen is an asset acquisition within the meaning of Section 7 of the Clayton Act, 15 U.S.C. § 18.

41. The effect of this acquisition has been to substantially lessen competition and to create or maintain a monopoly in PDA drugs for sale in the United States, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

COUNT II – MONOPOLIZATION

42. Paragraphs 1-38 above are realleged as if fully set forth.

43. Lundbeck has, and at all relevant times has had, monopoly power in the market for the sale of drugs for treatment of PDA in the United States.

44. Lundbeck willfully maintained its monopoly power by acquiring the U.S. rights to NeoProfen. Eliminating the competitive threat that an independent NeoProfen posed is conduct reasonably capable of contributing significantly to Lundbeck's maintenance of monopoly power.

45. With its monopoly power secure, Lundbeck raised the price of Indocin by nearly 1,300 percent, set the price of NeoProfen therapy at approximately the same level, and has maintained prices at or above this level since 2006.

46. Lundbeck's acts and practices are anticompetitive in nature and tendency and constitute an unfair method of competition, in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

WHEREFORE, the FTC respectfully requests that this Court, as authorized by 15 U.S.C. §§ 26 and 53(b)(2), and pursuant to the Court's inherent equitable powers:

1. Adjudge Lundbeck's acquisition of NeoProfen to violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45;

2. Order divestiture, rescission, and any further actions needed to establish the competition that would have existed but for the unlawful acquisition of NeoProfen;

3. Permanently enjoin Lundbeck, including any subsidiaries, joint ventures, and any persons acting on behalf of Lundbeck, from acquiring or maintaining any simultaneous legal or beneficial interest in NeoProfen and Indocin; and

4. Grant such other equitable relief, including disgorgement of all unlawfully obtained profits, as the Court finds just and proper to redress and prevent recurrence of Lundbeck's unlawful conduct.

Dated: April 10, 2009

Respectfully submitted,

/s/ Kyle Chadwick

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