IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

Civil Action No. _____

v.

OVATION PHARMACEUTICALS, INC.,
Four Parkway North, Suite 200,
Deerfield, IL 60015

Defendant.

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, Ovation Pharmaceuticals, Inc., for Ovation'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. 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 purchased the rights to Indocin, NeoProfen was awaiting approval by the Food and Drug Administration (FDA). Ovation expected that NeoProfen would take a substantial portion of sales from Indocin. To eliminate this competitive threat, Ovation acquired NeoProfen.

3. Once it acquired NeoProfen, Ovation immediately raised the price it charged hospitals for Indocin nearly 1,300 percent, from $36 to approximately $500 per vial. When Ovation launched NeoProfen in July 2006, it set a price of approximately $483 per vial, essentially matching Indocin's price. Ovation 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 Ovation'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. Ovation's acquisition of NeoProfen substantially reduced competition and illegally maintained Ovation'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, Ovation has obtained and continues to obtain substantial ill-gotten gains.

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

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

25. Ovation 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 Ovation'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 Ovation's acquisition of NeoProfen is the United States.

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

30. Direct evidence of Ovation's monopoly power in the relevant market includes Ovation'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. Ovation 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 Ovation's acquisition of NeoProfen include, among other things:

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

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

c. enabling Ovation 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 Ovation'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, Ovation has unlawfully maintained its monopoly and unlawfully profited from its ability to extract monopoly price increases.

38. Had Ovation 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 Ovation 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. Ovation'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. Ovation 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. Ovation 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 Ovation's maintenance of monopoly power.

45. With its monopoly power secure, Ovation 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. Ovation'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 Ovation'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 Ovation, including any subsidiaries, joint ventures, and any persons acting on behalf of Ovation, 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 Ovation's unlawful conduct.

Dated: December 16, 2008

Respectfully submitted,

/s/ Kyle Chadwick

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