IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

State of Minnesota, by its Attorney General Lori Swanson, Plaintiff, v. Ovation Pharmaceuticals, Inc., Four Parkway North, Suite 200, Deerfield, IL 60015, Defendant.	)	**COMPLAINT** **Case No.** 08cv6381 JRT/FLN

The State of Minnesota, by its Attorney General Lori Swanson, on behalf of and/or for the benefit of its citizens and government entities, complains against Ovation Pharmaceuticals, Inc., as follows:

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 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 all public and private payors.

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

JURISDICTION AND VENUE

6. Under 28 U.S.C. §§ 1331 and 1337, this Court has subject matter jurisdiction over the federal antitrust claims under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. § 18. Plaintiff State of Minnesota brings this action pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, to obtain injunctive relief based on Defendant's anticompetitive practices in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 7 of the Clayton Act, 15 U.S.C. § 18.

7. Plaintiff State of Minnesota also alleges violations of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66, Minn. Stat. ch. 8, and Minnesota common law for

unjust enrichment. This Court has supplemental jurisdiction over the state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claims that they form part of the same case or controversy. The exercise of supplemental jurisdiction avoids unnecessary duplication and multiplicity of actions and is in the interests of judicial economy, convenience, and fairness.

8. This Court has personal jurisdiction over Ovation in that Ovation has the requisite minimum constitutional contacts within the State of Minnesota.

9. Venue in this district is proper under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b), (c), and (d) because Ovation resides or transacts business in the District of Minnesota, and a substantial part of the events giving rise to this complaint occurred in the District of Minnesota.

THE PARTIES

10. Defendant, Ovation, is a privately owned, for-profit Illinois corporation with headquarters at Four Parkway North, Deerfield, Illinois, 60015. Ovation sells pharmaceuticals in more than 85 countries, including the United States.

11. Plaintiff State of Minnesota brings this action by and through its attorney general: (a) as parens patriae in its sovereign capacity to address injury to the State's general economy; and/or (b) as the chief law enforcement agency of the State to the extent that violations of the State's antitrust laws are alleged herein.

12. Ovation 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. Since May 2005, Ovation has sold Indocin in interstate commerce throughout the United States. Since July 2006, Ovation has sold NeoProfen in interstate commerce throughout the United States.

13. Indocin and NeoProfen have been transported across State lines and have been sold in the State of Minnesota. Ovation's unlawful activities alleged in this Complaint have occurred in and have had a substantial effect upon interstate commerce.

BACKGROUND

14. 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.

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

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

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

18. 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.

19. In August 2005, Ovation purchased the exclusive rights to Indocin from Merck & Co. Merck agreed to manufacture Indocin and supply it to Ovation.

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

OVATION ELIMINATES THE COMPETITIVE THREAT POSED BY NEOPROFEN

21. When it acquired Indocin, Ovation became the only seller of PDA drug treatment in the United States. But Ovation 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). Ovation expected NeoProfen to take substantial sales from Indocin. Acquiring NeoProfen would eliminate this threat.

22. In January 2006, Ovation 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 a few months later, in April 2006.

OVATION EXPLOITS ITS MONOPOLY POWER

23. Once Ovation 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.

24. 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.

25. 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.

26. 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

27. 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.

28. 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.

29. 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.

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

31. 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

32. 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.

33. 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.

34. 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.

35. 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.

36. 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

37. 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.

38. 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.

39. 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

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

41. 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.

42. 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.

COUNT II – MONOPOLIZATION UNDER SHERMAN ACT § 2

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

44. 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.

45. 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.

46. 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.

47. Ovation willfully and unlawfully maintained its monopoly power when it acquired United States rights to NeoProfen in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

48. As a direct and proximate result at Ovation's unlawful maintenance of monopoly power, Ovation has caused an injury to competition and Plaintiff State of Minnesota, payors, and consumers have been deprived of the benefits of competition to Indocin or NeoProfen.

COUNT III – STATE LAW CLAIMS

49. Plaintiff State of Minnesota repeats and realleges each and every allegation contained in paragraphs 1 through 48.

50. Defendant's acts violate, and Plaintiff State of Minnesota on behalf of itself, its state agencies, and as parens patriae on behalf of its consumers is entitled to relief under the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66, Minn. Stat. ch. 8, and Minnesota common law for unjust enrichment.

51. Plaintiff State of Minnesota is entitled to injunctive relief under Minn. Stat. § 325D.58. Plaintiff State of Minnesota is entitled to equitable relief as determined by the Court under Minn. Stat. § 8.31, subd. 3a. Plaintiff State of Minnesota is entitled to civil penalties under Minn. Stat. § 325D.56. Plaintiff State of Minnesota is entitled to costs and reasonable attorneys' fees under Minn. Stat. § 8.31, subd. 3a.

PRAYER FOR RELIEF

Accordingly, the Plaintiff State of Minnesota requests that this Court:

52. Adjudge and decree that Ovation violated Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 2 of the Sherman Act, 15 U.S.C. § 2;

53. Adjudge and decree that the foregoing activities violated the Minnesota Antitrust Law of 1971 and common law causes of action set forth in this complaint;

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

55. Award to Plaintiff State of Minnesota any other equitable relief as the Court finds appropriate to redress the Defendant's violations of federal or state antitrust laws or restore competition, including but not limited to restitution or equitable disgorgement;

56. 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;

57. Award to Plaintiff State of Minnesota civil penalties as provided under State law;

58. Award Plaintiff State of Minnesota its costs, including reasonable attorneys' fees, as provided under State and federal law;

59. Order any other relief that this Court deems proper.

Dated: December 16, 2008

Respectfully submitted,

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