UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Federal Trade Commission,

Plaintiff,

v.

Lundbeck, Inc.,

Defendant.

Civil No. 08-6379 (JNE/JJG)

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

State of Minnesota,

Plaintiff,

v.

Lundbeck, Inc.,

Defendant.

Civil No. 08-6381 (JNE/JJG)

(FILED UNDER SEAL)

Kyle Chadwick, Esq., Markus Meier, Esq., and Jon Nathan, Esq., Federal Trade Commission, appeared for Plaintiff Federal Trade Commission.

Karen Olson, Esq., and Benjamin Velzen, Esq., Office of the Minnesota Attorney General, appeared for Plaintiff State of Minnesota.

Alfred Pfeiffer, Esq., Sean Berkowitz, Esq., Karen Silverman, Esq., and Ashley Bauer, Esq., Latham & Watkins LLP, and Steve Gaskins, Esq., Flynn, Gaskins & Bennett LLP, appeared for Defendant Lundbeck, Inc.

These antitrust actions arose out of Lundbeck, Inc.'s acquisition of drugs that treat patent ductus arteriosus. In 2005, Lundbeck acquired Indocin IV, the only drug approved at that time by the U.S. Food and Drug Administration (FDA) to treat patent ductus arteriosus, from Merck & Co. In early 2006, Lundbeck acquired the contingent U.S. rights to NeoProfen, which was not yet approved by the FDA, from Abbott Laboratories. Two days after acquiring the rights to NeoProfen, Lundbeck raised the price of Indocin IV by almost 1300% to $1500 per

three-vial course of treatment. Consistent with its practice of focusing on its patent-protected drugs, Merck had not changed what was a below-profit-maximizing price of Indocin IV for many years before Lundbeck's acquisition.

The Federal Trade Commission (FTC) and the State of Minnesota brought these actions against Lundbeck in December 2008. The FTC claims that Lundbeck acquired the rights to NeoProfen in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18 (2006), and Section 5 of the FTC Act, 15 U.S.C. § 45 (2006), and that Lundbeck willfully maintained its monopoly power by acquiring the rights to NeoProfen in violation of Section 5 of the FTC Act. Minnesota claims that Lundbeck acquired the rights to NeoProfen in violation of Section 7 of the Clayton Act, that Lundbeck willfully maintained its monopoly power by acquiring the rights to NeoProfen in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2 (2006), that Lundbeck violated the Minnesota Antitrust Law of 1971, and that Lundbeck was unjustly enriched. The actions came before the Court for a consolidated trial in December 2009. The parties made post-trial submissions in January and February 2010. In March 2010, the Court admitted into evidence stipulated facts, and the parties made their closing arguments.[1] The next month, the Court took judicial notice of certain facts. Although the FTC's and Minnesota's cases are superficially appealing—Lundbeck bought the rights to NeoProfen, Indocin IV's price went up, therefore Lundbeck must have done wrong—a considered evaluation of the evidence reveals that

[1] The FTC and Minnesota began their closing argument by disclaiming the notion that these cases were "about unhappiness about the high price of Indocin." Nevertheless, the FTC and Minnesota cited in their post-trial response a press release issued by the FTC to announce its action's commencement. The press release asserts that the acquisition of NeoProfen resulted in the increase of Indocin IV's price by almost 1300%; characterizes the prices charged by Lundbeck as "artificially high"; and notes one commissioner's view that Lundbeck's "profiteering on the backs of critically ill premature babies is not only immoral, it is illegal."

Lundbeck did not engage in the alleged statutory violations. The Court therefore enters judgment in Lundbeck's favor.

Based on the evidence received at and after trial, the Court makes the following Findings of Fact, Conclusions of Law, and Order.[2]

I. FINDINGS OF FACT

A. Parties

1. The FTC is an administrative agency of the United States. It has the authority and responsibility to enforce Section 5 of the FTC Act and Section 7 of the Clayton Act.

2. The State of Minnesota brought its action by and through its Attorney General.

3. Ovation Pharmaceuticals, Inc., was founded in 2000. In March 2009, H. Lundbeck A/S acquired Ovation Pharmaceuticals and renamed it Lundbeck, Inc. Lundbeck is the successor in interest to Ovation Pharmaceuticals. In these Findings of Fact and Conclusions of Law, the Court refers to Ovation Pharmaceuticals and Lundbeck as "Lundbeck."

B. Patent ductus arteriosus and its treatment

4. Patent ductus arteriosus is a heart condition that primarily affects low-birth-weight, usually premature, babies. It occurs when the ductus arteriosus, a shunt that connects a fetus's pulmonary artery to its aortic arch, fails to close shortly after birth. Patent ductus arteriosus may endanger a baby's life if the condition is left untreated and does not resolve on its own.

5. Hospital neonatal intensive care units (NICUs) in the United States are generally classified as level I, II, or III. Patent ductus arteriosus is typically treated in level III NICUs.

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[2] To the extent that the Findings of Fact state Conclusions of Law, they are Conclusions of Law. To the extent that the Conclusions of Law state Findings of Fact, they are Findings of Fact.

6. More than 400,000 infants are prematurely born in the United States each year. Approximately 60,000 infants that weigh less than 1500 grams are born each year in the United States. Approximately 30,000 cases of patent ductus arteriosus are treated with drugs in the United States each year.

7. In many instances, a baby's patent ductus arteriosus will close spontaneously.

8. Some neonatologists prefer to treat patent ductus arteriosus by "watching and waiting," which includes fluid management and possible administration of diuretics.

9. Surgical ligation of the ductus is a treatment option for patent ductus arteriosus.

10. Pharmacological treatment of patent ductus arteriosus is also available.

11. Having determined that pharmacological or surgical intervention is required to close a patent ductus arteriosus, most neonatologists use drugs as a first-line treatment unless it is contraindicated for a particular patient. That is, by today's practice standards, neonatologists typically reserve surgery as "second-line" or "rescue" treatment for patent ductus arteriosus when other treatments prove ineffective.

12. The cost of treating patent ductus arteriosus with drugs is significantly less than the cost of treating it with surgical ligation.

13. Under the Federal Food, Drug, and Cosmetic Act, a company seeking approval from the FDA to market a new drug in the United States must file a new drug application demonstrating the safety and efficacy of the product. The label (package insert) approved by the FDA for a drug does not limit the uses for which physicians may prescribe it, but the marketing claims for a drug must be consistent with the FDA-approved label, i.e., the marketing claims may not include representations or suggestions that the drug is better, more effective, useful in a

broader range of conditions or patients, or safer, or that the drug has fewer, or less incidence of, or less serious side effects or contraindications than the label indicates.

14. The FDA has approved the following pharmacological treatments for patent ductus arteriosus: Indocin IV, NeoProfen, Bedford Laboratories' Indomethacin for Injection, and APP Pharmaceuticals, LLC's Indomethacin for Injection.

15. Indocin IV is an off-patent, injectable drug. Its active ingredient is indomethacin. The FDA approved Indocin IV for use in the United States as a treatment for patent ductus arteriosus in January 1985. The FDA-approved label states that Indocin IV is

> indicated to close a hemodynamically significant patent ductus arteriosus in premature infants weighing between 500 and 1750 g when after 48 hours of usual medical management (e.g., fluid restriction, diuretics, digitalis, respiratory support, etc.) is ineffective. Clear-cu[t] clinical evidence of a hemodynamically significant patent ductus arteriosus should be present, such as respiratory distress, a continuous murmur, a hyperactive pericardium, cardiomegaly and pulmonary plethora on chest X-ray.

Some neonatologists use Indocin IV "off-label" in susceptible neonates as concurrent prophylactic treatment for patent ductus arteriosus and intraventricular hemorrhage, which is bleeding into the fluid-filled areas surrounded by the brain. Indocin IV was first offered for sale in 1985.

16. NeoProfen is an injectable drug. Its active ingredient is ibuprofen lysine. Two United States patents claim ibuprofen lysine. One expires in November 2020, the other in March 2021. In 2001, Farmacon-IL, LLC, licensed to Abbott Laboratories the marketing rights to NeoProfen. Farmacon-IL submitted a new drug application to the FDA for approval of NeoProfen to treat patent ductus arteriosus on August 30, 2005. The FDA approved NeoProfen for use in the United States as a treatment for patent ductus arteriosus on April 13, 2006. The label approved by the FDA for NeoProfen in April 2006 differs from the one submitted by Farmacon-IL in August 2005. The FDA-approved label states that NeoProfen is

> indicated to close a clinically significant patent ductus arteriosus (PDA) in premature infants weighing between 500 and 1500 g, who are no more than 32 weeks gestational age when usual medical management (e.g., fluid restriction, diuretics, respiratory support, etc.) is ineffective. . . . [T]reatment should be reserved for infants with clear evidence of a clinically significant PDA.

NeoProfen was first offered for sale in July 2006.

17. Congress passed the Orphan Drug Act of January 1983 to encourage pharmaceutical companies to develop and supply drugs for diseases that serve small patient populations. The Orphan Drug Act provides orphan drugs with seven years of market exclusivity. With some exceptions, no other company can market the same drug for the same indication of use during that time. NeoProfen has orphan drug status for patent ductus arteriosus until 2013.

18. Indocin IV and NeoProfen are not bioequivalent compounds. Their FDA-approved labels are not identical.

19. On December 22, 2006, Bedford Laboratories submitted an abbreviated new drug application to the FDA for generic indomethacin. The FDA approved the application on July 16, 2008. Bedford Laboratories' Indomethacin for Injection is the generic bioequivalent of Lundbeck's Indocin IV. Bedford Laboratories' Indomethacin for Injection was first offered for sale in February 2010.

20. On March 17, 2010, the FDA approved APP Pharmaceuticals' Indomethacin for Injection, which is indicated to close a hemodynamically significant patent ductus arteriosus in premature infants weighing between 500 and 1750 grams.

21. Published clinical studies indicate that indomethacin and ibuprofen lysine are equally efficacious in closing a neonatal patent ductus arteriosus. Indomethacin and ibuprofen lysine are approximately 75% to 90% effective in closing a neonatal patent ductus arteriosus.

C. Lundbeck's acquisition of Indocin IV from Merck

22. On May 20, 2004, Merck gave notice of its proposed sale of several injectable pharmaceutical products, including Indocin IV. Pursuant to an Asset Purchase Agreement dated August 10, 2005, Lundbeck acquired the worldwide exclusive rights to Indocin IV and four other drugs from Merck. Lundbeck acquired the worldwide exclusive rights to a sixth drug from Merck on January 6, 2006. Lundbeck and Merck delayed the closing of Lundbeck's acquisition of the sixth drug because of a warning letter that the FDA had sent to Merck related to its manufacture of the drug's active ingredient.

23. The drugs sold by Merck to Lundbeck were subject to governmental price regulation in many countries other than the United States. Lundbeck's ability to raise drug prices in those countries was limited.[3]

24. Merck only offered to sell Indocin IV to Lundbeck in combination with the other five drugs.

25. Merck decided to sell the drugs so that it could convert the facility where they were manufactured to one dedicated to the manufacture of live virus vaccines. Merck concluded that deletion of the products was not feasible because the drugs were deemed medically significant. To transfer production of the drugs to a new Merck facility, Merck estimated that it would have incurred capital costs of approximately $40 million to $50 million and start-up costs of approximately $10 million. Merck also considered outsourcing production to a contract manufacturing organization. It received "lukewarm" bids from two contract manufacturing organizations. Merck also perceived risks in a contract manufacturing organization's ability to

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[3] In their closing argument, the FTC and Minnesota stated that "[t]here is no U.S. law against price gouging," that "[t]here is no government price regulation in America," and that a legal monopolist may charge a monopoly price.

terminate the relationship, the costs associated with outsourcing production, and the time required to outsource production.

26. Lundbeck undertook responsibility for the manufacture of all drugs that it acquired from Merck. Lundbeck uses contract manufacturing organizations to discharge its obligation. When Lundbeck acquired the five drugs from Merck, Lundbeck and Merck entered into a Supply Agreement under which Merck agreed to manufacture and supply unpackaged Indocin IV to Lundbeck until August 31, 2007.

27. In late 2005, Cardinal Health agreed to manufacture Indocin IV for Lundbeck. Later, Cardinal Health sold the facility where Indocin IV was to be manufactured to Catalent. For present purposes, the Court refers to Cardinal Health and Catalent as Catalent.

28. Catalent failed to produce Indocin IV for Lundbeck. Catalent produced a test batch that contained too much moisture. Catalent's first validation batch failed due to particulate in the effluent of a vial washer. In spring 2007, the facility where Catalent intended to produce Indocin IV became contaminated. In fall 2007, the FDA inspected the facility and found deficiencies. Catalent suspended production to address the deficiencies. The FDA issued a warning letter in March 2008. In late 2008 or early 2009, Catalent decided to divest the facility.

29. Before informing Lundbeck of the decision to divest the facility, Catalent informed Lundbeck that one of the three products Catalent was attempting to produce for Lundbeck had to leave the facility. Lundbeck decided to move Indocin IV out of Catalent's facility.

30. After learning of the problems at Catalent's facility, Lundbeck asked Merck to produce additional batches of Indocin IV. In May 2008, Merck agreed to manufacture two additional lots of Indocin IV for Lundbeck.

31. After removing Indocin IV from Catalent's facility, Lundbeck awarded a contract to manufacture Indocin IV to Hollister-Stier. Hollister-Stier produced three stability batches that were contaminated with particles. At the time of trial, Lundbeck was investigating the source of the particles.

32. As of December 2009, Lundbeck had no Indocin IV to distribute.

D. Lundbeck's acquisition of NeoProfen from Abbott Laboratories

33. In late June 2005, Lundbeck learned that Farmacon-IL and Abbott Laboratories were preparing to file a new drug application for intravenous ibuprofen lysine (NeoProfen). In late August 2005, after Lundbeck had acquired Indocin IV from Merck, Lundbeck contacted Abbott Laboratories to inform it of Lundbeck's acquisition of Indocin IV and interest in co-marketing or obtaining rights to NeoProfen. In a formal presentation to Abbott Laboratories on October 5, 2005, Lundbeck proposed a potential acquisition of rights to NeoProfen. During negotiations, Abbott Laboratories indicated that it wanted to close the deal by the end of 2005. In December 2005, Lundbeck and Abbott Laboratories ceased negotiations due to their inability to resolve a dispute related to a co-promotion agreement. Neither Lundbeck nor Abbott Laboratories knew whether it would attempt to restart the negotiations. In early January 2006, negotiations resumed. Pursuant to an Asset Purchase Agreement dated January 18, 2006, Lundbeck acquired from Abbott Laboratories the contingent U.S. rights to NeoProfen. Lundbeck agreed to pay Abbott Laboratories $2.5 million at closing, $15 million upon approval of the new drug application, annual milestone payments totaling $15 million for 2007 and 2008, and, provided sales reached certain thresholds, a royalty of 7%.

34. On February 24, 2006, Lundbeck and Abbott Laboratories entered into a Co-Promotion Agreement. Lundbeck and Abbott Laboratories agreed to undertake joint promotion,

marketing, and sales activities for Indocin IV and NeoProfen for eighteen months. Lundbeck agreed to pay Abbott Laboratories up to $2 million for Abbott Laboratories' services and for incentive compensation payments to Abbott Laboratories' sales representatives.

35. In fall 2005, Abbott Laboratories believed that the FDA would approve NeoProfen by July 2006. As of December 2005, Lundbeck believed that the FDA would approve NeoProfen in early 2007. In January 2006, when Lundbeck acquired NeoProfen, Lundbeck believed that the FDA would not approve NeoProfen in 2006. After the acquisition, Lundbeck acquired additional information that led it to believe that the FDA would approve NeoProfen earlier than Lundbeck's prior estimate.

36. After the FDA approved NeoProfen in April 2006, Lundbeck renegotiated Abbott Laboratories' royalty rate on sales of NeoProfen due to the differences between the label submitted by Farmacon-IL and the label approved by the FDA. Abbott Laboratories' royalty rate was temporarily reduced from 7% to 3.5% until that reduction offset up to 50% of Lundbeck's first $3 million worth of clinical research on NeoProfen.

E. Indocin IV's price

37. Merck sold Indocin IV for $77.77 per three-vial course of treatment immediately before Lundbeck's acquisition of Indocin IV. Merck had not changed the price of Indocin IV for several years before Lundbeck's acquisition of the drug. Merck had not actively promoted Indocin IV for at least ten years.

38. Before acquiring Indocin IV, Lundbeck decided to substantially raise its price if Lundbeck acquired it.

39. Michael Burke was responsible for the pricing of all drugs sold by Lundbeck, including Indocin IV. He joined Lundbeck in November 2001 as vice president of sales and

marketing. He held that position until February 2008, when he became Lundbeck's chief commercial officer. He resigned from Lundbeck in the middle of 2009.

40. To determine a drug's price, Burke performed a market review and assessment of the condition to be treated through literature reviews and interviews of experts; considered medical necessity and price sensitivity; and determined a profit-maximizing price adjustment.

41. With respect to Indocin IV, Burke completed a pricing analysis by August 2004. He identified three drugs deemed comparable to Indocin IV and analyzed their prices. The average of the three drugs' estimated low costs of therapy was $1282. The average of the three drugs' estimated high costs of therapy was $5555. The average of the three drugs' estimated average costs of therapy was $2658. Indocin IV's price in August 2004, approximately $78 per three-vial course of treatment, was substantially less than the prices of the three drugs. In the pricing analysis, Burke indicated that Indocin IV's current estimated low cost of therapy was $78, that the high was $155, and that the average was $116. The pricing analysis proposed substantially higher prices of Indocin IV. The proposed low cost of therapy was $1140, the proposed high was $2280, and the proposed average was $1710.

42. When Burke completed the pricing analysis of Indocin IV, he planned to raise Indocin IV's price to $1500 per three-vial course of treatment if Lundbeck acquired the drug.

43. In September 2004, Burke wrote that the drugs ultimately acquired by Lundbeck from Merck constituted "a group of medically niche small volume products that don't have substitutes and that are significantly under priced to the market. In the U.S. we can price these almost anywhere we want given the product profiles."

44. In a January 2005 summary of the potential acquisition of the drugs from Merck, Lundbeck described its anticipated price increase of Indocin IV: "We will raise Indocin's price

on a per vial basis from $26 to $380 which translates to about $1,500 per course of therapy, well below the cost of the alternative treatment – surgical ligation." A table followed that displayed an increase in Indocin IV's average sales price from approximately $23 to $341. In the summary, Lundbeck acknowledged that "Merck does not want the buyer to take significant price increases if the buyer is selling Merck labeled/trade dress goods. . . . The time [of] the introduction of new labels has significant 2005 sales and margin impact."

45. Financial projections prepared by Lundbeck before and after it learned of NeoProfen included an increase to Indocin IV's wholesale price from approximately $78 per three-vial course of treatment to approximately $1140 per three-vial course of treatment. After learning of NeoProfen, Lundbeck did not change its plan to increase Indocin IV's price.

46. A forecast dated January 12, 2005, assumed that the acquisition of drugs from Merck would take place on April 1, 2005, that Lundbeck would increase Indocin IV's price three months later by 1370%, and that Indocin IV's average sales price would increase from approximately $23 per vial to approximately $343 per vial.

47. A forecast dated April 15, 2005, assumed that Lundbeck's acquisition of drugs from Merck would take place on June 1, 2005, that Lundbeck would increase the price of Indocin IV approximately four months later by 1370%, that Indocin IV's wholesale price would increase from approximately $26 per vial to approximately $380 per vial, and that Indocin IV's average sales price would increase from approximately $24 per vial to approximately $350 per vial.

48. A forecast prepared in late May 2005 anticipated an increase in Indocin IV's average sales price from approximately $24 in 2005 to approximately $350 in 2006.

49. A forecast dated June 22, 2005, assumed that the acquisition would take place on July 1, 2005, that Lundbeck would increase Indocin IV's price approximately five months later by 1370%, that Indocin IV's wholesale price would increase from approximately $26 per vial to approximately $381 per vial, and that Indocin IV's average sales price would increase from approximately $24 per vial to approximately $350 per vial.

50. A forecast dated August 4, 2005, assumed that the acquisition had occurred on August 1, 2005, that Lundbeck would increase Indocin IV's price in December 2005 by 1370%, that Indocin IV's wholesale price would increase from approximately $26 per vial to approximately $381 per vial, and that Indocin IV's average sales price would increase from approximately $24 per vial to approximately $350 per vial.

51. An update prepared on December 22, 2005, displayed Indocin IV's average sales price in 2006 as $335 per vial. It cited expected charges from wholesalers to explain the variance from an earlier projection's average sales price in 2006 of $350 per vial.

52. Burke refrained from using his planned price of $1500 per three-vial course of treatment in forecasts to give more conservative financial projections.

53. Before and after Lundbeck's acquisition of Indocin IV and the other drugs from Merck, Merck expressed its sensitivity to Lundbeck about price increases while the drugs were still sold under a Merck label. Nevertheless, no agreement restricted Lundbeck's ability to raise the prices.

54. On September 1, 2005, Lundbeck increased the wholesale list price of Indocin IV by 40%, from $77.77 to $108.88 per three-vial course of treatment. Lundbeck also raised the wholesale list prices of the other four drugs it had acquired from Merck. The prices of two were

raised by approximately 40%, one by 25%, and one by approximately 15%. Lundbeck intended to implement further price increases that depended on the availability of Lundbeck labels.

55. On December 21, 2005, Lundbeck expected that the conversion from Merck labels to Lundbeck labels would be completed by January 9, 2006, for Indocin IV; by January 20, 2006, for two of the remaining four drugs that Lundbeck had acquired from Merck; and by February 1, 2006, for the remaining two drugs.

56. On January 10, 2006, Indocin IV was available for sale under a Lundbeck label. Lundbeck did not raise Indocin IV's price on that date.

57. On January 20, 2006, Lundbeck raised the price of Indocin IV by 1278% from $108.88 per three-vial course of treatment to $1500 per three-vial course of treatment. Lundbeck also raised the prices of the other four drugs acquired from Merck in August 2004. The price of Cogentin increased by 257% from $46.03 per five ampules to $164.40 per five ampules. The price of Cosmegen increased by 3437% from $13.43 per vial to $475 per vial. The price of Diuril increased by 864% from $12.36 per vial to $119.21 per vial. The price of Mustargen increased by 979% from $50.55 per four vials to $545.28 per four vials.

58. Sean Nolan joined Lundbeck in September 2004. He was responsible for communications related to the increase in Indocin IV's price in January 2006. In an e-mail dated January 18, 2006, he wrote, "We are still planning on announcing the adjustment on the 20th but that is contingent upon the timing of Hayes." Hayes refers to Lundbeck's acquisition from Abbott Laboratories of rights to NeoProfen. In an e-mail dated January 19, 2006, Nolan wrote, "The Hayes deal closed last night so we'll proceed with the price adjustment announcement as planned on January 20th." Burke instructed Nolan that the price adjustment's announcement was contingent on the timing of Hayes. Lundbeck was concerned that Abbott Laboratories would

demand a higher price for the rights to NeoProfen if the announcement of Indocin IV's price increase took place before Lundbeck's acquisition of the rights to NeoProfen. Lundbeck would have raised the price of Indocin IV to $1500 per three-vial course of treatment even if it had not acquired rights to NeoProfen from Abbott Laboratories.

59. On February 1, 2007, Lundbeck increased the wholesale list price of Indocin IV by 2%. On October 31, 2007, Lundbeck increased the wholesale list price of Indocin IV by 5%. At the end of 2008, the wholesale list price of Indocin IV was $1614.44 per three-vial course of treatment.

60. "Vial splitting" and "vial sparing" refer to using the contents of a single-use vial of an injectable drug to prepare doses administered to more than one patient, when the dose for one patient is less than a full vial. An increase in vial splitting of Indocin IV took place after the price increase in January 2006.

F. NeoProfen's price

61. Before Lundbeck acquired the rights to NeoProfen, Abbott Laboratories had consistently forecast NeoProfen's price at $450 to $500 per three-vial course of treatment. Abbott Laboratories' forecasts took place when Indocin IV's price was approximately $78 per three-vial course of treatment and Abbott Laboratories anticipated the FDA's approval of a NeoProfen label that claimed NeoProfen's superiority over Indocin IV. As noted above, the FDA did not approve the NeoProfen label that Farmacon-IL submitted in August 2005.

62. On July 24, 2006, Lundbeck announced the FDA's approval of NeoProfen for use in the United States as a treatment for patent ductus arteriosus. Lundbeck first offered NeoProfen for sale on July 31, 2006. Lundbeck initially set NeoProfen's wholesale list price at

$1450 for a package of three vials. On October 31, 2007, Lundbeck increased NeoProfen's wholesale list price by 5% from $1450 to $1522.50.

63. When launching NeoProfen, an independent owner would not have disregarded Indocin IV's price.

G. Generic indomethacin

64. Lundbeck expected its increase of Indocin IV's price to attract entry of generic indomethacin. For example, the forecast dated August 4, 2005, assumed the entry of generic indomethacin sixteen months after the increase of Indocin IV's price by 1370%. Burke used the early end of the range of dates of generic indomethacin's estimated entry. By the end of 2005, Burke forecasted that generic indomethacin's entry would take place in April 2008.

65. In January 2006, after Lundbeck had increased the price of Indocin IV to $1500 per three-vial course of treatment, group purchasing organizations informed Bedford Laboratories, a division of Ben Venue Laboratories, Inc., of the price increase and asked Bedford Laboratories to manufacture generic indomethacin. That month, Bedford Laboratories decided to develop generic indomethacin due to the increase of Indocin IV's price. According to David Gaugh, vice president and general manager of Bedford Laboratories, Bedford Laboratories regarded generic indomethacin at that time as a "pretty simple product." Bedford Laboratories estimated that it would file an abbreviated new drug application within one year, that the FDA would approve the application within one year of its filing, and that Bedford Laboratories' generic indomethacin would launch by the first quarter of 2008.

66. On December 22, 2006, Bedford Laboratories submitted an abbreviated new drug application for generic indomethacin to the FDA. The FDA approved the application on July 16, 2008. Bedford Laboratories' Indomethacin for Injection was first offered for sale in February

2010. On February 15, 2010, Bedford Laboratories' Indomethacin for Injection was listed at a wholesale acquisition cost of $500 per vial, effective February 11, 2010.

67. From November 16, 2007, to June 3, 2008, Bedford Laboratories' abbreviated new drug application for generic indomethacin could not be approved due to a warning letter issued by the FDA. The warning letter delayed the FDA's approval process.

68. In general terms, the manufacture of injectable indomethacin consists of (1) mixing the active pharmaceutical ingredient, dry powder indomethacin, with water and alcohol; (2) placing the solution in a vial; and (3) lyophilizing the solution.

69. In its abbreviated new drug application for generic indomethacin, Bedford Laboratories used a drug product release assay specification that was narrower than the one required by the USP monograph and used by Lundbeck. Bedford Laboratories used the narrower specification to render entry by other generic competitors more difficult.

70. A pharmaceutical manufacturer must produce three validation batches before launching a product. After the FDA's approval of Bedford Laboratories' abbreviated new drug application for generic indomethacin and before January 16, 2009, Bedford Laboratories produced three validation batches that failed.

71. In the three validation batches prepared before January 16, 2009, Bedford Laboratories had difficulty satisfying the narrower drug product release assay specification due to the small fill volume. By letter dated January 16, 2009, Bedford Laboratories informed the FDA that Bedford Laboratories amended the drug product release assay specification in its abbreviated new drug application to match that of the USP monograph. The FDA did not object to the request within thirty days, so the amendment was deemed approved.

72. Bedford Laboratories decided to use a slower, more manual process to fill vials.

73. The lyophilization process used by Bedford Laboratories as of early 2009 yielded, in Gaugh's words, an "ugly cake." Bedford Laboratories concluded that the product was not fit to present to a customer. Instead of releasing an "ugly cake," Bedford Laboratories decided to revamp its lyophilization process.

74. Although Bedford Laboratories regarded generic indomethacin as a "pretty simple product" in its initial discussions regarding production of generic indomethacin, the Court credits Gaugh's testimony that lyophilization of an alcohol-based product is very difficult and that generic indomethacin is among the most difficult generic products that he has developed at Bedford Laboratories.

75. Lundbeck described Indocin IV as a "difficult to manufacture product" in its January 2005 summary of the potential acquisition of the drugs from Merck. Marc Wipperman, Lundbeck's former vice president of operation, testified that Indocin IV "is not difficult to make" and that production of Indocin IV is, or should be, a "straightforward exercise." The Court does not credit this testimony because Wipperman did not acknowledge the use of alcohol in the production of injectable indomethacin, Lundbeck failed to transfer production of Indocin IV from Merck in the more than four years since acquiring Indocin IV in August 2005, and Lundbeck could not supply Indocin IV as of December 2009.

76. Bedford Laboratories did not forecast what, if any, effect its generic indomethacin would have on sales of NeoProfen. Assuming no other generic competition, Bedford Laboratories expected to take all sales of Indocin IV within five years.

77. Absent price adjustments to Indocin IV by Lundbeck, Lundbeck expected and expects generic indomethacin to replace a majority of Lundbeck's sales volume of Indocin IV

within the first year after generic indomethacin's launch. Many purchasers of Indocin IV may switch to generic indomethacin on the basis of price.

H. Marketing of Indocin IV and NeoProfen

78. In August 2005, Lundbeck prepared a strategic scenario that compared the acquisition of Indocin IV alone to the acquisition of Indocin IV and NeoProfen. Were Indocin IV alone acquired by Lundbeck, Indocin IV would be positioned as "the drug of first choice for the management of preterm infants with [patent ductus arteriosus] because it safely and effectively closes the [patent ductus arteriosus] and reduces all grades of [intraventricular hemorrhage] resulting in a reduced . . . incidence of surgical ligation and improvement in neurodevelopmental outcomes." The price adjustment to Indocin IV would take place in 2005, and NeoProfen would be priced 15% less than Indocin IV. Were Indocin IV and NeoProfen acquired by Lundbeck, Indocin IV would be positioned as "the drug of first choice for the management of preterm infants with [patent ductus arteriosus] who also have a risk of [intraventricular hemorrhage] because it safely and effectively closes the [patent ductus arteriosus] and reduces all grades of [intraventricular hemorrhage]." NeoProfen would be positioned as "the drug of first choice for the management of preterm infants with [patent ductus arteriosus] and renal dysfunction because it safely and effectively closes the [patent ductus arteriosus] without compromising renal function." The price adjustment to Indocin IV would take place in 2005, and NeoProfen would be priced 15% more than Indocin IV.

79. In November 2005, Lundbeck summarized the opportunity to acquire NeoProfen from Abbott Laboratories. The summary stated in part:

> When approved, NeoProfen will offer meaningful safety advantages when compared to Indocin IV. We estimate that NeoProfen will capture a significant portion of the pharmaceutical PDA market at the expense of Indocin IV.

> Our base case Indocin IV forecast assumed volume and sales loss due to new competition (generic entry and NeoProfen). Based on NeoProfen diligence completed to date and associated analysis, we have confirmed our deal model sales projections and the expected sales loss.
>
> Opportunity: Acquiring NeoProfen will allow us to cannibalize our Indocin IV sales in a controlled manner, retain sales for both products and continue to grow total company sales in the PDA market with an exclusivity protected product.

80. In December 2005, Lundbeck gave a presentation about the potential acquisition of NeoProfen to the owner of the majority of its shares. In an overview of the transaction, Lundbeck reiterated statements made in the November 2005 summary:

> We estimate that Ibuprofen IV [NeoProfen] will capture a significant portion of the pharmacotherapy PDA market at the expense of Indocin IV.
>
> This transaction will be beneficial not only from the cash flows derived from Ibuprofen IV but also from the complementary, positive benefit that will accrue to Indocin IV. Our volume and sales projections for Indocin IV in the original Merck acquisition model contemplated a rapid but short-lived increase in Indocin IV sales, followed by rapidly decreasing sales over the next five years due to new competitive threats, including generic entry and Ibuprofen IV. Acquiring Ibuprofen IV will allow [Lundbeck] to realize a more stable revenue stream for both products within the PDA market and continue to grow total company sales in the PDA market with an exclusivity protected product.

Lundbeck described its strategy: "Ibuprofen IV and Indocin IV will be positioned in a complementary fashion not only to increase the overall growth in the PDA pharmacotherapy market, but also to accelerate the conversion of first-line PDA treatment from Indocin IV to Ibuprofen IV."

81. In early 2006, Lundbeck stopped actively promoting Indocin IV. Shortly after acquiring the rights to NeoProfen, Lundbeck instructed its sales representatives to focus on Indocin IV's weaknesses relative to NeoProfen's anticipated benefits. Lundbeck sought to position NeoProfen as the first-line pharmaceutical treatment for patent ductus arteriosus.

Lundbeck's and Abbott Laboratories' sales representatives received incentives for selling NeoProfen. They received no incentives for selling Indocin IV.

82. In a presentation dated May 4, 2006, Lundbeck outlined its plan to launch NeoProfen. Its stocking plan for hospitals included: (1) secure formulary approval in early May; (2) price NeoProfen at a 3% discount to Indocin IV; and (3) offer a 20% on early stocking orders to drive NeoProfen's adoption. Lundbeck wrote that the 3% discount "[t]akes away potential pharmacoeconomic debate," "[a]llows rep to spend more time selling product differentiation in the NICU vs. spending time with the pharmacy director on price," and "[w]ill **not** convert the economic driven vial splitting crowd."

83. In its 2007 NeoProfen marketing plan, Lundbeck identified three key customer segments: (1) neonatologists and fellows; (2) neonatal nurses, clinical nurse specialists, and nurse practitioners; and (3) clinical pharmacists. Lundbeck identified neonatologists and fellows as "[t]he primary decision maker in the NICU and the most important customer segment for NeoProfen." It recognized that nurses "[h]ave a large influence in the NICU." As to clinical pharmacists, Lundbeck wrote, "Although they do not have prescribing/ordering authority, [clinical pharmacists] play an important role in the formulary approval and utilization process." The marketing plan contained a SWOT (strengths, weaknesses, opportunities, and threats) analysis. Lundbeck identified several weaknesses, including: (1) "Limited access because hospital formulary approval process not completed"; (2) "Safety advantages (e.g. renal function) not perceived as a feature/benefit significant enough to replace Indocin IV as the first line therapy for [patent ductus arteriosus]"; and (3) "Conservative nature of neonatologists and the desire for additional data/experience before adopting." Lundbeck identified several threats, including: (1) "Not approved on hospital formularies"; (2) "Early introduction of a generic

Indocin IV (estimate 1st half of 2008)"; (3) "Lingering price adjustment issues"; and (4) "Vial splitting with Indocin IV & NeoProfen."

84. In its 2008 NeoProfen marketing plan, Lundbeck reiterated the key customer segments. With regard to accounts that stopped ordering NeoProfen in 2007, Lundbeck noted "a combination of safety and efficacy as a primary objection for not using NeoProfen." Lundbeck noted the following objections among non-ordering accounts: (1) "Overall clinical benefit with regard[] to safety and efficacy not seen"; (2) "Indocin for [intraventricular hemorrhage] prophylaxis"; (3) "Lack of U.S. Pivotal Study publication"; (4) "Price"; and (5) "Vial splitting a common practice with Indocin." The marketing plan's SWOT analysis included the following weaknesses: (1) "Limited formulary access"; (2) "Not effective as a prophylactic agent for the prevention of grades III/IV intraventricular hemorrhage"; (3) "Safety advantages (e.g. renal function) not perceived as a feature/benefit significant enough to replace Indocin IV as the first line therapy for [patent ductus arteriosus]"; and (4) "Conservative nature of neonatologists and the desire for additional data/experience before adopting." Lundbeck included the following threats: (1) "Not approved on all hospital formularies"; (2) "Early introduction of a generic Indocin IV (estimate 1st half of 2008)"; (3) "Price adjustment issues (including publications in the lay press and medical journals)"; (4) "Vial splitting with Indocin IV & greater awareness of the plausibility of splitting NeoProfen"; and (5) "Perception of lack of efficacy as compared to Indocin."

85. Lundbeck prepared NeoProfen launch reports as part of its efforts to track use of NeoProfen at hospitals. Depending on an account's interest in NeoProfen, Lundbeck classified the account as red, yellow, or green. Lundbeck also classified the account as red, yellow, or green based on NeoProfen's "market share." In a report prepared in early 2007, green indicated:

> >40% market share for Neoprofen since launch. These accounts are maintenance but still [have] some room for growth as Indocin is still being ordered. Until an account has adopted Neoprofen as [its] only option to treating [patent ductus arteriosus] and replacing Indocin, there is still work to be done. It is important to not take these accounts for granted as they are our BREAD AND BUTTER. Things change and if you don't stay on top of the happenings in these accounts, they can easily switch back to their old ways if they run into a problem or if you neglect them.

Yellow indicated:

> >10% market share [for] Neoprofen since launch. They have ordered Neoprofen but there [are] still PLENTY of growth opportunities. These accounts typically have tried Neoprofen or it is sitting in their pharmacies collecting dust. They are in the process of determining what product to use or are indifferent. They can go either way so it is imperative to continue to provide value in these institutions and give them reasons to increase utilization of Neoprofen. Turning the yellow[s] to greens should be the easiest way to increase your market share and Neoprofen business as they already have it available. INCREASING UTILIZATION is key!!!

Red indicated:

> <10% market share for Neoprofen since launch or have never ordered. These are the accounts that will make or break us in 2007. They are our problem children that we must strategize ways to gain stocking and formulary approvals.

86. Lundbeck's sales representatives prepared opportunity plan sales activity reports to track their contacts with hospital staff. The reports included an opportunity contact grid. The grid contained four columns: pharmacy; physician, physician's assistant, and nurse practitioner; key staff (nursing); and members of the pharmacy and therapeutics committee. Within each column, individuals were classified as green, yellow, red, or blue. Green meant champion or supporter of NeoProfen; yellow meant neutral; red meant blocker; and blue meant unknown.

87. Lundbeck and Abbott Laboratories tracked their sales representatives' "details" related to NeoProfen. A detail refers to an encounter that a sales representative has with a healthcare professional. Through mid-December 2007, 45% of the details in 2007 took place

with neonatologists; 6% with pharmacists; 43% with nurses or nurse practitioners; and 6% with other professionals.

I. Hospitals, P&T committees, and neonatologists

88. Indocin IV and NeoProfen are hospital-based drugs that are dispensed and used in an inpatient setting. Hospitals order and pay for Indocin IV and NeoProfen. Neonatologists do not pay for Indocin IV or NeoProfen.

89. In general, when a private insurer or governmental payor reimburses a hospital for treating a patient, the reimbursement rate is not based on the actual costs of any individual patient's treatment. Instead, the hospital receives a fixed amount based on a system that classifies patients by diagnosis, type of treatment, age, and other factors.

90. Many hospitals are members of group purchasing organizations (GPOs). GPOs aggregate the purchase volume of their member hospitals in an effort to negotiate better prices. After Lundbeck increased the price of Indocin IV in January 2006, GPOs contacted Lundbeck about Indocin IV and asked other manufacturers to develop a generic version of the drug. Lundbeck declined to enter into contracts with GPOs for Indocin IV. Lundbeck has never contracted with GPOs for any of its drug products. Lundbeck distributes the vast majority of its drugs, including Indocin IV and NeoProfen, through distributors.

91. Most hospitals have a formulary, which is a continually updated list of medications and related information that represents the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. Hospital formularies can be generally categorized on a spectrum from open to closed. An open formulary includes the drugs endorsed by the pharmacy and therapeutics committee but does not affect the ability of physicians to prescribe other drugs. A closed

formulary allows for dispensing only the formulary drugs, absent special procedures or approvals. No formulary system will preclude hospital personnel from obtaining non-formulary, FDA-approved drugs if necessary.

92. Pharmacy and therapeutics committees often seek input from specialist physicians when evaluating whether to include a specialty drug on formularies. Pharmacy and therapeutics committees always consider clinical safety and efficacy when making formulary decisions.

93. Hospitals may try to control costs within their formularies. When two or more sellers of clinically substitutable drugs vie for inclusion on a formulary, a hospital may use its formulary system to negotiate price concessions by promising or threatening to use more or less of a drug.

94. As of March 2009, of the hospitals in the United States that purchased either NeoProfen or Indocin IV, 51% purchased only Indocin IV; approximately 42% purchased both Indocin IV and NeoProfen; and approximately 5% purchased only NeoProfen. The remainder is unknown. Indocin IV accounts for approximately 60% and NeoProfen accounts for approximately 40% of the Indocin IV and NeoProfen used in the United States.

95. Stephen Schondelmeyer, the chair of the Department of Pharmaceutical Care and Health Systems at the University of Minnesota, opined that hospitals would have been able to use their pharmacy and therapeutics committees to promote price competition between Indocin IV and NeoProfen, were the drugs independently owned. Joel Hay, a professor of pharmaceutical economics and policy at the University of Southern California, opined that pharmacy and therapeutics committees would not be able to promote price competition between Indocin IV and NeoProfen, were they owned by separate companies. The Court does not find Dr. Schondelmeyer's opinion persuasive. The Court credits Dr. Hay's opinion.

96. Amarylis Gutierrez, Pharm. D., is the system pharmacy director for the health care system of the Los Angeles County Department of Health Services. Four hospitals are in the system. Dr. Gutierrez and the chief medical officer of one of the system's hospitals are the co-chairs of the pharmacy and therapeutics committee. The system uses a single, closed formulary. In discussions of drugs that are used primarily in NICUs, the pharmacy and therapeutics committee relies on neonatologists. The pharmacy and therapeutics committee would not force any physician to use a drug that the physician thought was less safe than another.

In March and April 2007, the pharmacy and therapeutics committee considered NeoProfen's addition to and Indocin IV's removal from the formulary. After hearing that neonatologists at one hospital wanted to continue to use Indocin IV, the pharmacy and therapeutics committee kept Indocin IV on the formulary and added NeoProfen to it. NeoProfen cost approximately 8% less than Indocin IV. Given the volume of drugs used, the price differential was insignificant.

The system uses approximately eighty courses of treatment per year. Indocin IV accounts for approximately 70% of the system's purchases of the two drugs. In one hospital, Indocin IV is used almost exclusively. In two hospitals, use of NeoProfen and Indocin IV is split about evenly.

97. Ambrose Carrejo, Pharm. D., is the director of pharmaceutical contracting for Kaiser Permanente's nine regions. His responsibilities include purchases of drugs used by hospitals in an inpatient setting. In the twelve months ending September 2009, approximately twenty-three medical centers bought either NeoProfen or Indocin IV. NeoProfen accounts for approximately 15% of the purchases. Thirteen medical centers only bought Indocin IV. At one medical center, NeoProfen accounts for approximately 70% of the drugs' use. Use of NeoProfen

at the remaining facilities drops off rapidly. With regard to Indocin IV and NeoProfen, the opinions of neonatologists determine whether the drugs are on the formulary. NeoProfen and Indocin IV are both on the formulary.

After NeoProfen's launch, Lundbeck offered Dr. Carrejo a one-time 20% discount on purchases of NeoProfen for medical centers that had not previously used NeoProfen. Dr. Carrejo did not accept the offer due to concerns that the drug would not be used.

98. Debra Gardner, Pharm. D., is a specialty practice pharmacist for women and infants at Ohio State University Medical Center. She goes on rounds in the NICU with neonatologists. Neonatologists consult with her about which drugs to prescribe, but neonatologists make the final decision. Indocin IV and NeoProfen are on the formulary. Indocin IV is used primarily as a prophylactic treatment for intraventricular hemorrhage. NeoProfen is the primary treatment for patent ductus arteriosus.

At Dr. Gardner's request, NeoProfen was added to the formulary in October or November 2006. Before submitting the formulary request, Dr. Gardner discussed NeoProfen with the neonatologists. She convinced them that NeoProfen was as effective as Indocin IV in closing a patent ductus arteriosus. She believes that NeoProfen is safer than Indocin IV.

99. Kamal Behbahani, Pharm. D., is a clinical pharmacist at Jackson Memorial Hospital. Both Indocin IV and NeoProfen are on the formulary. To his knowledge, neonatologists had not used Indocin IV to treat patent ductus arteriosus in the year prior to his testimony. Perceived as having a better side effect profile relative to Indocin IV, NeoProfen became the pharmacological treatment for patent ductus arteriosus at Jackson Memorial Hospital. Dr. Behbahani recommends NeoProfen, would not alter his recommendation were Indocin IV's price to decrease by $500 per course of treatment, and would not alter his

recommendation were generic indomethacin priced substantially less than Indocin IV. Dr. Behbahani makes recommendations to neonatologists, but neonatologists ultimately decide what treatment a patient receives.

100. Michael Muller, Pharm. D., is a clinical pharmacy specialist in neonatology at Women & Infants Hospital in Providence, Rhode Island. The hospital uses Indocin IV to prophylactically treat intraventricular hemorrhage and to treat patent ductus arteriosus. NeoProfen is not on the formulary. Before the FDA's approval of NeoProfen as a treatment for patent ductus arteriosus, neonatologists discussed the drug. No neonatologist requested NeoProfen's addition to the formulary. In early 2007, a working group prepared guidelines for pharmacological treatment of patent ductus arteriosus. To Dr. Muller's knowledge, no neonatologist has departed from the guidelines by using NeoProfen. Neonatologists ultimately decide what medications and doses are used to treat patent ductus arteriosus. A neonatologist could make a non-formulary request for NeoProfen.

In choosing between two drugs of equal efficacy, Dr. Muller recommends the safer drug if there is a clinically different safety profile, even if that drug is more expensive.

The long-term studies of Indocin IV increase Dr. Muller's comfort level with Indocin IV. He would like to see long-term studies of NeoProfen.

101. Dr. Jeffrey Gerdes is a neonatologist at the University of Pennsylvania and Children's Hospital of Philadelphia. Dr. Gerdes' first-line treatment for patent ductus arteriosus is Indocin IV. Before trial, he had never used NeoProfen to treat patent ductus arteriosus. Describing himself as "maybe more conservative than some physicians in terms of worrying about long-term outcome," he chooses to use Indocin IV instead of NeoProfen because Indocin IV has a long-term clinical record. Given the shortage of Indocin IV in December 2009, he

recognized that he would likely use NeoProfen by the end of 2009 unless Indocin IV became available.

Dr. Gerdes acknowledges that neonatologists have a lot of influence with regard to drugs used in a NICU. He could not think of any situation in his thirty-one years of practice in which a pharmacy and therapeutics committee rejected the consensus view of neonatologists on what drug to use in the NICU. He agreed that it was "unthinkable" that the hospital administration would direct neonatologists to use a particular drug without soliciting the neonatologists' views.

Dr. Gerdes credibly described the differences in side effects of NeoProfen and Indocin IV. NeoProfen affects urine output and renal function less than Indocin IV. Indocin IV causes a decrease in blood flow to the brain. NeoProfen does not. Indocin IV causes a decrease in blood flow to the gastrointestinal tract. NeoProfen does not.

Notwithstanding the differences between Indocin IV and NeoProfen, Dr. Gerdes opined that the drugs are equally safe because he regards the differences in how the drugs affect babies as clinically insignificant. Dr. Gerdes did not present his opinion as one that represented the consensus of neonatologists that practice in the United States, and he acknowledged that other neonatologists and medical literature disputed his opinion. Dr. Gerdes has not adequately explained the differences of opinion. *Cf. Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001) ("Indeed, we regard the experts' claims with some suspicion since one leading treatise on medical toxicology concludes that bromocriptine has *no* vasoconstrictive properties."). The Court accepts Dr. Gerdes' opinion regarding the safety of NeoProfen and Indocin IV as indicative of his own view, but is not otherwise persuaded by it.

102. Dr. Mark Mammel is a neonatologist. He is employed by Associates in Newborn Medicine, P.A., a practice group that consists of eight neonatologists. The group practices in

hospitals located in St. Paul, Minnesota. It treats the vast majority of cases of patent ductus arteriosus at Children's Hospitals and Clinics of Minnesota in St. Paul.

Dr. Mammel's practice group has guidelines for the treatment of patent ductus arteriosus. The guidelines do not specify which drug to use. The group's use of pharmaceuticals to treat patent ductus arteriosus has changed over the years. In 2004, it discontinued prophylactic treatment for patent ductus arteriosus. That same year, it also discontinued prophylactic treatment for intraventricular hemorrhage. In 2006, NeoProfen was added to the formulary. Over the next three years, the group's use shifted toward NeoProfen such that NeoProfen accounted for approximately 80% of the group's use of NeoProfen and Indocin IV. Dr. Mammel explained that the group shifted toward NeoProfen because NeoProfen appears to have less impact on renal blood flow and on urine output. He would feel comfortable treating the vast majority of his patients with either NeoProfen or Indocin IV.

When deciding between two possible treatments, Dr. Mammel chooses the one that is safer, if he is persuaded that one is indeed safer. He makes that decision without regard to cost. Pharmacists provide Dr. Mammel with useful information about drugs, but he ultimately decides what treatment a patient will receive.

103. Dr. Nathaniel Payne is a neonatologist. He is employed by Minnesota Neonatal Physicians, a single specialty practice group that consists of approximately fourteen neonatologists. The group practices primarily at the NICU of the Children's Hospitals and Clinics of Minnesota in Minneapolis. The group uses Indocin IV to treat patent ductus arteriosus. It does not use NeoProfen. Dr. Payne explained the decision not to use NeoProfen: "Our ultimate decision was we didn't see any real advantages or differences and we had a system that seemed to work well using the indomethacin, and we felt it in everybody's best interest,

particularly the babies', to stay with what we were familiar with and know how to manage and administer." Dr. Payne characterized Indocin IV as "an old friend" and agreed that he would not change from a drug that he regards as a reliable old friend to one with which he had no experience without real careful consideration. He continued: "I think if the drugs appeared to be the same, if they had similar effect and one was ten times more expensive than the other, I'd probably call Mark Mammel and say, 'Mark, how do you use it? What do you do?' and 'We're interested in thinking about it.'" Dr. Payne does not consider price in deciding between drugs if he perceives a meaningful difference between them. Dr. Payne found it "hard to imagine" that a pharmacist on the pharmacy and therapeutics committee would be able to keep a drug that a neonatologist needed off the formulary.

104. Dr. Jae Kim is a neonatologist at the University of California, San Diego. Into 2006, he used Indocin IV to prophylactically treat intraventricular hemorrhage and to treat patent ductus arteriosus. In late summer or early fall 2006, he became aware of NeoProfen. Dr. Kim was responsible for NeoProfen's addition to the formulary. By 2007, he used NeoProfen almost exclusively to treat patent ductus arteriosus. He explained his decision to use NeoProfen as based on evidence that suggested to him that the drug had less deleterious effects.

Where two drugs are equally effective, he would not choose the drug that was less safe even if it was priced 20% less than the other drug. In neonatology, he acknowledged that a large team treats patients. The neonatologist ultimately decides on the course of treatment.

105. Dr. Phillip Smith teaches and practices neonatology at the Duke University Medical Center. A protocol calls for the use of Indocin IV to prophylactically treat intraventricular hemorrhage in a baby whose weight is less than 750 grams and gestational age is less than 27 weeks. The protocol calls for the use of NeoProfen to treat patent ductus arteriosus.

In late 2006 or early 2007, the protocol switched to NeoProfen based on the beliefs that NeoProfen and Indocin IV were equivalent in terms of efficacy and that NeoProfen was less toxic than Indocin IV. Were NeoProfen unavailable he would be comfortable using Indocin IV to treat patent ductus arteriosus.

The cost of a drug administered in the NICU generally does not factor into Dr. Smith's decision to use it. Were Indocin IV priced 20% less than NeoProfen, Dr. Smith would not change from NeoProfen to Indocin IV. Were a generic version of Indocin IV available at half the price of Indocin IV, Dr. Smith does not think he would switch from NeoProfen to the generic.

106. Dr. Ilene Sosenko is a neonatologist at Jackson Memorial Hospital. Before NeoProfen was available, she used Indocin IV to treat patent ductus arteriosus. After NeoProfen became available, Dr. Sosenko switched to NeoProfen to treat patent ductus arteriosus. The association of renal dysfunction with Indocin IV was the main reason she stopped using Indocin IV. Dr. Sosenko believes NeoProfen's safety profile is superior to that of Indocin IV. She is not aware of the costs of Indocin IV or NeoProfen. Cost does not factor into her decision to use NeoProfen instead of Indocin IV. Dr. Sosenko would not switch back to Indocin IV were the cost of Indocin IV decreased by $200. Nor would she switch to generic indomethacin.

107. Dr. Robert Tefft is the medical director of White Memorial Medical Center's NICU. At his request, NeoProfen was added to the formulary in mid-2006. To treat patent ductus arteriosus from July to December 2006, Indocin IV and NeoProfen were used. In late 2006 or early 2007, Dr. Tefft and the two other neonatologists in the NICU implemented a protocol that called for the use of NeoProfen when pharmacologically treating patent ductus arteriosus. Indocin IV was removed from the formulary in early 2008.

Dr. Tefft does not believe that use of Indocin IV is outside the standard of practice, but he believes that NeoProfen is a superior drug. He believes the side effects of NeoProfen are less severe than those of Indocin IV. A price differential would not lead him to change from NeoProfen to Indocin IV or a generic version of Indocin IV.

108. Dr. Mitchell Goldstein is an associate professor at the Loma Linda University School of Medicine and the director of Citrus Valley Medical Center's NICU. At the university's NICU, Indocin IV is used to treat patent ductus arteriosus. NeoProfen is not. At Citrus Valley Medical Center's NICU, Indocin IV is used to treat patent ductus arteriosus. In early 2008, NeoProfen was also used to treat patent ductus arteriosus at Citrus Valley Medical Center's NICU. The physicians there decided to cease use of NeoProfen because its behavior differed from that of Indocin IV. Dr. Goldstein is confident that his request for a drug's placement on a formulary would be granted. Asked whether a 10% or 20% decrease to NeoProfen's price would cause him to switch from Indocin IV to NeoProfen, Dr. Mitchell responded, "It is irrelevant."

J. The market

109. "The relevant market has two components—a product market and a geographic market." *HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 547 (8th Cir. 2007); *Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591, 596 (8th Cir. 2009), *cert. denied*, 130 S. Ct. 3506 (2010).

110. The United States is the relevant geographic market.

111. The parties dispute the scope of the relevant product market. "The relevant product market is a question of fact, which the plaintiff bears the burden of proving." *HDC Med.*, 474 F.3d at 547; *see H.J., Inc. v. Int'l Tel. & Tel. Corp.*, 867 F.2d 1531, 1537 (8th Cir.

1989). According to the FTC and Minnesota, the relevant product market is FDA-approved drugs to treat patent ductus arteriosus. Lundbeck maintains that the FTC and Minnesota failed to prove that Indocin IV and NeoProfen are in the same product market.

112. "A court's determination of the limits of a relevant product market requires inquiry into the choices available to consumers. The focus is on how 'consumers will shift from one product to the other in response to changes in their relative costs.'" *Little Rock Cardiology Clinic*, 591 F.3d at 596 (citation omitted) (quoting *SuperTurf, Inc. v. Monsanto Co.*, 660 F.2d 1275, 1278 (8th Cir. 1981)).

> The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it. However, within this broad market, well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes. The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.

Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962) (footnote omitted) (citation omitted); *see HDC Med.*, 474 F.3d at 547 (citing *Brown Shoe*); *H.J.*, 867 F.2d at 1538, 1540 (stating that cross-elasticity of demand is "[c]ritical to the determination whether certain products move in the same market" and that "[t]he 'practical indicia' identified in *Brown Shoe* have been described as 'evidentiary proxies for direct proof of substitutability'" (quoting *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986))); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988) ("Whether two particular products belong in the same relevant product market can be demonstrated by the extent of cross-elasticity of demand between the two products; in other words, the readiness and ability of consumers of one product to turn to the other product."); *SuperTurf, Inc. v. Monsanto Co.*, 660 F.2d 1275, 1278 (8th Cir. 1981) ("In determining whether two 'products' are in the same market, it is important to consider

the cross-elasticity of demand between the products, i.e., whether consumers will shift from one product to the other in response to changes in their relative costs.").

113. According to the FTC and Minnesota, hospitals are the relevant consumers. Lundbeck maintains that neonatologists are the relevant consumers. Although hospitals, not neonatologists, purchase Indocin IV or NeoProfen, neonatologists ultimately determine which drug, if any, is used to treat patent ductus arteriosus. Neonatologists are very influential with respect to which drugs used in a NICU will be on a formulary; pharmacy and therapeutics committees generally defer to neonatologists when making decisions related to drugs used in NICUs. Neonatologists may be influenced by pharmacists, nurses, and others, but neonatologists ultimately determine the demand for Indocin IV and NeoProfen. The Court finds that neonatologists are the relevant consumers.

114. The FTC retained an economist, Jonathan Arnold, Ph. D., in this case. Dr. Arnold testified that Indocin IV and NeoProfen are in the same product market based on the functional substitutability of NeoProfen and Indocin IV, data regarding hospitals' purchases of NeoProfen and Indocin IV, and Lundbeck's documents that refer to a market that consists of NeoProfen and Indocin IV. The Court does not find Dr. Arnold's testimony on this point persuasive. *Cf. Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009) (noting that internal marketing documents do not provide a sound economic basis for assessing a market in the way that a proper interchangeability analysis would); *Archer-Daniels-Midland*, 866 F.2d at 248 n.1 ("The evidence of the substantial displacement of sugar by HFCS is irrelevant because this displacement focuses on static, rather than dynamic, price and demand relationships."). Dr. Arnold did not offer any opinion as to the cross-elasticity of demand

between NeoProfen and Indocin IV, and he discounted the testimony of neonatologists and pharmacists in this case regarding their reasons for choosing between Indocin IV and NeoProfen.

115. Lundbeck called an economist, Thomas McCarthy, Ph. D., to testify in this case. Although he did not calculate a specific cross-price elasticity between NeoProfen and Indocin IV, he testified that that it is very low. The Court finds Dr. McCarthy's testimony on this point persuasive. Dr. McCarthy testified that NeoProfen and Indocin IV are not in the same product market. The Court also finds his testimony on this point persuasive.

116. To treat patent ductus arteriosus with drugs in the United States, neonatologists may choose Indocin IV (subject to the shortage that began in December 2009), generic indomethacin (launched in February 2010), or NeoProfen. Neonatologists pick NeoProfen or Indocin IV to treat patent ductus arteriosus for reasons such as perceived differences in the drugs' safety, differences in side effects, or the presence or lack of long-term studies. The cross-elasticity of demand between NeoProfen and Indocin IV is very low. Were NeoProfen and Indocin IV in the same product market, Lundbeck's attempt to persuade neonatologists to switch from Indocin IV to NeoProfen would not make sense. Bedford Laboratories did not forecast what, if any, effect generic indomethacin would have on sales of NeoProfen. NeoProfen and Indocin IV are distinct; their side effects differ. The Court finds that NeoProfen and Indocin IV are not in the same product market.

II. CONCLUSIONS OF LAW

A. Monopolization

1. The FTC claims that Lundbeck willfully maintained its monopoly power by acquiring the rights to NeoProfen in violation of Section 5 of the FTC Act. Minnesota claims that Lundbeck willfully maintained its monopoly power by acquiring the rights to NeoProfen in

violation of Section 2 of the Sherman Act. For present purposes, the parties agree that Section 5 of the FTC Act prohibits the same conduct as Section 2 of the Sherman Act.

2. To succeed on their monopolization claims, the FTC and Minnesota must demonstrate that Lundbeck possessed monopoly power in the relevant market and that Lundbeck "willfully acquired or maintained this monopoly power by anticompetitive conduct as opposed to gaining that power as a result 'of a superior product, business acumen, or historical accident.'" *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1060 (8th Cir. 2000) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)); *see HDC Med.*, 474 F.3d at 547.

3. "Antitrust claims often rise or fall on the definition of the relevant market." *Bathke v. Casey's Gen. Stores, Inc.*, 64 F.3d 340, 345 (8th Cir. 1995); *see Little Rock Cardiology Clinic*, 591 F.3d at 596. As noted above, "[t]he relevant market has two components—a product market and a geographic market." *HDC Med.*, 474 F.3d at 547; *see Little Rock Cardiology Clinic*, 591 F.3d at 596.

4. It is undisputed that the relevant geographic market is the United States.

5. The FTC and Minnesota did not satisfy their burden of demonstrating that the relevant product market is FDA-approved drugs to treat patent ductus arteriosus. The FTC and Minnesota did not satisfy their burden of demonstrating that NeoProfen and Indocin IV are in the same product market.

6. Having failed to demonstrate that the relevant product market is FDA-approved drugs to treat patent ductus arteriosus, the FTC and Minnesota failed to demonstrate that Lundbeck possessed monopoly power in a market for FDA-approved drugs to treat patent ductus arteriosus in the United States and that Lundbeck willfully acquired or maintained monopoly power in a market for FDA-approved drugs to treat patent ductus arteriosus in the United States.

B. Clayton Act

7. The FTC and Minnesota claim that Lundbeck acquired the rights to NeoProfen in violation of Section 7 of the Clayton Act.

8. Section 7 of the Clayton Act, as amended, bars acquisitions "where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. Section 7 of the Clayton Act "is primarily aimed at arresting, at their incipiency, acquisitions and mergers that substantially lessen competition or tend to create a monopoly." *Midwestern Mach., Inc. v. Nw. Airlines, Inc.*, 167 F.3d 439, 442 (8th Cir. 1999). "The determination of the relevant market is a 'necessary predicate' to a finding of a Clayton Act violation." *FTC v. Freeman Hosp.*, 69 F.3d 260, 268 (8th Cir. 1995).

9. Having failed to demonstrate that the relevant product market is FDA-approved drugs to treat patent ductus arteriosus, the FTC and Minnesota failed to demonstrate that Lundbeck's acquisition of the rights to NeoProfen substantially lessened competition or tended to create a monopoly in a market for FDA-approved drugs to treat patent ductus arteriosus in the United States.

C. Minnesota Antitrust Law of 1971

10. Minnesota asserts a claim under the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66 (2008). "The establishment, maintenance, or use of, or any attempt to establish, maintain, or use monopoly power over any part of trade or commerce by any person or persons for the purpose of affecting competition or controlling, fixing, or maintaining prices is unlawful." Minn. Stat. § 325D.52. "Minnesota antitrust law is generally interpreted consistently with federal antitrust law." *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 626 (Minn. 2007).

11. Having failed to demonstrate a violation of federal antitrust law, Minnesota failed to demonstrate that Lundbeck violated the Minnesota Antitrust Law of 1971.

D. Unjust enrichment

12. Minnesota asserts a claim against Lundbeck for unjust enrichment due to monopolization.

13. "To establish an unjust enrichment claim, the claimant must show that the defendant has knowingly received or obtained something of value for which the defendant 'in equity and good conscience' should pay." *ServiceMaster of St. Cloud v. GAB Bus. Servs., Inc.*, 544 N.W.2d 302, 306 (Minn. 1996); *see Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 554 (8th Cir. 2008); *First Nat'l Bank of St. Paul v. Ramier*, 311 N.W.2d 502, 504 (Minn. 1981).

14. Having failed to establish its monopolization claim, Minnesota failed to demonstrate that Lundbeck was unjustly enriched.

III. CONCLUSION

Unless otherwise ordered, the Court will either unseal or file a redacted version of the Findings of Fact, Conclusions of Law, and Order on September 10, 2010. The parties shall file under seal proposed redactions, if any, on or before September 7, 2010.

Based on the evidence received, the Findings of Fact, and the Conclusions of Law, IT IS ORDERED THAT:

1. The Federal Trade Commission recovers nothing.

2. The State of Minnesota recovers nothing.

3. The Federal Trade Commission's action against Lundbeck, Inc., Civil No. 08-6379, is DISMISSED WITH PREJUDICE.

4. The State of Minnesota's action against Lundbeck, Civil No. 08-6381, is DISMISSED WITH PREJUDICE.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: August 31, 2010

JOAN N. ERICKSEN
United States District Judge