IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

FEDERAL TRADE COMMISSION, Plaintiff, v. LUNDBECK INC., Defendant.	)	08-cv-6379 (JNE/JJG)
STATE OF MINNESOTA, Plaintiff, v. LUNDBECK INC., Defendant.	)	(Related Case) 08-cv-6381 (JNE/JJG)

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW OF PLAINTIFFS FEDERAL TRADE COMMISSION AND STATE OF MINNESOTA

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PROPOSED FINDINGS OF FACT

I. Introduction

1.1. The Federal Trade Commission ("FTC") and the State of Minnesota, by its Attorney General, Lori Swanson, challenge and seek to undo, as monopolistic and anticompetitive, the acquisition of rights to the branded drug NeoProfen by Ovation Pharmaceuticals, Inc. ("Ovation"), the predecessor of defendant Lundbeck Inc. ("Lundbeck") (hereafter, Lundbeck refers to both Lundbeck and Ovation).

1.2. Indocin IV and NeoProfen are the only drugs approved by the United States Food and Drug Administration ("FDA") to treat patent ductus arteriosus ("PDA"), a serious heart condition diagnosed primarily in premature babies. Joint Stipulations of Fact ("Stipulation") 27, (Docket # 264); Tr. 103:6-14 (Gerdes).

1.3 Indocin IV and NeoProfen drugs are purchased by hospitals and are only used in an inpatient setting. *See* PPFF ¶¶ 6.50-6.51.

1.4. Approximately 60 percent of babies treated for PDA with drugs are treated with Indocin IV while 40 percent are treated with NeoProfen. Tr. 92:12-13 (Gerdes), 895:14-16 (Schondelmeyer); PX 335 at 14 (Lundbeck December 2008 Monthly Financial Summary).

1.5. Lundbeck purchased the exclusive worldwide rights to Indocin IV in August 2005. Stipulation 53.

1.6. Five months later, in January 2006, Lundbeck purchased the exclusive United States rights to NeoProfen when the FDA was reviewing the application for approval of NeoProfen to treat PDA. Stipulations 53, 111.

1.7 Lundbeck had expected that NeoProfen would take a substantial portion of sales from Indocin IV. *See* PPFF § V.B. Lundbeck's acquisition of the rights to NeoProfen eliminated this competitive threat to sales of Indocin IV. *See* PPFF § V.B.

1.8. Lundbeck's acquisition of the rights to NeoProfen from Abbott Laboratories ("Abbott") fell below the threshold for the premerger reporting of acquisitions to the federal antitrust agencies. Def. Ans. FTC Am. Compl. ¶ 21.

1.9. Immediately after acquiring the rights to NeoProfen, Lundbeck raised the price of Indocin IV approximately 1,300 percent, from $108 to $1,500 for a three-vial course of treatment. Stipulations 65, 111.

1.10. Lundbeck began marketing and selling NeoProfen in the United States promptly upon its approval by the FDA in April 2006. Stipulation 116; PX 98 at 2.

1.11. Lundbeck initially priced NeoProfen at $1,450 for a three-vial course of treatment. Stipulation 119.

1.12. Lundbeck has maintained or increased the prices of Indocin IV and NeoProfen from 2006 to the present. Stipulations 67-68, 119-120.

1.13. Lundbeck's acquisition of the rights to NeoProfen has substantially increased the prices hospitals must pay for Indocin IV and NeoProfen to treat

PDA. *See* PPFF § V.C. Lundbeck's acquisition of the rights to NeoProfen also has deprived hospitals of the benefits of competition in purchasing Indocin IV and NeoProfen, including the lower prices hospitals would have been able to negotiate for these drugs absent Lundbeck's acquisition of NeoProfen. *See* § PPFF VI.C.

1.14. As a result of Lundbeck's acquisition of the rights to Indocin IV and NeoProfen, Lundbeck has owned the only two FDA-approved drugs to treat PDA in the United States. Stipulation 27; Tr. 103:6-14 (Gerdes).

1.15. Since Lundbeck's acquisition of NeoProfen in January 2006, Indocin IV and NeoProfen have remained the only two FDA-approved PDA drugs available for hospitals in the United States to purchase for treating PDA, a period of almost 4 years. Stipulation 27; Tr. 103:6-14 (Gerdes).

II. Lundbeck Inc.

2.1. Lundbeck is a for-profit Illinois corporation headquartered in Deerfield, Illinois. Lundbeck is the successor in interest to Ovation. Ovation was founded and incorporated in 2000. Stipulations 1-2; Def. Ans. FTC Am. Compl. ¶ 9.

2.2. From April 2002 until March 2009, GTCR Goldner Rauner, LLC, a private equity firm, owned approximately 77.6 percent of Ovation's outstanding shares, Ovation's management indirectly owned approximately 19.4 percent, and others owned approximately 3 percent. Stipulation 4.

2.3. Lundbeck was created in March 2009 following the acquisition of Ovation by H. Lundbeck A/S, a publicly traded pharmaceutical corporation based

in Copenhagen, Denmark. H. Lundbeck A/S agreed to pay Ovation's former shareholders $600 million upon closing and up to $300 million in additional compensation within one year of closing, contingent upon the achievement of certain regulatory approval milestones unrelated to this litigation. Stipulation 5; Def. Ans. FTC Am. Compl. ¶ 10. These milestones have been realized. Tr. 1269:8-15 (Morris).

2.4. Lundbeck does not manufacture or develop drugs. Instead, Lundbeck identifies, acquires, and then raises the prices of drugs developed and manufactured by other pharmaceutical companies. Stipulation 8; Tr. 1220:2-8 (Morris); Nolan Dep. 27:14-20.

2.5. Lundbeck sells the drugs it acquires from other pharmaceutical companies, primarily at wholesale and through distributors. Def. Ans. FTC Am. Compl. ¶ 9. This case focuses on sales of PDA drugs within the United States.

2.6. Ovation and Lundbeck have recorded net revenues in excess of $120 million from sales of Indocin IV and NeoProfen since January 2006, when Lundbeck acquired the rights to NeoProfen. PX 335; PX 395; PX 396.

2.7. The acquisition, marketing, and sales of NeoProfen have occurred in and affected interstate commerce. Def. Ans. FTC Am. Compl. ¶ 10.

2.8. Lundbeck has not challenged the Court's personal jurisdiction and, in any event, has the requisite minimum contacts with the United States of America and the State of Minnesota. Def. Ans. FTC Am. Compl. ¶ 7.

2.9. Lundbeck has not challenged venue.

III. Laws Governing Pharmaceutical Sales in the United States

A. Regulation of Pharmaceutical Sales in the United States

3.1. No one may market or sell any pharmaceutical products in the United States without approval from the FDA. Under the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended, a company seeking approval from the FDA to market a new drug in the United States must file a new drug application ("NDA"). Stipulation 25.

3.2. The FDA grants approval of a new drug based on a particular label (also called the package insert) that sets forth the prescribing information, side effects, and clinical evidence supporting the FDA approval. All marketing claims for a drug must be consistent with the FDA-approved label, *i.e.*, they may not include representations or suggestions that a drug is better, more effective, safer, or useful in a broader range of conditions or patients, or has fewer, or less incidence of, or less serious side effects or contraindications than the label indicates. 21 C.F.R. § 202.1; Stipulation 26; Tr. 797:14-798:11 (Stickler); Nolan Dep. 42:10-16.

3.3. Additionally, under the Hatch-Waxman Act, when a drug is no longer protected by an enforceable patent, a company may seek approval to market a generic version of the drug by submitting an abbreviated new drug application ("ANDA"). *See* Hatch-Waxman Act, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e); Stipulation 80.

3.4. To obtain FDA approval, the company must show that the generic is the equivalent of the branded drug, *i.e.*, it is bioequivalent to the branded drug because it contains the same active pharmaceutical ingredient ("API") and that there are no significant differences in quality, safety, or efficacy. *See* Hatch-Waxman Act, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e); Stipulations 80-81.

3.5. Bringing a generic drug to market typically requires at least 30 months. Gaugh Dep. 33:10-35:18, 36:2-41:5. Before even submitting an ANDA to the FDA for approval to market a generic equivalent, a manufacturer must, among other things, review any intellectual property issues associated with the branded drug, secure a supplier of the API, and obtain authorization from the FDA to use that supplier. *Id*. This pre-ANDA submission process requires at least a year. *Id.* Approval of the ANDA typically requires another 18 months. Gaugh Dep. 37:9-37:21.

3.6. The manufacturer must produce "validation batches" of the drug on a commercial scale using the same plant and equipment that will be used to manufacture the marketed drug before the FDA will approve the ANDA. Gaugh Dep. 39:18-40:12, 64:24-65:18, 110:3-110:21.

B. Patent Protection of Drugs

3.7. A U.S. patent grants 20 years of market exclusivity to the patent owner (or its licensee) from the date of the filing of the patent application that claims a drug, or its methods of use or manufacturing. *See* 35 U.S.C. § 154 (2008).

C. Exclusivity Under the Orphan Drug Act

3.8. The Orphan Drug Act of 1983 provides 7 years of marketing exclusivity for new drugs that treat conditions affecting fewer than 200,000 people per year in the United States. *See* 21 U.S.C. § 360ee & note; Stipulations 9-11. Although the FDA may grant a request for orphan exclusivity at any time, the 7 year period of exclusivity does not start until the FDA approves the NDA. *See* 21 C.F.R. § 316.31.

3.9. During the 7 years of orphan drug exclusivity, the FDA cannot approve the same drug for the same indication by another applicant unless the applicant can establish clinical superiority to the orphan drug. Stipulation 11. An orphan drug designation does not preclude competition from another drug that treats the same medical condition. Tr. 918:5-21 (Schondelmeyer).

IV. Indocin IV and NeoProfen Are the Only FDA-Approved Drugs Used to Treat Patent Ductus Arteriosus ("PDA")

A. Overview of PDA

4.1. PDA is a heart condition that primarily affects premature and low-birth-weight babies. PDA occurs when the ductus arteriosus, a shunt connecting a fetus's pulmonary artery to its aortic arch, fails to close shortly after birth. In normal newborns, the ductus arteriosus typically closes on its own within 24 hours after birth. Stipulation 17; Tr. 94:7-95:11 (Gerdes); PX 116 at 4. In premature babies, the ductus arteriosus may remain "patent" or open.

4.2. Untreated PDA causes increased pulmonary blood flow and abnormal patterns of blood flow to other organs. PDA is associated with bleeding in the brain, chronic lung disease, kidney problems, and bowel complications requiring surgery. PDA can lead to a baby's death if the condition is untreated and does not close on its own. Stipulation 18; Tr. 95:12-96:9, 98:12-19 (Gerdes); PX 238 at 2.

4.3. In some instances, a patient's PDA will close spontaneously. Stipulation 19; Tr. 95:22-96:24; Tr. 99:18-19 (Gerdes).

4.4. More than 400,000 babies are born prematurely in the United States each year. Of those babies, approximately 60,000 have very low birth weights (under 1,500 grams) and approximately 30,000 are treated with drugs for PDA. Stipulations 21, 22, 24; PX 116 at 5.

4.5. PDA is diagnosed and treated between the sixth hour and third day of life. Tr. 210:13-20 (Payne), 267:4-11 (Mammel). PDA is diagnosed by the presence of clinical symptoms or by diagnostic imaging. Tr. 267:13-15 (Mammel).

4.6. Infants with PDA are usually treated by neonatologists, physicians who specialize in premature and newborn infants, in hospital neonatal intensive care units ("NICUs"). Tr. 76:20 (Gerdes).

B. Treatment of PDA

4.7. When treatment is required, the vast majority of babies with PDA in the United States are treated using either Indocin IV or NeoProfen. Tr. 100:4-101:6 (Gerdes), 265:24-266:5 (Mammel). Indocin IV and NeoProfen are the only

two brand drugs approved by the FDA to treat PDA. Stipulation 27; Tr. 103:6-14 (Gerdes), 265:24-266:5 (Mammel).

4.8. Physicians differ in the timing of when they begin using drugs to treat PDA. Tr. 205:24-206:17 (Payne); 265:5-18; 256:8-18 (Mammel). In some instances, a PDA will close on its own. Therefore, some physicians may manage a patient's fluid balance and breathing while waiting for the ductus to close on its own. Stipulation 38; Tr. 264:7-18 (Mammel). This practice is known as "watchful waiting." If, however, the ductus remains open, these neonatologists will use either Indocin IV or NeoProfen. Tr. 99:14-100:3 (Gerdes), 265:8-12 (Mammel).

4.9. As a last resort, when treatment with drugs fails, neonatologists arrange for surgical ligation to close the PDA. Surgical ligation is significantly more costly and poses greater medical risks than using drugs to treat PDA. Stipulation 37. Therefore, drug treatment is favored unless specifically contraindicated for a given patient. That is, neonatologists typically reserve surgery as "second-line" or "rescue" treatment for PDA when other treatments prove ineffective. Stipulation 40; Tr. 101:23-102:1 (Gerdes).

4.10. Some neonatologists use Indocin IV prophylactically because premature babies less than 1,500 grams are highly likely to have PDAs. Tr. 207:14-24; 208:2-8; 209:1-7, 11-19; 209:25-210:4; 228:5-229:9 (Payne). Other neonatologists use drugs to treat only infants with diagnosed PDAs who are exhibiting significant clinical symptoms. Tr. 102:2-103:5 (Gerdes); 210:1-11

(Payne); 266:18-267:11 (Mammel). Some use drugs to treat asymptomatic PDAs. Tr. 208:2-8, 209:25-210:3 (Payne).

4.11. A number of neonatologists prescribe Indocin IV "off label" as prophylaxis to prevent intraventricular hemorrhage ("IVH"), which is bleeding into the fluid-filled areas (ventricles) surrounded by the brain. Stipulations 50-51; Tr. 208:2-8 (Payne). Indocin IV is the only prophylaxis for IVH. NeoProfen has not been shown to be effective against IVH. PX 50 at 19; Tr. 161:20-162:3 (Gerdes). Indocin IV is the only drug to both reduce the risk of IVH and treat PDA in premature babies. Stipulation 50; Tr. 161:20-162:3 (Gerdes); PX 50 at 14-19.

C. Indocin IV

4.12. Indocin IV was approved by the FDA for use in the United States as a treatment for PDA in January 1985. Stipulation 48; PX 241 at 2.

4.13. Until the FDA approved NeoProfen, Indocin IV was the only FDA-approved pharmacological treatment for PDA. Stipulation 49.

4.14. Indocin IV has no known, unexpired patent protection in the United States. Stipulation 47; PX 20 at 5.

4.15. Bedford Laboratories has an approved ANDA for a generic Indocin IV, but this drug is not yet on the market. Stipulation 90; Tr. 324:24-325:3 (Carrejo).

4.16. The API in Indocin IV is indomethacin for injection. Stipulation 28.

4.17. Indocin IV is an injectable drug that is only administered in a hospital inpatient setting. Stipulation 41. Indocin IV doses are given 12 to 24 hours apart. PX 238 at 12; PX 20 at 4. The recommended course of treatment for Indocin IV is 3 vials, thus the product is sold in three-vial packages. PX 241 at 6.

4.18. Indocin IV is sold in 43 countries around the world. Stipulation 44; PX 20 at 5.

4.19. The FDA-approved label states that Indocin IV "is indicated to close a hemodynamically significant PDA in premature infants weighing between 500 and 1750 g[rams] when after 48 hours usual medical management (*e.g.*, fluid restriction, diuretics, digitalis, respiratory support, etc.) is ineffective. PX 55 at 26. Clear-cut clinical evidence of a hemodynamically significant patent ductus arteriosus should be present, such as respiratory distress, a continuous murmur, a hyperactive precordium, cardiomegaly or pulmonary plethora on chest X-ray." PX 55 at 26.

4.20. "Hemodynamically significant" or "symptomatic" PDA refers to a PDA that has a significant effect on blood flow, and possibly presenting itself in complication including, for example, respiratory distress, a concurrent murmur, a hyperactive percordium, caridomegaly, or pulmonary plethora on a chest x-ray. Stipulation 39.

D. NeoProfen

4.21. Abbott and Farmacon-IL submitted an NDA for NeoProfen to the FDA on August 30, 2005. Stipulation 100. The FDA approved the NDA on April 13, 2006. Stipulations 100, 102-103; PX 269 at 03.

4.22. The active ingredient in the branded drug NeoProfen is ibuprofen lysine. Stipulations 29, 95; PX 238 at 10.

4.23. Farmacon-IL, the inventor of NeoProfen, is the holder of two patents claiming IV ibuprofen lysine, Patent No. 6,342,530, which expires on November 14, 2020, and Patent No. 6,344,479, which expires on March 20, 2021. Stipulation 99.

4.24. Before the FDA approved NeoProfen for sale in the United States, Farmacon-IL obtained orphan drug exclusivity for NeoProfen in October 1996 and then licensed the development rights for the drug to Abbott in 2001. Stipulation 101.

4.25. Marketing exclusivity for NeoProfen under the Orphan Drug Act extends from 2006, when the FDA approved NeoProfen, until 2013. PX 283 at 1.

4.26. NeoProfen is an injectable drug that is only administered in an inpatient hospital setting. NeoProfen doses are given 24 to 36 hours apart. PX 238 at 12; PX 20 at 4. The recommended course of treatment for NeoProfen is 3 vials, thus the product is sold in three-vial packages. PX 238 at 24.

4.27. The FDA-approved label states that NeoProfen is “indicated to close a clinically significant PDA in premature infants weighing between 500 and 1500

g[rams] 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." PX 238 at 11.

V. Lundbeck Acquired the Only Two FDA-Approved Drugs For the Treatment of PDA

A. Lundbeck's August 2005 Acquisition of Indocin IV from Merck

5.1. Lundbeck acquired the worldwide exclusive rights to Indocin IV and four other drugs — Cogentin, Mustargen, Diuril IV, and Cosmegen — from Merck & Co., Inc. ("Merck"), under an Asset Purchase Agreement dated August 10, 2005, for a combined price of $9.8 million. Stipulation 53.

5.2. Lundbeck's acquisition of the Merck drugs was representative of its corporate strategy of exploiting the market by acquiring medically-necessary drugs lacking competition and then substantially increasing the price. Tr. 563:19-566:8 (Burke), 1205:10-1206:8 (Morris); PX 25 at 4-5.

5.3. At the time Lundbeck acquired Indocin IV from Merck, Indocin IV was the only FDA-approved drug to treat PDA in the United States. Stipulation 49.

5.4. Had Merck not sold the rights to Indocin IV to Lundbeck, Merck did not have any plans to abandon Indocin IV or discontinue selling it in the United States. Neunaber Dep. 157:19-158:17 ("our position was [that] we would not abandon it").

5.5. Merck has been committed to making sure Indocin IV remains available for sale. Merck accepted Lundbeck's lower bid for Indocin IV and the other Merck drugs in exchange for Lundbeck's agreement to continue distributing the drugs internationally. Neunaber Dep. 55:21-56:13. Merck also agreed to continue manufacturing Indocin IV for a period of time after Lundbeck acquired the drug. Lundbeck must obtain Merck's approval of Lundbeck's choice for a new manufacturer. Tr. 1248:22-1249:25 (Morris).

5.6. Concurrent with Lundbeck's acquisition of the rights to Merck drugs, Lundbeck and Merck entered into a Supply Agreement under which Merck agreed, among other things, to manufacture and supply Indocin IV to Lundbeck for $2.15 per vial until August 31, 2007. Stipulation 61; Tr. 562:20-563:4 (Burke), 1247:16-22 (Morris).

5.7. In a May 2008 extension of the August 2005 Supply Agreement, Merck agreed to manufacture and supply two additional lots of Indocin IV to Lundbeck for $2.35 per vial for the first lot and $5.38 per vial for the second lot. Stipulation 62; Tr. 563:5-7 (Burke); PX 167 at 06.

5.8. Lundbeck needed to extend its Supply Agreement with Merck in 2008 because its anticipated replacement contract manufacturer, Catalent Pharma Solutions ("Catalent"), had difficulty manufacturing Indocin IV. Tr. 1253:24-1255:17, 1255:18-1256:1 (Morris); PX 236 at 1; Nolan Dep. 29:19-30:14. *See* PPFF ¶¶ 7.15-7.16.

B. Lundbeck Acquired NeoProfen to Maintain its Monopoly in the PDA Drug Market

5.9. Lundbeck became aware of the development of a second drug to treat PDA prior to acquiring Indocin IV. Upon learning about this potential new drug, Lundbeck sought to acquire it. Tr. 464:14-23 (Knocke); 575:11-16, 576:6-11 (Burke).

5.10. Lundbeck first became aware of an ibuprofen-based PDA drug to treat PDA in late June 2005 when planning for the Indocin IV acquisition. On or about June 23, 2005, Lundbeck learned about Pedea, an intravenous ibuprofen THAM treatment for PDA sold in Europe, during discussions with a Swedish drug company about the possibility of distributing Indocin IV in Europe. Stipulation 106; Tr. 460:14-17 (Knocke); PX 31. The Swedish company was already considering distributing ibuprofen THAM. The company told Lundbeck that distributing both drugs was a potential conflict of interest. Tr. 536:6-18 (Knocke).

5.11. Much like the Swedish company, Lundbeck considered this ibuprofen-based PDA treatment to be a "new indocin competitor." PX 29; Tr. 462:20-463:3 (Knocke). Therefore, Lundbeck investigated whether an ibuprofen-based PDA treatment would likely be approved in the United States. Tr. 463:14-19, 531:21-532:16 (Knocke).

5.12. As a result of its investigation, Michael Burke, Lundbeck's former Chief Commercial Officer, or someone reporting to him, likely David Knocke, Lundbeck's former director of NICU marketing, learned during the last week of

June 2005, that Abbott was planning to market an intravenous ibuprofen lysine known as NeoProfen in the United States. Stipulation 107; Tr. 463:20-464:8, 532:17-533:17 (Knocke), 573:25-574:13 (Burke). PX 33 at 2 (6/30/05 Business Development Action Items identifying Abbott as owner of NeoProfen).

5.13. At Mr. Burke's direction, Lundbeck almost immediately began to take steps in July and August 2005 toward acquiring the rights to NeoProfen. Tr. 464:14-23 (Knocke), 575:11-16, 576:7-11 (Burke); PX 33 at 2.

5.14. According to Lundbeck's former President and CEO, Jeffrey Aronin, Lundbeck expected Indocin IV to lose sales to NeoProfen, but that an acquisition of NeoProfen would allow Lundbeck to "cannibalize [its] Indocin IV sales in a controlled manner" and "retain sales for both products…" PX 51 at 3; PX 70 at 8, 9.

5.15. Similarly, Lundbeck explained to its outside investors that the original Indocin IV sales forecast projected that Indocin IV would lose sales to "competitive threats," including generic entry and NeoProfen, but that buying NeoProfen would allow Lundbeck to "realize a more stable revenue stream" in the PDA market. PX 68 at 3. *See also* PX 53 at 18 (market survey identifying IV ibuprofen as "direct competitor" to Indocin IV).

5.16. Mr. Burke and others at Lundbeck believed that NeoProfen posed a much more imminent threat to Indocin IV sales than entry of a generic Indocin IV. Lundbeck projected losing Indocin IV sales to a generic Indocin if Lundbeck raised the price of Indocin IV high enough to attract a generic to the market.

Indeed, Lundbeck estimated that NeoProfen would obtain FDA approval and come on the market well before a generic Indocin IV product was available.

5.17. In fall 2005, Abbott projected that NeoProfen would receive FDA approval in early to mid-2006. During the NeoProfen deal negotiations, Lundbeck and Abbott agreed to a "working assumption" of a June or July 2006 FDA approval for NeoProfen. McCoy Dep. 13:10-13, 72:7-10.

5.18. Meanwhile, however, Lundbeck predicted that a generic Indocin IV would not become available earlier than April 2008, and possibly as late as mid-2009. Tr. 581:4-582:13, 590:8-591:3, 632:19-22 (Burke); PX 51 at 4 (11/05 internal memorandum); PX 70 at 8-10 (12/21/05 internal slides); PX 84 at 5, 7 (1/27/06 Lundbeck presentation to GeneraMedix about potential authorized generic Indocin IV, incorporating estimates from PX 70 and 71), PX 110 at 11 (2007 NeoProfen Marketing Plan).

5.19 GreenField Chemical, Inc., a third-party consultant hired and relied upon by Lundbeck to estimate the time frame for potential generic Indocin IV entry, concluded that it would require an independent company at least 27 months (April 2008) and possibly as long as 42 months (mid-2009) to develop a saleable generic Indocin IV product. Tr. 583:2-585:13, 586:8-587:6 (Burke); PX 71 at 11 (12/22/05 draft report of GreenField Chemical, Inc.). As demonstrated by Lundbeck's own continuing difficulties trying to transfer manufacturing from Merck to a contract manufacturer, manufacturing Indocin IV is neither predictable nor easy. *See* PPFF ¶¶ 7.15-7.16.

5.20. Soon after Lundbeck acquired Indocin IV and first learned about NeoProfen, Mr. Burke contacted Abbott executives several times by late August or September 2005. He telephoned Ned McCoy, then the Director of Business Development for the Ross Products Division of Abbott, on or about August 30, 2005, to inform Abbott of Lundbeck's interest in co-marketing or obtaining the rights to NeoProfen. Stipulation 108.

5.21. Mr. Burke did not receive any clear indication that Abbott had any interest in selling the rights to NeoProfen. Tr. 575:11-16 (Burke). Indeed, prior to being contacted by Lundbeck, Abbott had not been looking to sell the rights to NeoProfen and had never looked for potential NeoProfen buyers or hired a third-party to broker a potential sale of NeoProfen. McCoy Dep. 39:4-22; 78:19-24.

5.22. When Lundbeck first contacted Abbott, Abbott responded that it was not in favor of selling NeoProfen. McCoy Dep. 30:20-31:13. Therefore, Lundbeck set out to convince Abbott to sell the rights to NeoProfen. Tr. 592:19-22 (Burke).

5.23. On September 22, 2005, Sean Nolan, Lundbeck's Vice President of Corporate Affairs, contacted Abbott to set up a meeting to discuss acquiring the rights to NeoProfen. McCoy Dep. 58:15-21; Nolan 12:2-8.

5.24. On October 5, 2005, Lundbeck executives including Barry Deutsch, former Chief Financial Officer and Vice President of Business Development, Mr. Burke, and Mr. Nolan, met with representatives of Abbott in Columbus, Ohio, to discuss Lundbeck's interest in acquiring rights to NeoProfen. Stipulations 109,

110; Nolan Dep. 20:12-21:2.

5.25. Under the Asset Purchase Agreement dated January 18, 2006, Lundbeck acquired from Abbott an exclusive license to the United States rights to NeoProfen, for a total price of $32.5 million plus future royalty payments on NeoProfen sales. *See* Stipulations 111-112; PX 240 (NeoProfen Asset Purchase Agreement).

5.26. Lundbeck agreed to pay Abbott $2.5 million at closing, $15 million upon NDA approval of NeoProfen, and annual milestone payments totaling $15 million in 2007 and 2008. In addition, Lundbeck agreed to a 7 percent royalty payment on NeoProfen sales provided NeoProfen sales reached certain thresholds. Stipulation 112.

5.27. Lundbeck's acquisition of NeoProfen from Abbott eliminated the competitive threat NeoProfen posed to Indocin IV and allowed Lundbeck to maintain its monopoly in the market for FDA-approved drugs to treat PDA.

5.28. Had Abbott not sold the United States rights to NeoProfen to Lundbeck, Abbott was sufficiently committed to NeoProfen to ensure that NeoProfen would be available on the market. Moreover, if Abbott had not sold the rights, it would have marketed NeoProfen on its own. McCoy Dep. 13:18-14:10, 15:12-15, 39:4-17. Indeed, Abbott was continuing to sell products to NICUs and hospital pediatric units, including at least one pharmaceutical product other than Indocin IV and NeoProfen. McCoy Dep. 21:23-22:7.

5.29. Lundbeck and Abbott requested the FDA to approve a label for NeoProfen that showed it was safer than Indocin IV. The FDA, however, refused to do so. Therefore, Lundbeck renegotiated downward Abbott's royalty payment on NeoProfen sales before NeoProfen came on the market. Stipulations 104-105; PX 101 at 10 (5/06 NeoProfen Situation Analysis Update).

5.30. Abbott also assigned to Lundbeck a contract between Abbott and Ben Venue Laboratories, Inc. ("Ben Venue"), dated November 14, 2005, under which Ben Venue agreed to manufacture NeoProfen. Stipulation 115, McCoy Dep. 38:2-8, 41:6-15. Lundbeck and Ben Venue renewed the agreement in or about October 2006. Ben Venue has manufactured NeoProfen for Lundbeck since approximately June 2006 at its Ohio manufacturing facility. Stipulation 114. At this same facility, Bedford Laboratories, a division of Ben Venue, has been testing and producing validation batches of a generic Indocin IV. Stipulation 114.

5.31. Lundbeck and Abbott also entered into a Co-Promotion Agreement dated February 24, 2006, which provided, among other things, that the companies would undertake joint promotion, marketing, and sales activities for Indocin IV and NeoProfen for 18 months, and Lundbeck would pay Abbott up to $2 million for Abbott's services and for incentive compensation payments to Abbott's sales representatives. Stipulation 113; Tr. 456:6-13 (Knocke).

C. Lundbeck Was Able To Charge Supracompetitive Prices By Maintaining Its Monopoly in the Market for FDA-Approved Drugs to Treat PDA

5.32. Lundbeck has charged supracompetitive prices for Indocin IV and NeoProfen since it acquired NeoProfen in 2006.

5.33. Monopolies can set prices at supracompetitive levels; firms in a competitive market cannot and must price competitively. Lundbeck's ability to charge supracompetitive prices indicates that it possesses market power.

1. Lundbeck Substantially Increased the Price of Indocin IV After Acquiring NeoProfen

5.34. When Lundbeck acquired the rights to Indocin IV from Merck in August 2005, Merck's list price per three-vial package of Indocin IV was $77.77. Stipulation 63; PX 157.

5.35. On September 1, 2005, Lundbeck increased the wholesale list price per three-vial package of Indocin IV by 40 percent, to $108.88. Stipulation 64.

5.36. Lundbeck did not want to risk imposing another Indocin IV price increase on hospitals until after it acquired the rights to NeoProfen. Lundbeck was concerned that if Abbott knew the extent of Lundbeck's intended price increase, Abbott might demand a higher price for the rights to NeoProfen. Tr. 1274:19-1275:2 (Morris); Nolan Dep. 110:16–114:2.

5.37. Therefore, Mr. Burke instructed his team in January 2006 that a further increase in the price of Indocin IV above $108.88 per three vials was contingent on Lundbeck's closing on the rights to NeoProfen. Nolan Dep. 108:24-

109:22, 114:16-115:11, 119:19-23; PX 78 (1/18/06 e-mail from Sean Nolan); PX 81 (1/19/06 e-mail from Sean Nolan).

5.38. Immediately after acquiring the rights to the Merck drugs, including Indocin IV, Lundbeck sold Indocin IV and the other Merck drugs in Merck's packaging. Lundbeck notified its distributors on January 10, 2006 that Indocin IV was now available in Lundbeck trade dress. PX 77. Lundbeck had planned another price increase once Indocin IV was in Lundbeck trade dress. Tr. 515:1-3 (Knocke).

5.39. Yet, Lundbeck waited 10 days *before* actually raising the price of Indocin IV. Stipulation 65, Tr. 1272:2-9 (Morris). Consistent with Mr. Burke's instructions, on January 20, 2006, two days after acquiring the United States rights to NeoProfen from Abbott, Lundbeck increased the list price for three vials of Indocin IV by 1,278 percent, from $108.88 to $1,500. Stipulation 65; Tr. 1272:2-9 (Morris).

5.40. Lundbeck's price of $1,500 per three-vial package was substantially higher than Merck's price of $77.77 per three-vial package. Merck had been earning a profit on each sale of Indocin IV at the price of $77.77 per three-vial package. Neunaber Dep. 151:9-152:21, 183:16-184:22 (Merck's "internal cost" per vial in 2008).

5.41. Lundbeck subsequently increased the price of Indocin IV by another 2 percent in February 2007 to $1,530 per course of treatment, 5 percent in October

2007 to $1,605.50 per course of treatment, and .5 percent to $1,614.44 per course of treatment during 2008. Stipulations 67-69; PX 157; PX 170.

5.42. There is no credible evidence that Lundbeck set $1,500 as the final price for Indocin IV until after it acquired the rights to NeoProfen.

5.43. Although Mr. Burke testified that he had determined "in [his] mind" Lundbeck's ultimate price of $1,500 per three vial course of treatment for Indocin IV by August 2004, over a year and a half before the actual price increase, his testimony is not credible. Tr. 648:9-15 (Burke).

5.44. First, it is incredulous that a business would set a price for a product more than a year before acquiring it. Second, even if Mr. Burke identified the $1,500 price as early as August 2004, this occurred well before Lundbeck was even aware of NeoProfen as potential competitor. Tr. 573:12-19 (Burke). Third, there are scant references in Lundbeck documents to pricing Indocin IV at $1,500 per three vials until immediately after acquiring NeoProfen. Tr. 1336:16-19 (McCarthy). Fourth, deal models presented to Lundbeck's investors and bankers contained a price of $1,140 per three vials rather than $1,500. Tr. 704:20-706:3 (Burke). Mr. Burke advised Lundbeck's shareholders before Lundbeck acquired the rights to Indocin IV that he expected to increase the price of Indocin IV to $1,140 per three-vial package (an increase of 1,361.5 percent over Merck's last price). Mr. Burke considered the $1,140 price to be an "acceptable [and] appropriate" price to use as part of a demonstration to Lundbeck's shareholders that the overall acquisition of the five Merck drugs would be profitable. Tr. 572:6-

11 (Burke). Finally, as Lundbeck's economics expert, Thomas R. McCarthy, acknowledged, Lundbeck's documents, created between August 2004 and the NeoProfen acquisition, contain a variety of different potential Indocin IV pricing points. Tr. 1336:16-1340:4 (McCarthy).

5.45. Significantly, the fluctuations in the proposed Indocin IV prices identified in various Lundbeck documents correlate with whether Lundbeck believed it might have to compete with NeoProfen. In fact, when Lundbeck believed that it might have to compete with NeoProfen, prices identified in its internal documents were often below $1,140. For example, after first learning about NeoProfen in Summer 2005, Lundbeck contemplated prices between $1,050 and approximately $1,140. Tr. 1338:17-1339:6 (McCarthy); PX 38 at 2 (multiplying the identified projected price increase (1370 percent) by the existing price for Indocin IV ($77.77 per three vials).

5.46. Then, during negotiations with Abbott to acquire NeoProfen, Lundbeck's documents suggest a higher price of $1,700 per three vials of Indocin IV. Tr. 1339:7-14 (McCarthy). When negotiations with Abbott began to falter in December 2005 over the co-promotion agreement, McCoy Dep. 40:22-41:15 (noting that Abbott's negotiations with Lundbeck hit a sticking point in late November or early December and that Abbott decided to limit discussions with Lundbeck to focus on another transaction); Tr. 1242:3-1244:14 (Morris), in internal documents, Lundbeck once again lowered its projected Indocin IV price to

between $1,005 and $1,050 per three vials. PX 383 at 3 (projecting an Indocin IV price of $335 per vial in 2006, $350 per vial in 2007 and $376 per vial in 2008).

5.47. Lundbeck did not settle on $1,500 per three vials of Indocin IV until immediately after closing on the NeoProfen acquisition in January 2006. *See* PPFF ¶ 5.39.

2. Lundbeck Set the Price for NeoProfen Similarly to Indocin IV's Supracomeptitive Price

5.48 Lundbeck announced the FDA approval of NeoProfen on July 24, 2006, and first offered NeoProfen for commercial sale on July 31, 2006, for $1,450 per three-vial package. Stipulations 116, 119.

5.49 Had Abbott not sold NeoProfen to Lundbeck, Abbott likely would have charged a lower price than Lundbeck for NeoProfen.

5.50 Abbott consistently assumed a NeoProfen price of $450 to $500 per course of treatment in its deal model and marketing presentations. McCoy Dep. 50:3-16; 51:11- 17. Abbott assumed these prices when it had anticipated an FDA label that contained superiority claims relative to Indocin IV. *See* PPFF § VI.A.3.

5.51 Abbott was concerned that co-promoting Indocin IV and NeoProfen at such high prices would "have an impact on [Abbott's] . . . reputation in the NICU" in a way that would "adversely affect [Abbott's] ability to compete" on other products it sold in the NICU. McCoy Dep. 35:13-36:14, 53:17-53:22, 53:15-55:3.

5.52 On October 31, 2007, Lundbeck increased the wholesale list price of NeoProfen by another 5 percent, from $1,450.00 to $1,522.50 per three-vial package. Stipulation 120; PX 157.

5.53 Lundbeck has recorded a total of more than $120 million in net revenues on sales of Indocin IV and NeoProfen since acquiring the rights to NeoProfen. PX 335; PX 395; PX 396. In 2007 and 2008, Lundbeck has consistently enjoyed gross margins of over 95% for both products. PX 335 at 14; PX 396 at 172.

VI. The Relevant Antitrust Market Is FDA-Approved Drugs to Treat PDA in the United States

6.1. A product market is the smallest set of products, which taken together would allow the owner of that set of products to raise the price above the competitive level. Tr. 984:24-985:4 (Arnold). The relevant product market is FDA-approved drugs to treat PDA. Tr. 1019:3-7 (Arnold). *See also* PPFF §§ VI.A-C. Neither surgical ligation of the ductus nor "watchful waiting" are in the relevant market. Tr. 996:16-997:4 (Arnold); 1318:5-11 (McCarthy); *see* Stipulation 40; PPFF ¶ 4.7, 4.8; Tr. 99:13-100:16 (Gerdes), 264:5-14, 265:8-12 (Mammel); Muller Dep. 44:12-21; Behbahani Dep. 17:18-18:16.

6.2. A geographic market is the geographic area over which a firm needs to have its products available for sale in order to exercise market power. Tr. 985:9-21 (Arnold). The relevant geographic market is the United States. Tr. 998:15-20

(Arnold). Lundbeck markets and sells FDA-approved drugs throughout the United States. Def. Ans. FTC Am. Compl. ¶ 10.

A. Indocin IV and NeoProfen Are Clinical Substitutes for the Treatment of PDA

1. Indocin IV and NeoProfen Are Both Effective and Safe for Treating a PDA

6.3. Indocin IV and NeoProfen are the only FDA-approved drugs to treat PDA. *See* PPFF ¶ 4.7. These drugs are clinical substitutes and can be used interchangeably for treating almost all PDA patients. Tr. 111:19-25 (Gerdes); 274:23-275:3 (Mammel).

6.4. Plaintiffs' medical expert, Dr. Jeffrey Gerdes, is a board-certified neonatologist with over 31 years of experience treating premature babies. He is the Associate Chief of the Neonatology Division of Children's Hospital of Philadelphia. Tr. 77:4-82:20. Dr. Gerdes testified that when treating PDA with drugs is required, Indocin IV and NeoProfen are equally effective and safe. Tr. 88:2-15; 111:19-25 (Gerdes).

6.5. Published, peer-reviewed clinical research indicates that neither Indocin IV nor NeoProfen is superior to the other drug for treating PDA. Tr. 136:14-137:18; 140:15-141:18; 145:8-16 (Gerdes).

6.6. Indocin IV and NeoProfen are equally effective at closing a neonatal PDA, with a success rate of approximately 75 to 90 percent. Stipulations 31-32; Tr. 86:10-87:2 (Gerdes); PX 50.

6.7. "Physicians rate NeoProfen and Indocin similarly with regard to overall performance in PDA treatment." PX 140 at 10 (2008 NeoProfen Marketing Plan).

6.8. Neither Indocin IV nor NeoProfen offers a meaningful safety advantage over the other for most patients. Tr. 87:22-88:1 (Gerdes). Both drugs have some side effects, including renal impairment, pulmonary hypertension, bowel disorders, and bleeding disorders. PX 238 at 12. NeoProfen has been associated with a higher rate of chronic lung disease and pulmonary hypertension. PX 238 at 20; PX 302 at 20.

6.9 The differences in side effect profiles between these two drugs are not clinically significant. Tr. 87:3-88:1; 107:15-109:4; 112:4-113:16; 118:9-14 (Gerdes). Side effects that are not clinically significant are those that do not require any change in the course of treatment, are transient, and resolve without any specific medical intervention. Tr. 88:9-15, 108:23-109:4, 109:19-110:20 (Gerdes). The drugs also show no differences in patient outcomes. Tr. 88:9-15, 108:23-109:4, 109:19-110:20 (Gerdes).

6.10. Both drugs may result in a short-term reduction in urine output. The observed reduction in urine output appears to be less with NeoProfen than with Indocin IV in some patients. This difference in urine output, however, is not clinically significant. Tr. 108:5-22 (Gerdes). The effect on urine output is transient and manageable, and there is no difference in kidney function over time. Tr. 108:13-109:8; 110:21-111:13 (Gerdes); PX 273 at 10.

6.11. In a December 15, 2005 NeoProfen due diligence report, Dr. Stephen Collins, Lundbeck's Chief Scientific Officer and Vice President of Clinical Affairs, stated, among other things, that the FDA was likely to approve the NeoProfen NDA, but the drug "did not come off all that well" against Indocin IV "and even against placebo in some areas," in the studies that Abbott submitted to the FDA with the NDA. PX 65 at 2; Nolan Dep. 21:24-22:22, 23:4-14. Dr. Collins also noted that babies in the studies treated with NeoProfen were more likely to experience intraventricular hemorrhage ("IVH"), sepsis, and anemia than those who received Indocin IV, although the studies' authors did not indicate whether those results were statistically significant. PX 65 at 9.

6.12. Dr. Gerdes has used only Indocin IV to treat PDA. He testified, however, that he would be comfortable using NeoProfen. In fact, Dr. Gerdes testified that he will soon use NeoProfen because of a recently announced shortage of Indocin IV. Tr. 115:2-6 (Gerdes); *see* PPFF ¶ 7.15.

6.13. Similarly, other neonatologists are comfortable using either Indocin IV or NeoProfen in treating PDA. For example, Dr. Brian Smith, a neonatologist at Duke University Medical Center, and Dr. Mark Mammel, a neonatologist at the Children's Hospital of Minnesota, both of whom use NeoProfen, testified that they would feel "comfortable" using either drug. Smith Dep. 55:6-10; Tr. 269:18-270:5, 274:23-275:3 (Mammel). In fact, Dr. Mammel is currently participating in a double-blinded research study in which patients are randomly treated with either Indocin IV or NeoProfen. Tr. 270:6-273:4 (Mammel). Dr. Mammel does not

know which drug patients are receiving during the study. Tr. 271:22-272:10 (Mammel). He testified that he believes the study is safe and that the two drugs can be used interchangeably for the patients. Tr. 272:11-273:2 (Mammel).

2. Indocin IV and NeoProfen Use Demonstrates That the Drugs Are Clinical Substitutes for the Treatment of PDA

6.14. Actual hospital purchases and use of Indocin IV and NeoProfen in the United States demonstrate that the two drugs are clinical substitutes.

6.15. A baby will receive whichever drug the hospital is using to treat PDA. Accordingly, a baby will receive Indocin IV at a hospital that exclusively uses Indocin IV. Likewise, a baby will receive NeoProfen at a hospital that exclusively uses NeoProfen. Thus, the choice between using Indocin IV and NeoProfen is not made based on differences in mothers, babies, or the PDA. Tr. 89:1-8 (Gerdes), 204:23-205:23, 212:25-213:4, 214:7-16, 215:20-216:4 (Payne), 259:23-260:2 (Mammel). Rather, the drug used to treat a baby depends on which hospital is treating the baby. Tr. 212:25-213:4 (Payne).

6.16. Approximately 55 percent of hospitals in the United States that purchase drugs to treat PDA buy either Indocin IV or NeoProfen exclusively. As of March 2009, approximately 50 percent of the NICUs in the United States purchased only Indocin IV to treat PDA and about 5 percent purchased only NeoProfen. Approximately 42 percent of hospitals purchased both drugs. The remaining 3 percent is unknown. Stipulation 35.

6.17. Hospitals can treat all of their PDA patients exclusively with one PDA drug only because Indocin IV and NeoProfen are clinically interchangeable. Dr. Gerdes testified that the data showing a large number of hospitals exclusively using either Indocin IV or NeoProfen strongly suggests that many neonatologists believe that the two drugs are interchangeable. Tr. 92:2-8; 133:3-8 (Gerdes).

6.18. Over half of the Kaiser medical centers that treat PDA are using Indocin IV exclusively. Tr. 319:2-16, 320:16-21 (Carrejo). Similarly, the largest hospital within the Los Angeles County Department of Health Services system ("LA County"), Los Angeles County + University of Southern California Medical Center ("LAC+USC"), exclusively uses Indocin IV. Tr. 836:6-16 (Gutierrez).

6.19. A baby treated at the Minneapolis campus of the Children's Hospital of Minnesota will receive Indocin IV because the neonatologists at that hospital use Indocin IV. Tr. 205:17-23, 206:18-207:9 (Payne). However, a baby that is treated across the Mississippi River at the St. Paul campus of the Children's Hospital of Minnesota will receive NeoProfen because the neonatologists at that hospital prefer NeoProfen. Tr. 266:6-17 (Mammel). There is no meaningful difference in the babies being treated for PDA at either hospital. Tr. 215:15-216:4 (Payne).

3. The FDA Rejected Lundbeck's Request for a Label Indicating that NeoProfen Has a Superior Safety Profile to Indocin IV

6.20. The NDA for NeoProfen sought approval for a label claiming that NeoProfen is safer than, and thus superior to, Indocin IV. PX 235 at 1.

6.21. The FDA, however, rejected that claim, finding that it lacked support in the clinical research. PX 235 at 1; Stipulation 104; Tr. 1353:10-17 (McCarthy).

6.22. Accordingly, under FDA regulations, *see* PPFF § III.A, Lundbeck is precluded from marketing NeoProfen as a superior product or claiming that it has a better safety profile than Indocin IV. Tr. 797:14-798:11 (Stickler).

6.23. Because the FDA refused to approve the proposed superior label for NeoProfen, Lundbeck lowered its estimate of the peak NeoProfen share of the PDA market from 34 percent to 29 percent. Indocin IV represented the remaining market share in Lundbeck's estimate. PX 101 at 7 (5/06 NeoProfen Situation Analysis Update).

6.24. Similarly, Lundbeck's final NeoProfen deal model assumed that NeoProfen sales would peak between 35 to 40 percent of the PDA market in four years. Tr. 680:9-16 (Burke). These low market share projections are hardly indicative of a superior drug. Nor do they show a one-way migration from Indocin IV to NeoProfen. Tr. 894:18-895:11, 895:20-896:2 (Schondelmeyer); 993:9-994:11 (Arnold).

4. Lundbeck's Marketing Approach Differed Depending on Whether Lundbeck Owned Only Indocin IV or Both Drugs, Showing that It Views Indocin IV and NeoProfen as Clinical Substitutes

6.25. Lundbeck's marketing behavior shows that it views Indocin IV and NeoProfen as clinical substitutes.

6.26. Before Lundbeck acquired NeoProfen, it viewed NeoProfen as a direct competitor to Indocin IV. Tr. 578:22-579:1, 677:6-14 (Burke); PX 375 at 1**;** PX 68 at 3; PX 51 at 3; PX 53 at 18. Accordingly, absent the NeoProfen acquisition, Lundbeck would have positioned Indocin IV to compete with an independently-owned NeoProfen. To do so, Lundbeck established a hospital-based sales force and devoted at least 18 sales representatives to marketing the drug. Tr. 449:23-450:8; 511:2-9 (Knocke). At that time, Lundbeck planned to continue marketing Indocin IV through 2008. Tr. 478:10-15 (Knocke).

6.27. Before selling the NeoProfen rights to Lundbeck, Abbott planned to market NeoProfen as a substitute for Indocin IV. McCoy Dep. 15:3-14, 15:21-16:25.

6.28. In August 2005, prior to acquiring NeoProfen, Lundbeck prepared market scenarios projecting what could be expected depending on whether Lundbeck or a competitor held the rights to NeoProfen. Tr. 469:11-17 (Knocke); PX 44 at 3; PX 337 at 2. These scenarios were titled, "Indocin IV + Acquisition of Ibuprofen Lysine" and "Indocin IV Alone," respectively. Tr. 470:2-6 (Knocke); PX 44 at 3; PX 337 at 2. If Lundbeck owned only Indocin IV, it planned to market Indocin IV as the first-line treatment for PDA, whereas if it owned both drugs, it would market NeoProfen as the first-line treatment. Tr. 471:11-473:15 (Knocke); PX 44 at 3. Notably, Lundbeck also predicted that the price of NeoProfen would differ depending on whether the drugs competed or were jointly owned. Tr. 539:19-24, 540:10-13 (Knocke); PX 44 at 3; PX 337 at 2.

6.29. In December 2005, Lundbeck told GTCR Goldner Rauner LLC, the private equity firm with a majority stake in Lundbeck, that after acquiring NeoProfen, it hoped to "accelerate the conversion of first-line PDA treatment from Indocin IV to Ibuprofen IV." PX 68 at 1, 3-4.

6.30. Following through on its strategy, Lundbeck eventually marketed NeoProfen as the "drug of first choice" for the management of PDA. Stipulation 122; PX 140 at 21 (2008 NeoProfen Marketing Plan).

6.31. As part of its effort to encourage hospitals to switch to NeoProfen, by March 2006, shortly after acquiring the rights to NeoProfen but prior to the drug's launch, Lundbeck not only stopped actively promoting Indocin IV, Tr. 455:16-23, 550:23-551:1 (Knocke); 799:19-23 (Stickler); PX 239 at 7, 43 (7/06 NICU Market Overview), but instructed its sales representatives to focus on the perceived weaknesses of the drug. Tr. 553:17-21 (Knocke); PX 239 at 123.

6.32. Upon NeoProfen's launch, Lundbeck treated NeoProfen as a substitute to Indocin IV, pitting NeoProfen against Indocin IV, and trying to persuade users to switch from Indocin IV to NeoProfen. Although Lundbeck sold both PDA drugs, it was motivated to switch customers from Indocin IV to NeoProfen. Unlike Indocin IV, NeoProfen did not face the direct threat of generic entry because NeoProfen had both orphan drug exclusivity and patent protection. Tr. 534:17-25 (Knocke), 994:13-995:9 (Arnold). While Lundbeck knew it would lose virtually all of its Indocin IV sales to a generic over a 2 to 3 year period, PX 84 at 5, Lundbeck hoped to retain at least some revenue from NeoProfen

customers who may not switch from NeoProfen to generic Indocin IV. Tr. 1080:3-19 (Arnold). *See also* PPFF ¶ 6.35. A minority of PDA drugs customers may be sufficiently committed to NeoProfen that they may not switch. *See, e.g.*, PX 101 at 7 (citing consumer research showing that neonatologists treating only 20 percent of patients were highly motivated to switch to NeoProfen).

6.33. Lundbeck and Abbott sales representatives received financial incentives for successfully selling NeoProfen, but no incentives for selling Indocin IV. The incentives were designed to encourage sales representatives to persuade hospitals to buy exclusively NeoProfen. Tr. 767:24-768:2, 802:14-803:18 (Stickler).

B. Hospitals Would Switch Between Indocin IV and NeoProfen Based on Price

1. Lundbeck Has Devoted Considerable Effort to Persuade Hospitals to Switch PDA Drugs

6.34. Lundbeck's massive marketing effort and promotional materials demonstrate that preferences for PDA drugs are not fixed. After acquiring NeoProfen, Lundbeck implemented a marketing strategy designed to persuade hospitals to use NeoProfen instead of Indocin IV. PX 239 at 123; Tr. 553:17-21 (Knocke). Although some health care providers may prefer one drug over the other, as Lundbeck's marketing program reveals, neonatologists and other hospital decision makers are persuadable and PDA drug preferences are flexible. *See, e.g.*, PX 349 at 1-2; PX 350 at 1-2; PX 351 at 1-2; PX 352 at 1-2; PX 353 at 1-2; PX 354 at 1-2; PX 355 at 1-2; PX 356 at 1-2.

6.35. Lundbeck consumer research showed that most neonatologists could be persuaded to use one drug or the other. Indeed, "[p]hysicians rate NeoProfen and Indocin similarly with regard to overall performance in PDA treatment." PX 140 at 10 (2008 NeoProfen Marketing Plan). Lundbeck consumer research revealed that neonatologists treating only 20 percent of PDA patients would be "highly motivated" to switch to NeoProfen from Indocin IV. PX 101 at 7. Accordingly, as David Knocke coached NeoProfen sales representatives at the NeoProfen launch meeting, "NICU physicians . . . **must** be sold on the benefits to prescribe NeoProfen over Indocin." Tr. 500:1-8 (Knocke); PX 239 at 56, 61 (sales training slides) (emphasis in original).

6.36. Lundbeck recognized "therapeutic substitution from NeoProfen and Indomethacin" as a "threat" to NeoProfen sales, and expressed concern that NeoProfen's claimed "[s]afety advantages" may not be "perceived as...significant enough to replace Indocin IV as the first-line therapy for PDA." PX 110 at 11; PX 140 at 19 (2007 and 2008 NeoProfen Marketing Plans).

6.37. Lundbeck heavily promoted NeoProfen directly to hospital, devoting at least 43 sales representatives to selling NeoProfen, Tr. 722:14-723:1 (Stickler). Abbott's NICU sales force of over 300 sales representatives also sold NeoProfen pursuant to the co-promotion agreement. Tr. 456:14-16 (Knocke).

6.38. Lundbeck and Abbott NICU sales personnel heavily promoted NeoProfen through frequent face-to-face meetings with hospital staff known as "details." Tr. 451:12-452:4 (Knocke); 719:18-720:4, 795:16-20 (Stickler).

Indeed, from NeoProfen's launch in July 2006 through November 2007, Lundbeck and Abbott drug representatives reported making an average of 5,330 NeoProfen product details each month. PX 232 at 11 (NeoProfen Launch Tracker).

6.39. Lundbeck used various marketing tools to encourage hospitals to switch from Indocin IV to NeoProfen. Tr. 723:24-733:13 (Stickler); PX 354 at 1. For example, Lundbeck paid neonatologists to promote NeoProfen to other neonatologists throughout the country under its promotional speaker program. Tr. 457:17-458:4 (Knocke). This program was designed to increase NeoProfen sales. Tr. 773:10-776:16, 778:2-23 (Stickler).

6.40. Lundbeck also made a "formulary kit" to assist physicians, pharmacists and nurses in advocating the addition of NeoProfen to hospital formularies, a key component in a hospital's decision to use PDA drugs.[1] The "formulary kit" includes all the published medical data that is currently available regarding NeoProfen. Tr.733:16-734:14, 739:24-740:20 (Stickler).

6.41. Lundbeck used various reports to assist sales representatives and management in their marketing efforts. Lundbeck sales representatives regularly prepared "NeoProfen Launch Trackers" that tracked the usage of NeoProfen at target hospitals. Tr. 761:13-767:23 (Stickler). These reports were routinely reviewed by Lundbeck senior management. Hospitals were color-coded based on their receptivity to NeoProfen. Tr. 769:20-772:12 (Stickler); PX 127.

[1] For a description of the formulary process, *see* PPFF § VI.C.

6.42. Hospitals that were "lukewarm" regarding NeoProfen were coded yellow. Tr. 768:3-769:4 (Stickler). Lundbeck considered these hospitals to be "indifferent" between using NeoProfen or Indocin IV. Their use of NeoProfen could increase or decrease depending on which drug the hospital administration decided to favor. Tr. 768:3-769:4, 769:20-770:4 (Stickler). A March 2007 NeoProfen Launch Tracker noted that hospitals coded yellow "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." PX 127 at 5. The NeoProfen Launch Trackers identify a large number of Lundbeck target hospitals that were undecided regarding NeoProfen. PX 301 at 2; PX 348.

6.43. Moreover, even for those hospitals that Lundbeck coded green (*i.e.*, hospitals that were using NeoProfen), Lundbeck believed those hospitals required monitoring to ensure that they did not switch back to Indocin IV, noting that "[u]ntil an account has adopted NeoProfen as their only option [for] treating PDA and replacing Indocin, there is still work to be done.... 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 ..." PX 127 at 5; Tr. 764:15-767:16 (Stickler); s*ee also* PX 237 at 4. Indeed, a number of hospitals tried NeoProfen but returned to using Indocin IV to treat PDA. Tr. 781:22-782:6 (Stickler); PX 300 at 1; PX 296 at 1-3, 12.

6.44. Lundbeck sales representatives also regularly prepared and submitted to management "Sales Activity Reports" that described NeoProfen sales contacts

with individual members of hospital staff. Tr. 724:15-726:19, 745:17-749:13 (Stickler); PX 348; PX 365.

6.45. Much like the Launch Tracker documents, the Sales Activity Reports relied on a "color-coded" system, here identifying specific individuals based on their receptivity to NeoProfen. Those coded green were NeoProfen "supporters," those coded red were "blockers," and those coded yellow were "neutral." "Blockers" were individuals who did not value the claimed clinical features and benefits that NeoProfen offered. Tr. 748:15-21 (Stickler). "Neutrals" were undecided between continuing to use Indocin IV or trying NeoProfen. Tr. 747:15-748:14 (Stickler); PX 348; PX 349; PX 350; PX 351; PX 352; PX 353; PX 354; PX 355; PX 356.

6.46. While neonatologists are important decision makers regarding a hospital's PDA drug choices, other hospital staff also have a significant role in the decision-making process. As Lundbeck's marketing efforts show, Lundbeck had to persuade other hospital staff in addition to neonatologists to support adopting and using NeoProfen. Tr. 735:9-21, 736:1-22, 751:9-752:14 (Stickler); 1155:18-23 (Hay); PX 239 at 56 (NICU Market Overview); PX 140 at 15-16, 22 (2008 NeoProfen Marketing Plan). Accordingly, Lundbeck's marketing efforts targeted the entire PDA hospital team. Tr. 751:9-752:14 (Stickler). In fact, in 2007, Lundbeck made more details to non-physicians than to neonatologists: 55 percent were made to nurses, pharmacists, and other hospital staff with only 45 percent to neonatologists. Tr. 795:16-796:14 (Stickler); 904:1-10 (Schondelmeyer).

6.47. Lundbeck referred to these non-physicians, who included hospital administrators, clinical pharmacists, and nurses, as "decision makers" and "influencers" in the choice of PDA drugs. Tr. 483:7-14 (Knocke), 736:1-22 (Stickler), 906:17-909:25 (Schondelmeyer); PX 55 at 12; PX 232 at 11. It even designated defendant's witness, Debra Gardner, Pharm.D., a clinical pharmacist at Ohio State University Medical Center ("Ohio State"), as a NeoProfen "champ[ion]" and touted her efforts to convince doctors and others at Ohio State to use more NeoProfen. PX 348 at 4-5.

6.48. Hospital administrators, such as hospital pharmacy directors, were crucial to adopting and using NeoProfen in the hospital because they most directly represent the hospital's interests in controlling costs and strongly influence purchasing decisions. PX 332 at 3 (5/4/06 NeoProfen Launch Price and Programs).

6.49. Clinical pharmacists and nurses accompany physicians on rounds and, along with physicians, collectively decide which drugs to use in treating babies in the NICU. Tr. 523:13-524:3 (Knocke), 1138:7-1139:14 (Gardner). Physicians frequently consult clinical pharmacists on drug choices and play a key role in drug adoption and use. Tr. 1138:7-1139:14, 1140:24-1141:6 (Gardner). For example, among other drugs, Ms. Gardner sponsored NeoProfen's adoption at Ohio State. Tr. 1140:24-1141:6, 1141:18-1142:6 (Gardner).

2. Hospitals Are Price Sensitive When Purchasing PDA Drugs

a. Hospitals Pay for PDA Drugs and Have an Interest in Controlling Costs

6.50. Indocin IV and NeoProfen are hospital-based drugs, dispensed and used in an inpatient setting. Def. Ans. FTC Am. Compl. ¶ 15.

6.51. Hospitals order and pay for hospital-based drugs, including Indocin IV and NeoProfen, to treat patients. Tr. 770:18-771:8 (Stickler). Therefore, hospitals have a strong incentive to control the cost of treatment. Tr. 308:8-9, 309:8-12 (Carrejo); 845:15-16 (Gutierrez); 1127:15-18 (Gardner); Muller Dep. 124:13-15; Bebahani Dep. 97:21-25; Smith Dep. 61:18-20.

6.52. Physicians do not directly or indirectly pay for PDA drugs. Tr. 770:18-22 (Stickler).

6.53. In general, when a hospital receives payment from third-party payers, including private insurers or a federal health care program, for treating a patient, including a PDA patient, the payment amount is not the actual cost of treatment. Rather, the hospital receives a pre-determined, fixed amount based on the Medicare Diagnosis Related Group ("DRG") system. Stipulation 132; Tr. 657:5-9 (Burke), 925:16-926:22 (Schondelmeyer); PX 331 at 22.

6.54. The DRG system classifies patients using diagnosis, type of treatment, age, and other related factors. PX 331 at 22. (Examples of DRGs include "386, Extreme immaturity or respiratory distress syndrome, neonate,"

"387, Prematurity with major problems," and "389, Full term neonate with major problems." *Id.*)

6.55. Under the DRG system, if the cost of care increases, *e.g.*, the price of a drug increases, the hospital is responsible for paying the increased price even though the hospital will receive the same fixed payment for the cost of care. As Lundbeck wrote, "[i]n an in-patient DRG hospital reimbursement system, reducing expenses improves the margin." PX 331 at 21. As plaintiffs' witness Amarylis Gutierrez, Pharm.D., Pharmacy Director for LA County, explained, if her system can save even small amounts of money on pharmaceutical purchases, it may mean that "a clinic may not close or an employee that may not be laid off." Tr. 833:9-22 (Gutierrez).

6.56. Consequently, hospitals have borne the brunt of the substantial Indocin IV price increase. Tr. 925:16-916:22 (Schondelmeyer).

b. Hospital Reaction to the Indocin IV Price Increase Shows Hospital Price Sensitivity for PDA Drugs

6.57. Lundbeck's announcement of the price increase for Indocin IV from $108.88 to $1,500 per course of treatment in January 2006 caught the attention of numerous hospital administrators, physicians, and pharmacists around the country. Wilson Dep. 16:8-17:3. As a result of the price increase, these constituencies viewed Lundbeck unfavorably. Tr. 486:4-7 (Knocke); PX 386 at 3.

6.58. Many hospitals contacted Lundbeck to complain about the price increase for Indocin IV. Nolan Dep. 36:1-6.

6.59. Dr. Alan Jobe, Director of Perinatal Biology and Professor of Pediatrics at Cincinnati Children's Hospital Medial Center, published an editorial in the June 2006 issue of the journal *Pediatrics*, titled "Drug Pricing in Pediatrics: The Egregious Example of Indomethacin," criticizing Lundbeck's dramatic price increase for Indocin IV. Tr. 500:14-501:3 (Knocke). Lundbeck prepared responses to Dr. Jobe's article to share with customers. Tr. 500:24-501:3 (Knocke); PX 374 at 2 (Top-Line Pricing Message); PX 393 (draft letter to the editor regarding Jobe editorial).

6.60. Concerned with the backlash over the substantial price increase, Lundbeck developed a public relations plan in an attempt to address the numerous complaints. *See, e.g.,* PX 372 at 2 (Price Adjustment Plan); PX 373 at 2; PX 374 at 2 (Top-Line Pricing Message); Nolan Dep. 36:1-6, 36:25-37:13.

6.61 Faced with a substantial price increase, hospitals have endeavored to obtain lower prices and reduce the high cost of Indocin IV.

6.62. Although Defendant's pharmaceutical economic expert, Dr. Joel W. Hay, opined that hospitals do not care about costs related to PDA drugs because the costs are too small, he ignored the relevant evidence that hospitals have attempted to reduce costs related to PDA drugs. Tr. 1152:25-1153:2, 1158:10-1162:12, 1192:9-1195:12 (Hay).

(1) Hospitals, Through Their GPOs, Attempted to Negotiate a Lower Indocin IV Price

6.63 Hospitals, through their Group Purchasing Organizations ("GPOs"), tried to negotiate lower prices for Indocin IV. Tr. 827:12-16, 828:2-9 (Gutierrez). GPOs, on behalf of their member hospitals, are often able to negotiate price advantages when two or more manufacturers sell clinically substitutable drugs. *See, e.g.*, Tr. 827:23-828:14 (Gutierrez); Russell Dep. 26:4-25, 34:4-35:16, 120:2-121:2; Wilson Dep. 73:23-74:1; Gaugh Dep. 44:22-45:18. The goal of GPOs is to aggregate the purchase volume of their member hospitals to negotiate better pricing than what the hospitals could obtain alone. Tr. 827:12-16, 828:2-9 (Gutierrez); Wilson Dep. 9:7-15, Russell Dep. 18:5-19:18.

6.64. If there are multiple competitors, GPOs can offer manufacturers higher sales of their drugs in exchange for lower prices. Russell Dep. 24:21-26:25. Where there is only one seller, however, GPOs lack the necessary leverage to negotiate lower prices. Russell Dep. 49:21-50:1; 120:17-22.

6.65. GPOs work with their member hospitals to steer market share toward the drug where they were able to negotiate a more favorable price. Russell Dep. 26:4-25.

6.66. Premier Inc. ("Premier"), one of the two largest GPOs in the country, reached out to Lundbeck on multiple occasions to try to negotiate a lower price for Indocin IV on behalf of its member hospitals. Russell Dep. 28:20-29:6, 29:21-30:20, 31:9-16.

6.67. Premier member hospitals were concerned that Lundbeck's price increase for Indocin IV constrained their budgets. Gaugh Dep. 49:16-50:11. Child Health Corporation of America ("CHCA"), an alliance of 44 children's hospitals throughout the United States, is one of Premier's largest members. CHCA and others urged Premier to contact Lundbeck in an effort to negotiate a discount. Russell Dep. 30:1-6.

6.68. In early to mid-2006, Wayne Russell, Premier's Senior Director of Pharmacy, first communicated with Lundbeck in an effort to negotiate a contract for Indocin IV during a meeting at Lundbeck's offices outside Chicago. Russell Dep. 28:20-29:6.

6.69. Despite Premier's offer to contract with Lundbeck for Indocin IV in exchange for access to certain Premier services, Lundbeck informed Mr. Russell after the meeting that it "had no interest in contracting for Indocin." Russell Dep. 30:7-20.

6.70. After NeoProfen's launch, Premier hospital members were interested in obtaining a GPO contract for NeoProfen as well. Russell Dep. 31:23-32:8. In Summer 2008, Premier once again contacted Lundbeck about contracting for Indocin IV and NeoProfen, but Lundbeck never responded. *Id.* at 32:9-33:20.

6.71. CHCA also independently tried to negotiate with Lundbeck for a volume-based discount on Indocin IV based on its members' large purchases of the drug. Wilson Dep. 15:19-17:3, 17:7-18:24; PX 89 at 1; PX 91 (2/13/05 e-mail chain between Linea Wilson, Group Purchasing Services, CHCA, and David

Knocke, Lundbeck). Lundbeck likewise rebuffed those efforts. Wilson Dep. 19:18-20:2.

6.72. Although Lundbeck has refused to contract with GPOs, Merck had sold Indocin IV under a GPO contract when it owned the rights to Indocin IV. Russell Dep. 28:9-19.

(2) Hospitals Encouraged Manufacturers To Develop a Generic Indocin IV to Compete With Indocin IV

6.73. In addition to trying to negotiate a lower price, hospitals requested their GPOs to contact potential manufacturers of generic Indocin IV to encourage them to develop the drug. Gaugh Dep. 47:12-50:11; Wilson Dep. 86:4-24.

6.74. If generic Indocin IV becomes available at a discount to Indocin IV's current price (Stipulation 91), at least some hospitals will choose which PDA drug to purchase based on price. Indeed, some hospitals expect to move from NeoProfen to generic Indocin IV for the cost savings. Tr. 326:17-24 (Carrejo).

6.75. Lundbeck was aware that hospitals could choose PDA drugs based on price. Lundbeck also recognized that hospitals would be less likely to switch to NeoProfen after the entry of generic Indocin IV because it expected generic Indocin IV to be priced lower. PX 387 at 4 (September 2006 NeoProfen LCM - Life Cycle Management). Accordingly, Lundbeck intended to encourage Indocin IV users to switch to NeoProfen "before generic [Indocin] reaches the market." PX 108 at 12 (Ovation Corporate Development Plan).

6.76. The top goal of the NeoProfen Life Cycle Management Plan was to "grow[] NeoProfen market share quickly, prior to the introduction of generic Indocin." PX 387 at 4 (September 2006 NeoProfen LCM - Life Cycle Management); *see also* PX 387 at 3 (noting that entry of generic Indocin "= a sense of urgency"); PX 386 at 2 (identifying "a timely conversion from Indomethacin to [NeoProfen]" as a "Short-Term Goal").

6.77. As a result of attempts by GPOs to find a generic Indocin IV manufacturer, Bedford Laboratories decided to investigate and, ultimately, pursue developing a generic Indocin IV. Gaugh Dep. 47:12-47:23. Bedford Laboratories, however, has faced difficulties in launching generic Indocin IV and has not yet been able to enter the market with a generic. Gaugh Dep. 49:06-50:3, 64:13-68:1.

(3) Hospitals Began Splitting Vials of Indocin IV

6.78. Unable to negotiate a lower price, and faced with delayed generic entry, hospitals sought other ways to directly control costs of PDA drugs by splitting vials. Splitting vials, also known as vial sparing, is a practice in which hospitals divide single-dose vials of a drug so that they can treat more than one patient with a single vial. Stipulation 70; Tr. 498:2-9 (Knocke).

6.79. Hospitals split vials in order to save money. Tr. 759:18-760:9 (Stickler), 970:11-22 (Schondelmeyer); PX 331 at 21 (sales training slides).

6.80. Lundbeck recognized that "[o]ne of the key ramifications of the price increase with Indocin has been the increase of vial splitting." PX 140 at 20

(Lundbeck 2008 NeoProfen Marketing Plan); *see also id.* at 17 ("[v]ial splitting [became] a common practice with Indocin."). Lundbeck also reported that since the price increase on Indocin IV, they "have seen some price sensitivity as the unit volume declines due to new vial splitting in the hospital." PX 130 at 2 (Key Business Strategies: Indocin).

6.81. Because vial splitting lowered Indocin IV's cost both overall and relative to NeoProfen, Lundbeck viewed vial splitting Indocin IV as a "threat" to NeoProfen sales and the adoption of the newer drug. PX 140 at 19 (2008 NeoProfen marketing Plan). In May 2006, Lundbeck concluded that "vial sparing post Indocin price change" would result in an "[a]pproximately 40% volume fall off for Indocin." PX 101 at 3 (5/06 NeoProfen Situation Analysis Update). Therefore, splitting vials of PDA drugs reduces Lundbeck's sales and revenues. PX 101 at 2, 8 (5/06 NeoProfen Situation Analysis Update).

6.82. Hospitals typically do not split vials of NeoProfen because it is more difficult than splitting vials of Indocin IV. PX 140 at 19-20 (2008 NeoProfen Marketing Plan); PX 101 at 8 (5/06 NeoProfen Situation Analysis Update).

6.83. Several reasons account for this difference. PX 331 at 20 (sales training slides); PX 101 at 8. First, Indocin IV is considered more stable. PX 331 at 20. Studies have shown that Indocin IV is stable for up to 14 days versus only 12 hours for NeoProfen. *Id.*; PX 101 at 8. Second, splitting vials of Indocin IV has support in the medical literature. PX 331 at 19. Finally, the amount of NeoProfen in each vial is small and makes splitting NeoProfen vials difficult. PX

101 at 8 (5/06 NeoProfen Situation Analysis Update) (splitting vials of NeoProfen less likely "due to less wastage").

6.84. Although splitting vials can yield cost savings, its use is limited because it can only be done by hospitals that have either a high number of PDA babies receiving the drug within a short period of time or those willing to overlook the USP sterility standards. PX 331 at 20.

3. Hospitals Consider Price When Deciding Which PDA Drug to Purchase

6.85. There is substantial evidence that hospitals decide between Indocin IV and NeoProfen based, in part, on price.

6.86. Despite virtual pricing parity between Indocin IV and NeoProfen, hospitals have indicated to Lundbeck sales representatives that "price" is a reason they purchase Indocin IV. PX 140 at 17 (2008 NeoProfen Marketing Plan).

6.87. The "price" of Indocin IV is lower per dose than NeoProfen as a result of splitting vials. PX 140 at 17 (2008 NeoProfen Marketing Plan); PX 355 at 1 ("Vial splitting causing difference in price" between Indocin and NeoProfen). Some hospitals have rejected introducing NeoProfen because of cost savings from splitting vials of Indocin IV.

6.88. Indeed, Lundbeck reported that many "accounts that rejected NeoProfen [in 2008] currently vial split Indocin." This demonstrates that price was an important factor for hospitals in the decision to use one PDA drug over another. PX 140 at 17 (2008 NeoProfen Marketing Plan). Lundbeck also noted

the three percent NeoProfen discount "[w]ill **not** convert the economic driven vial splitting crowd." PX 332 at 3 (5/4/06 NeoProfen Launch Price and Programs, emphasis in original); Tr. 498:10-19 (Knocke), 787:21-788:6 (Stickler).

6.89. Lundbeck's 2008 NeoProfen Marketing Plan noted that 30 of the 104 accounts that rejected NeoProfen during the preceding year, did so because they vial split Indocin IV. PX 140 at 17. Similarly, Lundbeck recognized that the three percent NeoProfen discount "[w]ill not convert the economic driven vial splitting crowd." PX 332 at 3.

6.90. For example, Saddbleback Memorial Medical Center in Laguna Hills, California, rejected NeoProfen because splitting vials of Indocin IV allowed it to "save approximately $300 per [PDA] patient." PX 368 at 11. Similarly, at Good Samaritan Hospital in Los Angeles, California, although Lundbeck sales representatives reported that the doctors wanted NeoProfen, "all the pharmacists decided since they cannot vial split, they will not bring [NeoProfen] on." PX 369 at 14; *see also* PX 133 at 2; PX 377 at 2.

6.91. When generic Indocin IV becomes available, at a discount to the current prices of Indocin IV and NeoProfen, Stipulation 91, at least some hospitals expect to move from NeoProfen to generic Indocin IV for the cost savings. Tr. 326:17-24 (Carrejo).

6.92. Lundbeck instructed its sales force not even to market NeoProfen to hospitals that purchased Indocin IV under the federal government's system for purchasing pharmaceuticals, known as the Federal Supply Schedule ("FSS").

Lundbeck recognized that those hospitals would never add NeoProfen to their formularies because of NeoProfen's higher price relative to the lower Indocin IV price that was grandfathered in the FSS. Tr. 501:18-503:2 (Knocke); PX 109 at 1.

4. Lundbeck Believes Hospitals Consider Price When Purchasing PDA Drugs

6.93. Lundbeck is very much aware that hospitals are price sensitive in purchasing drugs, including Indocin IV and NeoProfen.

6.94. Michael Kenston, then Lundbeck's Vice President of Commercial Analysis, predicted prior to NeoProfen's launch in 2006 that "[c]ost effectiveness will likely emerge as a driver with a 2nd [PDA] therapy on [the] market." PX 101 at 6. Accordingly, when determining how to price NeoProfen, Lundbeck embraced a pricing model recognizing that discounting a drug relative to its competition "may drive greater acceptance." PX 102 at 10.

6.95. Mr. Burke followed Mr. Kenston's recommendation to price NeoProfen 3 percent less than Indocin IV per three-vial course of treatment. Lundbeck used this "discount" to encourage greater use of NeoProfen by making NeoProfen more economically attractive to hospitals. Tr. 782:9-784:19 (Stickler); PX 332 at 3 (5/4/06 NeoProfen Launch Price and Programs). Lundbeck acknowledged, however, that the 3 percent NeoProfen discount "[w]ill **not** convert the economic driven vial splitting crowd." PX 332 at 3 (5/4/06 NeoProfen Launch Price and Programs, emphasis in original); Tr. 498:10-19 (Knocke), 787:21-788:6 (Stickler).

6.96. Lundbeck intentionally offered only a small discount for NeoProfen to "take[] away potential pharmacoeconomic debate" about PDA drugs. Paul L. Stickler, Lundbeck's Vice President of Sales, testified that the "pharmacoeconomic debate" refers to discussions among hospital staff regarding price differences between drugs. Tr. 785:6-14 (Stickler). Lundbeck's strategy was intended to eliminate debate on the relative prices of Indocin IV and NeoProfen so that NeoProfen sales representatives could "spend more time selling product differentiation in the NICU vs. spending time with the pharmacy director on price." PX 332 at 3 (5/4/06 NeoProfen Launch Price and Programs); Tr. 785:6-787:2 (Stickler).

6.97. In a price-related effort to drive NeoProfen adoption, Lundbeck offered a 20 percent rebate on hospitals' first purchases of NeoProfen. Tr. 321:9-24 (Carrejo), 788:7-788:13 (Stickler); PX 243 at 1-6 (6/4/07 e-mail from Bill White, West Regional Sales Manager, to Ambrose Carrejo, Kaiser).

6.98. Furthermore, Lundbeck is concerned that the introduction of a generic Indocin IV, at a price lower than NeoProfen, will reduce sales of NeoProfen. PX 140 at 19 (2008 NeoProfen Marketing Plan). Even Mr. Burke conceded that it is "theoretically possible" that generic Indocin IV could take sales from NeoProfen. Tr. 618:9-618:16 (Burke).

6.99. When generic Indocin IV becomes available, at a discount to Indocin IV's current price (Stipulation 91), some hospitals expect to move from NeoProfen

to generic Indocin IV for the cost savings. Tr. 326:18-24 (Carrejo), Muller Dep. 147:6-148:14.

6.100. Lundbeck recognized that hospitals would be less likely to switch to NeoProfen after the entry of generic Indocin IV because Lundbeck expected generic Indocin IV to be priced lower. Accordingly, Lundbeck encouraged Indocin IV users to switch to NeoProfen "before generic [Indocin] reaches the market." PX 108 at 12 (Lundbeck Corporate Development Plan). The top goal of the NeoProfen Life Cycle Management Plan was to "grow[] NeoProfen market share quickly, prior to the introduction of generic Indocin." PX 387 at 4 (September 2006 NeoProfen LCM - Life Cycle Management); *see also id.* at 3 (noting that entry of "generic Indocin "= a sense of urgency"); PX 386 at 2 (identifying "a timely conversion from Indomethacin to [NeoProfen]" as a "Short-Term Goal").

6.101. Lundbeck projected that generic Indocin IV would reduce NeoProfen sales among hospitals purchasing NeoProfen. PX 154 at 2 (NeoProfen: Potential Exposure of Indocin Generic Entry). Specifically, Lundbeck projected that the introduction of generic Indocin IV would reduce not only current sales at hospitals using mostly NeoProfen but also potential future sales to those that had never ordered NeoProfen. *Id.*

6.102. Lundbeck was sufficiently concerned that entry by generic Indocin IV would cut into NeoProfen's sales that it devoted resources to developing new uses for NeoProfen, such as treating cystic fibrosis, "that will not compete with

generic Indocin." PX 119 at 10 (1/5/07 e-mail from Mike Burke to Stephen Collins with attachment, Lundbeck Pharmaceuticals Market & Business Overview: January 2007); Tr. 517:16-518:11 (Knocke), 612:23-613:22 (Burke).

6.103. Lundbeck's NICU sales representatives also were concerned about entry by a generic Indocin IV. Their compensation included incentives based on their sales of NeoProfen. They were concerned in 2007 that the launch of generic Indocin IV, priced lower than NeoProfen, would reduce NeoProfen sales, and, thus, reduce their incentive compensation. Tr. 615:25-616:25 (Burke); PX 156.

6.104. Based on Lundbeck's pricing tactics regarding Indocin IV and NeoProfen, it is likely that had Lundbeck not owned both drugs, it would have discounted Indocin IV in order to compete with and maintain Indocin IV's market share of the PDA drug market.

C. Hospitals Could Be Promoting, and Benefiting From, Price Competition Today Using the Formulary System If Indocin IV and NeoProfen Were Independently Owned

1. Hospitals Use Formulary Systems to Purchase Clinically Appropriate, Safe, and Cost-Effective Drugs

6.105. The prices of Indocin IV and NeoProfen are significant enough to hospitals that purchase those drugs for the treatment of PDA to motivate them to seek ways to save money on the drugs. Tr. 318:13-319:1 (Carrejo), 321:2-323:4 (Carrejo), 759:12-760:20 (Stickler), 833:16-23, 836:22-840:23, 841:3-16 (Gutierrez), 907:16-20 (Schondelmeyer).

6.106. Virtually all hospitals have a formulary system. Tr. 896:6-897:9 (Schondelmeyer); Smith Dep. 61:18-20. The formulary system includes the hospital's policies and guidelines, updated as needed, for choosing and using clinically appropriate, safe and cost-effective drugs. Stipulation 127; Tr. 896:6-897:9 (Schondelmeyer), 1125:20-22 (Gardner); PX 341 at 1. The hospital medical staff, including physicians, is subject to the policies and guidelines included within the formulary system. Tr. 884:21-885:7; 905:12-25 (Schondelmeyer); Russell Dep. 50:7-51:3.

6.107. The basis of the hospital formulary system is the formulary, a continually updated list of medications and related information that represents the clinical judgment of physicians, pharmacists, and other experts regarding the drugs that are appropriate and approved for use in the hospital. Stipulation 127; Tr. 1125:20-22 (Gardner).

6.108. Formulary decisions represent the collective views of the hospital community regarding drug availability and use. Although hospital strive for a consensus among their providers regarding formulary decisions, complete agreement is not required. Tr. 832:16-833:3, 860:13-861:12 (Gutierrez). As Ms. Gutierrez explained, "one neonatologist doesn't represent the interests of the whole formulary. You have to take the group as a whole." Tr. 860:24-861:4 (Gutierrez).

6.109. Hospitals rely on pharmacy and therapeutics ("P&T") committees to manage the formulary system. P&T committees are multidisciplinary groups

composed of hospital physicians, pharmacists, nurses, administrators such as pharmacy directors, and other clinical experts who manage and maintain the formulary, including deciding which drugs to include on their hospitals' formularies and any policies and guidelines related to their use. Tr. 303:11-304:21 (Carrejo), 737:16-738:4 (Stickler), 889:16-890:11, 897:10-898:6, 899:6-14, 902:4-7 (Schondelmeyer); 1126:2-17 (Gardner); Russell Dep. 129:14-130:16, PX 341 at 1-2.

6.110. Hospital formularies can be generally categorized on a spectrum from open to closed. An open formulary includes the drugs endorsed by the P&T 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 and/or approvals. Stipulation 128; Tr. 1125:20-1126:1 (Gardner). Even in a closed formulary, hospital personnel still may obtain non-formulary, FDA-approved drugs if medically necessary. Stipulation 128.

6.111. In considering whether to include a drug on the hospital's formulary, a P&T committee considers the drug's safety and efficacy. Stipulation 130.

6.112. When a P&T committee determines that there are at least two drugs available to treat a particular medical condition, the P&T committee first evaluates the available drug options to determine whether the drugs have similar safety and efficacy for at least some group of patients. 310:18-311:7 (Carrejo), 899:15-900:5, 911:4-6 (Schondelmeyer). To reach a determination, the committee relies

on a review of the clinical literature and medical evidence. Tr. 310:18-311:7; PX 341 at 2. As long as safety and efficacy are similar, drugs do not need to be the same molecule to be considered clinically substitutable. Tr. 310:9-17 (Carrejo).

6.113. Once the P&T committee concludes that the drugs have similar efficacy and safety for at least some group of patients, the committee then considers price in its evaluation of the available drugs. Tr. 310:9-312:8 (Carrejo); 834:3-835:16, 844:3-20 (Gutierrez); 896:6-897:9, 899:15-900:5, 901:2-902:3, 910:2-25, 911:3-16 (Schondelmeyer); 1127:5-18, 1128:4-14, 1131:2-5, 1141:12-17 (Gardner); Gaugh Dep. 77:21-78:7; Smith Dep. 61:24-62:4. Hospitals, looking to save money on drug purchases, *see* PPFF § VI.B.2, will then often select or encourage using the less expensive drug.

2. Hospitals Leverage the Formulary System to Negotiate Discounts on Hospital-Based Drugs

6.114. Hospitals use the formulary system to help them negotiate prices for clinically substitutable drugs. When two or more sellers of clinically substitutable drugs vie for inclusion on a formulary, hospitals are often able to use the formulary system to negotiate price concessions by substituting between the available drugs. Tr. 355:16-356:5 (Carrejo), 830:20-831:12 (Gutierrez), 912:15-913:18 (Schondelmeyer), 1143:6-24 (Gardner).

6.115. In some cases, hospitals identify opportunities for potential market share discounts and approach drug companies about savings. Tr. 307:17-308:7 (Carrejo), 829:23-830:5, 834:22-25 (Gutierrez). At LAC+USC Medical Center,

the largest hospital in the LA County system, the P&T committee initiates a review of a category of drugs if it believes there is an opportunity for cost savings. Tr. 843:15-844:6 (Gutierrez).

6.116. In other cases, drug companies approach hospitals about potential discounts if they agree to buy more of a company's drug. Tr. 307:17-308:7 (Carrejo), 834:25-835:2 (Gutierrez).

6.117. Hospitals often promise (or threaten) to use more or less of a clinically substitutable drug to gain leverage in price negotiations with two or more sellers. Tr. 308:19-309:12 (Carrejo), 829:23-830:5, 830:20-831:12 (Gutierrez), 911:22-912:4 (Schondelmeyer), 1143:6-1144:6 (Gardner). A hospital that agrees to purchase more than one of the clinically substitutable products can negotiate "tiered" prices that decrease as a seller's sales volume or "market share" at the hospital increases. Tr. 912:15-913:18 (Schondelmeyer); Wilson Dep. 27:10-28:14, 29:4-8, 29:11-30:18, 31:6-32:10, 32:13-33:9; Russell Dep. 46:6-48:5, 118:1-119:5; Gaugh Dep. 44:22-45:18.

6.118. Hospitals do not need to promise or threaten to move 100 percent of their purchases to only one drug to obtain market share discounts. Tr. 313:12-21 (Carrejo).

6.119. Plaintiffs' witness, Ambrose Carrejo, Pharm.D., National Contracting Leader for Kaiser Permanente ("Kaiser"), a large integrated health system, testified that his system routinely negotiates discounts with pharmaceutical companies for drugs by promising (or threatening) to buy more or

less of one drug in place of other clinically substitutable drugs. Tr. 308:19-309:12, 312:9-313:8, 314:21-315:23, 317:9-23 (Carrejo). It then enters 3-5 year contracts with pharmaceutical companies that offer a significant price discount, sometimes up to 70 percent. Tr. 313:22-314:5, 317:9-23 (Carrejo). Similarly, Amy Gutierrez and Debra Gardner testified that their institutions, LA County and Ohio State, respectively, also routinely negotiate discounts with pharmaceutical companies that are based on meeting certain market share targets. Tr. 829:23-830:5 (Gutierrez), 1143:21-24(Gardner).

6.120. Hospitals are able to move share between clinically substitutable drugs. Tr. 312:15-313:8 (Carrejo), Tr. 829:23-830:5 (Gutierrez), 911:1-912:10 (Schondelmeyer).

6.121. Hospitals can move share by simply removing one or more clinically substitutable drugs from the formulary, ensuring that the hospital's drug purchases shift to the drug available on formulary. Tr. 841:11-842:11 (Gutierrez), Tr. 912:11-913:9 (Schondelmeyer).

6.122. Hospitals can also move share by implementing drug use guidelines restricting the use of a particular drug to a limited set of circumstances or to treat a subset of patients meeting certain criteria. These guidelines help the hospital shift share between drugs by requiring the use of a certain drug unless conditions specifically require the use of the other drug. Tr. 305:10-306:11 (Carrejo); 905:12-906:16, 912:15-913:18, 914:1-915:7 (Schondelmeyer). For example, Mr. Carrejo described guidelines implemented at Kaiser hospitals that limited the use

of a more expensive, but safer medication, to only those patients at risk for the serious side effect of the cheaper but effective drug. Tr. 305:19-306:8 (Carrejo).

6.123. Sometimes, the ability to shift share from one drug to another drug requires the hospital to coordinate with and to influence physicians to change their prescribing practices. Tr. 314:21-315:23 (Carrejo), 832:12-833:22; 861:5-12(Gutierrez). As shown by Lundbeck's NeoProfen marketing efforts, health care providers are persuadable regarding their choice of PDA drugs. *See* § VI.B.1.

6.124. To facilitate the success of the formulary system, hospitals employ a variety of measures to influence drug choices. Hospitals present medical evidence derived from either the medical literature or experiences at the individual institution to educate physicians and other healthcare providers about the substitutability of two drugs. Tr. 315:24-316:7 (Carrejo); 830:20-831:12, 861:5-12 (Gutierrez). For example, defendant's witness, clinical pharmacist Ms. Debra Gardner, described her successful effort at Ohio State, to convince physicians, based on her presentation of the medical evidence showing similar efficacy, to replace a high cost medication with a lower cost drug. Tr. 1139:9-1140:13 (Gardner).

6.125. To encourage switching, Kaiser employs drug education coordinators to educate physicians about the clinical substitutability. Mr. Carrejo testified that these drug education coordinators function "much like a pharmaceutical sales rep[resentative]." Tr. 315:12-18 (Carrejo). Similarly, LA

County works with physicians by providing them with data and articles regarding the interchangeability of drugs. Tr. 861:9-12 (Gutierrez).

6.126. Providing physicians with cost information is another means hospitals may use to shift market share. Although physicians do not purchase drugs and are often not aware of their price, when presented with cost information, physicians are willing to consider price when choosing drugs. Tr. 316:2-15 (Carrejo), 833:4-22 (Gutierrez). Consequently, hospitals present physicians with information about cost differences between drugs to encourage them to change their prescribing behavior.

6.127. Mr. Carrejo, who previously worked as a Kaiser drug education coordinator, testified that physicians may be initially uncomfortable talking about drugs prices. However, after they understood that price only became a consideration after the P&T committee determined that safety and efficacy between competing drugs were similar, they became comfortable with the hospital's efforts to use the cheaper drug. Tr. 315:24-316:15 (Carrejo). Similarly, Ms. Gutierrez, Co-chair of the LA County P&T committee, testified that when physicians at LA County are presented with information regarding cost differentials between two drugs, they are willing to take price into account when making drug decisions. Tr. 833:4-22 (Gutierrez).

6.128. Mr. Carrejo testified that Kaiser is willing to influence prescribing practices for all specialties or subspecialties of physicians. Tr. 316:16-24 (Carrejo).

3. The Formulary System Would Apply to PDA Drugs

6.129. The formulary system applies to all types of drugs, including both small population and NICU drugs. Tr. 348:24-349:6 (Carrejo); 916:9-917:6, 918:5-21 (Schondelmeyer); 1131:2-5 (Gardner); Russell Dep. 95:18-97:5. Accordingly, absent Lundbeck's monopoly, it would apply to PDA drugs.

6.130. Hospitals negotiate discounts and contract for small population drugs. For example, Ms. Gutierrez testified that her system has no minimum purchasing threshold for contracting for drugs and that it "look[s] at every opportunity" for savings related to drug purchases. Tr. 845:10-16 (Gutierrez). Savings of $100,000 or less are considered worthwhile and pursued. Tr. 833:16-22 (Gutierrez). Indeed, LA County is currently reviewing its use of PDA drugs to determine whether it could save money by including only one PDA drug on its formulary. Tr. 841:3-16 (Gutierrez).

6.131. The formulary system applies to small population drugs at Kaiser as well. Kaiser requires its hospitals to attempt to contract for all drugs that exceed $500,000 in annual purchases. Tr. 302:15-20 (Carrejo). Because Kaiser's system-wide purchases of PDA drugs exceed this threshold, Kaiser would be required to try to pursue a contract for the drugs. Tr. 329:9-17 (Carrejo). Moreover, even if spending for a particular drug falls below its system-wide threshold, Kaiser will continue to pursue opportunities for cost savings at either the system-wide or individual hospital level wherever they are available. To help with reducing drug costs, physicians and other Kaiser personnel are empowered to identify potential

pharmaceutical cost saving opportunities that may result from the ability to shift share from one drug to another. Tr. 307:8-308:11 (Carrejo).

6.132. Premier, one of the country's largest GPOs, does not have a minimum market size or revenue threshold for pursuing contract opportunities with competing pharmaceutical companies. Russell Dep. 40:12-16. After the Indocin IV price increase, Premier, at the urging of its members, reached out to Lundbeck in an effort to negotiate some type of volume-based discount or other price concession. *See* PPFF ¶¶ 6.66-6.67.

6.133. The formulary system also applies to NICU drugs. For example, there is strong competition for formulary placement and use within NICUs among the various surfactants, a class of three non-bioequivalent but similar drugs used primarily in the NICU to prevent respiratory failure in neonates. Tr. 1144:7-1145:2 (Gardner), 841:23-842:11 (Gutierrez). Each surfactant is sold by a different drug company. Tr. 842:1-6 (Gutierrez).

6.134. Ohio State currently has only one of the three surfactants on its formulary, but a competitor, seeking formulary access, provided the hospital with free samples of its medication to encourage its introduction and use. Tr. 1144:21-1145:2 (Gardner).

6.135. Similarly, LA County, which currently has all three surfactants on formulary, is considering the possibility of a market share discount on surfactants if it were to standardize to only one agent. Tr. 841:23-842:11 (Gutierrez).

6.136. Lundbeck viewed NeoProfen's addition to hospital formularies as crucial to the drug's success. Tr. 493:23-494:4 (Knocke); 919:13-920:1 (Schondelmeyer); PX 116 at 14 (2007 NeoProfen Marketing Plan); PX 140 at 19 (2008 NeoProfen Marketing Plan). If a drug is not on formulary, it is likely to get used much less or not at all. Tr. 732:10-733:5 (Stickler). Accordingly, Lundbeck devoted considerable resources to encouraging hospitals and its P&T committees to add NeoProfen to their formularies. *E.g.*, PX 104 at 6; PX 110 at 14; PX 351; Nolan Dep. 47:22-48:12. *See* PPFF § VI.B.1.

4. Lundbeck's Acquisition of NeoProfen Prevented Hospitals From Using the Formulary System to Promote Price Competition Between Indocin IV and NeoProfen

6.137. Because of hospital price sensitivity for PDA drugs, *see* § VI.B.2, independent owners of Indocin IV and NeoProfen likely would have discounted their drug to maintain or increase sales.

6.138. Because Lundbeck sells both PDA drugs, it had no incentive to discount either drug. Therefore, hospitals have been precluded from using their ordinary tools for driving hospital-based drug prices down where two or more therapeutically similar branded drugs treat a given condition. Tr. 309:17-310:8 (noting that hospitals have no leverage to negotiate discounts in a monopoly situation) (Carrejo). Specifically, Lundbeck's combined ownership of Indocin IV and NeoProfen prevents hospitals from maximizing price competition by promoting clinical substitution between Indocin IV and NeoProfen. Tr. 840:4-23

(Gutierrez), 887:19-888:7 (Schondelmeyer), 1070:20-24 (Arnold); Russell Dep. 38:4-21; Wilson Dep. 25:8-26:19.

6.139. A hospital P&T committee may have selected either Indocin IV or NeoProfen on the basis of price. Gaugh Dep. 77:21-78:15. *See* PPFF § VI.B.3.

6.140. Had hospitals independently, or through their GPOs, been able to use their usual tools to promote price competition between the two PDA drugs, the prices of Indocin IV and NeoProfen would be lower today. Tr. 887:2-888:7 (Schondelmeyer), 1001:14-19, 1092:10-22 (Arnold).

VII. Lundbeck Has Profited from Its Durable Monopoly Power in the PDA Drug Market for Four Years

7.1. Lundbeck's combined ownership of the only two FDA-approved drugs to treat PDA, Indocin IV and NeoProfen, began in January 2006 when Lundbeck acquired the rights to NeoProfen from Abbott, and it continues today, four years after that acquisition. Stipulations 27, 111-112.

7.2. Lundbeck has market power in the market for FDA-approved drugs. Market power is the ability to set and maintain prices above the competitive level. Tr. 982:17-18, 998:6-20 (Arnold).

7.3. Beginning in August 2005, after it acquired Indocin IV, Lundbeck had a 100 percent market share in the market for FDA-approved drugs to treat PDA. Lundbeck maintained its 100 percent market share by acquiring the rights to NeoProfen. Tr. 982:7-14 (Arnold). Lundbeck's 100 percent market share

provided Lundbeck with market power in the market for FDA-approved drugs to treat PDA.

7.4. Lundbeck has exercised this market power by charging supracompetitive prices for Indocin IV since the time it acquired NeoProfen in January 2006 and raising the price of Indocin IV from $108.88 per three vials, to $1,500 per three vials. Tr. 999:4-25 (Arnold). *See* PPFF § V.C.1.

7.5. Lundbeck has been able to charge supracompetitive prices for NeoProfen since July 2006, when NeoProfen was introduced, because it also owns Indocin IV. *See* PPFF § V.C.2.

7.6. Absent Lundbeck's acquisition of NeoProfen, the prices that hospitals pay for both Indocin IV and NeoProfen would be lower due to competition between two independently-owned drugs. Tr. 317:17-23 (Carrejo); 840:8-15 (Gutierrez), 1000:11-1001:19 (Arnold), 1092:10-22 (Arnold); *See* PPFF § VI.C.

7.7. All hospitals do not need to be willing to switch from one PDA drug to another to be able to stimulate meaningful competition. Rather, as long as a sufficient number of customers are willing to switch (or can credibly threaten to switch) for a reasonable price difference, competition ensues. Tr. 911:17-912:10 (Schondelmeyer).

7.8. Lundbeck's high prices for Indocin IV and NeoProfen have cost hospitals money while adding to defendant's revenues and profits. Tr. 925:16-926:33 (Schondelmeyer); *see* PPFF § VI.B.2.

7.9. There has been no entry to counter Lundbeck's market power and its supracompetitive prices. Tr. 591:15-18 (Burke); 998:21-999:3 (Arnold).

7.10. Since Lundbeck's acquisition of NeoProfen in January 2006, Indocin IV and NeoProfen have remained the only two FDA-approved PDA drugs available for purchase, a period of almost 4 years. Stipulation 49.

7.11. Although Bedford Laboratories has filed an Abbreviated New Drug Application ("ANDA") to sell generic Indocin IV, it has not yet begun selling the product and did not expect to be able to do so until December 2009, at the earliest, almost four years after Lundbeck's acquisition of NeoProfen. Gaugh Dep. 38:18-39:4, 94:11-94:14, 110:3-110:21. Other Bedford estimates do not project launching generic Indocin IV until October 2010. *Id.* at 93:19-94:14. Although Bedford has designated generic Indocin IV as a "top priority product," *id.* at 169:2-10, the wait is not surprising given the many hurdles that make developing and selling generic Indocin IV particularly difficult.

7.12. Bringing a generic drug to market typically requires at least 30 months. Gaugh Dep. 33:10-41:5. Before even submitting an ANDA to the FDA for permission to market a generic therapeutic equivalent, a manufacturer must, among other things, review any intellectual property issues associated with the branded drug, secure a supplier of the active pharmaceutical ingredient, and obtain authorization from the FDA to use that supplier. *Id.* This process requires at least a year. *Id.*

7.13. Approval of the ANDA typically requires another 18 months. Gaugh Dep. 37:9-21. Before obtaining approval, the manufacturer must produce "validation batches" of the drug on a commercial scale using the same plant and equipment that will be used to manufacture the marketed drug. Tr. 1259:1-10 (Morris); Gaugh Dep. 39:19-40:12, 64:24-65:18, 110:3-110:21; Wipperman Dep. 31:14-24.

7.14. In addition to the hurdles facing all generic drugs, generic Indocin IV is unusually difficult to manufacture. David Gaugh, Bedford's Vice President and General Manager, testified that the drug is among the most difficult to make of the 35 to 40 he has been personally involved in launching. Gaugh Dep. 63:24-64:12. Indeed, Mr. Gaugh described generic Indocin IV as "a differentiated product, a barrier to entry product, because of the difficulties . . . in its production." Gaugh Dep. 79:2-14.

7.15. Further underscoring the difficulty of manufacturing generic Indocin IV, Lundbeck itself experienced significant difficulties transferring manufacturing of Indocin IV from Merck to a contract manufacturer, resulting, by December 2009, in an Indocin IV shortage. Tr. 1245:14-25 (Morris). Lundbeck first began working with Catalent in August 2005, Tr. 1250:7-23 (Morris), but Catalent experienced a number of manufacturing complications and delays. Tr. 1253:24-1255:17 (Morris). As a result, by September 2008, Lundbeck became concerned that "projected delays" at Catalent could "jeopardize continuity of [the Indocin] supply." PX 236 at 1. Similarly, Jeffrey Aronin, Lundbeck CEO at the time,

complained about Catalent's manufacturing difficulties in Spring 2009. Nolan Dep. 29:19-30:14. Despite assistance from Merck, Catalent was unable to manufacture Indocin IV in over 4 years and Lundbeck had to look elsewhere to find a contract manufacturer for Indocin IV. Tr. 1257:20-25 (Morris).

7.16. Lundbeck next turned to another contract manufacturer, Hollister-Stier, to manufacture Indocin IV on its behalf. Tr. 1258:9-16 (Morris). Hollister-Stier, however, has also experienced complications manufacturing sellable vials of Indocin IV. Tr. 1259:11-20 (Morris). As a result, in December 2009, there is Indocin IV "stock-out" and the drug is not available for sale in the United States. Tr. 1245:14-25 (Morris).

VIII. Lundbeck Should Divest NeoProfen and Disgorge Its Ill-Gotten Profits

A. Divestiture of NeoProfen Is Necessary and Appropriate to Establish Competition

8.1. Following its acquisition of NeoProfen from Abbott in January 2006, Lundbeck owned the rights to the only two FDA-approved drugs to treat PDA.

8.2. Lundbeck's acquisition of NeoProfen eliminated the competitive threat Lundbeck faced in selling Indocin IV.

8.3. Divestiture of NeoProfen would establish, to the extent possible, the market conditions that would have existed absent Lundbeck's acquisition of NeoProfen by restoring a third-party owner of NeoProfen and by eliminating Lundbeck's monopoly in PDA drugs from its combined ownership of Indocin IV and NeoProfen.

8.4. Divestiture of NeoProfen would permit an independent marketer of NeoProfen to compete with Indocin IV.

8.5. Divestiture of NeoProfen would eliminate Lundbeck's ability to control the prices for the only two FDA-approved drugs to treat PDA.

8.6. Divestiture of NeoProfen would eliminate Lundbeck's ability to control marketing and other tactics to favor NeoProfen over Indocin IV.

8.7. Divestiture of NeoProfen would permit hospitals and their GPOs to negotiate the prices of NeoProfen and Indocin IV with competing owners of each drug.

8.8. The likelihood, timing and potential impact of Bedford's introduction of a generic version of Indocin IV remain uncertain, Tr. 591:15-18 (Burke), and there is no reason to believe that entry by the generic will fully offset Lundbeck's market power as a result owning both branded PDA drugs.

8.9. Lundbeck's models of generic penetration project a slow transition from branded Indocin IV to generic Indocin IV. PX 84 at 5. Accordingly, Lundbeck would retain a monopoly share of the PDA market for a substantial period after the generic is introduced unless it is required to divest NeoProfen.

8.10. Even if a generic Indocin IV enters the market, divestiture of NeoProfen is necessary to restore the number of competing firms selling PDA drugs to the level that would have prevailed but for Lundbeck's acquisition of NeoProfen since the generic would likely have entered regardless of the acquisition. With a NeoProfen divestiture, at least three companies would be

selling into the PDA market and greater competition is likely to result. Tr. 317:17-23 (Carrejo), 1358:5-10 (McCarthy) (commenting that scholarship in the field shows that prices are lower as the number of branded drugs competing in a market increases); Gaugh Dep. 72:14-73:4 (stating that Bedford prices its products lower in markets with more competitors).

8.11. Although not historically the case, brand name pharmaceutical companies now regularly compete with generic companies, particularly for hospital-based drugs like PDA drugs. Russell Dep. 90:20-92:8.

8.12. Lundbeck would be more likely to compete with generic Indocin IV, either directly or by launching an authorized generic, which it considered at various times, Tr. 587:8-588:20 (Burke); PX 84, PX 44 at 3, if it did not also own the rights to NeoProfen. Bedford has historically priced its generic drugs 10 to 15 percent below the brand price and 5 to 10 percent below another generic on the market. Gaugh Dep. 72:14-73:4. If it still owned both Indocin IV and NeoProfen, Lundbeck would be reluctant to launch an authorized generic because of a fear of hurting NeoProfen sales by driving the price of generic Indocin IV even lower and increasing the price differential between Indocin IV and NeoProfen. *See* PPFF § VI.B.4. (discussing how Lundbeck viewed generic Indocin IV as a threat to NeoProfen). Absent joint ownership, however, Lundbeck would not be deterred by harming NeoProfen sales and would be more likely to lower its prices to compete with generic Indocin IV.

B. Lundbeck Should Disgorge Unlawful Profits

8.13. Disgorgement is appropriate and necessary to deprive Lundbeck of its unlawfully obtained profits from its sales of Indocin IV and NeoProfen at supracompetitive prices during the existence of its monopoly.

8.14. Although there is strong evidence that the prices of Indocin IV and NeoProfen would have been lower had the PDA drugs been independently owned, *See* PPFF § VI.C; Tr. 1000:20-1001:19, 1002:2-19 (Arnold), calculating a disgorgement amount in this case based on Lundbeck's unlawful supracompetitive profits is complicated. NeoProfen was never on the market when owned by an independent competitor. There is no independent pricing history or data. As a result, information is not available to determine what competitive price would have prevailed for Indocin IV and NeoProfen absent Lundbeck's acquisition of NeoProfen. Tr. 987:4-988:8, 1000:11-19, 1003:7-20 (Arnold).

1. Lundbeck Should Disgorge Profits of Indocin IV and NeoProfen Based on the Last Market Price Prior to the Illegal Acquisition

8.15. A reasonable disgorgement amount, based on the best information available, is the difference between (1) Lundbeck's actual net sales of Indocin IV and NeoProfen between February 1, 2006, and April 30, 2009, and (2) the estimated net sales that Lundbeck, or Lundbeck and an independent competitor, would have earned on sales of both drugs in that same period, if both drugs had been sold at the list price of Indocin IV immediately prior to defendant's

acquisition of NeoProfen, $108.88 per three vials. Tr. 1003:21-1004:21, 1005:4-21 (Arnold).

8.16. $108.88 represents the last price Lundbeck charged for Indocin IV untainted by the illegal NeoProfen acquisition. Tr. 1004:13-21 (Arnold).

8.17. Lundbeck's actual net sales of Indocin IV and NeoProfen between February 1, 2006 and April 30, 2009, were approximately $117 million. Tr. 1006:5-1007:20 (Arnold).

8.18. At $108.88 per three vials of Indocin IV and NeoProfen, hospitals would likely would have purchased more vials of those drugs than they actually did, because they would have been less motivated to engage in splitting vials. Tr. 1009:3-1010:4 (Arnold).

8.19. After adjusting actual sales volume of Indocin IV and NeoProfen for increased purchases from less splitting vials, the estimated amount of net sales that Lundbeck, or Lundbeck and an independent competitor, would have earned on sales of both Indocin IV and NeoProfen at $108.88 for three vials between February 1, 2006, and April 30, 2009, is approximately $11.7 million. Tr. 1008:3-1010:4 (Arnold). These adjustments would not have a material impact on the variable costs associated with selling the two PDA drugs. Tr. 1011:4-1012:10 (Arnold).

8.20. The difference between (1) Lundbeck's actual net sales of Indocin IV and NeoProfen between February 1, 2006, and April 30, 2009, ($117 million), and (2) the estimated net sales that Lundbeck, or Lundbeck and an independent

competitor, would have earned on sales of both drugs in that same period at $108.88 for three vials ($11.7 million), yields a disgorgement amount of approximately $105 million. Tr. 1010:10-25 (Arnold).

2 Lundbeck Should Disgorge Unlawful Profits on Indocin IV Measured as the Difference Between Lundbeck's Actual Sales of Indocin IV and Sales at the Conservative Monopoly Price

8.21. Lundbeck's illegal profits on Indocin IV are the incremental profits that resulted from the illegal acquisition.

8.22. A reasonable and conservative way to measure disgorgement of illegal profits for Indocin IV would be to calculate disgorgement based on the difference between (1) Lundbeck's actual net sales of Indocin IV between February 1, 2006, and December 31, 2008,[2] and (2) the estimated net sales that Lundbeck would have earned on sales of Indocin IV in that same period, if Indocin IV had been sold at the price Lundbeck viewed as the drug's conservative monopoly price, $1,140 per three vials.

8.23. Lundbeck initially identified $1,140 per course of treatment as a conservative estimate for a potential Indocin IV price and repeatedly identified it as the lower end of the price range for Indocin IV. Tr. 571:21-24, 650:11-14 (Burke); PX 25 at 14; PX 436 at 5. Lundbeck viewed $1,140 as a "readily appropriate," reasonable and profitable price for Indocin IV. Tr. 572:6-11, 704:20-706:3 (Burke). Notably, when Lundbeck initially identified the $1,140

[2] The record contains data regarding sales of Indocin IV through December 2008.

price, it was unaware of potential competition from NeoProfen. Tr. 573:12-19 (Burke).

8.24. Lundbeck presented the $1,140 price to other drug companies to encourage their interest in partnering with Lundbeck to sell Indocin IV. *See* PX 25 at 14; PX 436 at 5; DX 77 at 23. Similarly, it relied on that price in its deal model when presenting the acquisition to its shareholders and outside investors to secure their consent and financing. Tr. 704:20-706:3 (Burke); DX 299 at 3.

8.25. Because it is impossible to calculate an exact competitive price for Indocin IV were NeoProfen independently owned, relying on the minimum monopoly price of $1,140 per three vial course of Indocin IV treatment represents a reasonable approximation of the maximum price Lundbeck would have set for Indocin IV in a competitive market. Accordingly, the difference in price between $1,140 and $1,500 for three vials of Indocin IV represents a conservative measure of the supracompetitive profits Lundbeck earned on Indocin IV by also selling NeoProfen.

8.26. Although Mr. Burke testified that he had determined "in [his] mind," Tr. 648: 9-15 (Burke), Lundbeck's ultimate price of $1,500 per three vial course of treatment for Indocin IV by August 2004, over a year and a half before the actual price increase and a year before the acquisition, this was not the case. Rather, Lundbeck considered a number of different prices before settling on $1,500 on January 20, 2006, immediately after acquiring NeoProfen. Between August 2004 and January 20, 2006, Lundbeck's internal documents show that the company

considered a number of different prices for Indocin IV, including several that fell below $1,140. Significantly, Lundbeck models and projections included high prices when it appeared that Lundbeck would own both PDA drugs and lower prices, below $1,140 per 3 vial course of treatment, when it feared that it would have to compete with an independent owner of NeoProfen. *See* PPFF ¶¶ 5.44-5.46.

8.27. Lundbeck's actual net sales of Indocin IV between February 1, 2006, and December 31, 2006, were $27.41 million. PX 396 at 175; PX 395 at 8 (subtracting January 2006 sales from 2006 total sales). During this period, Lundbeck sold 21,212 three-vial sets of Indocin IV (subtracting January 2006 units sold from 2006 total units sold). PX 396 at 175; PX 395 at 8. At a price of $1,140 per three-vial set, Lundbeck would have earned approximately $24.18 million between February 1, 2006, and December 31, 2006 (multiplying the number of Indocin IV three-vial sets sold for the relevant period by the $1,140 conservative monopoly price). Therefore, Lundbeck's estimated monopoly profits between February 1, 2006, and December 31, 2006, would be $3.23 million (subtracting sales at the conservative monopoly price from actual sales).

8.28. Lundbeck's actual net sales of Indocin IV between January 1, 2007, and December 31, 2007, were $24.58 million. PX 396 at 173. Lundbeck sold 16,359 three-vial sets of Indocin IV during this period. PX 335 at 2. At a price of $1,140 per three-vial set, Lundbeck would have earned approximately $18.65 million (multiplying the number of Indocin IV three-vial sets sold for the relevant

period by the $1,140 conservative monopoly price) between January 1, 2007, and December 31, 2007. Therefore, Lundbeck's estimated monopoly profits between January 1, 2007, and December 31, 2007, would be $5.93 million (subtracting sales at the conservative monopoly price from actual sales).

8.29. Lundbeck's actual net sales of Indocin IV between January 1, 2008, and December 31, 2008, were $27.73 million. PX 335 at 14. Lundbeck sold 15,222 three-vial sets of Indocin IV during this period. PX 335 at 2. At a price of $1,140 per three-vial set, Lundbeck would have earned approximately $17.35 million (multiplying the number of Indocin IV three-vial sets sold for the relevant period by the $1,140 conservative monopoly price) between January 1, 2008, and December 31, 2008. Therefore, Lundbeck's estimated monopoly profits between January 1, 2008, and December 31, 2008, would be $5.37 million (subtracting sales at the conservative monopoly price from actual sales).

8.30. In sum, Lundbeck's actual net sales of Indocin IV between February 1, 2006, and December 31, 2008, were approximately $74.71 million. At a price of $1,140 per three-vial set, Lundbeck would have earned approximately $60.18 million (multiplying the number of Indocin IV three-vial sets sold for the relevant period by the $1,140 conservative monopoly price) between February 1, 2006, and December 31, 2008.[3] The difference between (1) Lundbeck's actual net sales of Indocin IV between February 1, 2006, and December 31, 2008, ($74.71 million),

[3] Selling Indocin IV at $1,140 per three vials versus the actual price would not have a material impact on the variable costs associated with selling Indocin IV. Tr. at 1011:4-1012:10 (Arnold).

and (2) the estimated net sales that Lundbeck would have earned on sales of Indocin IV in that same period at $1,140 per three-vial set ($60.18 million), yields a disgorgement amount of approximately $14.53 million from February 2006 through December 2008. Any measure of disgorgement would require updated information to incorporate Indocin IV profits earned during the intervening period.

3. Lundbeck Should Disgorge Profits From NeoProfen Sales as Well as Net Proceeds Resulting From a NeoProfen Divestiture

8.31. Profits attributable to Lundbeck's illegal acquisition of NeoProfen include not only any profits from the sales from the drug, but also any proceeds derived from the court-ordered divestiture of NeoProfen to a third party.

8.32. Lundbeck prepared an analysis of Neoprofen accounting for the period 2006-2008 based on a mixture of actual and estimated results. This analysis includes a calculation of NeoProfen's profits as a measure of Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA"). DX 149 at 1. EBITDA is a typical and appropriate measure to evaluate the profits of an individual product line.[4] Tr. 1018:11-15 (Arnold).

8.33. The 2006-2008 NeoProfen EBITDA states a loss of approximately $7.5 million from sales of NeoProfen. DX 149 at 1.

[4] It is inappropriate to include interest expenses when calculating costs attributable to an individual product line because a company's decision to fund an acquisition with debt or equity is not product specific and Lundbeck had equity at the time of the purchase. Therefore, including interest expenses is just a way to improperly increases expenses for the product. Tr. 1018:7-1019:2.

8.34. The accounting that results in the $7.5 million loss shown in the 2006-2008 NeoProfen EBITDA has numerous shortcomings, which improperly inflate the expenses associated with NeoProfen and make the drug appear less profitable than it would if the accounting had been performed properly. Tr. 1016:13-22 (Arnold).

8.35. First, the 2006-2008 NeoProfen EBITDA calculation, compiled by Mr. Parhad, Lundbeck's Assistant Controller, does not conform with Generally Accepted Accounting Principles (GAAP) because (1) it is a multi-year income statement and (2) the cost allocations use a different methodology from Lundbeck's ordinary course of business accounting. Tr. 1013:18-1014:15 (Arnold); Parhad Dep. 17:23-18:6. Additionally, the document was not prepared in the ordinary course of business, but rather for potential buyers of Lundbeck to ascertain potential costs related to this litigation. Parhad Dep. 25:24-26:8, 36:24-37:8.

8.36. Second, the royalties Lundbeck paid under the Asset Purchase Agreement are calculated based on a percentage of total NeoProfen revenues. *See* PPFF ¶¶ 5.25-5.26. To the extent that NeoProfen's price is inflated and anti-competitively high, royalty payments would be overly high, thereby overstating costs and understating NeoProfen profitability. Tr. 1017:13-1018:6 (Arnold).

8.37. Finally, Lundbeck allocated many expenses to NeoProfen based on NeoProfen's percentage of the company's total revenues. Therefore, to the extent that Lundbeck charged an anticompetitively high price for NeoProfen, excessive

costs would have been attributed to NeoProfen, reducing the drug's profitability. Tr. 1016:18-1017:12 (Arnold). Examples of expenses inflated in this manner include the Manufacturing Management and Distribution expenses. Tr. 1017:3-12 (Arnold).

8.38. Despite these shortcomings that may cause the NeoProfen losses to be inflated, it is the only estimate of NeoProfen product line earnings in the record.

8.39. Lundbeck's improper gains on NeoProfen include its profits on sales of NeoProfen, as shown in the 2006-2008 NeoProfen EBITDA calculation, and any additional profits Lundbeck earns, up to the time of divestiture, as well as any profits on the sale of the divested asset itself.

PROPOSED CONCLUSIONS OF LAW

I. Jurisdiction

1.1. The United States District Court for the District of Minnesota (the "Court") has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), 1345 & 1367 (2009).

1.2. The Court has personal jurisdiction over Lundbeck pursuant to 15 U.S.C. § 53(b) because Lundbeck meets the requisite minimum constitutional contacts with the United States and the State of Minnesota.

1.3. The Court has supplemental jurisdiction over the State of Minnesota's state law claims under 28 U.S.C. § 1367 (2009) 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.

II. Interstate Commerce

2.1. Lundbeck is, and at all relevant times has been, engaged in "commerce" as defined in section 1 of the Clayton Act, 15 U.S.C. § 12 (2009).

2.2. Lundbeck's general business practices, the challenged acts and practices, including its NeoProfen acquisition, are in or affect commerce within the meaning of sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44 and 45 (2009).

III. Relevant Market

3.1. The sale of FDA-approved drugs to treat PDA is a relevant product market within which to assess the effects of Lundbeck's acquisition of NeoProfen (the "PDA drug market"). *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (holding that market boundaries are defined by the "reasonable interchangeability of use" of two products); *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956) (holding that the "market is composed of products that have reasonable interchangeability for the purposes for which they are produced").

3.2. The United States is the relevant geographic market within which to assess the effects of Lundbeck's acquisition of NeoProfen. *See United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 357-59 (1963); *Morton Bldgs. of Neb., Inc. v. Morton Bldgs.*, 531 F.2d 910, 918 (8th Cir. 1976).

IV. Section 7 of the Clayton Act, 15 U.S.C. § 18

4.1. Lundbeck's acquisition of the rights to NeoProfen is an asset acquisition within the meaning of section 7 of the Clayton Act. 15 U.S.C. § 18 (2009).

4.2. 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. Lundbeck's acquisition of NeoProfen substantially lessened competition or tended to create a monopoly in the PDA drug market in the United States. *See Philadelphia Nat'l Bank*, 374 U.S. at 362-63.

4.3 Under section 7 of the Clayton Act, plaintiffs must show that the acquisition has reduced competition and aided the exercise of market power — the ability to maintain prices above the competitive level — in a relevant market. *See Philadelphia Nat'l Bank*, 374 U.S. at 362-63; *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 246 (8th Cir. 1988). Plaintiffs have shown that, following Lundbeck's acquisition of NeoProfen, Lundbeck has profitably raised and maintained the prices for Indocin IV and NeoProfen substantially above the competitive level.

4.4. A transaction resulting in a literal monopoly is always anticompetitive and therefore virtually always illegal. *See United States v. El Paso Natural Gas Co.*, 376 U.S. 651, 660-62 (1964); *United States v. Franklin Elec. Co.*, 130 F.

Supp. 2d 1025, 1035 (W.D. Wis. 2000). Lundbeck has controlled 100 percent of the PDA drug market in the United States since it acquired NeoProfen.

4.5. There has been no entry into the PDA drug market since the NeoProfen acquisition in January 2006 to overcome the anticompetitive effects of the acquisition.

4.6. Lundbeck's acquisition of NeoProfen lacks any plausible or valid procompetitive justification that would overcome the anticompetitive effects of the acquisition. "[A] merger the effect of which 'may be substantially to lessen competition' is not saved because, on some ultimate reckoning of social or economic debits or credits, it may be deemed beneficial." *Philadelphia Nat'l Bank*, 374 U.S. at 371.

V. Section 2 of the Sherman Act, 15 U.S.C. § 2

5.1. Lundbeck has, and at all relevant times has had, monopoly power in the PDA drug market in the United States by controlling 100 percent of that market. *See* C*oncord 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)).

5.2. Lundbeck willfully maintained its monopoly power in the PDA drug market in the United States by acquiring NeoProfen when it already owned Indocin. The evidence that Lundbeck acquired NeoProfen and subsequently controlled 100 percent of the PDA drug market in violation of section 7 of the Clayton Act establishes that the NeoProfen acquisition was an act of

monopolization in violation of section 2 of the Sherman Act. *See Brown Shoe*, 370 U.S. at 328 (dicta).

5.3. Lundbeck has exercised significant market power by profitably raising and maintaining the prices for Indocin and NeoProfen substantially above the competitive level.

5.4. Lack of market entry since 2006 confirms Lundbeck's monopoly power.

VI. Section 5 of the FTC Act, 15 U.S.C. § 45

6.1. At all relevant times, Lundbeck has been, and is now, a "corporation" within the meaning of section 4 of the FTC Act, 15 U.S.C. § 44.

6.2. Lundbeck has monopolized the PDA drug market in the United States in violation of section 2 of the Sherman Act, 15 U.S.C. § 2, thus violating section 5 of the FTC Act, 15 U.S.C. § 45. *See FTC v. Cement Inst.*, 333 U.S. 683, 694 (1948).

VII. Minnesota State and Common Law

7.1. Minn. Stat. § 325D.52 states that "[t]he 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."

7.2. Lundbeck violated Minn. Stat. § 325D.52 by acquiring NeoProfen when it already owned Indocin, and by raising and maintaining the prices for Indocin and NeoProfen substantially above the competitive level.

7.3. In violation of Minnesota law, Lundbeck's establishment, maintenance, and use of its monopoly power was for the purpose of affecting competition in the PDA drug market in Minnesota.

7.4. To establish a claim for unjust enrichment in Minnesota, a plaintiff must establish that another party knowingly received something of value to which the party was not entitled, and that under the circumstances it would be unjust for the party to retain the benefit. *Schumacher v. Schumacher*, 627 N.W.2d 725, 729 (Minn. App. 2001). Although not a prerequisite, the term "unjustly" often times could mean illegally or unlawfully. *See ServiceMaster of St. Cloud v. GAB Business Services, Inc.*, 544 N.W.2d 302, 306 (Minn. 1996).

7.5. Here, Lundbeck's conduct was unjust in the sense that it was unlawful for it to raise and maintain the prices for Indocin and NeoProfen substantially above the competitive level through illegal use of its monopoly power. Lundbeck is not entitled to illegal, supracompetitive profits from its sales of Indocin and NeoProfen in Minnesota, and it would be unjust for Lundbeck to retain the benefit of these illegal profits, or the profits from any sale of NeoProfen to remedy its acquisition and maintenance of an illegal monopoly.

7.6. Minn. Stat. § 8.31, subd. 3a authorizes parties, expressly including the Minnesota Attorney General, to seek "equitable relief" for violations of state antitrust law. The plain language of this provision further states that these remedies are "[i]n addition to" any other remedies provided for elsewhere by Minnesota law. Minn. Stat. § 325D.59 also grants the Minnesota Attorney

General the authority to seek all "appropriate" relief when bringing an antitrust action.

7.7. Generally, divesture, restitution, and disgorgement are equitable remedies. *Du Pont*, 366 U.S. at 326 (divestiture); *United States ex rel. Zissler v. Regents of the University of Minnesota*, 992 F. Supp. 1097, 1109 (D. Minn. 1998) (disgorgement); *State by Humphrey v. Alpine Air, Inc.*, 490 N.W.2d 888, 896 (Minn. Ct. App. 1992), *aff'd*, 500 N.W.2d 788 (Minn. 1993) (restitution). Thus, Minn. Stat. § 8.31, subd. 3a expressly authorizes the Minnesota Attorney General to seek such equitable remedies against Lundbeck. In accordance with the fact that Minnesota antitrust law is to be broadly construed to effectuate its purpose, *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 624 (Minn. 2007), the Court concludes that Minn. Stat. § 325D.59 encompasses the ability to seek these equitable remedies against Lundbeck as well.

7.8. In regards to the remedies available under Minn. Stat. § 8.31 and Minnesota antitrust law, the Court rejects the interpretation of the court in *FTC v. Mylan Labs, Inc.*, 62 F. Supp. 2d 25, 48-49 (D.D.C. 1999), as contrary to the plain language of the relevant statutes, and for the other reasons detailed in Plaintiffs' post-trial briefing.

7.9. Moreover, regardless of her *statutory* authority to seek the equitable remedies of divesture, restitution, and disgorgement, the Minnesota Attorney General is entitled to seek such remedies pursuant to her common law *parens patriae* authority. *See State by Humphrey v. Standard Oil Co.*, 568 F. Supp. 556,

563-66 (D.Minn. 1983); *Slezak v. Ousdigian*, 110 N.W.2d 1, 5 (Minn. 1961); *State by Humphrey v. Ri-mel, Inc.*, 417 N.W.2d 102, 112 (Minn. Ct. App. 1987); *see also Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982) (protection of "the health and well-being—both physical and economic—of its residents in general" allows invocation of the *parens patriae* doctrine).

VIII. Remedies

8.1. A permanent injunction ordering Lundbeck to divest NeoProfen is necessary to remedy Lundbeck's illegal conduct and to protect the public now and in the future. *See Ford Motor Co. v. United States*, 405 U.S. 562, 573 (1972); *Du Pont*, 366 U.S. at 326.

8.2. Disgorgement is necessary and appropriate to deprive Lundbeck of its unlawfully obtained profits under both federal and Minnesota state law. *See* Minn. Stat. §§ 325D.49-66; Minn. Stat. § 8.31, subd. 3a.; *Paschall v. Kansas City Star Co.*, 695 F.2d 322, 335 (8th Cir. 1982); *Mylan Labs., Inc.*, 62 F. Supp. 2d at 36-37 (D.D.C. 1999); *Zissler*, 992 F. Supp. at 1109.

8.3. Pursuant to Minn. Stat. §§ 8.31, 325D.59, and the Minnesota Attorney General's common law *parens patriae* authority, the State of Minnesota is entitled to equitable relief against Lundbeck for its violation of Minnesota statue and as a result of its unjust enrichment, including divesture of NeoProfen, restitution on behalf of injured Minnesota hospitals, and disgorgement of any illegal profits including any profits from the divesture of NeoProfen. *See Du Pont*, 366 U.S. at 326; *Zissler*, 992 F. Supp. at 1109; *Alpine Air*, 490 N.W.2d at 896; *Ri-mel, Inc.*,

417 N.W.2d at 112; *State v. Directory Publ'g Servs., Inc.*, 1996 WL 12674 (Minn. Ct. App. 1996) (restitution awarded to businesses); *see also* Minn. Stat. § 8.31, subds. 2c, 3c (addressing restitution).

8.4. Pursuant to Minn. Stat. §§ 8.31 and 325D.58, Lundbeck, and any subsidiaries, joint ventures, and any persons acting on behalf of Lundbeck, are permanently enjoined from acquiring or maintaining any simultaneous legal or beneficial interest in NeoProfen and Indocin.

8.5. Pursuant to Minn. Stat. §§ 8.31 and 325D.56, the State of Minnesota is also entitled to civil penalties against Lundbeck. In accordance with section 325D.56, Lundbeck shall pay the State of Minnesota a civil penalty of $50,000.

8.6. Pursuant to Minn. Stat. § 8.31, the State of Minnesota is entitled to costs and reasonable attorneys' fees. The State of Minnesota shall be entitled to full reimbursement of its costs and attorneys' fees, based on market rates, upon serving and filing an affidavit detailing and itemizing such fees and costs.

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Respectfully submitted,

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