CONFIDENTIAL FINDINGS OF FACT

I. THE PARTIES

A. Plaintiffs Federal Trade Commission and State of Minnesota

1. Plaintiff, the Federal Trade Commission ("FTC"), is an administrative agency of the United States, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 et seq. The FTC has exclusive authority and responsibility for enforcing Section 5 of the FTC Act, which prohibits unfair methods of competition. The FTC also has authority under Section 7 of the Clayton Act to prohibit acquisitions that may substantially lessen competition or tend to create a monopoly. (FTC Am. Compl. ¶ 9).

2. Plaintiff State of Minnesota brought this action by and through its attorney general. (State of Minn. Am. Compl. ¶ 11).

B. Ovation/Lundbeck

3. Ovation Pharmaceuticals, Inc. ("Ovation") was a small, specialty pharmaceutical company founded in 2000. (Stip. Fact 1). Ovation's business model targeted treatments for rare diseases and/or small patient populations that were commercially neglected or at risk of discontinuation because they were no longer strategic to the big pharmaceutical companies that developed them, particularly after all patent protections expired. (Stip. Facts 6-8; Morris Trial Tr. 1205:10-14, 1205:24-1206:8, Dec. 14, 2009). To serve this unmet need, Ovation identified, acquired, developed, and (when necessary) revived orphan and orphan-like drugs in need of additional support and investment. (Stip. Facts 7-8; Burke Trial Tr. 673:21- 674:4, Dec. 10, 2009; Morris Trial Tr. 1205:10-14, Dec. 14, 2009). Ovation acquired a number of

drugs that were very important to small patient populations, but were not being further developed or actively marketed by their previous owners. (Burke Trial Tr. 636:13-637:13, Dec. 10, 2009; Morris Trial Tr. 1205:10-14, 1205:24-1206:8, Dec. 14, 2009).

4. On March 19, 2009, H. Lundbeck A/S purchased Ovation and renamed it Lundbeck Inc., keeping Lundbeck Inc. as a subsidiary with the same business model (hereinafter, Ovation and Lundbeck Inc. are referred to as "Ovation"). (Stip. Facts 2, 5).

5. Since August 2005, Ovation has owned and sold a drug called Indocin IV, a brand-name injectable form of indomethacin. In January 2006, Ovation acquired the contingent rights to NeoProfen, a brand-name injectable form of ibuprofen lysine. Plaintiffs' alleged antitrust claims pertain to Ovation's acquisition of the contingent rights to NeoProfen in January 2006.

II. THE MERCK BUNDLE ACQUISITION

A. Merck Sought a Single Buyer for Six Commercially Neglected Drugs

6. On May 20, 2004, Merck & Co. ("Merck") initiated an auction for a bundle of medically significant, off-patent, and commercially neglected drugs (collectively, "the Merck Bundle" or "the Bundle drugs"). (PX 7 at 2 / DX 79 at 1). The Bundle drugs were medically significant in that they addressed critical medical needs and, at the time of the auction, had no generic or other therapeutic substitutes available. (Neunaber Dep. 18:17-19:14). The Merck Bundle consisted of six drugs: Indocin IV, Cogentin, Cosmegen, Diuril, Mustargen, and Elspar, all of which served small patient populations and were off-patent. (Stip. Fact 55; DX 64 at 1).

7. Susan Neunaber, Merck's Senior Director of Corporate Business Development, was responsible for negotiating Merck's divestiture of the Merck Bundle. Ms. Neunaber testified regarding Merck's motivations in auctioning the Bundle drugs as well as Merck's historic experience with the Bundle drugs. Ms. Neunaber's testimony was credible.

8. Merck decided to auction the Bundle drugs so that it could convert the facility where they were manufactured from a multi-product classification to a facility dedicated to the manufacture of live virus vaccines. (Burke Trial Tr. 639:22-640:22, Dec. 10, 2009; Neunaber Dep. 31:7-22; DX 55 at 1; DX 57 at 1; DX 63 at 2; DX 64 at 1; DX 78 at 2). Merck could not manufacture the Bundle drugs in the same facility as live virus vaccines due to regulatory concerns regarding cross contamination. (Burke Trial Tr. 640:10-22, Dec. 10, 2009; Neunaber Dep. 14:7-24, 31:23-32:10; DX 63 at 2).

9. [redacted]

10. [redacted]

[redacted]

11. [redacted]

12. [redacted]

13. [redacted]

[redacted]

14. [redacted]

15. [redacted]

16. In December 2004, Merck estimated that the net present value of the Merck Bundle was as [redacted] not including the predicted capital expenditures Merck would have incurred if it had decided to transfer the production of the Bundle drugs to a different Merck facility. (Neunaber Dep. 32:12-33:6, 33:15-35:8; DX 63 at 13). Merck later revised the net present value of the Bundle drugs to [redacted] (Neunaber Dep. 124:11-24; DX 64 at 1).

17. Merck calculated the net present value of keeping the Bundle drugs, including the cost of manufacturing transfer, at [redacted] (Neunaber Dep. 38:12-21; DX 57 at 1).

18. Merck's 2004 sales of all of the Bundle drugs were approximately [redacted] (DX 57 at 1; DX 64 at 4).

19. Merck did not consider the Bundle drugs part of its core strategy for future growth. (Neunaber Dep. 49:20-51:9; DX 63 at 2, 16). Merck nonetheless felt a moral obligation to ensure the continued worldwide supply of the medically significant Bundle drugs because generic versions of the drugs were not available. (Neunaber Dep. 18:10-19:20).

20. When a large pharmaceutical company like Merck wants to stop selling a medically necessary drug, if it is unable to find a buyer like Ovation, it must inform the U.S. Food and Drug Administration ("FDA") of its intent to withdraw the product from the market, which might anger and/or disappoint the FDA. These large pharmaceutical companies have other drugs in registration with the FDA, and will be seeking approval for much bigger blockbuster drugs, so they do not want to upset the FDA. (Morris Trial Tr. 1205:17-23, 1206:10-21, 1207:7-17, Dec. 14, 2009).

21. Likewise, when a large pharmaceutical company like Merck wants to stop selling a medically necessary drug, if it is unable to find a buyer like Ovation and withdraws the product from the market, it might disappoint patient advocacy groups, which could lead to a backlash and public relations problems if it is a drug for a small patient population that needs it. (Morris Trial Tr. 1205:15-23, 1206:24-1207:5, Dec. 14, 2009).

22. Fearing that potential buyers might try to cherry-pick and take only the profitable drugs from the bundle, Merck made it clear in its request for proposal that the

buyer would be required to acquire the entire Bundle. (Morris Trial Tr. 1217:18-21, Dec. 14, 2009; Neunaber Dep. 151:24-152:11, 153:21-154:10; PX 7 at 2 / DX 79 at 1).

23. Merck did not want the buyer of the Merck Bundle to discontinue selling Indocin IV or the other medically necessary Bundle drugs in the U.S. or any other market. (Stip. Fact 57; DX 55 at 1; DX 63 at 5). To ensure that a prospective buyer of the Merck Bundle would not (1) abandon the drugs that were less profitable or harder to manufacture or (2) discontinue selling the drugs in unprofitable foreign markets, Merck also insisted that the buyer make substantial and costly commitments to manufacture and support all of the Bundle drugs, without exception, for five years, in 84 countries worldwide, which necessitated technology transfer and regulatory submissions. (Neunaber Dep. 52:23-53:10, 116:21-117:4, 117:11-22; DX 61 at 2; DX 64 at 2; DX 78 at 2). Merck made these conditions clear in its May 20, 2004 memorandum proposing the sale of the Merck Bundle drugs when it stated that the preferred buyer would "assume worldwide rights for the manufacture, marketing, sale and distribution" of the drugs and "commit to continue supply of certain products to all markets in which the products are currently distributed." (DX 79 at 1).

B. Ovation's Acquisition of the Merck Bundle Involved Substantial Costs and Risks

24. By acquiring the Merck Bundle, Ovation committed to guarantee supply of all of the Bundle drugs for five years after Ovation obtained market authorizations in all of the countries where Merck previously held them. (Burke Trial Tr. 641:8-23, Dec. 10, 2009; Morris Trial Tr. 1217:23-1219:18, Dec. 14, 2009; Neunaber Dep. 117:11-22;

Wipperman Dep. 160:17-161:3, 168:19-23; DX 64 at 2; DX 91 at 44). A market authorization is a local regulatory approval to sell a drug in a foreign country, similar to a New Drug Application ("NDA") in the U.S. (Morris Trial Tr. 1217:23-1219:18, Dec. 14, 2009). Obtaining market authorizations involved updating foreign regulatory filings and seeking approval for new Ovation labels in at least 44 countries. (Morris Trial Tr. 1217:23-1219:18, Dec. 14, 2009; Neunaber Dep. 100:14-101:18). The market authorization transfer process can take approximately three years, which would obligate Ovation to supply the drugs until 2013. (Morris Trial Tr. 1217:23-1219:18, Dec. 14, 2009). With respect to Indocin IV, market authorizations have not yet fully transferred in Japan. Accordingly, the start date of the supply commitment for Indocin IV in Japan has not even begun to run. (Burke Trial Tr. 641:17-25, Dec. 10, 2009; Morris Trial Tr. 1217:23-1219:18, Dec. 14, 2009).

25. Given that the Bundle drugs were medically necessary, Ovation understood that it was essentially committing to supplying the drugs beyond the five-year contractual obligation unless it could find a new buyer for the Bundle drugs who, in turn, would guarantee worldwide supply. (Morris Trial Tr. 1207:18-1210:2, Dec. 14, 2009).

26. Prior to acquiring the drugs from Merck, Ovation did not have existing manufacturing capabilities in place to manufacture any of the acquired drugs. (Stip. Fact 58; Morris Trial Tr. 1220:6-16, Dec. 14, 2009). Ovation did not have the personnel or expertise to manage international regulatory issues. Ovation also lacked the international facilities and distribution capabilities needed to market the Bundle drugs in the vast

majority of the 84 countries in which it was obligated to supply the drugs. (Morris Trial Tr. 1220:6-16, Dec. 14, 2009; DX 281 at 4, No. 20).

27. In August and September 2004, while Ovation was evaluating whether it could submit a bid that would satisfy each of the conditions set forth in Merck's request for proposal, Ovation contacted potential partners that would be able to provide the manufacturing, distribution, and regulatory services and expertise Ovation lacked in meeting Merck's requirements to acquire the worldwide rights to the Bundle drugs and maintain them worldwide. (Burke Trial Tr. 570:25-571:2, 645:7-23, Dec. 9-10, 2009; PX 12 at 1 / DX 87 at 1; DX 77).

28. In August 2004, Ovation made a presentation to Hospira (a manufacturer, seller, and marketer of injectable pharmaceuticals) regarding a potential partnership in the purchase, manufacture, and distribution of the Merck Bundle outside the U.S. where Hospira had established distribution systems. (Burke Trial Tr. 570:25-571:2, 645:7-23, Dec. 10, 2009; DX 77).

29. Ovation also evaluated a potential partnership with Pliva, another pharmaceutical company that manufactures and sells injectable pharmaceuticals outside the U.S. According to the proposed partnership plan, Pliva would manufacture all six drugs, and would arrange and pay for the ex-US distribution and regulatory compliance. (Burke Trial Tr. 570:22-24, 645:24-646:5, 647:7-14, Dec. 10, 2009; Morris Trial Tr. 1223:19-1224:13, Dec. 14, 2009).

30. Ovation shared its pricing plans for Indocin IV and the other Bundle drugs with its potential partners, Hospira and Pliva. (Burke Trial Tr. 654:4-7, Dec. 10, 2009).

31. Hospira visited Merck's production facilities in August 2004 as part of early diligence. (Morris Trial Tr. 1223:4-25, Dec. 14, 2009). Hospira expressed concerns about the high responsibilities and risks associated with the deal. Estimating that its minimum costs of partnering on just two of the drugs would have been $31.7 million (and $55.5 million to partner on four of the drugs), Hospira told Ovation that it would need a royalty revenue stream equivalent to an expected net present value of more than $40 million for just two drugs in order to justify the risks associated with international manufacture. (DX 80 at 1). Hospira ultimately opted not to join Ovation in the Merck acquisition.

32. Ovation and Pliva conducted financial, legal, manufacturing, regulatory, and clinical diligence on the Merck Bundle. (Morris Trial Tr. 1224:14-1225:2, Dec. 14, 2009; DX 78 at 3). As part of that diligence, Pliva obtained Merck's manufacturing batch records. (Burke Trial Tr. 654:11-23). Pliva and Merck also visited each other's production facilities and Merck confirmed that Pliva had the capability to manufacture the Bundle drugs. (Burke Trial Tr. 654:11-23, Dec. 10, 2009; Morris Trial Tr. 1224:4-1225:2, Dec. 14, 2009; DX 78 at 3). In June 2005, Ovation lost confidence in Pliva's willingness to manufacture and distribute each of the Bundle drugs in all of the necessary markets, and Pliva fell out of the deal. (Morris Trial Tr. 1225:25-1226:23, Dec. 14, 2009).

33. When Pliva fell out of the deal, Ovation's projected costs increased by approximately $79.3 million, including extra costs for manufacturing transition and headcount, higher U.S. and international distribution expenses, additional regulatory and

safety expenses, increased accounting and corporate overhead expenses and a higher cost of goods sold. (DX 163 at 2; DX 299 at 2). These additional expenses were partially offset by an additional $33 million in estimated revenue as a result of not having to pay royalties to Pliva, leaving Ovation with a net additional cost of approximately $46 million as a consequence of Pliva dropping out of the deal. (DX 299 at 2).

34. Ovation purchased the Merck Bundle, without Pliva's participation or contribution of $5 million toward the purchase price, on August 10, 2005 for $15 million. Ovation funded the purchase through a syndicated loan from Merrill Lynch. The purchase price consisted of $9.8 million paid on the immediate execution for Cogentin, Cosmegen, Diuril, Indocin, and Mustargen, with an additional $5.2 million to be paid at the deferred closing date for the Elspar drug asset – through a syndicated loan from Merrill Lynch. (DX 91 at 8-9; DX 147 at 16).

35. The Merck Bundle opportunity presented significant risk and expense for Ovation in the absence of an experienced partner like Pliva.

36. Ovation ultimately arranged and paid for manufacturing the Bundle drugs on its own. (Burke Trial Tr. 649:17-19, Dec. 10, 2009). Ovation partnered with CMOs because it did not have its own manufacturing capabilities. (DX 281 at 4, No. 20). Ovation hired a staff to work with the CMOs to ensure continued compliance and manage supply chain logistics (*e.g.*, counting and moving inventory and managing order quantities). (Parhad Dep. 54:25-55:3; Wipperman Dep. 171:10-16). These "manufacturing management costs" associated with the Merck Bundle totaled approximately $4.75 million between 2005 and September 2008. (DX 150 at 5).

Ovation also incurred manufacturing transition costs, or "technology transfer costs," related to purchasing equipment, updating manufacturing methods, validating production, and packaging. (Parhad Dep. 94:15-21; Wipperman Dep. 168:2-18). In September of 2004, eleven months prior to closing the Merck Bundle acquisition, Ovation estimated that these costs would run approximately $2 million per product. (DX 109 at 5). In June 2005, after conducting further diligence, Ovation estimated that technology transfer would cost somewhere between $15 million and $17 million for the five bundle drugs not including Elspar. (Wipperman Dep. 151:11-152:19, 175:19-176:8; DX 104; DX 162 at 32). Ovation's actual manufacturing transition costs associated with the Merck Bundle between 2005 and September 2008 totaled approximately $9 million. (DX 150 at 4).

37. Ovation ultimately worked to secure the necessary regulatory approvals, in the 84 countries where Merck sold the Bundle drugs, on its own, including the transfer of health registrations, active pharmaceutical ingredient ("API") CMO approvals, finished product CMO approvals, packaging CMO approvals, and package insert and label approvals. (Neunaber Dep. 99:8- 100:10, 100:14-101:18, 118:4-119:23, 120:12-121:3; DX 64 at 2; DX 91 at 44). Ovation also needed to develop a worldwide network to address patient education, patient safety events, and adverse event reporting. (Parhad Dep. 70:5-25). Ovation did not have any regulatory experience abroad and opened a foreign office in Ireland, specifically to handle all ex-U.S. regulatory and patient safety issues associated with the Bundle drugs. (Morris Trial Tr. 1220:6-1222:1, Dec. 14, 2009; Wipperman Dep. 158:25-159:17, 169:21-170:8). Ovation's actual worldwide regulatory

costs associated with the Merck Bundle between 2005 and September 2008 totaled approximately $13 million. (DX 150 at 6-7, 11).

38. Ovation did not have ex-U.S. distribution capabilities prior to the Merck Bundle acquisition and incurred significant costs in attempting to find international distributors for the Bundle drugs. (Knocke Trial Tr. 508:24-509:1, Dec. 9, 2009; Morris Trial Tr. 1220:6-16, Dec. 14, 2009). Because the Bundle drugs were small-population products, and heavily price regulated abroad, international distribution partners could not make money selling them, and therefore Ovation had to agree to pay some of its distribution partners to sell them. (Morris Trial Tr. 1222:8-1223:12, Dec. 14, 2009). As a result, Ovation sold Indocin at a net loss in some countries. (Morris Trial Tr. 1222:8-1223:12, Dec. 14, 2009; Wipperman Dep. 162:2-17, 162:20-24, 197:17-198:16). Ovation's worldwide distribution costs account for approximately 4.1 percent of its net sales of Bundle drugs, and its actual distribution costs associated with the Merck Bundle between 2005 and 2007 totaled approximately $6.1 million. (Parhad Dep. 67:13-22; DX 151 at 6).

C. Ovation's Motivation in Acquiring the Merck Bundle

39. Despite the significant risks and anticipated challenges associated with the Merck Bundle acquisition, Ovation was motivated to acquire the Merck Bundle, in part, because it provided an immediate opportunity to enter and build a presence in the oncology market and hospital channel. (Morris Trial Tr. 1270:11-25, Dec. 14, 2009). Three of the drugs in the Merck Bundle were oncology products (Elspar, Cosmegen, and Mustargen), and the Merck Bundle auction was the first opportunity that Ovation had to

purchase any oncology drugs. (Morris Trial Tr. 1270:11-25, Dec. 14, 2009; Neunaber Dep. 51:18-25).

40. Ovation viewed the Merck Bundle acquisition as a way to build sales and marketing infrastructure in anticipation of future hospital-based product launches as well. (Burke Trial Tr. 643:1-23, Dec. 10, 2009; Knocke Trial Tr. 449:11-16, 450:12-19, 477:21-478:4, 511:10-513:6, Dec. 9, 2009; Nolan Dep. 55:22-57:15; PX 37 / DX 135 at 3).

41. At the time that Ovation purchased the Merck Bundle, it planned to use its sales force to actively promote Indocin in the U.S. for a limited time of approximately one year in order to build the company's infrastructure in anticipation of future product launches. (Knocke Trial Tr. 511:10-513:6, Dec. 9, 2009; PX 37 at 3 / DX 135 at 3).

42. Ovation engaged in "usual customary promotion" of Indocin: Ovation invested in a neonatal intensive care unit ("NICU") sales force, created a basic sales aid that explained what PDA was and how Indocin could be used to treat it, and trained its sales staff to answer questions about and sell Indocin. (Knocke Trial Tr. 452:8-20, Dec. 9, 2009; Nolan Dep. 55:22-57:15, 144:23-145:3; PX 37 at 3 / DX 135 at 3).

43. Ovation funded some small-scale studies, but never intended to fund, nor did fund, larger-scale studies because Indocin's more than twenty years on the market had already yielded enough data and literature to adequately address most questions about the drug. Ovation believed that additional studies, regardless of their outcome,

would not change the current medical practice. (Knocke Trial Tr. 520:4-21, Dec. 9, 2009).

44. Ovation also never considered developing, nor did develop, life cycle management for Indocin (*i.e.*, develop an alternate indication/use for Indocin) because the cost and time required to do the appropriate studies would not make economic sense in light of anticipated generic entry. Regardless of what alternative use could have been developed, there would be nothing preventing customers from substituting the generic indomethacin for that use. (Knocke Trial Tr. 518:12-520:3, Dec. 9, 2009).

45. Ovation only intended to actively promote Indocin only so long as promotion was profitable or until Ovation had a more highly valued drug to promote. Ovation never planned to actively promote Indocin following generic indomethacin entry. (Knocke Trial Tr. 450:12-19, 477:21-478:4, 511:10-513:6, 517:1-9, Dec. 9, 2009; PX 37 at 3 / DX 135 at 3).

46. Ovation never planned to promote Indocin internationally because it would not have been profitable: Indocin was already well-known and well-established, having been on the market for twenty years, and the very low sales price abroad would not have justified the expense. (Knocke Trial Tr. 510:8-24, Dec. 9, 2009). Because of foreign price controls, Ovation did not have the same incentive to build sales infrastructure abroad that it had in the U.S.

47. At the time that Ovation purchased the Merck Bundle, Ovation awaited FDA approval of Sabril (vigabatrin), a pharmaceutical treatment for infantile spasms used in the NICU. (Knocke Trial Tr. 512:5-7, 512:11-14, Dec. 9, 2009). A different company

had submitted an NDA for vigabatrin in 1994, but later withdrew it. (Morris Trial Tr. 1211:13-1213:3, Dec. 14, 2009). When Ovation purchased Sabril in March 2004, Ovation expected it to be FDA-approved within two years. (Burke Trial Tr. 643:1-644:5, Dec. 10, 2009; Morris Trial Tr. 1211:13-1213:17, Dec. 14, 2009; Nolan Dep. 55:22-57:15; Wipperman Dep. 226:22-228:3).

48. At the time that Ovation purchased the Merck Bundle, it planned to transition the sales force off of Indocin and onto Sabril, or another pipeline or yet-to-be acquired drug, as soon as Sabril or that other drug received FDA approval. (Burke Trial Tr. 643:14-644:5, Dec. 10, 2009; Knocke Trial Tr. 450:12-19, 511:10-512:1, Dec. 9, 2009; Nolan Dep. 55:22-57:15). The desire to have a sales force ready for Sabril played a significant role in Ovation's decision to promote Indocin in the first place. (Knocke Trial Tr. 512:24-513:6, Dec. 9, 2009).

49. Ovation expected Sabril to launch in the second half of 2006. (Knocke Trial Tr. 512:15-16, Dec. 9, 2009; PX 37 at 3 / DX 135 at 3). Thus, Ovation expected its Indocin sales force to transfer to a new drug within twelve months after the Merck Bundle acquisition. (Knocke Trial Tr. 477:21-478:4, Dec. 9, 2009). Sabril did not receive FDA approval until August 2009. (Morris Trial Tr. 1214:6-8, Dec. 14, 2009).

50. Because Sabril's FDA approval was delayed, Ovation reallocated the resources that had been intended for Sabril to NeoProfen. (Knocke Trial Tr. 541:14-18, Dec. 9, 2009). However, Ovation's sales representatives continued to represent Indocin and answer questions about it. (Knocke Trial Tr. 551:3-5, Dec. 9, 2009). Through its

Co-Promotion Agreement with Abbott, Ovation also obligated Abbott sales staff to provide information about and sell Indocin. (DX 2 at 2; DX 281 at 20, No. 102).

D. Price Increases on the Merck Bundle Drugs Were Necessary

51. Even Merck realized that the buyer of the Merck Bundle could not viably continue to sell Merck-manufactured Bundle drugs at Merck's historic prices. (Neunaber Dep. 110:17-25). Unlike Merck, Ovation had to fund the purchase price, compensate investors for risk incurred, and make substantial upfront capital investments in order to secure requisite facilities and capabilities for manufacturing, international distribution, technology transfer and sales and marketing costs. (Wipperman Dep. 158:3-15). *See* Findings of Fact Nos. 33-38, *supra*.

52. As a result of foreign price regulation, the Bundle drugs were not profitable outside the U.S. (Wipperman Dep. 161:17-162:1). For example, the selling price for Indocin in the United Kingdom was less than the cost to Ovation of supplying it. (Wipperman Dep. 162:2-17, 162:20-24, 197:17-198:16). Ovation could not unilaterally take price increases on the Bundle drugs in foreign markets where local regulations required authorities to approve pharmaceutical pricing. (Neunaber Dep. 128:3-17).

E. Ovation Always Planned to Re-Price Indocin

53. Ovation always planned to substantially increase U.S. prices on all of the Bundle drugs in order to make the deal economically viable. (Burke Trial Tr. 641:18-642:25, Dec. 10, 2009; Wipperman Dep. 72:11-73:11; 159:18-160:16; DX 281 at 8, No. 38). Ovation factored its planned U.S. price increases for the Bundle drugs into its business plans, projections, forecasts, and deal models throughout the year leading up

closing the Merck Bundle acquisition. (Pls.' Opp'n to Def.'s Mot. for Summ. J. at 4; DX 78 at 4-5; DX 82 at 2; DX 86 at 1; DX 88; DX 104 at 6-8; DX 106 at 6-7; DX 109 at 3; DX 111 at 1; DX 121 at 2; DX 157 at 5; DX 158 at 1; DX 162 at 7; DX 281 at 8, No. 38; DX 298 at 12).

54. Michael Burke was responsible for pricing all of the drugs sold by Ovation, including the Bundle drugs. (Burke Trial Tr. 558:5-15, Dec. 9, 2009). Mr. Burke joined Ovation in November 2001 as Vice President of Sales and Marketing. He held that position until February 2008, when he became Ovation's Chief Commercial Officer. Mr. Burke is no longer employed by Lundbeck. Throughout his tenure at Ovation/Lundbeck, Mr. Burke reported to President and Chief Executive Officer Jeffrey Aronin. (Stip. Fact 13). Mr. Burke testified at trial regarding the approach he took to re-pricing Indocin and the other Bundle drugs. Mr. Burke's testimony was credible.

55. In evaluating the Merck Bundle acquisition in September 2004 or earlier, nearly a year before closing the Merck acquisition, Mr. Burke concluded that the Bundle drugs were "under-priced to the market", meaning that he felt there was room to increase the prices of the products in the U.S. (Burke Trial Tr. 565:1-4, Dec. 9, 2009; PX 12 / DX 87).

56. When determining drug prices, Mr. Burke generally performed a comprehensive market and disease state review (including a literature review and expert interviews). (Burke Trial Tr. 565:5-15, Dec. 9, 2009). With respect to Indocin and the Bundle drugs, Mr. Burke then made "a product specific medical necessity and price sensitivity [analysis] incorporating disease severity, availability of alternatives and risk of

product substitutions, pricing of comparable treatments and customer/hospital financial impact." (Burke Trial Tr. 565:16-566:3, Dec. 9, 2009).

57. Mr. Burke's analysis considered, among other things, market prices for comparable drugs in terms of the severity of illness, channel of care, and form of administration. (Burke Trial Tr. 569:9-17, Dec. 9, 2009). Mr. Burke followed the same benchmarking methodology for all of the Bundle drugs, including Indocin. (Burke Trial Tr. 644:6-14, Dec. 10, 2009; DX 88 at 5-7).

58. With respect to Indocin, Mr. Burke examined comparable NICU benchmark drugs, reimbursement analyses, and the minimum price needed to support Ovation's financial backing for the acquisition. (Burke Trial Tr. 566:14-568:25, Dec. 9, 2009; DX 77; DX 83; DX 88 at 5-7).

59. With respect to Indocin, Mr. Burke's benchmark drug analysis, which he completed in August 2004 or earlier, considered (1) Pfizer's Prostin VR, an injectable drug used to maintain a patent ductus arteriosus ("PDA") at an average cost of therapy of $1,403, (2) Abbott's Survanta, an injectable respiratory drug for premature infants at an average cost of therapy of $1,695, (3) MedImmune's Synagis, an injectable drug for high risk pediatric patients at an average cost of therapy of $4,875, and (4) InoTherapeutics' Inomax, a $10,000 inhalation drug. (Burke Trial Tr. 566:14-568:25, Dec. 9, 2009; DX 77 at 19-23). The average cost per course of treatment of these comparable, medically necessary, injectable drugs (not including Inomax) was $2,658. Mr. Burke selected each of the benchmark drugs because they were used to treat premature infants in the NICU and were comparable in terms of the severity of the illness treated and the channel of

care. (Burke Trial Tr. 566:14-568:25, 569:9-17, Dec. 9, 2009). Drugs used predominantly in the NICU are a very small select group of drugs. (Gutierrez Trial Tr. 867:10-21, Dec. 10, 2009).

60. Mr. Burke testified that he performed the above-described analyses and arrived at a price range for Indocin of between $1,140 and $2,280 per course of therapy prior to August 2004. (Burke Trial Tr. 647:21-648:8, Dec. 10, 2009; DX 77 at 23). Mr. Burke further testified that he decided to price Indocin at $1,500 per course of therapy prior to August 2004. (Burke Trial Tr. 648:9-15, Dec. 10, 2009).

61. Mr. Burke purposely did not use the $1,500 figure in financial projections, in order to leave flexibility in the targets Ovation committed to achieving, but he wrote down his plan to raise the price of a three-vial course of treatment to $1,500 in a document that provided an overview of the Merck Bundle Opportunity and that was presented to Ovation's private equity investor and majority owner, GTCR Goldner Rauner, in January 2005. (Burke Trial Tr. 650:8-20, 703:19-704:7, Dec. 10, 2009; DX 78 at 4).

62. The FTC admits that Ovation planned as early as April 2005 to price Indocin at $1,500 per three-vial course of treatment. (Pls.' Opp'n to Def.'s Mot. for Summ. J. at 4, n. 13 *citing* PX 25 at 14)

63. Ovation's investors would not have financed the Merck Bundle acquisition if Ovation had not intended to re-price the drugs in the Merck Bundle to significantly higher levels. (Burke Trial Tr. 705:11-17, Dec. 10, 2009; DX 115 at 1). In order to satisfy the lenders that the loan made financial sense, Ovation provided the financial

institutions with its projected revenue stream associated with sales of the drugs in the Merck Bundle, with certain pricing assumptions. (Burke Trial Tr. 703:19-705:17, Dec. 10, 2009; DX 162 at 1). If Ovation did not significantly increase the price of the drugs in the Merck Bundle post-acquisition, the acquisition of the Merck Bundle would not have made economic sense for Ovation or the financial institutions that financed the transaction. (McCarthy Trial Tr. 1331:15-1332:9, Dec. 15, 2009).

64. Independent consulting companies (the Tiber Group and Navigant) confirmed that the Indocin price that Mr. Burke selected in 2004 was well within standard reimbursement levels and would have an insignificant impact on total treatment costs. (Burke Trial Tr. 656:22-657:9, Dec. 10, 2009; DX 108 at 7; DX 124 at 16). In general, when a private insurer or governmental payor, including the Medicare or Medicaid program, reimburses a hospital for treating a patient, the reimbursement rate is not based on the actual costs of any individual patient's treatment. (Stip. Fact 132). Rather, the hospital receives a fixed payment amount. (Stip. Fact 132). By statute, governmental payments are adjusted annually, based on the average resources used to treat a patient with certain clinical conditions (diagnoses) and procedures performed during the hospital stay (*i.e.*, within the applicable Medicare Severity Diagnosis Related Group, or MS-DRG). (Stip. Fact 132).

65. Ovation retained the Tiber Group, a consulting company, to perform an analysis independent of Ovation's management's assessment of the planned pricing changes from a reimbursement perspective. (Burke Trial Tr. 655:18-656:2, Dec. 10, 2009; DX 108). Specifically, the Tiber Group's report ("Tiber Report") found that "the

planned price increase in the price of Indocin is unlikely to impact the volume projections reviewed by Tiber, given the low hospital penetration rate and small percentage of DRG reimbursement represented by drug cost." (DX 108 at 7). The Tiber Report further noted that "the economic impact on a hospital...multiplied by the number of cases per month per hospital...[is] an insignificant amount." (DX 108 at 6).

66. Ovation later hired another independent consulting company, Navigant Consulting ("Navigant"). Navigant concluded that, priced at $1,500, a course of treatment of Indocin would account for only 0.842-5% of total reimbursement to hospitals. (DX 124 at 16).

F. Ovation's Plans for Re-Pricing Indocin Anticipated Generic Entry

67. Ovation viewed the Bundle drugs as short-lived assets. (Burke Trial Tr. 642:22-25, Dec. 10, 2009). Because the Bundle drugs were all off patent, Ovation expected competitors would respond to its price increases by launching generic versions of the branded Bundle drugs. (Burke Trial Tr. 642:6-25, 652:6-11, Dec. 10, 2009). Ovation knew that increasing the price of Indocin to $1,500 per course of treatment would attract generic entry to skim U.S. sales off the bioequivalent branded drug. (Burke Trial Tr. 651:20-652:11, Dec. 10, 2009; DX 281 at 16, No. 76).

68. Ovation further expected that its sales of the branded drugs would drop off very rapidly as the generic products took volume away from the branded products. Ovation therefore understood that it would only have a short time to recoup the liabilities it would incur in connection with the Merck acquisition. (Burke Trial Tr. 642:6-21, 652:6-14, Dec. 10, 2009; DX 298 at 2, 9, 11).

69. On December 22, 2005, Ovation received a draft report from a third party consultant, Greenfield Chemical, ("the December 2005 Greenfield Chemical Report") which confirmed that generic entry was likely. (PX 71). The December 2005 Greenfield Chemical Report stated that an independent generic entrant for Indocin would be motivated to enter by sales in excess of $3 million, and the chances of an independent generic deciding to enter was "highly likely (75-100%)." (PX 71 at 11). Ovation projected over $28 million in annual revenue from Indocin in 2006 (after the price adjustment, but prior to generic entry). (DX 104 at 23; DX 121 at 3).

70. Ovation's pre- and post-Merck Bundle acquisition projections considered entry of generic IV indomethacin inevitable. Ovation expected generic indomethacin entry to decimate sales of branded Indocin. (Burke Trial Tr. 641:18-642:25, 671:25-673:5, Dec. 10, 2009; DX 298 at 2, 9, 11). As of January 2005, Ovation projected that generic indomethacin would, within two years of its introduction, displace over 80% of Indocin sales. (DX 158 at 7).

71. Ovation expected generic indomethacin entry would be quick. (Burke Trial Tr. 672:13-24, Dec. 10, 2009). In January 2005, Ovation projected that generic indomethacin would enter within 16 months of re-pricing Indocin and incorporated that projection into a presentation entitled "Overview of Merck Injectable Bundle Opportunity." (Burke Trial Tr. 642:22-25, Dec. 10, 2009; PX 20 / DX 78 at 5).

72. In March 2005, Ovation projected that generic indomethacin would enter in September 2006, after a January 1, 2006 price increase. (DX 157 at 2). Thus, Ovation expected generic entry within nine months of re-pricing Indocin.

73. In April 2005, Ovation projected that generic indomethacin would enter within 16 months of re-pricing Indocin and incorporated that projection into its deal models. (DX 82 at 2-3). The April 15, 2005 deal model assumed that the Merck Bundle acquisition would close on June 1, 2005, Ovation would re-price Indocin in October 2005, and generic indomethacin would enter in February 2007. (DX 82 at 2-3).

74. In May 2005, Ovation again projected that generic indomethacin would enter 16 months after the Indocin price increase. (DX 162 at 23). The May 26, 2005 deal model assumed that the Merck Bundle acquisition would close in July of 2005, Ovation would re-price Indocin six months later, and generic indomethacin would enter in April 2007. (DX 162 at 9-10, 23).

75. In August 2005, Ovation still projected that generic indomethacin would enter some time in 2007, 16 months after re-pricing Indocin. (Burke Trial Tr. 673:10-14, Dec. 10, 2009; PX 38 at 2, 40; DX 104 at 22-23; DX 298 at 9).

76. The draft December 2005 Greenfield Chemical Report concluded that generic indomethacin entry would occur between 27 and 42 months after the generic manufacturer decided to pursue a product or enter the market. (Burke Trial Tr. 583:5-24, 584:4-19, Dec. 9, 2009; PX 71 at 11). The December 2005 Greenfield Chemical Report was one of many data points that Mr. Burke considered in estimating generic indomethacin entry. (Burke Trial Tr. 579:19-580:9, 582:1-13, 653:9-14, Dec. 9-10, 2009).

77. Mr. Burke and Mr. Morris testified at trial that Ovation was concerned that a generic might have decided to enter before Ovation announced the price increases on

the Merck Bundle. (Burke Trial Tr. 653:25-655:3, Dec. 10, 2009; Morris Trial Tr. 1226:24-1227:4, Dec. 14, 2009). As a result of Ovation's efforts to partner with Hospira and Pliva on the Merck Bundle acquisition, both Hospira and Pliva were aware of Ovation's intended pricing plans even before Ovation announced the price increases and both had manufacturing and distribution capability for the Bundle drugs. *See* Findings of Fact Nos. 27-29, *supra*. A subsequent Greenfield Chemical Report dated April 2005 identified Hospira as one of the companies that could manufacture generic indomethacin. (DX 81 at 4).

G. Ovation Planned to Hold or Increase Indocin's Price When Generic Indomethacin Entered

78. Mr. Burke testified that his general practice at Ovation was to increase the price of the branded drugs in response to generic entry. (Burke Trial Tr. 664:8-24, Dec. 10, 2009; DX 78 at 5; DX 82 at 6-7; DX 120 at 4; DX 298 at 11). Mr. Burke explained that generic sales will erode the sales of the branded product regardless of the price of the brand and there is an opportunity to raise the price of the brand when the generic enters to gain incremental margin and thereby retain revenues during the time while the market switches to the generic product. (Burke Trial Tr. 664:13-665:11, Dec. 10, 2009). Mr. Burke has never decreased the price of a branded product in response to generic entry. (Burke Trial Tr. 665:12-14, Dec. 10, 2009).

79. Other industry witnesses, including the Vice President of Bedford Laboratories ("Bedford") (which is in the process of manufacturing generic indomethacin) and the Vice President of a GPO that buys drugs for children's hospitals,

testified that it is usual and reasonable for branded drug manufacturers to hold or raise the prices of branded drugs in response to generic entry. (Gaugh Dep. 152:12-15, 152:22-153:1; Wilson Dep. 81:1-9).

80. Both parties' economic experts agreed that it is not uncommon for branded drug manufacturers to hold or raise the prices of branded drugs in response to generic entry. (Arnold Trial Tr. 1046:17-1047:15, Dec. 11, 2009; McCarthy Trial Tr. 1310:24-1311:5, 1363:6-25, Dec. 15, 2009). Ovation's expert economist, Dr. Thomas McCarthy, explained that the reason that companies rationally raise branded prices upon generic entry is to earn more profits despite losing market share. (McCarthy Trial Tr. 1311:6-16, Dec. 15, 2009). Generic entry splits the market into two segments: (1) price-sensitive buyers who will buy the generic, and (2) core customers who are loyal and will pay a higher price to buy the branded drug. (McCarthy Trial Tr. 1311:6-16, Dec. 15, 2009).

81. Ovation always planned to hold the Indocin price steady or perhaps increase the price of Indocin in the face of generic indomethacin entry. (Burke Trial Tr. 713:1-713:10, Dec. 10, 2009; DX 120 at 4; DX 298 at 11).

82. Two other Bundle drugs, Cogentin and Diuril, presently compete with generics. Ovation's Cogentin sales averaged $8-9 million per year in the U.S., approximately one-third of Indocin's annual revenue (about $25 million in 2007). (Morris Trial Tr. 1262:20-1263:7, Dec. 14, 2009; PX 396 at 173). Two separate companies entered with generics to Cogentin in July or August 2009, and the first generic entered within days of receiving FDA approval of its ANDA. (Morris Trial Tr. 1262:20-1263:7, Dec. 14, 2009). Ovation increased the price of brand Cogentin by 20% in

response to the approval of a generic, and the generic came in 10-15% below Ovation's increased price. (Morris Trial Tr. 1263:7-13, Dec. 14, 2009). The FDA approved a generic Diuril in or around November 2009, and Ovation's pricing response was to raise the price of branded Diuril by 20%. (Morris Trial Tr. 1263:14-18, Dec. 14, 2009).

H. Ovation's Plans to Price Indocin at $1,500 Did Not Change After Ovation Learned about NeoProfen

83. Prior to closing the Merck acquisition, on or about June 23, 2005, Ovation learned about Pedea, an intravenous ibuprofen THAM treatment for PDA sold in Europe. (Stip. Fact 106; PX 31). The active ingredient in the branded drug Pedea, available only in Europe, is ibuprofen, and the salt form is ibuprofen THAM. Pedea is not approved for use in the U.S. (Stip. Fact 97).

84. Between June 23, 2005 and June 30, 2005, Ovation learned that Farmacon-IL and Abbott were preparing to file a New Drug Application ("NDA") with the U.S. FDA for intravenous ibuprofen lysine (NeoProfen). (Stip. Fact 107; PX 32). NeoProfen is not bioequivalent to Pedea. (Stip. Fact 98).

85. Two U.S. patents (granted on the same application) claim ibuprofen lysine: patent No. 6342530, which expires on November 14, 2020, and patent No. 6344479, which expires on March 20, 2021. (Stip. Fact 99). These patents were filed on November 14, 2000 and March 20, 2001, respectively.

86. Mr. Burke testified that he did not panic when he learned about intravenous ibuprofen (later to be named NeoProfen). (Burke Trial Tr. 658:23-25, Dec. 10, 2009). He did not consider calling off the Merck Bundle acquisition even though he learned

about intravenous ibuprofen before the Merck Bundle acquisition closed. (Burke Trial Tr. 659:1-3, Dec. 10, 2009). Mr. Burke did not contact Abbott prior to closing the Merck Bundle acquisition when he learned about intravenous ibuprofen. (Burke Trial Tr. 658:14-16, Dec. 10, 2009).

87. Rather, Mr. Burke factored the potential introduction of NeoProfen into the Merck Deal Model dated August 2005. (Burke Trial Tr. 658:20-22, 713:21-713:1, Dec. 10, 2009; PX 38 at 2). He assumed that once NeoProfen was approved and launched, it would cause a 10% decline in the volume of Indocin solely in the first year. (Burke Trial Tr. 660:19-661:7, 663:11-17, Dec. 10, 2009; PX 38 at 2). While Mr. Burke projected a decline of Indocin sales due to NeoProfen entry in the August 2005 deal model, he did not project a change in price for Indocin. (PX 38 at 6).

88. Mr. Burke never considered lowering his planned price for Indocin IV in the face of a potential launch of NeoProfen for the same reasons that he believed it would not make sense to lower Indocin's price in the face of generic entry. (PX 38 at 6; DX 298 at 11). First, he assumed the volume of Indocin that Ovation sold would decline much more dramatically when generic came on the market (by 80 to 90% in the first year) compared to when NeoProfen launched (10%). (Burke Trial Tr. 663:22-664:7; 672:13-672:24, Dec. 10, 2009). He believed it made more sense to maintain Indocin's price or even raise it in the face of a potential launch of a future product. (Burke Trial Tr. 690:15-18; 712:14-713:10, Dec. 10, 2009).

89. Mr. Burke's testimony regarding his response to learning about NeoProfen was credible. No evidence suggests that Ovation altered its Merck Bundle acquisition plans in response to learning about intravenous ibuprofen.

I. The Merck Bundle Acquisition Closed in August 2005

90. Ovation's bidding price for the Merck Bundle was not the highest offer, but Ovation was the only company that agreed to comply with Merck's requirement to keep the products available in all markets where they were then offered. (Neunaber Dep. 19:21-20:8, 55:12-57:2; DX 63 at 12). Merck selected Ovation as the winning bidder for the Merck Bundle because Ovation was willing to comply with Merck's supply requirements. (Neunaber Dep. 19:21-20:8; 55:12-57:2; DX 63 at 12).

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

92. Ovation acquired the worldwide exclusive rights to the sixth drug that Merck had offered for sale – Elspar – on January 6, 2006 for $5.2 million. Ovation and Merck delayed the close of the Elspar acquisition because of a warning letter that the FDA sent to Merck related to its manufacture of Elspar's API. (Stip. Fact 53 n.2; Morris Trial Tr. 1227:16-1228:1, Dec. 14, 2009; DX 64 at 1).

III. THE NEOPROFEN ACQUISITION

A. NeoProfen Development

93. The use of ibuprofen to treat PDA was first studied in Canada and Europe no later than 1997. (Stip. Fact 96).

94. Congress passed the Orphan Drug Act of January 1983 ("ODA") to encourage pharmaceutical companies to develop and supply drugs for diseases that serve small patient populations. (Stip. Fact 9). Under the ODA, an "orphan drug" treats a disease affecting fewer than 200,000 Americans per year. (Stip. Fact 10). The ODA provides orphan drugs with seven years of market exclusivity, during which time no other company can market the same drug for the same indication of use unless it can establish clinical superiority to encourage investment in important drugs for small patient population diseases. See 21 U.S.C. §§ 360aa-360dd (1983); H.R. REP. No. 97-840(I) (1982); 1982 U.S.C.C.A.N. 3579, 3580; http://www.fda.gov/orphan/oda.htm. (Stip. Fact 11).

95. ODA market exclusivity does not preclude competition from another chemical entity used to treat the same condition. (Schondelmeyer Trial Tr. 918:5-13, Dec. 11, 2009). ODA market exclusivity also would not preclude another ibuprofen-based IV drug from receiving FDA approval for other indications, such as pain and fever, which could then be purchased and used "off-label" for PDA treatment. (DX 250 at 1).

96. NeoProfen has orphan drug status for PDA until 2013. (DX 98 at 1).

97. 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 (*i.e.*, a

branded drug) in the U.S. must file an NDA, demonstrating the safety and efficacy of the product. (Stip. Fact 25). An NDA describes the product, its uses, its manufacture, and its safety issues. (Wipperman Dep. 167:18-168:1).

98. Prior to filing an NDA, the sponsor must complete the entire clinical development of the drug, including Phase II and III human studies. (Morris Trial Tr. 1237:23-1238:12, Dec. 14, 2009; Wipperman Dep. 221:20-222:12). The NDA also has a Chemistry, Manufacturing, and Control ("CMC") section and the drug's manufacturing process must go through a rigorous phase of development and validation. (Morris Trial Tr. 1237:23-1238:12, Dec. 14, 2009; Wipperman Dep. 221:20-222:12).

99. There is no guarantee that the FDA will approve a new drug. Drug development is a high risk proposition. (Wipperman Dep. 226:14-21). In some instances, drugs that appear to be much needed cannot be approved because manufacturers are unable to manufacture them to FDA standards. (Wipperman Dep. 222:13-18).

100. Farmacon-IL submitted an NDA to the FDA for approval of NeoProfen to treat PDA. (Stip. Fact 100). The CMC section of the NDA was filed on April 13, 2005, and the NDA was first filed on August 31, 2005, officially filed on October 31, 2005, and accepted for filing on November 14, 2005. (DX 8 at 7; DX 169 at 2).

101. The timing of NDA approvals is unpredictable. For example, the NDA for Sabril (vigabatrin) was submitted in the early 1990s, but the sponsor dropped it later in the 1990s. (Morris Trial Tr. 1211:13-1213:3, Dec. 14, 2009). Ovation later purchased Sabril with the expectation that it would be a two-year effort to get approval. (Morris

Trial Tr. 1213:4-17, Dec. 14, 2009). The project ended up taking five years because the FDA had questions about the safety data. (Wipperman Dep. 226:22-228:3).

102. Ovation also considered buying a drug called Surfaxin in 2006. The seller projected three to six months for FDA approval, but Ovation's then Vice President of Operations, Marc Wipperman, thought approval would take one and a half or two years. (Wipperman Dep. 228:4-23). Surfaxin is not yet FDA approved. (Wipperman Dep. 228:4-23).

103. The FDA granted Farmacon's NDA for NeoProfen "Priority Review" status, which is reserved for drugs that offer major treatment advances or provide treatment where no adequate treatment exists. (DX 246 at 3-4). The FDA's website characterizes NeoProfen as a review classification "P Priority Review" drug. (at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails).

B. NeoProfen Acquisition Negotiations

104. Ovation had no contact with Abbott about the purchase of NeoProfen until after it closed the deal to acquire the Merck Bundle in August 2005. (Burke Trial Tr. 658:14-16, Dec. 10, 2009; McCoy Dep. 14:11-15:2, 30:20-31:3, 58:15-21). Mr. Burke was the Ovation employee who initiated discussions with Abbott about a potential NeoProfen deal. (Nolan Dep. 17:14-17). Mr. Burke telephoned Ned McCoy, then the Director of Business Development for the Ross Products Division of Abbott ("Abbott"), on or about August 30, 2005, after closing the Merck Bundle acquisition, to inform

Abbott of Ovation's acquisition of the rights to Indocin IV and to express Ovation's interest in co-marketing or obtaining rights to NeoProfen. (Stip. Fact 108).

105. On or about September 15, 2005, Mr. Burke had a conference call with Gary Harmon, an Abbott employee, regarding divestiture of NeoProfen. (DX 9 at 1). Mr. Harmon initially did not favor selling NeoProfen, but Abbott did not reject the divestiture concept. (McCoy Dep. 31:4-13, 32:17-20).

106. In 2005, Abbott's Ross Products Division, which is the division that held the marketing rights to NeoProfen, independently decided to exit the pharmaceutical industry and therefore divest its drugs (including NeoProfen), so that it could focus on its nutritionals business. (McCoy Dep. 22:2-23:1, 39:23-40:1, 58:22-59:15). Abbott's Ross Division and Farmacon wanted to sell NeoProfen to a company with a strong commitment to actively marketing it. (McCoy Dep. 81:3-10). Ovation was one of a limited number of companies that had a NICU sales force and handled small population drugs. (McCoy Dep. 79:3-80:24, 81:11-22). Abbott felt it was important to get Farmacon's approval to proceed on a deal selling NeoProfen, and Farmacon became comfortable with Ovation's commitment to marketing the product. (McCoy Dep. 80:22-81:10).

107. Ovation's interest in acquiring NeoProfen was motivated by its desire to complement its existing portfolio of NICU drugs. Ovation believed that NeoProfen would allow it to utilize its newly-established NICU sales/marketing staff, once generic entry gutted Indocin sales as predicted. (Burke Trial Tr. 673:21-674:4, 679:13-680:8,

Dec. 10, 2009; Morris Trial Tr. 1271:1-13, Dec. 14, 2009; DX 122 at 3; DX 123 at 29). *See also* Findings of Fact Nos. 67-70, *supra.*

108. Similarly, to better utilize its sales force and expand its NICU presence, Ovation looked at several other NICU drugs as possible acquisition targets, including two surfactants (Abbott's Survanta and Discovery Labs' Surfaxin). (Morris Trial Tr. 1271:1-13, Dec. 14, 2009).

109. Ovation also believed that NeoProfen would have a long-life and that, after Ovation built NeoProfen sales, Ovation could sell NeoProfen to a different pharmaceutical company. (Burke Trial Tr. 673:21-675:2; Knocke Trial Tr. 534:17-25, Dec. 9, 2009).

110. Both Ovation and Abbott approached their negotiations from the perspective that NeoProfen is safer than, and therefore clinically superior to, Indocin. (McCoy Dep. 67:24-68:14; DX 122 at 3). Mr. McCoy testified that as of October 2005, Abbott consistently planned to price NeoProfen at between $450 and $500 per three-vial course of treatment once it was FDA-approved. (McCoy Dep. 74:3-10). Abbott's planned price was nearly 600% above Indocin's then-prevailing price ($77.77 per three-vial course of treatment, the Merck price). (McCoy Dep. 74:11-23).

111. Third-party studies generated or commissioned by Abbott recommended pricing NeoProfen at or above Indocin's prevailing price, and concluded that NeoProfen could be profitably sold at several multiples over Indocin's then-current price of $78 per three-vial course of treatment. (DX 7 at 1-2). Despite the pricing premium to Indocin's then-current price, Abbott expected neonatologists to quickly adopt NeoProfen and use it

in the vast majority of PDA cases – 60% to 80% – leaving to Indocin the small minority where neonatologists rely on Indocin's unique clinical uses (IVH prophylaxis) and established treatment history. (Kenston Trial Tr. 373:8-374:12, Dec. 8. 2009; DX 14 at 9, 11).

112. Negotiations and diligence began in October 2005. Ovation made a formal presentation to Abbott in Columbus, Ohio to propose a potential acquisition of rights to NeoProfen on October 5, 2005. (Stip. Fact 109; McCoy Dep. 30:5-17). The Ovation executives who attended Ovation's October 5, 2005 presentation to Abbott included Barry Deutsch, Michael Burke and Sean Nolan. (Stip. Fact 110). Mr. Nolan, together with his Ovation colleagues Timothy Cunniff and Steve Collins, conducted diligence on Abbott's Ohio campus in October 2005. (Nolan Dep. 23:4-25).

113. Abbott indicated to Ovation that the NeoProfen deal needed to close by December 31, 2005 or there would be no deal. (Morris Trial Tr. 1236:1-4, Dec. 14, 2009). The calendar-year-end close was important to Abbott because Abbott wanted to realize income from the sale in 2005. (McCoy Dep. 40:6-17, 59:16-21). Ovation understood that motivation and, from past experience, knew that if the deal did not close by December 31, it was possible that the deal would never come back. (Morris Trial Tr. 1236:5-21, Dec. 14, 2009).

114. In December 2005, negotiations between Abbott and Ovation reached a sticking point over a co-promotion agreement that was important to Ovation. Having Abbott's large sales force to ensure a successful launch of NeoProfen was extremely important to Ovation, and when Abbott took it off the table, Ovation walked away from

the deal. (Morris Trial Tr. 1243:5-21-1244:14, Dec. 14, 2009; McCoy Dep. 40:22-41:18). Abbott expressed a concern about revenue recognition surrounding the co-promotion agreement, as well as concerns about committing its sales force to NeoProfen, since one of the primary reasons Abbott wanted to sell NeoProfen was to transition its sales force to its nutritional products. (Morris Trial Tr. 1242:3-24, Dec. 14, 2009; McCoy Dep. 40:22-41:18). Ovation and Abbott were unable to reach a compromise and the deal "blew up." (Morris Trial Tr. 1242:3-10, Dec. 14, 2009). At the end of 2005, neither Abbott nor Ovation knew whether deal discussions would resume. (Morris Trial Tr. 1244:15-1245:10, Dec. 14, 2009; McCoy Dep. 41:19-42:5, 47:18-48:2; McCoy Dep. 60:22-61:7). Ovation walked away from the deal at the end of December 2005. (Morris Trial Tr. 1243:22-1244:14, Dec. 14, 2009). Ovation did not change its pricing plans for Indocin when the NeoProfen deal blew up. (Burke Trial Tr. 690:15-18; 713:1-713:10, Dec. 10, 2009).

115. In January 2006, deal discussions resumed after the parties were able to address Ovation's demand for the Co-Promotion Agreement. On January 18, 2006, Ovation acquired the contingent U.S. rights to NeoProfen. NeoProfen was not yet approved by the FDA in January 2006. (Stip. Fact 111). Under the January 18, 2006, Asset Purchase Agreement between Ovation and Abbott, Ovation agreed to pay Abbott $2.5 million at closing, $15 million upon NDA approval, annual milestone payments totaling $15 million for 2007 and 2008, and – provided that sales reached certain thresholds – a royalty of 7 percent. (Stip. Fact 112).

116. Ovation entered into a Co-Promotion Agreement with Abbott, 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 Ovation would pay Abbott up to $2 million for Abbott's services and for incentive compensation payments to Abbott's sales representatives. (Stip. Fact 113). The Co-Promotion Agreement contained a Liquidated Damages clause that provided that Abbott would pay Ovation $4,250,000 in liquidated damages in the event that Abbott failed to fulfill its requirements under the contract, in addition to a partial or total reduction in the $2 million Co-Promotion Fee. (DX 2 at 12-13, 31).

C. Ovation's Acquisition of NeoProfen Involved Substantial Costs and Risks

117. The NeoProfen acquisition involved substantial costs. Ovation's payments to Abbott totaled $32.5 million in addition to the 7% royalty payable to Abbott and the 10% royalty payable to Farmacon based on sales. *See* Findings of Fact Nos. 115-116, *supra*; (DX 92 at 13-14; DX 93 at 4, 9, 10, 22). In addition, Ovation expected to incur considerable expense for the manufacturing and distribution of NeoProfen. (DX 161 at 3).

118. One risk that Ovation faced in purchasing the contingent rights to NeoProfen was that NeoProfen did not have FDA approval then and might never have received it. (Morris Trial Tr. 1237:2-13, 1238:22-24, Dec. 14, 2009; DX 122 at 4). The FDA approval process for new drugs is complicated and the timing of approval is unpredictable. *See* Findings of Fact Nos. 97-99, 101, *supra*. Accordingly, Ovation

negotiated a payment schedule that made the majority of its payment contingent on FDA approval. (Morris Trial Tr. 1239:3-12, Dec. 14, 2009).

119. During the diligence process, Ovation's then Vice President of Operations, Mr. Wipperman, concluded that FDA approval was likely, but that the time frame for approval would be "longer than shorter." (Wipperman Dep. 224:15-22, 226:3-13, 229:7-21). As of December 2005, Mr. Wipperman did not think that approval was likely in 2006 due to deficiencies in NeoProfen's NDA. (Wipperman Dep. 230:14-231:12, 232:2-233:6; PX 65 / DX 170 at 1). Mr. Wipperman estimated that the FDA would approve NeoProfen in mid 2007. (Morris Trial Tr. 1241:5-19, Dec. 14, 2009; Wipperman Dep. 224:15-22, 226:3-13, 229:7-21, 236:14-237:11; DX 169 at 1). Mr. Wipperman testified that he was shocked when NeoProfen was approved in April 2006, less than a year after the NDA was filed. (Wipperman Dep. 237:12-17).

120. In January 2006, when Ovation acquired NeoProfen, Ovation believed that NeoProfen would not receive FDA approval before January 2007. (Kenston Trial Tr. 377:1-12, Dec. 8, 2009; Wipperman Dep. 236:14-237:11). During the diligence phase in December 2005, Ovation determined that there were CMC deficiencies in the NeoProfen new drug application ("NDA") that would cause delays in approval. (Wipperman Dep. 230:14-231:12, 232:2-233:6).

121. In January 2006, Ovation believed that the launch of NeoProfen would happen in early 2007. (Kenston Trial Tr. 377:1-12, Dec. 8, 2009).

122. In February 2006, after the NeoProfen deal closed, new information from the FDA indicated an earlier approval for NeoProfen than previously had been estimated. (PX 93).

123. Under the Purchase Agreement, Ovation took on Abbott's obligations to develop new indications pursuant to Abbott's agreement with Farmacon and committed to investing additional capital to do so. (DX 2 at 33-34, DX 10 at 9; DX 92 at 7-9).

124. Ovation only acquired the U.S. rights to NeoProfen, so it cannot seek approval for or sell it in other jurisdictions. (DX 93 at 8, 9).

IV. JANUARY 2006 INDOCIN PRICE INCREASE

A. Ovation Did Not Announce the Revised Prices of the Merck Bundle Drugs in the U.S. Until the Labels Were Transferred

125. Ovation always anticipated taking a substantial price increase on Indocin. *See* Findings of Fact Nos. 51-66, *supra*.

126. Prior to finalizing the Merck Bundle acquisition, Merck anticipated that Ovation would raise the prices of the Bundle drugs and expressed its unilateral wish that Ovation not increase the prices while the drugs were being sold under the Merck label. (Neunaber Dep. 72:6-73:21, 75:4-25, 78:13-79:18). Indocin is sold in labeled vials with the manufacturer's name, logo and national drug code ("NDC") number. (Burke Trial Tr. 667:14-23, Dec. 10, 2009). Merck was concerned that if Ovation re-priced the Bundle drugs in Merck trade dress (with Merck's name, logo, and NDC number on the vial), customers would believe that the re-pricing was directed by Merck when in fact it was not. (Neunaber Dep. 75:4-25, 78:13-79:18).

127. Ovation appreciated that Merck did not want to deal with a response to pricing changes which it did not control, and Ovation did not want to create a situation in which potential market response related to Ovation's prices increases were directed at Merck. (Burke Trial Tr. 666:18-22, Dec. 10, 2009; Morris Trial Tr. 1229:14-1230:6, Dec. 14, 2009).

128. Ovation was interested in maintaining a positive relationship with Merck because Ovation and Merck had entered into supply agreements related to the Bundle drugs. (Morris Trial Tr. 1230:8-1231:2, Dec. 14, 2009). Concurrent with the closing of Ovation's acquisition of the rights to the five Merck drugs, Ovation and Merck entered into a Supply Agreement under which Merck agreed, among other things, to manufacture and supply unpackaged Indocin IV to Ovation, while Ovation took over manufacturing each of the drugs. (Stip. Fact 61). Additionally, Ovation, as an acquisition-focused company, was interested in maintaining the goodwill of the companies from which it purchased products. (Morris Trial Tr. 1230:8-1231:2, Dec. 14, 2009).

129. On September 1, 2005, Ovation increased the wholesale list price of Indocin IV by 40 percent, from $77.77 to $108.88 per three-vial course of treatment. (Stip. Fact 64). In light of Ovation's planned price increase for Indocin from $77.77 to $1,500, the increase to $108.88 was a relatively small increase. On the same day, Ovation re-priced all of the other Bundle drugs by a similar percentage. On September 1, 2005, Ovation increased the wholesale list prices of Cogentin by 39.9 percent (from $32.88 to $46.03 per 5 ampules), Diuril by 38.8 percent (from $8.83 to $12.36 per vial),

Mustargen by 25 percent (from $40.44 to $50.55 per 4 vials), and Cosmegen by 14.9 percent (from $11.68 to $13.43 per vial). (Stip. Facts 71, 73, 75, 77; PX 451).

130. This provisional price increase was planned in the deal model created in August 2005 before the Merck Bundle acquisition closed. (Burke Trial Tr. 669:7-19, Dec. 10, 2009; PX 38 at 3). Ovation planned and implemented these relatively small price increases in order to reduce the amount of money that Ovation was losing by selling the Merck-labeled products at Merck's historic prices. (Morris Trial Tr. 1231:14-21, Dec. 14, 2009). Ovation felt that these relatively small price increases on Merck-labeled products would not alienate Merck. (Burke Trial Tr. 669:7-19, Dec. 10, 2009). The interim price increases were never intended to be the final price increases on any of the Bundle drugs. (Morris Trial Tr. 1228:21-1229:10, Dec. 14, 2009). Ovation intended to take much larger price increases as soon as the products were available in the Ovation trade label. (Burke Trial Tr. 670:15-25, 690:10-14, Dec. 10, 2009).

131. Ovation wanted to complete the label conversion of the Bundle drugs as quickly as possible in order to take substantial price increases on the Bundle drugs and to get its label out and be known by patient groups and bigger pharmaceutical companies. (Morris Trial Tr. 1232:8-1233:13, Dec. 14, 2009).

132. Although Merck and Ovation entered a supply agreement, Merck refused to package the Bundle drugs with Ovation's label and instead supplied nude vials. (Morris Trial Tr. 1231:22-1232:6, 1232:18-1233:1, Dec. 14, 2009; Neunaber Dep. 94:19-96:3).

133. Ovation therefore had to identify U.S. and international packaging companies to label the nude Merck-supplied vials, negotiate contracts with those

packaging companies, seek local regulatory approval of the packaging processes, and arrange for the nude vials to be shipped to the packaging companies and packaged and labeled prior to sale. (Burke Trial Tr. 668:2-669:4, Dec. 10, 2009; Morris Trial Tr. 1233:5-1234:2, Dec. 14, 2009). Ovation's pre-acquisition projections assumed that the U.S. labeling conversion could be completed within three to six months after closing. (Morris Trial Tr. 1233:2-4, Dec. 14, 2009; PX 38 / DX 121 at 2; DX 82 at 2; DX 158 at 2).

134. On December 21, 2005, Ovation anticipated that the labeling conversion would be completed as follows: Indocin on January 9, 2006, Cosmegen and Mustargen on January 20, 2006, and Diuril and Cogentin by February 1, 2006. (DX 89 at 1).

135. In planning for the re-launch of the Bundle drugs, Ovation also considered when the Merck-labeled inventory would be exhausted and recognized that the timing of the price increases might not correspond exactly with the timing of the label conversion. (DX 89 at 1 ("In some cases we may need to convert to the Ovation-labeled stock before an increase is announced; and in some cases (*i.e.*, Diuril), there is a chance we will be on backorder for 1-2 weeks until the Ovation-labeled product is available.")).

136. Ovation wanted to announce all of the substantial price increases at the same time and therefore delayed the announcement of the planned price increases until it was very close to having all of the Bundle drugs in Ovation trade dress. (Burke Trial Tr. 690:10-14, Dec. 10, 2009; Morris Trial Tr. 1272:6-13, Dec. 14, 2009).

B. Ovation Announced the Revised Prices of the Merck Bundle Drugs in the U.S. After the NeoProfen Transaction Closed

137. On January 20, 2006, Ovation simultaneously implemented price adjustments on the five Bundle drugs that it had acquired. Ovation increased the prices of the Bundle drugs as follows (per sales unit): Cogentin to $164.40 per five ampules, Cosmegen to $475.00 per vial, Diuril to $119.21 per vial, Indocin IV to $1,500 per three vials, and Mustargen to $545.28 per four vials. (Stip. Facts 65, 72, 74, 76, and 78).

138. Ovation announced the substantial price increases of the five Bundle drugs, including Indocin's increase to $1,500, two days after it closed the NeoProfen acquisition. In addition to waiting to announce the price increase until it had a sufficient volume of Ovation-labeled product available for sale, Ovation did not want to *announce* the Bundle drug price increases before the NeoProfen acquisition closed, so as not to affect the deal price for NeoProfen. (Morris Trial Tr. 1274:21-1275:2, Dec. 14, 2009; Nolan Dep. 110:2-111:12). Ovation was concerned that if Ovation communicated the Indocin price increase, Abbott might have demanded a higher price for the NeoProfen acquisition given that Abbott viewed NeoProfen as a superior product to Indocin. (Morris Trial Tr. 1274:21-1275:2, Dec. 14, 2009; Nolan Dep. 110:2-111:12). The NeoProfen deal closed on January 18, 2006, so Ovation was able to go ahead with its planned January 20, 2006 price increase on the Merck Bundle. (PX 78 at 1; PX 81 at 1)

C. Indocin's $1,500 Price Was Not Related to the NeoProfen Acquisition

139. The decision to price Indocin at $1,500 was made independent of and without regard to the NeoProfen acquisition. (Burke Trial Tr. 690:15-18). Plaintiffs did not proffer any evidence to suggest otherwise.

140. The $1,500 price for Indocin was set months before Ovation acquired the Merck Bundle or learned of NeoProfen's existence. *See* Finding of Fact No. 60, *supra.* Ovation did not change its planned Indocin price when it discovered the existence of intravenous ibuprofen, began negotiating its purchase from Abbott, or finalized the purchase, despite interruptions in negotiations and indications that the deal with Abbott might fail in late December 2005. *See* Findings of Fact Nos. 83-89, 114 *supra.*

D. Ovation Would Not Have Reduced Indocin's Price if NeoProfen Were Launched by an Independent Owner

141. Ovation had no incentive to reduce its planned price increase for Indocin in anticipation of NeoProfen, an unapproved product that was at least a year away from FDA approval and launch. (Burke Trial Tr. 713:1-10, Dec. 10, 2009; McCarthy Trial Tr. 1312:20-1313:4, Dec. 15, 2009). In response to a direct, bioequivalent generic competitor, Ovation planned to maintain or raise its price for Indocin and would have reacted similarly in response to NeoProfen's launch given the small volume of Indocin sales. (Burke Trial Tr. 713:1-10, Dec. 10, 2009; McCarthy Trial Tr. 1312:20-1313:4, Dec. 15, 2009). Ovation would have increased the price of Indocin to $1,500 per course of therapy regardless of whether NeoProfen was acquired. (Burke Trial Tr. 690:15-18, Dec. 10, 2009).

142. Dr. McCarthy testified credibly that the fact that Ovation will not lower Indocin's price to compete with the generic bioequivalent, which is the same molecule and automatically substitutable with branded Indocin at some hospitals, is persuasive evidence that Ovation would not have lowered the price of Indocin if NeoProfen entered under separate ownership because NeoProfen is a less perfect substitute for Indocin, if a substitute at all. (McCarthy Trial Tr. 1311:21-1313:14, 1366:2-20, Dec. 15, 2009).

V. NEOPROFEN LAUNCH

143. NeoProfen was approved by the FDA for use in the U.S. as a treatment for PDA on April 13, 2006. (Stip. Fact 102). The FDA approved the NDA for NeoProfen on April 13, 2006. (Stip. Fact 103).

144. Ovation announced the FDA approval and launch of NeoProfen on July 24, 2006, and first offered NeoProfen for sale on July 31, 2006. (Stip. Fact 116).

145. Ovation's initial wholesale list price for NeoProfen in July 2006 was $1,450 for a package of three vials. (Stip. Fact 119).

146. Plaintiffs' expert Dr. Arnold testified that Ovation's decision to price NeoProfen at $1,450 is consistent with what he would expect under competitive conditions. (Arnold Trial Tr. 1050:11-19, 1091:15-20, Dec. 11, 2009). Indocin is the pricing benchmark for NeoProfen, and an independent owner would have launched NeoProfen at "substantially the same price" as Indocin's then-current price of $1,500. (Arnold Trial Tr. 1050:11-19, 1053:10-18, 1091:15-20, Dec. 11, 2009). An independent owner would not disregard Indocin's price when setting NeoProfen's price. (Arnold Trial Tr. 1053:10-18, 1091:15-20, Dec. 11, 2009).

147. Both parties' experts rely on the Lu & Comanor empirical study of launch prices for new patent-protected drugs to project NeoProfen's pricing in the but-for world. Dr. Arnold assumes NeoProfen offers "little to no therapeutic gain" to Indocin, which would make it a "Class C" or "me-too" drug in the Lu & Comanor hierarchy. (Arnold Trial Tr. 1002:22-1003:6, Dec. 11, 2009). According to the Lu & Comanor article, 49% of Class C drugs are introduced without a discount off of the incumbent. (Arnold Trial Tr. 1056:1-14, Dec. 11, 2009; DX 201 at 6). However, the median price of Class C is a 23% premium to the incumbent drug price if used primarily in an acute care setting, like NeoProfen. (McCarthy Trial Tr. 1305:3-7, Dec. 15, 2009; DX 201 at 7). Using Dr. Arnold's assumption that NeoProfen is a "C" drug, the Lu & Comanor empirical study indicates that NeoProfen's but-for price would be higher than the $1450 Ovation selected. (McCarthy Trial Tr. 1306:2-23, Dec. 15, 2009).

148. Ovation's expert, Dr. McCarthy, testified that NeoProfen more likely resembles a "Class B" drug, based on Abbott's plans to market it as superior, premium-priced product to Indocin, and clinical testimony indicating that it offers therapeutic advantages over Indocin. (McCarthy Trial Tr. 1301:4-13; 1309:4-24, Dec. 15, 2009). According to Lu & Comanor, 79% of Class B drugs launched at a premium to the incumbent. (DX 201 at 6).

149. The Lu & Comanor study is a reliable and persuasive tool for estimating the competitive but-for price for NeoProfen. Regardless of whether NeoProfen is classified as C or B acute care drug, the study projects that the but-for price would be

above the Indocin $1,500 price. Thus, Ovation's decision to price NeoProfen at $1,450 was lawful and competitive.

150. When Ovation launched NeoProfen, it tasked its NICU sales force with selling NeoProfen. (Stip. Fact 117). Ovation's initial wholesale list price for NeoProfen in July 2006 was $1,450 for a package of three vials. (Stip. Fact 119).

151. The label (package insert) approved by the FDA for NeoProfen in April 2006 differs from the label submitted by Farmacon-IL in August 2005. (Stip. Fact 104).

152. Due to the differences between the proposed NeoProfen label submitted by Farmacon-IL (before the Ovation acquisition) and the FDA-approved label (after the Ovation acquisition), Ovation renegotiated Abbott's royalty rate on sales of NeoProfen before NeoProfen came on the market. Under the renegotiated terms, Abbott's royalty was temporarily reduced from 7 percent to 3.5 percent, until that reduction offset up to 50 percent of Ovation's first $3 million worth of clinical research on NeoProfen, *i.e.*, up to $1.5 million. (Stip. Fact 105).

153. Ovation did not continue to promote Indocin because Ovation expected generic indomethacin to almost immediately erode Indocin's sales. (Knocke Trial Tr. 517:1-9, Dec. 9, 2009).

154. Paul Stickler joined Ovation in April 2006 as Senior Director of Sales. He became Vice President of Sales in January 2009. Throughout Mr. Stickler's tenure at Ovation/Lundbeck, until Michael Burke's departure, Mr. Stickler reported to Mr. Burke. (Stip. Fact 16). Mr. Stickler was responsible for NeoProfen's launch and managed the sales team. (Stickler Trial Tr. 716:18-717:6, Dec. 10, 2009). Mr. Stickler testified at trial

that it is standard marketing practice in the industry to promote products that are clinically differentiated from existing products and around which there are intellectual property protections. (Stickler Trial Tr. 821:16-822:9, Dec. 10, 2009). Mr. Stickler credibly testified that it did not make sense from a business perspective to promote Indocin, which had no patent protection and thus was subject to generic entry at any moment. He believed that there was more business certainty around the promotion of NeoProfen, a product with orphan drug exclusivity and patent protection. (Stickler Trial Tr. 821:16-822:9, Dec. 10, 2009).

VI. SUBSEQUENT PRICE INCREASES

A. Indocin

155. Since re-pricing Indocin to $1,500 in January 2006, Ovation has made only a handful of nominal price increases, specifically: On February 1, 2007, Ovation increased the wholesale list price of Indocin IV by 2 percent, from $1,500 to $1,530 per three-vial course of treatment. (Stip. Fact 67). On October 31, 2007, Ovation increased the wholesale list price of Indocin IV by 5 percent, from $1,530 to $1,605.50 per three-vial course of treatment. (Stip. Fact 68). At the end of 2008, the wholesale list price of Indocin IV was $1,614.44 per three-vial course of treatment. (Stip. Fact 69).

B. NeoProfen

156. On October 31, 2007, Ovation increased the wholesale list price per three-vial package of NeoProfen by 5 percent, from $1,450 to $1,522.50. (Stip. Fact 120).

VII. GENERIC INDOMETHACIN

A. There Are No Barriers to Entry

157. There are and were no significant entry barriers for generic indomethacin. Indocin IV has had no known, unexpired patent protection in the U.S. since approximately 1981. (Stip. Fact 47).

158. Injectable indomethacin is not inherently difficult to manufacture. There is also a ready supply of API, and it is easy to obtain; indomethacin is a substantial pharmaceutical product worldwide. (Wipperman Dep. 78:24-79:10, 115:16-116:3, 119:5-120:10, 121:7-13, 121:22-122:9, 181:20-182:6, 182:13-183:15, 213:9-25, 214:12-17, 277:17-278:3; PX 71 at 11 (2 suppliers with a drug master file, or "DMF," and at least 3 other suppliers with an inactive DMF that could reactivate it with minimal effort); DX 81 at 2-3, 6 (abundance of drug substance supply from 8 API suppliers, 2 DMFs)).

159. A DMF, or drug master file, is a file kept by a CMO to describe the facilities and equipment that will be used to manufacture a particular product. (Wipperman Dep. 119:21-120:10). A competent API supplier can put together a DMF in a couple of days, weeks, or months. (Wipperman Dep. 121:7-13, 277:17-278:3). Mr. Wipperman testified that Ovation would have considered, and did in fact use, suppliers that did not have DMFs. (Wipperman Dep. 121:22-122:9). In some cases, Mr. Wipperman did not know whether a DMF existed or not when filing a supplemental NDA to the FDA with a new API supplier. (Wipperman Dep. 243:9-25).

160. A number of injectable drug manufacturers have the know-how and capability to manufacture and distribute generic indomethacin, including Bedford, Teva

Pharmaceuticals Industries Ltd. ("Teva"), Pliva, and Hospira. *See* Findings of Fact Nos. 27-29, 76, *supra.*

161. Filling vials is not difficult for an experienced manufacturer. Ovation's original CMO for Indocin, Cardinal Health (which later became Catalent), had no problems filling vials of Indocin. (Wipperman Dep. 115:16-116:3). Mr. Wipperman testified that he did not consider the fill volume of Indocin to be something that would cause manufacturing difficulties. Catalent used standard filling equipment. (Wipperman Dep. 238:5-21).

162. When Ovation signed a supply agreement with Cardinal Health for the Merck Bundle products, Mr. Wipperman had no misgivings about Cardinal Health's ability to manufacture Indocin or Diuril. (Wipperman Dep. 212:8-18). Merck pre-approved Cardinal Health as a manufacturer for the Bundle drugs before it closed the deal with Ovation. (Wipperman Dep. 79:23-80:8, 101:2-102:7, 211:12-212:3).

163. The management of the Cardinal Health / Catalent Raleigh facility operation was very good from 2004 to 2006, but sometime in 2007 it began to fall apart. (Wipperman Dep. 116:14-117:14).

164. Ovation considered giving Cardinal Health manufacturing responsibility for four or five of the Merck Bundle products, but it ultimately only assigned Indocin and Diuril to Catalent's Raleigh site because it was concerned that four or five products might be too much for the one facility to handle. There were technical concerns and additional risk from some of the other products, and four of the products were very tricky and

required elaborate and special manufacturing equipment, but two (Indocin and Diuril) were relatively easy. (Wipperman Dep. 81:9-21, 102:7-103:15).

165. As of July 2005, Catalent projected that it would submit regulatory approvals to manufacture Indocin in April 2007. Ovation projected it would then commercially launch Catalent-manufactured Indocin in the second quarter of 2007. Catalent projected that the remainder of the Indocin technology transfer project, which includes the stability program to validate the shelf life, would be completed by February 2008. (Wipperman Dep. 273:1-274:7, 275:23-276:25; DX 304 at 6). If Ovation had transferred technology for only one of the drugs, it could have done it quicker. (Wipperman Dep. 177:21-178:2).

166. Catalent was unable to produce a saleable batch of Indocin within the expected timeframe, but none of the issues that affected the manufacture of Indocin at Catalent were Indocin-specific. (Wipperman Dep. 183:25-184:12). Catalent's issues included: a test batch that failed due to a control problem, a glassware washer validation problem, remediation of an environmental event at the facility, and Catalent's decision to divest the facility. (Wipperman Dep. at 135:10-136:1, 137:24-138:1, 183:25-184:12). Mr. Wipperman testified that the difficulties Ovation experienced in lining up a CMO to manufacture Indocin were not because Indocin is difficult to make. (Wipperman Dep. 182:7-12).

167. Catalent produced a first Indocin test batch that had too much moisture in the vial because the equipment had an incorrect setting. After an adjustment of that setting, Catalent produced what was to be the first registration batch, and the batch was

good and within specifications. But the glassware vial washer, a secondary piece of equipment, failed validation and the batch became suspect. (Wipperman Dep. 87:18-88:17, 117:15-119:4, 185:16-186:22). The setting on the particular model of lyophilizer was quickly fixed for the next batch. (Wipperman Dep. 184:13-185:15). The glassware vial washer issue was a normal startup equipment problem. (Wipperman Dep. 104:4-19, 186:23-187:5).

168. In Spring 2007, Catalent's Raleigh facility suffered a serious environmental event, in which external environmental microbes got into the interior of the aseptically controlled facility and which caused remediation work at the facility. In fall 2007, the FDA inspected the facility and reviewed those activities. It found deficiencies at the facility and followed up with a warning letter in March 2008. The remediation experience was a major episode, which lasted more than a year. (Wipperman Dep. 86:7-87:11, 104:4-19, 187:13-188:1, 189:20-190:4; DX 311). Catalent suspended production at the Raleigh facility to address a number of the issues from the FDA inspection. (DX 300) Catalent had limited bandwidth to manage both the remediation efforts and the commercial and development commitments, which contributed to delays with the Indocin program. (DX 307). This environmental event was not Indocin-specific, and it rendered the entire facility suspect. (Wipperman Dep. 183:25-184:12, 187:13-188:1). Once Ovation became aware of the event and its seriousness, and the delays it would cause to the technology transfer program, Ovation requested four additional batches of Indocin from Merck. (Wipperman Dep. 86:7-87:11, 189:20-190:4).

169. The March 2008 FDA warning letter had a significant impact on Catalent's ultimate ability to produce Indocin, because it caused Catalent's customers and potential customers to move their products away from Catalent. As a result of losing business, Catalent questioned the viability of the site and began to off-load work, and eventually decided to divest the facility. (Wipperman Dep. 190:10-15, 191:2-192:7, 203:18-204:15). Catalent's decision to divest the Raleigh site in late 2008 or early 2009 exacerbated its problems. Ovation went into contingency-planning mode to figure out how to continue supply and protect patients. (Wipperman Dep. 90:8-16, 111:19-112:7, 191:25-192:7; DX 301 at 1).

170. Prior to notifying Ovation of its intent to divest the site, Catalent told Ovation that it would not be able to handle all three projects – Indocin, Diuril, and Panhematin – on schedule, and one would have to leave the facility. (Wipperman Dep. 111:19-112:7, 128:20-24). Ovation concluded that it would be most expedient to move Indocin, given that it still had two more validation batches to go. By comparison, FDA approval of the Diuril transfer was imminent, and Panhematin was a commercial product that could not be moved without a five year program. (Wipperman Dep. 136:2-137:1; DX 301 at 1). In addition, Indocin was the only of the three drugs that required facility registrations in ex-U.S. markets, which the internal Catalent resources were inadequate to support. (DX 301 at 1-2).

171. The only circumstances leading to the formal termination of Indocin at Catalent were the delays from the failure of the very first test batch, the washer validation problem, the year-plus of revising remediation after the environmental event at the

Raleigh facility, and Catalent's decision to divest the facility with no assurances that it would not be shut down. (Wipperman Dep. 135:10-136:1, 137:24-138:1). *See* Findings of Fact Nos. 166-169, *supra*.

172. Upon removing Indocin from Catalent, Ovation awarded the Indocin manufacturing contract to Hollister-Stier. (Wipperman Dep. 113:19-114:3). In addition to price and quality, Ovation selected Hollister-Stier because it was well equipped to run lyophilization processes and Indocin would not be anything special, unique, or complex for it to handle. Furthermore, Hollister-Stier had an ongoing business that involved international distribution of product manufactured at their site, so the regulatory aspects were not going to be a hurdle. (Wipperman Dep. 209:16-210:11; DX 3-2 at 1). In February 2009, Ovation expected early 2010 FDA approval at Hollister-Stier. (Wipperman Dep. 138:2-15).

173. It was important to Ovation to select an appropriate manufacturer for Indocin because Indocin is an important product. (Wipperman Dep. 210:12-211:2, 212:23-213:3).

174. Plaintiffs did not submit any evidence that Ovation engaged in any conduct with the intent to, or effect of, block, deter, hinder, or delay the entry of a generic competitor to Indocin.

B. Generic Entry Is and Was Likely

175. Drug manufacturers considering launching generic versions of the Bundle Drugs would not face the international cost burdens that Ovation faced. The typical generic company in the U.S. would not even consider selling generic versions of the

branded Bundle drugs abroad because of foreign price controls. Therefore, the typical generic manufacturer interested in these drugs would not have needed to meet the same international manufacturing requirements that Ovation's CMO needed to meet, and would not be subject to the same long-term international supply burden to which Ovation committed pursuant to the Merck Acquisition. (Wipperman Dep. 201:9-202:7).

176. Ovation's price adjustment on Indocin increased the financial incentives for another drug manufacturer to develop and market a generic indomethacin product. *See* Findings of Fact Nos. 67-69, *supra.*

C. Generic Entry Is and Was Capable Within Two Years

177. The Drug Price Competition and Patent Restoration Term Act of 1984, also known as the Hatch-Waxman Act, 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establishes a period of marketing exclusivity for new brand name drugs as well as an abbreviated application process for generic versions of those drugs. (Stip. Fact 79).

178. In order to obtain FDA approval to market a generic drug, a pharmaceutical company may submit an abbreviated new drug application ("ANDA") to the FDA. (Stip. Fact 80). An ANDA for approval of an "AB-rated" generic drug must demonstrate, among other things, that the proposed generic is bioequivalent to the branded drug, meaning that it contains the same API as the branded drug and there are no significant differences in quality, safety, or efficacy. (Stip. Fact 81).

179. Prior to filing an NDA, the sponsor must complete the entire clinical development of the drug, and manufacturing process for the product must go through a rigorous phase of development and validation to demonstrate the ability to manufacture

the product. The CMC section (Chemistry, Manufacturing, and Control) of an NDA addresses manufacturing and quality. (Morris Trial Tr., 1237:23-1238:12, Dec. 14, 2009; Wipperman Dep. at 221:20-222:12). The ANDA process is a more streamlined, quicker process. An ANDA is aimed at proving bioequivalence of the generic drug, so the sponsor does not have to do the Phase I, II, or III clinical trials. (Morris Trial Tr. 1238:13-21, Dec. 14, 2009). In an ANDA, the sponsor must show that the generic is comparable to the originator's NDA. (Wipperman Dep. 31:14-24). The ANDA sponsor need not build proof or justify the development or manufacturing processes or control systems. (Wipperman Dep. 31:14-24).

180. The FDA is currently required by statute under 21 U.S.C. Section 355(j)(5)(A) to approve or disapprove an ANDA within one hundred eighty days of the initial receipt of an ANDA, unless otherwise agreed upon by the FDA and the applicant. (Stip. Fact 82).

181. In October 2006, the FDA announced its "First Generic" policy, which indicated that it would prioritize ANDAs for the first generic versions of drugs no longer protected by a patent or market exclusivity. (Stip. Fact 83). The priority review goal for such drugs is six months. (DX 247 at 4).

D. Bedford Has FDA Approval and Plans to Launch Generic Indomethacin

182. Bedford, a division of Ben Venue Laboratories, Inc., is a pharmaceutical company based in Bedford, Ohio. (Stip. Fact 84). Bedford intends to launch generic

indomethacin. (Gaugh Dep. 78:16-18, 84:3-15, 109:9-20). Bedford has taken steps to launch generic indomethacin. (Stip. Fact 85).

183. In January 2006, shortly after Ovation increased the price of Indocin IV, representatives of two group purchasing organizations ("GPOs"), Wayne Russell from Premier and Ross Day from Novation, contacted Bedford and asked it to develop a generic indomethacin. (Gaugh Dep. 47:12-23, 49:6-8, 51:9-15, 52:2-16, 116:24-117:4, 187:16-188:1). Linea Wilson from Children's Health Corporation of America ("CHCA") also contacted Bedford after the price increase to see if it would be willing to bring a product to market. (Wilson Dep. 34:4-22). Bedford's Product Selection Committee first decided to develop generic indomethacin in or around January 2006. (Gaugh Dep. 67:21-68:1, 116:9-15, 117:22-23).

184. Ovation's price increase on Indocin increased the potential for revenues associated with indomethacin, which prompted Bedford's decision to develop generic indomethacin. Bedford's Vice President and General Manager, David Gaugh, testified that Bedford's decision to start down the path of evaluating and developing generic indomethacin was one hundred percent based on Ovation's January 2006 price increase. (Gaugh Dep. 116:16-117:4). Bedford initially projected that Indocin would become a [redacted] million product after the price increase. (Gaugh Dep. 119:5-18). Bedford later reduced its estimate to around [redacted] and it views the market for indomethacin to be continually shrinking as a result of one-way migration to NeoProfen. (Gaugh Dep. 89:18-90:8, 91:13-16, 181:25-182:17, 182:23-184:6, 186:17-21; DX 21 at 1; DX 39).

185. In its evaluation of whether to pursue generic indomethacin, Bedford believed that indomethacin was a "pretty simple product" and anticipated that it could file an ANDA in less than a year. (Gaugh Dep. 119:19-120:15, 123:13-15). Generally, Bedford takes roughly 12 months on average to submit an ANDA filing after it starts evaluating a product as a possible candidate. (Gaugh Dep. 36:17-37:8). Mr. Gaugh testified that it is possible to prepare an ANDA for filing in roughly nine months. (Gaugh Dep. 130:18-131:7).

186. Bedford actually submitted its ANDA for generic indomethacin to the FDA on December 22, 2006. (Stip. Fact 88). This was less than eleven months from learning of the Indocin price increase that prompted Bedford's decision to develop the product. *See* Finding of Fact No. 183-184, *supra*. Mr. Gaugh testified that Bedford could have completed that process more quickly if it had focused on fewer products and made generic indomethacin its number one priority. (Gaugh Dep. 130:18-131:7).

187. In its evaluation of whether to pursue generic indomethacin, in early 2006, Bedford expected that FDA approval would be granted within one year of its ANDA application. (Gaugh Dep. 119:19-120:15, 123:13-15). At the time that Bedford made the decision to pursue development of generic indomethacin, in early 2006, the FDA's general review process for ANDAs was a 12-month review process. (Gaugh Dep. 119:19-120:10, 131:19-23). At that time, Bedford expected to enter the market by December 2007, approximately one year after filing its ANDA. (Gaugh Dep. 119:19-120:15, 123:13-15). Bedford's earliest projected launch date for generic indomethacin was late 2007, or mid fourth quarter 2007. (Gaugh Dep. 179:25-180:4).

188. At the time Bedford filed its ANDA for generic indomethacin, in December 2006, Bedford expected ANDA approval for a product like generic indomethacin, where the brand product was the only product on the market, within 12 to 14 months. (Gaugh Dep. 132:8-133:10).

189. There were various deficiencies in Bedford's ANDA. (Gaugh Dep. 133:11-140:6).

190.

[redacted] None of the deficiencies related to Bedford's manufacture of generic indomethacin. (Gaugh Dep. 142:6-12; DX 248).

191. All firms referenced in an ANDA must be in compliance with current Good Manufacturing Practices ("cGMP"), which is legislation promulgated to empower the FDA to regulate pharmaceutical manufacturing operations. (Gaugh Dep. 136:23-137:6; Wipperman Dep. 54:8-19).

192. [redacted]

193. The FDA approved Bedford's ANDA for generic indomethacin on July 16, 2008. (Stip. Fact 90). [redacted]

194. The FDA requires a pharmaceutical manufacturer, before selling the first unit of product, to demonstrate through validation that its manufacturing processes are consistent, repeatable, adequate, and effective. (Wipperman Dep. 56:23-57:18). A manufacturer must produce three validation batches before launching a product. (Gaugh Dep. 39:18-25). Validation batches may be produced before the FDA approves an ANDA. (Gaugh Dep. 40:7-12). Some of Bedford's products are ready for launch the day of FDA approval. (Gaugh Dep. 37:22-38:5).

195. Bedford worked on launch batches of generic indomethacin in the March 2008 time period, before receiving ANDA approval. (Gaugh Dep. 157:25-158:12; DX 23 at 1). Bedford started manufacturing launch batches of indomethacin as early as January 2008. (DX 20 at 5).

196. [redacted]

197. In the manufacture of injectable indomethacin, a dry powder indomethacin API is mixed with alcohol and water, blended, and fed through a filling system similar to a hypodermic needle into a vial. (Gaugh Dep. 63:2-63:16). The finished vial must be

between certain specifications in the ANDA in order to validate and sell the product. (Gaugh Dep. 64:24-65:8).

198. Bedford originally applied for ANDA approval under an assay range specification of 95%-105%. (DX 27 at 1-2). The assay range specification in Bedford's ANDA was narrower than the one that Ovation has for Indocin and tighter than required by the USP monograph. The USP assay range specification for injectable indomethacin is 90%-110%, the same range in Ovation's Indocin NDA. (Gaugh Dep. 64:24-65:22, 160:8-15, 129:3-130:10; DX 27 at 1).

199. Bedford's tighter specification was hard to maintain based on indomethacin's small fill volume. (DX 27 at 2). Bedford fills other products with the same volume (0.5 ml and smaller) as indomethacin, but the assay specification for the other products was not as narrow as the indomethacin assay range Bedford requested in its ANDA. (Gaugh Dep. 162:23-163:16; DX 22 at 2).

200. [redacted]

201. Bedford also could have applied for its ANDA using the same specification that Ovation used, [redacted]

[redacted]

202. On January 16, 2009, Bedford filed a CBE-30 to widen the assay specification in its ANDA to the USP monograph for indomethacin for injection, equal to that of Ovation. (Gaugh Dep. 65:9-22, 129:3-11, 160:8-15, 161:6-17, 162:2-13; DX 27). The FDA did not object to Bedford's request in the CBE-30 during the 30-day response time, and so the wider specification has been approved, meaning Bedford could have begun manufacturing under the revised specifications in February 2009. (Gaugh Dep. 65:24-66:17, 129:7-11, 162:11-13; DX 34 at 3). [redacted]

203. [redacted]

204. Indocin is a lyophilized product. (Wipperman Dep. 33:15-20; Stip. Fact 45). A lyophilized product is a freeze dried product, which means its moisture has been removed. (Gaugh Dep. 23:19-24; Wipperman Dep. 33:5-14).

205. The Indocin package insert says, "Each vial contains indomethacin for injection equivalent to 1 mg indomethacin as a white to yellow lyophilized powder or plug. Variations in size of the lyophilized plug and the intensity of color have no relationship to the quality or amount of indomethacin in the vial." (PX 241 at 4). Indomethacin cake typically is tan or off-white in color, with a moon-shaped top, and is uniform in color and shape. (Gaugh Dep. 165:21-166:5). [redacted]

206. [redacted]

207. Ovation did not block, deter, hinder or delay Bedford's launch of generic indomethacin. (Gaugh Dep. 207:1-6). Bedford's delays in bringing generic indomethacin to market are attributable to its own internal issues and errors.

208. Plaintiffs do not argue or offer any evidence that Ovation engaged in any conduct intended to or that had the effect of, blocking, deterring, hindering, or delaying the entry of a generic competitor to Indocin.

209. As of April 13, 2009, Bedford planned to launch generic indomethacin in December 2009. (Gaugh Dep. 64:13-17, 66:24-67:15, 109:9-20, 110:3-112:3). As of

December 2009, Kaiser Permanente Health, a major and interested buyer of Indocin, understood that Bedford's generic entry was imminent. (Carrejo Trial Tr. 320:5-7, 324:24-325:5, Dec. 8, 2009).

210. Bedford plans to price generic indomethacin at a 10 to 15 percent discount to branded Indocin IV. (Stip. Fact 91; Gaugh Dep. 72:3-7).

211. Bedford expects generic indomethacin to take a majority of sales away from Indocin as soon as it comes to market. (Gaugh Dep. 146:15-22, 150:24-151:11; DX 18 at 2). Bedford expects generic indomethacin to take 100% of branded Indocin sales within five years. (Gaugh Dep. 74:20-75:4; 185:22-25).

212. [redacted]

213. [redacted]

E. Consumers Will Select Between Generic Indomethacin and Branded Indocin IV on Price

214. As a bioequivalent to Indocin IV, generic indomethacin has the same efficacy, side effects, and chemical composition. (Stip. Fact 86).

215. If generic indomethacin for injection is introduced, many purchasers of branded Indocin IV may switch to the generic on the basis of price. (Stip. Fact 93).

216. Ovation continues to expect that one or more manufacturers will offer generic indomethacin for sale in the U.S. Absent price adjustments to Indocin IV by Ovation, Ovation expected and currently expects generic indomethacin for injection to replace a majority of Ovation's sales volume of branded Indocin IV within the first year after generic indomethacin comes to market. (Stip. Fact 92).

217. Imminent generic indomethacin entry will restore any lost pricing competition and divest Ovation of any market power it may otherwise have in any relevant market containing Indocin.

F. Ovation Did Not Expect Consumers to Choose Between Generic Indomethacin and Branded NeoProfen on Price

218. Various Ovation employees testified at trial that Ovation did not expect generic indomethacin to compete with NeoProfen on the basis of price. Ovation's employees had every incentive to take the question of whether customers would switch from NeoProfen to Indocin based on price seriously, and all of them concluded that customers would not switch based on price. As Mr. Burke testified at trial, his personal compensation was based on whether he achieved his deal models. (Burke Trial Tr. 631:18-20).

219. Mr. Burke testified at trial that Ovation did not think that generic indomethacin would take sales from NeoProfen. (Burke Trial Tr. 617:16-620:1:, 629:8-630:4). Mr. Burke testified at trial that Ovation projected that the bulk of the loss of

Indocin sales would be to generic indomethacin, rather than NeoProfen. (Burke Trial Tr. 672:13-672:24, 679:25-680:22). Further, Mr. Burke thought that NeoProfen would help Ovation keep some of the sales it would otherwise have lost to generic indomethacin. (Burke Trial Tr. 672:13-672:24, 679:25-680:22).

220. Michael Kenston joined Ovation in May 2005 as Vice President of Commercial Analysis. He held that position until February 2008, when he became Vice President, Commercial Analysis/Business Development. Throughout Mr. Kenston's tenure at Ovation/Lundbeck, until Michael Burke's departure, Mr. Kenston reported to Mr. Burke. (Stip. Fact 14). During this time period, Mr. Kenston was responsible for running Ovation's market research efforts and one of his responsibilities involved forecasting future product performance. (Kenston Trial Tr. 360:22-25; 361:19-22, Dec. 8, 2009). Mr. Kenston gave credible testimony regarding Ovation's expectations for generic indomethacin and Ovation's NeoProfen forecasts. Mr. Kenston testified at trial that Ovation did not expect NeoProfen to be affected by the entry of generic indomethacin because physicians are not price sensitive. (Kenston Trial Tr. 424:6-425:8, 432:1-24, Dec. 8, 2009). Even if generic indomethacin were to enter the market at a discount, whether it was an initial 15 or 20 percent or even an 80 percent discount, Mr. Kenston did not believe that a physician who viewed NeoProfen as clinically superior would switch to indomethacin. (Kenston Trial Tr. 424:24-425:8, 432:21-24, Dec. 8, 2009).

221. David Knocke also testified at trial that Ovation did not believe generic indomethacin would erode NeoProfen sales. (Knocke Trial Tr. 546:8-11, Dec. 9, 2009).

Mr. Knocke joined Ovation in March 2002 as Senior Director of Marketing and has held various positions at the company since then. Mr. Knocke served as Executive Director of International Marketing from approximately early 2005 until November 2005. Mr. Knocke then became Ovation's Executive Director of NICU Marketing from approximately November 2005 until early 2008, when he became Executive Director of Managed Care and National Accounts. (Stip. Fact 15). In his role as NICU Director Marketing, Mr. Knocke was responsible for marketing of both NeoProfen and Indocin. (Knocke Trial Tr. 444:23-445:5, Dec. 9, 2009). Mr. Knocke's testimony regarding Ovation's expectations for generic indomethacin was credible.

222. Mr. Stickler, Ovation's Vice President, Sales testified at trial that the neonatologists who account for the vast majority of NeoProfen sales likely would not switch to Indocin based on price, for instance if Indocin were 25% cheaper. (Stickler Trial Tr. 815:25-816:22, Dec. 10, 2009).

223. Mr. Stickler was compensated for selling NeoProfen and thus had every incentive to understand whether NeoProfen and Indocin were subject to cross-price elasticity. (Stickler Trial Tr. 798:12-19, Dec. 10, 2009). Mr. Burke testified at trial that he asked Gerald McCluskey, a member of his team, to run the projections to appease members of Mr. Stickler's sales organization who were looking for a break in their sales targets. (PX 156; PX 147). The possibility that generic indomethacin could have an effect on NeoProfen sales was not incorporated into Ovation employees' bonus plans or the company's projections and assessment of the market. (Burke Trial Tr. 614:17-615:24, 616:18-620:1, 630:5-22, Dec. 9, 2009).

224. Ovation's financial and business plans, deal models, and commercial forecasts did not account for erosion of NeoProfen sales by generic indomethacin. The documents in fact projected that NeoProfen sales would increase while generic indomethacin would steal the large majority of Indocin sales. (PX 68 at 3, 8; PX 84 at 5-6; DX 112 at 1, 3, 5, 7, 8; DX 120 at 4; DX 125 at 2; DX 126 at 1, 3; DX 161 at 3). Mr. Burke testified at trial that Ovation did not incorporate generic indomethacin erosion into its deal models or business plans for NeoProfen. (Burke Trial Tr. 631:9-17, 633:4-633:12, Dec. 10, 2009).

225. The "base case" Indocin forecast dated November 2005 assumed volume and sales loss due to new competition from generic entry and NeoProfen: "By completing the proposed acquisition, we will accomplish the following: we will exceed our planned sales projections in each year beginning in 2006, at minimum, we will retain all of the PDA sales currently projected to be lost over the next five years...." (PX 57 at 2).

226. Ovation's decision to buy NeoProfen for $32.5 million does not make economic sense if it expected that generic indomethacin sales would quickly steal a majority of NeoProfen's sales. As Ovation's economic expert, Dr. McCarthy, testified at trial, the chart on page five of PX 84 shows that Ovation expected that, first, Ibuprofen IV would come to market and doctors would try it for clinical reasons. (McCarthy Trial Tr. 1326:4-1327:6, Dec. 15, 2009). Then, generic indomethacin would come on the market in April 2008 and the Indocin sales would fall off a cliff because the generic

would come in at a lower price and quickly undercut the sales of Indocin. (McCarthy Trial Tr. 1327:7-12, Dec. 15, 2009).

227. If branded Indocin and NeoProfen are economic substitutes, then generic indomethacin and NeoProfen are also logically economic substitutes. So, the demand for NeoProfen upon entry of generic indomethacin would be similarly impacted as that of the branded Indocin. In other words, if NeoProfen and indomethacin were economic substitutes, demand for NeoProfen would also fall off the cliff when the generic indomethacin entered. If Ovation thought that generic indomethacin and NeoProfen were economic substitutes, Ovation's strategy of acquiring NeoProfen to "corner the market" would be foolish and economically irrational. Mr. Burke testified credibly that Ovation "would not have done the [NeoProfen] acquisition, if that were the case." (Burke Trial Tr. 632:19-635:1, Dec. 10, 2009). The $32.5 million purchase price of NeoProfen was more than Ovation projected Indocin would lose in sales to NeoProfen over the course of the 14 months prior to generic indomethacin's entry. (McCarthy Trial Tr. 1327:13-1328:11, Dec. 15, 2009).

228. But Ovation did not view NeoProfen as an economic substitute for either branded Indocin or generic indomethacin. As Dr. McCarthy testified at trial, with regard to the chart on PX 84-006, the NeoProfen vial sales line does not fall off the cliff in April 2008, when generic indomethacin is assumed to enter. This chart shows that Ovation believed the degree of cross-price elasticity between NeoProfen and Indocin to be inconsequential. (McCarthy Trial Tr. 1328:12-1329:4, Dec. 15, 2009).

229. Mr. Burke testified at trial that, if Ovation assumed that generic indomethacin entry would occur in the first quarter of 2008, and NeoProfen was susceptible to losing sales to generic indomethacin, the NeoProfen acquisition would not have made sense. (Burke Trial Tr. 632:19-635:1, Dec. 10, 2009). Mr. Burke would not have recommended that the deal go forward if that were the case, and Ovation would not have done the deal. (Burke Trial Tr. 634:17-635:1, Dec. 10, 2009).

230. Mr. Burke also testified at trial that, in December 2005, Ovation expected that the FDA would approve NeoProfen in 2007 or later, and that not long after that, Indocin would become commercially irrelevant due to the entry of generic indomethacin. (Burke Trial Tr. 632:13-635:1, Dec. 10, 2009). Thus, there were not enough Indocin sales (as opposed to generic indomethacin sales) to protect from NeoProfen to justify NeoProfen's $32 million acquisition price. (Burke Trial Tr. 681:5-684:23, 686:2-687:4, 687:10-689:8, Dec. 10, 2009).

231. Even the FTC's economic expert, Dr. Arnold testified at trial that it would not make sense for Ovation in January 2006 to pay over $32 million to buy the rights to NeoProfen if Ovation thought that NeoProfen, if and when it received FDA approval and launched, would lose all of its sales to generic indomethacin. Dr. Arnold also testified that Indocin and NeoProfen are economic substitutes because they are in the same market, even though he did not offer any proof at trial that the drugs were economic substitutes. (Arnold Trial Tr. 1081:22-1082:9, Dec. 11, 2009). *See* Finding of Fact No. 339, *infra*.

232. Dr. McCarthy testified at trial that he looked at forecasts about the effect of the entry of generic indomethacin on NeoProfen, and concluded that, if most parties believe that generic indomethacin will not have much effect on NeoProfen, then that is instructive as to whether there is cross-price elasticity. (McCarthy Trial Tr. 1322:2-14, Dec. 15, 2009).

G. Independent Third Parties Did Not Believe that Generic Indomethacin Would Compete with NeoProfen on Price

233. Other pharmaceutical companies that have evaluated the impact of generic indomethacin on Indocin and NeoProfen, including Bedford, projected that generic indomethacin will eviscerate Indocin sales but have no impact on NeoProfen sales, even though generic indomethacin would be close to 10-15% cheaper than NeoProfen. (Gaugh Dep. 72:3-7, 74:20-75:4, 75:13-21, 91:5-9).

234. Bedford never expected its generic indomethacin product to take any share from NeoProfen. Bedford created a number of different sales projection models and updated them at various times, and it never projected that its generic indomethacin might have an effect on NeoProfen sales. (Gaugh Dep. 75:13-21).

235. Bedford viewed the market uptake for generic indomethacin to be only Ovation's Indocin. (Gaugh Dep. 121:23-122:7). Bedford expected to take share from an approximately [redacted] Indocin market. (DX 21 at 1).

236. Bedford did take NeoProfen into account when it determined that the market for indomethacin would shrink due to a one-way migration to NeoProfen. Bedford forecasted a shrinking total market for indomethacin. [redacted]

[redacted] Bedford projected a shrinking total market for indomethacin based on the assumption that the market was moving from indomethacin to ibuprofen. (Gaugh Dep. 182:23-184:6). Bedford most recently projected that the market for indomethacin (Indocin and generic indomethacin) would fall from about [redacted] from 2009 to 2013. (DX 39 at 1).

237. Thus, Bedford expected generic indomethacin and NeoProfen to take share from branded Indocin, but did not suggest that generic indomethacin and NeoProfen would take share from each other.

238. Abbott's market projections for NeoProfen also did not consider what effect, if any, generic indomethacin would have on NeoProfen. (McCoy Dep. 90:22-91:1).

H. Other Drug Companies Could Develop Generic Indomethacin

239. [redacted]

240. Other drug companies have the plans and potential to introduce new branded competitors to Indocin and NeoProfen. Cumberland Pharmaceuticals developed, and the FDA approved, an IV ibuprofen product, which was formerly called Amelior and is now called Caldolor, for pain and fever, which may be used off-label to treat PDA. (DX 250 at 1; DX 251 at 6; DX 253 at 4).

VIII. PATENT DUCTUS ARTERIOSUS

A. PDA Is a Serious Condition that Affects Some Premature Infants

241. Patent ductus arteriosus ("PDA") is a heart condition that primarily affects low-birth-weight, usually premature, babies. PDA occurs when the ductus arteriosus, a shunt connecting a fetus's pulmonary artery to its aortic arch, fails to close as is normal shortly after birth. (Stip. Fact 17). PDA can be life-threatening if the condition is untreated and does not resolve on its own. (Stip. Fact 18).

242. More than 400,000 infants are born prematurely in the U.S. each year. (Stip. Fact 21). Approximately 60,000 very low birth weight infants (less than 1,500 grams) are born each year in the U.S. (Stip. Fact 22). Approximately 30,000 cases of PDA are treated in the U.S. each year. (Stip. Fact 24).

243. PDA virtually never occurs in isolation, because low birth-weight babies typically suffer from multiple conditions simultaneously, one or more of which may be life-threatening. (Stip. Fact 23).

B. Multiple PDA Treatment Options Exist

244. PDA is treated in a hospital inpatient setting. Hospital NICUs in the U.S. are generally classified as level I, II, or III. PDA is typically treated at level III NICUs. (Stip. Fact 20).

245. In many instances, a patient's PDA will close spontaneously. (Stip. Fact 19).

246. Infants diagnosed with PDA are usually treated by neonatologists, physicians who specialize in premature and newborn infants, in NICUs. (Pls.' Proposed Findings of Fact 2.5).

247. Some neonatologists prefer a treatment protocol of "watching and waiting" to treat PDA, which includes fluid management and possible administration of diuretics. (Stip. Fact 38).

248. Surgical ligation (tying off) of the ductus is another treatment option for PDA. (Stip. Fact 36).

249. When a neonatologist determines that pharmacological or surgical intervention is required to close a PDA, most neonatologists use pharmacological management as first-line treatment unless it is contraindicated for a particular patient. That is, by today's practice standards, neonatologists typically reserve surgery as "second-line" or "rescue" treatment for PDA when other treatments prove ineffective. (Stip. Fact 40). Also, the cost of treating PDA with either NeoProfen or Indocin IV is significantly less than the cost of surgical ligation. (Stip. Fact 37).

C. Medical Testimony in the Record

250. Twelve neonatologist and clinical pharmacist fact witnesses and Plaintiffs' expert neonatologist proffered testimony regarding their personal clinical practices.

251. Dr. Behbahani is a pediatric clinical pharmacist at Jackson Memorial Hospital, the teaching hospital of the University of Miami Miller School of Medicine in Miami, Florida. He has been on the staff at Jackson Memorial for 21 years. (Behbahani Dep. 4:7-20). At Jackson Memorial Hospital, both Indocin and NeoProfen are on

formulary, however, at this time neonatologists only use NeoProfen to treat PDA; it is considered the first-line treatment for PDA in their NICU. (Behbahani Dep. 18:17-22, 20:8-23, 27:14-18). Prior to NeoProfen's approval and addition to their formulary, Dr. Behbahani observed many cases in which neonatologists used Indocin to treat PDA.

252. Dr. Goldstein is a practicing physician and Associate Professor of Pediatrics at Loma Linda University School of Medicine in Loma Linda, California. (Goldstein Dep. 5:18-6:8). He currently maintains a practice at Citrus Valley Medical Center in West Covina, California where he is the NICU Director. (Goldstein Dep. 5:18-6:9-16). He is board-certified in both Pediatrics and Neonatology, and is a Fellow of the American Academy of Pediatrics. In addition, he is the president of the National Perinatal Association. (Goldstein Dep. 28:23-29:10). Prior to 2006, Dr. Goldstein and his colleagues used Indocin to treat a PDA. When NeoProfen became available in 2006, Dr. Goldstein and his colleagues decided to try it. His colleagues ultimately decided to stop using NeoProfen because they felt its behavior was different from Indocin, and decided to continue using Indocin because they felt they wanted more research to be done on NeoProfen. (Goldstein Dep. 11:20-13:14; 22:9-20).

253. Dr. Kim is an attending neonatologist at The University of California, San Diego Medical Center ("UCSD"), where he is also appointed as a pediatric gastroenterologist. (Kim Dep. 4:23-5:18). At UCSD, Dr. Kim and the other neonatologists in his group began using NeoProfen as soon as it became available, and currently they all use it exclusively in their pharmacological treatment of PDA in the NICU. (Kim Dep. 17:5-16). Prior to using NeoProfen exclusively, Dr. Kim and the

other neonatologists in the Jackson Memorial NICU treated PDA pharmacologically using Indocin. Id.

254. Dr. Muller is a clinical pharmacist specializing in neonatology at Women and Infants Hospital in Providence Rhode Island, where he has been employed for the past 14 years. (Muller Dep. 6:12-23). At Women and Infants Hospital, neonatologists use only Indocin when treating PDA pharmacologically. (Muller Dep. 8:11-16). They also use Indocin to treat prophylactically against IVH and PDA. (Muller Dep. 8:17-25). NeoProfen is not on the formulary at Women and Infants Hospital, and the neonatologists there do not use it to treat PDA. (Muller Dep. 9:15-25).

255. Dr. Smith is a practicing neonatologist in Neonatal and Perinatal Medicine at Durham Regional Hospital, part of the Duke University Health System in Durham, North Carolina. (Smith Dep. 5:10-18, 6:8-10). In addition, he is an assistant professor of pediatrics at the Duke University School of Medicine and an unpaid scientific advisor to the Federal Drug Administration Office of Pediatric Therapeutics. (Smith Dep. 5:10-18). In his position with the FDA, he is involved in clinical research focusing on neonatal pharmacology and drug safety and efficacy in neonates. (Smith Dep. 7:10-9:9). At Durham Regional Hospital, the neonatologists use both Indocin and NeoProfen in different ways. They use Indocin exclusively when prophylactically treating IVH and PDA, and they use NeoProfen exclusively when treating a diagnosed PDA. (Smith Dep. 12:17-14:12).

256. Dr. Sosenko is an attending neonatologist at Jackson Memorial Hospital, the teaching hospital of the University of Miami, where she has worked for 27 years.

(Sosenko Dep. 5:11-21). In addition, Dr. Sosenko is the Associate Director of Clinical Development and Outreach and the Associate Director of the Fellowship Training Program at the School of Medicine. (Sosenko Dep. 5:24-6:18). At Jackson Memorial Hospital, Dr. Sosenko and her colleagues treat PDA exclusively using NeoProfen, and have done so since 2006, soon after it was approved, which means that when they treat PDA pharmacologically, the only drug they use is NeoProfen. (Sosenko Dep. 12:18-13:22). Prior to using NeoProfen exclusively, Dr. Sosenko and the other neonatologists in the Jackson Memorial NICU treated PDA pharmacologically using Indocin. (Sosenko Dep. 13:7-10).

257. Dr. Tefft is a neonatologist and Medical Director of the NICU at White Memorial Medical Center in East Los Angeles, California. (Tefft Dep. 5:8-13). He is currently the Director of the NICU at White Memorial, and has held that position for the past 29 years. (Tefft Dep. 5:13-17). At the White Memorial NICU, the protocol is to treat PDA when it is asymptomatic or early using the drug NeoProfen. (Tefft Dep. 50:23-51:3). That has been the protocol for over two years. (Tefft Dep. 12:7-17). Prior to becoming a NeoProfen-only NICU, neonatologists in Dr. Tefft's group, including Dr. Tefft, treated PDA pharmacologically using Indocin. (Tefft Dep. 29:1-10). Dr. Tefft's NICU has experienced a significant decrease in the surgical ligation rate since switching to NeoProfen. (Tefft Dep. 46:14-47:8).

258. Dr. Payne is a neonatologist with the Children's Hospital of Minnesota as well as with the Minnesota Neonatal Physicians, and he has worked for both since 1987 as a practicing neonatologist. At the Children's Hospital of Minnesota he also currently

serves also as the director of quality improvement. (Payne Trial Tr. 197:3-15, Dec. 7, 2009). Dr. Payne's group of neonatologists uses Indocin only when treating PDA pharmacologically. (Payne Trial Tr. 206:22-208:11, Dec. 7, 2009). They also use Indocin to treat prophylactically against IVH and PDA in very small babies. (Payne Trial Tr. 206:22-208:11, Dec. 7, 2009).

259. Dr. Mammel is a neonatologist at the Children's Hospital in St. Paul Minnesota, where he has practiced as a neonatologist since 1982. (Mammel Trial Tr. 246:2-6, Dec. 8, 2009). He is also on staff at the University of Minnesota. (Mammel Trial Tr. 246:2-6, Dec. 8, 2009). In his practice group, he serves as an associate director of newborn medicine and the director of newborn education and research. (Mammel Trial Tr. 247:18-24, Dec. 8, 2009). Although they have no official protocol on treating PDA, Dr. Mammel's practice group uses about 80% NeoProfen and 20% Indocin in treating babies with PDA, and they do not treat for IVH. (Mammel Trial Tr. 267:22-268:4, 269:21-270:5, Dec. 8, 2009).

260. Dr. Gardner is a clinical pharmacist at Ohio State University, where she has practiced since 1979. She currently serves as a NICU specialist. (Gardner Trial Tr. 1115:18-1116:13, Dec. 14, 2009). At Ohio State Medical Center, some neonatologists use indomethacin to treat IVH, and almost all of them use NeoProfen to treat a diagnosed PDA. (Gardner Trial Tr. 1122:25-1123:14, Dec. 14, 2009). Dr. Gardner has experience with both Indocin and NeoProfen in the treatment of PDA. (Gardner Trial Tr. 1123:15-17, Dec. 14, 2009).

261. Dr. Carrejo is a pharmacist at Kaiser Permanente in Northern California, and he serves as the national pharmaceutical contracting leader for Kaiser Permanente. (Carrejo Trial Tr. 300:10-13, Dec. 8, 2009). He has served in this position for a little over a year, but has been in the pharmaceutical contracting department since June 2006, and has been with Kaiser for 20 years. (Carrejo Trial Tr. 300:14-22, Dec. 8, 2009). In his position, he is involved in the purchases of inpatient drugs for hospital use. (Carrejo Trial Tr. 302:5-20, Dec. 8, 2009).

262. Dr. Gerdes testified as an expert witness. He is a neonatologist who has practiced at Children's Hospital of Philadelphia since 1984. (Gerdes Trial Tr. 77:8-78:7; 82:12-20, Dec. 7, 2009). He currently serves as the Associate Chief of the Children's Hospital of Philadelphia neonatology department. (Gerdes Trial Tr. 77:18-20, Dec. 7, 2009). Over his 31 years of experience in treating infants with PDA, he has personally treated or supervised the treatment of more than 2,000 infants with Indocin. (Gerdes Trial Tr. 82:21-24, Dec. 7, 2009). Dr. Gerdes has extensive experience with the treatment of PDA using Indocin, and his testimony regarding the science of the side effects caused by Indocin and the science generally describing PDA was credible.

263. While Dr. Gerdes's opinions on the manageability of Indocin's side effects are credible with respect to his own personal practices, they do not represent the consensus opinion among neonatologists practicing in the U.S. (Gerdes Trial Tr. 122:2-124:21, Dec. 7, 2009). Rather, that Indocin's side effects are easily manageable is his own personal belief, not scientific opinion, and the record is replete with contradictory testimony of other neonatologists and pharmacists. (Gardner Trial Tr. 1132:24-1133:7,

Dec. 14, 2009; Mammel Trial Tr. 293:3-19, Dec. 8, 2009; Payne Trial Tr. 230:23-232:5, Dec. 7, 2009).

264. Dr. Gerdes's opinions regarding NeoProfen have no foundation and thus lack any evidentiary value. He has no personal experience with NeoProfen; he has never used NeoProfen or any other form of ibuprofen to treat PDA in his 31 years of practice, and no hospitals at which he has worked have used NeoProfen to treat PDA. (Gerdes Trial Tr. 120:7-25, Dec. 7, 2009). He has never written anything comparing NeoProfen and Indocin (other than the report he was paid to write in this case), he has never given any lectures comparing NeoProfen and Indocin, and he has never conducted any clinical research regarding NeoProfen and Indocin. (Gerdes Trial Tr. 121:13-122:1, Dec. 7, 2009). The Court therefore assigns no evidentiary weight to Dr. Gerdes's testimony comparing the two drugs.

D. Indocin and NeoProfen Are Chemically Distinct Drugs with Different Composition and Dosing

265. Indocin IV is a well-known PDA treatment among neonatologists. (Stip. Fact 52; Knocke Trial Tr. 520:18-21, Dec. 9, 300). Indocin IV was approved by the FDA for use in the U.S. as a treatment for PDA in January 1985. (Stip. Fact 48). Until the FDA approved NeoProfen in 2006, Indocin IV was the only FDA-approved pharmaceutical treatment for PDA. (Stip. Fact 49).

266. Long-term safety and outcomes data are not available for NeoProfen because it has only had widespread use since 2006. Since Indocin IV has been in use for

more than 20 years, its long-term safety record is well known. (Pls.' Proposed Findings of Fact 2.42).

267. Indocin IV is an off-patent, injectable drug, the active ingredient of which is indomethacin. (Stip. Facts 28, 43). NeoProfen is an injectable drug the active ingredient of which is ibuprofen lysine. (Stip. Fact 29). NeoProfen is not a bioequivalent to Indocin IV; indomethacin for injection and ibuprofen lysine are different chemical compounds. (Stip. Facts 30, 124).

268. The FDA labels for NeoProfen and Indocin IV are not identical. (Stip. Fact 121). The label (package insert) approved by the FDA for a drug does not limit the uses for which physicians may prescribe it; but under 21 C.F.R. § 202.1, the marketing claims for a drug must be consistent with the FDA-approved label, *i.e.*, they may not include representations or suggestions that it is better, more effective, useful in a broader range of conditions or patients, safer, or that it has fewer, or less incidence of, or less serious side effects or contraindications than the label indicates. (Stip. Fact 26).

269. While physicians may freely prescribe drugs for legitimate "off label" uses, no one involved in marketing a drug may make any claims or promote any uses that are not on the label. (21 C.F.R. § 202.1; Pls' Proposed Findings of Fact 2.20).

270. The FDA approved NeoProfen to treat a "clinically significant" PDA, whereas the Indocin indication allows for treatment of a "hemodynamically significant" PDA. (DX 244; DX 245). "Hemodynamically significant" means having a significant effect on blood flow, and possibly presenting itself in complications including, for

example, respiratory distress, a concurrent murmur, a hyperactive percordium, cardiomegaly, or pulmonary plethora on a chest X-ray. (Stip. Fact 39).

271. The FDA approved Indocin for use "after 48 hours of usual medical management . . . is ineffective;" whereas there is no time limit in the NeoProfen indication for use "when usual medical management . . . is ineffective." (DX 244; DX 245).

272. Actual data from the European study comparing ibuprofen to Indocin is not included in the FDA-approved package insert, but references to both European studies are included in both the Clinical Studies and Adverse Reactions sections. This inclusion in the package insert permits the use of these published studies in the marketing of NeoProfen. The European study of ibuprofen THAM versus indomethacin is published in the New England Journal of Medicine, and as such is available and can be provided or conveyed to neonatologists. (DX 160 at 1-2). Abbott told Ovation that it believed that the approved NeoProfen label represented a broadening of the originally proposed indication, provided greater latitude in marketing, and would enhance actual usage based on current clinical practice. (DX 160 at 2).

273. One vial of NeoProfen contains 2 milliliters of a solution containing 10 milligrams of active ingredient per milliliter. (Stip. Fact 118).

274. One vial of Indocin IV for commercial sale contains a lyophilized powder that, when reconstituted in solution, is equivalent to 1 milligram of indomethacin. (Stip. Fact 45).

E. Indocin and NeoProfen Have Different Clinical Uses and Safety Profiles

275. Indomethacin and ibuprofen lysine differ in their relative degree of inhibition of the synthesis of cyclooxygenase-1 ("COX-I") and cyclooxygenase-2 ("COX¬2"), two enzymes that contribute to the formation of prostaglandins. (Stip. Fact 34).

276. NeoProfen and Indocin IV do not exhibit identical side effects. (Stip. Fact 125).

277. There is medical literature indicating that Indocin has been found to cause a decrease in blood flow to the brain. (Gerdes Trial Tr. 135:9-14, Dec. 7, 2009). NeoProfen has not been shown in the medical literature to cause any impact on blood flow to the brain. (Gerdes Trial Tr. 135:15-17, Dec. 7, 2009).

278. There is medical literature indicating that Indocin causes a reduction in mesenteric blood flow, which means blood flow to the gastrointestinal tract. (Gerdes Trial Tr. 136:5-13, Dec. 7, 2009). NeoProfen has not been shown in the medical literature to cause a decrease in mesenteric blood flow. (Gerdes Trial Tr. 136:14-16, Dec. 7, 2009).

279. There is medical literature indicating that the use of indomethacin may lead to complications such as transient or permanent renal dysfunction. (Gerdes Trial Tr. 145:8-23, Dec. 7, 2009). In the pivotal study, ibuprofen lysine was found to have minimal effect on renal function. (Gerdes Trial Tr. 146:13-15, Dec. 7, 2009). In fact, in

the pivotal study, giving NeoProfen compared to no treatment did not have an appreciable change in renal function. (Gerdes Trial Tr. 147:2-10, Dec. 7, 2009).

280. The differences in renal side effects between Indocin and NeoProfen was one of the key reasons why neonatologists and clinical pharmacists decided to start using NeoProfen rather than Indocin to treat patients with PDA. (Mammel Trial Tr. 292:5-293:2, Dec. 8, 2009; Behbahani Dep. 36:7-12; Kim Dep. 17:17-18:11; Smith Dep. 34:18-35:6; Sosenko Dep. 47:4-12, 47:17-22).

281. Moreover, neonatologists who use (or previously used) Indocin testified that they take certain measures to help avoid the risks that are associated with indomethacin with respect to decreased blood flow to the kidney, including closer monitoring of the patient and concomitant administration of a diuretic such as furosemide. (Hay Trial Tr. 1167:5-7, Dec. 14, 2009; Behbahani Dep. at 81:10-12, 81:17-82:5; Kim Dep. 73:21-74:19; Sosenko Dep. 38:2-39:14).

282. Because the use of Indocin causes a reduction in blood flow to the gastrointestinal tract, Indocin has the potential to cause negative effects on a fragile baby of the type being treated for PDA, including a serious gastrointestinal condition known as necrotizing enterocolitis. (Gerdes Trial Tr. 136:5-137:10, Dec. 7, 2009; Payne Trial Tr. 230:23-231:8, Dec. 7, 2009; DX 293 at 3). Plaintiffs' expert neonatology witness, Dr. Gerdes, is not aware of any evidence in the medical literature associating NeoProfen with necrotizing enterocolitis. (Gerdes Trial Tr. 141:19-23, Dec. 7, 2009). Reduced blood flow to the gut has not been shown with NeoProfen. (Gerdes Trial Tr. 142:10-14, Dec. 7, 2009; Tefft Dep. 48:4-19).

283. Because the use of Indocin causes a reduction in blood flow to the gastrointestinal tract, Indocin also may be a contributing factor to another serious condition that is associated with Indocin usage in neonates known as spontaneous intestinal perforation. (Gerdes Trial Tr. 141:24-142:14, Dec. 7, 2009).

284. Enteral feeding, which means feeding through the gut, gives the opportunity to provide human milk, and there is evidence in the literature from randomized controlled trials that human milk reduces the risk of necrotizing enterocolitis, and has many other benefits, including reduction in infections. Parenteral feeding means feeding by IV. (Gerdes Trial Tr. 143:19-144:3, Dec. 7, 2009; Hay Trial Tr. 1167:14-25, Dec. 14, 2009). Babies get more and better nutrition being fed enterally than parenterally. (Gerdes Trial Tr. 144:4-14, Dec. 7, 2009).

285. Enteral feedings are less costly than intravenous (parenteral) feedings, which can cost at least $500 per day. (Gerdes Trial Tr. 144:12-21, Dec. 7, 2009; Hay Trial Tr. 1168:20-25, Dec. 14, 2009).

286. Neonatologists take certain measures to help avoid the risks that are associated with indomethacin with respect to decreased blood flow to the gut. (Gerdes Trial Tr. 142:22-25, Dec. 7, 2009). Neonatologists, including Dr. Gerdes, do not feed babies enterally while receiving Indocin. (Gerdes Trial Tr. 143:1-3, Dec. 7, 2009; Hay Trial Tr. 1167:9-13, Dec. 14, 2009). Many neonatologists do feed babies enterally when they are being treated with NeoProfen. (Gardner Trial Tr. 1135:5-20, Dec. 14, 2009; Gerdes Trial Tr. 143:8-10, Dec. 7, 2009).

F. Only Indocin is Used for Prophylactic Treatment of IVH

287. Some neonatologists use Indocin IV "off-label" in susceptible neonates as concurrent prophylactic treatment for intraventricular hemorrhage ("IVH") and PDA. (Stip. Fact 50). IVH is bleeding (hemorrhage) into the fluid-filled areas (ventricles) surrounded by the brain, seen most often in premature neonates. (Stip. Fact 51).

288. NeoProfen is not effective for the concurrent prophylactic treatment of IVH and PDA. (Stip. Fact 126).

G. Neonatologists Select PDA Treatment Protocols Based on Experience and Evidence, Not Drug Prices

289. Neonatologists decide which treatments to adopt using evidence-based medicine, which is a practice in which physicians individually or by group look at research that has been done in any given subject and grade that research as to strength, belief, and how good the evidence is to determine the best practices. (Gerdes Trial Tr. 83:9-84:15, Dec. 7, 2009; Mammel Trial Tr. 286:20-287:15, Dec. 8, 2009).

290. Neonatologists and clinical pharmacists who have used both Indocin and NeoProfen perceive significant differences in the drugs' safety profiles that are important in their clinical treatment decisions. (Goldstein Dep. 53:25-55:12; Smith Dep. 34:18-35:6; Sosenko Dep. 47:4-12, 47:17-22; Tefft Dep. 39:8-16, 40:17-21, 41:3-14).

291. Neonatologists develop their treatment protocols for PDA using NeoProfen or Indocin, based on their review of medical literature, personal experience treating patients, and their discussions with colleagues. (Gardner Trial Tr. 1129:7-1130:3, Dec. 14, 2009; Smith Dep. 19:8-20:10; Sosenko Dep. 48:15-19).

292. Some neonatologists who use Indocin exclusively do so because: (1) they do not believe that Indocin and NeoProfen are equivalent in terms of efficacy, particularly since only Indocin is effective in treating PDA and IVH prophylactically, (2) they want to see longer-term clinical data on NeoProfen before switching, (3) they have extensive clinical experience with the drug, and/or (4) they want to see longer-term clinical data on NeoProfen or they feel more comfortable treating their patients with an established drug. (Gerdes Trial Tr. 112:7-113:16, Dec. 7, 2009; Payne Trial Tr. 232:24-233:5; 234:8-13, Dec. 7, 2009; Goldstein Dep. 22:9-20, 53:25-55:12).

293. Many neonatologists who use NeoProfen almost exclusively do so because they believe it is a safer drug than Indocin. (Gardner Trial Tr. 1125:2-7, 1129:7-1130:3, Dec. 14, 2009; Mammel Trial Tr. 273:10-274:6, Dec. 8, 2009; Behbahani Dep. 21:22-22:3; Kim Dep. 17:5-18:11; Sosenko Dep. 48:15-19; Tefft Dep. 39:8-16, 40:17-21, 41:3-14). They believe that the safety differences between Indocin and NeoProfen are meaningful and can have significant impact on fragile, premature babies in the NICU. (Gardner Trial Tr. 1125:2-7, 1129:7-1130:3, 1131:6-1133:7, 1134:25-1135:4, Dec. 14, 2009; Mammel Trial Tr. 273:8-274:6, 291:25-:292:19, Dec. 8, 2009; Behbahani Dep. 21:22-22:3, 81:17-82:5; Kim Dep. 73:21-74:16; Muller Dep. 69:18-21; Sosenko Dep. 39:25-40:6, 48:15-19, 97:4-15).

294. If generic indomethacin is introduced, many purchasers of branded Indocin may switch to the generic based on price. (Stip. Fact 93). Ovation has expected and currently expects generic indomethacin to replace a majority of sales from branded Indocin within the first year after generic indomethacin comes to market. (Stip. Fact 92).

295. There is no evidence that neonatologists who use NeoProfen to treat PDA will switch to generic indomethacin when it enters the market. All neonatologists and pharmacists who testified and who treat with NeoProfen perceive important safety differences between the two drugs. (Gardner Trial Tr. 1136:25-1137:9, Dec. 14, 2009; Behbahani Dep. 51.5-12; Kim Dep. 72:21-73:1; Sosenko Dep. 52:23-53:4).

296. Because of the different clinical attributes of the drugs (including clinical uses, side effects, the availability of clinical studies showing long-term outcomes, and the neonatologists' experience with the drugs), neonatologists would not switch between Indocin and NeoProfen based on changes in price. (Carrejo Trial Tr. 337:8-338:1, Dec. 8, 2009; Payne Trial Tr. 225:7-13, Dec. 7, 2009; Goldstein Dep. 62:22-63:1; Kim Dep. 29:11-30:8; Muller Dep. 34:12-21; Smith Dep. 40:2-8, 41:18-42:5; Sosenko Dep. 50:24-51:6, 52:5-7; Tefft Dep. 48:25-49:7).

297. Neonatologists are the relevant customers driving demand for NeoProfen and Indocin. In analyzing the underlying demand for NeoProfen, one has to look at how a physician understands and reacts to the product because, even if a pharmacist purchases the drug, he or she has no ability to influence market share unless the physicians are willing to use it. (McCarthy Trial Tr. 1320:18-1321:7; 1324:24-1326:3; 1364:25-1365:21, Dec. 15, 2009). Thus, neonatologists drive treatment demand in the NICU because they make actual prescribing decisions and dictate hospital treatment protocols or determine their own treatment protocols. (Carrejo Trial Tr. 337:12-15; 347:13-20, Dec. 8, 2009; Gardner Trial Tr. 1117:18-20, Dec. 14, 2009; Gutierrez Trial Tr. 837:23-

838:18, 849:15-17, Dec. 10, 2009; Payne Trial Tr. 219:2-220:15, Dec. 7, 2009; Behbahani Dep. 75:11-16; Kim Dep. 45:11-15).

298. Neonatologists have strong clinical preferences regarding Indocin and NeoProfen, and these strongly held preferences lead many hospitals to use either Indocin or NeoProfen exclusively. (Mammel Trial Tr. 273:8-274:6, Dec. 8, 2009; Behbahani Dep. 21:22-.22:3, 36:7-12; Kim Dep. 17:5-18:11; Smith Dep. 19:8-20:10).

299. Ovation's belief that clinical factors, rather than price, determine demand is confirmed by direct evidence of consumer responses. Virtually all fact medical witnesses testified that not even a large (much less a small) price difference would cause them to switch drugs. Three of Plaintiffs' trial witnesses reinforce the point. Dr. Payne, a neonatologist, testified that he might *consider* switching to NeoProfen for a 90% discount. (Payne Trial Tr. 226:3-11, Dec. 7, 2009). Dr. Carrejo, the lead pharmaceutical buyer for the Kaiser network, declined to accept a 20% discount on NeoProfen because he had no confidence he could convince the doctors to use it before expiration, simply because it was cheaper. (Carrejo Trial Tr. 321:2-323:1, Dec. 8, 2009). Dr. Gutierrez, the chair of the P&T committee for the Los Angeles County health system, testified that a $117 (equivalent to 8%) price differential in favor of what she regarded as the safer drug was too small to justify analyzing costs savings or depriving neonatologists access to their drug of choice. (Gutierrez Trial Tr. 864:9-866:15, Dec. 10, 2009).

IX. PHARMACY AND THERAPEUTICS COMMITTEES AND FORMULARIES

A. The Formulary Process

300. Greater than 90 percent of hospitals are accredited by the Joint Committee on the Accreditation of Health Care Organizations, and as a requirement of being accredited they have to have a formulary system in their hospital. (Schondelmeyer Trial Tr. 889:10-890:11, Dec. 11, 2009). A formulary is defined as a continually updated list of medications and related information that represents the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health. (Stip. Fact 127).

301. The formulary is created, managed, and maintained by an official body of the medical staff called the Pharmacy & Therapeutics ("P&T") committee. (Schondelmeyer Trial Tr. 897:10-898:6, Dec. 11, 2009). The P&T Committee includes physicians, often pharmacists, usually nurses, and sometimes hospital administrators. (Schondelmeyer Trial Tr. 899:1-14, Dec. 11, 2009; DX 191 at 2). A P&T committee, as an official body of the medical staff, serves in an advisory capacity to the medical staff, which includes neonatologists. (Schondelmeyer Trial Tr. 897:10-898:6, 899:5-14, Dec. 11, 2009; DX 191 at 2).

302. 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. No formulary system will preclude hospital personnel from obtaining non-formulary, FDA-approved drugs if necessary. (Stip. Fact 128).

303. Not every member of a P&T committee is familiar with all the drugs that come before it for consideration. (Gutierrez Trial Tr. 852:24-853:2, 854:13-20, Dec. 10, 2009). As a result, P&T committees rely on health care experts to help assess the drugs it is reviewing. (Gutierrez Trial Tr. 853:3-9, Dec. 10, 2009). P&T committees often seek input from specialist physicians when evaluating whether to include a specialty drug on the formulary. (Stip. Fact 129). In the case of drugs used predominantly in the NICU, the experts the P&T committee relies on are neonatologists. (Gutierrez Trial Tr. 853:15-854:3, Dec. 10, 2009). The need for physician support is paramount to the process. (DX 191 at 6). Neonatologists are given great deference in determining which drugs are placed on a hospital's formulary. (Carrejo Trial Tr. 304:4-21, Dec. 8, 2009; Gardner Trial Tr. 1130:22-1131:1, Dec. 14, 2009; Gutierrez Trial Tr. 837:23-838:18, Dec. 10, 2009; Payne Trial Tr. 221:22-222:1, Dec. 7, 2009; Schondelmeyer Trial Tr. 945:11-18, Dec. 11, 2009; Behbahani Dep. 25:11-21, 26:8-27:13; Goldstein Dep. 60:8-61:13).

304. P&T committees do not overrule neonatologists' treatment decisions, and neonatologists do not change their treatment decisions based on orders from pharmacists. (Carrejo Trial Tr. 347:13-20, Dec. 8, 2009; Gerdes Trial Tr. 129:22-130:1; Gutierrez Trial Tr. 854:4-8, 861:25-862:10, Dec. 10, 2009). Neonatologists are free to prescribe whatever drugs they deem appropriate for a given situation, regardless of whether a drug is on formulary. (Schondelmeyer Trial Tr. 906:13-16, 946:18-947:1, Dec. 11, 2009). Neonatologists drive decisions about which NICU drugs will be on formulary. (Stickler

Trial Tr. 813:15-18, Dec. 10, 2009). P&T committees give particular deference to neonatologists because of the unique fragility of their patients. (Behbahani Dep. 25:11-21, 27:1-9; Goldstein Dep. 60:8-61:13).

305. There is no evidence of any circumstance where a neonatologist wanted a particular drug on the formulary and the P&T committee tried to keep it off the formulary or otherwise discouraged the neonatologist from using his or her preferred drug of choice when treating any medical condition. (Carrejo Trial Tr. 303:11-304:21, Dec. 8, 2009; Payne Trial Tr. 221:22-222:1, Dec. 7, 2009; Goldstein Dep. 60:8-61:18; Tefft Dep. 75:10-20).

306. P&T committees consider clinical safety and efficacy first when making formulary decisions. (Schondelmeyer Trial Tr. 901:22-902:3, 949:7-13, Dec. 11, 2009). When determining what drugs to include on formulary, P&T committees consider cost only when safety and efficacy are roughly equivalent. (Schondelmeyer Trial Tr. 901:22-902:3, Dec. 11, 2009; DX 282 at 14-16, No. 9). If a P&T committee does not believe that two drugs are at least therapeutically interchangeable from a safety and effectiveness standpoint, then it will probably not look at cost. (Schondelmeyer Trial Tr. 949:18-22, Dec. 11, 2009). Accordingly, P&T committees sometimes make formulary decisions that result in an increase in cost to put a safer drug on formulary. (Gutierrez Trial Tr. 870:16-871:3, Dec. 10, 2009).

307. Hospitals can promise or threaten to move market share towards one drug over the other only after physicians have determined that the two drugs are therapeutically similar from a safety and efficacy point of view. (Carrejo Trial Tr.

308:19-309:12, Dec. 8, 2009). There is no evidence that any hospital, let alone a sufficient number of hospitals to have a market-wide impact, would be able to (1) persuade their physicians to change their drug of choice from Indocin to NeoProfen (or vice versa) to support a hospital's promise or threat to move market share to any extent and (2) thereby drive price competition between independent owners. (Carrejo Trial Tr. 322:7-323:6, Dec. 8, 2009; Hay Trial Tr. 1153:10-1154:10, Dec. 14, 2009; McCarthy Trial Tr. 1364:12-1365:21, 1374:22-1376:1, Dec. 15, 2009).

308. P&T committees would not force physicians to prescribe a drug that the physicians thought was less safe than another. (Gutierrez Trial Tr. 861:25-862:10, Dec. 10, 2009).

309. Generally, to the extent that costs are ever considered, neonatologists, hospital administrators, and pharmacists are concerned with the total cost of a drug therapy rather than just the price of a particular dose of a drug. (Schondelmeyer Trial Tr. 899:15-901:21, 911:1-16, 952:20-953:14, 956:4-10, 956:16-25, Dec. 11, 2009; Hay Trial Tr. 1166:10-20, 1168:7-14, Dec. 14, 2009). Consideration of drugs' total costs might include the costs of administration of the drug, and relative difference in cost per outcome. (Schondelmeyer Trial Tr. 911:1-16, 952:20-953:14, Dec. 11, 2009). When comparing two drugs' total costs, there are some cases where the cost of an individual drug may have other ancillary costs that wipe out the difference in price between the two drugs. (Schondelmeyer Trial Tr. 955:16-25, Dec. 11, 2009).

310. If a P&T Committee were to consider the overall costs (including non-drug costs) associated with Indocin treatment versus those associated with NeoProfen

treatment, there is no price an Indocin owner could charge that would make it cheaper than the overall cost of treating with NeoProfen. This is due in part to the additional costs incurred when treating with Indocin, including, for instance, the cost of diuretics and extended parenteral feeding. (Hay Trial Tr. 1166:10-1169:22, Dec. 14, 2009). It is also attributable to long-term outcomes, as treatment with NeoProfen (as opposed to Indocin) has been shown to reduce the instances of surgical ligation. (Hay Trial Tr. 1168:1-6, 1169:1172:1, Dec. 14, 2009).

311. To maximize cost savings, P&T committees tend to focus on higher volume drugs for cost savings. (Gutierrez Trial Tr. 862:19-23, 863:10-20, Dec. 10, 2009; Schondelmeyer Trial Tr. 923:25-926:13, 932:21-933:16, Dec. 11, 2009; DX 191 at 7). Most employers and payers do not monitor price increases on drugs other than the top 500 drugs most commonly prescribed. (Schondelmeyer Trial Tr. 932:21-933:16, Dec. 11, 2009). Indocin and NeoProfen are low volume drugs that are not high-cost centers for NICUs. (Hay Trial Tr. 1159:18-22, Dec. 14, 2009).

B. No Evidence of Therapeutic Interchange

312. Some hospitals have generic substitution policies that permit their pharmacies to automatically substitute a lower priced generic bioequivalent for the brand name drug without checking with a physician. (Carrejo Trial Tr. 325:15-326:14, Dec. 8, 2009; Gutierrez Trial Tr. 854:21-855:2, Dec. 10, 2009).

313. While a P&T committees may have a generic substitution policy outlining the conditions in which it automatically substitutes bioequivalent drugs, the P&T

committee's therapeutic interchange policy applies to a very limited subset of medications. (Gutierrez Trial Tr. 855:3-5, Dec. 10, 2009).

314. There is no evidence that any hospital has a therapeutic interchange policy that permits its pharmacy to automatically substitute between any two non-bioequivalent NICU or pediatric drugs. (Gutierrez Trial Tr. 855:6-9, Dec. 10, 2009; Mammel Trial Tr. 291:25-292:4, Dec. 8, 2009).

315. There is no evidence that any hospital has a therapeutic interchange policy that permits its pharmacy to automatically substitute Indocin for NeoProfen or vice versa. (Mammel Trial Tr. 291:13-16, Dec. 8, 2009; Gutierrez Trial Tr. 855:6-9, Dec. 10, 2009; McCarthy Trial Tr. 1311:25-1312:5, Dec. 15, 2009).

C. The Formulary Process Would Not Drive Price Competition Between NeoProfen and Indocin

316. Plaintiffs' expert, Dr. Stephen Schondelmeyer, opined that, if NeoProfen and Indocin were independently owned, hospital P&T committees would have been able to use the formulary system to promote price competition between Indocin and NeoProfen. (Schondelmeyer Trial Tr. 887:2-888:3, Dec. 11, 2009).

317. As Plaintiffs' expert, Dr. Schondelmeyer, testified, the key requirement for a hospital to be able to negotiate discounts with pharmaceutical companies using the formulary process is that the drugs have to first have an acceptable level of safety and appropriate level of effectiveness. (Carrejo Trial Tr. 308:19-309:8, Dec. 8, 2009; Schondelmeyer Trial Tr. 911:1-16, Dec. 11, 2009). Dr. Schondelmeyer's opinion that hospitals would have been able to use the formulary process to promote price competition

thus hinges on a finding that a sufficient percentage of neonatologists believe that the drugs have an equally acceptable level of safety and effectiveness.

318. Dr. Schondelmeyer admitted that he has no knowledge regarding how actual P&T committees evaluated NeoProfen and Indocin's effectiveness, safety, or total costs of treatment. (Schondelmeyer Trial Tr. 977:5-978:5, Dec. 11, 2009). He did not examine the deliberations of actual P&T committees. (Schondelmeyer Trial Tr. 947:2-6, Dec. 11, 2009).

319. Nor did Dr. Schondelmeyer attempt to replicate the analysis that a P&T Committee would do in evaluating Indocin and NeoProfen. (Schondelmeyer Trial Tr. 944:21-945:6, Dec. 11, 2009). He did not do a therapeutic comparison of Indocin and NeoProfen. (Schondelmeyer Trial Tr. 944:21-24, Dec. 11, 2009). He did not speak to any neonatologists in forming his opinion. (Schondelmeyer Trial Tr. 932:8-12, Dec. 11, 2009).

320. Dr. Schondelmeyer himself did not offer an opinion that NeoProfen and Indocin are therapeutically interchangeable. (Schondelmeyer Trial Tr. 952:11-19, Dec. 11, 2009). He instead relied on Dr. Gerdes's report and opinion in assuming that NeoProfen and Indocin are "therapeutically interchangeable", meaning that they are therapeutically similar and can be used to treat the same condition. (Schondelmeyer Trial Tr. 935:10-24, Dec. 11, 2009). While one expert may rely on another expert's opinion under Rule 702, at least one of the two experts must offer an objective analysis to confirm the underlying point. As explained above, Dr. Gerdes's opinion that NeoProfen and Indocin are "clinically interchangeable" because they are "similar enough" in both

safety and efficacy that a well-informed, rational physician could choose either drug and be well within the standard of care was not persuasive. Dr. Schondelmeyer's opinion is further undermined by his own failure to take into account (1) the undisputed record of neonatologists who have any personal experience with both NeoProfen and Indocin (which Dr. Gerdes does not) and (2) Dr. Gerdes's own review and understanding of the medical literature, which both show that there were in fact sufficient differences in the side effect profiles of the two drugs to motivate neonatologists to adjust their treatment protocols depending on which drug is used. Dr. Schondelmeyer himself testified that Indocin and NeoProfen have different safety profiles. (Schondelmeyer Trial Tr. 950:14-16, Dec. 11, 2009).

321. Dr. Schondelmeyer also assumed Indocin and NeoProfen were economic substitutes. (Schondelmeyer Trial Tr. 939:24-940:3, Dec. 11, 2009). Dr. Schondelmeyer did not analyze what price difference would move market share between the drugs. (Schondelmeyer Trial Tr. 960:18-22, Dec. 11, 2009). Dr. Schondelmeyer did not do any economic modeling or analyze economic substitutability or the relevant market in forming his opinion. (Schondelmeyer Trial Tr. 937:13-938:8, Dec. 11, 2009). Dr. Schondelmeyer did not analyze neonatal drugs in forming his opinion. (Schondelmeyer Trial Tr. 931:7-932:7, Dec. 11, 2009). Dr. Schondelmeyer did not analyze benchmark or comparison drug prices. (Schondelmeyer Trial Tr. 932:16-20, Dec. 11, 2009).

322. Dr. Schondelmeyer based his assumption of economic substitutability on Dr. Arnold's opinion. (Schondelmeyer Trial Tr. 939:24-940:20, 941:5-7, Dec. 11, 2009).

But Dr. Arnold did not offer any proof at trial that the drugs were economic substitutes and, in fact, confirmed that he did not consider or analyze the type of consumer demand evidence needed to determine whether Indocin and NeoProfen exhibit high or low cross-price elasticity of demand, which Dr. Arnold admits is necessary to determine whether two products are economic substitutes. (Arnold Trial Tr. 1063:23-1064:9, 1068:16-20, 1070:15-19, Dec. 11, 2009). Rather, Dr. Arnold testified that the drugs were functional substitutes, based only on non-economic evidence, and explained that functional substitutability and economic substitutability are not the same. (Arnold Trial Tr. 1072:24-1073:6, 1073:12-18, 1074:9-20, Dec. 11, 2009). And Dr. McCarthy agreed that functional substitutes are not the same as economic substitutes. (McCarthy Trial Tr. 1295:8-1296:1, 1314:1-17, 1315:7-24, 1318:10-23, Dec. 15, 2009). Thus, Dr. Schondelmeyer cannot rely on Dr. Arnold for the proposition that Indocin and NeoProfen were economic substitutes, meaning Dr. Schondelmeyer has no basis to assume neonatologists are indifferent between these drugs, much less indifferent to the point that price is the deciding factor.

323. Indocin and NeoProfen are not likely candidates for therapeutic interchange because they are used on fragile neonates in high-risk situations, and because of the low volume of the drugs, which constitute an insignificant portion of a hospital's total pharmacy budget. (Carrejo Trial Tr. 349:19-25, Dec. 8, 2009; DX 191 at 8-9). Moreover, P&T committees do not consider Indocin and NeoProfen to be therapeutically interchangeable because of their different side effect profiles. (Hay Trial Tr. 1199:6-23, Dec. 14, 2009). *See also* Findings of Fact Nos. 275-284, 290, *supra*.

324. Dr. Schondelmeyer's opinion ignores substantial evidence in the record that contradicts his and Dr. Gerdes's assumptions. Even a hospital that professes to be very cost conscious (Los Angeles County) does not apply its therapeutic interchange policies to any pediatric drug, let alone to Indocin and NeoProfen specifically. (Gutierrez Trial Tr. 854:21-855:9, Dec. 10, 2009). In fact, there is no evidence that any hospital has a therapeutic interchange policy that permits a hospital to substitute any NICU only or pediatric drug, let alone Indocin for NeoProfen or vice versa. *See* Findings of Fact Nos. 314-315, *supra.*

325. Dr. Schondelmeyer admitted that he did not do any analysis to determine whether any of the formulary tools that hospitals generally may use to reduce costs are applicable to Indocin or NeoProfen. (Schondelmeyer Trial Tr. 969:5-15, Dec. 11, 2009). Nor did he look for any specific examples of other neonatal orphan drugs where the type of price competition he describes has been spurred by the formulary. (Schondelmeyer Trial Tr. 969:25-970:7, Dec. 11, 2009). In fact, Dr. Schondelmeyer testified that *nothing* in his opinion relied upon the assumption that NeoProfen and Indocin are economic substitutes and in the same economic market. (Schondelmeyer Trial Tr. 934:13-15; 939:19-23, Dec. 11, 2009). Therefore, Dr. Schondelmeyer's opinion that hospital P&T committees would have been able to use the formulary system to promote price competition between two independent owners of Indocin and NeoProfen, *whether or not they are economic substitutes,* is unreliable and unpersuasive.

X. GROUP PURCHASING ORGANIZATIONS

326. Many but not all hospitals are members of GPOs and independent delivery networks. (Stip. Fact 133).

327. GPOs enable their member hospitals to aggregate purchase orders, for purposes of securing volume discounts and improving their leverage when negotiating rates and services with pharmaceutical companies. (Russell Dep. 18:13-18). Once the GPO has secured a price for its members, the members may or may not purchase the drug from the pharmaceutical manufacturer at the negotiated contract price. (Wilson Dep. 9:19-10:5).

328. GPOs derive income from administrative fees paid by manufacturers based on a percentage of sales revenue. (Stip. Fact 134). Accordingly, GPOs generally pursue high-volume, high-revenue drugs for contracts, and they are generally unsuccessful in obtaining contracts with small population, niche drug manufacturers. (Wilson Dep. 65:22-66:3, 68:11-15).

329. Ovation has never contracted with GPOs for any of its drug products. (Stip. Fact 135).

330. GPO representatives typically do not treat patients. (Stip. Fact 138).

331. GPO representatives typically do not serve on hospital P&T committees. (Stip. Fact 139).

332. GPO representatives typically do not directly participate in hospital P&T committee formulary decisions. (Stip. Fact 140)

333. GPOs typically do not have contacts with physicians. (Wilson Dep. 41:23-25).

334. Prior to January 2006, no GPO had ever expressed interest in contracting with Ovation for any of its drug products. (Wilson Dep. 39:12-15).

335. Pharmacy directors and pharmacy buyers (not doctors) complained to the GPOs regarding Indocin's price increase in January 2006. The price adjustment increased their 2006 budgets, and pharmacists were complaining that the price increase was a surprise they had not budgeted for. (Wilson Dep. 41:20-42:5).

336. The complaints from pharmacy directors and pharmacy buyers were directed broadly at all five Merck Bundle drugs whose prices increased on the same day. (Wilson Dep. 39:25-40:3).

337. If drugs are not therapeutically interchangeable, it is difficult for GPOs to affect price competition between them. (Russell Dep. 120:23-121:2). GPOs do not try to play drugs that are not therapeutic substitutes off of each other because to do so is unethical and ineffective. (Russell Dep. 121:3-16). GPOs do not create competition between drugs where there would otherwise be none; GPOs only aggregate the competition that hospitals create. (Schondelmeyer Trial Tr. 915:9-19, Dec. 11, 2009). Thus, if hospitals would not switch between drugs based on price, GPOs can have no effect on price. (Wilson Dep. 74:7-75:7).

XI. BUT FOR THE ACQUISITION

338. The market demand for Indocin and NeoProfen is highly inelastic. (McCarthy Trial Tr. 1307:17-21, Dec. 15, 2009; Arnold Trial Tr. 1045:19-22, Dec. 11,

2009). When market demand is inelastic, demand will not change as price changes. (McCarthy Trial Tr. 1307:22-25, Dec. 15, 2009). Lowering the price of a highly inelastic product will not increase revenue. (McCarthy Trial Tr. 1307:22-1308:13, Dec. 15, 2009). Independent owners of NeoProfen and Indocin would have no incentive to lower the price of their highly inelastic product. (McCarthy Trial Tr. 1307:17-1308:13, Dec. 15, 2009).

339. For NeoProfen and Indocin to be economic substitutes, NeoProfen would also have to be an economic substitute of generic indomethacin. (McCarthy Trial Tr. 1327:13-16, Dec. 15, 2009). If NeoProfen and generic indomethacin are economic substitutes, NeoProfen sales would be greatly eroded when generic indomethacin enters. (McCarthy Trial Tr. 1327:13-22, Dec. 15, 2009). If NeoProfen and generic indomethacin are economic substitutes, it would not make economic sense for Ovation to purchase NeoProfen for over $32 million. (McCarthy Trial Tr. 1327:23-1328:11, Dec. 15, 2009; Arnold Trial Tr. 1081:23-1082:5, Dec. 11, 2009). *See* Findings of Fact Nos. 226-231, *supra*.

340. In a but-for world, separate owners of Indocin and NeoProfen would not compete on price because there is very low, if any, cross-price elasticity between the two drugs. (McCarthy Trial Tr. 1297:20-1298:8, 1329:5-10, 1387:8-23, Dec. 15, 2009). The relevant consumers do not view the different drugs as so interchangeable or use them so interchangeably as to make them economic substitutes. (McCarthy Trial Tr. 1320:20-1321:16, 1323:6-1326:3, 1375:2-16, 1386:11-13, Dec. 15, 2009; *See* Findings of Fact Nos. 296, 299, *infra*). A price war between NeoProfen and Indocin would never start

because independent owners would gain no revenue from reducing price. (McCarthy Trial Tr. 1308:2-13, 1310:3-23, 1312:20-1313:14; 1375:21-1376:10, Dec. 15, 2009).

341. Dr. Arnold's duopoly "Game On" theory was not persuasive because NeoProfen and Indocin are not in the same antitrust product market. (McCarthy Trial Tr. 1329:5-15; 1387:8-25, Dec. 15, 2009). Dr. Arnold's "Game On" theory does not apply to products that are not in the same product market. (McCarthy Trial Tr. 1297:20-1298:8, 1310:1-23, 1329:16-1330:1, Dec. 15, 2009).

342. The price of $108.88 per three-vial course of treatment is not the but-for competitive price of either Indocin or NeoProfen, nor is it the marginal cost price of either drug. (Arnold Trial Tr. 1024:20-1025:4, 1030:7-21, 1038:16-18, Dec. 11, 2009; McCarthy Trial Tr. 1330:7-20, 1368:24-1369:13, 1370:1-1371:3, Dec. 15, 2009). If $108.88 per three-vial course of treatment is the but-for competitive price for Indocin, the Merck Bundle acquisition net present value would have been substantially negative. (McCarthy Trial Tr. 1331:9-1332:2, Dec. 15, 2009). If $108.88 per three vial course of treatment is the but-for competitive price of NeoProfen, the net present value for acquiring NeoProfen would be significantly negative. (McCarthy Trial Tr. 1331:9-1332:4, Dec. 15, 2009). It would not make economic sense for a company to acquire an asset it expected to have a negative net present value. (McCarthy Trial Tr. 1332:5-9, 1370:1-1371:3, Dec. 15, 2009).

343. Ovation's acquisition of NeoProfen did not result in Ovation gaining the ability to charge supracompetitive prices for Indocin or NeoProfen. (Arnold Trial Tr. 1045:4-11, 1046:12-16, 1050:11-19, 1091:10-20, 1092:10-20, Dec. 11, 2009; McCarthy

Trial Tr. 1292:16-1293:13, 1294:11-1295:2, 1301:4-17, 1303:12-21, 1307:8-11, Dec. 15, 2009). Ovation had every incentive to set the price of Indocin at $1,500 and maximize revenue before generic indomethacin entered. (Arnold Trial Tr. 1042:16-20, 1045:23-1046:4, Dec. 11, 2009; McCarthy Trial Tr. 1293:14-23, Dec. 15, 2009).

344. Separate ownership of NeoProfen and Indocin would be unlikely to restore any lost pricing competition between these two drugs because Indocin and NeoProfen do not compete on the basis of price. (McCarthy Trial Tr. 1297:5-9, 1297:14-1298:8, 1364:22-1365:21, Dec. 15, 2009; *see* Findings of Fact Nos. 228, 232. 338, 340).

345. Like Abbott, an independent owner of NeoProfen would have used the prevailing price of Indocin as a benchmark to price NeoProfen. (Arnold Trial Tr. 1026:11-15, 1027:4-8, 1050:11-19, 1053:10-18, Dec. 11, 2009).

346. Dr. Arnold assumes Indocin and NeoProfen are in the same antitrust market, primarily because both drugs are equally effective at treating PDA (*i.e.*, they are functional substitutes). (Arnold Trial Tr. 1072:9-1074:24, 1075:16-25, Dec. 11, 2009). Dr. Arnold further assumes a duopoly will always produce lower prices than a monopoly. (Arnold Trial Tr. 1002:7-19, Dec. 11, 2009).

347. Dr. Arnold's general assertion that prices are always lower in a duopoly contradicts real world evidence of how competition occurs in duopoly settings directly at issue in this case. The experts for both parties agree that branded drugs often hold or raise their prices in response to the first generic entrant. *See* Findings of Fact No. 80, *supra*. Likewise, both experts rely on the Lu & Comanor article, which demonstrated that new patented entrants that offer no therapeutic advantages enter at a price equal or at

a premium to the branded incumbent 49% of the time in general, and the median price of such drugs that are used in an acute care setting is 23% higher than the incumbent. (Arnold Trial Tr. 1056:5-16, Dec. 11, 2009; McCarthy Trial Tr. 1305:3-7, Dec. 15, 2009).

348. Dr. Arnold also opined on the mechanism that would drive Indocin and NeoProfen to price compete if owned by separate companies. Dr. Arnold assumed that Indocin, as the higher-priced incumbent drug, has a strong incentive to make the first move initiating price competition. He tesitified that to slow attrition to the less expensive NeoProfen, Ovation would reduce Indocin by $50 to eliminate price disparity, at which point it would be "Game On." The parties would continue trading discounts so long as it is profitable to do so, before settling in at some unknown competitive equilibrium below $1450. (Arnold Trial Tr. 1000:20-1001:19). This "Game On" theory contradicts the weight of the evidentiary record and assumes irrational actors.

349. The record provides no basis to expect that price competition would commence unless Ovation, as the first-mover, had a rational belief that a discounting strategy would increase profits, all things considered. Dr. Arnold's "Game On" theory is thus based on an implicit assumption that it would be profitable for Ovation to abandon its pre-determined strategy for dealing with generic indomethacin, its most direct and imminent competitive threat. But Dr. Arnold has not tested or analyzed whether it would be profitable for Ovation to change its strategy and discount Indocin in an effort to recapture sales from NeoProfen. Nor have Plaintiffs introduced other evidence indicating that it would be so. To the contrary, under Plaintiffs' market definition, Ovation would

rationally expect to lose any hypothetically recaptured NeoProfen sales with the entry of generic indomethacin.

350. Even if a third party acquired NeoProfen, it would not make any business sense to reduce the price of Indocin to prevent the use of NeoProfen as a substitute, because in the face of generic entry for product with a short life, it always makes the most sense to take the price up; it never makes sense to lower the price. (Burke Trial Tr. 712:15-713:10, Dec. 10, 2009; McCarthy Trial Tr. 1312:20-1313:4, Dec. 15, 2009).

XII. PROFITS AND LOSSES

351. In December of 2008, Darien Parhad, the Assistant Controller of Ovation and Certified Public Accountant, was asked by the controller of Ovation, Julie Hakim to create profit and loss statements for the drugs Indocin and NeoProfen. (Parhad Dep. 6:4-8; 28:1-5; 33:20-34:18). These profit and loss statements were created for the purpose of providing potential buyers of Ovation an estimate of Indocin's and NeoProfen's profitability. (Morris Trial Tr. 1263:25-1264:24, Dec. 14, 2009; Parhad Dep. 25:22-26:21; DX 90 at 1).

352. Ms. Hakim asked Mr. Parhad to prepare these income statements using actual results by drug, to the extent those results were available in the general ledger, and then make allocations for those costs that are not recorded by drug in the general ledger. (Parhad Dep. 34:11-18).

353. Most of the costs associated with NeoProfen did not have to be allocated and were recorded in the general ledger as NeoProfen costs since the acquisition of NeoProfen only involved one drug. (DX 90 at 1, 9). Most of the costs associated with

Indocin had to be allocated because Ovation does not record expenses associated with the Bundle drugs individually but instead accounts for them as one line item. (DX 90 at 1).

354. The NeoProfen Profit and Loss Statement was shown to potential buyers of Ovation. (Parhad Dep. 51:17-22; McCarthy Trial Tr. 1372:17-21, Dec. 15, 2009; PX 246 / DX 102). The NeoProfen Profit and Loss Statement demonstrated to potential buyers of Ovation that as of January 2009 Ovation believed NeoProfen to be at a negative loss of $25.91 million. (Morris Trial Tr. 1263:25-1265:14, Dec. 14, 2009; McCarthy Trial Tr. 1372:17-21, Dec. 15, 2009; PX 246 / DX 102). This negative $25.91 includes the remaining purchase price of $14.784 million that has yet to be amortized but already has been paid by Ovation. (Parhad Dep. 82:19-83:21; McCarthy Trial Tr. 1372:6-11, Dec. 15, 2009; PX 246 / DX 102).

355. Plaintiffs did not make any cost allocations for Indocin or NeoProfen and did not offer any analysis or opinion as to whether Indocin and NeoProfen are profitable after costs have been allocated. (Arnold Trial Tr. 1062:11-20, Dec. 11, 2009). Plaintiffs' expert Dr. Arnold could have made cost allocations but chose not to. (Arnold Trial Tr. 1062:13-17, Dec. 11, 2009).

CONCLUSIONS OF LAW

I. PLAINTIFFS' ANTITRUST CLAIMS

1. Plaintiffs have alleged monopolization claims under Section 7 of the Clayton Act, Section 2 of the Sherman Act, and Section 5 of the FTC Act (which for purposes of this case the FTC has stipulated is coextensive with Sherman Act Section 2). To establish their monopoly claims under either statute, Plaintiffs must demonstrate that Ovation possessed monopoly power in the relevant market and that Ovation "willfully acquired or maintained this monopoly power by anticompetitive conduct as opposed to gaining that power as a result 'of a superior product, business acumen, or historical accident.'" *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1060 (8th Cir. 2000) (quoting *United States v. Grinnell*, 384 U.S. 563, 570-71 (1966)). Monopoly power is the ability to control prices and exclude competition over the long-term. *Id.*

2. The antitrust laws do not condemn unilateral decisions to raise prices to profit-maximizing levels, nor do they regard "high-prices" as anticompetitive. *Verizon Commc'ns., Inc., v. Law Offices of Curtis V. Trinko, L.P.*, 540 U.S. 398, 407 (2004); *In the Matter of Evanston Nw. Healthcare Corp*, F.T.C. Docket No. 9315, 64 (Final Decision, Aug. 6, 2007) ("[P]rice increases do not by themselves establish the exercise of market power."). Instead, plaintiffs must show that Ovation's prices are supracompetitive, that is, above the competitive baseline level that the market would produce absent illegal conduct. *See, e.g., Rambus Inc. v. FTC*, 522 F.3d 456, 463-64 (D.C. Cir. 2008).

3. Because Indocin was the only FDA-approved pharmacological treatment of PDA prior to the launch of NeoProfen in July 2006, Ovation was a lawful monopolist and as such was free to price Indocin at any price the market would bear. *Verizon Commc'ns., Inc.*, 540 U.S. at 407; *see also* AREEDA & HOVENKAMP, ANTITRUST LAW, § 720a. (Pls.' Opening Statement, Trial Tr. 26:11-12, Dec. 7, 2009). Ovation's decision to re-price Indocin to $1,500 in January 2006 was made independent and regardless of the NeoProfen acquisition. Plaintiffs offer no contrary evidence, as they are required to do if disputing the lawfulness of the Indocin re-pricing. *See, e.g., In the Matter of Evanston Nw. Healthcare Corp*, F.T.C. Docket No. 9315, 64 (Final Decision, Aug. 6, 2007) ("[P]rice increases do not by themselves establish the exercise of market power.") Thus, the Indocin $1,500 price was lawful and competitive when set in January 2006 and at least up to the time of NeoProfen's launch in July 2006.

4. Ovation's decision to launch NeoProfen at a price roughly equal to the then-current price of Indocin in July 2006 is consistent with what the Plaintiffs' expert agrees should happen in a competitive market, and therefore does not reflect competitive harm. Thus, the NeoProfen $1,450 launch price was lawful and competitive when set.

5. Given that the launch prices for Indocin and NeoProfen were competitive and lawful as of NeoProfen's launch date, Plaintiffs' theory of harm is limited to an assertion that the acquisition unlawfully enabled Ovation to maintain its prices. Thus, the challenged acquisition could not cause anticompetitive effects prior to July 31, 2006. *United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 586, 598 (1957).

A. Relevant Market

6. Determination of the relevant antitrust market is essential to Plaintiffs' monopolization claims. *FTC v. Freeman Hosp.*, 69 F.3d 260, 268 (8th Cir. 1995); *Spectrum Sports v. McQuillan*, 506 U.S. 447, 457 (1993). Plaintiffs bear the burden of establishing the existence of the relevant product market. *See H.J., Inc. v. Int'l Tel. & Tel.*, 867 F.2d 1531, 1537 (8th Cir. 1989) ("The plaintiff carries the burden of describing a well-defined relevant market, both geographically and by product, which the defendants monopolized."). Because the parties do not dispute that the relevant geographic market is the United States, the focus of this analysis is on the proper contours of the relevant product market. Plaintiffs argue and have the burden of proving a relevant market for "PDA drugs" that includes both Indocin and NeoProfen and no other products.

7. For Plaintiffs to prove that Indocin and NeoProfen are in the same market, they must prove that they are "economic substitutes," not merely similar products or functional substitutes. *See United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988) (despite identical uses, sugar and high fructose corn syrup not in the same antitrust market because a small change in price of corn syrup would not affect demand for sugar); *U.S. Anchor Mfg. v. Rule Indus.*, 7 F.3d 986, 997 (11th Cir. 1993) (despite functional interchangeability, branded anchors and generic anchors not in the same market because the record provided "no basis other than guesswork" for concluding that a price increase would cause buyers to switch from one to the other).

8. Definition of the relevant market is a matter of careful economic analysis. The boundaries of a relevant market "must be drawn narrowly to exclude any other

product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross-elasticities of demand' are small." *Times-Picayune Publ'g Co. v. United States,* 345 U.S. 594, 613 n.31 (1953).

9. In defining the relevant antitrust market, Plaintiffs are required to conduct economic analysis of Indocin and NeoProfen's cross-price elasticity of demand. *Int'l Tel. & Tel.*, 867 F.2d at 1538 ("Critical to the determination whether certain products move in the same market is their cross-elasticity of demand."); *United States v. Empire Gas Corp.*, 537 F.2d 296, 303 (8th Cir. 1976); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988); *Worldwide Basketball & Sport Tours v. NCAA*, 388 F.3d 955, 962 (6th Cir. 2004), cert. denied, 126 S. Ct. 334 (2005).

10. Plaintiffs have failed to prove that Indocin and NeoProfen are sufficient economic substitutes that they belong in the same relevant antitrust market. The overwhelming weight of evidence establishes that neonatologists are the relevant customers who drive demand for Indocin and NeoProfen, and that they do not view the drugs as so interchangeable in use that small (or even large) differences in price will cause substantial substitution to the cheaper drug. *See SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978) (narrowing the relevant market to a single antibiotic because "prescribing physicians are not cost conscious in their choices of an antibiotic for a hospitalized patient, and so do not opt for a less expensive over a more costly medication").

11. Plaintiffs have failed to establish that the cross-price elasticity of demand for Indocin and NeoProfen is sufficiently high to expect these drugs to compete on price.

See Archer-Daniels-Midland Co., 866 F.2d at 248. While Plaintiffs performed no analysis of cross-price elasticity of demand, the record demonstrates that the cross-price elasticity between Indocin and NeoProfen is very low, because doctors choose between these drugs based on perceived differences in the drugs' clinical attributes, such as safety, efficacy, track-record, but never price. Plaintiffs have produced no evidence of doctors who are indifferent between these drugs, much less doctors who are indifferent to the point that small differences in price are the deciding factor. Thus, there is no reason to believe it is rational or profit-maximizing for separate owners of Indocin and NeoProfen to compete on price, meaning the drugs do not competitively constrain one another and occupy separate antitrust markets. *Archer-Daniels-Midland Co.*, 866 F.2d at 246; *SmithKline*, 575 F.2d at 1064; *In re Biovail Corp.*, 134 F.T.C. 407, at ¶ 19 (F.T.C. Oct. 2002).

12. Having failed to prove that Indocin and NeoProfen are economic substitutes in the same relevant market, Plaintiffs' monopolization claims necessarily fail. If NeoProfen is not in the same market as Indocin, then by definition the acquisition of NeoProfen did not unlawfully create or maintain any monopoly power, increase concentration in any market, or give Ovation any pricing power it did not already possess.

B. Illegal Market Power

13. Plaintiffs must prove that the NeoProfen acquisition enhanced Ovation's market power – which is to say, it gave Ovation market power it would not otherwise have had – in a relevant market containing both Indocin and NeoProfen. *Verizon*

Commc'ns., Inc., 540 U.S. at 407. Price increases alone do not establish the illegal exercise of market power. *In the Matter of Evanston Nw. Healthcare Corp.*, F.T.C. Docket No. 9315, 64 (Final Decision, Aug. 6, 2007). Market power means the ability to raise prices above competitive levels for a prolonged period without threat of losing sales. *See Verizon Commc'ns, Inc.*, 540 U.S. at 407.

14. Plaintiffs' failure to prove that NeoProfen and Indocin are in the same relevant market is dispositive. Because Indocin and NeoProfen are in separate antitrust markets, the acquisition was incapable of enhancing concentration or market power within any antitrust market.

15. Even if NeoProfen and Indocin are assumed to be in the same market, their cross-price elasticity of demand is too low to make price competition profitable or likely, meaning that the loss of such competition is competitively insignificant and incapable of enhancing Ovation's market power within a relevant market.

16. Similarly, if Indocin and NeoProfen are assumed to be in the same market, any enhancement in market power is not durable, and therefore not anticompetitive, because the market is capable of producing a meaningful competitive response in a timely manner. There can be no antitrust violation if monopoly prices cannot be sustained for a prolonged period. *Nat'l Reporting Co. v. Alderson Reporting Co.*, 763 F.2d 1020, 1024 (8th Cir. 1985).

17. As discussed above, Plaintiffs bear the burden of proving that any alleged increase in market power is sustainable. To establish durable market power, Section 2 Plaintiffs must prove that the market cannot self-correct because competitive entry is

gated by high structural barriers to entry. *See, e.g., W. Parcel Express v. UPS*, 190 F.3d 974, 975 (9th Cir. 1999) (with an allegedly "dominant share," could not possess monopoly power because there were no significant "barriers to entry"); *Lansdale v. Phila. Elec. Co.*, 692 F.2d 307, 313-14 (3d Cir. 1982) (finding no barrier to entry where city could have constructed its own power transmission line in 14-16 months in response to allegedly anticompetitive acts of power company). Similarly, if a Section 7 defendant makes a sufficient threshold showing of no substantial entry barriers, Plaintiffs are required to prove that market power is durable and likely to have an anticompetitive effect. *United States v. Baker Hughes*, 908 F.2d 981, 983 (D.C. Cir. 1990).

18. Entry is sufficient and timely if the market is capable of remedying Ovation's ability to maintain monopoly prices by producing a meaningful generic competitor within at least two years of NeoProfen's launch (that is, by approximately August 2008). The evidence does not establish that Ovation ever had durable market power, however the relevant market is defined, because the entry of generic indomethacin was expected shortly after the increase in the price of Indocin and is anticipated imminently. Entry of generic indomethacin was always expected to occur before July 31, 2008, and in fact, Bedford received FDA approval to enter before that date.

19. All intellectual property and market exclusivity protection for Indocin expired decades ago. Thus, at all relevant times there have been no significant barriers to the entry of generic indomethacin. Also, Ovation has not engaged in conduct that deterred, delayed, or hindered the competitive entry process.

20. Plaintiffs have suggested that the need for regulatory approval of a generic competitor constitutes a barrier to entry. That is incorrect. The FDA's regulatory approval process for generic drugs is not a barrier to entry. *See, e.g., Barr Labs., Inc. v. Abbott Labs.*, Inc., 978 F.2d 98, 113-14 (3d Cir. 1992) (six-month to two-year waiting period to enter a pharmaceutical market is not a significant entry barrier). Entry barriers are "particular characteristics of a market which impede entry by new firms." *Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, 899 F.2d 951, 968 (10th Cir. 1990).

21. Plaintiffs also point to the fact that Bedford has not yet actually entered with its proposed generic indomethacin, as support for the notion that the requisite structural barriers to entry exist in this market. But Bedford was able to obtain regulatory approval, despite apparent errors in its application process and temporary "unapprovable" status with the FDA, and additional delays caused by business decisions and judgments rather than market conditions. A potential entrant's lack of skill and business judgment are not structural barriers to entry. *See* MERGER GUIDELINES § 3.0; *Advo, Inc. v. Phila. Newspapers, Inc.*, 854 F. Supp. 367, 375 (E.D. Pa. 1994) ("competence is a prerequisite to enter any business, not a special or significant entry barrier to this one"); *Reazin*, 899 F.2d at 968.

22. Easy entry is a complete defense to a Section 7 challenge.

23. Entry of generic indomethacin is, and always was, expected to be sufficient to deplete Ovation of any market power attributable to Indocin. Generic indomethacin is expected to devastate Indocin sales immediately after its entry, while also proving the market with a low-cost alternative and enhanced price competition.

24. Entry of generic indomethacin is, and always was, likely and capable of occurring in sufficient time and magnitude to defeat the exercise of market power in any relevant market containing Indocin.

25. Entry of generic indomethacin would be sufficient to create competition in any hypothetical "PDA drugs" market and restore any lost pricing competition that may have resulted from Ovation's acquisition of NeoProfen. Here, one is to assume Indocin and NeoProfen are priced at monopoly levels and equally vulnerable to generic entry, such that generic indomethacin would quickly take virtually all sales from both drugs. With this economic incentive to motivate entry, the relevant inquiry is whether the market is capable of producing a generic competitor within two-years of NeoProfen's commercial launch.

26. Assuming that Plaintiffs are correct and Indocin and NeoProfen are economic substitutes in the same relevant product market (which they are not), then entry of generic indomethacin will also decimate NeoProfen sales and divest Ovation of any market power it may otherwise have in any relevant market containing Indocin or NeoProfen.

C. Causation of Competitive Harm

27. To prevail on their claims, Plaintiffs must prove an additional essential element, that acquiring NeoProfen enabled Ovation to maintain prices above competitive levels by eliminating a meaningful constraint on Indocin's pricing. *Verizon Commc'ns, Inc.*, 540 U.S. at 407. Absent proof that the acquisition eliminated price competition that otherwise would have forced lower prices, there is no competitive harm. *See, e.g.*,

Rambus Inc., 522 F.3d at 463-64 (dismissing FTC's complaint for failure to prove prices would have been lower absent the allegedly illegal conduct, even assuming it occurred).

28. The evidence does not establish that Indocin and NeoProfen were likely to price compete if the drugs were owned by separate companies. Plaintiffs' failure to establish high cross-price elasticity of demand between Indocin and NeoProfen leaves no basis to believe that discounting Indocin would be a likely or profitable strategy.

29. Additionally, even if Plaintiffs had produced evidence of high cross-price elasticity, they still produced no evidence to support the conclusion that the incentive to price compete with NeoProfen would change Ovation's pre-existing strategy to hold its price in anticipation of generic entry. Plaintiffs failed to produce any evidence or reliable expert analysis that, in the but-for world, NeoProfen posed a greater threat to Indocin than the expected entry of generic indomethacin. The record reveals that Ovation was committed to holding or raising Indocin's price in anticipation of generic entry, which it viewed to be the profit maximizing strategy for Indocin. There is no basis, and in fact it is unreasonable, to believe Ovation would find it rational to price compete with NeoProfen (an imperfect substitute with low cross-price elasticity), contrary to its established plan to hold price against a generic indomethacin (a perfect substitute expected to take all sales). Because generic indomethacin represents the dominant competitive constraint to Indocin, there is no basis to believe NeoProfen could cause Ovation to compromise its profit-maximizing strategy for Indocin.

30. Ovation's acquisition of NeoProfen did not have the effect of substantially lessening competition or tend to create a monopoly.

31. Ovation's acquisition of NeoProfen did not exclude meaningful competition, and therefore, did not enhance or maintain monopoly power.

D. Divestiture

32. Divestiture is inappropriate unless needed to restore a competitive market structure that natural market forces will not otherwise cure. *See Ford Motor Co. v. United States*, 405 U.S. 562, 573, 577 (1972); *United States v. Microsoft*, 253 F.3d 34, 79, 80, 103, 105 (D.C. Cir. 2001) ("[D]ivestiture is a remedy that is imposed only with great caution, in part because its long-term efficacy is rarely certain."). Divestiture is not a punitive remedy, and should only be ordered to engineer ideal conditions. *See Ford Motor Co.*, 405 U.S. at 573, 577; *Schine Chain Theatres, Inc. v. United* States, 334 U.S. 110, 128 (1948). To obtain divestiture, Plaintiffs must prove that the acquisition caused competitive harm, which continues to this day, and cannot be remedied without structural relief.

33. Plaintiffs' failure to prove the NeoProfen acquisition actually caused competitive harm precludes the Court from ordering divestiture. Likewise, Plaintiffs have failed to prove that separate ownership of NeoProfen and Indocin would facilitate aggressive price competition that was previously lost. Finally, imminent entry of generic indomethacin also militates against divestiture. Assuming Plaintiffs' definition of the relevant market is correct, entry by generic indomethacin will restore any lost pricing competition, deplete Ovation of any market power it may otherwise have in Indocin and, by definition, in NeoProfen as well (since Plaintiffs' market definition says the two drugs are economic substitutes). Thus, a divestiture remedy is unwarranted.

E. Unjust Enrichment

34. Plaintiffs are not entitled to recover for unjust enrichment because Ovation's acquisition of NeoProfen was not unconscionable or immoral, and did not violate § 7 of the Clayton Act, § 5 of the Federal Trade Commission Act, § 2 of the Sherman Act, and/or the Minnesota Antitrust Law of 1971.

35. Ovation did not unjustly benefit from the acquisition of NeoProfen.

36. It is not inequitable that Ovation keeps the benefit received from the acquisition of NeoProfen.

F. Disgorgement

37. Disgorgement of profits is not a punitive remedy and is limited to illegal gains causally related to the violation. *SEC v. First City Fin. Corp.*, 890 F.2d 1215, 1231 (D.C. Cir. 1989); *Rowe v. Maremont Corp.*, 850 F.2d 1226, 1241 (7th Cir. 1988). The calculation of ill-gotten profits must be a reasonable approximation; Plaintiffs cannot speculate. *First City Fin. Corp.*, 890 F.2d at 1231.

38. Because Plaintiffs have failed to identify a realistic competitive baseline, they have presented a measure of disgorgement that is incapable of distinguishing between gains that were lawful and unlawful (*i.e.*, causally related to the violation). Likewise, because Plaintiffs failed to analyze Ovation's costs, they have presented a measure of disgorgement that is incapable of distinguishing between profits and revenues. As such, Plaintiffs failed to satisfy their burden to provide a reasonable estimate of Ovation's ill-gotten profits, so Plaintiffs are not entitled to a disgorgement remedy.

39. A disgorgement remedy is available only where the underlying antitrust violation was objectively clear *ex ante*. *FTC's Policy Statement on Monetary Equitable Relief in Competition Cases*, 68 Fed. Reg. 45,820 at 45,822 n.10-11 (Aug. 4, 2003) (explaining the settlements in *Hearst* and *Mylan*, which allowed disgorgement: "there was general agreement that the conduct at issue was egregious" [*Hearst*], and "the Commissioners all characterized the conduct alleged as 'egregious', with one Commissioner observing that the facts alleged described 'a clear cut antitrust violation.'" [*Mylan*]); *Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony and Mozelle W. Thompson in FTC v. Mylan Laboratories, Inc.*, et al., File No. X990015 ("[T]he Commission should cautiously exercise its prosecutorial discretion to seek disgorgement in antitrust cases. Such relief is best reserved for cases, like this one, in which the defendants have engaged in particularly egregious conduct.").

40. Plaintiffs are not entitled to disgorgement as a remedy because, at the time Ovation acquired the contingent rights to NeoProfen (then an unapproved drug), the transaction was not a clear and obvious violation of § 7 of the Clayton Act, § 5 of the Federal Trade Commission Act, § 2 of the Sherman Act, and/or the Minnesota Antitrust Law of 1971, and Ovation had legitimate business reasons to acquire NeoProfen, unrelated to its ownership of Indocin.

41. Plaintiffs are not entitled to an equitable remedy of disgorgement because the FTC, by so rarely seeking disgorgement in the past and now attempting to enforce a new expansive interpretation of its authority that disregards the standards of its policy

guidelines, failed to provide fair notice to Ovation that its conduct could subject it to such severe punishment. *BMW of N. Am. v. Gore*, 517 U.S. 559, 574, 586 (1996).

42. Plaintiffs are not entitled to a disgorgement remedy where there is no reasonable basis for calculating the amount of unlawful gains derived from the violation.

43. Plaintiffs are not entitled to an equitable remedy of disgorgement or restitution because the prospect of monetary damages from private plaintiffs is likely to redress the alleged harms and/or lead to double recovery. *FTC v. Mylan Labs*, 62 F. Supp. 2d 25, 48-49 (D.D.C. 1999) ("[B]ecause *Minn. Stat. § 325D.57* states that Minnesota should 'take any steps necessary to avoid duplicative recovery,' the State may not seek restitution and disgorgement.").

44. The State of Minnesota does not have authority to pursue a disgorgement or restitution remedy. *Mylan Labs*, 62 F. Supp. 2d at 48-49 ("[T]he Minnesota Antitrust Law does not expressly authorize [disgorgement]. . . . and Minnesota is guided by federal antitrust law [which does not allow disgorgement or restitution under § 7 of the Clayton Act].").

G. Monetary Damages

45. The Federal Trade Commission is not entitled to any monetary damages.

46. The State of Minnesota is not entitled to any damages.

47. Lundbeck is not obligated to pay any of Plaintiffs' costs.

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Respectfully submitted,

s/Alfred C. Pfeiffer, Jr.

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