IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

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

POST-TRIAL BRIEF OF PLAINTIFFS
FEDERAL TRADE COMMISSION AND STATE OF MINNESOTA

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I. Introduction and Overview

The core of this case remains straightforward amid the voluminous record created at trial in December 2009. Indocin IV and NeoProfen are close substitutes for the treatment of patent ductus arteriosus ("PDA").[1] They would be competing today for hospital dollars on the basis of price had defendant Lundbeck Inc. (then called Ovation Pharmaceuticals, Inc.) not secured the rights to NeoProfen before that drug was approved in 2006.[2] In antitrust terms, the two drugs are in the same geographic and product market.[3] They are also the *only* products in that market.[4] The absence of competition benefits Lundbeck and harms consumers.[5]

These facts compel the conclusions that Lundbeck is liable for the violations alleged by the Federal Trade Commission ("FTC") and the State of Minnesota, and that the harm arising from the illegal NeoProfen acquisition, including the monopoly profits that Lundbeck has reaped by dramatically raising the price of PDA drug treatments, must be remedied.[6]

Defining the relevant market is often (though not always) crucial in antitrust cases. On this trial record, in light of Lundbeck's limited defenses and the stipulated or otherwise undisputed facts, market definition is *dispositive* of Lundbeck's liability. That

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[1] Plaintiffs' Proposed Findings of Fact ("PPFF") § VI.A.
[2] PPFF § 6.C. Lundbeck is the successor to Ovation Pharmaceuticals, Inc., which existed until February 2009, when it was acquired by H. Lundbeck A/S, a Danish pharmaceutical company. PPFF ¶ 2.3.
[3] PPFF ¶¶ 6.1, 6.2; *see also* PPFF § VI.
[4] PPFF ¶ 6.3.
[5] PPFF §§ VI.C.4, VII.
[6] *See generally* Plaintiffs' Proposed Conclusions of Law ("PPCL").

Indocin IV and NeoProfen would compete on price if independently owned necessarily means that Lundbeck monopolized the market for PDA drugs in 2006 and suppressed the competition that hospitals would otherwise have taken advantage of after NeoProfen's launch. All of the elements of liability — an anticompetitive acquisition, durable monopoly power, and consumer harm — unquestionably exist on this record once the market is correctly defined.[7]

In this post-trial brief, plaintiffs respectfully presume the Court's familiarity with the background and narrative facts, which are, in any event, detailed in our proposed findings of fact. We focus instead on the elements of liability and the grounds for remedies established at trial.

Section II of the brief sets out the elements of plaintiffs' claims. We establish there, in particular, that a monopolist that makes an acquisition that cuts off imminent entry into its monopoly market is presumed to violate the antitrust laws, subject to very limited defenses that Lundbeck has not raised.

Sections III and IV demonstrate that by acquiring the rights to NeoProfen, Lundbeck (which then held a monopoly by virtue of owning the rights to Indocin IV) illegally monopolized the market for PDA drugs and has harmed consumers by depriving hospitals of the opportunity to negotiate for lower prices based on the ability of their pharmacy and therapeutics ("P&T") committees to promote substitution between the

[7] PPFF § VII. Lundbeck raised no affirmative defenses.

drugs. The trial record reflects that the ingredients of a competitive market are in place except for the absence of another supplier.

Hospitals, the "customers" for PDA drugs, are sophisticated and price sensitive. Physicians could be persuaded to substitute between PDA drugs in the interest of cost savings. And the drug formulary system provides hospitals a reliable means of "shifting share" between substitutable drugs in order to stimulate competition between independent suppliers.[8] Lundbeck's contention that it would not make sense *under any circumstances* for competing suppliers to reduce the prices of PDA drugs in order to gain market share lacks evidentiary support.

Lundbeck is liable for violating the antitrust laws because its acquisition of NeoProfen was exclusionary conduct that has had the anticompetitive effect of precluding competition that would otherwise have occurred. Lundbeck cannot escape liability simply because its illegal conduct made it impossible to reconstruct the but-for world or to specify exactly what PDA drugs would cost today if there were no monopoly.

Finally, in section V, we address the appropriate remedies for the illegal acquisition. We show that to establish competition in the market for PDA drugs and rectify the consequences of Lundbeck's conduct, the Court should order Lundbeck to divest the rights to NeoProfen, through a divestiture trustee, and to disgorge the profits resulting from the violation. The disgorged funds should be placed in escrow for

[8] PPFF § VI.C.2.

distribution by the FTC and Minnesota to hospitals that purchased PDA drugs during the relevant period.

The trial record indicates that the ill-gotten gains to be disgorged exceed $105 million. The method of calculation that generates this figure is proposed by plaintiffs' economics and accounting expert, Dr. Jonathan Arnold, calls for the disgorgement of the difference between (1) Lundbeck's revenues on sales of Indocin IV and NeoProfen and (2) the revenues that Lundbeck would have earned on sales of the two drugs at the last observed market price of Indocin IV before the illegal acquisition. The resulting amount is $105 million for February 2006 to April 2009. Because Lundbeck continues to earn illegal profits even now, the final disgorgement amount should be calculated to include revenues earned until the divestiture of NeoProfen. This is a reasonable estimate, although any estimate is imperfect. Defendant's illegal conduct, preventing competition, makes it impossible to be more precise in determining the ill-gotten gains. The Court should not risk underestimating Lundbeck's ill-gotten gains because of uncertainty that Lundbeck caused.

The only other method of calculation supported by the record establishes the smallest possible appropriate disgorgement amount. This alternative method bases disgorgement on: (1) all of Lundbeck's profits on NeoProfen (the illegally acquired asset), including any profits realized from the divestiture sale, plus (2) its illegal profits on Indocin IV. The illegal Indocin IV profits may be calculated using as a benchmark for the competitive price the lowest monopoly price ($1,140 per course of treatment) that

Lundbeck projected in its contemporaneous business documents. As discussed in section V, under this approach, the illegal profits on Indocin IV are $14.53 million through 2008, and assuming that revenues in 2009 were similar to those in 2008, would amount to approximately $20 million through 2009. As noted above the final disgorgement amount should also include all of the profits from NeoProfen, an amount which would be finally determined after the divestiture. Although this alternative method meets the legal standard as a reasonable estimate, it actually underestimates the disgorgement amount, because Lundbeck has inflated its costs for NeoProfen (making its profits appear lower), and because the competitive benchmark price is conservative, decreasing the disgorgement figure for Indocin IV.

II. Elements of the Tried Claims: A Monopolist's Acquisition of an Imminent Entrant Faces a Nearly Irrebuttable Presumption of Illegality

The FTC and Minnesota challenge Lundbeck's acquisition of rights to NeoProfen under section 7 of the Clayton Act, 15 U.S.C. § 18, which forbids any merger or acquisition "where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be to substantially lessen competition or to tend to create a monopoly." Plaintiffs also allege that the acquisition constituted monopolization under section 2 of the Sherman Act, 15 U.S.C. § 2, and/or the section 2 standard as incorporated in other laws.[9] As Lundbeck now owns the only two

[9] Minnesota alleges a section 2 violation and unjust enrichment due to monopolization. The FTC alleges monopolization under section 5 of the FTC Act, 15 U.S.C. § 45, which prohibits, among other things, conduct barred by the Sherman Act. *See FTC v. Cement Inst.*, 333 U.S. 683, 694 (1948).

products that are candidates for inclusion in the relevant market for PDA drugs, the Clayton Act and monopolization claims merge and rest on the same facts. *See Gulf States Reorg. Group, Inc. v. Nucor Corp.*, 466 F.3d 961, 966 n.1 (11th Cir. 2006) (stating that "merger to monopoly" may be challenged under section 7 and/or section 2).

Moreover, since Lundbeck raised no affirmative defenses, its liability follows essentially as a matter of law from plaintiffs' demonstration at trial (summarized in section III below) that Indocin IV and NeoProfen are in the same market. An acquisition by a monopolist (which Lundbeck became upon acquiring Indocin IV) that forecloses imminent entry into its monopoly market "bears a very strong presumption of illegality that should rarely be defeated." Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶¶ 701d, 912 (3d ed. 2006). And Lundbeck raised no defenses that could defeat that presumption here.

The elements of a Clayton Act violation and monopolization are all present when a monopolist preserves its monopoly by means of an acquisition. Under section 7 of the Clayton Act, plaintiffs must show that the NeoProfen acquisition has reduced competition and aided the exercise of market power — the ability to maintain prices above the competitive level — in a relevant market. *See United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 362-63 (1963); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 246 (8th Cir. 1988). A transaction that creates or further concentrates a highly concentrated market is *prima facie* unlawful. *See United States v. General Dynamics Corp.*, 415 U.S. 486, 496-97 (1974); *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 714-15 (D.C.

Cir. 2001). This presumption of illegality can, in theory, be rebutted by showing that the market concentration is misleading (*e.g.*, due to low barriers to entry) and does not threaten harm to competition. *See General Dynamics*, 415 U.S. at 497-98; *Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 428 (5th Cir. 2008) (entry must be "timely, likely and sufficient" to constrain prices (quoting U.S. Department of Justice & FTC, Horizontal Merger Guidelines § 3.0 (1992)).[10]

A transaction resulting in a *literal monopoly*, however, is virtually always anticompetitive and essentially always illegal. *See United States v. El Paso Natural Gas Co.*, 376 U.S. 651, 660-62 (1964); *United States v. Franklin Elec. Co.*, 130 F. Supp. 2d 1025, 1035 (W.D. Wis. 2000) ("[A] merger to monopoly . . . by definition will have an anticompetitive effect[.]"); *cf.* Merger Guidelines § 1.0 (describing "hypothetical monopolist" test for coordinated market power). The rare exceptions are cases where, unlike here, a "failing" competitor (which would exit the market regardless) is being acquired, or entry is so easy that the monopolist could not profitably raise prices for *any* significant length of time. *See Franklin Elec.*, 130 F. Supp. at 1035-36; *United States*

[10] Some courts (not including the Supreme Court or the Court of Appeals for the Eighth Circuit) have held that defendants can rebut a *prima facie* section 7 case by showing that procompetitive effects of a transaction, such as "efficiencies" that will be passed on to consumers in lower prices, outweigh its anticompetitive effects. *See FTC v. University Health*, 938 F.2d 1206, 1223 (11th Cir. 1991) (weighing but rejecting defense). *But see FTC v. Procter & Gamble Co.*, 386 U.S. 568, 597-98 (1967) (questioning availability of defense). Lundbeck, however, made no such claims and presented no such evidence at trial. In any event, courts have consistently rejected this defense where there was very high concentration. *See, e.g., Heinz*, 246 F.3d at 720; *United States v. United Tote, Inc.*, 768 F. Supp. 1064, 1084-85 (D. Del. 1991); *see also* Merger Guidelines § 4.0 (efficiencies "almost never" justify merger to monopoly).

v. Maryland and Va. Milk Producers Ass'n, 167 F. Supp. 799 (D.D.C. 1958) (finding merger to near-monopoly anticompetitive, despite no evidence of price effect, but ruling for defendant on failing company defense), *aff'd in part and rev'd in part on other grounds*, 362 U.S. 458 (1960); *see also* Areeda ¶ 911b ("Even relatively easy entry should not ordinarily be a defense to a merger creating a monopolist or dominant firm.").

The Supreme Court held the protection of a monopolist from pending entry to be an anticompetitive effect, in and of itself, in, *El Paso Natural Gas*. *See* 376 U.S. at 661-62; *see also* Areeda ¶ 701d (endorsing this holding). *El Paso* concerned the merger of two interstate natural gas companies. The acquirer was the only supplier of wholesale natural gas to Southern California. The other firm had no pipeline into that region and had made no sales there, but was trying to enter the market. 376 U.S. at 654-55. Reversing the district court's judgment approving the merger, the Court ruled that although "[n]o one knows what success [the acquired firm] would have had" as a competitor, the merger had an "anticompetitive effect" barred by the Clayton Act because it denied buyers "a choice" of suppliers. *Id*. at 660-62; *see also FTC v. Consolidated Foods Corp*., 380 U.S. 592, 598 (1965) ("[O]nce the two companies are united no one knows what the[ir] fate . . . would have been but for the merger."); *Yamaha Motor Co. v. FTC*, 657 F.2d 971, 977 n.7 (8th Cir. 1981) (posing Clayton Act section 7 issue as whether "there would probably have been more competition without the [transaction] than with it").

Likewise, a monopolist that acquires a firm or product that is about to enter its monopoly market is almost inevitably guilty of monopolization. The elements of that offense are (1) willful acquisition or maintenance of monopoly power (2) by exclusionary conduct. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp*., 472 U.S. 585, 595-96, 600-01 (1985); *Concord Boat Corp. v. Brunswick Corp*., 207 F.3d 1039, 1060 (8th Cir. 2000).[11] "Exclusionary" is synonymous with "anticompetitive" and refers to acts that "harm the competitive *process* and thereby harm consumers." *United States v. Microsoft Corp*., 253 F.3d 34, 58 (D.C. Cir. 2001) (emphasis in original); *see also Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) ("The law directs itself . . . against conduct which unfairly tends to destroy competition itself.").

An acquisition by a monopolist that cuts off entry into the relevant market is patently exclusionary because it stops the competitive process in its tracks. *See Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 488 (1992) (listing "acquisition of competitors" as exclusionary conduct) (citing *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 75 (1911)); *United States v. Grinnell Corp*., 384 U.S. 563, 576 (1966) ("By . . . acquisitions [defendant] perfected the monopoly power to exclude competitors and fix prices."); *see also* Areeda ¶ 701b ("The monopolist's acquisition of a rival . . . [is] anticompetitive to the extent that it eliminates competition that might otherwise have dissipated the monopolist's power.").

[11] As under the Clayton Act, monopoly power can be established by direct evidence of supracompetitive pricing or, more often, inferred from a dominant or exclusive market share and the presence of entry barriers. *See Ryko Mfg. Co. v. Eden Serv*., 823 F.2d 1215, 1232 (8th Cir. 1987).

Courts have emphasized that for conduct to be considered exclusionary, it must have an anticompetitive effect. *See Microsoft*, 253 F.3d at 58-59 (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225-26 (1993) (applying Robinson-Patman Price Discrimination Act, 15 U.S.C. § 13(a))). Proof of such an effect does not, however, require proof that the conduct caused specific money damages to others in the market. Government agencies and other plaintiffs seeking equitable relief need only show, for purposes of liability, that the conduct has harmed competition "as a general matter" and "is reasonably capable of contributing significantly to . . . monopoly power." *Id.* at 71, 79; *see also Morgan v. Ponder*, 892 F.2d 1355, 1363 (8th Cir. 1989) (applying substantially the same exclusionary conduct test in private action); Areeda ¶ 657a. An acquisition that excludes imminent competition with the monopolist, as in this case, undoubtedly has an anticompetitive effect under this standard. *See, e.g.*, *Grinnell*, 384 U.S. at 576; *El Paso*, 376 U.S. at 661-62; *see also* Areeda ¶ 701b.

A monopolist may rebut a *prima facie* monopolization case by showing that its conduct promotes competition on the merits. *See Microsoft*, 253 F.3d at 59; *Concord Boat*, 207 F.3d at 1060-61. This inquiry is objective, and defendant's subjective intent is "relevant only to the extent it helps [explain] the likely effect of [its] conduct." *Microsoft*, 253 F.3d at 59; *see Aspen Skiing*, 472 U.S. at 601-02 & n.28 (quoting, *inter alia*, *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 432 (2d Cir. 1945) (L. Hand, J.) ("[N]o monopolist monopolizes unconscious of what he is doing.")). No such rebuttal issues are before the Court, however. Lundbeck made no effort at trial to prove that it

either intended or expected its acquisition of rights to NeoProfen from Abbott Laboratories to lead to more rather than less competition.

III. The Relevant Market: Independent Suppliers of Indocin IV and NeoProfen Would Have Been Competing on the Basis of Price Since 2006

An antitrust market is defined geographically and by product. *See Morton Bldgs. of Neb., Inc. v. Morton Bldgs.*, 531 F.2d 910, 918 (8th Cir. 1976). The relevant market in this case is drugs approved by the Food and Drug Administration ("FDA") to treat PDA in the United States.[12] That the United States is the relevant area of distribution and sale is undisputed.[13] The economics experts agree, meanwhile, that whether PDA drugs constitute a product market depends on the answer to one question: whether independent suppliers of Indocin IV and NeoProfen would compete for sales to hospitals on the basis of price. *See* Tr. 1000:24-1001:19 (Arnold); Tr. 1297:19-1298:4 (McCarthy); *see also Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (stating that "practical indicia" of product market include similar uses, similar customers, industry perceptions and price sensitivity); *HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 547 (8th Cir. 2007) (same).[14] The trial demonstrated that the answer is yes: Hospitals, as sophisticated

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[12] PPFF § VI.

[13] PPFF ¶¶ 3.2, 6.2.

[14] Even when the technical term is used, markets are often defined without directly or precisely measuring "cross-elasticity of demand." Tr. 989:25-991:8 (Arnold); Tr. 1333:12-24 (McCarthy); *see U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 995 (11th Cir. 1993); *Nobody in Particular Presents, Inc. v. Clear Channel Commun'cns*, 311 F. Supp. 2d 1048, 1082 (D. Colo. 2004) (listing cases). Neither side proposes a specific cross-elasticity number here. Tr. 986:10-988:8, 989:25-991:8 (Arnold); Tr. 1333:8-11 (McCarthy).

customers, could obtain price concessions from independent suppliers by leveraging their ability to substitute between the drugs.

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

Lundbeck did not genuinely dispute at trial that Indocin IV and NeoProfen are equally effective and substitutable for the treatment of virtually all babies with PDA.[15] The only testifying medical expert, Dr. Jeffrey Gerdes, expressed this judgment based on current medical literature, including the authoritative *Cochrane Review*.[16]

Dr. Gerdes's unequivocal and unrebutted testimony that the drugs are close clinical substitutes is corroborated by, among other evidence, the prescribing patterns of neonatologists nationwide, and in the Twin Cities in particular. Nearly four years after NeoProfen's launch at a price similar to that of Indocin IV, NeoProfen usage has leveled off (as Lundbeck expected at the time of launch) at approximately 40 percent of PDA courses of treatment, versus 60 percent for Indocin IV.[17] Which drug a PDA patient receives is typically determined, moreover, not by a medical assessment of the baby, but by where the baby happens to be treated.

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[15] *See generally* PPFF § VI.

[16] Tr. 115:15-117:23 (Gerdes). Lundbeck's Chief Scientific Officer, an M.D. and Ph.D., opined similarly in a December 2005 due diligence report. He advised Lundbeck's management that the studies submitted by Abbott to the FDA with the NeoProfen new drug application did not demonstrate a meaningful advantage over Indocin IV in terms of overall patient outcomes. PX 65 at 2; PPFF ¶ 6.11.

[17] PPFF ¶ 1.4.

More than half of U.S. hospitals that treat PDA administer only one drug or the other, with the single drug usually being Indocin IV.[18] (These statistics could change as a result of the Indocin shortage that Lundbeck announced just before trial, and that it forecasts will last well into the spring.[19]) Two local neonatologists explained in live testimony that, consistent with the national norm, they generally prescribe just one of the drugs. If a baby is treated pharmaceutically for PDA at Minneapolis Children's Hospital, where Dr. Nathaniel "Rob" Payne practices, she will (or would, until the shortage) receive Indocin IV as a matter of course.[20] Had the same baby been born east of the Mississippi River and treated at the affiliated St. Paul Children's Hospital by Dr. Mark Mammel's practice group, she typically would receive NeoProfen.[21] Physicians can use either drug exclusively, or substitute between them, because both drugs treat PDA in fundamentally the same way with equivalent results.[22]

Recognizing this, Lundbeck focused its marketing efforts on persuading hospital decision makers to adopt NeoProfen as their "drug of first choice" for PDA, and on discouraging substitution from NeoProfen back to Indocin IV (which, unlike NeoProfen, has no patent or orphan drug protection against the entry of a generic version).[23] In

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[18] PPFF ¶ 6.16.
[19] PPFF ¶¶ 6.12, 7.16.
[20] PPFF ¶ 6.19.
[21] PPFF ¶ 6.19. More than half of the Kaiser Health Plan hospitals that treat PDA use Indocin IV exclusively, as does the largest hospital in the Los Angeles County Department of Health Services system. *Id.* ¶ 6.18.
[22] PPFF ¶¶ 6.4-6.10. Lundbeck also designated deposition testimony of several neonatologists who prescribe either Indocin IV or NeoProfen exclusively.
[23] PPFF §§ VI.A.4, VI.B.1.

March 2006, after acquiring the rights to NeoProfen, but before that drug was for sale, Lundbeck instructed its sales representatives to stop all promotion of Indocin IV and, indeed, to emphasize what Lundbeck believed were *weaknesses* of Indocin IV versus NeoProfen with respect to side effects.[24] (By contrast, if Lundbeck had owned only Indocin IV, it would have marketed that drug as the "first choice."[25])

Lundbeck and Abbott subsequently fielded a sales force, which at its peak included 43 Lundbeck sales representatives, managed by live witness Paul Stickler, and more than 300 from Abbott, to promote NeoProfen through frequent face-to-face meetings with ("detailing of") physicians, pharmacists, hospital administrators, and nurses.[26] Lundbeck also invested in other marketing tools, such as a promotional speaker program and "formulary kits," for NeoProfen.[27] That NeoProfen's share of pharmaceutical PDA treatments has, as expected, leveled off at less than a majority, despite these extensive and one-sided promotional efforts and the lack of a significant price difference between the drugs, confirms that the market views the drugs as essentially interchangeable.

B. Preferences for PDA Drugs Are Not Fixed

At the same time, Lundbeck's heavy promotional activity, as well as its sales and marketing documents themselves, show that the company recognizes that health care providers can be persuaded to change their preferences regarding PDA drugs.

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[24] PPFF ¶ 6.31.
[25] PPFF ¶ 6.28.
[26] PPFF ¶ 6.37.
[27] PPFF ¶¶ 6.39-6.40.

Lundbeck's pre-launch market research suggested that only about 20 percent of neonatologists would strongly prefer NeoProfen over Indocin IV.[28] After the launch, in reports prepared from 2006 to 2008 tracking the usage of NeoProfen at target hospital accounts, Lundbeck's sales people color-coded large numbers of institutions as yellow, or "lukewarm" toward NeoProfen, meaning that they were "in the process of deciding what product to use or are indifferent. They can go either way . . . ." Sales representatives were told to maintain their promotional efforts at those accounts.[29] And even when hospitals were coded green, as NeoProfen users, Lundbeck believed those accounts required monitoring to discourage them from resuming their use of Indocin IV. "Things can change," management warned the sales people, "and if you don't stay on top of . . . these accounts, they can easily switch back to their old ways . . . ."[30] Indeed, a number of hospitals tried NeoProfen for a period of time and returned to using Indocin IV.[31]

Lundbeck's sales representatives also regularly prepared and submitted to management "Sales Activity Reports" describing their face-to-face contacts with individual staff members at target hospitals.[32] Those reports demonstrate, among other things, that decisions regarding PDA drugs are often made by consensus, and with input from professionals other than doctors. Lundbeck's "detailing" efforts focused not only

[28] PPFF ¶ 6.35.
[29] PPFF ¶ 6.42.
[30] PPFF ¶ 6.43.
[31] PPFF ¶ 6.43.
[32] PPFF ¶¶ 6.44-6.45.

on neonatologists, but also on administrators, clinical pharmacists, and nurses.[33] For example, a sales representative identified Debra Gardner, a live trial witness and a pharmacist at Ohio State University Medical Center, as a NeoProfen "champ[ion]" at her institution for sponsoring NeoProfen's addition to the formulary and encouraging its use.[34] In fact, in 2007, at the height of Lundbeck's marketing efforts, only 45 percent of details were conversations with neonatologists, while 55 percent were communications with pharmacists, nurses, and other hospital staff.[35]

The Sales Activity Reports are also noteworthy in that sales people color-coded individual hospital staff members according to their receptivity to NeoProfen — green for "supporters," red for "blockers" or opponents, and yellow for "neutrals."[36] Those coded as neutral or undecided between Indocin IV and NeoProfen at a given hospital often outnumbered the committed supporters and blockers.[37] Thus, although, as Dr. Mammel testified of his own group's experience, physicians may prefer and become accustomed to one or the other PDA drug because consistency is "simpler to . . . manage,"[38] Lundbeck's own marketing documents demonstrate the general absence of intense or immutable preferences between the drugs, which is not surprising, given their clinical similarity.

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[33] PPFF ¶¶ 6.46-6.49.
[34] PPFF ¶ 6.47.
[35] PPFF ¶ 6.46.
[36] PPFF ¶ 6.45.
[37] *See, e.g.*, PX 348 at 17; PX 351.
[38] Tr. 273:25–274:6 (Mammel).

C. Hospitals Would Leverage the Formulary Process to Negotiate Lower Prices for PDA Drugs

Hospitals order and pay for PDA drugs, and have strong incentives to control drug costs.[39] PDA drugs are a sufficiently large budget item to have attracted the attention of hospital administrators since Lundbeck's massive price increase for Indocin IV in January 2006.[40] Hospitals have demonstrated their sensitivity to the prices of PDA drugs by, among other things, asking their group purchasing organizations to attempt to negotiate with Lundbeck for lower prices for PDA drugs, and to encourage entry by a manufacturer of generic Indocin.[41] Many hospitals have also responded to the price increase by adopting the practice of "splitting" vials of Indocin IV, in order to save money by obtaining more courses of treatment per purchased vial.[42] Indeed, a number of those hospitals have selected a PDA drug based on its price: Lundbeck's 2008 NeoProfen Marketing Plan (prepared in 2007 by live witness David Knocke), for example, reported that 30 of the 104 hospital accounts that decided not to add NeoProfen to their formularies during the preceding year did so because splitting vials of Indocin IV made that drug less expensive than NeoProfen (which is more difficult to "vial split").[43]

There is ample additional evidence that the company understands that hospitals consider price when selecting PDA drugs. Indeed, Lundbeck priced NeoProfen at 3 percent less than Indocin IV per three-vial package in July 2006 specifically in order to

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[39] PPFF § VI.B.2.a.
[40] PPFF § VI.B.2.b.
[41] PPFF § VI.B.2.b.(1)-(2).
[42] PPFF § VI.B.2.b.(3).
[43] PPFF ¶¶ 6.88-6.90.

"drive [NeoProfen's] acceptance"[44] and to avert "pharmacoeconomic debate" within hospitals regarding the prices of the PDA drugs.[45] Lundbeck then offered a one-time 20 percent rebate to encourage initial purchases of NeoProfen.[46] Later, members of the sales and marketing team repeatedly identified the possible introduction of a low-priced generic Indocin as a threat to sales of higher-priced NeoProfen.[47]

Hospitals and hospital systems rely on P&T committees, made up of physicians, pharmacists, administrators, to manage their drug formularies.[48] The formulary system applies to all drugs, including those, such as PDA drugs, that are used with limited populations, such as newborns.[49] When a P&T committee determines, based on a review of the medical literature and other available evidence, that two (or more) drugs in a therapeutic class have similar safety and efficacy, regardless of whether they are the same molecule, the committee may consider cost when deciding whether, and if so, under what specific circumstances doctors at the hospital should prescribe those drugs.[50]

With their P&T committees' approval, hospital purchasing officials can routinely use the leverage of the formulary system to negotiate price concessions from independent suppliers of substitutable drugs.[51] Formulary guidance can allow hospitals to credibly promise (or threaten) to move some or all of their drug purchases in a therapeutic class

[44] PPFF ¶ 6.94.
[45] PPFF ¶ 6.96.
[46] PPFF ¶ 6.97.
[47] PPFF ¶¶ 6.99-6.103.
[48] PPFF ¶ 6.109.
[49] PPFF § VI.C.3.
[50] PPFF ¶¶ 6.112-6.113, 6.122.
[51] PPFF § VI.C.2.

toward or away from certain suppliers.[52] Hospitals need not move 100 percent of their purchases in a class to one drug. Customers can, for example, negotiate "tiered" prices that decrease as a seller's "market share" at the hospital increases.[53] The savings can be significant. Ambrose Carrejo of the Kaiser Permanente Health Plan testified that his large, integrated health system enters into three- to five-year contracts with pharmaceutical makers including discounts of up to 70 percent.[54]

"Shifting share" to achieve cost savings may require hospitals to coordinate with and persuade their physicians to change their prescribing behavior. Experience shows that hospitals can obtain the support of sufficient numbers of doctors by providing them with detailed evidence concerning the clinical similarity and costs of the drugs.[55] Strong opinions held by a minority of the staff need not be decisive. As Amarylis Gutierrez, who oversees pharmaceutical contracting for the Los Angeles County Department of Health Services and co-chairs the agency's P&T committee, testified, "one neonatologist doesn't represent the interests of the whole formulary. You have to [consult with] the group as a whole."[56] The Kaiser system employs drug education coordinators specifically to educate its physicians and answer their questions about the reasoning behind P&T committee decisions.[57]

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[52] PPFF ¶¶ 6.117, 6.119-6.123.
[53] PPFF ¶¶ 6.117-6.118.
[54] PPFF ¶ 6.119.
[55] PPFF ¶¶ 6.123-6.128.
[56] Tr. 860:24-861:4 (Gutierrez); PPFF ¶ 6.108.
[57] PPFF ¶ 6.125.

Ms. Gutierrez testified that her P&T committee is currently reviewing the use of Indocin IV and NeoProfen at the Department's hospitals to determine whether her cashed-strapped agency could save money by stocking only one PDA drug.[58] Lundbeck's ownership of both drugs, however, has deprived hospitals of the opportunity and incentive to undertake such reviews with an eye to negotiating lower prices.[59] Given the demonstrated clinical interchangeability of the two drugs, and hospitals' proactive interest in reducing costs, there is every reason to conclude that hospitals would have reaped the benefits of price competition if Indocin IV and NeoProfen were in separate hands. The ability to shift share between substitutable drugs at the margin allows hospitals to present competing suppliers with the choice of making sales at reduced prices, versus not making those sales at all. No evidence suggests that rational suppliers faced with that choice would not reduce their prices.

IV. Liability: Lundbeck Violated the Antitrust Laws and Harmed Consumers by Forestalling or Foreclosing Competitive Entry

For two decades, physicians and hospitals in the United States effectively had only one drug, Indocin IV, to treat PDA. By acquiring the rights to NeoProfen from Abbott in January 2006, five months after acquiring the rights to Indocin IV, Lundbeck put off indefinitely the entry of a competing supplier into the market for PDA drugs. The acquisition violated section 7 of the Clayton Act and constituted monopolization because it preserved and extended Lundbeck's monopoly and has had the anticompetitive *effect* of

[58] PPFF ¶ 6.130.
[59] PPFF § VI.C.

suppressing — for four years and counting — price competition from which hospitals and consumers would have benefited.[60]

Two days after acquiring the rights to NeoProfen, Lundbeck raised the price of Indocin IV by nearly 1,300 percent, to $1,500 per three-vial course of treatment.[61] Lundbeck launched NeoProfen in July 2006 at $1,450 per course of treatment, and has maintained those price levels, with periodic increases, ever since.[62] Plaintiffs' demonstration at trial that the NeoProfen acquisition curtailed competition that would otherwise have taken place — meaning that prices exceed the competitive level by *some* amount — is enough to establish a violation of the antitrust laws. *See El Paso Natural* Gas, 376 U.S. at 660-62; *Yamaha Motor*, 657 F.2d at 977; *Microsoft*, 253 F.3d at 78-80 (noting it is difficult or impossible to "reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct").

Lundbeck argued at trial that it had no reason to expect when it acquired NeoProfen in January 2006 that it would remain the only seller of PDA drugs several years later. It argues that to charge it with acquiring durable market power reflects hindsight bias, inasmuch as a generic Indocin IV was reasonably expected to enter the market before now.[63] As noted above, however, Lundbeck's specific intent is irrelevant; it is the objective consequences of its conduct that matter. *See United States v. E.I. du*

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[60] These same actions violated the Minnesota Antitrust Law, Minn. Stat. § 325D.49, *et. seq.*, and constituted unjust enrichment.
[61] PPFF ¶ 1.9.
[62] PPFF ¶¶ 1.11-1.12.
[63] *See e.g.*, Tr. 47:14-19 (Lundbeck opening statement).

Pont de Nemours & Co., 353 U.S. 586, 607 (1957) (Clayton Act); *Aspen Skiing*, 472 U.S. at 601-02 & n.28 (monopolization). Lundbeck knowingly acquired the only two PDA drugs and is responsible for the results of that course of action. We need not show that Lundbeck's "continued monopoly power is precisely attributable to its anticompetitive conduct." *Microsoft*, 253 F.3d at 79.

Lundbeck did, in any event, expect its monopoly to be durable as the law defines that term. Market power is generally considered sufficiently durable to raise antitrust concerns if it can be expected to last at least two years after the precipitating conduct. *See* Merger Guidelines § 3.2; *United States v. Syufy Enterps.*, 903 F.2d 659, 666 n.11 (9th Cir. 1990) (dictum) (citing Merger Guidelines); *FTC v. CCC Holdings Inc.*, 605 F. Supp. 2d 26, 59 (D.D.C. 2009) (citing Merger Guidelines but noting "two years may be a short time frame . . . in this [insurance claim estimating software] industry"). We established at trial that Lundbeck understood in January 2006 that a generic Indocin faced regulatory and manufacturing entry barriers[64] and that the generic's launch was more than two years, and possibly more than three years away.[65] At the time it acquired NeoProfen, Lundbeck saw NeoProfen as a much more imminent threat than the generic to sales of Indocin IV.[66]

Lundbeck has chosen to deny and ignore the fact that by January 2006, its own planning documents and financial models conservatively forecast generic entry in 2008 or 2009. Even those past predictions of generic entry are essentially irrelevant, moreover,

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[64] *See* PPFF ¶¶ 5.18-5.19.
[65] PPFF ¶¶ 5.16-5.18.
[66] PPFF ¶¶ 5.16-5.18.

because the possibility of generic competition had no constraining effect on Lundbeck's pricing behavior. *See Chicago Bridge*, 534 F.3d at 429 (noting relevant threat of entry must "constrain supracompetitive prices") (citing authorities). Lundbeck's four-year-old monopoly was illegal at the outset and remains so today.

V. Remedies: Lundbeck Should Divest NeoProfen and Disgorge Its Unlawful Financial Gains

Upon finding a violation, the district court has "both the duty and the authority" not only to "terminate[] the illegal acts of monopolization," but also to "ensure[] that they do not recur" and to "eliminate[] their consequences." *Paschall v. Kansas City Star Co.*, 695 F. 2d 322, 335 (8th Cir. 1982). To accomplish these aims, the Court should order Lundbeck to divest the illegally acquired asset, NeoProfen, and to disgorge the profits resulting from the violation. Disgorged funds would go into an escrow account to be administered by the FTC and the State of Minnesota, to be distributed to hospitals that Lundbeck overcharged for Indocin IV and NeoProfen. To assist the Court in fashioning the remedy, plaintiffs have attached a draft order.

A. Divestiture of NeoProfen Is Necessary to Establish Competition

Divestiture is the "natural remedy" for a violation of Section 7 of the Clayton Act. *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 329 (1961). "Complete divestiture is particularly appropriate where asset or stock acquisitions violate the antitrust laws." *Ford Motor Co. v. United States*, 405 U.S. 562, 573 (1972). Divestiture "should always be in the forefront of a court's mind when a violation of [Clayton Act] Section 7 has been found." *Du Pont*, 366 U.S. at 331. And in a monopolization case

premised on an illegal acquisition, divesture is an "essential feature" of the remedy. *Schine Chain Theaters v. United States*, 334 U.S. 110, 128 (1948).[67]

There can be little doubt that this "natural" remedy is warranted here. Lundbeck acquired NeoProfen to prevent its introduction as a competing PDA drug. It has remained the sole supplier of PDA drugs for more than four years, enjoying monopoly prices at hospitals' expense. The remedy for that violation should seek, to the extent possible, to restore competition in the PDA drug market to that which would have prevailed absent Lundbeck's illegal conduct. Nothing short of the divestiture of NeoProfen is likely to accomplish that goal.

Lundbeck's suggestion that divestiture is unnecessary because of the prospect of Bedford's introduction of a generic version of Indocin IV essentially asks the Court assume away the numerous uncertainties regarding the actual timing and market impact of Bedford's long-predicted entry.[68] According to Lundbeck's own models, market penetration of generic Indocin IV will be gradual, leaving Lundbeck with a dominant share of the PDA drug market for a substantial period of time after the generic is introduced.[69] Divestiture of NeoProfen is far more likely to restore the market to the competitive conditions that would otherwise have prevailed.

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[67] Divestiture has long been used to remedy monopolization violations. *See, e.g., United States v. United Shoe Mach. Corp.*, 391 U.S. 244 (1968); *United States v. Crescent Amusement Co.*, 323 U.S. 173 (1944); *United States v. Am. Tobacco Co.*, 221 U.S. 106, 187-88 (1911); *Standard Oil Co. v. United States*, 221 U.S. 1, 79 (1911).

[68] PPFF ¶¶ 6.77, 7.11, 7.14, 8.8.

[69] PPFF ¶ 8.9.

Moreover, absent Lundbeck's illegal conduct, Bedford's entry would mean a third competitor in the PDA drug market, which would likely lead to lower prices for hospitals, since Bedford prices its products lower in markets with more competitors.[70] In addition, as long as Lundbeck owns NeoProfen, it will likely be reluctant to launch its own generic version of Indocin IV because driving the price of generic Indocin IV even lower would increase the price differential between Indocin IV and NeoProfen and likely reduce NeoProfen sales. Absent ownership of both, however, Lundbeck would be more likely to lower its prices to compete with generic Indocin IV.[71]

The Court should not, in equity, draw uncertain inferences in favor of Lundbeck, the wrongdoer, particularly where doing so would allow defendant to retain a dominant share of a highly concentrated market. Indeed, "it is well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to remedy are to be resolved in its favor." *Du Pont*, 366 U.S. at 334.

The manner in which the divestiture is carried out is critically important to ensure an effective remedy. Plaintiffs' draft order provides for the appointment of a divesture trustee, to be responsible for identifying a suitable buyer for the NeoProfen assets and carrying out the sale. The trustee should ensure that the NeoProfen rights are divested, for a fair market price, to a party that will be a viable competitor in the PDA drug market. In addition, the draft order sets forth a process to ensure that prior to divestiture, Lundbeck maintains the full economic viability, marketability, and competitiveness of the

[70] PPFF ¶ 8.12.
[71] PPFF ¶ 8.12.

NeoProfen assets. Such provisions are routinely included in the FTC's divestiture orders and are based on the Commission's extensive experience implementing divestiture remedies.[72]

B. The Court Should Order Disgorgement

Adequate relief in a monopolization case should not only "put an end to the combination" but also "deprive the defendants of any of the benefits of the illegal conduct." *Grinnell*, 384 U.S. at 577. Divestiture will "put an end to the combination," but additional relief is needed to deny Lundbeck the benefits of its illegal conduct. The record establishes that Lundbeck illegally preempted competition in PDA drugs to protect its profits[73]; that its conduct has resulted in higher prices for both Indocin IV and NeoProfen[74]; and that, for four years, hospitals nationwide have been forced to pay 14 times what they paid for PDA drugs in 2005.[75] Divestiture alone would permit Lundbeck to profit handsomely from its unlawful conduct. The Court can and should order that Lundbeck disgorge its unlawful profits.

To be sure, the circumstances here do not permit a precise calculation of Lundbeck's gains from the illegal acquisition. In principle, those illegal gains include all profits from NeoProfen, plus the portion of Indocin IV profits attributable to selling the drug above the competitive price. Because Lundbeck made sure that there has never

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[72] *See, e.g.*, *Teva Pharm. Indus., Ltd.*, Decision and Order, FTC File No. 081-0224 (Feb. 10, 2009); *Pfizer, Inc.*, Decision and Order, FTC File No 091-0053 (Oct. 14, 2007); *Watson Pharms., Inc.*, Decision and Order, FTC File No. 061-1039 (Dec. 6, 2006).
[73] PPFF § V.B.
[74] PPFF § V.C.
[75] PPFF § V.C.

been a period of independent competition between Indocin IV and NeoProfen, there is no evidence of prices actually charged under competitive conditions. The determination of illegal profits is further obscured by Lundbeck's recordkeeping, because Lundbeck's accountants did not contemporaneously prepare profit and loss statements for individual drugs in its portfolio.[76] Moreover, the full extent of Lundbeck's ill-gotten gains cannot be tallied until a divestiture sale takes place. It may realize a sizable profit from the sale of the NeoProfen rights; in the meantime, it continues to exploit its monopoly.

But equity does not demand precision. Even in a private antitrust suit for damages, "[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created." *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265 (1946). All that is required here is a "reasonable approximation" of unlawful gains. *See, e.g.*, *FTC v. Febre*, 128 F.3d 530, 535 (7th Cir. 1997); *SEC v. Bilzerian*, 29 F.3d 689, 697 (D.C. Cir. 1994). The record provides the Court with alternative approaches that permit a just and reasonable estimate of Lundbeck's illegal gains. The Court also has the power to direct the divestiture trustee to assist in determining a reasonable estimate of Lundbeck's net gain after completing the sale of the NeoProfen assets. *See, e.g.*, *CFTC v. Am. Bd. of Trade, Inc.*, 803 F.2d 1242, 1253 (2d Cir. 1986).

[76] PPFF § V.C.

1. The Court Has Authority to Order Disgorgement

The FTC: Section 13(b) of the FTC Act authorizes the Court to grant a permanent injunction to restrain violations of "any provision of law enforced by the Federal Trade Commission." 15 U.S.C. § 53(b). Appellate courts have uniformly held that this authority to issue injunctions carries with it the power to grant the full range of equitable remedies, including monetary remedies such as disgorgement, rescission, and restitution. *See, e.g., FTC v. Security Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1314 (8th Cir. 1991).[77] These decisions rest on longstanding Supreme Court precedent holding that, absent a clear command to the contrary, a decision of Congress to vest jurisdiction in the district court to enforce a statute allows the court to use all of its inherent equitable powers. *See Porter v. Warner Holding Co.*, 328 U.S. 395, 397-98 (1946); *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291-92 (1960).

While apparently conceding that section 13(b) of the FTC Act allows for disgorgement in monopolization cases, Lundbeck has asserted that this grant of authority does not permit disgorgement for violations of the Clayton Act. *See* Def. Trial Br. 32 n.13. Section 13 (b), however, expressly applies to actions to enforce "any provision of law enforced by the Commission," and Lundbeck has offered no explanation or legal

[77] *See also FTC v. Gem Merchandising Corp.*, 87 F.3d 466, 468-69 (11th Cir. 1996); *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 571-72 (7th Cir. 1989); *FTC v. H.N. Singer, Inc.*, 668 F.2d, 1107, 1113 (9th Cir. 1982); *FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d 25 (D.D.C. 1999).

authority for the proposition that a court's powers are more limited when the FTC is enforcing the Clayton Act than when it enforces other laws.

The State of Minnesota: The State of Minnesota joins the FTC in seeking disgorgement of the ill-gotten gains. The Court's authority to grant injunctive relief to the State arises under section 16 of the Clayton Act, 15 U.S.C. § 26, and Minn. Stat. § 325D.58 for violations of federal and state antitrust laws, respectively the Office of the Minnesota Attorney General ("OAG" or "Attorney General") has authority to seek the remedies of disgorgement and restitution against Lundbeck pursuant to multiple Minnesota statutes and its independent, common law *parens patriae* authority.

Both Minn. Stat. §§ 8.31 and 325D.59 authorize the OAG to seek disgorgement and restitution here. First, Minn. Stat. § 8.31, subd. 1 specifically charges the OAG with enforcing Minnesota antitrust law, and the OAG-specific subdivision 3 authorizes it to seek the remedies of injunctive relief and civil penalties when doing so. Minn. Stat. § 8.31, subds. 1, 3. Subdivision 3a authorizes additional remedies available to *all* parties, including the ability to "receive other equitable relief." *Id*., subd. 3a. Subdivision 3a also unambiguously establishes that the remedies provided therein are "[i]n addition to the remedies otherwise provided by law."[78] *Id*. Because disgorgement of illegal profits and

[78] Similar language is also found (twice) in subdivision 3's grant of authority to the OAG. *Id*., subd. 3.

restitution are equitable remedies,[79] subdivision 3a's grant of the authority to seek "equitable relief" encompasses such remedies.[80]

Minn. Stat. § 325D.59 also authorizes "the attorney general [to] institute . . . a court action seeking appropriate relief" for violations of Minnesota's antitrust laws. By its plain meaning, this broad statutory grant of authority necessarily includes the ability to seek equitable relief when "appropriate" to remedy a defendant's illegal conduct, as it is here in regards to Lundbeck.

Lundbeck based its argument in its trial brief that Minnesota antitrust law does not authorize disgorgement and restitution solely on *FTC v. Mylan Labs*, 62 F. Supp. 2d at 48-49. However, the *Mylan* court's non-controlling holding was erroneous, and should be rejected here for several reasons. First, *Mylan*'s apparent conclusion—unsupported by any citation to case law—that the OAG-specific remedies provided for in Minn. Stat. § 8.31, subd. 3 somehow restrict the second set of remedies available to the OAG pursuant to subdivision 3a is at odds with the plain text of each provision. As already discussed, *both* subdivision 3 and 3a preface their respective grants of authority by stating that the penalties and remedies provided therein are "[i]n addition to" the penalties and remedies provided for elsewhere by law. Minn. Stat. § 8.31, subds. 3, 3a.

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[79] *United States ex rel. Zissler v. Regents of the Univ. of Minn.*, 992 F. Supp. 1097, 1109 (D. Minn. 1998) ("[d]isgorgement. . . is an equitable remedy"); *State by Humphrey v. Alpine Air, Inc.*, 490 N.W.2d 888, 896 (Minn. Ct. App. 1992), *aff'd*, 500 N.W.2d 788 (Minn. 1993) ("[r]estitution is an equitable remedy").

[80] *See State v. Directory Publ'g Servs., Inc.*, 1996 WL 12674 (Minn. App. 1996) (restitution sought on behalf of, and awarded to, businesses); *see also* Minn. Stat. § 8.31, subds. 2c, 3c (addressing restitution).

Second, the harmonization *Mylan* attempts to achieve between federal and Minnesota antitrust law sweeps too broadly. The desire for federal/state antitrust harmonization is limited to the *types of anti-competitive conduct prohibited* under both laws, not the myriad legal issues ancillary to every antitrust claim. *See Lorix v. Crompton Corp.*, 736 N.W.2d 619, 626 (Minn. 2007).

Finally, *Mylan*'s concern about duplicative recoveries appears to have improperly clouded its interpretation of Minnesota antitrust law: "While th[e] risk [of duplicative recovery] is a legitimate and important consideration, it is not a risk that our court may remedy by restricting Minnesota antitrust law in ways that our legislature has not." *Lorix*, 736 N.W.2d at 628.[81] *Mylan* also wholly fails to acknowledge the OAG's independent *parens patriae* authority — discussed further below — and Minn. Stat. § 325D.59's authorization to seek all "appropriate" relief in a state antitrust action.

In addition to the forgoing statutory authority, as the chief legal officer of the State, the Attorney General has "extensive common-law powers inherent in [the] office," and "may institute, conduct, and maintain all such actions and proceedings as [she] deems necessary . . . and the courts will not control the discretionary power of the attorney general in conducting litigation for the state." *Slezak v. Ousdigian*, 110 N.W.2d

[81] Neither does *Mylan*'s citation to Minn. Stat. § 325D.57 support its analysis on this point. When considered in its entirety, it is clear that the statute was meant to permit courts to avoid a *particular* duplicative *recovery*, not *categorically* exclude the availability of an entire *remedy* under state antitrust law.

1, 5 (Minn. 1961).[82] Consistent with this inherent authority, "the common law has recognized that under the doctrine of *parens patriae* a state may maintain a legal action on behalf of its citizens, where the citizens have been harmed and the state maintains a quasi-sovereign interest." *State by Humphrey v. Ri-mel, Inc.*, 417 N.W.2d 102, 112 (Minn. App. 1987).[83] This inherent, common law *parens patriae* authority provides an independent basis for the OAG to pursue the equitable remedies of disgorgement and restitution against Lundbeck for its violation of state antitrust law.

In *State by Humphrey v. Ri-mel, Inc.*, the defendants challenged the OAG's $491,000 restitution judgment against them, arguing that the OAG had no authority to bring such a claim on behalf of aggrieved Minnesota citizens. 417 N.W.2d at 105-06, 111. The court disagreed, and held "that under common law and the doctrine of *parens patriae* the state, through the attorney general, was authorized to bring an action [for equitable relief in the form of restitution] on behalf of the injured [consumers]." *Id*. at 112. Both Minnesota courts and this Court have since reaffirmed the Attorney General's invocation of *parens patriae* authority to seek equitable remedies in other public enforcement actions, including antitrust actions.[84] Thus, in accordance with this

[82] These extensive common law powers have been recognized by the Minnesota Supreme Court for more than a century. *See State ex rel. Young v. Robinson*, 112 N.W. 269, 272 (Minn. 1907).

[83] *See Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982) (stating protection of "the health and well-being—both physical and economic—of its residents in general" allows invocation of the *parens patriae* doctrine).

[84] *See State by Humphrey v. Standard Oil Co*., 568 F. Supp. 556, 563-66 (D. Minn. 1983) (action for illegal petroleum price overcharges); *State By Spannaus v. Northwestern Bell*

extensive common law authority and the mandate that state antitrust laws are to be "broadly construed to effectuate their purpose," *Lorix*, 736 N.W.2d at 624, the OAG is entitled to seek the equitable remedies of disgorgement and restitution against Lundbeck pursuant to Minn. Stat. §§ 8.31, 325D.59, and/or its inherent *parens patriae* authority.

2. Disgorgement Is an Appropriate Remedy in This Case

The record evidence amply demonstrates the need for disgorgement. For four years and counting, Lundbeck has reaped the benefits of an illegal acquisition that has forced hospitals to pay higher prices for PDA drugs.[85] Disgorgement is a well established equitable remedy that is "designed to deprive a wrongdoer of his unjust enrichment." *SEC v. First City Fin. Corp.*, 890 F.2d 1215, 1231 (D.C. Cir. 1989). Depriving the violator of the benefits of its illegal conduct has long been considered a proper and important element of an antitrust remedy. *See, e.g.*, *Grinnell*, 384 U.S. at 577; *Schine*, 334 U.S. at 128; s*ee also* Areeda ¶ 653a (denying the fruits of unlawful conduct may require disgorgement).

Lundbeck's claim that disgorgement remedies require proof of "egregious" or "blatant" misconduct (Def. Trial Br. 32) is wrong. Lundbeck offers no legal authority that limits disgorgement or any other civil antitrust remedy to instances of egregious violations of law. In fact, courts have rejected such claims. *See Am. Bd. of Trade*, 803 F.2d at 1252 (noting "[a] finding of fraud is not a prerequisite" for disgorgement); *Mylan*,

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Tel. Co., 304 N.W.2d 872, 876-777 (Minn. 1981) (action for illegally charged telephone rates); *Alpine Air*, 490 N.W.2d at 896 n.4 (antitrust and consumer-fraud action).

[85] PPFF §§ VI.C, VII.

62 F. Supp. 2d at 36-37 (holding disgorgement not limited to *per se* antitrust violations). Lundbeck's suggestion that disgorgement would be inappropriate because of a supposed conflict with the FTC's administrative policy regarding when to seek monetary equitable remedies (Def. Trial Br. 33-34) is likewise misplaced. The Commission decided that this is a proper case for seeking disgorgement. Now, the Court's decision is governed by established legal rules governing the availability of that remedy. If it finds a violation, the Court should craft a remedy that will deprive the defendant of "the fruits of its statutory violation." *United Shoe*, 391 U.S. at 244.

Finally, the possibility of damage awards in pending private antitrust suits does not make disgorgement inappropriate. Disgorgement and damages are distinct remedies with different purposes. Disgorgement seeks to ensure that the defendant does not reap the rewards of its unlawful conduct, while damages are to redress injury. Moreover, any concerns that these different remedies would result in unjust, duplicative recoveries can be addressed through the sorts of mechanisms that have been used in the past to coordinate remedies in government disgorgement actions and private damage actions. Courts in securities law cases have routinely provided for "set-offs" and credits to avoid duplicative payments. *See, e.g., SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1475 (2d Cir. 1996); *SEC v. Texas Gulf Sulphur Co.*, 446 F.2d 1301, 1307 (2d Cir. 1971). Such provisions could easily be applied in any follow-on private actions.

3. The Record Provides Reasonable Methods to Calculate Disgorgement

When courts seek to determine the financial gains attributable to the defendant's illegal conduct, a precise calculation is not required. It is sufficient for the plaintiff to offer a "reasonable approximation" of the illegal profits. *See, e.g.*, *First City Fin.*, 890 F.2d at 1231. The burden then shifts to the defendant to demonstrate that the plaintiff's estimate is unreliable. *Id.* When defendant's actions create the uncertainty, it should not be heard to protest a lack of precision in the calculation. When its own record keeping makes it difficult to distinguish lawful from unlawful profits, the risk of uncertainty falls on defendant, "whose illegal conduct created that uncertainty." *Id*. at 1232; *see also Am. Bd. of Trade*, 803 F.2d at 1252. Similarly, courts do not require precision where it would entail "inordinate expense." *SEC v. Calvo*, 378 F.3d 1211, 1217-18 (11th Cir. 2004).

The trial record provides the Court with a clear method to calculate a reasonable approximation of Lundbeck's illegal profits. Plaintiffs' economic expert, Dr. Arnold, calculated a disgorgement amount by using the last available market price, that is, the actual list price Lundbeck charged for Indocin IV immediately before it unlawfully acquired NeoProfen: $108.88 per three-vial package. Dr. Arnold calculated the difference between (1) Lundbeck's revenues on sales of Indocin IV and NeoProfen between February 2006, and April 2009 (the end of fact discovery in this matter), and (2) the estimated revenues on sales of both drugs in that same period if both drugs had been sold at the $108.88 benchmark price. After making appropriate adjustments in total estimated output, Dr. Arnold calculated the difference between Lundbeck's actual

revenues and its estimated revenues at the $108.88 price, yielding a disgorgement figure of $105 million for the period he analyzed.[86]

Dr. Arnold used the market price prior to the acquisition as the competitive price because that was the best available evidence he had. In the absence of any historical evidence of pricing in a competitive PDA drug market — a void created by Lundbeck's illegal acquisition — it is reasonable to use the last price that Lundbeck actually charged. As Dr. Arnold acknowledged, he could not use a different methodology to calculate the competitive price that would have prevailed absent the acquisition because "there's no extrinsic market evidence that [one] can use from an earlier time period to help give an estimate of what the prices would have been" absent the NeoProfen acquisition.[87] That lack of evidence is a direct result of Lundbeck's illegal preemption of competition between NeoProfen and Indocin IV.

Disgorgement law is clear: If Lundbeck's illegal actions prevent a precise calculation of harm, the court should use the best available alternative. *See First City Fin.*, 890 F.2d at1231. Here, the best available figure is based upon the last price in the market before the acquisition. Thus, Dr. Arnold's calculation that the profits attributable to Lundbeck's illegal acquisition are $105 million is a reasonable approximation of Lundbeck's illegal gains through April 2009. The final calculation of Lundbeck's illegal gains should include the period from May 2009 until it divests NeoProfen.

[86] PPFF ¶ 8.20.
[87] Tr.1003:12-18 (Arnold).

There is no doubt that prices would have been lower if Neoprofen and Indocin IV were competitors. Dr. Arnold explained that ample evidence — including economic models, empirical literature on pricing of pharmaceuticals, and Lundbeck's own documents — permits a confident conclusion that prices for both Indocin IV and NeoProfen would have been lower had they been independently owned.[88] Testimony from Professor Schondelmeyer and pharmacists Mr. Carrejo and Ms. Gutierrez also supports Dr. Arnold's conclusion that competitive pricing would have been less than $1,500 per course of treatment.[89] But Lundbeck's preemption of competition between NeoProfen and Indocin IV means "there's no extrinsic market evidence that [one] can use from an earlier time period to help give an estimate of what the prices would have been" absent the NeoProfen acquisition.[90]

In the absence of historical evidence of pricing in a competitive PDA drug market — a void created by Lundbeck's illegal acquisition — it is reasonable to use the last price that Lundbeck actually charged. Thus, Dr. Arnold's calculation that the profits attributable to Lundbeck's illegal acquisition are $105 million is a reasonable approximation of Lundbeck's illegal gains through April 2009. The final calculation of Lundbeck's illegal gains should include the period from May 2009 until it divests NeoProfen.

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[88] PPFF ¶ 8.14; Tr. 990:200-991:8, 993:9-995:9, 997:8-998:20, 1000:20-1001:19, 1002:7-1003:6, 1019:3-18 (Arnold).
[89] PPFF §§ VI.C.2-4.
[90] Tr. 1003:12-18 (Arnold).

Although Lundbeck has not suggested a better estimate than Dr. Arnold's, the evidentiary record also provides the Court with an alternative approach to reasonably estimate the absolute minimum disgorgement amount. It considers Lundbeck's total profits on NeoProfen, because all of those profits are the product of the illegal acquisition; it also includes those additional Indocin IV profits generated by the illegal acquisition.[91] This alternative methodology meets the legal standard, *i.e.*, it produces a reasonable estimate, but it does underestimate the ill-gotten gains in two different respects. One, Lundbeck's accounting of its costs is inflated, masking the true profitability of Neoprofen. Two, the benchmark competitive price used to calculate illegal Indocin IV profits under this method is very conservative, and almost certainly underestimates the disgorgement attributable to Indocin IV.

Regarding NeoProfen, the trial record contains an analysis prepared by Lundbeck of NeoProfen profits for the period 2006-2008. Defendant's exhibit 149 sets forth Lundbeck's calculation of NeoProfen's profits in terms of a measure of profitability known as the EBITDA (Earnings Before Interest, Taxes, Depreciation, and Amortization). As Dr. Arnold observed, the EBITDA is an appropriate measure to evaluate the profits of a product.[92] He also explained that the 2006-2008 EBITDA figure in DX 149, which states a loss of $7.5 million, improperly inflates the expense side of the ledger in various respects, and thus makes NeoProfen appear less profitable than would

[91] Dr. Arnold did not estimate the total profits on NeoProfen because, in his judgment, the NeoProfen income statement prepared by Lundbeck did not provide a reliable basis to make that estimate. PPFF ¶¶ 8.35-8.37.

[92] PPFF ¶ 8.32.

be the case under standard accounting principles.[93] With an additional year of revenue, Lundbeck has certainly now earned a profit even with its inflated costs. But despite its flaws, the cost allocation method that Lundbeck itself used to calculate the EBITDA for NeoProfen provides a readily available tool for approximating Lundbeck's ill-gotten gains on NeoProfen.

Lundbeck's total profits on NeoProfen will include its profits on its sales of NeoProfen up to the time of divestiture, as well as profits on the sale of the divested asset. Thus, the calculation of Lundbeck's unjust enrichment as to NeoProfen is:

> Net Profit from NeoProfen sales from 2006 to date of divestiture +
> Net Profit from sale of asset (i.e., Divestiture Price minus Purchase Price)

The calculations under this approach are straightforward. At the time of divestiture, the divestiture trustee obtains from Lundbeck actual revenue and cost information for 2009 and forward. Using the same cost allocation method that Lundbeck used for the 2006-2008 EBITDA in DX 149, and verifying that the allocated costs were actually incurred for the purposes reported, the trustee calculates Lundbeck's profits on NeoProfen sales. The other component of the calculation is a subtraction of the purchase price for NeoProfen from the divestiture sale price the trustee obtains.[94]

Illegal Indocin IV Profits: Whereas all of Lundbeck's profits on NeoProfen sales are illegal gains, the ill-gotten gains from Indocin IV are the incremental profits that

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[93] For example, certain costs, such as sales force and marketing costs, as well as royalties paid to Abbott, are inflated because they were computed based on a percentage of NeoProfen revenues, and those revenues are the product of high prices Lundbeck obtained as a result of its illegal monopoly. PPFF ¶ 8.36.

[94] PPFF ¶¶ 8.31, 8.39.

resulted from the violation. A conservative means to calculate those profits is to use Lundbeck's projected minimum monopoly price — $1,140 per three-vial course of treatment — as a proxy for the price it would have charged absent the illegal acquisition. A variety of evidence demonstrates that using $1,140 as the benchmark price is the highest estimate of the competitive price and provides a reasonable approximation of Lundbeck's minimum unjust gains on Indocin IV sales.[95]

Lundbeck repeatedly identified $1,140 as the lower end of the price range at which it expected to sell Indocin IV.[96] It presented this price to shareholders and potential investors, as well as to other drug companies to encourage their interest in partnering to sell Indocin IV. Lundbeck initially identified the $1,140 price in August 2004, before it even became aware of potential competition from NeoProfen.[97]

This minimum monopoly price of $1,140 represents a conservative approximation of the *maximum* price Lundbeck would have charged had it been faced competition from NeoProfen. Lundbeck's repeated use of this figure shows that it deemed $1,140 to be not only profitable, but also sufficiently profitable to attract investors. While the competitive price might well have been lower, it is reasonable to conclude that had Lundbeck been

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[95] One could also calculate Lundbeck's supracompetitive profits on sales of NeoProfen in a similar manner, based on the record evidence, by merely comparing Lundbeck's actual sales revenues for NeoProfen to the revenues it would have earned by selling the same number of units at $1,140. Using this method, the total additional profits on NeoProfen are the sum of Lundbeck's net profits on sales until the divestiture date; of course, this method only captures the ill-gotten gains above the price of $1,140, not all of the ill-gotten gains.

[96] PPFF ¶¶ 5.44-5.45, 8.22-8.26.

[97] PPFF ¶¶ 8.22-8.26.

forced to compete with an independently owned NeoProfen, it would have charged no more than $1,140, its conservative price under monopoly conditions.

Although Mr. Burke insisted at trial that by August 2004 he had determined "in his mind" to set the Indocin IV price at $1,500 per course of treatment (Tr. 648:9-15), his testimony is not credible. As Lundbeck's economic expert, Dr. McCarthy, acknowledged, Lundbeck's own documents reflect a variety of different potential price points for Indocin IV, not a firm decision to charge $1,500.[98] Moreover, the fluctuations in the proposed Indocin IV prices in Lundbeck's documents over time correlate with Lundbeck's expectations that it would face competition from NeoProfen.[99] Mr. Burke's testimony that he decided "in his mind" on a firm price of $1,500 a year before Lundbeck actually owned Indocin IV, and a year and a half before implementing the price increase, is both implausible and contradicted by Lundbeck's contemporaneous business documents. The Court should disregard it.

Using $1,140 as the benchmark price, Lundbeck's net sales of Indocin IV from February 2006 through December 2008 would have been approximately $60.18 million -- $14.53 million less than its actual net sales during the same period.[100] Because Lundbeck continues to profit from its illegal acquisition, Lundbeck's net sales above the $1,140 benchmark price from 2009 to the time of divestiture of NeoProfen should be determined by the divestiture trustee and included in the disgorgement figure as well. While a

[98] PPFF 5.44; Tr. 1336:16-1339:1 (McCarthy); PX 25 at 14; PX 436 at 5.
[99] PPFF ¶¶ 5.40-5.47.
[100] PPFF ¶ 8.30.

calculation as of the divestiture date should be based on actual Indocin IV sales data, using a projection for 2009 based on 2008 data yields estimated illegal profits of approximately $20 million for 2006-2009.[101]

In fashioning a remedy for an antitrust violation, the Court "is clothed with 'large discretion' to fit the decree to the special needs of the individual case." *Ford*, 405 U.S. at 573. In this instance, the Court can and should consider that Lundbeck continues to profit from its illegal acquisition, so that the full extent of Lundbeck's illegal profits cannot be determined until divestiture, and all of those profits must be disgorged in order to fulfill the mandate to take away defendant's ill-gotten gains.

Evidence in the record provides the Court with a clear method to find that over $105 million must be disgorged; in the alternative, there is also evidence supporting a minimum disgorgement amount of at least $20 million of profits on Indocin IV, based on sales to date, plus a yet-to-be-calculated figure for NeoProfen profits. Based on the Court's choice, the divestiture trustee can assist in the Court's ultimate determination of the amount to be disgorged.

Lundbeck's wrongful conduct has forced hospitals to pay higher prices for PDA drugs for over four years. Uncertainty about the precise measure of Lundbeck's illegal profits should not deter the Court from ordering disgorgement. As the leading antitrust treatise states, in determining equitable relief to eradicate the effects of an illegal

[101] Lundbeck's net sales above the $1,140 benchmark price for 2008 were $5.37 million. PPFF ¶ 8.29.

acquisition, it is "proper to invoke" the principle that "the monopolist bears the risk of the uncertain consequences created by its exclusionary acts . . . any plausible doubts should be resolved against the monopolist." Areeda ¶ 653f. To require greater precision in approximating defendant's illegal profits would simply encourage antitrust malefactors such as Lundbeck to do just what was done here: take preemptive action to eliminate competitive threats at the earliest opportunity.

VI. Conclusion

Based on the foregoing; plaintiffs' proposed findings of fact and conclusions of law; and all of the evidence received at trial, plaintiffs respectfully request that the Court grant substantially the relief set forth in the attached draft order, to include without limitation ordering Lundbeck to (1) divest without undue delay all rights to NeoProfen, through a duly appointed divestiture trustee, and (2) disgorge an amount calculated using Dr. Arnold's method, or the alternative method described above, plus appropriate interest, into an escrow account administered by the FTC and Minnesota, for the purpose of equitably compensating purchasers of PDA drugs since January 2006. Plaintiffs further request such other or ancillary relief as the Court may deem just, equitable, and necessary to fashion an adequate remedy.

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Respectfully submitted,

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