IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

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) 08-cv-6379 (JNE/JJG)
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) (Related Case)) 08-cv-6381 (JNE/JJG)
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POST-TRIAL RESPONSE OF PLAINTIFFS
FEDERAL TRADE COMMISSION AND STATE OF MINNESOTA

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The Federal Trade Commission and the State of Minnesota established at trial and in our post-trial filings that by acquiring the rights to NeoProfen from Abbott

Laboratories in 2006, Lundbeck Inc. cut off Abbott's imminent entry into the market for drugs approved by the Food and Drug Administration to treat patent ductus arteriosus ("PDA"), and that in so doing, Lundbeck deprived hospitals of the ability they would otherwise have had to negotiate competitive prices for PDA drugs. The record shows that the imminent prospect of head-to-head competition with Abbott (or a different transferee) would have constrained Lundbeck from dramatically raising the price of Indocin IV to \$1,500 per course of treatment in January 2006, and that competition between Indocin IV and NeoProfen would have brought the prices of PDA drugs down further after NeoProfen's launch six months later.

To rectify, at least in part, the anticompetitive and distorting effects that Lundbeck's illegal acquisition has had, and continues to have, on this market, and to prevent Lundbeck from profiting from its illegal conduct, the Court should order Lundbeck to divest the illegally acquired NeoProfen asset and to disgorge a reasonable approximation of its ill-gotten gains. Those gains include the profits that Lundbeck has earned and will earn as a result of selling Indocin IV for more than the competitive price, and *all* profits that it realizes as a result of owning NeoProfen until the divestiture date.

In its lengthy post-trial brief, Lundbeck advances three basic arguments against holding it liable for violating the antitrust laws. *See*, *e.g.*, Def. Post-Trial Br. 1. But two of those arguments are, in substance, one and the same: Lundbeck argues that (1) Indocin IV and NeoProfen are not in the same antitrust market, and (2) plaintiffs did

not show anticompetitive effects arising from Lundbeck's ownership of both drugs (that is, its acquisition of the NeoProfen rights when it owned the rights to Indocin IV). *See id.* at 5, 21-59.¹ To the contrary, as we demonstrated in our post-trial brief, the evidence presented at trial that hospitals would capitalize on price competition between independent suppliers of Indocin IV and NeoProfen establishes that the relevant market is FDA-approved PDA drugs, *and* that the NeoProfen acquisition was exclusionary and harmful to competition. *See* Pl. Post-Trial Br. 5-14.

The evidence that PDA drug prices paid by hospitals are *higher than they would* be under competitive conditions is sufficient to establish Lundbeck's antitrust liability. Lundbeck's contention that there is no path or mechanism by which price competition would occur is mistaken. See Def. Post-Trial Br. 39-52. There is ample evidence that hospitals are the relevant "customers" for in-patient pharmaceuticals, and that hospitals obtain price concessions every day by offering or threatening to use the formulary system to shift market share toward or away from substitutable drugs sold by independent firms.² Competing sellers, in turn, respond by negotiating to gain or retain sales, at lower prices.³ The price effect will vary case by case, based on the circumstances of each negotiation.⁴ As Lundbeck's expert Dr. McCarthy testified, economics provides no basis to find a

¹ The argument about price effects precedes the market definition argument in Lundbeck's brief.

² PPFF §§ VI.B.2.A, VI.C.2.

³ PPFF § VI.C.2.

⁴ PPFF ¶¶ 6.119–6.122, 6.130–6.135.

priori that such bargains could not be struck for PDA drugs — provided that (as the record shows) hospitals could bargain credibly.⁵

Lundbeck's third basic argument why it should not be held liable is that it has allegedly not held *durable* monopoly power, owing to the possibility, still unrealized at the time of trial, that Bedford Laboratories might begin selling a generic version of Indocin IV. *See* Def. Post-Trial Br. 1, 59-72. Although Bedford may finally be entering, Lundbeck's durability argument should require little further rebuttal. As shown in our prior brief, a market share of 100 percent lasting for four years is clearly durable. *See* Pl. Post-Trial Br. 21-23. Events — including Lundbeck's continuing inability to transfer the manufacturing of Indocin IV from Merck & Co. to a new contract manufacturer — have shown that the technical barriers to making and selling the drug are at least as significant as the regulatory hurdles, and that Lundbeck's consultants underestimated these challenges even when they predicted that a generic would most likely enter the market about *three years* after the 1,300 percent price increase in January 2006.⁶

Lundbeck further argues that, assuming it has violated the antitrust laws, the Court should order no remedy. It argues, first, that divestiture of NeoProfen is unnecessary because "imminent market entry of generic indomethacin will achieve the same result as a structural remedy." Def. Post-Trial Br. 89. But that is incorrect. Divestiture of NeoProfen is needed to restore the competitive structure of the "but-for" world, in which Bedford's generic Indocin entry adds a third, rather than a second, competitor to the PDA

⁵ Tr. 1367:24–1368:14 (McCarthy).

⁶ PPFF ¶¶ 5.18-5.19, 7.11-7.15 For our response to Lundbeck's argument that there are no barriers to entry, see Pl. Resp. DPFF ¶¶ 157, 185, and 188.

drug market. Moreover, Bedford's entry does not assure that the market dominance that Lundbeck's illegal acquisition preserved will be effectively terminated. Finally, Lundbeck argues that disgorgement is inappropriate, or even unconstitutional, and that there are, in any event, no ill-gotten gains to disgorge. *Id.* at 73-75. But these arguments, too, lack merit, and as we demonstrated in our prior filings and revisit below, the trial record supports two reasonable approximations of the amount to be disgorged.

I. PDA Drugs Constitute the Relevant Product Market

We demonstrated in our post-trial brief that the definition of the relevant market is determinative of Lundbeck's liability in this case, because Lundbeck raised no defenses that could justify an acquisition that protected its PDA drug monopoly from imminent competitive entry by a seller of NeoProfen. *See* Pl. Post-Trial Br. 5-11. Lundbeck's acquisition of rights to NeoProfen was illegal because it preserved a monopoly where there would have been competition. *See*, *e.g.*, *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[.]").

Lundbeck argues that Indocin IV and NeoProfen are in separate, monopoly markets, and that the trial record reveals no "mechanism" by which price competition between independent suppliers would take place. *See* Def. Post-Trial Br. 37-59. Similarly, Lundbeck denies that its conduct has led to supracompetitive prices. *See id.* at 21-37. But as we demonstrated in our brief, these arguments reduce to a single issue — namely, whether independent suppliers of PDA drugs would compete for hospital dollars

on the basis of price — and they are refuted by the evidence that price competition would, in fact, occur. *See* Pl. Post-Trial Br. 16-20. PDA drugs would be less expensive if hospitals could negotiate with independent sellers of Indocin IV and NeoProfen, because hospitals would leverage the ability of their pharmacy and therapeutics ("P&T") committees to effect substitution between the drugs upon economic grounds. *See id.* at 18-20. Thus, Lundbeck's acquisition of the rights to NeoProfen was exclusionary conduct that has curtailed competition and inflated prices in this market. *See id.* at 20-22.

Lundbeck's theory that independent suppliers would *never* compete on the basis of price rests on several flawed premises. The first is that the relevant customers for PDA drugs are physicians, who are relatively insensitive to price, rather than hospitals, which are far more price sensitive. *See* Def. Post-Trial Br. 43-57. Relatedly, Lundbeck presumes that the preferences for PDA drugs that are seen today — absent a meaningful price difference between the drugs, and absent any incentive or ability among hospitals to negotiate for better prices — are fixed, and would necessarily exist an environment in which hospitals saw opportunities to economize by shifting share between suppliers. *See id.* at 54-57. Moreover, Lundbeck asks the Court to draw unwarranted inferences about brand-to-brand competition between PDA drugs based on, among other things, the dissimilar dynamics that occur when a *generic* drug enters a market. *See id.* at 34-39.

A. Hospitals Are the Relevant Customers for PDA Drugs

The identity of the relevant purchasers (like all other aspects of market definition) is a question of fact to be decided in light of all the circumstances of record. *See*, *e.g.*, *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962); *Geneva Pharms. Tech. Corp.*

v. Barr Labs., Inc., 386 F.3d 485, 496 (2d Cir. 2004) ("The emphasis always is on the actual dynamics of the market rather than rote application of any formula."). Lundbeck asserts that "[i]n analogous situations, courts and even the FTC have found that doctors are the relevant consumers." Def. Post-Trial Br. 44. However, the only judicial decision that Lundbeck cites as support was decided more than three decades ago, based on evidence dating from the late 1960s and early 1970s. See SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063-64 (3d Cir. 1978). More recent authority recognizes that "there is not just one relevant customer group" for prescription drugs, and that the determination is case-specific. Geneva Pharms., 386 F.2d at 496.

Lundbeck also mistakenly relies on an FTC decision. The Commission noted in that case that the definition of the relevant market depends in part on the challenged conduct, and that, had the FTC been assessing a merger, "a broad[er] market definition . . . might well [have been] appropriate." *Schering-Plough Corp.*, 136 F.T.C. 956, 978 (2002). In any event, the FTC observed in *Schering-Plough* simply that market definition for prescription drugs *begins* with "the array of therapeutically *substitutable* choices *available* to the doctor." *Id.* at 1213-14 (emphasis added). Here, that "array" includes

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⁷ See also SmithKline Corp. v. Eli Lilly & Co., 427 F. Supp. 1089, 1099-1100 (E.D. Pa. 1976) (table showing hospital purchases of cephalosprorins from 1970-75; citing "ten years" of price data), aff'd, 575 F.2d 1056 (3d Cir. 1978).

⁸ See also Barton & Pittinos, Inc. v. SmithKline Beecham Corp., 118 F.3d 178, 182 (3d Cir. 1997) (treating nursing homes as customers for vaccines); Barr Labs., Inc. v. Abbott Labs., 978 F.2d 98, 115-16 (3d Cir. 1992) (sustaining jury instruction that "left [jury] free to decide whether the pharmacist, the physician, or both should be considered the consumer"); see generally W.E. Afield, The New Drug Buyer: The Changing Definition of the Consumer for Antitrust Enforcement in the Pharmaceutical Industry, 2001 Colum. Bus. L. Rev. 203, 214 ("[R]adical changes in the pharmaceutical industry . . . have led to a more expansive definition [of the customer].").

Indocin IV and NeoProfen. *Schering-Plough* does not support Lundbeck's argument that in defining the relevant market, the Court should consider *only* a snapshot of physicians' preferences.⁹

The trial record shows that hospital administrations as a whole, not physicians, order and pay for inpatient drugs, and must be considered the relevant customers for PDA drugs. ¹⁰ Unlike physicians, who typically do not know the prices of the drugs they prescribe, hospitals are motivated to control costs, as they typically are not reimbursed by private or public insurance plans for their actual costs of treating patients, but instead receive fixed amounts determined by the factors in the Medicare Diagnosis Related Group system. ¹¹ Hospitals use P&T committee reviews and the formulary process to influence doctors' prescribing practices and to communicate the P&T committees' rationales for favoring or restricting the use of particular drugs. ¹² Those reasons may include price where, as here, drugs in a therapeutic class have similar safety and efficacy. ¹³ Hospitals routinely succeed in persuading prescribing professionals to move share between substitutable drugs for economic reasons. ¹⁴

Lundbeck's own conduct demonstrates that the company understands that it sells PDA drugs to price-conscious hospitals, rather than to thousands of individual

⁹ Tellingly, Lundbeck chose not to call any medical or other expert to support its theory that physicians' preferences fall into "two camps." In any event, the record refutes Lundbeck's claim that neonatologists have such strong preferences that they will not substitute between Indocin IV and NeoProfen. *See* PPFF ¶¶ 6.34–6.36, 6.42–6.45.

¹⁰ PPFF § VI.B.2.a.

¹¹ PPFF ¶¶ 6.50–6.56; see also id. \S VI.B.2.b.

¹² PPFF ¶¶ 6.106–6.136.

¹³ PPFF \P 6.117–6.119.

¹⁴ PPFF ¶¶ 6.108–6.120, 6.117–6.128.

neonatologists. Significantly, Lundbeck priced NeoProfen three percent less than Indocin IV per three-vial package in July 2006 specifically in order to "drive [NeoProfen's] acceptance" by P&T committees and other price-conscious decision makers¹⁵ and to avert "pharmacoeconomic debate" among pharmacists and administrators regarding the prices of the two PDA drugs.¹⁶ A 20 percent rebate to hospitals on first-time purchases of NeoProfen served a similar purpose.¹⁷ In the field, the NeoProfen sales and marketing team made placement on hospital formularies a top priority¹⁸ and did the majority of its face-to-face marketing to hospital staff members other than physicians, including clinical pharmacists, administrators, and nurses.¹⁹ Furthermore, as we demonstrated at trial and in our prior filings, Lundbeck's marketing behavior confirms that in general, physicians' preferences for Indocin IV or NeoProfen are not fixed and can be changed by new information, such as P&T committee guidance.²⁰

Lundbeck cites, as a supposed example of physicians' resistance to price considerations, an obviously rhetorical remark by Dr. Payne, which Lundbeck construes to mean that he would consider prescribing NeoProfen only if Indocin IV cost 10 times more. Def. Post-Trial Br. 48 (citing Tr. 226:3-11 (Payne)). Yet Dr. Payne (who, of course, does not purchase PDA drugs) testified more relevantly that he would be

¹⁵ PPFF ¶ 6.94.

¹⁶ PPFF ¶ 6.96; Tr. 785:6-14 (Stickler); PX 332 at 3.

¹⁷ PPFF ¶ 6.97; PX 332 at 3.

¹⁸ PPFF ¶ 6.136.

¹⁹ PPFF ¶¶ 6.37–6.40, 6.46–6.49.

²⁰ PPFF § VI.B.1; Pl. Resp. DPFF ¶¶ 303-304.

comfortable switching, provided the drugs "had [a] similar effect," which other record evidence shows they do. ²² Dr. Payne is thus among the probable majority of neonatologists who could be persuaded by their P&T committees and administrators to substitute one PDA drug for the other. ²³

B. Independent Sellers Would Compete on the Basis of Price

Lundbeck argues that even if price-sensitive hospitals are the relevant customers, Lundbeck and an independent seller would *never* compete on price. Specifically, Lundbeck argues that (1) it has always been "committed to" a strategy of refusing to compete on price with generic Indocin (if and when that drug enters the market), and (2) it has no "more compelling economic incentive to price compete with NeoProfen than it had to price compete with generic indomethacin." Def. Post-Trial Br. 32. Both prongs of this argument are incorrect. Lundbeck ignores the evidence that it planned a price response to the entry of generic Indocin; and it draws a specious comparison between brand-to-generic and brand-to-brand competition. *See id.* at 34-39.

First, as two Lundbeck witnesses — Michael Burke and Dr. McCarthy — testified, Lundbeck planned to respond to the entry of generic Indocin by launching a "private label" or "authorized" generic.²⁴ A branded drug maker launches an authorized generic to compete on price with other companies selling the generic molecule, without

²¹ Tr. 226:3-11 (Payne).

²² PPFF § VI.A.

²³ See PPFF ¶¶ 6.117–6.119, 6.123–6.128; Pl. Resp. DPFF ¶¶ 296, 303-304.

²⁴ Tr. 579:11-18, 587:8-21 (Burke); Tr. 1341:6–1342:12 (McCarthy); *see also* PPFF ¶ 8.12; PX 84; PX 44 at 3.

affecting the price it charges for the branded drug.²⁵ Therefore, contrary to its alleged "commitment," Lundbeck contemplated competing against the generic on price.

Furthermore, the economic logic of brand-to-generic competition between sellers of bioequivalent (or nearly equivalent) drugs does not support predictions regarding competition between substitutable *branded* drugs, such as Indocin IV and NeoProfen. As Lundbeck acknowledges, the principal reason for a branded manufacturer not to respond to generic entry in the hospital setting is the prevalence of formulary policies requiring automatic substitution of generic drugs for brands.²⁶ A branded seller knows that given such rules, no price sensitive customers will buy the brand (although they may buy an authorized or "private label" generic — which allows a branded manufacturer to compete on price).²⁷

However, the seller of a branded drug competing with a similar, but not identical, branded drug faces a fundamentally different market response. When drugs are "differentiated" and close, but less-than-perfect clinical substitutes, automatic substitution does not occur, and it is rational — as in any other competitive market — for sellers to negotiate with price-sensitive customers to win or retain market share. Sellers know that customers can move share toward or away from a drug to obtain price concessions, but

²⁵ See PPFF ¶ 8.12; Pl. Resp. DPFF ¶¶ 78, 347.

²⁶ See Def. Post-Trial Br. 35. In retail and over-the-counter markets, a manufacturer might maintain or raise the price of a branded drug in response to generic entry if it believes some customers will insist on buying the brand, regardless of price. But there is no evidence that such customers exist in the hospital setting. See Pl. Resp. DPFF ¶ 78.

²⁷ Tr. 579:11-18, 587:8-21 (Burke); Tr. 1341:6-1342:12 (McCarthy); see PPFF ¶8.12.

that shifts in share are not inevitable and (unlike generic substitution) may be reversible on economic grounds.²⁸

If Lundbeck's categorical assertions about branded manufacturers' economic incentives were accurate, no brands would compete on price. Yet the two hospital contracting officials, Ambrose Carrejo of the Kaiser Health Plan and Amarylis Gutierrez of the Los Angeles County Department of Health Services, testified that price competition between substitutable, branded drugs is common.²⁹

Attempting to minimize this uncontradicted evidence, Lundbeck asserts incorrectly that Dr. Carrejo testified that the 20 percent rebate offered by Lundbeck for first-time purchases of NeoProfen "was not enough to make him . . . try NeoProfen." Def. Post-Trial Br. 54 (citing Tr. 352:3-23 (Carrejo)). He actually testified that the drawback was not the size, but the one-time nature of that discount, as Kaiser shifts share between drugs based upon three- to five-year purchase contracts. Lundbeck also claims that Dr. Gutierrez "admitted that an 8% price differential was not enough to make her even consider the relative costs of the two drugs." *Id.* at 54 (citing Tr. 65:17-25, 866:9-15 (Gutierrez)). But Dr. Gutierrez testified that this occurred when her hospital system was catching up with a P&T committee review backlog and focusing on ways to obtain large cost savings with the least effort ("low-hanging fruit"). Although, due to the

²⁸ PPFF ¶¶ 6.108–6.113; 6.117–6.128.

Tr. 317:17-23 (Carrejo); Tr. 831:8-23 (Gutierrez). Testimony by officials of the Child Health Corporation of America and Premier Inc., a group purchasing organization, supports the same conclusion. *See* Wilson Dep. 27:10–28:14; Russell Dep. 25:2-13.

Tr. 318:22–319:1 (Carrejo).

³¹ Tr. 829:1-14 (Gutierrez).

monopoly, the hospitals still cannot negotiate lower prices for PDA drugs, the P&T committee is now revisiting the issue of whether Los Angeles County could save money by buying only one PDA drug.³²

C. Indocin IV and NeoProfen Are Economic Substitutes

Lundbeck argues that even if Indocin IV and NeoProfen are functional substitutes, they are not economic substitutes, as there is allegedly no "real-world evidence" of crosselasticity of demand between them. Def. Post-Trial Br. 43, 51 n.9, 52. As Lundbeck concedes, however, "a mathematical calculation [of cross-elasticity] is not required." *Id.* at 56; *see also id.* at 58; *JamSports & Entm't, LLC v. Paradama Prods., Inc.*, 336 F. Supp. 2d 824, 841 (N.D. Ill. 2004). And the evidence that there would be price competition between independent suppliers of PDA drugs is very real, and establishes that the products are economic substitutes. *See, e.g., SuperTurf, Inc. v. Monsanto Co.*, 660 F.2d 1275, 1278 (8th Cir. 1981); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 995 (11th Cir. 1993). All of the factors that routinely lead to price competition between *other* substitutable, branded, hospital drugs — including price sensitivity among hospitals; clinical substitutability of the drugs; and physician preferences that can be influenced and changed — are present, except that Lundbeck owns both PDA drugs.³³

To support its argument concerning economic substitutability, Lundbeck relies on a number of cases in which courts found that plaintiffs did not establish a relevant antitrust market, for one reason or another. *See* Def. Post-Trial Br. 39-40, 55-58. None

³² Tr. 840:24–842:11 (Gutierrez).

³³ See PPFF ¶¶ 6.3–6.19, 6.51–6.56, 6.61, 6.123–6.128.

of those cases, however, advances Lundbeck's product market argument. Market definition is highly case-specific. As the Court of Appeals for the Eighth Circuit has noted, because "every case requires an *ad hoc* determination of the relevant market . . . , '[t]he decided cases give no real help for an *a priori* determination of interchangeability." *Acme Precision Prods., Inc., v. American Alloys Corp.*, 484 F.2d 1237, 1242 (8th Cir. 1973) (quoting *Diamond Int'l Corp. v. Walterhoefer*, 289 F. Supp. 550, 577 (D. Md. 1968)); *accord Geneva Pharms.*, 386 F.3d at 496.

Indeed, in each case Lundbeck cites, the court based its market definition on evidence, or lack of evidence, specific to that case — and not relevant here. *See, e.g.*, *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 (8th Cir. 1999) (reversing district court's "too narrow" geographic market definition; citing "[t]he proximity of many patients to hospitals in other towns [and] compelling and essentially unrefuted evidence that the switch to another provider by a small percentage of patients would constrain a price increase"); *H.J., Inc. v. Int'l Tel. & Tel. Corp.*, 867 F.2d 1531, 1538 (8th Cir. 1989) (noting the only evidence of *low* cross-elasticity in jury trial was "(1) testimony of the submersible pump's advantages over other types, (2) the suggestion of a trend toward purchase of submersibles, and (3) general (and not consistent) statements of [third-party] personnel as to the lack of competition from the other types"); *United States v. Archer Daniels Midland Co.*, 866 F.2d 242 (8th Cir. 1988) (sugar and high fructose corn syrup not economic substitutes because of government sugar price supports); *U.S. Anchor*, 7

F.3d at 996-97 (branded and generic anchors not economic substitutes in light of "unusual" customer brand loyalty and persistent and significant price differentials).³⁴

Moreover, to the extent relevant, one case cited by Lundbeck shows that courts have long recognized brand-to-brand competition between hospital pharmaceuticals. In *SmithKline*, the Third Circuit upheld the district court's ruling that cephalosporins, a type of antibiotic, constituted the relevant product market. 575 F.2d at 1064-65, *cited in* Def. Post-Trial Br. 40. That market included not just one drug, but numerous competing, branded cephalosporins. *Id.* at 1065. By contrast, non-cephalosporins were excluded from the market because they were not functional substitutes, *i.e.*, there were "significant differences between [the] groups in . . . effectiveness and toxicity." *Id.* at 1064. Similar in this respect to *SmithKline*, the record here demonstrates that Indocin IV and NeoProfen are equivalently safe and effective, and are substitutable for the treatment of virtually all babies with PDA. 35

II. Lundbeck's Acquisition of NeoProfen Illegally Maintained Its PDA Drug Monopoly and Is Anticompetitive

Lundbeck's acquisition of the rights to NeoProfen preserved and extended

Lundbeck's PDA drug monopoly and has had the anticompetitive effect of suppressing,

Lundbeck also cites two matters in which the FTC alleged drug markets that included generics but not branded substitutes. *See* Def. Post-Trial Br. 40 (citing *Biovail Corp.*, 134 F.T.C. 407 (2002), and *Bristol-Meyers Squibb Co.*, FTC Dkt. No. C-4076 (April 2003) (complaint)). In both cases, however, the relevant consumer harm arose directly from the loss of generic competition. In circumstances more similar to this case, the FTC has identified markets including all drugs treating a given condition. *See, e.g., Pfizer, Inc. & Pharmacia Corp.*, FTC Dkt. No. C-4075 (May 2003) (complaint challenging merger in market for "prescription drugs for the treatment of [erectile dysfunction]").

See PPFF § VI.

for four years and counting, price competition from which hospitals and consumers would have benefited. *See* Pl. Post-Trial Br. 20-23. Accordingly, all of the elements of antitrust liability — durable monopoly power, an exclusionary acquisition, and prices above the competitive level — are established. *See*, *e.g.*, *El Paso Natural Gas*, 376 U.S. at 660-62; *Yamaha Motor Co. v. FTC*, 657 F.2d 971, 977 (8th Cir. 1981); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 78-80 (D.C. Cir. 2001).

Lundbeck argues that the record does not show "actual" anticompetitive effects, *i.e.*, that "the NeoProfen acquisition eliminated price competition that otherwise would have forced the prices of both drugs down from their lawful launch prices." Def. Post-Trial Br. 14. Lundbeck hypothesizes that the prices charged even by two *competing* sellers of FDA-approved PDA drugs would be identical to the prices charged by a monopolist. *See id.* at 6-14. But that argument — essentially, "competition doesn't work" — conflicts with black-letter antitrust law, which incorporates fundamental economic principles recognizing the benefits of competition. In any event, the record confirms what the law presumes and economic theory predicts — that purchasers of PDA drugs would benefit from the competition precluded by Lundbeck's illegal acquisition.

A. Lundbeck Charges Monopoly Prices for Indocin IV and NeoProfen

To begin, Lundbeck unquestionably charges monopoly prices for both PDA drugs. There is no dispute that when Lundbeck acquired Indocin IV, it acquired a monopoly and could set the price of Indocin IV essentially wherever it wanted. *See* Def. Post-Trial Br. 15, 30; Tr. 1091:9-20 (Arnold). Lundbeck exercised this power to its full extent only after it acquired NeoProfen in January 2006, setting the price of Indocin IV at \$1,500 per

course treatment, which was higher than any competitive price indicated by Lundbeck's own models (*i.e.*, the price level following generic entry). Lundbeck later set a similar price for NeoProfen, and has maintained those prices over the last four years.³⁶

Lundbeck's demonstrated ability to control prices is the textbook definition of monopoly pricing. *See United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956) (defining monopoly power as "the power to control prices"). And monopoly prices are, by definition, above competitive levels, *i.e.*, supracompetitive. The issue, therefore, is not whether Lundbeck is currently charging monopoly or supracompetitive prices for Indocin IV and NeoProfen — of course it is. Rather, the issue is whether Lundbeck could charge the same monopoly prices if it faced competition from an independent seller of NeoProfen.

B. The Law Presumes Consumer Harm When an Acquisition Creates or Protects Monopoly Power

According to Lundbeck, the presence or absence of competition makes no difference to purchasers of PDA drugs. But that argument flies in the face of basic economics and is directly at odds with settled law. As the Supreme Court put it nearly 60 years ago: "The heart of our national economic policy long has been faith in the value of competition." *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951). Indeed, the antitrust laws reflect "a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services." *National Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978).

³⁶ Stips. 65, 67-69, 111, 119; PPFF \P 7.1.

These tenets underlie the rule, demonstrated in our prior brief, that an acquisition that creates or protects a *literal monopoly* "bears a very strong presumption of illegality that should rarely be defeated." Pl. Post-Trial Br. 6 (quoting Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 912a (3d ed. 2006)); *see*, *e.g.*, *El Paso Natural Gas*, 376 U.S. at 660-62; *Franklin Elec.*, 130 F. Supp.2d at 1035 (noting merger to monopoly is anticompetitive "by definition"); *Chicago Bridge & Iron Co.*, 138 F.T.C. 1024, 1065 (2005) (merger to monopoly carries a "very strong presumption that [it] is anticompetitive"), *aff'd*, 534 F.3d 410, 423 (5th Cir. 2008); *see also United States v. General Dynamics Corp.*, 415 U.S. 486, 496-97 (1974) (holding that transaction that creates or exacerbates high market concentration is *prima facie* unlawful).

Lundbeck argues that, because the NeoProfen acquisition is completed, this presumptive condemnation of monopolies disappears, and we must prove that "the transaction resulted in actual anticompetitive harm, not just the prospect of harm." Def. Post-Trial Br. 22. This statement of the required proof of anticompetitive effects is simply wrong. Under section 7 of the Clayton Act, plaintiffs must demonstrate that the effect of the NeoProfen acquisition "may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. The word "may" indicates that Congress' "concern was with probabilities, not certainties." *Brown Shoe*, 370 U.S. at 323.

As the Supreme Court makes clear in *FTC v. Consolidated Foods*, 380 U.S. 592 (1965), this "probabilities" standard is the same whether the acquisition has been consummated or not: "[T]he force of [section] 7 is still in probabilities, not in what later transpired." *Id.* at 598. The Court explained that examining the "probable anti-

competitive effect of the [consummated] merger" – rather than the actual effect – is appropriate because "once the two companies are united no one knows what the fate of the acquired company and its competitors would have been but for the merger." *Id.*; *see also Midwestern Mach., Inc. v. Northwest Airlines, Inc.*, 167 F.3d 439, 442 (8th Cir. 1999) ("[A] violation can occur when there is a *threat or possibility* of substantially lessening competition . . . [n]o restraints, monopolies, or substantial lessening of competition need actually occur.") (emphasis in original); *Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008) (applying incipiency standard to consummated merger); *Yamaha*, 657 F.2d at 977 ("[T]he question under Section 7 is not whether competition was actually lessened, but whether it 'may be' lessened substantially.").

Similarly, plaintiffs' monopolization claims require proof that the acquisition was "reasonably capable of contributing significantly to . . . continued monopoly power." *Microsoft*, 253 F.3d at 79; *see also United States v. Grinnell Corp.*, 384 U.S. 563, 576 (1966) (finding monopolization where monopolist "eliminated any possibility of an outbreak of competition"); 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.").

The "reasonably capable" standard is satisfied where, as here, a monopolist has made an acquisition that protected its monopoly. *See* Pl. Post-Trial Br. 5-10. Lundbeck's proposed "actual harm" standard for a completed acquisition has no basis in the case law. None of the three cases that Lundbeck cites as support for it is on point. *See* Def. Post-Trial Br. 22-23. None of them involved a merger or acquisition, and none even addresses

liability under the Clayton Act.³⁷ And one of the cases, *Microsoft*, actually holds that monopolization claims do *not* require proof of "actual harm." *See* 253 F.3d at 78-79.³⁸

Moreover, Lundbeck's attempts to reconcile the Eighth Circuit's *Yamaha* decision and the decision of the Supreme Court in *Consolidated Foods* with its heightened "actual harm" standard fail. *See* Def. Post-Trial Br. 24-25. The *Yamaha* Court did not, as Lundbeck claims, require "substantial proof" that an agreement eliminating competition by a potential entrant had a specific price effect. *Id.* at 24. Rather, the Eighth Circuit considered whether Yahama was, in fact, a potential entrant. After finding that it was, the Court readily concluded that additional competition would lead to lower prices: "Any new entrant . . . would have had an obvious procompetitive effect leading to some deconcentration." *Yamaha*, 657 F.2d at 979. Here, since NeoProfen was an imminent entrant into the PDA drug market, it follows that independent entry by NeoProfen would likewise be "obvious[ly] procompetitive." *Id.*

Lundbeck does not dispute that in *Consolidated Foods*, the Supreme Court applied a traditional section 7 inquiry focused on "probabilities, not [o]n what later transpired." 380 U.S. at 598. Instead, Lundbeck suggests that the holding of *Consolidated Foods* is

³⁷ See Rambus Inc. v. FTC, 522 F.3d 456 (D.C. Cir. 2008) (monopolization claims under Sherman Act section 2 alleging abuse of standard-setting process); *Microsoft*, 253 F.3d 34 (monopolization count alleging that Microsoft maintained software monopoly with licensing restrictions, product designs, and other conduct); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785 (8th Cir. 2006) (restraint of trade claim under Sherman Act section 1 alleging conspiracy to prevent importation of prescription drugs).

In *Rambus*, the D.C. Circuit held that the evidence before the FTC suggested that Rambus's conduct increased its monopoly prices, but that this was not the result of reducing *competition*, as Rambus would have been a monopolist in the but-for world as well. 533 F.3d at 464-69. *Rambus* does not purport to overrule *Microsoft*.

somehow limited to circumstances in which the defendant declines to exercise newly-acquired market power. *See* Def. Post-Trial Br. 24-25. This holding of *Consolidated Foods*, however, has never been limited to the facts of that case. Indeed, nearly a decade after *Consolidated Foods*, the Supreme Court repeated that, when evaluating a consummated merger, post-acquisition evidence has "extremely limited" probative value. *General Dynamics*, 415 U.S. at 576.

Thus, Lundbeck points to no reason not to enforce in this case the heavy presumption against conduct by a monopolist that prevents "an outbreak of competition." *Grinnell*, 384 U.S. at 576.

C. Lundbeck's Illegal Acquisition Led to Higher Prices

Moreover, the trial record demonstrates that, as expected, consumers would benefit from the competition eliminated by Lundbeck's acquisition. Because Lundbeck made sure that there has never been a period of independent competition between Indocin IV and NeoProfen, there is no evidence of the specific prices actually charged under competitive conditions. It stands to reason, however, that competition between Indocin IV and NeoProfen would result in lower prices. Indeed, the economics experts agree that a duopoly price generally is lower than a monopoly price.³⁹ As Dr. Arnold explained:

[E]very model of duopoly competition that economists have teach that the price, as a result of duopoly competition, would be lower than the price that one would get in a monopoly . . . [a]nd how much lower is the part that's not possible to know, but the fact that the price would be lower is something that I have an extremely high degree of confidence in. ⁴⁰

³⁹ Tr. 1297:20-21 (McCarthy) ("[I]t is true that most duopoly models would predict some level of competition.").

⁴⁰ Tr. 1002:8-19 (Arnold).

The record confirms that if NeoProfen and Indocin IV were separately owned, prices of both drugs would be lower today.⁴¹

Lundbeck attempts to make much of Dr. Arnold's testimony that Lundbeck "could have" charged as much as it wanted for Indocin IV before entry of an independentlyowned NeoProfen. See Def. Post-Trial Br. 18, 85 (quoting Tr. 1091:9-14 (Arnold)). But, as Dr. Arnold explained, "the expectation of NeoProfen's approval and entry would have disciplined" Lundbeck's pricing of Indocin IV. 42 Dr. Arnold emphasized that the price competition that would occur once NeoProfen was on the market – when the two independently-owned PDA drugs would have vied for placement on hospital formularies – would have lowered prices for both drugs. Thus, he agreed that elimination of this competition could properly be termed "the major portion" of the competitive dynamic affected by the acquisition. ⁴³ But he also testified that, absent the NeoProfen acquisition, Lundbeck would not have raised the price of Indocin IV to \$1,500 in January 2006.⁴⁴ As he noted, in the "but for" world, Lundbeck would have put itself at risk, because a very high initial price for Indocin IV would affect later competition with NeoProfen for placement on hospital formularies.⁴⁵

Lundbeck's contemporaneous business documents support Dr. Arnold's conclusion. As noted in our post-trial brief, the evidence concerning Lundbeck's price

⁴¹ Tr. 317:17-23 (Carrejo); 840:8-15 (Gutierrez).

⁴² Tr. 1044:4-6 (Arnold).

⁴³ Tr. 1092:10-20 (Arnold).

⁴⁴ Tr. 1001:1-10 (Arnold).

⁴⁵ Tr. 1044:14-21 (Arnold).

projections for Indocin IV prior to the January 2006 price increase shows that these prices fluctuated depending on whether Lundbeck expected that it would face competition from NeoProfen. Lundbeck's models and projections included higher prices when it appeared that Lundbeck would own both PDA drugs, and lower prices (below \$1,140 per three-vial course of treatment) when it feared that it would have to compete with an independent owner of NeoProfen.

The evidence also shows that Abbott would have been unlikely to price NeoProfen at anything near \$1,500 per course of treatment. Ned McCoy of Abbott Laboratories explained that Abbott consistently assumed a NeoProfen price of \$450 to \$500 per course of treatment in its deal model and marketing presentations. Mr. McCoy also described Abbott's concern about its "reputation in the NICU" when it learned of Lundbeck's dramatic price increase for Indocin IV. Abbott sells nutritional products for NICUs and pediatric units, and these products were "by far the bulk of sales" relative to pharmaceutical products for the NICU and pediatric units. Thus, Mr. McCoy testified, Abbott was concerned that co-promoting Indocin IV and NeoProfen at the high prices that Lundbeck had set would "have an impact on [Abbott's]... reputation in the NICU"

⁴⁶ PPFF ¶ 8.26.

⁴⁷ See PPFF ¶¶ 5.44-5.46.

⁴⁸ PPFF ¶¶ 5.49-5.51.

⁴⁹ McCoy Dep. 50:3-16; 51:11-17. Abbott projected these prices when it had anticipated an FDA label that contained superiority claims relative to Indocin IV, which did not in fact occur. *See* PPFF §VI.A.3.

⁵⁰ McCoy Dep. 53:23-54:7.

⁵¹ McCoy Dep. 21:23-23:1.

and adversely affect Abbott's marketing of other products.⁵² These concerns make it unlikely that Abbott would have tripled the price it projected for NeoProfen. In sum, the record indicates that competition between Indocin IV and NeoProfen would have resulted in lower prices.

III. Divestiture of NeoProfen Is Required to Restore the Competition That Lundbeck's Illegal Acquisition Foreclosed

Lundbeck's illegal acquisition of NeoProfen has given it a durable, four-years-and-running monopoly in PDA drugs. An "undoing of the acquisition" is the "natural remedy" for that violation. *du Pont*, 366 U.S. at 329. Lundbeck insists, however, that the recently announced entry by Bedford with a generic version of Indocin IV makes divestiture unnecessary. Def. Post-Trial Br. 87-89. Lundbeck's argument misstates the law and ignores the record.

Lundbeck cites no case in which a court has held an acquisition illegal but deemed divestiture unnecessary because of post-acquisition entry, let alone a case involving a merger to monopoly.⁵³ Instead, it invents a new rule that turns the law on its head. In place of long-standing Supreme Court precedent establishing a presumption in favor of divestiture in cases of illegal mergers and acquisitions,⁵⁴ Lundbeck offers a presumption

⁵² McCoy Dep. 35:13-36:14, 53:17-53:22, 53:15- 55:3.

⁵³ The section of the Areeda & Hovenkamp treatise Lundbeck cites merely suggests that divestiture should be inappropriate in a hypothetical scenario in which the merged firm's 20 percent market share has fallen to 2 percent by the time of suit. Areeda ¶ 1205b. ⁵⁴ *See, e.g., du Pont*, 366 U.S. at 331 (divestiture "should always be in the forefront of a

court's mind when a violation of § 7 has been found"); *California v. Am. Stores Co.*, 495 U.S. 271, 280-81, 285 (1990) (stating "in Government actions divestiture is the preferred remedy for an illegal merger or acquisition" and referring to divestiture as "the remedy best suited to redress the ills of an anticompetitive merger").

against divestiture, declaring it "inappropriate unless needed to restore a competitive market structure that natural market forces will not otherwise cure." Def. Post-Trial Br. 87. Lundbeck's proposed rule flies in the face of Supreme Court authority; rather than demanding certainty that divestiture is the only possible way to restore competition, the Supreme Court has stressed the need for certainty that the violation has been effectively remedied. Thus, in *du Pont*, the Supreme Court rejected remedies short of complete divestiture, because "under this arrangement there can be little assurance of the dissolution of the intercorporate community of interest which we found to violate the law." 366 U.S. at 331. Divestiture provides a "surer, clearer remedy" and "it is well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *Id.* at 334. These principles have particular force in this case, where the illegal acquisition served to preserve a monopoly.

In any event, the record amply supports the conclusion that divestiture of NeoProfen is necessary to restore competition foreclosed by Lundbeck's unlawful acquisition. First, Lundbeck's assertion that "imminent market entry of generic indomethacin will achieve the same result as a structural remedy" ignores the competitive structure of the "but-for" world that an effective remedy must seek to restore: a market in which Bedford's generic Indocin entry introduces a third, rather than a second, competitor. Def. Post-Trial Br. 89. Lundbeck effectively asks the Court to assume –

contrary to both the law and the record evidence⁵⁵ – that a two-competitor PDA drug market would provide the same intensity of competition as the but-for world of three competitors.⁵⁶

Moreover, the record demonstrates that the impact of Bedford's entry into the PDA market remains uncertain. As plaintiffs have previously noted, there is considerable uncertainty about Bedford's ability to compete effectively given its difficulties in bringing its generic product to market, as well as the time it might take to substantially reduce Lundbeck's market share.⁵⁷ Divestiture would immediately deprive Lundbeck of the significant share of the PDA drug market currently represented by NeoProfen sales.⁵⁸ After four years of Lundbeck's illegal monopoly, "the public is entitled to the surer, clearer remedy of divestiture." *du Pont*, 366 U.S. at 334.

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⁵⁵ See, e.g., FTC v. H.J. Heinz Co., 246 F. 3d 708, 716-17 (D.C. Cir. 2001) (noting strong legal presumption against 3 to 2 mergers); PPFF ¶¶ 8.10-8.12 (evidence showing that a market including both Bedford and an independently-owned NeoProfen would mean greater competition and lower prices for PDA drugs).

While claiming any divestiture is unnecessary, Lundbeck suggests in a footnote that divestiture of either NeoProfen or Indocin IV would be equally effective. Def. Post-Trial Br. 87 n.27. It is the NeoProfen acquisition, however, that is illegal and thus it is NeoProfen that Lundbeck should be required to divest. Moreover, divesting Indocin IV would be less likely to restore the competition that Lundbeck's violation foreclosed. Factors such as NeoProfen's patent protection and the difficulties involved in making Indocin IV (PPFF ¶¶ 7.11-7.16), make it more likely that NeoProfen would attract a divestiture buyer that will be committed to remain in the market and compete.

⁵⁷ Pl. Post-Trial Br. 24-25; Stipulation 90 (Bedford received FDA approval in July 2008); PPFF ¶ 7.11 (in April 2009, Bedford's earliest projected entry date was December 2009); PPFF ¶ 7.14 (Bedford has found generic Indocin IV difficult to make); PPFF ¶ 8.9 (Lundbeck's own models project a slow transition from branded Indocin IV to generic indomethacin).

⁵⁸ PPFF § VIII.A.

IV. Disgorgement of Ill-Gotten Gains Is Necessary to Deprive Lundbeck of the Benefits of Its Unlawful Conduct

A. Disgorgement Is Appropriate in This Case

Lundbeck does not challenge this Court's well-established authority to order disgorgement of Lundbeck's ill-gotten gains. *See, e.g., United States v. Perry*, 152 F.3d 900, 903 (8th Cir. 1998) ("[t]he disgorgement remedy . . . has long been upheld as within the general equity powers granted to the district court.") (internal quotation omitted)). Nor does Lundbeck contest the FTC's well-established authority to seek disgorgement under Section 13(b) of the FTC Act. *See FTC v. Security Rare Coin & Bullion Corp.*, 931 F.2d 1312, 1314 (8th Cir. 1991) ("Section 13(b) authorizes district courts to grant ancillary equitable relief in proper cases."). ⁵⁹ Indeed, in *FTC v. The Hearst Trust*, the FTC sought and obtained \$19 million in disgorgement for an unlawful merger to monopoly. ⁶⁰

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⁵⁹ See also QT, 512 F.3d at 863 ("Disgorging profits is an appropriate remedy."); FTC v. Magui Publishers, Inc., 1991 U.S. Dist. LEXIS 20452, *48 (C.D. Cal. Mar. 28 1991) ("The authority to issue an order requiring the defendants to disgorge their profits is also included within the power of Section 13(b)."); cf. FTC v. Southwest Sunsites, Inc., 665 F.2d 711, 719 (5th Cir. 1982) ("Section 13(b) contains no express limitations on the otherwise full powers of the district court to mold appropriate decrees under its traditional equitable jurisdiction, and we decline to tie the hands of the district court without such express limitation.").

⁶⁰ See Final Order and Stipulated Permanent Injunction, FTC File No. 01-734 (Dec. 14, 2001), available at http://www.ftc.gov/os/2001/12/hearstfinalorder.pdf; Complaint, FTC File No. 01-734 (Apr. 4, 2001), available at http://www.ftc.gov/os/2001/04/hearstcmp.htm. Lundbeck incorrectly asserts that the disgorgement award in *Hearst* stemmed from the defendant's failure to submit required documents in its pre-merger government filing. Def. Post-Trial Br. 74-75 n.14. The government obtained a separate \$4 million civil penalty for that violation. See United States v. The Hearst Trust, Final Judgment, No. 01-2119 (D.D.C. Oct. 15, 2001).

Instead, Lundbeck claims that a 2003 Commission policy statement concerning monetary remedies makes disgorgement in this particular case inappropriate and even unconstitutional. Def. Post-Trial Br. 75-80. Lundbeck begins by mischaracterizing the policy statement as the FTC's interpretation of when the agency "can seek equitable monetary remedies." *Id.* In fact, however, the policy statement makes clear that it merely describes factors the Commission considers in its own internal deliberations about when to "seek, as a matter of prosecutorial discretion, monetary equitable remedies (particularly disgorgement or restitution) in competition cases brought pursuant to Section 13(b) of the FTC Act." Indeed, the policy statement expressly provides:

This statement sets forth some observations and intentions of the Commission regarding its exercise of discretion in determining whether to seek monetary equitable remedies in competition cases. It does not create any right or obligation, impose any element of proof, or adjust the burden of proof or production of evidence on any particular issue, as those standards have been established by the courts.

Id. at n.4.

The bipartisan Commission decided unanimously that seeking disgorgement of Lundbeck's ill-gotten gains is appropriate and consistent with its policy guidelines.⁶² The only issue now is whether the Court should exercise its broad equitable powers to order

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⁶¹ FTC, "Policy Statement on Monetary Equitable Remedies in Competition Cases," July 25, 2003 [hereinafter *FTC Policy Statement*] (emphasis added), *available at* http://www.ftc.gov/os/2003/07/disgorgementfrn.htm.

⁶² See Press Release, FTC, FTC sues Ovation Pharmaceuticals for Illegally Acquiring Drug Used to Treat Premature Babies with Life-Threatening Heart Condition (Dec. 16, 2008), available at http://www.ftc.gov/opa/2008/12/ovation.shtm. Notably, the Commission voted out its complaint after Lundbeck availed itself of the opportunity to meet with individual Commissioners and present its arguments.

disgorgement. The Commission's internal policy statement has no relevance to that question.

In any event, Lundbeck's claim that the Commission deviated from the three factors set forth in the policy statement is spurious. First, the conduct at issue – effectively a merger to monopoly – is a "clear violation" of the antitrust laws. *Id.* As the policy statement observes:

It is axiomatic that a merger of the only significant competitors in a market (absent unusual circumstances such as proof of the "failing firm" criteria of Section 5 of the Horizontal Merger Guidelines) violates the letter of the Clayton and Sherman Acts. ⁶³

Lundbeck's suggestion that its illegal conduct was no more than a "garden variety merger" merely repeats its (unpersuasive) arguments on the merits. Def. Post-Trial Br. 75-76, 79. Second, there is a reasonable basis for calculating the disgorgement amount. *See infra* Section IV.B. Third, neither the policy statement nor the case law provides that the mere possibility of damage awards in the pending follow-on private actions makes disgorgement inappropriate in a government action brought to vindicate the public interest. *See SEC v. Tome*, 833 F.2d 1086, 1096 (2d Cir. 1987) ("Whether or not any investors may be entitled to money damages is immaterial" to the government's disgorgement award); *Magui Publishers*, 1991 U.S. Dist. LEXIS 20452, at *49 ("Whether or not any consumers are entitled to damages is immaterial" to disgorgement). 64 Moreover, as the policy statement points out, procedural mechanisms

⁶³ FTC Policy Statement, at n.10.

Lundbeck's claim that the policy statement "state[s] that disgorgement is inappropriate where there is a viable threat of class actions or risk of double recovery" is manifestly

are routinely employed to avoid duplicative recoveries. *FTC Policy Statement* at 3 & n. 16; *see also* Pl. Post-Trial Br. 34.

Lundbeck's attempt to invoke principles of "fair notice" is also without merit.

Def. Post-Trial Br. 79-80. Lundbeck claims disgorgement would violate what it calls "the Equitable Doctrine of Fair Notice," but it relies on cases concerning the imposition of penalties — not equitable remedies. *Id*. Disgorgement, however, is not punishment. It seeks merely to deprive a violator of ill-gotten gains. The other cases Lundbeck cites address whether a defendant had fair notice that its action could be deemed unlawful, not whether an equitable remedy for a violation could be imposed. Here, there is no question that Lundbeck's NeoProfen acquisition is subject to the antitrust laws. In any event, the policy statement and the FTC's past cases provide ample notice that disgorgement may be sought in certain merger cases, especially mergers to monopoly. Moreover, it is well understood that antitrust violators may face treble damages awards in

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untrue. Def. Post-Trial Br. 79. The policy statement merely observes that seeking disgorgement may be "an unnecessary and unwise expenditure of limited agency resources" when other remedies are likely to accomplish fully the purposes of the antitrust laws. *FTC Policy Statement* at 2. As explained previously, disgorgement is an appropriate equitable remedy in this case, and necessary to ensure that Lundbeck does not reap the rewards of its unlawful conduct.

⁶⁵ See BMW of N. Am. v. Gore, 517 U.S. 559 (1996) (stating that punitive damage award that is "grossly excessive" in relation to legitimate interests in punishment and deterrence violates Due Process Clause); *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (holding that Due Process Clause forbids use of punitive damage award to punish defendant for injuries to non-parties).

⁶⁶ See Grayned v. City of Rockford, 408 U.S. 104 (1972) (holding anti-noise ordinance not unconstitutional); see also Gen. Elec. Co. v. United States EPA, 53 F.3d 1324 (D.C. Cir. 1995) (reversing violation and fine where defendant did not have fair notice of agency's new interpretation of the regulation defendant was charged with violating).

suits brought by private parties. Lundbeck can hardly claim surprise that antitrust liability could result in its having to return money to overcharged customers.

B. Lundbeck's Ill-Gotten Gains Are Substantial

In addition to arguing that a disgorgement remedy would be inappropriate in this case as a matter of policy, Lundbeck claims that, in any event, there are no ill-gotten gains to disgorge. Def. Post-Trial Br. 73. This claim is without merit. In our initial post-trial brief and in more detail here, plaintiffs put forward two methods to reasonably approximate Lundbeck's ill-gotten gains. Both of these methods are supported by the evidentiary record.

1. Last Available Market Price Approach

A reasonable approximation of Lundbeck's illegal gains can be calculated by using the last available market price of Indocin IV, that is, the actual price Lundbeck charged immediately before it unlawfully acquired NeoProfen. Using this last market price, and comparing it to the price Lundbeck charged after the illegal acquisition, Dr. Arnold reasonably calculated the ill-gotten gains attributable to Lundbeck's illegal acquisition at \$105 million through April 2009. Pl. Post-Trial Br. 35-37. This is a simple, straightforward, and effective method to calculate gains.

Lundbeck claims that this approach is unreliable because it is not based on a "but-for" competitive price. Def. Post-Trial Br. 82. Although paying lip-service to the appropriate "reasonable approximation" standard, Lundbeck then wrongly seeks to hold the plaintiffs' disgorgement calculation to the same standard that courts apply in private damage actions. *See* Def. Post-Trial Br. 81-84. To be sure, the circumstances here

created by Lundbeck do not permit a precise identification of a competitive price.

Because of Lundbeck's illegal acquisition, there is no evidence of prices actually charged under competitive conditions. Equity, however, does not require precision, and the standards are less exacting in government actions brought to vindicate the public interest. *See, e.g., Am. Stores Co.*, 495 U.S. at 295-96 (in a government antitrust case "the proof of the violation of law may itself establish sufficient public injury to warrant relief"). ⁶⁷

Thus, as the court in *SEC. v. First City Financial Corp.*, 890 F.2d 1215 (D.C. Cir. 1989), observed, "in a private action, the party seeking monetary compensation may have a greater burden to prove its claim to the amount requested." *Id.* at 1232 & n.24.

Dr. Arnold relies on record evidence — the last observable market price of \$108.88 per three-vial package — in his disgorgement calculation. Pl. Post-Trial Br. 35. Dr. Arnold's estimate is a reasonable approximation that comports with the equitable standards that apply in this case. *See, e.g., FTC v. QT, Inc.*, 512 F.3d 858, 864 (7th Cir. 2008) (upholding FTC disgorgement computation as "in the ballpark," stating that a "monetary award often depends on estimation, for defendants may not keep (or may conceal) the data required to make an exact calculation"). Indeed, Dr. Arnold's approach, which only considers incremental revenues generated by sales above the benchmark price, actually understates the NeoProfen ill-gotten gains. Because

⁶⁷ See also Virginian Ry. Co. v. Sys. Fed'n No. 40, 300 U.S. 515, 552 (1937) ("Courts of equity may, and frequently do, go much farther both to give and withhold relief in furtherance of the public interest than they are accustomed to go when only private interests are involved."); *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1058 (10th Cir. 2006) (stating that because the action was filed by the government, the court's equitable jurisdiction is much broader and more flexible).

Lundbeck's acquisition of NeoProfen is illegal, all gains earned as a result of the acquisition are ill-gotten. *First City*, 890 F.2d at 1230 (violator of securities law disclosure requirements required to disgorge all profits realized on sale of stock purchases made after deadline for disclosure). Dr. Arnold's calculation, however, allows Lundbeck to keep the revenues it would have obtained from sales of NeoProfen at the benchmark price.

2. Conservative Minimum Disgorgement Approach

In the alternative, an absolute minimum disgorgement amount can be calculated based on the following three factors:

- The value of ill-gotten gains from NeoProfen sales from 2006 until divestiture, which includes all gains as a result of the illegal acquisition. As discussed below, the illegal gains are about \$25 million as of December 2008, and growing;
- The net proceeds from the divestiture of NeoProfen i.e., the divestiture sale price minus the purchase price;
- The value of ill-gotten gains from Indocin IV sales from 2006 until divestiture. This calculation is based on the difference between the revenues Lundbeck actually received for Indocin IV and the revenues it would have received using a conservative benchmark price of \$1,140 per three-vial treatment. Under this approach, the illegal Indocin IV gains are estimated at \$20 million, as of the end of 2009. Pl. Post-Trial Br. 41-42.

In its brief, Lundbeck tries to take issue with plaintiffs' disgorgement calculation.

Each of its complaints, however, falls far short.

Costs Related to NeoProfen: Lundbeck mistakenly asserts that plaintiffs ignored evidence about costs. Def. Post-Trial Br. 82. Plaintiffs' disgorgement calculation includes appropriate offsets for costs related to NeoProfen, including costs of good sold and royalties payments.⁶⁸ Lundbeck suggests, however, that the disgorgement award should be reduced further to account for every conceivable form of overhead, and other fixed expenses, including general administration, allocations for sales force, marketing and advertising costs, as well as payroll and non-payroll costs associated with virtually every department in the company. When these costs are taken into account, Lundbeck asserts, NeoProfen still is "not profitable" and Indocin IV is making only "meager profits." Def. Post-Trial Br. 84. Lundbeck's position is implausible and not supported by the case law.

Deducting a share of these fixed expenses may be appropriate when accounting for a product's profitability on a financial statement. But calculating the amount of disgorgement is not an accounting exercise. Rather, it is a legal assessment of ill-gotten gains "designed to deprive a wrongdoer of his unjust enrichment." *First City*, 890 F.2d at 1231. In calculating the disgorgement amount, courts in equity routinely prohibit deductions for overhead and other fixed expenses that might be included in ordinary

⁶⁸ *See* Pl. Resp. DRFF ¶ 354.

⁶⁹ See Vitex Mfg. Corp. v. Caribtex Corp., 377 F.2d 795, 798-99 (3d Cir. 1967) (distinguishing the accounting treatment of overhead from treatment of overhead for calculating lost profits).

business profit measurements in order to ensure that a wrongdoer does not profit from its illegal conduct. *See, e.g., SEC v. Blavin*, 760 F.2d 706, 713 (6th Cir. 1985) (awarding disgorgement based on defendant's revenues; no deduction taken for expenses). As the court in *SEC v. Great Lakes Equities Co.*, explained:

[T]here is no basis for deducting the costs of fixed expenses since those expenses would be incurred whether or not the illegal conduct took place. By allowing a deduction for fixed expenses, part of the proceeds of the [illegal conduct] is being used to defer costs that defendants . . . had to pay in any event, and they would be unjustly enriched by those payments. Clearly defendants . . . should not be allowed to profit by their [illegal conduct].

775 F. Supp. 211, 215 (E.D. Mich. 1991); see also Zippertubing Co., v. Teleflex, Inc., 757 F.2d 1401, 1412 (3d Cir. 1985) ("The wrongdoer should not be permitted [to use the illegal profits] to help absorb fixed expenses of its own business."); SEC v. Hughes Capital Corp., 917 F. Supp. 1080, 1087 (D.N.J. 1996) ("[T]he overwhelming weight of authority holds that securities law violators may not offset their disgorgement liability with business expenses."); SEC v. World Gambling Corp., 555 F. Supp. 930, 935 (S.D.N.Y. 1983) (not appropriate to reduce disgorgement award by overhead costs); see also Taylor v. Meirick, 712 F.2d 1112, 1120 (7th Cir. 1983) (in calculating lost profits, "[c]osts that would be incurred anyway should not be subtracted, because by definition they cannot be avoided by curtailing the profit-making activity").

Similarly, courts have refused to offset the disgorgement total merely because the wrongdoer spent some of the ill-gotten gains, whether it was spent for good purposes or merely to exploit the unlawful conduct and further enlarge its profits. As one court put it:

"Whether [the defendant] chose to use this money to enhance his social standing through

charitable contributions, to travel around the world, or to keep his co-conspirators happy is his own business." *SEC v. Benson*, 657 F. Supp. 1122, 1134 (S.D.N.Y. 1987). The manner in which a defendant chooses to spend the ill-gotten gains, the court held, will not affect the calculation of these gains. *Id.* (refusing to exclude charitable contributions from disgorgement amount). In this instance, the fact that Lundbeck chose to use a portion of its ill-gotten NeoProfen gains to exploit its illegal monopoly through marketing and promoting the illegally-acquired product provides no legal basis to reduce the disgorgement award. *See id.; see also Great Lakes Equities*, 775 F. Supp. at 215. As a practical matter, allowing a defendant to avoid disgorgement and preserve its ill-gotten gains by pouring them back into the sale of the illegally-acquired product would defeat the purpose of the remedy.

Applying these legal principles to Lundbeck's own financial statements demonstrates that Lundbeck has grossly understated its ill-gotten NeoProfen gains. Lundbeck claims an \$11 million loss for NeoProfen as of December 2008.⁷⁰ But as the above case law makes clear, overhead, fixed expenses, and expenditures that exploit the unlawful conduct cannot be deducted from revenues for purposes of calculating disgorgement. When these improper deductions are stripped away, Lundbeck's illegal

⁷⁰ See DPFF ¶ 354, DX 102. Lundbeck relies on DX 102, a draft NeoProfen profit-and-loss statement which reflects an EBIT of negative \$11 million. EBIT includes amortization of the NeoProfen purchase price. Plaintiffs have relied on DX 149, which appears to be the final version of the NeoProfen profit-and-loss statement, and which reflects an EBITDA of negative \$7.5 million. EBITDA excludes amortization of the NeoProfen purchase price. For purposes of calculating disgorgement, however, the relevant numbers are essentially the same because plaintiffs account for the purchase price in the calculation of net proceeds of the divestiture sale. See Pl. Resp. DPFF ¶ 354.

NeoProfen gains were about \$25 million, as of December 2008.⁷¹ These illegal gains, of course, continue to accrue until divestiture. When the NeoProfen asset is sold, the divestiture trustee can apply the same legal principles to calculate NeoProfen's illegal gains after January 2009, and then add that figure to the pre-2009 gains to determine the overall NeoProfen illegal gains to disgorge.

Costs Related to Indocin: Cost considerations are not relevant in determining the ill-gotten gains from Indocin IV because Lundbeck's Indocin IV costs are the same whether it owns NeoProfen or not. The Indocin IV ill-gotten gains are the additional revenues that resulted from the illegal acquisition of NeoProfen. Thus, the key variable in this calculation is the benchmark price for Indocin IV – *i.e.*, the price Lundbeck would have charged had it faced competition from NeoProfen, as compared to the price it actually charged – \$1,500 or more. The record evidence supports a \$1,140 price per three-vial treatment as a highly conservative estimate of the maximum price Lundbeck would have charged had it faced competition. Pl. Post-Tr. Br. 40. The illegal gains are calculated based on the difference between the revenues Lundbeck actually received for Indocin IV at its \$1,500 monopoly price and the revenues it would have received at the \$1,140 price. Since Lundbeck's Indocin IV costs are the same in either scenario, costs are properly ignored in calculating the illegal Indocin IV gains.⁷²

Proceeds of Divestiture of NeoProfen: Lundbeck incorrectly asserts that plaintiffs seek forfeiture of the entire value of the NeoProfen asset at divestiture. Def.

⁷¹ See DX 149; Pl. Resp. DPFF ¶ 354 (explaining in detail the appropriate calculation of the NeoProfen disgorgement amount).

⁷² Tr. 1011:6-1012:2 (Arnold).

Post-Tr. Br. 85-86. Plaintiffs' disgorgement calculation properly accounts for Lundbeck's cost in purchasing NeoProfen, not merely the price Lundbeck obtains from divesting it. Thus, plaintiffs do not seek a forfeiture of the entire divestiture proceeds, as Lundbeck asserts. Instead, plaintiffs seek merely the net proceeds from the sale. Accordingly, the revenues from the divestiture sale should be added to, and the purchase price should be subtracted from, the disgorgement amount. Allowing Lundbeck to retain any net proceeds from the divestiture would reward the violation and undermine the paramount purpose of disgorgement to deprive the wrongdoer of gains "causally related to the wrongdoing." *First City*, 890 F.2d at 1231.

C. Minnesota's Disgorgement Request Is Well-Supported

Notwithstanding Lundbeck's argument to the contrary (Def. Post-Trial Br. 89), *FTC v. Mylan Labs*, 62 F.Supp.2d 25, 48-49 (D.D.C. 1999), does not preclude Minnesota from seeking disgorgement and restitution for all the reasons discussed in pages 29-33 of Plaintiffs' Post-Trial Brief. Minn. Stat. § 8.31, subd. 1 specifically charges the Office of the Minnesota Attorney General ("OAG") with enforcing Minnesota antitrust law. Subdivision 3a of section 8.31 further states that, "[i]n addition to the remedies otherwise provided by law," the OAG is authorized to seek "other equitable relief," such as the equitable remedies of disgorgement and restitution.⁷³ Lundbeck's citation to *Mylan* on

Moreover, subdivision 3a also states that "[i]n any action brought by the attorney general pursuant to this section, the court may award any of the remedies allowable under this subdivision."

this matter also fails to acknowledge that, pursuant to a motion for reconsideration, ⁷⁴ Mylan reversed certain of its prior conclusions, and recognized that state statutes permitting parties to seek equitable relief (such as Minn. Stat. § 8.31) encompass restitution. See FTC v. Mylan Labs, 99 F.Supp.2d 1, 5 (D.D.C. 1999). Lundbeck's assertion that Minnesota antitrust law does not "expressly" authorize equitable relief overlooks the broad grant of antitrust-specific authority in Minn. Stat. § 325D.59 for the OAG to seek all "appropriate" relief in an antitrust action. ⁷⁵ Furthermore, Lundbeck's invocation of *Illinois Brick* has no bearing on Minnesota antitrust law; the Minnesota Supreme Court has recognized that the Minnesota legislature amended state antitrust law by enacting an "*Illinois Brick* repealer" due to the its disagreement with the precedent. Lorix v. Crompton Corp., 736 N.W.2d 619, 626-27 (Minn. 2007).

Secondly, Lundbeck's contention that the OAG has failed to prove its unjust enrichment claim because there is no proof of "un-reimbursed costs incurred by Minnesota hospitals" is wide of the mark. Def. Post-Trial Br. 25. An unjust enrichment claim is a measurement of the benefit unjustly received by a defendant, not of the injury to an aggrieved party, Anderson v. DeLisle, 352 N.W.2d 794, 796 (Minn. App. 1984), and its "computation . . . involves no overriding individual question." Bokusky v. Edina Realty, Inc., 1993 WL 515827, *9 (D. Minn. 1993). Accordingly, any determination by the Court in regards to Lundbeck's liability for any antitrust violations also suffices as a

The motion for reconsideration was brought on behalf of 16 states, although Minnesota was not among them.

⁷⁵ In addition to overlooking the OAG's statutory authority, Lundbeck also fails to realize that the OAG has inherent, common law parens patriae authority to pursue disgorgement and restitution. See Pl. Post-Trial Br. 31-33.

measurement of the improperly retained benefit under the OAG's unjust enrichment claim. The appropriate portion of such relief can then be distributed to Minnesota hospitals in accordance with the larger process that the Court establishes to allocate any monies awarded.

V. Conclusion

Plaintiffs respectfully renew our request for relief. *See* Pl. Post-Trial Br. 43. We have attached to this brief a corrected version of the draft remedial order that we attached to our post-trial brief. The corrected draft order, which was served on Lundbeck on February 10, 2010, is identical to the draft order that we previously filed for Court's convenience, except that it includes a provision requiring Lundbeck to provide prior notification to plaintiffs of future acquisitions (section VIII), which we had inadvertently omitted. We regret any inconvenience to the Court.

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Respectfully submitted,

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