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.	08-cv-6381 (JNE/JJG)

DEFENDANT LUNDBECK INC.'S
REPLY TO PLAINTIFFS' POST TRIAL BRIEF

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I. INTRODUCTION

At trial, Ovation demonstrated that it did not purchase the contingent rights to NeoProfen, as Plaintiffs alleged, in an effort to "corner the market" and eliminate otherwise-inevitable price competition. Ovation purchased NeoProfen precisely because the expected arrival of generic indomethacin would devastate Indocin's future sales, but not those of NeoProfen, thus making NeoProfen a better longer-term opportunity to build an entrée into hospital markets. Neonatologists resoundingly testified they – and not hospital administrators – drive demand for NICU drugs and would not switch between Indocin and NeoProfen to save money. Unchallenged trial evidence also demonstrated that Ovation was committed to the standard industry strategy of not lowering Indocin's price to maintain market share, regardless of generic indomethacin or NeoProfen. As expected, recent developments have confirmed these facts.

Bedford recently introduced generic indomethacin at a price of $500 per vial (or $1,500 per three-vial course of treatment), the same price Ovation lawfully set for Indocin in January 2006. As such, generic indomethacin is seven percent cheaper than branded Indocin's current price, but virtually the same price as NeoProfen. Bedford's pricing strategy is compelling proof that NeoProfen does not compete with generic indomethacin or Indocin. After all, Bedford expects to take virtually all of Indocin's sales at just a seven percent discount, but consistent with its testimony, apparently concluded that a similar discount strategy would not capture NeoProfen sales. Bedford's real-world decisions confirm what Ovation demonstrated at trial – there is no basis to

conclude Ovation rationally would have adopted a different pricing strategy for Indocin in response to NeoProfen if it had been launched by a third-party.

Because Plaintiffs failed to prove the case they charged, they try to oppose facts with theories and speculation. They openly ask the Court to *presume* liability based on just one fact: Indocin and NeoProfen effectively treat the same condition, PDA. From this lone fact, they say, the Court *must* conclude that Indocin and NeoProfen are in the same relevant antitrust market, and once it does so, it *must further presume* that any rational owners of Indocin and NeoProfen would necessarily have engaged in price competition, so that the Court *must further presume* that the NeoProfen acquisition maintained a monopoly. But if Plaintiffs' approach were valid, there would have been no need for a trial – Plaintiffs would have moved for summary judgment. They did not because the one undisputed fact on which they now rest their case – that NeoProfen and Indocin both treat PDA – is not nearly enough to establish liability, nor to justify the extreme remedies Plaintiffs seek.

Plaintiffs' burden at trial was not as simple or low as Plaintiffs wish. Plaintiffs are not entitled to any presumptions, much less the stack of irrebuttable ones they effectively request. (*E.g.,* Pls.' Post Trial Br., Doc. No. 279, at 6 ("liability follows essentially as a matter of law" if Indocin and NeoProfen "are in the same market").) Plaintiffs bear the burden of proving all of the elements established by law, including specifically: (1) the relevant product market; (2) causation of harm to competition; *and* (3) durable market power. Proof of any one of those elements, including market definition, does not obviate

proof of each of the others. Plaintiffs' antitrust claims founder because they did not prove any of those elements, much less all of them.

Market Definition.

Plaintiffs admit that they must prove the relevant market and that market definition turns on proof of cross-price elasticity of demand – *i.e.,* whether the two drugs are economic substitutes. (Pls.' Opp'n to Def.'s Mot. Summ. J., Doc. 117, at 16 ("A product market includes items that buyers can reasonably substitute for one another, *i.e.*, that have reasonably cross-elastic demand.").) But they have offered literally no analysis of cross-price elasticity. Instead, they ask the Court to ignore the overwhelming and uncontradicted evidence that cross-price elasticity is very low, and to focus solely on the simplistic notion that the two drugs must be in the same market because they treat the same condition. That showing of functional substitutability is not enough to prove the relevant market.

Plaintiffs argue that market definition is "dispositive," but they are only half-right. Failure to prove that Indocin and NeoProfen are in the same relevant market is dispositive of Plaintiffs' claims in Ovation's favor, because (1) monopolization claims require definition of the relevant market and (2) the acquisition cannot have harmed the competitive process nor increased market power because two products that are not in the same relevant market do not constrain each other's pricing. The converse, however, is not true. Even if Plaintiffs had met their burden to prove the relevant market – which they did not – that would not excuse them from proving the other elements of their case

which, by their vehement request for presumptions, they implicitly concede they have not done.

Causation of Harm.

Whatever the relevant market may be, Plaintiffs did not prove the essential element of harm to competition: would there have been price competition between Indocin and NeoProfen in the but-for world? They falsely suggest that Ovation bears the burden of proving that there would be no price competition if separate companies owned the two drugs. (Pls.' Post Trial Br., Doc. No. 279, at 20 ("No evidence suggests that rational suppliers faced with that choice [losing sales or reducing price] would not reduce their prices.").) But while Ovation does not bear that burden, it would meet it if it did. As Plaintiffs' own economist showed, there are many situations when two drugs treat the same condition but do not compete with one another on the basis of price – the "Game On" scenario he assumes here is certainly *not* inevitable. Though Plaintiffs ignore it, the evidence is undisputed that Ovation's plan and its rational economic incentive was to keep Indocin's pricing high in the face of all competitive threats, because Indocin offered only a short window in which to recoup Ovation's substantial investment. Thus, in economic terms, there was no mechanism of causation of harm to competition here. Plaintiffs' failure to prove causation of harm by itself defeats Plaintiffs' claims.

Durable Market Power.

Plaintiffs once more ask the Court to assume away reality and presume liability when they address the element of durable market power. Plaintiffs say there "must" be high barriers to entry because actual generic indomethacin entry took longer than

expected. But that is not the test. Durable market power cannot exist unless there are specific, structural characteristics of the market that would be expected to preclude competitive entry. Plaintiffs only claim one such characteristic, the need for regulatory approval, and that is not a barrier to entry here as a matter of law. The lack of entry barriers precludes a finding of market power and, so, dooms Plaintiffs' antitrust claims.

Remedies.

Even if Plaintiffs could prove everything in the Amended Complaint, which they cannot, there is no basis for granting the remedies they seek. Bedford's long-expected entry with generic indomethacin became reality in February 2010. The parties agree generic entry will devastate Indocin's sales. It will immediately deplete Ovation of any market power it allegedly maintained by acquiring NeoProfen. Thus, generic entry has restored the market to competitive conditions, mooting Plaintiffs' request for divestiture. Plaintiffs' implausible suggestion that divestiture will spur more price competition is further undercut by generic indomethacin's recent entry at pricing parity to NeoProfen. Ovation is (and always has been) committed to not lowering Indocin's price to keep sales, particularly during the short remainder of its commercial life.

Nor is there any basis for the disgorgement remedy Plaintiffs seek. No case has considered and awarded the extreme disgorgement sanction that Plaintiffs seek in the absence of truly outrageous conduct. Plaintiffs began this case with a furor of publicity and strident language, accusing Ovation of egregious and "immoral" behavior, but their statements are inconsistent with the actual evidence introduced at trial. Public pronouncements are not enough; the failure to plead and prove outrageous conduct is

dispositive. Although Plaintiffs may wish to expand their authority to obtain divestiture and disgorgement more broadly than the law provides, this case is not the platform to do so.

Even if Plaintiffs were otherwise entitled to disgorgement, Plaintiffs failed to prove that they are entitled to any amount of relief, much less $105 million. Their disgorgement analyses are based entirely on assumptions and do not even purport to approximate Ovation's supposed unlawful profits. In an effort to retreat from their impossible $105 million assessment, they announced a new (beyond eleventh hour) disgorgement analysis never mentioned at trial; their own experts apparently would not attempt to support it. Nothing else supports it either. In the end, Plaintiffs' disgorgement analyses are more than creative; they are unfounded and unsupportable.

II. PLAINTIFFS FAILED TO PROVE THEIR ANTITRUST CLAIMS

A. Plaintiffs Did Not Prove Indocin and NeoProfen Are in the Same Relevant Market

Plaintiffs say that market definition is a simple question of whether Indocin and NeoProfen both treat PDA, and also claim that market definition is dispositive of the case. Plaintiffs are wrong on both counts. First, market definition is but one of several essential elements that Plaintiffs must prove, and does not absolve them from proving any of the others. Second, market definition looks at more than whether two products serve the same basic function; it requires rigorous economic examination of how sensitive demand for one product is to the price of a different product (cross-price elasticity of

demand). Plaintiffs' failure to introduce evidence of, much less prove, high cross-price elasticity of demand between Indocin and NeoProfen defeats Plaintiffs' antitrust claims.

1. Market definition is only "dispositive" against Plaintiffs

Plaintiffs indisputably have to prove that Indocin and NeoProfen are in the same antitrust relevant market, or their antitrust claims fail, as a matter of law. (Pls.' Post Trial Br., Doc. No. 279, at 1, 6.) This is not a mere technicality. If NeoProfen and Indocin are in separate relevant antitrust markets, then by definition, a merger did not have an anticompetitive effect because it neither increased market share/concentration nor eliminated a competitive relationship that would otherwise have meaningfully constrained Ovation's pricing. Market definition is, in that setting, dispositive – in favor of Ovation. But a finding that NeoProfen and Indocin are in the same relevant market would not be dispositive. Plaintiffs would still need to prove the remaining elements of their case – that the acquisition of the rights to NeoProfen caused competitive harm and that Ovation has durable market power. *See* Sections B, C *infra*.

Market definition is thus the beginning of the analysis, not the end, precisely because there is no basis to assess the existence or extent of anticompetitive effects, without first identifying the economic relationships the antitrust laws are designed to protect. *Walker Process Equip. Inc., v. Food Mach. and Chem. Corp.*, 382 U.S. 172, 177 (1965) ("Without a definition of that market there is no way to measure [a defendant's] ability to lessen or destroy competition."); *FTC v. Freeman Hosp.*, 69 F.3d 260, 268 (8th Cir. 1995) ("Without a well-defined relevant market, an examination of a transaction's

competitive effects is without context or meaning.") (quoting *United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957)).

Market definition requires the Court to identify those products that are sufficiently close economic substitutes that they are likely to compete on the basis of relatively small differences in price. *See, e.g., United States v. Empire Gas Corp.*, 537 F.2d 296, 303 (8th Cir. 1976); *see also* Def.'s Post Trial Br., Doc. No. 276, at 39-40. That is the point of the Merger Guidelines' SSNIP test – to assess whether a small but significant price increase would be profitable, in terms of the amount of demand it would cause to shift to substitute products. FTC & U.S. DEP'T OF JUSTICE, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 5-6 (2006). Plaintiffs did not meet their burden of proof on this threshold economic question.

2. Plaintiffs' evidence of functional substitutability is largely irrelevant

Plaintiffs focus most of their market definition discussion on an issue that no one has ever disputed, but that does not answer the relevant market question. Everyone agrees that Indocin and NeoProfen are functional substitutes in that they both effectively treat PDA. (Joint Stipulations of Fact, Doc. No. 264, at No. 32.) That they are functionally similar does not mean they are clinically the same, much less that they are *economic* substitutes (as Plaintiffs must prove).[1] The overwhelming weight of the

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[1] Plaintiffs' simplistic argument here is at odds with the FTC's position in numerous past antitrust cases involving pharmaceutical products; it is common for individual drugs to occupy separate antitrust markets even where multiple drugs treat the same condition. In those cases, the FTC asked whether, in their specific market setting, the drugs are likely to compete with each other *based on price*. *See*

evidence reveals that, despite treating the same condition, they are not economic substitutes. The neonatologists who drive demand choose between these drugs based on perceived clinical differences, such as safety profile, side-effects, drug and treatment

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COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 5-6 (proper approach is to start with the "narrowest possible market" and broadening it only as necessary to capture economic substitutes).

The following are some of the cases brought by the FTC narrowing the relevant market to drugs sharing the same active ingredient, and at times, further narrowing by differences in dosage of chemically identical drugs:

- *In re Biovail Corp.*, Doc. No. C-4060, 134 F.T.C. 407, 412 ¶¶ 18-19 (F.T.C. Oct. 2002) (consent order) (limiting market to hypertension treatments Tiazac and its generic even though "other agents can be used to treat high blood pressure and chronic chest pain");
- *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 81-82 & n.4 (D.D.C. 2006) (placing generic lorazepam and generic clorazepate in their own markets; excluding each other and their branded versions as well as all other anti-anxiety drugs);
- *In re Bristol-Myers Squibb Co.*, Doc. No. C-4076, at 13 ¶¶ 64-66 (Apr. 2003) (complaint), *available at* http://www.ftc.gov/os/2003/03/bristolmyerscmp.pdf (limiting market to only branded BuSpar; excluding its generic and other anti-anxiety drugs);
- *In re Glaxo Wellcome plc and SmithKline Beecham plc*, Doc. No. C-3990, at 2 ¶10, 3-4 ¶16(i) (Jan. 2001) (complaint), *available at* http://www.ftc.gov/os/2000/12/glaxosmithklinecmp.pdf (limiting market to one type of drug used to treat migraines; excluding other migraine drugs);
- *In re Biovail Corp. and Elan Corp.*, Doc. No. C-4057, 134 F.T.C. 302, 305-06 ¶¶ 5-10, 312-17 (F.T.C. Aug. 2002) (consent order) (holding there were two relevant markets, one for 30 mg dosages of generic Adalat and one for 60 mg dosages of Adalat; excluding the 90 mg dosage forms, different dosage forms of generic Adalat, as well as all other drugs that treat hypertension);
- *In re IVAX Corp.*, Doc. No. C-3565, 119 F.T.C. 357 ¶ 11 (FTC Mar. 1995) (consent order) (limiting product market to generic verapamil);

interactions, personal familiarity/experience, and established clinical history. As a result of these perceived differences, doctors have strong opinions about and allegiances to these particular drugs; that evidence prevents Plaintiffs from making the required showing of high cross-price elasticity of demand.

a. *Dr. Gerdes only opined as to functional substitutability*

Plaintiffs put much emphasis on the opinion of their medical expert, Dr. Gerdes, that Indocin and NeoProfen are "clinically interchangeable," meaning both are effective PDA treatments for most babies. (*E.g.*, Pls.' Post Trial Br., Doc. No. 279, at 12.) Plaintiffs did not need an expert for that – it is a stipulated fact. (Joint Stipulations of Fact, Doc. No. 264, at No. 32.) Market definition turns on whether Indocin and NeoProfen are *economic* substitutes. Plaintiffs admit that Dr. Gerdes did not opine as to economic substitutability. (Pls.' Opp'n to Def.'s Mot. to Exclude Arnold, Doc. No. 185, at 8-9.)

b. *Dr. Gerdes may not opine as to economic substitutability, under Daubert*

It is unclear whether Plaintiffs now intend to argue that Dr. Gerdes's opinion also shows that Indocin and NeoProfen are economic substitutes, (Pls.' [Proposed] Findings of Fact, Doc. No. 278, at 6.17); if so, Ovation renews its *Daubert* challenge to Dr. Gerdes's opinion. As Dr. Gerdes confirmed at trial (and as Plaintiffs admitted in their opposition to Ovation's *Daubert* motion), he used the term "clinical interchangeability"

- *In re Activas Group and Abrika Pharm, Inc.*, C-4190 (Apr. 2007) (complaint) *available at* http://www.ftc.gov/os/caselist/0710063/index.shtm (limiting market

to convey the drugs' comparable efficacy and indications; but did not opine that neonatologists are indifferent between these drugs, or that they do not perceive meaningful clinical differences between the drugs. (Gerdes Trial Tr. 122:2-5, 122:12-15, 123:18-124:6, 124:9-18, Dec. 7, 2009.) Nor did he opine that neonatologists choose either of the two drugs based on price. As such, neither Plaintiffs nor their other experts may rely on any part of Dr. Gerdes's opinion as indicative of consumer demand (other than his own personal choices).

In addition, Ovation renews its *Daubert* challenge to the extent Plaintiffs offer or rely upon Dr. Gerdes to assess the *degree* of clinical differentiation between the drugs. Dr. Gerdes has no basis to compare the drugs' attributes. For example, Dr. Gerdes testified that NeoProfen and Indocin are "equally safe." (Gerdes Trial Tr. 86:10-14, Dec. 7, 2009.) But he admits he has no experience with NeoProfen. (Gerdes Trial Tr. 120:7-11, 120:20-25, Dec. 7, 2009 ("[Y]ou've never used NeoProfen to treat any case of PDA in your 31 years of practice, have you? A. Correct.").) The hospitals at which he has spent his entire career have never used NeoProfen. (Gerdes Trial Tr. 120:7-11, 120:20-25, Dec. 7, 2009.) He did not supplement his limited knowledge by interviewing other neonatologists who did have direct experience with NeoProfen or by reading the literature and studies on NeoProfen. (Gerdes Trial Tr. 90:20-24, 122:2-5, 124:2-8, 155:17-156:5, Dec. 7, 2009.) For instance, Dr. Gerdes chose not to review a prominent *New England Journal of Medicine* article entitled "A Comparison of Ibuprofen and

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to generic isradipine capsules; excluding the branded version and all other drugs that treat hypertension and depression).

Indomethacin for Closure of Patent Ductus Arteriosis." (Gerdes Trial Tr. 155:25-156:5, Dec. 7, 2009.) In fact, although Dr. Gerdes referred to his "general knowledge of medical literature," he named only one article on which he relied to support his opinion about NeoProfen.[2] Dr. Gerdes's opinions on clinical differences between NeoProfen and Indocin are devoid of any meaningful analysis and amount to pure speculation. As such, they must be excluded. *See Elcock v. Kmart Co.*, 233 F.3d 734, 745, 746-48 (3d Cir. 2000); *In re Aluminum Phosphide Antitrust Litig.*, 893 F. Supp. 1497, 1506-07 (D. Kan. 1995).

Dr. Gerdes's failure to take into account contrary evidence from those familiar with NeoProfen who believe there are meaningful differences between NeoProfen and Indocin, is independent grounds to exclude Dr. Gerdes's opinions. *See Turpin v. Merrill Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (6th Cir. 1992) (no scientific basis for testimony of expert who did "not testify on the basis of the collective view of his scientific discipline, nor . . . . take issue with his peers and explain the grounds for his differences"); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1024 (S.D. Ohio 1992), *aff'd* 24 F.3d 809 ("when an expert expresses an opinion which is not generally accepted within the medical and scientific communities, he has an obligation to provide a reasoned explanation of why his methodology and opinions differ"). For these reasons, the Court should exclude Dr. Gerdes's opinions (1) as to the degree of clinical interchangeability of

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[2] This one article, the 2009 Cochrane Review, was neither included in Dr. Gerdes's Report nor included in Plaintiffs' Proposed Exhibit List. (Gerdes Trial Tr. 115:11-117:23, Dec. 7, 2009.)

the drugs, (2) that other neonatologists consider the drugs interchangeable, and (3) that Indocin and NeoProfen are equally safe.

c. *Dr. Gerdes's personal practices disprove cross-elasticity*

While Dr. Gerdes did not and could not offer any expert opinion as to economic substitutability, his testimony as a lay witness about his personal experience helps confirm that cross-price elasticity between Indocin and NeoProfen is very low. Dr. Gerdes concedes Indocin generates adverse side effects, and that research seems to indicate those side effects are not as prevalent in NeoProfen. (Gerdes Trial Tr. 135:8-17, 136:5-137:10, 141:9-14, 141:19-143:13, 144:25-145:23, Dec. 7, 2009.) But he uses Indocin exclusively to treat PDA, in part because he values the drug's more established and tested clinical history. (Gerdes Trial Tr. 112:7-113:16, Dec. 7, 2009.) In this respect, Dr. Gerdes represents well the reality that doctors choose between Indocin and NeoProfen based on those clinical differences that each doctor feels are most important. For some, reduced side effects are most important; for others like Dr. Gerdes and Dr. Payne, the known long-term history of Indocin prevails. Regardless, Dr. Gerdes confirms that in his 30+ years of experience, neonatologists decide which drug to use, and it is "unthinkable" that a hospital administrator could ever dictate or influence a clinical-based decision in order to save money. (Gerdes Trial Tr. 170:21-171:20, Dec. 7, 2009.) In short, Dr. Gerdes confirms that neonatologists drive demand for these NICU-specific drugs, doctors choose based on non-economic, clinical factors, and a hospital administrator could never influence that choice unless a doctor was truly indifferent, despite all of the clinical differences, between these drugs.

d. *The Premier hospital purchasing data is not evidence that NeoProfen and Indocin would ever compete on price*

Plaintiffs ask the Court to infer that, because some neonatologists only use Indocin or only use NeoProfen, neonatologists are indifferent between which drug they use and would freely switch between the two on the basis of price. (Pls.' Post Trial Br., Doc. No. 279, at 12-14, 19.) The evidence actually shows the opposite; the data simply reflects the natural result of a one-way migration to new technology. When NeoProfen entered the market, some neonatologists who had previously used Indocin switched to NeoProfen. Indeed, the testimony showed that based on the medical literature, some doctors were waiting eagerly for NeoProfen to become available, so they could switch to it. (Gardner Trial Tr., 1129:7-1130:3, Dec. 11, 2009.) These physicians made the switch not because NeoProfen was cheaper – though it was priced below Indocin – but because, based on their review of the medical literature and research, they believed NeoProfen would be safer for their patients. (Gardner Trial Tr. 1125:2-13, Dec. 14, 2009; Kim Dep. 28:21-29:10; Smith Dep. 19:8-20:10; Sosenko Dep. 47:4-12, 47:17-22; Tefft Dep. 81:1-11.) Other physicians chose instead to stick with Indocin, and wait for more long-term studies of NeoProfen. (Gerdes Trial Tr. 112:7-113:16, Dec. 7, 2009; Payne Trial Tr. 232:24-233:5, 234:8-13, Dec. 7, 2009; Goldstein Dep. 22:9-20, 53:25-55:13.) Both camps made clear that they did not consider price in making that decision. (Payne Trial Tr. 225:7-13, Dec. 7, 2009; Kim Dep. 29:11-30:8 (a 20 percent price difference would not cause switch to a drug he perceives as less safe); Goldstein Dep. 62:22-63:1 ("a 10 percent or even 20 percent decrease in the price of NeoProfen" would not cause switch from Indocin to

NeoProfen; price is "irrelevant"); Smith Dep. 40:2-8, 41:18-42:5 (if Indocin were 10 or 20 percent cheaper than NeoProfen, it would not change his decision to treat with NeoProfen); Sosenko Dep. 50:24-51:6, 52:5-7 (cost plays no role in decision to treat with NeoProfen, safety is the major factor, and would not switch from NeoProfen to Indocin even if Indocin's price was reduced by $200); Tefft Dep. 48:18-49:7, 80:20-24 ("any price difference between Indocin and NeoProfen" would not change decision to choose NeoProfen); Carrejo Trial Tr. 321:2-323:2, 351:19-352:23, Dec. 8, 2009 (declined to accept 20% discount on NeoProfen because he did not believe he could convince physicians to switch to it on the basis of it being cheaper).)

Plaintiffs' economist acknowledged this migration, and did not offer any analysis of how much it (or any other factors) affected the trends in drug usage reflected by the Premier data:

> Q. And you . . . think that the pace of migration from Indocin to NeoProfen could be attributable to this costly adjustment phenomenon, don't you?
>
> A. The actual pace of migration may have been effected [sic] by that, yes.
>
> Q. But you haven't done any analysis of how much that is or isn't the case, right?
>
> A. Right.

(Arnold Trial Tr. 1075:8-15, Dec. 11, 2009.) Moreover, Dr. Arnold conceded that the Premier data is only evidence of functional substitutability and does not show that doctors are indifferent nor why they select one drug over the other:

> Q. Isn't it the case, sir, that you relied in your opinion on the Premier evidence only as evidence that the two drugs were functional substitutes not economic substitutes?

A. Yes.

Q. Okay. We can agree that the Premier data don't indicate anything about doctors or hospitals are choosing one drug or the other, right?

A. Yes.

(Arnold Trial Tr. 1074:17-24, Dec. 11, 2009.) This data does not show, as Plaintiffs must, that NeoProfen and Indocin have a high cross-price elasticity of demand.

e. *Ovation's efforts to educate other clinical NICU practitioners is not evidence of neonatologist indifference or cross-elasticity between the drugs*

Plaintiffs argue that, because Ovation sales people "detailed" hospital employees other than just neonatologists, that must mean hospital administrators can persuade neonatologists to switch between Indocin and NeoProfen based on price. (Pls.' Post Trial Br., Doc. No. 279, at 15-16.) Plaintiffs' argument disregards the evidence and logic. Ovation sales people approached and educated non-neonatologists who also practiced in the NICU as a way to spread their message to neonatologists.[3] Mr. Stickler testified without contradiction that it has become difficult for sales individuals to get close to some physicians. (Stickler Trial Tr. 758:15-759:9, Dec. 10, 2009.) In some cases, approaching other members of the NICU clinical team and explaining the benefits of NeoProfen to them may be the only means of communicating to the neonatologist. (*See* Def.'s Post Trial Br., Doc. No. 276, at 46.) And clinical pharmacists can clearly play a role in advocating for NICU drugs when they see safety advantages – as they did for

NeoProfen. (Gardner Trial Tr. 1124:7-9, 1125:2-7, Dec. 14, 2009.) All of that further disproves Plaintiffs' theory that neonatologists would let hospital administrators direct them to use one drug or the other based on price. The evidence is overwhelming that neonatologists would only switch back and forth between drugs where they are indifferent – as they are more likely to be with a brand and its generic. That is not the case here. Neonatologists believe there are meaningful differences between Indocin and NeoProfen; therefore, they are not indifferent.

3. Plaintiffs ignore their burden of proving that Indocin and NeoProfen are economic substitutes that exhibit high cross-elasticity

a. *Dr. Arnold performed no cross-elasticity analysis at all*

Plaintiffs rely upon their economist, Dr. Arnold, to opine as to the relevant market they propose.[4] Dr. Arnold's testimony does not meet Plaintiffs' burden to prove the relevant product market.

Ovation renews its *Daubert* challenge to the extent Dr. Arnold's opinions are offered as proof that the drugs are economic substitutes in the same relevant antitrust market because Dr. Arnold did not perform any analysis of economic substitutability of the sort he recognizes is necessary. He admits that two products cannot be in the same

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[3] If Plaintiffs' theory were correct, Ovation logically would have focused its sales efforts on hospital administrators. Instead, it is undisputed that well over 90% of those efforts were directed at neonatologists and NICU nurses and clinical pharmacists. (PX 232 at 11.)

[4] Dr. Gerdes appropriately declined that responsibility; he is not an economist and did not opine as to whether other neonatologists agree with his beliefs on

market unless they are economic substitutes that exhibit high-cross elasticity of demand. He agrees with the FTC's Merger Guidelines that this inquiry is determined "solely by consumer demand evidence." (Arnold Trial Tr. 1064:14-1065:5, Dec. 11, 2009.) He admits two products would never engage in price competition in the absence of high-cross elasticity. Yet Dr. Arnold offers no opinion on the two drugs' cross-price elasticity:

> Q. And you would agree that two products are not economic substitutes unless they have meaningful cross elasticity of demand, right?
>
> A. Yes.
>
> Q. So, and two products that don't have meaningful cross elasticity of demand and are not economic substitutes logically won't compete on the basis of price, right?
>
> A. Right.
>
> Q. But you're not offering any opinion as to what the cross elasticity of demand is between NeoProfen and Indocin, are you?
>
> A. Correct. Yes, I'm not.

(Arnold Trial Tr. 1063:23-1064:9, Dec. 11, 2009.) Consequently, his opinions on economic substitution are unreliable, because he ignored all the available consumer demand evidence he admits is determinative and conducted no supporting economic analyses.

Even if Dr. Arnold's opinion that Indocin and NeoProfen are in the same relevant antitrust market were admissible, it is insufficient to meet Plaintiffs' burden. He relies, for the most part, on Dr. Gerdes and evidence that the drugs are *functional* substitutes, not

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functional interchangeability, much less economic substitutability. (Gerdes Trial Tr. 122:2-5, 122:12-124:23, 133:8-13, Dec. 7, 2009.)

economic substitutes (*see* 2.a, *supra*). Dr. Arnold admits that the use of the word "market" in internal Ovation documents is unreliable, insufficient, and not an assessment of cross-price elasticity of demand, yet he acknowledges this is the only other evidence on which he relies to show economic substitution. (Arnold Trial Tr. 1075:16-25, Dec. 11, 2009); *accord Nobel Scientific Indus., Inc. v. Beckman Instruments, Inc.*, 670 F. Supp. 1313, 1318-19 (D. Md. 1986), *aff'd*, 832 .2d 537 (4th Cir. 1987) ("Product markets for antitrust analysis depend on cross-elasticity and interchangeability, and so the fact that a company may refer to a 'market' does not necessarily mean that its reference will be to a market for purposes of the Sherman Act."); *Home Health Specialists, Inc. v. Liberty Health Sys.*, No. CIV. A. 92-3413, 1994 WL 463406, at *3 (E.D. Pa. Aug. 24, 1994); COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 11 ("Agencies are careful, however, not to assume that a 'market' identified for business purposes is the same as a relevant market defined in the context of a merger analysis.").

Dr. Arnold conducted no economic analysis and ignored evidence about neonatologists in arriving at his opinions, rendering them unreliable. *See Blue Dane Simmental Corp. v. American Simmental Ass'n*, 178 F.3d 1035, 1041 (8th Cir. 1999) ("[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered") (citations omitted); *SMS Sys. Maint. Servs. v. Digital Equip. Corp.*, 188 F.3d 11, 25 (1st Cir. 1999) ("Expert opinions . . . are no better than the data and methodology that undergird them."); *Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Group L.P.*, 247 F.R.D. 156, 172 (C.D. Cal. 2007) (economist's opinion unreliable because he "has shown no basis to believe that all customers choose vendors

based on price alone, sufficient to drive Tyco prices down . . . because, beyond any other deficiency, he simply never asked"). And Dr. Arnold ignored a plethora of contrary record evidence. *See Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056-57 (8th Cir. 2000) (expert who ignores "inconvenient evidence" that contradicts proffered assumptions is engaging in "mere speculation"); *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 n.13 (8th Cir. 1998) ("When an expert opinion [on market definition] is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a decision.").

Bottom line: for Plaintiffs to prove that Indocin and NeoProfen are in the same relevant antitrust market, they must demonstrate that the drugs have a high cross-price elasticity of demand, not merely that they both treat PDA. *See H.J., Inc. v. Int'l Tel. & Tel. Corp.*, 867 F.2d 1531, 1538 (8th Cir. 1989) ("Critical to the determination whether certain products move in the same market is their cross-elasticity of demand – the degree that buyers of one product switch to the other in response to price changes"); Pls.' Opp'n to Def.'s Mot. Summ. J., Doc. 117, at 16. Only one expert economist, Dr. McCarthy, considered the whole body of demand-related evidence. Dr. McCarthy's opinion that the cross-price elasticity between these drugs is extremely low is uncontradicted and supported by the overwhelming weight of the trial record. (McCarthy Trial Tr. 1308:14-23, Dec. 15, 2009; Def.'s [Proposed] Findings of Fact, Doc. No. 275, at Nos. 289-293, 295, 298-299.)

b. *Plaintiffs offer no evidence of cross-elasticity of demand among those who truly drive demand*

As Dr. McCarthy explained, to determine if these drugs are economic substitutes one must identify the number of hospitals that can shift substantial volume to save money. (McCarthy Trial Tr. 1316:18-1317:25, 1324:24-1326:3, 1375:17-1376:25, Dec. 15, 2009.) That requires examining whether the amount of "movable volume" is sufficiently large at most hospitals to make it likely that hospital administrators would take the steps necessary to pursue a savings opportunity (*i.e.*, analyze total costs of care, confirm that a consensus of doctors support the plan, and guide the formulary process). (McCarthy Trial Tr. 1320:18-1322:14, 1374:19-1375:16, Dec. 15, 2009.) The FTC's own Merger Guidelines agree: "Market definition focuses solely on demand substitution factors – *i.e.*, possible consumer responses." MERGER GUIDELINES § 1.0. Dr. Arnold concedes he declined to do this analysis; therefore, he cannot address cross-price elasticity. (Arnold Trial Tr. 1063:20-1064:9, Dec. 11, 2009.)

c. *Hospitals would not be able to negotiate lower prices because neonatologists are not indifferent between Indocin and NeoProfen*

Plaintiffs try to create an argument for cross-price elasticity by side-stepping neonatologists in their demand analysis. They rely on the testimony of two administrative (*i.e.*, non-clinical) pharmacists to claim that, if NeoProfen and Indocin had separate owners, hospitals would be able to negotiate lower prices for PDA drugs by threatening to shift share from one drug to the other. But even Plaintiffs admit that, for "shifting share" to work as a leverage strategy, *neonatologists* would have to be

persuaded to switch between NeoProfen and Indocin, specifically, based on price: "'Shifting share' to achieve cost savings may require hospitals to coordinate with and persuade their physicians to change their prescribing behavior. . . . by providing them with detailed evidence concerning the clinical similarity and costs of the drugs." (Pls.' Post Trial Br., Doc. No. 279, at 19.) Plaintiffs also implicitly concede they must show that "physicians could be persuaded to substitute between PDA drugs in the interest of cost savings." (Pls.' Post Trial Br., Doc. No. 279, at 3.) This hypothetical argument is both unsupported and contrary to the evidence.

First, it simply does not apply here. Plaintiffs' argument has to assume as objective truth that there are no meaningful clinical differences between these particular drugs. They made no effort to prove that (Gerdes Trial Tr. 134:24-135:1, 147:12-149:13, 161:5-14, Dec. 7, 2009 (saying he did not look into this)), and the evidence shows the opposite. Multiple neonatologists do believe there are meaningful clinical differences between NeoProfen and Indocin and treat their patients accordingly. (Gardner Trial Tr. 1125:2-7, 1129:7-1130:3, 1131:6-1133:7, 1134:25-1135:4, Dec. 14, 2009; Mammel Trial Tr. 273:10-274:6, 292:5-24, Dec. 8, 2009; Behbahani Dep. 21:22-22:3, 81:10-82:5; Kim Dep. 73:21-74:16; Muller Dep. 69:18-21; Sosenko Dep. 39:25-40:6, 48:15-19, 97:4-15.)

Second, Plaintiffs' argument irrationally assumes the neonatologists currently using these drugs as life-saving therapies on the most fragile, premature babies do not have a proper understanding of the drugs' virtues and vices, yet for some reason, hospital administrators might be in a better position to assess them. In their Post Trial Brief, Plaintiffs try to persuade the Court that hospitals, such as those in the Kaiser system,

could use their "drug education coordinators specifically to educate [their] physicians" to use the cheaper drug. (Pls.' Post Trial Br., Doc. No. 279, at 19.) This "shifting share" hypothetical is based entirely on assumptions and already has been proven illogical. Dr. Carrejo, a Kaiser pharmacist, testified that he did not purchase NeoProfen when it was 20% cheaper than Indocin because he did not believe he could persuade the physicians to use it. (Carrejo Trial Tr. 321:2-323:2, 351:19-352:23, Dec. 8, 2009.) He was worried that if he bought NeoProfen, it would spoil on the shelf. (Carrejo Trial Tr. 321:2-323:2, 351:19-352:23, Dec. 8, 2009.) And that is despite NeoProfen's two-year shelf life. Similarly, Dr. Gutierrez testified that an 8% price difference was not sufficient to investigate the relative pricing of Indocin and NeoProfen, given the small total volumes at issue. (Gutierrez Trial Tr. 865:20-25, Dec. 10, 2009.) By contrast, all parties expect generic Indocin will lose the vast majority of its sale to generic indomethacin, priced at a seven percent discount.

Plaintiffs' theory about sophisticated hospitals using their "drug education coordinators" to drive the selection of cheaper drugs also contradicts hospitals' real-world experience with vial splitting. As Plaintiffs noted, Indocin can be vial split. That dramatically reduces its cost relative to NeoProfen – even if just two babies are treated with one vial of Indocin, Indocin is then half the price of NeoProfen. By Plaintiffs' reasoning, that means all hospitals should be using 100% Indocin. Yet Plaintiffs agree that 40% of PDA cases are treated with NeoProfen. That is because, as the neonatologists uniformly testified, they are not indifferent between the two. They decide

to treat a premature baby with either Indocin or NeoProfen based on their clinical assessment of which is the safer drug.

Most fundamentally, Plaintiffs' hypothetical musing about what hospitals "could" do is no substitute for the evidence of what hospitals and neonatologists did do in the real world. Plaintiffs simply do not offer any evidence on "how many" neonatologists are indifferent, and the neonatologist evidence they did offer was far from indifferent. (Gerdes Trial Tr. 170:21-171:20, Dec. 7, 2009 ("unthinkable" that an administrator could ever dictate or influence a clinical-based decision to save money.)) Plaintiffs' own witnesses confirm that even if a P&T committee wanted to commission additional inquiry into these drugs, it would ultimately rely on these not-indifferent neonatologists to guide the initiative. (Gutierrez Trial Tr. 852:24-854:3, Dec. 10, 2009; Schondelmeyer Trial Tr. 945:11-18, Dec. 11, 2009.) While it undisputed that most hospital P&T committees have automatic generic substitution policies in place to facilitate the rapid switch from branded drugs to their cheaper generic bio-equivalents, those policies rarely (if ever) apply to differentiated branded drugs—and there is zero evidence they do or ever could apply to Indocin and NeoProfen.. *See Rhone-Poulenc Rorer Pharms. v. Marion Merrell Dow*, 93 F.3d 511, 513 (8th Cir. 1996) ("[p]harmacists may freely substitute among AB [bioequivalent] drugs, but only a prescribing physician may substitute one BC [non-bioequivalent] drug for another."); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 310-11 (E.D. Mich. 2001) (hospitals automatically switch move to cheaper generics drugs they are "freely substitutable and . . . perfect substitutes for their brand name drug.") There is no record of any – much less a substantial percentage of –

neonatologists who are sufficiently indifferent between these drugs that they would yield their clinical decision to an administrator to save money. Plaintiffs' generalized theory is untethered to reality and cannot meet their burden of proving high cross-price elasticity of demand.

4. Plaintiffs' market definition makes no economic sense

Throughout the course of this litigation, Plaintiffs have faced a logical quandary that they cannot (and so never try to) explain: if their market definition were correct, then the impending entry of generic indomethacin would immediately take a majority of NeoProfen's sales volume upon entry and would leave Ovation with two essentially worthless assets. Under those circumstances, why would Ovation rationally spend $32 million to purchase the rights to NeoProfen? Both experts agree: Ovation would not. Plaintiffs' expert, though he asserts that Indocin and NeoProfen are economic substitutes and thereby in the same relevant market, concedes that Ovation could not rationally attempt to "corner the market" under those circumstances. (Arnold Trial Tr. 1081:23-1082:5, Dec. 11, 2009.) In short, Plaintiffs' fundamental theory of the case, by their own admission, assumes Ovation acted irrationally. But that is not allowed; as Plaintiffs' economist concedes, Plaintiffs must assume that Ovation acted in a rational, profit-maximizing manner. (Arnold Trial Tr. 1030:19-1031:4, Dec. 11, 2009.) *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (antitrust claims must make economic sense); *Concord Boat Corp.*, 207 F.3d at 1056-57; *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) (must assume economic rationality and profit-maximizing behavior).

This is not a mere matter of whether Ovation acted with bad intent; market definition is supposed to take into account industry players' perceptions of the attributes of the two products at issue. *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1102 (N.D. Cal. 2004). Ovation was the actor with the most acute economic incentives to assess accurately the cross-price elasticity of demand between these two products, and it acted upon its assessments. And Ovation was not alone – all other manufacturers who considered the issue (again, from the perspective of their own profit-maximizing behavior) agreed that NeoProfen would not be susceptible to meaningful competition from generic indomethacin. (Def.'s [Proposed] Findings of Fact, Doc. No. 275, at Nos. 218-238.) Plaintiffs implicitly suggest everyone just got it wrong, yet they cannot point to any evidence to defend that assumption. Bedford's actual pricing decision, however, disproves Plaintiffs' position and confirms Ovation's expectations were accurate. (*See* Joint Stipulations of Fact, Doc. No. 264, at Nos. 69, 120; Def.'s Mot. to Supplement R.)

B. Plaintiffs Did Not Prove Causation of Harm to Competition

Even if Plaintiffs' market definition was correct, which it is not, Plaintiffs must also prove that the NeoProfen acquisition caused actual harm to the competitive process – here, that the acquisition actually prevented price competition between Indocin and NeoProfen that otherwise would have occurred. Plaintiffs try to assume their way to proof of harm to competition by two separate mechanisms: once through Dr. Arnold's unsupported "Game On" assumption, and once by claiming entitlement to an irrebuttable presumption of illegality. Both gambits are invalid, and leave Plaintiffs with a total failure of proof.

1. The NeoProfen acquisition did not cause competitive harm

Plaintiffs claim they demonstrated at trial "that the NeoProfen acquisition curtailed competition that would otherwise have taken place – meaning that prices exceed the competitive level by *some* amount." (Pls.' Post Trial Br., Doc. No. 279, at 21.) Plaintiffs, however, did not prove either thing: they utterly failed to show prices were supracompetitive (indeed, they refused to offer even an approximate competitive baseline) or that price competition would have resulted absent the NeoProfen acquisition.

First, Plaintiffs admit they made no showing of "the competitive level" of prices; they offer no opinion whatsoever on what the competitive price for either drug would have been or could be in the future if NeoProfen is divested. (Arnold Trial Tr. 1028:10-19, Dec. 11, 2009.) But that is a mandatory requirement; Plaintiffs get no free pass on competitive impact. *See Concord Boat Corp.*, 207 F.3d at 1055 (plaintiffs are required "to construct a hypothetical market, a 'but for' market, free of the restraints and conduct alleged to be anticompetitive" to prove competitive harm); *id.* at 1057 (dismissing plaintiffs' attempt to model a competitive baseline as "mere speculation" because it did not "incorporate all aspects of the economic reality . . . [or] separate lawful from unlawful conduct"); *In the Matter of Evanston Nw. Healthcare Corp.*, F.T.C. Docket No. 9315, at 26-27, 64 (Final Decision, Aug. 6, 2007) (to prove competitive harm, plaintiffs demonstrate but-for prices using economic evidence that accounts for all "competitively-benign factors").

Second, Plaintiffs offer only one untested theory to show that the acquisition of NeoProfen *caused* any allegedly supracompetitive prices. Their "Game On" theory is

unsupported, facially implausible, and contrary to a wealth of uncontested evidence. Assuming rational actors, prices would not be any lower absent the NeoProfen acquisition. (McCarthy Trial Tr. 1308:2-23, Dec. 15, 2009.) As Dr. McCarthy explained and the record confirms, the "Game On" theory's key assumption – that Ovation would make the first move and reduce Indocin's price $50 if the drugs were owned by separate companies – would never happen because it would not be a rational or profitable choice. (McCarthy Trial Tr. 1308:2-23, Dec. 15, 2009; *see also* Arnold Trial Tr. 1001:1-19, Dec. 11, 2009; Burke Trial Tr. 712:15-713:10, Dec. 10, 2009.) Bedford's recent launch of generic indomethacin at virtual parity to NeoProfen confirms that there is no rational profit incentive for an independent owner of indomethacin (or Indocin) to initiate "Game On" price competition with NeoProfen.

Plaintiffs do not dispute or attempt to remedy their failure of proof. As discussed below, they simply ask the Court to ignore it and to condemn a merger proven incapable of anticompetitive effects. Plaintiffs say the right rule is to presume – without possibility of rebuttal and in disregard of all the contrary evidence – anticompetitive effects, durable market power, causation, and consumer harm. (Pls.' Post Trial Br., Doc. No. 279, at 2, 5-7.) There is no support for these arguments.

2. Plaintiffs are not entitled to a presumption of illegality based on high market-shares

Plaintiffs contend that, "essentially as a matter of law," Ovation is guilty of violating Section 2 and Section 7 if this Court holds that Indocin and NeoProfen are in the same market, so the Court need not address causation of harm to competition. (Pls.'

Post Trial Br., Doc. No. 279, at 6 ("A transaction that creates or further concentrates a highly concentrated market is *prima facie* unlawful.").)[5] Plaintiffs cite *United States v. General Dynamics Corp.*, 415 U.S. 486 (1974), for the proposition that if Indocin and NeoProfen are in the same relevant market, the acquisition is automatically illegal – no further analysis required or allowed. Not so. The Supreme Court in *General Dynamics* made clear that proof of high market shares in a Section 7 challenge – even when brought by the government – never confers automatic liability:

> In *Brown Shoe v. United States*, we cautioned that statistics concerning market share and concentration, while of great significance, were not conclusive indicators of anticompetitive effects: . . . "Statistics reflecting the shares of the market controlled by the industry leaders and the parties to the merger are, of course, the primary index of market power; but only a further examination of the particular market – its structure, history and probable future – can provide the appropriate setting for judging the probable anticompetitive effect of the merger."

415 U.S. at 498 (quoting *Brown Shoe Co., Inc. v. United States*, 370 U.S. 294, 322 n.38 (1962)). Further examination into market conditions is necessary to determine whether anticompetitive effects are substantially likely, because evidence of current and historical market shares "does not, as a matter of logic, necessarily give a proper picture of a company's future ability to compete." *Gen. Dynamics*, 415 U.S. at 501. That is particularly true where, as here, as of "the time of trial" it appears pending changes in market structure will likely render the future value of the defendant's assets "unpromising" (and here, those changes in fact occurred before closing arguments). *Id.*

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5 Plaintiffs overstate the importance of that concept – even had they made a *prima facie* case (which they did not), Ovation would still be able to rebut it with

at 502. Indeed, in *General Dynamics*, the Court held that the acquisition did not violate Section 7 because the government failed to "establish that a substantial lessening of competition was likely to occur in any market" – despite the government's demonstration of high market shares. *Id.* at 511.

Since *General Dynamics*, no court has even suggested that proof of high market shares ensures victory in a merger challenge. *See, e.g., FTC v. H.J. Heinz Co.*, 246 F.3d 708, 717 n.12 (D.C. Cir. 2001) ("The Supreme Court has cautioned that statistics reflecting market share and concentration, while of great significance, are not conclusive indicators of anticompetitive effects."). To the contrary, the courts and antitrust agencies themselves confirmed that plaintiffs are not entitled to any presumptions from high market shares (1) absent proof of high entry barriers, *United States v. Syufy Enters.*, 903 F.2d 659, 664 (9th Cir. 1990); *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 983-84 (D.C. Cir. 1990); or (2) in consummated merger settings where the parties have the opportunity to examine direct, post-acquisition evidence that helps to inform whether current market conditions will permit the exercise of durable market power. *See Gen. Dynamics*, 415 U.S. at 501-02; *In the Matter of Evanston*, F.T.C. Docket No. 9315, at 2 (Rosch, concurring). In either of these situations, "the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Baker Hughes*, 908 F.2d at 982-83.

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evidence showing lack of harm to competition (which Ovation, in fact, presented).

In any event, even if Plaintiffs' market share evidence had given rise to a presumption, that would at most have caused the burden to shift to Ovation to rebut Plaintiffs' evidence; no case law says that market definition leads to an *irrebuttable* presumption of harm to competition. If the burden shifted, Ovation fully rebutted everything Plaintiffs offered. All of Plaintiffs' claims of competitive harm rest on the simple fact that NeoProfen and Indocin both treat PDA. Ovation rebutted the FTC's weak offer of proof with ample, uncontested evidence that neonatologists do not and would not choose whether to treat a premature infant with Indocin or NeoProfen based on price. Indeed, Ovation's burden on rebuttal would be very low, given the weakness of Plaintiffs' proffered "*prima facie*" case. *See FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 129 (D.D.C. 2004) ("[T]he FTC's prima facie case is not strong. Certainly less of a showing is required from defendants to rebut a less-than-compelling prima facie case."); *FTC v. Foster*, No. 07-352, 2007 U.S. Dist. LEXIS 47606, at *142-43 (D.N.M. May 29, 2007) (same); *H.J. Heinz*, 246 F.3d at 725. At worst, the burden shifted back to Plaintiffs to prove anticompetitive effects, *Baker Hughes*, 908 F.2d at 982-83, which they failed to do.

3. Plaintiffs are not entitled to a presumption of anticompetitive harm if Ovation "has a monopoly"

Plaintiffs again play fast and loose with the rules, saying that if Ovation is a monopolist, its acquisition of NeoProfen must necessarily be anticompetitive: "A transaction resulting in a *literal monopoly*, however, is virtually always anticompetitive and essentially always illegal. . . . [A] monopolist that acquires a firm or product that is

about to enter its monopoly market is almost inevitably guilty of monopolization." (Pls.' Post Trial Br., Doc. No. 279, at 7, 9.) The cases that Plaintiffs cite do not support this grand claim of *per se* liability. To the contrary, the courts condemned those mergers because they eliminated an important and demonstrated pricing constraint; never once have the courts endorsed the notion of an automatic and irrebuttable presumption of harm where, as here, the plaintiff failed to show that the merger would change pricing behavior.

Thus, in *United States v. El Paso Natural Gas Co.*, the Supreme Court explained that the merger removed an actual competitor, and prior to the acquisition that competitor had caused the acquiring firm to make significant price and delivery concessions in order to retain its customers. 376 U.S. 651, 654-55, 661 (1964). No presumption of competitive harm was needed or condoned in that case.

The same is true for the only other authorities Plaintiffs cite. Plaintiffs selectively quote *United States v. Franklin Electric. Co.*, 130 F. Supp. 2d 1025, 1035 (W.D. Wis. 2000), as saying "a merger to monopoly . . . by definition will have an anticompetitive effect." (Pls.' Post Trial Br., Doc. No. 279, at 7.) In reality, the court found that the merger to monopoly actually caused an anticompetitive effect because the two companies had competed on price pre-merger, and substantial barriers to entry (including patents and possible catastrophic explosions) would prevent any entry for at least three years. *Franklin Elec. Co.*, 130 F. Supp. 2d at 1029, 1031-32, 1035. No such facts exist here.

Plaintiffs similarly mischaracterize *Maryland and Virginia Milk Producers* as "finding merger to near-monopoly anticompetitive, despite no evidence of price effect."

(Pls.' Post Trial Br., Doc. No. 279, at 8, citing *United States v. Md. and Va. Milk Producers Assoc., Inc.*, 167 F. Supp. 799 (D.D.C. 1958).) The court actually condemned the merger for "excluding a rival that had been in the habit of cutting prices and under-bidding dealers who bought from the Association."[6] *Md. and Va. Milk Producers Assoc.*, 167 F. Supp. at 807. Again, no presumption was needed or given. And here, the evidence is that Abbott planned to price NeoProfen at a premium to Indocin; there is no record of any habit of under cutting its competitors on price, nor of any intent on Ovation's part to compete with generic indomethacin on price. (Burke Trial Tr. 664:8-665:14, Dec. 10, 2009; Morris Trial Tr. 1262:20-1263:18, Dec. 14, 2009; DX 78 at 5; DX 82 at 6-7; DX 120 at 4; DX 298 at 11.) Multiple industry players with the economic incentive to forecast accurately – including Ovation, Bedford, and Abbott – all reached the same conclusion: NeoProfen and generic indomethacin will not price compete. (Burke Trial Tr. 617:16-620:1, 629:8-630:4, 631:9-17, 633:3-12 672:13-24, 679:25-680:22, Dec. 9-10, 2009; Kenston Trial Tr. 424:6-425:8, 432:1-24, Dec. 8, 2009; Knocke Trial Tr. 546:8-11, Dec. 9, 2009; McCarthy Trial Tr. 1328:12-1329:4, Dec. 15, 2009; Stickler Trial Tr. 815:25-816:22, Dec. 10, 2009; Gaugh Dep. 72:3-7, 74:20-75:4, 75:13-21, 91:5-9, 121:23-122:7; McCoy Dep. 90:22-91:1; PX 57 at 2; PX 68 at 3; PX 84 at 5-6;

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6 The same is true of Plaintiffs' misplaced reliance on *United States v. Grinnell Corp.*, 384 U.S. 563 (1966), where the defendant conspired to end pre-existing price competition with its only rivals, and then "perfected" its monopoly power by acquiring its rivals before the underlying price-fixing agreements dissipated. *Id.* at 576. The Court made no reference to relieving the burden to prove anticompetitive effects. To the contrary, it expressly stated that the acquisitions eliminated the only proven constraints on the defendant's pricing. *Id.*

DX 112 at 1, 3, 5, 7, 8; DX 120 at 4; DX 125 at 2; DX 126 at 1, 3; DX 161 at 3.) In fact, Bedford priced generic indomethacin at virtual parity with NeoProfen, rather than at a level that would compete with NeoProfen.

Plaintiffs also distort the holding in *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001), claiming that any exclusionary act that a monopolist directs at an imminent entrant is conclusive and irrebuttable evidence of competitive harm. (Pls.' Post Trial Br., Doc. No. 279, at 9.) But the D.C. Circuit could not have been more clear that, notwithstanding Microsoft's undisputed 95% market share and high entry barriers, the government *had to prove* actual anticompetitive effects from various contracts and exclusionary practices directed at suppressing a nascent technology threat.

> [T]he plaintiff, on whom the burden of proof of course rests, *must demonstrate that the monopolist's conduct indeed has the requisite anticompetitive effect*. . . . [Even] in a case brought by the Government, it must demonstrate that the monopolist's conduct harmed competition, not just a competitor.

253 F.3d at 58-59 (emphasis added) (internal citations omitted). Plaintiffs agree *Microsoft* sets the controlling standard,[7] yet they pretend it does not apply unless the monopolist's conduct is justified by pro-competitive efficiencies. (Pls.' Post Trial Br., Doc. 279, at 10-11.)[8] In effect, they claim *Microsoft* reverses the burden of proof for

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7 Plaintiffs acknowledge *Microsoft* requires proof that the exclusionary conduct at issue had "an anticompetitive effect . . . reasonably capable of contributing significantly to . . . monopoly power." (Pls.' Post Trial Br., Doc 279, at 10.)

8 Plaintiffs try to hedge their unsupported claim they have no burden of proof, by suggesting the government need only prove harm as a "general matter." (Pls.' Post Trial Br., Doc. No. 279, at 10.) Not so. In both *Microsoft* and *Rambus*, the

monopolists – but it does no such thing. Plaintiffs have missed the crucial step. Before an inquiry into pro-competitive efficiencies is warranted, Plaintiffs must first demonstrate actual anticompetitive effects. *Microsoft* makes clear that no presumptions of harm flow from a defendant's "monopoly" status nor because the exclusionary conduct in question was directed at a competitive entry threat. Rather, the government "must demonstrate that the monopolist's conduct indeed has the requisite anticompetitive effect." *Id.* As such, the government could not infer harm simply because Microsoft used its monopoly power to exclude emerging rivals from leading distribution channels. The government also had to prove the foreclosed distribution channels were essential for rivals to achieve the scale needed to compete with Microsoft.

Even more curiously, Plaintiffs rely on Justice Scalia's dissent in *Kodak* for the proposition that a monopolist's acquisition of a competitor is automatically anticompetitive. (Pls.' Post Trial Br., Doc. No. 279, at 9, citing *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 488 (1992).) *Kodak* did not involve an acquisition and says nothing about presuming competitive harm when a monopolist acquires a competitor – it involved a *per se* tying claim. Plaintiffs' implicit request to treat the NeoProfen acquisition as *per se* unlawful calls for an extreme extension of existing law – no court has ever held that a mere acquisition, even by a monopolist, is a *per se* illegal offense. There is no basis for this Court to do so either.

D.C. Circuit held the government to exacting standards of proof for all elements, including anticompetitive effects. *Rambus*, 522 F.3d at 463, 467; *Microsoft*, 253 F.3d at 58-59. This is even more so where, as here, structural or money damages are at issue. *Rambus*, 522 F.3d at 462; *Microsoft*, 253 F.3d at 79, 105.

Finally, Plaintiffs cite to Areeda ¶ 701b, but the quoted passage itself disproves Plaintiffs' theory; Areeda states that a monopolist's acquisition of a rival is only "anticompetitive *to the extent that it eliminates competition that might otherwise have dissipated the monopolist's power.*" AREEDA & HOVENKAMP, ANTITRUST LAW ¶ 701b (3d ed. 2006) (emphasis added). In other words, the NeoProfen acquisition only violates the antitrust laws if Plaintiffs prove that NeoProfen would have competed with Indocin on the basis of price. That is precisely the showing Plaintiffs failed to make here.

4. Consummation of the acquisition does not excuse Plaintiffs' failure of proof

Plaintiffs also say the Court should excuse their failure of proof because the NeoProfen acquisition "made it impossible to reconstruct the but-for world." (*See, e.g.,* Pls.' Post Trial Br., Doc. No. 279, at 3, 4, 21, 36; Pls.' [Proposed] Findings of Fact, Doc. No. 278, at 8.14.) Nonsense. Far *more* evidence is available now than would have been available had Plaintiffs challenged the NeoProfen acquisition prospectively.[9] These drugs have both been on the market for nearly four years, which has provided mountains of real-world evidence regarding consumer demand (*i.e.,* neonatologist and pharmacist

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[9] To the extent Plaintiffs try to diminish the significance of the voluminous real-world post-acquisition evidence, their argument is baseless. *See, e.g.,* Pls.' Trial Br., Doc. No. 193, at 6 (citing *FTC v. Consolidated Foods*, 380 U.S. 592, 598-99 (1965)). In *General Dynamics*, the Court clarified that *Consolidated Foods* simply stands for the proposition that post-complaint evidence subject to defendant's control is tainted, and therefore deserving of little weight. 415 U.S. at 504-505. Both *General Dynamics* and *Evanston* expressly state that post-acquisition evidence not subject to defendant's control is highly probative and uniquely relevant to the court's ultimate inquiry into competitive effects, because it allows direct observation of demand characteristics, market dynamics, entry

testimony) and the economic realities of both drugs (*i.e.*, market and pricing analyses). The hypothetical nature of the but-for world inquiry does not permit Plaintiffs to ignore actual market evidence, *Concord Boat Corp.*, 207 F.3d at 1055, 1057, and no authority justifies the reduced evidentiary burden Plaintiffs seek here. (*See* Defs.' Post Trial Br., Doc. No. 276, at 24-25.)[10]

Plaintiffs' decision to throw up their hands is especially curious given that their own expert, Dr. Schondelmeyer, elsewhere opined that indirect evidence could be used to conduct the very analysis Plaintiffs claim is impossible in this case. *See In re Cardizem CD Antitrust Litig.*, 200 F.R.D. at 322-23. In *Cardizem*, the plaintiffs alleged that a branded drug manufacturer entered into an agreement with a generic manufacturer to delay generic entry, which purportedly would have occurred years earlier but-for the agreement. *Id.* at 300. To attempt to create a model of but-for world pricing at the class certification stage, Dr. Schondelmeyer proposed that he would analyze, among other things, historical pricing of "comparable" branded and generic benchmark drugs – the commonly used "yardstick approach." *Id.* at 322-23. Dr. Arnold agrees that this analysis of potential revenue asks the right question (*i.e.*, whether "Game On" is likely). (*See*

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conditions, and market power. *Id.* at 501-504; *In re Evanston*, F.T.C. Docket No. 9315 at 73; *see also id.* at 2 (Rosch concurring).

10 Plaintiffs also cannot support their suggestion that market evidence was tainted by the NeoProfen acquisition. *See, e.g.*, Pls.' Trial Br., Doc. No. 193, at 6 (citing *FTC v. Consolidated Foods*, 380 U.S. 592, 598-99 (1965)). The acquisition did not affect the numerous contemporaneous analyses – by Ovation, Bedford, and Abbott – that judged generic indomethacin to be irrelevant to NeoProfen's future sales. Nor did Ovation do anything to impede generic entry, so Plaintiffs cannot claim that evidence is unavailable to assess entry conditions.

Arnold Trial Tr. 1001:1-19, Dec. 11, 2009.) Thus, although it is by no means certain that Dr. Arnold (or anyone else) could have developed an economic model that satisfied the test for admissibility, let alone carried Plaintiffs' burden of persuasion, the point is that Dr. Arnold and Plaintiffs did not even attempt to do so here.

5. Loss of non-price competition that is not profitable or sustainable long term is not an anticompetitive effect

Plaintiffs also now assert a non-price theory of competitive harm; they argue that if Ovation never acquired NeoProfen, it would have actively continued to promote and market Indocin as the "first choice" PDA treatment. (Pls.' Post Trial Br., Doc. No. 279, at 14.) For this theory to go anywhere, Plaintiffs must show that (1) marketing had and was likely to have a meaningful impact on Indocin's sales; and (2) Ovation was rationally likely to continue investing significant funds in marketing Indocin for the long term. The record says just the opposite, refuting Plaintiffs' theory.

Ovation had no rational incentive to invest in marketing Indocin over the long term, as demonstrated by Merck's decision to terminate all marketing support decades ago. Indocin is a well-known drug with a nearly 30-year clinical history that achieved market acceptance without Merck marketing it; loyal Indocin users prescribe it precisely because they value its demonstrated track record and are skeptical of marketing claims of newer drugs. (Gerdes Trial Tr. 112:7-113:16, Dec. 7, 2009; Payne Trial Tr. 232:24-233:5, 234:8-13, Dec. 7, 2009; Goldstein Dep. 11:20-13:14, 22:9-20, 53:25-55:12.) For the same reasons, and because Indocin treats a single condition with a relatively stable and small patient population, active promotion would not be likely to increase total

demand for Indocin, under any conditions. (Burke Trial Tr. 643:14-644:5, Dec. 10, 2009; Knocke Trial Tr. 510:8-24, 511:10-513:6, 520:4-21, Dec. 9, 2009; Stickler Trial Tr. 822:1-6, Dec. 10, 2009.) There is no evidence that promoting Indocin *ever* influenced treatment decisions, much less that it would be likely to do so in the future. That is especially true given that Ovation expected rapid entry by generic indomethacin. This is the sort of "might have" approach to causation that the D.C. Circuit rejected as insufficient in *Rambus*. 522 F.3d at 463-64, 466-67; *see also*, *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 556 F. Supp. 825, 1072-73 (D.D.C. 1982) (finding no injury in fact and rejecting remedies when premised on hypothetical "but for" scenarios not grounded in reality and with no foundation in defendant's business plans).

C. Plaintiffs Did Not Prove that the NeoProfen Acquisition Gave Ovation Durable Market Power

Plaintiffs once again ask this Court to assume the necessary element of durable market power, because (1) actual entry took longer than expected and (2) they claim it never impacted Ovation's pricing. Plaintiffs are wrong on both accounts.

1. Plaintiffs cannot escape their burden to prove durable market power

The Eighth Circuit has made clear that to establish market power, Plaintiffs must prove not merely high market share, but also that "there are significant barriers either to the entry of new firms or to increased output by existing firms." *Ryko Mfg. Co. v. Eden Serv.*, 823 F.2d 1215, 1232 (8th Cir. 1987); *accord W. Parcel Express v. UPS*, 190 F.3d 974, 975 (9th Cir. 1999) (firm with an allegedly "dominant share" could not possess monopoly power because there were no "significant barriers to entry"). Even if Plaintiffs

made a *prima facie* case of high market share and likely anticompetitive effects, Ovation could, and did, rebut with evidence that the market would likely be remedied with timely and sufficient entry. *Baker Hughes*, 908 F.2d at 983-85, 987-88 (finding defendant need only make a "sufficient" but not "clear" showing of no "substantial barriers" to switch the burden to plaintiffs to prove anticompetitive effect); *Microsoft*, 253 F.3d at 55-56 ("[B]ecause of the possibility of competition from new entrants, looking to [Microsoft's] current [95%] market share alone can be 'misleading,'" evidence of market power if there is no "structural barrier that protects the company's future position.") (internal citations omitted); *W. Parcel Express*, 190 F.3d at 975 (Section 2 requires proof of "significant barriers to entry"); *Syufy*, 903 F.2d at 665-66 & n.6 (high market share does not lead to antitrust violation when evidence also indicates no barriers to entry).

2. Ease of entry is a complete defense

Easy entry is a complete defense to a Section 7 merger challenge; *i.e.*, when the market is capable of producing a meaningful competitive threat in approximately two years and there is sufficient economic incentive to think it would. Plaintiffs concede the economic incentive was present. (Pls.' Opp'n to Def.'s Mot. Summ. J., Doc. No. 117, at 29 ("Lundbeck's monopoly pricing has been providing enormous incentives for generic indomethacin manufacturers to enter since 2006."); Gaugh Dep. 67:21-68:1, 116:9-23, 119:5-18; DX 281 at 16, No. 76.) And the evidence is clear that the market was *capable* of producing timely entry. (Joint Stipulations of Fact, Doc. No. 264, Nos. 82, 88; Burke Trial Tr. 642:22-25, 672:13-24, Dec. 10, 2009; Gaugh Dep. 36:17-37:8, 67:21-68:1, 116:9-117:4, 119:19-120:15, 123:13-15, 130:18-131:7, 179:25-180:4; PX 20/DX 78 at 5.)

To meet their burden to prove high entry barriers, Plaintiffs must show that, at the time of the allegedly unlawful conduct, the market contained a structural barrier that prevented a competitor from entering. *See e.g.*, *E. I. du Pont de Nemours & Co.*, 353 U.S. at 597; *Lansdale v. Phila. Elec. Co.*, 692 F.2d 307, 313-14 (3d Cir. 1982) (no barrier to entry where city *could have* constructed its own power transmission line within 14-16 months of allegedly anticompetitive acts of power company); *Metro Mobile CTS, Inc. v. NewVector Commc'ns, Inc.*, 661 F. Supp. 1504, 1521-23 (D. Ariz. 1987), *aff'd*, 892 F.2d 62 (9th Cir. 1989). Plaintiffs offer only regulatory approval as a barrier to entry. But (1) Indocin lacked intellectual property protection; (2) multiple qualified manufacturers existed; and (3) even with all its self-inflicted delays, Bedford gained FDA approval in July 2008, and could have entered the market at any point thereafter. (Joint Stipulations of Fact, Doc. No. 264, Nos. 47, 90; DX 41; DX 78 at 5; DX 81 at 3; DX 281 at 16, No. 78.) Moreover, as a matter of law and fact, the FDA approval process for a generic pharmaceutical is not a "significant barrier to entry." *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 113-14 (3d Cir. 1992).

Plaintiffs retort that easy entry is a viable merger defense "in theory" but is rarely enough to save a "merger to monopoly" from automatic condemnation. (Pls.' Post Trial Br., Doc. No. 279, at 7.) Plaintiffs' authorities do not support this mistaken proposition. Unlike this case, *Franklin Electrical* involved a market with substantial barriers to entry, 130 F. Supp. 2d at 1031-32 (market involves high costs, patents around which a competitor would have to design or wait until they expired, extremely dangerous

products and small "realizable profits"), and *Maryland and Virginia Milk Producers* did not even discuss entry, 167 F. Supp. at 807.

Plaintiffs also cite Areeda ¶ 911b out of context to suggest that "even relatively easy entry should not ordinarily be a defense to a merger creating a monopolist or dominant firm." (Pls.' Post Trial Br., Doc. No. 279, at 8, quoting AREEDA, ANTITRUST LAW, at ¶ 911b.) But Areeda explained that easy entry is not a defense only when it is *not sufficient.* Areeda cited to *United States v. Syufy Enterprises*, 903 F.2d 659 (9th Cir. 1990), to illustrate that a meaningful entry threat is a complete defense even to a merger creating 100% market share. AREEDA, ANTITRUST LAW, at ¶ 911b; *see also Syufy*, 903 F.2d at 665-66, 669 (in the absence of substantial "structural barriers to entry," acquiring all three competitors and a 100% market share did not violate Section 2 or Section 7 because "Syufy lacked the power to exclude competitors").

3. Entry has occurred and has not changed Ovation's pricing

Sufficiency does not depend, as Plaintiffs claim, on whether entry will change Indocin's pricing. Plaintiffs' argument simply proves too much, and would hold that generic entry – that is, entry by a perfect substitute – would always be irrelevant as a matter of law so long as the branded incumbent chose to hold its price and cede share.[11] In this context, the proper analysis is whether a generic is likely and capable of quickly taking meaningful sales if the brand does not change its pricing. *Syufy*, 903 F.2d at 665-

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[11] Plaintiffs' argument also highlights the internal inconsistency of their theories – Plaintiffs on the one hand say generic entry is irrelevant because it would not have caused Ovation to lower Indocin's price, but simultaneously ask the Court to

66. Here, generic indomethacin has entered, (Def.'s Mot. to Supplement R.), and is expected to take a majority of Indocin's sales. (DX 158 at 7 (as of January 2005, Ovation projected that generic indomethacin would displace over 80% of Indocin sales within two years of its introduction); *see also* Joint Stipulations of Fact, Doc. No. 264, No. 92; Gaugh Dep. 74:20-75:4, 146:15-22, 150:24-151:11, 185:22-25; DX 18 at 2, DX 39.)

4. Timing of actual entry is irrelevant

The significance of entry never turns on whether or when it actually happened. Actual entry is irrelevant – the test is whether competitive entry is expected or can be achieved within the relevant time period. *See Baker Hughes*, 908 F.2d at 987-88; *Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.*, 810 F.2d 243, 252 (D.C. Cir. 1987); *FTC v. CCC Holdings Inc.*, 605 F. Supp. 2d 26, 59 (D.D.C. 2009); MERGER GUIDELINES §§ 3.0, 3.2. Antitrust only protects the competitive process; it does not empower Plaintiffs to retroactively change results of the competitive process that they do not like. As they have done from the start, Plaintiffs simply pretend that Ovation acted with foreknowledge it could not have had. Their theories necessarily imply that Ovation knew as of January 2006 that NeoProfen would be approved in April 2006, and that Bedford would make business mistakes and choices that would delay generic indomethacin entry until February 2010. But everyone knows, and Plaintiffs grudgingly concede, that such foresight is impossible. (Pls.' Opp'n to Def.'s Mot. Summ. J., Doc.

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assume that Ovation would have automatically lowered Indocin's price in response to NeoProfen.

No. 117, at 5; Pls.' Trial Br., Doc. No. 193, at 16; Arnold Trial Tr. 1039:1-7, Dec. 11, 2009.)[12]

Antitrust liability does not turn on the ineptitude of one's competitors, but on whether market conditions are conducive to entry. Where there are no substantial structural barriers, the market is capable of correcting itself via competitive entry, and high (even monopoly) share is not an antitrust concern. *Syufy*, 903 F.2d at 665-66 & n.6 ("In evaluating monopoly power, it is not market share that counts, but the ability to *maintain* share."); *Colo. Interstate Gas Co. v. Natural Gas Pipeline Co.*, 885 F.2d 683, 695-96 (10th Cir. 1989) (no monopoly power "[i]f . . . a firm's ability to charge monopoly prices will necessarily be temporary"); *Nat'l Reporting Co. v. Alderson Reporting Co. Inc.*, 763 F.2d 1020, 1024 (8th Cir. 1985) (no monopoly power despite 100% market share because no prolonged power over price). The lack of entry barriers precludes a finding of monopoly power and therefore dooms Plaintiffs' antitrust claims.

III. MINNESOTA CANNOT RECOVER ON A *PARENS PATRIAE* THEORY

The State of Minnesota purports to pursue restitution here pursuant to a common law *parens patriae* theory (Pls.' Post Trial Br., Doc. No. 279, at 29), but its ability to do so is, at best, unclear. The one case Plaintiffs cite as allowing *parens patriae* restitution in an antitrust case appears to have based its restitution award entirely on the state's

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12 Plaintiffs claim that Ovation's expectation that generic indomethacin would enter the market about 16 months post-price increase is irrelevant. (Pls.' Post Trial Br., Doc 279, at 21.) That is wrong. Ovation's well-documented belief that entry would occur within two years was consistent with Bedford's own view, and both Ovation and Bedford had obvious economic incentives to get the estimate right.

consumer protection claims. *See Humphrey v. Alpine Air Products, Inc.*, 490 N.W.2d 888, 896 (Minn. Ct. App. 1992) ("Alpine's fraud infected every single sale of its air purifiers. Therefore we conclude the trial court did not err in ordering complete restitution to all purchasers of the Alpine air purifiers.") *Alpine Air* does not clearly show that the attorney general can pursue restitution on the basis of antitrust violations alone.

Even if the State could seek restitution under a *parens patriae* theory, it would still bear the burden to prove the *amount* of unjust enrichment. Plaintiffs' own authority (Pls.' Post Trial Br., Doc. No. 279, at 31, 33) makes clear that "plaintiffs bear the burden of proving the damages caused by a defendant's wrongful conduct. If the plaintiffs cannot present admissible and convincing proof, they cannot recover." *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 635 (Minn. 2007). Here, the State offered literally no evidence of its claimed damages. It has not even proposed a measure of unjust enrichment, much less any evidence of hospitals' out of pocket costs resulting from Ovation's alleged wrongful conduct. (Arnold Trial Tr. 1082:10-16, Dec. 11, 2009.) As with their antitrust claims, Plaintiffs suffer a complete failure of proof.

(*See, e.g.*, Burke Trial Tr. 631:18-20, Dec. 10, 2009.) That is all substantial evidence that entry was *capable* of occurring within approximately two years.

IV. PLAINTIFFS ARE NOT ENTITLED TO DIVESTITURE OR DISGORGEMENT

A. Plaintiffs Are Not Entitled to Disgorgement

1. Plaintiffs do not reconcile their extreme disgorgement request with their own Guidelines and past practices

The FTC claims its authority to seek disgorgement pursuant to Section 13(b) of the FTC Act is a well-established, "longstanding" bedrock of antitrust law. (Pls.' Post Trial Br., Doc. No. 279, at 28.) That is not true. The FTC seeks here to create the very precedent it lacks, in order to support broader disgorgement requests by the FTC in future cases.

Plaintiffs argue that a string of "[a]ppellate courts have...held that this [Section 13(b)] authority to issue injunctions carries with it the power to grant the full range of equitable remedies, including monetary remedies such as disgorgement..." (Pls.' Post Trial Br., Doc. No. 279, at 28.) But Plaintiffs fail to mention that all but one of the cases in that string of authority is either an unfair trade practices case or *entirely unconnected* to the FTC Act. *See Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291-92 (1960) (Fair Labor Standards Act), and *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946) (Emergency Price Control Act). Cases unconnected to antitrust, especially those unconnected to the FTC Act, are not controlling on this issue.

Only one court has ever said the FTC has any authority to seek disgorgement under Section 13(b) *in an antitrust case*, *FTC v. Mylan Laboratories, Inc.*, 62 F. Supp. 2d 25 (D.D.C. 1999) – a case that Plaintiffs criticize in another context as "non-controlling" and "erroneous." (Pls.' Post Trial Br., Doc. No. 279, at 30.) Even *Mylan* does not

support the availability of disgorgement in this case, by the FTC's own telling. One FTC Commissioner openly disagreed with the disgorgement holding in *Mylan,* stating that decisions broadening Section 13(b)'s reach in consumer protection cases should not necessarily extend to the antitrust context, where a large body of federal law already governs remedies for federal antitrust violations and *Illinois Brick* precludes indirect purchaser recoveries. *Statement of Commissioner Thomas B. Leary, Dissenting in Part and Concurring in Part in FTC v. Mylan Pharmaceuticals, Inc.,* FTC File No. X990015. Here, Plaintiffs request that disgorged profits be put into an escrow account and paid out to indirect purchaser hospitals, in direct contravention of *Illinois Brick*'s bar to indirect purchaser recovery. (Compare *Id.* and Pls.' Post Trial Br., Doc. No. 279, at 3-4.)

In response to Commissioner Leary's objection, three other then-FTC Commissioners effectively limited *Mylan,* defending its decision to order disgorgement as appropriate "for cases, like this one, in which the defendants have engaged in *particularly egregious conduct.*" *Statement of Chairman Robert Pitofsky and Commissioners Sheila F. Anthony and Mozelle W. Thompson, Federal Trade Commission v. Mylan Laboratories, Inc.,* File No. X990015 (emphasis added).

Mylan's conduct stands in stark contrast to the evidence here. Mylan actively procured long-term exclusive contracts that tied up the entire supply of the API needed to make two of its unpatented drugs – including a source of supply that Mylan was not FDA-authorized to use. In other words, it consciously and aggressively went out and made sure that generic competitors would not be able to enter the market to compete against it, specifically so it could raise prices. *Mylan*, 62 F. Supp. 2d at 33-34. Nothing

like that is even alleged here. The evidence is overwhelming that Ovation did not think it would gain any pricing power by acquiring NeoProfen. (Def.'s [Proposed] Finding of Fact, Doc. No. 275, Nos. 67-89, 104-116, 125-149, 230.) And Plaintiffs concede that Ovation did nothing at all to exclude generic competitors; indeed, Plaintiffs admit that Ovation expected its Indocin price increase to *spur* generic competition (Pls.' [Proposed] Finding of Fact, Doc. No. 278, No. 5.16), and even their own expert agrees that NeoProfen might never have hit the market absent Indocin's price increase. (Arnold Trial Tr. 1050:11-1051:14, Dec. 11, 2009.)

The Court need not decide whether or not Section 13(b) authorizes the FTC to pursue disgorgement in antitrust cases, because Plaintiffs have not proffered even one decision granting disgorgement on facts like this case.[13] Nor have Plaintiffs offered a

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[13] *SEC v. First City Fin. Corp.*, 890 F.2d 1215, 1231 (D.D.C. 1989) was not an antitrust case. It is a Securities Exchange Act case and offers no guidance on the appropriateness of disgorgement in the antitrust context.

Commodity Futures Trading Comm'n v. American Bd. Of Trade, 803 F.2d 1242, 1252 (2d Cir. 1986) likewise was not an antitrust case ("It is clear that the district court had the power to order disgorgement....[Disgorgement] effectuates the purpose underlying the Commodities Exchange Act.")

United States v. Grinnell Corp., 384 U.S. 563, 577 (1966) is an antitrust case, but it had nothing to do with disgorgement. *Grinnell* involved *per se* illegal antitrust violations, and the Court only considered divestiture and other structural remedies.

Schine Chain Theaters, Inc. v. United States, 334 U.S. 110 (1948) is another antitrust case that did not address disgorgement. *Schine* involved *per se* illegal antitrust violations and the Court merely remanded for more findings on the possibility of various divestiture remedies. *Id.* at 126-29.

FTC v. Mylan Laboratories, Inc., 62 F. Supp. 2d 25 (D.D.C. 1999) does not support disgorgement here because (1) FTC commentary explained that disgorgement was warranted in *Mylan* only because of the "egregious" nature of the facts (FTC's *Policy Statement on Monetary Equitable Relief in Competition*

standard for the Court to use in assessing the appropriateness of disgorgement here. They do not offer a standard for two reasons: First, the FTC has obtained disgorgement in so few antitrust matters (and then only by settlement, including in *Mylan*) that the case law does not set out a coherent standard. Second, the guidance that does emerge from *Mylan* and the few other disgorgement settlements shows that disgorgement only applies in exceptional cases involving *per se* violations of the antitrust laws and/or cases where the defendant's conduct is so egregiously lacking in legitimate business purpose as to be plainly anticompetitive. *See* Def.'s Post Trial Br., Doc. No. 276, at 73-78, n. 14-18. Those precedents do not justify disgorgement here. *Id.*

2. Plaintiffs' disgorgement calculations do not attempt to approximate Ovation's alleged illegal profits

Ovation does not, as Plaintiffs suggest, merely "protest a lack of precision in [Plaintiffs'] calculation" of disgorgement. (Pls.' Post Trial Br., Doc. No. 279, at 35.) Plaintiffs' calculations do not even purport to *approximate* the alleged harm. Plaintiffs must show that their proffered "reasonable estimate" of harm is causally connected to the alleged illegal acts. They may not include any amounts that are not illegal profits, *i.e.* not causally related to the alleged harm of supracompetitive pricing; that would constitute a penalty assessment, and disgorgement is not a penalty. Equity does not demand precision, but also does not allow an "approximation" to include anything other than the illegal profits causally related to the harm.

Cases, 68 Fed. Reg. 45,800 n.10-11 (Aug. 4, 2003); and (2) disgorgement in *Mylan* was decided by settlement. The District Court merely ruled that it is

Plaintiffs' own cases demonstrate their shortcomings.[14] For example, *SEC v. Bilzerian* held that a disgorgement calculation must seek to determine the amount of overcharge above a competitive baseline. 29 F.3d 689, 696-97 (D.C. Cir. 1994). In that securities fraud case, "the district court ordered Bilzerian to disgorge the difference between the price he received for the sale of his shares – inflated artificially by his false filings with the SEC – and *the price the shares would have brought were it not for his untimely and misleading filings*." *Id.* (emphasis added). The court went on to say: "We find that the district court's disgorgement order reasonably approximated Bilzerian's illicit profits. The court was careful to order disgorgement of the profits caused by Bilzerian's securities violations only." *Id.* (noting that court "ensur[ed] that any pre-violation appreciation was not disgorged").

Neither of Plaintiffs' proposed disgorgement calculations attempts to approximate supracompetitive profits earned above the competitive baseline. Plaintiffs' expert claimed that such a price is "unknowable," but that is always the challenge when dealing with the but-for world, and does not relieve Plaintiffs of the burden to conduct some reasoned analysis to arrive at an approximation of that price. The law recognizes a number of methodologies for approximating conditions in the but-for world; Plaintiffs just elected not to employ any of them here.

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available under Section 13(b). The District Court did not consider whether or not it was warranted in that case, much less under the facts here.

[14] In *FTC v. Febre*, a consumer protection case, the defendants quibbled with the sources from which the plaintiffs drew their restitution numbers, but never

3. Plaintiffs admit their proffered but-for price of $108.88 is the product of assumption, not analysis

Plaintiffs make themselves clear in their Post Trial Brief: they are not contending that $108 (the basis for their $105 million disgorgement calculation) was an approximation of a but-for competitive price. Rather, it is unequivocally nothing more than the "last observed market price." (Pls.' Post Trial Br., Doc. No. 279, at 4.) That admission proves beyond question that this $108 price is not a reasonable approximation of anything causally related to the wrongdoing.

Because Plaintiffs do not assert that $108 is even an estimate of the competitive price, their disgorgement calculation is literally unprincipled. It is merely an assumption with no connection to any theory of liability advanced by Plaintiffs. "Illegal profits" to Plaintiffs simply means all revenues above the last observed market price prior to the NeoProfen acquisition. That would seem to flow from a liability theory that Ovation would have never increased the price of Indocin above $108 in the absence of the NeoProfen acquisition, and that an independent owner of NeoProfen would have priced it at the same. But Plaintiffs do not advance this liability theory in their Post Trial Brief, nor could they, since their expert economist conceded that liability theory away.

Plaintiffs also admit that Dr. Arnold's calculation is limited to "revenues," with no attempt to identify "profits," much less profits above the competitive baseline. (Pls.' Post Trial Br., Doc. No. 279, at 35-36.) So they just insist without explanation that they are calculating "profits attributable to Lundbeck's illegal acquisition." (Pls.' Post Trial Br.,

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disputed that the method of calculation "reasonably approximate[d] the amount of

Doc. No. 279, at 37.) Plaintiffs' arguments are no substitute for evidence and economic analysis; nothing ties their disgorgement calculation to reality.

4. Plaintiffs' alternate method of calculation, including its proffered but-for price of $1,140, is not even supported by assumption

After the trial, Plaintiffs now propose a new, alternative method for calculating disgorgement, never supported by any witness (or other evidence). Dr. Arnold provided no expert testimony to vouch for it, nor could he have done so, under the Court's pretrial rulings. *See* Pretrial Conference Tr., 16:10-17:18 ("You can't have an expert up there, have them get – or at least some part of his or her analysis get ripped apart on cross-examination, and then have that expert come up with an alternate theory on the stand."). Plaintiffs' "Hail Mary Pass" attempt to offer a new, smaller disgorgement calculation is not merely unsupported, it is illogical and inconsistent with Plaintiffs' own theories and the Court's pretrial admonitions.

a. *Indocin calculation*

For the first time, Plaintiffs claim that the Court should use $1,140 as the benchmark for the disgorgement of illegal Indocin profits. (Pls.' Post Trial Br., Doc. No. 279, at 4.) But as with $108, they do not even propose that this is the competitive but-for price. They offer this price as merely a "proxy" price (*Id.* at 40) in direct conflict with their expert's testimony that (1) the best price available for him to use for the disgorgement calculation was the last observed market price, $108.88 (Arnold Trial Tr. 1024:20-1025:21, Dec. 11, 2009), and (2) there was no other price "reliable enough to

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customers' net losses." 128 F.3d 530, 535 (7th Cir. 1997).

use" as a proxy (Arnold Trial Tr. 1027:19-1027:23, Dec. 11, 2009). Plaintiffs argued in their Arnold *Daubert* Opposition that Dr. Arnold chose the last market price on record, and not any other price, because he "does not speculate." (Pls.' Opp'n to Def.'s Mot. to Exclude Arnold, Doc. No. 200, at 12.) Plaintiffs' new $1,140 proffer is precisely such speculation, which perhaps explains why it comes only after their economist testified, and without his blessing.[15]

Plaintiffs' $1,140 proffer suffers the same flaws as their initial $108.88 proffer. It has no connection to their theory of liability, which concedes that Ovation lawfully set (1) the January 2006 price of Indocin at $1,500 and (2) the July 2006 price of NeoProfen at $1,450. They offer no evidence, analysis, or even lay explanation as they are required to do – of how their "Game On" theory of competitive harm would ever drive prices to $1,140. Plaintiffs have advanced no liability theory that would result in Ovation pricing Indocin at $1,140, the lowest benchmark price that it had projected. Mr. Burke testified without contradiction that he always intended to set Indocin's price at $1,500, and not at $1,140. (Burke Trial Tr. 648:9-15, Dec. 10, 2009.) Plaintiffs disparage Mr. Burke, but cannot dispute his testimony. Nor can Plaintiffs explain why, on the one hand, it was "anticompetitive" for Ovation not to consider NeoProfen's potential entry when setting Indocin's price at $1,500, but, on the other hand, it was rational and competitive for Bedford to ignore NeoProfen's actual presence when pricing

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15 Plaintiffs' calculated decision not to offer this new disgorgement calculation in a time and manner allowing it to be tested by cross-examination speaks volumes and is independent grounds to disregard it. Fed. R. Civ. P. 26(a)(1)(A)(iii).

generic indomethancin. Their proposed $1,140 price is, literally, just pulled as one of the figures found in Ovation's benchmarking analyses during the year-plus prior to the NeoProfen acquisition. Plaintiffs do not and cannot contend that it is a reasoned approximation of supracompetitive profits causally connected to the challenged acquisition. *See Bilzerian,* 29 F.3d at 696-97.

b. *NeoProfen calculation*

Plaintiffs' Post Trial Brief also tries to raise new arguments, not addressed at trial, regarding disgorgement of alleged unlawful profits on sales of NeoProfen. Plaintiffs finally address, for the first time, the NeoProfen profit and loss statement Ovation produced in connection with its sale to Lundbeck. They now arbitrarily credit select portions of that statement in an effort to say that NeoProfen is actually profitable. But their selective methodology is false and, once again, one they consciously chose not to present at trial. Although Dr. Arnold testified about some characteristics of the profit and loss statement, he never hinted that Plaintiffs would try to use it to calculate disgorgement of illegal profits. Plaintiffs are now making up a new calculation, without their economist's blessing. Furthermore, Plaintiffs' selective application of the data in the profit and loss statement leaves out any accounting for the purchase price of NeoProfen, meaning that it does not reflect the real world situation, in which Ovation actually paid over $32.5 million for the rights to NeoProfen and has yet to make a profit on the drug. That is, at best, a curious and economically vacant view of a "profitable" experience.

Plaintiffs also seek to combine the divestiture and disgorgement remedies, with no support in the case law or economics, by asserting another last-minute claim, this time for any profits realized from the divestiture sale. Despite their contention that divestiture has long been an available remedy for antitrust cases, they provide no case where the defendant has had to forfeit the proceeds from a divestiture sale under the guise of disgorgement. Nor, though the trial is over, have Plaintiffs proffered any evidentiary basis (expert or otherwise) to determine what portion of any divestiture proceeds would properly qualify as unlawful profits causally connected to the alleged unlawful conduct.

5. Minnesota would not be entitled to disgorgement in any event

The *only* case to uphold the FTC's Section 13(b) authority to pursue disgorgement in antitrust cases explicitly rejected the State of Minnesota's authority to do so. (*Mylan Labs*, 62 F. Supp. 2d at 41-42, 48-49). Plaintiffs ask the Court to take the rather unusual step of simultaneously following *Mylan*'s holding on remedies available to the FTC and rejecting its holding on remedies available to the State of Minnesota. And they do so without offering any authority on which the Court could properly rely.

Plaintiffs erroneously claim entitlement to monetary equitable relief under Minnesota's Private Attorney General Statute (MPAGS) and, for the first time, under Section 325D.59 of the Minnesota Antitrust Law, based solely on the "plain meaning" of the statutes. (Pls.' Post Trial Br., Doc. No. 279, at 29-30.) Plaintiffs cannot cite even one case supporting their position that such relief is statutorily authorized in antitrust cases. The only case Plaintiffs rely on for the proposition monetary equitable relief is available here, *State by Humphrey v. Directory Publ'g Servs., Inc.*, 1996 WL 12674 (Minn. App.

1996), is a Minnesota unfair trade practice case, not an antitrust case, and it is officially designated as an unpublished decision. It is not precedential. Minn. St. Sec. 480A.08(3).

Plaintiffs did not cite *any case* supporting their boundless interpretation of "appropriate relief" available under Minn. Stat. § 325D.59. Plaintiffs essentially argue that "appropriate relief" means any relief that a court deems fair. Such an expansive interpretation would render meaningless Minn. Stat. §§ 325D.56-58, which provide the types of remedies available under the Minnesota Antitrust Law, specifically: civil penalties of not more than $50,000, actual damages sustained, and injunctive relief.

B. Plaintiffs Are Not Entitled to Divestiture

1. Divestiture is not necessary to restore competition

Plaintiffs offer generic statements about antitrust remedies to justify their request for divestiture, but still offer no justification for why divestiture is necessary to restore competition *in this market*. They cite several Supreme Court decisions for the mundane proposition that "divestiture has long been used to remedy monopolization offenses." (Pls.' Post Trial Br., Doc. No. 279, at 24 n.67.) All of these cases, however, support the showing in Ovation's Post Trial Brief that divestiture is a drastic remedy and is only appropriate when it is necessary to restore competition, which involves a forward-looking assessment that takes into account the conditions of the particular market.[16]

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16 In *United States v. United Shoe Mach. Corp.*, 391 U.S. 244, 250 (1968), the Court noted that, upon a finding of violation of Section 2, the trial court "may, if circumstances warrant, [order relief] by means less drastic than immediate dissolution or divestiture. The decree in the present case was carefully devised within the limits of this principle. Measures short of divestiture were prescribed with provisions for review and possible revision after 10 years."

Here, divestiture is not necessary, and thus not justified, because generic indomethacin has entered the market (Def.'s Mot. to Supplement R.) and everyone expects that customers will rapidly shift to the generic product from branded Indocin. (Def.'s [Proposed] Findings of Fact, Doc. No. 275, at Nos. 211, 213, 216.) Ovation's inability to maintain Indocin's sales means that Ovation has lost any market power it allegedly "maintained" by acquiring NeoProfen. Natural market forces have already corrected any alleged harm. *See Ford Motor Co. v. United States*, 405 U.S. 562, 573, 577 (1972) (divestiture remedy is not punitive and may not be used to engineer ideal conditions, only appropriate if necessary to re-establish competitive constraints needed to eliminate market power that was illegally acquired or maintained); *E. I. du Pont de Nemours*, 366 U.S. 316, 326 (1961); *Microsoft*, 253 F.3d at 79, 80, 103, 105; *Rambus Inc.* 522 F.3d at 461-62.

Plaintiffs' speculative arguments about "uncertainties" simply show how unnecessary divestiture is. Plaintiffs cite to the GeneraMedix presentation, (PX 84 at 5), for the proposition that "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

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In *United States v. Crescent Amusement Co.*, 323 U.S. 173, 188-90 (1944), the Court required divestiture precisely to ensure that the conspiracy not continue in the future, which was likely to occur absent divestiture.

In *United States v. Am. Tobacco Co.*, 221 U.S. 106, 186-88 (1911), the Court determined that it was not appropriate to order the immediate divestiture, despite the defendants' unlawful conduct.

Lastly, *Standard Oil Co. v. United States*, 221 U.S. 1, 78-79 (1911), noted that, in fashioning the remedy, courts must not overlook that "injury to the public by the

time after the generic is introduced." (Pls.' Post Trial Br., Doc. No. 279, at 24.) That is not what the evidence shows. The cited slide shows that Indocin volume will decline approximately 50% in the first five months (from close to 6,000 units sold in April 2008 to 3,000 units by September 2008) – hardly the gradual market penetration that Plaintiffs allege.

Plaintiffs speculate that, if NeoProfen and Indocin were separately owned, Bedford's generic indomethacin would mean a third competitor in the "PDA market," and this would likely lead to lower generic prices because Bedford prices its products lower in markets with more competitors (*i.e.*, three is better than two). (*See* Pls.' Post Trial Br., Doc. No. 279, at 25.) Again, Plaintiffs seek to elevate speculation over evidence. There is no evidence that three is better than two here; the evidence is to the contrary. Bedford testified that it will not adjust its price to account for a different branded product in the space – it will only account for the existence of *another generic competitor* offering the same molecule. (Gaugh Dep. 70:20-72:2, 72:14-73:4, 75:5-21, 121:23-122:7, 174:18-175:4.) In reality, that is what actually happened. Bedford launched generic indomethacin at $500 per vial, approximately seven percent cheaper than Indocin's current price, to execute on its plans to take virtually all of Indocin's sales. (Joint Stipulations of Fact, Doc. No. 264, at No. 69; Def.'s Mot. to Supplement R.) Bedford's decision not to apply the same strategy against NeoProfen (to which it is priced at virtual parity), confirms that there is no rational profit incentive for indomethacin to

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prevention of . . . the monopolization of trade or commerce is the foundation upon which the prohibitions of the statute rest."

price compete with NeoProfen. (Joint Stipulations of Fact, Doc. No. 264, at No. 120; Def.'s Mot. to Supplement R.) The existence of a third owner in the alleged "PDA market," thus would not affect the pricing of generic indomethacin.

Nor would divestiture create any more price competition between the branded drugs. The entry of generic indomethacin cemented Ovation's incentives to maintain Indocin's price. Ovation will now see rapid migration from Indocin to generic indomethacin and has no incentive to lower price during the short remainder of its commercial life. Lowering the price of Indocin to compete with NeoProfen would make no sense given that a cheaper, exact substitute for Indocin already exists (generic indomethacin) and will always attract any price-sensitive consumers.

Moreover, an independent owner of NeoProfen would be faced with the same pricing issues. If Indocin and NeoProfen were economic substitutes, which they are not, then the independent NeoProfen owner would have the exact same incentives as Ovation and would hold NeoProfen's price in response to generic indomethacin entry. If they are not economic substitutes, then the independent NeoProfen owner has nothing to fear with regard to generic indomethacin and will maintain its price. Bottom line: divestiture of NeoProfen to create a third "competitor" will not have any effect on the price of Indocin, NeoProfen, or generic indomethacin; spinning off NeoProfen is unnecessary.

Plaintiffs also proposed that Ovation might launch an authorized generic for Indocin to drive the price of the incoming generic down and create a greater differential relative to NeoProfen if NeoProfen were independently owned. (Pls.' Post Trial Brief, Doc. No. 279, at 25.) Aside from the obvious evidentiary flaws in this contention – it is

pure speculation and it also makes no sense.[17] Ovation would have no rational economic incentive to price compete with an independently owned NeoProfen, because it will soon lose most of its Indocin sales volume to the generic regardless; in this setting, Ovation wants to maintain the highest Indocin price possible, so as to retain as much revenue as possible. (McCarthy Trial Tr. 1311:8-16, Dec. 15, 2009.) Lastly, Plaintiffs argue that Ovation would be more likely to lower its prices to compete with generic indomethacin if it did not own NeoProfen, (Pls.' Post Trial Br., Doc. No. 279, at 25), but this argument is counter to the rich (and uncontroverted) record that it is Ovation's policy never to price compete with generics. (Burke Trial Tr. 664:8-665:14, 713:1-10, Dec. 10, 2009; McCarthy Trial Tr. 1310:24-1311:21, Dec. 15, 2009; Morris Trial Tr. 1262:20-1263:18, Dec. 14, 2009; PX 396 at 173; DX 78 at 5; DX 82 at 6-7, DX 120 at 4; DX 298 at 11.)

Plaintiffs seek draconian remedies, yet brazenly claim that they do not need to prove harm and causation to obtain them, just market definition. That is false. *See, e.g., Microsoft*, 253 F.3d at 79, 80, 103, 105 (court "must base its relief on some clear 'indication of a significant causal connection between the conduct enjoined or mandated and the violation found directed toward the remedial goal intended.'") (quoting AREEDA & HOVENKAMP, ANTITRUST LAW, ¶ 653b, at 91-92 (1996)); *Rambus Inc.*, 522 F.3d. at 461-62 ("remedies beyond injunction against future anticompetitive conduct would

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17 It bears noting that after much study, the FTC has yet to reach a consensus view on whether or not authorized generics are pro-competitive; that also precludes any argument that the absence of an authorized generic should be considered harm to competition. *See* Statement of Chairman Jon Leibowtiz on the Release of the

require stronger proof that they were necessary to restore competitive conditions"; upholding FTC's refusal to compel defendant to license its relevant patents royalty-free because there was insufficient evidence that, in the but-for world, the consumer would have chosen another firm's technologies [*i.e.*, no proof of causation]); AREEDA & HOVENKAMP, ANTITRUST LAW, ¶ 650c ("While proving anticompetitive behavior 'capable' of contributing to monopoly may be sufficient in a government equity suit seeking a prohibitory injunction, more may be required for structural relief or for all private suitors.").

Having failed to identify how divestiture is necessary to nurture competition, and especially in light of the entry of generic indomethacin achieved by natural market forces, Plaintiffs cannot get by on speculation that separate ownership would inject more competition into the market. Ovation no longer has a monopoly in any alleged "PDA drugs" market, if it ever did, which means that divestiture is unnecessary, regardless of any argument that three is better than two.

2. Plaintiffs' insistence on divestiture of NeoProfen disproves their claims

Plaintiffs demand that Ovation divest NeoProfen – not NeoProfen *or* Indocin. Tellingly, they insist that "[n]othing short of the divestiture of NeoProfen" will accomplish the goal of "restor[ing] competition in the PDA drug market." (Pls.' Post Trial Br., Doc. No. 279, at 24.) That assertion makes no sense, if the two drugs are truly

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Commission's Interim Report on Authorized Generics, (June 24, 2009), *available at* http://www.ftc.gov/os/2009/06/P062105authgenstatementLeibowitz.pdf.

economic substitutes, and equally susceptible to loss of sales to generic indomethacin, as Plaintiffs insist. Divestiture of either one should have the same competitive effects.

Plaintiffs' request and justifications for divestiture are even less compelling when read in conjunction with their proposed remedy order. The order provides for the appointment of a Divestiture Trustee, who would have ***two years*** from the date that the FTC approves the Trust Agreement to accomplish the divestiture. (Pls.' [Proposed] Remedy Order, Doc. No. 279-1, at 7.) Plaintiffs assert in their Post Trial Brief that divestiture is necessary to establish competition because there are uncertainties regarding the actual timing and market impact of Bedford's generic product. (Pls.' Post Trial Br., Doc. No. 279, at 24.) Bedford's entry, however, has already occurred and has cured any "uncertainties." Generic entry will have an immediate competitive impact on Indocin. Bedford has quickly and effectively injected competition into the alleged "PDA drug market" by launching at a seven percent discount to Indocin.

3. Plaintiffs' proposed divestiture order is unworkable

Even if divestiture was necessary to restore competition, which it is not, Plaintiffs' proposed order betrays an incomplete understanding of what Ovation owns with regard to NeoProfen. Farmacon-IL is the innovator of NeoProfen (and still holds the patents and NDA), and assigned to Abbott an exclusive license in the United States to NeoProfen in June 2001 ("Farmacon Agreement"). (*See* DX 92 at 5.) Pursuant to the Asset Purchase Agreement of January 18, 2006, Abbott assigned to Ovation its exclusive license, which it effectuated by assigning the Farmacon Agreement. (*See* DX 93 at 9.) The Farmacon Agreement and the Asset Purchase Agreement together make clear that Ovation must

receive prior written consent from Farmacon before assigning or sublicensing its exclusive license, and also must receive prior written consent from Abbott before assignment. (*See* DX 92 at 5, 28; DX 93 at 4, 9, 22, 29.) Plaintiffs' proposed remedy order does not provide for any input or written consent from Farmacon or Abbott, and thus as currently written would breach both contracts.

V. CONCLUSION

For the foregoing reasons, the Court should grant judgment in favor of Ovation as to all of Plaintiffs' claims.

Dated: February 19, 2010

Respectfully submitted,

s/Alfred C. Pfeiffer, Jr.

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