IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

10-3458 and 10-3459 (Consolidated)

FEDERAL TRADE COMMISSION AND STATE OF MINNESOTA,
Plaintiffs-Appellants,

v.

LUNDBECK, INC.,
Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA (Nos. 08-cv-6379 and 08-cv-6381)

REPLY BRIEF OF PLAINTIFFS-APPELLANTS FEDERAL TRADE COMMISSION AND STATE OF MINNESOTA

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No merger or acquisition can be more destructive of competition than one that creates or extends a monopoly. Accordingly, when a monopolist acquires an actual or likely potential competitor, it "is properly classified as anticompetitive, for it tends to augment or reinforce the monopoly by means other than competition on the merits." III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 701a, at 194 (3d ed. 2008).

In its brief, Lundbeck does not dispute that it was a monopolist, because it owned the *only* drug approved for the treatment of a patent ductus arteriosus ("PDA") – *i.e.*, Indocin IV. LB.2.[1] Lundbeck saw NeoProfen, which it expected to be priced lower than, and to take away sales from, Indocin IV, FF.78, 79, as the most imminent threat to its monopoly. Rather than face that competition, it simply bought out this potential competitor.

Lundbeck then proceeded with its plan to reap the rewards of its monopoly over the two drugs. Shortly after acquiring NeoProfen, Lundbeck raised Indocin IV's price from $108.88 to $1500 for a three-vial course of treatment. FF.57. And while Lundbeck understood that a rival would have priced NeoProfen 15% less

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[1] "LB." refers to Lundbeck's brief, while "FTC/MN Br." refers to the FTC and Minnesota's opening brief. "FF." refers to the district court's findings of fact, and "CL." refers to its conclusions of law. "App." refers to the Appendix.

than Indocin IV, FF.78, Lundbeck did not do that. Instead, as part of its plan "to cannibalize our Indocin IV sales in a controlled manner, retain sales for both products and continue to grow total company sales in the PDA market with an exclusivity protected product," FF.79, it introduced the new drug at nearly the same price as Indocin. In so doing, it eliminated price competition, and foiled the efforts of hospitals to reduce costs by promoting competition. FF.82, FF.88-93.

While making numerous findings of fact establishing the competition between Indocin IV and NeoProfen, the court below failed to see the starkly anticompetitive nature of Lundbeck's conduct, because it mistakenly concluded that Indocin IV and NeoProfen were not in the same market. FF.116, CL.5. The court fell into this error largely by asking the wrong question: determining only what prescribing physicians currently prefer, instead of ascertaining what likely *would have happened* had a competitor owned NeoProfen. The court compounded this error of law by ignoring its own findings, which themselves establish the necessary predicates to the market definition (not to mention liability) urged by the FTC and Minnesota.

Lundbeck's brief fails to rebut our showing that the district court committed legal error by concluding, contrary to its own findings, that Indocin IV and NeoProfen are not in the same product market. This Court must reverse, lest

monopolists be given free rein to extend their market power by acquiring potential competitors.

I. THE "CLEAR ERROR" STANDARD OF REVIEW DOES NOT APPLY WHEN A COURT'S MARKET DEFINITION RESULTS FROM LEGAL ERROR

As described in our principal brief, the district court made numerous findings of fact establishing that "reasonable interchangeability of use or the cross-elasticity of demand," *Brown Shoe Co., Inc. v. United States*, 370 U.S. 294, 325 (1962), existed between Indocin IV and NeoProfen. The court's own findings demonstrated the functional interchangeability of the drugs, including, *inter alia*, the economically relevant facts that Indocin IV and NeoProfen are both marketed by Lundbeck to treat a patent ductus arteriosus ("PDA"), FF.78, the drugs are equally efficacious at doing so, FF.21, and no industry consensus exists that one drug is better than the other for treating a PDA. FF.94. The findings also show that buyers and sellers recognized the drugs as therapeutic and economic substitutes, which is evidenced, among other ways, by Lundbeck's decision to price the drugs at virtual parity to eliminate price as a competitive factor and to "sell[] product differentiation." FF.82. Significantly, the findings further demonstrated that there were enough buyers who viewed the drugs as substitutes

that Lundbeck could not ignore them. FF.82-85.[2]

In concluding that Indocin IV and NeoProfen are not in the same market, FF.116, CL.5, the district court "applied an incorrect legal standard" by failing to "examin[e] all of the pertinent factors which make up cross-elasticity of supply and demand." *United States v. Empire Gas Corp.*, 537 F.2d 296, 303-04 (8th Cir. 1976). Contrary to Lundbeck's protests (LB.39-43), such errors are legal, not factual. "[I]f the trial court bases its findings upon a mistaken impression of applicable legal principles, the reviewing court is not bound by the clearly erroneous standard." *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 855 n.15 (1982); *see also Pullman-Standard v. Swint*, 456 U.S. 273, 287 (1982) (same); *Universal Title Ins. Co. v. United States*, 942 F.2d 1311, 1314 (8th Cir. 1991) (Rule 52(a) does not prevent a reviewing court from correcting "'a finding of fact that is predicated on a misunderstanding of the governing rule of law'") (quoting *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 501 (1984)); *Baker v. Stuart Broad. Co.*, 560 F.2d 389, 392 (8th Cir. 1977) (same). "[T]he case for deference vanishes when a court's ultimate conclusion is infected by legal

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[2] Lundbeck cannot credibly claim that we "virtually ignore consumer demand and cross-elasticity, and focus instead on the drugs' functional similarities," LB.38, given the wide range of findings discussed in the FTC and Minnesota's opening brief. *See, e.g.*, FTC/MN Br.36-39, 46-57.

error." *Vinick v. United States*, 205 F.3d 1, 6 (1st Cir. 2000).

Despite this settled law, Lundbeck disputes the standard of review, incorrectly asserting that "[t]he case law is unanimous that market definition is reviewed only for clear error." LB.40 (citing, *inter alia*, *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 380-81 (1956)). As the Supreme Court explained in *du Pont*, however, an appellant "must show that erroneous legal tests were applied to essential findings of fact *or* that the findings of fact themselves were 'clearly erroneous' within our rulings under Rule 52(a) of the Rules of Civil Procedure." 351 U.S. at 381 (emphasis added) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 393-95 (1948)). In *United States Gypsum*, the Supreme Court further explained that the reviewing court can correct findings of fact based on legal errors, such as misapplication of the law. The "clearly erroneous" standard applies only when the challenge is to the "inferences drawn from documents or undisputed facts." 333 U.S. at 394. Such is not the case here. This Court can correct a market definition based on legal error. *Empire Gas*, 537 F.2d at 303-04; *see also FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1055 (8th Cir. 1999).

Lundbeck's lengthy brief thus addresses an appeal that the FTC and Minnesota did not bring, namely, a challenge to the evidentiary underpinnings of

the district court's findings of fact.[3] Because the FTC and Minnesota do not claim that the district court's findings of fact are "clearly erroneous," many of Lundbeck's arguments, which are based upon extended discussions of the trial testimony rather than the district court's findings of fact, are irrelevant to the issues on appeal. The FTC and Minnesota limit this reply to those arguments that are relevant to the issues actually raised in this appeal.

II. THE DISTRICT COURT IGNORED "PERTINENT FACTORS" CONCERNING REASONABLE INTERCHANGEABILITY AND CROSS-ELASTICITY

A. The District Court Ignored its Findings Addressing Likely Competition in the But-For World While Relying on Neonatologists' Current Preferences

Market definition does not occur in a vacuum. As this Court has stated, market definition "'is merely an aid for determining whether [market] power exists.'" *Gen. Indus. Corp. v. The Hartz Mountain Corp.*, 810 F.2d 795, 805 (8th Cir. 1987) (quoting L. Sullivan, *Antitrust* 41 (1977)). We explained in our opening brief (FTC/MN Br.30-31) that the purpose of market definition in this case is to

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[3] For this reason, Lundbeck is wrong to assert that we "quibble with how the court weighed the evidence." LB.ii. Lundbeck also makes the baseless accusations that the FTC and Minnesota failed in their brief's Statement of Facts to describe the evidence below and misleadingly presented it. LB.5-6. But, because the Statement of Facts principally relied upon the lower court's findings of fact, there was no need to burden this Court with a detailed review of each side's evidence.

assess the competitive effects of Lundbeck's acquisition of NeoProfen when it already owned the only FDA-approved drug for treating a PDA.

In the typical pre-acquisition case involving two products, the analysis compares the current market where the parties to the transaction compete to the hypothetical market that would be created if one party owned both products. Here, in contrast, the district court needed to compare the current market, where Lundbeck owns both drugs, with the likely but-for hypothetical market, where a competitor would have owned NeoProfen. FTC/MN Br.30-31. The harm analysis and, accordingly, the market definition should have compared the world where Lundbeck owned Indocin IV (without a generic alternative) and a competitor owned NeoProfen with the world where Lundbeck owned both drugs.

The court's findings of fact, based on real-world evidence, establish the competition that would likely have existed in the but-for world. The findings concerned, *inter alia*, Lundbeck's assessment of the likely but-for market with a competitively owned NeoProfen, *e.g.*, FF.63, 78, and Lundbeck's pre-litigation actions seeking to modify medical professionals' preferences for drugs to treat a PDA and its responses to hospitals' price sensitivity, *e.g.*, FF.82-86. The court, however, erred by focusing market definition only on the current marketplace, emphasizing the views of the eight testifying neonatologists who had never had the

opportunity to choose between independently marketed Indocin IV and NeoProfen. *See* FTC/MN Br.30-35. The FTC and Minnesota do not claim that "doctor's testimony about their preferences was inherently unreliable or contaminated, so that the court should have disregarded it." LB.68; *see also* LB.74-76. Nor do we do not seek to exclude such testimony. *See id.* Rather, the court could not conclude its legal analysis by emphasizing the current views of neonatologists while ignoring its findings of fact that addressed likely competition in a market where a competitor owned NeoProfen.

Lundbeck claims that the current views of neonatologists necessarily reflect the likely but-for world, because the acquisition did not make neonatologists less price sensitive or affect their long-held drug preferences. LB.69-70. Lundbeck is wrong as a matter of law and fact. This Court has repeatedly recognized that an acquisition can change the competitive stimuli faced by market participants; in other words, their current preferences may not reflect where they "could practicably turn" for alternatives in the hypothetical market. *FTC v. Freeman Hosp.*, 69 F.3d 260, 270 (8th Cir. 1995); *Tenet*, 186 F.3d at 1054. The question is not, as Lundbeck asserts (LB.76-77), whether consumers are aware of the alternatives. Rather, the question is what the demand for PDA drugs could have been had an independent competitor owned NeoProfen. The current views of

neonatologists, developed in a non-competitive market, are not sufficient to predict how the market would have evolved if Indocin IV and NeoProfen were competitively promoted as alternatives. *See id.*

Indeed, the district court's findings show that, at the time NeoProfen was introduced, Lundbeck itself believed neonatologists' views were not fixed, that Indocin IV and NeoProfen were practicable alternatives, and that hospital demand for PDA drugs was price sensitive – all factors that indicate the market would likely have been different had NeoProfen and Indocin IV competed. Specifically, the findings establish that Lundbeck believed it could affect neonatologists' preferences and hospitals' purchases by ceasing to promote Indocin IV, FF.81,[4] and pricing the drugs at parity to remove price as a competitive factor, thus allowing "rep to spend more time selling product differentiation in the NICU vs. spending time with the pharmacy director on price." FF.82. The findings further show that Lundbeck specifically believed that market participants were

[4] Lundbeck suggests that, because Merck did not promote Indocin IV (FF.37), Lundbeck's decision not to promote it could not have affected neonatologists' views. LB.70. Lundbeck is wrong because Merck owned Indocin IV in a market very different from the likely but-for market. Merck faced no competition from NeoProfen, so did not need to promote Indocin IV. In the likely but-for market, Indocin IV would have faced competition from NeoProfen. Indeed, despite Lundbeck's citation to testimony indicating that it did not plan to promote Indocin IV, LB.70 (citing App.1482-84), the district court specifically found that Lundbeck planned originally to promote Indocin IV, even if it owned only that drug. FF.78.

persuadable and that accounts that started buying NeoProfen could return to buying Indocin IV. FF.85-86.[5]

The district court could not assess market demand based solely on findings of fact about neonatologists' current preferences. It also needed to analyze its findings of fact concerning likely demand in a market where a competitor owned NeoProfen. The court ignored these latter findings when it concluded that Indocin IV and NeoProfen are not in the same product market. FF.109-16. As this Court has made clear, that was legal error. *Empire Gas*, 537 F.2d at 303-04 (reversing market definition because pertinent factors ignored); *Tenet*, 186 F.3d at 1053-55 (same).

B. The Court's Findings Demonstrate that Marginal Customers Likely Could Have Constrained Pricing for Drugs to Treat a PDA

The FTC and Minnesota demonstrated in our opening brief that the district court committed legal error by ignoring its findings demonstrating the likely existence of sufficient marginal customers to have constrained pricing in the but-for market (FF.82-86) and concluding (FF.116) that low cross-elasticity meant that two products could not be in the same market. FTC/MN Br.36-40. As we showed, the legal standards for market definition were met here because a sufficient number

[5] During the relevant time period, generic indomethacin had not entered the market, so the choice was between Indocin IV and NeoProfen.

of customers were likely willing to switch (or threaten to switch) and, thus, could constrain prices. *Tenet*, 186 F.3d at 1054; *United States v. Engelhard Corp.*, 126 F.3d 1302, 1306 (11th Cir. 1997). The district court's findings established that there were several sets of purchasers who were up for grabs, including accounts that had not determined whether to purchase Indocin IV or NeoProfen, accounts that had chosen NeoProfen but were at risk for reverting to Indocin IV (or generic indomethacin), and the "economic driven vial splitting crowd." FTC/MN Br.39 (citing FF.82-84).

Lundbeck does not dispute that a small number of switchable customers can suffice to constrain pricing, but rather claims that the FTC and Minnesota cannot raise these arguments, because we allegedly failed to identify marginal customers or show that there were a sufficient number of them to matter. LB.80-85.[6] Lundbeck is incorrect, because the FTC and Minnesota demonstrated below that,

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[6] To the extent Lundbeck's argument is that the existence of marginal customers or the sufficiency of cross-elasticity, including whether it must be high or low, are new issues, that is clearly wrong. As seen in the parties' pre- and post-trial briefs (Docs.171, 182, 276, 279, 284, 290), the issues were among the many contested below. The FTC and Minnesota are not precluded from making, and this Court does not refrain from considering, new arguments that do not present new issues. *See, e.g.*, *Universal Title*, 942 F.2d at 1314 ("'We think it would be in disharmony with one of the primary purposes of appellate review were we to refuse to consider each nuance or shift in approach urged by a party simply because it was not similarly urged below.'") (quoting *In re Osweiler*, 346 F.2d 617, 621 (C.C.P.A. 1965)).

based on all the facts, there were hospitals and neonatologists "on the margin that [were] willing to swing share," App.723, and that Lundbeck responded accordingly, App.720-21; *see also* FTC/MN Post-Trial Br. 14-16 (Doc.279). The district court's findings of fact establish the same thing: Lundbeck's pre-litigation conduct (*e.g.*, switch and pricing strategies, tracking system and marketing plans) shows that there were switchable and persuadable buyers in sufficient numbers such that Lundbeck could not, *and did not*, ignore them. FF.83-86; FTC/MN Br.37-39, 50.

Lundbeck also disputes the court's findings regarding the marginal customers' motivation. It states that the findings merely describe the categories used in Lundbeck's Launch Tracker, but do not establish that there would have been switching based upon price. LB.83-84. Lundbeck's unsupported gloss on these findings fails to show an absence of price motivation, given the court's related findings that identified price concerns (as well as non-price concerns) threatening NeoProfen sales. FF.83-34. It is sophistry for Lundbeck to suggest that the accounts identified as switchable and persuadable in the Launch Tracker had nothing to do with the price concerns expressed in Lundbeck's marketing plans and discussed in the court's findings of fact.

With respect to accounts that used vial-splitting or viewed generics as

alternatives, Lundbeck claims that the FTC and Minnesota pulled phrases "from two marketing documents, similarly taken out of context, neither of which provides any indication of how many consumers' views they represent, how price sensitive those consumers may be, or how they would affect pricing." LB.84. Lundbeck's critique is not valid, because the quantification that Lundbeck claims is needed could not occur due to the lack of a "before" period where NeoProfen competed freely. By necessity, the best evidence concerning possible marginal customers was found in Lundbeck's documents and contemporaneous actions, not its trial testimony. This evidence underlies the court's factual findings. In effect, Lundbeck is accusing the district court of cherry-picking phrases unfavorable to Lundbeck. As for the significance of these marginal consumers, the findings show that Lundbeck did not write them off as inconsequential. Rather, Lundbeck specifically identified vial-splitting and generic entry as "threats" in both 2007 and 2008, and noted that vial-splitting and price concerns were among the reasons accounts were not ordering NeoProfen. FF.83-84.[7]

Lundbeck also wrongly asserts that the FTC and Minnesota failed to provide

[7] Lundbeck tries to claim that FF.84 "say[s] nothing about causation," LB.63 n.46, but the finding clearly identified pricing and vial-splitting as causes of objections to NeoProfen: "Lundbeck noted the following objections among non-ordering accounts: … (4) 'Price'; and (5) 'Vial splitting a common practice with Indocin.'" FF.84.

the district court with the data and econometric analysis needed to conclude "that either Lundbeck or an independent owner of NeoProfen would be unable to raise prices a small amount without causing the 'critical loss' of enough 'on the fence' neonatologists to make the price increase profitable." LB.81. As Lundbeck conceded (App.1699-700), the data to perform a quantitative analysis did not exist here.[8] Lundbeck's acquisition of NeoProfen before it reached the market meant there was no significant variation in prices of the two drugs to have a record that would permit an econometric estimation of the critical loss (not to mention cross-elasticity). Instead, Lundbeck's pre-litigation conduct, as established by the court's findings of fact, showed persuadable hospitals and neonatologists sufficient in number to require Lundbeck to stop marketing Indocin IV, price the drugs to eliminate price competition, and still have to worry about NeoProfen converts switching back to Indocin IV. FF.81-86. Were the drugs in separate markets, Lundbeck's actions would not have been necessary.

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[8] In any event, a critical loss or cross-elasticity analysis would have been based on the change in demand resulting from a change in prices, not the identification of the neonatologists whose choices would change, as Lundbeck incorrectly says was needed (LB.82-83). *See In re: Live Concert Antitrust Litig.*, 247 F.R.D. 98, 127 (C.D. Cal. 2007) ("when calculating the cross-elasticity of demand, economists examine the aggregate demand of consumers as represented by a demand curve rather than the purchasing decisions of an individual consumer").

III. THE DISTRICT COURT'S FINDINGS OF FACT ESTABLISH THAT THE DRUGS WERE IN THE SAME MARKET

In our opening brief (FTC/MN Br.43-54), the FTC and Minnesota showed that, had the district court applied, rather than just quoted, the standards for determining reasonable interchangeability of use or the cross-elasticity of demand, *see* FF.112, it should have concluded that FDA-approved drugs for the treatment of a PDA is the relevant market for assessing the competitive effects of Lundbeck's acquisition of NeoProfen. The court's findings of fact established that practical indicia, including functional interchangeability, industry recognition and price sensitivity, *see Brown Shoe*, 370 U.S. at 326, demonstrated reasonable interchangeability and cross-elasticity between Indocin IV and NeoProfen. Lundbeck's effort to explain away these findings of facts cannot overcome the logical conclusion that, during the relevant time period, the only two FDA-approved drugs for the treatment of a PDA occupied the same market.

A. Lundbeck's Argument that Functional Interchangeability and Industry Recognition are Second-Tier Indicia is Wrong

Despite (and, perhaps, because of) the economic importance of functional interchangeability and industry recognition as to whether products are substitutes, Lundbeck attempts to assign these indicia to a "non-economic" category. It claims that the indicia are somehow "less probative" (LB.52-53) (citing *Rothery Storage*

& Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 218 n.4 (D.C. Cir. 1986)) than what it characterizes as "economic" indicia and "do not trump evidence of economic substitutability." LB.38 (citing *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 995 (11th Cir. 1993)). Lundbeck is incorrect that these indicia are not evidence of economic substitutability or are less probative.

This Court does not treat products' functional interchangeability as non-economic evidence of reasonable interchangeability. In *H.J., Inc. v. International Telephone & Telegraph Corp.*, 867 F.2d 1531, 1538 (8th Cir. 1989), and *HDC Medical, Inc. v. Minntech Corp.*, 474 F.3d 543, 547 (8th Cir. 2007), the Court's conclusions that products occupied the same markets and were economic substitutes rested principally on the products' identical uses, *i.e.*, functional interchangeability. *Id.* Similarly, then-Judge Sotomayor wrote in *Todd v. Exxon Corp.* that industry recognition is "significant because 'we assume that the economic actors usually have accurate perceptions of economic realities.'" 275 F.3d 191, 205 (2d Cir. 2001) (quoting *Rothery*, 792 F.2d at 218 n.4). Moreover, neither *U.S. Anchor Manufacturing* nor *Rothery* articulated the economic/non-economic hierarchy urged by Lundbeck. In short, there is no legal support for Lundbeck's distinction.

There is also no factual support for Lundbeck's claim. The district court's

findings of fact (*e.g.*, FF.14, 21, 78, 88, 94) undeniably established the functional and economic substitutability of Indocin IV and NeoProfen, because the drugs have the "same basic function," are sold to the "same customers," and are handled by "similar, or even the same dealers and distributors." *See H.J., Inc.*, 867 at 1538. Although Lundbeck tries to diminish the significance of these findings by pointing out clinical differences between the drugs, LB.51-52, it ignores the court's other findings that, for many hospitals and neonatologists practicing in them, the clinical differences are not significant enough to require hospitals to carry both drugs. FF.94. Moreover, when a PDA is treated with drugs, Indocin IV is used 60 percent of the time, while NeoProfen is used 40 percent of the time. FF.94. This lack of market consensus is not surprising given the drugs' identical effectiveness, FF.21, similar FDA labels, FF.15-16, 18, and the FDA's refusal to approve a label claiming that NeoProfen is safer than, or superior to, Indocin IV. FF.36; App.119; App.316-51; App.734.

The findings (*e.g.*, FF.58, 63, 82-84) also demonstrated that the industry recognized the competition that existed between the drugs. *See Todd*, 275 F.3d at 205 (market defined based on litigants' own recognition that products competed). The district court found that "[w]hen launching NeoProfen, an independent owner would not have disregarded Indocin IV's price." FF.63. The court similarly found

that Lundbeck was concerned that, if it disclosed a higher sales price for Indocin IV, Abbott would demand a higher price for the sale of the rights to NeoProfen. FF.58.

Contrary to Lundbeck's claims, these findings do not "simply recognize that new entrants commonly benchmark their prices off of comparable incumbent drugs." LB.53. With respect to benchmarking, the court found only that Lundbeck had looked to non-substitutable, non-PDA drugs when deciding its price for Indocin IV. FF.41. It did not find that Abbott's or Lundbeck's actions with respect to NeoProfen were part of a benchmarking effort. Indeed, Abbott and Lundbeck renegotiated and lowered Lundbeck's royalty payments to Abbott after NeoProfen failed to obtain an FDA label superior to Indocin IV's, FF.36,[9] which simply underscores that both companies understood the competitive price relationship between the drugs. *See U.S. Anchor Mfg.*, 7 F.3d at 995 (monitoring prices of competing products is indicator of cross-elasticity).

Finally, the district court found that Lundbeck expected an independent NeoProfen would be priced 15% less than Indocin IV, FF.78, but that Lundbeck priced NeoProfen and Indocin IV to eliminate price as a competitive variable.

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[9] In effect, the parties reduced the NeoProfen purchase price because Lundbeck could not use an FDA label to promote NeoProfen as superior to Indocin IV.

FF.82. Thus, not only did the industry recognize these products as substitutes, but Lundbeck's own pricing actions show that *it* recognized that the demand for the drugs would be influenced by their respective prices.

B. Lundbeck Recognized and Responded to Hospitals' Price Sensitivity When It Set the Prices of Indocin IV and NeoProfen

The district court's findings of fact also show that Lundbeck understood that hospitals' cost-consciousness and price sensitivity would lead them to seek to use the formulary process to promote price competition. FF.82, 84, 91-93. Lundbeck adopted pricing parity to "[t]ake away potential pharmacoeconomic debate" and "[a]llow[] rep to spend more time selling product differentiation in the NICU vs. spending time with pharmacy director on price." FF.82. The court also found that in response to the Indocin IV price increases, hospitals, through group purchasing organizations ("GPOs"), tried to engage Lundbeck in price negotiations and reached out to other manufacturers about a generic version of Indocin IV. FF.90. They also sought to lower PDA drug costs through vial-splitting. FF.60, 82, 83-84.

Accordingly, the district court's findings of fact undermine Lundbeck's counter-intuitive argument that hospitals were not price sensitive or lacked incentives to reduce the costs of PDA drugs. *See* LB.56-57. When Lundbeck significantly increased Indocin IV's price, hospitals began to split Indocin IV vials

to lower that drug's cost. FF.60. They also used vial-splitting to avoid similarly priced NeoProfen. FF.84. In other words, economics drove hospitals to split vials, which Lundbeck recognized when it noted that its slight, 3% discount for NeoProfen "will **not** convert the economic driven vial splitting crowd." FF.82 (emphasis in original). Vial-splitting more than "simply shows that hospitals attempted to reduce waste," LB.57, but instead supports the conclusion that hospitals were concerned about and responded to price.

The court's own findings of fact also preclude Lundbeck from maintaining that hospitals were "unlikely to switch between Indocin and NeoProfen based on price, even to obtain cost savings," LB.54, or that factors other than pricing pressure from hospitals affected Lundbeck's pricing strategy, LB.60-61. For example, FF.82 states that Lundbeck offered "a 20% [discount] on early stocking orders to drive NeoProfen's adoption." Lundbeck tries to dismiss the finding as merely "describ[ing] a NeoProfen launch presentation," LB.60, but the court found that it was Lundbeck's "stocking plan for hospitals." FF.82. Lundbeck claims that pricing NeoProfen at a 3% discount to Indocin IV was "a means to rebuild relationships with hospitals that were upset with Lundbeck about the earlier Indocin price increase." LB.60. But, the court found that hospitals' desire to negotiate on price resulted in Lundbeck's decision to use virtual pricing parity to

eliminate price negotiations and focus on product differentiation. FF.82.

Moreover, Lundbeck's pricing actions directly rebut its claim that demand for the PDA drugs was not sensitive to price. LB.13-14, 83. If Lundbeck were correct, it should have charged more for NeoProfen, because it did not need to worry about losing sales to Indocin IV on price grounds. But, the substitutability of Indocin IV and NeoProfen affected how Lundbeck, even as owner of both products, priced NeoProfen, which simply demonstrates that the two drugs were in the same market.

Lundbeck (LB.55) cannot overcome these findings of fact by relying on the opinion testimony of Professor Joel Hay that "pharmacy and therapeutics committees would not be able to promote price competition between Indocin IV and NeoProfen, were they owned by separate companies." FF.95. The district court credited his opinion, FF.95,[10] but the opinion does not support the conclusion that Indocin IV and NeoProfen were not in the same market, because it is inconsistent with the court's findings of fact and does not make economic sense. *See Rebel Oil Co., Inc. v. Atl. Richfield Co.*, 51 F.3d 1421, 1435-36 (9th Cir. 1995) (otherwise admissible opinion must still be economically reasonable). Similarly,

[10] The district court did not credit his other opinion that hospitals did not have an incentive to try to promote price competition. *See* App.1654-55; FF.95.

the opinion cannot substitute for the court's findings of fact regarding hospital efforts to use their formulary process to promote competition, FF.88-93, their specific responses to Lundbeck's price increases, FF.60, 90, and Lundbeck's efforts to eliminate price competition, FF.82. *See Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000) ("Expert testimony is useful as a guide to interpreting market facts, but it is not a substitute for them.") (quoting *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)). "When an expert opinion 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." *Tenet*, 186 F.3d at 1053 n.13. Such is the case here.

IV. THE DISTRICT COURT INCORRECTLY TREATED LUNDBECK'S BUSINESS DOCUMENTS AS LEGALLY IRRELEVANT TO AN ECONOMIC ANALYSIS

The district court incorrectly stated that "internal marketing documents do not provide a sound economic basis for assessing a market in the way that a proper interchangeability analysis would." FF.114 (citing *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc*. 588 F.3d 908, 919 (6th Cir. 2009)). Rather than rely on those documents to define the market, the court concluded that Indocin IV and NeoProfen are not in the same market largely based on trial testimony from

a handful of neonatologists regarding their current preferences. FTC/MN Br.32. The Court did, however, rely on the documents elsewhere and, as Lundbeck admits (LB.67), many of the district court's findings of fact are based upon these documents. These findings demonstrate that the drugs are in the same market based upon their reasonable interchangeability and cross-elasticity of demand. Nonetheless, the court ignored the findings in its analysis of the product market. FF.109-16. Thus, contrary to Lundbeck's contention, the district court did not limit the impact of its legally flawed observation about internal marketing documents to its rejection of Dr. Arnold's opinion. *See* LB.65.

For example, Lundbeck priced the drugs similarly to "[t]ake[] away potential pharmacoeconomic debate." FF.82. This finding clearly indicates that Lundbeck itself believed the two drugs were being evaluated on price. Other findings show the effect of competition in the "but-for" world, such as Lundbeck's internal forecast predicting, *inter alia*, pricing differences depending on whether it owned both PDA drugs or only Indocin IV. FF.78.[11] Still other findings show Lundbeck

[11] FF.78 is an example of Lundbeck's use of its own evidence to challenge the district court's findings of fact. Lundbeck attempts to lessen the significance of FF.78 by claiming that the document upon which it is based "was created by an employee who (1) had no responsibility for or experience with pricing decisions, and (2) created the documents as a 'very first-pass preliminary overview' before doing any relevant marketing or pricing research." LB.63-64 n.47. The district court did not adopt Lundbeck's argument and found that Lundbeck's strategy

concerned about switching in both directions – from Indocin IV to NeoProfen and vice versa – on price, as well as non-price, grounds. FF.83-85. Again, these findings played no role in the court's market definition (FF.109-16), which is clear legal error. *See* Part II., *supra*.

The remedy for the district court's error is not, as Lundbeck urges (LB.64), to re-weigh the evidence. The Court can simply give the district court's findings of fact their due using the proper legal standards discussed above and in our opening brief. Such an analysis compels the conclusion that Indocin IV and NeoProfen are in the same product market.

V. THE DISTRICT COURT'S CONCLUSION THAT LUNDBECK'S SWITCHING STRATEGY WOULD NOT MAKE SENSE IF INDOCIN IV AND NEOPROFEN WERE IN THE SAME MARKET IS LOGICALLY AND ECONOMICALLY ERRONEOUS

As we have shown, Lundbeck's strategy to switch customers from Indocin IV to NeoProfen prior to the introduction of generic indomethacin made economic sense, because Indocin IV and NeoProfen are in the same market. FTC/MN Br.54-57.[12] Nonetheless, Lundbeck repeats its claim from below (accepted by the district

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depended upon whether it owned one or both products. FF.78.

[12] The FTC and Minnesota's pre-trial brief did not concede, as Lundbeck claims (LB.14 n.4), that NeoProfen faced no competition from generic indomethacin. The FTC and Minnesota merely described the undisputed fact that there would be no generic form of NeoProfen in the near term because of the drug's orphan status.

court, FF.116) that its switch strategy would not have made sense if Indocin IV and NeoProfen were in the same market. LB.27, 45, 46, 59.[13] The apparent reasoning behind Lundbeck's claim and the court's conclusion is that, if Indocin IV and NeoProfen were in the same market, the eventual entry of generic indomethacin at a lower price would cause NeoProfen to lose sales to the generic, because its effect on both of the branded drugs would be the same. Under their theory, Lundbeck would not have sought to switch hospitals and neonatologists to NeoProfen, if generic entry would cause everyone to switch later to generic indomethacin.

This argument rests on the economically false premise that if the products were in the same market, then generic indomethacin would necessarily have the same effect on NeoProfen's sales as it would have on Indocin IV's sales. This is incorrect. Lundbeck and the court fail to grasp that two products that are in the same market, *e.g.*, Indocin IV and NeoProfen, would not necessarily be affected equally by a third product in that market, *e.g.*, generic indomethacin. This is

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See FF.17.

[13] Lundbeck even goes so far as to claim that, if the drugs were in the same market, its acquisition of NeoProfen would have made no sense. LB.59. Such a claim is wrong, because it requires one to assume that Lundbeck would not have found it profitable during the approximately four years before entry of generic indomethacin to have a monopoly over, and to charge monopoly prices for, the only two drugs approved to treat a PDA.

especially true where the third product would be identical to one of the first two products but not to the other, which would be the situation once generic indomethacin reached the market.

Because Indocin IV and NeoProfen are not bio-equivalent, some customers would not substitute one for the other. On the other hand, because generic indomethacin and Indocin IV would be bio-equivalent, customers would more readily substitute a lower-priced generic indomethacin for Indocin IV. It does not follow that generic indomethacin would take sales away from NeoProfen to the same extent that it takes sales away from Indocin IV.

Because Indocin IV and NeoProfen are close enough substitutes to be in the same market, but not as close substitutes as Indocin IV and generic indomethacin, generic indomethacin, once available, would be less of a threat to NeoProfen sales than it was to Indocin IV sales. Thus, Lundbeck's switch strategy sought to convert as many customers as possible to NeoProfen, thereby reducing the number of customers who would defect from a Lundbeck product once generic indomethacin came into the market. This switch strategy is entirely consistent with the conclusion that Indocin IV and NeoProfen are in the same market.

In short, the district court excluded NeoProfen from the market, because of the future existence of a closer competitor to Indocin IV, generic indomethacin,

that was not in the but-for hypothetical market. Market definition, however, is supposed to elucidate the competitive effects of the conduct under review by the court, not some future case. *Hartz Mountain*, 810 F.2d at 805; *see also U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993).[14] No case law suggests that a product should be excluded from the market, because some future product might be a closer substitute. Indeed, the Supreme Court has held just the opposite. *United States v. Cont'l Can Co.*, 378 U.S. 441, 452-53 (1964).

VI. THE COURT SHOULD NOT AFFIRM ON ALTERNATIVE GROUNDS

If the Court reverses the district court's product market determination, Lundbeck urges it to affirm the dismissal anyway on grounds that the FTC and Minnesota did not prove adverse price effects from Lundbeck's monopolization of the PDA drug market. LB.91-99. The Court should not affirm on this basis. It has repeatedly declined to affirm a district court's decision on alternative grounds where "there are factual questions still to be resolved or where we would benefit from having the District Court decide the issue in the first instance." *Schweiss v.*

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[14] As pointed in our opening brief, courts have defined relevant product markets in pharmaceutical cases in various ways depending upon different stages of a product's life cycle or the conduct or transaction under review. FTC/MN Br.56-57.

Chrysler Motors Corp., 922 F.2d 473, 476 (8th Cir. 1990); *Reeder v. Kansas City Bd. of Police Comm'rs*, 733 F.2d 543, 548 (8th Cir. 1984) (same); *see also Percefull v. Claybaker*, 312 Fed. Appx. 827, 2008 U.S. App. LEXIS 24227, at *2-3 (8th Cir. Nov. 25, 2008) (unpublished) (after reversing district court's decision on *res judicata* grounds, Court refused to decide case on the merits).

Here, the district court did not reach, or make findings concerning, the issue of price effects, because it dismissed the case on market definition grounds. The parties below contested numerous questions related to the issue of price effects, including whether duopoly prices would be lower than monopoly prices and Lundbeck's profits and losses. Given these factual disputes, the need to analyze the evidence concerning them, and the knowledge gleaned by the district court from seven days of live trial testimony, the Court would be better served to remand the case so the district court can resolve the disputes and make appropriate findings.

In any event, Lundbeck fails to demonstrate that its monopolization of the market was not harmful and, as a matter of both law and economics, it is unlikely that Lundbeck could make that showing. A transaction resulting in a literal monopoly is virtually always anticompetitive and essentially always illegal. *United States v. El Paso Natural Gas Co.*, 376 U.S. 651, 660-62 (1964). Further,

an acquisition by a monopolist that cuts off entry into the relevant market is patently exclusionary because it stops the competitive process in its tracks. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 488 (1992); III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 701b (3d ed. 2008). Accordingly, if this Court reverses on market definition, the district court's findings of fact support the conclusion that Lundbeck is liable for unlawful monopolization.

Lundbeck's specific claims for why there was no harm do not withstand scrutiny. It maintains that the supposed absence of high cross-price elasticity meant that not enough doctors would shift on price grounds to make price competition profitable. LB.97-98. As the FTC and Minnesota have shown, that is neither economically nor legally correct. Especially for these high margin products, only a small number of customers needed to shift for there to have been price competition and to make a price cut profitable.[15] *See* U.S. Dep't of Justice and the Federal Trade Commission, Horizontal Merger Guidelines §§ 4.1.3, 6.1 (Aug. 19, 2010). Lundbeck also claims that it would have raised Indocin IV's price in the face of generic entry and thus would not have lowered the price to compete against a less close substitute. LB.98-99. But, Lundbeck's response to

[15] Lundbeck agrees. LB.82.

the actual entry of generic indomethacin is irrelevant; the relevant time frame is the four years prior to generic entry when Lundbeck's monopolization thwarted the competition that otherwise likely would have existed between branded Indocin IV and NeoProfen.

CONCLUSION

The Court should vacate the judgment of the district court, hold that Indocin IV and NeoProfen are in the same product market, and remand the case for further proceedings consistent with the Court's decision and the findings of fact.

Respectfully submitted,

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March 21, 2011

CERTIFICATE OF COMPLIANCE

We certify that this brief complies with the type-volume limitation set forth in Federal Rule of Appellate Procedure 32(a)(7)(B). It is proportionally spaced and contains 6,929 words, as counted by the WordPerfect word processing program. We further certify that the electronic version of the brief has been scanned for viruses and is virus free.

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March 21, 2011

CERTIFICATE OF FILING AND SERVICE

U.S. COURT OF APPEALS FOR THE EIGHTH CIRCUIT
NOS. 10-3458 and 10-3459

We hereby certify that on March 21, 2011, we electronically filed the REPLY BRIEF OF PLAINTIFFS-APPELLANTS FEDERAL TRADE COMMISSION AND STATE OF MINNESOTA with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

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