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)

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

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SUMMARY OF THE CASE

In January 2006, Lundbeck owned a drug called Indocin IV, which at that time was the only drug available to treat a life-threatening heart condition called patent ductus arteriosis ("PDA"). This case is about how Lundbeck maintained that monopoly. By acquiring rights to NeoProfen, a drug awaiting FDA approval to treat PDA, Lundbeck preempted competition that likely would have enabled hospitals, who are the buyers of PDA drugs, to play off rival sellers and obtain price discounts. Lundbeck raised the price of Indocin IV by almost 1,300 percent and introduced NeoProfen at a similar price. It also ceased promoting Indocin IV, seeking to move as many customers as possible to NeoProfen.

The Federal Trade Commission and the State of Minnesota brought suit alleging that Lundbeck's acquisition of NeoProfen substantially lessened competition and monopolized the market in violation of federal and state antitrust laws. The district court held that the two drugs are not in the same antitrust product market and that Lundbeck's acquisition therefore did not violate the law.

The issues presented concern the district court's legally erroneous product market determination, which was contradicted by its own findings and reflected the court's failure to follow applicable legal standards and this Court's precedents. The FTC and Minnesota believe oral argument, at 15 minutes per side, would assist the Court in resolving these issues.

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JURISDICTIONAL STATEMENT

The Federal Trade Commission ("Commission" or "FTC") and the State of Minnesota ("Minnesota") appeal the dismissal of their antitrust actions against Lundbeck, Inc. ("Lundbeck"). The Commission brought its action under Section 13(b)(2) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b)(2), alleging that Lundbeck unlawfully acquired assets and obtained monopoly power in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45. Minnesota brought its action under Section 16 of the Clayton Act, 15 U.S.C. § 26, alleging that Lundbeck engaged in anticompetitive practices in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 7 of the Clayton Act, 15 U.S.C. § 18, Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66, and Minnesota common law for unjust enrichment. The district court had subject matter jurisdiction over the actions pursuant to 15 U.S.C. §§ 45(a), 53(b), and 28 U.S.C. §§ 1331, 1337(a), 1345 and 1367.

This Court has jurisdiction under 28 U.S.C. § 1291. The decision under review denied all relief sought by the Commission and Minnesota and resolved all issues before the district court. The judgment appealed from was entered on August 31, 2010, and the FTC and Minnesota timely filed their notices of appeal on October 28, 2010. The Court consolidated the appeals on November 4, 2010.

STATEMENT OF ISSUES

This case required the district court to determine the relevant product market in which to assess the competitive effects of a monopolist's acquisition of a potential competitor. The questions presented are:

1. Whether the district court's conclusion that two products were not in the same antitrust product market is contradicted by its own factual findings and constituted legal error given the court's obligation to examine the competitive dynamics and practical alternatives available to consumers that likely would have existed if the monopolist had not controlled both products? *Bathke v. Casey's Gen. Stores,* Inc., 64 F.3d 340 (8th Cir. 1995); *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045 (8th Cir. 1999); *Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591 (8th Cir. 2009); *Yamaha Motor Co., Ltd. v. FTC*, 657 F.2d 971 (8th Cir. 1981).
2. Whether the district court committed legal error by ignoring the role of marginal customers in defining the relevant product market as well as its findings showing that marginal customers would likely have constrained prices had the acquisition not occurred? *Tenet*, 186 F.3d 1045; *H.J. Inc. v. Int'l Tel. & Tel. Corp.*, 867 F.2d 1531 (8th Cir. 1989).
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contemporaneous, pre-litigation internal marketing documents cannot provide a proper basis for analyzing interchangeability? *Spirit Airlines, Inc. v. Nw. Airlines, Inc.*, 431 F.3d 917 (6th Cir. 2005); *Cmty Publ'rs, Inc. v. Donrey Corp.*, 892 F. Supp. 1146 (W.D. Ark. 1995), *aff'd, Cmty Publ'rs, Inc. v. DR Partners*, 139 F.3d 1180 (8th Cir. 1998); *United States v. Waste Mgmt., Inc.*, 743 F.2d 976 (2d Cir. 1984); *FTC v. Staples, Inc.*, 970 F. Supp. 1066 (D.D.C. 1997).

4. Whether, applying the correct legal standards, the district court's own findings establish that Indocin IV and NeoProfen are in the same product market where the products are equally effective at treating the same condition, market participants deem the drugs to be economic substitutes, and the monopolist's marketing strategy reflected that substitutability? *Brown Shoe Co., Inc. v. United States*, 370 U.S. 294 (1962); *Cmty Publ'rs, Inc.*, 892 F. Supp. 1146, *aff'd*, 139 F.3d 1180; *H.J. Inc.*, 867 F.2d 1531; *Todd v. Exxon*, 275 F.3d 191 (2d Cir. 2001).

STATEMENT OF THE CASE

This case is about Lundbeck's acquisition of a drug called NeoProfen. When Lundbeck purchased the rights to NeoProfen, it already owned Indocin IV. Both drugs treat the same medical condition affecting premature babies, patent

ductus arteriosus ("PDA"). At the time of the acquisition, Indocin IV was the only drug on the market for that condition, so Lundbeck had a monopoly. NeoProfen was awaiting approval by the Food and Drug Administration ("FDA"); the two drugs had not yet competed in the marketplace.

Lundbeck, knew, however, that once on the market, NeoProfen would compete with Indocin IV and reduce the company's future Indocin IV revenues. NeoProfen would give hospitals, which buy these drugs, something they had never had before – a competitive alternative to Indocin IV. Unfortunately for these hospitals, Lundbeck denied them this opportunity. It bought NeoProfen and preempted competition between Indocin IV and NeoProfen before it could occur. Lundbeck thereby avoided any constraint on its pricing and retained all sales of drugs treating a PDA for nearly four years.

On December 18, 2008, in the United States District Court for the District of Minnesota, the Commission and Minnesota filed complaints challenging Lundbeck's acquisition of NeoProfen and maintenance of its original monopoly position. The case was tried before the Honorable Joan N. Ericksen during a 7-day bench trial in December 2009. The district court issued its decision on August 31, 2010. It dismissed the complaints, holding that the FTC and Minnesota had failed to show that Indocin IV and NeoProfen are in the same product market. This

appeal followed.

STATEMENT OF FACTS

A. Factual Background

Indocin IV and NeoProfen

Indocin IV and NeoProfen treat a heart condition affecting premature babies known as a patent ductus arteriosus or PDA. FF.4, 14.[1] A PDA occurs when a shunt in the heart that connects a fetus's pulmonary artery to its aortic arch fails to close shortly after birth. FF.4; JS.17 (App.111); App.609-10. Left untreated, a PDA can be fatal. FF.4. Approximately 30,000 infants receive drug treatment for a PDA annually. FF.6. The only alternative to drug therapy is surgery, which is much more costly and carries increased risks. FF.11-12; JS.37 (App.113).

For many years, the only drug on the market for treating a PDA was Indocin IV. FF.15, 16. Indocin IV's active ingredient is indomethacin. FF.15. Lundbeck acquired rights to Indocin IV from Merck in August 2005. FF.22. Lundbeck acquired rights to a second PDA drug, NeoProfen, in January 2006. FF.33. NeoProfen's active ingredient is ibuprofen lysine. The U.S. Food and Drug

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[1] "FF" refers to the district court's factual findings, while "CL" refers to its conclusions of law. Both are contained in the Addendum as well as the Appendix. "JS"refers to the parties' Joint Stipulation, which is also in the Appendix. "App." refers to the Appendix.

Administration ("FDA") approved NeoProfen in April 2006, and Lundbeck began marketing it in July 2006. FF.16.

Although not identical, Indocin IV and NeoProfen have been proven equally effective in treating a PDA. Both drugs close a PDA 75 percent to 90 percent of the time. FF.21. Although the two drugs have different side effects, FF.101, their FDA-approved labels are similar. FF.15-16, 18. Indeed, the FDA refused to approve a label for NeoProfen that would have claimed NeoProfen was safer than, or otherwise superior to, Indocin IV. FF.36; App.316-51; JS.104 (App.119); App.734. Market data on hospital purchases and use of the two drugs shows that there is no consensus that either drug is safer than the other. As of March 2009, 51 percent of hospitals had purchased only Indocin IV, 5 percent had purchased only NeoProfen, and 42 percent had purchased both drugs. FF.94. Overall, Indocin IV is used to treat a PDA 60 percent of the time, while NeoProfen is used 40 percent of the time to treat a PDA. FF.94.

Until 2010, Lundbeck's products, Indocin IV and NeoProfen, were the only two choices for hospitals that treat babies with a PDA. A generic indomethacin for injection product came on the market after the trial in this case, in February 2010. A second received FDA approval in March 2010. FF.19-20. No generic version of NeoProfen is available. NeoProfen enjoys "orphan drug" status for PDA treatment

under the Orphan Drug Act until 2013, which means that no other company can market a generic version of NeoProfen to treat a PDA until that time. FF.16. Patents relating to NeoProfen do not expire until 2020 and 2021. FF.16.

Lundbeck's Acquisitions

Lundbeck acquired the worldwide exclusive rights to Indocin IV and four other drugs from Merck in August 2005. FF.22. At that time, Indocin IV was the only FDA-approved drug for treating a PDA. FF.15-16, 19, 64. When Lundbeck began to consider acquiring Indocin IV, the company recognized that the Merck drugs, including Indocin IV, were "a group of medically niche small volume products that don't have substitutes" and that it could price the drugs "almost anywhere we want." FF.43. Lundbeck expected that if it raised the price of Indocin IV by a large amount it would likely attract generic entry, but it predicted that generic entry was still several years off. FF.64.[2] In the meantime, the company could profit from Indocin IV's position as the only PDA drug.

But late in the negotiation of its purchase of Indocin IV, Lundbeck learned that Farmacon-IL and Abbott Laboratories were preparing to file a new drug application for NeoProfen, a potential competitor to Indocin IV. FF.33.

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[2] Lundbeck predicted that the earliest generic entry would occur was in April 2008, FF.64, and possibly as late as mid-2009. App.134-47; App.626-28. As it turned out, generic Indocin IV did not enter until February 2010. FF.19.

Immediately following the Indocin IV acquisition, Lundbeck contacted Abbott about acquiring the rights to NeoProfen. FF.33. Lundbeck expected Indocin IV to lose sales to NeoProfen, and saw acquisition of the drug as an opportunity to enable Lundbeck to "cannibalize [its] Indocin IV sales in a controlled manner" and "retain sales for both products." FF.79.

In an August 2005 document, Lundbeck compared strategic scenarios with and without the acquisition of NeoProfen. Lundbeck predicted that if owned by a competitor, NeoProfen's price would be 15 percent lower than Indocin IV's, but, if Lundbeck owned both products, NeoProfen would be priced 15 percent higher than Indocin IV. FF.78.

Shortly after it acquired Indocin IV in September 2005, Lundbeck raised the wholesale list price of the drug by 40 percent. FF.54. Lundbeck held off on further price increases for a time because of Merck's sensitivity to having Indocin IV sold at a higher price while the drug was still being sold under the Merck label. FF.53-54. Even after it was able to sell Indocin IV under its own label, however, Lundbeck continued to hold off on raising the drug's price. FF.56. Announcing a larger price increase for Indocin IV was contingent on the timing of the NeoProfen acquisition. FF.58. Lundbeck was concerned that increasing the Indocin IV price would cause Abbott to demand a higher purchase price for NeoProfen. FF.58.

Two days after closing the agreement to acquire rights to NeoProfen, Lundbeck raised Indocin IV's price by nearly 1,300 percent, to $1,500 per 3-vial treatment. FF.57.

Hospital Purchasers and PDA Drugs

Hospitals purchase Indocin IV and NeoProfen for use in neonatal intensive care units ("NICUs"). FF.88. Private insurers, Medicaid and other government programs reimburse hospitals for PDA treatment at a flat, fixed rate according to the patient's diagnosis and other factors. FF.89; JS.132 (App.121-22). Hospitals do not receive higher reimbursement if the cost of PDA drugs increases. Because hospitals directly bear the cost of the drugs used in their institution, they have an incentive to negotiate lower prices for their drug purchases. App.636.

As a result, hospitals were concerned about Lundbeck's dramatic price increase for Indocin IV following Lundbeck's acquisition of NeoProfen, and took several steps in response. They first approached their group purchasing organizations ("GPOs") about trying to negotiate a lower price for Indocin IV. GPOs aggregate purchases from their member hospitals in an effort to negotiate better prices. FF.90. Lundbeck refused to contract with these GPOs. FF.90. After being rebuffed by Lundbeck, the GPOs then asked generic drug manufacturers to develop a generic version of Indocin IV. FF.65, 90. Generic entry was not,

however, an immediate solution. FF.19-20.

Some hospitals resorted to "vial splitting" or "vial sparing" in an effort to lower the cost of PDA drug therapy. FF.60. Vial splitting saves the hospital money because it may permit the hospital to treat more than one patient with a single vial of the drug. FF.60; App.630-31. Vial splitting is viewed as more feasible with Indocin IV than with NeoProfen due to the former's longer stability and greater familiarity to medical personnel. FF.84; App.155; App.284-85; App.547.

When alternative drugs to treat the same medical condition are owned by separate firms, however, the primary tool hospitals use to reduce their drug costs is to shift demand through the formulary system. A "formulary" is the list of medications that a hospital has approved for use and makes available in its pharmacy. FF.91. Through use of a formulary, hospitals are able to leverage competition between two or more drugs that treat the same condition and negotiate better prices by promising or threatening to use more or less of a drug. FF.93.

Hospitals rely on assessments by pharmacy and therapeutics ("P&T") committees to determine which drugs to add to or keep on their formulary, and to evaluate potential opportunities to leverage competition between sellers of drugs that treat the same condition. FF.91-92. If a P&T committee determines that the

clinical efficacy and safety of two drugs are similar, the hospital can then consider price in its evaluation of the available drug options. App.617-19; App.637-38; App.697-700. Once a P&T committee identifies an opportunity for price savings, P&T committees rely on a variety of tools to leverage competition by moving share between competing drugs. These tools include removing a drug from the formulary, or implementing drug-use guidelines that restrict the use of a drug to a limited set of circumstances or to treat only patients meeting certain criteria. App.613-14; App.641-42. When hospitals use the formulary in this way, competing drug manufacturers routinely respond by offering better prices to maintain sales. *See* App.615-16; App.619-22; App.624; App.632-33; App.725.

The ability to shift share from one drug to another often requires the hospital to influence physicians to change their prescribing practices. App.621-22; App.635-36; App.661. Hospitals accomplish this by presenting medical evidence derived from medical literature, often in conjunction with clinical experiences, to educate physicians about the interchangeability of two drugs. App.622-23; App.633-34. As part of the process, hospitals also present doctors with information about the price differential between drugs, which can further influence physician prescription choices. App.623; App.636.

But hospitals had no opportunity to try to use the formulary system to

leverage competition to contain their costs for PDA drugs, because the only two alternatives for PDA drug therapy were both owned by Lundbeck. Lundbeck had no incentive to discount: It was going to capture the sale regardless of a hospital's drug choice.

Lundbeck's Post-Acquisition Switch Strategy

Through a "switch strategy," Lundbeck wanted to shift PDA buyers from Indocin IV to NeoProfen before the expected entry of a lower-priced, generic version of Indocin IV. FF.80, 83. Lundbeck expected that its large price increase for Indocin IV would prompt the eventual entry of a generic version. FF.64. The impact on Indocin IV – for which the generic would be a close substitute – would be dramatic. FF.77, 83-84. A generic Indocin IV would not be identical to NeoProfen. FF.15-16. Lundbeck expected less effect on NeoProfen from generic Indocin IV, but anticipated that NeoProfen would not be immune from competition from generic Indocin IV. FF.83-84.

Although generic Indocin IV would not be as close a substitute for NeoProfen, Lundbeck deemed "[e]arly introduction of generic Indocin IV" a "threat" to NeoProfen sales. FF.83-84. Lundbeck projected that the introduction of generic Indocin IV would reduce not only current sales at hospitals using mostly NeoProfen, but also potential future sales to those that had never ordered

NeoProfen. App.295. Lundbeck was sufficiently concerned that entry by generic Indocin IV would cut into NeoProfen's sales that it devoted resources to developing new uses for NeoProfen "that w[ould] not compete with generic Indocin." App.219. But its immediate tactic was the switch strategy, which had several components.

First, soon after Lundbeck acquired NeoProfen, it stopped promoting Indocin IV, and took various steps to try to position NeoProfen as the preferred treatment for PDA. FF.81. It also offered its sales representatives financial incentives for selling NeoProfen, but none for selling Indocin IV. FF.81.

Second, prior to NeoProfen's launch in 2006, Lundbeck had predicted that "[c]ost effectiveness will likely emerge as a driver with a 2nd [PDA] therapy on [the] market." App.153. So when it introduced NeoProfen, Lundbeck priced NeoProfen at only a very slight discount to Indocin IV (3 percent) in order to "[t]ake[] away potential pharmacoeconomic debate" from hospital decisions on which PDA drug to purchase. FF.82; App.559. By pricing the drugs at virtual parity, Lundbeck hoped to allow its sales representatives to "spend more time selling product differentiation in the NICU vs. spending time with the pharmacy director on price." FF.82; App.559.

Third, Lundbeck sought to make Indocin IV appear to be a less attractive

choice. Shortly after the NeoProfen acquisition, Lundbeck began instructing its NICU sales representatives to stop actively promoting Indocin IV and to focus instead on Indocin IV's weaknesses relative to NeoProfen's anticipated benefits. FF.81. Lundbeck told its marketing team that hospitals and neonatologists "must be sold on the benefits to prescribe NeoProfen over Indocin." App.460; *see also* App.465. Even with these efforts, Lundbeck found some hospitals skeptical that NeoProfen offered safety advantages relative to Indocin IV. FF.83 ("Safety advantages (*e.g.*, renal function) not perceived as a feature/benefit significant enough to replace Indocin IV as first line therapy for PDA"); FF.84 (same).

Tracking and Keeping Converts to NeoProfen

Lundbeck's system for tracking NeoProfen's inroads against Indocin IV shows the extent to which it believed hospitals and doctors could be influenced to switch PDA drugs during the period following NeoProfen's introduction. A "green-yellow-red" color coding system reflected hospital purchases and health care professionals' attitudes toward NeoProfen. FF.85; App.235-265. Green denoted "supporters" (App.566), namely, hospitals where NeoProfen's share of PDA drug purchases exceeded 40 percent, and Lundbeck referred to these accounts as its "BREAD AND BUTTER." FF.85 (emphasis in original); App.239. The red accounts – "blockers" (App.566) – were ones where NeoProfen's market share was

less than 10 percent. FF.85; App.239.

Yellow denoted the "neutrals" (App.566), that is, the accounts that "can go either way." FF.85; App.239. But Lundbeck also considered both the "greens" and the "reds" to be in play. Even for accounts Lundbeck designated as green, *i.e.*, significant NeoProfen users, Lundbeck believed that "[t]hings change and if you don't stay on top of the happenings in these accounts, they can easily switch back to their old ways if they run into a problem or if you neglect them." FF.85; App.239. And Lundbeck deemed even the red accounts, *i.e.*, those resistant to NeoProfen, to be potentially persuadable: "we must strategize ways to gain stocking and formulary approvals" at these hospitals. FF.85; App.239. It used its pro-NeoProfen marketing strategy to try to influence all of these persuadable parties.

Lundbeck also appreciated the important role of hospital formularies in determining the relative sales of NeoProfen and Indocin IV. *See, e.g.*, FF.83-84 (2007 and 2008 marketing plans identified limited formulary access as one of several NeoProfen marketing weaknesses); App.203, App.206, App.284. Although Lundbeck had sought to eliminate price as a factor for buyers of PDA drugs, it still recognized that price could drive decisions. Lundbeck offered a one-time, 20 percent "early stocking" discount to encourage initial sales of NeoProfen. FF.82.

This strategy had limited success, however, because a one-time discount is inconsistent with the formulary system model many hospitals use, which seeks to foster more long-term price concessions. App.620-21.

By the time of trial in December 2009, Lundbeck had enjoyed nearly four years with no rival seller of a PDA drug, thanks to its preemptive acquisition of NeoProfen. As the court's findings set forth above show, hospitals, though concerned about the costs of PDA drugs, had no alternatives to Lundbeck, and had no opportunity to try to leverage the formulary process to obtain price concessions. Meanwhile, Lundbeck had virtually eliminated price as a factor in the purchase of PDA drug therapy. The acquisition also eliminated anticipated non-price competition between Indocin IV and NeoProfen, leaving Lundbeck free to pursue its one-sided marketing campaign that it hoped would mitigate the impact of the eventual entry of a generic version of Indocin IV.

B. Proceedings Below

The Trial

At trial, the FTC and Minnesota argued that the relevant product market for assessing the effects of Lundbeck's acquisition of NeoProfen is the sale of FDA-approved drugs to treat a PDA. They presented persuasive evidence that: (a) the drugs are clinical substitutes for the vast majority of PDA patients; and (b) had

the drugs been owned by rival sellers, hospitals (which bear the cost of PDA drugs), would likely have used the formulary process to obtain price concessions. The primary dispute regarding product market was whether hospitals likely would have been able to use the formulary process to constrain prices of PDA drugs.

Lundbeck argued that hospitals could not. Its argument was based on a theory of "two camps/two markets," meaning that neonatologists held strong preferences for PDA drugs and that hospitals would be unable to persuade doctors to use the other drug. App.727-28; App.730a-730b; App.733. The theory principally relied on the current views of eight neonatologists whose testimony was offered at trial, largely through deposition.

In contrast, the FTC and Minnesota argued that hospitals, using the formulary process, would likely have been able to promote competition between the drugs, if they had been owned by independent firms. App.639-697; App.701-02; App.702a-702c; App.703-16. They argued that the current preferences of selected neonatologists was of limited use in a sound economic analysis of the market that likely would have existed but for Lundbeck's acquisition. App.722-23. Instead, the FTC and Minnesota relied on objective evidence concerning likely competition, absent the acquisition, found in Lundbeck's contemporaneous, pre-litigation business documents. App.716-17; App.719-22.

Lundbeck's documents showed the likely price dynamics in the world but for the acquisition, reflecting that the company made business decisions based on its belief that some hospitals could be influenced to shift PDA drug purchases based on price. App.722-23. As discussed at trial by Lundbeck's marketing director, Lundbeck's documents also showed that in the early years after NeoProfen's launch, many hospitals and doctors had no fixed view of the relative merits of Indocin and NeoProfen. App.629a-629*l*; App.631a-631i; *see also* App.721 (describing marketing documents indicating customers Lundbeck considered to be persuadable); FF.83-86. The FTC and Minnesota further demonstrated that hospitals could obtain price discounts, assuming competing sellers, even if they were able to threaten to shift only a percentage of their purchases from one drug to another. App.620; App.723.

Cross-elasticity of demand is the measure of the degree to which a change in the price of one product affects demand for another product; if the price of one product affects demand for another product, that is one possible indication that both products are in the same market. The parties' economic experts agreed, however, that one need not analyze cross-elasticity to define the product market and that here, the absence of any period when the two drugs were independently owned made it impossible to do a statistical analysis of cross-elasticity of demand.

FF.112; App.715-20; App.732a.

Lundbeck, nonetheless, maintained that cross-elasticity between Indocin IV and NeoProfen is low, based on the "two camps/two markets" theory that overall physicians' current PDA drug preferences (or at least those of the eight neonatologists) are so firm that hospitals could not credibly threaten to shift share to obtain any discounts through the formulary process. *See*, *e.g.*, App.730a-730b; App.733. Lundbeck never explained, however, why evidence of the neonatologists' *current* preferences is a more reliable indication of what would have happened absent the acquisition than the evidence in Lundbeck's own documents that the company believed many hospitals and doctors had no fixed preferences and that price would have affected hospital purchasing decisions.

The Decision Below

The district court held that NeoProfen and Indocin are not in the same product market and dismissed the complaints. FF.116, CL.6. The court ascribed great importance to its finding that the neonatologist witnesses (who do not pay the costs of the drugs) choose a PDA drug based on their personal views of the drugs' relative merits, rather than on relative prices (which Lundbeck set at parity). FF.116. Notwithstanding that the drugs have never been sold by competing sellers, the court adopted Lundbeck's claim that cross-elasticity between NeoProfen and

Indocin IV "is very low" and criticized the FTC and Minnesota for failing to offer an opinion on cross-elasticity. FF.114, 115.

The district court made numerous factual findings that, contrary to its ultimate determination, directly supported the Plaintiffs' demonstration that the relevant product market for assessing the challenged acquisition includes both Indocin IV and NeoProfen. First, the court made various findings that show the two products are "reasonably interchangeable" therapeutic substitutes. The court found, and it was undisputed, that Indocin IV and NeoProfen are equally effective in treating a PDA, FF.21, and that Lundbeck sold the drugs on that basis, FF.78. In addition, the court made numerous findings showing that Lundbeck failed to convince the marketplace that NeoProfen is superior to Indocin IV. For example, Lundbeck's marketing documents show that some customers had either declined to try NeoProfen or switched back to Indocin IV because the claimed safety advantages were "not perceived as a feature/benefit significant enough to replace Indocin IV as the first line therapy" for a PDA. FF.83-84. The court also found that in 2006 the FDA found insufficient evidence that NeoProfen offers meaningful safety advantages over Indocin IV, FF.36, and that the actual market behavior of hospitals and doctors is consistent with that judgment. FF.94 (Indocin IV accounts for 60% and NeoProfen accounts for 40% of drugs' use in U.S.).

Second, the court made numerous findings reflecting that it was probable that price-based demand shifts would likely have occurred in the hypothetical but-for world. The court's findings show: hospitals were (and are) price sensitive buyers, both in general and with regard to PDA drugs, *see, e.g.*, FF.60, 65, 89-91, 93; that Lundbeck recognized the potential for price considerations to move PDA sales to one product or the other, FF.82; that Lundbeck deemed it necessary to price the drugs at parity to eliminate "the pharmacoeconomic debate" in hospital decisions about PDA drug purchasing, FF.82; and that an independent owner of NeoProfen "would not have disregarded Indocin IV's price" in setting the price of NeoProfen, FF.63.

The court, however, did not account for these findings in reaching its product market determination. Instead, the court focused on the present time period, describing the alternative PDA drugs currently available to neonatologists, and the reasons for neonatologists' current preferences. FF.116.

As to the key issue in dispute, the district court acknowledged that – when there are alternative sellers of clinically substitutable drugs – hospitals are able to use the formulary process to negotiate price concessions "by promising or threatening to use more or less of a drug." FF.93. But the court nonetheless accepted Lundbeck's "two camps/two markets" theory that, given neonatologists'

strong preferences, hospital P&T committees "would not be able to promote price competition between Indocin IV and NeoProfen, were they owned by separate companies." FF.95.

The court did not try to reconcile this conclusion with its findings that show Lundbeck perceived a credible threat that some purchasers would factor price into their choice of PDA drug. Instead, it rejected the FTC's and Minnesota's reliance on Lundbeck's contemporaneous, pre-litigation marketing documents showing that Lundbeck made decisions conscious of consumers' price sensitivities. The court expressed a belief 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)).

SUMMARY OF ARGUMENT

"The antitrust laws are as much violated by the prevention of competition as by its destruction." *United States v. Griffith*, 334 U.S. 100, 107 (1948). This principle has particular force when a monopolist acquires a potential competitor. As the leading treatise on antitrust law explains: "Whatever the original source of a monopoly, a monopolist's acquisition of the productive assets or stock of an actual or likely potential competitor 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* ¶ 701, at 194 (3d ed. 2008).

This case squarely presents this core concern of antitrust law. It is undisputed that in 2006, Lundbeck, as the owner of the sole FDA-approved drug for the treatment of a PDA, was a monopolist. And, as the district court found, Lundbeck's contemporaneous business documents show that the company expected NeoProfen, once approved, to take sales from its existing monopoly product, Indocin IV. Lundbeck, however, acquired NeoProfen before that could occur, and thereby retained all sales of PDA drugs for nearly four years. Lundbeck thus avoided the threat that it perceived from NeoProfen and thereby protected and reinforced its monopoly.

All of these essential, straightforward factual findings are set forth in the district court's opinion. Contrary to and despite these findings, the district court concluded that the FTC and Minnesota had failed to show that Indocin IV and NeoProfen had any meaningful competitive relationship. It did so based on Lundbeck's "two-camps/two-markets" theory, which reflected testimony from just eight neonatologists about their current preferences for PDA drug therapy. The district court's acceptance of this theory, and its resulting conclusion that the two

drugs occupy separate antitrust product markets, are the product of multiple legal errors that fatally infect the court's product market determination. As a matter of logic, economics, and law, the court was incorrect.

First, despite making numerous own findings (which reflect contemporaneous real-world evidence including Lundbeck's business documents and accounts of hospitals' actual behavior) about likely competition absent the acquisition, the court focused narrowly on the absence of competition today in the post-acquisition world. The court's findings concerning the views of a handful of neonatologists reflect the post-acquisition market environment that Lundbeck created via its elimination of price and non-price competition. The court's findings, which show the practicable alternatives that likely would have been available to consumers absent Lundbeck's conduct, contradicted its conclusion that Indocin IV and NeoProfen are not in the same market. By ignoring its findings concerning likely competition in a market absent Lundbeck's acquisition, the district court corrupted its entire assessment of the product market. In effect, it allowed Lundbeck to justify its maintenance of a monopoly in PDA drugs based on the absence of competition that resulted from Lundbeck's own anticompetitive conduct.

Second, the court was required to consider whether there would have been

so called "marginal customers" (that is, those not firmly committed to one of the products) who could have constrained pricing had there been competing sellers. This Court has repeatedly emphasized the need to examine whether some meaningful portion of customers for a product are likely able and willing to choose alternatives, and has reversed district courts that fail to do so. Although the district court's own findings also demonstrate the existence of persuadable marginal customers, the district court ignored theses findings, too.

Third, the court committed further legal error by treating Lundbeck's contemporaneous, pre-litigation marketing documents as legally irrelevant to its product market analysis. Courts have long recognized that such documents can provide highly relevant and reliable evidence to aid in defining a relevant product market. The district court's erroneous dismissal of these documents (which was based upon a misreading of a case from another circuit) further compromised its product market analysis.

Fourth, applying the proper mode of legal analysis to the district court's findings establishes that Indocin IV and NeoProfen are in the same product market. The court's findings demonstrate that: (1) the drugs are clinical substitutes for the treatment of a PDA; and (2) it is reasonably probable that, in the absence of Lundbeck's preemptive acquisition, the availability of rival sellers of PDA drugs

would have given buyers of those drugs the ability to obtain price concessions. Indeed, Lundbeck's switch strategy made sense only because the drugs are in the same market. The court overlooked the unique competitive relationship that exists between a branded drug and its generic equivalent, which would not preclude competition between the two branded drugs, Indocin IV and NeoProfen, especially during the nearly four years when Lundbeck had a monopoly over both.

ARGUMENT

STANDARD OF REVIEW

In an appeal from a civil bench trial, this Court reviews conclusions of law *de novo*. *Cooper Tire & Rubber Co. v. St. Paul Fire & Marine Ins. Co.*, 48 F.3d 365, 369 (8th Cir. 1995). "Mixed questions of law and fact that require the consideration of legal concepts and the exercise of judgment about the values underlying legal principles are also reviewed *de novo*." *Id.* Although product market definition is part of the plaintiff's factual burden, it cannot be defined without application of relevant legal principles. *Acme Precision Prods., Inc. v. Am. Alloys Corp.*, 484 F.2d 1237, 1241 (8th Cir. 1973). Where a district court, as here, rests its decision on a mistaken interpretation or application of law, this Court also engages in *de novo* review. *Torres v. Bayer Corp.*, 616 F.3d 778, 782 (8th Cir. 2010).

I. THE DISTRICT COURT'S PRODUCT MARKET CONCLUSION IS CONTRADICTED BY ITS OWN FINDINGS AND SUFFERS FROM MULTIPLE LEGAL ERRORS

The basic principles of product market definition are well-established. "Defining a relevant product market," this Court has explained, "is primarily a process of describing those groups of producers which, because of the similarity of their products, have the ability – actual or potential – to take significant amounts of business away from each other." *Gen. Indus. Corp. v. The Hartz Mountain Corp.*, 810 F.2d 795, 805 (8th Cir. 1987) (internal quotations omitted). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325. "Whether two particular products belong in the same relevant product market can be demonstrated by the extent of cross-elasticity of demand between the two products; in other words, the readiness and ability of consumers of one product to turn to the other product." *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988).[3]

[3] Like any quantity, the "extent of cross-elasticity of demand" must be evaluated relative to some benchmark of what is or is not substantial. Under the economics of competitive effects and of market definition, *see, e.g.*, IV Phillip E. Areeda and Herbert Hovenkamp, *Antitrust Law* ¶ 914a (3d ed. 2009), the relevant question is that ratio of (1) the number of customers that would substitute away from product "A" to product "B" in response to an increase in the price of "A" to (2) the total number of customers switching away from product "A". A higher ratio indicates

But, "[i]t is usually impossible to reliably quantify cross-elasticity of demand, which is why the Supreme Court allows reliance on 'practical indicia.'" *Cmty Publ'rs, Inc.*, 892 F. Supp. at 1154 (citing *U.S. Anchor Mfg. v. Rule Indus.*, 7 F.3d 986, 995 (11th Cir. 1993)). "Practical indicia" include "industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to prices changes, and specialized vendors." *Brown Shoe*, 370 U.S. at 325; *H.J., Inc.*, 867 F.2d at 1540; *HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 547 (8th Cir. 2007). When "viewed as proxies for cross-elasticities, they assist in predicting a firm's ability to restrict output and hence to harm consumers." *Rothery Storage and Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 219 (D.C. Cir. 1986).

Market definition is a pragmatic inquiry. "Reasonable interchangeability and cross-elasticity of demand are not used to obscure competition but to recognize competition, or the lack of competition, to the extent such exists." *Archer-Daniels-Midland*, 866 F.2d at 246. "[T]he boundaries of the relevant market must be drawn with sufficient breadth to include the competing products of each of the merging

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that the firm owning products "A" and "B" enjoys market power that is due, in part, to the closeness of the products. *Id.*

companies and to recognize competition where, in fact, competition exists." *Brown Shoe*, 370 U.S. at 326; *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482 (1992) ("The proper market definition in this case can be determined only after a factual inquiry into the 'commercial realities' faced by consumers.") (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 572 (1966).

This case concerns the application of those legal principles to a monopolist's preemptive acquisition of a potential competitor. Here, neither economic expert attempted to calculate a cross-elasticity statistic, FF.114-15; App.715-20; App.732a, nor was it necessary to do so to define an antitrust product market. *U.S. Anchor Mfg., Inc.*, 7 F.3d at 995; *Nobody Particular Presents, Inc. v. Clear Channel Communc'ns*, 311 F. Supp. 2d 1048, 1082 (D. Colo. 2004) (listing cases). Indeed, it was not possible to do so because the two products have never been owned or marketed by independent firms. Nonetheless, the court was required to "inquir[e] into the choices available to consumers." *Little Rock Cardiology Clinic*, 591 F.3d at 596. For such an inquiry, this Court has consistently focused on the alternatives to which consumers could practicably turn, and it has rejected analyses focused solely on current customer perceptions and habits. *Tenet*, 186 F.3d at 1052; *FTC v. Freeman Hosp.*, 69 F.3d 260, 270 (8th Cir. 1995); *Bathke*, 64 F.3d at 346; *see also Little Rock Cardiology Clinic*, 591 F.3d at 596-98.

The district court failed to apply these standards. Although it cited several relevant legal principles, the court erred in its application of these principles to the type of challenged conduct at issue here – a monopolist's acquisition of a potential competitor. As a result, its own findings contradicted its product market conclusion. It incorrectly ignored the ability of marginal consumers to constrain pricing. And, the court erred by treating significant pre-litigation Lundbeck business documents as legally irrelevant.

A. The District Court Erred by Defining the Product Market Contrary to its Own Findings Concerning the Competition that Likely Would Have Existed Absent the Acquisition

Market definition is merely a tool to assess the competitive effects of the challenged conduct. *Hartz Mountain Corp.*, 810 F.2d at 805. To determine a transaction's "potential for creating, enhancing, or facilitating the exercise of market power …," *Archer-Daniels-Midland*, 866 F.2d at 246, a court must compare competition in the existing marketplace with competition that would likely exist were the parties to consummate their transaction. Market definition in such a case involves a prospective analysis of alternatives (whether products or geographic areas) available to consumers, if a proposed merger or acquisition is consummated. *See, e.g., Tenet*, 186 F.3d at 1052; U.S. Dep't of Justice and the Federal Trade Commission, Horizontal Merger Guidelines, Section 4 (Aug. 19,

2010).

The competitive effects question here, however, involves an already consummated transaction. Rather than comparing the market as it exists to the one that would likely exist if the transaction were permitted, the district court needed to compare the market that exists with the one that would likely have existed, but for the transaction. The central question for the district court, therefore, was the likely competitive dynamics in the hypothetical marketplace absent Lundbeck's conduct. *See Yamaha Motor Co., Ltd. v. FTC*, 657 F.2d 971, 977 (8th Cir. 1981) ("To put the question in terms applicable to the present case, would Yamaha, absent the joint venture, probably have entered the U.S. outboard-motor market … ."); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (when monopolist excludes nascent competition, focus is the marketplace absent the anticompetitive conduct).

Given Lundbeck's preemptive acquisition, the product market question then is whether, absent that acquisition, Indocin IV and NeoProfen would likely have competed. As discussed below, the district court made numerous findings concerning that but-for world, but it based its product market conclusion solely on its findings concerning the post-acquisition world. The court could not define the market and assess the harm from the transaction based only on these latter findings,

while ignoring its findings concerning the but-for world.

The court's ultimate determination that Indocin IV and NeoProfen are not in the same market largely reflected eight neonatologists' current preferences. These preferences were formed in the post-acquisition world in which Lundbeck had eliminated the possibility of any price and non-price competition between the two drugs. Finding that the neonatologists would not change their preferences based on pricing, FF.102-08, 113, the court reasoned:

> Neonatologists pick NeoProfen or Indocin IV to treat patent ductus arteriosus for reasons such as perceived differences in the drugs' safety, differences in side effects, or the presence or lack of long-term studies. The cross-elasticity of demand between NeoProfen and Indocin IV is very low.

FF.116. The court's findings regarding neonatologists' current views do not address the likely competition in the PDA drug marketplace absent Lundbeck's acquisition.

First, neonatologists' current preferences reflect a marketplace where both drugs are owned by Lundbeck, where the drugs are priced at parity, and where Lundbeck has undertaken several years of marketing aimed at shifting consumers from Indocin IV to NeoProfen for reasons other than price. During this time, Lundbeck stopped promoting Indocin IV, FF.81, priced NeoProfen to eliminate price as a competitive variable as much as possible, FF.82, and refused to negotiate

with GPOs. FF.90. In short, Lundbeck preempted competition between Indocin IV and NeoProfen that might otherwise have existed and thwarted the ability of hospitals to try to negotiate price concessions through their formulary processes. Indeed, the neonatologists' views were arguably subject to manipulation from Lundbeck's one-sided marketing. *See Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 435 (5th Cir. 2008) ("evidence's probative weight is lessened if it is arguably *subject* to possible manipulation") (emphasis in original). Because the court needed also to assess the demand for PDA drugs in a marketplace that would likely have existed absent Lundbeck's conduct, it committed legal error by basing its product market conclusion only on the non-competitive, post-acquisition marketplace created by Lundbeck's preemptive conduct.

Second, as courts and commentators have explained, even testimony from actual purchasers can be unreliable.[4] Areeda and Hovenkamp, for example, note that "'subjective' testimony by customers that they would or would not defect in response to a given price increase" is "often unreliable, especially when the

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[4] *See, e.g., United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1131 (N.D. Cal. 2004) (rejecting certain customer testimony as unreliable, while noting that such testimony, when backed by "serious analysis" of alternatives "can put a human perspective or face on the injury to competition that plaintiffs allege"). Where customer "testimony fails to specifically address the practicable choices available to consumers," however, such views are not "sufficient to establish a relevant market." *Freeman*, 69 F.3d at 270.

question is oversimplified." IIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 538b, at 297 (3d ed. 2008). And the neonatologists who testified, while an important part of hospitals' purchasing decisions, do not actually pay the cost of their choices, FF.88. Thus, the district court's reliance on the neonatologists' responses to questions about a hypothetical price increase was flawed on multiple grounds.

Third, this Court has repeatedly reversed district courts that based product market determinations on the current preferences of consumers without sufficient attention to the practicable alternatives available to them. In *Tenet*, the Court ruled that the FTC had failed to "present evidence on the critical question of where consumers of hospital services could practicably turn for alternative services should the merger be consummated and prices become anticompetitive." 186 F.3d at 1052. In *Freeman*, this Court rejected testimony that "spoke mainly to current competitor perceptions and current consumer habits and not to the crucial question of where consumers could practicably go to seek alternative acute care inpatient hospital services should Freeman Hospital and Oak Hill Hospital merge." 69 F.3d at 270. In *Bathke*, this Court said that "even if we fully credit the testimony from a number of the plaintiffs that consumers in the class towns prefer to buy gasoline close to home, there is still an absence of evidence on a critical question: where

those gasoline consumers could practicably turn for alternatives." 64 F.3d at 346. Neonatologists' current views formed in the post-acquisition marketplace did not address the practicable alternatives available to consumers, if Lundbeck had not acquired NeoProfen.

The post-acquisition world and the opinions formed in that world could not determine the price and demand dynamics that would likely have existed between Indocin IV and NeoProfen absent Lundbeck's challenged conduct. The lower court turned antitrust law on its head by allowing Lundbeck to justify its merger to monopoly based on the absence of competition that resulted from the very conduct that is being challenged. *Cf. Microsoft*, 253 F.3d at 79 ("To require that § 2 liability turn on a plaintiff's ability or inability to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct would only encourage monopolists to take more and earlier anticompetitive action."). By basing its product market determination on preferences in a post-acquisition world controlled by Lundbeck, while ignoring its numerous findings showing that the products would likely have competed in the marketplace absent the acquisition, the court committed reversible legal error.

B. The District Court Ignored the Ability of Marginal Customers, in the Hypothetical Marketplace Absent the Acquisition, to Constrain the Exercise of Market Power

The district court made numerous findings showing the existence of "marginal consumers" for PDA drugs, that is, customers whose preferences were not firmly fixed and might have been persuaded to shift their purchases, if Indocin IV and NeoProfen had been owned by competing sellers. The court, however, ignored these findings, which was contrary to this Court's precedents. Moreover, the findings, which show that customer preferences were mutable, contradicted the district court's own conclusion that Indocin IV and NeoProfen are not in the same market.

In *H.J., Inc.*, 867 F.2d 1531, for example, the Court addressed a narrow-product market argument where there was a new product with admittedly superior technology, a fact not present in this case (*see* FF.16, 36; App.316-51; JS.104 (App.119); App.734). Even in this circumstance, the Court rejected a single-product market definition because not all customers of an old product would switch to a new one.

> Products always face at least the possibility of competition from the products they are meant to supercede. "It makes no sense to say that an entrant with a new technology has monopoly power by defining the market as those customers whom the entrant has so far managed to persuade. All new entrants, indeed most competitors, would then be

monopolists."

H.J., Inc., 867 F.2d at 1358 (quoting *Neumann v. Reinforced Earth Co.*, 786 F.2d 424, 429 (D.C. Cir. 1986)). In *Tenet*, the Court reversed the district court for failing to assess and credit the ability of a subset of customers to choose alternative hospitals. 186 F.3d at 1054. The district court here similarly undertook no analysis of – indeed, ignored its findings concerning – the extent to which customers would likely reject NeoProfen and stick with or return to Indocin IV in a marketplace where Lundbeck was not the monopolist.

Because the court ignored its findings about the significant portion of hospitals and doctors that Lundbeck believed could potentially "go either way" (see FF.85 and Part II.B.2. *infra*), its finding that cross-elasticity is "very low" is legally and economically insufficient to support a conclusion that Indocin IV and NeoProfen are not in the same market. Lundbeck's preemptive acquisition means there is no way to calculate how many lost sales would make a given price increase unprofitable. But even if only a small number of customers would have switched in response to a price increase, that alone may have been sufficient to constrain prices. *See Tenet*, 186 F.3d at 1054 (rejecting narrow market definition because "small percentage of patients would constrain a price increase"); *United States v. Engelhard Corp.*, 126 F.3d 1302, 1306 (11th Cir. 1997) ("[I]t is possible for only a

few customers who switch to alternatives to make the price increase unprofitable, thereby protecting a larger number of customers who would have acquiesced in higher [clay] prices.").

The relevant question is not whether cross-elasticity is nominally low or high, but rather whether it suffices to restrain market power. *Cmty Publ'rs*, 892 F. Supp. at 1154; *Archer-Daniels-Midland*, 866 F.2d at 246. Even where cross-elasticity is low, a single company owning the only two alternatives has the ability and incentive to profitably raise price, because it recaptures the revenues from sales lost by one product to the other.[5] Thus, while high cross-elasticity indicates that products are close substitutes, *Rothery*, 792 F.2d at 218, low cross-elasticity

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[5] Whether Lundbeck maintained its monopoly by purchasing NeoProfen depends, *inter alia*, on where customers likely would have gone in response to a price increase for Indocin IV or NeoProfen. The record indicates that surgery is a second-line treatment, both in terms of risk and cost. FF.11-12. As a result, in response to an increase in the price of Indocin IV or NeoProfen, most lost sales would have been to the other product or vice versa. Because of the acquisition, Lundbeck owned both products, which allowed it to internalize the sales loss and realize a profit on the price increase. The acquisition gave it the incentive and ability to raise prices. *See FTC v. Swedish Match*, 131 F. Supp. 2d 151, 169 (D.D.C. 2000) ("diversion ratio is important because it calculates the percentage of lost sales that" the merged firms can recapture; the higher the ratio recaptured, the greater the incentive to raise prices). As noted above, *supra* n.3, the relevant economic question is not precisely how many customers are on the margin or how many customers leave, but how many of the ones that do leave go to the product acquired by the firm. The capture of a high percentage of the customers that do switch (even if the total number of switching customers is small) indicates that the products are substitutes. IV Areeda & Hovenkamp, *supra*, ¶ 914a.

does not necessarily mean that the alternative product, if independently owned, would have no competitive significance.

The district court's findings, had they not been ignored, show that there was an economically significant portion of marginal customers that might have constrained Lundbeck's pricing. The color-coded system Lundbeck used to track the switch strategy was predicated on the existence of marginal customers. These customers included: (1) accounts that had not yet determined which drugs to use – under Lundbeck's marketing scheme, the "yellow" accounts that "can go either way," FF.85; (2) "green" accounts at risk for returning to Indocin IV, absent marketing efforts by Lundbeck to keep them in the NeoProfen camp, FF.85: (3) "red" accounts where NeoProfen's share was less than 10% "red," which Lundbeck referred to "our problem children," FF.85; (4) the "economic driven vial splitting crowd," FF. 82-84;[6] and (5) those for whom generics were an alternative, FF.83-84. Even where NeoProfen's market share exceeded 40%, it identified the need to "stay on top of the happenings in these accounts," because "they can easily switch back to their old ways if they run into a problem or if you neglect them." FF.85.

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[6] Although NeoProfen and Indocin IV are similarly priced, the ability to split vials of Indocin IV can permit hospitals to lower the effective price for treating a PDA by spreading the per vial cost of Indocin IV over multiple doses.

Because the district court ignored its own findings indicating that a significant number of customers and accounts would likely have been in play in the but-for world absent the acquisition, it failed to follow applicable precedent and committed legal error requiring reversal of its product market determination.

C. The District Court Erred by Treating Lundbeck's Contemporaneous Documents as Legally Irrelevant

The district court committed further legal error when it categorically rejected reliance on Lundbeck's contemporaneous, pre-litigation documents. As the court's findings reflect, these documents demonstrate that Lundbeck sought to minimize price as a competitive variable between Indocin IV and NeoProfen, understood that customer preferences were mutable, recognized the price sensitivity of hospitals and considered Indocin IV and NeoProfen to be in the same market.

The court, however, criticized the FTC's and Minnesota's reliance on "Lundbeck documents that refer to a market that consists of NeoProfen and Indocin IV," stating 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. As its sole support for this proposition, the court cited by analogy *Kentucky Speedway, LLC v. National Association of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009). But the court misconstrued the

Sixth Circuit's opinion. Moreover, the particular documents at issue here are clearly relevant to a proper analysis of the product market. Indeed, the documents that the court swept aside provide the best available, real-world evidence of the competition between Indocin IV and NeoProfen that likely would have existed absent Lundbeck's acquisition.

In *Kentucky Speedway*, the court determined that the internal NASCAR marketing documents the plaintiff relied on did not address interchangeability and, thus, did not suffice to define the product market. *Id.* Contrary to the district court's belief, *Kentucky Speedway* does not hold, or even suggest, that internal marketing documents are categorically excluded from an interchangeability analysis. Indeed, the law is to the contrary: Internal marketing documents are frequently the basis for product market definition.

In *Spirit Airlines, Inc. v. Northwest Airlines, Inc.*, 431 F.3d 917, 934-35 (6th Cir. 2005), the Sixth Circuit itself affirmed a district court's product market determination based, in part, on internal Northwest fare documents distinguishing between business and leisure passengers. Similarly, in *Community Publishers, Inc.*, 139 F.3d 1180, this Court affirmed a lower court ruling that had defined the relevant product market based on "compelling … contemporaneous, prelitigation records of the various newspaper organizations and personnel involved in the

case." *Cmty Publ'rs, Inc.*, 892 F. Supp. at 1155. In *United States v. Waste Management, Inc.*, 743 F.2d 976, 980 (2d Cir. 1984), the Second Circuit upheld the district court's product market definition, stating: "Indeed, for all of the smoke blown by WMI over Judge Griesa's market definition, internal TIDI documents fully support his findings." *See also FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1079 (D.D.C. 1997) ("In document after document, the parties refer to, discuss, and make business decisions based upon the assumption that 'competition' refers to other office superstores only."); *Meijer, Inc. v. Barr Pharm., Inc.*, 572 F. Supp. 2d 38, 60 (D.D.C. 2008) ("The views of individuals in the industry, and particularly the internal documents of Warner Chilcott, are all probative areas of inquiry for determining the outer boundaries of the relevant product market."); *cf. United States v. United States Gypsum Co.*, 333 U.S. 364, 395-96 (1948) (recognizing reliability of contemporaneous documents).

The district court thus erred when it concluded that Indocin IV and NeoProfen are not in the same market, despite its findings based on Lundbeck's highly relevant and probative documents. *See, e.g.*, FF.78-87. Unlike the current views of neonatologists, formed after several years of Lundbeck's marketing solely in favor of NeoProfen, Lundbeck's pre-litigation internal marketing documents show that Lundbeck made business decisions based on the prospect of buyer

substitution in response to changes in the relative prices of the products in question. App.154; App.203; App.235-65; App.285; App.294-95; App.566-93; App.599-607. In addition, far from mere casual passing references to a "market," the documents show that Lundbeck consistently and repeatedly calculated market shares based on a market comprising Indocin IV and NeoProfen only. App.161; App.196-97; App.217; App.235-65; App.276-81; App.297-98; App.300-05; App.559; App.596. These documents spoke to the competitive dynamics absent Lundbeck's acquisition, and the district court's total disregard for the documents further undermined its product market determination.

II. APPLICATION OF THE CORRECT LEGAL STANDARDS TO THE COURT'S FINDINGS DEMONSTRATES THAT THE RELEVANT MARKET TO ASSESS THE EFFECT OF THE ACQUISITION INCLUDES BOTH INDOCIN IV AND NEOPROFEN

Had the court not ignored, or ruled contrary to, its findings regarding the marketplace absent Lundbeck's acquisition, it would have concluded, based on those findings,[7] that the product market for PDA drugs includes Indocin IV and NeoProfen. The findings present precisely the kind of "practical indicia," such as

[7] The FTC and Minnesota stress that they do not challenge the court's factual findings. Rather, as shown above, the court's errors involved use of incorrect legal standards, including legal standards for assessing product markets, and misapplication of the law to facts, which this Court reviews under the *de novo* standard.

functional interchangeability and industry recognition, that this Court and others have held demonstrate the reasonable interchangeability or cross-elasticity of demand between the drugs. The findings show "the readiness and ability of consumers of one product to turn to the other product," *Archer-Daniels-Midland*, 866 F.2d at 248, in a market that had not yet been successfully monopolized by Lundbeck. Because the court failed to afford its own findings proper legal significance, this Court should reverse and hold that Indocin IV and NeoProfen are in the same market. *Tenet*, 186 F.3d at 1053-54 (rejecting district court's geographic market conclusion in the face of contrary evidence).

A. The District Court's Own Findings Show that Indocin IV and NeoProfen Are Reasonably Interchangeable Therapeutic Substitutes

This Court's precedents make clear that functional interchangeability between two products is an important factor in determining whether the products are in the same market. But Indocin IV and NeoProfen are much more than merely functionally interchangeable. As the district court's own findings show: Indocin IV and Neoprofen treat exactly the same medical condition, patent ductus arteriosus, FF.14; they are equally efficacious, FF.21; Lundbeck sells both drugs "for the management of preterm infants with [patent ductus arteriosus]," FF.78; and the drugs are ordered and paid for by the same customers, FF.88. Indeed,

precisely because these drugs are so therapeutically similar, the majority of hospitals that treat premature babies with a PDA purchase and stock only one or the other, FF.94. The district court's conclusion that Indocin IV and NeoProfen are not in the same market is contradicted by these findings concerning Indocin IV's and NeoProfen's functional interchangeability.

This Court treats functional interchangeability as a practical indicator that products are in the same market. In *H.J., Inc.*, this Court overturned a jury verdict that submersible liquid manure pumps were in a market separate from other kinds of pumps. 867 F.2d at 1538. It found that the pumps' same basic functions, same customers and same distribution and sales networks indicated that they occupied the same market. *Id.* In *HDC Medical*, this Court held that the identical uses for single-use and multiple-use dialyzers precluded a conclusion that the products were in separate markets, despite pricing differences between the products. 474 F.3d at 547. *See also United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956) (holding that the "market is composed of products that have reasonable interchangeability for the purposes for which they are produced").

The district court's findings that Indocin IV and NeoProfen are not bioequivalent (FF.18) and have different side effects (FF.101) do not diminish the legal and economic significance of the products' functional interchangeability.

Products need not be fungible to be in the same market. *E.I. du Pont de Nemours & Co.*, 351 U.S. at 394. Products may have price and non-price differences yet compete in the same market. *Brown Shoe*, 370 U.S. at 325; *H.J., Inc.*, 867 F.2d at 1538; *HDC Med.*, 474 F.3d at 547. For example, in *H.J., Inc.*, the Court found that the newer submersible pump's technological advances over the existing pumps did not make the new pump a discrete product market. 867 F.3d at 1538. Moreover, products need not be perfect substitutes, so long as there is sufficient overlap to constrain the exercise of market power. *Id.*; *Tenet*, 186 F.3d at 1053; *United States v. Cont'l Can Co.*, 378 U.S. 441, 455, 457 (1964).

In sum, the district court's findings showing the drugs' substitutability for the treatment of a PDA support the conclusion that the drugs are in the same market.

B. The District Court's Own Findings Show that Indocin IV and NeoProfen Are Economic Substitutes

1. Industry Recognition Demonstrates that Indocin IV and NeoProfen Are in the Same Market

The district court also failed to reconcile its legal conclusion that the FTC and Minnesota had not proven a PDA drug product market with its own findings that Lundbeck and others recognize that Indocin IV and NeoProfen would likely have been part of such a market absent Lundbeck's acquisition. As then Judge

Sotomayor wrote in *Todd v. Exxon*, 275 F.3d 191, 205 (2d Cir. 2001):

> Industry recognition is well established as a factor that courts consider in defining a market. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). It is significant because "we assume that the economic actors usually have accurate perceptions of economic realities." *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 219 n.4 (D.C. Cir. 1986). In *AD/SAT*, for example, this Court noted that the litigants themselves considered the electronic transmission of advertisements to be in competition with physical carriers, and used this information in finding that the market included both products. [*AD/SAT v. Associated Press*, 181 F.3d 216, 228 (2d Cir. 1999].

See also Geneva Pharm. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 498 (3d Cir. 2004) ("Industry recognition is also notable."); *HDC Med.*, 474 F.3d at 547. The findings here are particularly significant, because they demonstrate Lundbeck's assessment of the competitive pressure each drug imposed as next-best alternatives to each other, the pricing pressure that hospitals could create, and the measures Lundbeck would need to take to preempt the competitive dynamic that otherwise would have existed.

The district court acknowledged that the industry recognizes that Indocin IV and NeoProfen could compete on price when it found that "[w]hen launching NeoProfen, an independent owner would not have disregarded Indocin IV's price." FF.63. Similarly, the court found that, because of fears that a higher selling price for Indocin IV could lead Abbott to demand a higher purchase price for rights to

NeoProfen, Lundbeck delayed announcing a substantial Indocin IV price increase until after it had concluded the deal with Abbott. FF.58. The court thus implicitly found that Abbott likely viewed the drugs as in the same market. The district court's legal conclusions failed to recognize that, if the drugs were in separate markets, the Indocin IV price should have been irrelevant to an independent owner of NeoProfen or to the valuation of the NeoProfen deal.

Lundbeck's actions, particularly, speak to the relevance of price to hospitals' decisions to purchase the drugs. Initially, Lundbeck used price to try to drive demand to NeoProfen, offering a one-time 20% discount as part of its launch plan so that hospitals would stock NeoProfen. FF.82. Later, in its NeoProfen marketing plans, Lundbeck repeatedly expressed concerns about the effect of price on NeoProfen sales. For example, Lundbeck concluded that some hospitals would not order NeoProfen because of its price and because of hospitals' ability to lower costs through splitting of Indocin IV vials. FF.84. Lundbeck determined that the availability of lower-priced generic Indocin IV would affect NeoProfen sales, identifying as a "threat" to NeoProfen, "[e]arly introduction of a generic Indocin IV." FF.83-84. If demand for PDA drugs were price insensitive or if Indocin IV and NeoProfen were in separate markets, these price threats should not have mattered to Lundbeck and the switching strategy would not have been attempted.

The fact that such concerns appear in the plans by which Lundbeck sought to "cannibalize" sales of Indocin IV (*see* FF.79) is significant because "we assume that the economic actors usually have accurate perceptions of economic realities." *Rothery*, 792 F.2d at 219 n.4.

The district court findings also show that the drugs competed along non-price variables (FF.98, 100-02, 108), which the court erroneously ignored. *See Tenet*, 186 F.3d at 1054 (district court reversed for placing "inordinate emphasis on price competition" and ignoring non-price competition). To focus sales on these non-price considerations, Lundbeck set the NeoProfen price at a small discount to the Indocin IV price, because it "[t]akes away potential pharmacoeconomic debate," and "[a]llows rep to spend more time selling product differentiation in the NICU vs. spending time with the pharmacy director on price." FF.82. The court found that Lundbeck "stopped actively promoting Indocin IV" in early 2006, "instructed its sales representatives to focus on Indocin IV's weaknesses relative to NeoProfen's anticipated benefits," and "sought to position NeoProfen as the first-line pharmaceutical treatment for patent ductus arteriosus." FF.81. Nonetheless, the district court's findings show that NeoProfen sales were vulnerable to sales losses to Indocin IV because "[s]afety advantages (e.g. renal function) not perceived as a feature/benefit significant enough to replace Indocin IV as the first-

line therapy for [patent ductus arteriosus]." FF.83-84.

Indeed, the court's ultimate conclusion that Indocin IV and NeoProfen are not in the same market is directly rebutted by its own findings that demonstrate the two drugs' cross-elasticity, *i.e.*, "the readiness and ability of consumers of one product to turn to the other product." *Archer-Daniels-Midland*, 866 F.2d at 248. As previously noted, even where it had succeeded in moving customers from Indocin IV to NeoProfen, Lundbeck remained concerned that customers would nonetheless choose to stay with or move back to Indocin IV. FF.85. Where NeoProfen had a market share in excess of 40%, Lundbeck stated:

> It is important not to take these accounts for granted as they are our BREAD AND BUTTER. Things change and if you don't stay on top of the happenings in these accounts, they can easily switch back to their old ways if they run into a problem or if you neglect them.

FF.85 (emphasis in original). In fact, some accounts that had ordered NeoProfen stopped doing so, including for reasons of price. FF.84.[8] In short, Lundbeck recognized and responded to the fact that the drugs were substitutes and developed a switching strategy to dampen eventual competition from generic Indocin IV that took advantage of this substitutability. The court's conclusion that the FTC and

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[8] Because customers did, and would likely, switch in both directions, the court's belief that one-way migration precludes two products from being in the same market, even if correct, does not apply here. *See* FF.114 (quoting *Archer-Daniels-Midland*, 866 F.2d at 248 n.1).

Minnesota had not proven a relevant product market cannot be squared with these findings. Properly understood, the findings establish that Indocin IV and NeoProfen are in the same market.

2. Had Lundbeck Not Preempted It, Hospitals Would Likely Have Promoted Price Competition

The court's findings also show how hospitals and their medical personnel, and not just neonatologists, likely would have affected demand for the drugs and promoted competition. In *Tenet*, this Court reversed the district court on grounds, among others, that it had not considered the impact of managed care organizations and insurance plans on patients' hospital and doctor choices. 186 F.3d at 1055. According to the Court, "the district court did not properly evaluate evolving market forces in the rapidly-changing healthcare market." *Id.* *Compare Cont'l Can*, 378 U.S. at 455 ("[T]hough the interchangeability of use may not be so complete and the cross-elasticity of demand not so immediate as in the case of most intraindustry mergers, there is over the long run the kind of customer response to innovation and other competitive stimuli that brings the competition between these two industries within § 7's competition-preserving proscriptions."). As in *Tenet*, the district court's findings showing the ability of hospitals to promote competition compel the conclusion that the product market is broader than just one

of the drugs.

The district court's findings show that hospitals, as the actual purchasers of Indocin IV and NeoProfen, had incentives to lower the drugs' costs, FF.89, and took concrete steps to do so, FF.60, 65, 83-84, 90. It further found that "[h]ospitals order and pay for Indocin IV and NeoProfen," while neonatologists do not pay for the drugs. FF.88. Generally, "when a private insurer or government payor reimburses a hospital for treating a patient, the reimbursement rate is not based on the actual costs of any individual patient's treatment. Instead, the hospital receives a fixed amount based on a system that classifies patients by diagnosis, type of treatment, age, and other factors." FF.89. This means that savings that a hospital realizes in its treatment costs accrue to a hospital's bottom line, App.636, thus encouraging cost-cutting efforts.

The court recognized that hospitals generally engage in efforts to reduce costs through price competition. "Many hospitals are members of group purchasing organizations, [which] aggregate the purchase volume of their member hospitals in an effort to negotiate better prices." FF.90. They may urge entry of generic versions of branded drugs. FF.90. They may use their formularies "to negotiate price concessions by promising or threatening to use more or less of a drug," when two or more are available to treat the same condition. FF.93. *See also*

In Re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 787 (7th Cir. 1999) ("[A] hospital, nursing home, or HMO or other managed-care enterprise has a more elastic demand because it can influence (for example through a "formulary," a list of approved or recommended drugs) the physician's choice of which brand (or no brand--a generic) to prescribe.").

The court further found that hospitals here took concrete steps to lower their drug costs for treating a PDA following Lundbeck's price increase. They approached other drug manufacturers to produce generic versions of Indocin IV. FF.90. They engaged in "vial splitting" and "vial sparing," FF.60, which spread the per-vial cost of the drugs among multiple doses.

The findings further show that Lundbeck did not ignore the hospitals' cost-saving measures. It identified "limited formulary access" as both a weakness and a threat to its NeoProfen sales. FF.83-84. It concluded that NeoProfen faced the threats of lost sales from "[e]arly introduction of a generic Indocin IV." FF.83-84. It identified vial splitting involving Indocin IV as another threat to NeoProfen sales. FF.83-84.[9]

In the end, though, Lundbeck's anticompetitive conduct thwarted the

[9] In the 2008 NeoProfen Marketing Plan, Lundbeck reported that 30 of 104 accounts that rejected NeoProfen did so because they vial split Indocin. App.282.

hospitals' cost-cutting efforts. It refused to contract with GPOs. FF.90. It set prices for Indocin IV and NeoProfen to eliminate "potential pharmacoeconomic debate," and allow "rep to spend more time selling product differentiation in the NICU vs. spending time with the pharmacy director on price." FF.82. In the absence of the acquisition, hospitals likely would have promoted price competition between Indocin IV and NeoProfen, but Lundbeck's ownership of both drugs neutralized the hospitals' leverage.

C. Lundbeck's Switch Strategy Made Sense Only Because the Drugs Are in the Same Market

As is discussed above (and is undisputed), Lundbeck's post-acquisition behavior was aimed at shifting hospitals and doctors from Indocin IV to NeoProfen, as well as preventing their return to their "old ways." Having eliminated NeoProfen's imminent threat to Indocin IV's revenues, Lundbeck focused on the eventual threat of a lower priced, generic Indocin IV product. The generic version would be essentially identical to branded Indocin IV, and, as a perfect substitute, would pose a much more direct threat to Indocin IV than to NeoProfen. Lundbeck thus sought to shift demand for PDA drug therapies to NeoProfen because it would be less threatened by eventual entry by generic Indocin IV. Moreover, NeoProfen's orphan drug status and patent protection

means that the drug enjoys protection from competition from generic NeoProfen for several years. Until entry of generic Indocin IV actually occurred (and finally did occur only in early 2010), however, NeoProfen and Indocin IV were each other's closest, and indeed only, substitutes. *See* pages 12-16, *supra*.

The eventual entry of an even closer competitor to Indocin IV does not mean that the only two branded drugs that treat a PDA would not have competed absent the challenged acquisition. The existence of a perfect substitute does not preclude competition between branded drugs whose substitution is merely close. After all, "reasonably interchangeable" does not mean "perfectly interchangeable." *Cont'l Can*, 378 U.S. at 455. Economic substitution is not a zero-sum game. Nonetheless, the district court accepted Lundbeck's claim that its switch strategy corroborated its conclusion that Indocin and IV occupy separate product markets. "Were NeoProfen and Indocin IV in the same market," the court stated, "Lundbeck's attempt to persuade neonatologists to switch from Indocin IV to NeoProfen would not make sense." FF.116. But the switch strategy was feasible only because the drugs were substitutes.

The switch strategy also made sense given the unique competitive relationship between a branded drug and its generic equivalent. As support for its conclusion that the switch strategy would not make sense if the branded drugs were

not in the same market, the court stated (correctly) that "Bedford Laboratories [one of the manufacturers of generic indomethacin] did not forecast what, if any, effect generic indomethacin would have on sales of NeoProfen." FF.116. The court drew the wrong conclusion from Bedford's forecast. Generic drug manufacturer Bedford's forecast says nothing about the existence of competition that would have existed between Indocin IV and NeoProfen from 2006-2010 absent Lundbeck's preemptive acquisition. It simply reflects the very close competition that exists between a branded drug and its generic equivalent. Indeed, Bedford explained that it always assesses generic drug entry opportunities by examining the impact of such entry on sales of the branded drug counterpart only, and does not consider other drugs in the therapeutic class. App.738-41. Moreover, the Bedford witness testified that he believed generic Indocin IV could have an impact on NeoProfen sales. App.736-37. If the district court's logic were correct, Bedford's forecasting practices alone would mean that two branded drugs would *never* be in the same product market.

In fact, competition in pharmaceutical markets takes many forms, and at different stages in the life cycle of a branded drug, different competitive dynamics may predominate. Moreover, as this Court has observed, a relevant product market definition is merely a tool to assess the competitive effects of the particular

conduct alleged to be anticompetitive. *Hartz Mountain Corp.*, 810 F.2d at 805; *see also U.S. Healthcare, Inc., v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993) (markets are defined in relation to the challenged conduct). As a result, courts have defined relevant product markets in pharmaceutical cases in various ways. *See, e.g, Geneva Pharm.*, 386 F.3d 485 (relevant market defined as generic warfarin sodium tablets, excluding branded product); *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089 (E.D. Pa. 1976), *aff'd*, 575 F.2d 1056 (3d Cir. 1978) (relevant market was all cephalosporins, a class of antibiotics, and included multiple branded drugs within the class).

The district court's task was to assess the effects of the particular conduct challenged here – a monopolist's preemptive acquisition of a branded drug that was a potential competitor. The eventual entry of a generic that would in the future provide especially close competition to one of the two drugs lends no support to the court's conclusion that Indocin and NeoProfen are separate product markets. Lundbeck's switch strategy demonstrates precisely the opposite; it was economically feasible only because the products are in the same market.

CONCLUSION

For the foregoing reasons, 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.

Respectfully submitted,

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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 12,939 words, as counted by the WordPerfect word processing program. We further certify that the electronic versions of the brief and its addendum have been scanned for viruses and are virus free.

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December 27, 2010

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 December 27, 2010, we electronically filed the BRIEF AND ADDENDUM FOR 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.

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