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

LORI SWANSON
Attorney General
State of Minnesota

KAREN D. OLSON
Deputy Attorney General

BENJAMIN VELZEN
Assistant Attorney General
445 Minnesota Street, Suite 1400
St. Paul, MN 55101-2130
(651) 757-1235
benjamin.velzen@state.mn.us

DAVID C. SHONKA
Acting General Counsel

JOHN F. DALY
Deputy General Counsel for Litigation

MARK S. HEGEDUS
Office of the General Counsel
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580
(202) 326-2115
mhegedus@ftc.gov

Counsel continued on inside cover

RICHARD A. FEINSTEIN
Director

PETER J. LEVITAS
Deputy Director

MARKUS H. MEIER
Assistant Director

ELIZABETH R. HILDER
JON J. NATHAN
Attorneys
Health Care Division
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

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.

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES*

CASES **PAGE**

* Authorities principally relied upon.

FEDERAL STATUTES

STATE STATUTES

MISCELLANEOUS

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).
3. Whether the district court committed legal error by concluding that

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 H

[1] "FF" refers to the district court's factual findings, while "CL" refers to its conclusions of law. Both are contained

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

[2] Lundbeck predicted that the earliest generic entry would occur was in April

Immediately following the Indocin IV acquisition, Lundbeck contacted Abbott about acquiring the rights to NeoProfen.

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 approve

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

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

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

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

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.

would have given buyers of those drugs the ability to obtain price concessions. Indeed, Lundbeck's switch strategy made se

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

---

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 …," , *80 Ffse176 1 Tf8 91 0 TD.0 0eewdDaniels-Midlje94 0 TD.0 0 -0.06 Tw[business documB6o*

The district co

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*

[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.

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

[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

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.

---

[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

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;

[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.

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

Sotomayor wrote in *Todd v. Exxon*

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 0 TDe

[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

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.

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*

[9] In the 2008 NeoProfen Marketing Plan, Lundbeck reported that 30 of 104 accounts that rejected NeoProfen did so

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,

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 existen

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.*

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 REPLY AND ADDENDUM TO PLAINTIFFS-APPELLANTS' PETITION FOR REHEARING AND SUGGESTION FOR REHEARING EN BANC with the Clerk of the United States Court of Appeals for the EIGHTH CIRCUIT using the CM/ECF system.

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

/s/ Benjamin Velzen
Benjamin Velzen

/s/ Mark S. Hegedus
Mark S. Hegedus