No. 10-3458 and 3459 (Consolidated)

IN THE
UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

FEDERAL TRADE COMMISSION and STATE OF MINNESOTA,
Plaintiffs-Appellants,
v.
LUNDBECK, INC.,
Defendant-Appellee.

Appeal from the United States District Court,
District of Minnesota
Civil No. 08-6379 (JNE/JJG) and 08-6381(JNE/JJG)
Joan N. Erickson, United States District Judge

BRIEF OF AMICI CURIAE STATES OF MISSOURI, ILLINOIS, ARKANSAS, IOWA, MARYLAND, NEVADA, NEW MEXICO, NORTH DAKOTA, SOUTH DAKOTA, AND WEST VIRGINIA IN SUPPORT OF PLAINTIFFS-APPELLANTS

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STATEMENT OF THE ISSUE

Products are in the same relevant market if reasonably interchangeable. Hospitals and physician groups treat patent ductus arteriosus, a congenital heart defect in newborns, with either Indocin IV or NeoProfen. The district court ruled that the two drugs were not in the same market. Did the district court err?

INTEREST OF AMICI CURIAE

Amici Curiae are the Attorneys General for the States of Missouri, Illinois, Arkansas, Iowa, Maryland, Nevada, New Mexico, North Dakota and West Virginia, who have law enforcement authority under their respective state antitrust laws and the Sherman and Clayton Antitrust Acts, 15 U.S.C. §§ 1-38. Pursuant to Rule 29(a) of the Federal Rules of Appellate Procedure, a State may file an amicus brief without the consent of the parties or leave of court.

ARGUMENT

The issue for this Court is whether two drugs—Indocin IV and NeoProfen—are in the same relevant product market. The facts, as the district court found them, lead to only one reasonable conclusion: they are in the same market. Although two drugs within a therapeutic class are not always in the same relevant product market, market definition is context-sensitive. Here, not only does the district court's ruling on market definition lack evidence, but the facts that the district court found are consistent with—and often support—the opposite conclusion: Indocin IV and NeoProfen are reasonably interchangeable and therefore compete in the same market.

The antitrust laws prohibit acquisitions that give the acquirer too much market power. Section 7 of the Clayton Act prohibits an asset acquisition "where . . . the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."[1] Although a plaintiff may prove that an acquisition will likely be anticompetitive through direct evidence, the plaintiff may also use indirect evidence by proving that the

[1] Clayton Act § 7, 15 U.S.C. § 18.

acquirer will have market power in a relevant market.[2] The legality of an acquisition, therefore, may depend on the definition of the relevant market.

A relevant market has two components: a geographic market and a product market. Here, only the product market is at issue. A relevant product market includes all products that are reasonably interchangeable—that is, the product at issue and its reasonable substitutes.[3] Market definition, however, "does not take place in a vacuum: in any particular case, demand substitution must be evaluated with reference to the specific allegations of anticompetitive effect in the matter under review."[4]

Economists sometimes determine whether two products are substitutes by calculating their cross-price elasticity of demand. The cross-price elasticity of demand measures the responsiveness of demand for one good to changes in the price of another good.[5] If an increase in the price of one good leads to an increase in the demand for another good, the goods' cross-price

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[2] *United States v. Falstaff Brewing Co.*, 410 U.S. 526, 535 n.13 (1973) (recognizing that direct evidence of harm is unnecessary and that "circumstantial evidence is the life blood of antitrust law").

[3] *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962).

[4] Jonathan B. Baker, *Market Definition: An Analytical Overview*, 74 Antitrust L.J. 129, 173 (2007).

[5] William A. McEachern, *Microeconomics: A Contemporary Introduction* 125 (3d ed. 1994).

elasticity is positive, which means the goods are substitutes. For example, an increase in the price of Coke leads to more demand for Pepsi, which suggests that some consumers are substituting Pepsi for Coke.[6] If the substitution effect is relatively strong, the products are in the same market.

However, the cross-price elasticity of demand often depends on time.[7] Any calculation of cross-price elasticity is only a snapshot of the demand, so an early calculation may fail to reveal the true substitution effect in markets where consumers are slow to change their purchasing habits. Brand loyalty, for example, can delay the substitution effect. If the price of Coke increases, consumers loyal to Coke will not likely switch to Pepsi in the short run, but over time more and more consumers will switch because of the temptation of Pepsi's lower price.

Calculating the cross-price elasticity of demand has practical difficulties, so courts often look to a variety of related factors to determine if two products are reasonable substitutes. Those factors include "industry or public recognition of the products as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized

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[6] *Id.*

[7] E. Thomas Sullivan & Jeffrey L. Harrison, *Understanding Antitrust & Its Economic Implications* 30 (4th ed. 2003).

vendors."[8] But the predominant factor courts consider is the interchangeability in use—whether the two products are used for the same purpose.[9]

In this case, NeoProfen and Indocin IV are used for the same purpose: treating patent ductus arteriosus ("PDA"). The FDA approved both drugs for this purpose.[10] Evidence that physicians may prefer one or the other reflects brand loyalty and some product differentiation. But it says nothing about whether NeoProfen and Indocin IV are reasonably interchangeable in treating PDA or whether they are in the same market. And speculation that the cross-price elasticity of demand is low is not evidence that the two drugs are in different markets.[11] Without some substantiation, it is not evidence at all.

A. NeoProfen and Indocin IV are reasonably interchangeable in treating PDA.

Both NeoProfen and Indocin IV may be—and are—used to treat PDA. The Federal Drug Administration approved both drugs for pharmacological

[8] *HDC Medical., Inc. v. Minntech Corp.*, 474 F.3d 543, 547 (8th Cir. 2007).

[9] *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956) ("The market is composed of products that have reasonable interchangeability for the purposes for which they are produced . . . .").

[10] Findings of Fact, Conclusions of Law, and Order, Facts ¶ 14, No. 08-cv-6379 (D. Minn. Aug. 31, 2010) (Findings of Fact hereinafter "Facts"].

[11] Facts ¶ 114.

treatment of PDA. Although the drugs have different side effects, so one or the other may be preferable to some subsets of patients, the FDA allows physicians to prescribe either NeoProfen or Indocin IV. In fact, clinical studies indicate that they are equally efficacious in resolving neonatal PDA.[12]

Further, both NeoProfen and Indocin IV are used in practice to treat PDA. Many hospitals buy only Indocin IV; many other hospitals buy both Indocin IV and NeoProfen; and some hospitals buy only NeoProfen.[13] For example, Ohio State University Medical Center uses primarily NeoProfen for PDA,[14] while one hospital in the Los Angeles County Department of Health Services system uses Indocin IV almost exclusively.[15] A Minnesota practice group shifted its use of drugs for PDA from Indocin IV to NeoProfen.[16] Given the hospitals' and practice groups' purchasing patterns for PDA drugs, NeoProfen and Indocin IV must be reasonably interchangeable.

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[12] Facts ¶ 21.

[13] Facts ¶ 94.

[14] Facts ¶ 98.

[15] Facts ¶ 96.

[16] Facts ¶ 102.

Lundbeck, Inc., which owns the rights to both drugs, confirmed the drugs' interchangeability through a marketing strategy to switch purchasers from Indocin IV to NeoProfen. After deciding to acquire NeoProfen, Lundbeck planned to promote migration from Indocin IV to NeoProfen.[17] Lundbeck planned to cannibalize its own Indocin IV sales by selling NeoProfen—a drug that would enjoy both patent protection and orphan-drug exclusivity.[18] In anticipation of NeoProfen's approval, Lundbeck discontinued its promotion of Indocin IV and concentrated all marketing efforts to persuade prescribers and purchasers of Indocin IV to switch to NeoProfen.[19] Lundbeck closely monitored the intended migration and the increasing market share held by NeoProfen, noting in one report that until every account adopted NeoProfen as its only treatment, thereby "replacing Indocin, there is still work to be done."[20]

If the drugs were not reasonably interchangeable, purchasers might buy both for different purposes, but few would *switch*. The district court got the

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[17] Facts ¶ 78 (finding that initial marketing plans called for NeoProfen to be promoted as the drug of first choice due to reduced risk of side effects and offered with a 15% discount off the price of Indocin IV).

[18] Facts ¶¶ 16 – 17, 78, 80.

[19] Facts ¶ 81.

[20] Facts ¶ 85.

point exactly backwards: "Were NeoProfen and Indocin IV in the same product market, Lundbeck's attempt to persuade neonatologists to switch from Indocin IV to NeoProfen would not make sense."[21] In fact, the hospitals and physician groups would not change from Indocin IV to NeoProfen were they not reasonably interchangeable. Promoting one product over the other only makes sense if they are in the same market: The Pepsi Challenge featured a blind taste test between Pepsi and Coke—not Pepsi and, say, carrots.

B. Physicians' preferences for one drug over the other reflect brand loyalty and product differentiation within a market—not two separate markets.

Physicians' preferences for NeoProfen or Indocin IV do not mean that the two drugs are in different markets. In reaching its conclusion that NeoProfen and Indocin are not in the same market, the district court reasoned that physicians choose between them to treat PDA based on "perceived differences in the drugs' safety, differences in side effects, or the presence or lack of long-term studies."[22] This fact reveals only that NeoProfen and Indocin IV are somewhat differentiated products and that some physicians are loyal to NeoProfen, while other physicians are loyal to

[21] Facts ¶ 116.

[22] Facts ¶ 116.

Indocin IV. In fact, Lundbeck recognized the "conservative nature of neonatologists and the desire for additional data/experience before adopting" a new PDA drug.[23]

But evidence of brand loyalty should not be mistaken for a lack of functional interchangeability. Indeed, some cola drinkers would never substitute Pepsi for Coke—and vice versa—and no one disputes that they are in the same market. The same is true for NeoProfen and Indocin IV. Differences in physicians' preferences do not mean that the drugs are in different markets.

C. Bedford Laboratories' forecasting is irrelevant in determining whether NeoProfen and Indocin IV are in the same market.

The district court also relied on the fact that "Bedford Laboratories did not forecast what, if any, effect generic indomethacin would have on sales of NeoProfen."[24] But that is not surprising. Generic-drug companies focus on taking away sales from the high-priced, brand-name drugs under the automatic or permissive drug-substitution laws that most, if not all, States have enacted.[25] Consequently, a generic drug is usually the closest

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[23] Facts ¶ 83.

[24] Facts ¶ 116; *see also* Facts ¶ 76.

[25] *See, e.g.,* 35 Pa. Cons. Stat. § 960.3(a) (West, Westlaw through 2010-60 Sess.) (automatic substitution); Ark. Code Ann. 17-92-503 (West, Westlaw

competitor to a brand drug, but no generic entered the market during the 4-year period between Lundbeck's acquisition of NeoProfen and the trial in this case. Any sales that Bedford's later generic indomethacin might take from NeoProfen would be gravy. But Bedford's lack of prescience does not mean generic indomethacin would not take NeoProfen sales. At most it illustrated Bedford's primary target was Indocin IV from which it might enjoy automatic substitution. Through a "switch strategy," Lundbeck wanted to shift buyers of PDA drugs from Indocin IV to NeoProfen before the anticipated entry of a lower-priced, generic version of Indocin IV.[26] In fact, throughout its planning, Lundbeck expected that its large price increase for Indocin IV would prompt the eventual entry of a generic version of Indocin IV.[27] Prior to discovering NeoProfen— and creating its switch strategy—Lundbeck's plan after it increased the price of Indocin IV was simply to sell as much Indocin as it could until a generic version entered the market. Acquisition of NeoProfen proved a means to shore up sales of PDA drugs.

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through 2010 Fiscal Sess.) (permissive substitution); Neb. Rev. Stat. § 71-5403 (West, Westlaw through 101st Second Regular Sess. 2010) (permissive substitution).

[26] Facts ¶¶ 80, 83.

[27] Facts ¶ 64.

But the unique relationship that exists between brand-name drugs and their generics does not necessarily exclude competition between branded drugs. That was the case here when Lundbeck saw generic indomethacin as an eventual threat to its NeoProfen sales. If generic indomethacin was introduced early, purchasers might not switch from indomethacin drugs to NeoProfen because of generic indomethacin's lower cost. That is why, in Lundbeck's marketing plans for 2007 and 2008, "early introduction of a generic Indocin IV" was identified as a threat for Neoprofen.[28]

D. Speculation about cross-price elasticity of demand is not evidence that a court should consider, much less rely on, to trump practical evidence of reasonable interchangeability.

The district court's decision also rested on the notion that the "cross-elasticity of demand between NeoProfen and Indocin IV is very low."[29] The basis for this conclusion is testimony from Lundbeck's expert, but, as the district court itself acknowledged, he did not calculate a specific cross-elasticity.[30] The district court's opinion offers no explanation why his testimony is persuasive[31] rather than mere speculation. A merely speculative

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[28] Facts ¶¶ 83, 84.

[29] Facts ¶ 116.

[30] Facts ¶ 115.

[31] *Id.*

opinion offers no "legally sufficient evidentiary basis" as to whether or not the drugs are interchangeable.[32]

If the district court had endeavored in an analysis of the drugs' cross-price elasticity of demand, it should have considered the issue in the long run. As the district court found, physicians "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-run studies."[33] These perceived differences create brand loyalty and slow the rate at which physicians will substitute one drug for the other due to a price change. Any cross-price-elasticity calculation would have to account for a slow substitution effect. But the district court's opinion makes no reference to the time period for cross-elasticity of demand. Without an appropriate time period, even if the speculation were true, the cross-price-elasticity calculation would have no meaning for the relevant product market.

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[32] *Concord Boat Corp. v. Brunswick Corp*., 207 F.3d 1039, 1057 (8th Cir. 2000) (citations omitted) (rejecting as mere speculation an expert's opinion that ignored inconvenient evidence).

[33] Facts ¶ 116.

CONCLUSION

Although the district court cited three factual findings, none of them is actual evidence that Indocin IV and NeoProfen are in the different product markets.

- Physician preferences for Indocin IV or NeoProfen means that the drugs are differentiated and have brand loyalty—not that they do not compete against each other in the same market.
- Lundbeck's marketing strategy to switch customers from Indocin IV to NeoProfen confirms, not undermines, that the two drugs are in the same market.
- Speculation about the cross-elasticity of demand—even by an expert—is still speculation and not evidence.

Instead, all the evidence of interchangeability—how Indocin IV and NeoProfen are used—supports the conclusion that the two drugs are in the same market: the drug market to treat PDA. Since the district court concluded the contrary, its opinion should be reversed.

Respectfully submitted,

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CERTIFICATE OF SERVICE AND COMPLIANCE

I certify that this brief was prepared using Microsoft Word 2007, in 14-point, proportionally spaced typeface. I further certify that the brief contains 2,680 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

I further certify that on January 19, 2011, I electronically filed this brief with the Clerk of the Court for the United States of Appeals for the Eighth Circuit by using the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the Appellate CM/ECF system.

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