United States Court of Appeals

FOR THE EIGHTH CIRCUIT

No. 10-3458/3459

Federal Trade Commission; State of Minnesota, by and through its Attorney General, Lori Swanson,

Plaintiffs - Appellants,

v.

Lundbeck, Inc.,

Defendant - Appellee,

Ben Venue Laboratories, Inc.,

Intervenor Below.

American Antitrust Institute; States of Missouri, Illinois, Arkansas, Iowa, Maryland, Nevada, New Mexico, North Dakota, South Dakota, and West Virginia,

Amici Curiae on behalf of Appellants.

Appeal from the United States District Court for the District of Minnesota.

Submitted: June 16, 2011
Filed: August 19, 2011

Before COLLOTON and BENTON, Circuit Judges, and KOPF,[1] District Judge.

BENTON, Circuit Judge.

The Federal Trade Commission and Minnesota (collectively the FTC) sued Lundbeck, Inc., alleging its acquisition of the drug NeoProfen violated the Federal Trade Commission Act, the Sherman Act, the Clayton Act, the Minnesota Antitrust Law of 1971, and unjustly enriched Lundbeck. After a bench trial, the district court[2] ruled for Lundbeck based on the FTC's failure to identify a relevant market.

Patent ductus arteriosus (PDA) is a life-threatening heart condition that primarily affects low-birth-weight, usually premature, babies. There are two primary treatments: pharmacological and surgical. Pharmacological treatment (a drug) is the first-line treatment; surgical ligation is considered after other treatments are ineffective. Approximately 30,000 cases of PDA are treated with drugs in the U.S. yearly.

When this case was brought, there were two FDA-approved drugs for PDA: Indocin IV and NeoProfen. (In 2010, two generic alternatives to Indocin IV were introduced by Bedford Laboratories and APP Pharmaceuticals, LLC.) Indocin IV–an off-patent, injectable drug with the active ingredient indomethacin–has been FDA-approved for PDA since 1985. NeoProfen–a patented injectable drug with the active ingredient ibuprofen lysine–has been FDA-approved for PDA since 2006. Because their active ingredients differ, Indocin IV and NeoProfen are not bioequivalents and have different side effects.

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[1] The Honorable Richard G. Kopf, United States District Judge for the District of Nebraska, sitting by designation.

[2] The Honorable Joan N. Ericksen, United States District Judge for the District of Minnesota.

Lundbeck purchased the rights to Indocin IV from Merck & Co. in 2005, and the rights to NeoProfen from Abbott Laboratories in 2006 (before it was put on the market). Until generics appeared in 2010, Lundbeck owned all the drugs for PDA.

When Lundbeck purchased Indocin IV, Merck charged $77.77 per treatment. Lundbeck immediately raised the price of Indocin IV. Two days after acquiring the rights to NeoProfen, Lundbeck raised the price thirteen-fold. By 2008, the price of Indocin IV settled at $1614.44. When Lundbeck introduced NeoProfen in 2006, it charged $1450 per NeoProfen treatment, and its price eventually settled at $1522.50.

Both Indocin IV and NeoProfen are hospital-based drugs dispensed and used in inpatient care. Most hospitals assemble a formulary–a list of recommended drugs–to streamline purchasing. The formulary-listed drugs are chosen by pharmacy and therapeutics committees who often seek input from specialist physicians. Some hospitals use closed formularies (special approval is required to prescribe non-listed drugs). Others apply open formularies (physicians can prescribe non-listed drugs at their discretion). Hospitals use inclusion in the formulary to extract better prices from sellers of clinically-substitutable drugs.

After a bench trial, the district court determined that the FTC did not meet its burden to prove that Indocin IV and NeoProfen were in the same product market and thus failed to identify a relevant market.

"The determination of the relevant market is an issue for the trier of fact." ***Ryko Mfg. Co. v. Eden Servs.***, 823 F.2d 1215, 1232 (8th Cir. 1987); *see also* ***General Indus. Corp. v. Hartz Mountain Corp.***, 810 F.2d 795, 805 (8th Cir. 1987). After a bench trial, this court reviews for clear error the district court's fact-findings supporting its ultimate determination of the existence of a relevant market. *See* ***Community Publishers, Inc. v. DR Partners***, 139 F.3d 1180, 1183-84 (8th Cir. 1998); *see also* ***Pullman-Standard v. Swint***, 456 U.S. 273, 287 (1982) (noting that Fed. R.

determination of a relevant market is a necessary predicate to the finding of an antitrust violation."); ***FTC v. Freeman Hosp.***, 69 F.3d 260, 268 (8th Cir. 1995) (relevant market is a threshold determination under the FTC Act and the Clayton Act); ***Lorix v. Crompton Corp.***, 736 N.W.2d 619, 626 (Minn. 2007) ("Minnesota antitrust law is generally interpreted consistently with federal antitrust law"); ***First Nat'l Bank of St. Paul v. Ramier***, 311 N.W.2d 502, 504 (Minn. 1981) (an unjust enrichment claim requires allegations "that a party was unjustly enriched in the sense that the 'unjustly' could mean illegally or unlawfully"). "Without a well-defined relevant market, a court cannot determine the effect that an allegedly illegal act has on competition." ***Southeast Missouri Hosp. v. C.R. Bard, Inc.***, 642 F.3d 608, 613 (8th Cir. 2011). "Antitrust claims often rise or fall on the definition of a relevant market." ***Bathke v. Casey's Gen. Stores, Inc.***, 64 F.3d 340, 345 (8th Cir. 1995). A relevant market consists of both a geographic market and a product market. ***Little Rock Cardiology Clinic PA v. Baptist Health***, 591 F.3d 591, 596 (8th Cir.), *cert. denied*, 130 S.Ct. 3506 (2010). The parties agree that the geographic market is the United States, but dispute the product market.

The outer boundaries of a product market can be identified by the reasonable interchangeability, or cross-elasticity of demand, between the product and possible substitutes for it. ***Brown Shoe Co. v. United States***, 370 U.S. 294, 325 (1962). Determining a product market requires identifying the choices available to consumers, focusing on "whether consumers will shift from one product to the other in response to changes in their relative costs." ***SuperTurf, Inc. v. Monsanto Co.***, 660 F.2d 1275, 1278 (8th Cir. 1981); *see also* Horizontal Merger Guidelines § 1, 57 Fed. Reg. 41, 552 (1992) ("Market definition focuses solely on demand substitution factors–i.e., possible consumer responses.").

In its fact-findings, the district court credited the testimony of five clinical pharmacists, representing approximately 43 hospitals throughout the country. The pharmacists uniformly stated that while they make drug recommendations, the

neonatologists decide which drug a patient receives. The court also credited the testimony of seven neonatologists who said that treatment decisions are based solely on perceived clinical advantages/disadvantages of Indocin IV versus NeoProfen. The neonatologists' preferences differed (some prescribe Indocin IV, others NeoProfen), but each echoed the same concept: The relative price of the drugs does not factor into the choice of drug treatment. The court was not persuaded by the testimony of one neonatologist (cited often by the FTC and its experts), who believed the drugs to be equally safe, implying he was comfortable using either one for PDA.

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[3] The FTC asserts that the district court failed to examine a hypothetical market where Indocin IV and NeoProfen were owned separately. In determining the relevant market, the district court need not consider a hypothetical market, especially here where the FTC offered no evidence about such a hypothetical market. *See* ***Yamaha Motor Co., Ltd. v. FTC***, 657 F.2d 971, 977 (8th Cir. 1981) (examining a hypothetical

neonatologists' testimony, the FTC argues that the hospitals, not the neonatologists, are the consumers, and the hospitals would switch between Indocin IV and NeoProfen based on price differences. The FTC offers no evidence that hospitals would disregard the preferences of the neonatologists and make purchasing decisions based on price. The district court did not err in finding more persuasive the testimony of the pharmacists and most neonatologists, compared to the one neonatologist favorable to the FTC.

According to the FTC, the district court (and the neonatologists) ignored the fact that Indocin IV and NeoProfen are practicable alternatives, relying instead on stated consumer preference. In fact, the practicable alternatives here are clear, were the subject of testimony by the neonatologists, and were considered by the district court. When the case was tried, Indocin IV and NeoProfen were the two drug treatments available for PDA. Aware of the drug options–the "practicable alternatives"–the neonatologists preferred one treatment or the other (without regard for cost), which the court credited as persuasive evidence of low cross-elasticity.

In a variation of the "practicable alternatives" argument, the FTC asserts that functionally similar products must be in the same product market. To the contrary, functionally similar products may be in separate product markets, depending on the facts of the case. *Compare* ***Henry v. Chloride, Inc.***, 809 F.2d 1334, 1342-43 (8th Cir. 1987) (batteries sold through route-truck distribution was a separate market from identical batteries sold through warehouses); ***United States v. Archer-Daniels-Midland Comp.***, 866 F.2d 242, 248 (8th Cir. 1988) (functionally interchangeable sweeteners were separate product markets because "a small change in the price of

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market, absent the challenged conduct, in order to determine whether a violation occurred, not to determine the relevant market); ***United States v. Microsoft***, 253 F.3d 34, 78-79 (D.C. Cir. 2001) (examining the market before the anticompetitive conduct in order to determine whether a violation occurred, not to determine the relevant market).

[one] would have little or no effect on the demand for [the other]"), ***Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.***, 386 F.3d 485, 496 (2d Cir. 2004) (bioequivalent, functionally-interchangeable branded and generic drugs were in separate product markets), *and* ***SmithKline Corp. v. Eli Lilly & Co.***, 575 F.2d 1056, 1064 (3d Cir. 1978) (despite a certain degree of functional interchangeability among antibiotics, specific class of antibiotics was separate product market based on court's finding that there was a lack of price sensitivity and cross-elasticity of demand); *with* ***HDC Med., Inc.***, 474 F.3d at 547-48 (rejecting argument that dialyzers with identical uses can be separated into two product markets based solely on a price diffeu(fundal),

1990) ("The question of the expert's credibility and the weight to be accorded the expert testimony are ultimately for the trier of fact to determine."). Critically, the district court did credit Lundbeck's expert who stated that the number of neonatologists willing to switch between the drugs based on price was insufficient to exercise price constraint. *See* ***Pioneer Hi-Bred Int'l v. Holden Found. Seeds, Inc.***, 35 F.3d 1226, 1238 (8th Cir. 1994) ("[This court] will not disturb the district court's decision to credit the reasonable testimony of one of two competing experts."). Lundbeck's expert was clear that even those neonatologists who might be willing to switch in response to a price difference would do so only if there was a very significant price decrease, indicating that the level of cross-elasticity was low.

Finally, the FTC contends that the district court ignored its own findings about Lundbeck's internal documents, claiming they indicate Indocin IV and NeoProfen are in the same market. True, industry recognition is a factor in a product market definition. *See* ***Brown Shoe Co.***, 370 U.S. at 325 (a submarket may be identified by a number of a factors, including industry or public recognition of its separate economic character). It is not, however, dispositive. *See* ***C.R. Bard, Inc.***, 642 F.3d at 614, 617 (holding that a hospital did not identify a relevant market even though there was evidence of industry recognition). According to Lundbeck's internal documents, it anticipated that a dramatic price increase of Indocin IV would draw generic competitors into the market. As a result, it ceased promoting Indocin IV, focusing instead on increasing the market share of NeoProfen–as a superior PDA treatment. The FTC argues that this business strategy–to market NeoProfen as better than Indocin IV–means that Lundbeck viewed NeoProfen as a direct competitor to Indocin IV, and thus the drugs must be in the same product market. However, Lundbeck's strategy to discontinue promoting Indocin IV in favor of NeoProfen can also be interpreted to mean that while Indocin IV was vulnerable to generics, NeoProfen was not, and thus the products are not interchangeable. If there are two permissible views of evidence, the factfinder's choice between them is not clearly erroneous. *Anderson*

in the best position to assess the market long term" and that is particularly so where their testimony is "contrary to the payers' economic interests and thus is suspect"). That oddity seems especially strange where, as here, there is no real dispute that (1) both drugs are effective when used to treat the illness about which the doctors testified and (2) internal records from the defendant raise an odor of predation.

The foregoing having been said, the standard of review carries the day in this case as it does in so many others. As a result, I fully concur in Judge Benton's excellent opinion.
