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.

Civ. P. 52(a) does not "purport to exclude certain categories of factual findings" from the clearly erroneous standard of review. "[I]t does not divide findings of fact into those that deal with 'ultimate' and those that deal with 'subsidiary' facts"). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." ***Anderson v. City of Bessemer City***, 470 U.S. 564, 574 (1985). If the district court's fact-findings are "plausible in light of the record viewed in its entirety," they must be affirmed, regardless of how this court might have weighed the evidence in the first instance. ***Moore v. Forrest City Sch. Dist.***, 524 F.3d 879, 884 (8th Cir. 2008) (quotations omitted). When a factual finding is supported by substantial evidence, it is not clearly erroneous. ***Dixon v. Crete Med. Clinic, P.C.***, 498 F.3d 837, 847 (8th Cir. 2007).

The FTC argues that this court should review the district court's judgment de novo because the court "applied an incorrect legal standard" by failing to "examin[e] all the pertinent factors" determining a relevant market. ***United States v. Empire Gas Corp.***, 537 F.2d 296, 303, 304 (8th Cir. 1976). *See also* ***Universal Title Ins. Co. v. United States***, 942 F.2d 1311, 1314 (8th Cir. 1991), *quoting* ***Bose Corp. v. Consumers Union of United States, Inc.***, 466 U.S. 485, 501 (1984) (despite Rule 52(a), a court can correct "a finding of fact that is predicated on a misunderstanding of the governing rule of law"). Contrary to the FTC's argument, the district court examined the pertinent factors determining a relevant market, including the "readiness and ability of consumers to turn to reasonable alternatives to the product in question." ***Empire Gas Corp.***, 537 F.2d at 303. Though cloaked as a legal argument, the FTC really challenges the district court's weighing of the relevant market factors, which this court reviews for clear error.

To prevail, the FTC bears the burden of identifying a relevant market. *See* ***HDC Med., Inc. v. Minntech Corp.***, 474 F.3d 543, 547 (8th Cir. 2007) ("The relevant product market is a question of fact, which the plaintiff bears the burden of proving."); *see also* ***FTC v. Tenet Health Care Corp.***, 186 F.3d 1045, 1051 (8th Cir. 1999) ("The

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 cost." ***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.

Based on this evidence, the court determined that the neonatologists "ultimately determine the demand for Indocin IV and Neoprofen," and that these treatment decisions are made "without regard to price." Thus, an increase in the price of Indocin IV would not drive a hospital to purchase NeoProfen, and vice versa. Considering these facts, as well as testimony by Lundbeck's expert whom the court found "persuasive," the court ruled that there is low cross-elasticity of demand between Indocin IV and Neoprofen, and thus the drugs are not in the same product market. *See* ***H.J., Inc. v. International Tel. & Tel. Corp.***, 867 F.2d 1531, 1538, 1540 (8th Cir. 1989) (holding that cross-price elasticity is essential to market definition. Plaintiff did not identify a relevant market because it offered only "casual statements, not made as part of a serious market analysis" and there was "no market data concerning sales . . . nor was there any testimony describing the degree of cross-elasticity").

The FTC contends that the district court relied too much on the testimony of the neonatologists, and ignored evidence demonstrating that Indocin IV and NeoProfen are in the same product market.[3] Challenging the court's reliance on the

[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 differential), *and* ***H.J., Inc.***, 867 F.2d at 1538-40 (holding that a new product and the product it was meant to supercede were in same product market because competitor did not produce evidence sufficient to establish low cross-elasticity of demand).

Further attacking the district court's reliance on consumer preference, the FTC argues that the court ignored the ability of marginal customers to constrain prices. Whether there are enough marginal consumers to constrain prices is a factual question that requires analyzing consumer-demand and profit-margins. *See* ***Tenet Health Care Corp.***, 186 F.3d at 1050-51, 1054 (marginal consumer substitution and profit-margins must be supported with more than "common sense." This court pointed to the "compelling and essentially unrefuted [critical loss analysis] evidence that the switch to another [product] by a small percentage of [consumers] would constrain a price increase" as evidence of marginal consumer's ability to constrain prices in a broader geographic market); *see also* ***United States v. Engelhard Corp.***, 126 F.3d 1302, 1306 (11th Cir. 1997) (requiring evidence in order to evaluate the possibility that losing marginal customers responsible for high-margin purchases may constrain prices). The FTC offered testimony of one expert explaining that "marginal customers"–neonatologists who are ambivalent between prescribing Indocin IV or NeoProfen–may constrain prices on either drug. Although not addressing this testimony in its fact-findings, the district court did state that it generally found the FTC expert unpersuasive. *See* ***Fox v. Dannenberg***, 906 F.2d 1253, 1256 (8th Cir.

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***, 470 U.S. at 574.

In the end, the FTC disagrees with the district court's weighing of the facts applicable to the relevant market determination. The district court reached its decision after "careful consideration based upon the entire record." ***United States v. Cont'l Can Co.***, 378 U.S. 441, 449, 453 (1964) (holding that metal and glass containers were in the same relevant market based on the facts, which demonstrated a "general confrontation between metal and glass containers and competition between them for the same end uses which [was] insistent, continuous, effective, and quantitywise, very substantial . . . ." lasting "over the long run"). It is precisely the job of the district court to consider the evidence offered by both sides and render a judgment. *See* ***Sloan v. Hartford Life & Accident Ins. Co.***, 475 F.3d 999, 1005-006 (8th Cir. 2007) (even though appellant could identify evidence in support of its case theory, the district court's ultimate finding was not erroneous). Whether this court would come to the same conclusion is irrelevant. The district court's fact-finding was not clearly erroneous.

The judgment is affirmed.

KOPF, District Judge, concurring.

When defining the product market, and considering the issue of cross-elasticity of demand, the district court relied heavily upon the testimony of doctors that they would use Indocin or NeoProfen without regard to price. Admittedly, those doctors had no responsibility to pay for the drugs or otherwise concern themselves with cost. Thus, the doctors had scant incentive to conserve the scarce resources that would be devoted to paying for the medication. Why the able and experienced trial judge relied upon the doctors' testimony so heavily is perplexing. In an antitrust case, it seems odd to define a product market based upon the actions of actors who eschew rational economic considerations. *See, e.g.,* *F.T.C. v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 & n.14 (8th Cir. 1999) (observing that "market participants are not always

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.
