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-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
(Nos. 08-cv-6379 and 08-cv-6381)

BRIEF FOR DEFENDANT-APPELLEE LUNDBECK INC.

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SUMMARY OF THE CASE

Appellants contend that Lundbeck "cornered the market" for drugs that treat patent ductus arteriosus ("PDA"), and used that power to maintain supracompetitive prices for Indocin and NeoProfen. After a seven-day trial in which the district court heard 26 witnesses and reviewed voluminous documentary evidence, the court found as a fact that no such "market" exists in the antitrust sense. The court found that neonatologists drive demand for these drugs, perceive significant clinical differences between them, and make treatment decisions based on clinical factors, not price. Because the price of Indocin does not affect demand for NeoProfen (and vice versa), independent owners of these drugs would have priced them the same way Lundbeck did, and would not have engaged in price competition. The court concluded the two drugs were in separate antitrust markets, and as such, Lundbeck's acquisition of NeoProfen was no antitrust violation. The court dismissed Appellants' Complaints.

Those factual findings are unchallenged on appeal, and they are fatal to Appellants' claims. Appellants' various assertions of *legal* error really just quibble with how the court weighed the evidence.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Appellee Lundbeck Inc. states that it is indirectly wholly owned by H. Lundbeck A/S, a Danish company. H. Lundbeck A/S is itself publicly owned, and The Lundbeck Foundation, through LFI a/s, holds 70% of the shares. LFI a/s is the only shareholder of H. Lundbeck A/S who has notified the company that it holds more than 10% of the share capital.

H. Lundbeck A/S, through its wholly owned subsidiary Lundbeck USA Holding Inc., acquired Ovation Pharmaceuticals, Inc. on March 18, 2009, and on that same date Ovation Pharmaceuticals, Inc. changed its name to Lundbeck Inc.

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STATEMENT OF THE ISSUES

1. Whether the district court's findings that two drugs have "very low" cross-elasticity of demand and "are not in the same product market" are fact findings that cannot be disturbed on appeal unless they are clearly erroneous and without any evidentiary support. *H.J., Inc. v. Int'l Tel. & Tel. Corp.*, 867 F.2d 1531 (8th Cir. 1989); *United States v. Engelhard Corp.*, 126 F.3d 1302 (11th Cir. 1997); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978).

2. Whether evidence of functional similarity of two products alone, without proof of high cross-elasticity of demand between them, mandates a finding that the two products occupy the same relevant antitrust market. *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594 (1953); *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039 (8th Cir. 2000); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242 (8th Cir. 1988); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485 (3d Cir. 2004).

3. Whether the fact finder must disregard consumer testimony that provides direct insight into how and why consumers react to changes in price or quality, in assessing market definition in any monopolization or consummated merger challenge where the alleged violation has already occurred. *United States v. Gen. Dynamics Corp.*, 415 U.S. 486 (1974);

SmithKline, 575 F.2d 1056; *In re Evanston Nw. Healthcare Corp.*, F.T.C. Docket No. 9315 (FTC Op. Aug. 6, 2007); FTC & U.S. DEP'T OF JUSTICE, HORIZONTAL MERGER GUIDELINES (2010).

4. Whether independent grounds exist to affirm the judgment based on the court's unchallenged factual findings regarding the NeoProfen acquisition's failure to cause anticompetitive effects. *Rambus Inc. v. FTC*, 522 F.3d 456 (D.C. Cir. 2008); *Evanston*, F.T.C. Docket No. 9315 (Aug. 6, 2007); MERGER GUIDELINES.

STATEMENT OF THE CASE

This is a complex antitrust case, but the district court's unchallenged findings and Appellants' concessions simplify it considerably.

Lundbeck's *initial pricing* of Indocin and NeoProfen is not at issue, because Appellants (1) do not challenge the district court's finding that "Lundbeck would have raised the price of Indocin IV to $1500 per three-vial course of treatment even if it had not acquired rights to NeoProfen" (FF.58); and conceded at trial that (2) Lundbeck was within its rights to acquire and charge whatever it wanted for Indocin (App.1386 (Pls.' Opening Statement); App.1602-04, 1638 (Arnold); App.1720-21 (Pls.' Closing Arguments)); and (3) NeoProfen, which was not yet FDA-approved when Lundbeck acquired

it, would have launched at about the same price as Indocin had another company owned it. (App.1600-01 (Arnold).)

The only question at trial was whether Lundbeck's acquisition of the rights to NeoProfen enabled Lundbeck to *maintain* the prices of both drugs above competitive levels by eliminating price competition that would have erupted between them had someone else owned NeoProfen. Appellants' theory was that Lundbeck would have discounted Indocin if the drugs were separately owned, and it would have been "Game On" for price competition. (App.1596, 1639 (Arnold).) Both parties and their experts agreed that the plausibility of that theory, and whether the drugs are in the same antitrust product market, turns on cross-elasticity of demand – *i.e.*, whether consumers are so indifferent between these drugs that small discounts would profitably drive substantial share shift to the cheaper drug. (App.1618-19 (Arnold); App.1698-70 (McCarthy).) *See* MERGER GUIDELINES § 4.1.2 ("The Agencies most often use a SSNIP of five percent of the price paid by customers for the products . . . .").

At trial, Lundbeck demonstrated the pricing of the two drugs would not have been any different if someone else owned NeoProfen. The two drugs have different side effects, treatment protocols and clinical histories, and neonatologists powerfully influence their hospitals to choose PDA

treatments based on safety, efficacy, long-term data and experience/familiarity factors, not price. Some neonatologists migrated from Indocin to NeoProfen for its reduced side effects and potential safety advantages, and others chose to remain with Indocin for its established clinical history, but neonatologists did not and would not switch back and forth between the two drugs based on price. Lundbeck also proved that imminent generic Indocin ("indomethacin") entry would devastate Indocin sales almost instantly, but would not diminish NeoProfen sales.

Appellants focused on superficial evidence that both drugs treat PDA and were acquired close in time, that Lundbeck set the price of NeoProfen with reference to Indocin, and that Lundbeck planned to promote NeoProfen rather than Indocin. Appellants also presented evidence that, in the abstract, hospital administrators prefer to play two or more equivalent drugs off each other to seek discounts. Both sides offered neonatologist and pharmacist testimony, Lundbeck executive testimony, manufacturer and competitor testimony, business records and experts in economics and pharmacoeconomics. Appellants also offered hospital administrator and expert physician testimony.

The court weighed the evidence and made detailed and careful findings. The court credited the testimony (including from Appellants' lay

and expert medical witnesses) that neonatologists drive hospitals' decision-making about which PDA drug(s) to purchase and that neonatologists base those decisions entirely on clinical factors and experience, not price. The court credited both sides' economists' view that cross-elasticity is the proper tool for assessing whether two products are in the same relevant market. Considering all of the evidence before it, the court made the factual findings that the drugs had low cross-elasticity and were in separate antitrust markets.

STATEMENT OF THE FACTS

Appellants waived any challenge to the district court's findings of fact. (Br. 43 n.7.) Under Federal Rule of Appellate Procedure 28, Appellants had an obligation to present a full and not misleading or one-sided view of the evidence. *Hayes v. Invesco, Inc.*, 907 F.2d 853, 854 n.3 (8th Cir. 1990) ("[I]t is inappropriate to paint a picture so one-sided that it is misleading."); *see also Wiesmueller v. Kosobucki*, 547 F.3d 740, 741 (7th Cir. 2008) ("It is forbidden for the statement of facts to misstate the record or omit unfavorable material facts . . . ."); *Lawson v. Trowbridge*, 153 F.3d 368, 371 (7th Cir. 1998) (chastising appellant for presenting favorably incomplete facts and "includ[ing] in their factual summary 'facts' that were contested at trial"); EIGHTH CIRCUIT INTERNAL OPERATING PROCEDURES I.4 (2010) ("The statement of facts should be complete, concise, and

nonargumentative."). Instead, Appellants omit all reference to the evidence – including their own – that supports the district court's findings, and pretend to have prevailed on contested issues that they lost. *See Markowitz & Co. v. Toledo Metro. Hous. Auth.*, 608 F.2d 699, 704 (6th Cir. 1979) (absent a finding of a clear error, district court's factual determinations "must always be the starting place in any statement of facts for appellate review"). A brief overview of the evidence actually presented at trial relevant to the issues on appeal follows.

I. FACTUAL BACKGROUND

A. PDA and Its Treatment

PDA is a heart condition that primarily affects very low birth-weight, usually premature, babies. (FF.4.) Neonatologists are the doctors who treat the most critically ill preterm babies in level III neonatal intensive care units ("NICUs"). (FF.5, 11.) PDA is one of several interrelated, life-threatening conditions afflicting these babies that neonatologists treat simultaneously with various drugs. (JS.23; App.1644-46 (Gardner); App.1761-62 (Goldstein); App.1788-89 (Muller); App.1818-19 (Sosenko).)

The FDA approved Indocin for use in the treatment of PDA in January 1985; it is an off-patent injectable drug with a long clinical history. (FF.15, 100, 101.) The FDA approved NeoProfen (injectable ibuprofen

lysine) for treatment of PDA 21 years later, in April 2006, months *after* Lundbeck purchased the rights to it. (FF.16, 33.) Two U.S. patents claim ibuprofen lysine (one expiring in November 2020, the other in March 2021). (FF.16; JS.99.) NeoProfen also has orphan drug status for treatment of PDA until 2013. (FF.17.)

The FDA-approved NeoProfen label differs from the Indocin label. Indocin is indicated to treat a "hemodynamically significant" PDA after 48 hours of usual medical management is ineffective. (FF.15.) NeoProfen is indicated to treat a "clinically significant" PDA with no such time restrictions. (FF.16.)

Appellants admit and the court found that Indocin and NeoProfen also have different side effects. (FF.116; JS.125.) For instance, Indocin decreases blood flow to the brain, gastrointestinal tract and kidneys, (FF.101; App.1395-96 (Gerdes)), which may affect organ function. Indocin's impact on gastrointestinal blood flow can lead to potentially life-threatening conditions, including necrotizing enterocolitis and spontaneous intestinal perforation. (App.1368; App.1396-97, 1398-99 (Gerdes); App.1414-15 (Payne).) Reduced renal blood flow may lead to complications such as transient or permanent renal dysfunction. (App.1402 (Gerdes).) The same has not been shown for NeoProfen. (FF.101;

App.1395-96, 1399 (Gerdes); App.1824 (Tefft).) The Pivotal Study for NeoProfen found it had minimal effect on renal function, even compared to no treatment at all. (App.1403-04 (Gerdes).)

The choice between Indocin and NeoProfen may affect other aspects of NICU care. Feeding is one example. Appellants' expert, Dr. Jeffrey Gerdes, testified that infants get more and better nutrition – and may be at less risk of infection and dangerous intestinal complications – if fed enterally (by mouth) rather than parenterally (intravenously). (App.1398-401 (Gerdes); *see also* App.1657 (Hay).) Feeding enterally is also far less expensive. (App.1401 (Gerdes); *see also* App.1658 (Hay).) But Gerdes acknowledged that, because of the differences in safety profiles, some neonatologists, including himself, will not feed babies enterally while administering Indocin, though many do while administering NeoProfen. (App.1400 (Gerdes); *see also* App.1648 (Gardner); App.1657 (Hay).)

B. Lundbeck's Acquisition and Pricing of Indocin and NeoProfen

***The Merck Bundle*:** In May 2004, Merck announced its desire to sell a bundle of six injectable, small-population, medically necessary drugs ("the Merck Bundle"), including Indocin. (FF.22; App.942; App.1509-12 (Burke).) Merck would only sell the drugs as a bundle, with long-term, worldwide production and distribution commitments. (FF.22, 24, 26;

App.1668-71 (Morris); App.1790-91, 1792-93, 1794, 1795-96 (Neunaber).) Lundbeck determined that Merck had under-priced these drugs for many years, and that the market would bear the very substantial price increases needed to recoup the costs of acquiring, transferring and supplying the drugs.[1] (FF.38, 43, 64; App.1511-13, 1537-39 (Burke); App.1664-67, 1669-75 (Morris); App.1709-10 (McCarthy).)

The Lundbeck executive responsible for pricing, Michael Burke, completed his Indocin pricing analysis by August 2004. Burke considered literature and expert interviews, medical necessity and price sensitivity, and the pricing of three comparable NICU benchmark drugs that cost, on average, $2,658 per course of therapy. (FF.40-41.) He concluded Indocin should be priced between $1,140 and $2,280, and that $1,500 was the right price. (FF.41-42.)

Lundbeck understood that substantial price increases would quickly attract generic competitors because the drugs were off-patent. (FF.64; App.1480 (Knocke); App.1513, 1516-17 (Burke).) Lundbeck projected losing the majority (up to *eighty to ninety* percent) of its Indocin sales to generic indomethacin soon after generic entry. (App.776; App.986, 988,

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[1] Lundbeck needed to re-price the Merck Bundle drugs to satisfy its investors' requirements for financing the acquisition. (App.1537-38 (Burke).)

1006; App.1025; App.1034, 1036; App.1049; App.1111, 1114; App.1306, 1323; App.1371, 1380; App.1526-27 (Burke); *see* FF.77; JS.92.) Lundbeck nonetheless always planned to hold Indocin's price, even in the face of cheaper generic indomethacin. (App.945; App.956; App.1046; App.1527-28 (Burke); App.1680 (Morris); App.1748-49 (Gaugh).) This is a common reaction to generic entry, and Lundbeck determined it was the profitable strategy and necessary to recoup quickly its substantial upfront investments in the Merck Bundle. (App.1512-13, 1527-28, 1540-41 (Burke); App.1604-05 (Arnold); App.1692-93, 1711 (McCarthy); App.1747-49 (Gaugh).)

Lundbeck acquired the exclusive worldwide rights to five of the Merck Bundle drugs (including Indocin) in August 2005 and the sixth drug in January 2006. (FF.22, 24.) Lundbeck assumed responsibility for manufacturing all the Merck Bundle drugs and committed to supplying them worldwide for five years. (FF.26; App.1668-71 (Morris); App.1790-91, 1792-93, 1794, 1795-96 (Neunaber).)

In June 2005, Lundbeck learned that Abbott Laboratories ("Abbott") was preparing to file a new drug application for NeoProfen to treat PDA. (FF.33.) Lundbeck did not consider calling off the Merck Bundle acquisition upon learning this news, nor did Lundbeck contact Abbott to inquire about purchasing NeoProfen prior to acquiring Indocin. (FF.33;

JS.106-08; App.1520-24, 1526 (Burke).) Instead, Lundbeck purchased Indocin without knowing whether or when the FDA might approve NeoProfen, or who might own it. (App.1521-22 (Burke).)

Lundbeck's final deal model for the Merck acquisition, dated August 4, 2005, forecast that Indocin would lose sales to NeoProfen – and made *no* corresponding change to its Indocin pricing assumptions. (App.775; App.1523-24, 1526 (Burke); *see, e.g.*, App.952.) Lundbeck believed NeoProfen would somewhat erode Indocin sales until generic indomethacin entered a short time later to wipe Indocin out almost entirely. (App.882; App.888; App.1371, 1380; App.1512-13, 1523-27, 1529-31, 1534-35 (Burke); App.1448-49, 1450-52 (Kenston).) As of August 2005, Lundbeck assumed generic indomethacin would enter within 16 months of Indocin's planned price increase (*i.e.*, April 2007). (FF.64.) At year-end 2005, Lundbeck forecast that generic indomethacin would enter by April 2008, and that the FDA would approve NeoProfen in early 2007. (FF.35, 64.)[2]

[2] For reasons unrelated to Lundbeck or its acquisitions, the FDA approved NeoProfen far earlier than Lundbeck expected, in April 2006 (FF.35, 36; App.892-93), and the first generic indomethacin product entered far later than Lundbeck and the generic manufacturer expected, in February 2010. (FF.19, 64, 65.)

Lundbeck intended to re-launch and re-price the entire Merck Bundle as soon as practicable. (App.1676 (Morris).) Lundbeck did not change its Indocin re-pricing plans after it learned about NeoProfen. (FF.45, 50; App.1521-24, 1526, 1536, 1541 (Burke).) Lundbeck would have raised Indocin's price to $1,500 even if it had not acquired NeoProfen. (FF.58.) On January 20, 2006, Lundbeck raised the price of all the Merck Bundle drugs it had acquired.[3] (FF.57.)

***NeoProfen*:** After the Merck Bundle deal closed, Lundbeck contacted Abbott to discuss an interest in working together with regard to NeoProfen. In October 2005, Lundbeck proposed acquiring the contingent rights to NeoProfen. (FF.33.) Abbott wanted to close the deal by the end of 2005, but in December 2005, negotiations ceased due to a disagreement, and neither company knew whether negotiations would resume. (FF.33.) Negotiations eventually resumed in January 2006 and the deal closed; Lundbeck agreed to pay Abbott $32.5 million plus a royalty for the contingent U.S. rights to NeoProfen. (FF.33; JS.111-12.)

Lundbeck launched NeoProfen in July 2006 at a price of $1,450 per three-vial course of treatment. (FF.62.) In 2005, Abbott had planned to

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[3] Lundbeck was awaiting the transition from Merck's packaging to its own before raising prices on the Merck Bundle drugs. (App.1676-79 (Morris).)

price NeoProfen about six times higher than Merck's price for Indocin. (FF.61; App.1779-80, 1781 (McCoy).)

The threat of generic indomethacin is what made the NeoProfen acquisition attractive to Lundbeck. Lundbeck forecast that Indocin would be a short-lived product that would rapidly lose sales to generic entry and NeoProfen, but that NeoProfen would not lose sales to cheaper generic indomethacin. (FF.77, 79-80.) Lundbeck saw NeoProfen as an eventual successor – not back-and-forth competitor – to Indocin. Lundbeck expected NeoProfen to offer meaningful safety advantages over Indocin (FF.79), and Lundbeck and Abbott negotiated the NeoProfen acquisition convinced that NeoProfen was safer than and clinically superior to Indocin. (App.879; App.1458-49 (Kenston); App.1468-69 (Knocke); App.1779-80 (McCoy).) Lundbeck believed neonatologists would switch to NeoProfen on clinical grounds. (App.855-57; App.1446-48 (Kenston); App.1505-06 (Burke); App.1562, 1564, 1566-67 (Stickler).) Lundbeck viewed neonatologists as the consumers that drove demand in hospitals, and made business decisions accordingly. (App.306; App.1460-61 (Kenston); App.1466-67, 1485-87 (Knocke); App.1502-04 (Burke); App.629h-i, 631i, App.1542-43, 1567 (Stickler).) It did not view these relevant consumers as price-sensitive.

(App.1460-61, 1463-64 (Kenston); App.1487-88 (Knocke); App.1502-04, 1506 (Burke); App.1568-69 (Stickler).)

The district court recognized that the NeoProfen acquisition strategy and financial investment would not make sense if Lundbeck believed NeoProfen and Indocin were economic substitutes – because then NeoProfen would lose sales to generic indomethacin. (FF.116.) Lundbeck believed generic indomethacin would *not* erode NeoProfen sales (*see, e.g.*, App.1494 (Knocke); App.1791 (Nolan)),[4] and Lundbeck never incorporated any erosion into its deal models, business plans, or employee bonus considerations. (*See, e.g.*, App.1444-45, 1460-61, 1463 (Kenston); App.1498-99, 1500-04, 1507, 1534-35 (Burke).) Like Lundbeck, Abbott never projected generic indomethacin having any effect on NeoProfen sales. (App.1782-83 (McCoy).) NeoProfen's insulation from generic indomethacin made it a longer-lived PDA drug than Indocin, which would help Lundbeck leverage its growing NICU sales force. (App.847; App.863; App.1681 (Morris).) That goal of capturing through NeoProfen the sales that Indocin would inevitably lose to generic indomethacin was key to the NeoProfen acquisition. (App.1489 (Knocke); App.1530-33, 1534-35 (Burke); *see also* App.1779-80 (McCoy).)

[4] Appellants' pre-trial briefing concedes this. (App.756 (Pls.' Trial Br.); *see also* App.1631 (Arnold).)

C. Generic Indomethacin

Lundbeck's January 2006 price increase precipitated Bedford Laboratories' ("Bedford's") decision to develop generic indomethacin. (FF.65; App.1738-39 (Gaugh).) Bedford expected the FDA to approve its abbreviated new drug application ("ANDA") within one year. (FF.65; App.1740-41, 1744 (Gaugh).) Bedford initially expected to launch generic indomethacin by early 2008. (FF.65; App.1740-41, 1744, 1750-51 (Gaugh).)

Bedford projected generic indomethacin would quickly eviscerate Indocin sales. (App.1732, 1733-34, 1737 (Gaugh).) Bedford did not formally forecast what effect, if any, generic indomethacin would have on NeoProfen sales. (FF.116.) But Bedford expected the market uptake for generic indomethacin to come only from Lundbeck's Indocin sales. (App.1742-43 (Gaugh).) Bedford never expected generic indomethacin to take any share from NeoProfen, creating and revising several different sales projection models over time but never projecting generic indomethacin to affect NeoProfen sales. (App.1734 (Gaugh).)

Appellants criticize the court's reliance on Bedford's analyses, deeming Bedford's lack of focus on NeoProfen irrelevant because Bedford "always" focuses "on the branded counterpart only." (Br. 56.) But Bedford

did take NeoProfen into account; it just *did not* project taking sales from NeoProfen. Bedford projected a shrinking indomethacin market over time due to one-way migration to NeoProfen (*i.e.*, NeoProfen would take sales from Indocin and generic indomethacin, but generic indomethacin would not take sales from the more expensive NeoProfen). (App.894; App.1735-37, 1745, 1746, 1752-55 (Gaugh).)

D. Hospitals, P&T Committees and Neonatologists

Neonatologists make prescribing decisions and determine personal and hospital treatment protocols; they are the primary decision-makers who choose which drug, if any, is used to treat PDA; and they wield great influence over which NICU drugs hospitals include on formulary because they practice in a specialty area with extremely fragile patients. (FF.96, 97, 113; App.1640, 1643-44 (Gardner); App.1724-25, 1729 (Behbahani); App.1766-67 (Goldstein); App.1775 (Kim).) Appellants' own witnesses agree on this. (App.649, 652-54, 661-62, 1575-76 (Gutierrez); App.1406-09 (Payne); App.1429, 1438, 1441 (Carrejo); App.1785-86 (Muller); *see also* App.1585 (Schondelmeyer).)

Appellants stipulated that P&T Committees often seek input from specialist physicians when evaluating whether to include a specialty drug on the formulary. (JS.129.) P&T Committees do not overrule neonatologists'

treatment decisions or determinations of therapeutic equivalency, and neonatologists do not change their treatment decisions based on orders from pharmacists. (App.654, 661-62 (Gutierrez); App.1393-94, 1404a-b (Gerdes); App.1441 (Carrejo).) Moreover, the record contained no evidence that any P&T Committee had kept off formulary (or otherwise discouraged use of) any neonatologist's preferred drug of choice to treat any medical condition. (*Cf.* App.1408-09 (Payne); App.1428-29 (Carrejo); App.1766-67 (Goldstein); *see also* App.1827 (Tefft).)

Neonatologists choose treatments based on evidence-based medicine, in which physicians review research in a given subject area to determine best practices. They make decisions and develop PDA treatment protocols based on familiarity, personal treatment experience, collaboration with colleagues, and most importantly clinical studies and medical literature. (App.1389-90 (Gerdes); App.1421-22 (Mammel); App.1642-43 (Gardner); App.1784 (Muller); App.1800-01 (Smith); App.1813 (Sosenko).)

Neonatologists choose Indocin or NeoProfen for reasons such as perceived differences in safety and/or side effects, or the presence or lack of long-term studies. (FF.116.) Despite similar efficacy, neonatologists are far from indifferent between the drugs. Rather, perceived meaningful differences between the drugs create strongly held convictions about PDA

treatment protocols. For example, perceived differences in renal side effects between Indocin and NeoProfen led many neonatologists to use NeoProfen rather than Indocin to treat patients with PDA. (App.1424-25 (Mammel); App.1770-71 (Kim); App.1803-04 (Smith); App.1812 (Sosenko); *see also* App.1642-43, 1645-47 (Gardner); App.1727 (Behbahani).) Many NeoProfen proponents use it because they believe it is safer than Indocin. (App.1419-20, 1423-24 (Mammel); App.1641, 1642-48 (Gardner); App.1722-23, 1730-31 (Behbahani); 1170-71, 1776-77 (Kim); App.1810-11, 1813, 1820 (Sosenko); App.1821-23 (Tefft).)

Other neonatologists continue to use Indocin due to its long-term track record. (App.1391-92 (Gerdes); App.1756 (Goldstein); *see also* JS.52.) They are wary of NeoProfen, for which long-term safety and outcomes data are not available because the FDA only approved it in 2006. (App.1391-92 (Gerdes); App.1756 (Goldstein); *see also* App.879.) Some Indocin proponents use it exclusively because: (1) they do not see Indocin and NeoProfen as equivalent in terms of efficacy, particularly because only Indocin is effective in treating intraventricular hemorrhage ("IVH") prophylactically;[5] (2) they want to see longer-term clinical data on

[5] IVH, bleeding into the fluid-filled areas surrounding the brain, occurs most often in premature neonates. (JS.51.) Some neonatologists use Indocin in susceptible neonates as concurrent prophylactic treatment

NeoProfen before switching; and/or (3) they have extensive clinical experience with Indocin. (App.1391-92 (Gerdes); App.1416-18 (Payne); App.1756, 1763-65 (Goldstein).)

Even neonatologists who use (or previously used) Indocin testified that they take concrete measures to help manage its associated risks. For example, Indocin users may adjust for its tendency to decrease blood flow to the kidney by closer monitoring of the patient and administration of a diuretic. (App.1730-31 (Behbahani); App.1776-77 (Kim); App.1809-10 (Sosenko); *see also* App.1657 (Hay).) Neonatologists may also take extra measures to help mitigate the risks associated with Indocin's reduction of gastrointestinal blood flow. (App.1399 (Gerdes).) These extra precautionary steps can increase the overall cost of using Indocin. (App.1399-401 (Gerdes); *see also* App.1658 (Hay).)

The clinical differences between the drugs (including uses, side effects, availability of long-term studies and experience using the drugs), led neonatologists to testify uniformly and emphatically that they would not switch between Indocin and NeoProfen based on changes in price. (App.1412 (Payne); App.1768-69 (Goldstein); App.1173-74 (Kim); App.1787 (Muller); App.1805-07 (Smith); App.1814-16 (Sosenko);

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for IVH and PDA. (JS.50.) NeoProfen is not effective as prophylactic treatment for IVH. (JS.126.)

App.1824-25 (Tefft); *see also* App.1438-39 (Carrejo).) Price does not enter into their decision of which drug to prescribe to treat PDA. (App.1405, 1410-12 (Payne); App.1426-27 (Mammel); App.1438-39 (Carrejo); App.1756-57, 1759-60, 1767-69 (Goldstein); App.1772-74 (Kim); App.1787 (Muller); App.1805-06 (Smith); App.1814-17 (Sosenko); App.1824-25, 1826-28, 1829-30 (Tefft).) Most neonatologists are not even aware of drug prices. (App.636 (Gutierrez); App.1411 (Payne); App.1426 (Mammel); App.1438-39 (Carrejo); App.1816 (Sosenko); *see also* App.1594-95 (Arnold).) Moreover, doctors who use NeoProfen to treat PDA testified they would not switch to cheaper generic indomethacin when it enters the market. (App.1649-50 (Gardner); App.1728 (Behbahani); App.1807 (Smith).)

Appellants' economist was unaware of any evidence that any doctors' choice between Indocin and NeoProfen could be affected by any difference in price.[6] (App.1624.) Appellants' own witnesses testified that even a very large price difference would not cause them to switch drugs. Carrejo, the lead pharmaceutical buyer for the Kaiser network, turned down a 20% NeoProfen rebate because he feared he could not convince doctors to use it

[6] Arnold acknowledged that, although Payne testified he might consider switching to NeoProfen if it were ten times cheaper than Indocin, a 1,000 percent price change would not be a SSNIP-qualifying price change. (App.1623-24 (Arnold).)

before it expired. (App.1430-32.)[7] Gutierrez, the P&T Committee chair for the Los Angeles County Department of Health Services, testified that an 8% price differential in favor of NeoProfen – which she considered the safer drug – was too small to justify even analyzing cost savings, much less depriving neonatologists of access to their drug of choice. (App.664-66.) Neonatologist Dr. Payne testified that he "might" *consider* switching to NeoProfen – for a *90% discount*. (App.1413.)

When multiple sellers of clinically substitutable drugs vie for inclusion on a formulary, hospitals hope to gain price concessions by promising or threatening to move market share (FF.93), and sometimes do so, especially when drugs are automatically substitutable bioequivalents. (App.654-55 (Gutierrez); App.1433-34 (Gutierrez).) But hospitals would not be able to do so with NeoProfen and Indocin even if separate companies owned the drugs. (FF.95.) Hospitals can effectively propose to move share from one drug to another that treats the same condition only after treating physicians agree to switch. (App.613-14, 615-20, 622 (Carrejo) ("It's only when the physicians are on board and have selected the drug for that process

[7] Contrary to Appellants' contention (Br. 15-16), Carrejo rejected the discount after consulting with a specialist pharmacist who worked with Kaiser neonatologists, because he feared neonatologists would not use the drug. (FF.97; App.1430-32.)

that it can happen. It's not a pharmacy top down . . . ."); App.635, 653-54, 661, 1575-76 (Gutierrez); *see also* App.1440 (Carrejo).)

Appellants' own witnesses noted instances in which their P&T Committees added more expensive drugs to formulary in place of functional equivalents because doctors perceived them as safer. (App.670-71 (Gutierrez); App.1435-37 (Carrejo).) And Appellants admit that P&T Committees did not consider costs when making formulary decisions, unless doctors first determined the drugs were equally safe and effective. (App.1360-63 No. 8; JS.130.) Indocin and NeoProfen are not likely candidates for therapeutic interchange because they are used on fragile neonates in high-risk situations, and are used in such low volume that they constitute an insignificant portion of a hospital's total pharmacy budget. (App.1442 (Carrejo); *see also* App.1340-41.) Even a hospital system that professes to be very cost conscious (Los Angeles County) does not apply its therapeutic interchange policies to any pediatric drug, much less to Indocin and NeoProfen. (App.654-55 (Gutierrez).) Carrejo offered examples of instances where Kaiser won price concessions by threatening to shift usage,

but none involved small population drugs, life-saving intensive care unit drugs, or drugs used on premature babies. (App.619-20.)[8]

The administrators/pharmacists also conceded that they typically focus on contracts to reduce prices for much more widely used, high-volume drugs.[9] They similarly acknowledged that the small volumes of Indocin and NeoProfen make them unlikely candidates for cost savings, even if therapeutically interchangeable. Specifically, Carrejo said drugs costing Kaiser under $1 million annually do not hit his radar, and the annual spend for PDA drugs at Kaiser does not reach that threshold. (App.1435, 1442.) Similarly, Gutierrez testified that her hospitals prioritize higher volume (App.662, 1573-74) and highly used (App.663) drugs for cost savings, monitoring the top 25, 50 or 100 most-used drugs. (App.662-63, 1573-74.)

Lundbeck's pharmacoeconomist, Dr. Joel Hay, opined that P&T Committees could not promote price competition between Indocin and NeoProfen, were they separately owned. (App.1651-53.) He relied on the

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8 Appellants claim they showed hospitals can obtain discounts from competing sellers "even if they [are] able to threaten to shift only a percentage of their purchases from one drug to another." (Br. 18 (selectively citing Carrejo testimony and their economist repeating that testimony).) Appellants left vague the "percentage" of share shift that would suffice to obtain a discount, but Carrejo testified that "[g]reater than 90 percent is standard." (App.620.)

9 Indocin and NeoProfen are small-population drugs by definition, treating only 30,000 PDA patients per year combined. (FF.6.)

absence of evidence that any hospitals, much less a sufficient number to significantly affect pricing, would (1) be able to persuade their physicians to change their drug of choice from Indocin to NeoProfen (or vice versa) and (2) thereby drive price competition between independent owners. (App.727-28 (Hay); *see also* App.1431-32 (Carrejo); App.1712-13, 1714-16 (McCarthy).) He also concluded that P&T Committees do not consider Indocin and NeoProfen to be therapeutically interchangeable, due to their different side effect profiles. (App.1663.) And he reinforced that Indocin and NeoProfen are low-volume drugs that are not high cost centers for NICUs. (App.1654-55.) In fact, on average, hospitals only spend around $90,000 annually on PDA drugs. (App.1654-55 (Hay).)

Hay testified that, even if a P&T Committee were to consider the overall treatment costs associated with Indocin versus NeoProfen, there is no price an Indocin owner could charge that would make it cheaper than the overall cost of treating with NeoProfen. (App.1661-62.) This is due in part to the additional costs associated with Indocin, including, for instance, the need for diuretics and extended parenteral feeding. (App.1656-59 (Hay).) It is also attributable to long-term outcomes because treatment with NeoProfen (as opposed to Indocin) has been shown to reduce the instances of surgery. (App.1658-62 (Hay).)

The district court ultimately credited Hay's opinions over those of Appellants' pharmacoeconomist, Dr. Stephen Schondelmeyer. (FF.95.) Nonetheless, in some respects, Schondelmeyer's testimony supported important aspects of Hay's opinions. For example, Schondelmeyer agreed that for a hospital to use the formulary process to negotiate discounts with pharmaceutical companies, the drugs must first have an acceptable level of safety and appropriate level of effectiveness; they will not even consider cost unless safety and efficacy are roughly equivalent. (App.1579-80, 1582, 1586 (Schondelmeyer); *see also* App.1363-65 No. 9.) Schondelmeyer testified that generally, to the extent costs are ever considered, neonatologists, hospital administrators and pharmacists are concerned with the total cost of a drug therapy rather than just a drug's per-dose price. (App.1577-79, 1582, 1587-88, 1590-91.) The overall cost of using a given drug may include ancillary costs that wipe out a difference in price between it and another drug. (App.1590 (Schondelmeyer).) Schondelmeyer also agreed with Gutierrez that size matters; most employers and third-party payors only monitor price increases on the top 500 drugs most commonly prescribed. (App.1583-84 (Schondelmeyer).)

Finally, because group purchasing organizations ("GPOs") make money from fees paid by manufacturers based on a percentage of sales

revenue (JS.134), they are not a good potential source of Indocin-NeoProfen price competition. For example, Child Health Corporation of America ("CHCA") sets a minimum dollar volume threshold for contracts, to prioritize its contracting workload. (App.1831 (Wilson).) Further, if drugs are not therapeutically interchangeable, it is difficult for GPOs to effect price competition between them. (App.1798-99 (Russell); App.1833 (Wilson).) GPOs do not create competition between drugs where there would otherwise be none; GPOs only aggregate competition that hospitals create. (App.702c (Schondelmeyer).) Thus, if hospitals would not switch between drugs based on price, GPOs cannot affect prices. (App.1834-35 (Wilson).)

E. Market Definition

Lundbeck's economist, Dr. Thomas McCarthy, relied on the fact-witness testimony and documents to determine there was "low cross-elasticity" between Indocin and NeoProfen. (App.1682, 1697-708.) McCarthy concluded that neonatologists are the relevant consumers driving demand for NeoProfen and Indocin, because the evidence showed that hospitals have no ability to influence market share toward a given drug unless the prescribing physicians are willing to use it. (App.1699-700, 1703-05, 1712-13.)

McCarthy also noted that NeoProfen and Indocin could not be economic substitutes and, thus, in the same relevant market, unless generic indomethacin was also an economic substitute for NeoProfen. (App.1706.) If that was true, NeoProfen sales would be greatly eroded by generic indomethacin entry (App.1706 (McCarthy)), and it would have made no economic sense for Lundbeck to spend more than $32 million for NeoProfen when generic entry was thought to be imminent. (App.1706-07 (McCarthy); *see also* App.1634-35 (Arnold).) In other words, Lundbeck's own acquisition behavior demonstrates that it did not believe that Indocin (or generic indomethacin) competed in economic terms with NeoProfen.

McCarthy explained that, in a but-for world, separate owners of Indocin and NeoProfen would not compete on price because there is very low, if any, cross-price elasticity between the two drugs. (App.1684-85, 1708, 1718.)[10] Because the relevant consumers do not view Indocin and NeoProfen as so interchangeable that they would choose based on price, a price war would never start because independent owners would gain no

[10] McCarthy also testified that it would make no sense to cut the price of either drug, whoever owned them, because demand for each is highly inelastic, and lowering the price of a highly inelastic product will not increase revenue. (App.1689-90 (McCarthy); *see also* App.1603 (Arnold).)

revenue from it. (App.1690, 1692, 1694-95, 1699-700, 1702-05, 1715-16, 1717 (McCarthy).)

The district court agreed with McCarthy and found that Indocin and NeoProfen have low cross-elasticity and occupy separate antitrust markets (FF.115-16), and rejected the ultimate opinions of Appellants' economist, Dr. Jonathan Arnold, regarding market definition. (FF.114.) Arnold, however, supported important aspects of McCarthy's opinions. Arnold testified that two products are not economic substitutes unless they have meaningful cross-elasticity of demand, but he refused to offer any opinion as to the level of cross-elasticity of demand between Indocin and NeoProfen. (App.1618-19.) And he agreed that Lundbeck's decision to purchase NeoProfen for more than $32 million would not have made sense if Lundbeck thought that NeoProfen would lose its sales to generic indomethacin. (App.1634-35.)

II. PROCEEDINGS BELOW

Appellants brought this suit nearly three years after Lundbeck acquired the contingent rights to NeoProfen, alleging only that the NeoProfen acquisition harmed *price* competition. (App.742-48 at ¶¶ 1, 3-5, 22-24, 30-31, 36(d)-(f), 37-38 (Am. Compl.); *see also* App.69 at n.1 (Order).)

During and after trial, Appellants contended that market definition, and the outcome of the case, turned on one clearly factual question: "whether independent suppliers of Indocin IV and NeoProfen would compete for sales to hospitals on the basis of price." (App.767 (Pls.' Post-Trial Br.).)[11] Instead of answering that question, Appellants asked the district court to presume market definition, and then liability, based on a single, undisputed fact – that Indocin and NeoProfen effectively treat the same condition, PDA. As they do now, Appellants argued that the drugs were in the same relevant product market based on functional substitutability alone, regardless of the mountains of evidence that showed low cross-elasticity of demand.

On August 31, 2010, the district court held that Appellants "did not satisfy their burden of demonstrating that NeoProfen and Indocin IV are in the same product market." (COL.5.) The court found unpersuasive the testimony of their economist that Indocin and NeoProfen are in the same product market. (FF.114.) It also found unpersuasive the opinion of their pharmacoeconomist that P&T Committees would have been able to foster

[11] Appellants still concede that "[t]he primary dispute regarding product market was whether hospitals likely would have been able to use the formulary process to constrain prices of PDA drugs." (Br. 17.) Appellants never alleged or proved that *non-price* competition would have ensued or that non-price competition informs the product market definition in this case. Such theories simply are not part of this case.

price competition between the two drugs (FF.95), and it took the opinion of their expert neonatologist as reflecting his personal views regarding the two drugs, rather than a consensus among neonatologists. (FF.101.) The court's ultimate factual findings were that "[t]he cross-elasticity of demand between NeoProfen and Indocin IV is very low" and that "NeoProfen and Indocin IV are not in the same product market." (FF.116.)

SUMMARY OF ARGUMENT

Whether two products are in the same antitrust market is a question of fact that turns on consumer behavior. If consumers will respond to a small but significant price increase for product A by switching to product B, in sufficient numbers to make the attempted price increase unprofitable, then the two are in the same market. Otherwise, not. Plenty of products are functional substitutes but not in the same "market" for antitrust purposes – including, sometimes, a branded drug and its generic equivalent, or identical office supplies sold by different kinds of retail stores. *See, e.g., Geneva Pharms.*, 386 F.3d at 496; *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074-80 (D.D.C. 1997).

Market definition is highly fact-intensive and case-specific. Here, the district court weighed all the evidence and found that Indocin and NeoProfen are not in the same antitrust market, and that the relevant consumers are

almost entirely indifferent to price and instead make their decisions on other (mostly clinical) grounds. The law is clear: market definition is a matter of fact, within the court's purview to determine by weighing the evidence, and owed great deference on appeal.

Appellants do not challenge any of the district court's factual findings (Br. 43 n.7) or its evidentiary rulings. Even had they challenged its factual findings, those findings cannot be disturbed on appeal unless the court committed *clear error*, which it did not. Appellants have expressly renounced any challenge under that standard, and in any event, the court's findings are amply supported. That should be the end of the matter.

Appellants are not entitled to a *de novo* second-guessing of the court's factual findings under the guise of manufactured "legal" questions that really just disagree with how the court weighed the evidence. That the court agreed with Appellants on a few subsidiary issues does not make its findings internally contradictory; it shows the court was careful and fair. The court did not refuse to consider Appellants' favorite documents; it just found them less persuasive, on balance, than the countervailing evidence. The court did not improperly rely on consumers' post-acquisition choices between Indocin and NeoProfen; it relied on the fact, now uncontested, that both before and after the acquisition those choices had nothing to do with *price*. And the

court certainly did not ignore evidence of price-sensitive "marginal" consumers; Appellants simply defaulted on their burden to prove that such consumers existed, particularly in sufficient numbers to matter.

Finally, the rest of the district court's unchallenged findings make clear that the judgment should be affirmed on other grounds disclosed by the record. Independent owners of Indocin and NeoProfen would have priced them the same way, and would not have engaged in price competition. Lundbeck's acquisition of NeoProfen thus cannot have caused any antitrust harm.

ARGUMENT

III. THE DISTRICT COURT'S HOLDING RESTS ON FACTUAL FINDINGS THAT ARE UNCHALLENGED AND WELL-SUPPORTED.

Appellants do not challenge the district court's statement of the legal test for defining the relevant market. (Br. 30 (admitting the court "cited several relevant legal principles," but arguing that it erred in applying them).) Nor do they challenge the court's factual findings (Br. 43 n.7), which are well-supported by the evidentiary record and dispositive. That leaves Appellants with no cognizable claim of legal error. Appellants plainly disagree with the court's weighing of the evidence, but they have

waived any objection to the court's admission, assessment and weighing of the evidence.

A. Whether Two Products Are in the Same Antitrust Market Is a Question of Fact.

1. Appellants Bore the Burden of Proving the Relevant Market.

Market definition is an indispensable and necessary component of Appellants' antitrust claims. *See United States v. Marine Bancorp., Inc.*, 418 U.S. 602, 618 (1974); *United States v. Syufy Enters.*, 712 F. Supp. 1386, 1396 (N.D. Cal. 1989) ("[R]elevant market is the *threshold question* in . . . Section 2 of the Sherman Act or Section 7 of the Clayton Act.") (emphasis added), *aff'd*, 903 F.2d 659 (9th Cir. 1990). Appellants bore the burden to prove a properly defined market at all times. *H.J., Inc.*, 867 F.2d at 1537; *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 119 (D.D.C. 2004) ("FTC bears the burden of proof and persuasion in defining the relevant market.").

2. Cross-Elasticity of Demand Is the Key Factual Component of Market Definition.

The factual determination of whether two facially "interchangeable" products occupy the same market turns on whether they exhibit high cross-price elasticity of demand.[12] *H.J., Inc.*, 867 F.2d at 1538 ("Critical to the

[12] In an argument first raised on appeal, Appellants suggest that "low cross-elasticity does not necessarily mean that the alternative product, if independently owned, would have no competitive significance"

determination whether certain products move in the same market is their cross-elasticity of demand . . . . The higher the cross-elasticity . . . the more sensible it is to describe them as within the same market."); *In re The Coca Cola Bottling Co.*, 118 F.T.C. 452, at *13-14 (1994) (FTC labels cross-elasticity "the most important factor in product market definition"). In the absence of price-driven substitution, the Merger Guidelines and case law mandate separate product markets. *SuperTurf, Inc. v. Monsanto Co.*, 660 F.2d 1275, 1278 (8th Cir. 1981) (product market determined by analyzing consumer shift from one product to the other in response to price changes); MERGER GUIDELINES § 4.0 ("Market definition focuses *solely* on . . . customers' ability and willingness to substitute away from one product to another in response to a price increase or a corresponding . . . reduction in product quality or service." (emphasis added)); FTC & U.S. DEP'T OF

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because Lundbeck "recaptures the revenues from sales lost by one product to the other." (Br. 38-39 & n.5.) This waived argument conflicts with settled case law, the Merger Guidelines, and Appellants' economist's testimony, which all confirm that cross-elasticity determines an acquisition's competitive significance for purposes of market definition and competitive effects analysis. (App.1618-19 (Arnold); App.1698-700 (McCarthy).) Appellants' only cited authority, *FTC v. Swedish Match N. Am., Inc.*, supports Lundbeck's argument that minimal price-based substitution is evidence of a narrow market. 131 F. Supp. 2d 151, 162-64 (D.D.C. 2000). Regardless, generic indomethacin would preclude the very "recapture" Appellants imagine – by their theory, any lost NeoProfen sales would divert to generic indomethacin (not Indocin). *See supra* 13-16.

JUSTICE, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES ("COMMENTARY") 5-6, 12 (2006) (products are in the same market if a small but significant price increase ("SSNIP") of 5%-10% will cause consumers to switch).

Courts apply these bedrock principles of market definition rigorously, even when they lead to narrow relevant markets that exclude products with common end-uses (*i.e.*, functional substitutes). *Times-Picayune*, 345 U.S. at 613 n.31 (market "must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross-elasticities of demand' are small"); *United States v. Empire Gas Corp.*, 537 F.2d 296, 303 (8th Cir. 1976) (regardless of whether products "serve the same function . . . [w]hether a particular product's sales constitute a relevant market . . . depends on the cross-elasticity of demand for that product").

The Merger Guidelines instruct that "properly defined antitrust markets often exclude some substitutes to which some customers might turn in the face of a price increase even if such substitutes provide alternatives for those customers." MERGER GUIDELINES § 4.0; ("[P]roperly defined antitrust markets" should be no broader than necessary to capture the range of economic substitutes (*i.e.*, products that price compete)); *see also*

COMMENTARY 5-6 (product markets often do not "include the full range of functional substitutes from which customers choose"). As such, the Merger Guidelines advocate starting with the "narrowest possible market" definition, and only expanding it to include economic substitutes with high cross-price elasticity. COMMENTARY 5-6.

This Court and many others have upheld findings that two products are not in the same market despite being functional substitutes. *See Archer-Daniels-Midland*, 866 F.2d at 248 & n.1 (separate product markets for two functionally interchangeable sweeteners because small price change would not affect consumer demand); *SmithKline*, 575 F.2d at 1063-64 (separate product markets for two antibiotics used in intensive care with the same indication because of low cross-elasticity); *U.S. Anchor Mfg. v. Rule Indus.*, 7 F.3d 986, 997 (11th Cir. 1993) (separate product markets for functionally interchangeable branded and generic anchors); *FTC v. Swedish Match N. Am., Inc.*, 131 F. Supp. 2d 151, 162-64 (D.D.C. 2000) (separate product markets for moist snuff and loose leaf tobacco despite functional interchangeability).

Indeed, the FTC has frequently advocated for narrow product markets in past antitrust cases involving drugs that treat the same condition. In those cases, the FTC asked whether, in their specific market settings, the drugs

were likely to compete with each other *based on price*.[13] The FTC has even argued that the exact same product may be in two different economic markets when sold through different retail channels. *Staples*, 970 F. Supp. at 1074 ("No one disputes the functional interchangeability of consumable office supplies. However, as the [FTC] has argued, functional interchangeability should not end the Court's analysis."); *FTC v. Whole Foods Mkt., Inc.*, 533 F.3d 869, 880 (D.C. Cir. 2008). *None* of the cases cited in Appellants' brief found broad markets based solely on functional interchangeability. (*See* Br. 44-46.)[14]

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[13] *See* Compl. at ¶ 19, *In re Biovail Corp.*, 134 F.T.C. 407 (2002) (No. C-4060)); Compl. at ¶¶ 64-66, *In re Bristol-Myers Squibb Co.* (F.T.C. Apr. 14, 2003) (No. C-4076)), http://www.ftc.gov/os/2003/04/bristolmyerssquibbcmp.pdf; *In re Schering-Plough Corp,* 136 F.T.C. 956, *22-24 (June 27, 2002), (limiting relevant market to K-Dur 20 and its generic equivalents; excluding from market all other brands of potassium chloride treating same condition), *vacated on other grounds*, 402 F.3d 1056 (11th Cir. 2005).

[14] *HDC Medical Inc. v. Minntech Corp.*, 411 F. Supp. 2d 1096, 1104 (D. Minn. 2006), rejected plaintiff's separate markets theory after considering contrary use *and price* evidence. This Court affirmed. 474 F.3d 543, 547-49 (8th Cir. 2007).

H.J., Inc., 867 F.2d at 1538, 1540, deemed cross-price elasticity – not functional interchangeability – the determinative factor.

United States v. E.I. du Pont de Nemours, 351 U.S. 377, 400 (1956), similarly focused on cross-elasticity, namely, "the responsiveness of sales of one product to price changes of the other." Because "[t]he record sustain[ed]" the lower court's finding of customers' "great

Appellants, here as in the trial court, virtually ignore consumer demand and cross-elasticity, and focus instead on the two drugs' functional similarities. They protest that a precise mathematical calculation of cross-elasticity is not possible here. But precise calculations are not required, and their unavailability is no excuse for Appellants' complete failure to address the central issue. Plaintiffs must produce real-world, economically meaningful evidence of cross-elasticity and price-driven substitution. The Merger Guidelines themselves treat cross-elasticity not as a mechanical calculation but a "conceptual framework" and "methodological tool for gathering and analyzing evidence pertinent to customer substitution." MERGER GUIDELINES § 4.1.3.

Appellants err by relying exclusively on the non-price components of the so-called "*Brown Shoe* factors"[15] that focus on product commonality, such as functional attributes and industry recognition. (Br. 43-44.) These factors do not trump evidence of economic substitutability. *U.S. Anchor Mfg.*, 7 F.3d at 995. Because they are merely "practical aids," "their presence or absence" will not "dispose, in talismanic fashion" of the definition of the relevant product market. *Staples*, 970 F. Supp. at 1075; *see*

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sensitivity" to price and quality changes, the Supreme Court upheld a broad market definition. *Id.*

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

also H.J., Inc., 867 F.2d at 1538 (finding for defendant where plaintiff produced "no market data concerning sales . . . nor was there any testimony describing the degree of cross-elasticity of demand"); *Whole Foods*, 533 F.3d at 880 ("We look to the *Brown Shoe* indicia, among which the economic criteria are primary."); *U.S. Anchor Mfg.*, 7 F.3d at 997 (exclusive focus on functional substitution evidence provided "no basis other than guesswork" for concluding that a price increase would cause buyers to switch from one to the other); *Moore v. Jas. H. Matthews & Co.*, 550 F.2d 1207, 1218-19 (9th Cir. 1977) (failure to address the extent of cross-elasticity made it "impossible" for the court to identify the product market's boundaries).

B. This Court Reviews the District Court's Market Definition Determination for Clear Error.

Market definition is a fact question for the fact finder. *HDC Med. Inc. v. Minntech Corp.*, 474 F.3d 543, 547 (8th Cir. 2006); *H.J., Inc.*, 867 F.2d at 1537; *Acme Precision Prods., Inc. v. Am. Alloys Corp.*, 484 F.2d 1237, 1241 (8th Cir. 1973); *U.S. Anchor Mfg.*, 7 F.3d at 994.[16] This Court has held that

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[16] Appellants suggest that *Acme* held that market definition is a mixed question of law and fact subject to *de novo* review. 484 F.2d at 1241. (Br. 26.) This strained interpretation finds no support in the case law. *Gen. Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795, 805 (8th Cir. 1987) ("Determination of relevant product market is a fact question . . . .") (citing *Acme*).

market definition "is highly fact sensitive" and "can be determined only after a factual inquiry into the commercial realities faced by consumers." *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1052 (8th Cir. 1999). Appellants cite no case in which an appellate court has treated a district court's relevant market determination as anything but a finding of fact. Appellants themselves argued in their opposition to Lundbeck's motion for summary judgment that product market definition is "fact intensive." (App.750 (Pls.' Opp'n Mot. Summ. J.).)

Federal Rule of Civil Procedure 52(a) mandates that all findings of fact are reviewable for clear error, including findings of "ultimate" fact that represent "inferences from other facts." *Pullman-Standard v. Swint*, 456 U.S. 273, 288 (1982), *vacated on other grounds*, 493 U.S. 929 (1989); *see also Anderson v. Bessemer City*, 470 U.S. 564, 574 (1985); *Dixon v. Crete Med. Clinic, P.C.*, 498 F.3d 837, 846-47 (8th Cir. 2007); *El Deeb v. Comm'r*, 766 F.2d 381, 383 (8th Cir. 1985); *Yarlott v. Comm'r*, 717 F.2d 439, 442-43 (8th Cir. 1983).

The case law is unanimous that market definition is reviewed only for clear error. *Int'l Boxing Club of N.Y., Inc. v. United States*, 358 U.S. 242, 251 (1959); *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 380-81 (1956); *Cmty. Publishers v. DR Partners*, 139 F.3d 1180, 1184 (8th

Cir. 1998); *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 212 (3d Cir. 2005); *United States v. Microsoft Corp.*, 253 F.3d 34, 52 (D.C. Cir. 2001); *Monfort of Colo. v. Cargill, Inc.*, 761 F.2d 570, 579 (10th Cir. 1985), *rev'd on other grounds*, 479 U.S. 104 (1986); *D.E. Rogers Assocs., Inc. v. Gardner-Denver Co.*, 718 F.2d 1431, 1434-35 (6th Cir. 1983); *Twin City Sportservice, Inc. v. Charles O. Finley & Co.*, 676 F.2d 1291, 1299 (9th Cir. 1982); *SmithKline*, 575 F.2d at 1062. The Government has conceded that point repeatedly in past briefs.[17] *United States v. Engelhard*, which reviewed a district court's conclusion that appellants did not meet their market definition burden, is directly on point. 126 F.3d at 1302. In *Engelhard*, "the Government on appeal . . . roundly criticized the district court's view of the evidence." *Id.* at 1305. The Eleventh Circuit reviewed for clear error the district court's finding that the Government did not prove its relevant product market, and affirmed. *Id.* at 1308.

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[17] *See* Br. for Plaintiff-Appellee at 32, *United States v. Visa U.S.A., Inc.*, 344 F.3d 229 (2d Cir. 2003) (No. 02-6074(L)), http://www.justice.gov/atr/cases/f11700/11793.pdf; Br. for Plaintiffs-Appellees at 53, *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (Nos. 00-5212 & 00-5213) , http://www.justice.gov/atr/cases/f221300/221393.pdf; Br. for Plaintiff-Appellee at 9 n.7, *Cmty. Publishers v. DR Partners*, 139 F.3d 1180 (8th Cir. 1998) (Nos. 95-2976 & 95-3165), http://www.justice.gov/atr/cases/f0400/0472.pdf.

The objecting party bears the burden to prove that a factual finding is clearly erroneous. *Aetna Cas. & Sur. Co. v. Gen. Elec. Co.*, 758 F.2d 319, 323 (8th Cir. 1985); *Craft v. Metromedia, Inc.*, 766 F.2d 1205, 1212 (8th Cir. 1985). The reviewing court views the evidence in the light most favorable to the prevailing party. *Aetna*, 758 F.2d at 323; *Craft*, 766 F.2d at 1212; *Sun Oil Co. v. Vickers Ref. Co.*, 414 F.2d 383, 389 (8th Cir. 1969). If the district court's factual findings – including the relevant product market – are "plausible," they must be affirmed, even if the appellate court might have weighed the evidence differently. *Anderson*, 470 U.S. at 573-74; *Moore v. Forrest City Sch. Dist.*, 524 F.3d 879, 884 (8th Cir. 2008); *Dixon*, 498 F.3d at 847; *Sloan v. Hartford Life & Accident Ins. Co.*, 475 F.3d 999, 1005 (8th Cir. 2007); *Engelhard*, 126 F.3d at 1305; *D.E. Rogers*, 718 F.2d at 1434-35. If a factual finding is supported by substantial evidence, it is not clearly erroneous. *Dixon*, 498 F.3d at 847; *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1101 (8th Cir. 2006); *Safley v. Turner*, 777 F.2d 1307, 1315 (8th Cir. 1985), *aff'd in part, rev'd in part*, 482 U.S. 78 (1987); *Nat'l Bancard Corp. (NaBanco) v. VISA U.S.A., Inc.*, 779 F.2d 592, 604 (11th Cir. 1986). Thus, the trial court's choice between two permissible views of the evidence cannot be clearly erroneous. *Anderson*, 470 U.S. at 574; *Forrest*

City, 524 F.3d at 884; *Dixon*, 498 F.3d at 847; *Sloan*, 475 F.3d at 1005; *Engelhard*, 126 F.3d at 1305.

C. The District Court's Factual Findings Are Unchallenged and Amply Supported.

By failing to challenge the district court's factual findings in their opening brief, Appellants have waived any argument that they are clearly erroneous. *See Mayer Hoffman McCann, P.C. v. Barton*, 614 F.3d 893, 899 n.9 (8th Cir. 2010) ("[Appellant] does not challenge this factual finding on appeal and, thus, has waived any argument to the contrary."); *Jenkins v. Winter*, 540 F.3d 742, 751 (8th Cir. 2008) ("Claims not raised in an opening brief are deemed waived."); *United States v. Lester*, 283 Fed. Appx. 421, 423 (8th Cir. 2008) (unpublished) (argument regarding sufficiency of the evidence is waived if not raised in opening brief).

Regardless, the evidence supporting the district court's findings is overwhelming. It falls into four categories: (1) neonatologist and pharmacist testimony; (2) Lundbeck testimony and business documents; (3) interested industry participants' testimony and documents; and (4) expert testimony. The court properly considered and weighed this body of evidence, and applied the correct "relevant legal principles" to it. The record amply supports the court's conclusion that Appellants failed to prove Indocin and NeoProfen are in the same relevant product market.

1. Neonatologist and Pharmacist Testimony

Trial testimony, including from Appellants' own witnesses, overwhelmingly established that neonatologists: (a) drive demand for NICU drugs;[18] (b) choose NICU drugs based on non-price clinical factors;[19] (c) hold strong convictions about what they perceive to be meaningful differences between Indocin and NeoProfen;[20] and (d) would not be influenced to switch between Indocin and NeoProfen based on price differences.[21] The testimony further established various clinical differences between Indocin and NeoProfen.[22] Despite Appellants' persistent argument that cost-sensitive pharmacists would somehow facilitate price competition between these drugs under separate ownership, even their own testifying pharmacists supported the court's determination that doctors are the relevant consumers and that the cross-elasticity of demand between Indocin and NeoProfen is very low.[23]

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18 *See supra*, 16.

19 *See supra*, 17.

20 *See supra*, 17-19.

21 *See supra*, 19-21.

22 *See supra*, 7-8.

23 *See supra*, 21-23.

2. Lundbeck's Documents and Employee Testimony

Lundbeck's own documents and employee testimony also overwhelmingly demonstrated Lundbeck's belief that Indocin and NeoProfen would not compete on price.[24] Lundbeck based business decisions with huge financial consequences on that belief, including its decision to purchase NeoProfen for over $32 million.[25] *Cf. Concord Boat*, 207 F.3d at 1056-57 (antitrust analysis must reflect economic reality); *Tenet*, 186 F.3d at 1054 (conclusory testimony suggesting sophisticated, for-profit parties act "contrary to . . . economic interests . . . is suspect"); *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) (courts must assume economic rationality and profit maximizing behavior.).

Lundbeck's beliefs about the low cross-price elasticity between Indocin and NeoProfen derive from its views about who the relevant consumers are and how they choose between these drugs.[26]

3. Third Party Industry Analyses

Lundbeck's conclusion that generic indomethacin would not take sales from NeoProfen was hardly an outlier position. Testimony and contemporaneous analyses of other economically motivated industry

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[24] *See supra*, 10-14.

[25] *See supra*, 12, 14.

[26] *See supra*, 13-14.

participants (Bedford and Abbott) also support the court's separate markets determination, including the finding that Lundbeck's strategy to switch users from Indocin to NeoProfen makes no sense unless there is low cross-elasticity of demand between the drugs.[27] Further, they support Lundbeck's initial pricing of the drugs and the belief that NeoProfen would provide important clinical benefits over Indocin.[28] GPO testimony also supports that Indocin and NeoProfen would not compete on price if separately owned.[29]

4. Expert Testimony

In addition to the abundant lay evidence, expert testimony supported the district court's key factual findings, including that P&T Committees would not cause price competition between Indocin and NeoProfen were they separately owned (FF.95),[30] that neonatologists are the relevant consumers (FF.113),[31] and that cross-elasticity of demand between the two drugs is very low. (FF.115.)[32]

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27 *See supra*, 14-16.

28 *See supra*, 12-13, 15.

29 *See supra*, 25.

30 *See supra*, 23-26.

31 *See supra*, 16-17, 26-28.

32 *See supra*, 26-28. *Amici* Missouri, et al.'s dismissal of McCarthy's opinion as "mere speculation" because it contained no specific calculation of cross-elasticity (Missouri Br. 13-14) is baseless. Market definition does not require a specific, mathematical

The court's findings crediting Lundbeck's expert witnesses – and not Appellants' – are dispositive of these ultimate facts. Appellants do not challenge the court's expert credibility and persuasiveness determinations, which are owed great deference and reviewed for clear error. *Dixon*, 498 F.3d at 848-49; *Robinson*, 447 F.3d at 1101-02 (reviewing for clear error the district court's decision to credit one expert's opinion over another); *Pioneer Hi-Bred Int'l v. Holden Found. Seeds*, 35 F.3d 1226, 1233, 1238 (8th Cir. 1994) ("We will not disturb the district court's decision to credit the reasonable testimony of one of two competing experts."); *Taylor Bay Protective Ass'n v. EPA*, 884 F.2d 1073, 1077 (8th Cir. 1989) (reviewing questions of credibility and weight of expert testimony for clear error); *Hoefelman v. Conservation Comm'n of Mo.*, 718 F.2d 281, 285 (8th Cir. 1983); *Jackson v. Hartford Accident & Indem. Co.*, 422 F.2d 1272, 1275 (8th Cir. 1970) ("It is the trial court's function, not ours, to assess the weight to be given such testimony even though it be from an expert. . . . [T]he resolution of conflicting testimony, including that of expert witnesses, is for the trier of fact."). "It is axiomatic that a district court has the discretion to evaluate the credibility of expert witnesses and accept the testimony it finds most plausible." *FTC v. Freeman*, 69 F.3d 260, 269 n.13 (8th Cir. 1995).

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calculation. *See supra*, 38. Further, Appellants never moved to exclude McCarthy's opinion.

IV. APPELLANTS' ARGUMENTS MISCHARACTERIZE THE STANDARD OF REVIEW, THE DECISION BELOW AND THE GOVERNING LAW.

Appellants labor to ascribe various "legal errors" to the district court's analysis to avoid the deferential standard of review that properly applies to its market definition findings.[33] Appellants' purported "errors" just quarrel with how the court weighed various pieces of evidence. This Court "will not assess the weight given by the district court to the testimony and the evidence," even if it "would have weighed the evidence differently," but instead must affirm "[i]f the district court's account of the evidence is plausible in light of the record viewed in its entirety." *United States v. S. Inv. Co.*, 876 F.2d 606, 611 (8th Cir. 1989). So long as there is "substantial evidence to support each finding of fact," this Court will not second-guess whether "the district court gave improper weight or significance" to particular evidence or findings. *Safley*, 777 F.2d at 1315.

Specifically, Appellants claim the court: (1) "ignored" its own purportedly contradictory findings concerning the but-for world; (2) "categorically rejected" Lundbeck's pre-litigation business documents; (3) improperly based its product market determination on post-acquisition consumer testimony reflecting "current preferences;" and (4) "ignored"

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[33] *See supra*, § III.B.

evidence of marginal consumers. Not so. The district court did not reject or ignore any evidence, much less any of its own factual findings. The court did precisely its job as fact finder: it considered and weighed the evidence adduced at trial, and determined that Appellants did not meet their burden of proving their asserted relevant antitrust market. Having asserted no "clear errors," Appellants have no basis for this appeal.

A. The District Court's Findings Are Not Internally Contradictory.

Throughout their brief, Appellants claim that the district court "ignored," "did not account for," or "did not try to reconcile" certain of its factual findings with its ultimate market definition, which they argue is "contradicted" by the findings. (Br. 20-25, 30, 35-37, 39, 42-43, 45-46, 50-51.) But Appellants do not and cannot point to any factual finding that actually contradicts the court's market definition. Instead, they select particular portions of findings that they believe support a broad view of the market and then argue – incorrectly – that those findings *compel* their proposed market definition.

More often than not, both parties prove some facts in support of their respective positions at trial. *See, e.g.*, *Gen. Indus. Corp. v. Hartz Mountain Corp.*, 810 F.2d 795, 805 (8th Cir. 1987) ("Although there was some evidence to the contrary, the relevant market in which GI competed . . .

could reasonably have been found by the jury to be pet supplies."); *Sloan*, 475 F.3d at 1005-06 (although appellant could point to evidence that supported its case theory, the ultimate finding was not clearly erroneous); *Patterson v. Masem*, 774 F.2d 251, 256-57 (8th Cir. 1985); *Swedish Match*, 131 F. Supp. 2d at 163 (evidence of dual usage relevant but ultimately insufficient to establish a broad market in light of "all the evidence against price based substitution"). The trier of fact then weighs any competing evidence and inferences and makes its ultimate factual findings. That is why appellate courts find no clear error if there is *any* factual support for the ultimate findings.

Appellants' brief reads like an opposition to summary judgment – as if the existence of *any* support for their position means that the district court was compelled to draw all the inferences they prefer. Their arguments rely on unwarranted inferences and/or mischaracterizations of the law to make certain of the district court's findings appear incompatible with its market determination when they are not. The findings on which they rely fall into four categories.

1. Functional Substitutability Findings

Appellants argue that the findings demonstrating functional similarity between Indocin and NeoProfen "contradict[]" the court's findings on

market definition. (Br. 44-45.) There is no contradiction. It is well-established that products can be functionally interchangeable and still be in separate markets.[34]

Even Appellants' economist conceded functional and economic substitutability are distinct concepts. (App.1618-19, 1626-28.) That either drug can effectively treat the same condition, PDA, may be *necessary* to a finding that they are in the same market, but it is by no means *sufficient*. *See, e.g., Geneva Pharms.*, 386 F.3d at 496 (bioequivalent generic and branded warfarin sodium belonged in separate markets despite their functional and therapeutic interchangeability); *SmithKline*, 575 F.2d at 1064 (cephalosporin antibiotics in separate market than other antibiotics, despite "a certain overlap in therapeutic capability"). Appellants' argument simply ignores the court's numerous well-supported findings explaining why those consumers who prefer Indocin will not switch in response to a price drop for NeoProfen (and vice versa) despite the functional overlap.[35]

Appellants' cited findings do not compel a contrary result. Finding 14 notes that both drugs are FDA-approved to treat the same disease. Finding 21 acknowledges the drugs have similar efficacy. Finding 78

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[34] *See supra*, 36-38.

[35] *See supra*, 17-22.

describes a document highlighting the different ways to position the drugs based on their perceived clinical differences: Indocin's unique ability to prophylactically treat IVH and NeoProfen's unique ability to treat PDA without compromising renal function. Finding 88 recognizes that "Indocin IV and NeoProfen are hospital-based drugs that are dispensed and used in an inpatient setting." Finding 94 accepts the stipulated fact that some hospitals use only one or the other of the drugs, which is the kind of data that Appellants' economist conceded was not indicative of economic substitutability. (JS.35; App.1627-28.) None of these is inconsistent with the court's ultimate findings.

2. Benchmark Pricing Findings

Appellants likewise assert that the court's benchmark pricing findings are inconsistent with a finding that NeoProfen and Indocin are in separate markets because they represent "industry recognition" that the drugs are in the same market. (Br. 46-48.)

Industry recognition, like functional interchangeability, is modestly relevant to market definition but not remotely dispositive. As Appellants' own cases establish, industry recognition is "merely one factor to consider in the subtle, fact-specific inquiry which focuses on the ultimate issue of cross-elasticity and interchangeability." (Br. 47, citing *Todd v. Exxon*, 275 F.3d

191, 206 (2d Cir. 2001).) It is a less probative one at that. Courts divide the *Brown Shoe* factors into those "go[ing] directly to the economic criteria that make one market distinct from another" (including sensitivity to price changes) and those that "bear less directly upon the economic definition of a market," but that "may be helpful where other indicia are ambiguous" (including industry recognition).[36] *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 219 n.4 (D.C. Cir. 1986). Thus, even if the court had found that industry participants recognized a market for PDA drugs, such a finding would not preclude a separate markets conclusion.

This argument also fails because the factual findings do not establish industry recognition of Appellants' proposed market. Findings 58 and 63 simply recognize that new entrants commonly benchmark their prices off of comparable incumbent drugs, not that benchmarking implies a competitive pricing relationship. (*See* App.1333; App.1597-98, 1609-12 (Arnold); App.1686-87, 1688, 1691 (McCarthy).) Appellants' theory that

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[36] Appellants also incorrectly claim *Geneva Pharmaceuticals*, 386 F.3d at 498, and *HDC Medical*, 474 F.3d at 547, make industry recognition paramount. *HDC Medical* merely listed all seven *Brown Shoe* practical indicia in the course of quoting the standard. 474 F.3d at 547. Industry recognition did not factor into the decision; it was never raised. *Geneva Pharmaceuticals* found branded and generic warfarin sodium were in separate markets based on a number of factors (including inelasticity of demand). 386 F.3d at 497-99. It accorded industry recognition no more weight than any other factor. *Id.*

manufacturers should view the prices of drugs in other markets as "irrelevant" (Br. 48) ignores reality, common industry practice and the record. As the court found, Lundbeck determined the price for Indocin by "identif[ying] three drugs deemed comparable to Indocin IV and analyz[ing] their prices." (FF.41.) The three drugs Lundbeck used as pricing benchmarks were other injectable NICU drugs, *none* of which treat PDA. (App.917; App.978; App.1495-97, 1514-15 (Burke).) That Lundbeck used these dissimilar drugs as pricing benchmarks does not place them in the same antitrust market.

3. Hospital Cost Consciousness Findings

Appellants also claim the district court "did not account for" its findings demonstrating that "hospitals were (and are) price sensitive buyers" in many settings. (Br. 21.) But these findings do not establish price sensitivity and high cross-price elasticity between Indocin and NeoProfen. These generalized cost consciousness findings are countered by specific, well-supported findings that hospitals are unlikely to switch between Indocin and NeoProfen based on price, even to obtain cost savings.[37]

For instance, Findings 91 and 93 note that most hospitals have a formulary and that hospitals "may" try to control costs within formularies,

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[37] *See supra*, 21-26.

i.e., "[w]hen two or more sellers of *clinically substitutable drugs* vie for inclusion on a formulary, a hospital *may* use its formulary system to negotiate price concessions." (Emphasis added.) These findings about what hospitals "may" do in general are not inconsistent with the court's ultimate determination of what hospitals cannot or will not do with respect to Indocin and NeoProfen.[38] Both sides offered expert opinion to assist the court's assessment of whether these general principles would apply to Indocin and NeoProfen in the but-for world. After reviewing the evidence, the court credited Hay's opinion that P&T Committees would *not* promote price competition between the drugs under separate ownership (FF.95; App.1651-52 (Hay)), and found unpersuasive Schondelmeyer's opinion that "hospitals would have been able to use their pharmacy and therapeutics committees to promote price competition between Indocin IV and NeoProfen, were the drugs independently owned." (FF.95.) Appellants do not challenge the district court's expert credibility and persuasiveness determinations, which in any event are given great deference and reviewed for clear error.[39]

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[38] Ironically, Carrejo and Gutierrez, Appellants' purported star price-sensitivity witnesses (whose testimony they cite extensively here) gave some of the most damaging testimony to Appellants' case on this point. *See supra*, 20-23.

[39] *See supra*, 47-47.

Appellants' attempt to create the appearance of inconsistency from Findings 65 and 90 (as they relate to GPO activity) fails as well. As discussed above, findings about what GPOs attempt to do in general say nothing about what GPOs could accomplish with regard to low-volume specialty NICU drugs like Indocin and NeoProfen.[40] Notably, Lundbeck has never contracted with a GPO for any of its drugs. (FF.90; JS.135.) Thus, there is no basis to assume GPOs would have affected either drug's price had Lundbeck not acquired NeoProfen.[41] Certainly nothing in Findings 65 or 90 *compels* a finding that Indocin and NeoProfen are in the same market.

Appellants also cannot show any inconsistency between the court's market definition and Finding 89. (Br. 9, 52.) Putting aside whether hospitals' incentives to cut costs necessarily translate into an ability to do so, Appellants disregard the undisputed evidence that PDA-drug costs represent a negligible fraction of total patient costs for PDA babies. Moreover, governmental reimbursement "payments are adjusted annually, based on the *average* resources used to treat a patient with certain clinical conditions (diagnoses) and procedures performed during the hospital stay." (JS.132

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40 *See supra*, 25.

41 Carrejo and Gutierrez similarly indicated Indocin and NeoProfen are unlikely candidates for cost savings, even if therapeutically interchangeable, due to low-volume usage. *See supra*, 22-23.

(emphasis added).) Appellants did not prove at trial that reimbursement processes uniquely incentivized (much less empowered) hospitals to cut drug costs with respect to Indocin and NeoProfen. In fact, Lundbeck commissioned two independent third-party analyses, both of which concluded that the planned price increase would not affect demand for Indocin in light of overall reimbursement levels. (App.1014; App.1106-07; App.1518-19 (Burke).)

Appellants' reliance on Finding 60 is similarly unavailing. This finding regarding vial-splitting simply shows that hospitals attempted to reduce waste. While vial-splitting may demonstrate some cost consciousness, it does not demonstrate cross-elasticity between Indocin and NeoProfen. *See, e.g.*, *Swedish Match*, 131 F. Supp. 2d at 163 (evidence that purchase behavior was impacted by price was not sufficient to compel a broad market definition without evidence of price-based switching to another product). Regardless, vial-splitting supports the court's decision: the ability to split Indocin vials makes it 50% cheaper than NeoProfen. If the two were economic substitutes, one would expect that price differential to lead to near-100% Indocin usage.

At bottom, Appellants urge this Court to infer that hospitals' general desire to minimize costs, and their success in doing so *in some instances*,

would necessarily result in hospitals using their formularies to induce price-based switching between *these drugs* if they were separately owned, despite all of the (frankly overwhelming) specific evidence to the contrary that the court chose to credit.

4. Lundbeck Document Findings

Appellants quote selectively from the district court's findings referring to a handful of Lundbeck's internal business documents to argue that Lundbeck "made business decisions based on its belief that some hospitals could be influenced to shift PDA drug purchases based on price." (Br. 18; *see also* Br. 42-43.) Nonsense. Appellants' efforts to cull isolated lines from a few Lundbeck documents might suffice in opposition to a summary judgment motion, but cannot overcome the abundant evidence supporting the court's findings, much less compel a contrary result.

Appellants cite several findings that directly support the district court's decision. For example, Findings 79 and 80 are based on strategic assessments that (1) explain the rationale for Lundbeck's $32 million acquisition of NeoProfen and (2) describe its strategy to convert Indocin prescribers to NeoProfen to stem future sales losses of Indocin to generic indomethacin. (App.859; App.863-64.) The evidence overwhelmingly shows that Lundbeck predicted NeoProfen would minimally erode Indocin

sales until generic indomethacin entered a short time later to wipe Indocin out almost entirely.[42] Lundbeck believed that the NeoProfen acquisition presented an opportunity to acquire a longer-lived asset in the NICU space.[43]

As the court found and Appellants' economist conceded, the NeoProfen acquisition would not have made economic sense if Lundbeck thought NeoProfen was also subject to competition from generic indomethacin. (FF.116; App.1632, 1634-35 (Arnold).) Appellants confirm the concession on appeal, arguing that Lundbeck "sought to shift demand for PDA drug therapies to NeoProfen because it would be less threatened by eventual entry by generic Indocin IV." (Br. 54.) This admission effectively defeats their appeal. Their entire case rests on the theory that, given the opportunity, NeoProfen users would switch to a lower-priced Indocin. Generic indomethacin *is a lower-priced Indocin*. Appellants' acknowledgement that NeoProfen users would not switch to the generic in sufficient numbers to make the NeoProfen acquisition a money-loser concedes away their own "Game On" theory.

Similarly, Finding 87 confirms that Lundbeck focused the vast bulk of its marketing efforts on practicing medical specialists, rather than hospital

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42 *See supra*, 9-11, 12-16.

43 *See supra*, 9-11, 12-16.

administrators. (App.306; App.1466-67, 1485-87 (Knocke).) That is perfectly consistent with the court's unchallenged finding that neonatologists are the relevant consumers. (*See* FF.113.)

Appellants misquote or misconstrue the substance of other findings to urge unwarranted inferences that the court properly refused to draw. For example, Finding 82 does not, as Appellants imply, establish that Lundbeck "used price to try to drive demand to NeoProfen." (Br. 48.) It simply describes a NeoProfen launch presentation. Explaining that launch, Lundbeck's Vice President of Commercial Analysis, Michael Kenston, testified that the decision to price NeoProfen at 3% less than (rather than equal to) Indocin did not change Lundbeck's volume predictions for either drug. (App.1462-63.) Lundbeck opted for the slight discount as a means to rebuild relationships with hospitals that were upset with Lundbeck about the earlier Indocin price increase. (App.166; App.1462-63 (Kenston).) Similarly, Lundbeck's Director of Sales, Paul Stickler, testified that initial stocking discounts are "standard practice" for any new drug launch, along with educational roundtables, dinners and sales details. (App.1569-70.)

Appellants' witness, Carrejo, confirmed that Lundbeck's stocking discount did not drive demand to NeoProfen.[44]

Appellants rely on Findings 83 and 84 to argue that "Lundbeck did not ignore the hospitals' cost-saving measures," and that "hospitals likely would have promoted price competition" between the drugs under separate ownership. (Br. 50, 53-54.) That is not remotely what the findings (or underlying documents) say. Appellants describe the 2008 NeoProfen Marketing Plan as reporting that "30 of 104 accounts that rejected NeoProfen did so *because* they vial split Indocin." (Br. 53 n.9, citing App.282 (emphasis added).) The Plan actually says that "30/104 accounts that rejected NeoProfen currently vial split Indocin" – not that the accounts

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[44] *See supra,* 20-21. Appellants likewise claim that Findings 85 and 86 establish cross-elasticity because they show the existence of "neutral[]" or "persuadable" consumers and accounts that "can go either way" or "easily switch back." (Br. 15, 18, 50.) But neither the court's findings, nor the underlying documents, indicate that accounts would ever switch between the drugs *based on price*. Appellants mistakenly conflate two distinct types of documents (NeoProfen Launch Trackers and Sales Opportunity Plans) claiming that "yellow" denotes "'neutrals,' that is accounts that 'can go either way.'" (Br. 15 (internal citations omitted).) However, "neutral" refers to *individuals* in the Sales Opportunity Plans, whereas "can go either way" refers to *accounts* in the Launch Trackers. (*See, e.g.*, App.239; App.631g-i, 1570 (Stickler).) Stickler testified that *accounts* might be "indifferent" if they had multiple doctors with differing opinions about which drug to use, but the *doctors* themselves, who are "100 percent driving demand and utilization," are generally not indifferent about the drugs and certainly will not choose based on price. (App.631g-i; *see also* App.629d-e, 1542-43, 1564-67.)

rejected NeoProfen because they vial split Indocin. (App.282.) More than seventy percent of the accounts rejecting NeoProfen did *not* vial-split Indocin, which means they rejected NeoProfen despite its lower price. Regardless, the fact that some accounts might be sensitive to a 50% price cut achieved by vial-splitting falls far short of establishing that two products are in the same market. MERGER GUIDELINES § 4.1.2 ("The Agencies most often use a SSNIP of five percent" to determine if the level of cross-elasticity is sufficiently high to drive enough customer substitution to constrain pricing and define a relevant product market.); *see also Engelhard*, 126 F.3d at 1304-05.[45]

Moreover, both the 2007 and 2008 NeoProfen Marketing Plans identify neonatologists and fellows as "the primary decision maker[s] in the NICU and the most important customer segment," while also recognizing the "large influence" of neonatal nurses. (App.183; App.202; App.280.) The 2008 Plan's assessment of potential obstacles to NeoProfen acceptance

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[45] Appellants also overstate the potential "vulnerability" that NeoProfen's safety advantages might not be "perceived as a feature/benefit significant enough to replace Indocin IV as the first-line therapy." (Br. 49-50.) The assessment that some accounts might hold this view is consistent with the testimony of those neonatologists who remained Indocin users because they were more comfortable with it – for reasons unrelated to price. *See supra*, 18-19. It is not, as Appellants pretend, a finding by the district court that neonatologists would have been willing to use Indocin if it were cheaper.

also supports the ultimate product market determination by suggesting that doctors are the key decision makers, and that they decide between the drugs based on a number of non-price factors. (FF.84.) Appellants ignore these aspects of the Plans (and the court's findings) because they do not support their position.[46]

Appellants' hand-picked selection of out-of-context sound bites from isolated marketing documents are part of the record, not all of it. They do not trump the overwhelming evidence in support of the court's many detailed (and unchallenged) findings.[47] Appellants have shown no contradictions.

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[46] Appellants' other arguments about select portions of Findings 83 and 84 are equally unavailing. First, they argue that some accounts stopped ordering NeoProfen because of price (Br. 50), but the documents and findings say nothing about causation (FF.84; App.282), and the "stopped ordering" accounts represented only 9% of accounts, and 1% of the overall NeoProfen market into which Lundbeck sold. (App.280; App.1492-93 (Knocke).) Second, Appellants presume Lundbeck's concern about formulary access was price-related, but Lundbeck's actual concern was that neonatologists could not easily prescribe NeoProfen if it was not approved on a hospital's formulary. (App.1475-76 (Knocke).) That says nothing about whether hospitals would demand (or Lundbeck would give) price concessions to add it to formularies. Third, Appellants' focus on Lundbeck's inclusion of generic indomethacin as a "threat" to NeoProfen ignores a wealth of contrary evidence that Lundbeck did not view generic indomethacin as a competitive threat to NeoProfen sales. *See supra*, 13-14.

[47] Appellants' reliance on Finding 78 is misplaced. (Br. 8.) The underlying Plaintiffs' Exhibit 44 is the only exhibit discussed at trial

B. The District Court Did Not Hold that Internal Documents Are Irrelevant as a Matter of Law.

In another attempt to manipulate their challenge to the district court's factual analysis into a more favorable standard of review, Appellants argue that the court committed "legal error" by "concluding that [Lundbeck's] contemporaneous, pre-litigation internal marketing documents cannot provide a proper basis for analyzing interchangeability." (Br. 2-3.) Even if the court committed that mistake, it would only justify a remedy for a reweighing of the evidence. But the court never treated Lundbeck's documents as "legally irrelevant." It did not "categorically reject[]" them or "swe[ep them] aside." (Br. 40-41.) The court considered Appellants'

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positing that NeoProfen's launch price could differ depending on whether Lundbeck or a separate company bought it, and it was created by an employee who (1) had no responsibility for or experience with pricing decisions, and (2) created the document as a "very first-pass preliminary overview" before doing any relevant marketing or pricing research. (App.1470; *see also* App.129; App.1471-73, 1490-91 (Knocke).) Knocke testified that he was not aware of any follow-up discussion about the document within Lundbeck (App.1490-91) and, indeed, the predictions proved to be entirely wrong. Abbott projected pricing NeoProfen substantially higher than Indocin's then-prevailing price (FF.61; App.1778-79, 1781-82 (McCoy).) The district court correctly recognized that Knocke's unresearched and ultimately incorrect pricing assumptions did not compel a different relevant market finding.

favorite documents; it just found them less persuasive, on balance, than other relevant evidence.[48]

Appellants' single citation to the district court's order is telling. (*See* Br. 40 (citing FF.114).) Appellants argue that the district court erred because "*Kentucky Speedway* does not hold, or even suggest, that internal marketing documents are categorically excluded from an interchangeability analysis." (Br. 41, citing *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908 (6th Cir. 2009).) But the court cited *Kentucky Speedway* for the proposition that internal marketing documents *alone* do not provide a "sound economic basis for assessing a market in the way that a proper interchangeability analysis would." (FF.114.) The court declined to credit Arnold's testimony as to the relevant product market because the *only* evidence on which he relied to support his view of economic substitutability was carefully selected Lundbeck marketing documents (primarily ones containing the phrase "market").[49] (App.1626, 1629 (Arnold); App.1697-98 (McCarthy).) The court found McCarthy's

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[48] *See supra*, § IV.A.4.

[49] Appellants conceded in response to Lundbeck's *Daubert* motion that the only other two categories of evidence upon which Arnold relied – Gerdes's testimony and hospital purchasing data – merely went to functional substitutability, not economic substitutability. (App.762-63 (Pls.' Opp'n Mot. Exclude Arnold Test.); App.1626-28 (Arnold).)

competing testimony more persuasive, in part, because McCarthy considered the full range of available evidence – including, but not limited to, dozens of pre-litigation Lundbeck documents. (FF.115; App.1682-83, 1697-708 (McCarthy).) The court never indicated that it believed a proper interchangeability analysis (like McCarthy's) could not consider internal documents in their proper place.

Despite testifying that meaningful cross-elasticity was critical to economic substitutability, Arnold performed no cross-elasticity analysis, relied only on one select category of internal documents, and disregarded other compelling evidence of low cross-price elasticity, such as how and why neonatologists choose between the drugs, and Lundbeck and third parties' internal projections about the potential exposure of NeoProfen to generic indomethacin. (FF.114; App.1618-19, 1621-1626 (Arnold); App.1682, 1700-01, 1704-05 (McCarthy).) The district court was well within its discretion to decline to credit Arnold's testimony because he failed to consider evidence probative of cross-elasticity. *See Concord Boat*, 207 F.3d at 1055-56 (expert's analysis was flawed because he ignored "inconvenient evidence" about the but-for world that contradicted his assumptions); *Tenet*, 186 F.3d at 1054 n.13. Appellants do not challenge the court's decision to credit McCarthy's testimony over Arnold's. (Br. 43 n.7.)

Nor could they. *Freeman*, 69 F.3d at 269 n.13; *Pioneer Hi-Bred*, 35 F.3d at 1238.

Appellants' arguments as to the relevance and reliability of a company's internal documents miss the point. The district court's order repeatedly cites and discusses Lundbeck's documents and related testimony. (FF.41, 43-51, 58, 64, 75, 77-87, 115-16.) None of Appellants' cases hold, or even suggest, that courts *must* give more weight to Appellants' favorite marketing-document excerpts than to any other type of evidence, like expert analysis of those documents and lay testimony (FF.95-108, 115), or other internal or external documents. (FF.61, 76, 116.) Those cases weighed all types of evidence in determining the appropriate product market, and did not determine that internal marketing documents somehow trumped the analysis. *See, e.g., Spirit Airlines, Inc. v. Nw. Airlines, Inc.*, 431 F.3d 917, 934-35 (6th Cir. 2005) (finding narrow product market "[b]ased on . . . Northwest's own documents, the testimony of its officials, and the opinions of Spirit's experts"); *Cmty. Publishers v. DR Partners*, 892 F. Supp. 1146, 1155-56 (W.D. Ark. 1995), *aff'd*, 139 F.3d 1180 (8th Cir. 1998) (defining narrow product market after weighing testimony from industry participants, pre-litigation records and expert opinion). In the end, Appellants are inviting the very same error they wrongly accuse the court of committing – by

pretending that the portions of internal documents they cite necessarily, as a matter of law, deserve more weight than all of the other evidence adduced at trial.[50]

C. The District Court Did Not Err by Considering Consumer Testimony.

Appellants again challenge the district court's weighing of the evidence with the rather remarkable argument (first asserted on appeal) that doctors' testimony about their preferences was inherently unreliable or contaminated, so that the court should have disregarded it.

First, Appellants waived these arguments because they never moved to exclude the neonatologists' testimony on these grounds and cannot do so for the first time on appeal. *See Pub. Water Supply Dist. No. 3 v. City of Lebanon*, 605 F.3d 511, 523-24 (8th Cir. 2010) (new issues cannot be raised on appeal because the record would be devoid of the necessary findings); *Dream Palace v. Cnty. of Maricopa*, 384 F.3d 990, 1005 (9th Cir. 2004); *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 791 n.5 (6th Cir. 2002) (refusing to consider arguments about reliability of expert testimony not raised below); *Kramer v. Kemna*, 21 F.3d 305, 308 (8th Cir. 1994) ("Failure to give the district court a first opportunity to decid[e] the merits of an argument constitutes a waiver of that argument."); *Morrow v. Greyhound*

[50] *See supra*, § III.B.

Lines, Inc., 541 F.2d 713, 723-24 (8th Cir. 1976) (failure to properly object to admissibility of testimony precludes consideration of the issue on appeal). And Appellants do not claim to meet the abuse of discretion standard that would apply even if they *had* objected below. *See Bonner v. Isp Techs.*, 259 F.3d 924, 928-29 (8th Cir. 2001).

Second, doctor-consumer testimony is a mainstay of pharmaceutical antitrust cases, and regardless, there is no basis to conclude that Lundbeck's acquisition of NeoProfen made neonatologists any less price-sensitive than they otherwise would have been. The court certainly did not commit a *legal* error by considering it, along with all of the other evidence.

1. Arguments Regarding "Current Preferences"

Appellants argue categorically that the district court should not have considered the neonatologist testimony at all, because testimony about "current preferences" from actual consumers can be manipulated by the defendant's conduct in a post-acquisition world. (Br. 32-35.)

First, this argument is a red herring. Appellants advance no coherent argument that Lundbeck's acquisition of NeoProfen somehow made neonatologists less *price-sensitive* than they otherwise would have been. Appellants concede that the two products would have been priced similarly regardless. The most Appellants assert is that Lundbeck's decision to

promote NeoProfen made doctors more likely to choose it. That is irrelevant to their market definition arguments, which turn on whether price differences would matter. As the district court concluded, they would not.

Second, there is no factual foundation for Appellants' suggestion that the acquisition affected neonatologists' non-price clinical preferences. Indocin promotion would have been minimal at best, regardless of who owned the drugs. Merck had not actively promoted it for at least ten years (FF.37), and there is no rational business motive to invest money in a drug that has been on the market for 25 years and faces imminent generic entry. (App.1571-72 (Stickler).) Thus, for example, Lundbeck never planned to engage in life cycle management or large-scale clinical studies for Indocin, regardless of whether it owned NeoProfen. (App.1482-84 (Knocke).) And contrary to Appellants' assertion that neonatologists' views were formed only in the context of Lundbeck's "anticompetitive" conduct (Br. 32-33), these neonatologists all began practicing medicine in the NICU and developing their independent views on these drugs long before the NeoProfen acquisition. The Indocin proponents among them cannot have been influenced by Lundbeck's NeoProfen marketing, by definition. And many NeoProfen proponents read about, and eagerly awaited, injectable ibuprofen long prior to NeoProfen's launch. (App.1642-43 (Gardner);

App.1808 (Sosenko); *see also* App.1424-25 (Mammel); App.1800-01, 1802-03 (Smith).)

Third, the underlying premise of Appellants' argument – that consumer testimony is so inherently unreliable that courts must exclude it *as a matter of law*, whenever it comes after a completed merger or acquisition – is unfounded. Consumer testimony reveals reasons for consumers' marketplace decisions. Predictably, Appellants suggest that in post-acquisition cases courts should define markets purely on the basis of functional substitutability and ignore everything else. Needless to say, that blinkered approach finds no support in the cases they cite. Appellants' concerns go *at most* to the weight to be given to consumer testimony, and are not persuasive at all on the facts and evidence here.

As a general matter, *all* Section 2 (15 U.S.C. § 2) monopolization cases rely on "post-violation" evidence to assess market dynamics and consumer demand.[51] Courts discount post-acquisition evidence only when it

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[51] Appellants' suggestion that the court had to examine "likely competitive dynamics in the hypothetical marketplace *absent Lundbeck's conduct*" is off base. (Br. 30-31 (emphasis added).) No case holds that the court had to exclude all post-acquisition evidence when analyzing market definition. *Yamaha Motor Co., Ltd. v. FTC* was discussing competitive effects; appellants did not challenge market definition. 657 F.2d 971, 977 (8th Cir. 1981). And the court required substantial proof Yamaha was a likely and capable entrant that would have had a meaningful impact on competition in the "but

pertains to defendants' behavior, and is therefore subject to manipulation to hide anticompetitive effects. *Gen. Dynamics*, 415 U.S. at 506 (affirming reliance on post-acquisition changes in the pattern and structure of the industry, which went to future competitive conditions).[52] But that rationale has no application here; Appellants do not allege that Lundbeck changed its own behavior "by refraining from aggressive or anticompetitive behavior when [a Section 7] suit was threatened or pending." *Id.* at 505; *see also Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1384 (7th Cir. 1986) (approving FTC's disregard of post-acquisition transaction that occurred after investigation began, that may have been made to improve company's litigation position). The one case Appellants cite in support of their theory, *Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 434-35 (5th Cir. 2008),

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for" world, even though the FTC had no opportunity to observe the counterfactual. *Id.* at 978-79. Similarly, the cited portion of *Microsoft* analyzed causation, not market definition. 253 F.3d at 78-79. The court separately addressed, and affirmed, the district court's factual findings regarding market definition, which considered post-violation evidence. *Id.* at 51-54.

[52] In *Republic Tobacco Co. v. N. Atl. Trading Co.*, 381 F.3d 717, 738 (7th Cir. 2004), the appellant based its market definition on the notion that restrictive sales contracts already in place made it impossible for relevant consumers to turn outside of their region to other suppliers. The court responded: "This argument puts the cart before the horse – contracts represent transactions that have occurred within the market. The question of what transactions have occurred in the market is subsequent to and therefore irrelevant to the definition of the market itself." *Id.*

confirms the point; it addresses the probative weight of events the defendant could unilaterally control, like a price change or the decision to bid. These cases do not require courts to discount (let alone ignore) the testimony of independent consumers, who provide direct insight into market dynamics, including how and why consumers react to particular real-world stimuli. *See also United States v. Archer-Daniels-Midland Co.* 781 F. Supp. 1400, 1422 (S.D. Iowa 1991) (where market exhibits "significant factors that are not, and cannot be, controlled by defendants," reliance on post-acquisition evidence is legitimate).

The neonatologists' testimony is not evidence subject to manipulation by a defendant looking to avoid liability. Lundbeck did not and could not alter neonatologists' dominant role in selecting between PDA drugs, or their lack of price sensitivity. With NeoProfen priced "substantially the same" as Indocin in the but-for world (App.1607; *see also* App.1609, 1638 (Arnold)),[53] Appellants provide no rational basis to assume that a slightly different but substantially similar price level would have affected

[53] There is no evidence an independent owner of NeoProfen would have competed on price with Indocin. With (1) an independent owner launching NeoProfen at or above Indocin's prevailing price, and (2) Lundbeck committed to holding *or raising* Indocin's $1,500 price in the face of generic entry (App.944-45; App.956-57; App.1046; App.1378, 1380; App.1527-28 (Burke)), there is no reason to believe prices would have been any lower but-for the acquisition.

neonatologists' willingness to switch between the two products in the event of a price increase.

In the end, Appellants' arguments are off-point because the medical witnesses testified to much more than their static current preferences. Their voluminous testimony was rich with explanation of the factors and kinds of evidence that they take into account in deciding how to treat PDA, their evolving views of the clinical differences between Indocin and NeoProfen, and the lack of price-sensitivity in their decisions about life-saving critical care drugs they prescribe to fragile neonates.

2. General Complaints about Consumer Testimony

Appellants also complain that testimony from actual purchasers "can be" unreliable in antitrust cases. They cite a few authorities (Br. 33-34), none of which mandates that courts disregard consumer testimony. The FTC's own Horizontal Merger Guidelines explain: "Information from customers about how they would likely respond to a price increase, and the relative attractiveness of different products or suppliers, may be highly relevant, especially when corroborated by other evidence such as historical purchasing patterns and practices." MERGER GUIDELINES § 2.2.2; *see also* COMMENTARY 9-10 ("Customers typically are the best source, and in some cases they may be the only source, of critical information on the factors that

govern their ability and willingness to substitute in the event of a price increase. The Agencies routinely solicit information from customers regarding their product and supplier selections. . . . Customers also provide relevant information that they uniquely possess on how they choose products and suppliers.").

In practice, the FTC routinely relies on consumer testimony, and courts routinely agree it can be relevant and reliable. *See Freeman*, 69 F.3d at 270 n.14 (giving weight to consumer testimony that only a significant price increase would cause them to shift); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1131 (N.D. Cal. 2004) (accepting some customer testimony that explained practical alternatives and behavior); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1292-93 (W.D. Mich. 1996) (finding consumer views "most persuasive" "[i]n support of [FTC's] contention that a 5 to 10% price increase would not drive defendants' patients to hospitals outside of greater Kent County"), *aff'd*, 121 F.3d 708 (6th Cir. 1997); *FTC v. Owens-Illinois, Inc.*, 681 F. Supp. 27, 29 n.32 (D.D.C.) (FTC methodology "explore[d] buyers' perceptions of substitutability by inquiring directly of them whether they would switch to alternative packaging 'in the event of a 5 to 10% increase' in the price of glass containers"), *vacated on other grounds*, 850 F.2d 694 (D.C. Cir. 1988);

see also St. Francis Med. Ctr. v. CR Bard, Inc., 657 F. Supp. 2d 1069, 1094-95 (E.D. Mo. 2009) (crediting clinician testimony regarding product choices), *aff'd sub nom. Se. Mo. Hosp. v. CR Bard, Inc.*, 616 F.3d 888 (8th Cir. 2010); *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1368 (5th Cir. 1976) (crediting consumer testimony regarding price sensitivity). As in these cases, the district court here made credibility determinations, weighed the evidence, and made factual findings about the value and weight of consumer testimony that may not be disturbed unless clearly erroneous (a claim Appellants expressly waive).

Appellants also argue that the district court should have excluded the neonatologists' testimony about their current preferences because they did not pay sufficient attention to the practicable alternatives available to them. (Br. 34-35.) Again, Appellants' authorities do not support their argument, even if they had not waived it. In all three cases – *Tenet*, *Freeman* and *Bathke*[54] – the appellate courts reviewed whether they could exclude from the geographic market those alternatives that consumers could have selected but were not currently (and had not considered) using. By focusing on current consumer habits, the district courts in those cases omitted consideration of various sellers on the geographic outskirts to whom

[54] *Bathke v. Casey's Gen. Stores, Inc.*, 64 F.3d 340 (8th Cir. 1995).

consumers could potentially travel should prices become anticompetitive. This issue simply did not arise in this case; the neonatologists were well aware of the various PDA treatment options available.

3. Complaints about Selection of Witnesses

Appellants criticize the district court for relying on the testimony of "a handful" of neonatologists who "do not actually pay the cost of their choices." (Br. 24, 33-34.)

First, Appellants imply that the court's entire market definition finding depended solely on the testimony of eight neonatologists handpicked by Lundbeck. Not true. In fact, the court considered the testimony of 13 medical witnesses – eight neonatologists and five clinical pharmacists – half of whom Appellants sponsored (one of them as Appellants' expert).[55] They all supported the critical findings that neonatologists: drive decision-making between PDA drugs in their hospitals; make their decisions based on clinical factors and perceived differences between the drugs; and are not

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[55] Appellants note that the neonatologist testimony was offered "largely through deposition" (Br. 17), presumably to discount the value of the district court's credibility determinations about these witnesses. But they all testified on video, which involves a credibility determination as well. *Sandidge v. Salen Offshore Drilling Co.*, 764 F.2d 252, 260 n.6 (5th Cir. 1985) (video deposition allows fact finder to gauge "the witness' attitude reflected by his motions, facial expressions, demeanor, and voice inflections" when making credibility determinations).

sensitive to small but significant non-transitory changes in price (or even large ones). Even Appellants' hand-chosen witnesses did not dissent on those key facts.

Second, Appellants never moved to exclude the medical testimony as unrepresentative; they only sought to exclude portions of it as improper "lay opinion[]." (App.758-59, 760 (Pls.' Mot. Exclude Lay Op. Test.); App.751-54 (Pls.' Opp'n Mot. Summ. J.).) They largely lost that battle. Appellants tried to find a witness to support their theory of the case. They had ample opportunity to find a price-sensitive neonatologist from one of the 19 hospitals listed in their initial and supplemental disclosures, or from one of the nine hospitals listed in Lundbeck's disclosures, but could not find even one. Appellants produced a new, previously unannounced pharmacist witness right before trial, but even she agreed with the consensus view on the key economic points.[56] They raise belated relevance arguments now only because the evidence ultimately did not support, and the district court did not credit, their interpretation of the facts.

Third, no matter how frequently Appellants point out that neonatologists do not write the checks for the drugs they prescribe, the

[56] When Lundbeck moved to exclude Gutierrez as an eleventh-hour undisclosed witness, Appellants fought to put her on the stand as "relevant to important issues in this litigation." (App.765 (Pls.' Opp'n Mot. Exclude Gutierrez Test.).)

district court's conclusion that neonatologists are the relevant consumers remains a factual finding – and one that Appellants chose not to challenge as "clear error." Appellants conceded this in their post-trial brief, arguing that "[t]he identity of *the relevant purchasers (like all other aspects of market definition) is a question of fact* to be decided in light of all the circumstances of record." (App.769 (Pls.' Post-Trial Resp. Br.) (emphasis added).) That is exactly what the court did here. (FF.113; *see also* FF.95-108.)[57]

Appellants chose not to challenge the court's factual findings; they cannot continue to argue factual positions inconsistent with those findings. *See Republic Tobacco Co. v. N. Atl. Trading Co.*, 381 F.3d 717, 738-39 (7th Cir. 2004) (appellant's argument about identity of relevant consumers was beside the point for market definition, when it advanced and lost that argument at district court, and did not explicitly reassert it on appeal); *SmithKline*, 575 F.2d at 1064.

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[57] It is not unusual for a district court to find that prescribing physicians are the relevant consumers. *See, e.g.*, *SmithKline*, 575 F.2d at 1063 (product market limited to single antibiotic because "[p]rescribing physicians are not cost conscious in their choices of an antibiotic for a hospitalized patient, and so do not opt for a less expensive over a more costly medication"); *St. Francis*), 657 F. Supp. 2d at 1094-95 (crediting testimony that, "against his instincts," buyer "purchases Bard catheters although Tyco's are lower in price and does so because that is what the physicians want").

D. The District Court Did Not Improperly Ignore Any Evidence of "Marginal" Consumers.

Appellants contend that the district court's market definition finding is legally "insufficient" because it failed to analyze the role of "marginal consumers that might have constrained Lundbeck's pricing." (Br. 37, 39.) Appellants fail to show any legal error for several reasons.

First, whether marginal consumers were "economically significant" (Br. 39) is a highly factual question on which Appellants bore the burden of proof. Yet Appellants literally provided the district court no evidentiary basis to reach the conclusions they urge on appeal. Appellants never defined what a marginal consumer is, never analyzed how many exist, and never analyzed whether they were sufficient in number to alter Lundbeck's pricing strategy in the but-for world. Lundbeck's economist noted that Appellants did not advance any evidence or analysis of marginal consumers to rebut, and that their economist did not even "think about [convertible doctors], much less quantify [them]." (App.1696, 1716 (McCarthy).) Having defaulted so thoroughly on their burden below, Appellants waived any argument that the district court erred by failing to address marginal consumers. *See Public Water Supply Dist.*, 605 F.3d at 524 ("[D]istrict courts cannot be expected to consider matters that the parties have not expressly called to their attention . . . .").

Even if they could assert this new theory now, Appellants could not demonstrate – as they must – that either Lundbeck or an independent owner of NeoProfen would be unable to raise prices a small amount without causing the "critical loss" of enough "on the fence" neonatologists to make the price increase unprofitable. *See Tenet*, 186 F.3d at 1053-54; *United States v. SunGard Data Sys.*, 172 F. Supp. 2d 172, 190 (D.D.C. 2001); *United States v. Visa U.S.A., Inc.*, 163 F. Supp. 2d 322, 335 (S.D.N.Y. 2001), *aff'd*, 344 F.3d 229 (2d Cir. 2003). Appellants first had to prove that supposed "marginal" neonatologists were actually willing to switch drugs *on the basis of price*. Appellants then had to prove "a large enough number" of these price-sensitive neonatologists exist to constrain Indocin's pricing if Lundbeck did not own both drugs. *Visa*, 163 F. Supp. 2d at 335; *see also SunGard*, 172 F. Supp. 2d at 191-92. Appellants proved none of that.

Appellants argue that *Engelhard* and *Tenet* demonstrate that a small number of lost sales "may have been sufficient to constrain prices," implying this is a hollow requirement that is easily met.[58] (Br. 37.) In reality, both cases confirm this is a highly factual inquiry requiring detailed

[58] *H.J., Inc.* held that cross-price elasticity is critical to market definition, and that the plaintiff could not meet its burden to prove a product market without evidence and analysis of the lack of price-based switching. 867 F.2d at 1538-40. That case clearly does not show legal error here.

analysis of consumer demand and profit-margins to show the amount of lost sales or consumers necessary to constrain prices. In *Engelhard*, the court explained that although "it is possible" that losing a small number of high-margin consumers may be sufficient to "make [a] price increase unprofitable," the Government's evidence was insufficient "[t]o evaluate such possibilities" and therefore it could not prove its proposed market. 126 F.3d at 1306. Likewise, in *Tenet*, the court rejected the FTC's reliance on expert analysis and a supposed "common sense" proposition "to identify the threshold number of [marginal] patients" to support its proposed market, without validating its assumptions about consumer substitution and profit margins. 186 F.3d at 1050-51, 1053 n.13.

Here, *no* evidence supports Appellants' new-found theory. Appellants do not and cannot rely on their economist, who performed no analysis of marginal consumers, just as he offered no opinion concerning cross-price elasticity.[59] Arnold did not: define what discount would cause a representative "marginal consumer" to switch; estimate how many (if any)

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[59] These same deficiencies doom Appellants' attempt to claim legal error under *Tenet*. In *Tenet*, this Court reversed a narrow geographic market definition based on "compelling" and "essentially unrefuted" economic analysis (drawn from hospitals' financial data) that the loss of only a few patients would make a 5% price increase unprofitable. 186 F.3d at 1050, 1054. Appellants, though they bore the burden of proof, made no attempt to make such a showing here.

existed (based on a survey, the Launch Tracker documents, or any other evidence); specify the degree of shift needed to constrain but-for prices; or analyze whether a sufficient number of marginal consumers would actually shift.[60]

Lacking any analysis, Appellants are left arguing that a handful of internal marketing documents, alone, establish the existence of an "economically significant" number of marginal consumers. These documents say nothing of the kind, and cannot show that marginal consumers would have constrained pricing in the but-for world. *See H.J., Inc.*, 867 F.3d at 1539-40 (criticizing reliance on "casual" and "conclusory" statements not made as part of a "serious market analysis").

For example, the Launch Tracker does not show that *any* neonatologist was price sensitive.[61] Even assuming the existence of some such neonatologists, this document does not establish how many there are, or how price sensitive they are. Appellants just presume that all physicians in each category (green, yellow and red) would switch based on price (Br. 39),

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60 Arnold did not analyze Lundbeck's costs or profit margin. (App.1615 (Arnold).) *Cf. Visa*, 163 F. Supp. 2d at 336 (discussing FTC expert's use of "price-cost margin" of 26% and analysis that a 5% increase in price would have to reduce output by 16% in order to be unprofitable); *California v. Sutter Health Sys.*, 130 F. Supp. 2d 1109, 1130-31 (N.D. Cal. 2001).

61 *See supra*, n.44.

but that assumption – along with the assumption that enough marginal consumers exist to affect Lundbeck's pricing – lacks a reliable basis and was proven false at trial.[62] *Tenet*, 186 F.3d at 1050-51, 1053 n.13 (rejecting FTC's proposed market in part because its expert failed to validate reliability of assumptions for defining marginal consumers). The two other "categories" of marginal consumers purportedly identified in the findings of fact (the "vial splitting crowd" and "those for whom generics were an alternative") (Br. 39), are phrases pulled from two marketing documents, similarly taken out of context, neither of which provides any indication of how many consumers' views they represent, how price sensitive those consumers may be, or how they would affect pricing.[63]

Finally, the district court credited overwhelming evidence – unchallenged on appeal – showing that marginal consumers would not exist in sufficient number to constrain the pricing of Indocin and NeoProfen in the but-for world. Lundbeck, Abbott and Bedford all projected *no* loss of NeoProfen sales to lower-cost generic indomethacin[64] – thus, Lundbeck's profit-maximizing strategy was to maintain its NeoProfen price regardless of any purported "marginal customers" that might be sensitive to price.

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62 *See supra*, 17-21.

63 *See supra*, 61-63.

64 *See supra*, 10-16.

Finally, Lundbeck's economist testified that it was "very unlikely" that price competition would be profit maximizing given the clinical "rigidity of the neonatologists." (App.1717.)

V. AAI'S NON-PRICE COMPETITION ARGUMENTS CONTRADICT APPELLANTS' THEORY OF THE CASE, RAISE NEW ISSUES BEYOND THE SCOPE OF APPEAL, AND ARE LEGALLY AND FACTUALLY FLAWED.

Appellants' exclusive focus on price competition permeated all facets of this case, from the Complaint, through discovery, trial, and most prominently the requested disgorgement of all revenues as ill-gotten profits resulting from lost price competition.[65] Thus, *amicus curiae* American Antitrust Institute's ("AAI's") argument that cross-elasticity is legally irrelevant not only contradicts Appellants' theory of the case,[66] but also raises a new issue well beyond the scope of this appeal. *See Golden Gate*

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65 *See supra* 28-29 & n.11. *See also, e.g.*, App.742 at ¶ 1 (Am. Compl.) ("This action challenges an anticompetitive acquisition that is forcing hospitals to pay monopoly prices for drugs . . . ."); App.767 (Pls.' Post-Trial Br.) ("[W]hether PDA drugs constitute a product market depends on the answer to one question: whether independent suppliers of Indocin IV and NeoProfen would compete for sales to hospitals on the basis of price."); App.1592-93 (Arnold) (identifying maintenance of monopoly prices as "the anti-competitive effect").

66 AAI argues that low (or even zero) cross-price elasticity does not mean two products occupy separate product markets, if price is irrelevant to consumers and not the primary basis of competition. (AAI Br. 7, 13.) This argument is irreconcilable with Appellants' entire case, which presumes that price is the primary basis to win sales.

Rest. Ass'n v. City & Cnty. of San Francisco, 546 F.3d 639, 653 (9th Cir. 2008) (declining to consider arguments raised solely by *amicus curiae*, "particularly when they were not raised before the district court and when they are in tension with the strategic positions taken by the litigants"); *Peltier v. Henman*, 997 F.2d 461, 475 (8th Cir. 1993) ("Ordinarily, we consider only issues argued in the briefs filed by the parties and not those argued in the briefs filed by interested nonparties.").

Assuming Appellants had pursued a fundamentally different antitrust case based on AAI's new theory of harm to non-price competition, that still would not disturb the district court's separate product market findings, because AAI's argument, applied to the record, is both factually and legally flawed.

AAI grossly understates the burden of proof for a non-price competition claim, implying the court may simply presume Indocin and NeoProfen are in the same product market even if "consumers are not price sensitive" so long as they value unique differences in the drugs' attributes and qualities. (AAI Br. 13-14.) Contrary to AAI's claim, the Merger Guidelines confirm that antitrust analysis of non-price competition "employ[s] an approach analogous to that used to evaluate price competition . . . based on the[] impact on customers." MERGER GUIDELINES

§ 1. "Non-price" variables – such as product quality and services – are just additional facets of the ultimate competition – price competition to win sales. *See Cmty. Publishers*, 892 F. Supp. at 1158-59. Cross-elasticity and "demand substitution factors" remain the focal point of market definition, *i.e.*, whether small discounts "or corresponding non-price change . . . in product quality or service" will cause a substantial percentage of customers to switch to the cheaper (or better) product. MERGER GUIDELINES (2010) § 4; *see also Tenet*, 186 F.3d at 1054 (reversing district court for failing to recognize that more expensive, higher quality hospitals could "constrain a price increase" at less expensive, lower quality hospitals). Non-price competition has antitrust significance only if it is a real competitive constraint, meaning such "non-price" factors are an effective and profitable way to drive and compete for sales. *Cmty. Publishers*, 892 F. Supp. at 1153 ("To say that two products are in the same market means that they constrain each other's ability to . . . rais[e] prices and lower[] quality for fear that consumers will switch to the competitor's product."). Appellants offered no proof of such non-price constraints on sales here.

AAI hypothesizes that Lundbeck would have invested heavily to protect Indocin's sales in the but-for world by challenging NeoProfen's claim of superior safety. (AAI Br. 14.) AAI makes no attempt to show that

such promotion would, in the but-for world, profitably retain or recapture sales from NeoProfen.[67] AAI simply opines that "information about safety and effectiveness is critical." (AAI Br. 14.) There is literally no evidence that Lundbeck's attempts to promote Indocin ever influenced treatment decisions, much less that *additional* investment in product promotion would profitably impact future sales.

AAI's theory is contrary to overwhelming and uncontested evidence that Lundbeck had no rational long-term incentive to invest in Indocin. Indocin is a well-known drug with a 25-year clinical history that maintained market acceptance without Merck marketing it. (*See* JS.48, 52, 60; App.1391-92 (Gerdes); App.1484 (Knocke).) Loyal Indocin users prescribe it precisely because of their familiarity with its use and demonstrated track record, and are skeptical of marketing claims of newer drugs in the absence of long-term data.[68] Likewise, loyal NeoProfen users migrated away from

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[67] Any marketing would be constrained by the FDA-approved label, so could "not include representations or suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, or that it has fewer, or less incidence of, or less serious side effects or contraindications than the label indicates." (JS.26; *see also* App.1562-64 (Stickler).) There is no evidence that marketing is an effective or rational form of "non-price" competition once neonatologists are familiar with a drug, as with Indocin. (*See* App.1484 (Knocke).)

[68] *See supra*, 17-19.

Indocin precisely because of their concerns with Indocin's well-documented toxicities and side effects.[69] Appellants' economist agreed that branded products facing generic entry are at the end of their product life cycles and have reduced returns from promotional activities. (App.1612-13 (Arnold).) Investments to differentiate Indocin from NeoProfen would at most benefit only the generic entrant. For these and many other reasons AAI fails to address, Lundbeck had no long-term promotion plan in place for Indocin, and always planned to shift resources away from it as soon as generic indomethacin entered or Lundbeck launched a new, longer-lived asset. (App.1465, 1473-74, 1477-79, 1481 (Knocke); *see also* App.772.)

AAI relies on *Tenet* and *United States v. Continental Can Co.*, 378 U.S. 441 (1964) for the proposition that any non-price competition between merging products necessarily defines a market and proves antitrust harm, without regard to and despite low cross-price elasticity. (AAI Br. 11-13.) These cases say no such thing, but rather confirm that antitrust analysis of non-price competition focuses on whether the products are meaningfully competitive, such that they constrain pricing and drive sales.

In *Tenet*, the FTC challenged a hospital merger it argued would increase the cost of health care. As here, all parties and the district court

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[69] *See supra*, 7-8, 17-18.

agreed that market definition turned on price-elasticity, namely, the willingness and ability of "a small percentage of patients [to] constrain a price increase" by switching to other hospitals. 186 F.3d at 1050, 1054. *Tenet* never suggested that pricing was irrelevant or that the mere existence of "quality-based" competition is determinative. *Id.* at 1054. Just the opposite, *Tenet* confirmed that the significance of non-price competition (here, higher quality care) depends on whether it can drive a "significant amount of migration" that will constrain pricing of other hospitals. *Id.*

In *Continental Can*, the Government challenged a merger of industrial container manufacturers differentiated primarily by their material composition (glass versus plastic). 378 U.S. 441. The Court observed that a "compelling" history of "substantial and vigorous" back-and-forth competition on multiple factors, including product quality and innovation, proved the products competitively constrain each other. 378 U.S. at 448, 450, 465-66. From this, AAI wrongly assumes the mere existence of "quality competition" overcomes low cross-elasticity and proves a market and antitrust harm. But the Court did not hold cross-elasticity was "low," only that unique industry characteristics – absent from this case – made it inappropriate to measure in the short-run. *Id.* More importantly, the decision reveals a far more robust analysis: whether competition (price or

non-price) is meaningful is measured by the degree of competitive constraint. *Id.* at 448. The Court confirmed that market definition is ultimately determined by whether the mixture of price and non-price competition "acts as a deterrent against attempts . . . to reap the possible benefits . . . by raising prices above the competitive level." *Id.* at 465-66.

VI. THE JUDGMENT SHOULD BE AFFIRMED ON OTHER GROUNDS DISCLOSED BY THE RECORD.

The Court "may affirm the district court's judgment on any ground supported by the record." *Ballinger v. Culotta*, 322 F.3d 546, 548 (8th Cir. 2003). Even if Indocin and NeoProfen occupied the same broad "PDA Drugs" product market – which they do not – Appellants' failure to show high cross-elasticity and price-driven substitution still dooms their case. The district court's unchallenged factual findings establish that Appellants failed to prove that the NeoProfen acquisition caused competitive harm. Specifically, they failed to prove the NeoProfen acquisition eliminated meaningful price competition that otherwise would have occurred. Instead, they merely presume that, if NeoProfen were independently owned, Lundbeck would automatically have initiated price competition and discounted Indocin after NeoProfen's launch. This failure of proof provides independent grounds to affirm judgment for Lundbeck.

A. Appellants Have the Burden to Prove the NeoProfen Acquisition Caused Anticompetitive Effects.

The ultimate issue in any merger challenge is whether the transaction "is likely to *affect adversely the competitive process*, resulting in higher prices, lower quality, or reduced innovation." COMMENTARY 2 (emphasis added); *see also Oracle*, 331 F.Supp. 2d at 1110-11; MERGER GUIDELINES §§ 2.1.1, 4.1.4. This is particularly true in challenges to consummated mergers, which evaluate "whether adverse competitive effects have already resulted from the merger." MERGER GUIDELINES § 2.1.1. The focus of competitive effects analysis is "not whether certain products competed against each other in a broad sense, but instead whether such products were sufficiently substitutable that they could constrain each other's pricing." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 1215 (June 27, 2002) (internal quotation omitted), *vacated on other grounds*, 402 F.3d 1056 (11th Cir. 2005).

Antitrust plaintiffs must prove competitive effects.[70] A Section 2 plaintiff "must demonstrate that the monopolist's conduct indeed has the

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[70] Plaintiffs seeking drastic equitable remedies like those requested below – divestiture, rescission, disgorgement, restitution – must produce clear proof of both harm and causation. *See Ford Motor Co. v. United States*, 405 U.S. 562, 573, 577 (1972) (divestiture inappropriate unless necessary to re-establish competitive constraints to remedy continuing harm caused by the violation); *United States v.*

requisite anticompetitive effect. . . . [Even i]n a case brought by the government, it must demonstrate the monopolist's conduct harmed competition." *Microsoft*, 253 F.3d at 58-59 (notwithstanding defendant's undisputed 95% market share and high entry barriers, government had to prove actual anticompetitive effects from various contracts and exclusionary practices directed at suppressing a nascent technology threat) (internal citation omitted); *see also Rambus*, 522 F.3d at 463-64 (dismissing FTC's complaint for failure to prove prices would have been lower absent the allegedly illegal conduct, even assuming the violation occurred and that it made the harm "somewhat more likely").[71]

E. I. du Pont de Nemours & Co., 366 U.S. 316, 326 (1961); *Concord Boat*, 207 F.3d at 1055-57 (plaintiffs must offer a reasoned analysis of competitive baseline prices to infer ill-gotten profits from supra-competitive prices); *Rambus*, 522 F.3d at 461-62; *Microsoft*, 253 F.3d at 79-80, 103, 105; *SEC v. First City Fin. Corp.*, 890 F.2d 1215, 1231 (D.C. Cir. 1989) (disgorgement requires government to "distinguish between legally and illegally obtained profits").

[71] The D.C. Circuit's decision in *Rambus* is instructive. The FTC alleged Rambus achieved a monopoly by deceiving the standard-setting body into adopting technology that infringed its patents, after which Rambus demanded royalty payments. 522 F.3d at 460-61. The FTC could not prove that the standard-setting organization would have excluded Rambus's patents from the standard assuming full disclosure. *Id.* at 463-64. Without a viable mechanism to drive price competition, the FTC failed to show Rambus's alleged violation actually caused higher prices. That was fatal to the FTC's liability claims. *Id.* at 466.

Appellants bear the same burden to prove competitive harm under Section 7 of the Clayton Act (15 U.S.C. § 18). Courts will not presume harm from high market shares where, as here: (1) there are no "significant" barriers to entry at the time of the acquisition, *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 983-84, 987 (D.C. Cir. 1990); *United States v. Syufy Enters.*, 903 F.2d 659, 664 (9th Cir. 1990);[72] or (2) there is direct, post-acquisition evidence of consumer demand and market conditions to assess whether the acquisition eliminated a meaningful competitive constraint. *See Gen. Dynamics*, 415 U.S. at 501-04; *Evanston*, F.T.C. Docket No. 9315 at 73 (Aug. 6, 2007) (consummated merger analysis is "a retrospective inquiry based on empirical evidence" of competitive effects); *see also id*. at 2 (Rosch, concurring). In either of these situations, "the burden of producing additional evidence of anticompetitive effects shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Baker Hughes*, 908 F.2d at 983. Both factors apply here.

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[72] The district court found that, at the time of the NeoProfen acquisition, Lundbeck and Bedford believed generic indomethacin would easily and quickly enter the market and devastate Indocin's sales. (*See* FF.64-65, 77.)

B. Appellants Do Not Challenge Lundbeck's Initial Setting of Drug Prices.

Appellants "proclaimed" Lundbeck could lawfully price Indocin at whatever the market would bear (App.1720-21 (Pls.' Closing Arguments); *see also* App.1386 (Pls.' Opening Statement); App.1638 (Arnold)), and do not challenge the district court's finding that Lundbeck decided to re-price Indocin at $1,500 independent of and without regard to the NeoProfen acquisition. (FF.58.) Thus, Indocin's January 2006 price of $1,500 was lawful, and Appellants made no effort to prove otherwise. *See Evanston*, F.T.C. Docket No. 9315 at 26-27, 64 (Aug. 6, 2007) (post-merger price increases do not reflect competitive harm, absent proof of lower but-for prices using robust economic analysis and economic evidence that accounts for all contributing "competitively-benign factors"); *see also Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) ("The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system."); MERGER GUIDELINES § 2.1.1; AREEDA & HOVENKAMP, ANTITRUST LAW § 720a (3d ed. 2007) ("Monopoly pricing and monopoly profits are neither an 'exclusionary' act nor an 'abuse' of monopoly power under §2.").

Appellants also accept the district court's finding that an independent owner of NeoProfen would not have disregarded Indocin's $1,500 price when choosing NeoProfen's launch price. (FF.63.) At trial, Appellants' economist admitted that NeoProfen would launch around Indocin's price. (App.1600-01.) Lundbeck's economist reached a similar conclusion. (App.1688 ("[A]cute care drugs come in at a higher premium . . . ."), 1686-87 (NeoProfen likely to launch at a larger premium if it shows even "modest therapeutic gain," which is consistent with beliefs of Abbott and loyal NeoProfen consumers that NeoProfen is a safer and superior drug).)

C. Appellants Did Not Prove a Monopoly Maintenance Claim.

Appellants' failure to challenge Lundbeck's initial pricing of Indocin and NeoProfen reduces their case to a single, monopoly-maintenance theory of harm: they had to prove that Lundbeck could not have maintained an initially lawful $1,500 Indocin price in the but-for world. (App.1636-39 (Arnold).)

Appellants offered only one untested theory to show the NeoProfen acquisition *caused* allegedly supracompetitive prices. Their economist speculated that, absent the acquisition, Lundbeck would have made the first move and discounted Indocin by $50 to slow attrition to NeoProfen, at which point it would be "Game On." (App.1596 (Arnold).) Appellants

offer no glimpse of what the rest of the "Game" would look like, except that the drugs would trade discounts before settling at some unknown competitive equilibrium price below $1,450. (App.1596 (Arnold).) This "Game On" theory is speculative and contrary to a wealth of uncontested evidence and factual findings, making it no better than the generalized theory of causation rejected in *Rambus*. 522 F.3d at 463-64; *cf. Concord Boat*, 207 F.3d at 1055; *Evanston*, F.T.C. Docket No. 9315 at 26-27, 64 (Aug. 6, 2007) (FTC used expert analysis and real-world evidence to show a material loss in negotiating leverage with real price effects, even after accounting for all "competitively benign factors").

Three evidentiary flaws destroy the "Game On" theory and, thus, Appellants' monopoly maintenance claim. First, "Game On" causation is premised on high cross-price elasticity of demand. But Appellants' economist offered no opinion about cross-elasticity and ignored all direct consumer testimony, market analyses and pricing analyses. (FF.114.)[73] The court's conclusion of "very low" cross-elasticity is well-supported and uncontested. (FF.115-16.)[74]

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[73] *See supra*, 65-67.

[74] *See supra*, § I.E; 65.

Second, there is no basis for the predicate assumption that Lundbeck would initiate a price war, because there is no evidence that engaging in a price war with NeoProfen would shift the views of enough doctors to make such a move profitable. The evidence was overwhelmingly to the contrary.[75] Appellants' economist ignored all evidence relating to Lundbeck's profit margins or pricing analyses. (App.1615-18 (Arnold); *see also* FF.114.)

Finally, the "Game On" theory illogically assumes that Lundbeck would discount to protect Indocin's sales from a clinically differentiated drug like NeoProfen, even though it was already committed to holding or raising Indocin's price in the face of a perfect substitute, generic indomethacin.[76] Stated differently, to support their causation theory, Appellants must show that Lundbeck had a more compelling economic incentive to price compete with NeoProfen than it had to price compete with generic indomethacin. *See In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 310-11 (E.D. Mich. 2001) ("[G]enerics are freely substitutable and . . . perfect substitutes for their brand name drug . . . . [T]he pharmaceutical market is fundamentally different from the market for other products.").

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75 *See supra*, §§ I.C, I.D.

76 *See supra*, 9-11.

Appellants made no effort to prove this thesis. (App.1614-15, 1633-35 (Arnold).)

Appellants failed to prove the existence of a causal mechanism to trigger meaningful price competition between the drugs under separate ownership. This failure of proof is fatal to their case, independent of the court's market definition determination.

CONCLUSION

For the foregoing reasons, Lundbeck respectfully requests that the Court affirm the judgment below.

Respectfully submitted,

February 16, 2011

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Federal Rule of Appellate Procedure 32(a)(7)(B). It is proportionally spaced and contains 20,787 words, as counted by the Microsoft Word word processing program. We further certify that the electronic versions of the brief and its addendum have been scanned for viruses and are virus free.

February 16, 2011

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IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

FEDERAL TRADE COMMISSION AND STATE OF MINNESOTA,	)	
Appellants,	)	No. 10-3458 and No. 10-3459 (Consolidated)
v.	)	
LUNDBECK INC.,	)	
Appellee.	)	

CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2011, I electronically filed the **BRIEF FOR DEFENDANT-APPELLEE LUNDBECK INC.** with the Clerk of the Court for the United States Court 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 CM/ECF system. I further certify that some of the participants in the case are not CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid, or have dispatched it to a third-party commercial carrier for delivery within 3 calendar days, to the following non-CM/ECF participants:

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