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Eisai Inc v. Sanofi Aventis U.S. LLC

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PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 14-2017

EISAI, INC.,
Appellant

v.

SANOFI AVENTIS U.S., LLC;
SANOFI U.S. SERVICES, INC. f/k/a
Sanofi-Aventis U.S. Inc.

On Appeal from the United States District Court
for the District of New Jersey
(D. C. Civil Action No. 3-08-cv-04168)
District Judge: Honorable Mary L. Cooper

Argued on January 13, 2015

Before: AMBRO, FUENTES and ROTH, Circuit Judges

(Opinion filed: May 4, 2016)

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OPINION

ROTH, Circuit Judge:

The antitrust laws are concerned with “the protection of competition, not competitors.”¹ Eisai complains that the conduct of Sanofi Aventis U.S., LLC, and Sanofi U.S. Services, Inc., (Sanofi) jointly and severally harmed competition in the market for anticoagulant drugs by preventing hospitals from replacing Lovenox, one of Sanofi’s drugs, with competing drugs. The facts, however, do not bear out Eisai’s characterization of market events. For the reasons stated below, we conclude that what Eisai calls “payoffs”

¹ *Brown Shoe Co v. United States*, 370 U.S. 294, 320 (1962).

were, in reality, discounts offered by Sanofi to its customers; what Eisai calls “agreements with hospitals to block access” were, in reality, provisions proscribing customers from favoring competing drugs over Lovenox; what Eisai calls “a campaign of ‘fear, uncertainty, and doubt’” was, in reality, Sanofi’s marketing of Lovenox. Analyzing Eisai’s claims under the rule of reason, we find no evidence that Sanofi’s actions caused broad harm to the competitive nature of the anticoagulant market. To the extent that Sanofi’s conduct caused damage to its competitors, that is not a harm for which Congress has prescribed a remedy. We will therefore affirm the order of the District Court, granting summary judgment in favor of Sanofi.

I.

A.

Lovenox is an anticoagulant drug used in the treatment and prevention of deep vein thrombosis (DVT), a condition in which blood clots develop in a person’s veins. Lovenox belongs to a category of injectable, anticoagulant drugs known as low molecular weight heparin (LMWH). Lovenox was the first LMWH approved by the Food and Drug Administration and has been sold by Sanofi in the United States since 1993. Lovenox has at least seven FDA-approved uses (known as indications), including the treatment of certain severe forms of heart attack.

Fragmin is a competing injectable LMWH, which Pfizer, Inc., initially sold only abroad. In September 2005, Pfizer sold Eisai an exclusive license to market, sell, and distribute Fragmin in the United States. Fragmin has five

FDA-approved indications, some of which overlap Lovenox's indications. Fragmin is also indicated to reduce the reoccurrence of symptomatic venous thromboembolism in cancer patients, while Lovenox is not. Lovenox, however, is indicated for treating certain more severe forms of heart attack, an indication that Fragmin does not have.

The relevant product market also consists of two other injectable anticoagulant drugs, Innohep and Arixtra. Innohep, a LMWH, was manufactured and sold by LEO Pharma Inc. in the United States from 2000 to 2011. Arixtra is an injectable anticoagulant approved by the FDA in 2001 and sold in the United States by GlaxoSmithKline from 2005 to 2010. While not a LMWH, Arixtra is clinically comparable to LMWHs in its treatment of DVT.

Relevant to Eisai's claims is the market for Lovenox, Fragmin, Innohep, and Arixtra in the United States from September 27, 2005 (when Eisai was able to begin selling Fragmin) until July 25, 2010 (when Sanofi ended certain marketing practices after a generic entered the market). During that time, Lovenox had the most indications of the four drugs, the largest sales force, and maintained a market share of 81.5% to 92.3%. Fragmin had the second largest market share at 4.3% to 8.2%.

B.

Eisai's antitrust claims relate to Sanofi's marketing of Lovenox to U.S. hospitals. Most hospitals are members of group purchasing organizations (GPOs), which negotiate drug contracts and discounts from pharmaceutical companies on behalf of their members. From September 2005 until July 2010, Sanofi offered GPOs the "Lovenox Acute Contract Value Program" (Program), featuring a contractual offer to sell Lovenox on certain terms and conditions. Eisai's allegations of anticompetitive conduct relate to three elements of this program: (1) market-share and volume discounts, (2) a restrictive formulary access clause, and (3) aggressive sales tactics used to market the program.

(1) Under the terms of the Program, hospitals received price discounts based on the volume of Lovenox they purchased and their market-share calculation tied to their purchases of the four anticoagulant drugs.² The Program generally treated a GPO's members as individual customers when determining the volume and market share. When a hospital's purchases of Lovenox were below 75% of its total purchases of LMWHs, it received a flat 1% discount regardless of the volume of Lovenox purchased. But when a hospital increased its market share above that threshold, it would receive an increasingly higher discount based on a combination of the volume purchased and the market share. For example, in 2008, the discount ranged from 9% to 30% of the wholesale price. Additionally, if certain criteria were met,

² Specifically, the market share was defined as the rolling four months of Lovenox units purchased by the hospital divided by the rolling four months of all units purchased within the market for Lovenox, Fragmin, Arixtra, and Innohep.

a multi-hospital system could have the hospitals' volumes and market shares calculated as one entity. For a multi-hospital system, the discount started at 15% for a market share meeting the threshold, and increased to 30%.

Although this discount structure motivated GPOs to purchase more Lovenox, they were not contractually obligated to do so. The consequence of not obtaining 75% market share was that a customer would receive only the 1% discount. If a customer chose to terminate the contract, it was required to give thirty days' notice and could still purchase Lovenox "off contract" at the wholesale price.

(2) The Program also included a formulary access clause that limited a hospital's ability to give certain drugs priority status on its formulary. Generally, a hospital maintains a formulary, a list of medications approved for use in the hospital based on factors such as a drug's cost, safety, and efficacy. The formulary access clause in the Lovenox contract required customers to provide Lovenox with unrestricted formulary access for all FDA-approved Lovenox indications so that the availability of Lovenox was not more restricted or limited than the availability of Fragmin, Innohep, or Arixtra. Hospitals were also forbidden by the contract to adopt any restrictions or limitations on marketing or promotional programs for Lovenox. In essence, the contract did not prohibit members from putting other anticoagulant drugs on their formularies, but did prohibit them from favoring those drugs over Lovenox. Noncompliance with the contract did not limit a customer's access to Lovenox; it merely caused a customer's discount to drop to the 1% base level.

(3) According to Eisai, Sanofi further engaged in a long-term campaign to discredit Fragmin by spreading “fear, uncertainty and doubt” about its safety and efficacy. Eisai asserts that the so-called “FUD” campaign consisted of the following conduct: Sanofi paid doctors to publish articles attacking Fragmin on false grounds, without properly disclosing such payments, and distributed those articles broadly; Sanofi paid doctors to present educational programs regarding the medical and legal risks of switching from Lovenox, casting doubt on Fragmin’s effectiveness and promoting a belief that Fragmin use would expose hospitals to malpractice liability; Sanofi’s representatives claimed that Lovenox was superior to other drugs, in violation of FDA regulations; and Sanofi promoted Lovenox for non-indicated cancer-related uses, also in violation of FDA regulations.

C.

Eisai commenced this action on August 18, 2008, in the U.S. District Court for the District of New Jersey, asserting (1) willful and unlawful monopolization and attempted monopolization in violation of Section 2 of the Sherman Act;³ (2) *de facto* exclusive dealing in violation of Section 3 of the Clayton Act;⁴ (3) an unreasonable restraint of trade in violation of Section 1 of the Sherman Act;⁵ and (4) violations of the New Jersey Antitrust Act.⁶ Sanofi moved to dismiss the complaint for failure to state a claim and for being untimely under the applicable statute of limitations. After a

³ 15 U.S.C. § 2.

⁴ 15 U.S.C. § 14.

⁵ 15 U.S.C. § 1.

⁶ N.J. Stat. Ann. §§ 56:9-3 and 56:9-4.

hearing, the District Court denied the motion and referred the case to a magistrate judge for further proceedings.

The parties then engaged in extensive discovery. On one particularly contentious discovery issue, Eisai moved to compel discovery of deposition transcripts from a 2003 antitrust lawsuit brought by Organon Sanofi-Synthelabo (OSS) against Aventis Pharmaceuticals (Sanofi's predecessor) relating to a contractual offer similar to the terms of the Lovenox Program. On February 27, 2012, the Magistrate Judge denied Eisai's motion on the basis that the 2003 transcripts were irrelevant to the current action and unlikely to lead to the discovery of admissible evidence, and because the burden or expense of the discovery outweighed its likely benefit. The District Court affirmed the order.

Both parties subsequently moved for summary judgment. Eisai relied largely on an expert report by Professor Einer Elhauge, who determined that customers occupying a certain spectrum of market share would not save money by partially switching to a rival drug, even if the rival drug was cheaper than Lovenox. According to Professor Elhauge, the Lovenox Program restricted rival sales by bundling each customer's contestable demand for Lovenox (the units that the customer is willing to switch to rival products) with the customer's incontestable demand for Lovenox (the units that the customer is less willing to switch to rival products). The incontestable demand for Lovenox was based, at least partially, on its unique cardiology indication, which no other anticoagulant in the market possessed and which hospitals needed to treat certain of their patients. Based on Lovenox's and Fragmin's April 2007 prices, Professor Elhauge determined that bundling resulted

in an enormous “dead zone” spanning Fragmin’s market share: For any system choosing to increase its Fragmin market share from 10% to any amount less than 62%, it would actually cost hospitals more to switch from Lovenox to Fragmin despite Fragmin’s lower price. Professor Elhaug also determined that the Program foreclosed between 68% and 84% of the relevant market.

On March 28, 2014, the District Court granted Sanofi’s motion for summary judgment. The District Court held first that price was the predominant mechanism of exclusion under Sanofi’s practices, and therefore Eisai’s antitrust claims could not succeed because Sanofi’s prices were above cost. Next, the court held that, even when analyzed under an exclusive dealing framework, Eisai’s claims still failed because the evidence could not support Eisai’s contention that Sanofi engaged in unlawful exclusive dealing. Eisai also could not satisfy the antitrust-injury requirement because it could not establish that its lower market share was attributable to anticompetitive conduct by Sanofi as opposed to other factors.

II.

The District Court had jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1337. We have appellate jurisdiction under 28 U.S.C. § 1291.

We employ “a *de novo* standard of review to grants of summary judgment, ‘applying the same standard as the

District Court.”⁷ We “view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion.”⁸ A court “shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”⁹ We review discovery decisions for abuse of discretion.¹⁰

III.

A.

The applicable law is the same for each of Eisai’s four claims.¹¹ To establish an actionable antitrust violation, Eisai must show both that Sanofi engaged in anticompetitive conduct and that Eisai suffered antitrust injury as a result.¹²

⁷ *Montone v. City of Jersey City*, 709 F.3d 181, 189 (3d Cir. 2013) (quoting *Pa. Coal Ass’n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995)).

⁸ *Id.* (internal quotation marks omitted).

⁹ Fed. R. Civ. P. 56(a).

¹⁰ *Country Floors, Inc. v. P’ship Composed of Gepner & Ford*, 930 F.2d 1056, 1062 (3d Cir. 1991).

¹¹ See *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9, 281 (3d Cir. 2012) (analyzing claims under Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act); *State v. N.J. Trade Waste Ass’n*, 472 A.2d 1050, 1056 (N.J. 1984) (“[T]he New Jersey Antitrust Act shall be construed in harmony with ruling judicial interpretations of comparable federal antitrust statutes.”).

¹² See *Atl. Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 339-40 (1990); *ZF Meritor*, 696 F.3d at 269 n.9.

Courts employ either a *per se* or a rule of reason analysis to determine whether conduct is anticompetitive.¹³ The “*per se* illegality rule applies when a business practice ‘on its face, has no purpose except stifling competition.’”¹⁴ When conduct does not trigger a *per se* analysis, we apply a rule of reason test, which focuses on the “particular facts disclosed by the record.”¹⁵

One form of potentially anticompetitive conduct is an exclusive dealing arrangement, which is an express or *de facto* “agreement in which a buyer agrees to purchase certain goods or services only from a particular seller for a certain period of time.”¹⁶ While exclusive dealing arrangements may deprive competitors of a market for their goods, they can also offer consumers various economic benefits, such as assuring them the availability of supply and price stability.¹⁷ As such, an exclusive dealing arrangement does not constitute a *per se*

¹³ *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 99 (3d Cir. 2010).

¹⁴ *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011) (quoting *Eichorn v. AT&T Corp.*, 248 F.3d 131, 143 (3d Cir. 2001)); see, e.g., *N. Pac. R.R. Co. v. United States*, 356 U.S. 1, 5 (1958) (“Among the practices which the courts have heretofore deemed to be unlawful in and of themselves are price fixing, division of markets, group boycotts, and tying arrangements.” (internal citations omitted)).

¹⁵ *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 467 (1992).

¹⁶ *ZF Meritor*, 696 F.3d at 270; see *LePage’s Inc. v. 3M*, 324 F.3d 141, 157 (3d Cir. 2003) (en banc).

¹⁷ See *ZF Meritor*, 696 F.3d at 270-71.

violation of the antitrust laws and is instead judged under the rule of reason.¹⁸

Eisai argues that Sanofi's conduct, as a whole, operated as a *de facto* exclusive dealing arrangement that unlawfully hindered competition. An exclusive dealing agreement is illegal under the rule of reason "only if the 'probable effect' of the arrangement is to substantially lessen competition, rather than merely disadvantage rivals."¹⁹ While there is no set formula for making this determination, we must consider whether a plaintiff has shown substantial foreclosure of the market for the relevant product.²⁰ We also analyze the likely or actual anticompetitive effects of the exclusive dealing arrangement, including whether there was reduced output, increased price, or reduced quality in goods or services.²¹

¹⁸ *See id.* at 271.

¹⁹ *See id.* (quoting *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 329 (1961)); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005).

²⁰ *See ZF Meritor*, 696 F.3d at 271.

²¹ *See id.*; *W. Penn Allegheny Health Sys.*, 627 F.3d at 100; *see also Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 264 (2d Cir. 2001).

1.

To demonstrate substantial foreclosure, a plaintiff “must both define the relevant market and prove the degree of foreclosure.”²² Although “[t]he test is not total foreclosure,” the challenged practices must “bar a substantial number of rivals or severely restrict the market’s ambit.”²³ “There is no fixed percentage at which foreclosure becomes ‘substantial’ and courts have varied widely in the degree of foreclosure they consider unlawful.”²⁴ In analyzing the amount of foreclosure, our concern is not about which products a consumer chooses to purchase, but about which products are reasonably available to that consumer.²⁵ For example, if customers are free to switch to a different product in the marketplace but choose not to do so, competition has not been thwarted—even if a competitor remains unable to increase its market share.²⁶ One competitor’s inability to compete does not automatically mean competition has been foreclosed.

In certain circumstances, however, we have recognized that a monopolist “may use its power to break the competitive

²² *United States v. Microsoft Corp.*, 253 F.3d 34, 69 (D.C. Cir. 2001) (en banc) (per curiam).

²³ *Dentsply, Int’l, Inc.*, 399 F.3d at 191.

²⁴ *ZF Meritor*, 696 F.3d at 327 (Greenberg, J., dissenting); see *McWane, Inc. v. FTC*, 783 F.3d 814, 837 (11th Cir. 2015).

²⁵ See *S.E. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 616 (8th Cir. 2011).

²⁶ See, e.g., *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 997 (9th Cir. 2010); *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1059 (8th Cir. 2000).

mechanism and deprive customers of the ability to make a meaningful choice.”²⁷ That was the case in *LePage’s Inc. v. 3M*, where we held that the use of bundled rebates, when offered by a monopolist, foreclosed portions of the market to competitors that did not offer an equally diverse line of products.²⁸ Similarly, in *United States v. Dentsply International, Inc.*, we held that a dominant manufacturer of prefabricated teeth hindered competition when it prohibited dealers from adding competing tooth lines to their product offerings and retained the ability to terminate the dealer relationships at will.²⁹ Finally, in *ZF Meritor*, we found the defendant’s conduct to be anticompetitive when the defendant leveraged its position as a dominant supplier of necessary products to force manufacturers into long term agreements and there was proof that the manufacturers were concerned that they would be unable to meet consumer demand without doing so.³⁰ Although consumers had a choice between products in *LePage’s*, *Dentsply*, and *ZF Meritor*, in each case the defendant’s anticompetitive conduct rendered that choice meaningless.

Eisai argues that Sanofi’s practices substantially foreclosed the market for anticoagulant drugs because hospitals had no choice but to purchase Lovenox despite its increasing price. In support, Eisai points to what it characterizes as “extensive evidence” of hospitals that wanted to purchase Fragmin but allegedly were prevented from doing so due to Sanofi’s conduct. But identification of a few dozen

²⁷ *ZF Meritor*, 696 F.3d at 285.

²⁸ *See* 324 F.3d at 154-58.

²⁹ *See* 399 F.3d at 185.

³⁰ *See* 696 F.3d at 285.

hospitals out of almost 6,000 in the United States is not enough to demonstrate “substantial foreclosure”³¹ – particularly, if the reason a hospital did not change to Fragmin was due to price, *i.e.*, the loss of the discounts offered by the Program.

Eisai also relies on the findings of Professor Elhauge, who described two purported examples of “foreclosure.” First, Professor Elhauge claims that the discount offered by Sanofi foreclosed rivals from 68% to 84% of the LMWH market. Professor Elhauge calculated this percentage by “treat[ing] as restricted any customer that was receiving loyal Lovenox prices and thus would have been penalized with higher Lovenox prices if they purchased a higher percentage of their LTC drugs from rivals.” In other words, Professor Elhauge assumed that all Lovenox customers utilizing the discount program were foreclosed from switching to another LMWH drug. Second, Professor Elhauge asserts that the Lovenox discount created a “dead zone” that prevented customers from increasing their Fragmin purchases to anywhere between 10% and 62% of their LMWH needs. Again, Professor Elhauge focuses on consumer preference as the basis for foreclosure. Specifically, he calculates this “dead zone” based on the fact that “many customers are

³¹ See *McWane, Inc.*, 783 F.3d at 837 (“Traditionally, a foreclosure percentage of at least 40% has been a threshold for liability in exclusive dealing cases.” (citing Jonathan M. Jacobson, *Exclusive Dealing, “Foreclosure,” and Consumer Harm*, 70 *Antitrust L.J.* 311, 362 (2002)); *but see id.* (“However, some courts have found that a lesser degree of foreclosure is required when the defendant is a monopolist.” (citing *Microsoft*, 253 F.3d at 70)).

willing to switch only a portion of their Lovenox purchases to rival LTC drugs.”

Professor Elhauge’s examples of foreclosure ultimately derive from a theory of bundling of Lovenox demand. But a bundling arrangement generally involves discounted rebates or prices for the purchase of multiple products.³² For example, in *LePage’s*, the plaintiffs alleged that 3M, a dominant seller of transparent tape in the United States, used its monopoly to gain a competitive advantage in the private label tape portion of the transparent market by offering a “multi-tiered ‘bundled rebate’ structure, which offered higher rebates when customers purchased products in

³² See, e.g., *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 894 (9th Cir. 2008) (“Bundling is the practice of offering, for a single price, two or more goods or services that could be sold separately.”); *Virgin Atl. Airways Ltd.*, 257 F.3d at 270 (“[A] bundling arrangement offers discounted prices or rebates for the purchase of multiple products, although the buyer is under no obligation to purchase more than one item.”); *Concord Boat*, 207 F.3d at 1062 (“[B]undling or tying . . . ‘cannot exist unless two separate product markets have been linked.’” (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 21 (1984))); see also *LePage’s*, 324 F.3d at 155 (“‘In the anticompetitive case [of package discounting], . . . the defendant rewards the customer for buying its product *B* rather than plaintiff’s *B*, not because defendant’s *B* is better or cheaper. Rather, the customer buys the defendant’s *B* in order to receive a greater discount on *A*, which the plaintiff does not produce.’” (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 794, at 83 (Supp. 2002))).

a number of 3M's different product lines.”³³ Analogizing this practice to tying, which is *per se* illegal, we found such bundling anticompetitive because it could “foreclose portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer.”³⁴ In *ZF Meritor*, we limited the reasoning in *LePage's* “to cases in which a single-product producer is excluded through a bundled rebate program offered by a producer of multiple products, which conditions the rebates on purchases across multiple different product lines.”³⁵ Significantly, Eisai does not claim that

³³ 324 F.3d at 145.

³⁴ *See id.* at 155. “Tying” is “an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier.” *Eastman Kodak*, 504 U.S. at 461-62 (internal quotations omitted); *see Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 80 (3d Cir. 2011).

³⁵ 696 F.3d at 274 n.11. While *LePage's* remains the law of this Circuit, it has been the subject of much criticism. *See, e.g., Cascade Health Solutions*, 515 F.3d at 899-903 (“Given the endemic nature of bundled discounts in many spheres of normal economic activity, we decline to endorse the Third Circuit’s definition of when bundled discounts constitute the exclusionary conduct proscribed by § 2 of the Sherman Act.”); *LePage's*, 324 F.3d at 179 (Greenberg, J., dissenting) (arguing that the majority’s opinion “risks curtailing price competition and a method of pricing beneficial to customers because the bundled rebates effectively lowered [the seller’s] costs”); Antitrust Modernization Comm’n, Report and Recommendations 94, 97 (2007), *available at*

Sanofi conditioned discounts on purchases across various product lines, but on different types of demand for the same product. Such conduct does not present the same antitrust concerns as in *LePage's*, and we are aware of no court that has credited this novel theory.

We are not inclined to extend the rationale of *LePage's* based on the facts presented here. Even if bundling of different types of demand for the same product could, in the abstract, foreclose competition, nothing in the record indicates that an equally efficient competitor was unable to compete with Sanofi. Professor Elhauge defines incontestable demand as the “units that the customer is less willing to switch to rival products” because of “unique indications, departmental preferences, and doctor habit.” Of course, obtaining an FDA indication requires investing a significant amount of time and resources in clinical trials. But Eisai does not offer evidence demonstrating that fixed costs were so high that competitors entering the market were unable to obtain a cardiology indication. In fact, Eisai has its own unique cancer indication, which it presumably obtained because of its calculated decision to focus on that area, above others. Nor does Eisai explain what percentage of incontestable demand for Lovenox was based on its unique cardiology indication as opposed to the other factors. While

http://govinfo.library.unt.edu/amc/report_recommendation/amc_final_report.pdf (“The lack of clear standards regarding bundling, as reflected in *LePage's v. 3M*, may discourage conduct that is procompetitive or competitively neutral and thus may actually harm consumer welfare.”); *see also* *FTC v. Church & Dwight Co., Inc.*, 665 F.3d 1312, 1316-17 (D.C. Cir. 2011) (collecting academic criticisms of *LePage's*).

Professor Elhauge certainly explains why, in theory, a customer might hesitate to switch from Lovenox to one of its lower priced competitors, Eisai fails to tie Professor Elhauge's model to concrete examples of anticompetitive consequences in the record. Accordingly, we cannot credit Eisai's bundling claims, at least on the facts before us.³⁶

Eisai's reliance on our holdings in *ZF Meritor* and *Dentsply* is also misplaced. As a preliminary matter, although Eisai cites extensively to these cases for the proposition that Lovenox customers lacked any meaningful ability to switch products, its supposed evidence of foreclosure is grounded in Professor Elhauge's unsupported bundling theory. Moreover, Sanofi's conduct is distinguishable from the anticompetitive practices at issue in *ZF Meritor* and *Dentsply*. In *ZF Meritor*, the plaintiff "introduced evidence that compliance with the market penetration targets was mandatory because failing to meet such targets would jeopardize the [customers'] relationships with the dominant manufacturer of transmissions in the market."³⁷ If customers did not comply with the targets for one year, they had to repay all contractual savings.³⁸ We observed that the situation was similar to *Dentsply*, where we applied an exclusive dealing analysis because "the defendant threatened to refuse to continue dealing with customers if customers purchased rival's

³⁶ *Accord Virgin Atl. Airways Ltd.*, 257 F.3d at 264 ("Although [the expert's] affidavit purports to be useful in interpreting market facts affecting this litigation, expert testimony rooted in hypothetical assumptions cannot substitute for actual market data.").

³⁷ 696 F.3d at 278.

³⁸ *Id.* at 265.

products.”³⁹ The threat to cut off supply ultimately provided customers with no choice but to continue purchasing from the defendants.

Here, Lovenox customers did not risk penalties or supply shortages for terminating the Lovenox Program or violating its terms. The consequence of not obtaining the 75% market share threshold or meeting the formulary requirements was not contract termination; rather, it was receiving the base 1% discount. If a customer chose to terminate the contract entirely, it could still obtain Lovenox at the wholesale price. In fact, nothing in the record demonstrates that a hospital’s supply of Lovenox would be jeopardized in any way or that discounts already paid would have to be refunded. Attempting to draw a comparison with *ZF Meritor*, Eisai argues that the threat of not obtaining a higher discount (ranging up to 30% off) “handcuffed” hospitals to the Lovenox Program. Yet, Eisai points to no evidence of this. Moreover, the threat of a lost discount is a far cry from the anticompetitive conduct at issue in *ZF Meritor* or *Dentsply*. On the record before us, Eisai has failed to point to evidence suggesting the kind of clear-cut harm to competition that was present in these earlier cases. Accordingly, Eisai fails to demonstrate that hospitals were foreclosed from purchasing competing drugs as a result of Sanofi’s conduct.

2.

Eisai also cannot demonstrate that Sanofi’s conduct, as a whole, caused or was likely to cause anticompetitive effects in the relevant market. Eisai claims that the District Court

³⁹ *Id.* at 278 (citing *Dentsply*, 399 F.3d at 189-96).

ignored “proof” of reduction of output, denial of consumer choice, and increasing price. As to output, Eisai relies on two pages of Professor Elhauge’s description of the annual growth rate in the anticoagulant market as more than doubling after generic entry. Because there was a large reduction in promotional spending that year, Professor Elhauge concluded that Sanofi *must* have previously been reducing output. Such an assumption cannot serve as a substitute for actual evidence at the summary judgment stage. Moreover, Eisai fails to identify any record evidence in support of its argument that Sanofi’s conduct restricted consumer choice, instead presumably relying on its theory of foreclosure.

Eisai’s sole example of actual or likely anticompetitive effect is that Lovenox’s price increased from 2005 until a generic entered the market in 2010. According to Eisai, the rising price is particularly significant considering Sanofi’s long-term monopoly in the market and therefore provides ample basis for us to find a likelihood of anticompetitive effect. Specifically, Sanofi had as high as a 92% share of the market and Lovenox’s price was the highest in the market. For example, in 2009, the average price per converted unit of Lovenox was \$162.72 compared to \$140.28 for Fragmin. While these figures certainly suggest that Lovenox’s prices were high, we have no reason to believe that Sanofi’s allegedly anticompetitive conduct was the cause. In fact, Sanofi’s list prices increased at a rate similar to Eisai’s prices and the Pharmaceutical Producer Price Index. As a result, we find little evidence to suggest that Sanofi’s practices caused or were likely to cause anticompetitive effects.

Without evidence of substantial foreclosure or anticompetitive effects, Eisai has failed to demonstrate that

the probable effect of Sanofi's conduct was to substantially lessen competition in the relevant market, rather than to merely disadvantage rivals.⁴⁰ Unlike in *LePage's, Dentsply*,

⁴⁰ See *ZF Meritor*, 696 F.3d at 281; see also *Tampa Elec.*, 365 U.S. at 328-29. Eisai's allegations regarding the so-called "FUD" campaign are more properly analyzed under the law of deceptive marketing. While false or deceptive statements may violate the antitrust laws in "rare[]" circumstances, see *W. Penn Allegheny Health Sys.*, 627 F.3d at 109 n.14; see also *Santana Prods., Inv. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 132 (3d Cir. 2005), at minimum, a plaintiff must show that such statements induced or were likely to induce reasonable reliance by consumers, see, e.g., *Nat'l Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs., Div. of/and Am. Home Prods. Corp.*, 850 F.2d 904, 916-17 (2d Cir. 1988); *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997). The District Court held that Eisai failed to put forth evidence demonstrating reliance and Eisai does not explicitly challenge this finding. Eisai's brief, in passing, provides only a handful of examples of hospitals that decided not to switch to Fragmin after their representatives attended meetings presented by Sanofi or its consultants. But, even if these examples were enough to demonstrate reliance, Eisai has given us no reason to believe that it could not have corrected Sanofi's misstatements by supplying the hospitals with accurate information. See *Santana Prods., Inv.*, 401 F.3d at 133 (holding that a defendant did not violate Section 1 of the Sherman Act by criticizing a competitor's partitions, in part, when the plaintiff "remain[ed] free to tout its products to the [customers] and remain[ed] equally free to reassure them that its partitions are superior to [defendant's] partitions and to

and *ZF Meritor*, Lovenox customers had the ability to switch to competing products. They simply chose not to do so. We will therefore affirm the District Court’s grant of summary judgment in favor of Sanofi under a rule of reason analysis.

B.

Turning to Safofi’s argument that its discounts amounted to no more than price-based competition and Eisai’s suit must be dismissed under the so-called price-cost test, we disagree. We are not persuaded that Eisai’s claims fundamentally relate to pricing practices.

Unlawful predatory pricing occurs when a firm reduces its prices to below-cost levels to drive competitors out of the market and, once competition is eliminated, reduces output and raises its prices to supracompetitive levels.⁴¹ Reducing prices to only above-cost levels, however, generally does not have an anticompetitive effect because “the exclusionary effect of prices above a relevant measure of cost . . . reflects the lower cost structure of the alleged predator, and so represents competition on the merits.”⁴² While there may be situations where above-cost prices are anticompetitive, it “is beyond the practical ability of a judicial

prove [defendant] wrong with respect to the flammability of [its] partitions”).

⁴¹ See *Weyerhaeuser v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 318 (2007); *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222-24 (1993); see also *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 584-85 (1986).

⁴² *Brooke Grp.*, 509 U.S. at 223.

tribunal” to ascertain this “without courting intolerable risks of chilling legitimate price-cutting.”⁴³ In light of this “economic reality,” a plaintiff can succeed on a predatory pricing claim only if it can show that (1) the rival’s low prices are below an appropriate measure of its costs and (2) the rival had a dangerous probability of recouping its investment in below-cost prices.⁴⁴ This is known as the price-cost test.

When a competitor complains that a rival’s sales program violates the antitrust laws, we must consider whether the conduct constitutes an exclusive dealing arrangement or simply a pricing practice. Defendants may argue that the challenged conduct is fundamentally an above-cost pricing scheme and therefore the price-cost test applies, ultimately dooming a plaintiff’s claims. But not all contractual practices involving above-cost prices are *per se* legal under the antitrust laws.⁴⁵ We previously explained in *ZF Meritor* that the price-cost test may be utilized as a “specific application of the ‘rule of reason’” only when “price is the clearly predominant mechanism of exclusion.”⁴⁶ There, the defendant urged us to apply the price-cost test because the plaintiff’s claims were, “at their core, no more than objections to . . . offering prices . . . through its rebate program.”⁴⁷ We declined to adopt this “unduly narrow characterization of the case as a ‘pricing practices’ case.”⁴⁸ We explained that price itself did not

⁴³ *Id.*

⁴⁴ *Weyerhaeuser*, 549 U.S. at 318; *see also Brooke Grp.*, 509 U.S. at 222-24.

⁴⁵ *ZF Meritor*, 696 F.3d at 278.

⁴⁶ *Id.* at 273, 275.

⁴⁷ *Id.* at 273.

⁴⁸ *Id.* at 269.

function as the exclusionary tool: “Where, as here, a dominant supplier enters into *de facto* exclusive dealing arrangements with every customer in the market, other firms may be driven out not because they cannot compete on a price basis, but because they are never given an opportunity to compete, despite their ability to offer products with significant customer demand.”⁴⁹

Under *ZF Meritor*, when pricing predominates over other means of exclusivity, the price-cost test applies. This is usually the case when a firm uses a single-product loyalty discount or rebate to compete with similar products.⁵⁰ In that situation, an equally efficient competitor can match the loyalty price and the firms can compete on the merits. More in-depth factual analysis is unnecessary because we know that “the balance always tips in favor of allowing above-cost pricing practices to stand.”⁵¹ As a result, we apply the price-cost test as an application of the rule of reason in those circumstances and conclude that the above-cost pricing at issue is *per se* legal. But our conclusion may be different under different factual circumstances. Here, for example,

⁴⁹ *Id.* at 281.

⁵⁰ See, e.g., *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 452 (6th Cir. 2007) (en banc); *Concord Boat Corp.*, 207 F.3d at 1061-63; *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 236 (1st Cir. 1983).

⁵¹ *ZF Meritor*, 696 F.3d at 273; see *Brooke Grp.*, 509 U.S. at 223; see also *ZF Meritor*, 696 F.3d at 275 (“[W]hen price is the clearly predominant mechanism of exclusion . . . so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects.”).

Eisai alleges that its rival, having obtained a unique FDA indication, offered a discount that bundled incontestable and contestable demand. On Eisai's telling, the bundling – not the price – served as the primary exclusionary tool. Because we have concluded that Eisai's claims are not substantiated and that they fail a rule of reason analysis, we will not opine on when, if ever, the price-cost test applies to this type of claim.

IV.

Eisai also argues that the District Court abused its discretion in holding that discovery of deposition transcripts from the OSS litigation was irrelevant and unduly burdensome. Assuming the transcripts were relevant, Eisai must still show that the order resulted in “actual and substantial prejudice.”⁵² Eisai cannot show prejudice when it appears to have engaged in ample discovery in this case: Sanofi claims that Eisai took over thirty depositions, received millions of pages of documents, and subpoenaed approximately 350 third parties. Eisai was free to elicit information regarding the OSS litigation during this extensive discovery process and—in fact—did so by deposing at least one witness from that litigation. We therefore conclude that the District Court did not abuse its discretion in denying Eisai's request for production of the 2003 OSS deposition transcripts.

V.

⁵² See *Cyberwold Enter. Tech., Inc. v. Napolitano*, 602 F.3d 189, 200 (3d Cir. 2010).

For the foregoing reasons, we will affirm the District Court's order, granting summary judgment in favor of Sanofi, and its order denying Eisai's motion to compel discovery of transcripts from a prior litigation.