

14-2017

IN THE
United States Court of Appeals
FOR THE THIRD CIRCUIT

——
EISAI INC.,

Plaintiff-Appellant,

v.

SANOFI-AVENTIS U.S. LLC and
SANOFI US SERVICES INC. (formerly known as sanofi-aventis U.S. Inc.),

Defendants-Appellees.

—
*On Appeal from the United States District Court
for the District of New Jersey*

REDACTED REPLY BRIEF FOR PLAINTIFF-APPELLANT

Jay N. Fastow
Counsel of Record
Denise Plunkett
Justin W. Lamson
BALLARD SPAHR LLP
425 Park Avenue
New York, New York 10022
212-223-0200

Timothy I. Duffy
Joseph Amoroso
COUGHLIN DUFFY, LLP
350 Mount Kemble Avenue
P.O. Box 1917
Morristown, New Jersey 07962-2075
973-267-0058

Thomas J. Cullen, Jr.
Kamil Ismail
James A. Frederick
Derek M. Stikeleather
GOODELL, DEVRIES, LEECH
& DANN, LLP
One South Street, 20th Floor
Baltimore, Maryland 21202
410-783-4000

Attorneys for Plaintiff-Appellant

TABLE OF CONTENTS

	PAGE
INTRODUCTION	1
ARGUMENT	7
I. SANOFI CANNOT REVISE THE STANDARDS FOR DECIDING THIS APPEAL	7
II. SANOFI CANNOT SUPPORT APPLICATION OF THE LOW PRICE EXCEPTION.....	11
III. SANOFI CANNOT AVOID THE ANTICOMPETITIVE EFFECTS OF ITS CONDUCT UNDER THE RULE OF REASON	21
IV. SANOFI CANNOT SHOW A LACK OF ANTITRUST INJURY.....	26
V. SANOFI CANNOT JUSTIFY WITHHOLDING THE OSS TRANSCRIPTS.....	29
CONCLUSION.....	30

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Advo, Inc. v. Philadelphia Newspapers, Inc.</i> , 51 F.3d 1191 (3d Cir. 1995)	4
<i>Barry Wright Corp. v. ITT Grinnell Corp.</i> , 724 F.2d 227 (1st Cir. 1983).....	13
<i>Berkey Photo, Inc. v. Eastman Kodak Co.</i> , 603 F.2d 263 (2d Cir. 1979)	26
<i>Big Apple BMW, Inc. v. BMW of N. Am., Inc.</i> , 974 F.2d 1358 (3d Cir. 1992)	10
<i>Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.</i> , 509 U.S. 209 (1993).....	passim
<i>Cascade Health Solutions v. PeaceHealth</i> , 515 F.3d 883 (9th Cir. 2008)	14
<i>Concord Boat Corp. v. Brunswick Corp.</i> , 207 F.3d 1039 (8th Cir. 2000)	13, 25
<i>Cont'l Ore Co. v. Union Carbide Corp.</i> , 370 U.S. 690 (1962).....	8
<i>Cont'l T.V., Inc. v. GTE Sylvania Inc.</i> , 433 U.S. 36 (1977).....	11, 20
<i>Conwood Co., L.P. v. U.S. Tobacco Co.</i> , 290 F.3d 768 (6th Cir. 2002)	21
<i>Eastman Kodak Co. v. Image Technical Servs., Inc.</i> , 504 U.S. 451 (1992).....	2, 3
<i>FTC v. Indiana Fed'n of Dentists</i> , 476 U.S. 447 (1986).....	22
<i>In re Flat Glass Antitrust Litig.</i> , 385 F.3d 350 (3d Cir. 2004)	9, 10

<i>InterVest, Inc. v. Bloomberg, L.P.</i> , 340 F.3d 144 (3d Cir. 2003)	10
<i>LePage’s, Inc. v. 3M Co.</i> , 324 F.3d 141 (3d Cir. 2002)	8, 28
<i>Matsushita Elec. Indus. Co. v. Zenith Radio Corp.</i> , 475 U.S. 574 (1986).....	9-10, 11
<i>N. Pac. Ry. Co. v. United States</i> , 356 U.S. 1 (1958).....	19
<i>NCAA v. Bd. of Regents of Univ. of Okla.</i> , 468 U.S. 85 (1984).....	12
<i>NicSand, Inc. v. 3M Co.</i> , 507 F.3d 442 (6th Cir. 2007)	13, 14
<i>Race Tires Am., Inc. v. Hoosier Racing Tire Corp.</i> , 614 F.3d 57 (3d Cir. 2010)	9, 10
<i>Santana Prods., Inc. v. Bobrick Washroom Equip., Inc.</i> , 401 F.3d 123 (3d Cir. 2005)	20
<i>Schachar v. Am. Acad. of Ophthalmology, Inc.</i> , 870 F.2d 397 (7th Cir. 1989)	20
<i>Se. Mo. Hosp. v. C.R. Bard, Inc.</i> , 642 F.3d 608 (8th Cir. 2011)	14
<i>Sterling Merchandising, Inc. v. Nestle, S.A.</i> , 656 F.3d 112 (1st Cir. 2011).....	27
<i>Tampa Elec. Co. v. Nashville Coal Co.</i> , 365 U.S. 320 (1961).....	14, 22, 23
<i>Trace X Chem., Inc. v. Canadian Indus., Ltd.</i> , 738 F.2d 261 (8th Cir. 1984)	25-26
<i>United States v. AMR Corp.</i> , 335 F.3d 1109 (10th Cir. 2003)	14

United States v. Dentsply Int’l, Inc.,
399 F.3d 181 (3d Cir. 2005)3, 22, 23, 24

Virgin Atl. Airways Ltd. v. British Airways Plc,
257 F.3d 256 (2d Cir. 2001)14

W. Penn Allegheny Health Sys., Inc. v. UPMC,
627 F.3d 85 (3d Cir. 2010)20

Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.,
549 U.S. 312 (2007)15

White Motor Co. v. United States,
372 U.S. 253 (1963).....11

Zenith Radio Corp. v. Hazeltine Research, Inc.,
395 U.S. 100 (1969).....27

ZF Meritor LLC v. Eaton Corp.,
696 F.3d 254 (3d Cir. 2012)passim

RULES

Fed. R. Civ. P. 56.....9, 10

INTRODUCTION

Unable to avoid the anticompetitive effects of its broad plan to both raise price and exclude competitors, sanofi fills its Brief with misstatements and fallacies.

Sanofi does not challenge key facts, which preclude summary judgment in its favor, including that:

- It persistently held monopoly power (82%-92% share) (Eisai Br. at 31, 52);
- [REDACTED]
[REDACTED], despite rival products that were interchangeable for most purposes (*id.* at 2, 12, 34-35);
- [REDACTED]
[REDACTED]
[REDACTED] (*id.* at 2, 17-30);
- Its payments to all or virtually all U.S. hospitals for near-total exclusivity did not benefit consumers, [REDACTED]
[REDACTED]
[REDACTED]
- Its Formulary Access Clauses blocked rivals from ever getting ahead of it on hospital formularies regardless of any competitive efforts they might make,

cementing sanofi's monopoly power [REDACTED]

[REDACTED] (*id.* at 4, 23-26, 51); and

- Its campaign of deception, which even its CEO could not countenance, falsely increased the perceived cost of rival products, [REDACTED]

[REDACTED] (*id.* at 4, 17, 26-30).

To all this consumer harm, sanofi can offer no procompetitive justification. *Id.* at 8, 49-50. Nor can sanofi dispel Eisai's extensive evidence of causal injury, including evidence of particular lost sales, multiple "yardsticks" showing further lost sales, and 68%-84% market foreclosure. *Id.* at 1-2, 9-10, 16-17, 32.

Sanofi instead creates an imaginary world. It says that the District Court assumed that sanofi had "market power," and that the matter therefore "is not relevant to Eisai's appeal." Sanofi Br. at 13 n.7. But, the District Court found that sanofi had "monopoly power," not the lesser standard of market power. A64; *see Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 481 (1992) ("Monopoly power under § 2 requires, of course, something greater than market power under § 1."). And, sanofi's monopoly power is very relevant to this appeal; it enabled sanofi to obtain [REDACTED] exclusionary agreements, and defeats its effort to hide behind asserted, substantially different conduct by a far smaller market participant. *See Sanofi Br.* at 12, 54. As the Supreme Court

explained in *Eastman Kodak*, 504 U.S. at 488: “Behavior that might otherwise not be of concern to the antitrust laws -- or that might even be viewed as procompetitive -- can take on exclusionary connotations when practiced by a monopolist.” *Accord United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) (“Behavior that otherwise might comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist.”).

In declaring that “Eisai offers no citations to record evidence” showing increased price, reduced output and loss of consumer choice (Sanofi Br. at 44), sanofi blithely ignores the many pages in Eisai’s Brief providing such citations. Eisai Br. at 2-5, 16-26, 31, 37, 45-49. And, in contending that Eisai caused its own losses by pricing Fragmin too high (Sanofi Br. at 10-11, 55-56), sanofi disregards that (1) [REDACTED], and (2) sanofi’s unlawful conduct prevented Eisai from significantly increasing Fragmin sales by further reducing its price -- by artificially raising the actual and perceived cost to hospitals of buying Fragmin, and by preventing Fragmin from topping hospitals’ formulary lists no matter how much Eisai reduced its price. Eisai Br. at 4-7, 16-26, 31, 45, 48.

Still trying to support its injury argument, sanofi repeats the erroneous refrain of the District Court that Eisai maintained an 85% profit margin (Sanofi Br. at 8) -- while simultaneously admitting that this figure related only to “incremental

cost” (*id.* at 9 n.3), and while sanofi’s own expert stated that Eisai suffered losses on Fragmin during 2006-2010. A2747 (Kelly Report Tbl. 6). Sanofi then cites *Advo, Inc. v. Philadelphia Newspapers, Inc.*, 51 F.3d 1191, 1198 (3d Cir. 1995), for the remarkable contention that the law requires Eisai to price at incremental cost (and thus eventually abandon its Fragmin business) in order to bring this case. *See* Sanofi Br. at 9. *Advo* does not discuss the issues of injury or pricing by plaintiff at all; it involved the pricing and costs of the *defendant*. 51 F.3d at 1198.

Sanofi also distorts the evidence. As examples:

- [REDACTED]

[REDACTED]

[REDACTED] Sanofi Br.

at 10. However, sanofi itself cites evidence that Lovenox’s actual price [REDACTED]

[REDACTED]

[REDACTED] (A3403; A3890-93; A3910-15).

And, while sanofi argues that the Pharmaceutical Producer Price Index [REDACTED]

[REDACTED] (Sanofi Br. at 10), reference to that industry-wide average does

nothing to diminish the anticompetitive effect of [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

- Sanofi states that Eisai's market share decreased over the two years after sanofi [REDACTED] and abandoned its Lovenox Contracts in 2010 (Sanofi Br. at 13), but ignores that, as explained by sanofi's own expert, the generic entry that led to sanofi's changed conduct cut substantially into the share of all branded LTC drugs. [REDACTED] (A4021; A6505).

- Sanofi asserts that the market foreclosure opinions of Eisai's expert Professor Einer Elhauge are "legal conclusions" (Sanofi Br. at 5), when it knows that: he is a recognized, published authority on antitrust economics; he has been qualified as an expert in antitrust economics by five courts; and his opinions in this case involve economic analysis. A3861-62. Relatedly, shortly after contending that "Eisai failed to offer evidence of any foreclosure" (*id.* at 42), sanofi acknowledges that Eisai has adduced direct evidence of foreclosure. *Id.* at 42-43.

Sanofi also tries to argue by re-defining terms. In an effort at subliminal persuasion that would make any advertising agency smile, sanofi re-names its Lovenox contracts as "Lovenox Discount Contracts" (Sanofi Br. at 2), and repeats the phrase more than 40 times -- in the apparent hope that, if it intones the word "Discount" often enough, it will convince the Court that it applies [REDACTED]

[REDACTED] *Compare* A15 (District Court opinion referring to the "Lovenox® Program" or "Lovenox® contract"). Likewise, while not denying the falseness or illegality of what its business people called their "fear,

uncertainty, and doubt” campaign (*see, e.g.*, Eisai Br. at 26-30; A3425-26 (describing launch of “OPERATION DOCTOR FUD”)), sanofi now tries to re-brand it as mere “marketing conduct.” Sanofi Br. at 3-4, 28-35.

Nor is this the end of sanofi’s creativity: Seeking to wrap itself in a cloak of fairness, sanofi calls its Formulary Access Clauses “non-discrimination” provisions. Sanofi Br. at 3. To the contrary, they are highly discriminatory, ensuring that sanofi could never fall below the top rung of a hospital’s formulary while providing no such protection for any competitor. And they are dramatically anti-consumer, preventing lower prices by competitors from significantly reducing sanofi’s monopoly share [REDACTED] Eisai Br. at 23-24; A3399-400 ¶54; A3910-12; A3943-44 n.228; A4135-52.

Despite its own forensic lexicography, sanofi complains about Eisai’s use of the word “payoffs.” Sanofi Br. at 24-25. That is an accurate term, since sanofi paid hospitals for exclusivity -- for not buying rival products -- regardless of whether they bought more Lovenox. Eisai Br. at 3-8, 17-19. Eisai’s Brief explained the exclusionary workings of this scheme in several numerical examples. *Id.* at 6-8, 17-21. Sanofi does not mention these illustrations, much less dispute them. *See, e.g., id.* at 7 (to benefit from buying the less expensive Fragmin, a hospital would have to switch at least 62% of its LTC drug purchases to Fragmin at

once because of the “dead zone” created by sanofi’s scheme; such large-scale switching was unlikely due to certain “incontestable demand” for Lovenox).

Nevertheless, Eisai’s appeal does not depend on that terminology. As the Supreme Court has stated (Eisai Br. at 39-40), the scope of an exception to the presumptive Rule of Reason depends not on word choice but on the economic substance of defendant’s conduct -- here, whether sanofi’s conduct is, as in *Brooke Group*, so inherently pro-consumer that the case should be dismissed without a full Rule of Reason inquiry. Sanofi’s actions cannot meet that test.

ARGUMENT

I. SANOFI CANNOT REVISE THE STANDARDS FOR DECIDING THIS APPEAL

Sanofi’s Brief does not identify any decision holding in its favor based on facts like those here. It therefore relies on snippets and dicta, and flouts fundamental standards of analysis, as described below:

1. While the *ZF Meritor* decision limits the safe harbor to cases in which lowering price was the “clearly predominant mechanism of exclusion” (*ZF Meritor LLC v. Eaton Corp.*, 696 F.3d 254, 277 (3d Cir. 2012)), sanofi repeatedly tries to invert that test, claiming that the safe harbor “question is whether non-price mechanisms are the predominant mechanisms of alleged exclusion. . . .” Sanofi Br. at 22; *accord id.* at 21, 35. Sanofi cannot transform this narrow exception into the general rule, especially since low price was the sole

exclusionary conduct in the Supreme Court safe harbor cases involving sellers' conduct. *See* Eisai Br. at 41-42.

2. Sanofi asks the Court to follow the decision below and consider each aspect of its anticompetitive activities in isolation, indeed discussing its deception campaign as if it were the subject of a separate case. Sanofi Br. at 4, 28-36. However, as explained in Eisai's Brief at 47, the challenged conduct must be viewed as a whole, which is how it affected the market. *Cont'l Ore Co. v. Union Carbide Corp.*, 370 U.S. 690, 699 (1962) (anticompetitive conduct must be viewed "as a whole"); *LePage's, Inc. v. 3M Co.*, 324 F.3d 141, 162 (3d Cir. 2002) ("The relevant inquiry is the anticompetitive effect of [the defendant's] exclusionary practices considered together."). Even the dissent in *ZF Meritor* recognized that "the question . . . is whether Eaton's rebate program and conduct as a whole was procompetitive or anticompetitive." *See ZF Meritor*, 696 F.3d at 320 (Greenberg, J., dissenting).

Sanofi tries to avoid this principle by asserting that the *ZF Meritor* majority discussed only provisions of defendant's agreements (*see* Sanofi Br. at 28-29). But that decision nowhere limits the analysis to contractual terms where, as here, defendant also engaged in extensive exclusionary conduct beyond its contracts. To the contrary, the *ZF Meritor* decision recognized that additional tortious conduct may be involved. 696 F.3d at 278-79 ("The law has long

recognized forms of exclusionary conduct that do not involve below-cost pricing, including . . . other unfair tortious conduct targeting competitors” (citations and quotations omitted)). Sanofi thus cannot avoid *ZF Meritor* through the ironic argument that its anticompetitive behavior was more extensive than the conduct held unlawful there.

3. Sanofi attempts to rewrite the rules for summary judgment. Seeking to continue errors in the District Court opinion (*see* Eisai Br. at 34-36, 46-51), sanofi repeatedly asks this Court to find facts in its favor despite Eisai’s contrary evidence. As just one example, sanofi asserts that “the undisputed facts demonstrate that Eisai had every opportunity to compete for customers’ business” (Sanofi Br. at 25), simply disregarding the extensive evidence showing the opposite, [REDACTED]

[REDACTED] *See* Eisai Br. at 20, 24-25, 31, 50-51.

Sanofi also asks this Court to amend Rule 56 to apply a “heightened threshold” for summary judgment here. Sanofi Br. at 15 (quoting *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 73 (3d Cir. 2010) (quoting *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 (3d Cir. 2004))). Both the Supreme Court and this Court have rejected that position, applying the conventional summary judgment standard in antitrust cases. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585 (1986) (applying in antitrust case

conventional summary judgment standard under Rule 56 (c) & (e)); *InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159 (3d Cir. 2003) (“Generally, the movant’s burden on a summary judgment motion in an antitrust case ‘is no different than in any other case.’” (quoting *Big Apple BMW, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1363 (3d Cir. 1992) (“A non-movant’s burden in defending against summary judgment in an antitrust case is no different than in any other case.”))))).

Sanofi cannot use *Race Tires* to escape from this principle. Indeed, the language *Race Tires* quoted is part of a paragraph in *Flat Glass* that begins by observing that “normal summary judgment principles apply in antitrust cases” *Flat Glass*, 385 F.3d at 357; Sanofi Br. at 15. The court’s subsequent reference to a “higher threshold” was in a different context -- noting that substantive antitrust law limits the inferences that may be drawn from circumstantial evidence to find a price fixing conspiracy, an issue with no application here. *Flat Glass*, 385 F.3d at 357 (quoting *Matsushita*, 475 U.S. at 588). Moreover, sanofi’s claim that antitrust plaintiffs must overcome a higher summary judgment threshold “to avoid deterring innocent conduct that reflects enhanced, rather than restrained, competition” (Sanofi Br. at 15, quoting *Race Tires*) assumes the conclusion that sanofi’s conduct enhanced competition, a conclusion belied by the proof here [REDACTED], reduced output compared to the but-for world, and impaired consumer choice -- evidence that prevents sanofi from meeting even the erroneous

standard it proposes. *Compare Matsushita*, 475 U.S. at 594-97 (addressing issue of inferring a conspiracy to charge *below cost* prices).

II. SANOFI CANNOT SUPPORT APPLICATION OF THE LOW PRICE EXCEPTION

Eisai's Brief explained that the low price safe harbor is based on the conclusion by the Supreme Court that lower prices will always or virtually always benefit consumers. Eisai Br. at 40-41. The sole exclusionary conduct at issue in those Supreme Court decisions challenging sellers' conduct was "low prices." *See id.* at 41-42. Indeed, *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 231 (1993), and *Matsushita*, 475 U.S. at 584, both involved claims of below-cost pricing.

As with other exceptions to the Rule of Reason, this safe harbor should be limited to conform to its consumer protection rationale. *See* Eisai Br. at 39-40. It should be based on the economic effect of the challenged conduct, not "formalistic line drawing." *Id.*; *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58 (1977) ("[D]eparture from the rule-of-reason standard must be based upon demonstrable economic effect rather than . . . formalistic line drawing."). And, it should be applied only when the courts have sufficient experience with the conduct at issue that they can be "certain" it is inherently procompetitive. *See White Motor Co. v. United States*, 372 U.S. 253, 263 (1963) (refusing to apply per se exception to particular conduct because the Court did not know enough to be "certain" of

their economic effect); *accord NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 100 n.21 (1984) (“[J]udicial inexperience with a particular arrangement counsels against extending the reach of per se rules.”).

Sanofi does not contest these concepts. It does try to create a diversionary issue of terminology, insisting that the safe harbor is not called the low price exception, but the “price/cost test.” Sanofi Br. at 20. Whatever label a court may have used, the applicable Supreme Court cases challenging sellers’ conduct all involve low and lowered prices (Eisai Br. at 41) -- [REDACTED]

[REDACTED] *See id.* at 44-46. And, as set forth in *Brooke Group*, the court embarks on a “price/cost test” (comparing defendant’s prices to its costs) *after* it has decided to apply the safe harbor. *See* 509 U.S. at 221-22.¹

Here, the monopolist sanofi engaged in a broad scheme that included payments in return for near-total exclusivity, extensive market share monitoring and enforcement, protection against relegation on hospitals’ formularies regardless of competitive merit, and a campaign of concededly false and illegal statements directed against rival products. These actions created barriers to competition,

¹ Sanofi also argues that *ZF Meritor* called the safe harbor an “application” of the Rule of Reason. Sanofi Br. at 20. The court there was not distinguishing between “application” and “exception,” and the safe harbor is an exception to the presumptive rule because (like the per se exception) its implementation replaces normal Rule of Reason analysis.

artificially raised the actual and perceived costs of rival products, and allowed sanofi to [REDACTED]

[REDACTED]. The nature and effect of this conduct have nothing to do with the facts or rationale of the Supreme Court's safe harbor decisions.

Sanofi's focus on dicta in *ZF Meritor* does not change this result. Sanofi Br. at 2, 19. Reading its selective quotations the way sanofi would have it, the defendant would have won. It did not. Nor could the *ZF Meritor* court "join" sister circuits (*id.*) in doing something none of them has done -- expand the low price exception beyond situations in which plaintiff was simply challenging "pricing practices," i.e., asserting predatory pricing claims. As discussed in Eisai's Brief at 44 n.5, in *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1058-60, 1062-63 (8th Cir. 2000), and *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 235-38 (1st Cir. 1983), cited by the District Court, the courts applied a "price-cost test" where plaintiffs challenged only defendants' low prices, and otherwise applied the Rule of Reason. In *NicSand, Inc. v. 3M Co.*, 507 F.3d 442 (6th Cir. 2007), the court engaged in an extensive Rule of Reason examination of the "realities of this market" (*id.* at 452-55), and recognized that "exclusive agreements in some instances may create impermissible barriers for new entrants

to a market.” *Id.* at 454 (citing *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961)).²

A review of the facts discussed in the *ZF Meritor* decision shows that sanofi’s conduct is even less appropriate for safe harbor treatment than was the conduct held illegal there. In both situations:

- Defendant long held monopoly power, including certain “incontestable demand” (*compare* the performance transmissions in *ZF Meritor with, e.g.*, sanofi’s unique cardiology indication and deception campaign);³

² Sanofi’s additional cites (Sanofi Br. at 19-20) are equally distinguishable. *See Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608 (8th Cir. 2011) (holding for defendant because plaintiff failed to identify a relevant market; nowhere does the majority analyze defendant’s pricing practices); *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008) (plaintiff’s only claim was that it had been excluded by defendant’s bundled discounts (which, in any event, addressed only 9%-15% of the market)); *United States v. AMR Corp.*, 335 F.3d 1109, 1113 (10th Cir. 2003) (“the anticompetitive conduct at issue is predatory pricing”); *Virgin Atl. Airways Ltd. v. British Airways Plc*, 257 F.3d 256, 267 (2d Cir. 2001) (applying *Brooke Group* where plaintiff claimed harm from predatory pricing, and noting that defendant had no market power and that plaintiff was excluded from a small portion of the market, if at all).

³ While sanofi quarrels about the amount of the portion of the incontestable demand here that resulted from the unique cardiology indication (*compare* Sanofi Br. at 49 *with* A3880 (Elhauge Report)), it cannot contest either (1) that it expanded the scope of the incontestable demand through, e.g., its orchestrated plan of disparagement, or (2) that it abused the aggregate incontestable demand to harm competition. *See* Eisai Br. at 7, 16, 19-20; A4231 [REDACTED]

- defendant did not offer unilateral price reductions, but used its monopoly power to obtain agreements from all or virtually all the customers in the market providing it with near-total exclusivity (*see Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 322 (2007) (Supreme Court safe harbor cases involve “*unilateral pricing measures*”) (emphasis added));
- defendant’s agreements contained provisions directly limiting consumer access to rival products (*compare* the data book restrictions in *ZF Meritor with sanofi’s Formulary Access Clauses*); and
- defendant’s agreements imposed restraints on the sale of rival products (*compare, e.g.*, the artificial price penalties on plaintiffs’ products imposed by defendant in *ZF Meritor with sanofi’s market share requirements, formulary access restrictions, and commercial disparagement*).

Beyond these similarities, the facts in this case render the low price exception *a fortiori* inapplicable here:

- While the court in *ZF Meritor* found that the defendant offered lower prices on average than did plaintiffs (696 F.3d at 266), [REDACTED] [REDACTED] (A3404, A3436-37, A6292);

[REDACTED]

- while the defendant in *ZF Meritor* offered its customers protection against price increases (696 F.3d at 288), [REDACTED] [REDACTED] (A3404, A3436-37, A6292, A3910-15);
- sanofi embarked on a pre-meditated and broad-based campaign of deceptive and illegal conduct to falsely raise the perceived cost of buying rival products (*see generally* A3424-34); and
- [REDACTED] [REDACTED] (*see* A3398, A3907-08, A3910-11, A4103, A6293-94).

Sanofi nevertheless claims that *ZF Meritor* is inapplicable because it assertedly was based on threats of termination. Sanofi Br. at 27. But, that opinion referenced no threats of termination. It did discuss the concern of customers as to whether they would be paid for exclusivity (*see ZF Meritor*, 696 F.3d at 282-83) -- the same concern sanofi's roving national account managers impressed on hospitals here. Eisai Br. at 25.

Sanofi also gets nowhere through quibbling [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See A3907; A3892; A3925-46.⁴

Sanofi also imagines that its payments to hospitals were designed to increase Lovenox sales and not decrease rival sales, and resulted in savings. Sanofi Br. at 24-25. The real world was very different. Unlike the defendant in *Brooke Group*, sanofi was not a company with (at most) a 12% market share trying to increase its sales by offering volume discounts. 509 U.S. at 213, 220. It was a monopolist that [REDACTED] by imposing huge market share requirements for payments to hospitals for not buying rival products --

⁴ Sanofi presents a chart purporting to compare [REDACTED] Lovenox's and Fragmin's "list" prices to that of the Pharmaceutical Producer Price Index ("PPPI"). Sanofi Br. at 10. The PPPI reflects an overall industry average; it offers no insight into the dynamics of the particular market relevant here. [REDACTED]

[REDACTED] isai Br. at 10 (citing A4771-72), 30.

regardless of whether they bought any more Lovenox. Sanofi does not deny that the Lovenox volume thresholds in its Lovenox Contracts were irrelevant unless a hospital gave sanofi at least a 75% market share. Eisai Br. at 18-19. Nor does it deny that, when Eisai invigorated Fragmin's marketing (*id.* at 30), sanofi quickly initiated its Systems Agreements, which contained no volume thresholds at all but only market share requirements. *Id.* at 3-4, 6, 20-21; *cf.* Sanofi Br. at 12 n.6 ([REDACTED]). In its Brief at 6-8 and 17-21, Eisai discussed the exclusionary operation of sanofi's market share requirements. Sanofi does not contest those explanations.

Likewise, sanofi is unable to cite evidence that its payments to hospitals were contractually required to be, or were in fact, passed along to consumers (the focus of the Supreme Court's safe harbor rationale), rather than kept by the hospitals as payments for exclusivity. Sanofi's failure is not surprising, since it structured those payments -- making them subject to retroactive cancellation -- in a way that inhibited pass along to consumers. *See* A4121-22, A4124.

Undeterred, sanofi argues that competition is not limited to price, but can include quality. Sanofi Br. at 21. But, non-low price conduct is not sheltered by the low price safe harbor. And sanofi concedes that the LTC products were generally interchangeable (*id.* at 49), [REDACTED]

[REDACTED] See Eisai Br. at 29; A3392-93.

Sanofi also fails in its effort to apply *Brooke Group* to its Formulary Access Clauses. Far from sanofi's confused assertion (Sanofi Br. at 26-27), these provisions do not become "low price" under *Brooke Group* because breach would deny hospitals money. And, far from benefitting consumers, by protecting sanofi from ever falling from the top of a hospital's formulary regardless of price cuts by rivals, these clauses limited the ability of rivals to take sales from sanofi, [REDACTED] [REDACTED]. A3943-46; Eisai Br. at 23. As a sanofi executive explained, [REDACTED] [REDACTED] Eisai Br. at 24 (citing A4164-65; A4806-10); cf. *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 12 (1958) (provisions allowing defendant to control sales by matching rivals' prices denied "competitors access to the fenced-off market on the same terms as the defendant").

Sanofi likewise cannot transform its "marketing conduct" into low price. Sanofi does not deny that its FUD tactics [REDACTED] were deceptive, illegal and designed to exclude rivals by falsely increasing the perceived cost of buying their products. See, e.g., A4659-62, A4666-67 [REDACTED] [REDACTED] [REDACTED]

Apparently recognizing that this conduct has no place under *Brooke Group*, sanofi tries to isolate it from the rest of its plan, and to argue that deception can rarely violate the antitrust laws. Sanofi Br. at 28-32. Sanofi's separation gambit is barred by *Continental Ore, et al.*, and sanofi's view of the antitrust treatment of false statements arises (at most) only when disparagement is the sole challenged conduct. As this Court explained in *West Penn Allegheny Health System, Inc. v. UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010): "false statements about a rival, without more, rarely interferes with competition enough to violate the antitrust laws. But in some cases, such defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts." *Accord ZF Meritor*, 696 F.3d at 279 (forms of exclusionary conduct include "unfair tortious conduct targeting competitors") (citations and quotations omitted).⁵

Sanofi also contends that Eisai has failed to adduce evidence that competition suffered because hospitals relied on sanofi's deceptive and illegal statements. Sanofi Br. at 31-32. Not only does sanofi ignore the record evidence

⁵ See Sanofi Br. at 29-30, 35, citing *Santana Prods., Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 132 (3d Cir. 2005) (plaintiff's "claim is built on allegations that the defendants criticized the safety of HDPE partitions"); *Schachar v. Am. Acad. of Ophthalmology, Inc.*, 870 F.2d 397, 398 (7th Cir. 1989) ("All the [defendant] did is state as its position that radial keratotomy was 'experimental' and issue a press release with a call for research.").

(*see* Eisai Br. at 26-29), but it offers no possible purpose for this conduct besides causing hospitals to avoid rival products for false reasons. *See* Eisai Br. at 26, 49-50. Moreover, this is not a detrimental reliance claim brought simply against misrepresentations; injury to competition here is assessed in light of sanofi's conduct in its entirety, with its abundant anticompetitive effects. *See supra* at 7-8; *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 788 (6th Cir. 2002) (observing that the jury apparently found "that USTC's pervasive practice of destroying Conwood's racks and POS materials and reducing the number of Conwood facings through exclusive agreements with and misrepresentations to retailers was exclusionary conduct without a sufficient justification").

Sanofi cannot justify application of the low price exception at all, much less on summary judgment.

III. SANOFI CANNOT AVOID THE ANTICOMPETITIVE EFFECTS OF ITS CONDUCT UNDER THE RULE OF REASON

Sanofi's Rule of Reason discussion follows the District Court in disregarding the extensive evidence of injury to competition:

- The actual anticompetitive effects [REDACTED] [REDACTED] compared to the "but-for" world, and restricted consumer choice (Eisai Br. at 8, 31, 47-51, 55-57);
- the likely anticompetitive effects of persistent monopoly power [REDACTED] [REDACTED] (*id.* at 2, 31, 49, 52); and

- the conceded lack of any procompetitive justification (*id.* at 8, 19, 49-50).

This evidence establishes a violation of the Rule of Reason, as demonstrated by the Supreme Court decisions cited in Eisai's Brief at 48-49. *See, e.g., FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 459-461 (1986) (proof of detrimental effects on competition established violation of Rule of Reason).

Sanofi does not address those cases. It instead raises arguments that have been rejected time and again by this Court (and which routinely ignore sanofi's deceptive and illegal "marketing conduct"). *See* Eisai Br. at 52-56.

First, sanofi contends that its agreements were not 100% exclusive. Sanofi Br. at 38-39. Not only is this assertion meaningless in light of the established anticompetitive effects discussed above, but both *ZF Meritor* and *Dentsply* (a case sanofi never mentions) have rebuffed this position, since 100% foreclosure is not necessary to injure competition. Eisai Br. at 53; *ZF Meritor*, 696 F.3d at 270, 282, 289 (claim does not require a contract that covers 100% of the buyer's needs, only a "substantial share" of the market (citing *Tampa Electric*, 365 U.S. at 328-29)); *Dentsply*, 399 F.3d at 191 ("The test [for determining anticompetitive effect] is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." (internal citations omitted)).

Sanofi also contends that the effects of its agreements were mitigated because assertedly they contained a 30-day termination period and there was no threat of non-supply of Lovenox. Sanofi Br. at 39. Once again, sanofi cannot avoid the evidence of substantial anticompetitive effects. And, regardless of any theoretical possibilities, sanofi's monopoly power and exclusionary conduct resulted in no significant contract terminations; in "practical effect" (*Tampa Electric*, 365 U.S. at 326-27), its agreements were as ongoing as those in *ZF Meritor*. See Eisai Br. at 54-55. Indeed, in *Dentsply* this Court found an antitrust violation even though the exclusionary terms were provisions in purchase orders that were "essentially terminable at will," which customers theoretically could have avoided any time but did not because of Dentsply's economic power. *Dentsply*, 399 F.3d at 189 ("Although its rivals could theoretically convince a dealer to buy their products and drop Dentsply's line, that has not occurred.").

Sanofi also fails in its argument that there is no proof of foreclosure. Sanofi Br. at 41-52. Sanofi acknowledges the testimony by Professor Elhaug that sanofi's conduct foreclosed rivals from 68%-84% of the LTC market (*id.* at 45). Its proposed lines of cross examination (*id.* at 47-49) cannot annul this evidence on summary judgment. Nor is sanofi able to avoid the other evidence of foreclosure, including multiple yardsticks showing lost sales. See, e.g., Eisai Br. at 9-10, 32, 56-58; A4780-82 (Rosenblatt Report); A6137-38 (Economides Report). In any

event, the proof here remains in the pudding: neither the narrow window allowed to competitors, nor their small growth in share, [REDACTED]

[REDACTED] See *ZF Meritor*, 696 F.3d at 271 (“Consumer injury results from the delay that the dominant firm imposes on the smaller rival’s growth” (citation omitted)); *Dentsply*, 399 F.3d at 193 (“The minuscule 5% and 3% market shares eked out by . . . Dentsply’s ‘primary competitors’ . . . reveal that direct selling poses little threat to Dentsply.”).

Sanofi also gains nothing from claiming that Eisai could have increased its sales by reducing its price. Sanofi Br. at 10-11, 49-50, 55-56. [REDACTED]

[REDACTED] generally comparable product, offered additional discounts, and spent more in promotional support per unit than did sanofi [REDACTED]

[REDACTED] A1474. With these efforts, [REDACTED] [REDACTED] A2750 (Kelly Report, Tbl. 8). Contrary to sanofi’s contention (Sanofi Br. at 5), the law does not require Eisai to price so low that it must close its Fragmin business -- and thereby further entrench sanofi’s monopoly.

Moreover, sanofi ignores that its anticompetitive conduct prevented rivals from significantly increasing their sales through additional price cuts -- by

artificially increasing the actual and perceived cost to hospitals of buying rival products through sanofi's market share requirements and product disparagement, and by restricting rivals' sales regardless of any price reductions through its Formulary Access Clauses. *See ZF Meritor*, 696 F.3d at 281 (exclusive-dealing arrangements can exclude equally efficient rivals "because [those rivals] are never given the opportunity to compete").

Finally, sanofi seeks immunity on the grounds that its conduct assertedly constitutes "ordinary business practices." Sanofi Br. at 54. The issue under the Rule of Reason is not whether conduct is "ordinary," but whether, as here, it harms competition. *Eisai Br.* at 47-49. In any event, sanofi has failed to establish that its multiple exclusionary practices were "ordinary," and certainly cannot do so on summary judgment. This is, e.g., not a case involving 25% or 50% market share thresholds (*see Sanofi Br.* at 12), but 75%-90% requirements; not a case involving a single contractual term intended to increase the sale of defendant's products, but an array of exclusionary, deceptive and unlawful behavior designed to restrict the sale of rival products; and not a case involving a procompetitive justification, but the concession by sanofi that there is none. *See supra* at 22.⁶ And crucially, as discussed *supra* at 2-3, this is not a case involving

⁶ Compare sanofi's conduct here with that in: *Concord Boat*, 207 F.3d at 1062-63 (ordinary business practice referenced was to reduce prices); *Trace X Chem., Inc. v. Canadian Indus., Ltd.*, 738 F.2d 261, 267 (8th Cir. 1984) (ordinary practices

such action taken by an 8% or even 50% market participant defendant, but by a persistent monopolist, with all the extra-ordinary economic consequences of that monopoly power.

IV. SANOFI CANNOT SHOW A LACK OF ANTITRUST INJURY

Still disregarding much of the evidence, sanofi contends that Eisai suffered no antitrust injury as a matter of law. Sanofi is wrong; Eisai has adduced compelling proof of both injury to competition and causal injury to itself.

Eisai has demonstrated that, with a huge swathe of the market foreclosed to other products by sanofi's exclusionary conduct, [REDACTED] [REDACTED] A3889; A3907-08; A3911-13. [REDACTED] with hospitals restricted in purchasing additional quantities of rival products by Formulary Access Clauses, and with sanofi's deceptive and unlawful "marketing conduct" falsely increasing the perceived cost of competitive products, output was reduced compared to the level it would have reached and consumer choice was denied. A6288-89.

were refusals to extend credit to certain customers, and refusing, in good faith, to replace alleged defective product); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 291-92 (2d Cir. 1979) (ordinary practice was keeping innovations secret from rivals).

As to causal injury, sanofi first disregards the applicable law. In *Zenith Radio Corp. v. Hazeltine Research, Inc.*, the Supreme Court declared that an antitrust plaintiff's:

burden of proving the fact of damage under § 4 of the Clayton Act is satisfied by its proof of some damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage. It is enough that the illegality is shown to be a material cause of the injury. . . .

395 U.S. 100, 114 n.9 (1969) (internal citations omitted); *see ZF Meritor*, 696 F.3d at 289 (antitrust injury follows where a defendant's conduct unlawfully forecloses a substantial share of the market that otherwise would have been available for rivals).

Ignoring this authority, sanofi cites *Sterling Merchandising, Inc. v. Nestle, S.A.*, 656 F.3d 112 (1st Cir. 2011), to claim that the asserted fact that Eisai's "sales, profits, and market share have increased during the relevant period provides further indication that no antitrust injury exists here." Sanofi Br. at 53 (citing *Sterling*, 656 F.3d at 122-23). Not only is this argument fanciful [REDACTED]

[REDACTED]

[REDACTED] but

the court in *Sterling* held that plaintiff there had not shown an impairment of competition where, e.g., the exclusive arrangements covered only 30% of the market, prices had declined during the period at issue, and there was no evidence

of decreased output. Here, sanofi's conduct has harmed competition, and, but for that conduct, Eisai would have sold more Fragmin, potentially accrued greater cost economies of scale, and earned greater profits. *See* Eisai Br. at 31-32; *LePage's*, 324 F.3d at 165 (antitrust plaintiff may claim damages based on profitability it would have obtained but for defendant's conduct); *see also ZF Meritor*, 696 F.3d at 271 (foreclosure by a dominant firm may deprive rivals of the opportunity to achieve economies of scale).

Sanofi also fails in its attempt to negate Eisai's extensive evidence of causal injury. *See* Eisai Br. at 56-58. For example, sanofi admits that its disparagement persuaded [REDACTED], a "highly sophisticated customer," to reverse its decision to switch to Fragmin. Sanofi Br. at 33. Similarly, sanofi cannot deny that, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(A4395). *See* Eisai Br. at 25-26. And, while sanofi maintains that two hospitals "had Fragmin on formulary" (Sanofi Br. at 34 n.18), the placement of Eisai's product at some level of formulary at two hospitals sheds no light on whether Eisai would have made more sales and profits -- as to those hospitals and many others -- but for sanofi's misconduct.

Nor can sanofi avoid Eisai's expert testimony showing causal injury based on the facts of record, as discussed in depth in Eisai's Brief at 51, 55-58.

See also A6114-93 (Economides Report) ([REDACTED]); A3930-35 (Elhauge Report) ([REDACTED]); A4780, A4782 (Rosenblatt Report) ([REDACTED]).

Finally, sanofi repeats its contention that Eisai could have increased its sales by just reducing the price of Fragmin. Sanofi Br. at 54-55. Once again, sanofi disregards that [REDACTED] sanofi's misconduct operated to prevent rivals from significantly increasing their sales by further reducing their prices. Sanofi cannot use this argument, or any of its others, to support summary judgment in its favor under the Rule of Reason.

V. SANOFI CANNOT JUSTIFY WITHHOLDING THE OSS TRANSCRIPTS

Far from supporting its effort to withhold deposition transcripts from the OSS Case, sanofi undermines its position. Sanofi does not defend the notion that production of existing transcripts would be burdensome. *See* Dkt.127 at 17. It does contend that the transcripts are irrelevant (Sanofi Brief at 56-57), but then

concedes this argument away, when it notes that Eisai was able to take depositions on the same topics as the transcripts involve, without any motion by sanofi to bar those questions as irrelevant. Sanofi Br. at 57. Moreover, sanofi admits that the cases involve different products only “on the plaintiff’s side” (A221), and the sole contract difference sanofi cites is that the earlier Lovenox program involved one market share tier. A222. These “differences” cannot defeat the potential significance of information detailing the antitrust challenge to similar conduct by sanofi’s own predecessor.

CONCLUSION

The Court should grant Eisai the relief it has requested.

Dated: November 12, 2014

Respectfully submitted,

/s/ Jay N. Fastow

Jay N. Fastow
Denise Plunkett
Justin W. Lamson
BALLARD SPAHR LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 223-0200

Thomas J. Cullen, Jr.
Kamil Ismail
James A. Frederick
Derek M. Stikeleather
GOODELL, DEVRIES, LEECH
& DANN, LLP

One South Street, 20th Floor
Baltimore, MD 21202
Tel: (410) 783-4000 61

Timothy I. Duffy
Joseph Amoroso
COUGHLIN DUFFY, LLP
350 Mount Kemble Avenue
P.O. Box 1917
Morristown, NJ 07962-2075
Tel: (973) 267-0058

*Attorneys for Plaintiff-Appellant
Eisai Inc.*

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with Fed. R. App. P. 32(a)(7)(B). It contains 6,987 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). I certify under L.A.R. 31.1(c) that the text of the electronic brief is identical to the text in paper copies, and that a virus detection program (Symantec AntiVirus version 10.1.5.5000) has been run on the file and that no virus was detected.

I certify under L.A.R. 28.3(d) that at least one of the attorneys whose names appear on the brief, is a member of the bar of this court.

Dated: November 12, 2014

/s/ Jay N. Fastow

Jay N. Fastow

Attorneys for Plaintiff-Appellant

CERTIFICATE OF SERVICE

I certify under Fed. R. App. P. 25(d)(1)(B) that, on the date indicated below, I filed the foregoing brief with the Clerk using the CM/ECF system, which will send notification of such filing to counsel of record for Defendant-Appellees. I further certify that counsel for Defendant-Appellees are registered CM/ECF users.

Dated: November 12, 2014

/s/ Jay N. Fastow

Jay N. Fastow

Attorneys for Plaintiff-Appellant