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

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CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellant Eisai Inc. is a wholly-owned subsidiary of Eisai Corporation of North America, which is a wholly-owned subsidiary of Eisai Co., Ltd. Eisai Co., Ltd. is a publicly traded Japanese company, the stock of which trades on the Tokyo Stock Exchange and the Osaka Securities Exchange, and is listed in the United States under an American Depositary Receipt with the ticker symbol of ESALY.

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JURISDICTIONAL STATEMENT

A. The District Court had jurisdiction under 28 U.S.C. §§ 1331, 1337, and 15 U.S.C. §§ 15, 26, because this civil action arises under the antitrust laws of the United States.

B. This Court has jurisdiction under 28 U.S.C. § 1291 because this is an appeal from a final decision of the District Court.

C. On March 28, 2014, the District Court issued a Memorandum and Order granting defendants summary judgment (Joint Appendix at A8) (hereinafter "A__"), and entered Judgment in favor of defendants. A4. On April 23, 2014, plaintiff timely filed its notice of appeal. A1.

D. This is an appeal from a final order and judgment of the District Court that disposes of all parties' claims.

STATEMENT OF RELATED CASES

This case has not previously been before this Court, except:

The District Court granted sanofi's motion for certification of an interlocutory appeal of the court's August 10, 2010 decision denying sanofi's motion to dismiss or, in the alternative, for summary judgment. District Court Docket Nos. 75, 122, 132 (hereinafter "Dkt.__"); A214. This Court denied sanofi's request for interlocutory appeal. Order, *Eisai Inc. v. Sanofi Aventis, U.S.*, No. 10-8053 (3d Cir. Nov. 2, 2010), ECF No. 7.

To Eisai's knowledge, no other related cases or proceedings are completed, pending, or about to be presented before this Court or any other court or agency, state or federal, except:

After the District Court denied sanofi leave to file counterclaims against Eisai and a third-party complaint against certain of Eisai's employees (Dkts. 175, 180), sanofi filed a new case against those persons, *sanofi-aventis U.S., LLC v. Eisai Inc.*, SOM-C-12002-12 (N.J. Super. Ct., Ch. Div.), alleging contract and tort claims; and

In 2003, a sanofi corporate predecessor brought an antitrust case against another sanofi predecessor relating to the same sanofi product and similar conduct as are at issue here. *Organon Sanofi-Synthelabo, LLC v. Aventis Pharm., Inc., et al.*, No. 6:03 CU224-ORL-31DAB (M.D. Fla.) (complaint filed Feb. 25, 2003; voluntarily dismissed with prejudice August 25, 2004).

ISSUES PRESENTED FOR REVIEW

1. Whether the District Court erred as a matter of law in granting summary judgment to defendants sanofi-aventis US LLC and Sanofi US Services Inc. (collectively, "sanofi")?

   a. Whether the District Court erred in granting summary judgment to sanofi under the "low price" exception to the antitrust Rule of Reason? Raised: Dkt.311 at 3-19; Resolved: A67-77.

   b. Whether the District Court erred in granting summary judgment to sanofi under the court's "exclusive dealing" approach? Raised: Dkt.311 at 3-19; Resolved: A86-93.

   c. Whether the District Court erred in granting summary judgment to sanofi for lack of antitrust injury to Eisai? Raised: Dkt.311 at 24-27; Resolved: A81-84.

2. Whether the District Court erred in denying Eisai's pending motions as moot? Raised: Dkts. 261, 255, 257, 259, 291; Resolved: A4-7.

3. Whether the District Court abused its discretion in denying Eisai's request for production of deposition materials from a prior antitrust litigation between two of sanofi's predecessors relating to the same sanofi product and similar conduct as are at issue here? Raised: A218-24; Resolved: A223-24; A303-22; A323-29.

STATEMENT OF THE CASE

In the fall of 2005, defendant sanofi held a commanding position. Through its product Lovenox®, sanofi had monopoly power (with a 92% share) in the market for Lovenox Therapeutic Class ("LTC") drugs. A3887-88. The LTC market was huge, involving approximately [redacted] in annual sales in the United States at that time. A4797.

Sanofi also faced a challenge. Plaintiff Eisai was beginning its marketing of a branded competitive product called Fragmin®. Fragmin was, for most patients, at least clinically comparable to Lovenox, was priced significantly lower than Lovenox, and would be propelled by [redacted] the promotional spend per unit sold as Lovenox. A3390; A3893; A6345; A6106. The entry of relatively inexpensive, generic LTC products also was on the horizon. A3398; A4568-72; A2903; A4748.

How would sanofi respond?

Supreme Court precedent offered sanofi a lawful path, a "low price" antitrust safe harbor. Even as a monopolist, sanofi could have simply reduced its price -- to any level above cost -- to make Lovenox relatively more attractive to consumers. *See, e.g., Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993) (antitrust safe harbor for seller's "low prices"). But that

approach would have reduced sanofi's profit margin, at a time it was seeking to milk its monopoly.

Sanofi did not lower its price. [redacted]. A3404, 3436-37; A6292.

Sanofi did not stop there. Facing growing competition from quality, lower priced competitive products, [redacted]. *See* A4207. So sanofi entrenched its monopoly [redacted] by: (1) using its monopoly power and profits to obtain agreements from its hospital customers not to buy or use any significant amount of rival LTC products; and (2) deploying a campaign of deceptive and unlawful conduct to raise the perceived cost of competitive products. This plan worked, foreclosing sanofi's competitors from 68-84% of the LTC market. A3926-29. By drastically limiting the availability of those lower-priced alternatives, sanofi prevented them from imposing downward pressure on its prices for Lovenox, and allowed sanofi to hit the monopolist Perfecta -- [redacted] *and* excluding competition. *Compare United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) (monopoly power is ability "to control prices *or* exclude competition" (emphasis added)). During 2005-2010, sanofi made over [redacted]

in profits from Lovenox (A3438), while consistently maintaining its market share over 80%. A3887-88; A4805 (42:18).

Like the defendant held to have broken the antitrust laws in *ZF Meritor LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012), sanofi had monopoly power in the relevant market, and even stronger control over a segment of the market, in this case LTC drugs to be used for certain cardiology purposes. A957; *see ZF Meritor*, 696 F.3d at 277, 283. And, like the defendant in *ZF Meritor*, sanofi abused that power to prevent competition. *See ZF Meritor*, 696 F.3d at 286-89.

Sanofi entered into "Lovenox Contracts" and "Systems Agreements" governing all or virtually all of the hospitals and hospital systems in the United States (collectively, "hospitals"). A3397, 3409-10; A895. Under those contracts, sanofi used a portion of its monopoly profits to "pay-off" "loyal" customers, those that would buy 75-100% of their LTC drugs from sanofi. A898; *see ZF Meritor*, 696 F.3d at 286 (finding substantial foreclosure from agreements imposing market share requirements of at least 80%). Sanofi's agreements: [redacted] to both "disloyal" and "loyal" [redacted], even though Lovenox was

not approved by the FDA for this use. A4260; A957. During 2005-2010, sanofi spent over $1.4 billion on these payoffs, plus more in contract monitoring and enforcement expenses, to protect its monopoly pricing and profits. A3901-02, 3929-30.

Nor did sanofi even stop there. Further to safeguard its [redacted] profits, it:

(1) incorporated into its contracts "Formulary Access" clauses, under which all contracting hospitals agreed not to place any competitive product ahead of Lovenox on their formularies (list of approved drugs); A3399; A4136; A4342;

(2) engaged in a campaign of "fear, uncertainty, and doubt" ("FUD") to deceive hospitals and others into believing that the use of rival products -- especially Fragmin -- was less efficacious, unsafe and legally risky, and therefore more costly to use; A4327; A4611-13; and

(3) otherwise engaged in an array of deceptive and illegal conduct targeted at falsely discrediting other LTC products compared to Lovenox. A3422-34.

Sanofi's "access" agreements and product disparagement programs cannot possibly be argued to constitute "price," much less low price. Indeed, in applying the low price safe harbor in its summary judgment decision, the District Court offered no basis to consider them as such, except for the assertion that they may *affect* price (A72, 74) -- an approach that would include virtually all business conduct and extend that narrow exception to the Rule of Reason far beyond its limited scope and rationale.

Likewise, no matter how frequently it says the word "discount," sanofi cannot use its market share payoffs [redacted] that are the subject of the Supreme Court's safe harbor decisions. Contrary to the District Court's suggestion, this exception to the Rule of Reason is not invoked as a matter of semantics (A72), protecting everything that can possibly be called "price"; its application turns on economic substance, and only covers claims that defendant excluded competitors through prices that were "too low." *Brooke Group*, 509 U.S. at 222-23. In explaining its rationale for the low price exception, the Supreme Court has emphasized that it focuses on promoting consumer welfare -- a lower price benefits consumers by providing them a better choice. *Id*. at 223. A discount is designed to increase the seller's business by making its product relatively more attractive for consumers to select. It does not prohibit customers from obtaining supplies from competitors. It does not affect the cost of *competitors'* products. A3916.

Sanofi's conduct has nothing in common with this low price/consumer choice/consumer welfare paradigm. Sanofi harmed consumer welfare [redacted]. A6292. And, [redacted] by making payoffs to hospitals (1) not to buy less expensive competitive drugs, and (2) to deny consumers the ability freely to

choose such rival products, as well as by falsely discrediting those other products. In so doing, sanofi even contrived to raise the cost of competitive products.

Sanofi's anticompetitive plan of making payoffs to hospitals *for not purchasing rival products* is manifest in its agreements. Under its Lovenox Contracts, if a hospital bought $1,500,000 of Lovenox during a four month period in 2008, but also bought $501,000 of competitive products, it would receive no payoff from sanofi beyond the universal 1% sanofi paid under the contract. A15-17; A898; A1440-41. But, if the hospital bought a mere $1,000 worth of Lovenox during that four month period, it would receive an 18% payoff from sanofi on its next four months of purchases -- if it bought no rival products. A898; A1440-41. For hospitals making the same amount of purchases (e.g., $1,500,000), sanofi's payoffs would range from 1% to 30% depending only on how little the hospital bought of other LTC drugs. A898; A1440-41. Sanofi's Systems Agreements with hospital systems were even more explicit, omitting any reference to purchase volume altogether, and calculating payoffs solely on the extent to which the hospitals in the system refrained from buying rival products. A17; A898-99; A1443.

This payoff scheme operated to artificially raise the effective cost of buying rival products. For example, if a hospital system purchased 100 units of Lovenox in a four-month period, and bought no competitive products, it would

receive a sizeable payoff from sanofi on its purchases of Lovenox in the next four month period. *See, e.g.*, A1440-43; A4260-62. If instead, the system purchased the same 100 units of Lovenox, but also purchased 100 units of Fragmin, it would pay the same price for the Lovenox but would receive no such payoff from sanofi, thus dramatically increasing the effective cost of buying Fragmin. *See* A1440-43; A4260-62.

Nor could a hospital, much less an entire system, practicably avoid the artificial cost increase that sanofi imposed on Fragmin: sanofi's payoff scheme created an anticompetitive "dead zone," a range of purchases in which hospitals were coerced into buying Lovenox even though Eisai was charging significantly less for Fragmin. A3911-14. This dead zone entrenched sanofi's pre-existing monopoly, creating in practical effect an exclusive dealing arrangement, by preventing hospitals from gradually expanding their purchases of rival products. Unless a hospital switched from Lovenox to Fragmin for at least 62% of its LTC drug purchases overnight, it would actually lose money by moving to the less expensive Fragmin. *Id.* Such extensive and immediate switching was rarely practical, since most hospitals had to stock significant amounts of Lovenox to satisfy the "incontestable demand" arising out of, e.g., its unique cardiology indication, and resulting from sanofi's false and unlawful marketing tactics. A3874-80 (Elhauge Report discussing incontestable demand); A4327.

In contrast to a lower price, this market share payoff scheme had no basis in consumer welfare. Indeed, [redacted] A3400. This is not surprising since, even in sanofi's view, these contracts were purely an exercise of monopoly power designed to protect its [redacted]. While the defendant in *Brooke Group* offered the volume discounts at issue there even though it had no more than 12% of the market (*Brooke Group*, 509 U.S. at 209), [redacted] within days after generic entry broke its monopoly power [redacted]. A901; A3907-08; A3911-13. [redacted] A4103.

Protected by its anticompetitive conduct, sanofi both [redacted] and maintained its monopoly position from 2005 until the generic entry in 2010. Competitors' share increased, but very slowly. While the District Court found as fact that the small increase in competitors' market shares showed that sanofi's conduct had no harmful effect on their ability to compete (A68), the opposite is true; the increase in rivals' shares despite sanofi's exclusionary conduct demonstrates that the demand for their products was strong. This strength was supported by vigorous competitive efforts by Eisai, including: [redacted]

[redacted]; offering discounts, including special discounts for new and transitioning customers; devoting nearly three times the promotional spend per unit sold as sanofi; and using an experienced hospital sales force to promote Fragmin. A3893; A1418; A1413; A6106; A6345; A1000. Sanofi itself acknowledged that [redacted] A1474.

The District Court tried to downplay Eisai's competitive efforts by repeatedly stating that Eisai maintained an 85% "profit margin" on Fragmin. A70, 71, 80, 84. However, the 85% figure used by the court was calculated by including only the cost to Eisai of obtaining the physical product -- a small fraction of Eisai's total cost of licensing, marketing, selling and distributing Fragmin. A3890-91.

[redacted]

But for sanofi's illegal tactics, Fragmin would have done much better, and profitably achieved far more than the 8% market share it reached in 2010. *E.g.*, A6115-93 (Economides Report, *passim*). This conclusion is demonstrated by a number of yardsticks showing that, in circumstances in which it was unencumbered by sanofi's anticompetitive conduct, Fragmin obtained an LTC

market share ranging from [redacted] *See*, *e.g.*, A3930-35 (Elhauge Report); A4782 (Rosenblatt Report); *see also* A6137 (Economides Report).

Sanofi's hobbling of Eisai and its other competitors was intended to, and did, harm consumers. Unable to benefit freely from lower priced competitive offerings, both "loyal" and "disloyal" sanofi customers were forced to pay [redacted] for Lovenox, with sanofi retaining over 80% of all LTC drug purchases. Sanofi's contracts also effectively increased the cost of buying Fragmin and other rival products, and its deception campaign further increased the perceived cost of using such products.

By so foreclosing a huge portion of LTC sales from free competition, sanofi created a dysfunctional market -- [redacted] -- one that is highly atypical of maturing pharmaceutical markets, in which quality, [redacted] competitors regularly make substantial inroads and thereby provide consumer benefits. A4771-72. Indeed, a sanofi corporate predecessor (Organon Sanofi-Synthelabo "OSS") itself identified the harm to competition caused by such practices in an antitrust case it brought against another sanofi predecessor, challenging very similar market share payoff practices regarding Lovenox ("OSS Antitrust Case"). A3407; *see infra* at 22-23.

The District Court erred in granting sanofi summary judgment (A67-77, 86-93), and in denying Eisai discovery from the OSS Antitrust Case. A303.

This Court should reverse, and remand for decision on Eisai's pending motions and trial.

STATEMENT OF FACTS

A. The Parties

Fragmin is an injectable, low molecular weight heparin ("LMWH") drug, which works as an anticoagulant (i.e., prevents blood clotting). A3386-87. Fragmin is manufactured in [redacted] A3571-74. In September 2005, Eisai obtained from Pfizer an exclusive (even as to Pfizer) license to market, sell and distribute Fragmin in the United States, agreeing to pay over [redacted] for those rights. A3387, 3570, 3590-92. Since then Eisai has marketed, sold and distributed Fragmin throughout the U.S. A3887.

Defendants/Appellees sanofi-aventis US LLC and Sanofi US Services Inc. (together, "sanofi") market, sell and distribute Lovenox, also an injectable LMWH drug. A3386-87.

B. The Relevant Market

There was no dispute below that the relevant geographic market here is the United States. A3883. As the District Court correctly assumed, the relevant product market consists of the four injectable LMWH drugs, Lovenox, Fragmin, Arixtra, and Innohep (the "Lovenox Therapeutic Class" or "LTC" drugs). A64. Sanofi's Lovenox Contracts expressly addressed the "Lovenox® Therapeutic Class" or "LTC market." A3397; A15.

As anticoagulants, LTC drugs are used to prevent or treat venous thromboembolism ("VTE"), a potentially fatal condition arising from the development of a blood clot in a vein. Doctors use anticoagulants to treat a variety of patient populations who are at risk for VTE. A9-14; A3386. Prior to 1993, the primary anticoagulant drugs available in the U.S. were the "first generation" products, unfractionated heparin ("UFH") and Vitamin K Antagonists, most commonly warfarin. A14, 16. These products have a number of drawbacks, including that their use requires frequent blood tests and patient monitoring because of significant risk of harmful side effects. A3864-70; A3531-35.

In 1993, the second generation, LTC drugs began to come to market in the U.S. The first of the LTC drugs approved by the Food and Drug Administration ("FDA") was Lovenox, which was marketed in the U.S. by sanofi's predecessors beginning in May 1993. A3386. Fragmin was approved by the FDA in December 1994. A3881-82. A third LMWH Innohep was approved by the FDA in 2000. A3387. The fourth LTC product Arixtra was launched in the U.S. in early 2002. A3862. Although Arixtra technically is not an LMWH, it is viewed as clinically comparable to the LMWH drugs, and thus sanofi included it in the LTC market definition in its Lovenox Contracts. A3386, 3394.

The four LTC drugs generally are comparable and reasonably interchangeable. A3864-70; A3547. Each of these products targets the same

coagulation-causing agents in the blood, and produces very similar effects. A3864-70. Eisai's expert Dr. Melvin testified that [redacted] A3547.[1]

The LTC products are not, however, reasonably interchangeable with, and are in a separate product market from, the first generation drugs. A3863-70. LTC drugs generally have greater efficacy and consistency, are easier to administer, and engender fewer side effects, than UFH and warfarin. A3864-70; A3551-35. By virtue of these substantial medical advantages, the LTC drugs have supplanted their predecessors for many uses even though their prices are much higher. A3864; A3386, 3394-97; *see* A3395 ([redacted]).

The demand for LTC drugs has been enormous. Before the entry of a generic product in 2010, [redacted] A3550. During the period 2005-2010, LTC drug sales revenues in the U.S. reached approximately [redacted] annually, and sanofi earned [redacted] in profits from its U.S. sales of Lovenox alone. A3438.

[1] A "therapeutic interchange" occurs when a hospital substitutes one drug or treatment "for another drug or treatment, either primarily or exclusively, for a condition or conditions where either drug or treatment is effective for the same condition(s)." A19.

Although they generally are comparable, each of the LTC drugs has certain FDA-approved indications. A3388-90; A3548-49; *see also* A3779 (a pharmaceutical company cannot promote or market a drug in the U.S. for an indication as to which it does not have FDA approval). While Fragmin and Lovenox have a number of indications in common (A3548-49; A3880), Lovenox was the only LTC drug with an indication for treatment of certain more severe forms of heart attack (its "Unique Cardiology Indication"). A12; A3388-90. Fragmin has a "Unique Cancer Indication;" it is the only LTC drug approved for the extended treatment of symptomatic venous thromboembolism to reduce the recurrence of VTE in patients with cancer. A12-13; A3388-90.

After [redacted] (A1474; A2525), the FDA approved a generic form of Lovenox (enoxaparin) in July 2010. A544. Within days of enoxaparin becoming available, [redacted] A901; A3892. [redacted]

[redacted]

A3398; A3907-08; A6293-94.

C. Sanofi's Monopoly Power

The District Court correctly held that "Sanofi had monopoly power in the relevant market during the relevant period . . . ." A64. When Lovenox went on

sale in the U.S. in 1993, it enjoyed 100% of the LTC market. A3881-82. Fragmin, Innohep, and Arixtra later entered the market, and Eisai took over the U.S. marketing of Fragmin beginning in 2005. A3862. Although these rival drugs were [redacted] clinically comparable to Lovenox for most patients, sanofi remained entrenched; the competitive products were unable, individually or collectively, to make significant inroads. As the District Court found, "during the relevant period, Lovenox had an LTC market share of 81.5% to 92.3%," while Fragmin had a market share of 4.3% to 8.2%, Arixtra had a market share of 2.3% to 9.9%, and Innohep had a market share of 0% to 1%. A14; A3888; A6121.

While the level and persistence of such shares alone shows monopoly power,[2] they actually understate the extent of sanofi's power here, since it was able to maintain those shares despite [redacted] A4160; A3437; A3892. During 2005-2010, [redacted]. A3403; A3890-93; A3910-15; *see* A3436; A4744 (sanofi executive: [redacted]); *see also* A86 at n.13 ("Here,

[2] *See, e.g., United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956) (75 percent market share would constitute monopoly power); *United States v. Dentsply Int'l Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) (dominant share for over ten years sufficient to find monopoly power).

it is undisputed that there are significant barriers to entry in a branded, pharmaceutical drug market based, in part, on the cost of research and the complexity of the FDA-approval process.").

Not only did sanofi have monopoly power in the LTC market overall, it had particular strength in the sale of LTC drugs for cardiology uses, since it was the only drug that could lawfully be promoted and marketed for its Unique Cardiology Indication. Sanofi used its power over these "incontestable sales" (*see, e.g.*, A3875; A3911-18; A3936-37) also to leverage control of sales for uses as to which its competitors were free to, and did, promote their products. *See infra* at 19-20, 31-32. As sanofi explained: "The more we can grow our cardiology franchise the more we can fend off the competition by increasing the financial penalty for a therapeutic interchange based on marketshare . . . . This will raise the entry cost for future competitors." A4231; *see ZF Meritor*, 696 F.3d at 277, 285 (defendant used its control over non-contested products to induce customers to agree to high overall market share requirements).

D. Sanofi's Exclusionary Conduct To Protect [redacted]

From Eisai's September 2005 market arrival to the generic entry in July 2010, sanofi used exclusionary agreements, and a variety of other non-price conduct, to maintain [redacted] its monopoly market share, foreclosing 68% to 84% of the LTC market from competitors of Lovenox. *See*

A3925-46 (Elhauge Report explaining foreclosure calculations). That conduct included: payoffs to hospitals for not purchasing rival products; agreements mandating that hospitals not position a rival product ahead of Lovenox on their formularies where Lovenox had an FDA-approved indication; and a campaign of deceptive and unlawful conduct designed to deter doctors and hospitals from using rival products other than on the competitive merits.

1. Sanofi's Payoffs To Hospitals For Not Purchasing Rival Products

During 2005-2010, sanofi entered into "Lovenox Contracts" with group purchasing organizations ("GPOs"), the members of which included all or virtually all U.S. hospitals and hospital systems. A895.[3] These agreements allowed [redacted] based on satisfying huge (75%-90%) LTC market share requirements. *E.g.*, A4252-79; A4157 (Lovenox Contracts). Over that period, sanofi spent over [redacted] on these payoffs (A3929-30), plus the cost of monitoring and enforcing its contracts (A3944-45).

By way of example, sanofi's program for individual hospitals, as of June 16, 2008, is shown in the following table:

[3] Although sanofi did not sell directly to hospitals, it sold to pharmaceutical wholesalers, which then sold the product to the hospital at the price negotiated between sanofi and the group purchasing organization. A15; A895-96; A1398.

	LTC Share				
Gross Sales Volume	**0-74%**	**75-79%**	**80-84%**	**85-89%**	**≥ 90%**
$0 to $99,999	**1.00%**	**9.00%**	**12.00%**	**15.00%**	**18.00%**
$100,000 to $399,999		**12.00%**	**15.00%**	**18.00%**	**21.00%**
$400,000 to $799,999		**15.00%**	**18.00%**	**21.00%**	**24.00%**
$800,000 to $1,199,999		**18.00%**	**21.00%**	**24.00%**	**27.00%**
≥ $1,200,000		**21.00%**	**24.00%**	**27.00%**	**30.00%**

See A16; A898.

While this matrix purports to relate to both volume and market share, the volume aspect is largely window dressing; indeed, it is meaningless if Lovenox does not comprise at least 75% of a hospital's LTC purchases. A hospital could be "off the chart" in terms of its volume of purchases of Lovenox, e.g., at $10 million for a four month period, and [redacted] receive no payoff (other than the universal 1%), if it also bought 26% of its LTC drug needs from others. In contrast, a hospital that bought a mere $10,000 of Lovenox during that period would receive an 18% payoff -- so long as it purchased no other LTC products.

While sanofi calls its payoffs "discounts," they are not discounts in economic substance. They were not designed to reduce the price of sanofi's product and thereby encourage consumers to buy more of that product as a matter of choice. They were designed: to allow sanofi [redacted];

and to do so by deterring hospitals from buying significant amounts of [redacted], rival products and thereby preventing those products from pressuring sanofi [redacted]. *See, e.g.*, A4195; A4481-84; A4818. Thus, for the same $1 million in Lovenox purchases, sanofi would make a 1% payoff to a hospital if Lovenox comprised 74% of the hospital's LTC purchases, an 18% payoff if Lovenox had a 75% share, and a 27% payoff at a 90-100% share. A898. [redacted]. *See ZF Meritor*, 696 F.3d at 266, 288 (defendant refused to make exception to market share calculation for product as to which it had no comparable alternative).

Nor does a discount raise the cost of a competitive product. But sanofi's payoffs did just that. For example, if a hospital contemplated buying $1,500,000 of LTC drugs including $501,000 of Fragmin, it would realize that, if it refrained from buying the Fragmin, sanofi would provide a 27% payoff on its next four months of purchases -- in effect artificially increasing the cost of buying the Fragmin by that amount. A16; A898.

As explained by Dr. Elhauge (A3912-14), sanofi's imposition of this cost on buying rival products created a "dead zone," which effectively required

exclusive dealing by preventing hospitals from gradually shifting to less expensive products. Although Eisai was [redacted], hospitals were forced to buy Lovenox unless they were prepared largely to abandon that product, and to do so all at once. [redacted] wholesale overnight switching was impracticable, not just due to normal switching costs, but also due to, e.g., Lovenox's Unique Cardiology Indication and sanofi's scare-mongering about rival products. A3876-77; A3910-15; A3947-49.

Sanofi's creation of this anticompetitive dead zone [redacted] A3398; A4103; *see also* A4195 ([redacted]). To prevent hospitals from buying larger quantities of [redacted], rival products, [redacted] *See* A3404, 3410-21; A4383-87 ([redacted]).

In 2006, as Eisai was beginning its marketing of Fragmin, sanofi supplemented its exclusionary efforts by introducing "Systems Agreements," which applied to multi-hospital systems and conditioned higher, system-level

payoffs on compliance with the contract requirements by every hospital in the system. *See, e.g.*, A4116, 4122, 4124; A4258; A4419-20. In 2007, approximately [redacted] of all Lovenox sales were made to such systems. A3912.

As shown by the chart below, these agreements abandoned even the pretense of any volume-based component; they based payoffs purely on "loyalty," i.e., eschewing any significant purchases from competitors. At any volume of purchases of Lovenox, the less the system bought of rival products, the higher percentage sanofi would pay it. A low volume buyer of Lovenox with few purchases of other products would receive a higher payoff rate than a much higher volume purchaser that also bought a significant amount of competitive products.

	Market Share				
Gross Sales Volume	**0 – 74%**	**75% - 79%**	**80% - 84%**	**85% - 89%**	**≥ 90%**
N/A	**N/A**	**15.00%**	**18.00%**	**27.00%**	**30.00%**

A17; A898.

Sanofi's Lovenox Contracts and Systems Agreements had their intended effect. [redacted]. A4340. [redacted]

[redacted]. A3403. [redacted] A4303-05; A3403.

In July 2010, sanofi's conduct changed dramatically. After the generic enoxaparin entered the market, sanofi immediately [redacted]. A3892, A3907-08 (Elhauge Report). Moreover, [redacted], a step it would not have needed to take if they had provided efficiency benefits. *See* A3893-94, A3907-08 (Elhauge Report); A3398.

Not only was sanofi's payoff plan anticompetitive, but one of its own predecessor companies has forthrightly said so. In 2003, OSS (the company marketing Arixtra at the time) brought an antitrust case against Aventis (which was marketing Lovenox at the time), explaining that the Lovenox Contracts' LTC market share condition (then involving a single threshold at 90%) was an "exclusionary" tactic that "prevent[s] competition on the merits" among LTC drugs. *See* Compl., *Organon Sanofi-Synthelabo, LLC v. Aventis Pharm., Inc., et al.*, No. 6:03 CU224-ORL-31DAB (M.D. Fla. Feb. 25, 2003) at ¶¶10-11; A3406-08. The OSS Antitrust Case ended only after a merger that resulted in both parties

becoming part of Sanofi-Aventis, S.A., and the divestiture of Arixtra. A3790; A3388; A3408. Although the resulting sanofi entity dismissed the case, it did not end its anticompetitive conduct.

2. Sanofi's Agreements With Hospitals To Block Access To Their Formularies

A hospital's "formulary" lists drugs approved for use within the hospital. A3399. "In essence, a formulary 'determines what treatments are available for use at a particular hospital." A19; A918; A4105-06; A4313-14.

Sanofi's Formulary Access clauses prohibited hospitals from "disfavor[ing]" Lovenox by according any other LTC drug a superior formulary position for any indication for which Lovenox had FDA approval. A3943-44. Under these provisions, hospitals also were forbidden from adopting "any restrictions . . . on any marketing or promotional programs for Lovenox, including (but not limited to) documentation or communication that disfavors Lovenox, identifies Lovenox in a less than equal status with other products in the [LTC], or places greater restrictions on access by [sanofi] sales representatives to healthcare professionals than . . . other . . . sales representatives." A4136; A3399-400.

The Formulary Access clauses thus guaranteed that Lovenox always remained first, or tied for first, wherever it had an indication, on all contracting hospitals' formularies, as well as in their promotional programs and access granted to sales representatives. No matter what its price or qualities, a competitive

product was barred from gaining primacy at any contracting hospital. Although the District Court dismissed the significance of these clauses by stating that their language only protected sanofi against being disfavored (A73-74), the practical effect of those requirements was to entrench sanofi's existing monopoly and protect [redacted]. The possibility of being disfavored is the very essence and driving force of competition -- the threat that suppliers may lose out with customers to their rivals keeps all competitors on their toes. But these provisions relieved sanofi of that competitive pressure, eliminating any need for it to [redacted]. A3910-12; *see ZF Meritor*, 696 F.3d at 287 (involving agreements between defendant and its customers to downplay availability of plaintiffs' products in databooks shown to consumers).

Sanofi recognized the importance of these agreements. [redacted] A4164-65; A4806-10.

The consequences for violation of the Formulary Access clause were severe -- an immediate, retrospective elimination of all "loyalty" payoffs down to the universal 1%, even though the hospital already would have "earned" its payoff

by having met the market share requirement during the prior four month period. A20. Under the Systems Agreements, if any single hospital within a system did not comply with this clause, the entire hospital system's payoffs were immediately reduced, and the payoffs of the "violator" hospital would be cut [redacted] to the 1%. *See* A4116, 4122, 4124.

Identification of violations was not left to chance. [redacted]. A4121; *see also* A4342-47; A3929-30; A4453-54; A4455-57. [redacted] A3411. [redacted] A3410-21; *see ZF Meritor*, 696 F.3d at 289 (defendant "sought to aggressively enforce the agreements, even when [direct purchasers] voiced objections").

These provisions, too, had their intended effect. For example, after an extensive review, Mountainview Hospital (part of the Hospital Corporation of America (HCA) system) (A3411-12) decided to conduct a therapeutic interchange to a combination of Lovenox and Fragmin, [redacted] A3414. But, after sanofi informed

HCA that the system would [redacted], Mountainview decided not to proceed with this change. A3414.

3. Sanofi's "FUD" Campaign And Other Deceptive And Unlawful Marketing Conduct To Thwart Competition

Apparently concerned that even its payoffs for meeting huge market share requirements, and formulary restrictions, could not stem the tide of lower priced, quality competitive products, sanofi also engaged in a long-term campaign designed to attribute false risks and costs to the use of those products, and thereby inhibit their purchase despite their merits. Without medical basis, sanofi persistently described Fragmin and other competitive products as [redacted] *See generally* A3424-34. Sanofi described this program as spreading "fear, uncertainty and doubt" or "FUD" among hospital pharmacists and prescribing physicians. A3826; A3829-30; A4327; A4537-38; A4603; A4606; A4607-10; A4612; A4613-14; A4615; A4616-17; *see also* A3425-26 (describing launch of "OPERATION DOCTOR FUD").

As sanofi told its sales representatives, they were to "spin this out of control to where the Pharmacist and MD's are scared to use a novel product . . . [redacted] . . . ." A4327 (sanofi's "Therapeutic Interchange Roadmap"). Thus, one sanofi sales representative promised to "[m]ake sure that

all Doctors admitting to [Citrus Memorial Hospital] feel the 'FUD.'" A4612.

A4616-17.

As a result, physicians and pharmacists attending sanofi programs were led to fear that therapeutic interchange could subject hospitals to A4672. Audience members at one such program A4669.

. *See* A3839-42. *See* A4721-22; A4708-19; A4541.

Sanofi also paid doctors to attack Fragmin on false grounds. One of sanofi's physician "consultants," Dr. Gordon Vanscoy, co-authored an article that asserted that switching to competing LTC drugs increased the risks of complications, extended hospital costs and raised "legal implications." A752-58.

[redacted] A4659-62. [redacted] *See id.*; A4666-67. [redacted] *See* A4638-41; A4626-28. [redacted]. *See* A752-58; A4649-50; A4651-58; *see also* A4630-33. [redacted] A4606.

Although it "unequivocally could have saved hundreds of thousands of dollars in the first year" by switching, the university decided not to do so after attending the meeting because of "the cost of switching, the concern for patient safety and the risk of litigation." *Id.*

[redacted] A759; A3430. [redacted] A4669.

Complementing sanofi's FUD campaign to falsely discredit rival products, sanofi made unsubstantiated claims of superiority of Lovenox over other LTC drugs. *See* A4573; *see also* A3422-23. Sanofi made these claims even though FDA regulations prohibited it from promoting Lovenox as clinically "superior" to any other LTC drug that had the same approved indication, unless it had demonstrated such superiority in head-to-head controlled clinical trials, which sanofi had not done. A3392-93; A3836; 21 C.F.R. §§ 202.1(e)(6), 202.1(e)(4)(ii)(B). [redacted] A3392-93. [redacted] *See, e.g.*, A3422-28; A4542; A4545; A4573.

[redacted] Fragmin's Unique Cancer Indication, [redacted] 21 C.F.R. § 202.1(e)(6); A4728-38. Thus, [redacted]

[redacted] (*see, e.g.*, A4728-38; A4739-40), [redacted] A4819, 4823, 4825; *see also* A3434-36.

E. Eisai's Efforts to Compete Despite Sanofi's Anticompetitive Conduct

When Eisai took over the promotion and sale of Fragmin from Pfizer in September 2005, it sought to compete vigorously. Eisai kept Fragmin's price [redacted] throughout the period 2005-2010. A6100; A3893; A6292. Moreover, Eisai offered discounts, including special discounts for new and transitioning customers. A1413, 1418; A1000. Eisai also spent heavily on marketing; Eisai's promotional spend on Fragmin was [redacted] that of sanofi's spend on Lovenox on a per unit sold basis. A6106; A6231; A6345; A3988-89.

As a result, Eisai did not, by any means, have an "85% profit margin," as the District Court found. A70-71, 80, 84. That figure was based solely on the product's "standard cost," the transfer price between Pfizer and Fragmin for the physical product; it does not include the vast majority of the costs Eisai incurred with respect to Fragmin, such as license costs and regulatory, marketing, sales and distribution costs. *See* A3890-91. [redacted]

[redacted] A2747.

F. The Injury to Competition Caused by Sanofi's Conduct

By preventing lower priced, quality products from having a meaningful impact on customer choice, and thereby protecting Lovenox from [redacted], sanofi's conduct harmed competition. With 68% to 84% of the LTC market foreclosed to other products by sanofi's exclusionary conduct, buyers of LTC drugs were forced [redacted], which maintained its market share of 82-92% throughout 2005-2010. A3889. Buyers also faced artificially higher costs for other LTC drugs. A3939. And, [redacted], with hospitals deterred from purchasing additional quantities of rival LTC products, with consumers blocked from access to competitive products, and with sanofi's deceptive and unlawful marketing conduct increasing the perceived cost of such other products, output was reduced compared to the level it would have reached, and consumer choice was stifled. A6288-6289 (Elhauge Reply Report). This harm to competition is [redacted] for Lovenox upon generic entry. A901; A3907-08; A3911-13.

G. The Injury to Eisai Caused by Sanofi's Conduct

Sanofi's conduct likewise injured Eisai, by restraining the growth of Fragmin's market share and its sales and profits. *See* A6115-93 (Economides Report, *passim*). Where sanofi's wrongful conduct was absent, Eisai obtained from [redacted] market share, as shown by a number of yardsticks, including Fragmin's share: of the purchases of non-"loyal" sanofi customers; at hospitals that did not comply with the Formulary Access clause; and in Canada. *See, e.g.*, A3930-35, A4782, A6137.

In addition, Eisai's expert Professor Rosenblatt explained that, in other pharmaceutical markets, clinically-comparable, second-entrant drugs similarly situated to Fragmin obtained on average a [redacted] market share during the first seven years after entering the market, compared with the maximum 8% share Fragmin achieved. *See* A4780; *see also* A4782 (opining that Fragmin could have achieved at least [redacted] market share but for sanofi's anticompetitive conduct). Sanofi's restraint of Fragmin's growth also denied Eisai the prospect of accruing additional cost economies of scale, and thereby prevented it from making additional profitable sales by further lowering its price to reflect any such cost savings. A3940-43.

PROCEDURAL HISTORY

H. The Preliminary Proceedings Below

Eisai filed its Complaint in August 2008, asserting claims under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; Section 3 of the Clayton Act, 15 U.S.C. § 14; and the New Jersey Antitrust Act, N.J.S.A. 56:9-3 and 56:9-4. A173, 188-192. In June 2009, the District Court denied sanofi's motion to dismiss the complaint. Dkt.59.

In November 2009, sanofi again moved to dismiss, or for summary judgment, based on Eisai's asserted lack of standing. Dkt.75. The District Court denied that motion, construing it as one for summary judgment. A214. Sanofi moved for certification of that order for interlocutory appeal. Dkt.122. The District Court granted that motion (Dkt.132), and this Court denied sanofi's request for interlocutory appeal. Order, *Eisai Inc. v. Sanofi Aventis, U.S.*, No. 10-8053 (3d Cir. Nov. 2, 2010), ECF No. 7.

During two years of vigorous fact discovery, Eisai sought information from sanofi from the OSS Antitrust Case. A306. After sanofi refused to produce transcripts (and related exhibits) of witnesses whose depositions were taken in both this case and the OSS Antitrust Case, Eisai moved to compel their production. A341-352. Although Magistrate Judge Arpert previously had recognized that the transcripts were potentially relevant to "all sorts of issues" (A380), he denied

Eisai's request as "irrelevant and . . ." unduly "burdensome." A99-105. Eisai timely appealed to District Judge Cooper, who affirmed that ruling. A106-11.

On June 3, 2013, sanofi moved for summary judgment on liability. Dkt.245. On the same day, Eisai moved for partial summary judgment (Dkt.261), and to preclude or strike certain expert opinions (Dkts. 255, 257, 259, 291). Sanofi also filed a number of other motions. *See* A4-7. On March 28, 2014, the District Court granted sanofi's motion for summary judgment on liability, denied the other pending motions as moot, and entered judgment in favor of sanofi. *Id.*

I. The District Court's Summary Judgment Decision

In its summary judgment decision, the District Court assumed that the relevant product market in this case consists of the LTC drugs (A14, 64), and found "that Sanofi had monopoly power in the relevant market during the relevant period . . . ." A14. It then granted sanofi's motion.

The court first applied the low price exception to the Rule of Reason, stating that the "inescapable conclusion is that the price is the predominant mechanism of exclusion." A74. Finding that sanofi did not engage in below-cost pricing, it held that "Eisai cannot recover under the antitrust laws." A76-77. In reaching this result, the District Court failed to recognize that, far from using low prices to benefit consumers and exclude competitors, [redacted], and

[redacted]. A3404, 3436-37; A6292. Nor did the court recognize that the non-price measures sanofi deployed to exclude competitors -- payoffs to hospitals for not buying rival products, agreements blocking other products from freely competing for formulary access, FUD tactics, and other deceptive and/or unlawful marketing conduct -- [redacted], and block consumer choice. The District Court cited no decision applying the low price exception under such circumstances.

The District Court also ruled that "Eisai cannot establish violations of the antitrust laws under an exclusive-dealing analysis." A87. Although the District Court posited this discussion as an "alternative" to its low price exception holding (A77), it was not an independent analysis; continuing its view that "market-share discounting practices generally do not foreclose a plaintiff from competing" (A92), the court largely transported its safe harbor conclusion into its "exclusive-dealing" result. In so doing, the District Court did not consider: the demonstrated actual anticompetitive effects of sanofi's conduct on price, quantity and consumer choice; sanofi's persistent monopoly market share [redacted] despite increased competition; or the admitted lack of any procompetitive justification for sanofi's conduct. Instead, it discussed its view of the likely impact on competition of various aspects of sanofi's conduct, considering each in isolation

rather than sanofi's behavior as a whole, and deciding numerous factual disputes in favor of sanofi.

Notwithstanding Eisai's extensive evidence showing that sanofi's conduct had caused it harm, the District Court also held that Eisai had failed to show antitrust injury. Again deciding contested factual issues in favor of sanofi, it speculated that "there are numerous reasons [other than sanofi's anticompetitive conduct] why Fragmin *may* have underperformed in relation to Lovenox . . . ." A83 (emphasis added). The District Court did not try to explain why, if Eisai were so self-defeating, sanofi would have spent so much money on payoffs and payoff enforcement to block Eisai's progress.

SUMMARY OF ARGUMENT

The District Court erred in applying the low price exception to the Rule of Reason. *See* A77; *see, e.g., Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006) (Rule of Reason is mode of analysis presumptively applied to antitrust claims). This is not a case where lowering price was the sole, or even the "clearly predominant," mechanism of exclusion of competitors, so that the court can be extremely confident that the conduct at issue benefits consumers without employing a full Rule of Reason inquiry. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 243 (1993) (addressing challenge to below cost pricing, and concluding that low pricing almost always benefits

consumers); *ZF Meritor*, 696 F.3d at 277 ("because price itself was not the clearly predominant mechanism of exclusion, the price-cost test cases are inapposite").

Sanofi's prices -- [redacted] -- were neither pro-consumer nor a means of excluding competitors. Sanofi used its prices to harm consumers and obtain monopoly profits. To exclude competitors, and thereby maintain [redacted] its prices, sanofi deployed an array of non-price conduct, including payoffs to hospitals for not purchasing rival drugs, other exclusionary contractual provisions, and a deceptive and unlawful marketing campaign, including its "[redacted]." The Rule of Reason applies here. *ZF Meritor*, 696 F.3d at 281.

The District Court also erred in its "exclusive dealing" discussion, failing to conduct a proper Rule of Reason analysis. *See* A77-97. The court did not take into account the demonstrated actual adverse effects of sanofi's conduct on price, output and consumer choice, nor did it consider the significance of sanofi's continuing combination of monopoly market share [redacted] notwithstanding increasing competition. The court also impermissibly evaluated each aspect of sanofi's conduct in isolation, rather than assessing sanofi's conduct, and its effect on competition, as a whole. And it contravened the standards of Rule 56 by deciding contested issues of fact. Viewing all the facts and circumstances

together and correctly under Rule 56, the District Court should have denied sanofi's summary judgment motion under the Rule of Reason. *See infra at* 51-56.

The District Court further erred in finding as fact that sanofi's conduct did not cause Eisai any antitrust injury, but rather that Eisai itself "may" have been at fault. A82-84. Eisai offered a quality, [redacted], and made substantial promotional efforts. As demonstrated by a number of yardsticks, it would have done much better but for sanofi's array of anticompetitive conduct, readily meeting the "material cause" standard for showing antitrust injury. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 (1969).

The District Court also abused its discretion in denying Eisai's request for production of deposition transcripts and related exhibits from the OSS Antitrust Case, which involved a challenge by a sanofi predecessor to very similar Lovenox payoff practices. Far from being unduly burdensome and irrelevant, that request seeks information that is simple to provide, and potentially highly relevant.

ARGUMENT

II. The Standards of Review

Whether the District Court erred in granting sanofi summary judgment is subject to plenary (de novo) review by this Court. *Trenton Metro. Area Local of Am. Postal Workers Union, AFL-CIO v. U.S. Postal Serv.*, 636 F.3d 45, 52 (3d Cir. 2011). This Court should decide whether the record, viewed in the

light most favorable to Eisai, shows that there is no genuine issue of material fact and that sanofi is entitled to judgment as a matter of law. *Morton Intern., Inc. v. A.E. Staley Mfg. Co.*, 343 F.3d 669, 679 (3d Cir. 2003).

This Court reviews discovery decisions under the abuse of discretion standard, in light of the liberal federal discovery rules. *Hart v. Elec. Arts, Inc.*, 717 F.3d 141, 148 (3d Cir. 2013); Fed. R. Civ. P. 26(b)(1).

III. The District Court Erred In Granting Sanofi Summary Judgment Under The "Low Price" Exception To The Antitrust Rule Of Reason

The Rule of Reason is the presumptive standard of review in cases under Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act. *See Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007) ("The rule of reason is the accepted standard for testing whether a practice restrains trade in violation of §1."); *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006) (Rule of Reason is the method of analysis presumptively applied to antitrust claims).[4]

The Supreme Court has created exceptions to the Rule of Reason for conduct that it has concluded "always or almost always" injures competition (the "*per se*" rule), *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 20 (1979), or is virtually always procompetitive. *Brooke Group*, 509 U.S. at 223. The Court has emphasized that the scope of these exceptions does not turn on the

[4] The New Jersey Antitrust Act is construed in harmony with the federal antitrust laws. *State v. N.J. Trade Waste Ass'n*, 96 N.J. 8, 19 (1984).

elasticity of nomenclature, but is narrowly limited to implementation of their underlying rationales. *See, e.g.*, *Leegin*, 551 U.S. at 899 (narrowing application of *per se* exception to conform to its rationale) (and cases discussed therein); *Texaco*, 547 U.S. at 8 (exceptions to the Rule of Reason are limited to a narrow range of activity).

In *Broadcast Music*, 441 U.S. at 8-9, the Court held that, although the blanket license at issue there constituted "price fixing" in the "literal sense," it was not the type of price fixing that comes within the rationale of the *per se* exception, and therefore was subject to the Rule of Reason. Likewise, in *Texaco*, 547 U.S. at 6, the Court explained that, "though Equilon's pricing policy may be price fixing in a literal sense, it is not price fixing in the antitrust sense."

In one such exception, the Supreme Court has created a limited "safe harbor" for conduct that it deems virtually always procompetitive -- *viz.*, cases in which the plaintiff claims that defendant's prices were "too low." *Brooke Group*, 509 U.S. at 220-23; *accord Pac. Bell Tel. Co. v. linkLine Commc'n, Inc.*, 555 U.S. 438, 451 (2009) ("[i]n cases seeking to impose antitrust liability for prices that are too low" (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986) (internal quotation marks omitted)); *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 319 (2007) ("plaintiff seeking to establish competitive injury resulting from a rivals' low prices") quoting *Brooke*

Group, 509 U.S. at 222)); *Atl. Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 337 (1990) ("When a firm . . . lowers prices . . . .").

The rationale for this exception is to promote consumer welfare -- because the Supreme Court has concluded that lowering prices virtually always benefits consumers, *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 116 (1986); *see ZF Meritor*, 696 F.3d at 275, and that too liberally allowing claims that defendant's prices are unduly low "could, perversely, 'chil[l] legitimate price cutting,' which directly benefits consumers." *Weyerhaeuser*, 549 U.S. at 319 (quoting *Brooke Group*, 509 U.S. at 223-34); *see Atl. Richfield Co. v. USA Petrol. Co.*, 495 U.S. 328, 340 (1990) ("Low prices benefit consumers regardless of how those prices are set . . . .").

Consistent with this rationale of promoting consumer welfare through lower prices, the Supreme Court has established a "low price" exception, not an "any price" exception or an "affecting price" exception. In each of the Supreme Court decisions applying the exception to sellers, the *sole* conduct challenged by plaintiff was a price that allegedly was too low. *See linkLine*, 555 U.S. 438 (challenging low retail prices); *Brooke Group*, 509 U.S. at 216-17 (challenging volume discounts as too low, indeed below cost); *Atl. Richfield*, 495 U.S. 328, 337 (challenging low retail prices). Thus, in *ZF Meritor*, this Court stated that, "in

contrast to *Cargill*, *Atlantic Richfield*, and *Brooke Group*, Plaintiffs did not rely solely on the exclusionary effect of Eaton's prices . . . ." 696 F.3d at 277.

In *ZF Meritor*, this Court declined defendant's invitation to expand this exception beyond its rationale. Plaintiffs there brought antitrust claims challenging market share requirements and other exclusionary conduct. *ZF Meritor*, 696 F.3d at 263. Defendant argued for application of the low price exception, claiming that "Plaintiffs have identified nothing, other than [defendant's] pricing practices, that incentivized the [direct customers] to enter into the LTAs [long term agreements], and because price was the incentive, we must apply the price-cost test." *Id*. at 273. Concluding that the exception applies only where lowering price is the "clearly predominant mechanism of exclusion" (*id.* at 269), this Court rejected this contention. *Id.* at 281. It reached that result even though it found that defendant's prices were on average lower than plaintiffs' (*id.* at 273), and that defendant had offered its customers protection against price increases. *Id*. at 266-67.

The court explained that:

> Plaintiffs did not rely solely on the exclusionary effect of Eaton's prices, and instead highlighted a number of anticompetitive provisions in the LTAs. Plaintiffs alleged that Eaton used its position as a supplier of necessary products to persuade OEMs to enter into agreements imposing de facto purchase requirements of roughly 90% for at least five years, and that Eaton worked in concert with the OEMs to block customer

> access to Plaintiffs' products, thereby ensuring that Plaintiffs would be unable to build enough market share to pose any threat to Eaton's monopoly. Therefore, because price itself was not the clearly predominant mechanism of exclusion, the price-cost test cases are inapposite, and the rule of reason is the proper framework within which to evaluate Plaintiffs' claims.

ZF Meritor, 696 F.3d at 277. The court added that:

> Although the Supreme Court has created a safe harbor for above-cost discounting, it has not established a per se rule of non-liability under the antitrust laws for all contractual practices that involve above-cost pricing. We decline to impose such an unduly simplistic and mechanical rule because to do so would place a significant portion of anticompetitive conduct outside the reach of antitrust laws without adequate justification.

ZF Meritor, 696 F.3d at 278 (citations omitted); *cf. LePage's Inc. v. 3M Co.*, 324 F.3d 141, 152 (3d Cir. 2003) (en banc) (application of the low price exception without unambiguous legal basis would "overturn [] decades of Supreme Court precedent that evaluated a monopolist's liability under § 2 by examining its exclusionary, i.e., predatory, conduct" under the Rule of Reason); *United States v. Microsoft*, 253 F.3d 34, 58 (D.C. Cir. 2001), *cert. denied*, 534 U.S. 952 (2001) ("the means of illicit exclusion . . . are myriad").

The District Court nevertheless applied the low price exception here, relying in part on *dicta* in a *ZF Meritor* footnote stating that: "'we join our sister circuits in holding that the price-cost test applies to market-share or volume rebates offered by suppliers within a single-product market.'" A59 (District Court opinion

quoting *ZF Meritor*, 696 F.3d at 274 n.11). In so doing, the District Court failed to recognize that, although *ZF Meritor* itself was a single-product market case (*see id.*), this Court rejected application of the low price exception there, because reduced price was not the "clearly predominant" mechanism of exclusion. Moreover, the quoted language refers to "rebates," i.e., retrospective price reductions for buying the seller's products -- [redacted] supported by payoffs for refraining from buying rivals' products. *See Brooke Group*, 509 U.S. at 215-16 (referring interchangeably to defendant's "volume rebates" and "volume discounts"). And, none of the "sister circuit" decisions this Court cited in that footnote extended the low price exception beyond its role in assessing claims of unduly low pricing.[5]

A fortiori to the situation in *ZF Meritor*, this is not a case in which lower price was the sole mechanism (indeed, any mechanism) that "functioned as the exclusionary tool." 696 F.3d at 281. While the *ZF Meritor* court refused to

[5] *See NicSand, Inc. v. 3M Co.*, 507 F.3d 442 (6th Cir. 2007) (engaging in an extensive Rule of Reason examination of the "realities of this market," including plaintiff's prior dominance of the market; the contracts at issue; and the structure and customs of the industry, even though defendant had not priced below cost); *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1058-60 (8th Cir. 2000) (applying price-cost test to plaintiffs' pricing challenge to defendant's "discount programs," but applying the Rule of Reason to plaintiffs' exclusive dealing claim); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 230-31, 236-38 (1st Cir. 1983) (applying price-cost test to plaintiff's predatory pricing claim that defendant's "prices were unreasonably low," but applying the Rule of Reason to plaintiff's claim that certain requirements contracts were anticompetitive).

apply the low price exception even though it found that defendant's prices were on average lower than plaintiffs' and were subject to price protection, [redacted]. A6292. High pricing is the opposite of an exclusionary practice; in the absence of barriers to competition, it facilitates entry and expansion by competitors. *See Matsushita*, 475 U.S. at 591 n.15 (if defendants try to raise prices to a supracompetitive level, they would attract new competition); *Rebel Oil Co. Inc. v. Atl. Richfield*, 51 F.3d 1421, 1439 (9th Cir. 1995) (when entry is easy, a company "charging supracompetitive prices will quickly lose market share . . . as new rivals enter the market and undercut its high price").

Rather than being any mechanism of excluding competitors, "clearly predominant" or otherwise, [redacted]. Its exclusionary conduct, [redacted], was all non-price, including: sanofi's payoffs to hospitals for refraining from buying rival products; agreements to provide Lovenox unchallenged priority at hospitals; "FUD" tactics; and other deceptive and unlawful conduct. Far from clearly benefiting consumers, as the Supreme Court's safe harbor decisions require, sanofi's market share requirement "[redacted]" and other exclusionary conduct harmed consumers -- by protecting sanofi's ability to [redacted],

reducing quantity and limiting consumer choice. In contrast, only after generic entry in July 2010 [redacted]

The low price exception does not apply here. Indeed, applying it here -- where sanofi's conduct has caused serious anticompetitive effects and cannot survive Rule of Reason scrutiny (*see infra* at 51-56) -- would turn on its head the Supreme Court's effort to create a limited exception to foster plainly *pro*competitive conduct.

IV. The District Court Erred In Granting Sanofi Summary Judgment Under An "Exclusive Dealing" Analysis

A. The District Court Misapplied The Rule of Reason

Because the low price safe harbor does not apply here, the District Court was required to assess the challenged conduct under a full Rule of Reason analysis. It failed to do so.

The Rule of Reason involves a plenary review of the nature of the challenged conduct, its rationale, its market impact, and its offered justifications, in order to determine whether its anticompetitive effects outweigh any procompetitive benefits. *See, e.g.*, *Leegin*, 551 U.S. at 905-07; *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918). As the Supreme Court has explained, anticompetitive effects may be shown by proof of actual anticompetitive effects (e.g., adverse impact on price, output or quality) or by a market analysis showing that the challenged conduct likely will create anticompetitive effects. *See, e.g.*,

FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 460-61 (1986); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984).

In assessing those effects, the court is required to consider defendant's conduct as a whole, not each aspect in isolation; because that is how the conduct affects the market. *See Continental Ore Co. v. Union Carbide Corp.*, 370 U.S. 690, 698-99 (1962) (anticompetitive conduct must be viewed "as a whole"; "[P]laintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after the scrutiny of each." (citations omitted)); *ZF Meritor*, 696 F.3d at 289, n.20 (defendant's agreements "as a whole functioned as exclusive dealing agreements that adversely affected competition."); *LePage's*, 324 F.3d at 162 ("The relevant inquiry is the anticompetitive effect of [the defendant's] exclusionary practices considered together."). A business justification is valid only "if it relates directly or indirectly to the enhancement of consumer welfare;" merely "act[ing] in furtherance of [defendant's] economic interests does not constitute the type of business justification that is an acceptable [antitrust] defense." *LePage's*, 324 F.3d at 163-64 (quoting *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1183 (1st Cir. 1994)).

Far from scrutinizing the competitive effects of sanofi's conduct in this way, the District Court largely imported its conclusion from its erroneous safe

harbor ruling -- declaring that "market share discounting practices generally do not foreclose a plaintiff from competing" (A92), and adopting each of sanofi's arguments denying the likelihood of anticompetitive effects in light of that conclusion. *See, e.g.*, A86-89. In so ruling, the District Court ignored the proof that sanofi's conduct had caused actual anticompetitive effects by:

- increasing price;
- reducing output compared to the level it would have reached (as a result of increased prices, as well as sanofi's conduct paying hospitals not to buy rival LTC products even if they purchased no more Lovenox, blocking consumers from ready access to rival products, and falsely raising the perceived cost of rival products); and
- denying consumer choice.

See Indiana Fed'n of Dentists, 476 U.S. at 460-61 ("'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power;" challenged restraint violated Rule of Reason where plaintiff showed a reduction of output) (quoting 7 P. Areeda, Antitrust Law ¶1511, p. 429 (1986)); *NCAA v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 111 (1984) (affirming holding that defendant's television plan violated Rule of Reason where it resulted in actual anticompetitive effects of higher prices and reduced output, which were not offset by sufficient procompetitive justifications). As the Supreme Court stated in *Indiana Fed'n of Dentists*, 476 U.S. at 459: "Absent some countervailing procompetitive virtue . . . an agreement limiting consumer choice

by impeding the 'ordinary give and take of the market place,' cannot be sustained under the Rule of Reason." (citations omitted).

Moreover, in its analysis of likely competitive impact, the court disregarded the significance of sanofi's long term monopoly share [redacted] despite increased competition. *See United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) (proof of defendant's market power is sufficient to establish the likelihood of anticompetitive effects). Instead, it based its discussion on a fallacy -- that this case involves "discounting practices," rather than an array of non-price conduct designed to do just the opposite -- to allow sanofi to [redacted]

The District Court also failed to recognize that there was no procompetitive justification to balance against the actual and likely anticompetitive effects of sanofi's market share requirements, formulary restrictions, [redacted]," FUD campaign, and other exclusionary practices. [redacted] A3400-01; A4153-167. To the contrary, sanofi has admitted that it terminated its hospital payoffs and Formulary Access clauses as soon as generic entry broke its monopoly power, demonstrating that they had no basis in efficiency. A901 ([redacted]) (citing A2273-

77, exemplar Addendum to GPO contract); A2281; A3907-08; A6293-94. Thus, nowhere in its summary judgment motion did sanofi even proffer a procompetitive efficiency rationale for its conduct. *Compare ZF Meritor*, 696 F.3d at 288-89 (although they were deemed insufficient, the defendant sought to assert procompetitive justifications).

The District Court also admittedly violated the mandate to view defendant's conduct as a whole, expressly considering the various aspects of sanofi's anticompetitive program separately. *See* A77 (considering the "Lovenox Program" separately); A93-94 (considering sanofi's false and unlawful marketing practices "in-and-of themselves").

Furthermore, the District Court failed to apply properly Rule 56 in addressing this summary judgment motion, constantly drawing inferences and deciding contested facts in favor of sanofi, rather than leaving such determinations to the jury. *See Big Apple BMW, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1363 (3d Cir. 1992). Perhaps most prominently, the court erred in treating as "discounting practices" (A92) sanofi's [redacted] and its array of exclusionary conduct designed to enable [redacted] The court below also erred in finding that:

- "there was no evidence that any customers wanted to buy more Fragmin® but were prevented from doing so because of Sanofi's conduct or the Lovenox® Program" (A15)

-- when Eisai adduced extensive evidence (including an Appendix of examples) of customers that wanted to buy more Fragmin but were prevented from doing so by sanofi's anticompetitive conduct -- including [redacted] *See, e.g.*, Dkts. 345 (Redacted), 346 (Sealed) (Eisai's Reply Brief to Motion for Partial Summary Judgment, Appendix at 1-4); citations *infra* at 55-56.

- The "Formulary Access clause" did not harm competition because it only required that Lovenox® receive equal treatment on a hospital's formulary in order for that hospital to benefit from the Lovenox® Program's discounting structure" (A20-21)

  -- when the Formulary Access clause ensured that Lovenox always remained first or tied for first wherever it had an indication, entrenching sanofi's monopoly and eliminating any need for it to lower its price to avoid falling below lower priced competitors on a hospital's formulary. A3399-400 ¶54; A4135-52; A3943-44, at n.228.

- "Eisai's profit margins on Fragmin® in 2009 were approximately 85%" (A70; *accord* A71, A80, A84)

  -- when that purported measure included only a small portion of Eisai's costs, and [redacted]. A2747.

- Eisai "could have competed for business by offering a 'superior product at a lower price'" (A70)

  -- when Fragmin was clinically comparable to Lovenox for most patients, had its Unique Cancer Indication, and [redacted], yet was losing money because of sanofi's anticompetitive conduct. A3388-90 ¶12; A3892-93, Fig. 3.

B. Sanofi's Summary Judgment Motion Should Be Denied

Had the District Court viewed all of the facts and circumstances of the case properly, it could not have granted summary judgment in favor of sanofi. *See*

ZF Meritor, 696 F.3d at 286-89 (upholding jury verdict for plaintiffs under Rule of Reason in case involving de facto partial exclusive dealing agreements).

As described *supra* at 47-49, the extensive evidence of actual anticompetitive effects -- [redacted], reduced output, and constrained consumer choice -- combined with the lack of any procompetitive justification, alone defeats sanofi's motion. Moreover, the District Court erred in finding that there was no likelihood of anticompetitive effects. Sanofi's persistent monopoly share (82-92%) and [redacted], despite increased competition, provide ample basis to find a likelihood of anticompetitive effects. As this Court explained in *Brown University*, 5 F.3d at 668: "Market power, the ability to raise prices above those that would prevail in a competitive market, is essentially a 'surrogate for detrimental effects.'" (quoting *Indiana Fed'n of Dentists*, 476 U.S. at 460-61) (internal citations omitted); *accord Copperweld*, 467 U.S. at 768 (the Rule of Reason is an "inquiry into market power and market structure").

Nor could the District Court correctly avoid that conclusion on the grounds that: (1) the Lovenox Contracts were not "even exclusive"; (2) customers would not be cut off from supply if they did not comply with the market share restrictions; (3) Fragmin's and Arixtra's shares grew over time; (4) the Lovenox Contracts were terminable at will; and (5) there was no evidence that anyone

wanted to buy more Fragmin but was prevented from doing so by sanofi's conduct. *See* A86-89.

This Court twice has rejected the argument that contracts cannot be anticompetitive if they are not 100% "exclusive." In *ZF Meritor*, 696 F.3d at 289, the court held "*de facto* partial exclusive dealing" agreements anticompetitive even though they did not provide "total" foreclosure:

> "De facto partial exclusive dealing" accurately represents that an exclusive dealing claim does not require a contract that imposes an express exclusivity obligation, *Tampa Elec.*, 365 U.S. at 326; *Dentsply*, 399 F.3d at 193; *LePage's*, 324 F.3d at 157, nor a contract that covers 100% of the buyer's needs, *Tampa Elec.*, 365 U.S. at 328 ("[T]he competition foreclosed by the contract must be found to constitute a substantial share of the relevant market.").

Id. at 47 n.14; *accord United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) ("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)). These holdings reflect market realities, as shown by the proof here that sanofi's foreclosure of 68-84% of the market, rather than 100%, substantially harmed competition.

Relatedly, the observation that, during 2005-2010, Fragmin's and Arixtra's market shares grew slightly (A6325) does not immunize sanofi's

conduct. To the contrary, it shows that rival products were attractive enough to customers to grow somewhat despite sanofi's exclusionary conduct, and that, absent that conduct, they would have been able to benefit consumers more by pressuring price, increasing quantity and promoting consumer choice. In *ZF Meritor*, this Court explained just this -- that slowing a rival's growth through exclusionary practices harms consumer welfare and supports an antitrust claim:

> [S]uppose an established manufacturer has long held a dominant position but is starting to lose market share to an aggressive young rival. A set of strategically planned exclusive dealing contracts may slow the rival's expansion by requiring it to develop alternative outlets for its product, or rely at least temporarily on inferior or more expensive outlets. Consumer injury results from the delay that the dominant firm imposes on the smaller rival's growth.

696 F.3d at 271 (quoting P. Areeda, Antitrust Law ¶1802c at 64 (2d Ed. 2002)).

This result is not changed by the theoretical possibilities that hospitals could terminate sanofi's agreements on 30 days' notice, or might not suffer any loss of supply if they did not satisfy sanofi's market share requirements. A87-88. The hypothetical "option" of a hospital to walk away did not avert any of the actual anticompetitive effects discussed above; in "practical effect," sanofi's Lovenox Contracts and Systems Agreements were, as sanofi put it, "handcuffs," exclusive dealing arrangements that foreclosed a huge portion of the market from competitors and adversely affected price, quantity and consumer choice. *See*

Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 326-27 (1961) (referring three times in one paragraph alone to the "practical effect" of exclusionary conduct); *ZF Meritor*, 696 F.3d at 282 ("there was sufficient evidence from which a jury could infer that, although the LTAs did not expressly require the OEMs to meet the market penetration targets, the targets were as effective as mandatory purchase requirements").

Nor should the practical effect of sanofi's conduct be surprising, when each day the hospitals were faced with the same sanofi monopoly power, and the same deceptive attacks on rival products, that led them to enter into the contracts in the first place -- a conclusion that is confirmed by a history lacking any significant number of contract terminations. *See* A5601; *Dentsply*, 399 F.3d at 193-94 (theoretical ability of dealers to end their exclusive relationship at any time was irrelevant in light of Dentsply's market power and barriers to entry).

Finally, as noted above, the District Court was flat wrong in stating that there was "no evidence" that any hospital wanted to purchase more Fragmin but was prevented from doing so by sanofi's conduct. A88. Eisai adduced extensive evidence of such effects (*see, e.g.*, A3403-30 (Eisai's Rule 56.1 Statement at ¶¶70, 79, 96, 101, 107-23, 125-26, 165)), and submitted an Appendix of examples to the District Court. Dkts. 345 (Redacted), 346 (Sealed) (Eisai's Reply Brief to Motion for Partial Summary Judgment, Appendix at 1-4). Nor, in

any event, was such anecdotal evidence required, given Eisai's extensive expert evidence. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 116 n.11, 124-25 (1969) (affirming antitrust violation based on expert evidence comparing United States and Canadian market shares, and despite lack of evidence of specific lost sales).

The District Court thus erred in holding that Eisai's claims do not survive summary judgment under the Rule of Reason.

V. The District Court Erred In Granting Sanofi Summary Judgment for Lack of Antitrust Injury To Eisai

The District Court also erred in holding that Eisai had not shown that it suffered antitrust injury. A82-84. The court tried to support its conclusion by noting the increase in Fragmin's market share during 2005-2010. *See* A82-83. The question here, however, is not whether Fragmin's share grew a bit despite sanofi's anticompetitive conduct, but whether Eisai -- with its quality product, lower pricing and vigorous promotional efforts -- would have done better but for that illegal conduct. *See ZF Meritor*, 696 F.3d at 289 (antitrust injury follows where a defendant's conduct unlawfully forecloses a substantial share of the market, which otherwise would have been available for rivals); *LePage's*, 324 F.3d at 165 (plaintiff may pursue recovery by measuring would have happened 'but for' the defendant's unlawful activities). As described *supra* at 32, but for sanofi's anticompetitive conduct Eisai would have sold more Fragmin, potentially accrued

greater cost economies of scale, and earned greater profits. *See* A6116-47 (Economides Report); A4782 (Rosenblatt Report); A3935-46 (Elhauge Report).

The court below also suggested that Eisai could have avoided any injury by further reducing its price by some unidentified amount, and thereby averted any lost unit sales. A80, 83-84. On its face, this speculation violates Rule 56, ignoring, *inter alia*, sanofi's foreclosure of Eisai from 68-84% of the LTC market. A3925-46. Moreover, this assertion shows that the District Court misapprehended the nature of antitrust injury. Even if low enough prices hypothetically could have allowed Eisai to avoid *any* lost unit sales, Eisai still would have suffered antitrust injury because it would have been less profitable than it would have been but for sanofi's illegal acts. *ZF Meritor*, 696 F.3d at 288-89 (upholding finding of antitrust injury despite conclusion that plaintiffs' prices were on average higher than defendant's); *see Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 323 (1971) (upholding antitrust damages award for the "difference between the profits [plaintiff] actually made and the profits it would have made in a free market during the four years").

The court also made numerous other findings in favor of sanofi in disregard of Rule 56. *See supra* at 50-51. Indeed, it explicitly engaged in conjecture on sanofi's behalf, stating that, "as Sanofi rightly points out, there are

numerous reasons why Fragmin® *may* have underperformed in relation to Lovenox® . . . ." A78 (emphasis added).

In any event, Eisai does not need to establish that the defendant's antitrust violation was the only cause of injury it suffered, just a "material cause." *Zenith*, 395 U.S. at 114 n.9 (1969) ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury . . . ."). And, on summary judgment, plaintiff does not need to prove such causation, only show that it is a triable issue. *See Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 484 (3d Cir. 1998) (evidence that the defendants' alleged conspiracy resulted in lost sales "is enough by itself to satisfy [plaintiff's] burden on causation for the purposes of summary judgment"). Eisai has done so here.

VI. The District Court Erred In Denying Eisai's Pending Motions As Moot

The District Court denied Eisai's pending motions as moot. A47; Dkts. 255, 257, 259, 261, 291. Since this Court should reverse the grant of summary judgment to sanofi, Eisai's motions are not moot, and this Court should reinstate them for decision by the District Court. *See, e.g., Legal Assistance for Vietnamese Asylum Seekers v. Dept. of State, Bureau of Consular Affairs*, 74 F.3d 1308, 1312 (D.C. Cir. 1996).

VII. The District Court Abused Its Discretion In Denying Discovery Concerning A Previous Antitrust Case Challenging Sanofi's Lovenox Payoffs

The court below abused its discretion in holding that production of the prior deposition transcripts (and exhibits thereto) of witnesses who testified in both this case and the OSS Antitrust Case was "irrelevant and . . . unduly burdensome." Dkt.162 at 17. The court offered no explanation as to how production of such existing materials could pose an undue burden on sanofi. *See Guiden v. Leatt Corp.*, No. 5:10-CV-00175, 2013 WL 4500319, at *6 (W.D. Ky. Aug. 21, 2013) (not overly burdensome to produce deposition transcripts and expert reports that "already exist").

Nor is there any basis to conclude that the testimony and exhibits of witnesses in the prior antitrust lawsuit -- in which one predecessor of sanofi sued another, challenging similar Lovenox market-share contracts -- could not lead to the discovery of relevant evidence. The OSS Antitrust Case occurred well within the discovery period allowed by the District Court (back to 1998). *See* Dkt.141 at 1-2. And, plaintiffs in both cases claimed injury to competition and to themselves in the LTC market. A487. The testimony of witnesses in a case in which sanofi's predecessor urged that such conduct is anticompetitive could easily be relevant, and of interest to a jury, with respect to sanofi's efforts to deny that conclusion now. *Cf. ZF Meritor*, 696 F.3d at 300 (private antitrust suits promote the public interest and foster competition).

CONCLUSION

The Court should (1) reverse the District Court's award of summary judgment to sanofi; (2) reverse the District Court's denial of Eisai's pending motions as moot; (3) reverse the District Court's denial of Eisai's motion to compel production of the requested materials from the OSS Antitrust Case; and (4) remand the case to the District Court for trial.

Dated: July 30, 2014

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with Fed. R. App. P. 28.1(e)(2) and 32(a)(7)(B). It contains 13,967 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.

I further certify that the text of the electronic brief and hard copies are identical.

Dated: July 30, 2014

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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 and fourteen volumes of the Joint Appendix 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.

I further certify that I caused seven (7) copies of the redacted and unredacted brief and four (4) copies of the unsealed Volumes I and II and sealed Volumes III through XIV of the joint appendix to be delivered by overnight carrier to the Clerk of the Court at the following address:

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