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

UNSEALED JOINT APPENDIX
VOLUME I OF XIV
Pages A1 to A111

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EISAI INC.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Case No. 3:08-cv-4168 (MLC/DEA)

EISAI INC.,

Plaintiff,

v.

SANOFI-AVENTIS, U.S., LLC, AND SANOFI-AVENTIS, U.S., INC.,

Defendants.

NOTICE OF APPEAL

Plaintiff, Eisai Inc., hereby gives notice that it appeals to the United States Court of Appeals for the Third Circuit from: the Order & Judgment (ECF No. 412) entered in this action on March 28, 2014, which, without limitation, granted Defendants' motion for summary judgment on liability issues (ECF No. 245) and denied as moot Eisai's motion for partial summary judgment (ECF No. 261) and all other pending motions; the Order (ECF No. 202) issued in this action on April 16, 2012, which denied Plaintiff's appeal of a Memorandum Opinion and Order (ECF No. 183) of the Magistrate Judge issued on February 27, 2012, which denied Plaintiff's motion to compel certain discovery from Defendants, as well as the

aforementioned Memorandum Opinion and Order (ECF No. 183) of the Magistrate Judge issued on February 27, 2012 ; and all other judgments and orders adverse to Plaintiff in this case. *See* Fed. R. App. Proc. 3.

Respectfully submitted,

/s/

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4836-3421-0586, v. 1

CERTIFICATION OF SERVICE

I do hereby certify that on this date, a copy of Plaintiff Eisai Inc.'s Notice of Appeal was electronically filed with the United States District Court for the District of New Jersey and served via overnight mail on:

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The Honorable Mary L. Cooper, U.S.D.J.
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I certify that the foregoing statements by me are true. I am aware that if any of the foregoing statements made by me is willfully false, I am subject to punishment.

COUGHLIN DUFFY LLP
Attorneys for Plaintiff
Eisai Inc.

By: */s/ Timothy I. Duffy*
Timothy I. Duffy

Dated: April 23, 2014

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI INC., Plaintiff, v. SANOFI-AVENTIS U.S., LLC, et al., Defendants.	CIVIL ACTION NO. 08-4168 (MLC) **ORDER & JUDGMENT**

For the reasons stated in the Court's Memorandum Opinion dated March 28, 2014, **IT IS** on this 28th day of March, 2014, **ORDERED** that the motion for summary judgment as to liability issues by Defendants, Sanofi-Aventis U.S., LLC and Sanofi-Aventis, U.S., Inc. (collectively "Sanofi") (dkt. entry no. 245) is **GRANTED** as to all claims asserted against Sanofi; and it is further

ORDERED that the motion for summary judgment as to damages issues and/or statute of limitations by Sanofi (dkt. entry no. 246) is **DENIED WITHOUT PREJUDICE AS MOOT**; and it is further

ORDERED that the motion for partial summary judgment by Plaintiff, Eisai Inc. ("Eisai") (dkt. entry no. 261) is **DENIED WITHOUT PREJUDICE AS MOOT**; and it is further

ORDERED that the motion for sanctions by Sanofi (dkt. entry no. 252) is **DENIED WITHOUT PREJUDICE AS MOOT**; and it is further

ORDERED that the motion to exclude the testimony of Nicholas Economides by Sanofi (dkt. entry no. 234) is **DENIED WITHOUT PREJUDICE AS MOOT;** and it is further

ORDERED that the motion to exclude the testimony of Einer Elhauge by Sanofi (dkt. entry no. 236) is **DENIED WITHOUT PREJUDICE AS MOOT;** and it is further

ORDERED that the motion to exclude the testimony of Stephen Fredd by Sanofi (dkt. entry no. 238) is **DENIED WITHOUT PREJUDICE AS MOOT;** and it is further

ORDERED that the motion to exclude the testimony of Tony Casanova, Stephen Melvin, Ronald Sacher, and Sheila Weiss Smith by Sanofi (dkt. entry no. 240) is **DENIED WITHOUT PREJUDICE AS MOOT;** and it is further

ORDERED that the motion to exclude the testimony of Jerry A. Rosenblatt by Sanofi (dkt. entry no. 242) is **DENIED WITHOUT PREJUDICE AS MOOT;** and it is further

ORDERED that the motion to preclude the expert opinion of George P. Sillup by Eisai (dkt. entry no. 255) is **DENIED WITHOUT PREJUDICE AS MOOT;** and it is further

ORDERED that the motion to preclude the expert opinion of Harvey R. Kelly by Eisai (dkt. entry no. 257) is **DENIED WITHOUT PREJUDICE AS MOOT;** and it is further

ORDERED that the motion to preclude the expert opinion of Jerry Hausman by Eisai (dkt. entry no. 259) is **DENIED WITHOUT PREJUDICE AS MOOT**; and it is further

ORDERED that the motion to strike the declaration of Jerry A. Hausman by Eisai (dkt. entry no. 291) is **DENIED WITHOUT PREJUDICE AS MOOT**; and it is further

ADJUDGED that judgment is entered on the 15 U.S.C. § 2 claims for willful and unlawful monopolization and attempted monopolization in contravention of Section 2 of the Sherman Act against Eisai and in favor of Sanofi; and it is further

ADJUDGED that judgment is entered on the 15 U.S.C. § 14 claims for de facto exclusive dealing in violation of Section 3 of the Clayton Act against Eisai and in favor of Sanofi; and it is further

ADJUDGED that judgment is entered on the 15 U.S.C. § 1 claims for unreasonable restraint of trade in violation of Section 1 of the Sherman Act against Eisai and in favor of Sanofi; and it is further

ADJUDGED that judgment is entered on the N.J.S.A. 56:9-3, and 56:9-4 claims for violations of the New Jersey Antitrust Act against Eisai and in favor of Sanofi; and it is further

ORDERED that the Clerk of the Court designate this action as **CLOSED.**

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI INC.,

Plaintiff,

v.

SANOFI-AVENTIS U.S., LLC, et al.,

Defendants.

CIVIL ACTION NO. 08-4168 (MLC)

MEMORANDUM OPINION

COOPER, District Judge

This antitrust dispute concerns parties marketing certain brand-name pharmaceuticals used to treat blood clots in patients with deep vein thrombosis ("DVT"). Specifically, Eisai Inc. ("Eisai"), the plaintiff, marketed Fragmin®, an anticoagulant drug product known as a low molecular weight heparin ("LMWH"). The defendants, Sanofi-Aventis U.S., LLC, and Sanofi-Aventis, U.S., Inc. (collectively "Sanofi"), marketed Lovenox®, another LMWH. Eisai sued Sanofi based on Sanofi's alleged anticompetitive and monopolistic conduct in its marketing of Lovenox®. Eisai's claims primarily relate to Sanofi's use of loyalty-discount contracts. Eisai asserts that this conduct violates § 1 and § 2 of the Sherman Act, § 3 of the Clayton Act, and New Jersey state law. Before the Court is Sanofi's motion for summary judgment as to its liability under the antitrust laws. (Docket entry no. ("dkt.") 245, Sanofi's

Notice of Mot. for Summ. J. on Liability Issues.) For the reasons that follow, this motion is granted in its entirety.[1]

I. UNDISPUTED FACTS

A. Overview of the Drugs

The undisputed facts are based on the summary judgment record following the close of discovery. DVT, a condition in which a blood clot develops in the body's veins, can result in a pulmonary embolism ("PE") if the clot travels to the lungs. (Dkt. 287, Pl.'s Response to Defs.' Rule 56.1 Statement at ¶ 1.)[2] LMWHs are used in the treatment and prevention of DVT. (Id. at ¶ 2.) Lovenox®, marketed in the United States by Sanofi, and Fragmin®, marketed in

[1] There are several other motions pending on the Court's docket. (See dkt. 234, 236, 238, 240, 242, 246, 252, 255, 257, 259, 261, 291.) These include: a motion for summary judgment on damages, a cross motion for summary judgment by Eisai, numerous motions to exclude expert testimony, a sanctions motion, and a motion to strike an expert's declaration. Given the resolution of this motion, these other pending motions need not be addressed.

[2] Eisai's response to Sanofi's statement of undisputed material facts includes Sanofi's original statement, Eisai's response thereto, and citations to corresponding exhibits in the summary judgment record. (See dkt. 287; dkt. 249, Defs.' Rule 56.1 Statement.)

the United States by Eisai, are two such LMWHs. (Id. at ¶¶ 3, 4.)[3] The relevant period for the Court's analysis in this case is the time during which Eisai was selling Fragmin® in the United States and Sanofi was using loyalty-discount contracts to sell Lovenox®, September 27, 2005 to July 25, 2010. (Dkt. 250, Walsh Decl., Ex. 42, Expert Report of Professor Nicholas Economides dated 9-10-12 ("Economides Report") at ¶ 10; see also id. at Ex. 35, Expert Report of Professor Einer Elhauge dated 9-10-12 ("Elhauge Report") at ¶ 8 n.1.)[4]

Innohep® is another LMWH that was manufactured by a company known as LEO Pharma Inc. and sold in the United States from 2000 to

[3] Fragmin® was initially manufactured and sold by Pharmacia Corp. However, in 2003, Pfizer Inc. ("Pfizer") acquired Pharmacia Corp., thus succeeding to Fragmin®'s ownership. (Dkt. 287 at ¶ 4.) On September 27, 2005, Pfizer entered into "the Supply, Distribution and Profit Sharing Agreement" ("the 2005 Agreement") with Eisai. (Id. at ¶¶ 4, 67, 69.) In this 2005 Agreement, Pfizer granted Eisai, for the seven-year term of the agreement, "the exclusive right, even as to Pfizer, . . . to purchase and resell (for Eisai's own account), accept orders for, and to distribute" and "to market, promote and detail" products under the Fragmin® trademark in the United States and Puerto Rico. (Dkt. 250, Walsh Decl., Ex. 5, 2005 Agreement at 11, 40.) The 2005 Agreement was subsequently extended to March 2015. (Dkt. 287 at ¶ 75.)

[4] Motions to exclude the expert testimony of Professor Economides and Professor Elhauge are pending concurrently with this motion for summary judgment. (See dkt. 234; dkt. 236.) The Court's citation to these experts and their reports in this memorandum opinion is not an indication of the Court's inclinations as to those motions to exclude the experts' testimony. Professor Economides and Professor Elhauge are Eisai's experts, and as the Court views the record in a light most favorable to Eisai, the Court relies on some portions of their reports and testimony for the purposes of this motion.

2011. (Dkt. 287 at ¶¶ 6, 140.) It was approved by the United States Food & Drug Administration ("FDA") for "the treatment of acute symptomatic [DVT] with or without [PE] when administered in conjunction with warfarin sodium." (Dkt. 287-1, Duffy Certif., Ex. 7, Innohep Approval Letter, NDA 20-484 at 1.)

Arixtra®, while not an LMWH, is "a synthetic pentasaccharide, injectable anticoagulant" that was approved by the FDA in 2001. (Dkt. 287 at ¶ 5.) From 2005 to 2010, Arixtra® was sold in the United States by a company known as GlaxoSmithKline. (Id.) Arixtra® has six indications:

> prophylaxis of [DVT], which may lead to [PE]:
> - in patients undergoing hip fracture surgery, including extended prophylaxis;
> - in patients undergoing hip replacement surgery;
> - in patients undergoing knee replacement surgery;
> - in patients undergoing abdominal surgery who are at risk for thromboembolic complications.
>
> . . . the treatment of acute [DVT] when administered in conjunction with warfarin sodium.
>
> . . . the treatment of acute [PE] when administered in conjunction with warfarin sodium when initial therapy is administered in the hospital.

(Dkt. 250, Ex. 20, FDA Prescribing Information for Arixtra® at 3; see also dkt. 287 at ¶ 129.)

Lovenox®, which was approved by the FDA in 1993, is indicated:

> for the prophylaxis of [DVT], which may lead to [PE]:
> - in patients undergoing abdominal surgery who are at risk for thromboembolic complications.
> - in patients undergoing hip replacement surgery, during and following hospitalization.

- in patients undergoing knee replacement surgery.
- in medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.

. . . for:

- the **inpatient treatment** of acute [DVT] **with or without [PE]**, when administered in conjunction with warfarin sodium.
- the **outpatient treatment** of acute [DVT] **without [PE]** when administered in conjunction with warfarin sodium.

. . . for the prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin.

. . .

Lovenox, when administered concurrently with aspirin, has been shown to reduce the rate of the combined endpoint of recurrent myocardial infarction or death in patients with acute ST-segment elevation myocardial infarction (STEMI) receiving thrombolysis and being managed medically or with percutaneous coronary intervention (PCI) [("the Unique Cardiology Indication")].

(Dkt. 250, Ex. 1, FDA Prescribing Information for Lovenox® at 2 (internal cross references omitted); see also dkt. 287 at ¶¶ 3, 16-24.) Sanofi asserts that Lovenox® has a total of eight indications, but, by Eisai's count, Lovenox® has seven. (Dkt. 287 at ¶ 16.)

Fragmin® has five FDA-approved indications:

. . . prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin therapy.

. . . prophylaxis of [DVT], which may lead to [PE]:

- In patients undergoing hip replacement surgery;
- In patients undergoing abdominal surgery who are at risk for thromboembolic complications;

> - In medical patients who are at risk for thromboembolic complications due to severely restricted mobility during acute illness.
>
> . . . extended treatment of symptomatic venous thromboembolism (VTE) (proximal DVT and/or PE), to reduce the recurrence of VTE in patients with cancer [("the Cancer Indication")].
> . . .
>
> FRAGMIN is not indicated for the acute treatment of VTE.

(Dkt. 250, Ex. 10, FDA Prescribing Information for Fragmin® at 2 (internal cross references omitted); see also dkt. 287 at ¶¶ 51-55, 59.) While Fragmin® was initially approved by the FDA for some uses in 1994, Fragmin® received FDA approval for the Cancer Indication in 2007. (Dkt. 287 at ¶¶ 4, 59.)

Lovenox® has more FDA-approved indications than Arixtra®, Innohep®, or Fragmin®. (Id. at ¶ 25.) Arixtra® also has more indications than Fragmin®. (Id. at ¶ 66.)

As the foregoing illustrates, Arixtra® and the LMWHs -- Lovenox®, Fragmin®, and Innohep® -- all had indications that related to the treatment and/or prevention of DVT. According to Sanofi, some individuals in the medical field view unfractionated heparin ("UFH") and warfarin as serving a similar purpose to Arixtra® and the LMWHs, i.e., treatment and prevention of blood clots and DVT. (Id. at ¶ 7.)

Generic versions of Lovenox® and Arixtra® were approved by the FDA in July 2010 and July 2011 respectively. (Id. at ¶¶ 8-9.) In the United States, no generic version of Fragmin® is available.

(Id. at ¶ 10.) Innohep® was voluntarily removed from the market in 2011 by LEO Pharma Inc. following a contamination recall. (Id. at ¶¶ 6, 142.)

It is undisputed that during the relevant period, as between Lovenox®, Arixtra®, Fragmin®, and Innohep® --- the Lovenox® Therapeutic Class ("LTC") -- Lovenox® has enjoyed the greatest market share.[5] Specifically, during the relevant period, Lovenox® had an LTC market share of 81.5% to 92.3%. (Economides Report at ¶¶ 10, 12; see also Elhauge Report at ¶ 1; dkt. 247, Sanofi Br. in Support of Mot. for Summ. J. ("Sanofi Br.") at 18.)

B. Sale of Drugs to Hospitals

1. Sanofi's Marketing of Lovenox®

The focus of Eisai's claims against Sanofi is Sanofi's marketing of Lovenox® to hospitals.

a. Group Purchasing Organizations and Wholesalers

The United States had about 6,000 hospitals in 2006, and most were members of a group purchasing organization ("GPO"). (Dkt. 287 at ¶ 12.) A GPO is an organization comprised of hospital members "that uses the aggregated purchase power of its individual members to negotiate contracts and discounts on drug products from pharmaceutical manufacturers." (Id. at ¶ 11.) Many GPOs had contracts for the purchase of Lovenox®, Arixtra®, and Fragmin®

[5] The Court refers to these four drugs collectively as the "LTC market" or the "LTC drugs" for short because this is the name used by Sanofi to describe these drugs collectively. (Dkt. 287 at ¶ 29.)

available to their member hospitals. (Id. at ¶ 13.) Sanofi does not sell Lovenox® directly to hospital customers. Rather, it sells Lovenox® to pharmaceutical wholesalers, who ultimately distribute the product to the hospitals. (Id. at ¶¶ 14-15.) These wholesalers sell Lovenox® to the hospital at the price negotiated by the GPO. (Dkt. 250, Ex. 21, Brunken Decl. at ¶ 6.)

b. Sanofi's Market-Share Discounts

Beginning in September 2005, Sanofi began offering its "Lovenox® (enoxaparin sodium) Acute Contract Value Program" ("Lovenox® Program" or "Lovenox® contract") to GPOs in the form of contracts. (Dkt. 287 at ¶ 26.) The Lovenox® Program provided for "discounts" off the wholesale acquisition cost ("WAC"), also known as the list price, of Lovenox® based on the amount of Lovenox® purchased by a customer. (Id.) These discounts were calculated based on both the customer's volume of Lovenox® purchases and a market-share calculation. (Id. at ¶ 28; see also dkt. 250, Ex. 23, First Addendum to Premier Purchasing Partners, L.P./sanofi-aventis U.S. LLC Group Purchase Agreement.) The contracts defined the market share as "the rolling four (4) months of Units of Lovenox® purchased" by the customer "divided by the rolling four (4) months of Units of all products within the" LTC market, defined as Lovenox®, Fragmin®, Arixtra®, and Innohep®, that were purchased by the customer. (See dkt. 250, Ex. 23 at 9.) Greater discounts were

offered where customers purchased higher volumes and higher market shares of Lovenox®. (See dkt. 287 at ¶ 30.)[6]

The Lovenox® Program generally treated a GPO's hospital members as the individual customers for the purposes of determining the volume and market share. However, if certain criteria were satisfied, multiple hospitals could be classified as a system, which would result in their volumes being aggregated and their market shares being measured collectively for the purposes of determining system discounts. (Id. at ¶ 31.)

The discount structure for individual hospital customers, as of June 16, 2008, is demonstrated in the following table:

	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%**

(Id. at ¶ 30.) As this table shows, the discounts off the wholesale price for individual hospital customers ranged from 1% to

[6] Eisai takes issue with the use of the term "discount," asserting instead that the Lovenox® Program provided for the imposition of a "penalty" for failing to meet the specified volume and market-share levels. (See, e.g., dkt. 287 at ¶ 26.) For the ease of the reader, the Court will use the word "discount," as that is the chosen nomenclature in the contracts.

30%. For hospitals treated as a system, the discount structure is depicted in the following table:

LTC 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%**

(Id. at ¶ 32.)

It is undisputed that between September 2005 and August 2010, Sanofi did not sell Lovenox® to hospitals at a price that was below Sanofi's cost even after the discounts were applied. (Id. at ¶ 45.) Moreover, whether described as a discount or a penalty program, it is undisputed that the Lovenox® Program did not contractually obligate customers to purchase any amount of Lovenox® from Sanofi. (See id. at ¶ 34.) The consequence of not achieving a certain volume or market-share level was that the customer would not earn the corresponding discount. (See id. at ¶ 35.) The Lovenox® Program contracts were also terminable at any time by any party for any reason upon thirty days' written notice. (Id. at ¶ 41.) Terminating the contract meant that a member hospital would not receive the tiered discounts on purchases of Lovenox®, but instead, the hospital could purchase "off contract" from wholesalers at the wholesale price. (Id. at ¶¶ 42-43.) Sanofi ended the Lovenox® Program when the first generic came on the market in July 2010. (Id. at ¶ 44.)

c. Formulary Access Clauses

In addition to these structured discounts, the Lovenox® Program contracts contained Formulary Access Clauses that Eisai asserts are part of the overall picture of anticompetitive conduct by Sanofi. A "formulary" is a health-care organization's (such as a hospital) "continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health." (ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System, American Society of Health-System Pharmacists, 172, http://www.ashp.org/DocLibrary/BestPractices/FormGdlPTCommFormSyst.aspx.) The hospital "establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population." (Id.) Generally, a hospital's pharmacy and therapeutics committee ("P&T Committee"), which is comprised of doctors and health-care providers from various disciplines, manages a formulary and makes decisions -- based on factors such as safety, efficacy, and cost -- regarding what treatments and medications (such as LMWHs) are "on formulary" and whether certain medications should be added or deleted from the formulary. (See id. at 172-74; dkt. 287 at ¶¶

145, 146.)[7] In essence, a formulary "determines what treatments are available for use at a particular hospital." (Dkt. 287 at ¶ 144.)

It is possible, at least in some hospitals disclosed in the record, for a physician to prescribe anticoagulants that are not on formulary. (See id. at ¶ 157.) Additionally, many hospitals have multiple drugs with similar indications on formulary. Hospitals may have more than one anticoagulant on formulary, and there are several examples in the record where a hospital's formulary contained multiple LTC drugs, such as Lovenox® and Fragmin®. (See id. at ¶¶ 152-56.)

Hospitals may also do a "therapeutic interchange," meaning that one drug or treatment is substituted 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). (See id. at ¶ 170.) Thus, following a therapeutic interchange, if a physician wrote a prescription for a drug that was no longer the preferred or exclusive drug, a hospital would do one of two things. Either (a) the pharmacy would automatically substitute that drug "with the equivalent dose with the correct indication" of the drug that was preferred or exclusive following

[7] Eisai generally agrees, but explains that, with respect to hospitals that are members of a system and bound by a Lovenox® systems contract, P&T Committees themselves are not the decision makers. Instead, the decision makers are the corporate officers at the system level. (See dkt. 287 at ¶¶ 145, 146.)

the therapeutic interchange (dkt. 250, Ex. 47, Dep. of Michael Edwards at 38), or (b) "the pharmacy department would notify the physician" and ask whether "he would like to use the medication that was on our therapeutic interchange." (Id. at Ex. 41, Dep. of Monty Person at 71-72.)

Against this backdrop, the Court can evaluate the Formulary Access Clauses. The Formulary Access Clauses in the Lovenox® Program contracts required members to provide "unrestricted formulary access for Lovenox for all Lovenox FDA-approved indications, as noted in the Lovenox prescribing information, in such manner that Lovenox is not more restricted or limited in its availability than any other product in the [LTC]." (Dkt. 287 at ¶ 36.) Moreover, the clause dictated that members of the program

> shall not impose any restrictions or limitations 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 is permitted for other pharmaceutical manufacturer sales representatives (except in situations where there may have been a violation of [a member's] policies).

(Id.) Noncompliance with this provision did not inhibit the member's access to Lovenox®, but instead caused the discount to immediately drop to the lowest discount tier at 1%. (See id. at ¶ 38.) The clause also did not prohibit a member from putting other LTC drugs on its formulary; rather, it prevented a member from

favoring another LTC drug over Lovenox® on the formulary. (See id. at ¶ 36.) The clause 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.

d. Evidence of Sanofi's Intent

Internal Sanofi documents reveal that Sanofi's intent and strategy in marketing Lovenox® was to remain the market leader amongst the LTC drugs and to inhibit the advancement of competitors. For example, Sanofi's marketing plan for 2001 to 2005 listed as objectives, "[m]aximize all contracting opportunities where appropriate to block competitive intrusion" and "[b]lunt launch success of competitive brands [i]n all managed market segments." (Dkt. 262-4, Duffy Certif., Ex. 49, Lovenox® 2001 Marketing Plan.) The marketing plan acknowledged that Lovenox®, with a market share of greater than 95%, was the market leader within the United States. (Id.) Another Sanofi document addressing the three-year strategy for Lovenox® from around 2000 listed, as part of the Lovenox® strategy, "Create Competitive Barriers" and "Leverage Leadership Position." (Id. at Ex. 46, 3-Year Strategy – Kick-off Meeting, Summary Notes for April 7, 2000 Discussion.)

Sanofi's strategy to remain the market leader included use and enforcement of its contractual market-share discounts. For example, a goal of the 2001 Marketing Plan was to "[i]ncrease the

Price of Poker," which involved leveraging Lovenox®'s Unique Cardiology Indication. Specifically, the plan stated, "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 have a spill-over effect for other indications." (Id. at Ex. 49.) A Sanofi document dated October 20, 2010 stated, "Contracting is best used" -- inter alia -- to "[c]reate obstacles for competitive products (e.g. Lovenox discount cliff strategy)." (Id. at Ex. 45, Contracting Strategies.) A presentation dated June 2001 described, as a contract strategy, "[t]ake price increase on Lovenox (ASAP) across the non-contracted market segments to strengthen current market share contract penalty for non-compliance." (Id. at Ex. 55, AT Regional Directors/Area Managers Meeting, June 11-15, 2001.)

Sanofi's strategy also included discussions of limiting individual competitors from entering the market and gaining market share. A presentation entitled "Pre-empting Launch of Arixta [sic]" listed as a strategic imperative to "[t]rain representatives to plant land mines to Arixta [sic] use" and listed as a supporting tactic, "[i]mplement aggressive market share driven contract to limit Arixta [sic] use." (Id. at Ex. 48, Pre-empting Launch of Arixta [sic].) An internal Sanofi letter dated August 6, 2010, which was actually after the end of the relevant period and after the entry of the generic version of Lovenox® in the market,

referenced getting "sole source access" and stated "we need to get in front of prescribers and sell against UFH, Fragmin and Arixtra." (Id. at Ex. 33, Letter from Mindy Duffy to Mary Roseman and others dated 8-6-10.) The letter also referred to the Lovenox® contracts as "handcuffs." (Id.)

e. Selling Tactics of Sanofi Sales Representatives

Sanofi was active in promoting Lovenox®. Sanofi had a sales force consisting of, at times during the relevant period, over 850 sales representatives. (Id. at ¶ 46.) Moreover, according to Sanofi's documents, Sanofi spent (1) over $1.6 billion on its sales force, marketing, and promotion of Lovenox® and (2) over $175 million on Lovenox® research and development. (Id. at ¶¶ 47-48.)

Eisai takes issue with some of the conduct of Sanofi sales representatives during the relevant period. Specifically, Eisai asserts, inter alia, that Sanofi aggressively enforced the market-share condition of the Lovenox® Program and that Sanofi sales representatives distributed misleading information about Eisai and Fragmin®. (Dkt. 1, Compl. at ¶ 71.) The Court will detail some, but not all, of the examples provided by Eisai in the record.

i. Aggressive Enforcement

In approximately 2007, Holmes Regional Medical Center ("Holmes Regional") and the hospital system to which it belonged, Health First Hospital System ("Health First"), conducted a therapeutic interchange from Lovenox® to Fragmin®. (Dkt. 287 at ¶ 193; dkt.

287-1, Ex. 10, Email chain between Ingrid Olsen and Chris Bitterman dated Sept. 2007.) On September 17, 2007, a Sanofi Regional Sales Director sent an email to a Sanofi contract administrator, directing her to drop the contractual discount for Health First and Holmes Regional from "Tier 8 – 24% to Tier 1 – 1% ASAP" because "Health First is in violation of the Lovenox contract." (Dkt. 287-1, Ex. 10.) In May 2008, Sanofi representatives had a meeting at Holmes Regional. A Sanofi representative believed that the meeting "could be the first step in reversing the [therapeutic interchange] at this system." (Id. at Ex. 11, Email chain between Jack Griffin and Mike Holmes dated May 2008.) Documents from September 2008 and May 2009 reveal that Sanofi was aware that its promotional efforts had been viewed negatively, at least with regard to Holmes Regional. (See id. at Ex. 12, Email from Hedy Kent to Karen Smith, Ann Peterson, and Courtney Peikes dated 9-5-08; id. at Ex. 14, Email chain between Kenneth Tustin, Kathy Weiss, and others dated May 2009 (Health First's system director warned another administrator who was considering a therapeutic interchange away from Lovenox® to be prepared because "Sanofi Aventis will play very dirty").)

Another example is Savoy Medical Center ("Savoy"), which is part of the HCA Hospital System. (Dkt. 287 at ¶ 198.) In approximately 2004 or 2005, Fragmin® was the preferred drug on Savoy's formulary and was used for the majority of its LMWH needs.

(Id. at ¶¶ 199-200.) Savoy's Director of Pharmacy, Monty Person, testified that "I got a lot of conversations saying that I was going to hurt HCA by not using Lovenox," mainly from Sanofi. (Dkt. 250, Ex. 41 at 181.) He testified that Sanofi representatives "tried" to convince him to buy less Fragmin® than he wanted, "but it didn't sway [him] that much." (Id. at 184.) For example, Sanofi representatives would ask him how he could be "right" about his preference for Fragmin® over Lovenox® but every other hospital in the nation is "wrong". (Id. at 185.)

The record contains another example where Mountain View Hospital, which is also part of the HCA Hospital System, wished to conduct a therapeutic interchange from Lovenox® to Fragmin®. (Dkt. 287-1, Ex. 47, Email chain between Louis Rossi, Chris Clay, Glenn Harter, and others dated Jan. 2010.) When Sanofi found out, a Sanofi employee contacted a corporate officer of the HCA Hospital System to inform the officer of the risk of Mountain View Hospital's therapeutic interchange to the system's Lovenox® contract. (Id.) "HCA Pharmacy staff contacted Mountain View Pharmacy [and] requested an immediate change back to Lovenox." (Id.)

The Froedtert Health System, which included Froedtert Hospital and two other hospitals, purchased Lovenox® under a system contract whereby the LTC market share was calculated by aggregating all three hospitals in the system. (Dkt. 287 at ¶¶ 204, 207.) In

2009, Froedtert Hospital did a therapeutic interchange from Lovenox® to Fragmin®, but the other two hospitals in the system did not conduct the therapeutic interchange. (Id. at ¶¶ 206, 209.) Sanofi tried to prevent and reverse Froedtert Hospital's therapeutic interchange. An internal Sanofi email discussed the fact that a Froedtert Hospital representative was warned about the possible effects of the therapeutic interchange, including that if the hospital's market share dropped, the hospital would lose its Lovenox® discount, which could result in a net gain on cost, and that another hospital in the system would also lose the discount. (Dkt. 287-1, Ex. 18, Email chain between Dina Tanner, Bob Butler, Pete Shalback, Scott Lynn, and others dated 5-15-08.) Nonetheless, Sanofi was officially informed on June 18, 2009 that Froedtert Hospital was going through with the therapeutic interchange to Fragmin®. (Id. at Ex. 19, Email chain between Kevin Patrick, Matthew Hawes, and others dated 6-18-09.)

Sanofi did not desist in its efforts to bring Froedtert Hospital back to Lovenox®. On June 24, 2009, the Director of Pharmacy at Froedtert Hospital wrote to a Sanofi district sales manager complaining that a Sanofi sales representative that covers Lovenox® at a neighboring hospital was on site at Froedtert Hospital. The Director of Pharmacy stated, "I thought I was completely clear when I informed you of the P & T decision . . . to [convert] to Fragmin and my request for you not to counter

detail [hospital employees and staff] regarding this decision." (Id. at Ex. 20, Email chain between Todd Karpinski and Kevin Patrick dated June 2009.) He concluded, "If I continue to hear about Sanofi reps onsite speaking about Lovenox, I will work with our P & T chair to ban all Sanofi representatives from Froedtert Hospital." (Id.) Sanofi still did not give up. On July 20, 2009, the Director of Pharmacy emailed the same district sales manager indicating that the manager had violated his prior request. (Id. at Ex. 22, Email chain between Todd Karpinski, Kevin Patrick, and others dated July 2009.) Later, in September 2009, following the therapeutic interchange, Sanofi notified Froedtert Hospital of the "contract violation"; Sanofi dropped the hospital's discount from 30% to 1%, and the other two hospitals in the system were dropped from 30% to 18%. (Id. at Ex. 24, Letter from Patricia Adams to Todd Karpinski dated 9-16-09; id. at Ex. 25, Letter from Tracey Jones to Todd Karpinski dated 9-16-09.)

Citrus Memorial Hospital ("CMH") conducted a therapeutic interchange from Lovenox® to Innohep® in 2005 based, in part, on cost-saving concerns. (Dkt. 287 at ¶¶ 219-20.) CMH administrators had hoped that CMH would not immediately lose the discount price on Lovenox® following the therapeutic interchange, but Sanofi, describing the therapeutic interchange as a "violation" of the Lovenox® contract, dropped CMH's discount down to 1%. (Dkt. 287-1, Ex. 34, Email chain between Mike Holmes, Scott Jacobs, and others

dated May 2006; id. at Ex. 39, Email chain between Tricia Baisley and Chris Bitterman dated 4-21-06.) A Sanofi email addressing the drop in discount rationalized that "[n]ot only does it send a message to those accounts but also to any other accounts who may be considering such actions." (Id. at Ex. 37, Email chain between Scott Jacobs, Chris Bitterman, and Mike Holmes dated Mar. 2006.)

Following the drop in CMH's discount, CMH's Director of Pharmacy informed Sanofi that its "decision to rescind any discount pricing on Lovenox is being viewed as a hostile measure by hospital administration and that [certain Sanofi employees] are no longer welcome within this account." (Id. at Ex. 34.) A Sanofi employee responded to CMH's Director of Pharmacy that the perceived hostility from Sanofi "is no different than the hostility one may perceive when an institution implements an unjustified therapeutic interchange." (Id.) CMH ultimately switched back to Lovenox® in December of 2008. (Id. at Ex. 42, Email chain between Scott Jacobs, Mike Holmes, Chris Bitterman, and others dated Oct. 2006; id. at Ex. 33, Email chain between Scott Jacobs, Mike Holmes, and others dated Dec. 2008.) CMH added Fragmin® to its formulary in 2010. (Dkt. 287 at ¶¶ 223-24.)

University Community Hospital ("UCH") conducted a therapeutic interchange from Lovenox® to Fragmin® and Arixtra® in 2008. (Id. at ¶¶ 211-13.) Sanofi took efforts to prevent and reverse the therapeutic interchange. Such efforts included approaching the

doctors as opposed to the P&T Committee about the potential effects of the switch. (See dkt. 287-1, Ex. 26, Email chain between Mitch Stallings and several colleagues dated 9-16-09 (A Sanofi employee stated in an email, "Please continue to work with the physicians we have quality relationships with to question the [therapeutic interchange] at UCH regarding outcomes, FDA labeling, 15 years of successful use of enoxaparin and the 'true costs of [therapeutic interchange].'").) Sanofi also enforced the consequences of "violations" of the Formulary Access Clause by dropping UCH's discount from tier 9 to tier 1, 1%. (See id. at Ex. 27, Email chain between Scott Jacobs and several colleagues dated 10-31-08.)

ii. Alleged Deception by Sanofi Sales Representatives

According to an article in CHEST Journal about anticoagulants, the LMWH medicines have a similar efficacy and safety profile. (See dkt. 262-4, Ex. 53, Antithrombotic and Thrombolytic Therapy 8th Ed.: ACCP Guidelines, CHEST Journal, June 2008 Supplement, at 464S-465S.) Despite this, the record reveals that Sanofi often presented Lovenox® as superior to the other LTC drugs. (See, e.g., id. at Ex. 111, Email from Jess Hales dated 7-28-02 ("as always we must sell our clinical superiority every day to maintain our market leader position"); id. at Ex. 112, Email from Gregory Tilton dated 6-12-08 (directing sales representatives working on new contracting to present "GOOD NEWS" to customers by saying, in part, "you want

to use the BEST LMWH that prevents the MOST hospital acquired DVTs and PEs. And you know the clinical evidence shows Lovenox to be the Best of them all").)

Examples in the record also show that when customers were considering using an LTC drug other than Lovenox®, Sanofi sales representatives used, and were instructed by superiors to use, "fear, uncertainty, and doubt" ("FUD") tactics. These tactics included initiating discussions with hospital administrators and physicians about the purported risks associated with the other LTC drugs and the potential for litigation accompanying the use of the other LTC drugs. (See, e.g., id. at Ex. 128, Sanofi Memo entitled "PharMerica Awarded Fragmin as Preferred LMWH" ("Ask your physicians, is it worth the additional risk for DVT and safety for approximately 7 days of therapy?"); id. at Ex. 123, 2006 Business (BATTLE) Plan (directing employees to make sure that doctors at hospitals conducting therapeutic interchanges away from Lovenox® "feel the 'FUD'"); id. at Ex. 137, Sanofi document entitled "To Error is Human; To Sue is American" ("'Seed of Doubt' and Litigation issues hit home with customers practicing medicine."); id. at Ex. 60, Sanofi document entitled "Therapeutic Interchange Roadmap" ("[I]t is up [to] the Representatives to spin this out of control to where the Pharmacist and MD's are scared to use a novel product."); id. at Ex. 121, Email from Gordon Vanscoy to Janet Haymes dated 5-15-02 (customer who had just reversed a therapeutic

interchange to Fragmin® stated "I saw firsthand that this was an issue of patient safety. Even though we unequivocally could have saved hundreds of thousands of dollars in the first year, the cost of switching, the concern for patient safety and the risk of litigation caused me to rethink our position."); id. at 69, Email from Kathleen Macchio dated 12-18-09 (directing sales representatives, in response to a threatened therapeutic interchange away from Lovenox®, to "[h]elp [your physician advocates and clinical pharmacists] understand what would be at risk if a switch is made to a competitor; poor outcomes, liability, etc. all translating in to higher costs to the patient, the hospital and the health care system".); id. at Ex. 146, Email between Joseph Canzolino, Donna Leslie, and others dated March 2009 (detailing a health-care provider's complaints that the Lovenox® representatives had been "threatening" providers and "visiting [them] to tell them they could be sued for using [Fragmin®] for non-FDA indications.").)

With respect to the previously discussed therapeutic interchange at Froedtert Hospital, the Director of Pharmacy there also testified that Sanofi representatives made things difficult for him in implementing the therapeutic interchange because, from what he heard, "they were misinforming physicians and nursing and case managers regarding the switch and why the switch was made." (Dkt. 250, Ex. 49, Dep. of Todd Karpinski at 88.) He asserted that

the representatives also provided misinformation regarding "the clinical efficacy of the drugs," "product availability," and "patient assistance." (Id. at 89.) The therapeutic interchange was not reversed, however, as a result of this conduct. (Id. at 88.)

Despite the allegedly misleading and inappropriate sales practices by Sanofi representatives, several hospital administrators testified that they would not rely on the statements of sales representatives without independently verifying that information before conducting a therapeutic interchange or making other treatment decisions. (See, e.g., id. at 78-79; id. at Ex. 47, at 154-55, 169-70; id. at Ex. 41, at 184-86; dkt. 287 at ¶¶ 217, 248.) Other administrators testified that they did not have issues with Sanofi's marketing practices. (See dkt. 287 at ¶¶ 231, 241.)

2. Eisai's Marketing of Fragmin®

Prior to Eisai obtaining commercial rights to Fragmin®, Pfizer had not actively promoted Fragmin® in the United States in the hospital setting from 2003 to 2005. (Id. at ¶ 78.) Eisai recognized, before beginning its marketing efforts, "that a longer period during which there was a lack of a sales force could be a risk in having a negative impact on the brand." (Id. at ¶ 82.) As Eisai prepared to enter the market, Eisai acknowledged that Lovenox® was already the market leader and that Lovenox® had more

indications that Fragmin®, strong cardiology support, and a large sales force. (Dkt. 250, Ex. 90, 2005 Fragmin Marketing Plan.) Eisai began promoting Fragmin® in the United States in 2006 with 113 sales associates, 14 district sales managers, 2 regional managers, and 1 field director. (Dkt. 287 at ¶ 79; see also dkt. 250, Ex. 7, Eisai Situational Analysis at 1.)

Despite the identified hurdles, Fragmin® ultimately experienced growth during the time it was marketed by Eisai. In various earnings calls between 2008 and 2010, Eisai representatives reported Fragmin®'s growth; in fact, 44% growth was reported on the Full Year 2010 call. (Dkt. 287 at ¶ 111.)

Between 2005 and 2010, like Sanofi, Eisai provided discounts ranging from 1% and 40% off the wholesale price of Fragmin® depending on the volume and LTC market share of a hospital's Fragmin® purchases. (Id. at ¶¶ 77, 116, 117.) The chart below is the tiered discount structure that Eisai offered to hospitals in 2009:

Package	WAC Price	Tier 1 0-4.99%Share	Tier 2 5-24.99% Share	Tier 3 25-50%Share	Tier 4 >50%Share
2,500 IU syringe NDC 00013-2406-91	$170.92	1% discount ($169.21)	5% discount ($162.37)	25% discount ($128.19)	40% discount ($102.55)
5,000 IU syringe NDC 00013-2426-91	$277.33	1% discount ($274.56)	5% discount ($263.46)	25% discount ($208.00)	40% discount ($166.40)
7,500 IU syringe NDC 00013-2426-01	$416.02	1% discount ($411.86)	5% discount ($395.22)	25% discount ($312.02)	40% discount ($249.61)
10,000 IU syringe NDC 00013-5190-01	$554.68	1% discount ($549.13)	5% discount ($526.95)	25% discount ($416.01)	40% discount ($332.81)
10,000 unit/mL 9.5 mL MDV	$476.74	1% discount ($471.97)	5% discount ($452.90)	25% discount ($357.56)	40% discount ($286.04)
12,500 IU .5ml syringe	$693.36	1% discount	5% discount	25% discount	40% discount
15,000 IU .6ml syringe	$832.00	1% discount	5% discount	25% discount	40% discount
18,000 IU .72ml syringe NDC 62856-0180-10	$998.41	1% discount ($988.43)	5% discount ($948.49)	25% discount ($748.8l)	40% discount ($599.05)
25,000 IU MDV NDC 00013-5191-01	$476.74	1% discount ($471.97)	5% discount ($452.90)	25% discount ($357.56)	40% discount ($286.04)

(Id. at ¶ 118.) Eisai offered, and some customers requested, even greater discounts. (Id. at ¶¶ 123-26.) For example, Eisai offered Memorial Sloan Kettering a 48% discount for achieving 70% LTC market share. (Id. at ¶ 124.) There was evidence that Eisai had more success when it offered even greater discounts. (See, e.g., dkt. 250, Ex. 39, Dep. of Kurt Hartman at 252-54 ("Offers that have been outside the guidelines have been more readily accepted with almost half of the offers eventually being executed.").) Additionally, in about December of 2009, Eisai hired a "Formulary Implementation Team," which consisted of nurses who assisted "hospitals switching from Lovenox to Fragmin," specifically by

educating staff about Fragmin®'s uses and helping to revise hospital protocols. (Dkt. 287 at ¶¶ 103-04.)

With respect to some hospitals, Fragmin® had the highest market share of the LTC drugs. By August 2008, "at least 277 hospitals had a greater than 50% Fragmin LTC share." (Id. at ¶ 187.) In some hospitals, it had 100% LTC share as of January 2008. (Id. at ¶ 188.) In approximately 2004, Fragmin® was on the formulary of about 2,400 hospitals in the United States. (Id. at ¶ 158.) An Eisai Business Plan from 2006-2007 for Fragmin® indicated that over 900 hospitals in the United States had added Fragmin® to their formularies. (Id. at ¶ 159; see also id. at ¶¶ 161-67.) Furthermore, during the relevant period, while some hospitals conducted therapeutic interchanges away from Fragmin®, some hospitals did therapeutic interchanges to Fragmin® (in whole or in part) and, in some cases, from Lovenox®. (See id. at ¶¶ 170, 172-85, 193.)[8]

II. PROCEDURAL HISTORY

Eisai commenced this action on August 18, 2008 by filing a complaint with this Court objecting to Sanofi's market-share contracting and sales practices. (See Compl.) The complaint

[8] Because of Lovenox®'s Unique Cardiology Indication that Fragmin® did not have, many hospitals that did therapeutic interchanges from Lovenox® to Fragmin® or that had Fragmin® as the preferred drug on formulary would still use Lovenox® for its Unique Cardiology Indication. (See dkt. 250, Ex. 47, at 38-39; id. at Ex. 41, at 160.)

alleges (1) willful and unlawful monopolization and attempted monopolization in contravention of § 2 of the Sherman Act, 15 U.S.C. § 2; (2) de facto exclusive dealing in violation of § 3 of the Clayton Act, 15 U.S.C. § 14; (3) an unreasonable restraint of trade in violation of § 1 of the Sherman Act, 15 U.S.C. § 1; and (4) violations of the New Jersey Antitrust Act, N.J.S.A. 56:9-3 and 56:9-4. (See id. at ¶¶ 12, 82-111.)

The complaint asserts that Sanofi "aggressively protected the monopoly position of Lovenox® against competitor penetration in the LTC Market through the monopoly-share condition in its Lovenox® contracts." (Id. at ¶ 60.) This monopoly-share condition purportedly caused anticompetitive effects by (a) operating as a de facto exclusive-dealing arrangement and (b) by restricting competitors' abilities to "obtain formulary status at hospitals." (Id. at ¶ 66; see also id. at ¶ 63.)

As to the allegation that the market-share condition operated as a de facto exclusive-dealing arrangement, the complaint elaborates that, in order for a customer to achieve the maximum discount, the customer must purchase 90% of its requirements from Sanofi, thereby capping the potential market share of competitors at 10%. (Id. at ¶ 63.) This deterred hospitals from switching to other competitor LTC drugs, which were clinically comparable and lower priced. (See id.)

As to Eisai's claim that the market-share condition limited a competitor's ability to "obtain formulary status," Eisai alleges that there are significant costs to switching a drug on formulary. (Id. at ¶¶ 66, 67.) Lovenox® enjoyed a 90% market share and had a "comparative stronghold with respect to certain indications" (specifically the cardiology and orthopedic markets relating to those indications). (Id. at ¶¶ 66, 68.) These factors "enable[d] the monopoly-share condition to create this anticompetitive barrier." (Id. at ¶ 66.) "[B]y conditioning or effectively conditioning a hospital's receipt of the Lovenox® monopoly share discount on sales in the [cardiology and/or orthopedic markets, Sanofi used] its monopoly power in those Relevant Use Markets to acquire, maintain, and/or enhance its monopoly power in additional Relevant Use Markets," particularly the oncology market. (Id. at ¶¶ 68, 69.)

Eisai further alleges that Sanofi has aggressively enforced its monopoly-share condition and that Sanofi sales representatives have engaged in conduct to prevent Fragmin® from being placed on formularies. (Id. at ¶ 71.) "This conduct includes distributing misleading information regarding Eisai's ability to supply Fragmin®, providing misleading information regarding the medical and legal risks involved in hospitals' use of Fragmin®, and suggesting that speaking engagements and/or research grants would be withheld if a hospital places Fragmin® on formulary." (Id.)

Sanofi moved to dismiss the complaint on October 27, 2008. (Dkt. 28, Notice of Mot. to Dismiss.) The Court denied that motion on June 12, 2009. (Dkt. 59, 6-12-09 Order.) Sanofi then filed an answer on July 10, 2009. (See dkt. 62, Answer.)

Sanofi moved on November 27, 2009 to dismiss, or in the alternative, for summary judgment for Eisai's lack of standing (see dkt. 75, Notice of Mot. to Dismiss/Mot. for Summ. J. for Pl.'s Lack of Standing), and the Court denied that motion on August 10, 2010. (Dkt. 120, 8-10-10 Order.) On August 10, 2010, Sanofi moved for a certification of the August 10, 2010 Memorandum Opinion and Order for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) and for a stay of the action pending the resolution of that appeal. (Dkt. 122, Notice of Mot. for 28 U.S.C. § 1292(b) Certification and Stay of Proceedings.) That motion was granted on September 9, 2010. (Dkt. 132, 9-10-10 Order.) The Court of Appeals for the Third Circuit denied the interlocutory appeal. See 3d Cir. No. 10-8053, dkt. entry no. 7, 11-2-10 Order.

On November 4, 2011, Sanofi moved in this Court for leave to amend its answer to file counterclaims and a third-party complaint (see dkt. 158, Notice of Mot. for Leave to Amend), but the Magistrate Judge denied this motion. (See dkt. 175, 1-5-12 Order.) Sanofi appealed this order on January 19, 2012 (see dkt. 176, Notice of Appeal), and this Court affirmed the Magistrate Judge's Order on February 23, 2012. (See dkt. 180, 2-23-12 Order.)

Fact and expert discovery are complete. (See dkt. 212, 7-2-12 Order; dkt. 230, 3-27-13 Order.) Sanofi now moves for summary judgment on liability. (Dkt. 245.) For the reasons that follow, that motion will be granted. Several other motions were filed by both parties, but given the Court's resolution of Sanofi's summary judgment motion on liability, the Court need not address those motions. Those motions will be denied without prejudice as moot.[9]

III. JURISDICTIONAL STATEMENT

This Court has jurisdiction over the Sherman Act and Clayton Act claims pursuant to 28 U.S.C. §§ 1331 and 1337(a). W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 97 (3d Cir. 2010). The Court has jurisdiction over the supplemental state-law claims under 28 U.S.C. § 1367. Id.

[9] These other motions include: (1) Sanofi's motion for summary judgment as to damages issues (dkt. 246); (2) Eisai's motion for partial summary judgment (dkt. 261); (3) Sanofi's motion for sanctions (dkt. 252); (4) Sanofi's motion to exclude the testimony of Nicholas Economides (dkt. 234); (5) Sanofi's motion to exclude the testimony of Einer Elhauge (dkt. 236); (6) Sanofi's motion to exclude the testimony of Stephen Fredd (dkt. 238); (7) Sanofi's motion to exclude the testimony of Tony Casanova, Stephen Melvin, Ronald Sacher, and Sheila Weiss Smith (dkt. 240); (8) Sanofi's motion to exclude the testimony of Jerry A. Rosenblatt (dkt. 242); (9) Eisai's motion to preclude the expert opinion of George P. Sillup (dkt. 255); (10) Eisai's motion to preclude the expert opinion of Harvey R. Kelly (dkt. 257); (11) Eisai's motion to preclude the expert opinion of Jerry Hausman (dkt. 259); and (12) Eisai's motion to strike the declaration of Jerry A. Hausman (dkt. 291).

IV. STANDARD OF REVIEW

Motions for summary judgment are governed by Federal Rule of Civil Procedure 56, which provides that the Court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). The movant has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. Celotex Corp. v. Catrett, 477 U.S. 317, 323, 331 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the non-moving party." Lamont v. New Jersey, 637 F.3d 177, 181 (3d Cir. 2011) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Celotex Corp., 477 U.S. at 322-23).

If the movant demonstrates an absence of genuinely disputed material facts, then the burden shifts to the non-moving party to demonstrate, through specific facts, the existence of at least one genuine issue for trial. Williams v. Borough of W. Chester, 891 F.2d 458, 460-61 (3d Cir. 1989). Evidence submitted by the non-moving party at the summary judgment stage must be "reduc[ible] to admissible evidence," though it need not be submitted "in a form that would be admissible at trial." Id. at 465 n.12 (quoting

Celotex Corp., 477 U.S. at 324, 327); J.F. Feeser, Inc. v. Serv-A-Portion, Inc., 909 F.2d 1524, 1542 (3d Cir. 1990).

"[C]redibility determinations are not the function of the judge; instead the non-movant's evidence must be credited at this stage." J.F. Feeser, Inc., 909 F.2d at 1531 (citing Anderson, 477 U.S. at 249, 255). Summary judgment is "proper if, viewing the record in the light most favorable to the non-moving party and drawing all inferences in that party's favor, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009).

These general summary judgment standards apply when summary judgment is requested in an antitrust case. See InterVest, Inc. v. Bloomberg, L.P., 340 F.3d 144, 159 (3d Cir. 2003); J.F. Feeser, Inc., 909 F.2d at 1531; Miller v. Ind. Hosp., 843 F.2d 139, 144 (3d Cir. 1988).

V. LEGAL ANALYSIS

A. Legal Framework

The general thrust of Sanofi's arguments in favor of summary judgment is that, under the precedent of the Supreme Court of the United States, specifically Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209 (1993) (hereinafter "Brooke Group"), the price-cost test applies whenever a plaintiff challenges the pricing practices of a defendant. Under the price-cost test, the

plaintiff must first establish that the defendant's prices "are below an appropriate measure of its . . . costs" and second, that the defendant "had a reasonable prospect [under § 1 of the Sherman Act], or, under § 2 of the Sherman Act, a dangerous probability, of recouping its investment in below-cost prices." Id. at 222-24. It is undisputed that Lovenox® was never sold below price, and Sanofi argues that this fact is dispositive. Eisai in contrast argues that the price-cost test applies only where a plaintiff brings a predatory pricing claim, but here, Eisai is not alleging that Sanofi's prices were below cost, nor that Sanofi's prices were the primary method of exclusion. Rather, Eisai argues that Sanofi's Lovenox® Program amounted to de facto exclusive-dealing arrangements, and thus, the rule of reason applies.

To determine whether the price-cost test or the rule of reason applies, the Court must examine the history of the Supreme Court and the Third Circuit's treatment of challenges to pricing practices. Beginning in 1986 with Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 116 (1986), the Supreme Court has emphasized that above-cost price competition is the essence of competition and does not, as a general matter, offend the antitrust laws. In that case, the plaintiff and defendant were both beef packers, and the plaintiff sought to enjoin the defendant's prospective merger with another beef packer under § 16 of the Clayton Act, 15 U.S.C. § 26. Id. at 106-07. The plaintiff argued

that the effect of the merger would be to lessen competition because, following the merger, the defendant could "bid up the price it would pay for cattle, and reduce the price at which it sold boxed beef." Id. at 114. The plaintiff termed this a "price-cost squeeze" and asserted that the defendant had access to financial reserves that would enable it to stay afloat while its profits were reduced during this period. Id. Eventually, smaller competitors lacking such reserves would be unable to compete and would be forced out of the market. Then, the defendant could raise its prices and recoup the profit it lost during the initial "squeeze." Id.

The Court analyzed this theory of antitrust liability along two tracks -- first assuming the defendant's prices were above cost and then assuming the defendant's prices were below cost. As to defendant's above-cost prices, the Court determined that the impending threat of a loss of profitability to the plaintiff from above-cost price competition did not violate the antitrust laws. Id. at 116. The antitrust laws do not protect businesses from the loss of profits due to competition; rather, the laws only protect against the loss stemming from practices forbidden by the antitrust laws. Id. Competition for market share is not forbidden by the antitrust laws. Id. It is simply "vigorous competition." Id.

The possibility of below-cost pricing by the defendant during the "squeeze period," however, had the potential to cause antitrust injury. Id. at 118. The Court explained,

> Predatory pricing may be defined as pricing below an appropriate measure of cost for the purpose of eliminating competitors in the short run and reducing competition in the long run. It is a practice that harms both competitors and competition. In contrast to price cutting aimed simply at increasing market share, predatory pricing has as its aim the elimination of competition.

Id. at 117-18. "[P]redatory pricing is an anticompetitive practice forbidden by the antitrust laws." Id. at 121. The Court ultimately concluded that the plaintiff had not adequately brought or proven a claim of predatory pricing at the district court level. Id. at 119.

The Supreme Court reiterated that non-predatory price competition generally does not violate the antitrust laws in Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 337-38 (1990). In that case, USA Petroleum Company ("USA"), an independent retailer of gasoline that bought gasoline from other companies for resale under its name, alleged that its competitor, Atlantic Richfield Company ("ARCO"), a retailer that sold gasoline through its own stations and through dealers, violated the antitrust laws through a price-fixing scheme. Id. at 331-32. Specifically, ARCO encouraged its dealers to match the gasoline prices of independent retailers by offering its dealers short-term

discounts and by eliminating credit-card sales to dealers. Id. at 332. The prices that resulted were below market but above cost.

The issue before the Supreme Court was whether USA could show an antitrust injury under § 1 of the Sherman Act. Id. at 335. USA argued that the injury requirement was satisfied by the business it lost as a result of the "low prices produced by the vertical restraint." Id. at 337. The Court disagreed and reasoned, "When a firm, or even a group of firms adhering to a vertical agreement, lowers prices but maintains them above predatory levels, the business lost by rivals cannot be viewed as a an 'anticompetitive' consequence of the claimed violation." Id. "[C]utting prices in order to increase business often is the very essence of competition." Id. at 338 (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 594 (1986)). The Court explained that, "[a]lthough a vertical, maximum-price-fixing agreement is unlawful under § 1 of the Sherman Act, it does not cause a competitor antitrust injury unless it results in predatory pricing." Id. at 339. Importantly for current purposes, the Court also stated, "Low prices benefit consumers regardless of how those prices are set, and so long as they are above predatory levels, they do not threaten competition. Hence, they cannot give rise to antitrust injury. We have adhered to this principle regardless of the type of antitrust claim involved." Id. at 340. "When prices are not predatory, any losses flowing from them cannot be said to

stem from an anticompetitive aspect of the defendant's conduct." Id. at 340-41.

Cargill and Atlantic Richfield address the relationship between pricing and the antitrust-injury requirement. They do not resolve the question of whether pricing practices can be the source of the antitrust violation under § 1 and § 2 of the Sherman Act and § 3 of the Clayton Act. The Supreme Court closed this gap in 1993 in Brooke Group, where, in the context of an alleged § 2 violation, it found that below-cost pricing was necessary to establish liability. See 509 U.S. at 223. In that case, the plaintiff Liggett had pioneered the market for generic cigarettes and held a dominant market share. Id. at 212-13. Brown & Williamson Tobacco Corporation ("Brown") then introduced its own line of generic cigarettes, and Liggett and Brown began a "rebate war" at the wholesale level, ultimately resulting in Brown selling its generic cigarettes at a loss. Id. at 212-16. Liggett alleged that Brown's intention was to pressure Liggett to raise retail list prices on generic cigarettes, which would reduce the percentage price difference between branded and generic cigarettes. This would restrain the growth of the generic segment of the market and would allow Brown to reap supracompetitive profits on its branded cigarettes. Id. at 216-17.

The Court ruled that the first prerequisite to recovery for a pricing claim under § 2 is below-cost prices. Id. at 222. The Court reasoned,

> As a general rule, the exclusionary effect of prices above a relevant measure of cost either reflects the lower cost structure of the alleged predator, and so represents competition on the merits, or is beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price-cutting.

Id. at 223. Next, the Court ruled, "[t]he second prerequisite to holding a competitor liable under the antitrust laws for charging low prices is a demonstration that the competitor had a reasonable prospect [under § 1 of the Sherman Act], or, under § 2 of the Sherman Act, a dangerous probability, of recouping its investment in below-cost prices." Id. at 224. Finally, "[t]he plaintiff must demonstrate that there is a likelihood that the predatory scheme alleged would cause a rise in prices above a competitive level that would be sufficient to compensate for amounts expended on the predation, including the time value of money invested in it." Id. at 225. On the facts of that case, the Court found that there was a lack of "an adequate basis for a finding of liability" because "[n]o inference of recoupment is sustainable on this record." Id. at 231-32.

The Court, most recently, in Pacific Bell Telephone Co. v. Linkline Communications, Inc., 555 U.S. 438 (2009), once again rejected a challenge to above-cost pricing. In that case, AT&T

sold digital subscriber line ("DSL") service at the wholesale level, selling DSL transport service to independent Internet service providers ("ISPs"), and at the retail level, selling DSL service directly to consumers. The plaintiffs were ISPs competing with AT&T at the retail level and leasing DSL transport service. Id. at 442-43. The plaintiffs sued AT&T, contending that AT&T violated § 2 by engaging in a "price squeeze" -- i.e. "squeez[ing] their profit margins by setting a high wholesale price for DSL transport and a low retail price for DSL Internet service." Id. at 443. The effect of this practice was to raise the costs of competitors, such as the plaintiffs, by requiring competitors to pay more for inputs and lowering competitors' revenues because competitors will have to match the lower retail prices set by the dominant firm. Id. at 449.

As to the plaintiffs' challenge to AT&T's wholesale prices, the Court ruled that a "defendant has no antitrust duty to deal with its rivals at wholesale." Id. at 450. With respect to the retail prices, because the plaintiffs were alleging that AT&T's prices were too low, the Court applied the Brooke Group price-cost test. Id. at 452. The Court explained, "the Sherman Act does not forbid -- indeed, it encourages -- aggressive price competition at the retail level, as long as the prices being charged are not predatory." Id. at 455. AT&T's prices were not below its cost, and thus, the plaintiffs could not proceed. See id. at 457.

The Third Circuit has wrestled with the application of the Brooke Group price-cost test on several occasions. In LePage's Inc. v. 3M, 324 F.3d 141 (2003), the Third Circuit found that the price-cost was not determinative in a claim under § 2 based on exclusive dealing and bundled rebates. In that case, 3M, a manufacturer of Scotch tape, dominated the transparent tape market in the United States in the early 1990s. Id. at 144. Beginning around 1980, LePage's "decided to sell 'second brand' and private label transparent tape," meaning tape sold under the name of the retailer rather than the manufacturer. Private-label tape was cheaper than branded tape. Id. By 1992, LePage's sold 88% of the private-label transparent tape sold in the United States. Id. 3M entered the private-label and second-brand market in the early 1990s as well. Id. It began a bundled rebate program, whereby it "offered higher rebates when customers purchased products in a number of 3M's different product lines." Id. at 145. 3M also offered "some of LePage's customers large lump-sum cash payments, promotional allowances and other cash incentives to encourage them to enter into exclusive dealing arrangements with 3M." Id.

The issue before the court was whether 3M violated § 2 of the Sherman Act, which prohibits monopolization and attempted monopolization. Section 2 has been interpreted to require a finding that: (1) the defendant possessed "monopoly power in the relevant market" and (2) that the defendant willfully acquired or

maintained "that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" Id. at 149 (quoting United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966)). "A monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits." Id. at 147 (citing Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 605 n.32 (1985)).

In reliance on Brooke Group, 3M's primary argument was that its conduct was legal, even though it offered bundled rebates and some exclusive-dealing contracts, because it never priced below cost. Id. at 147. The court rejected this contention and expressed its views on the limited reach of Brooke Group. Id. at 151-52. Unlike the plaintiff in Brooke Group, LePage's was not alleging a pricing claim. Id. at 151. Moreover, "[n]othing in any of the Supreme Court's opinions in the decade since the Brooke Group decision suggested that the opinion overturned decades of Supreme Court precedent that evaluated a monopolist's liability under § 2 by examining its exclusionary, i.e., predatory, conduct." Id. at 152. Brooke Group "does not discuss, much less adopt, the proposition that a monopolist does not violate § 2 unless it sells below cost." Id. Thus, the court concluded that the Brooke Group price-cost test was not dispositive.

Turning to the 3M's bundled rebates, the court explained, "[r]ather than competing by offering volume discounts which are

concededly legal and often reflect cost savings, 3M's rebate programs offered discounts to certain customers conditioned on purchases spanning six of 3M's diverse product lines." Id. at 154. In addition to the bundled rebates, 3M's rebate programs set target growth rates for each customer in each product line. The number of targets that a customer met determined the rebate 3M would provide to that customer on all of its purchases. Id. If the customer failed to meet the target for one product, it would lose the rebate across the line; "[t]his created a substantial incentive for each customer to meet the targets across all product lines to maximize its rebates." Id. The court reasoned that such bundled rebates can have an anticompetitive effect even if they result in above-cost prices in the aggregate because an efficient rival "who does not manufacture an equally diverse group of products . . . cannot make a comparable offer." See id. at 155 (citing SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056 (3d Cir. 1978)). Thus, the court concluded that a jury could find a § 2 violation with respect to the bundled rebates. Id. at 157.

As to LePage's exclusive-dealing claim under § 2, the court rejected 3M's argument that, because its arrangements did not have an express exclusivity requirement, they were not exclusive-dealing arrangements. Id. The court explained that some arrangements, while "not expressly exclusive, effectively foreclose[] the business of competitors." Id. (citing Tampa Elec. Co. v. Nashville

Coal Co., 365 U.S. 320, 327 (1961)). There was powerful evidence that 3M's rebates and discounts "were designed to induce [customers] to award business to 3M to the exclusion of LePage's." Id. at 158. For example, there was testimony that some stores were offered rebates if the stores gave their business to 3M and not LePage's. Id. Therefore, a jury could find a § 2 violation based on 3M's exclusionary conduct.

Two years later, the Third Circuit evaluated another alleged exclusive-dealing arrangement. See United States v. Dentsply Int'l, Inc., 399 F.3d 181 (3d Cir. 2005). In Dentsply, a manufacturer of artificial teeth, Dentsply, which had a 75-80% market share and which also sold other dental products to dental-product dealers, utilized policies that discouraged dealers from adding competitors' teeth to their product lines. Id. at 184-85. Specifically, in 1993, Dentsply adopted a policy that dealers "may not add further tooth lines to their product offering." Id. at 185. This was enforced against dealers with the exception of those who were "grandfathered" for sales of competing products that they had carried before 1993. Id. Dentsply and its dealers operated on a purchase-order basis, and, thus, the relationship was terminable at will. Id. Dentsply also had a reputation for aggressive marketing of its teeth and for aggressive price increases. Id.

The court explained that exclusive-dealing arrangements, while "not illegal in themselves . . . can be an improper means of

maintaining a monopoly." Id. at 187. To demonstrate a violation of § 2, proof of "[p]redatory or exclusionary practices in themselves are not sufficient. There must be proof that competition, not merely competitors, has been harmed." Id.

In evaluating whether Dentsply had market power, the court emphasized the need to examine the economic realities as opposed to formalities. Id. at 189. While "rivals could theoretically convince a dealer to buy their products and drop Dentsply's line, that has not occurred." Id. The court also noted the fact that Dentsply's prices were not the lowest in the market and that its prices did not drop when its competitors did not follow its price increases. Id. at 191. "The picture is one of a manufacturer that sets prices with little concern for its competitors, something a firm without a monopoly would have been unable to do." Id. (internal quotation marks and citation omitted). This, combined with Dentsply's 75%-80% market share, convinced the court that Dentsply had market power. Id. at 188, 191.

With respect to the second element of a § 2 claim, that the defendant used market power to foreclose competition, "[t]he test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Id. at 191. One factor considered by the court was that, for dental laboratories, dealers were the preferred source of artificial teeth because of the ease of "one stop-shopping,"

decreased transaction costs, discounts provided by dealers, ease of returns, and efficiencies of scale for the manufacturers. Id. at 192. Direct sales from the manufacturers to laboratories were theoretically possible, but not practical or feasible based on the realities of the market. Id. at 193. The court also noted that, while the relationships between Dentsply and the dealers were easily terminable, dealers had a strong incentive to carry Dentsply's artificial teeth. Id. at 193-94. It was not realistic to expect that a new entrant to the market could "steal" a Dentsply dealer with "a superior product at a lower price" because dealers feared losing the right to sell Dentsply's teeth by introducing competitor products to their lines. Id. at 194-95. Thus, Dentsply's policy limited the choices of products available to dental laboratories. Id. at 194. Based on the foregoing, the court concluded that Dentsply's policies violated § 2. Id. at 196-97.

The Third Circuit once again discussed the application of the price-cost test in 2012 in ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254 (3d Cir. 2012) (hereinafter "Meritor"), cert. denied, 133 S.Ct. 2025 (2013). Meritor involved the heavy-duty truck transmission market in North America. Id. at 263. There are only four direct purchasers of these transmissions, known as Original Equipment Manufacturers ("OEMs"). Id. at 264. Truck buyers would purchase finished trucks from the OEMs. Id. Truck buyers could select many

of the components used in their trucks from OEM catalogues, known as "data books." Id. These data books included "standard" offerings, the component provided unless the customer expressly designates the product of another supplier, and "preferred" offerings, the lowest priced component in the OEM data book as amongst comparable products. Id. Data book positioning was essential in the industry because standard or preferred positioning typically meant that a truck buyer was more likely to purchase that supplier's components. Id. While it was possible for customers to request components that were not published in the data book, this was a cumbersome process that often increased the cost of the component. Id.

Eaton Corp. ("Eaton") had been a monopolist in the market for many years and was the only significant manufacturer until Meritor Transmission Co. ("Meritor") entered the market years later. Id. Meritor later entered a joint venture with ZF Friedrichshafen ("ZF") in part to adapt ZF's two-pedal automated mechanical transmission used in the European market for the North American market. Id. This new product was called FreedomLine, which was released in 2001, and Eaton expected it to have approximately 30-50% of the market for these transmissions by 2004 or 2005. Id. Since the entry of Meritor and the ZF-Meritor joint venture ("ZF Meritor"), no significant competitor entered the market within the last twenty years. Id.

The trucking industry experienced a decline in 1999-2000 for new heavy-duty trucks. Id. at 265. At that time, Eaton entered long-term supply agreements ("LTAs") with each OEM that were effective for a period of at least five years. Id. Each LTA had a conditional rebate provision, which provided for rebates to an OEM only if the OEM purchased a specified percentage, ranging from 70% to 97.5% of its requirements from Eaton. Id. Some of the agreements provided for an up-front payment to the OEM from Eaton. See id. The LTAs did not expressly require OEMs to purchase the specified percentage of their needs from Eaton. However, some LTAs gave Eaton the right to terminate the LTAs if targets were not met, and if an OEM did not meet its percentage target for one year, Eaton could require reimbursement of all the rebate savings under the LTAs. Id.

As to the data books, in the 1990s, Meritor's transmissions were listed in all the data books and in some cases had preferred positioning. Id. at 266. However, under the LTAs, Eaton required the OEM to publish Eaton as the standard offering, and, with respect to two out of the four LTAs, Eaton required the OEMs to remove competitor products from their data books. Id. at 265. "The LTAs also required the OEMs to 'preferential price' Eaton transmissions against competitors' equivalent transmissions." Id. at 266. There was evidence that, rather than passing the savings on to truck buyers, the OEMs achieved this preferential pricing by

lowering the prices of Eaton's products and raising the prices of Eaton's competitors' products. Id. Finally, the LTAs also contained a "competitiveness" clause, which allowed OEMs to purchase competitor transmissions if: (a) the competitor offered the OEM a lower price or better product; (b) the OEM gave Eaton notification of the offer; and (c) Eaton could not match the quality or price of that offer. Id.

After Eaton's use of the LTAs, ZF Meritor tried unsuccessfully to market directly to the truck buyers rather than the OEMs. Id. During Eaton's use of the LTAs, the OEMs and Eaton worked together to stunt ZF Meritor's growth, by, inter alia, imposing price penalties on customers who selected ZF Meritor's products and persuading customers to use Eaton products. Id. Eaton's prices were generally lower than ZF Meritor's prices, but Eaton never priced below its cost. Id. at 266-67. ZF Meritor ultimately dissolved the joint venture, and Meritor left the business in 2007. Id. at 267.

Based on the foregoing, the plaintiffs, ZF Meritor and Meritor, filed suit against Eaton under § 1 and § 2 of the Sherman Act and § 3 of the Clayton Act, alleging that Eaton "used its dominant position to induce all heavy truck manufacturers to enter into de facto exclusive dealing contracts with Eaton," and that 90% of the heavy-duty transmission market was foreclosed to the plaintiffs as a result. Id. A jury returned a complete verdict

for the plaintiffs, and Eaton then moved for judgment as a matter of law. Id.

The issue before the court was whether the price-cost test or the rule of reason applied to the exclusive-dealing claims. Id. at 268. "Under the rule of reason, an exclusive dealing arrangement will be unlawful only if its 'probable effect' is to substantially lessen competition in the relevant market." Id. As an initial matter, the court explained that its "analysis regarding the applicability of the price-cost test is the same for all of Plaintiffs' claims." Id. at 269 n.9. While each claim articulates the standard for anticompetitive conduct slightly differently, the price-cost test may be applicable to determining the existence of anticompetitive conduct for all three sections. Id.

The court first examined the law of exclusive dealing. "An exclusive dealing arrangement is an agreement in which a buyer agrees to purchase certain goods or services only from a particular seller for a certain period of time." Id. at 270. Express exclusivity is not required, and "de facto exclusive dealing claims are cognizable under the antitrust laws." Id. The court recognized that the legality of exclusive-dealing arrangements, which "are of special concern when imposed by a monopolist," is judged under the rule of reason. Id. at 271.

The court then examined the Supreme Court's skeptical treatment of predatory pricing claims and the price-cost test from

Brooke Group. See id. at 272-73. The court explained, "in the context of exclusive dealing, the price-cost test may be utilized as a specific application of the 'rule-of-reason' when the plaintiff alleges that price is the vehicle of exclusion." Id. at 273 (citing Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1060-63 (8th Cir. 2000) (hereinafter "Concord Boat")). The court gleaned from Supreme Court precedent that "generally, above-cost prices are not anticompetitive." Id. at 275.

With regard to the application of LePage's, the court explained that it should be interpreted narrowly and that LePage's construed Brooke Group more narrowly than the Supreme Court did in subsequent cases. Id. LePage's involved bundled rebates, which were analogized to tying practices and which can only exist when two separate product markets are linked. Id. at 274 n.11. The court concluded that LePage's did not apply to the facts of Meritor, which involved a single-product market with no allegations of bundling or tying. Id. Notably, the court stated, "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." Id.; see also id. at 275 ("These principles extend to above-cost discounting or rebate programs, which condition the discounts or rebates on the customer's purchasing of a specified volume or a specified percentage of its

requirements from the seller." (citing NicSand, Inc. v. 3M Co., 507 F.3d 442, 451-52 (6th Cir. 2007))).

The court further clarified that, even though a plaintiff may cast a claim as an exclusive-dealing claim, the price-cost test may still apply as "contracts in which discounts are linked to purchase (volume or market share) targets are frequently challenged as de facto exclusive dealing arrangements," as the discounts induce customers to exclusively deal with the firm offering the discount program. Id. at 275. "However, when price is the clearly predominant mechanism of exclusion, the price-cost test tells us that, so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects." Id.

Turning to the facts of Meritor, the court found that, unlike the plaintiffs in "Cargill, Atlantic Richfield, and Brooke Group, Plaintiffs did not rely solely on the exclusionary effect of Eaton's prices, and instead highlighted a number of anticompetitive provisions in the LTAs." Id. at 277; see also id. at 279. Specifically, Eaton persuaded OEMs to enter into the LTAs, which "impos[ed] de facto purchase requirements of roughly 90% for at least five years," and Eaton also "worked in concert with the OEMs to block customer access to Plaintiffs' products." Id. at 277. As a result, the court concluded that "price itself was not the

clearly predominant mechanism of exclusion" and the rule of reason was the proper framework. Id.

There was considerable evidence that OEMs did not want to remove competitor transmissions from their data books but were forced to do so or risk supply shortages and financial penalties. Id. There was still a demand for Eaton's products as Eaton was the dominant manufacturer of transmissions, so OEMs could not risk losing Eaton as a supplier by not meeting penetration targets. Meeting the targets was mandatory, because failure to meet the targets could jeopardize an OEM's relationship with Eaton. Id. at 277-78. "Accordingly, this is not a case in which the defendant's low price was the clear driving force behind the customer's compliance with purchase targets, and customers were free to walk away if a competitor offered a better price." Id. at 278 (comparing Concord Boat, 207 F.3d at 1063, which applied the price-cost test where customers can and did walk away if a competitor provided a better price, and Dentsply, 399 F.3d at 189-96, which applied the exclusive-dealing analysis where the defendant had refused to deal with customers who had purchased rival products).

Even though Eaton's prices were above its cost, this did not insulate Eaton from liability where it engaged in an otherwise unlawful exclusive-dealing arrangement. See id. The court found nothing in recent Supreme Court precedent indicating that it "intended to overturn decades of other precedent holding that

conduct that does not result in below-cost pricing may nevertheless be anticompetitive." Id. at 279. Prices are unlikely to exclude equally efficient rivals unless they are below cost, but exclusive-dealing arrangements can exclude equally efficient rivals because those rivals are never given the opportunity to compete. Id. at 281.

After the Meritor court concluded that the rule of reason applied, the court turned to the exclusive-dealing analysis under the rule of reason. "Under the rule of reason, an exclusive dealing arrangement is anticompetitive only if its 'probable effect' is to substantially lessen competition in the relevant market, rather than merely disadvantage rivals." Id. (citing Tampa Elec., 365 U.S. at 328-29). The court concluded that, while the LTAs did not require express exclusivity, they were de facto exclusive-dealing arrangements because there was a possibility that an OEM's failure to meet the targets would result in Eaton's termination of the contracts, and no OEM could risk the loss of Eaton as a supplier. Id. at 282-83. To constitute an unlawful exclusive-dealing arrangement, complete exclusivity is not required, and the "legality of such an arrangement ultimately depends on whether the agreement foreclosed a substantial share of the relevant market such that competition was harmed." Id. at 283-84 (noting that the four OEMs were the only purchasers of the transmissions in the relevant market, the LTAs were long-term and

were entered with each of the OEMs, and the market-share targets were roughly 90%).

The court also examined the contours of the relevant market because the existence of a defendant with significant market power is generally required for exclusive dealing to be unlawful. See id. at 284. The heavy-duty transmissions market was dominated by Eaton, was highly concentrated, and had significant barriers to entry for new competitors; thus, Eaton was able to leverage its position to coerce OEMs into agreeing to the LTAs. Id. at 284-85. The court found that there was sufficient evidence that the LTAs contained many anticompetitive provisions without procompetitive justifications and that the LTAs foreclosed a substantial share of the market for an extended period of time. See id. at 286-89. Finally, the court found that the record supported the jury's finding that Eaton's exclusionary conduct caused the plaintiffs' antitrust injury, namely, the plaintiffs' inability to grow. Id. at 289.

B. Application

Before determining whether the price-cost test applies, the Court will first address the relevant market and Sanofi's market power. "[D]efining a relevant product market is a process of describing those groups of producers which, because of the similarity of their products, have the ability actual or potential to take significant amounts of business away from each other."

SmithKline Corp., 575 F.2d at 1063. For the purposes of this motion, the Court assumes, arguendo, that the relevant market is the LTC market -- Lovenox®, Fragmin®, Innohep®, and Arixtra®. (See Compl. at ¶ 52.) While Sanofi argues that the relevant market includes UFH and warfarin in addition to the LTC drugs (see Sanofi Br. at 46), the Court, for summary judgment purposes, adopts the more limited market definition provided by Eisai. Additionally, the relevant period in this case is the time during which Eisai was selling Fragmin® in the United States and Sanofi was using loyalty contracts to sell Lovenox®, September 27, 2005 to July 25, 2010. (See Economides Report at ¶ 10; see also Elhauge Report at ¶ 8 n.1.)

The Court finds that Sanofi had monopoly power in the relevant market during the relevant period. "[T]he existence of monopoly power may be inferred from a predominant share of the market." Dentsply, 399 F.3d at 187 (citing Grinnell, 384 U.S. at 571). "Absent other pertinent factors, a share significantly larger than 55% has been required to establish prima facie market power. Other germane factors include the size and strength of competing firms, freedom of entry, pricing trends and practices in the industry, ability of consumers to substitute comparable goods, and consumer demand." Id. (citations omitted). Here, Lovenox® had a share of 81.5% to 92.3% of the LTC market during the relevant time period. (See Economides Report at ¶¶ 10, 12; see also Elhauge Report at ¶

1; Sanofi Br. at 18.) This is a predominant share of the LTC market, and thus, for the purposes of this motion with inferences drawn in Eisai's favor, the Court assumes that Sanofi had monopoly power.

1. Price-Cost Test or Exclusive-Dealing Analysis?

The primary dispute between the parties on this motion is whether the price-cost test applies, or whether this is more properly analyzed under an exclusive-dealing analysis.

Sanofi argues that the price-cost test applies to Eisai's claims challenging the legality of its market-share and volume discounts. (Sanofi Br. at 10-12.) Sanofi asserts that, in Meritor, the court concluded that price was not the predominant form of exclusion, in particular, because: (a) the LTAs required two out of four OEMs to remove competitor products from their data books entirely; (b) the LTAs required other OEMs to list Eaton's products as the preferred offering; and (c) Eaton threatened to cut off its supply to OEMs if OEMs allowed purchases to drop below percentage targets. (Id. at 12-13.)

Sanofi argues that this case is not factually analogous to Meritor. Sanofi did not prohibit customers from placing competitive products on their formularies, nor did Sanofi threaten to cut off the supply of Lovenox® to customers. (Id. at 13.) The Formulary Access Clause conditioned the discounts on equal treatment of drugs on hospital formularies, and "the only

consequence of favoring another drug on the formulary was a reduction in the discount." (Id.; dkt. 352, Sanofi Reply Br. in Supp. of Mot. for Summ. J. on Liability ("Sanofi Reply Br.") at 5.) Sanofi argues that, unlike Eaton in Meritor, the only thing it did to encourage purchases of Lovenox® was to adjust the discount based on volume and market share -- a purely pricing incentive. (Sanofi Br. at 13.) Sanofi asserts that, despite Eisai's efforts to avoid the price-cost test, all of Eisai's arguments come back to price. (Sanofi Reply Br. at 2.)

Eisai replies that Sanofi misconstrues Meritor as imposing a per se rule for the price-cost test. (Dkt. 312, Eisai Br. in Opp'n to Sanofi's Mot. for Summ. J. on Liability ("Eisai Br.") at 6.) Rather, under Meritor, the price-cost test applies only when price is the predominant form of exclusion, and, here, as in Meritor, price is not the predominant form of exclusion. (Id. at 6-7.) Eisai argues that this case is factually like Meritor and that, if Sanofi were right about its reading of Meritor, Eaton would have won. (Id. at 7.) Eisai disagrees with Sanofi's assertion that Meritor is limited to cases where the defendant monopolist threatened to cut off supply to customers for not meeting targets. (Id. at 12.)

According to Eisai, price is not the predominant method of exclusion in this case because Sanofi's "practices (a) prevented customers from buying less expensive rival products; (b) bundled

contestable and incontestable demand for Lovenox; (c) imposed disloyalty penalties that were not the same as 'discounts'; (d) raised buyer switching costs; (e) worsened rival efficiency; and (f) used formulary access clauses to preserve monopoly power." (Id. at 9-10.) According to Eisai, Sanofi leveraged its market power to maintain its monopoly. A portion of a hospital's demand for the LTC drugs could only be satisfied by Lovenox®. (Id. at 11.) This prevented hospitals from switching entirely to a competitor LTC drug. (See id.) Eisai asserts that Sanofi's discounts "bundled incontestable and contestable demand," and "[t]he potential financial penalties on the incontestable portion of hospitals' Lovenox purchases compelled them to exclude rivals." (Id.) Moreover, Eisai contends that the presence of the formulary access clauses "created an unlevel playing field, where hospitals can and do give sanofi a favorable formulary position for some indications, but cannot give rivals favorable formulary position for other indications." (Id. at 17.)

The Court finds that price is the predominant mechanism of exclusion under Sanofi's practices, and thus, the price-cost test applies. In Meritor, the court explained that market-share or volume rebates in a single-product market are evaluated under the price-cost test unless, essentially, something more is happening. 696 F.3d at 274 n.11, 275. Thus, the market-share and volume discounts offered by Sanofi are not, in-and-of themselves,

problematic for antitrust purposes. The question becomes, was something more than "the exclusionary effect of [Sanofi's] prices" going on here? See id. at 277.

Eisai has named six ways in which the Lovenox® Program purportedly excluded rivals, aside from cost. (See Eisai Br. at 9-10.) The first, that Sanofi's practices "prevented customers from buying less expensive rival products" (id. at 9), is not supported by the record. The record demonstrates that customers can and did purchase rival products, some instead of Lovenox®, some in addition to Lovenox®. In fact, Eisai's own expert, Nicholas Economides, revealed that Arixtra®'s market share increased from 3% in 2006 to 9.9% in 2010 and that Fragmin®'s share increased from 3.7% to 8.2% during the same time period. (Economides Report at ¶ 12.) Additionally, the terms of the Lovenox® contracts did not prohibit hospitals from purchasing competitor LTC drugs. And while Eisai has adduced evidence that Sanofi sales representatives actively tried to prevent customers from conducting therapeutic interchanges to rival LTC drugs and attempted to reverse therapeutic interchanges, their only leverage was price, specifically the loss of the steep discounts. Unlike the circumstances in Meritor, Sanofi did not threaten to cut off its customers' supply, and there is no evidence that hospitals feared the loss of Sanofi as a supplier by buying rival drugs. Thus, this factor does not support

Eisai's claim that price was not the predominant method of exclusion.

Eisai's second factor, that Sanofi's contracts "bundled contestable and incontestable demand for Lovenox" (see Eisai Br. at 9), likewise does not support the existence of predominant non-pricing exclusionary tactics. Eisai does not claim that Sanofi bundled separate products in separate markets but rather that Sanofi bundled the demand for Lovenox® that could be satisfied by other LTC drugs with the demand for Lovenox® that could not be satisfied by the other LTC drugs. Boiled down, Eisai's argument is that Lovenox® had a Unique Cardiology Indication that the other LTC drugs did not have. (See dkt. 250, Ex. 1 at 2.) Even if hospitals wanted to use a rival drug or to conduct a therapeutic interchange to a rival LTC drug, hospitals would continue to have some demand for Lovenox® because of this unique indication. And hospitals would have to pay more for the Lovenox® required for this unique usage because of the loss of, or decrease in, the discount.

Eisai's expert, Professor Elhauge, put numbers to this theory. Using Sanofi's April 2007 pricing structure offered to hospital systems and Eisai's maximum discount at that same time of 40% off the WAC (or list price), Professor Elhauge calculated that there was a "dead zone" in which it would cost hospitals more to switch from Lovenox® to Fragmin® even though Fragmin® was less expensive. (Elhauge Report at ¶¶ 85-88.) This dead zone was between 10% and

62% Fragmin® market share, meaning that it was more expensive for hospitals to use Fragmin® for 10% to 62% of its needs in the LTC market. (Id. at ¶¶ 85-88.) This was because hospitals using Fragmin® would still need to carry Lovenox® for the incontestable demand, but the increased market share of another LTC drug would make Lovenox® more expensive because of the loss of, or decrease in, the discount.

Variations in FDA-approved indications amongst the LTC drugs are common in the LTC market. Notably, Fragmin® also has a unique oncology indication -- the Cancer Indication -- that the other LTC drugs do not have. (See dkt. 250, Ex. 10 at 2.) Seemingly, the incontestable demand relating to these unique indications is attributable to the inherent properties of the product at issue, and thus competition on the merits. Cf. LePage's, 324 F.3d at 147. Therefore, Eisai was not excluded and could have competed for business by offering a "superior product at a lower price." Cf. Dentsply, 399 F.3d at 194-95.

The Court finds further support for its conclusion that this is a pricing case from the fact that Eisai could have increased its discounts to decrease the span of Professor Elhauge's "dead zone." Professor Elhauge testified that in 2009, for example, Eisai charged a price for Fragmin® that was 7.8 times its cost, or, in other words, Eisai's profit margins on Fragmin® in 2009 were approximately 85%. (Elhauge Report at ¶ 51; dkt. 250, Ex. 37, Dep.

of Einer Elhauge at 174-75.) Professor Elhauge's dead zone calculations assumed that Eisai was offering its maximum discount of 40%. Eisai could have increased its discounts, which would have been a decrease in the price of Fragmin® to hospitals, and thereby the span of the dead zone would have been reduced. In fact, according to Sanofi's expert, Dr. Jerry A. Hausman, increasing the discount on Fragmin® to 48% would decrease the dead zone from 62% to 53%. (Dkt. 262-4, Ex. 31, Expert Report of Dr. Jerry A. Hausman dated 1-9-13, at ¶ 103.)[10] The span of the dead zone continues to decrease as the Fragmin® discount increases.

Any alleged incontestable demand did not prevent Eisai from reducing its 85% profit margins to decrease the span of the dead zone and increase its market share. See Atl. Richfield Co., 495 U.S. at 338 ("[C]utting prices in order to increase business often is the very essence of competition." (quoting Matsushita Elec. Indus. Co., 475 U.S. at 594)). It may well be that Sanofi had even larger profit margins. In 2009 for example, Sanofi was able to charge a price that was 17.7 times higher than its costs, while Eisai charged 7.8 times its cost. (Elhauge Report at ¶ 51.) But

[10] A motion to exclude the expert testimony of Dr. Hausman is pending concurrently with this motion for summary judgment. (See dkt. 259.) The Court's citation to Dr. Hausman's report is not an indication of the Court's inclinations as to that motion. While Dr. Hausman is an expert of Sanofi, and the record must be viewed in the light most favorable to Eisai for the purposes of this motion, the Court cites Dr. Hausman's report here for demonstrative purposes only as to how the inputs for Professor Elhauge's dead zone calculations can be varied to alter the result.

the antitrust laws do not protect businesses from the loss of profits due to vigorous competition. See Cargill, Inc., 479 U.S. at 116 ("To hold that the antitrust laws protect competitors from the loss of profits due to such price competition would, in effect, render illegal any decision by a firm to cut prices in order to increase market share.").

Eisai's third reason why its exclusive-dealing claims are not predominantly based on price -- that Sanofi "imposed disloyalty penalties that were not the same as 'discounts'" (see Eisai Br. at 9) -- is a matter of semantics. The label given does not change the nature of Eisai's claim.

Eisai's fourth reason, that Sanofi's practices "raised buyer switching costs," and fifth reason, that Sanofi's practices "worsened rival efficiency" (see id.), are both better understood as an effect of the Lovenox® Program as opposed to mechanisms of exclusion. And even if these could possibly be considered mechanisms of exclusion, Eisai's arguments still relate back to price. Eisai's argument about the alleged impact on rival efficiency is essentially that the cost of production per unit decreases as the number of units produced increase and that the Lovenox® Program deprived Eisai these economies of scale. (See Elhauge Report at ¶ 137.) This argument again relates to price and profit margins because it relates to the costs of production in the first place. Similarly, the effect on buyer switching costs is

also linked to price. Specifically, any costs to a hospital that was in the process of switching from one LTC drug to another, such as the cost of rewriting hospital protocols and of training staff (see id. at ¶ 128), could be addressed through a reduction in the price of the drug. And while hospitals may be deterred from partially switching from Lovenox® to another LTC drug because of the price "penalty" associated with a decreased Lovenox® market share, this again comes back to price. Moreover, these switching costs would exist irrespective of any anticompetitive conduct, and are better understood as a reality of the market.

Eisai's final argument in support of its assertion that price is not the predominant form of exclusion is that Sanofi "used formulary access clauses to preserve monopoly power." (See Eisai Br. at 9-10.) This practice is unlike Eaton's practices in Meritor of requiring: (a) OEMs to give Eaton the "standard offering" in the data books; (b) two OEMs to remove competitor products from the data books entirely; and (c) OEMs to preferentially price Eaton's products as compared to equivalent competitor products. 696 F.3d at 265-66. Here, Sanofi did not require hospitals to remove competitor LTC drugs from formularies or to give Lovenox® preferential treatment on these formularies. The formulary access clauses provided that hospitals could not "impose restrictions" on the promotion or marketing of Lovenox®, including by identifying "Lovenox in a less than equal status" with other LTC drugs. (Dkt.

287 at ¶ 36.) Thus, these clauses required equal treatment for Lovenox® only and did not restrict the ability of hospitals to place Fragmin® on their formularies. In this respect, Sanofi's conduct here is unlike that of Eaton in Meritor.

The effect of a "violation" of the Lovenox® contracts is also unlike the effect discussed by the court in Meritor. In Meritor, there was a threat that noncompliance with Eaton's requirements could result in a termination of the contracts by Eaton and that OEMs feared the loss of Eaton as a supplier. 696 F.3d at 282-83. Here, however, a violation of the formulary access clauses' requirement that Lovenox® be given equal treatment with other LTC drugs did not restrict the member's access to Lovenox®, but instead accelerated the loss of the contractual discount and dropped the hospital to the lowest discount tier of 1%. (See dkt. 287 at ¶ 38.) This loss of the discount relates, once again, to price.

The Court has viewed the record in the light most favorable to Eisai. Even Eisai's description of the non-pricing mechanisms for exclusion in the Lovenox® Program relates back to price. The inescapable conclusion is that the price is the "predominant mechanism of exclusion." See Meritor, 696 F.3d at 275, 277.

One final issue on the applicability of the price-cost test is the effect of prior rulings by this Court on this determination. In arguing that the price-cost test does not apply, Eisai relies on this Court's rulings from a June 12, 2009 hearing (see dkt. 61) and

an August 2010 decision (see dkt. 119) on Sanofi's motion to dismiss, or alternatively, for summary judgment based on Eisai's alleged lack of standing, wherein -- according to Eisai -- the Court ruled that the rule of reason applies here. (Eisai Br. at 4-5.) Sanofi responds that this ruling predated the Third Circuit's decision in Meritor and relied heavily on LePage's. (Sanofi Reply Br. at 6.) Meritor clarified the law in this circuit, and Sanofi argues that this Court has a duty to apply "a supervening rule of law despite its prior decisions to the contrary." (Id. (quoting Zichy v. City of Phila., 590 F.2d 504, 508 (3d Cir. 1979)).)

The Court rejects Eisai's contention that its earlier rulings bind it to the rule of reason instead of the price-cost test. First, the Court is not persuaded that it actually even decided that the rule of reason and not the price-cost test applied. The Court stated, when denying the motion to dismiss from the bench, that, based on its reading of the case law, the complaint contained "at least a plausible economic theory of a rule of reason adverse economic effect based upon the ability to monopolize through these contracts." (Dkt. 61, 6-12-09 Hearing Tr. at 72.) This language is far too qualified and contextual to constitute a ruling with regard to which test applies at this stage. Second, these decisions focus on standing (see dkt. 119, 8-10-10 Op.), but the issue before the Court today is what test applies in determining whether Sanofi's conduct was unlawful. And finally, even if the

Court's prior rulings could be read to resolve the instant issue, i.e., whether the price-cost test applies, Meritor, by clarifying LePage's and the price-cost test in this circuit, constitutes an "extraordinary circumstance[]" warranting "reconsideration of an issue decided earlier in the course of litigation." See Pub. Interest Research Grp. of N.J., Inc. v. Magnesium Elektron, Inc., 123 F.3d 111, 116-17 (3d Cir. 1997) ("a supervening new law" is an "extraordinary circumstance[]").

Applying the price-cost test in these circumstances is consistent with the approach of other circuits. See Meritor, 696 F.3d at 273 (citing the Court of Appeals for the Eighth Circuit's opinion in Concord Boat, 207 F.3d at 1060-63, for the proposition that "in the context of exclusive dealing, the price-cost test may be utilized as a specific application of the 'rule of reason' when the plaintiff alleges that price is the vehicle of exclusion."). For example, in Barry Wright Corp. v. ITT Grinnell Corp., 724 F.2d 227, 229-30 (1st Cir. 1983), the plaintiff challenged, among other practices, a monopolist's use of discounts to prevent the plaintiff from obtaining one of the monopolist's customers under § 2. The Court of Appeals for the First Circuit, in rejecting this challenge, "conclude[d] that the Sherman Act does not make unlawful prices that exceed both incremental and average costs." Id. at 236.

Based on the foregoing, the Court concludes that price was the "predominant mechanism of exclusion" of the Lovenox® Program, and thus, the price-cost applies. See Meritor, 696 F.3d at 275, 277. Pursuant to this test, "so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects." Id. at 275; see also Brooke Group, 509 U.S. at 222-23. Below-cost pricing is a prerequisite to recover under the antitrust laws for a claim based on the defendant's pricing practices. Brooke Group, 509 U.S. 222-23. Here, there is no dispute that Lovenox® was never sold to hospitals at a price that was below Sanofi's cost even after discounts were applied. (Dkt. 287 at ¶ 45.) Thus, Eisai cannot recover under the antitrust laws, and summary judgment must be granted in favor of Sanofi.

2. Same Result Under Exclusive-Dealing Analysis

Even if the Court were to analyze Eisai's claims as if pricing were not the predominant form of exclusion and therefore the price-cost test would not apply, the result would be the same. Viewing the record in the light most favorable to Eisai, the Court concludes that Eisai cannot establish that the Lovenox® Program violated the antitrust laws.

Sanofi argues that, even if the price-cost test does not apply, summary judgment should still be granted for several reasons. (Sanofi Br. at 16.) As an initial matter, Sanofi's

market-share discount agreements are not exclusionary because there was no obligation to purchase any Lovenox® at all under the contracts, and "[t]he only consequence of failing to meet a set percentage of Lovenox purchases was that the customer 'simply lost its negotiated discount.'" (Id. at 17.) During the relevant period, hospitals kept multiple LTC drugs on formulary and conducted therapeutic interchanges away from Lovenox®. (Id. at 17-18.) In fact, Lovenox®'s market share dropped from 92% to 81% during the relevant period. (Id. at 18.)

Sanofi further argues that the Lovenox® Program did not foreclose competition "in a substantial share of the relevant market." (Id.) Eisai failed to show that any customers wished to purchase more Fragmin® but could not as a result of the Lovenox® contracts. (Id. at 19-22; Sanofi Reply Br. at 7, 18.) Sanofi surmises that if Eisai's claim of foreclosure had any merit, Eisai would have been able to find health-care providers who would testify that they wanted to purchase more Fragmin® but were prevented from doing so because of Sanofi's conduct. (Sanofi Reply Br. at 7.) This absence of customer testimony of foreclosure or the coercive effect of Sanofi's conduct "stands in stark contrast to the cases in which antitrust liability has been found," such as LePage's or Meritor. (Id. at 8.) Moreover, both Fragmin® and Arixtra® achieved commercial success during the relevant period; some hospitals added Fragmin® to their formularies and some

hospitals switched away from Lovenox® to competing LTC drugs. (Sanofi Br. at 23-25.) This shows that "hospitals can and did walk away from Sanofi's discounts when they so desired." (Sanofi Reply Br. at 8-9 (citing Concord Boat, 207 F.3d at 1059 (court rejected antitrust claims where customers testified that they switched a substantial share of their purchases to a competitor's products, despite the existence of the defendant's market-share discounts)).)

Sanofi contends that, in addition to Eisai's inability to demonstrate anticompetitive conduct, Eisai cannot establish the antitrust-injury requirement. (Sanofi Br. at 34.) First, the record is devoid of evidence of causation of any alleged injury, specifically evidence that, absent the Lovenox® Program or Sanofi's alleged deceptive marketing practices, hospitals would have selected Fragmin® over Lovenox®. (Id. at 35.) Sanofi also argues that there were many obstacles to Fragmin®'s growth apart from any alleged anticompetitive conduct by Sanofi, including but not limited to: fewer FDA-approved indications for Fragmin®; lack of promotional efforts for Fragmin® before Eisai entered into the 2005 Agreement with Pfizer; physician preferences; a smaller sales force than Sanofi; and lack of clinical data. (Id. at 36.)

Sanofi also argues that the fact that it was able to charge more for Lovenox® is not indicative of an antitrust injury because "[t]he antitrust laws do not prohibit a company from charging a higher price for a superior product." (Sanofi Reply Br. at 16.)

Moreover, the loss of sales due to price competition is not an antitrust injury; in fact, consumers benefit from competition. (Id.; Sanofi Br. at 38.) Fragmin® grew during the relevant period, and competition "caused Eisai to offer larger discounts on Fragmin." (Sanofi Br. at 40.) Sanofi's discount program did not prevent Eisai from competing, and "when Eisai chose to discount more, it was able to win more customers." (Sanofi Reply Br. at 17.) "The antitrust laws do not protect Eisai's desire to preserve an 85% profit margin." (Id. at 16.)

Eisai responds that empirical data shows that 68% to 84% of the market was foreclosed and that the Lovenox® Program "changed hospital's usage of LTC drugs." (Eisai Br. at 15.) And while under an exclusive-dealing arrangement, the buyer can always incur penalties to buy products from a rival, these arrangements are foreclosing because they create a "clog on competition." (Id. at 15-16 (quoting Standard Oil & Standard Stations v. United States, 337 U.S. 293, 314 (1949)) (citing N. Pac. Ry. Co. v. United States, 356 U.S. 1, 9, 11-12 (1958); Int'l Salt Co. v. United States, 332

U.S. 392, 396-97 (1947)).)[11] Eisai argues that a mere 4% of hospitals switched, to some degree, away from Lovenox® to rival drugs in the LTC market, which "hardly disproves a substantial foreclosure share." (Id. at 16.) Moreover, Eisai asserts, the relevant question is whether more hospitals would have switched to Fragmin® or included Fragmin® on formulary with other LTC drugs if not for the Lovenox® Program and the formulary access clauses. (Id. at 16-17.) The fact that Lovenox®'s market share decreased during the relevant period is likewise not fatal to Eisai's claims because this "tells us nothing about but-for market shares." (Id. at 19.)

In order to establish an antitrust violation under any section of the antitrust laws, a plaintiff must show that the defendant engaged in anticompetitive conduct, as defined by the relevant

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[11] Sanofi argues that Eisai erroneously relies on these older precedents in an effort to lower its burden. (Sanofi Reply Br. at 9-10.) While these decisions are not particularly relevant to the circumstances presented here, the Court does not find Meritor to be inconsistent with these older decisions. These cases primarily deal with the practice of "tying" -- "an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier," Eastman Kodak Co. v. Image Tech. Servs., 504 U.S. 451, 461-62 (1992) (quoting N. Pac. Ry. Co., 356 U.S. at 5-6) -- and are of minimal use in analyzing the single-product loyalty contracts before the Court. See Standard Oil, 337 U.S. at 305-06 ("Tying agreements serve hardly any purpose beyond the suppression of competition. . . . Requirements contracts, on the other hand, may well be of economic advantage to buyers as well as to sellers, and thus indirectly of advantage to the consuming public.").

statute, and "that the plaintiff suffered an antitrust injury as a result." Meritor, 696 F.3d at 269 n.9, 281. Regardless of which section of the antitrust laws are implicated by the anticompetitive conduct, "[t]o establish antitrust injury, the plaintiff must demonstrate: (1) harm of the type the antitrust laws were intended to prevent; and (2) an injury to the plaintiff which flows from that which makes defendant's acts unlawful." Id. at 281 (internal quotation marks and citation omitted).

The Court finds that Eisai's claims must fail because Eisai cannot satisfy the antitrust-injury requirement.[12] Initially, the Court notes that, while not dispositive, the increase in Fragmin®'s

[12] Eisai has argued that this Court in August of 2010 already decided that it had antitrust standing. (See Eisai Br. at 24-25.) Specifically, in ruling on Sanofi's motion to dismiss or, in the alternative, for summary judgment based on Eisai's alleged lack of standing, this Court found that the nature of Eisai's alleged injury was the "of the type for which the antitrust laws were intended to provide redress." (8-10-10 Op. at 23 (citation omitted).) Relying on LePage's, the Court stated that this type of exclusive-dealing arrangement "effectively forecloses competitors." (Id. at 24.) Sanofi argues that this prior decision does not constitute a "rul[ing] as a matter of law that Eisai has suffered antitrust injury." (Sanofi Reply Br. at 14.) The Court agrees with Sanofi that the August 2010 decision is not a ruling on the existence of Eisai's antitrust injury. The primary basis for Sanofi's motion to dismiss or for summary judgment based on Eisai's alleged lack of standing was its belief that Pfizer rather than Eisai would be the party most affected by any anticompetitive conduct. (See id.) Moreover, the Court found that the analysis favored standing "at this juncture." (8-10-10 Op. at 30.) Since this decision, the record has expanded exponentially. (Sanofi Reply Br. at 14.) And since the August 2010 decision, the Third Circuit issued Meritor and clarified the antitrust framework for single-product loyalty discount practices. (See id. at 15.) Thus, the Court's August 2010 decision does not preclude a conclusion that Eisai cannot establish an antitrust injury.

and Arixtra®'s market shares and the corresponding decrease in Lovenox®'s market share during the relevant period are most unusual in antitrust cases where liability has been found. This fact undercuts Eisai's assertion that it was injured by its foreclosure (at least partial) from the market. Moreover, as Sanofi rightly points out, there are numerous reasons why Fragmin® may have underperformed in relation to Lovenox®, including that Fragmin® had not been promoted actively in the United States for several years until Eisai entered into the 2005 Agreement with Pfizer; that physicians were more familiar with Lovenox®, particularly given Fragmin®'s lack of promotion for several years; that Lovenox® had more FDA-approved indications; and that Sanofi had a greater sales force promoting Lovenox®. (See, e.g., dkt. 287 at ¶ 235 (director of pharmacy at one hospital system was approached by Eisai representatives about the money to be saved by switching by Fragmin®, but she "did not want to switch because Fragmin lacked the indications Lovenox had").) Even when the record is viewed in the light most favorable to Eisai, Eisai cannot establish that its allegedly depressed market share was attributable to anticompetitive conduct by Sanofi as opposed to a multitude of other factors.

The record also indicates that Eisai could, and at times did, compete more vigorously to increase its market share. (See, e.g., dkt. 250, Ex. 39 at 252-54.) The fact that Eisai might lose some

profit in its effort to maintain or increase its market share is not an anticompetitive effect of Sanofi's conduct, but instead, a procompetitive one. See Atl. Richfield Co., 495 U.S. at 337 ("When a firm . . . lowers prices but maintains them above predatory levels, the business lost by rivals cannot be viewed as a an 'anticompetitive' consequence of the claimed violation."); NicSand, Inc., 507 F.3d at 455 ("While NicSand's loss of business may have propelled 3M into a dominant market position, its injury does not correspond to any allegedly anticompetitive effect on the market but rather a truly competitive one."). The problem for Eisai here is that "cutting prices in order to increase business often is the very essence of competition." Atl. Richfield Co. 495 U.S. at 338 (quoting Matsushita Elec. Indus. Co., 475 U.S. at 594). As a result, the fact that Eisai could not maintain its 85% profit margins (see dkt. 250, Ex. 37 at 174-75), and compete with Sanofi for business does not translate into an injury for antitrust purposes. Because Eisai cannot establish an antitrust injury, Sanofi is entitled to summary judgment.

Sanofi is entitled to summary judgment for the additional reason that the evidence cannot support Eisai's contention that Sanofi engaged in unlawful exclusive dealing. Exclusive-dealing arrangements do not necessarily violate the antitrust laws. See Tampa Elec., 365 U.S. at 327; Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 83 (3d Cir. 2010) ("It is well

established that competition among businesses to serve as an exclusive supplier should actually be encouraged."); Dentsply, 399 F.3d at 187 (exclusive-dealing arrangements are "not illegal in themselves"). "Exclusive dealing will generally only be unlawful where the market is highly concentrated, the defendant possesses significant market power, and there is some element of coercion present." Meritor, 696 F.3d at 284.

Exclusive-dealing arrangements are challenged under various sections of the antitrust laws, including the three sections at issue here -- § 1 and § 2 of the Sherman Act and § 3 of the Clayton Act. Id. at 269 n.9. While the essence of exclusive dealing is the same under all three sections, the requirement of anticompetitive conduct in each is articulated slightly differently. Id. For recovery under § 1, "a plaintiff must establish that the defendant was a party to a contract, combination or conspiracy that imposed an unreasonable restraint on trade." Id. (internal quotation marks and citation omitted). Section 2 requires that a plaintiff "demonstrate that the defendant willfully acquired or maintained its monopoly power in the relevant market," meaning that the defendant competed "on some basis other than the merits." Id. (internal quotation marks and citation omitted). Under § 3 of the Clayton Act, it is "unlawful for a person to enter into an exclusive dealing contract when the effect of such an agreement is to substantially lessen competition or create a

monopoly." Id. While there is no set formula for determining the legality of an exclusive-dealing agreement, important factors include: significant market power by the defendant; the duration of the agreements; any procompetitive/anticompetitive effects; whether the dominant firm engaged in behavior that was coercive; customers' ability to terminate the agreements; and whether the defendant's competitors also engaged in such arrangements. Id. at 271-72.[13]

For several reasons, the Court concludes that Eisai cannot establish violations of the antitrust laws under an exclusive-dealing analysis. While Sanofi had significant market power in the LTC market -- 81% to 92% during the relevant period -- this is not dispositive. First, the Court is not persuaded that Lovenox® contracts were even exclusive.[14] The undisputed facts show that customers could still benefit from the Lovenox® contract's discount structure even if they purchased some of their requirements from a rival. (See dkt. 287 at ¶ 30.) In fact, customers would still

[13] Another factor used by courts to evaluate exclusive-dealing arrangements under a rule-of-reason analysis is whether there were significant barriers to entry in the relevant market. See, e.g., Concord Boat, 207 F.3d at 1059. Here, 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.

[14] The basis for the Court's conclusion that the Lovenox® Program was not an unlawful exclusive-dealing arrangement is not that the contracts lacked an express exclusivity requirement or that the contracts involved less than 100% of the market. A de facto, partial exclusive-dealing arrangement may still violate the antitrust laws. See Meritor, 696 F.3d at 282-83.

obtain some additional discount -- 9% to 21% depending on volume -- under the Lovenox® Program (as it existed on June 16, 2008) if they purchased as much as 25% of their LTC drug requirements from a competitor of Sanofi. (Id.) The contracts did not require customers to purchase any Lovenox® from Sanofi, and the only consequence of not meeting a given market share and volume was forgoing the discount associated with that market share and volume. (Id. at ¶¶ 34, 35.) Customers were not cut off from their supply of Lovenox® if they failed to comply with the formulary access clause or meet the market-share and volume thresholds in the contracts. Furthermore, during the relevant period, LTC drugs other than Lovenox® were added to many hospital formularies, and some hospitals conducted therapeutic interchanges away from Lovenox® to competitor LTC drugs. Lovenox®'s market share dropped from 92.3% in 2005 to 81.5% in 2010, while Fragmin®'s market share increased from 4.3% to 8.2% and Arixtra®'s from 2.3% to 9.9%. (Economides Report at ¶ 12.)

Second, the contracts were terminable at any time by any party for any reason upon thirty days' written notice. (Dkt. 287 at ¶ 41.) The consequence of terminating the contracts was that the member hospitals would not receive the tiered discount on purchases of Lovenox®. Instead, customers could purchase "off contract" from wholesalers at the wholesale price. (Id. at ¶¶ 42-43.) Unlike the situation in Meritor, the record lacks evidence that Sanofi

threatened to cut customers off from a supply of Lovenox® or that customers feared that their termination or failure to comply with the contracts would result in an inability to obtain Lovenox®.[15]

Third, the Lovenox® contracts did not foreclose competition in the LTC market because 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. Unlike the plaintiffs in Meritor and LePage's, Eisai failed to produce the testimony of health-care providers to this effect. Moreover, both Fragmin®'s and Arixtra®'s market shares grew during the relevant period, which indicates that customers could walk away from the Lovenox® discounts when they so desired, and they did. See Concord Boat, 207 F.3d at 1059. And while there was evidence in the record that Sanofi aggressively enforced its agreements and sought to preserve and increase its market share and customer base, this conduct is the essence of competition. Vigorous competition does not amount to anticompetitive behavior. Cargill, Inc., 479 U.S. at 116 ("[C]ompetition for increased market share[] is not activity forbidden by the antitrust laws. It is simply . . . vigorous competition."); see also Brooke Group, 509 U.S. at 225 ("Even an act of pure malice by one business competitor against another does

[15] Even if the discounts were terminated, "Sanofi US did not have the ability to cut a particular customer off from supply of Lovenox because, among other things, Sanofi US did not have a direct selling relationship with customers, who instead purchased Lovenox from wholesalers." (Dkt. 287 at ¶ 40.)

not, without more, state a claim under the federal antitrust laws."). There is no evidence in the record that Sanofi's sale tactics led customers to buy more Lovenox® when they really wanted more Fragmin®. Notably, there was evidence in the record that when Eisai competed more aggressively by offering greater discounts, it won more business. (See, e.g., dkt. 250, Ex. 39 at 252-54.)

Finally, the record demonstrates that market-share discounts were common in this market. Eisai offered similar agreements for Fragmin®, and GlaxoSmithKline offered market-share based discounts for Arixtra®. (Dkt. 287 at ¶¶ 77, 116-18, 136-38.) For these reasons, the Court concludes that Sanofi did not engage in unlawful exclusive dealing in violation of § 1 and § 2 of the Sherman Act and § 3 of the Clayton Act.

This result is consistent with the approach in other circuits under similar facts. For example, the Court of Appeals for the Ninth Circuit considered agreements offering market-share discounts in Allied Orthopedic Appliances Inc. v. Tyco Health Care Group LP, 592 F.3d 991 (9th Cir. 2010). There, hospitals that were customers of Tyco, a creator of pulse oximetry ("pulse ox") technology, sued Tyco alleging that its marketing agreements foreclosed competition from manufacturers of generic pulse ox equipment. Id. at 993-94. Pulse ox equipment measures a patient's oxygen level in the blood. Id. at 994. Tyco had developed new proprietary technology -- the OxiMax system, which included pulse ox monitors and sensors -- that

was patented. Equipment from generic manufacturers was not compatible with this new technology. Id. To market the OxiMax system, Tyco used market-share discount agreements, which allowed customers to purchase Tyco's products at a discount off the list price if they committed to buy a minimum percentage of their pulse ox equipment requirements from Tyco. Id. at 995. "The agreements did not contractually obligate Tyco's customers to buy anything from Tyco. The only consequence of purchasing less than the agreed upon percentage of Tyco's products was loss of the negotiated discounts." Id. Tyco additionally offered sole-source agreements to GPOs, whereby the GPOs would agree not to enter into purchasing contracts with other vendors of pulse ox equipment, and in return would receive deeper discounts. Id. As with the market-share discount agreements, the sole-source agreements did not contractually obligate the GPOs to purchase anything from Tyco. Id.

The Ninth Circuit held that the plaintiffs could not show that either of the agreements had the potential to foreclose competition for purposes of § 1 of the Sherman Act because any customer could choose to forgo the discounts offered by Tyco and to purchase from a competitor instead. Id. at 997. Moreover, competitors were not foreclosed from competition because "a competing manufacturer need[ed] only offer a better product or a . . . better deal to

acquire [a customer's business]." Id. (internal quotation marks and citation omitted).

The Eighth Circuit in Concord Boat similarly concluded that market-share and volume discounts that did not obligate buyers to purchase anything and that did not preclude buyers from purchasing from competitors did not violate antitrust laws. 207 F.3d at 1044-45, 1058. The court notably referenced the fact that customers "were free to walk away" from the discounts and that customers did in fact walk away when competitors offered better discounts. Id. at 1059, 1063. This fact discredited the plaintiffs' "theory that the discounts created 'golden handcuffs' and entry barriers for other engine manufacturers." Id. at 1063.

The Court of Appeals for the Sixth Circuit in NicSand, Inc. also found that a plaintiff challenging a defendant's discounting practices could not establish an antitrust injury. The plaintiff had challenged the defendant's practice of providing up-front payments to customers to obtain their business. 507 F.3d at 452. The court found that the nature of the market (automotive sandpaper) required suppliers to offer customers up-front payments because, before customers would consider switching, suppliers needed to purchase the retailer's existing supply and provide a discount on the first order. Id. The court explained that these up-front payments "are nothing more than price reductions offered to the buyers for the exclusive right to supply a set of stores

under multi-year contracts." Id. (internal quotation marks and citation omitted).

As to the multi-year nature of the contracts, the court stated that the plaintiff could have approached its customers and offered a similar deal. Id. at 453. While offering similar deals would have decreased the profit margins that the plaintiff enjoyed before the entry of the defendant in the market, the plaintiff offered "no explanation why this modest reduction in profit margins on a product of this sort is a concern of the antitrust laws." Id. Finally, as to the plaintiff's challenge to the exclusivity of the agreements, the court explained that the retailers preferred exclusive-dealing arrangements, and the plaintiff failed to compete. Id. at 454. The court concluded that the up-front discounts did not result in the defendant selling below cost and that the plaintiff's loss of profits stemming from the defendant's conduct did "not correspond to any allegedly anticompetitive effect on the market but rather a truly competitive one." Id. at 455.

These cases from other courts demonstrate that market-share discounting practices generally do not foreclose a plaintiff from competing. These antitrust plaintiffs could have offered greater discounts or improved their products in order to maintain and increase their market shares. The fact that they did not and suffered a loss in profits is of no concern to the antitrust laws. These cases show that, in general, antitrust claims fail if

customers are able to walk away from the defendant's discounts and still use the defendant as a supplier. These cases describe exactly the situation here -- market-share discounts that hospitals could walk away from and still continue to obtain Lovenox® and that hospitals did walk away from especially when Eisai offered greater discounts.

One final issue that the Court must consider is the impact of Sanofi's marketing practices on Eisai's claims. Eisai also relies on the allegedly deceptive marketing practices of Sanofi as part of its antitrust claims. The record contains multiple incidents of "FUD" tactics by Sanofi. There are examples of Sanofi sales representatives disparaging Fragmin® and the other LTC drugs and discouraging hospitals from considering other LTC drugs. The Court will not repeat these examples. Eisai argues that "Sanofi's unlawful superiority claims and disparagement of its competitors enhanced the impact of its anti-competitive contracting practices." (Eisai Br. at 22; see also Compl. at ¶ 71.) Sanofi counters that, while a plaintiff may have a remedy for deceptive sales practices by a competitor, it is generally not through the antitrust laws. (Sanofi Br. at 28.) This stems in part because such advertising is believed to have a "de minimis effect on competition." (Id.; Sanofi Reply Br. at 13.) Furthermore, Sanofi argues that there is no evidence that any alleged deceptive practices "had a negative impact on any competitor's ability to sell its products." (Sanofi

Br. at 29.) Hospital administrators making formulary decisions are sophisticated and base their decisions on clinical data and other literature. (See id.) Every third-party witness "testified that he or she would not simply believe anything said by sales representatives, but would instead investigate and seek independent verification." (Id. at 30; see also Sanofi Reply Br. at 12.) Finally, Sanofi argues that there is also no evidence that Eisai could not neutralize the allegedly deceptive practices, and several witnesses testified that they switched away from Lovenox® notwithstanding Sanofi sales practices. (Sanofi Br. at 31-32.)

Consideration of Sanofi's allegedly problematic and deceptive marketing practices does not alter the Court's conclusion.[16] The Court has already concluded that Sanofi has not otherwise engaged in anticompetitive conduct in violation of the antitrust laws. The Third Circuit explained recently that defamatory statements, "which plainly [are] not competition on the merits, can give rise to

[16] Eisai, in support of its claims that Sanofi engaged in anticompetitive conduct, has relied upon alleged FDA violations by Sanofi and a Senate investigation into Sanofi's practices. As to the FDA violations, Eisai claims that sales representatives violated FDA promotional regulations by touting Lovenox®'s alleged superiority to Fragmin® and other LTC drugs and by marketing Lovenox® to oncologists and oncology patients despite the fact that Fragmin® -- and not Lovenox® -- had the Cancer Indication. (See dkt. 289-1, Sanofi's Response to Eisai's Statement of Undisputed Material Facts at ¶¶ 21-27, 182-88.) As to the Senate investigation, Eisai submitted documents indicating that a Senate Committee investigated whether Sanofi had financial ties with the North American Thrombosis Forum, the Society of Hospital Medicine, and Dr. Victor Tapson. (See dkt. 262-4, Ex. 34, U.S. Senate Committee on Finance, New Release, Baucus Grassley Report Details Financial Relationship Between Drug Company, Physician Who Lobbied the FDA (May 25, 2011); id. at Ex. 35, Committee on Finance, United States Senate, Staff Report On Sanofi's Strategic Use Of Third Parties To Influence The FDA (May 2011).) These two medical groups and Dr. Tapson had submitted letters to the FDA supporting Sanofi's citizen petition seeking to delay the FDA's approval of a generic version of Lovenox®. (Id. at Ex. 35 at 1.) The Committee initiated an investigation because the existence of these financial ties created a concern that "there may have been an abuse of the citizen petition process." (Id.) Assuming arguendo that this evidence would be admissible, consideration of this evidence would not change the result. As to the alleged FDA violations, the fact that Sanofi may have run afoul of FDA regulations does not mean that it also violated the antitrust laws. With respect to the Senate investigation, Sanofi's motivation and efforts to keep the generic drugs out of the market have no impact on the antitrust analysis of whether Sanofi engaged in improper monopolistic behavior toward other branded drugs in the market during the relevant period.

antitrust liability, especially when [they are] combined with other anticompetitive acts." W. Penn, 627 F.3d at 109 n.14. While it is theoretically possible that "false statements about a rival to potential investors and customers" can be a form of anticompetitive conduct, it would be a rare case in which such false statements in-and-of themselves would be sufficient to support an antitrust violation. See id. at 109 & n.14 (citing Santana Prods, Inc. v. Bobrick Washroom Equip., Inc., 401 F.3d 123, 132 (3d Cir. 2005) (stating with regard to a claim under § 1 of the Sherman Act, "deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned")). This is not such a rare case, and the Court has yet to find a case in this circuit that is that sort of rare case.

Eisai has also failed to come forward, in response to Sanofi's motion for summary judgment, with evidence of hospitals' reliance on these alleged deceptive acts by Sanofi. Specifically, several third-party witnesses, who were health-care providers, testified that, in making their treatment and formulary decisions, they would not rely on statements from sales representatives without independently verifying such statements. (See, e.g., dkt. 250, Ex. 47 at 154-55, 169-70; id. at Ex. 41 at 184-186; id. at Ex. 49 at 78-79; dkt. 287 at ¶¶ 217, 248.) In fact, some hospitals went through with therapeutic interchanges away from Lovenox® despite Sanofi's allegedly misleading efforts to thwart the switch. (See,

e.g., dkt. 250, Ex. 49 at 88.) Eisai has not presented testimony to the contrary. As a result, Eisai cannot show that hospitals relied on any alleged misrepresentations by Sanofi representatives. Thus, Sanofi's alleged deceptive marketing practices do not amount to an antitrust violation.

The Court has considered all of the parties' remaining arguments and finds that they are without merit and do not require further discussion.

C. The State Law Claims

Eisai has also asserted parallel antitrust claims under New Jersey State law, N.J.S.A. 56:9-3 and N.J.S.A. 56:9-4. New Jersey's antitrust act is to be construed in harmony with federal interpretations of analogous statutes. N.J.S.A. 56:9-18; State v. N.J. Trade Waste Ass'n, 96 N.J. 8, 19 (1984). Because the state-law claims are premised on the same conduct as the federal claims, summary judgment must be granted on the state-law claims for the same reasons.

VI. CONCLUSION

For these reasons, the Court holds that Sanofi has carried its burden of demonstrating its entitlement to summary judgment on all claims. Accordingly, Sanofi's motion for summary judgment (dkt. 245) will be granted in its entirety. The remaining motions on the docket will be denied without prejudice as moot. The Court will issue an appropriate order and judgment.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: March 28, 2014

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI INC.,	:	**Civil Action No.: 08-4168 (MLC)**
	:	
Plaintiff,	:	
	:	
v.	:	**MEMORANDUM OPINION**
	:	**AND ORDER**
SANOFI-AVENTIS U.S., LLC, et al.,	:	
	:	
Defendants.	:	
_____	:	

ARPERT, U.S.M.J

This matter having come before the Court on the application of Plaintiff Eisai Inc. ("Plaintiff" or "Eisai"), by letter to the Court dated November 15, 2011, to compel Defendants Sanofi-Aventis U.S., LLC and Sanofi-Aventis, U.S., Inc. (collectively, "Defendants") to produce the deposition transcripts of those witnesses who gave sworn deposition testimony in a 2003 lawsuit brought by Organon Sanofi-Synthelabo LLC ("OSS") against Aventis Pharmaceuticals, Inc. ("Aventis") in which it was alleged that Aventis' Lovenox discount program was anticompetitive ("2003 OSS Litigation") and who are also being deposed in this action. Defendants submitted opposition to Plaintiff's application in a letter dated November 21, 2011. The Court conducted oral argument on October 19, 2011. Pursuant to an agreement among the Parties, the resolution of Plaintiff's application was deferred pending the mediation of this matter. For the reasons stated on the record and herein, Plaintiff's application to compel the production of deposition transcripts of those witnesses who gave sworn deposition testimony in the 2003 OSS Litigation is **DENIED**.

Because the facts of this case are well known to the parties, and in light of the numerous Opinions and Orders previously issued by this Court, the Court will simply recite the facts

relevant to this application and incorporates the facts set forth in its previous Opinions and Orders.

Plaintiff maintains that "prior sworn testimony...in an antitrust action over Lovenox contracting...is plainly relevant and discoverable" and "there can be no possible burden in forwarding copies of the small number [of] deposition...[transcripts]". *See* Pl.'s Letter dated November 15, 2011 at 1. Noting that this issue was raised with the Court as part of its application to compel the production of prior investigations, lawsuits and other proceedings (collectively, "prior proceedings") involving the sales, marketing, contracting, distribution and/or promotion of Lovenox (*see* dkt. entry no. 162), Plaintiff reiterates that during oral argument on October 19, 2011 the Court "indicated that such narrowly limited discovery could be relevant to 'all sorts of issues'" (Pl.'s Letter dated November 15, 2011 at 1). At that time, the Court also "suggested that [defense counsel]...have a conversation...[with Plaintiff's counsel]", to which defense counsel agreed. *Id.* Plaintiff's counsel asserts that his "understanding from this exchange was that...[Defendants] had no objection to producing the transcripts by themselves because their discoverability was 'obvious' to even defense counsel". *Id.* at 1-2. Further, Plaintiff contends that "the Court's subsequent correspondence with both parties indicated it shared...[this] view". *Id.* at 2. Since the hearing on October 19, 2011, however, Plaintiff argues that Defendants have "changed [their] position" and "now refuse to produce any of these transcripts without a Court Order to do so" despite the fact that they "have already indicated...[that production] is not objectionable". *Id.* Plaintiff requests that the Court "compel production of the transcripts", maintaining that "[b]ecause of the discrete nature of this issue and the fact that [it] already moved for this limited discovery in its prior briefing and at the hearing, [Plaintiff] does not believe this [issue] warrants another round of time-consuming briefing". *Id.*

In opposition, Defendants maintain that Plaintiff has misrepresented their position on this issue and "has not demonstrated that these transcripts are at all relevant to the instant lawsuit". *See* Def.'s Letter dated November 21, 2011 at 1. Defendants claim that "[a]t no time did...[they] concede the relevance of these depositions or agree to produce them and...[defense counsel's] statements in this regard are taken out of context". *Id*. Noting that the Court included language supporting their position related to this issue in its Memorandum Opinion and Order (*see* dkt. entry no. 162), Defendants argue that defense counsel "agreed only 'to meet and confer with Plaintiff's counsel regarding the production of prior sworn testimony'" from the 2003 OSS Litigation (*see* Def.'s Letter dated November 21, 2011 at 1). Thus, after the October 19, 2011 hearing, Defendants "considered...[their] position with respect to these deposition transcripts and determined that just as the 2003 OSS Litigation is irrelevant and not likely to lead to the discovery of admissible evidence in this matter, so too are the depositions that took place in connection with that litigation". *Id*. at 1-2. The parties met and conferred on this issue on October 27, 2011 and Defendants advised Plaintiff of their position on October 31, 2011. *Id*. at 2. Defendants claim that Plaintiff is attempting to circumvent the Court's determination that "the subject matter of the 2003 OSS Litigation is not relevant to the instant lawsuit" by speculating that "the deposition transcripts could be relevant...to show the bias of a particular witness". *Id*. Citing *Rhone-Poulenc Rorer Inc. v. Aetna Cas. & Sur. Co.*, 1991 WL 183842, at *3 (E.D. Pa. 1991), Defendants argue that Plaintiff fails to "give any explanation as to what bias might exist for these witnesses" and "[m]ere speculation about potential bias or motive is not enough to justify discovery into irrelevant material". *Id*. As such, Plaintiff's "request for these transcripts should not be permitted". *Id*.

The Court notes that pursuant to FED. R. CIV. P. 26(b)(1), "parties may obtain discovery

regarding any nonprivileged matter that is relevant to any party's claim or defense...including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter" and "the court may order discovery of any matter relevant to the subject matter involved in the action", although "relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence". "The Court notes...that there is a general policy of allowing liberal discovery in antitrust cases" and that, "[p]articularly where allegations of conspiracy or monopolization are involved, ...broad discovery may be needed to uncover evidence of invidious design, pattern or intent". *Kellam Energy, Inc. v. Duncan*, 616 F. Supp. 215, 217-18 (D. Del. 1985). "Where there is doubt over relevance...[in antitrust cases], the rule indicates that the court should be permissive" assuming the discovery is relevant to either party's claim or defense or is relevant to the subject matter involved in the action. *American Health Systems, Inc. v. Liberty Health System*, 1991 WL 30726, at *2 (E.D. Pa. 1991); *see also Morgan Smith Automotive Products, Inc. v. General Motors Corp.*, 54 F.R.D. 19 (E.D. Pa. 1971). Further, the Court acknowledges that "[t]he party resisting discovery has the burden of clarifying and explaining its objections and to provide support therefor". *Tele-Radio Systems, Ltd. v. De Forest Electronics, Inc.*, 92 F.R.D. 371, 375 (D.N.J. 1981); *see also Gulf Oil Corp. v. Schlesinger*, 465 F. Supp. 913, 916-17 (E.D. Pa. 1979); *Robinson v. Magovern*, 83 F.R.D. 79, 85 (E.D. Pa. 1979).

"However, despite this breadth, discovery is not without bounds...and courts will not permit parties to engage in fishing expeditions" because "the discovery rules are designed to assist a party to prove a claim that it reasonably believes to be viable without discovery, not to find out if it has any basis for a claim" such that "the fact that discovery might uncover evidence

showing that a plaintiff has a legitimate claim does not justify the discovery request". *MacDermid Printing Solutions, L.L.C., v. E.I. du Pont de Nemours and Co.*, 2008 WL 323764, at *1 (D.N.J. 2008); *see also Unicasa Mktg. Group, LLC v. Spinelli*, 2007 WL 2363158, at 2 (D.N.J. 2007). Further, pursuant to FED. R. CIV. P. 26(b)(2)(C), "the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that:

> (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
>
> (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
>
> (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.

"[A] discovery request may be denied if, after assessing the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues, the District Court finds that there exists a likelihood that the resulting benefits would be outweighed by the burden or expenses imposed as a consequence of the proposed discovery". *Takacs*, 2009 WL 3048471, at *1; *see also Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999). "The purpose of this rule of proportionality is to guard against redundant or disproportionate discovery by giving the court authority to reduce the amount of discovery that may be directed to matters that are otherwise proper subjects of inquiry". *Takacs*, 2009 WL 3048471, at *1 (*citing Bowers v. National Collegiate Athletic Assoc.*, 2008 WL 1757929, at *4 (D.N.J. 2008)); *see also Leksi, Inc. v. Federal Ins. Co.*, 129

F.R.D. 99, 105 (D.N.J. 1989); *Public Service Group, Inc. v. Philadelphia Elec. Co*., 130 F.R.D. 543, 551 (D.N.J. 1990).

Initially, the Court notes that correspondence dated October 20, 2011 emanating from these Chambers inaccurately stated that "defense counsel indicated that he was amenable to providing...[prior sworn testimony]" during the hearing held on October 19, 2011 and that the Court's ruling would correspond to this outcome. *See* October 20, 2011 E-mail from Chambers to Counsel attached to Pl.'s Letter dated November 15, 2011; *see also* October 19, 2011 Hearing Transcript attached to Pl.'s Letter dated November 15, 2011. Having had the benefit of reviewing the October 19, 2011 Hearing Transcript, the Court's Memorandum Opinion and Order dated November 7, 2011 denied Plaintiff's request to compel the production of prior proceedings and settlement materials related to the 2003 OSS Litigation while also indicating that defense counsel "agreed to meet and confer with Plaintiff's counsel regarding the production of prior sworn testimony related to the 2003 OSS Litigation". *See* dkt. entry no. 162 at 17-18; *see also* October 19, 2011 Hearing Transcript attached to Pl.'s Letter dated November 15, 2011. Given that the parties failed to reach agreement with respect to the deposition transcripts at issue here, and given the Court's previous finding that "the 2003 OSS Litigation involved different parties, different contractual structures, a different anticoagulant product (Arixtra) that had only very limited approved indications at the time, and related to Arixtra's inability to break into the market as a new entrant" (*see* dkt. entry no. 162 at 17; *see also* Def.'s Opp'n Letter dated April 28, 2011 at 6-7), the Court finds that prior sworn testimony related to the 2003 OSS Litigation is equally irrelevant and unlikely to lead to the discovery of admissible evidence in this matter. *See MacDermid Printing*, 2008 WL 323764, at *1; *see also Takacs*, 2009 WL 3048471, at *1. Pursuant to FED. R. CIV. P. 26(b)(2)(C), despite the fact that production of the materials requested

herein may be less burdensome than Plaintiff's request for the production of prior proceedings and settlement materials related to the 2003 OSS Litigation, the Court finds that "the burden or expense of the proposed discovery outweighs its likely benefit".

Having considered the papers submitted and the opposition thereto together with the parties' arguments during oral argument, and for the reasons set forth above and on the record;

IT IS on this 27th day of February, 2012,

ORDERED that Plaintiff's application to compel Defendants to produce the deposition transcripts of those witnesses who gave sworn deposition testimony in the 2003 OSS Litigation and are also being deposed in this action is **DENIED**.

s/ *Douglas E. Arpert*
DOUGLAS E. ARPERT
UNITED STATES MAGISTRATE JUDGE

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI INC.,	:	CIVIL ACTION NO. 08-4168 (MLC)
Plaintiff,	:	**O R D E R**
v.	:	
SANOFI-AVENTIS U.S., LLC, et al.,	:	
Defendants.	:	

PLAINTIFF, Eisai Inc. ("Eisai"), appealing pursuant to Federal Rule of Civil Procedure ("Rule") 72 and Local Civil Rule 72.1(c) from a Memorandum Opinion and Order of the Magistrate Judge filed on February 27, 2012 ("2-27-12 Order") (dkt. entry no. 183, 2-27-12 Order; dkt. entry no. 188, 3-16-12 Appeal); and the 2-27-12 Order denying Eisai's motion to compel defendants, sanofi-aventis U.S. LLC and sanofi-aventis U.S. Inc. (collectively, "sanofi-aventis"), to produce the deposition transcripts of witnesses who gave sworn testimony in a 2003 lawsuit brought by Organon Sanofi-Synthelabo LLC ("OSS") against Aventis Pharmaceuticals, Inc. ("2003 OSS Litigation") (2-27-12 Order); and the Magistrate Judge basing the decision in the 2-27-12 Order, in part, on a previous finding that "the 2003 OSS Litigation involved different parties, different contractual structures, a different anticoagulant product (Arixtra) that had only very limited approved indications at the time, and related

to Arixtra's inability to break into the market as a new entrant," in concluding that with respect to Eisai's application for production of the 2003 OSS Litigation deposition transcripts, "prior sworn testimony related to the 2003 OSS Litigation is equally irrelevant and unlikely to lead to the discovery of admissible evidence in this matter" (id. at 6 (citing dkt. entry no. 162, 11-7-11 Order at 17-18)); and

EISAI contending, inter alia, that the Magistrate Judge improperly denied its motion to compel production of the 2003 OSS Litigation deposition transcripts because (1) the 2003 OSS Litigation is relevant to the current action, insofar as both concern the alleged Lovenox monopoly of the low molecular weight heparin market, (2) the burden of producing the deposition transcripts does not outweigh the potential benefits, (3) the deposition transcripts would be admissible under the Federal Rules of Evidence, and (4) sanofi-aventis has raised defenses independently requiring it to produce the deposition testimony from the 2003 OSS Litigation (dkt. entry no. 189, Eisai Br.); and sanofi-aventis opposing Eisai's appeal (dkt. entry no. 193, sanofi-aventis Br.); and sanofi-aventis suggesting that Eisai's appeal improperly "appears to seek to make an end run and out-of-time challenge to the Court's November 7th, 2011 Memorandum Opinion and Order" (id. at 1-2); and

IT APPEARING that a motion to compel production of documents is not dispositive, and thus, may be entered by a magistrate judge, see 28 U.S.C. § 636(b)(1)(A); and it appearing that a district court, in reviewing a magistrate judge's order in a non-dispositive matter, may modify, vacate, or reverse the order only if it was "clearly erroneous or contrary to law," Cipollone v. Liggett Grp., Inc., 785 F.2d 1108, 1113 (3d Cir. 1986); see also Jackson v. Chubb Corp., 45 Fed.Appx. 163, 166 n.7 (3d Cir. 2002); and it further appearing that (1) "a finding is clearly erroneous 'when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed,'" Schering Corp. v. Mylan Pharms., Inc., No. 09-6383, 2011 WL 3651343, at *2 (D.N.J. Aug. 18, 2011) (citations omitted), and (2) a ruling is contrary to law if a magistrate judge has misinterpreted or misapplied applicable law, Gunter v. Ridgewood Energy Corp., 32 F.Supp.2d 162, 164 (D.N.J. 1998); see also Kounelis v. Sherrer, 529 F.Supp.2d 503, 517 (D.N.J. 2008); and the Court further observing that when an appeal "seeks review of a matter within the purview of the Magistrate Judge, such as a discovery dispute, an even more deferential standard, the 'abuse of discretion' standard, must be applied," Salamone v. Carter's Retail, Inc., No. 09-5856, 2012 WL 821494, at *4 (D.N.J. Mar. 9, 2012) (citing Kounelis, 529 F.Supp.2d at 518); and

IT APPEARING that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or other tangible things. . . . For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action," Fed.R.Civ.P. 26(b)(1); and it further appearing that a court "must limit the frequency or extent of discovery otherwise allowed" if it determines that:

> (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
>
> (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
>
> (iii) the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues,

Fed.R.Civ.P. 26(b)(2)(C); and it further appearing that there is "particularly broad deference given to a magistrate judge's discovery rulings," Farmers & Merchants Nat'l Bank v. San Clemente Fin. Grp. Secs., Inc., 174 F.R.D. 572, 585 (D.N.J. 1997); and

THE COURT finding no error in the Magistrate Judge's denial of Eisai's motion to compel production of the 2003 OSS Litigation deposition transcripts; and the Court further finding that the Magistrate Judge's 2-27-12 Order was consistent with the earlier 11-7-11 Order, which went unchallenged by Eisai; and nothing in the record suggesting that the Magistrate Judge's 2-27-12 Order was "arbitrary, fanciful, or unreasonable," in light of the Magistrate Judge's 11-7-11 Order denying Eisai's discovery request for "all documents that relate or pertain to the 2003 [OSS] Lawsuit" (11-7-11 Order at 4, 17-18), see Salamone, 2012 WL 821494, at *6 (denying appeal of order denying a discovery request regarding "similarly-situated employees located anywhere in the United States...", where the magistrate judge "had previously ruled that Plaintiff could not seek nationwide discovery"); and

THE COURT having reviewed and considered carefully the papers in support of and opposition to the appeal; and the Court having considered the matter without oral argument pursuant to Local Civil Rule 78.1(b); and Eisai having failed to demonstrate that the 2-27-12 Order was clearly erroneous, contrary to law, or an abuse of the Magistrate Judge's discretion; and for good cause appearing;

IT IS THEREFORE on this 16th day of April, 2012, **ORDERED** that the 2-27-12 Memorandum Opinion and Order (dkt. entry no. 183), from which plaintiff, Eisai, Inc., appeals (dkt. entry no. 188), is **AFFIRMED**; and

IT IS FURTHER ORDERED that the Clerk of the Court should designate the appeal (dkt. entry no. 188) as **TERMINATED**.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

JOINT APPENDIX CONTINUED
IN FOLLOWING VOLUME