IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Eisai Inc., Plaintiff, v. sanofi-aventis U.S. LLC, and sanofi-aventis U.S. Inc., Defendants.	Civil Action No. 08-04168 (MLC/DEA) **REDACTED** Return Date: August 3, 2013

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON LIABILITY ISSUES

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PRELIMINARY STATEMENT

[redacted] Defendants sanofi-aventis U.S. LLC and Sanofi US Services Inc. (f/k/a sanofi-aventis U.S. Inc.) manufacture and sell Lovenox, a leading injectable anticoagulant used to treat and prevent blood clots, which was first approved in the early 1990s. Since September 2005, plaintiff Eisai has had a contractual right to distribute a competing product, Fragmin, in the United States. Fragmin is also an injectable anticoagulant but has fewer FDA-approved indications than Lovenox [redacted]

[redacted]

[redacted]

For these reasons and others discussed below, the Court should grant summary judgment for Sanofi US on liability.[1]

STATEMENT OF FACTS

A. The Parties And Products

Lovenox is an injectable anticoagulant that prevents and treats the formation of potentially life threatening blood clots known as deep vein thrombosis ("DVT").[2] [redacted] It is a type of anticoagulant known as a low molecular weight heparin ("LMWH"). Lovenox was the first LMWH approved by the Food and Drug Administration ("FDA") and has been sold in the United States since 1993. [redacted]

[1] By separate motion, Sanofi US is also filing for summary judgment on damages issues. [redacted]

[redacted]

Eisai Inc. is a U.S. subsidiary of Eisai Co., Ltd., a Japanese pharmaceutical company. [redacted] Eisai distributes the LMWH Fragmin in the United States.

[redacted]

[redacted]

Innohep is another LMWH product that was sold in the United States starting in 2000. Innohep had one FDA approved indication for the treatment of acute DVT but was withdrawn from the U.S. market in 2011 after a contamination recall. (*See* LEO Pharma Inc. Press Release, LEO Pharma Inc. Voluntarily Recalls Innohep (Tinzaparin Sodium Injection) Multidose Vials (Feb. 10, 2011), http://www.leo-pharma.us/Files/Billeder/LEO_local_images/LEO-Pharma.US/10%20Feb%202011_Firm_Press_Release_LEO_Pharma_Inc.pdf.)

[redacted]

In July 2010, the FDA approved a generic version of Lovenox (Momenta Pharmaceutical Inc.'s enoxaparin). (*See* FDA News Release, FDA Approves First Generic Enoxaparin Sodium Injection (July 23, 2010), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220092.htm.) [redacted]

[redacted]

PROCEDURAL HISTORY

On August 18, 2008, Eisai filed its complaint against Sanofi US in the United States District Court for the District of New Jersey [redacted] Sanofi US's motion to dismiss Eisai's complaint was denied on June 12, 2009. [redacted] Its subsequent Motion to Dismiss or in the Alternative for Summary Judgment for Plaintiff's Lack of Standing was denied August 10, 2010. [redacted] The District Court granted Sanofi US's Motion for 28 U.S.C. §1292(b)

[8] [redacted]

Certification and Stay of Proceedings on August 10, 2010. [redacted] The United States Court of Appeals for the Third Circuit denied the interlocutory appeal on November 2, 2010. [redacted]

ARGUMENT

I. LEGAL STANDARD

A. Summary Judgment Standard

Under Rule 56 of the Federal Rules of Civil Procedure, a court must enter summary judgment if there is "no genuine dispute as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Although the moving defendant bears the initial burden of explaining that no genuine issues of material fact exist, that burden "'may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case' when the nonmoving party bears the ultimate burden of proof." *Singletary v. Pa. Dep't of Corrs.*, 266 F.3d 186, 192 n.2 (3d Cir. 2001) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)); *see also Conoshenti v. Pub. Serv. Elec. & Gas Co.*, 364 F.3d 135, 140 (3d Cir. 2004). The burden then shifts to the nonmoving party to "set forth specific facts" and "present actual evidence" proving that there is a genuine issue for trial. *Rest. Techs., Inc. v. Jersey Shore Chicken*, No. 05-5356 (MLC), 2007 WL 4081737, at *5 (D.N.J. Nov. 15, 2007).

A plaintiff cannot overcome a Rule 56 motion with hearsay or other inadmissible evidence. *Philbin v. Trans Union Corp.*, 101 F.3d 957, 961 n.1 (3d Cir. 1996). Neither can a plaintiff rely on the "unsubstantiated allegations of its pleadings" nor "economic theories that may or may not apply to the facts of the case or on conclusory or incomplete expert analyses." *Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc.*, 920 F. Supp. 455, 471 (S.D.N.Y. 1996). A

"mere existence of a scintilla of evidence in support of the [nonmovant's] position" is insufficient to defeat a motion under Rule 56. *Restaurant Techs.*, 2007 WL 4081737, at *6 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)).

The Third Circuit recently has clarified that "the plaintiff in an antitrust case responding to a summary judgment motion must overcome a 'higher threshold,' which is imposed in order 'to avoid deterring innocent conduct that reflects enhanced, rather than restrained, competition.'" *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 73 (3d Cir. 2010) (quoting *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 357 (3d Cir. 2004)).

B. Elements Of Eisai's Antitrust Claims

Eisai's complaint asserts four separate causes of action under the federal antitrust statutes including claims for unlawful monopolization[9] and attempted monopolization[10] of the LTC Market in violation of Section 2 of the Sherman Act (First and Second Claims for Relief), exclusive dealing in violation of Section 3 of the Clayton Act (Third Claim For Relief),[11] and an unreasonable agreement in restraint of trade in violation of Section 1 of the Sherman Act (Fourth

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[9] To establish monopolization under Section 2 of the Sherman Act, a plaintiff must prove: (1) that the defendant possesses monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power through anticompetitive conduct as distinguished from "growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

[10] To state a claim of attempted monopolization under Section 2 of the Sherman Act, Eisai must prove: "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993); *Barr Labs., Inc. v. Abbott Labs., Inc.*, 978 F.2d 98, 111-12 (3d Cir. 1992).

[11] To state a valid exclusive dealing claim under Section 3 of the Clayton Act, Eisai needs to establish that (1) Sanofi US entered into sales agreements that prohibited purchasers from using or dealing with competitors *and* (2) that the probable effect of the arrangement was to foreclose competition in a substantial share of the relevant market. 15 U.S.C. § 14; *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327, 329-30 (1961); *Barr Labs.*, 978 F.2d at 110-11.

Claim for Relief).[12] In addition, Eisai alleges parallel violations of the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-3 and § 56:9-4 (2008) (Fifth Claim For Relief).

There are several essential elements common to the statutes under which Eisai asserts its claims.[13] *See ZF Meritor*, 696 F.3d at 269 n.9. For challenges to pricing practices, a showing of below-cost pricing is required irrespective of which of the three sections is invoked. *See Brooke Grp. Ltd. v. Brown & Williamson*, 509 U.S. 209, 222-23 (1993); *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 339-40 (1990); *ZF Meritor,* 696 F.3d at 269 n.9. For non-pricing practices, the statutes all require proof of (1) anticompetitive or exclusionary conduct that (2) had the effect of foreclosing competition from a substantial share of the relevant market. *ZF Meritor*, 696 F.3d at 271. All antitrust claims also require proof of a properly defined relevant product market, antitrust injury, proximate causation, and damages. *See J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 562, 568 (1981); *Queen City Pizza, Inc. v. Domino's Pizza*, 124 F.3d 430, 436 (3d Cir. 1997); *Atl. Richfield*, 495 U.S. at 334; *Van Dyk Research Corp. v. Xerox Corp.*, 631 F.2d 251, 255 (3rd Cir. 1980), *cert. denied*, 452 U.S. 905 (1981).

[redacted]

[12] To state a valid exclusive dealing claim under Section 1 of the Sherman Act, Eisai must show: (1) existence of an exclusive agreement, (2) substantial foreclosure in a relevant market, and (3) under the rule of reason, harm to competition resulting from the foreclosure outweighs any procompetitive justifications. *See Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP,* 592 F.3d 991, 997 (9th Cir. 2010); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 315-16 (3d Cir. 2010).

[13] The analysis is the same for both the federal and state statutes at issue here. [redacted]

[redacted] The Court repeatedly has made clear that when an antitrust plaintiff challenges a defendant's "pricing practices, only predatory [*i.e.*, below-cost] pricing has the requisite anticompetitive effect" to give rise to an antitrust violation. *Atl. Richfield*, 495 U.S. at 339-40; *see also Pac. Bell Tel. Co. v. LinkLine Commc'ns, Inc.*, 555 U.S. 438, 451-52 (2009); *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 319 (2007); *Brooke Grp.*, 509 U.S. at 222; *Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 117-18, n.12 (1986). The Court has adhered to this rule "regardless of the type of antitrust claim involved." *Atl. Richfield*, 495 U.S. at 340; *Brooke Grp.*, 509 U.S. at 223. [redacted] *Ortho Diagnostic,* 920 F. Supp. at 469-70; *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.* , 475 U.S. 574, 594 (1986) ("[C]utting prices in order to increase business often is the very essence of competition.").

Condemning discounting practices would "chill the very conduct the antitrust laws are designed to protect." *LinkLine*, 555 U.S. at 451 (quoting *Matsushita*, 475 U.S. at 594);

see also Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 414 (2004)

[redacted] "the consequence of a mistake here is not simply to force a firm to forego legitimate business activity it wishes to pursue; rather, it is to penalize a procompetitive price cut, perhaps the most desirable activity (from an antitrust perspective) that can take place in a concentrated industry where prices typically exceed costs." *Barry Wright Corp. v. ITT Grinnell Corp.,* 724 F.2d 227, 235 (1st Cir. 1983).

Accordingly, a plaintiff challenging a defendant's pricing practices must prove "that the [defendant's] prices are below an appropriate measure of [the defendant's] costs." *Brooke Grp.*, 509 U.S. at 222. [redacted] *See ZF Meritor*, 696 F.3d at 275 n.11 [redacted]

[redacted]

III. THE LOVENOX DISCOUNT PROGRAM WAS NOT EXCLUSIONARY

[redacted]

Exclusive contracts are generally permissible under the antitrust laws because firms can compete to become an exclusive supplier. *See, e.g., Race Tires*, 614 F.3d at 83 ("It is well established that competition among businesses to serve as an exclusive supplier should actually be *encouraged*."); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 663 (7th Cir. 2004) [redacted] For exclusive dealing to violate the law, "opportunities for other traders to enter into or remain in the market must be significantly limited." *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 328 (1961). Moreover, exclusive or semi-inclusive contracts are virtually never viewed as exclusionary where they are short in duration, easily terminable, and competitors have an opportunity to compete for the same contracts by offering their products at better prices. *See Church & Dwight Co. v. Mayer Labs., Inc.*, 868 F. Supp. 2d 876, 903 (N.D. Cal. 2012), *order vacated in part on reconsideration on unrelated grounds*, 2012 WL 1745592, (N.D. Cal. 2012);

Allied Orthopedic, 592 F.3d at 997; *C. R. Bard*, 642 F.3d at 617; *Concord Boat,* 207 F.3d at 1059-60.

[redacted]

[redacted]

[14] *See also* Ex. 38, XI Areeda & Hovenkamp, Antitrust Law ¶ 1821, at 186 (3d ed. 2011) (distinguishing between market-share *discounts,* which still allow competitors to "steal" the customer by matching the discount and are therefore even less exclusive, from market-share *contracts,* which may be of long duration and are therefore more similar to exclusive dealing).

[15] [redacted]

[redacted]

[redacted]

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Put simply, Eisai's allegations of substantial market foreclosure are unsupported by any record evidence and all of its antitrust claims must therefore be dismissed. *See Church & Dwight,* 868 F. Supp.2d at 884, 910-11; *El Aguila Food Prods. Inc. v. Gruma Corp.*, 301 F. Supp. 2d 612, 625, 631 (S.D. Tex. 2003) [redacted]

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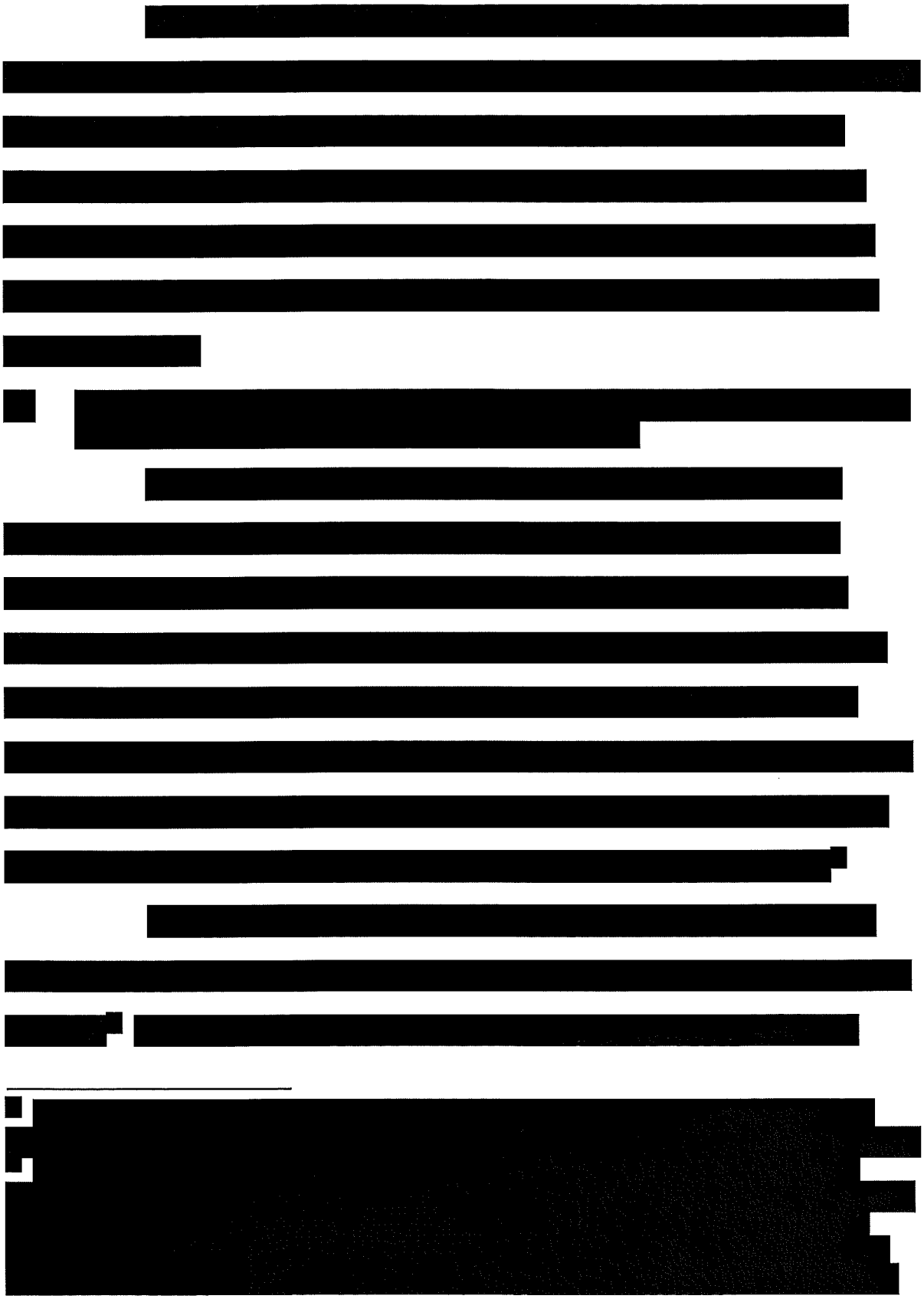

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In *Santana Products, Inc. v. Bobrick Washroom Equipment, Inc.*, 401 F.3d 123, 132-35 (3d Cir. 2005), the Court held that false statements – even by an alleged monopolist concerning a rivals' goods – could not violate the antitrust laws because those statements had no coercive effect. The defendant's allegedly false statements were "irrelevant" for antitrust purposes because "deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." *Id.* (citations and quotations omitted). As the *Santana* court noted, "the natural remedy would seem to be an increase in [competitors'] efforts on future [opportunities], not an antitrust suit." *Id.* at 133 (citation omitted); *see also W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010) [redacted]

In dismissing an antitrust claim based on disparagement of a rival similar to Eisai's claim here, the Seventh Circuit stated "[w]arfare among suppliers and their different

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products *is* competition. Antitrust law does not compel your competitor to praise your product or sponsor your work." *Schachar v. Am. Acad. of Ophthalmology, Inc.*, 870 F.2d 397, 399 (7th Cir. 1989) (citations omitted). The *Schachar* court also observed that "[i]f such [information] should be false or misleading or incomplete or just plain mistaken, the remedy is not antitrust litigation but more speech – the marketplace of ideas." *Id.* at 400. Simply put, "[s]ome other law may require judicial intervention in order to increase the portion of truth in advertising; the Sherman Act does not." *Sanderson*, 415 F.3d at 624. [redacted]

Courts have adopted a presumption that even deceptive commercial speech or advertising has only a *de minimis* effect on competition, not rising to the level of an antitrust violation. *Am. Council of Cert. Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc.*, 323 F.3d 366, 370 (6th Cir. 2003) ("antitrust claim[s] premised primarily on advertising or speech must overcome a presumption that . . . [there is only] a *de minimis* effect on competition."); *TYR Sport, Inc. v. Warnaco Swimwear, Inc.*, 709 F. Supp. 2d 821, 832 (C.D. Cal. 2010) (same). In order to overcome this presumption, the plaintiff must show that the alleged sales pitches are (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization. *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 149, 152 (D.D.C. 2008); *see also Am. Prof'l Testing Serv.*, 108 F.3d at 1152 (finding that an antitrust plaintiff "must satisfy *all* six elements"

to overcome the "presumption" that false and misleading advertising has a "*de minimis*" effect on competition). And even if the presumption can be overcome, the plaintiff still has the burden of proving that the allegedly deceptive conduct had a "significant and enduring adverse impact on competition." *See Am. Prof'l Testing Serv.*, at 1151-52; *TYR Sport, Inc.*, 709 F. Supp. 2d at 832. For the reasons discussed below, Eisai cannot possibly satisfy this heavy burden here.

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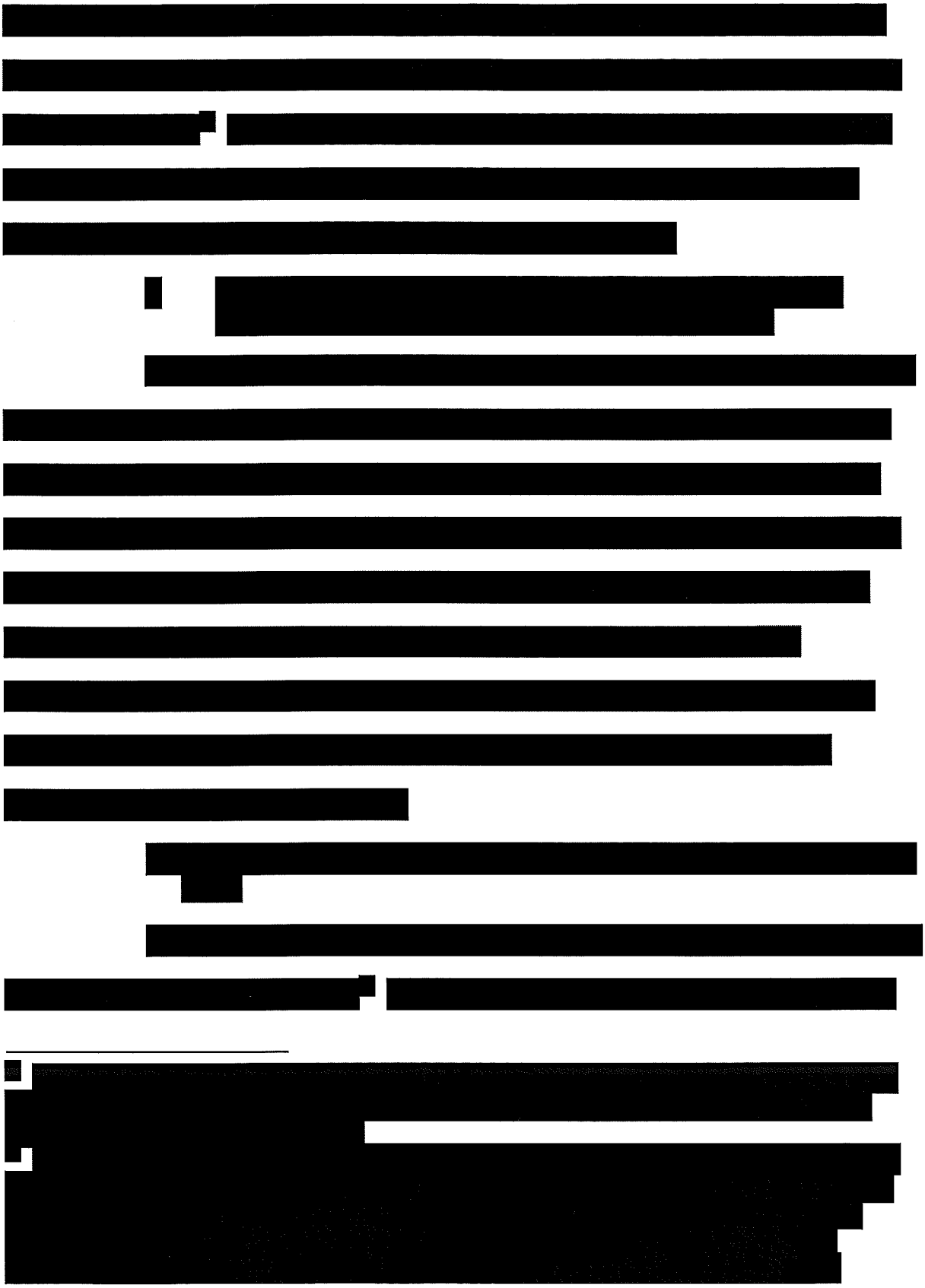
Eisai has the burden of proving that it was impossible to neutralize Sanofi US's allegedly deceptive sales pitches. *Am. Prof'l Testing Serv.*, 108 F.3d at 1152 ("The argument that its neutralization efforts were not completely successful is unavailing; the test refers to 'susceptible to neutralization' not 'successful in neutralization.'"); *Covad v. Bell Atl. Corp.*, 398 F.3d 666, 674 (D.C. Cir. 2005) (holding that plaintiff's need to increase its own advertising to offset a rival's deceptive ads did not harm but rather enhanced competition); *Walgreen Co.*, 534 F. Supp. 2d at 149, 152. [redacted]



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The Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations set forth a comprehensive regulatory scheme pertaining to the promotion of drugs, the enforcement of which is the exclusive province of the FDA. [redacted] Here, the relevant statute, 21 U.S.C. § 337(a), provides that proceedings to enforce or restrain violations of the FDCA "shall be by and in the name of the United States." [redacted]

[redacted]

[redacted]

V. EISAI CANNOT PRESENT SUFFICIENT EVIDENCE TO SATISFY THE ANTITRUST INJURY REQUIREMENT

[redacted]

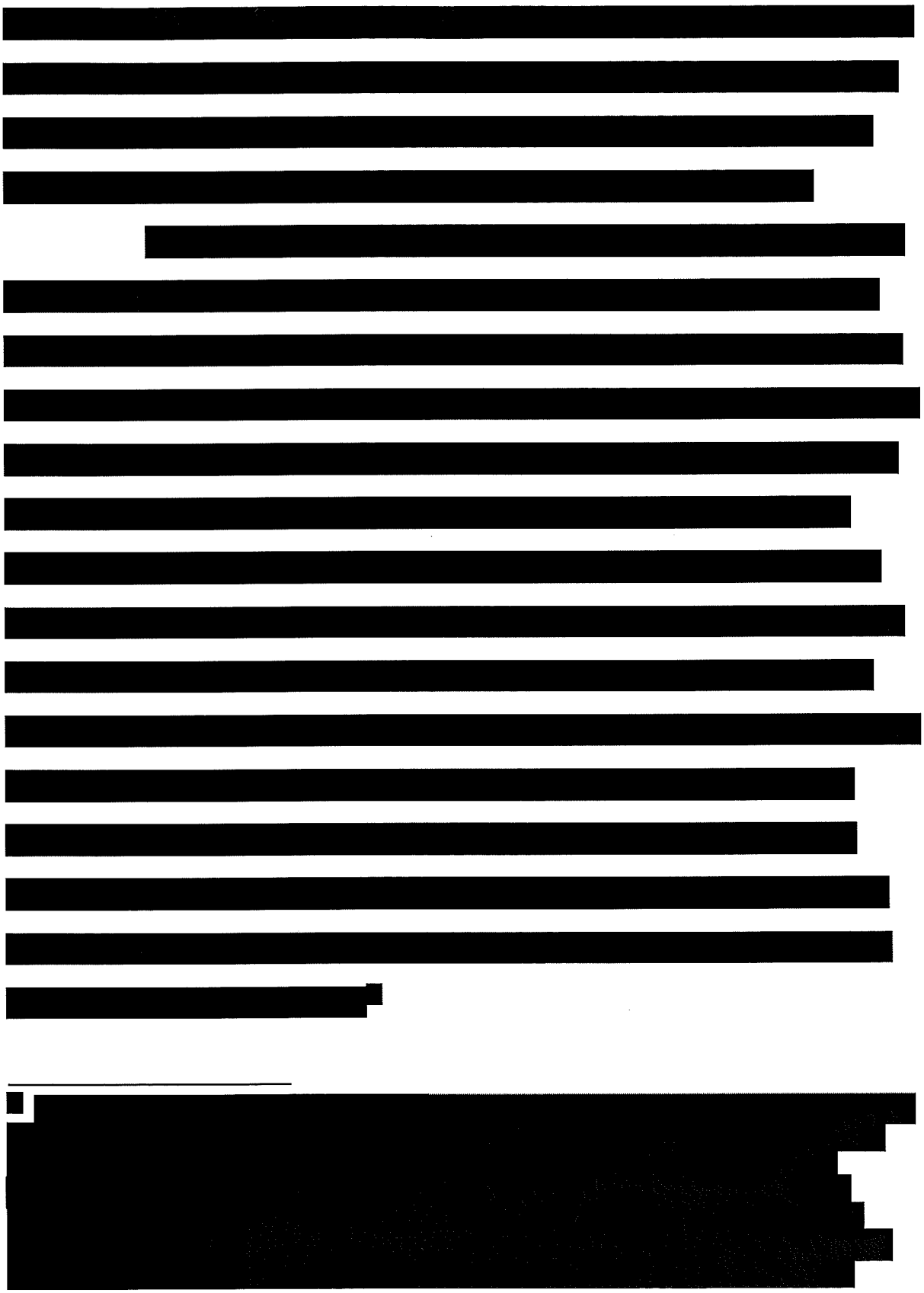
An essential and distinct element of every antitrust claim is proof of "antitrust injury;" that is, an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant's acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); *see also Atl. Richfield,* 495 U.S. at 340; *Church & Dwight*, 868 F. Supp. 2d at 918. "It is axiomatic that the antitrust laws were passed for 'the protection of *competition,* not *competitors.*'" *Brooke Grp.,* 509 U.S. at 224 (quoting *Brown Shoe Co. v. United States,* 370

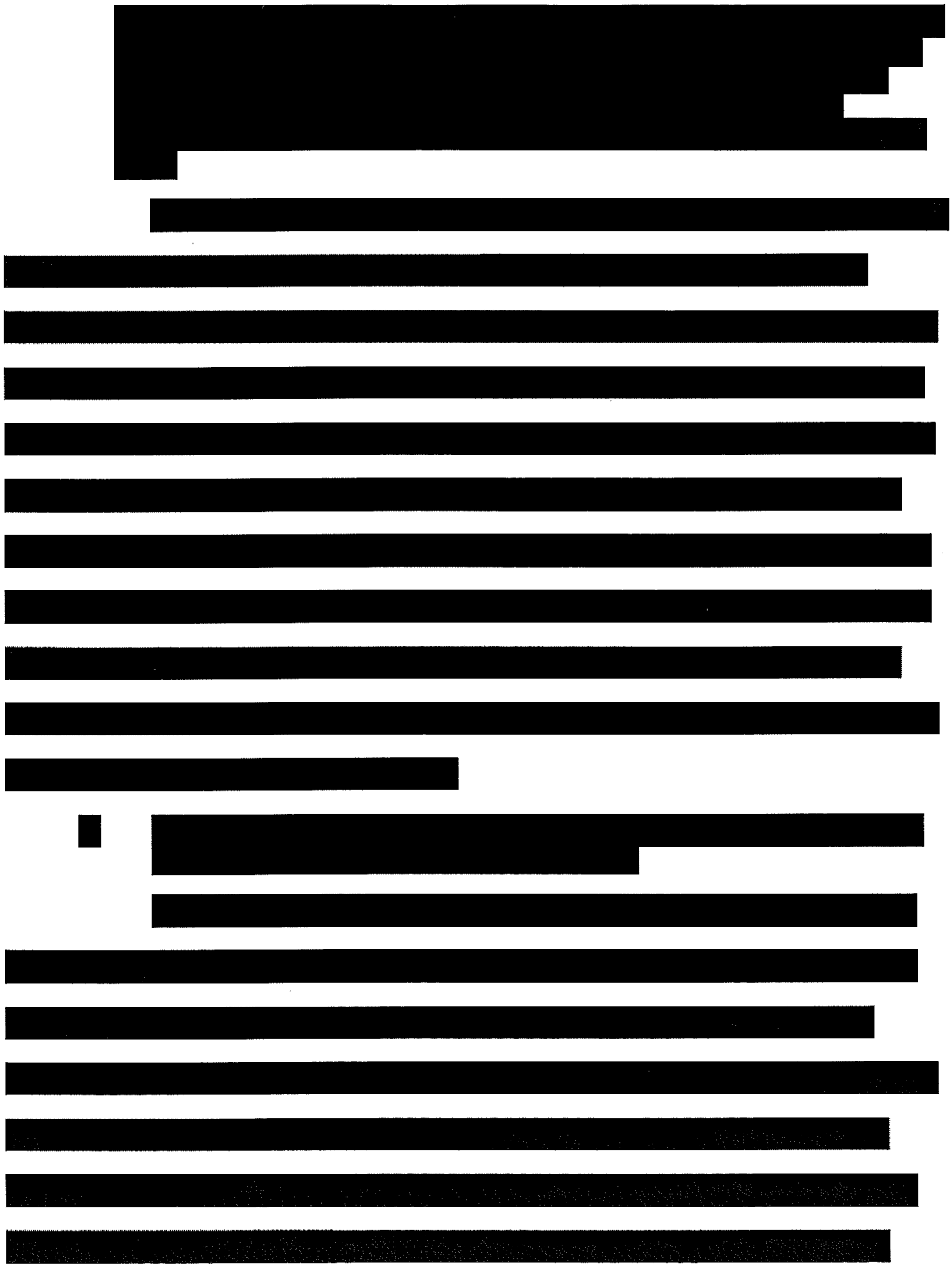
[redacted]

U.S. 294, 320 (1962)) (emphasis in original). To evaluate a plaintiff's claim of antitrust injury, courts must first determine "whether the injury is "causally link[ed]" to the antitrust violation." *Church & Dwight*, 868 F. Supp. 2d at 919. In addition, an antitrust plaintiff must prove "harm to the competitive process" and thereby demonstrate "harm to consumers." *Id.* (citations omitted).

[redacted]

A plaintiff bears the burden of showing that the alleged antitrust violation was a "material cause of its injury." *Van Dyk Research*, 631 F.2d at 255 (citation omitted); *see also J.B.D.L. Corp.*, 485 F.3d at 887. [redacted]





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VI. EISAI LACKS ANTITRUST STANDING

Sanofi US previously challenged Eisai's standing to bring an antitrust action pursuant to 15 U.S.C. § 15. [redacted] The Court denied that motion [redacted]

[redacted]

[redacted]

[redacted]

VII. EISAI HAS FAILED TO ESTABLISH A PROPERLY DEFINED RELEVANT PRODUCT MARKET

Proof of a properly defined relevant product market is yet another essential element of any antitrust claim—whether brought under Sections 1 or 2 of the Sherman Act or Section 3 of the Clayton Act. *See, e.g., Tampa Elec.*, 365 U.S. at 328-29; *Queen City Pizza,* 124 F.3d at 437; *Beuff Enter. Fla., Inc. v. Villa Pizza, LLC,* No. 07-2159, 2008 WL 2565008, at *3, *7 (D.N.J. June 25, 2008). [redacted]

VIII. SANOFI US IS ENTITLED TO SUMMARY JUDGMENT ON EISAI'S NEW JERSEY ANTITRUST ACT CLAIM

Finally, Eisai asserts parallel antitrust claims under Sections 56:9-3and 56:9-4 of the New Jersey Antitrust Act alleging that Sanofi US "willfully, knowingly, and with specific intent, unlawfully monopolized commerce, attempted to monopolize commerce, restrained trade,

and/or conditioned sales in the Relevant Markets within the State of New Jersey." [redacted] [redacted] New Jersey's antitrust statute is construed in harmony with ruling judicial interpretations of the comparable federal antitrust statutes. *See* N.J. Stat. Ann. § 56:9-18 (2008); *State v. N.J. Trade Waste Ass'n*, 96 N.J. 8, 19 (1984). Thus, because Eisai's state law antitrust claims are founded on the same allegations that form the basis of its federal claims, summary judgment should be granted in Sanofi US's favor as to Eisai's Fifth Claim For Relief for the same reasons described above. *See Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 748 (3d Cir. 1996) (upholding the dismissal of a New Jersey antitrust claim because the federal antitrust claim was properly dismissed for lack of sufficient evidence, and citing the New Jersey Antitrust Act); *Regency Oldsmobile, Inc. v. General Motors Corp.*, 723 F. Supp. 250, 270 (D.N.J. 1989) (granting summary judgment on state antitrust claims when summary judgment was granted on federal antitrust claims, and citing the New Jersey Antitrust Act).

CONCLUSION

For the foregoing reasons, Sanofi US is entitled to summary judgment on all of Eisai's claims.

Respectfully Submitted,

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