

**UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

STEAMFITTERS INDUSTRY WELFARE FUND
and METAL TRADES BRANCH WELFARE
FUND , and all others similarly situated,,

Docket No.

Plaintiffs,
vs.

CLASS ACTION COMPLAINT

AVENTIS PHARMA S.A., and AVENTIS
PHARMACEUTICALS, INC.,

Jury Trial Demanded

Defendants.

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CLASS ACTION COMPLAINT

Plaintiffs, STEAMFITTERS INDUSTRY WELFARE FUND and METAL TRADES BRANCH WELFARE FUND, on behalf of themselves and the class of End-payors as defined below, upon personal knowledge as to facts pertaining to itself, and upon information and belief, and upon the investigation of their counsel as to all other matters, alleges as follows:

NATURE OF ACTION

1. This is a nationwide class action brought under federal and state antitrust laws, state consumer protection laws, and state common law seeking damages, declaratory and injunctive relief arising from the manufacture and marketing of the brand-name drug Lovenox, a drug used for its antithrombotic properties. Defendants' unlawful conduct prevented generic versions of Lovenox from coming to the United States market, thereby causing injury to Plaintiff and members of the Class. The generic name for Lovenox is enoxaparin.

2. Lovenox (Enoxaparin), a low-molecular-weight heparin, is an anticoagulant used to treat or prevent blood clots and their complications. Lovenox is sold by Aventis throughout the United States for the treatment of deep vein thrombosis, prophylaxis of ischemic complications of unstable angina, and non-Q wave myocardial infarction when concurrently administered with aspirin. In its natural form, heparin is a mixture of large and small molecules. The large molecules are thought to prevent blood from coagulating, while the smaller molecules help prevent the formation of blood clots. By cutting the molecules down to smaller sizes, drug makers are able to retain the beneficial anti-clot properties of heparin while reducing the chance that the anticoagulant properties will prevent wounds from healing over. Through its patent of

the product, Aventis controlled roughly 90 percent of the drugs \$2 billion market.

3. At least two manufacturers of generic versions of medicines, including Amphastar Pharmaceuticals, Inc. (“Amphastar”) and Teva Pharmaceuticals USA, Inc. (“Teva”), have filed applications with the Food and Drug Administration (“FDA”) requesting approval to manufacture, market and sell a generic versions of Lovenox. These manufacturers assert in their applications that their respective products are “bioequivalent” to the Lovenox brand name product and do not infringe any valid patent owned by or licensed to the Defendants.

4. Defendants’ commenced a baseless patent infringement action against Amphastar and Teva in an attempt to thwart production of generic versions of Lovenox from entering the United States market. In trying to extend its patent, essentially delaying the manufacture of its generic version, Aventis misrepresented evidence to the Trademark and Patent Office to gain approval of a patent for Lovenox to expire in 2012. Ensuing litigation relative to the misrepresentation resulted in a summary judgment finding due to inequitable conduct.

5. As a direct and proximate result of Defendants' unlawful conduct, consumers have been denied the benefits of free and unrestrained competition in the low-molecular-weight heparin market. More specifically, Plaintiff and members of the Class have been denied the opportunity to choose between the brand name prescription drug and lower priced generic versions by being forced to pay supracompetitive prices.

6. In Count I of this Complaint, Plaintiffs, on behalf of themselves and all others who are members of the consumer class, seek equitable, injunctive and declaratory relief against Defendants based on allegations of monopolization of, and an attempt to monopolize, the market for Lovenox and its generic bioequivalents, in violation of Section 2 of the Sherman Act, 15

U.S.C. § 2.

7. Counts II and III are brought by Plaintiffs on behalf of themselves and those Class members who purchased or paid for Lovenox and its generic bio-equivalents in Arizona, California, the District of Columbia, Florida, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin (the “Indirect Purchaser States”). Counts II and III are brought pursuant to the antitrust and unfair and deceptive trade practices acts of the Indirect Purchaser States.

8. Count IV is brought by Plaintiffs on their own behalf and on behalf of the Class, seeking a constructive trust and disgorgement of the unjust enrichment of Defendants.

II.

PARTIES

9. Plaintiffs STEAMFITTERS INDUSTRY WELFARE FUND and METAL TRADES BRANCH WELFARE FUND are duly organized union Health and Welfare Funds in the State of New York. During the Class Period as described herein, Plaintiffs paid for Lovenox which was prescribed for their members and they have thereby been injured as a result of Defendants’ conduct. Plaintiffs Steamfitters Industry Welfare Fund and Metal Trades Branch Welfare Fund are members of the class defined herein, will adequately represent the interests of the class, and seek to be certified as Class Representatives of this class.

10. Defendant, Aventis Pharma S.A. is a French corporation having its principal place of business in Antony, France. Defendant, Aventis Pharmaceuticals Inc. is a Delaware

Corporation having its principal place of business in Bridgewater, New Jersey.

11. Various persons, partnerships, sole proprietors, firms, corporations and individuals not named as defendants in this lawsuit, and individuals, the identities of which are presently unknown, may have participated as co-conspirators with Defendants in the offenses alleged in this complaint, and have performed acts and made statements in furtherance of the alleged conspiracy to monopolize.

III.

JURISDICTION AND VENUE

12. This action is brought under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of the federal antitrust laws, particularly Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 26. In addition, this Court has jurisdiction over the state law claims pursuant to 28 U.S.C. § 1332(d), as amended in 2005, and 28 U.S.C. § 1367.

13. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1407 and 15 U.S.C. § 22 in that Defendants do business in this judicial district.

14. The illegal monopolization and attempt to monopolize the market for Lovenox and generic versions of Lovenox, as alleged herein, have substantially affected interstate and foreign commerce.

IV.

INTERSTATE TRADE AND COMMERCE

15. Defendants' efforts to monopolize and restrain competition in the market for Lovenox alleged herein has substantially affected interstate and foreign commerce.

16. During all or part of the Class Period, Defendants manufactured and sold substantial amounts of Lovenox in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Defendants maintained an exclusive license to market and sell Lovenox in the United States.

17. At all material times, Defendants manufactured and sold Lovenox and shipped it across state lines and sold to customers located outside its state of manufacture.

18. During all or part of the Class Period (defined below), Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Lovenox.

19. In furtherance of its efforts to monopolize and/or restrain competition in the market for Lovenox and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

V.

RELEVANT MARKET

20. During the class period, the relevant market is the manufacture and sale of Lovenox, enoxaparin, sold in the United States. The relevant geographic market for Lovenox is

the United States.

21. During the class period, Defendants' share of each relevant market was 100%, and Defendants maintained monopoly power in each relevant market during that time period.

VI

MARKET EFFECTS

22. The acts and practices of Defendants, as herein alleged, had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Lovenox from generic competition in the relevant market.

23. If a generic competitor had been able to enter the relevant market and compete with Defendants, End-Payers such as Plaintiffs would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for Lovenox products. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payors of prescription drugs (*e.g.*, managed care plans) encourage or insist on the use of generic drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year.

24. By preventing generic competitors from entering the market, Defendants injured Plaintiffs and the other Class members in their business or property by causing them to pay more for Lovenox than they otherwise would have paid. Defendants' unlawful conduct deprived

Plaintiff and other End-Payers of the benefits of competition that the antitrust laws and applicable state consumer protection laws were designed to preserve.

VI.

FACTUAL ALLEGATIONS

A. Federal Regulation of Prescription Drugs

1. Brand-name Drugs v. Generic Drugs

25. The laws governing pharmaceutical products are meant to balance the competing policy goals of providing new drug inventors an economic return on their investment while also ensuring consumers access to additional and more affordable generic versions of brand name drugs.

26. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at double digit rates for years, and the cost of drugs dispensed in the United States in the most recent year exceeded \$2 billion.

27. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

28. To be deemed a therapeutic equivalent and assigned an “AB” rating by the FDA, the generic drug must contain the same active ingredient(s); dosage form and route of administration; and strength. If so, the generic drug, as a therapeutic equivalent, can be substituted (and in some instances must be substituted) for the pioneer or brand-name drug at the pharmacy dispensing the drug.

29. Generic drugs are generally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office (the “CBO”) concluded that generic drugs save consumers and third-party payors between \$8 billion and \$10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed, “Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs.”

30. The Federal Trade Commission (“FTC”) estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

31. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug’s market share in just the first year of sale.

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manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

3. Prescriptions for Generic Drugs

33. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer, brand-name drugs. Where a generic drug is completely equivalent to a pioneer or brand-name drug, the FDA assigns the generic drug an "AB" rating.

34. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

35. Once a physician writes a prescription for a brand-name drug such as Lovenox, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent. Only drugs which carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug.

4. New Drug Applications (NDA)

36. The statute regulating the manufacture and distribution of drugs and medical devices in the United States is the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "FD&C Act").

37. Under the FD&C Act, approval by the FDA, the governmental body charged with

regulation of the pharmaceutical industry, is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

38. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to exclude others from making, using or selling that new drug in the United States for the duration of the patents, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").

39. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

40. Once the NDA is approved, any claimed patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations. This publication is commonly called the "Orange Book."

41. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer is issued a new patent that claims the drug or methods of its use, the company must supplement its NDA by listing such new patent within 30 days of issuance, whereupon the FDA publishes the new patent in a supplement to the Orange Book. The FDA is required to accept as true patent information it obtains from patent holders, such as whether a patent covers a particular drug product. If an unscrupulous patent holder is willing to provide false information

to the FDA to delay the onset of generic competition, the FDA is powerless to stop it.

42. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a doctor who writes a prescription specifying the drug, which must be purchased from a licensed pharmacist. Generally, the pharmacist must, in turn, fill the prescription with the drug specified by the physician unless a generic version is available that has been approved by the FDA for substitution as bioequivalent.

5. Abbreviated New Drug Applications ("ANDAs") For Generic Drugs

43. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA"), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug.

44. The Hatch-Waxman Act permits ANDA applicants to perform all necessary testing, submit an application for approval, and receive tentative approval before the relevant patents expire. Prior to the Hatch-Waxman Act, a generic applicant had to wait until all patents had expired prior to beginning the approval process or otherwise face an infringement suit.

45. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. *See* 21 U.S.C. § 355(j)(5)(5)(iii). If no action is initiated within 45 days, the process for FDA

approval of the generic product is not delayed by patent issues. However, if a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

46. The ANDA must include information concerning the applicant's position *vis-a-vis* the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications:

- I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");
- II. that the patent for the pioneer drug has expired (a "Paragraph II Certification");
- III. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
- IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV Certifications.

47. Accordingly, brand-name drug patent holders need only to file a patent infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to

automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.

48. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. 355(j)(5)(B)(iv). This 180 day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

B. Defendants' Unlawful Scheme to Thwart Generic Competition

1. Lovenox

49. Heparin is a mixture of long polysaccharide molecules obtained from the internal organs of animals such as pigs and cattle. The longer molecules in heparin are broken down through a chemical process creating what is called low molecular weight heparins (LMWH).

50. Lovenox is a sterile solution containing enoxaparin sodium, an anticoagulant that is derived from low molecular weight heparin, that helps prolong the clotting time of blood. Lovenox is administered by injection for treatment of thrombosis, the formation of blood clots in veins deep in a muscle, most often in the legs. Deep vein thrombosis may lead to pulmonary embolism, a condition in which a piece of the clot (the embolus) breaks loose and travels through the veins to the lung.

51. Aventis is a pharmaceutical company that manufactures Lovenox. Lovenox is a blood thinner that inhibits the formation of certain venous blood clots called thromboses. Lovenox is derived from heparin. Heparin is a mixture of long polysaccharide molecules obtained from the internal organs of animals such as pigs and cattle. Through a chemical process, heparin's longer molecules can be broken down into shorter molecules. A group of these shorter molecules are called low molecular weight heparins ("LMWHs"). U.S. Patent No. 5,389,618 ("the '618 patent") covers a range of defined LMWHs, including Lovenox, and their administration to patients who are susceptible to blood clots.

52. Aventis filed an action in the United States District Court Central District of California against Amphastar and Teva Pharmaceuticals USA, Inc (collectively, "Amphastar and Teva). for infringement of the '618 patent. Amphastar and Teva disputed infringement and claimed that the '618 patent was invalid and unenforceable. One of Amphastar's grounds for unenforceability was the affirmative defense and counterclaim of inequitable conduct by Aventis. The following paragraphs are drawn from the decision of the patent proceeding where the Court ultimately granted Summary Judgment in favor of Amphastar and Teva.

53. On May 8, 1981, Aventis filed European Patent Application No. 81/400728.2 ("European Patent Application") based upon French Patent Application No. 80/10791 ("French '791 application"). The European Patent Application was subsequently published on November 18, 1981 as European Patent 40,144.¹

54. On June 26, 1990, Aventis filed French Patent Application No. 90/3013 ("French '013 application"), the priority application of the '618 patent. The French '013 application lists the

¹ This order will refer to European Patent 40,144 as "Mardiguian 40,144." Mardiguian was the inventor of

sole inventor as Roger Debrie (“Debrie”).

55. In early 1991, Aventis had begun the process of obtaining drug approval for “Lovenox” in the United States. Aventis had no patent protection for Lovenox in the United States at that time.

56. In a January 1991 internal memorandum, Aventis acknowledges the lack of and need for patent protection in the United States and noted an April 1991 target deadline for filing its New Drug Application (“NDA”).

57. On June 17, 1991, a month before filing its NDA, in another Aventis’ internal memorandum discussing Mardiguian 40,144, Aventis states: “Enoxaparin is not expressly described in this application but is comprised in the claims.” The memorandum then notes that the Mardiguian 40,144 patent was revoked and goes on to state, “A patent application concerning the molecular distribution of enoxaparin has been filed on June 26, 1990 in France and must be filed in different countries before June 26, 1991.”

58. On June 26, 1991, Aventis filed United States Patent Application Serial No. 721,315 (“the ‘315 application”) to the United States Patent and Trademark Office (“PTO”), claiming a priority date of June 26, 1990 based upon the French ‘013 application. Undisputed footnote 5: On July 16, 1993, Aventis filed a continuation of the ‘315 application, United States application No. 92,577, which ultimately issued as the ‘618 patent, the patent in suit.²

59. In July 1991, shortly after filing the patent application, Aventis filed its NDA for Lovenox.

European Patent 40,144.

² The ‘315 application issued as the ‘618 patent.

60. In its 1991 NDA submissions, Aventis claimed that the '315 application covered Lovenox.

61. In 1992, Aventis represented to the PTO that the invention claimed in the '315 application was patentably distinct from Mardiguian 40,144 (which was the same as the French '611 patent).

62. Aventis distinguished the compositions of Mardiguian 40,144 in the '618 patent's written description.

63. The '315 application was filed with 28 original claims with original Claim 1 being the only independent claim.

64. In an Office Action dated April 2, 1992, the PTO rejected all the original claims for various reasons and in particular rejected Claims 1-7 and 24-28 for being anticipated or obvious over several references, including Mardiguian 40,144.

65. On August 3, 1992, Aventis responded to the Office Action by arguing that the prior art did not render the claims unpatentable.

66. On October 16, 1992, the PTO issued another Office Action rejecting all the pending claims including rejecting Claims 1-7, 24-28, and 29-31 as both anticipated and obvious in view of the prior art including Mardiguian 40,144.

67. On April 16, 1993, Aventis filed an "Amendment After Final Rejection" responding to the PTO's rejections. In its response, Aventis refers to arguments that were discussed during the interview with the PTO examiner on March 2, 1993.

68. In support of its April 1993 arguments, Aventis submitted an expert declaration of its employee, Dr. Andre Uzan ("Dr. Uzan") ("First Uzan Declaration"), which specifically addressed

the Examiner's statement that the half-life data reported in Example 6 of the '315 application was not significant.

69. The First Uzan Declaration also includes an analysis of a purported reproduction of Example 8 of Mardiguian 40,144, finding 21% of molecules below 200 daltons, 6% greater than 8,000, and 73% between 2,000 and 8,000, which the declaration states "is clearly outside the scope of the present invention."

70. On July 16, 1993, Aventis filed a continuation application, which ultimately issued into the '618 patent.

71. On September 9, 1993, Aventis filed a Preliminary amendment which amended the claims and responded to the Examiner's May 13, 1993 Advisory Action.

72. On November 20, 1993, the PTO issued another Office Action once again rejecting the pending claims over Mardiguian 40,144.

73. On May 16, 1994, Aventis filed another Amendment responding to the Examiner's objections.

74. After another interview with the Examiner on May 17, 1994, Aventis filed a Supplemental Response dated June 17, 1994 and another Declaration from Dr. Uzan ("Second Uzan Declaration"). This Second Uzan Declaration presented five tables: "Tables, I, X and XI which refer to the compound of the invention and Tables A and III which refer to the compound of Mardiguian."

75. The Second Uzan Declaration goes on to compare the half-life data in Table X (4.36 hours +/- 1.07) with the data in Table III (3.33 hours +/- .69), and asserts that the difference is statistically significant.

76. A 1984 Aventis study by Aiach and Fourtillan (“Aiach/Fourtillan Study”) is the source of the data in paragraph (3) of Example 6 of the ‘618 patent (as well as Table III attached to the Second Uzan Declaration filed during the prosecution of the ‘618 patent).

77. Aventis acknowledged that paragraph (3) of Example 6 in the ‘618 patent was “a product prepared according to the process described in European Patent EP 40,144.”

78. In November/December 1985, in connection with Aventis’ application for marketing approval in Europe, Aventis prepared a dose-ranging study on PK 10169³ by, among others, Frydman/Duchier (“Frydman/Duchier Study”). The Frydman/Duchier dose-ranging study shows a half-life of 4.36 hours +/- 1.07 for 40 mg dose and 3.70 +/- 0.82 for 60 mg dose.

79. The Frydman/Duchier study is described in Example 6 of the ‘618 patent, and is the source of the data in paragraph (1) of Example 6 and Tables X and XI in the Second Uzan Declaration. The results of the 1986 Frydman/Duchier Study were published in 1988: Frydman, et al., The Antithrombotic Activity and Pharmacokinetics of Enoxaparine..., 28 Journal of Clinical Pharmacology 609-618 (1988).

80. The information in the ‘315 application and the ‘618 patent regarding the biological properties of the claimed invention and those of prior compounds was provided by Dr. Uzan.

81. Dr. Uzan testified at his deposition that he recalled the following four sources of the data regarding the biological properties of the claimed invention and those of the prior art compounds: (1) the 1984 Aiach/Fourtillan Study; (2) the 1986 Dawes publication; (3) the 1986 Frydman/Duchier Study (results published in 1988); and (4) a later study referred to in paragraph 4 of Example 6, perhaps attributable to Guibert.

³ PK 10169 is a specific LMWH. It is also known as enoxaparin.

82. Amphastar contended the undisputed facts, even with all reasonable inferences in Aventis' favor, establish that Dr. Uzan engaged in inequitable conduct to obtain the '618 patent. Generally, patent applicants owe a "duty of candor and good faith" to the PTO. "A breach of this duty constitutes inequitable conduct." *Id.* Inequitable conduct can render a patent unenforceable.

2. Relevant Prosecution History of the '618 Patent

83. The Background of the Invention section of the '618 patent states: "The processes described in the prior art, and especially in EP 40,144, do not permit the production of mixtures possessing the requisite pharmacological properties for improved therapeutic applications, namely, a sufficiently long plasma half-life, a fairly high absorption rate, a high bioavailability or alternatively, a low clearance." It also states that "**the mixtures of the ['618 patent] exhibit a half-life longer than other known preparations.**" (emphasis added).

84. Aventis supported the half-life assertion with Example 6 of the '618 patent ("Example 6"). Example 6 states:

This example illustrates the increase in stability, in vivo, of the mixtures of the invention, expressed by their plasma half-life.

A first pharmacokinetic study was carried out on volunteers between 21 and 30 years of age. Subcutaneous injections of doses ranging from 20 to 80 mg/ml were performed. At intervals of time, samples were drawn (4.5 ml) and stored at approximately 4[deg] C. The samples were then centrifuged for 15 minutes at 2,300 g and the platelet-poor plasma was separated and frozen prior to analysis. The half-life of the mixtures was then determined by measuring the anti-Xa activity. The results obtained were as follows:

(1) From the mixtures produced in Examples 3 and 4⁴.

40 mg dose: in 75% of the cases, the half-life was longer than 4 hours, and was even longer than 4½ hours in approximately 45% of the cases;

60 mg dose: in 75% of the cases, the half-life was longer than 3.7 hours.

(2) Under identical dosage conditions, intact heparin injected intravenously possessed a half-life of approximately 0.6 hours.

⁴ Examples 3 and 4 illustrate the preparation, properties, and certain structural characteristics of the '618 patent.

(3) When the product was prepared according to the process described in European Patent EP 40,144 the half-life was longer than 4½ hours in 17% of the cases.

(4) A second study carried out under similar conditions on 20 patients provided the following results for the mixtures according to the present invention:

40 mg dose: in 80% of cases, the half-life was longer than 4 hours, and it was longer than 4½ hours in approximately 40% of the cases;

20 mg dose: in 60% of the cases, the half-life was longer than 3.9 hours.

85. A significant portion of the '618 patent's prosecution history focused on Example 6 and its subject: half-life. In an Office Action dated April 2, 1992, the PTO rejected all claims of the '618 patent. The Examiner stated that Aventis must "provide some unexpected or unobvious property not demonstrated by the prior art products." In response, on August 3, 1992, Aventis referred the Examiner to Example 6 and stated, "[i]n this regard, the Examiner is referred to Example 6 of the originally filed application wherein the product was prepared in accordance with the European patent and found to have a half-life significantly shorter than was observed with the formulation of the present invention...Here, therefore, it should be apparent that formulations as claimed, having significantly improved half-lives as compared to the formulations of the European patent, are necessarily different from those of the European patent."

86. The Examiner rejected Aventis' response. He wrote, "[a]pplicant's arguments filed August 3, 1992...are not deemed to be persuasive...Applicants assertions regarding the comparative data in the specification (comparison to EP 40144-Mardiguian) are not convincing...since the half-life for [the Mardiguian patent] appears to be essentially the same as that for the instant mixtures."

87. On April 16, 1993, Aventis again responded to the Examiner's rejection. Aventis reiterated its position that the '618 patent was patentable over Mardiguian 40,144. Aventis wrote, "[i]n particular, Example 6 clearly demonstrates that the claimed compounds exhibit improved

pharmacokinetic properties and, in particular, the products of the invention were found to have a plasma half-life longer than 4-1/2 hours in 40-45% of the cases where such half-life was observed in accordance with Mardiguian in only 17% of the cases. This represents an increase in 250% in half-life.”

88. In support of the April 16, 1993 response, Aventis submitted the First Uzan Declaration. In addition to reiterating the purported increase in half-life, Dr. Uzan stated, “[t]his represents an increase in 250% in half-life and is very significant because it enables the same effect to be achieved with lower dosages.”

89. On July 16, 1993, Aventis filed a continuation application that ultimately issued as the ‘618 patent. In the application, Aventis responded to the Examiner’s May 19, 1993 Advisory Action. Among other things, Aventis represented, “the data to which applicant presented in the Declaration Pursuant to 37 C.F.R. § 1.132 have a high degree of accuracy.”

90. On November 20, 1993, the Examiner responded. He stated that Aventis “has failed to provide evidence that the alleged difference between the half-life of the Mardiguian product and that of the instant mixture is statistically significant.” On May 16, 1994, Aventis responded:

“The results also demonstrate that different half lives were obtained for the claimed preparation versus the closest preparation for Mardiguian. **In particular, the half-life obtained for the claimed preparation was 4.36 +/- 1.07 hours whereas that for Mardiguian was 3.33 +/- 0.2 hours. This is approximately a 30% difference in results and is significant in that it means that the claimed preparations can be administered at significantly lower doses.**”

91. On May 17, 1994, after another interview with the Examiner, Aventis filed a Supplemental Response and the Second Uzan Declaration. The Second Uzan Declaration presented five tables: Tables I, X and XI which refer to the ‘618 patent and Tables A and III which refer to

Mardiguian EP 40,144.

92. Table III “refer[s] to the compound of Mardiguian.” Without mentioning dose amount, Table III reflects a mean half-life of 3.33 hours with a standard deviation of 0.82. Table X “refer[s] to the compound of the [‘618 patent].” At a dose of 40 mg, it reflects a mean half-life of 4.36 hours with a standard deviation of 1.07. Table XI also “refer[s] to the compound of the [‘618 patent].” At a dose of 60 mg, it reflects a mean half-life of 3.70 hours with a standard deviation of 0.82.

93. In the patent proceeding, Amphastar contended that Dr. Uzan’s representations constituted a failure to disclose material information because the unspecified dose amount in Table III was actually 60 mg and Dr. Uzan repeatedly⁵ compared it to a disclosed 40 mg dose of the ‘618 patent. Comparing the 60 mg dose amount of Mardiguian 40,144 and the 60 mg dose amount of the ‘618 patent resulted in a much closer mean half-life.⁶

94. The Court concluded that Aventis’ actions constituted an affirmative misrepresentation of a material fact because Dr. Uzan’s declarations affirmatively stated that the half-life of the ‘618 patent was improved over Mardiguian EP 40,144 while the data before him did not support such a conclusion.

95. Amphastar also contended that Dr. Uzan should have disclosed to the Examiner additional evidence known to Dr. Uzan. This evidence established that had Dr. Uzan compared the

⁵ The comparisons of the 40 mg dose of the ‘618 patent to the 40 mg dose of Mardiguian 40,144 were represented in paragraph (3) of Example 6, the May 17, 1994 Supplemental Response, the First Uzan Declaration, and the Second Uzan Declaration.

⁶ This closer mean half-life is evident by comparing Table III with Table XI. Table III reported the half-life for Mardiguian EP 40,144 at 60 mg dose as 3.33 hours with a standard deviation of 0.2. Table XI reported the half-life for the ‘618 patent at a 60 mg dose as 3.70 hours with a standard deviation of 0.82.

same dose amounts, the '618 patent would not have been improvement over Mardiguian EP 40,144 as to half-life. The Court also held that Aventis committed a series of additional misrepresentations of fact.

96. The Aiach/Fourtillian Study contains the data that formed the basis of Table III, which reported the half-life for Mardiguian 40,144 as 3.33 hours with a standard deviation of 0.2. The Aiach/Fourtillian Study was conducted at a 60 mg dose. This dose was not apparent from Table III, which was submitted with the Second Uzan Declaration.

97. The second study is Bara, et al., Comparative Pharmacokinetics of a Low Molecular Weight Heparin (PK 10169)..., 39 Thrombosis Research 631-36 (1985) ("Bara Study"). The Bara Study also conducted tests on PK 10169. Amount other things, the Bara Study reported the mean half-life of a 40 mg dose of PK 10169 was 4.6 hours.⁷ Dr. Uzan did not cite the Bara Study to the PTO during the prosecution of the '618 patent.

98. A related study with J. Dawes entitled Relationship Between Biological Activity and Concentration of a Low-Molecular-Weight Heparin (PK 10169) and Unfractionated Heparin after Intravenous and Subcutaneous Administration, 15 Haemostasis 116-122 (1986) ("Dawes Study"). Like the Bara Study, Dr. Uzan did not cite the Dawes Study to the PTO during the prosecution of the '618 patent. Amount other things, the Dawes Study reported the half-life of a 40 mg dose of PK 10169 was 4.6 hours.⁸

99. The Court also concluded that Aventis did not disclose that it derived the half-life date reported in paragraph (3) of Example 6, the May 17, 1994 Supplemental Response, the First

⁷ This was reported in the study as 275 minutes.

⁸ This was reported in the study as 275 minutes.

Uzan Declaration, and the Second Uzan Declaration from a comparison of the Mardiguian LMWH at a different dose than the claimed LMWH. Moreover, the Court also concluded that Aventis did not disclose that a comparison of the same dosages did not yield significantly different half-lives. When Dr. Uzan submitted his two declaration affirmatively representing that there was a “significant” difference in the half-life between Mardiguian EP 40,144 and the ‘618 patent, he was comparing a 60 mg dose of Mardiguian EP 40,144 to a 40 mg dose of the ‘618 patent. Thus, Aventis compared different doses to show a difference in half-lives, but a comparison of available data regarding the same dose actually showed that there was little if any difference between the half-lives of Mardiguian EP 40,144 and the ‘618 patent.

100. Based on the foregoing, the Court concluded that Amphastar, by clear and convincing evidence, had met “its initial burden of identifying for the court those portions of the materials on file that it believes demonstrates the absence of any genuine issue of material fact” with respect to Aventis’ failure to disclose material information.⁹

101. These repeated misrepresentations establish that Aventis created high materiality for half-life. Militating even further in favor of a high materiality was the fact the Examiner allowed the patent after the last representation purporting to establish a statistically significant improvement in half-life based on the half-life obtained for the ‘618 patent, which was 4.36 +/- 1.07 hours, whereas that for Mardiguian EP 40,144 was 3.33 +/- 0.2 hours.

102. Based on the totality of the circumstances, including Amphastar’s weighty uncontroverted evidence establishing materiality and intent to deceive and Aventis’ scintilla of

⁹ As discussed more fully below, the court notes that in determining whether Amphastar met its initial burden, the court did not consider the Dawes Study and the Bara Study.

evidence in opposition thereto, the court concluded that no genuine issues of material fact exist and Amphastar is entitled, as a matter of law and equity, to summary judgment against Aventis on its affirmative defense and counterclaim based on equitable conduct. As a result, the '618 patent is unenforceable.¹⁰

3. Monopoly Powers

103. Through the anticompetitive conduct alleged herein, Defendants were able to charge supracompetitive prices for enoxaparin, and thus, by definition, maintained monopoly power with respect to enoxaparin sold in the United States. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is all enoxaparin products - i.e., Lovenox (in all its forms and dosage strengths), and bioequivalent enoxaparin products. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which enoxaparin is prescribed. For the entire period relevant to this case, Defendants have been able to profitably maintain the price of their branded enoxaparin products well above competitive levels.

104. The relevant geographic market is the United States and its territories.

105. Defendants' market share in the relevant market is and was 100% at all times.

106. Defendants' actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or

¹⁰ By reason of having granted Amphastar's motion for summary judgment based on inequitable conduct, the court will deny as moot Amphastar's remaining motions for summary judgment, namely Amphastar's motion for summary judgment of invalidity based on indefiniteness and Amphastar's motion for summary judgment of invalidity based on 35 U.S.C. § 102.

representatives while actively engaged in the management of Defendants' affairs.

107. Defendants' illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of Lovenox resulted in Plaintiff and the Class paying more than they would have paid for enoxaparin, absent Defendants' illegal conduct.

4. Effects on Competition and Damages to Plaintiff and Class

108. Defendants' exclusionary conduct has delayed or prevented the sale of generic enoxaparin in the United States, and unlawfully enabled Defendants to sell Lovenox at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of Lovenox capsules by at least June 24, 2003, and additional generic competitors would have entered the market thereafter. Moreover, to the extent that demand for 54mg and 160mg enoxaparin tablets would have existed but for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of Lovenox at an earlier point in time.

109. Defendants' pattern and practice of delaying generic entry is exclusionary and unreasonably restrains competition. To the extent that Aventis had any valid business purpose for their conduct, that purpose could be served by means that are less restrictive of competition, and would at all events be outweighed by the anticompetitive effects of the conduct.

110. If manufacturers of generic enoxaparin had been able to enter the marketplace and effectively compete with Defendants earlier, as set forth above, Plaintiff and other members of the Class would have substituted lower-priced generic enoxaparin for the higher-priced

brand-name Lovenox for some or all of their enoxaparin requirements, and/or would have received discounts on some or all of their remaining Lovenox purchases.

CLASS ACTION ALLEGATIONS

111. Plaintiffs bring this action on behalf of themselves and as representatives of a

Class defined as follows:

All persons or entities throughout the United States and its territories who purchased and/or paid for Lovenox or generic versions of Lovenox during the period June 24, 2003 to the present (“the Class Period”) for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the “Class”). For purposes of the Class definition, persons and entities “purchased” Lovenox if they paid some or all of the purchase price.

Excluded from the Class are all Defendants, their officers, subsidiaries and affiliates; all government entities (except for government-funded employee benefit plans); all persons or entities that purchased Lovenox for purposes of resale, or directly from any of the Defendants or their affiliates; and the judge in this case and any members of his/her immediate family.

112. Plaintiffs seek class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory and equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.

113. Although Plaintiffs do not know the exact number of class members, they believe it to be, at a minimum, in the tens of thousands. Lovenox has annual U.S. sales of approximately \$1.6 billion for the twelve months ending December 2004 and are expected to exceed that by the end of 2006. Thus, members of the Class are numerous and joinder is impracticable. The Class

members are identifiable, *inter alia*, from information and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefits managers, and managed care organizations.

114. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members, in part because Defendants have acted and refused to act on grounds generally applicable to the entire Class, thereby making appropriate equitable, injunctive and declaratory relief with respect to the Class as a whole. Such conduct includes the Defendants' exclusionary and anti-competitive efforts (i) in committing fraud on The United States Patent and Trade Office, (ii) in filing sham litigation, and (iii) converting the relevant market from one confronted with generic competition to one that is not for the sole purpose of monopolizing and attempting to monopolize the market for Lovenox.

1. Questions of law and fact common to the Class include:

- (a) whether Defendants maintained or attempted to maintain monopoly power by delaying generic entry;
- (b) whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;
- (c) to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- (d) whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- (e) whether Defendants' litigation asserting infringement of its patents described herein was baseless;
- (f) whether Defendants engaged in sham litigation for the purpose of preventing competition;
- (g) whether Defendants intentionally and unlawfully excluded competitors and potential competitors from the market for Lovenox and generic bio-equivalents to Lovenox;
- (h) whether Plaintiffs and members of the Class are entitled to declaratory, equitable and/or injunctive relief; and
- (I) whether Plaintiffs and the Class have been damaged and the aggregate amount of damages.

115. Plaintiffs' claims are typical of the members of the Class, in that Plaintiffs purchased and/or paid for Lovenox throughout the United States, including the Indirect Purchaser States, during the Class Period. Such purchases and payments were made for consumer consumption of Lovenox. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants.

116. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiffs is not antagonistic to those of the Class. In addition, the

Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

117. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

118. Plaintiffs know of no difficulty to be encountered by litigating this action that would preclude its maintenance as a class action.

FIRST CAUSE OF ACTION

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

119. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

120. As described above, Defendants knowingly and willfully engaged in a course of conduct designed to improperly obtain and extend their monopoly power in the Relevant Market. This course of conduct included, *inter alia*, the following acts: (i) committing fraud on the United States Patent and Trade Office, (ii) the prosecution of baseless, sham patent litigation(s) against a potential generic manufacturer(s), (iii) the intentional conversion of the

relevant market from one confronting generic competition to one that is not, and (iv) the intentional frustration of generic competition by effectively eliminating the ability for a generic therapeutical equivalent to be substituted for a LovenoX product. The result of Defendants' unlawful conduct has been to obtain and extend their monopoly.

121. Defendants intentionally and wrongfully created and maintained a monopoly power in the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

122. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of LovenoX, and paying higher prices for such products than they would have paid in the absence of the antitrust violation. The injury to Plaintiffs and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

123. Plaintiffs and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Section 2 of the Sherman Act.

124. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

SECOND CAUSE OF ACTION

**FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER
THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES
OF THE INDIRECT PURCHASER STATES**

125. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

126. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

- e. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statutes §§ 480-2, 480-3, and 480-4.
- f. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);
- g. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;
- h. Kentucky: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;
- i. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;
- j. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;
- k. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;
- l. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the

Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

m. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

n. Mississippi: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*;

o. Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

p. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

q. New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, *et seq.*, and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, *et seq.*;

r. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

s. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

t. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et*

seq.;

u. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

v. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

w. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

x. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

y. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

z. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*

127. As a result of the conduct described above, Plaintiffs and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of Lovenox, and paying prices for such products that were higher than they would have been but

for Defendants' improper actions. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

128. Plaintiffs and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

THIRD CAUSE OF ACTION

FOR INJUNCTIVE AND DECLARATORY RELIEF UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

129. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

130. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were

and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statutes §§ 480-2, 480-3, and 480-4.

f. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);

g. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

h. Kentucky: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;

i. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

j. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;

k. Massachusetts: The aforementioned practices by Defendants were and are

in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;

l. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;

m. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

n. Mississippi: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*;

o. Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

p. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;

q. New Jersey: The aforementioned practices by Defendants were and are in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, *et seq.*, and the New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8-1, *et seq.*;

r. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

s. New York: The aforementioned practices by Defendants were and are in

violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

t. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

u. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

v. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

w. Tennessee: The aforementioned practices of Defendants were and are in violation the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;

x. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

y. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and

z. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*

131. Plaintiffs and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic versions of LovenoX, and paying higher prices for LovenoX and generic versions of LovenoX than they would have paid but for Defendants' improper actions. The injury to Plaintiffs and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from Defendants' unlawful conduct.

132. Plaintiffs and the Class, pursuant to laws of the Indirect Purchaser States, hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through scheme set forth herein is unlawful. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to the laws of the Indirect Purchaser States to correct for the anti-competitive market effects and other harms to purchasers caused by the unlawful conduct of Defendants, and other relief so as to assure that similar conduct does not occur in the future.

FOURTH CAUSE OF ACTION

UNFAIR AND DECEPTIVE TRADE PRACTICES IN VIOLATION OF ALL STATES' CONSUMER PROTECTION ACTS

133. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

134. Alternatively, Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes listed below:

- (a) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Ala. Code § 8-19-1, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. Code § 45.50.471, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq.*;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. § 10-1-392, *et seq.*;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.1b, *et seq.*;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Mich. Stat. § 445.901, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1 *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

(ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

(pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1; *et seq.*;

(qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

(rr) Defendants have engaged in unfair competition or unfair or deceptive or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

(ss) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

(tt) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

(uu) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

(vv) Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et seq.*;

(ww) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101 , *et seq.*;

(xx) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*; and

(yy) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

135. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and the Class have suffered actual economic damage by paying for Lovenox instead of the equally efficacious generic version.

FIFTH CAUSE OF ACTION

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

136. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

137. As a result of their unlawful conduct described above, Defendants have been and

will continue to be unjustly enriched. Specifically, Defendants have been unjustly enriched, to the detriment of the Plaintiffs and the Class by the receipt of, at a minimum, unlawfully inflated prices and/or illegal monopoly profits on their sale of Lovenox.

138. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains resulting from the overpayments for Lovenox made by Plaintiffs and the Class.

139. Plaintiffs and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiffs and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and the Class members may make claims on a *pro rata* basis.

WHEREFORE, Plaintiffs pray that:

(a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and declare the Plaintiffs as the representatives of the Class;

(b) the conduct alleged herein be declared, adjudged and decreed to be in violation of Section 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;

(c) Plaintiffs and each member of the Class be awarded damages and, where applicable, treble, multiple, and other damages, according to the laws of the Indirect Purchaser States, including interest;

(d) Plaintiffs and each member of the Class recover the amounts by which Defendants have been unjustly enriched;

(e) Defendants be enjoined from continuing the illegal activities alleged herein;

(f) Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

(g) Plaintiffs and the Class be granted such other and further as the Court deems just and necessary.

JURY DEMAND

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: _____

Hagens Berman Sobol Shapiro LLP

BY: _____

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