Sheila McShane
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4637
(973) 639-6482 (Fax)
smcshane@gibbonslaw.com

Attorney for Plaintiffs
Merck Sharp & Dohme Corp. and
MSD International GmbH

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., and MSD INTERNATIONAL GMBH, *Plaintiffs*, v. SANDOZ INC. *Defendant*.	Civil Action No. _____

COMPLAINT

Plaintiffs Merck Sharp & Dohme Corporation and MSD International GmbH (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant Sandoz Inc. of Abbreviated New Drug Application ("ANDA") No. 203-931 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Zetia® prior to the expiration of U.S. Patent No. RE42,461 (the " '461 Patent"), U.S. Patent No.

5,846,966 (the " '966 Patent"), U.S. Patent No. 7,030,106 (the " '106 Patent") and U.S. Patent 7,612,058 (the " '058 Patent"). The '461 Patent issued on June 14, 2011 and is a reissue of U.S. Patent No. RE 37,721 (the " '721 Patent").

PARTIES

2. Plaintiff Merck Sharp & Dohme Corporation is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at One Merck Drive, Whitehouse Station, NJ 08889-0100.

3. Schering Corporation was a corporation organized and existing under the laws of the State of New Jersey, which had its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

4. Merck Sharp & Dohme Corporation merged into Schering Corporation. After the merger, Schering Corporation changed its name to Merck Sharp & Dohme Corporation.

5. Plaintiff MSD International GmbH is a company incorporated in Switzerland and having its registered office address at Weystrasse 20, 6000 Lucerne 6, Switzerland.

6. Merck Sharp & Dohme Corporation and MSD International GmbH are both owned, directly or indirectly, by Merck & Co., Inc.

7. On information and belief, Defendant Sandoz Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America and this Court has jurisdiction over the subject matter of this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Sandoz by virtue of the fact that, *inter alia*, Sandoz has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to a New Jersey corporation, Plaintiff Merck Sharp & Dohme Corporation, in New Jersey. This Court has personal jurisdiction over Sandoz for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

11. Sandoz has recently submitted to the personal jurisdiction of the United States District Court for the District of New Jersey at least in *Pfizer Inc., et al. v. Sandoz Inc.*, Civ. A. No. 12-cv-3880 (PGS)(LHG) (filed June 25, 2012); *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, Civ. A. No. 12-cv-3289 (MAS)(LHG) (filed May 31, 2012); *United Therapeutics Corp. v. Sandoz, Inc.*, Civ. A. No. 12-cv-1617 (PGS)(LHG) (filed March 14, 2012); *Shire LLC, et al. v. Sandoz Inc.*, Civ. A. No. 11-cv-3787 (PGS)(LHG) (filed June 30, 2011); *Insite Vision Inc., et al. v. Sandoz Inc., et al.*, Civ. A. No. 11-cv-3080 (MLC)(LHG) (filed May 26, 2011); and *Abbott Labs., et al. v. Sandoz Inc.*, Civ. A. No. 11-cv-1415 (DMC)(JAD) (filed March 10, 2011).

12. On information and belief, Defendant Sandoz is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States. On information and belief, Sandoz either directly or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey.

13. On information and belief, this Court has personal jurisdiction over Sandoz by virtue of, among other things: (1) its presence in New Jersey; (2) its registration to do business in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; (4) its

prior consent to be sued in New Jersey; (5) its systematic and continuous contacts with New Jersey; and (6) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

BACKGROUND

14. Zetia® contains ezetimibe, a cholesterol absorption inhibitor. According to its approved label, Zetia® "is indicated as an adjunct to diet to: reduce elevated total-C, LDL-C, and Apo B in patients with primary hyperlipidemiea, alone or in combination with an HMG-CoA reductase inhibitor (statin); reduce elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with mixed hyperlipidemia in combination with fenofibrate; reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), in combination with atorvastatin or simvastatin; reduce elevated sitosterol and campesterol in patients with homozygous sitosterolemia (phytosterolemia)."

15. Plaintiffs sell Zetia® in the United States pursuant to a New Drug Application that has been approved by the FDA.

INFRINGEMENT OF U.S. PATENT NO. RE42,461, U.S. PATENT NO. 5,846,966, U.S. PATENT NO. 7,030,106 AND U.S. PATENT NO. 7,612,058

16. Plaintiffs incorporate each of the preceding paragraphs 1-15 as if fully stated herein.

17. On June 14, 2011, the United States Patent and Trademark Office ("USPTO") issued the '461 Patent to Schering Corporation. A true and correct copy of the '461 Patent is attached hereto as **Exhibit A.**

18. Merck Sharp & Dohme Corporation is the assignee of the '461 Patent.

19. The '461 Patent is a reissue of U.S. Patent No. RE37,721 (the " '721 Patent"), which issued on May 28, 2002. Schering Corporation was the assignee of the '721 Patent.

Concurrent with the issuance of the '461 Patent, Schering Corporation surrendered the '721 Patent to the USPTO as required by law.

20. MSD International GmbH is the exclusive licensee of Merck Sharp & Dohme Corporation for the product Zetia®, the drug covered by FDA-approved New Drug Application ("NDA") No. 21-445, and thus has the exclusive right to practice the '461 Patent in connection with making, using, offering to sell, selling and importing ezetimibe in the United States. The active ingredient in Zetia® is ezetimibe, which is an embodiment of the '461 Patent claims.

21. Plaintiffs own all rights, title and interest in the '461 Patent, including all rights needed to bring this action in Plaintiffs' own names.

22. Zetia® is covered by one or more claims of the '461 Patent.

23. The '461 Patent has been listed in connection with Zetia® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is referred to as the "Orange Book," as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Zetia®.

24. Zetia® was covered by one or more claims of the '721 Patent prior to the surrender of the '721 Patent, and the '721 Patent was listed in connection with Zetia® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is referred to as the "Orange Book," as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Zetia®.

25. On December 8, 1998, the USPTO issued the '966 Patent to Schering Corporation. A true and correct copy of the '966 Patent is attached hereto as **Exhibit B**.

26. Merck Sharp & Dohme Corporation is the assignee of the '966 Patent.

27. MSD International GmbH is the exclusive licensee of Merck Sharp & Dohme Corporation for the product Zetia®, the drug covered by FDA-approved NDA No. 21-445, and thus has the exclusive right to practice the '966 Patent in connection with making, using, offering to sell, selling and importing ezetimibe in the United States. Two of the approved indications for Zetia® are (1) the reduction of total-C, LDL-C, and Apo B in patients with primary hyperlipidemia in combination with an HMG-CoA reductase inhibitor, and (2) the reduction of elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia in combination with atorvastatin or simvastatin, and these combinations are embodiments of the '966 Patent claims.

28. Plaintiffs own all rights, title and interest in the '966 Patent, including all rights needed to bring this action in Plaintiffs' own names.

29. The use of Zetia® in combination with a statin is covered by one or more claims of the '966 Patent, and the '966 Patent has been listed in connection with Zetia® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book," as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Zetia®.

30. On April 18, 2006, the USPTO issued the '106 Patent to Schering Corporation. A true and correct copy of the '106 Patent is attached hereto as **Exhibit C**.

31. Merck Sharp & Dohme Corporation is the assignee of the '106 Patent.

32. MSD International GmbH is the exclusive licensee of Merck Sharp & Dohme Corporation for the product Zetia®, the drug covered by FDA-approved NDA No. 21-445, and

thus has the exclusive right to practice the '106 Patent in connection with making, using, offering to sell, selling and importing ezetimibe in the United States. According to its approved label, Zetia® contains ezetimibe, croscarmellose sodium NF, lactose monohydrate NF, magnesium stearate NF, microcrystalline cellulose NF, povidone USP, and sodium lauryl sulfate NF, and this pharmaceutical composition is an embodiment of the '106 Patent claims.

33. Plaintiffs own all rights, title and interest in the '106 Patent, including all rights needed to bring this action in Plaintiffs' own names.

34. The '106 Patent has been listed in connection with Zetia® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is referred to as the "Orange Book," as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Zetia®.

35. On November 3, 2009, the USPTO issued the '058 Patent to Schering Corporation. A true and correct copy of the '058 Patent is attached hereto as **Exhibit D**.

36. Merck Sharp & Dohme Corporation is the assignee of the '058 Patent.

37. MSD International GmbH is the exclusive licensee of Merck Sharp & Dohme Corporation for the product Zetia®, the drug covered by FDA-approved NDA No. 21-445, and thus has the exclusive right to practice the '058 Patent in connection with making, using, offering to sell, selling and importing ezetimibe in the United States. The approved indications for Zetia® include (1) the reduction of total-C, LDL-C, and Apo B in patients with primary hyperlipidemia, and (2) the reduction of elevated sitosterol and campesterol levels, and these uses are embodiments of the '058 Patent claims.

38. Plaintiffs own all rights, title and interest in the '058 Patent, including all rights needed to bring this action in Plaintiffs' own names.

39. The '058 Patent has been listed in connection with Zetia® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is referred to as the "Orange Book," as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Zetia®.

40. By letter dated August 15, 2012 (the "Notice Letter"), Sandoz notified Plaintiffs that it had submitted to the FDA ANDA No. 203-931, for Sandoz's 10 mg ezetimibe tablets ("Sandoz's ANDA Product"), a drug product that is a generic version of Zetia.

41. The purpose of the submission of the ANDA was to obtain permission under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA Product prior to the expiration of the '461, '966, '106 and '058 Patents. Plaintiffs received the Notice Letter on August 17, 2012.

42. This action is being commenced before the expiration of forty-five days from the date of the Notice Letter.

43. In the Notice Letter, Sandoz also notified Plaintiffs that, among other things, as a part of its ANDA, Sandoz had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '461, '106 and '058 Patents. On information and belief, Sandoz submitted ANDA No. 203-931 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '461, '106 and '058 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Sandoz's ANDA Product.

44. The notice included an offer of confidential access to ANDA No. 203-931. In an effort to gain confidential access on reasonable terms, Plaintiffs proposed edits to Sandoz on the offer of confidential access, but received no response regarding the proposed edits. In such circumstances Plaintiffs have satisfied their obligation to conduct a pre-filing investigation prior to bringing an action for infringement. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 693 F.Supp.2d 409, 416-417 (D. Del. 2010) (Holding that "plaintiffs did not run afoul of Rule 11 in bringing this infringement action" where plaintiffs made good faith efforts to obtain access to the ANDA and defendants rebuffed those efforts.)

45. On information and belief, the use of Sandoz's ANDA Product is covered by one or more claims of the '461, '966, '106 and '058 Patents.

46. Sandoz had knowledge of the '461, '966, '106 and '058 Patents when it submitted ANDA No. 203-931.

47. Sandoz's filing of ANDA No. 203-931 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA Product before the expiration date of the '461, '966, '106 and '058 Patents is an act of infringement of the '461, '966, '106 and '058 Patents, under 35 U.S.C. § 271(e)(2).

48. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Sandoz's ANDA Product would infringe one or more claims of the '461, '966, '106 and '058 Patents.

49. On information and belief, the use of Sandoz's ANDA Product in accordance with and, as directed by, Sandoz's proposed labeling for that product would infringe one or more claims of the '461, '966, '106 and '058 Patents.

50. On information and belief, unless enjoined by this Court, Sandoz intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Sandoz's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 203-931.

51. On information and belief, unless enjoined by this Court, Sandoz plans and intends to, and will, actively induce infringement of the '461, '966, '106 and '058 Patents when its ANDA No. 203-931 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

52. On information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '461, '966, '106 and '058 Patents, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Sandoz plans and intends to, and will, contribute to the infringement of the '461, '966, '106 and '058 Patents immediately and imminently upon approval of ANDA No. 203-931.

53. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '461, '966, '106 and '058 Patents, active inducement of infringement of the '461, '966, '106 and '058 Patents, and/or contribution to the infringement by others of the '461, '966, '106 and '058 Patents.

54. On information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringing the '461, '966, '106 and '058 Patents, actively inducing infringement of the '461, '966, '106 and '058 Patents, and/or contributing to the infringement by others of the '461, '966, '106 and '058 Patents.

55. Unless Sandoz is enjoined from infringing the '461, '966, '106 and '058 Patents, actively inducing infringement of the '461, '966, '106 and '058 Patents, and/or contributing to the infringement of the '461, '966, '106 and '058 Patents, Plaintiffs will suffer irreparable injury.

56. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Sandoz's ANDA to be a date which is not earlier than July 25, 2022, the expiration date of the '106 and '058 Patents. (The '461 Patent expires on April 25, 2017 and the '966 Patent expires on March 21, 2014.)

57. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A. A declaration that the '461, '966, '106 and '058 Patents are valid and enforceable;

B. A judgment that the '461, '966, '106 and '058 Patents would be infringed by Sandoz's ANDA Product; that submission of ANDA No. 203-931 is an act of infringement of the '461, '966, '106 and '058 Patents; and that Sandoz's making, using, offering to sell, selling, marketing, distributing, or importing Sandoz's ANDA Product, or any product or compound that infringes the '461, '966, '106 and '058 Patents, prior to the expiration dates of the '461, '966, '106 and '058 Patents, would infringe, actively induce infringement, and contribute to the infringement of the '461, '966, '106 and '058 Patents;

C. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Sandoz's ANDA No. 203-931, or any product or compound that infringes the '461, '966, '106 and '058 Patent, shall be a date which is not earlier than July 25, 2022, the expiration date of the '106 and '058 Patents (the '461 Patent expires on April 25, 2017 and the '966 Patent expires on March 21, 2014);

D. An Order permanently enjoining Sandoz, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Sandoz's ANDA Product, or any other product or compound, not colorably different, that infringes the '461, '966, '106 and '058 Patents, or inducing or contributing to the infringement of the '461, '966, '106 and '058 Patents until after the expiration of the '461, '966, '106 and '058 Patents;

E. Damages or other monetary relief, including prejudgment interest, if Sandoz engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Sandoz's ANDA Product, or any product or compound that infringes the '461, '966, '106 and '058 Patents, or the inducement or contribution of the foregoing, prior to the expiration of the '461, '966, '106 and '058 Patents;

F. A declaration that this is an exceptional case and an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

G. Plaintiffs' reasonable costs of suit incurred; and

H. Such other and further relief as this Court may deem just and proper.

Dated: September 27, 2012

Respectfully submitted,

s/ Sheila F. McShane

Sheila McShane
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4637
(973) 639-6482 (Fax)
smcshane@gibbonslaw.com

Attorney for Plaintiffs
Merck Sharp & Dohme Corp. and
MSD International GmbH

Of Counsel:

David T. Pritikin
William H. Baumgartner, Jr.
SIDLEY AUSTIN LLP
1 S. Dearborn Street
Chicago, Illinois 60603
(312) 853-7000
(312) 853-7036 (Fax)
dpritikin@sidley.com
wbaumgartner@sidley.com

Todd L. Krause
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, New York 10019
(212) 839-5300
(212) 839-5599 (Fax)
tkrause@sidley.com