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Schering Corporation and MSD International GmbH

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORPORATION and, MSD INTERNATIONAL GMBH, *Plaintiffs/Counterclaim Defendants*, v. MYLAN PHARMACEUTICALS INC. *Defendant/Counterclaim Plaintiff*.	Civil Action No. 09-6383 (JLL)(MAH) Civil Action No. 10-3085 (JLL)(MAH)
SCHERING CORPORATION and MSD INTERNATIONAL GMBH, *Plaintiffs*, v. TEVA PHARMACEUTICALS USA, INC., *Defendant*.	Civil Action No. 10-1058 (JLL)(ES) Civil Action No. 10-4473 (JLL)(ES) (CONSOLIDATED)

SECOND AMENDED COMPLAINT

Plaintiffs Schering Corporation and MSD International GmbH (collectively, "Plaintiffs"), by their attorneys, hereby amend their Complaint in *Schering Corporation and MSP Singapore Company LLC v. Mylan Pharmaceuticals Inc.*, Civ. A. No. 10-3085 (JLL)(MAH) (D.I. 1), and 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 Mylan Pharmaceuticals Inc. of Abbreviated New Drug Application ("ANDA") No. 201-790 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") and U.S. Patent No. 5,846,966 (the ' '966 Patent"). The '461 Patent recently issued on June 14, 2011 and is a reissue of U.S. Patent No. RE 37,721 (the " '721 Patent).

PARTIES

2. Plaintiff Schering Corporation is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

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

4. Schering Corporation and MSD International GmbH are both owned, directly or indirectly, by Merck & Co., Inc.

5. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized under the laws of the State of West

Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. On information and belief, Defendant Mylan Inc.[1], formerly known as Mylan Laboratories Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

7. Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. On information and belief, Mylan Pharmaceuticals and Mylan Inc. have officers or directors in common.

8. On information and belief, Mylan Pharmaceuticals' preparation and submission of ANDA No. 201-790 was done collaboratively with, and at least in part for the benefit of, Mylan Inc.

9. Mylan Pharmaceuticals and Mylan Inc. hereinafter are referred to collectively as "Mylan."

JURISDICTION AND VENUE

10. 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.

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

[1] Pursuant to the July 30, 2010 Stipulation Regarding Mylan, Inc. (Civ. A. No. 10-3085, D.I. 19), which applies and remains in effect, Mylan, Inc. was removed as a named defendant in this action.

12. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant 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 Schering Corporation, in New Jersey. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

13. Mylan Pharmaceuticals and Mylan Inc. have submitted to the personal jurisdiction of the United States District Court for the District of New Jersey at least in *Warner Chilcott Laboratories Ireland Ltd. et al.* v. *Mylan Pharmaceuticals Inc. and Mylan Inc., 09-2073* (WJM) (MF); *Hoffmann-La Roche Inc.* v. *Mylan Inc. and Mylan Pharmaceuticals Inc., 09-1692* (WJM) (CCC); *Novartis Pharmaceuticals Corp. v. Mylan Pharmaceuticals Inc. and Mylan Inc.,* 08-5042 (PGS) (ES); and *Sankyo Company, Ltd. and Daiichi Sankyo, Inc.* v. *Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc.*, 06-3462 (WJM) (RJH). Mylan Pharmaceuticals recently submitted to the personal jurisdiction of the United States District Court for the District. of New Jersey in a related case, *Schering Corp., et al. v. Mylan Pharmaceuticals Inc.*, 09-6383 (JLL) (ES).

14. On information and belief, Mylan Inc., directly or through Mylan Pharmaceuticals, 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. Mylan Inc., either directly or through Mylan Pharmaceuticals and/or through one or more of its subsidiaries, agents, and/or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey.

15. On information and belief, this Court has personal jurisdiction over Mylan Inc. by virtue of, among other things: (1) its presence in New Jersey; (2) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey (located at 830 Bear Tavern Road, West Trenton, New Jersey 08628) for the receipt of service of process; (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.

16. On information and belief, Defendant Mylan Pharmaceuticals 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, the acts of Mylan Pharmaceuticals complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation and assistance of Mylan Inc.

17. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals by virtue of, among other things: (1) its presence in New Jersey; (2) its registration to do business in New Jersey including its appointment of a registered agent in New Jersey (located at 830 Bear Tavern Road, West Trenton, New Jersey 08628) for the receipt of service of process; (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.

18. On information and belief, Mylan Pharmaceuticals and Mylan Inc. operate as an integrated business ultimately controlled by Mylan Inc. For example, Mylan Inc.'s website, located at http://www.mylan.comiour_businesses/north_america.aspx., lists "Mylan Pharmaceuticals Inc." as one of "Our Businesses" in "North America."

BACKGROUND

19. 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 hyperlipidemia, 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)."

20. 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 AND U.S. PATENT NO. 5,846,966

21. Plaintiffs incorporate each of the preceding paragraphs 1-20 as if fully stated herein.

22. On May 28, 2002, the United States Patent and Trademark Office ("USPTO") issued the '721 Patent to Schering Corporation. A true and correct copy of the '721 Patent is attached hereto as **Exhibit A**.

23. Schering Corporation is the assignee of the '721 Patent.

24. On June 9, 2010, Schering Corporation filed a reissue patent application for the '721 Patent (the "reissue application"). The application for reissue has been examined by the USPTO, and the USPTO reissued the '721 Patent as the '461 Patent on June 14, 2011. The '461 Patent includes claims 3, 10-13, which are substantially identical to claims 3, 10-13, respectively, in the '721 Patent. A true and correct copy of the '461 Patent is attached hereto as **Exhibit B.**

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

26. Schering Corporation is the assignee of the '461 Patent.

27. MSD International GmbH is the exclusive licensee of Schering Corporation for the product Zetia®, the drug covered by FDA-approved New Drug Application ("NDA") No. 21-445. The active ingredient in Zetia® is ezetimibe, which is an embodiment of the '461 Patent claims.

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

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

30. On June 20, 2011, Plaintiffs submitted to the FDA patent information on the '461 Patent in connection with Zetia® for listing 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®.

31. 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®.

32. 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 C.**

33. Schering Corporation is the assignee of the '966 Patent. MSD International GmbH is the exclusive licensee of Schering Corporation for the product Zetia®, the drug covered by FDA-approved NDA No. 21-445. 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.

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

35. 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®.

36. By letter dated May 25, 2010 (the "Notice Letter"), Mylan Pharmaceuticals notified Plaintiffs that it had submitted to the FDA ANDA No. 201-790, for

Mylan's ezetimibe tablets ("Mylan's ANDA Product"), a drug product that is a generic version of Zetia®. 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 Mylan's ANDA Product prior to the expiration of the '966 and '721 Patents, at a time when the '721 Patent had not been surrendered to the USPTO and was listed in the Orange Book. Plaintiffs received the Notice Letter on or about May 26,2010.

37. Plaintiffs filed and served the original complaint in this action before the expiration of forty-five days from the date of the Notice Letter.

38. In the Notice Letter, Mylan also notified Plaintiffs that, as a part of its ANDA, Mylan had filed certifications 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 '721 and '966 Patents. Upon information and belief, Mylan submitted ANDA No. 201-790 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '721 and '966 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Mylan's ANDA Product.

39. The use of Mylan's ANDA Product is covered by one or more claims of the '966 Patent and claims 3, 10-13 of the '461 Patent.

40. Mylan had knowledge of the '966 and '721 Patents when it submitted ANDA No. 201-790.

41. Mylan also had knowledge of the reissue application when Plaintiffs disclosed the reissue application in their Complaint, served on June 16, 2010. In addition, on October 22, 2010, Plaintiffs disclosed in their *Disclosure of Asserted Claims and Infringement Contentions Pursuant to Local Patent Rules 3.1 and 3.6* that Plaintiffs would assert reissue

claims 3, 7, 8, 9, 10, 11, 12, and 13 (as then numbered in the reissue application), corresponding to claims 3, 7, 8, 9, 10, 11, 12, and 13 of the '461 Patent. Plaintiffs similarly disclosed to Mylan the reissue application in their *Asserted Claims and Infringement Contentions* in the related action, *Schering Corporation and MSP Singapore Company LLC v. Mylan Pharmaceuticals Inc.*, Civ. A. No. 09-6383 (JLL)(ES), on June 11, 2010. Plaintiffs produced to Mylan a copy of the reissue application on or about June 11, 2010.

42. Mylan's filing of ANDA No. 201-790 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product before the expiration date of the '966 and '461 Patents is, under 35 U.S.C. § 271(e)(2), an act of infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent.

43. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product would infringe one or more claims of the '966 Patent and claims 3, 10-13 of the '461 Patent.

44. Upon information and belief, the use of Mylan's ANDA Product in accordance with and as directed by Mylan's proposed labeling for that product would infringe one or more claims of the '966 Patent and claims 3, 10-13 of the '461 Patent.

45. On information and belief, unless enjoined by this Court, Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 201-790.

46. On information and belief, unless enjoined by this Court, Mylan plans and intends to, and will, actively induce infringement of the '966 Patent and claims 3, 10-13 of the

'461 Patent when its ANDA No. 201-790 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

47. On information and belief, Mylan knows that Mylan's ANDA Product and its proposed labeling are especially made or adapted for use in infringing claims 3, 10-13 of the '461 Patent, and that Mylan's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Mylan plans and intends to, and will, contribute to the infringement of claims 3, 10-13 of the '461 Patent immediately and imminently upon approval of ANDA No. 201-790.

48. The foregoing actions by Mylan constitute and/or will constitute infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent, active inducement of infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent, and/or contribution to the infringement by others of claims 3, 10-13 of the '461 Patent.

49. On information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '966 Patent and claims 3, 10-13 of the '461 Patent, actively inducing infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent, and/or contributing to the infringement by others of claims 3, 10-13 of the '461 Patent.

50. Unless Mylan is enjoined from infringing the '966 Patent and claims 13, 10-13 of the '461 Patent, actively inducing infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent, and/or contributing to the infringement of claims 3, 10-13 of the '461 Patent, Plaintiffs will suffer irreparable injury.

51. 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

Mylan Pharmaceuticals' ANDA to be a date which is not earlier than April 25, 2017, the expiration date of the '461 Patent. (The '966 Patent expires on March 21,2014.)

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

PRAYER FOR RELIEF

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

A. A declaration that the '966 Patent and claims 3, 10-13 of the '461 Patent are valid and enforceable.

B. A judgment that the '966 Patent and claims 3, 10-13 of the '461 Patent would be infringed by Mylan's ANDA Product; that submission of ANDA No. 201-790 was an act of infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent; and that Mylan's making, using, offering to sell, selling, marketing, distributing, or importing Mylan's ANDA Product, or any product or compound that infringes the '966 Patent and claims 3, 10-13 of the '461 Patent, prior to the expiration dates of the '461 and '966 Patents, would infringe, actively induce infringement, and/or contribute to the infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent.

C. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Mylan's ANDA No. 201-790, or any product or compound that infringes the '966 Patent and claims 3, 10-13 of the '461 Patent, shall be a date which is not earlier than April 25, 2017, the expiration date of the '461 Patent (the '966 Patent expires on March 21,2014);

D. An Order permanently enjoining Mylan, 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 Mylan's ANDA Product, or any other product or compound, not colorably different, that infringes the '966 Patent and claims 3, 10-13 of the '461 Patent, or inducing or contributing to the infringement of the '966 Patent and claims 3, 10-13 of the '461 Patent until after the expiration of the '461 and '966 Patents;

E. Damages or other monetary relief, including prejudgment interest, if Mylan engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Mylan's ANDA Product, or any product or compound that infringes the '966 Patent and claims 3, 10-13 of the '461 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '461 and '966 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: November 17, 2011

Respectfully submitted,

s/Donald A. Robinson

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CERTIFICATE OF SERVICE

I certify that on November 17, 2011 I served the Second Amended Complaint upon all counsel of record via the Court's CM/ECF electronic filing system and e-mail.

s/Donald A. Robinson

Donald A Robinson