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Schering Corporation and MSP Singapore Company LLC

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORPORATION, and MSP SINGAPORE COMPANY LLC, Plaintiff, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC. Defendants.	Civil Action No. _____ **COMPLAINT**

Plaintiffs Schering Corporation and MSP Singapore Company, LLC (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 Mylan Pharmaceuticals Inc. of Abbreviated New Drug Application ("ANDA") No. 200-082 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic

version of Vytorin® prior to the expiration of U.S. Patent No. RE37,721 and U.S. Patent No. 5,846,966.

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 MSP Singapore Company LLC is a company organized and existing under the laws of the State of Delaware, with a place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

4. Schering Corporation and MSP Singapore Company LLC 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., 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. 200-082 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."

10. Mylan manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

11. 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.

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

13. 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.

14. 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); *Hoffman-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).

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.com/our_businesses/north_america.aspx., lists "Mylan Pharmaceuticals Inc." as one of "Our Businesses" in "North America."

BACKGROUND

20. Vytorin® contains ezetimibe (a cholesterol absorption inhibitor) and simvastatin (a HMG-CoA reductase inhibitor (statin)). According to its approved label, Vytorin® "is indicated for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and non-high density lipoprotein cholesterol (non-HDL-C), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia." Vytorin® is also "indicated for the reduction of elevated total-C and

LDL-C in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable."

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

INFRINGEMENT OF U.S. PATENT NO. RE37,721 AND U.S. PATENT NO. 5,846,966

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

23. On May 28, 2002, the United States Patent and Trademark Office issued U.S. Patent No. RE37,721 (the " '721 Patent") to Schering Corporation. A true and correct copy of the '721 Patent is attached hereto as **Exhibit A**.

24. Schering Corporation is the assignee of the '721 Patent. MSP Singapore Company LLC is the exclusive licensee of Schering Corporation for the product Vytorin®, the drug covered by FDA-approved New Drug Application ("NDA") No. 21-687. One of the active ingredients in Vytorin® is ezetimibe, which is an embodiment of the '721 Patent claims.

25. Plaintiffs own all rights, title and interest in the '721 Patent, including all rights needed to bring this action in Plaintiffs' own names.

26. Vytorin® is covered by one or more claims of the '721 Patent, and the '721 Patent has been listed in connection with Vytorin® 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" Vytorin®.

27. On December 8, 1998, the United States Patent and Trademark Office issued U.S. Patent No. 5,846,966 (the " '966 Patent") to Schering Corporation. A true and correct copy of the '966 Patent is attached hereto as **Exhibit B**.

28. Schering Corporation is the assignee of the '966 Patent. MSP Singapore Company LLC is the exclusive licensee of Schering Corporation for the product Vytorin®, the drug covered by FDA-approved New Drug Application ("NDA") No. 21-687. The active ingredients in Vytorin® are a combination of simvastatin and ezetimibe, and this combination is an embodiment of the '966 Patent claims.

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

30. Vytorin® is covered by one or more claims of the '966 Patent, and the '966 Patent has been listed in connection with Vytorin® 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" Vytorin®.

31. By letter dated November 5, 2009 (the "Notice Letter"), Mylan Pharmaceuticals notified Plaintiffs that it had submitted to the FDA ANDA No. 200-082, for Mylan's ezetimibe/simvastatin tablets, a drug product that is a generic version of Vytorin® ("Mylan's ANDA Product"). 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. Plaintiffs received the Notice Letter on November 6, 2009.

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

33. 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 '966 and '721 Patents. Upon information and belief, Mylan submitted ANDA No. 200-082 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '966 and '721 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Mylan's ANDA Product.

34. The use of Mylan's ANDA Product is covered by one or more claims in each of the '966 and '721 Patents.

35. Mylan had knowledge of the '966 and '721 Patents when it submitted ANDA No. 200-082.

36. Mylan's filing of ANDA No. 200-082 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 '721 Patents is an act of infringement of the '966 and '721 Patents, under 35 U.S.C. § 271(e)(2).

37. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Mylan's ANDA Product would infringe one or more claims in each of the '966 and '721 Patents.

38. 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 in each of the '966 and '721 Patents.

39. 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. 200-082.

40. On information and belief, unless enjoined by this Court, Mylan plans and intends to, and will, actively induce infringement of the '966 and '721 Patents when its ANDA No. 200-082 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

41. On information and belief, Mylan knows that Mylan's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '966 and '721 Patents, 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 the '966 and '721 Patents immediately and imminently upon approval of ANDA No. 200-082.

42. The foregoing actions by Mylan constitute and/or will constitute infringement of the '966 and '721 Patents, active inducement of infringement of the '966 and '721 Patents, and/or contribution to the infringement by others of the '966 and '721 Patents.

43. On information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '966 and '721 Patents, actively inducing

infringement of the '966 and '721 Patents, and/or contributing to the infringement by others of the '966 and '721 Patents.

44. Unless Mylan is enjoined from infringing the '966 and '721 Patents, actively inducing infringement of the '966 and '721 Patents, and/or contributing to the infringement of the '966 and '721 Patents, Plaintiffs will suffer irreparable injury.

45. 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 '721 Patent. (The '966 Patent expires on March 21, 2014.)

46. 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 '966 and '721 Patents are valid and enforceable.

B. A judgment that the '966 and '721 Patents would be infringed by Mylan's ANDA Product; that submission of ANDA No. 200-082 is an act of infringement of the '966 and '721 Patents; 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 and '721 Patents, prior to the expiration dates of the '966 and '721 Patents, would infringe, actively induce infringement, and contribute to the infringement of the '966 and '721 Patents.

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. 200-082, or any product or compound that infringes the '966 and '721 Patents, shall be a date which is not earlier than April 25, 2017, the expiration date of the '721 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 and '721 Patents, or inducing or contributing to the infringement of the '966 and '721 Patents until after the expiration of the '966 and '721 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 and '721 Patents, or the inducement or contribution of the foregoing, prior to the expiration of the '966 and '721 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: December 16, 2009

Respectfully submitted,

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