UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SCHERING CORPORATION, and MSP SINGAPORE COMPANY LLC, Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC. Defendants.	Civil Action No. 1:10-cv-99-IMK

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. 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 Nos. RE37,721 and 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. 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."

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

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. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals by virtue of, among other things: (1) it is a corporation registered and doing business under the laws of the State of West Virginia; (2) it has designated Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302, for the receipt of service of process; and (3) it has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 25302. Moreover, Mylan Pharmaceuticals has also engaged in continuous and systematic contacts with the State of West Virginia and purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of West Virginia including in this Judicial District and deriving revenue from such activities.

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 West Virginia 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 West Virginia.

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 West Virginia 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 its pharmaceutical products in West Virginia.

16. 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."

17. On information and belief, this Court has personal jurisdiction over Mylan Inc. by virtue of, among other things: (1) it is doing business in the State of West Virginia, including in this Judicial District; and (2) it has designated Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302, for the receipt of service of process. Moreover, Mylan Inc., directly or through its subsidiaries, has also engaged in continuous and systematic contacts with the State of West Virginia and purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of West Virginia including in this Judicial District and deriving revenue from such activities.

BACKGROUND

20. 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)."

21. 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. 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 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 '721 Patent claims.

25. On June 10, 2010, Schering Corporation filed a reissue patent application for the '721 Patent (the "reissue application"). A true and correct copy of the reissue application is attached hereto as **Exhibit B**.

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

27. Zetia® is covered by one or more claims of the '721 Patent, and the '721 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®.

28. 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 C**.

29. Schering Corporation is the assignee of the '966 Patent. MSP Singapore Company LLC 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.

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

31. 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®.

32. 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 '721 and '966 Patents. Plaintiffs received the Notice Letter on or about May 26, 2010.

33. This action is being commenced within forty-five days of the date of the Notice Letter.

34. 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.

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

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

37. 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 '721 and '966 Patents is, under 35 U.S.C. § 271(e)(2), an act of infringement of the '721 and '966 patents.

38. 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 the '721 and '966 Patents.

39. 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 the '721 and '966 Patents.

40. 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.

41. On information and belief, unless enjoined by this Court, Mylan plans and intends to, and will, actively induce infringement of the '721 and '966 Patents when its ANDA No. 201-790 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

42. 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 '721 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 the '721 Patent immediately and imminently upon approval of ANDA No. 201-790.

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

44. On information and belief, Mylan acted without a reasonable basis for believing that it would not be liable for infringing the '721 and '966 Patents, actively inducing infringement of the '721 and '966 Patents, and/or contributing to the infringement by others of the '721 Patent.

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

46. 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.)

47. 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 '721 and '966 Patents are valid and enforceable.

B. A judgment that the '721 and '966 Patents would be infringed by Mylan's ANDA Product; that submission of ANDA No. 201-790 was an act of infringement of the '721 and '966 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 '721 and '966 Patents, prior to the expiration dates of the '721 and '966 Patents, would infringe, actively induce infringement, and/or contribute to the infringement of the '721 and '966 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. 201-790, or any product or compound that infringes the '721 and '966 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 '721 and '966 Patents, or inducing or contributing to the infringement of the '721 and '966 Patents until after the expiration of the '721 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 '721 and '966 Patents, or the inducement or contribution of the foregoing, prior to the expiration of the '721 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: June 29, 2010

Respectfully submitted,

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