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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, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD. 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 Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva" or "Defendants") of Abbreviated New Drug Application ("ANDA") No. 078-724 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 Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized under the laws of Delaware having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

6. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a company organized and existing under the laws of Israel with its principal place of business at 5 Basel St. Petach Tikva 49131, Israel.

7. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

8. On information and belief, Teva USA's preparation and submission of ANDA No. 078-724 was done collaboratively with, and at least in part for the benefit of, Teva Ltd.

9. Teva USA and Teva Ltd. hereinafter are referred to collectively as "Teva."

10. Teva 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. On information and belief, Teva USA 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, Teva USA is registered to do business in New Jersey and engages in continuous and systematic contacts with New Jersey.

15. On information and belief, Teva Ltd, directly or through Teva USA, 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. Such business activities by Teva Ltd. include, but are not limited to, Teva Ltd.'s direction of the operations and management of Teva USA inclusive of Teva USA's New Jersey facilities and the shipment of drugs to Teva USA from locations outside the United States for distribution by Teva USA within the United States generally, and New Jersey specifically.

16. On information and belief, Teva USA acts under the direction, control, and influence of Teva Ltd. with respect to, at least, the acts and conduct alleged in this Complaint.

17. Teva USA's acts and continuous and systematic contacts with the State of New Jersey, as an agent of Teva Ltd., are also attributable to Teva Ltd. for jurisdictional purposes.

18. On information and belief, Teva Ltd. and Teva USA have jointly filed numerous complaints in this judicial district in the last five years, including patent infringement cases, and therefore, have submitted themselves to the jurisdiction of this Court and availed themselves of the laws and protections of New Jersey. These cases include, but are not limited to: *Teva Pharm. Indus. Ltd. et al. v. Glenmark Generics Inc., USA et al.*, Civ. A. No. 3:08-cv-04355 (GEB/DEA), filed August 29, 2008; *Teva Pharm. Indus. Ltd. et al. v. Apotex, Inc. et al.*, Civ. A. No. 3:07-cv-05514 (GEB/JJH), filed November 15, 2007; *Teva Pharm. Indus. Ltd. et al. v. Zydus Pharms., Inc. et al.*, Civ. A. No. 3:07-cv-0942 (GEB/TJB), filed October 12, 2007; *Teva Pharm. Indus. Ltd. et al. v. Dr. Reddy's Labs., Ltd.*, Civ. A. No. 3:07-cv-02894 (GEB/JJH), filed June 21, 2007; *Teva Pharm. Indus. Ltd. et al. v. Cobalt Pharms., Inc. et al.*, Civ. A. No. 2:07-cv-04214 (WHW-CCC), filed April 10, 2007.

19. This Court has personal jurisdiction over Teva USA 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 811 Church Road, Suite 150, Cherry Hill, NJ 08002) for the receipt of service of process; (3) its sale of a substantial volume of prescription drugs in New Jersey; (4) its filing of lawsuits in New Jersey; (5) its continuous and systematic 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.

20. This Court has personal jurisdiction over Teva Ltd. by virtue of, among other things, (1) its presence in New Jersey; (2) its sale of a substantial volume of prescription drugs in New Jersey; (3) its filing of lawsuits in New Jersey; (4) its continuous and systematic contacts with New Jersey; and (5) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in New Jersey.

21. Four related lawsuits are currently pending in this Court. On December 16, 2009, Plaintiffs filed suit in this Court against Mylan Pharmaceuticals Inc. seeking a judgment that each of the '721 and '966 Patents is infringed by Mylan Pharmaceuticals Inc.'s filing of its ANDA No. 200-082. *See Schering Corporation and MSP Singapore Company LLC v. Mylan Pharmaceuticals Inc.* (Civ. Action No. 09-6383) (JLL/ES). On March 2, 2010, Plaintiffs filed suit in this Court against Teva Pharmaceuticals USA, Inc. seeking a judgment that each of the '721 and '966 Patents is infringed by Teva Pharmaceuticals USA, Inc.'s filing of its ANDA No. 200-909. *See Schering Corporation and MSP Singapore Company LLC v. Teva Pharmaceuticals USA, Inc.* (Civ. Action No. 10-1058) (JLL/ES). On June 16, 2010, Plaintiffs filed suit in this Court against Mylan Pharmaceuticals Inc. and Mylan Inc. seeking a judgment

that each of the '721 and '966 Patents is infringed by Mylan Pharmaceuticals Inc. and Mylan Inc.'s filing of their ANDA No. 201-790. *See Schering Corporation and MSP Singapore Company LLC v. Mylan Pharmaceuticals Inc. and Mylan Inc.* (Civ. Action No. 10-3085) (JLL/ES). On August 19, 2010, Plaintiffs filed suit in this Court against Impax Laboratories, Inc. seeking a judgment that each of the '721 and '966 Patents is infringed by Impax Laboratories, Inc.'s filing of its ANDA No. 201-890. *See Schering Corporation and MSP Singapore Company LLC v. Impax Laboratories, Inc.* (Civ. Action No. 10-4270) (JLL/CCC). All four related lawsuits involve the '721 and '966 Patents which are asserted in the current controversy.

BACKGROUND

22. 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)."

23. 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

24. Plaintiffs incorporate each of the preceding paragraphs 1-23 as if fully stated herein.

25. 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**.

26. 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.

27. On June 9, 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**.

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

29. 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®.

30. 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**.

31. 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.

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

33. 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®.

34. By letter dated July 20, 2010 (the "Notice Letter"), Teva USA notified Plaintiffs that it had submitted to the FDA ANDA No. 078-724, for Teva's ezetimibe tablets ("Teva'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 Teva's ANDA Product prior to the expiration of the '721 and '966 Patents. Plaintiffs received the Notice Letter on or about July 21, 2010.

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

36. In the Notice Letter, Teva USA also notified Plaintiffs that, as a part of its ANDA, Teva USA 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, Teva USA submitted ANDA No. 078-724 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 Teva's ANDA Product.

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

38. Teva had knowledge of the '721 and '966 Patents when it submitted ANDA No. 078-724.

39. Teva USA's filing of ANDA No. 078-724 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva'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.

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

41. Upon information and belief, the use of Teva's ANDA Product in accordance with and as directed by Teva's proposed labeling for that product would infringe one or more claims in each of the '721 and '966 Patents.

42. On information and belief, unless enjoined by this Court, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 078-724.

43. On information and belief, unless enjoined by this Court, Teva plans and intends to, and will, actively induce infringement of the '721 and '966 Patents when its ANDA No. 078-724 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

44. On information and belief, Teva knows that Teva's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '721 Patent, and that Teva's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Teva plans and intends to, and will, contribute to the infringement of the '721 Patent immediately and imminently upon approval of ANDA No. 078-724.

45. The foregoing actions by Teva 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.

46. On information and belief, Teva 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.

47. Unless Teva 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.

48. 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 Teva 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.)

49. 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 Teva's ANDA Product; that submission of ANDA No. 078-724 was an act of infringement of the '721 and '966 Patents; and that Teva's making, using, offering to sell, selling, marketing, distributing, or importing Teva'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 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 Teva's ANDA No. 078-724, 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 Teva, 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 Teva'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 Teva engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Teva'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: September 1, 2010

Respectfully submitted,

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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is the subject of other civil actions pending in this court. Those actions are *Schering Corporation and MSP Singapore Company LLC v. Mylan Pharmaceuticals Inc.* (Civ. Action No. 09-6383) (JLL/ES), *Schering Corporation and MSP Singapore Company LLC v. Mylan Pharmaceuticals Inc. and Mylan Inc.* (Civ. Action No. 10-3085) (JLL/ES), *Schering Corporation and MSP Singapore Company LLC v. Teva Pharmaceuticals USA, Inc.* (Civ. Action No. 10-1058) (JLL/ES), and *Schering Corporation and MSP Singapore Company LLC v. Impax Laboratories, Inc.* (Civ. Action No. 10-4270) (JLL/CCC), which involve the patents (U.S. Patent Nos. RE37,721 and 5,846,966) asserted in the current controversy. The matter in controversy is not the subject of any pending arbitration or administrative proceeding.

Dated: September 1, 2010

By: s/ Jason Halper
Jason Halper