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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. IMPAX LABORATORIES, INC. Defendant.	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 Impax Laboratories, Inc. of Abbreviated New Drug Application ("ANDA") No. 201-890 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 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 Impax Laboratories, Inc. ("Impax") is a corporation organized under the laws of the State of Delaware, having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544, and having its primary commercial center at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124. On information and belief, Impax is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products.

JURISDICTION AND VENUE

6. This is an action for patent infringement, arising under 35 U.S.C. § 1 et seq. generally, and 35 U.S.C. § 271(e)(2) specifically.

7. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

9. This Court has specific personal jurisdiction over the Defendant by virtue of the fact that, *inter alia*, the 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 Plaintiff Schering Corporation in New Jersey, where Schering Corporation

has its principal place of business. This Court has general personal jurisdiction over the Defendant for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

10. On information and belief, Impax carries on a continuous and systematic part of its general business within the state of New Jersey. On information and belief, Impax regularly and systematically sells pharmaceutical products in the state of New Jersey and has registered prescription drug products in the *New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services*.

11. On information and belief, Impax regularly seeks out business relationships and enters into contracts with New Jersey corporations. For example, on May 25, 2010, Impax announced that it entered into a development and supply agreement with IGI Laboratories, in which IGI Laboratories is responsible for developing two topical drug products, obtaining FDA approval, and manufacturing. According to the agreement, Impax will market and distribute the products. IGI Laboratories, which will be performing the bulk of the work, is located in Buena, New Jersey. Similarly, on November 7, 2005, Impax announced that it signed an exclusive supply and distribution agreement with DAVA Pharmaceuticals, Inc. for oxycodone hydrochloride extended release tablets. DAVA Pharmaceuticals, Inc. is located in Fort Lee, New Jersey. On June 24, 2002, Impax announced that it entered into an agreement with Schering-Plough to supply Claritin-D® 12 hour for over-the-counter marketing. Schering-Plough (now "Schering Corporation") has its principal place of business in Kenilworth, New Jersey.

12. Impax has been registered to do business in New Jersey since February 2005. On information and belief, Impax makes sufficient sales within New Jersey (and has other

commercial contacts with the State) to subject itself to the general jurisdiction of New Jersey courts.

13. Impax has repeatedly submitted to the personal jurisdiction of the United States District Court for the District of New Jersey. For example, it did so in *Schering Corporation v. Impax Laboratories, Inc.*, Civil Action No. 01-0279; *Schering Corporation v. Impax Laboratories, Inc.*, Civil Action No. 01-0009; *Schering Corporation v. Impax Laboratories, Inc.*, 01-0520; *Pfizer Inc. et al. v. Impax Laboratories, Inc.*, Civil Action No. 08-2137; *Pfizer Inc. et al. v. Impax Laboratories, Inc.*, Civil Action No. 08-4357; *Warner Chilcott Laboratories Ireland Limited et al. v. Impax Laboratories, Inc. et al.*, Civil Action No. 08-6304; *Eli Lilly and Company v. Impax Laboratories, Inc.*, Civil Action No. 08-6139; *Warner Chilcott Laboratories Ireland Limited et al. v. Impax Laboratories, Inc.*, Civil Action No. 09-1233; *Abbott Laboratories et al. v. Impax Laboratories, Inc.*, Civil Action No. 09-5517; *Elan Pharma International Ltd. et al. v. Impax Laboratories, Inc.*, Civil Action No. 09-5541; and *Abbott Laboratories et al. v. Impax Laboratories, Inc.*, Civil Action No. 10-1322.

14. Three 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/CCC). All three related lawsuits involve the '721 and '966 Patents which are asserted in the current controversy.

BACKGROUND

15. 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 choelsterol (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."

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

CLAIM

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

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

18. 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**.

19. 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.

20. 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**.

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

22. 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®.

23. 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**.

24. 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 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.

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

26. 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®.

27. By letter dated July 8, 2010 (the "Notice Letter"), Impax notified Plaintiffs that it had submitted to the FDA ANDA No. 201-890, for Impax's ezetimibe/simvastatin tablets, ("Impax's ANDA Product") a drug product that is a generic version of Vytorin®. 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 Impax's ANDA Product prior to the expiration of the '721 and '966 Patents. Plaintiffs received the Notice Letter on or about July 9, 2010.

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

29. In the Notice Letter, Impax also notified Plaintiffs that, as a part of its ANDA, Impax 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, Impax submitted ANDA No. 201-890 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 Impax's ANDA Product.

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

31. Impax had knowledge of the '721 and '966 Patents when it submitted ANDA No. 201-890.

32. Impax's filing of ANDA No. 201-890 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Impax'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.

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

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

35. On information and belief, unless enjoined by this Court, Impax intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Impax's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 201-890.

36. On information and belief, unless enjoined by this Court, Impax plans and intends to, and will, actively induce infringement of the '721 and '966 Patents when its ANDA No. 201-890 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

37. On information and belief, Impax knows that Impax's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '721 and '966 Patents, and that Impax's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Impax plans and intends to, and will, contribute to the infringement of the '721 and '966 Patents immediately and imminently upon approval of ANDA No. 201-890.

38. The foregoing actions by Impax 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 and '966 Patents.

39. On information and belief, Impax 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 and '966 Patents.

40. Unless Impax 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 and '966 Patents, Plaintiffs will suffer irreparable injury.

41. 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 Impax 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.)

42. 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 Impax's ANDA Product; that submission of ANDA No. 201-890 was an act of infringement of the '721 and '966 Patents; and that Impax's making, using, offering to sell, selling, marketing, distributing, or importing Impax'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 Impax's ANDA No. 201-890, 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 Impax, 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 Impax'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 Impax engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Impax'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: August 19, 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.* (Civ. Action No. 10-3085) (JLL/ES), and *Schering Corporation and MSP Singapore Company LLC v. Teva Pharmaceuticals USA, Inc.* (Civ. Action No. 10-1058) (JLL/ES) 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: August 19, 2010

By: /s Donald A. Robinson
Donald A. Robinson