Douglas S. Eakeley
Jason Halper
**LOWENSTEIN SANDLER PC**
Attorneys at Law
65 Livingston Avenue
Roseland, New Jersey 07068
(973) 597-2500

Donald A. Robinson
**ROBINSON WETTRE & MILLER LLC**
One Newark Center
Newark, New Jersey 07102
(973) 690-5400

*Attorneys for Plaintiffs*
*Schering Corporation and MSP Singapore Company LLC*

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| SCHERING CORPORATION and MSP SINGAPORE COMPANY LLC,<br><br>*Plaintiffs*,<br><br>v.<br><br>ACTAVIS INC. and ACTAVIS GROUP HF<br><br>*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 Actavis Inc. of Abbreviated New Drug Application ("ANDA") No. 202-968 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. RE42,461 ( the " '461 Patent") and U.S. Patent No. 5,846,966 (the " '966 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 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 Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

6. On information and belief, Defendant Actavis Group hf. is a limited liability company organized and existing under the laws of Iceland, having a principal place of business at Dalshrauni 1, 220 Hafnarfirdi, Iceland.

7. On information and belief, Actavis Inc. is a wholly-owned subsidiary of Actavis Group hf. On information and belief, Actavis Inc. and Actavis Group hf. have officers and directors in common.

8. On information and belief, Actavis Inc.'s preparation and submission of ANDA No. 202-968 was done collaboratively with, and at least in part for the benefit of, Actavis Group hf.

9. Actavis Inc. and Actavis Group hf. hereinafter are referred to collectively as "Actavis."

10. Actavis 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. Actavis Inc. and Actavis Group hf. have submitted to the personal jurisdiction of the United States District Court for the District of New Jersey at least in *Abbott Labs., et al. v. Actavis Elizabeth LLC, Actavis Inc., and Actavis Group hf*, Civ. A. No. 10-cv-2352 (DMC)(JAD) (filed May 7, 2010) and *Warner Chilcott Labs. Ireland Ltd., et al. v. Actavis Elizabeth LLC, Actavis Inc., and Actavis Group hf.*, Civ. A. No. 09-0469 (WJM)(MF) (filed Jan. 30, 2009).

15. On information and belief, Defendant Actavis Inc. 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,

Actavis Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey. On information and belief, the acts of Actavis Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Actavis Group hf.

16. On information and belief, this Court has personal jurisdiction over Actavis 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 United Corporate Services Inc., 80 Main Street 5th Floor, West Orange, NJ 07052) 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, Actavis Group hf., directly or through Actavis Inc. and/or through one or more of its subsidiaries, 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, Actavis Group hf., either directly or through Actavis Inc. and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures, markets, sells and/or distributes a substantial volume of its pharmaceutical products in New Jersey.

18. On information and belief, this Court has personal jurisdiction over Actavis Group hf. 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 prior consent to be sued in New

Jersey; (4) its systematic and continuous 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.

19. On information and belief, Actavis Inc. and Actavis Group hf. operate as an integrated business ultimately controlled by Actavis Group hf. For example, Actavis Group hf.'s website, located at http://www.actavis.com/en/corporate+directory/northamerica/us.htm, directs visitors to "visit our US Website at www.activis.us," which is the website for Actavis Inc. Activis Inc.'s website, at http://www.actavis.us, and Actavis Inc.'s press releases available on its website state that Actavis Inc. is "the US subsidiary of Actavis Group hf."

## 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. RE42,461 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 June 14, 2011, the United States Patent and Trademark Office ("USPTO") issued the '461 Patent to Schering Corporation. A true and correct copy of the '461 Patent is attached hereto as **Exhibit A.**

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

25. The '461 Patent is a reissue of U.S. Patent No. RE37,721 (the " '721 Patent"), which issued on May 28, 2002. Schering Corporation was the assignee of the '721 Patent. Concurrent with the issuance of the '461 Patent, Schering Corporation surrendered the '721 Patent to the USPTO as required by law.

26. 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 '461 Patent claims.

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

28. Vytorin® is covered by one or more claims of the '461 Patent, and the '461 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®.

29. Vytorin® 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 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®. After the surrender of the '721 Patent, Plaintiffs requested the delisting of the '721 Patent from the Orange Book.

30. 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 B**.

31. 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.

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. 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®.

34. By letter dated September 6, 2011 (the "Notice Letter"), Actavis Inc. notified Plaintiffs that it had submitted to the FDA ANDA No. 202-968, for Actavis's ezetimibe/simvastatin tablets, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg, drug products that are generic versions of Vytorin® ("Actavis's ANDA Products"). 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 Actavis's ANDA Products prior to the expiration of the '461 and '966 Patents. Plaintiffs received the Notice Letter on September 7, 2011.

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

36. In the Notice Letter, Actavis also notified Plaintiffs that, as a part of its ANDA, Actavis 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 '461, '721, and '966 Patents. On information and belief, Actavis submitted ANDA No. 202-968 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '461, '721, and '966 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Actavis's ANDA Products.

37. The use of Actavis's ANDA Products is covered by one or more claims of the '461 Patent and one or more claims of the '966 Patent.

38. Actavis had knowledge of the '461 and '966 Patents when it submitted ANDA No. 202-968.

39. Actavis's filing of ANDA No. 202-968 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Actavis's ANDA Products before the expiration date of the '461 and '966 Patents is an act of infringement of the '461 and '966 Patents, under 35 U.S.C. § 271(e)(2).

40. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Actavis's ANDA Products would infringe one or more claims of the '461 Patent and one or more claims of the '966 Patent.

41. On information and belief, the use of Actavis's ANDA Products in accordance with and as directed by Actavis's proposed labeling for that product would infringe one or more claims of the '461 Patent and one or more claims of the '966 Patent.

42. On information and belief, unless enjoined by this Court, Actavis intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Actavis's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 202-968.

43. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, actively induce infringement of the '461 and '966 Patents when its ANDA No. 202-968 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

44. On information and belief, Actavis knows that Actavis's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '461 and '966 Patents, and that Actavis's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, contribute to the infringement of the '461 and '966 Patents immediately and imminently upon approval of ANDA No. 202-968.

45. The foregoing actions by Actavis constitute and/or will constitute infringement of the '461 and '966 Patents, active inducement of infringement of the '461 and '966 Patents, and/or contribution to the infringement by others of the '461 and '966 Patents.

46. On information and belief, Actavis acted without a reasonable basis for believing that it would not be liable for infringing the '461 and '966 Patents, actively inducing infringement

of the '461 and '966 Patents, and/or contributing to the infringement by others of the '461 and '966 Patents.

47. Unless Actavis is enjoined from infringing the '461 and '966 Patents, actively inducing infringement of the '461 and '966 Patents, and/or contributing to the infringement of the '461 and '966 Patents, 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 Actavis Inc.'s 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.)

49. 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 '461 and '966 Patents are valid and enforceable;

B. A judgment that the '461 and '966 Patents would be infringed by Actavis's ANDA Products; that submission of ANDA No. 202-968 is an act of infringement of the '461 and '966 Patents; and that Actavis's making, using, offering to sell, selling, marketing, distributing, or importing Actavis's ANDA Products, or any product or compound that infringes the '461 and '966 Patents, prior to the expiration dates of the '966 and '461 Patents, would infringe, actively induce infringement, and contribute to the infringement of the '461 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. 202-968, or any product or compound that infringes the '461 and '966 Patents, 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 Actavis, 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 Actavis's ANDA Products, or any other product or compound, not colorably different, that infringes the '461 and '966 Patents, or inducing or contributing to the infringement of the '461 and '966 Patents until after the expiration of the '461 and '966 Patents;

E. Damages or other monetary relief, including prejudgment interest, if Actavis engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Actavis's ANDA Products, or any product or compound that infringes the '461 and '966 Patents, 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: October 13, 2011

Respectfully submitted,

s/ Jason Halper
Douglas S. Eakeley
Jason Halper
**LOWENSTEIN SANDLER**
Attorneys at Law
65 Livingston Avenue
Roseland, New Jersey 07068
(973) 597-2500
(973) 597-2400 (Fax)
jhalper@lowenstein.com

Donald A. Robinson
**ROBINSON WETTRE & MILLER LLC**
One Newark Center
Newark, New Jersey 071 02
(973) 690-5400
(973) 466-2760 (Fax)
drobinson@RWMLegal.com

*Attorneys for Plaintiffs*
*Schering Corporation and*
*MSP Singapore Company LLC*

*Of Counsel:*

David T. Pritikin
William H. Baumgartner, Jr.
**SIDLEY AUSTIN LLP**
1 S. Dearborn Street
Chicago, Illinois 60603
(312) 853-7000
(312) 853-7036 (Fax)
dpritikin@sidley.com
wbaumgartner@sidley.com

Todd L. Krause
**SIDLEY AUSTIN LLP**
787 Seventh Avenue
New York, New York 10019
(212) 839-5300
(212) 839-5599 (Fax)
tkrause@sidley.com

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

I hereby certify that the matter in controversy is the subject of another civil action pending in this court. That action is *Schering Corp. v. Mylan Pharms. Inc.*, Civ. A. Nos. 09-cv-6383, 10-cv-3085 (JLL)(MAH) and *Schering Corp. v. Impax Labs., Inc.*, Civ. A. No. 2:10-cv-04270 (JLL)(ES) which involve the patents U.S. Patent No. RE42,461 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: October 13, 2011

By: s/ Jason Halper
Jason Halper