IN THE UNITED STATES DISTRICT COURT
FOR DELAWARE

ASTRAZENECA PHARMACEUTICALS LP,

and

ASTRAZENECA UK LIMITED,

and

IPR PHARMACEUTICALS, INC.,

and

SHIONOGI SEIYAKU KABUSHIKI KAISHA,

Plaintiffs,

v.

APOTEX INC.,

and

APOTEX CORP.,

Defendants.

Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha, for their Complaint against Apotex Inc. and Apotex Corp., hereby state as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. §§ 271(e) and (a). This action relates to an Abbreviated New Drug Application ("ANDA") filed by and/or for the benefit

of Apotex Inc. and Apotex Corp. ("the Apotex ANDA") with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' highly successful Crestor® pharmaceutical products that are sold in the United States.

Parties

2. Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

3. Plaintiff AstraZeneca UK Limited is a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England.

4. Plaintiff IPR Pharmaceuticals, Inc. ("IPR") is a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

5. Plaintiff Shionogi Seiyaku Kabushiki Kaisha is a corporation operating and existing under the laws of Japan with its principal place of business at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan.

6. On information and belief, Defendant Apotex Inc. is a corporation operating and existing under the laws of Canada with its principal place of business at 150 Signet Drive, Weston, Ontario M9L 1T9 Canada.

7. On information and belief, Defendant Apotex Corp. ("Apotex USA") is wholly owned subsidiary of Apotex Inc. and is a corporation operating and existing under the laws of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326 USA.

Background

8. IPR is the holder of approved New Drug Application ("NDA") No. 021366 for Crestor® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium. AstraZeneca is IPR's authorized agent for matters related to NDA No. 021366.

9. CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. Crestor® is one of the most effective lipid-lowering statins available. Over 11 million patients have been prescribed Crestor®, and over 110 million prescriptions have been written worldwide for Crestor®.

10. Plaintiffs, among other things, manufacture, market, promote, educate the public and physicians about, and conduct research and development on existing and new indications for Crestor® Tablets. Plaintiffs financially benefit from sales of Crestor® Tablets in the United States.

11. On information and belief, Apotex Inc. and/or Apotex USA filed with the FDA, in Rockville, Maryland, ANDA No. 79-145 under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, which are

generic versions of Plaintiffs' Crestor® Tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, respectively.

12. By letters dated November 5, 2007 and December 4, 2007, Apotex Inc. notified Plaintiffs that it had filed an ANDA seeking FDA approval to market rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths (hereinafter referred to as "the Apotex Rosuvastatin Calcium Tablets"), and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

13. On information and belief, Apotex Inc. is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Apotex Inc. sells and delivers its pharmaceutical products to Apotex USA in Florida. On information and belief Apotex USA is the agent, affiliate, representative, and/or alter ego of, and/or acts in concert with, Apotex Inc. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

14. On information and belief, Apotex USA, as the authorized agent of Apotex Inc. and/or in its own capacity, participated in the preparation and filing with the FDA of the Apotex ANDA for approval to market generic rosuvastatin calcium in the United States.

Jurisdiction and Venue

15. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

16. On information and belief, Apotex Inc. develops and manufactures generic drugs and, directly or indirectly through Apotex USA, markets, distributes, and sells its generic drugs throughout the United States, including the State of Delaware.

17. Personal jurisdiction over Apotex Inc. is proper because it purposefully avails itself of the privilege of selling its generic products in the state of Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware. Among other things, upon information and belief, Apotex Inc., directly or through its subsidiary Apotex USA, places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

18. Personal jurisdiction over Apotex USA is proper because Apotex USA is incorporated in Delaware and has purposely availed itself of the privilege of doing business in this State. Further, Apotex USA maintains continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over it.

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

Count I

Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(e)(2)

20. Plaintiffs incorporate by reference paragraphs 1-19 of this Complaint as if fully set forth herein.

21. United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives," was duly and legally reissued by the United States Patent and Trademark Office on August 7, 2001. Plaintiffs hold all substantial rights in the '314 patent and have the right to sue for infringement thereof. A true and correct copy of the '314 patent is attached as Exhibit A.

22. On information and belief, Apotex Inc. and Apotex USA filed ANDA No. 79-145 in order to obtain approval to market the Apotex Rosuvastatin Calcium Tablets in the United States before the expiration of the '314 patent. On information and belief, Apotex Inc. and Apotex USA also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification letter dated December 4, 2007, alleging that the claims of the '314 patent are invalid.

23. On information and belief, Apotex Inc. and Apotex USA do not assert that Apotex Rosuvastatin Calcium Tablets are not covered by one or more claims of the '314 patent.

24. Under 35 U.S.C. § 271(e)(2)(A), the submission by Apotex Inc. and/or Apotex USA to the FDA of ANDA No. 79-145 to obtain approval for the commercial manufacture, use, or sale of the Apotex Rosuvastatin Calcium Tablets before the expiration date of the '314 patent constitutes infringement of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

25. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

Count II

Declaratory Judgment of Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(a)

26. Plaintiffs incorporate by reference paragraphs 1-25 of this Complaint as if fully set forth herein.

27. Upon information and belief, Apotex Inc. and Apotex USA have made substantial preparations to sell Apotex Rosuvastatin Calcium Tablets labeled for the same dosages as the Crestor® products.

28. Upon information and belief, Apotex Inc. and Apotex USA intend to commence sale of Apotex Rosuvastatin Calcium Tablets immediately upon receiving approval from the FDA.

29. The manufacture, importation, sale, and offer for sale of Apotex Rosuvastatin Calcium Tablets, once approved by the FDA, will directly infringe, induce and/or contribute to the infringement of one or more claims of the '314 patent under 35 U.S.C. § 271(a).

30. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

31. An actual controversy exists relating to Apotex Inc. and Apotex USA's threatened infringement of the '314 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

(1) holding that the claims of the '314 patent are valid and enforceable;

(2) holding that the submission of ANDA No. 79-145 by Apotex Inc. and Apotex USA infringes one or more claims of the '314 patent under 35 U.S.C. § 271(e)(2);

(3) declaring that the manufacture, use, offering for sale, or sale of the Apotex Rosuvastatin Calcium Tablets within the United States or importing the Apotex Rosuvastatin Calcium Tablets into the United States before expiration of the '314 patent will infringe one or more claims of the '314 patent;

(4) ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Apotex Rosuvastatin Calcium Tablets shall be no earlier than the expiration date of the '314 patent;

(5) enjoining Apotex Inc., Apotex USA, and all persons acting in concert with them, from commercially manufacturing, using, offering for sale, or selling the Apotex Rosuvastatin Calcium Tablets within the United States or importing into the United States the Apotex Rosuvastatin Calcium Tablets, prior to the expiration of the '314 patent;

(6) declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;

(7) awarding Plaintiffs their costs and expenses in this action; and

(8) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

This 11th day of December 2007.

Respectfully submitted,

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