

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., Shionogi Seiyaku Kabushiki Kaisha,
Plaintiffs,

v.

Glenmark Generics Inc., USA,
Defendant.

Civ. 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 Glenmark Generics Inc., USA, 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). This action relates to an Abbreviated New Drug Application (“ANDA”) filed by and/or for the benefit of Glenmark Generics Inc., USA (formerly known as Glenmark Pharmaceuticals Inc., USA) with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of AstraZeneca Pharmaceuticals LP’s 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.

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 Glenmark Generics Inc., USA (formerly known as Glenmark Pharmaceuticals Inc., USA) (“Glenmark”) is a corporation operating and existing under the laws of Delaware with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

Background

7. 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.

8. 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 19 million patients have been prescribed Crestor[®], and over 240 million prescriptions have been written worldwide for Crestor[®]. Rosuvastatin calcium is the active ingredient in Crestor[®].

9. 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.

10. On information and belief, Glenmark filed with the FDA, in Rockville, Maryland, ANDA No. 79-172 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.

11. By letter dated May 17, 2010, Glenmark notified AstraZeneca and IPR 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 (the "Glenmark Rosuvastatin Calcium Tablets"), and that it was providing information to those Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(II) and 21 C.F.R. § 314.95.

Jurisdiction and Venue

12. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

13. On information and belief, Glenmark is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Glenmark markets, distributes, and sells generic pharmaceutical products throughout the United States, including the State of Delaware.

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

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

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

16. Plaintiffs incorporate by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

17. 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.

18. On information and belief, Glenmark filed ANDA No. 79-172 in order to obtain approval to market the Glenmark Rosuvastatin Calcium Tablets in the United States before the expiration of the ‘314 patent. On information and belief, Glenmark also filed with the FDA, pursuant to 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV) and 355(j)(2)(B) and 21 C.F.R. §§ 314.94(a)(12)(i)(A)(4) and 314.95(c)(5), a certification alleging that the claims of the ‘314 patent are invalid.

19. On information and belief, Glenmark does not assert that the Glenmark Rosuvastatin Calcium Tablets are not covered by one or more claims of the ‘314 patent.

20. On information and belief, Glenmark does not assert that the ‘314 patent is unenforceable.

21. On information and belief, if the FDA approves ANDA No. 79-172, Glenmark intends to market, offer for sale, and sell the Glenmark Rosuvastatin Calcium Tablets in the United States before the expiration of the ‘314 patent.

22. Under 35 U.S.C. § 271(e)(2)(A), the submission by Glenmark to the FDA of ANDA No. 79-172 to obtain approval for the commercial manufacture, use, or sale of the

Glenmark 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.

23. 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.

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 and/or amendment of ANDA No. 79-172 by Glenmark 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 Glenmark Rosuvastatin Calcium Tablets within the United States or importing the Glenmark 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 Glenmark Rosuvastatin Calcium Tablets shall be no earlier than the expiration date of the '314 patent;
- (5) enjoining Glenmark, and all persons acting in concert with Glenmark, from commercially manufacturing, using, offering for sale, or selling the Glenmark Rosuvastatin Calcium Tablets within the United States or importing into the United States the Glenmark 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.

<p>Ford F. Farabow Charles E. Lipsey Kenneth M. Frankel York M. Faulkner FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 901 New York Avenue, N.W. Washington, D.C. 20001 Telephone: (202) 408-4000 Facsimile: (202) 408-4400</p> <p>Henry J. Renk FITZPATRICK, CELLA, HARPER & SCINTO 1290 Avenue of the Americas New York, NY 10104-3800 Telephone: (212) 218-2100 Facsimile: (212) 218-2200</p> <p><i>Of Counsel for Plaintiffs</i></p> <p>Dated: June 21, 2010</p>	<p>Respectfully Submitted:</p> <p><u>/s/ Mary W. Bourke</u> Mary W. Bourke (#2356) CONNOLLY BOVE LODGE & HUTZ LLP 1007 N. Orange Street P.O. Box 2207 Wilmington, DE 19899 Telephone: (302) 658-9141 Facsimile: (302) 658-5614 mbourke@cblh.com</p> <p><i>Attorneys for Plaintiffs</i></p> <p>Thomas A. Stevens (#3039) ASTRAZENECA PHARMACEUTICALS LP 1800 Concord Pike Wilmington, DE 19850-5437 (302) 885-5457 (302) 886-8037</p> <p><i>Attorney for AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and IPR Pharmaceuticals, Inc.</i></p>
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