**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**TAMPA DIVISION**

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| APOTEX INC.,<br>Plaintiff,<br>v.<br>ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and IPR PHARMACEUTICALS, INC.<br>Defendants. | No.: |

**COMPLAINT FOR DECLARATORY RELIEF**

Apotex Inc., for its Complaint against AstraZeneca Pharmaceuticals, LP, AstraZeneca UK Limited, and IPR Pharmaceuticals, Inc. ("Defendants") alleges as follows:

**INTRODUCTION**

1. This is an action for declaratory judgment of patent non-infringement under, *inter alia*, the federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

2. This action arises out of, *inter alia*, Apotex Inc.'s submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Defendants' brand-name medication CRESTOR®, known generically as rosuvastatin calcium, and used to treat high cholesterol.

## PARTIES AND JURISDICTION

3. Apotex Inc. is a Canadian corporation that manufactures and sells generic drugs, with offices at 150 Signet Drive, Toronto, Canada M9L 1T9. Apotex Inc. prepared and submitted Abbreviated New Drug Application ("ANDA") No. 79-145 to the FDA for a proposed drug product consisting of rosuvastatin calcium tablets.

4. Apotex Inc. appointed Apotex Corp., whose principal place of business is located at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326, to act as Apotex Inc.'s U.S. agent for purposes of ANDA No. 79-145, under 21 C.F.R. § 314.52(c)(7)(c).

5. Upon Information and Belief after a reasonable opportunity for further investigation or discovery, there is likely to be evidentiary support that (hereafter "Upon Information and Belief") AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a Delaware corporation with offices at 3000 Bayport Drive, Suite 600, Tampa, Florida 33607. Upon Information and Belief, AstraZeneca is the owner and/or assignee of U.S. Patent No. 6,316,460 ("'460 patent"), for a pharmaceutical composition which purportedly claims the drug Crestor. A copy of the '460 patent is attached as Exhibit A.

6. Upon Information and Belief, IPR Pharmaceuticals, Inc. ("IPR") is a Puerto Rico corporation with offices at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729. Upon Information and Belief, IPR is an affiliate or related entity of Defendant AstraZeneca Pharmaceuticals LP, and is the holder of Approved New Drug Application ("NDA") No. 021366 for rosuvastatin calcium tablets. Upon Information and Belief, AstraZeneca is IPR's authorized agent for matters related to NDA No. 021366.

7. Upon Information and Belief, AstraZeneca UK Limited ("AstraZeneca UK") is a United Kingdom corporation with offices at 15 Stanhope Gate, London W1K 1LN, England. Upon Information and Belief, AstraZeneca is a subsidiary of AstraZeneca UK Limited.

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 21 U.S.C. § 355(j)(5)(C)(i).

9. Upon Information and Belief, personal jurisdiction over Defendants is proper because Defendants, either directly or through an affiliated entity or agent, conduct substantial business in, and have regular and systematic contact with, this District.

10. Upon Information and Belief, Defendants, either directly or through an affiliated entity or agent, maintain a continuous and systematic contact with the State of Florida and this District by conducting substantial, regular and systematic business therein through, *inter alia*, maintaining business offices in this District and through the marketing and sale of pharmaceutical products, including Crestor—the purported commercial embodiment of the patent in suit.

11. Upon Information and Belief, the conduct of Defendants, either directly or through an affiliated entity or agent, is such that assertion of personal jurisdiction over Defendants is reasonable and fair.

12. Upon Information and Belief, Defendants, either directly or through a related entity or agent, purposely avail themselves of the privilege of doing business in the State of Florida and in this District.

13. Venue is proper in this district under 28 U.S.C. §§ 1391(c), 1391(d), 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II).

## BACKGROUND

14. Upon Information and Belief, Defendants purport to own all substantial rights in, and purport to have the right to sue for infringement of, the '460 patent. Upon submission by Defendants, the '460 patent was listed in the FDA's compilation of approved drugs and their respective patents entitled "Approved Drugs With Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book." As a consequence of such Orange Book listing, Defendants maintain, and have affirmatively represented to the world, that the '460 patent claims the approved drug Crestor®, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Apotex Inc., attempting to market a generic rosuvastatin calcium product before the expiration of the '460 patent.

15. On Information and Belief, Defendants hold all substantial rights in the '460 patent and have the right to sue for infringement thereof.

16. Apotex Inc. has submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Defendants' brand name medication Crestor, known generically as rosuvastatin calcium, ANDA No. 79-145, in which Apotex Inc. seeks to market a generic rosuvastatin product before the expiration of the '460 patent.

17. In ANDA No. 79-145, as amended, Apotex Inc. has certified, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that its proposed rosuvastatin tablets will not infringe the '460 patent.

18. Apotex Inc.'s submission of the paragraph IV certifications to the '460 patent puts Apotex Inc. at considerable risk of being sued by Defendants both before and after market entry.

19. In a letter dated November 5, 2007, Apotex Inc. sent to AstraZeneca a certification under 21 U.S.C. § 355(j)(2)(B)(i) and (ii) that the FDA had received an ANDA submitted by Apotex Inc. certifying the noninfringement of the '460 patent. Over 45 days have passed, and Defendants have not sued Apotex Inc. for infringement of the '460 patent.

20. There is an actual, substantial and continuing justiciable case and controversy between Apotex Inc. and Defendants regarding the '460 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties. Apotex Inc. is entitled by law to bring and maintain this action for declaratory judgment of patent-non infringement under the Declaratory Judgment Act and the MMA where, as here, Defendants did not sue Apotex Inc. within 45 days of receipt of Apotex Inc.'s notice of paragraph IV certification to the '460 patent, and Apotex Inc. has offered Defendants an Offer of Confidential Access to Apotex Inc.'s ANDA for generic rosuvastatin calcium.

## COUNT I – DECLARATORY RELIEF

21. Apotex Inc. incorporates by reference paragraphs 1-20 of this Complaint as if fully set forth herein.

22. Apotex Inc. cannot be held liable for infringement of the '460 patent because the claims of the patent are limited to a composition comprising a tribasic phosphate salt in which the cation is multivalent, and Apotex Inc.'s tablets will not comprise a tribasic phosphate salt in which the cation is multivalent or an obvious equivalent.

23. As a consequence of the foregoing, there exists a justiciable controversy as to whether the '460 patent is infringed. Apotex Inc. is entitled to a declaration that the '460 patent is not infringed.

## DEMAND FOR JUDGMENT AND PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. prays for judgment:

A. Finding that the '460 patent is not infringed;

B. Finding that this is an exceptional case under 35 U.S.C. § 285;

C. Awarding Apotex Inc. its costs, expenses, and reasonable attorney's fees; and

D. Awarding such other relief as the Court deems just and appropriate.

## JURY DEMAND

Apotex Inc. demands a trial by jury for all issues triable by a jury.

Dated: January 31, 2008

Respectfully submitted,

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