IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,	)	C.A. No. 07-809-JJF-LPS
Plaintiffs,	)	(MDL No. 08-1949)
v.	)	**JURY TRIAL DEMANDED**
APOTEX INC., and APOTEX CORP.,	)	
Defendants.	)	

ANSWER, DEFENSES AND COUNTERCLAIMS
OF DEFENDANTS APOTEX INC. AND APOTEX CORP.

Defendant Apotex Inc. and Apotex Corp. hereby answer the Complaint of Plaintiffs AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharma"), AstraZeneca UK Limited ("AstraZeneca UK"), IPR Pharmaceuticals, Inc. ("IPR"), and Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") (collectively "Plaintiffs") 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.

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Apotex Inc. and Apotex Corp. admit that this action purports to be an action for alleged patent infringement; and that Apotex Inc. has submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration

("FDA") for Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

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.

ANSWER: Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

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.

ANSWER: Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

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.

ANSWER: Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

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.

ANSWER: Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

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.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. is a Canadian corporation with its principal place of business in Ontario, Canada. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

7. On information and belief, Defendant Apotex Corp. ("Apotex USA") is a 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.

Answer: Apotex Inc. and Apotex Corp. admit that Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suited 400, Weston, Florida 33326. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

Background

8. IPR is the holder of approved New Drug Application ("NDA") No. 021366 for Tablets, in Crestor® 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.

ANSWER: Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Apotex Inc. and Apotex Corp. admit that the electronic version of the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book"), identifies "IPR" as the applicant for approved New Drug Application ("NDA") No. 21-366 for Crestor® (rosuvastatin calcium) Tablets, 5 mg, 10 mg, 20 mg, and 40 mg. Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

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®.

ANSWER: Apotex Inc. and Apotex Corp. admit that the FDA-approved product labeling for Crestor® (rosuvastatin calcium) states that Crestor® is an HMG-CoA reductase inhibitor indicated as, among other things, an adjunctive therapy to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Type IIa and IIb). Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph, and therefore deny the same.

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.

ANSWER: Apotex Inc. and Apotex Corp. are without knowledge and information sufficient to form a belief as to the truth of the allegations of this Paragraph, and therefore deny the same.

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.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. submitted ANDA No. 79-145 to the FDA seeking approval to commercially manufacture, use or sell Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

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.

ANSWER: Admitted.

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.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. manufactures numerous quality generic drugs for sale and use throughout the United States. Apotex Inc. and Apotex Corp. further admit that Apotex Corp. sells generic drug products manufactured by Apotex Inc. throughout the United States. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

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.

ANSWER: Apotex Inc. and Apotex Corp. admit that, as is required under 21 C.F.R. § 314.94(a)(1) and §314.50(a), Apotex Corp. signed ANDA 79-145. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

Jurisdiction and Venue

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

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Apotex Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction for the claims asserted against Apotex Inc. under 28 U.S.C. §§ 1331, 1338(a). Apotex Inc. and Apotex Corp. deny the remaining allegations of this paragraph.

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.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. manufactures numerous quality generic drugs for sale and use throughout the United States. Apotex Inc. and Apotex Corp. further admit that Apotex Corp. sells generic drug products manufactured by Apotex Inc. throughout the United States. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

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.

ANSWER: Apotex Inc. and Apotex Corp. expressly deny that personal jurisdiction is proper over Apotex Inc. However, Apotex Inc. and Apotex Corp. acknowledge that by order dated January 12, 2009 the Court denied Apotex Inc.'s motion to dismiss for lack of personal jurisdiction, without prejudice. Apotex Inc. and Apotex Corp. further deny the remaining allegations of this Paragraph.

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.

ANSWER: Apotex Inc. and Apotex Corp. admit that personal jurisdiction over Apotex Corp. is proper. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

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

ANSWER: Admit that venue is proper in this judicial district under 28 U.S.C. §1391 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.

ANSWER: Apotex Inc. and Apotex Corp. repeat their answers to Paragraphs 1-19 as though 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.

ANSWER: Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Apotex Inc. and Apotex Corp. admit that, according to the records of the U.S. Patent and Trademark Office ("PTO"), on or about August 7, 2001, the PTO reissued the '314 patent, entitled "Pyrimidine Derivatives," to Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe; that the cover page of the '314 patent identifies "Shionogi Seiyaku Kabushiki Kaisha" as the assignee; and that what purports to be a copy of the '314 patent is attached to the Complaint as Exhibit A. Apotex Inc. and Apotex Corp. expressly deny that the '314 patent was "duly and legally reissued." Apotex Inc. and Apotex Corp. further deny the remaining allegations of this Paragraph.

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.

ANSWER: Apotex Inc. and Apotex Corp. admit that Apotex Inc. has submitted ANDA No. 79-145 to the FDA, seeking approval to commercially manufacture, use or sell Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg; and that Apotex's ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking to obtain approval to engage in the commercial manufacture, use or sale of Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, prior to the expiration of the '314 patent. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

Count II

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

By Order dated January 12, 2009 (D.I. # 90), Count II of Plaintiffs' Complaint was dismissed, therefore no response to ¶ 26-31 of the Complaint is required.

* * *

Apotex Inc. and Apotex Corp. deny all remaining allegations not specifically admitted herein. Apotex Inc. and Apotex Corp. further deny that Plaintiffs are entitled to the relief requested, or to any relief whatsoever.

DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Defendants Apotex Inc. and Apotex Corp. aver and assert the following defenses to the Complaint:

First Defense: Invalidity

The claims of U.S. Patent No. RE 37,314 E ("the '314 patent") are invalid and/or unenforceable on grounds specified in United States Code, Title 35, including the failure to comply with one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, 112 and/or 251.

Second Defense: Non-Infringement

Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid claim of the '314 patent. The proposed drug products for which approval is sought under ANDA No. 79-145 do not directly or indirectly infringe any valid claim of the '314 patent.

Third Defense: Failure to State a Claim

The Complaint fails to state a claim upon which relief can be granted.

Fourth Defense: Unenforceability

For the reasons set forth in more detail in Count III of the Counterclaims below, the '314 patent is unenforceable due to inequitable conduct.

Fifth Defense: Misuse

The '314 patent is invalid and was obtained improperly by inequitable conduct. Knowing that the '314 patent was invalid and unenforceable, Plaintiffs commenced this infringement action against Apotex Inc. and Apotex Corp. Plaintiff's efforts to enforce the '314 patent by suing for infringement and by maintaining the patents' listings in the Orange Book constitute patent misuse.

COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. for their Counterclaims against AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharma"), AstraZeneca UK Limited ("AstraZeneca UK"), IPR Pharmaceuticals, Inc. ("IPR"), and Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") (collectively "Plaintiffs"), alleges as follows:

Parties

1. Apotex Inc. is a Canadian corporation with a place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario Canada L4C 5H2.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suited 400, Weston, Florida 33326.

3. AstraZeneca Pharma purports to be a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

4. AstraZeneca UK purports to be a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K lLN, England.

5. IPR purports to be 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.

6. Shionogi purports to be 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 5410045 Japan.

Background

7. On or about August 7, 2001, the U.S. Patent and Trademark Office ("PTO") reissued U.S. Reissued Patent No. RE 37,314 E ("the '314 patent"), entitled "Pyrimidine Derivatives," to Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

8. Plaintiffs purport to hold all substantial rights in the '314 patent and purport to have the right to sue for infringement thereof.

9. Apotex Inc. has submitted, and the Food and Drug Administration (FDA) has received, an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, importation, offer for sale, and sale of Apotex's Proposed Products, Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg, and 40 mg, as defined in ANDA No. 79-145.

10. Pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii) and 21 C.F.R. § 314.95, Apotex Inc. certified to Plaintiffs that the '314 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the proposed product for which ANDA No. 79-145 is submitted.

11. On or about December 11, 2007, Plaintiffs sued Apotex Inc. and Apotex Corp. in this District alleging infringement of the '314 patent.

Jurisdiction and Venue

12. This case arises under the Constitution, laws, or treaties of the United States, viz., 35 U.S.C. §§ 1-376, which is an Act of Congress relating to patents, and 21 U.S.C. § 355, which provides subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. §271(e)(5).

13. A real, actual, and justiciable controversy exists between Apotex Inc. and Apotex Corp. on the one hand and Plaintiffs on the other hand regarding the invalidity and unenforceability of the '314 patent and Apotex's non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28, U.S.C. §§ 2201 and 2202.

14. This Court has personal jurisdiction over Plaintiffs because Plaintiffs, *inter alia*, have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Apotex Inc. and Apotex Corp. in this District, and/or because Plaintiffs conduct substantial business in this District.

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

Count I: Declaratory Judgment of Invalidity of the '314 Patent

16. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1-15 as though fully set forth herein.

17. The claims of the '314 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, 112 and/or 251.

Count II: Declaratory Judgment of Non-Infringement of the '314 Patent

18. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1-17 as though fully set forth herein.

19. Neither Apotex Inc. nor Apotex Corp. infringes, either directly or indirectly, any valid, enforceable claim of the '314 patent. The proposed products for which approval is sought in ANDA 79-145 do not directly or indirectly infringe any valid claim of the '314 patent.

Count III: Declaratory Judgment of Unenforceability of the '314 Patent

20. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 19 as though set forth fully herein.

21. On information and belief, the '314 patent is unenforceable due to the inequitable conduct of one or more persons who owed a duty of candor to the PTO with respect to the '314 patent and/or U.S. Patent No. 5,260,440 ("the '440 patent") who, with the intent to deceive the PTO, violated their duty of candor to the PTO by intentionally failing to disclose material information to the PTO and by submitting a declaration in support of patentability that contained false and misleading information.

22. The U.S. patent application which issued as the '440 patent was filed with the PTO by Wenderoth, Lind & Ponack on June 12, 1992, and claims priority to Japanese Application Serial No. 188015, filed July 1, 1991.

23. The U.S. patent application for the '440 patent lists Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe as inventors.

24. The '440 patent was issued by the PTO on November 9, 1993.

25. European patent application serial number 92111090.4 ("Corresponding European Patent Application") is the European counterpart to the U.S. application for the '440 patent.

26. The Corresponding European Patent Application was filed with the European Patent Office by Vossius & Partner on June 30, 1992, and claims priority to Japanese Application Serial No. 188015.

27. The Corresponding European Patent Application lists as inventors Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

28. As filed, claim 1 of the Corresponding European Patent Application was identical to original claim 1 of the U.S. Patent application for the '440 patent.

29. On October 7, 1992, the European Patent Office transmitted a European search report ("European Search Report") concerning application number 92111090.4 to Vossius & Partner, the patent attorneys and/or agents responsible for prosecuting the Corresponding European Patent Application in the European Patent Office.

30. The European Search Report stated that EP-A-O 367 895 ("the '895 patent") was a category "X" reference which, according to the European Search Report, is "particularly relevant if taken alone."

31. The '895 patent is prior art to the '440 and '314 patents.

32. Both the European Search Report and the '895 patent are material to claims in the '440 patent and the '314 patent.

33. On information and belief, the named inventors and/or one or more other persons owing a duty of candor to the PTO were aware that the '895 patent had been cited in the European Search Report as a Category "X" reference during the prosecution of the '440 patent. Support for this belief is based, in part, on the fact that members of the Shionogi Intellectual Property Department were involved in both the prosecution of the '440 patent and the European counterpart to the '440 patent. Further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

34. No one associated with prosecution of the '440 patent submitted either the European Search Report or the '895 patent to the PTO during prosecution of the '440 patent.

35. Upon information and belief, individuals substantively involved with the prosecution of the '440 patent were aware of the materiality of both the European Search Report and the '895 patent during the prosecution of the '440 patent. Support for this belief is based, in part, on the fact that the European Search Report stated that the '895 patent was a category "X" reference which, according to the European Search Report, is "particularly relevant if taken alone." Further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

36. The failure to disclose the European Search Report and/or the '895 patent to the United States Patent Office during prosecution of the '440 patent amounts to a material and misleading representation and/or omission on the part of one or more persons who owed a duty of candor to the PTO.

37. Upon information and belief, the failure to disclose the European Search Report and the '895 was intentional and was intended to deceive or mislead the United States Patent Office. Support for the allegations that the failure to disclose the European Search Report and the '895 was intentional and intended to deceive or mislead the PTO comes at least from the highly material nature of the European Search Report and the '895 patent. Further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

38. On August 27, 1998, Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe filed an application to reissue the '440 patent ("Reissue Application"). The Reissue Application issued as the '314 patent on August 7, 2001.

39. In a declaration filed in support of the Reissue Application ("Declaration"), it is stated that: "Patentee claimed more than he had a right to claim by reason of the disclosure of

European Patent Application 0 367 895, published May 16, 1990. The amended claims of the reissue application are considered to fully overcome any grounds for unpatentability based upon this reference."

40. In the Declaration in the Reissue Application, it was stated that: "All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant." The named inventors and/or one or more other persons owing a duty of candor to the PTO submitted the Declaration in support of patentability, and such submission constituted a material misstatement and/or misrepresentation and/or omission and, upon information and belief, was made with intent to deceive the Patent Examiner so as to induce the PTO to issue the '314 patent. Further evidentiary support for this allegation is likely to be identified after a reasonable opportunity for further investigation and discovery.

Count IV: Misuse

41. Apotex Inc. and Apotex Corp. repeat, reallege and incorporate by reference each of the allegations of paragraphs 1 through 40 as though set forth fully herein.

42. The '314 patent is invalid and was obtained improperly by inequitable conduct. Knowing that the '314 patent was invalid and unenforceable, Plaintiffs commenced this infringement action against Apotex Inc. and Apotex Corp. Plaintiff's efforts to enforce the '314 patent by suing for infringement and by maintaining the patents' listing in the Orange Book constitute patent misuse.

Prayer for Relief

WHEREFORE, Apotex Inc. and Apotex Corp. respectfully pray for judgment in their favor and against Plaintiffs:

(a) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Apotex Inc. and Apotex Corp.;

(b) declaring that the manufacture, use, sale, offer for sale, or importation of the rosuvastatin tablets that are the subject of ANDA No. 79-145 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '314 patent;

(c) declaring that each of the claims of the '314 patent are invalid;

(d) declaring that each of the claims of the '314 patent are unenforceable;

(e) declaring this case exceptional and awarding Apotex Inc. and Apotex Corp. their reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(f) awarding Apotex Inc. and Apotex Corp. such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Apotex Inc. and Apotex Corp. hereby demand a jury trial on all issues so triable.

POTTER ANDERSON & CORROON LLP

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Dated: January 28, 2009
900434 / 32546

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, D. Fon Muttamara-Walker, hereby certify that on January 28, 2009, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on January 28, 2009, the attached document was Electronically Mailed to the following person(s):

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