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,	)	
Plaintiffs,	)	C.A. No. 07-808-UNA-JJF
v.	)	
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

ANSWER AND COUNTERCLAIMS

Defendant Par Pharmaceutical, Inc. (hereinafter "Par"), by its attorneys, responds to the averments made in the numbered paragraphs of the complaint filed by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha, (collectively "AstraZeneca" or "Plaintiffs") as follows:

ANSWER

Complaint Paragraph 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 Par Pharmaceutical, Inc. ("the Par 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: With respect to paragraph 1, Par admits that Plaintiffs purport to bring this action under title 35, United States Code. Par is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1, and therefore denies

them. Par expressly denies any allegation of patent infringement and denies that Plaintiffs are entitled to any relief.

Complaint Paragraph 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: With respect to paragraph 2, on information and belief, Par admits that AstraZeneca Pharmaceuticals LP has a place of business at 1800 Concord Pike, Wilmington, Delaware 19803. Par is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 2, and therefore denies them.

Complaint Paragraph 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 lLN, England.

Answer: With respect to paragraph 3, on information and belief, Par admits that AstraZeneca UK Limited has a place of business at 15 Stanhope Gate, London W1K 1LN, England. Par is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 3, and therefore denies them.

Complaint Paragraph 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: With respect to paragraph 4, on information and belief, Par admits that IPR Pharmaceuticals, Inc. has a place of business at Lot 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729. Par is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 4, and therefore denies them.

Complaint Paragraph 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: Par is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5, and therefore denies them.

Complaint Paragraph 6: On information and belief, Defendant Par Pharmaceutical, Inc. ("Par") is a corporation operating and existing under the laws of Delaware with its principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677 USA.

Answer: Par admits the allegations in paragraph 6.

Complaint Paragraph 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 formatters related to NDA No. 021366.

Answer: On information and belief, Par admits the allegations of the first sentence of paragraph 7. Par is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7, and therefore denies them.

Complaint Paragraph 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 11 million patients have been prescribed Crestor®, and over 110 million prescriptions have been written worldwide for Crestor®.

Answer: Par admits the allegations of the first sentence of paragraph 8. Par is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8, and therefore denies them.

Complaint Paragraph 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.

Answer: Par is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9, and therefore denies them.

Complaint Paragraph 10: On information and belief, Par filed with the FDA, in Rockville, Maryland, ANDA No. 79-168 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: Par admits that it has requested the FDA to approve ANDA No. 79-168 and that the ANDA product is rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths. Par denies any remaining allegations in Paragraph 10.

Complaint Paragraph 11: By letter dated November 5, 2007, Par 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 Par 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: Par admits the allegations in paragraph 11.

Complaint Paragraph 12: On information and belief, Par is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Par markets, distributes, and sells generic pharmaceutical products throughout the United States, including the State of Delaware.

Answer: Par admits the allegations in paragraph 12. Par avers that its business is not limited to generic pharmaceutical products.

Complaint Paragraph 13: Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Answer: With respect to paragraph 13, Par states that it does not contest subject matter jurisdiction.

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

Answer: With respect to paragraph 14, Par states that it does not contest personal jurisdiction in Delaware for the purposes of this action.

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

Answer: With respect to paragraph 15, Par states that it does not contest venue in this judicial district for the purposes of this action.

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

Answer: Defendant incorporates by reference its responses to the averments made in paragraphs 1-15 of the complaint.

Complaint Paragraph 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.

Answer: With respect to paragraph 17, Par admits that United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives" was reissued by the United States Patent and Trademark Office on August 7, 2001, and that what appears to be an accurate copy of the '314 patent is attached as Exhibit A to the Complaint. Par denies that the '314 patent was duly and legally reissued by the United States Patent and Trademark Office. Par is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17, and therefore denies them.

Complaint Paragraph 18: On information and belief, Par filed ANDA No. 79-168 in order to obtain approval to market the Par Rosuvastatin Calcium Tablets in the United States before the expiration of the '314 patent. On information and belief, Par 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)(l2)(i)(A)(4), a certification alleging that the claims of the '314 patent are invalid and that the '314 patent is unenforceable.

Answer: Par admits that it has filed ANDA No. 79-168 seeking FDA approval to market rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths. Par also admits that it has filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. §

314.94(a)(l2)(i)(A)(4), stating that the '314 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Par's proposed product. Par denies any remaining allegations in paragraph 18.

Complaint Paragraph 19: On information and belief, Par does not assert that Par Rosuvastatin Calcium Tablets are not covered by one or more claims of the '314 patent.

Answer: Par denies the allegations in paragraph 19.

Complaint Paragraph 20: Under 35 U.S.C. § 271(e)(2)(A), the submission by Par to the FDA of ANDA No. 79-168 to obtain approval for the commercial manufacture, use, or sale of the Par 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: Par denies the allegations in paragraph 20.

Complaint Paragraph 21: 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: Par denies the allegations in paragraph 21.

Complaint Paragraph 22: Plaintiffs incorporate by reference paragraphs 1-21 of this Complaint as if fully set forth herein.

Answer: Defendant incorporates by reference its responses to the averments made in paragraphs 1-21 of the complaint.

Complaint Paragraph 23: Upon information and belief, Par has made substantial preparations to sell Par Rosuvastatin Calcium Tablets labeled for the same dosages as the Crestor® products.

Answer: Par admits the allegations in paragraph 23.

Complaint Paragraph 24: Upon information and belief, Par intends to commence sale of Par Rosuvastatin Calcium Tablets immediately upon receiving approval from the FDA.

Answer: Par is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24, and therefore denies them..

Complaint Paragraph 25: The manufacture, importation, sale, and offer for sale of Par 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).

Answer: Par denies the allegations in paragraph 25.

Complaint Paragraph 26: 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.

Answer: Par denies the allegations in pargraph 26.

Complaint Paragraph 27: An actual controversy exists relating to Par's threatened infringement of the '314 patent.

Answer: With respect to paragraph 27, Par admits that an actual controversy exists. Par expressly denies any allegation of patent infringement and denies that Plaintiffs are entitled to any relief.

RESPONSE TO PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to any of the relief that they seek in their prayer for relief or otherwise.

Defenses

Without any admission as to the burden of proof or as to any of the averments in the Complaint, Par sets forth the following defenses:

1. Par has not infringed any valid and enforceable claim of the '314 patent.

2. The '314 patent and all its claims are invalid under 35 U.S.C. § 1 *et seq.*

3. The '314 patent and all its claims are invalid and unenforceable due to Plaintiffs' inequitable conduct before the United States Patent and Trademark Office.

4. The '314 patent, entitled "Pyrimidine Derivatives," matured from U.S. Patent Application No. 09/141,731 ("the '731 application") filed on August 27, 1998.

5. The '314 patent is a reissue of U.S. Patent No. 5,260,440 ("the '440 patent") which issued on November 9, 1993 and matured from U.S. Patent Application No. 07/897,793 ("the '793 application") filed on June 12, 1992.

6. During prosecution of the '440 patent, Plaintiffs did not disclose European Patent Application 0 367 895 ("the '895 application"), U.S. Patent No. 4,868,185 to Chucholowski et al., U.S. Patent No. 5,925,852 to Kesseler et al., U.S. Patent No. 5,026,708 to Fujikawa et al., European Patent Application No. 0 330 057 to Fey et al., and two articles from the Journal of Medicinal Chemistry: G. Beck et al, J. Med. Chem., 33, 52-60 (1990) and B. Roth et al, J. Med. Chem., 34, 463-466 (1991).

7. The '895 application was material to the patentability of the '440 patent.

8. The '895 application is not cumulative of any prior art reference disclosed during prosecution of the '440 patent.

9. The '895 application was published on May 16, 1990, more than one year prior to the June 12, 1992 filing date of the '793 application, and therefore qualifies as prior art under 35 U.S.C. § 102(b).

10. During prosecution of corresponding Canadian Patent Application 2 027 945 ("the '945 application"), Plaintiffs conceded that "claim 1 of Patent Number 5,260,440 has an overlap with claim 1 of EPA 267 895 [sic]." '731 Application, Submission of Prior Art dated December 11, 1997.

11. During prosecution of corresponding European Patent No. 0 521 471, the European patent office indicated that the '895 application anticipated original claims 1-3, 5, and 7-9, which were identical to original claims 1-3, 5, and 7-9 of the '793 application. '731 Application, European Search Report dated October 5, 1992.

12. AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., Shionogi Seiyaku Kabushiki Kaisha, their respective attorneys, and others involved in the prosecution of the '440 patent admitted that the '895 application was highly material to the patentability of the '440 patent because their stated reason for seeking reissue of the '440 patent was 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." '731 Application, Reissue Application Declaration by the Assignee filed August 27, 1998.

13. AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., Shionogi Seiyaku Kabushiki Kaisha, their respective attorneys, and others involved in the prosecution of the '440 patent were aware of the materiality of the '895 application during prosecution of the '440 patent.

14. The application that led to the '440 patent ("the '793 application") was filed on June 12, 1992.

15. Corresponding European Patent Application No. 92111090.4 ("the '090.4 application") was filed 18 days after the '793 application was filed with identical claims.

16. Both the '793 application and the '090.4 application name the same four Japanese inventors (Hirai, Ishiba, Koike, and Watanabe) and the same assignee (Shionogi).

17. The European search report disclosing the '895 application was published as an appendix to the '471 application on January 7, 1993, and thus the search report was publicly available for more than a year prior to the issuance of the '440 patent.

18. Section 2001.06(a) of the Manual of Patent Examining Procedure explicitly directs that "[a]pplicants and other individuals, as set forth in 37 CFR 1.56, have a duty to bring to the attention of the Office any material prior art or other information cited or brought to their attention in any related foreign application. The inference that such prior art or other information is material is especially strong where it has been used in rejecting the same or similar claims in the foreign application or where it has been identified in some manner as particularly relevant."

19. Under these circumstances, applicant's intent to deceive the PTO may be inferred. *See Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) ("[I]ntent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application.")

20. AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., Shionogi Seiyaku Kabushiki Kaisha, their respective attorneys, and others involved in the prosecution of the '314 patent withheld the '895 application from the United

States Patent and Trademark Office ("the Patent Office") during prosecution of the '440 patent, with intent to mislead the Patent Office.

21. Plaintiffs may not cure their inequitable conduct through reissue. *Hoffman-La Roche, Inc. v. Lemmon Co.*, 906 F.2d 684, 688-89 (Fed. Cir. 1990).

COUNTERCLAIMS

Par Pharmaceutical, Inc. (hereinafter "Par") asserts the following claims against AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "Plaintiffs"):

Parties

1. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. On information and belief, AstraZeneca Pharmaceuticals LP 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. On information and belief, 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. On information and belief, IPR Pharmaceuticals, Inc. is a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Lot 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

5. On information and belief, 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.

Nature of the Action

6. These claims arise 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. Par seeks declaratory relief, i.e., a declaration that U.S. Patent No. RE37,314 ("the '314 Patent") is not infringed and that it is invalid and unenforceable. Par also seeks a declaration that U.S. Patent No. 6,316,460 ("the '460 patent") is not infringed and that it is invalid and unenforceable.

Jurisdiction and Venue

7. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

8. This court has personal jurisdiction over Plaintiffs because of their substantial, continuous, and systematic contacts with this judicial district.

9. Venue is proper in this judicial district based on 28. U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c), and (d).

Background

10. The '314 patent, entitled "Pyrimidine Derivatives," was reissued on August 7, 2001.

11. On information and belief, the '314 patent is assigned to Shionogi Seiyaku Kabushiki Kaisha.

12. The '460 patent, entitled "Pharmaceutical Compositions," was issued on November 13, 2001.

13. On information and belief, the '460 patent is assigned to AstraZeneca AB.

14. The '314 patent concerns rosuvastatin.

15. The '460 patent concerns pharmaceutical formulations containing rosuvastatin.

16. On information and belief, IPR Pharmaceuticals, Inc. ("IPR") is the current holder of New Drug Application ("NDA") No. 21-366 for Crestor® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium.

17. On information and belief, AstraZeneca Pharmaceuticals LP is IPR's authorized agent for matters related to NDA No. 21-366.

18. On information and belief, on August 12, 2003 the FDA approved IPR's NDA 21-366. This permitted AstraZeneca to market its rosuvastatin tablets.

19. The Federal Food, Drug and Cosmetic Act ("FFDCA") authorizes a generic company to file an ANDA, which the FDA will approve if the generic company shows that its product has the same active ingredient as, and is bioequivalent to, a product that the FDA has already approved. Typically, the ANDA applicant submits data showing that its product is bioequivalent to a product that has been the subject of an approved NDA.

20. The FFDCA requires NDA holders to submit to the FDA the patent number and expiration date of any patent(s) that the NDA holder believes "a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA--with no substantive review of the patents—lists the patent number(s) and expiration date(s) in the Orange Book.

21. If an ANDA applicant seeks approval to market its generic product before the patents listed in the Orange Book expire, the applicant must include in its ANDA a certification that its proposed product would not infringe those patents, and/or that the patents are invalid or

unenforceable. The applicant must then send a notice letter to the NDA holder and patent owner that includes a detailed statement of the factual and legal bases of the applicant's opinion that the patent is invalid, unenforceable, or would not be infringed.

22. If the patent owner sues the ANDA applicant for infringement within 45 days of receiving the notice letter, on that basis alone the FDA is prohibited by statute from approving the ANDA for 30 months or until the infringement action is over, absent a court order shortening the period.

23. On information and belief, AstraZeneca, as the NDA holder for Crestor® (NDA 21-366), filed with the FDA a patent certification pursuant to 21 U.S.C. § 355(b)(1) requesting that the '314 and '460 patents be listed by the FDA in the Orange Book.

24. AstraZeneca's listing of these two patents means that AstraZeneca asserts that any one of these patents is a "patent which claims the drug for which the application was submitted [i.e., Crestor®, NDA No. 21-366] . . . and 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." See 21 U.S.C. § 355(b)(1).

25. To engage in the commercial manufacture, use, or sale of rosuvastatin tablets, Par filed with the FDA ANDA No. 79-168.

26. Par's ANDA seeks approval to market generic rosuvastatin calcium oral tablets, 5 mg, 10 mg, 20 mg, and 40 mg based on AstraZeneca's NDA No. 21-366. By preparing and filing this ANDA, Par has made substantial preparation to make, use, import, offer to sell, and sell generic rosuvastatin calcium oral tablets in the United States before the expiration of the '314 and '460 patents. Par certified to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (hereinafter "Paragraph IV certification(s)"), that Par 's rosuvastatin calcium oral tablets will not

infringe any claim of the '314 and '460 patents, and that those patents are invalid and/or unenforceable.

27. On November 5, 2007, Par, in accordance with 21 U.S.C. § 355(j)(2)B)(i) and (ii), mailed IPR, AstraZeneca Pharmaceuticals LP, AstraZeneca AB, and Shionogi Seiyaku Kabushiki Kaisha a notice that it had filed an ANDA for its rosuvastatin calcium oral tablets indicating that its ANDA contained Paragraph IV certifications regarding the '314 and '460 patents. The notice provided the factual and legal bases as to why the '314 and '460 patents were invalid, unenforceable, or will not be infringed, by the commercial manufacture, use, or sale of Par's rosuvastatin calcium oral tablets before expiration of the '314 and '460 patents. The notice also included an offer of confidential access to Par's ANDA, as provided for in 21 U.S.C. § 355 (j)(5)(C)(i)(I)(cc), (j)(5)(C)(i)(III).

28. Par's offer of confidential access to Par's ANDA contained "restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." 21 U.S.C. § 355 (j)(5)(C)(i)(I)(cc) and 21 U.S.C. § 355 (j)(5)(C)(i)(III).

29. Plaintiffs did not accept Par's offer of confidential access.

30. On December 11, 2007, Plaintiffs filed a Complaint alleging "the submission by Par to the FDA of ANDA No. 79-168 to obtain approval for the commercial manufacture, use, or sale of the Par 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."

31. In the Complaint, however, Plaintiffs did not sue Par for infringement of the '460 patent. Because the '460 patent is listed in the Orange Book for Crestor®, Par remains faced with the threat of litigation concerning this patent, and that threat is impairing Par's ability to bring to market its generic rosuvastatin calcium tablets.

32. The 45-day period after the date on which Plaintiffs received Par's notice that Par had filed an ANDA for its rosuvastatin calcium tablets containing Paragraph IV certifications as to the '314 and '460 patents has expired, as provided by § 505(j)(5)(B)(iii) of the FFDCA. Par thus seeks a declaratory judgment of noninfringement, invalidity, and/or unenforceability of the '460 patent, pursuant to the Declaratory Judgment Act and 21 U.S.C. § 355(j)(5)(C)(i)(II).

33. Plaintiffs have not provided Par with a covenant not to sue based on the '460 patent, nor any other assurance that it would not assert a case for infringement of the '460 patent against Par.

34. Plaintiffs have demonstrated an intention to prevent generic competition for their products by attempting to enforce Orange Book-listed patents against one or more generic companies in numerous instances. Plaintiffs have commenced the following actions in the U.S. District Court for the District of Delaware, the U.S. District Court for the Middle District of Florida, and the U.S. District Court for the Northern District of West Virginia: *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc.*, D. Del., Civil Action No. 07-CV-805; *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc.*, N.D.W.V., Civil Action No. 07-CV-177; *AstraZeneca Pharmaceuticals LP et al. v. Sun Pharmaceutical Industries Ltd. et al.*, D. Del., Civil Action No. 07-CV-806; *AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc.*, D. Del., Civil Action No. 07-CV-807; *AstraZeneca Pharmaceuticals LP et al. v. Par Pharmaceutical, Inc.*, D. Del., Civil Action No. 07-CV-808; *AstraZeneca Pharmaceuticals LP et*

al. v. Apotex Inc. et al., D. Del., Civil Action No. 07-CV-809; *AstraZeneca Pharmaceuticals LP et al. v. Aurobindo Pharma Limited et al.*, D. Del., Civil Action No. 07-CV-810; *AstraZeneca Pharmaceuticals LP et al. v. and Cobalt Pharmaceuticals Inc. et al.*, D. Del., Civil Action No. 07-CV-811; and *AstraZeneca Pharmaceuticals LP et al. v. and Cobalt Pharmaceuticals Inc. et al.*, M.D. Fl., Civil Action No. 07-CV-815.

35. Plaintiffs' decision not to bring suit at this time for infringement of the '460 patent creates uncertainty as to Par's legal rights under its ANDA.

36. Par suffers from the possibility of future litigation created by Plaintiffs electing to challenge Par's ANDA on only one of the patents listed in the Orange Book for Crestor®. Plaintiffs' suit on the '314 patent alone leaves open the possibility of future litigation regardless of whether Par wins or loses the '314 patent-infringement suit. The possibility that Par will be subject to multiple infringement suits from Plaintiffs based on the submission of its single ANDA containing two Paragraph IV certifications is an injury relevant to finding a justiciable controversy.

37. Par, therefore, has a reasonable apprehension and justiciable controversy under the Declaratory Judgment Act that Plaintiffs would likely assert the '460 patent against Par if Par commercially marketed its generic rosuvastatin calcium oral tablets.

Count I
(Declaration of Noninfringement of the '314 Patent)

38. Par repeats and realleges paragraphs 1 through 37 of the counterclaim.

39. AstraZeneca has asserted the '314 patent against Par. AstraZeneca maintains -- and Par denies -- that the '314 patent's claims cover Par's rosuvastatin tablets.

40. The '314 patent's claims do not, either literally or under the doctrine of equivalents, cover Par's rosuvastatin tablets. Thus, Par has not infringed and will not infringe

the '314 patent by making, using, selling, offering for sale, marketing, or importing Par rosuvastatin tablets.

41. AstraZeneca and Par have adverse legal interests, and there is a substantial controversy between AstraZeneca and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the noninfringement of the '314 patent.

42. Par is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of Par's rosuvastatin tablets does not infringe the '314 patent.

Count II
(Declaration of Invalidity of the '314 Patent)

43. Par repeats and realleges paragraphs 1 through 37 of the counterclaim.

44. The '314 patent and all its claims are invalid under 35 U.S.C. § 1 *et seq.*

45. AstraZeneca maintains -- and Par denies -- that the '314 patent is valid.

46. AstraZeneca and Par have adverse legal interests, and there is a substantial controversy between AstraZeneca and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '314 patent.

47. Par is entitled to a judicial declaration that the '314 patent is invalid.

Count III
(Declaration of Unenforceability of the '314 Patent)

48. Par repeats and realleges paragraphs 1 through 37 of the counterclaim.

49. The '314 patent and all its claims are invalid and unenforceable due to Plaintiffs' inequitable conduct before the United States Patent and Trademark Office.

50. The '314 patent, entitled "Pyrimidine Derivatives," matured from U.S. Patent Application No. 09/141,731 ("the '731 application") filed on August 27, 1998.

51. The '314 patent is a reissue of U.S. Patent No. 5,260,440 ("the '440 patent") which issued on November 9, 1993 and matured from U.S. Patent Application No. 07/897,793 ("the '793 application") filed on June 12, 1992.

52. During prosecution of the '440 patent, Plaintiffs did not disclose European Patent Application 0 367 895 ("the '895 application"), U.S. Patent No. 4,868,185 to Chucholowski et al., U.S. Patent No. 5,925,852 to Kesseler et al., U.S. Patent No. 5,026,708 to Fujikawa et al., European Patent Application No. 0 330 057 to Fey et al., and two articles from the Journal of Medicinal Chemistry: G. Beck et al, J. Med. Chem., 33, 52-60 (1990) and B. Roth et al, J. Med. Chem., 34, 463-466 (1991).

53. The '895 application was material to the patentability of the '440 patent.

54. The '895 application is not cumulative of any prior art reference disclosed during prosecution of the '440 patent.

55. The '895 application was published on May 16, 1990, more than one year prior to the June 12, 1992 filing date of the '793 application, and therefore qualifies as prior art under 35 U.S.C. § 102(b).

56. During prosecution of corresponding Canadian Patent Application 2 027 945 ("the '945 application"), Plaintiffs conceded that "claim 1 of Patent Number 5,260,440 has an overlap with claim 1 of EPA 267 895 [sic]." '731 Application, Submission of Prior Art dated December 11, 1997.

57. During prosecution of corresponding European Patent No. 0 521 471, the European patent office indicated that the '895 application anticipated original claims 1-3, 5, and 7-9, which were identical to original claims 1-3, 5, and 7-9 of the '793 application. '731 Application, European Search Report dated October 5, 1992.

58. Plaintiffs admitted that the '895 application was highly material to the patentability of the '440 patent because their stated reason for seeking reissue of the '440 patent was 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." '731 Application, Reissue Application Declaration by the Assignee filed August 27, 1998.

59. Plaintiffs were aware of the materiality of the '895 application during prosecution of the '440 patent and intentionally withheld it from the PTO.

60. The '314 patent is invalid because Plaintiffs may not cure their inequitable conduct through reissue. Hoffman-La Roche, Inc. v. Lemmon Co., 906 F.2d 684, 688-89 (Fed. Cir. 1990).

61. AstraZeneca maintains -- and Par denies -- that the '314 Patent claims are valid and enforceable.

62. AstraZeneca and Par have adverse legal interests, and there is a substantial controversy between AstraZeneca and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the validity and enforceability of the '314 patent.

63. Par is entitled to a judicial declaration that the '314 patent is invalid and unenforceable.

Count IV
(Declaration of Noninfringement of the '460 Patent)

64. Par repeats and realleges paragraphs 1 through 37 of the counterclaim.

65. The '460 patent's claims do not, either literally or under the doctrine of equivalents, cover Par's rosuvastatin tablets. Thus, Par has not infringed and will not infringe the '460 patent by making, using, selling, offering for sale, marketing, or importing Par rosuvastatin tablets.

66. AstraZeneca and Par have adverse legal interests, and there is a substantial controversy between AstraZeneca and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the noninfringement of the '460 patent.

67. Par is entitled to a judicial declaration that any making, use, sale, offer for sale, marketing, or importation of Par's rosuvastatin tablets does not infringe the '460 patent.

Count V
(Declaration of Invalidity of the '460 Patent)

68. Par repeats and realleges paragraphs 1 through 37 of the counterclaim.

69. The '460 patent and all its claims are invalid under 35 U.S.C. § 1 *et seq.*

70. AstraZeneca and Par have adverse legal interests, and there is a substantial controversy between AstraZeneca and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '460 patent.

71. Par is entitled to a judicial declaration that the '460 patent is invalid.

Prayer for Relief

WHEREFORE, Par demands judgment in its favor and against Plaintiffs as follows:

A. Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs;

B. Declaring the '314 patent and all its claims not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's rosuvastatin tablets;

C. Declaring the '314 patent and all its claims invalid;

D. Declaring the '314 patent and all its claims unenforceable;

E. Declaring the '460 patent and all its claims not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's rosuvastatin tablets;

F. Declaring the '460 patent and all its claims invalid;

G. Enjoining Plaintiffs, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with any Plaintiff from threatening to assert or otherwise attempting to enforce the '314 or '460 patents against Par, its customers, suppliers, or anyone in privity with Par.

H. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Par its attorneys' fees, costs, and expenses in this action;

I. Adjudging this to be an exceptional case under 35 U.S.C. § 285 and awarding Par its attorney fees;

J. Awarding Par its costs and expenses; and

K. Awarding Par such other and further relief as the Court deems just and proper.

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Dated: January 31, 2008

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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I hereby certify that on January 31, 2008, I have sent by electronic mail, the foregoing document to the following non-registered participants:

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