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

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| ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,<br><br>Plaintiffs,<br><br>v.<br><br>PAR PHARMACEUTICAL, INC.,<br><br>Defendant. | Civil Action No.: 07-808-JJF-LPS |

**PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS**
**OF DEFENDANT PAR PHARMACEUTICAL, INC.**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, "Plaintiffs"), through their undersigned counsel, reply to the defenses and counterclaims of Defendant Par Pharmaceutical Inc. ("Par") as follows:

**ANSWER TO DEFENSES**

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

**Answer:** Plaintiffs deny the allegations in Paragraph 1.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 2.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 3.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 4.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 5.

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).

**Answer:** Plaintiffs admit that European Application 0 367 895 ("the '895 application"), U.S. Patent No. 4,868,185 to Chucholowski et al., U.S. Patent No. 5,925,825 to Kesseler et al., U.S. Patent No. 5,026,708 to Fujikawa et al., European Patent Application No. 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, 436-466 (1991), were not cited to the PTO during prosecution of the '440 patent. Plaintiffs deny the remaining allegations in Paragraph 6.

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

**Answer:** Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 7.

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

**Answer:** Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 8.

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).

**Answer:** Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the '895 application was published on

May 16, 1990 and that the '793 application was filed on June 12, 1992. Plaintiffs deny the remaining allegations in Paragraph 9.

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.

**Answer:** Plaintiffs admit that in a submission dated December 11, 1997 to the Canadian Patent Office, a statement was made that "claim 1 of Patent Number 5,260,440 has an overlap with claim 1 of EPA 267 895 [sic]." Plaintiffs deny the remaining allegations in Paragraph 10.

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.

**Answer:** Plaintiffs admit that in European Patent Publication No. 0 521 471 ("the '471 publication"), the '895 application was referenced in the rejection of the pending European claims 1-3, 5, and 7-9. Plaintiffs deny that original claims 1-3, 5, and 7-9 of the '471 publication were identical to the original claims in the '793 application. Plaintiffs deny the remaining allegations in Paragraph 11.

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.

**Answer:** Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the Reissue Application Declaration by the Assignee contained the statement, "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."

Plaintiffs deny the remaining allegations in Paragraph 12.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 13.

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

**Answer:** Plaintiffs admit the allegations in Paragraph 14.

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.

**Answer:** Plaintiffs admit that the '090.4 application was filed 18 days after the '793 application. Plaintiffs deny the remaining allegations in Paragraph 15.

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).

**Answer:** Plaintiffs admit the allegations in Paragraph 16.

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.

**Answer:** Plaintiffs admit that the European Search Report which listed the '895 application was published on January 7, 1993 with the '471 application. Plaintiffs deny the remaining allegations in Paragraph 17.

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."

**Answer:** Paragraph 18 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs lack knowledge or information sufficient to

form a belief as to the truth of the allegations in Paragraph 18, because Paragraph 18 does not specify which version of the MPEP is quoted. Plaintiffs deny the remaining allegations in Paragraph 18.

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.")

**Answer:** Paragraph 19 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 19.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 20.

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).

**Answer:** Paragraph 21 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 21.

## ANSWER TO COUNTERCLAIMS

## 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.

**Answer:** On information and belief, Plaintiffs admit the allegations in Paragraph 1.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 2.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 3.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 4.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 5.

## 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.

**Answer:** Plaintiffs admit that Par's counterclaims relating to the '314 patent purport to 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 and deny that Par's counterclaims are valid and sustainable. Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

## 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).

**Answer:** Plaintiffs admit that this Court has subject matter jurisdiction over the counterclaims arising under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D), concerning the '314 patent. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy.

Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4). Plaintiffs deny the remaining allegations in Paragraph 7.

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

**Answer:** Plaintiffs admit that this Court has personal jurisdiction over Plaintiffs for purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 8.

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).

**Answer:** Plaintiffs admit that venue is proper in this judicial district for purposes of this action only.

## BACKGROUND

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

**Answer:** Plaintiffs admit the allegations in Paragraph 10.

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

**Answer:** Plaintiffs admit the allegations in Paragraph 11.

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

14. The '314 patent concerns rosuvastatin.

**Answer:** Plaintiffs admit that the '314 patent covers certain salts of rosuvastatin.

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 16.

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

**Answer:** Plaintiffs admit the allegations in Paragraph 17.

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.

**Answer:** Plaintiffs admit that the FDA approved NDA 21-366 on August 12,2003, granting permission for commercial marketing or use under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(b)). Plaintiffs deny the remaining allegations in Paragraph 18.

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.

**Answer:** Paragraph 19 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs lack knowledge or information sufficient to form a belief as to the truth of the allegations relating to typical ANDA applicant submissions. Plaintiffs deny the remaining allegations in Paragraph 19.

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.

**Answer:** Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 20.

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.

**Answer:** Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 21.

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.

**Answer:** Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 22.

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)(l) requesting that the '314 and '460 patents be listed by the FDA in the Orange Book.

**Answer:** Plaintiffs admit that the '314 patent is listed by the FDA in the Orange Book. Plaintiffs deny the remaining allegations in Paragraph 23 as to the '314 patent. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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)(l).

**Answer:** Paragraph 24 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 24.

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

**Answer:** On information and belief, Plaintiffs admit the allegations in Paragraph 25.

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.

**Answer:** Plaintiffs, on information and belief, admit the allegations in Paragraph 26 as to the '314 patent. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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).

**Answer:** Plaintiffs admit that they have received a notice dated November 5, 2007, from Par stating that it had filed an ANDA for its rosuvastatin calcium oral tablets indicating that its ANDA contained Paragraph IV certifications regarding the '314 patent. Plaintiffs admit that the notice also included an offer of confidential access to Par's ANDA. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for

lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4). Plaintiffs deny the remaining allegations in Paragraph 27.

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)(lll).

**Answer:** Plaintiffs deny the allegations in Paragraph 28.

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

**Answer:** Plaintiffs admit that they attempted to negotiate with Par reasonable conditions of access, which Par refused. Plaintiffs deny the remaining allegations in Paragraph 29.

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."

**Answer:** Plaintiffs admit the allegations in Paragraph 30.

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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).

**Answer:** Plaintiffs admit that the 45-day period after the date on which Plaintiffs received Par's notice has expired as to the '314 patent. With regard to the '460 patent, Plaintiffs

have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs deny the allegations of Paragraph 33.

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

**Answer:** Plaintiffs admit that they filed the following actions: *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. *Cobalt Pharmaceuticals Inc., et al.,* D. Del., Civil Action No. 07-

CV-811; and *AstraZeneca Pharmaceuticals LP et al.* v. *Cobalt Pharmaceuticals Inc., et al.,* M.D, Fl., Civil Action No, 07-CV-815. Plaintiffs deny the remaining allegations in Paragraph 34.

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 36.

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

**COUNT I - '314 PATENT**

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

**Answer:** Plaintiffs repeat and incorporate by reference Plaintiffs' responses to Paragraphs 1 through 37, as set forth above.

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.

**Answer:** Plaintiffs admit that Plaintiffs have asserted the '314 patent against Par and have asserted 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.

**Answer:** Plaintiffs deny the allegations in Paragraph 40.

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.

**Answer:** Paragraph 41 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that there is a substantial controversy between Plaintiffs and Par regarding infringement of the '314 patent. Plaintiffs deny the remaining allegations in Paragraph 41.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 42.

**COUNT II - '314 PATENT**

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

**Answer:** Plaintiffs repeat and incorporate by reference Plaintiffs' responses to Paragraphs 1 through 42, as set forth above.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 44.

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

**Answer:** Plaintiffs admit that they maintain 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.

**Answer:** Paragraph 46 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that AstraZeneca and Par have adverse legal interests regarding the validity of the '314 patent, and there is a substantial controversy between Plaintiffs and Par. Plaintiffs deny the remaining allegations in Paragraph 46.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 47.

**COUNT III - '314 PATENT**

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

**Answer:** Plaintiffs repeat and incorporate by reference Plaintiffs' responses to Paragraphs 1 through 47, as set forth above.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 49.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 50.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 51.

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).

**Answer:** Plaintiffs admit that during prosecution of the '440 patent the following references were not cited to the PTO: European Application 0 367 895 ("the '895 application), U.S. Patent No. 4,868,185 to Chucholowski et al., U.S. Patent No. 5,925,825 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, 436-466 (1991). Plaintiffs deny the remaining allegations in Paragraph 52.

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

**Answer:** Paragraph 53 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 53.

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

**Answer:** Paragraph 54 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 54.

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).

**Answer:** Paragraph 55 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that the '895 application was published on May 16, 1990 and that the '793 application was filed on June 12, 1992. Plaintiffs deny the remaining allegations in Paragraph 55.

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.

**Answer:** Plaintiffs admit that in a submission dated December 11, 1997 to the Canadian Patent Office, a statement was made that "claim 1 of Patent Number 5,260,440 has an overlap with claim 1 of EPA 267 895 [sic]." Plaintiffs deny the remaining allegations in Paragraph 56.

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.

**Answer:** Plaintiffs admit that in European Patent Publication No. 0 521 471 ("the '471 publication"), the '895 application was referenced in the rejection of the pending European claims 1-3, 5, and 7-9. Plaintiffs deny that original claims 1-3, 5, and 7-9 of the '471 publication were identical to the original claims in the '793 application. Plaintiffs deny the remaining allegations in Paragraph 57.

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.

**Answer:** Paragraph 58 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the Reissue Application Declaration by the Assingee form contained the statement, "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." Plaintiffs deny the remaining allegations in Paragraph 58.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 59.

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).

**Answer:** Plaintiffs deny the allegations in Paragraph 60.

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

**Answer:** Plaintiffs admit that they maintain 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.

**Answer:** Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Plaintiffs and Par have adverse legal interests relating to the validity and enforeability fo the '314 patent, and there is a substantial controversy between Plaintiffs and Par. Plaintiffs deny the remaining allegations in Paragraph 62.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 63.

**COUNT IV - '460 PATENT**

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

**COUNT V - '460 PATENT**

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

* * *

Plaintiffs deny all remaining allegations not specifically admitted and deny that Par is entitled to the relief requested or to any relief at all.

**REQUEST FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Par as follows:

(a) dismissing Par's counterclaims with prejudice;

(b) finding that this is an exceptional case and granting Plaintiffs' reasonable attorney fees pursuant to 35 U.S.C. § 285; and

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

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*Of Counsel for Plaintiffs,*
AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha

Dated: March 21, 2008

Respectfully Submitted:

*/s/ Mary W. Bourke*

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## CERTIFICATE OF SERVICE

I hereby certify on this 21st day of March, 2008 I electronically filed the foregoing PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS OF DEFENDANT PAR PHARMACEUTICAL, INC. with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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The undersigned counsel further certifies that, on March 21, 2008, copies of the foregoing document were also served upon the following individuals in the manner indicated:

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600087

**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,<br><br>Plaintiffs,<br><br>v.<br><br>PAR PHARMACEUTICAL, INC.,<br><br>Defendant. | Civil Action No.: 07-808-JJF-LPS |

**PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS**
**OF DEFENDANT PAR PHARMACEUTICAL, INC.**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, "Plaintiffs"), through their undersigned counsel, reply to the defenses and counterclaims of Defendant Par Pharmaceutical Inc. ("Par") as follows:

**ANSWER TO DEFENSES**

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

**Answer:** Plaintiffs deny the allegations in Paragraph 1.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 2.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 3.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 4.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 5.

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).

**Answer:** Plaintiffs admit that European Application 0 367 895 ("the '895 application"), U.S. Patent No. 4,868,185 to Chucholowski et al., U.S. Patent No. 5,925,825 to Kesseler et al., U.S. Patent No. 5,026,708 to Fujikawa et al., European Patent Application No. 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, 436-466 (1991), were not cited to the PTO during prosecution of the '440 patent. Plaintiffs deny the remaining allegations in Paragraph 6.

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

**Answer:** Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 7.

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

**Answer:** Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 8.

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).

**Answer:** Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the '895 application was published on

May 16, 1990 and that the '793 application was filed on June 12, 1992. Plaintiffs deny the remaining allegations in Paragraph 9.

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.

**Answer:** Plaintiffs admit that in a submission dated December 11, 1997 to the Canadian Patent Office, a statement was made that "claim 1 of Patent Number 5,260,440 has an overlap with claim 1 of EPA 267 895 [sic]." Plaintiffs deny the remaining allegations in Paragraph 10.

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.

**Answer:** Plaintiffs admit that in European Patent Publication No. 0 521 471 ("the '471 publication"), the '895 application was referenced in the rejection of the pending European claims 1-3, 5, and 7-9. Plaintiffs deny that original claims 1-3, 5, and 7-9 of the '471 publication were identical to the original claims in the '793 application. Plaintiffs deny the remaining allegations in Paragraph 11.

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.

**Answer:** Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the Reissue Application Declaration by the Assignee contained the statement, "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."

Plaintiffs deny the remaining allegations in Paragraph 12.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 13.

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

**Answer:** Plaintiffs admit the allegations in Paragraph 14.

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.

**Answer:** Plaintiffs admit that the '090.4 application was filed 18 days after the '793 application. Plaintiffs deny the remaining allegations in Paragraph 15.

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).

**Answer:** Plaintiffs admit the allegations in Paragraph 16.

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.

**Answer:** Plaintiffs admit that the European Search Report which listed the '895 application was published on January 7, 1993 with the '471 application. Plaintiffs deny the remaining allegations in Paragraph 17.

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."

**Answer:** Paragraph 18 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs lack knowledge or information sufficient to

form a belief as to the truth of the allegations in Paragraph 18, because Paragraph 18 does not specify which version of the MPEP is quoted. Plaintiffs deny the remaining allegations in Paragraph 18.

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.")

**Answer:** Paragraph 19 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 19.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 20.

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).

**Answer:** Paragraph 21 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 21.

## ANSWER TO COUNTERCLAIMS

## 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.

**Answer:** On information and belief, Plaintiffs admit the allegations in Paragraph 1.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 2.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 3.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 4.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 5.

## 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.

**Answer:** Plaintiffs admit that Par's counterclaims relating to the '314 patent purport to 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 and deny that Par's counterclaims are valid and sustainable. Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

## 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).

**Answer:** Plaintiffs admit that this Court has subject matter jurisdiction over the counterclaims arising under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D), concerning the '314 patent. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy.

Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4). Plaintiffs deny the remaining allegations in Paragraph 7.

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

**Answer:** Plaintiffs admit that this Court has personal jurisdiction over Plaintiffs for purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 8.

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).

**Answer:** Plaintiffs admit that venue is proper in this judicial district for purposes of this action only.

## BACKGROUND

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

**Answer:** Plaintiffs admit the allegations in Paragraph 10.

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

**Answer:** Plaintiffs admit the allegations in Paragraph 11.

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

14. The '314 patent concerns rosuvastatin.

**Answer:** Plaintiffs admit that the '314 patent covers certain salts of rosuvastatin.

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 16.

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

**Answer:** Plaintiffs admit the allegations in Paragraph 17.

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.

**Answer:** Plaintiffs admit that the FDA approved NDA 21-366 on August 12,2003, granting permission for commercial marketing or use under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355(b)). Plaintiffs deny the remaining allegations in Paragraph 18.

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.

**Answer:** Paragraph 19 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs lack knowledge or information sufficient to form a belief as to the truth of the allegations relating to typical ANDA applicant submissions. Plaintiffs deny the remaining allegations in Paragraph 19.

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.

**Answer:** Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 20.

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.

**Answer:** Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 21.

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.

**Answer:** Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 22.

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)(l) requesting that the '314 and '460 patents be listed by the FDA in the Orange Book.

**Answer:** Plaintiffs admit that the '314 patent is listed by the FDA in the Orange Book. Plaintiffs deny the remaining allegations in Paragraph 23 as to the '314 patent. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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)(l).

**Answer:** Paragraph 24 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 24.

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

**Answer:** On information and belief, Plaintiffs admit the allegations in Paragraph 25.

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.

**Answer:** Plaintiffs, on information and belief, admit the allegations in Paragraph 26 as to the '314 patent. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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).

**Answer:** Plaintiffs admit that they have received a notice dated November 5, 2007, from Par stating that it had filed an ANDA for its rosuvastatin calcium oral tablets indicating that its ANDA contained Paragraph IV certifications regarding the '314 patent. Plaintiffs admit that the notice also included an offer of confidential access to Par's ANDA. With regard to the '460 patent, Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for

lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4). Plaintiffs deny the remaining allegations in Paragraph 27.

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)(lll).

**Answer:** Plaintiffs deny the allegations in Paragraph 28.

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

**Answer:** Plaintiffs admit that they attempted to negotiate with Par reasonable conditions of access, which Par refused. Plaintiffs deny the remaining allegations in Paragraph 29.

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."

**Answer:** Plaintiffs admit the allegations in Paragraph 30.

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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).

**Answer:** Plaintiffs admit that the 45-day period after the date on which Plaintiffs received Par's notice has expired as to the '314 patent. With regard to the '460 patent, Plaintiffs

have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs deny the allegations of Paragraph 33.

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

**Answer:** Plaintiffs admit that they filed the following actions: *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. *Cobalt Pharmaceuticals Inc., et al.,* D. Del., Civil Action No. 07-

CV-811; and *AstraZeneca Pharmaceuticals LP et al.* v. *Cobalt Pharmaceuticals Inc., et al.,* M.D, Fl., Civil Action No, 07-CV-815. Plaintiffs deny the remaining allegations in Paragraph 34.

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs deny the allegations in Paragraph 36.

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

**COUNT I - '314 PATENT**

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

**Answer:** Plaintiffs repeat and incorporate by reference Plaintiffs' responses to Paragraphs 1 through 37, as set forth above.

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.

**Answer:** Plaintiffs admit that Plaintiffs have asserted the '314 patent against Par and have asserted 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.

**Answer:** Plaintiffs deny the allegations in Paragraph 40.

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.

**Answer:** Paragraph 41 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that there is a substantial controversy between Plaintiffs and Par regarding infringement of the '314 patent. Plaintiffs deny the remaining allegations in Paragraph 41.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 42.

**COUNT II - '314 PATENT**

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

**Answer:** Plaintiffs repeat and incorporate by reference Plaintiffs' responses to Paragraphs 1 through 42, as set forth above.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 44.

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

**Answer:** Plaintiffs admit that they maintain 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.

**Answer:** Paragraph 46 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that AstraZeneca and Par have adverse legal interests regarding the validity of the '314 patent, and there is a substantial controversy between Plaintiffs and Par. Plaintiffs deny the remaining allegations in Paragraph 46.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 47.

**COUNT III - '314 PATENT**

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

**Answer:** Plaintiffs repeat and incorporate by reference Plaintiffs' responses to Paragraphs 1 through 47, as set forth above.

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.

**Answer:** Plaintiffs deny the allegations in Paragraph 49.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 50.

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.

**Answer:** Plaintiffs admit the allegations in Paragraph 51.

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).

**Answer:** Plaintiffs admit that during prosecution of the '440 patent the following references were not cited to the PTO: European Application 0 367 895 ("the '895 application), U.S. Patent No. 4,868,185 to Chucholowski et al., U.S. Patent No. 5,925,825 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, 436-466 (1991). Plaintiffs deny the remaining allegations in Paragraph 52.

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

**Answer:** Paragraph 53 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 53.

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

**Answer:** Paragraph 54 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations in Paragraph 54.

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).

**Answer:** Paragraph 55 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that the '895 application was published on May 16, 1990 and that the '793 application was filed on June 12, 1992. Plaintiffs deny the remaining allegations in Paragraph 55.

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.

**Answer:** Plaintiffs admit that in a submission dated December 11, 1997 to the Canadian Patent Office, a statement was made that "claim 1 of Patent Number 5,260,440 has an overlap with claim 1 of EPA 267 895 [sic]." Plaintiffs deny the remaining allegations in Paragraph 56.

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.

**Answer:** Plaintiffs admit that in European Patent Publication No. 0 521 471 ("the '471 publication"), the '895 application was referenced in the rejection of the pending European claims 1-3, 5, and 7-9. Plaintiffs deny that original claims 1-3, 5, and 7-9 of the '471 publication were identical to the original claims in the '793 application. Plaintiffs deny the remaining allegations in Paragraph 57.

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.

**Answer:** Paragraph 58 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the Reissue Application Declaration by the Assingee form contained the statement, "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." Plaintiffs deny the remaining allegations in Paragraph 58.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 59.

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).

**Answer:** Plaintiffs deny the allegations in Paragraph 60.

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

**Answer:** Plaintiffs admit that they maintain 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.

**Answer:** Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Plaintiffs and Par have adverse legal interests relating to the validity and enforeability fo the '314 patent, and there is a substantial controversy between Plaintiffs and Par. Plaintiffs deny the remaining allegations in Paragraph 62.

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

**Answer:** Plaintiffs deny the allegations in Paragraph 63.

**COUNT IV - '460 PATENT**

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

**COUNT V - '460 PATENT**

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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.

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

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

**Answer:** Plaintiffs have moved to dismiss Defendants' counterclaims against the '460 patent for lack of case or controversy. Any answer to allegations concerning the '460 patent will be made pursuant to Fed. R. Civ. P. 12(a)(4).

* * *

Plaintiffs deny all remaining allegations not specifically admitted and deny that Par is entitled to the relief requested or to any relief at all.

**REQUEST FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Par as follows:

(a) dismissing Par's counterclaims with prejudice;

(b) finding that this is an exceptional case and granting Plaintiffs' reasonable attorney fees pursuant to 35 U.S.C. § 285; and

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

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*Of Counsel for Plaintiffs,*
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Dated: March 21, 2008

Respectfully Submitted:

*/s/ Mary W. Bourke*

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## CERTIFICATE OF SERVICE

I hereby certify on this 21st day of March, 2008 I electronically filed the foregoing PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS OF DEFENDANT PAR PHARMACEUTICAL, INC. with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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The undersigned counsel further certifies that, on March 21, 2008, copies of the foregoing document were also served upon the following individuals in the manner indicated:

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