IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AstraZeneca Pharmaceuticals LP, IPR Pharmaceuticals, Inc., AstraZeneca AB, and The Brigham and Women's Hospital, Inc., Plaintiffs, v. Par Pharmaceutical, Inc., Defendant.	Civ. No.: 10-343

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, IPR Pharmaceuticals, Inc., AstraZeneca AB, and The Brigham and Women's Hospital, Inc., for their Complaint against Par Pharmaceutical, Inc., hereby state as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to an Abbreviated New Drug Application ("ANDA") filed and amended by and/or for the benefit of Par Pharmaceutical, Inc. with the United States Food and Drug Administration ("FDA") for approval to market generic versions of AstraZeneca's highly successful Crestor® pharmaceutical products that are sold in the United States.

Parties

2. Plaintiff AstraZeneca Pharmaceuticals LP ("AZPLP") is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

3. Plaintiff 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.

4. Plaintiff AstraZeneca AB is a corporation operating and existing under the laws of Sweden with its principal place of business at S-151 85 Södertälje, Sweden.

5. Plaintiff The Brigham and Women's Hospital, Inc. ("Brigham") is a not-for-profit corporation operating and existing under the laws of Massachusetts with its principal place of business at 75 Francis Street, Boston, MA 02115.

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.

Background

7. IPR is the holder of approved New Drug Application ("NDA") No. 021366 for Crestor® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium. AstraZeneca is IPR's authorized agent for matters related to NDA No. 021366.

8. Crestor® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. Crestor® is one of the most effective lipid-lowering statins available. Over 19 million patients have been prescribed Crestor®, and over 240 million prescriptions have been written worldwide for Crestor®. Rosuvastatin calcium is the active ingredient in Crestor®.

9. Plaintiffs AZPLP, IPR, and AstraZeneca AB 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.

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.

11. By letter dated November 5, 2007, Par notified Plaintiffs AZPLP, IPR, and AstraZeneca AB 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 ("Par Rosuvastatin Calcium Tablets"), and that it was providing information to those Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

Jurisdiction and Venue

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

13. On information and belief, 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.

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

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

Count I

Infringement of United States Patent No. 6,858,618 Under 35 U.S.C. § 271(e)(2)

16. Plaintiffs AZPLP, IPR, and AstraZeneca AB (collectively, "the '618 Patent Plaintiffs") incorporate by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

17. United States Patent No. 6,858,618 B2 ("the '618 patent"), entitled "Use of Rosuvastatin (ZD-4522) in the Treatment of Heterozygous Familial Hypercholesterolemia," was duly and legally issued by the United States Patent and Trademark Office on February 22, 2005. The '618 Patent Plaintiffs hold all substantial rights in the '618 patent and have the right to sue for infringement thereof. A true and correct copy of the '618 patent is attached as Exhibit A. The exclusive rights provided by the '618 patent, as extended by applicable regulatory exclusivities, will expire on June 17, 2022.

18. As of August 1, 2007, IPR had listed the '618 patent with the FDA for publication in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1) and the FDA had published that listing on the FDA's Internet website.

19. 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 '618 patent.

20. On information and belief, if the FDA approves ANDA No. 79-168, Par intends to market, offer for sale, and sell the Par Rosuvastatin Calcium Tablets in the United States before the expiration of the '618 patent.

21. On October 15, 2009, the FDA approved adding to the Crestor® label a separate indication for the use of Crestor® to treat pediatric patients 10 to 17 years of age having Heterozygous Familial Hypercholesterolemia ("HeFH"), and adding to the label additional

material information supporting the use, safety, and efficacy of the drug for that use by prescribers and their patients. A copy of that amended label is attached as Exhibit B.

22. The label for the Par Rosuvastatin Calcium Tablets must be the same as the label for Crestor®, except as provided by 21 C.F.R. § 314.127(a).

23. On information and belief, the FDA will require the label for the Par Rosuvastatin Calcium Tablets to include information relating to the use to treat pediatric patients 10 to 17 years of age having HeFH.

24. On information and belief, in view of the label amendment, Par will need to satisfy, *inter alia*, 21 U.S.C. § 355(j)(2)(A), and the regulations promulgated there under, to obtain FDA approval for ANDA No. 79-168.

25. On information and belief, the labeling associated with the Par Rosuvastatin Calcium Tablets causes ANDA No. 79-168 to be an application for a drug the use of which is claimed in the '618 patent in violation of 35 U.S.C. § 271(e)(2)(A).

26. On information and belief, if the FDA approves ANDA No. 79-168, the sale of the Par Rosuvastatin Calcium Tablets with their associated labeling before the expiration of the '618 patent will cause infringement of one or more claims of the '618 patent.

27. On information and belief, the Par Rosuvastatin Calcium Tablets, if approved by the FDA, will be prescribed and administered to human patients to treat HeFH, which uses will constitute direct infringement of the '618 patent. On information and belief, these uses will occur with Par's specific intent and encouragement, and will be uses that Par knows or should know will occur. On information and belief, Par will actively induce, encourage, aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of the '618 Patent Plaintiffs' rights under the '618 patent.

28. Under 35 U.S.C. § 271(e)(2)(A), the submission by Par to the FDA of amended 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 '618 patent, which claims a use of those Tablets, constitutes infringement of one or more claims of the '618 patent, either literally or under the doctrine of equivalents.

29. The '618 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. The '618 Patent Plaintiffs have no adequate remedy at law.

Count II

Infringement of United States Patent No. 7,030,152
Under 35 U.S.C. § 271(e)(2)

30. Plaintiffs AZPLP, IPR, and Brigham (collectively, "the '152 Patent Plaintiffs") incorporate by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

31. United States Patent No. 7,030,152 B1 ("the '152 patent"), entitled "Systematic Inflammatory Markers as Diagnostic Tools in the Prevention of Atherosclerotic Diseases and as Tools to Aid in the Selection of Agents To Be Used for the Prevention and Treatment of Atherosclerotic Disease," was duly and legally issued by the United States Patent and Trademark Office on April 18, 2006, and was assigned to Brigham. IPR licensed the '152 patent from Brigham and holds all relevant and substantial rights in the '152 patent, including the right to sue for infringement thereof. A true and correct copy of the '152 patent is attached as Exhibit C. The exclusive rights provided by the '152 patent will expire on April 2, 2018.

32. As of March 8, 2010, IPR had listed the '152 patent with the FDA for publication in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1) and the FDA thereafter published that listing on the FDA's Internet website.

33. 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 '152 patent.

34. On information and belief, if the FDA approves ANDA No. 79-168, Par intends to market, offer for sale, and sell the Par Rosuvastatin Calcium Tablets in the United States before the expiration of the '152 patent.

35. On February 8, 2010, the FDA approved adding to the Crestor® label a separate indication for the use of Crestor® for the primary prevention of cardiovascular disease and adding to the label additional material information supporting the use, safety, and efficacy of the drug for that use by prescribers and their patients. A copy of that amended label is attached as Exhibit D.

36. The label for the Par Rosuvastatin Calcium Tablets must be the same as the label for Crestor®, except as provided by 21 C.F.R. § 314.127(a).

37. On information and belief, the FDA will require the label for the Par Rosuvastatin Calcium Tablets to include information relating to the use for the primary prevention of cardiovascular disease.

38. On information and belief, in view of the label amendment, Par will need to satisfy, *inter alia*, 21 U.S.C. § 355(j)(2)(A), and the regulations promulgated thereunder, to obtain FDA approval for ANDA No. 79-168.

39. On information and belief, the labeling associated with the Par Rosuvastatin Calcium Tablets causes ANDA No. 79-168 to be an application for a drug the use of which is claimed in the '152 patent in violation of 35 U.S.C. § 271(e)(2)(A).

40. On information and belief, if the FDA approves ANDA No. 79-168, the sale of the Par Rosuvastatin Calcium Tablets in the United States with their associated labeling before the expiration of the '152 patent will cause infringement of one of more claims of the '152 patent.

41. On information and belief, the Par Rosuvastatin Calcium Tablets, if approved by the FDA, will be prescribed and administered to human patients for the primary prevention of cardiovascular disease, which uses will constitute direct infringement of the '152 patent. On information and belief, these uses will occur with Par's specific intent and encouragement, and will be uses that Par knows or should know will occur. On information and belief, Par will actively induce, encourage, aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of the '152 Patent Plaintiffs' rights under the '152 patent.

42. 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 offer for sale or sale of the Par Rosuvastatin Calcium Tablets before the expiration date of the '152 patent, which claims a use of those Tablets, constitutes infringement of one or more claims of the '152 patent, either literally or under the doctrine of equivalents.

43. The '152 Patent Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

(1) holding that the claims of the '618 and '152 patents are valid and enforceable;

(2) holding that the submission and/or amendment of ANDA No. 79-168 by Par infringes one or more claims of each of the '618 and '152 patents under 35 U.S.C. § 271(e)(2);

(3) ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Par Rosuvastatin Calcium Tablets shall be no earlier than the expiration date of the last to expire of the '618 and '152 patents held to be valid, enforceable, and infringed;

(4) enjoining Par and all persons acting in concert with it from commercially offering for sale or selling in the United States the Par Rosuvastatin Calcium Tablets prior to the expiration of the last to expire of the '618 and '152 patents held to be valid, enforceable, and infringed;

(5) declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;

(6) awarding Plaintiffs their costs and expenses in this action; and

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

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Respectfully Submitted:

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