UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PAR PHARMACEUTICAL, INC., Plaintiff, v. UCB, INC., and UCB PHARMA S.A., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff, Par Pharmaceutical, Inc. ("Par"), for its Complaint against Defendants, UCB, Inc. ("UCB") and UCB Pharma S.A. ("UCB Pharma") (UCB and UCB Pharma are collectively referred to as the "Defendants"), alleges as follows:

NATURE OF ACTION

1. Par seeks a declaratory judgment of invalidity and noninfringement of U.S. Patent Nos. 7,858,122 and 7,863,316 pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

JURISDICTION

2. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a), 21 U.S.C. § 355(j)(5)(C)(i)(II), and 35 U.S.C. § 271(e)(5).

3. This Court has personal jurisdiction over Defendants, as they reside or engage in significant business activities in this judicial district, including selling products in this district, soliciting business in this district and deriving substantial revenue from this district.

VENUE

4. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c) and 21 U.S.C. § 355(j)(5)(C)(i)(II), as Defendants reside or engage in significant business activities in this district.

PARTIES

5. Par is a corporation organized under the laws of New Jersey, with its principal place of business in Woodcliff Lake, New Jersey.

6. Upon information and belief, UCB is a corporation organized under the laws of Delaware, with its principal place of business in Smyrna, Georgia.

7. Upon information and belief, UCB Pharma is a corporation organized under the laws of Belgium, with its principal place of business in Brussels, Belgium and subsidiaries or business units located within this judicial district.

FACTUAL BACKGROUND

8. U.S. Patent No. 7,858,122 ("the '122 patent"), entitled "Extended Release Formulation of Levetiracetam," issued on December 28, 2010.

9. Upon information and belief, the '122 patent is currently scheduled to expire on September 17, 2028.

10. U.S. Patent No. 7,863,316 ("the '316 patent"), entitled "Extended Release Formulation of Levetiracetam," issued on January 4, 2010.

11. Upon information and belief, the '316 patent is currently scheduled to expire on September 13, 2028.

12. According to the United States Patent and Trademark Office ("USPTO") assignment database, UCB Pharma is the named assignee of the '122 and '316 patents.

13. Upon information and belief, UCB is a licensee of the '122 and '316 patents. UCB markets in the United States levetiracetam extended release tablets, 500 mg and 750 mg, for oral administration under the brand name KEPRRA XR®.

14. Upon information and belief, UCB caused the Food and Drug Administration ("FDA") to list the'122 patent in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with KEPPRA XR®. By doing so, UCB represented that a claim of patent infringement could reasonably be asserted against any unlicensed manufacture, use or sale of oral levetiracetam extended release tablets. By listing the '122 patent in the Orange Book, UCB created a reasonable apprehension that it would file a patent infringement action against applicants seeking regulatory approval for oral levetiracetam extended release tablets based on the '122 patent.

15. The '316 patent is a continuation-in-part of the '122 patent and also purports to claim levetiracetam extended release tablets. Accordingly, Par has a reasonable apprehension that UCB would file a patent infringement action against applicants seeking regulatory approval for oral levetiracetam extended release tablets based on the '316 patent.

16. Par submitted to the FDA an Abbreviated New Drug Application in order to obtain regulatory approval to engage in the commercial manufacture, use or sale of generic oral levetiracetam extended release tablets, 500 mg and 750 mg ("Par's ANDA"). The oral levetiracetam extended release tablets that are the subject of Par's ANDA are bioequivalent to

UCB's KEPPRA XR® and have the same active ingredient, strength, dosage form, and route of administration.

17. Par also submitted to the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the '122 patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the oral levetiracetam extended release tablets that are the subject of Par's ANDA .

18. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and § 314.95 of Title 21 of the U.S. Code of Federal Regulations, on January 10 and 13, 2011, Par provided notice to UCB Pharma and UCB of the paragraph IV certification that it submitted.

19. Par's notification triggered a 45-day statutory period during which Defendants had the first opportunity to initiate patent infringement litigation. Defendants did not bring an action for patent infringement during the 45-day statutory period.

20. Where no action for patent infringement is filed within the statutory period, 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5) provide for a civil action to obtain patent certainty and allow Par to obtain a declaratory judgment with respect to patents listed in the Orange Book.

21. Par expects to receive tentative approval from the FDA to engage in the commercial manufacture, use or sale of generic oral levetiracetam extended release tablets within thirty months from the filing date of Par's ANDA.

22. Par has made substantial preparations for the commercial manufacture, use or sale of generic oral levetiracetam extended release tablets.

COUNT ONE

(Declaratory Judgment Regarding U.S. Patent No. 7,858,122)

23. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

24. The claims of the '122 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

25. The submission of Par's ANDA does not infringe any valid claim of the '122 patent.

26. The commercial manufacture, use, offer for sale, sale, or importation of the oral levetiracetam extended release tablets that are the subject of Par's ANDA would not infringe any valid claim of the '122 patent.

27. An actual and justiciable controversy exists between the parties with respect to the '122 patent, and Par is entitled to a declaratory judgment that the '122 patent is invalid and not infringed.

COUNT TWO

(Declaratory Judgment Regarding U.S. Patent No. 7,863,316)

28. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

29. The claims of the '316 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

30. The submission of Par's ANDA does not infringe any valid claim of the '316 patent.

31. The commercial manufacture, use, offer for sale, sale, or importation of the oral levetiracetam extended release tablets that are the subject of Par's ANDA would not infringe any valid claim of the '316 patent.

32. An actual and justiciable controversy exists between the parties with respect to the '316 patent, and Par is entitled to a declaratory judgment that the '316 patent is invalid and not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. Declare that the claims of the '122 patent are invalid;

B. Declare that the submission of Par's ANDA does not infringe any valid claim of the '122 patent;

C. Declare that the manufacture, use, offer for sale, sale or importation of Par's generic oral levetiracetam extended release tablets would not infringe any valid claim of the '122 patent;

D. Declare that the claims of the '316 patent are invalid;

E. Declare that the submission of Par's ANDA does not infringe any valid claim of the '316 patent;

F. Declare that the manufacture, use, offer for sale, sale or importation of Par's generic oral levetiracetam extended release tablets would not infringe any valid claim of the '316 patent;

G. Award Par its costs and reasonable attorney fees; and

H. Award Par such other and further relief as the Court deems just and proper.

Respectfully submitted,

VAIRA & RILEY PC

Dated: March 23, 2011

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