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

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| UCB, INC., Plaintiff, v. ALZA CORPORATION, Defendant. | ) | CA. No. _____ |

**COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff UCB, Inc. ("UCB") brings this action against Defendant Alza Corporation ("Alza"), and in support states as follows:

**NATURE OF THE ACTION**

1. This is an action for declaratory judgment of invalidity, noninfringement, and unenforceability of United States Patent Number 6,440,457 ("the '457 patent") under 28 U.S.C. §§ 2201 and 2202.

**PARTIES**

2. Plaintiff UCB is a corporation organized and existing under the laws of Delaware, having a place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

3. On information and belief, Defendant Alza is a corporation organized under the laws of Delaware, having its principal place of business at 700 Eubanks Drive, Vacaville, California 95688.

4. On information and belief, Alza is a wholly-owned subsidiary of Johnson & Johnson, a corporation organized under the laws of Delaware, having its principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

## JURISDICTION AND VENUE

5. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338 because there is an actual controversy between UCB and Alza.

6. There is an actual, substantial, and continuing justiciable case or controversy between UCB and Alza regarding the validity, infringement, and enforceability of the '457 patent.

7. This Court has personal jurisdiction over Alza at least because Alza is incorporated in the State of Delaware, and because Alza has purposefully availed itself of this Court's jurisdiction. (*See, e.g.*, *Alza Corp. et al. v. Sandoz Inc.*, No. 14-cv-744-RGA (D. Del. Jun. 13, 2014); *Alza Corp. et al. v. Mylan Pharm. Inc. et al*, No. 14-cv-594-RGA (D. Del. May 12, 2014); *Alza Corp. et al. v. Par Pharm., Inc. et al.*, No. 13-cv-1104-RGA (D. Del. Jun. 19, 2013); *Alza Corp. et al. v. Impax Labs., Inc. et al.*, No. 11-cv-395-RGA (D. Del. May 5, 2011); *Alza Corp. et al. v. Kremers Urban, LLC et al.*, No. 10-cv-023-LPS (D. Del. Jan. 8, 2010) .)

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

## THE PATENT IN SUIT

9. The United States Patent and Trademark Office ("USPTO") issued the '457 patent, bearing the title "Method of Administering Antidepressant Dosage Form," on August 27, 2002. The '457 patent lists David Emil Edgren, Gurdish Kaur Bhatti, Zahedeh Hatamkhani, and Patrick S.L. Wong as its inventors. On May 3, 2011, the USPTO issued Reexamination

Certificate Number 6,440,457 C1. A true and correct copy of the '457 patent and its reexamination certificate are attached as Exhibit A.

10. The sole claim of the '457 patent is generally directed to, *inter alia*, a method of administering to the gastrointestinal tract of a human venlafaxine hydrochloride over an extended period of time, to produce antidepressant therapy.

11. On information and belief, Alza is the sole assignee and current owner of the '457 patent.

**UCB'S FDA-APPROVED VENLAFAXINE EXTENDED-RELEASE TABLETS**

12. On December 12, 2006, Osmotica Pharmaceutical Corp. ("Osmotica") filed New Drug Application ("NDA") No. 22-104 with the United States Food and Drug Administration ("FDA") seeking approval for 37.5 mg, 75 mg, 150 mg, and 225 mg strength Venlafaxine Extended Release Tablets ("VERT").

13. On May 20, 2008, the FDA approved Osmotica's NDA 22-104 and the VERT product for its indication of treatment of Major Depressive Disorder ("MDD") and Social Anxiety Disorder.

14. In connection with its NDA No. 22-104, Osmotica listed United States Patent Numbers 6,403,120 and 6,419,958 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), as patents "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 VERT product. *See* 21 U.S.C. § 355(b)(1).

15. In July 2008, UCB entered into an exclusive license agreement with Osmotica whereby UCB and its affiliates became responsible for the commercial marketing and distribution of the VERT product in the United States.

16. UCB's VERT product was first sold in the United States in October 2008, and has been on sale in the United States continuously since that time.

**THE PRESENCE OF AN ACTUAL CONTROVERSY**

17. On January 19, 2015, Johnson & Johnson, on behalf of Alza, sent a letter to UCB alleging that "UCB's Venlafaxine XR product infringes claim 1 of the 457 patent" and offering to "discuss the potential for UCB's consideration of a license under the '457 patent directly from Alza." A true and correct copy of this letter is attached as Exhibit B.

18. In response, UCB communicated that its VERT product did not infringe claim 1 of the '457 patent. In particular, on or around March 11, 2015, UCB communicated its belief that its VERT product did not and could not infringe the '457 patent because of Alza's unequivocal disclaimer of subject matter during prosecution of the application that led to the '457 patent.

19. On November 16, 2015, Johnson & Johnson, on behalf of Alza, sent a second letter, reiterating that "[i]t is Alza's position that UCB's product infringes claim 1 of the 457 patent." A true and correct copy of this letter is attached as Exhibit C.

20. Since January 19, 2015, Alza has alleged and maintained that UCB's VERT product infringes the sole claim of the '457 patent. Alza's conduct demonstrates a real and immediate threat to UCB's sale of the VERT product within the United States, which has been actively marketed and sold since 2008. There is an actual and justiciable controversy between UCB and Alza with respect to whether UCB's offering to sell and selling of the VERT product will infringe any valid and enforceable claim of the '457 patent. This dispute is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

**COUNT I**
**Non-Infringement**

21. Paragraphs 1 to 20 as set forth above are incorporated herein.

22. As set forth above, an actual and justiciable controversy exists regarding whether UCB's VERT product infringes any valid and enforceable claim of the '457 patent.

23. The offer for sale and/or sale of UCB's VERT product has not infringed, does not infringe, and will not directly or indirectly infringe any valid and enforceable claim of the '457 patent, either literally or under the doctrine of equivalents.

24. For example, UCB's VERT product has not infringed, does not infringe, and will not infringe the '457 patent because of Alza's unequivocal disclaimer of subject matter during prosecution of the application that led to the '457 patent. Thus, any claim for infringement of the '457 patent is barred, in whole or in part, by the doctrine of prosecution history estoppel.

25. UCB is entitled to a judgment declaring that the offer for sale and/or sale of UCB's VERT product before the expiration of the '457 patent does not and will not infringe any valid and enforceable claim of the '457 patent.

**COUNT II**
**Patent Invalidity**

26. Paragraphs 1 to 25 as set forth above are incorporated herein.

27. As set forth above, an actual and justiciable case or controversy exists between UCB and Alza regarding the validity of the '457 patent.

28. The sole claim of the '457 patent is invalid for failure to comply with one or more of the conditions for patentability as set forth in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

29. For example, the sole claim of the ’457 patent is invalid as anticipated and/or obvious under 35 U.S.C. §§ 102(a), 102(b), 102(e) and/or 103 at least in view of the following prior art references alone or in combination:

a. United States Patent Number 4,761,501, issued August 2, 1988 (*Husbands*);

b. United States Patent Number 4,111,201, issued September 5, 1978 (*Theeuwes ‘201*);

c. United States Patent Number 3,916,899, issued November 4, 1975 (*Theeuwes ‘899*);

d. Montgomery, Stuart A., *Efficacy and Safety of b.i.d. Doses of Venlafaxine in a Dose-Reponse Study*, 29 Psychopharmacology Bull. 169 (1993);

e. Gupta, Pardeep K. & Robinson, Joseph R., *Oral Controlled Release Delivery Treatise on Controlled Drug Delivery*, 255-313 Kyodonieus (NY: Marcel Dekker Inc., 1992); and

f. Longer, Mark A. & Joseph R. Robinson, *Sustained-Release Drug Delivery Systems*, Remington’s Pharmaceutical Sciences 1644-1661 (Mack Printin Co. 17th ed. 1985).

30. In addition, the sole claim of the ’457 patent is invalid under 35 U.S.C. § 112 for lack of written description and/or enablement, or as being indefinite.

31. Accordingly, UCB is entitled to a judgment declaring that claim 1 of the ’457 patent is invalid.

**COUNT III**
**Laches**

32. Paragraphs 1 to 31 as set forth above are incorporated herein.

33. An actual controversy has arisen and now exists between the parties concerning whether Alza unreasonably delayed raising UCB's alleged infringement and whether Alza's delay was justified.

34. UCB is entitled to a judgment declaring that any claim for infringement of the '457 patent is barred, in whole or in part, by the doctrine of laches.

**COUNT IV**
**Equitable Estoppel**

35. Paragraphs 1 to 34 as set forth above are incorporated herein.

36. An actual controversy has arisen and now exists between the parties concerning whether Alza's misleading statements or conduct led UCB to infer that Alza did not intend to enforce the '457 patent against UCB, such that UCB would suffer material prejudice as a result of its reliance on Alza's misleading statements or conduct if Alza is permitted to proceed with any claim of infringement.

37. UCB is entitled to a judgment declaring that any claim for infringement of the '457 patent is barred, in whole or in part, by the doctrine of equitable estoppel.

**PRAYER FOR RELIEF**

WHEREFORE, UCB respectfully requests that this Court enter an Order with the following relief under 28 U.S.C. §§ 2201 and 2202:

a. A declaration under 28 U.S.C. § 2201 that the offer for sale and/or sale of UCB's VERT product before the expiration of the '457 patent does not and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '457 patent;

b. A declaration under 28 U.S.C. § 2201 that the claim of the '457 patent is invalid for failure to comply with one or more of the conditions for patentability as set

forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112;

c. A declaration under 28 U.S.C. § 2201 that any claim for infringement by UCB of the '457 patent is barred, in whole or in part, by the doctrine of laches;

d. A declaration under 28 U.S.C. § 2201 that any claim for infringement by UCB of the '457 patent is barred, in whole or in part, by the doctrine of equitable estoppel;

e. An order enjoining Alza from enforcing the '457 patent;

f. An award to UCB of its costs and attorneys' fees; and

g. All other and further relief that the Court deems just and proper.

Respectfully submitted,

Dated: December 22, 2015

*/s/ Mary W. Bourke*

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