

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION

UCB, INC. AND UCB	)	
MANUFACTURING, INC.,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. <u>1:12-CV-4420-CAP</u>
v.	)	
	)	
TEVA PHARMACEUTICALS	)	
USA, INC., and TEVA	)	<u>JURY TRIAL DEMANDED</u>
PHARMACEUTICAL	)	
INDUSTRIES, LTD.,	)	
	)	
Defendants.	)	

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs UCB, Inc. and UCB Manufacturing, Inc. (collectively, “Plaintiffs” or “UCB”), for their complaint herein against Defendant Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, “Defendants” or “TEVA”), allege as follows:

**NATURE OF ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

**THE PARTIES**

2. Plaintiff UCB, Inc. is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

3. Plaintiff UCB Manufacturing, Inc. is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 755 Jefferson Road, Rochester, New York 14623.

4. On information and belief, defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

5. On information and belief, defendant Teva Pharmaceutical Industries, Ltd. (“Teva Industries”) is an Israeli corporation having its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

**JURISDICTION AND VENUE**

6. This action arises under the federal Patent laws and the federal Food and Drug laws, Titles 35 and 21, respectively, of the United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, TEVA derives substantial revenue from selling various products and doing or soliciting business throughout the United States, including in Georgia and this District. TEVA has maintained continuous and systematic contacts in Georgia.

8. On information and belief, Teva USA is registered to do business in the State of Georgia, and Corporate Creations Network Inc., 2985 Gordy Parkway, 1st Floor, Marietta, Georgia 30066 is authorized to accept service on behalf of Teva USA.

9. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries, and these two companies have common officers and directors.

10. On information and belief, the acts of Teva USA complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, assistance of, and at least in part the benefit of, Teva Industries.

11. On information and belief, this Court has personal jurisdiction over Teva Industries pursuant to O.C.G.A. § 9-10-91 because Teva Industries transacts business regularly in Georgia, including through its wholly owned subsidiary Teva USA, deriving substantial revenue from selling various products.

12. On information and belief, this Court has personal jurisdiction over Teva Industries pursuant to O.C.G.A. § 9-10-91 because Teva Industries, through its wholly owned subsidiary Teva USA, has committed the tortious act of patent infringement by engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of generic methylphenidate hydrochloride capsules, 10, 20, 30, 40, and 50 mg (“TEVA’s Drug Products”) throughout the United States and in this District.

13. On information and belief, Teva Industries manufactures bulk pharmaceuticals and pharmaceutical products that are sold—including by Teva USA—throughout the United States and in this District.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

### **CLAIM FOR RELIEF**

15. UCB realleges paragraphs 1-14 above, as if set forth specifically here.

16. United States Patent No. 6,344,215 (“the ‘215 patent”), entitled “Methylphenidate Modified Release Formulations,” was duly and legally issued on February 5, 2002. The ‘215 patent claims, *inter alia*, a modified release

formulation of methylphenidate hydrochloride. A true and correct copy of the '215 patent is attached hereto as Exhibit A.

17. UCB Manufacturing, Inc. is the owner of the entire right, title, and interest in the '215 patent and has the right to sue for infringement of the '215 patent.

18. UCB, Inc. holds an approved New Drug Application ("NDA") from the United States Food and Drug Administration ("FDA") for a methylphenidate hydrochloride formulation, which it sells under the name METADATE CD<sup>®</sup>.

19. The FDA granted approval of NDA No. 21-259 to UCB, Inc. to sell capsules containing 10, 20, 30, 40, 50, and 60 mg of methylphenidate hydrochloride. The capsules approved under UCB, Inc.'s NDA are prescribed and sold in the United States under the trade name METADATE CD<sup>®</sup>.

20. TEVA has filed with the FDA Abbreviated New Drug Application ("ANDA") Nos. 77-707 and 78-873 ("TEVA's ANDAs") under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and/or sale of generic methylphenidate hydrochloride capsules, 10, 20, 30, 40, 50, and 60 mg.

21. On information and belief, on or about July 19, 2012, the FDA approved TEVA's ANDAs.

22. On information and belief, in September 2012, TEVA began commercial manufacture, use, offer for sale, sale, and/or importation of TEVA's Drug Products under TEVA's ANDAs.

23. By manufacturing, using, offering for sale, selling, and/or importing into the United States TEVA's Drug Products under TEVA's ANDAs, TEVA committed acts of infringement of one or more claims of the '215 patent under 35 U.S.C. § 271(a).

24. On information and belief, TEVA's Drug Products are administered to human patients for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD"). This administration directly infringes the '215 patent. This infringement occurs at TEVA's active behest, and with its specific intent, knowledge, and encouragement. On information and belief, TEVA actively induces, encourages, aids, and abets this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '215 patent.

25. By actively inducing, encouraging, aiding, and abetting administration of TEVA's Drug Products under TEVA's ANDAs, TEVA has

committed an act of infringement of one or more claims of the '215 patent under 35 U.S.C. § 271(b).

26. On information and belief, TEVA continues to sell TEVA's Drug Products in the United States under TEVA's ANDAs, and that infringement continues to this day.

27. Plaintiffs have been monetarily damaged by TEVA's past and continued sales of TEVA's Drug Products. As a result of TEVA's infringement, Plaintiffs are owed damages to the full extent allowed by law under 35 U.S.C. § 284.

28. TEVA's infringement of Plaintiffs' exclusive rights under the '215 patent will continue to damage Plaintiffs due to TEVA's ongoing sales of TEVA's Drug Products, causing irreparable harm, for which there is no adequate remedy at law, unless enjoined by this Court.

29. On information and belief, TEVA is aware that TEVA's Drug Products are made, used, and/or sold in contravention of UCB's rights under the '215 patent.

30. This is an exceptional case, and UCB is entitled to its costs and reasonable attorney fees.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. Judgment that the '215 patent remains valid and enforceable;
- B. Judgment that TEVA has infringed one or more claims of the '215 patent by filing TEVA's ANDAs relating to TEVA's Drug Products;
- C. Judgment that TEVA has infringed one or more claims of the '215 patent under 35 U.S.C. § 271(a) by making, using, selling, offering for sale, and/or importing into the United States TEVA's Drug Products;
- D. Judgment that TEVA has infringed one or more claims of the '215 patent under 35 U.S.C. § 271(b) by actively inducing, encouraging, aiding, and abetting administration of TEVA's Drug Products under TEVA's ANDAs;
- E. Judgment that, as a result of those infringing activities, TEVA owes Plaintiffs monetary damages to the full extent allowed by law;
- F. A permanent injunction under 35 U.S.C. § 283 restraining and enjoining TEVA and its officers, agents, attorneys, and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of TEVA's Drug Products;



G. Judgment that TEVA's infringement has been willful, that this is an exceptional case, and that Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285;

H. To the extent that TEVA has committed any acts with respect to the subject matter claimed in the '215 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

I. Pre-judgment and post-judgment interest;

J. Costs and expenses in this action; and

K. Such other and further relief as this Court may deem just, equitable, and proper.

### **DEMAND FOR JURY TRIAL**

Under Federal Rule of Civil Procedure 38, Plaintiffs hereby demand a trial by jury of all issues in this case that are so triable as of right.

*/s/ Fredric J. Bold, Jr.* \_\_\_\_\_

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December 21, 2012

**RULE 7.1D CERTIFICATE OF FONT SIZE**

Under Local Rule 7.1D of the United States District Court of the Northern District of Georgia, I certify that the foregoing submission was prepared using 14 point Times New Roman font.

*/s/ Fredric J. Bold, Jr.* \_\_\_\_\_

Fredric J. Bold, Jr.

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