

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UCB, INC. and UCB MANUFACTURING, )  
INC., )  
 )  
Plaintiffs, )  
 )  
v. ) C.A. No. \_\_\_\_\_  
 )  
MALLINCKRODT, INC., )  
 )  
Defendant. )

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs UCB, Inc. and UCB Manufacturing, Inc., for their complaint herein against Defendant Mallinckrodt, Inc., allege as follows:

**PARTIES**

1. 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.
2. 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, NY 14623.
3. UCB, Inc. and UCB Manufacturing, Inc. are at times collectively referred to hereinafter, as “Plaintiffs” or “UCB.”
4. On information and belief, Defendant Mallinckrodt Inc. (hereinafter “Mallinckrodt”) is a corporation organized and existing under the laws of the State of Delaware, and having an office and place of business at 675 McDonnell Blvd., Hazelwood, MO 63042.

**JURISDICTION AND VENUE**

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

6. This Court has personal jurisdiction over Mallinckrodt because it is incorporated in the State of Delaware. Mallinckrodt also does business and sells its generic pharmaceutical products in this District as well as throughout the United States.

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

**CLAIM FOR RELIEF**

8. UCB realleges paragraphs 1-7 above, as if set forth specifically here.

9. United States Patent No. 6,344,215 (“the ‘215 patent”), entitled “Methylphenidate Modified Release Formulations,” 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.

10. 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.

11. UCB 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®.

12. 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 tradename METADATE CD®.

13. On information and belief, Mallinckrodt has filed with the FDA an Abbreviated New Drug Application ("ANDA") No. 203583 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and/or sale of generic methylphenidate hydrochloride capsules before the expiration of the '215 patent.

14. On information and belief, Mallinckrodt has included in its ANDA a notice of certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, its generic product does not infringe the '215 patent. UCB received a notice of certification on or about March 1, 2012.

15. Mallinckrodt has infringed the '215 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 203583 seeking approval by the FDA to engage in the commercial manufacture, use, and/or sale of generic methylphenidate hydrochloride capsules before the expiration of the '215 patent.

16. Mallinckrodt's proposed methylphenidate hydrochloride capsules would, if approved and marketed, infringe the '215 patent.

17. On information and belief, Mallinckrodt is aware that its proposed methylphenidate hydrochloride capsules, if approved, will be made, used and/or sold in contravention of UCB's rights under the '215 patent.

18. UCB is entitled to full relief from Mallinckrodt's acts of infringement under 35 U.S.C. § 271(e)(4), including an Order by this Court that the effective date of any approval of Mallinckrodt's ANDA be a date that is not earlier than the expiration date for the

'215 patent (currently October 27, 2020), or any other expiration of exclusivity to which UCB is or becomes entitled.

19. Mallinckrodt was aware of the existence of the '215 patent and, upon information and belief, was aware that the filing of its ANDA and certification with respect to the '215 patent constituted an act of infringement of that patent.

20. 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. A judgment that the '215 patent has been infringed by Mallinckrodt;
- B. A judgment declaring that the effective date of any approval of Mallinckrodt's ANDA No. 203583 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for Mallinckrodt's proposed methylphenidate hydrochloride capsules be no earlier than October 27, 2020, the expiration date of the '215 patent, or any later date of exclusivity to which UCB is or becomes entitled;
- C. A permanent injunction against any infringement of the '215 patent by Mallinckrodt, its officers, agents, attorneys, and employees, and those acting in privity or concert with them;
- D. Costs and expenses in this action, including reasonable attorney fees pursuant to 35 U.S.C. §285; and
- E. Such other and further relief as this Court may deem proper.

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