IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	C.A. No. _____

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc. ("Par") and Alkermes Pharma Ireland Limited ("Alkermes") (collectively, "Plaintiffs"), for their Complaint against Defendant Breckenridge Pharmaceutical, Inc., allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 6,592,903 (the "'903 patent") and 7,101,576 (the "'576 patent") pursuant to the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

PARTIES

2. Plaintiff Par is a corporation organized under the laws of Delaware, with its principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey.

3. Plaintiff Alkermes is an Irish corporation having a principal place of business at Monksland, Athlone, Co. Westmeath, Ireland.

4. Upon information and belief, Defendant is an entity organized under the laws of Florida, with its principal place of business at 1141 S. Rogers Circle, Boca Raton, Florida.

JURISDICTION

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271(e)(2).

6. Upon information and belief, Defendant is in the business of making and selling generic pharmaceutical products, which it distributes, markets, and/or sells in Delaware, and throughout the United States.

7. Upon information and belief, Defendant has previously submitted to the jurisdiction of the United States District Court for the District of Delaware, for example, in C.A. Nos. 11-1070-GMS and 12-810-SLR.

8. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, Defendant's continuous and systematic contacts with corporate entities within this judicial district, its previous submission to the jurisdiction of this judicial district, and its marketing and sales activities in this judicial district, including, but not limited to the substantial, continuous and systematic distribution, marketing and/or sales of generic pharmaceutical products to residents of this judicial district.

VENUE

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

PATENTS-IN-SUIT

10. Plaintiff Alkermes is the lawful owner of the '903 patent.

11. The ’903 patent, entitled “Nanoparticulate Dispersions Comprising a Synergistic Combination of a Polymeric Surface Stabilizer and Dioctyl Sodium Sulfosuccinate,” duly and legally issued on July 15, 2003, naming Niels P. Ryde and Stephen B. Ruddy as inventors. A copy of the ’903 patent is attached as Exhibit A.

12. Plaintiff Alkermes is the lawful owner of the ‘576 patent.

13. The ’576 patent, entitled “Nanoparticulate Megestrol Formulations,” duly and legally issued on September 5, 2006, naming Douglas Hovey, John Pruitt, and Tuula Ryde as inventors. A copy of the ’576 patent is attached as Exhibit B.

MEGACE® ES

14. Plaintiff Par is the holder of New Drug Application (“NDA”) No. 21-778 for Megace® ES (megestrol acetate) oral suspension, 125 mg/mL, and is an exclusive licensee of the ’576 and ’903 patents with respect to Megace® ES in the United States.

15. On July 5, 2005, the FDA approved NDA No. 21-778 for the manufacture, marketing, and sale of Megace® ES (megestrol acetate) oral suspension for the treatment of appetite loss, severe malnutrition, or unexplained, significant weight loss in AIDS patients. Plaintiff Par has sold Megace® ES under NDA No. 21-778 since its approval.

16. The ’903 and ’576 patents are listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) as covering Par’s product Megace® ES.

DEFENDANT’S ANDA

17. Upon information and belief, Defendant submitted ANDA No. 20-4688 to the FDA under 35 U.S.C. § 355(j), seeking approval to engage in commercial manufacture, use,

and/or sale of megestrol acetate oral suspension, 125 mg/mL, ("Defendant's Generic Product") before expiration of the '903 and '576 patents.

18. Upon information and belief, ANDA No. 20-4688 refers to and relies upon Plaintiff Par's NDA for Megace® ES and purports to contain data showing bioequivalence of Defendant's Generic Product with Megace® ES.

19. Plaintiffs received from Defendant a letter dated May 16, 2013 (the "Notification Letter"), stating that ANDA No. 20-4688 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the '903 and '576 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Defendant's Generic Product.

20. Plaintiffs commenced this action within 45 days of receiving the Notification Letter.

COUNT ONE

(Infringement of the '576 Patent under 35 U.S.C. § 271(e)(2))

21. Plaintiffs reallege paragraphs 1-20 above as if fully set forth herein.

22. Defendant's submission of ANDA No. 20-4688 to the FDA with a Paragraph IV certification regarding the '576 patent, seeking approval to engage in commercial manufacture, use, and/or sale of Defendant's Generic Product before the expiration of the '576 patent, constitutes infringement of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT TWO

(Declaratory Judgment of Infringement of the '576 Patent under 35 U.S.C. § 271(a)-(c))

23. Plaintiffs reallege paragraphs 1-20 above as if fully set forth herein.

24. Upon information and belief, Defendant intends, soon after the FDA has approved its ANDA No. 20-4688, to begin the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product.

25. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, Defendant's Generic Product before expiration of the '576 patent.

26. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product before expiration of the '576 patent.

27. Defendant's actions, including without limitation the filing of ANDA No. 20-4688, exhibit a refusal to change the course of its action despite Plaintiffs' patent rights.

28. Upon information and belief, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product before expiration of the '576 patent, and the active inducement of and/or contribution to any of those activities, will constitute infringement, inducement of infringement and/or contributory infringement of the '576 patent.

29. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product before expiration of the '576 patent by

Defendant or its agents, will constitute infringement, inducement of infringement and/or contributory infringement of the ’576 patent.

COUNT THREE

(Infringement of the ’903 Patent under 35 U.S.C. § 271(e)(2))

30. Plaintiffs reallege paragraphs 1-20 above as if fully set forth herein.

31. Defendant’s submission of ANDA No. 20-4688 to the FDA with a Paragraph IV certification regarding the ’903 patent, seeking approval to engage in commercial manufacture, use, and/or sale of Defendant’s Generic Product before the expiration of the ’903 patent, constitutes infringement of the ’903 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT FOUR

(Declaratory Judgment of Infringement of the ’903 Patent under 35 U.S.C. § 271(a)-(c))

32. Plaintiffs reallege paragraphs 1-20 above as if fully set forth herein.

33. Upon information and belief, Defendant intends, soon after the FDA has approved its ANDA No. 20-4688, to begin the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant’s Generic Product.

34. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, or sell within the United States, and/or import into the United States, Defendant’s Generic Product before expiration of the ’903 patent.

35. Upon information and belief, Defendant has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant’s Generic Product before expiration of the ’903 patent.

36. Defendant's actions, including without limitation the filing of ANDA No. 20-4688, exhibit a refusal to change the course of its action despite Plaintiffs' patent rights.

37. Upon information and belief, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product before expiration of the '903 patent, and the active inducement of and/or contribution to any of those activities, will constitute infringement, inducement of infringement and/or contributory infringement of the '903 patent.

38. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Defendant's Generic Product before expiration of the '903 patent by Defendant or its agents, will constitute infringement, inducement of infringement and/or contributory infringement of the '903 patent.

INJUNCTIVE RELIEF

39. Plaintiffs will be substantially and irreparably damaged and harmed by Defendant's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

EXCEPTIONAL CASE

40. Defendant has at all relevant times been aware of the '576 and '903 patents, and has had no good faith basis for its infringement of that patent. This is an exceptional case under 35 U.S.C. §285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

A. Enter a judgment that Defendant has infringed the ’576 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-4688 to the FDA, seeking approval to engage in commercial manufacture, use, offer to sell or sale of Defendant’s Generic Product before expiration of the ’576 patent;

B. Enter a declaration under 28 U.S.C. § 2201 that Defendant would infringe the ’576 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell or sale within the United States, or importation into the United States, of Defendant’s Generic Product before expiration of the ’576 patent;

C. Enter a judgment that Defendant has infringed the ’903 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 20-4688 to the FDA, seeking approval to engage in commercial manufacture, use, offer to sell or sale of Defendant’s Generic Product before expiration of the ’903 patent;

D. Enter a declaration under 28 U.S.C. § 2201 that Defendant would infringe the ’903 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell or sale within the United States, or importation into the United States, of Defendant’s Generic Product before expiration of the ’903 patent;

E. Enter an order under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA No. 20-4688, if any, shall be no earlier than the date of expiration of each patent-in-suit Defendant is found to infringe, including any extensions;

F. Enter an injunction under 35 U.S.C. §§ 271(e)(4)(b) and 283 permanently enjoining Defendant, its officers, agents, servants, employees, licensees, representatives, and

attorneys, and all other persons acting or attempting to act in concert or participation with them or on their behalf, from engaging in commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendant's Generic Product before the expiration of each patent-in-suit Defendant is found to infringe, including any extensions;

G. Grant Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Defendant commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Defendant's Generic Product before the expiration of each patent-in-suit Defendant is found to infringe, including any extensions;

H. Declare that Defendant's activities have made this an exceptional case under 35 U.S.C. § 285 and grant Plaintiffs their attorneys' fees; and

I. Award Plaintiffs any further and additional relief as this Court may deem just and proper.

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