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.	Civil Action No. _____

COMPLAINT

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

NATURE OF ACTION

1. This is a civil action for infringement of U.S. Patent Nos. 9,101,540 (the "'540 Patent"), 9,101,549 (the "'549 Patent"), and 9,107,827 (the "'827 Patent") (collectively, the "Patents-in-Suit") pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, including 35 U.S.C. § 271, 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.* This action relates to Defendant Breckenridge's Abbreviated New Drug Application ("ANDA") No. 20-4688. Defendant filed or caused to be filed ANDA No. 20-4688 under 21 U.S.C. § 355(j) with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiff Par's successful Megace® ES (megestrol acetate) drug product that is sold in the United States, including in the State of Delaware.

2. Plaintiffs also seek to enjoin and restrain Defendant's efforts to export, import, distribute, market, offer to sell, and/or sell a generic version of Plaintiff Par's Megace® ES (megestrol acetate) drug product.

PARTIES

3. Plaintiff Par is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Chestnut Ridge, NY 10977.

4. Plaintiff Alkermes is an Irish corporation having a principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland.

5. Upon information and belief, Defendant Breckenridge is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, Florida 33487.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Breckenridge because, *inter alia*: (a) Breckenridge has purposefully directed its activities at residents and corporate entities within the State of Delaware; (b) the claims set forth herein arise out of or relate to those activities; (c) Breckenridge's contacts with the State of Delaware (direct and/or indirect) are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Breckenridge.

8. Upon information and belief, Breckenridge is, *inter alia*, in the business of researching, developing, seeking regulatory approval for, commercializing, producing, and manufacturing drug products. Breckenridge further markets, distributes, transfers, offers to sell, and sells its drug products (directly and through affiliates) throughout the United States, including the State of Delaware.

9. Upon information and belief, Breckenridge has affirmatively engaged in continuous and systematic contacts with corporate entities in the State of Delaware.

10. Upon information and belief, Breckenridge has appeared as a litigant in the State of Delaware as a: (a) plaintiff alleging four causes of action, including patent infringement, in *Pamlab L.L.C., et al. v. Acella Pharma., LLC*, 1:12-cv-01403-SLR (D. Del.); and (b) defendant in approximately thirteen (13) cases, with Breckenridge filing counterclaims in eight (8) of those cases.

11. Upon information and belief, Breckenridge has never contested jurisdiction in the United States District Court for the District of Delaware in any case where it was named as a defendant, including two related cases currently pending before Judge Sue L. Robinson where Plaintiffs Par and Alkermes allege that Breckenridge infringes other patents covering Par's Megace® ES (megestrol acetate) drug product, based on Breckenridge's submission of the same ANDA No. 20-4688.

a. In *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, 1:13-cv-01114-SLR-SRF (D. Del.), Plaintiffs allege that Breckenridge's ANDA Product infringes U.S. Patent Nos. 6,592,903 (the "'903 Patent") and 7,101,576 (the "'576 Patent"). Breckenridge filed an Amended Answer and Counterclaims requesting that this Court enter declarations of invalidity,

non-infringement, and collateral estoppel as to those two patents covering Par's Megace® ES (megestrol acetate) drug product.

b. In *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, 1:15-cv-00486-SLR-SRF (D. Del.), Plaintiffs allege that Breckenridge's ANDA Product infringes U.S. Patent No. 9,040,088. Breckenridge's response to that action is to be filed on or before December 2, 2015.

12. Breckenridge sent Plaintiffs a letter dated May 16, 2013 (the "Breckenridge 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 Breckenridge's ANDA Product (the "Breckenridge Paragraph IV Certification"). The '903 and '576 Patents, like the Patent-in-Suit, cover Par's Megace® ES drug product.

13. On June 28, 2013, Breckenridge issued a press release announcing the Breckenridge Paragraph IV Certification. Breckenridge's press release describes Megace® ES, stating that it "generated sales of $81M, based on industry sales data." The press release further states that "Breckenridge's latest patent challenge regarding megestrol acetate is a continuing part of its larger aggressive Paragraph IV strategy commenced a few years ago." A copy of the Breckenridge press release is attached hereto as Exhibit A.

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

PATENTS-IN-SUIT

15. Plaintiff Alkermes is the lawful owner of the '540, '549, and '827 Patents.

16. The '540 Patent, entitled "Nanoparticulate Megestrol Formulations," duly and legally issued on August 11, 2015 naming Douglas Hovey, John Pruitt, and Tuula Ryde as

inventors. The claims of the ’540 Patent cover Par’s Megace® ES (megestrol acetate) drug product. A copy of the ’540 Patent is attached hereto as Exhibit B.

17. The ’549 Patent, entitled “Nanoparticulate Megestrol Formulations,” duly and legally issued on August 11, 2015 naming Douglas Hovey, John Pruitt, and Tuula Ryde as inventors. The claims of the ’549 Patent cover Par’s Megace® ES (megestrol acetate) drug product. A copy of the ’549 Patent is attached hereto as Exhibit C.

18. The ’827 Patent, entitled “Nanoparticulate Megestrol Formulations,” duly and legally issued on August 18, 2015 naming Douglas Hovey, John Pruitt, and Tuula Ryde as inventors. The claims of the ’827 Patent cover Par’s Megace® ES (megestrol acetate) drug product. A copy of the ’827 Patent is attached hereto as Exhibit D.

MEGACE® ES

19. 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 ’540, ’549, and ’827 Patents with respect to Par’s Megace® ES (megestrol acetate) drug product in the United States.

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

DEFENDANT’S ANDA

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

manufacture, use, and/or sale of megestrol acetate, oral suspension, 125 mg/mL (the "Breckenridge ANDA Product") before expiration of the '540, '549, and '827 Patents. Breckenridge's ANDA No. 20-4688 is currently the subject of two related actions currently pending in this district. *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, 1:13-cv-01114-SLR-SRF (D. Del.); *Par Pharm., Inc. v. Breckenridge Pharm., Inc.*, 1:15-cv-00486-SLR-SRF (D. Del.).

22. Upon information and belief, Breckenridge's ANDA No. 20-4688 refers to and relies upon the NDA for Par's Megace® ES (megestrol acetate) drug product (*i.e.*, NDA No. 21-778) and purports to contain data showing bioequivalence of the Breckenridge ANDA Product with Par's Megace® ES (megestrol acetate) drug product.

23. The filing of ANDA No. 20-4688 evidences Breckenridge's intent to compete with Par and place the Breckenridge ANDA Product into the State of Delaware where Par's Megace® ES (megestrol acetate) drug product is currently sold.

COUNT ONE

(Breckenridge's Infringement of the '540 Patent under 35 U.S.C. § 271(e)(2)(A))

24. Plaintiffs reallege Paragraphs 1 to 23 above as if fully set forth herein.

25. Breckenridge's submission of ANDA No. 20-4688 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of the Breckenridge ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the '540 Patent constitutes infringement of the '540 Patent under 35 U.S.C. § 271(e)(2)(A).

COUNT TWO

(Declaratory Judgment of Breckenridge's Infringement of the '540 Patent under 35 U.S.C. §§ 271(a)-(c))

26. Plaintiffs reallege Paragraphs 1 to 25 above as if fully set forth herein.

27. Upon information and belief, Breckenridge submitted ANDA No. 20-4688 to the FDA seeking approval for the commercial manufacture, use, and sale of the Breckenridge

ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the ’540 Patent.

28. Upon information and belief, Breckenridge 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, the Breckenridge ANDA Product before expiration of the ’540 Patent.

29. Upon information and belief, Breckenridge 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 the Breckenridge ANDA Product before expiration of the ’540 Patent.

30. Breckenridge’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.

31. 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 the Breckenridge ANDA Product before expiration of the ’540 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 ’540 Patent.

32. 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 the Breckenridge ANDA 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 the Breckenridge ANDA Product before expiration of the

’540 Patent by Breckenridge or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the ’540 Patent.

COUNT THREE

(Breckenridge’s Infringement of the ’549 Patent under 35 U.S.C. § 271(e)(2)(A))

33. Plaintiffs reallege Paragraphs 1 to 32 above as if fully set forth herein.

34. Breckenridge’s submission of ANDA No. 20-4688 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of the Breckenridge ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the ’549 Patent constitutes infringement of the ’549 Patent under 35 U.S.C. § 271(e)(2)(A).

COUNT FOUR

(Declaratory Judgment of Breckenridge’s Infringement of the ’549 Patent under 35 U.S.C. §§ 271(a)-(c))

35. Plaintiffs reallege Paragraphs 1 to 34 above as if fully set forth herein.

36. Upon information and belief, Breckenridge submitted ANDA No. 20-4688 to the FDA seeking approval for the commercial manufacture, use, and sale of the Breckenridge ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the ’549 Patent.

37. Upon information and belief, Breckenridge 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, the Breckenridge ANDA Product before expiration of the ’549 Patent.

38. Upon information and belief, Breckenridge 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 the Breckenridge ANDA Product before expiration of the ’549 Patent.

39. Breckenridge'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.

40. 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 the Breckenridge ANDA Product before expiration of the '549 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 '549 Patent.

41. 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 the Breckenridge ANDA 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 the Breckenridge ANDA Product before expiration of the '549 Patent by Breckenridge or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the '549 Patent.

COUNT FIVE

(Breckenridge's Infringement of the '827 Patent under 35 U.S.C. § 271(e)(2)(A))

42. Plaintiffs reallege Paragraphs 1 to 41 above as if fully set forth herein.

43. Breckenridge's submission of ANDA No. 20-4688 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of the Breckenridge ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the '827 Patent constitutes infringement of the '827 Patent under 35 U.S.C. § 271(e)(2)(A).

COUNT SIX

(Declaratory Judgment of Breckenridge's Infringement of the '827 Patent under 35 U.S.C. §§ 271(a)-(c))

44. Plaintiffs reallege Paragraphs 1 to 43 above as if fully set forth herein.

45. Upon information and belief, Breckenridge submitted ANDA No. 20-4688 to the FDA seeking approval for the commercial manufacture, use, and sale of the Breckenridge ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the ’827 Patent.

46. Upon information and belief, Breckenridge 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, the Breckenridge ANDA Product before expiration of the ’827 Patent.

47. Upon information and belief, Breckenridge 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 the Breckenridge ANDA Product before expiration of the ’827 Patent.

48. Breckenridge’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.

49. 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 the Breckenridge ANDA Product before expiration of the ’827 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 ’827 Patent.

50. 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 the Breckenridge ANDA 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 the Breckenridge ANDA Product before expiration of the '827 Patent by Breckenridge or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the '827 Patent.

INJUNCTIVE RELIEF

51. Plaintiffs reallege Paragraphs 1 to 50 above as if fully set forth herein.

52. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

A. Enter a Declaration under 28 U.S.C. § 2201 that Breckenridge would infringe the '540, '549, and '827 Patents 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 the Breckenridge ANDA Product before expiration of the '540, '549, and '827 Patents, including any extensions;

B. 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 the '540, '549, and '827 Patents, including any extensions;

C. 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 Defendant or on its behalf, from engaging in the commercial manufacture, use, offer to sell, or

sale within the United States, or importation into the United States, of the Breckenridge ANDA Product before expiration of the ’540, ’549, and ’827 Patents, including any extensions;

D. 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, the Breckenridge ANDA Product before expiration of the ’540, ’549, and ’827 Patents, including any extensions;

E. Declare that Defendant’s activities have made this an exceptional case under 35 U.S.C. § 285 and grant Plaintiffs’ attorney’s fees; and

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

DATED: November 11, 2015

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