IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC. and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., TWI PHARMACEUTICALS, INC., and TWI PHARMACEUTICALS USA, INC., Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc. ("Par") and Alkermes Pharma Ireland Limited ("Alkermes") (collectively, "Plaintiffs"), for their Complaint against Defendants Breckenridge Pharmaceutical, Inc. ("Breckenridge"); TWi Pharmaceuticals, Inc. ("TWi-Taiwan"); and TWi Pharmaceuticals USA, Inc. ("TWi-USA") (collectively, "Defendants"), herein allege as follows:

NATURE OF ACTION

1. This is a civil action for infringement of U.S. Patent No. 9,040,088 (the "'088 Patent") 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: (a) Defendant Breckenridge's Abbreviated New Drug Application ("ANDA") No. 20-4688; and (b) Defendants TWi-Taiwan and TWi-USA's (collectively, "TWi") ANDA No. 20-3139. These Defendants respectively filed or caused to be filed ANDA Nos. 20-4688 and 20-3139 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 Defendants' efforts to export, import, distribute, market, 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.

6. Upon information and belief, Defendant TWi-Taiwan is a corporation organized and existing under the laws of Taiwan, having a principal place of business at No. 41, Lane 221, Kang Chien Road, Nei Hu District, Tai Pei 114, Taiwan.

7. Upon information and belief, Defendant TWi-USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8001 Irvine Center Drive, Irvine, California 92618. TWi-USA is a wholly-owned subsidiary of TWi-Taiwan. TWi-USA acts at the direction, under the control, and for the benefit of TWi-Taiwan. TWi-USA is controlled and/or dominated by TWi-Taiwan.

JURISDICTION AND VENUE

8. 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).

9. This Court has personal jurisdiction over Breckenridge, *inter alia*, because: (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.

10. 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.

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

12. 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 twelve (12) cases, with Breckenridge filing counterclaims in eight (8) of those cases.

13. Upon information and belief, Breckenridge has never contested jurisdiction in the U.S. District Court, District of Delaware in any case where it was named as a defendant, including a related case currently pending before Judge Sue L. Robinson where Plaintiffs Par and Alkermes allege that Breckenridge infringes two other patents covering Par's Megace® ES (megestrol acetate) drug product. *Par Pharm., Inc., et al. v. Breckenridge Pharm., Inc.*, 1:13-cv-01114-SLR-SRF (D. Del.). In that case, Breckenridge filed an Amended Answer and Counterclaims requesting that this Court enter declarations of invalidity, non-infringement, and collateral estoppel as to those patents.

14. This Court has personal jurisdiction over TWi-Taiwan, *inter alia*, because TWi-Taiwan has waived any objection and consented to this Court's jurisdiction. TWi-Taiwan availed itself of the benefits and protections of this Court when it filed a Motion to Compel and two briefs in support thereof in *In re Aptalis Pharma, Inc.*, 1:12-mc-00234-GMS (D. Del.).

15. This Court also has personal jurisdiction over TWi-Taiwan, *inter alia*, because: (a) TWi-Taiwan has purposefully directed its activities and the activities of its wholly-owned subsidiary, TWi-USA, at residents and corporate entities within the State of Delaware; (b) the claims set forth herein as to TWi-Taiwan arise out of or relate to those activities; (c) TWi-Taiwan'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 TWi-Taiwan.

16. Upon information and belief, TWi-Taiwan and TWi-USA are agents of each other and/or work in concert with each other to develop, seek regulatory approval for, commercialize, produce, manufacture, market, export, import, distribute, transfer, and sell drug products

throughout the United States, including the State of Delaware. TWi-USA acts on behalf of and/or at the direction of TWi-Taiwan.

17. Upon information and belief, TWi-Taiwan is, *inter alia*, in the business of researching, developing, seeking regulatory approval for, commercializing, producing, and manufacturing drug products. TWi-Taiwan then arranges (directly and through its wholly-owned subsidiary, TWi-USA) for the export to and import into the United States of those drug products. TWi-Taiwan further markets, distributes, transfers, offers to sell, and sells its drug products (directly and through TWi-USA and/or its affiliates) throughout the United States, including the State of Delaware.

18. Upon information and belief, TWi-Taiwan has assembled a sales and distribution team in the United States with plans to launch several drug products in the United States under TWi-Taiwan's label in 2015. TWi-Taiwan knows and intends that these efforts will result in the marketing, distribution, transfer, offer to sell, and sale of its products throughout the United States, and the export of its products to and import of its products into the United States, including the State of Delaware.

19. Upon information and belief, TWi-Taiwan personnel have been in contact with distributors and wholesalers in the United States, including those who distribute and sell drug products in the State of Delaware, with the expectation that TWi-Taiwan will sell its drug products under its own labels through those distribution channels.

20. Upon information and belief, TWi-USA has obtained licenses to sell TWi-Taiwan's drug products in all 50 states, including the State of Delaware.

21. Upon information and belief, TWi-Taiwan has already begun (directly and through its wholly-owned subsidiary, TWi-USA) marketing, exporting, importing, distributing,

transferring, offering to sell, and/or selling its drug products under its own name and label in all 50 states, including the State of Delaware. That label represents to U.S. consumers, including consumers in the State of Delaware, that the drug product is: (a) manufactured by "TWi Pharmaceuticals, Inc., Chungli City, Taoyuan County 320, Taiwan"; and (b) distributed by "TWi Pharmaceuticals USA, Irvine, CA 92618." TWi's label for the sale of a generic version of Plaintiff Par's Megace® ES (megestrol acetate) drug product is attached hereto as Exhibit A. *See also* TWi Label for Megestrol Acetate Oral Suspension, USP, *available at* http://medlibrary.org/ lib/rx/meds/megestrol-acetate-10/page/4/.

22. Upon information and belief, TWi-Taiwan intends to market, export, import, distribute, transfer, offer to sell, and sell a generic version of Par's Megace® ES (megestrol acetate) drug product throughout the United States, including the State of Delaware.

23. Should TWi-Taiwan deny all bases for personal jurisdiction alleged in Paragraphs 14 to 26, this Court has personal jurisdiction over TWi-Taiwan under: (a) Fed. R. Civ. P. 4(k)(1); and/or (b) Fed. R. Civ. P. 4(k)(2).

24. This Court has personal jurisdiction over TWi-USA, *inter alia*, because TWi-USA is a resident and citizen of the State of Delaware. TWi-USA has therefore availed itself of the rights, benefits, and privileges of Delaware's laws by incorporating in Delaware. TWi-USA has further appointed a registered agent in the State of Delaware: B. Christopher Daney, 4550 New Linden Hill Road, Suite 201, Wilmington, DE 19808.

25. This Court also has personal jurisdiction over TWi-USA, *inter alia*, because: (a) TWi-USA has purposefully directed its activities at residents and corporate entities within the State of Delaware; (b) the claims set forth herein as to TWi-USA arise out of or relate to those activities; (c) TWi-USA'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 TWi-USA.

26. Upon information and belief, TWi-USA is, *inter alia*, in the business of researching, developing, seeking regulatory approval for, commercializing, producing, and manufacturing drug products. TWi-USA then arranges (directly and through its parent, TWi-Taiwan) for the export to and import into the United States of those drug products. TWi-USA further markets, distributes, transfers, offers to sell, and sells (directly and through TWi-Taiwan and/or its affiliates) those drug products throughout the United States, including the State of Delaware.

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

PATENT IN-SUIT

28. Plaintiff Alkermes is the lawful owner of the ’088 Patent.

29. The ’088 Patent, entitled “Nonoparticulate Megestrol Formulations,” duly and legally issued on May 26, 2015 naming Douglas Hovey, John Pruitt, and Tuula Ryde as inventors. A copy of the ’088 Patent is attached hereto as Exhibit B.

MEGACE® ES

30. 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 ’088 Patent with respect to Par’s Megace® ES (megestrol acetate) drug product in the United States.

31. 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.

DEFENDANTS' ANDAS

32. 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 '088 Patent. Breckenridge's ANDA No. 20-4688 is currently the subject of a related litigation currently pending in this district. *Par Pharm., Inc., et al. v. Breckenridge Pharm., Inc.*, 1:13-cv-01114-SLR-SRF (D. Del.).

33. 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. 21-788) and purports to contain data showing bioequivalence of the Breckenridge ANDA Product with Par's Megace® ES (megestrol acetate) drug product.

34. Upon information and belief, TWi submitted ANDA No. 20-3139 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 "TWi ANDA Product") before expiration of the '088 Patent.

35. Upon information and belief, TWi's ANDA No. 20-3139 refers to and relies upon the NDA for Par's Megace® ES (megestrol acetate) drug product (*i.e.*, NDA No. 21-788) and purports to contain data showing bioequivalence of the TWi ANDA Product with Par's Megace® ES (megestrol acetate) drug product.

36. The filing of ANDA Nos. 20-4688 and 20-3139 evidence Defendants' intent to compete with Par and respectively place the Breckenridge and TWi ANDA Products into every

market where Par's Megace® ES (megestrol acetate) drug product is currently found, including the State of Delaware.

COUNT ONE

(Breckenridge's Infringement of the '088 Patent under 35 U.S.C. § 271(e)(2)(A))

37. Plaintiffs reallege Paragraphs 1 to 36 above as if fully set forth herein.

38. 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 '088 Patent constitutes infringement of the '088 Patent under 35 U.S.C. § 271(e)(2)(A).

COUNT TWO

(Declaratory Judgment of Breckenridge's Infringement of the '088 Patent under 35 U.S.C. §§ 271(a)-(c))

39. Plaintiffs reallege Paragraphs 1 to 38 above as if fully set forth herein.

40. 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 '088 Patent.

41. 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 '088 Patent.

42. 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 ’088 Patent.

43. 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.

44. 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 ’088 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 ’088 Patent.

45. 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 ’088 Patent by Breckenridge or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the ’088 Patent.

COUNT THREE

(TWi’s Infringement of the ’088 Patent under 35 U.S.C. § 271(e)(2)(A))

46. Plaintiffs reallege Paragraphs 1 to 45 above as if fully set forth herein.

47. TWi’s submission of ANDA No. 20-3139 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of the TWi ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the ’088 Patent constitutes infringement of the ’088 Patent under 35 U.S.C. § 271(e)(2)(A).

COUNT FOUR

(Declaratory Judgment of TWi's Infringement of the '088 Patent under 35 U.S.C. §§ 271(a)-(c))

48. Plaintiffs reallege Paragraphs 1 to 47 above as if fully set forth herein.

49. Upon information and belief, TWi submitted ANDA No. 20-3139 to the FDA seeking approval for the commercial manufacture, use, and sale of the TWi ANDA Product throughout the United States, including the State of Delaware, prior to the expiration of the '088 Patent.

50. Upon information and belief, TWi has stated in judicial proceedings that they are ready to immediately begin the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or export to and importation into the United States, of the TWi ANDA Product. TWi has further announced publicly that they have "completed the pre-launch preparation" of a generic Megace® ES (megestrol acetate) drug product, and "the product will be launched immediately" once other constraints to its entry to the U.S. market are removed.

51. Upon information and belief, TWi 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 export to and import into the United States, the TWi ANDA Product before expiration of the '088 Patent. TWi has stated publicly that they have "been in close contact with the major nationwide retail pharmacy distributors and wholesalers and expects to have [their] own label specialty generic products," which could include the TWi ANDA Product, "sold through these nationwide pharmacy distribution channels soon in the U.S. pharma market." *See TWi Pharmaceuticals USA Announces the Receipt of State Sales Licenses from All 50 States in the U.S.*, TWi Press Release (April 17, 2014) *available at* http://www.prnewswire.com/news-

releases/twi-pharmaceuticals-usa-announces-the-receipt-of-state-sales-licenses-from-all-50-states-in-the-us-300067721.html.

52. Upon information and belief, TWi 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 export to and importation into the United States, of the TWi ANDA Product before expiration of the '088 Patent.

53. TWi's actions, including without limitation the filing of ANDA No. 20-3139, exhibit a refusal to change the course of their actions despite Plaintiffs' patent rights.

54. 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 TWi ANDA Product before expiration of the '088 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 '088 Patent.

55. 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 TWi 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 TWi ANDA Product before expiration of the '088 Patent by TWi or its agents, will constitute infringement, inducement of infringement, and/or contributory infringement of the '088 Patent.

INJUNCTIVE RELIEF

56. Plaintiffs reallege Paragraphs 1 to 55 above as if fully set forth herein.

57. Plaintiffs will be substantially and irreparably damaged and harmed by Defendants' 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 each Defendant would infringe the '088 Patent under one or more of 35 U.S.C. §§ 271(a)-(c) by their respective manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Breckenridge or TWi ANDA Products before expiration of the '088 Patent, including any extensions;

B. Enter an Order under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA Nos. 20-4688 and 20-3139, if any, shall be no earlier than the date of expiration of the '088 Patent, including any extensions;

C. Enter an injunction under 35 U.S.C. §§ 271(e)(4)(b) and 283 permanently enjoining Defendants, their 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 their respective commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the Breckenridge or TWi ANDA Products before expiration of the '088 Patent, 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, respectively, Defendants commercially manufacture, use, offer to sell, or sell in the United States, or import into the

United States, the Breckenridge or TWi ANDA Products before expiration of the '088 Patent, including any extensions;

E. Declare that Defendants' 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.

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