IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC. and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. TWI PHARMACEUTICALS, INC. and TWI PHARMACEUTICALS USA, INC., Defendants.	Civil Action No. _____ **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc. ("Par") and Alkermes Pharma Ireland Limited ("Alkermes") (collectively, "Plaintiffs") for their Complaint against TWi Pharmaceuticals, Inc. ("TWi-Taiwan") and TWi Pharmaceuticals USA, Inc. ("TWi-USA") (collectively, "Defendants" or "TWi") 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") and 9,101,549 (the "'549 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, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i). This action relates to Defendants' ANDA No. 20-3139. Defendants filed or caused to be filed ANDA No. 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, 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 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.

6. 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

7. 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, and pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over TWi-Taiwan because, *inter alia*, TWi-Taiwan has waived any objection and consented to suit in the U.S. District Court for the

District of Delaware. 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.).

9. Upon information and belief, TWi-Taiwan and TWi-USA have waived any objection and consented to suit in the U.S. District Court for the District of Delaware on patent infringement claims brought by Plaintiffs Par and Alkermes on U.S. Patent No. 9,040,088 (the "'088 Patent"). *Par Pharm., Inc., et al. v. Breckenridge Pharm., Inc., et al.*, 1:15-cv-00486-SLR-SRF (D. Del.) (the "Related Megace Action"). The '088 Patent is a family member of the Patents-in-Suit. The claims of patent infringement alleged in the Related Megace Action, which concern the '088 Patent, are related to the claims of patent infringement alleged in this suit.

10. This Court also has personal jurisdiction over TWi-Taiwan because, *inter alia*,: (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.

11. 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, offer to sell, and sell drug products in the State of Delaware. TWi-USA acts on behalf of and/or at the direction of TWi-Taiwan.

12. Upon information and belief, TWi-Taiwan and TWi-USA are, *inter alia*, in the business of researching, developing, seeking regulatory approval for, commercializing, producing, and manufacturing drug products. TWi-Taiwan has arranged (directly and through its wholly-owned subsidiary, TWi-USA) for the export to and import into the State of Delaware a generic version of Par's Megace® ES (megestrol acetate) drug product (the "TWi ANDA Product"). TWi-Taiwan further markets, distributes, transfers, offers to sell, and sells the TWi ANDA Product (directly and through TWi-USA and/or its affiliates) in the State of Delaware under its own label and/or the label of other generic drug manufacturers. The TWi ANDA Product's label represents to consumers in the State of Delaware that the TWi ANDA 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 the TWi ANDA 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/.

13. Upon information and belief, TWi-Taiwan and TWi-USA have assembled a sales and distribution team with plans to launch several drug products in the State of Delaware under TWi-Taiwan's label in 2015. That sales and distribution team has marketed and arranged for the export, import, distribution, transfer, and sale of the TWi ANDA Product in the State of Delaware.

14. Upon information and belief, TWi-Taiwan and TWi-USA personnel have been in contact with distributors and wholesalers who distribute and sell drug products in the State of Delaware. TWi-Taiwan (directly and through TWi-USA and/or its affiliates) has contracted with such distributors and wholesalers to sell the TWi ANDA Product in the State of Delaware.

15. Upon information and belief, TWi-USA has obtained or intends to obtain a license to sell TWi-Taiwan's drug products in the State of Delaware, including the TWi ANDA Product.

16. Should TWi-Taiwan deny all bases for personal jurisdiction alleged in Paragraphs 8 to 18, 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).

17. This Court has personal jurisdiction over TWi-USA because, *inter alia*, 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.

18. This Court also has personal jurisdiction over TWi-USA because, *inter alia*,: (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.

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

PATENTS-IN-SUIT

20. Plaintiff Alkermes is the lawful owner of the Patents-in-Suit.

21. The '540 Patent, entitled "Nonoparticulate 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.

22. The '549 Patent, entitled "Nonoparticulate 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.

MEGACE® ES

23. 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 Patents-in-Suit with respect to Par's Megace® ES (megestrol acetate) drug product in the United States.

24. 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' ANDA

25. 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 Patents-in-Suit. TWi's ANDA No. 20-3139 is the subject of a related litigation currently pending in this District. *Par Pharm., Inc., et al. v. Breckenridge Pharm., Inc., et al.*, 1:15-cv-00486-SLR-SRF (D. Del.).

26. 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. 21-778) and purports to contain data showing bioequivalence of the TWi ANDA Product with Par's Megace® ES (megestrol acetate) drug product.

27. The filing of ANDA No. 20-3139 evidences Defendants' intent to compete with Par and place the TWi ANDA Product into the State of Delaware where Par's Megace® ES (megestrol acetate) drug product is currently found.

HARM RESULTING FROM LAUNCH OF THE TWI ANDA PRODUCT

28. Upon information and belief, on July 29, 2015, TWi-Taiwan issued a Press Release announcing the launch of the TWi ANDA Product. A copy of the Press Release is attached hereto as Exhibit D. Since its launch, TWi-Taiwan (directly and through TWi-USA and/or its affiliates) has engaged in the marketing, exportation, importation, distribution, transfer, and sale of the TWi ANDA Product in the State of Delaware

29. On July 29, 2015, Par launched its own generic version of Par's Megace® ES (megestrol acetate) drug product (the "Par Generic Product"). Par was forced to launch the Par Generic Product due to the prospect of market erosion from the at-risk launch of the TWi ANDA Product.

30. Upon information and belief, since its launch in 2005, sales of Par's Megace® ES (megestrol acetate) drug product in the United States have exceeded $517 million and estimated profits exceeded $378 million.

31. Upon information and belief, absent the at-risk launch of the TWi ANDA Product (and the responsive launch of the Par Generic Product), future profits from the sale of Par's Megace® ES (megestrol acetate) drug product are estimated to have been at least $63.1 million.

32. Upon information and belief, over the next 24 months, even taking into account the projected sales of its own generic product, Par stands to lose an estimated $17 million to $26 million in lost profits from the at-risk launch of the TWi ANDA Product.

33. Indeed, the at-risk launch of the TWi ANDA Product (and the responsive launch of the Par Generic Product) has already resulted in erosion of the market for Par's Megace® ES (megestrol acetate) drug product. In the two weeks prior to the at-risk launch, Par shipped 2,124 units of its Megace® ES (megestrol acetate) drug product. Since the at-risk launch, Par has only shipped 216 units of its Megace® ES (megestrol acetate) drug product. This represents an 89.83% decline in the market for Par's Megace® ES (megestrol acetate) drug product.

34. Upon information and belief, erosion of the market for Par's Megace® ES (megestrol acetate) drug product due to the at-risk launch of the TWi ANDA Product (and the responsive launch of the Par Generic Product) is further reflected in prescription data. In the last full week before the at-risk launch, there were 952 prescriptions fulfilled with Par's Megace® ES (megestrol acetate) drug product. That number declined to 875 prescriptions in the first week after the at-risk launch. This reflects a one-week decline of 8.1% in fulfillment of prescriptions with Par's Megace® ES (megestrol acetate) drug product, and Par anticipates a much more significant decline throughout August 2015.

35. Since the at-risk launch of the TWi ANDA Product (and the responsive launch of the Par Generic Product), generics have already flooded the supply chain and begun to displace Par's Megace® ES (megestrol acetate) drug product from the market. Since the launch of the competing generic products on July 29, 2015, Par has shipped 5,368 units of the Par Generic Product. Upon information and belief, the TWi ANDA Product has also been sold in high volumes since July 29, 2015.

36. This high volume of sales shows that generic products are flooding the market – as high volumes of the generic products hit the market in the first few weeks of their existence, sales of the generics will rapidly displace sales of Par's Megace® ES (megestrol acetate) drug product.

37. Upon information and belief, displacement of Par's Megace® ES (megestrol acetate) drug product from the market by generic competition has already caused Par significant financial harm. Par's Megace® ES (megestrol acetate) drug product, which has sold only 216 units since the at-risk launch, has a wholesale acquisition cost ("WAC") of $832.05. The Par Generic Product, which has sold 5,368 units since the at-risk launch, has a WAC of $332.82. Assuming those orders for the Par Generic Product would have eventually been filled with Par's Megace® ES (megestrol acetate) drug product, Par has already suffered $2,679,866.64 in lost profits due to the price difference between those two products. This figure does not even take into account Par's lost profits due to sales of the TWi ANDA Product.

COUNT ONE

(TWi's Infringement of the '540 Patent under 35 U.S.C. § 271(a))

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

39. TWi's making, using, offering to sell, and sale of the TWi ANDA Product within the United States, and importation of the TWi ANDA Product into the United States, including the State of Delaware, prior to expiration of the '540 Patent constitutes infringement of the '540 Patent under 35 U.S.C. § 271(a).

40. By reason of the acts alleged herein, Plaintiffs have suffered, are suffering, and unless restrained by the Court will continue to suffer injury to their business and property rights, for which they are entitled to damages pursuant to 35 U.S.C. § 284 in an amount to be proven at

trial.

COUNT TWO

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

41. Plaintiffs reallege Paragraphs 1 to 40 above as if fully set forth herein.

42. 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 '540 Patent constitutes infringement of the '540 Patent under 35 U.S.C. § 271(e)(2)(A).

43. By reason of the acts alleged herein, Plaintiffs have suffered, are suffering, and unless restrained by the Court will continue to suffer injury to their business and property rights, for which they are entitled to damages pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

COUNT THREE

(TWi's Infringement of the '549 Patent under 35 U.S.C. § 271(b) and/or (c))

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

45. Upon information and belief, the TWi ANDA Product will be administered to human patients within the scope of the '549 Patent claims. TWi will actively induce, encourage, and abet this infringement with knowledge of the '549 Patent and that its acts will induce infringement of the '549 Patent.

46. Upon information and belief, the TWi ANDA Product will contain instructions for administering the TWi ANDA Product within the scope of the '549 Patent claims.

47. Upon information and belief, there are no substantial non-infringing uses for the TWi ANDA Product.

48. TWi's commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the TWi ANDA Product, prior to the expiration of the '549 Patent, induces infringement and/or contributes to the infringement of one or more claims of the '549 Patent under 35 U.S.C. § 271(b) and/or (c).

49. By reason of the acts alleged herein, Plaintiffs have suffered, are suffering, and unless restrained by the Court will continue to suffer injury to their business and property rights, for which they are entitled to damages pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

COUNT FOUR

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

50. Plaintiffs reallege Paragraphs 1 to 49 above as if fully set forth herein.

51. 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 '549 Patent constitutes infringement of the '549 Patent under 35 U.S.C. § 271(e)(2)(A).

52. By reason of the acts alleged herein, Plaintiffs have suffered, are suffering, and unless restrained by the Court will continue to suffer injury to their business and property rights, for which they are entitled to damages pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

INJUNCTIVE RELIEF

53. Plaintiffs reallege Paragraphs 1 to 52 above as if fully set forth herein.

54. 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 judgment that Defendants have directly infringed the claims of the ’540 Patent under 35 U.S.C. § 271(a) by the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the TWi ANDA Product before expiration of the ’540 Patent, including any extensions;

B. Enter a judgment that Defendants have induced infringement of and/or contributorily infringed the claims of the ’549 Patent under 35 U.S.C. § 271(b) and/or (c) by the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the TWi ANDA Product before expiration of the ’549 Patent, including any extensions;

C. Enter an Order under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of ANDA No. 20-3139, if any, shall be no earlier than the date of expiration of the Patents-in-Suit, including any extensions;

D. 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 TWi ANDA Product before expiration of the Patents-in-Suit, including any extensions;

E. Grant Plaintiffs compensatory damages against TWi in an amount to be determined at trial, plus both pre-judgment and post-judgment interest;

F. Declare that Defendants' infringement is and/or will be willful, warranting increased damages under 35 U.S.C. § 284;

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

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

DEMAND FOR JURY TRIAL

In accordance with Fed. R. Civ. P. 38(b), Plaintiffs Par and Alkermes demand a trial by jury on all issues so triable.

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