IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DARAVITA LIMITED,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ALVOGEN PINE BROOK, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Daravita Limited ("Daravita" or "Plaintiff"), for its Complaint against Defendant Alvogen Pine Brook, Inc. ("Alvogen"), alleges as follows:

PARTIES

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

2. On information and belief, Alvogen is a Delaware corporation having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington DE 19801.

3. On information and belief, Alvogen is in the business of, among other things, marketing and distributing pharmaceutical products throughout the United States, including in the State of Delaware.

NATURE OF ACTION

4. This is an action for infringement of United States Patent Nos. 6,228,398 ("the '398 patent") and 6,902,742 ("the '742 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Alvogen because it is a Delaware corporation and has purposefully availed itself of the privilege of selling its pharmaceutical products in the State of Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Alvogen conducts marketing and sales activities in the State of Delaware, including, but not limited to, the distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

7. In addition, Alvogen has previously submitted to the jurisdiction of this Court and has availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction. *See, e.g.*, Alvogen Pine Brook, Inc. and Alvogen Group, Inc.'s Answer and Counterclaims, *Novartis Pharm. Corp. v. Alvogen Pine Brook, Inc.*, No. 13-052-RGA (D. Del. Jan. 31, 2013) (D.I. 14); Alvogen Pine Brook Inc.'s and Alvogen Group, Inc.'s Answer and Counterclaims, *Novartis Pharm. Corp. v. Alvogen Pine Brook, Inc.*, No. 13-370-RGA (D. Del. Mar. 26, 2013) (D.I. 13, 17); Answer and Counterclaims for Defendant Alvogen Pine Brook, Inc., *Reckitt Benckiser Pharm., Inc. v. Alvogen Pine Brook, Inc.*, No. 13-2003-RGA (D. Del. Feb. 4, 2014) (D.I. 30).

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

FACTUAL BACKGROUND

9. On May 8, 2001, the ’398 patent, entitled “Multiparticulate Modified Release Composition,” was duly and legally issued to Elan Corporation, plc (“Elan”) as assignee. Elan’s rights were subsequently transferred to Alkermes Pharma Ireland Limited (“APIL”). APIL’s rights were subsequently transferred to Alkermes Science One Limited, which changed its name to Daravita Limited. A true and correct copy of the ’398 patent is attached as Exhibit A.

10. On June 7, 2005, the ’742 patent, entitled “Multiparticulate Modified Release Composition,” was duly and legally issued to Elan as assignee. Elan’s rights were subsequently transferred to APIL. APIL’s rights were subsequently transferred to Alkermes Science One Limited, which changed its name to Daravita Limited. A true and correct copy of the ’742 patent is attached as Exhibit B.

11. On October 25, 2013, the United States Food And Drug Administration (“FDA”) approved new drug application No. 202880 for Zohydro™ ER extended-release capsules, which contain hydrocodone bitartrate, under § 505(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The ’398 and ’742 patents are listed in Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for Zohydro™ ER capsules.

12. On information and belief, Defendant submitted abbreviated new drug application (“ANDA”) No. 206986 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths, as generic versions of the Zohydro™ ER 10, 15, 20, 30, 40, and 50 mg capsules.

13. By letter dated September 26, 2014 (the "Notice Letter"), Defendant advised Plaintiff that it had submitted ANDA No. 206986 seeking approval to manufacture, use, or sell generic hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths prior to the expiration of the '398 and '742 patents.

14. The Notice Letter also advised Plaintiff that Defendant's ANDA included a certification under 21 U.S.C. § 355(j)(2)(B)(ii) that, in Defendant's opinion, the claims of the '398 and '742 patents are invalid or unenforceable.

COUNT I

15. Plaintiff incorporates each of the preceding paragraphs 1 to 14 as if fully set forth herein.

16. Defendant's submission of ANDA No. 206986 to the FDA for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths, including the § 505(j)(2)(B)(ii) allegations, constitutes infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A). Defendant's commercial manufacture, offer for sale, or sale of the proposed generic for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths would infringe the '398 patent.

17. On information and belief, Defendant was aware of the existence of the '398 patent and was aware that the filing of ANDA No. 206986 and certification with respect to the '398 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

18. Plaintiff incorporates each of the preceding paragraphs 1 to 17 as if fully set forth herein.

19. Defendant's submission of ANDA No. 206986 to the FDA for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths, including the § 505(j)(2)(B)(ii) allegations, constitutes infringement of the '742 patent under 35 U.S.C. § 271(e)(2)(A). Defendant's commercial manufacture, offer for sale, or sale of the proposed generic for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths would infringe the '742 patent.

20. On information and belief, Defendant was aware of the existence of the '742 patent and was aware that the filing of ANDA No. 206986 and certification with respect to the '742 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment that Defendant has infringed the '398 and '742 patents;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206986 for hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration dates of the '398 and '742 patents, including any extensions;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendant, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from infringement of the '398 and '742 patents for the full terms thereof, including any extensions;

D. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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