

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ALLERGAN, INC.,

Plaintiff,

v.

FAMY CARE LIMITED,

Defendant.

Civil Action No. 2:16-cv-401

JURY TRIAL DEMANDED

ALLERGAN, INC.'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”), for its Complaint against Defendant Famy Care Limited (“Famy Care”) by its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 8,629,111 (“the ’111 Patent”), 8,633,162 (“the ’162 Patent”), 8,642,556 (“the ’556 Patent”), 8,648,048 (“the ’048 Patent”), 8,685,930 (“the ’930 Patent”), and 9,248,191 (“the ’191 Patent”) under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, relating to Allergan’s treatment for chronic dry eye, Restasis®.

2. This is also an action under 35 U.S.C. §§ 2201-02 for a declaratory judgment of infringement of the ’111, ’556, and ’930 Patents under 35 U.S.C. § 271 (a), (b), and (c), and for a declaratory judgment of infringement of the ’162, ’048, and ’191 Patents under 35 U.S.C. § 271 (b) and (c).

The Parties

3. Allergan is a corporation organized and existing under the laws of the State of Delaware with a place of business at 2525 Dupont Drive, Irvine, California 92612.

4. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including RESTASIS® (cyclosporine ophthalmic emulsion, 0.05%). Allergan coordinates the nationwide distribution of RESTASIS® from Texas. Allergan employs over 800 individuals in Texas, more than in any other state except California.

5. On information and belief, Famy Care is organized and exists under the laws of the Republic of India and has a principal place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai – 400 001, Maharashtra, India.

6. On its Paragraph IV Notification, Famy Care lists its attorney, William Rakoczy as its agent in the United States authorized to accept service of process. On information and belief, Famy Care has no physical location in the United States.

Venue and Jurisdiction

7. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

8. This Court has personal jurisdiction over Famy Care by virtue of its systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Allergan in this forum arising from Famy Care's ANDA filing and the causes of action Allergan raises, as alleged herein. *See Acorda Therapeutics Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, No. 2015-1456 (Fed. Cir. March 18, 2016).

9. Alternatively, if this Court does not have jurisdiction over Famy Care because of its contacts with this jurisdiction as described below, this Court has personal jurisdiction over Famy Care under Federal Rule of Civil Procedure 4(k)(2).

10. On information and belief, Famy Care submitted ANDA No. 208469 under section 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.

11. On information and belief, Famy Care is in the business of researching and developing generic drug products.

12. On information and belief, Famy Care has engaged in continuous and systematic contacts with the United States by, among other things, entering into an exclusive partnership with Mylan, Inc. that dates back to 2008 to file ANDAs for generic contraceptive products and to supply such products to customers in the United States. *See* Exhibit 1.

13. On information and belief, in the United States, Famy Care and Mylan Inc. have a portfolio of 12 approved products. As of November 2015, Famy Care and Mylan Inc. had ANDAs for 30 drugs pending the approval of the FDA. *See* Exhibit 1.

14. On information and belief, Famy Care partners with Mylan Inc. for the purposes of marketing, selling, and distributing the generic drug products that Famy Care develops throughout the United States, including in this judicial district.

15. On information, and belief, Mylan Pharmaceuticals is an agent of Mylan Inc. and works in active concert with Mylan Inc. to market, sell, and distribute pharmaceutical products.

16. On information and belief, Mylan Pharmaceuticals is a licensed drug distributor of prescription drugs sold in the State of Texas.

17. On information and belief, Mylan Pharmaceuticals is actively registered with the Texas Secretary of State to conduct business in Texas.

18. On information and belief, Mylan Pharmaceuticals has a registered agent in Texas located at 211 East 7th Street, Suite 620, Austin Texas 78701-3218.

19. On information and belief, Mylan Inc. markets and sells numerous generic drugs in Texas. On information and belief, since 2014 Mylan Inc. has sold over \$1.3 billion worth of products in Texas, over \$460 million of which were sold in this judicial district.

20. Texas is the second largest market for prescription drugs in the United States and thus a lucrative target for sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 208469.

21. In view of the lucrative Texas market for generic RESTASIS®, on information and belief, Famy Care knows and intends that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 208469 will be distributed and sold in Texas, including through the extensive distribution networks established by Famy Care's distribution partner, Mylan Inc. and/or Mylan Pharmaceuticals.

22. On information and belief, Famy Care knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 208469 will displace sales of Allergan's RESTASIS® product causing injury to Allergan in Texas.

23. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

Factual Background

A. Patents-In-Suit

1. U.S. Patent No. 8,629,111

24. On January 14, 2014, the '111 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '111 Patent is attached to this complaint as Exhibit 2.

25. Allergan, as assignee, owns the entire right, title, and interest in the '111 Patent.

26. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

27. The '111 Patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for RESTASIS®.

28. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '111 Patent.

2. U.S. Patent No. 8,633,162

29. On January 21, 2014, the '162 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '162 Patent is attached to this complaint as Exhibit 3.

30. Allergan, as assignee, owns the entire right, title, and interest in the '162 Patent.

31. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

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