

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EPI HEALTH, LLC and ALLERGAN, INC.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
PERRIGO UK FINCO LIMITED)
PARTNERSHIP,)
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs EPI Health, LLC (“EPI Health”) and Allergan, Inc. (“Allergan”) (EPI Health and Allergan, collectively, “Plaintiffs”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Perrigo UK FINCO Limited Partnership (“Perrigo”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 211942 submitted by Perrigo to the U.S. Food and Drug Administration (“FDA”).

2. In ANDA No. 211942, Perrigo seeks approval to market an oxymetazoline cream product (the “Perrigo ANDA Product”), a generic version of RHOFADE® (oxymetazoline HCl) cream, 1%, prior to expiration of U.S. Patent Nos. 7,812,049 (the “’049 patent”); 8,420,688 (the “’688 patent”); 8,815,929 (the “’929 patent”); 8,883,838 (the “’838 patent”); 9,974,773 (the “’773 patent”); 10,335,391 (the “’391 patent”), and 10,751,325 (the “’325 patent”). The ’049 patent, ’688 patent, ’929 patent, ’838 patent, ’773 patent, ’391 patent, and ’325 patent are collectively referred to herein as the “Patents-in-Suit.”

PARTIES

3. Plaintiff EPI Health, LLC is a limited liability company organized and existing under the laws of South Carolina with its headquarters at 134 Columbus St., Charleston, South Carolina 29403.

4. EPI Health is a specialty pharmaceutical company focused on acquiring, developing and marketing prescription medical dermatological products. RHOFADÉ® is a product marketed by EPI Health for the treatment of persistent facial redness associated with rosacea. EPI Health sells RHOFADÉ® in this judicial district and throughout the United States.

5. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of Delaware with a place of business at 2525 DuPont Drive, Irvine, California 92612.

6. Allergan, Inc. is an affiliate of AbbVie Inc., a global research and development-based biopharmaceutical company incorporated in Delaware and with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064-6400. Allergan brought RHOFADÉ® to the market in 2017.

7. On information and belief, Defendant Perrigo UK FINCO Limited Partnership is a corporation organized and existing under the laws of the United Kingdom, having its principal place of business at Wrafton, Braunton Devon, EX33 2DL, United Kingdom.

JURISDICTION AND VENUE

8. This case arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq. This Court has jurisdiction over its subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has jurisdiction over Perrigo because, *inter alia*, Perrigo has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct

that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including Delaware corporation Allergan, in Delaware. For example, on information and belief, following approval of ANDA No. 211942, Perrigo will make, use, import, sell, and/or offer for sale the Perrigo ANDA Product in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

10. This Court also has jurisdiction over Perrigo because, *inter alia*, this action arises from actions of Perrigo directed toward Delaware, and because Perrigo has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Perrigo regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. On information and belief, Perrigo derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

11. Venue is proper against Perrigo in this District under 28 U.S.C. §§ 1391(c)(3) and/or 1400(b), because venue in a patent infringement action against a foreign defendant is proper in any judicial district. *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 n.2 (2017) (citing *Brunette Mach. Works, Ltd. v. Kochum Indus., Inc.*, 406 U.S. 706, 711-714 (1972)).

12. Perrigo, through its counsel, by e-mail dated March 22, 2021, agreed that Perrigo does not contest jurisdiction or venue in this Court for purposes of this case.

PATENTS-IN-SUIT

13. On October 12, 2010, the U.S. Patent and Trademark Office duly and legally issued the '049 patent, titled "Method and Therapeutic/Cosmetic Topical Compositions for the Treatment

of Rosacea and Skin Erythema Using α_1 -Adrenoceptor Agonists.” A true and correct copy of the ’049 patent is attached hereto as Exhibit A. The claims of the ’049 patent are valid, enforceable, and not expired. Allergan is the owner of the ’049 patent, and EPI Health is the exclusive licensee of the ’049 patent.

14. On April 16, 2013, the U.S. Patent and Trademark Office duly and legally issued the ’688 patent, titled “Method and Therapeutic/Cosmetic Topical Compositions for the Treatment of Rosacea and Skin Erythema Using α_1 -Adrenoceptor Agonists.” A true and correct copy of the ’688 patent is attached hereto as Exhibit B. The claims of the ’688 patent are valid, enforceable, and not expired. Allergan is the owner of the ’688 patent, and EPI Health is the exclusive licensee of the ’688 patent.

15. On August 26, 2014, the U.S. Patent and Trademark Office duly and legally issued the ’929 patent, titled “Method and Therapeutic/Cosmetic Topical Compositions for the Treatment of Rosacea and Skin Erythema Using α_1 -Adrenoceptor Agonists.” A true and correct copy of the ’929 patent is attached hereto as Exhibit C. The claims of the ’929 patent are valid, enforceable, and not expired. Allergan is the owner of the ’929 patent, and EPI Health is the exclusive licensee of the ’929 patent.

16. On November 11, 2014, the U.S. Patent and Trademark Office duly and legally issued the ’838 patent, titled “Pharmaceutical Cream Compositions and Methods of Use.” A true and correct copy of the ’838 patent is attached hereto as Exhibit D. The claims of the ’838 patent are valid, enforceable, and not expired. EPI Health is the owner of the ’838 patent.

17. On May 22, 2018, the U.S. Patent and Trademark Office duly and legally issued the ’773 patent, titled “Stabilized Oxymetazoline Formulations and Their Uses.” A true and

correct copy of the '773 patent is attached hereto as Exhibit E. The claims of the '773 patent are valid, enforceable, and not expired. EPI Health is the owner of the '773 patent.

18. On July 2, 2019, the U.S. Patent and Trademark Office duly and legally issued the '391 patent, titled "Stabilized Oxymetazoline Formulations and Their Uses." A true and correct copy of the '391 patent is attached hereto as Exhibit F. The claims of the '391 patent are valid, enforceable, and not expired. EPI Health is the owner of the '391 patent.

19. On August 25, 2020, the U.S. Patent and Trademark Office duly and legally issued the '325 patent, titled "Stabilized Oxymetazoline Formulations and Their Uses." A true and correct copy of the '325 patent is attached hereto as Exhibit G. The claims of the '325 patent are valid, enforceable, and not expired. EPI Health is the owner of the '325 patent.

20. EPI Health is the holder of New Drug Application ("NDA") No. 208552, by which FDA granted approval for the marketing and sale of a 1% oxymetazoline hydrochloride cream. EPI Health markets 1% oxymetazoline hydrochloride cream in the United States, under the trade name "RHOFADÉ®." The FDA's official publication of approved drugs, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), lists the Patents-in-Suit for RHOFADÉ®.

21. The active ingredient of RHOFADÉ® is an α_{1A} adrenoceptor agonist used on the skin (topically) of the face to treat persistent facial redness, also referred to as erythema, associated with rosacea in adults. RHOFADÉ® is a vasoconstrictor and works by constricting facial blood vessels to reduce facial redness associated with rosacea.

22. The prescribing information for RHOFADÉ® identifies the product as including "an α_{1A} adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults."

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