

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAYNE PHARMA LLC,

Plaintiff,

v.

PERRIGO ISRAEL PHARMACEUTICALS
LTD. and PERRIGO CO. PLC,

Defendant.

C.A. No. _____

COMPLAINT

Plaintiff Mayne Pharma LLC (“Mayne” or “Plaintiff”), by its undersigned attorneys, brings this action against Defendants Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company plc (collectively, “Perrigo” or “Defendants”), and hereby alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement of U.S. Patent No. 10,857,159 (the “’159 patent” or “patent-in-suit”) under the patent laws of the United States, Title 35, United States Code § 100, *et seq.* This action arises from Perrigo’s submission of Abbreviated New Drug Application (“ANDA”) No. 215266 to the U.S. Food and Drug Administration (“FDA”). Through its ANDA, Perrigo seeks approval to market 0.05% halobetasol propionate topical foam, a generic version of Mayne’s LEXETTE® drug product (“Perrigo ANDA product”), prior to the expiration of the patent-in-suit.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. §§ 271(a), (b), and/or (c).

THE PARTIES

3. Mayne is a Delaware limited liability company with a place of business at 1240 Sugg Parkway, Greenville, North Carolina 27834.

4. Upon information and belief, Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”) is an Israeli corporation with a place of business at 1 Rakefet St., Shoham 608500, Israel.

5. Upon information and belief, Perrigo Company plc (“Perrigo Ireland”) is an Irish corporation with a place of business at The Sharp Building, Hogan Place, Dublin 2, Ireland.

6. Upon information and belief, Perrigo Israel is a wholly-owned subsidiary by Perrigo Ireland.

7. Upon information and belief, Perrigo prepared and submitted ANDA No. 215266 and continues to collaborate in seeking FDA approval of that application.

8. Upon information and belief, Perrigo intends to commercially manufacture, market, offer for sale, and sell the Perrigo ANDA product throughout the United States, including in the State of Delaware, in the event the FDA approves ANDA No. 215266.

9. Upon information and belief, Perrigo Israel manufactures, sells, markets, and distributes generic pharmaceutical products throughout the United States, including in this district, in conjunction with or under the direction of Perrigo Ireland.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, 2201, 2202 because this is a patent infringement action that arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act.

11. This Court has personal jurisdiction over Perrigo Israel because, *inter alia*, it has purposefully availed itself of the benefits and protections of Delaware’s laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Perrigo Israel

develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in Delaware and therefore transacts business within Delaware related to Mayne's claims, and/or has engaged in systematic and continuous business contacts within Delaware.

12. This Court has personal jurisdiction over Perrigo Ireland because, *inter alia*, Perrigo Ireland, itself and through its wholly-owned subsidiary Perrigo Israel, has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Perrigo Ireland regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Perrigo Ireland derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. In addition, Perrigo Ireland is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Perrigo Israel and therefore the activities of Perrigo Israel in this jurisdiction can be attributed to Perrigo Ireland.

13. 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 Mayne, a Delaware limited liability company, in Delaware. For example, on information and belief, following approval of ANDA No. 215266, 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 patent-in-suit.

14. Perrigo reported in its 2020 Annual Report its "customers include major global, national, and regional retail drug, supermarket, and mass merchandise chains such as Walmart,

Costco, CVS, Target, Walgreens Boots Alliance, Kroger, Dollar General, Sam's Club, Topco, e-commerce stores including Amazon, and major wholesalers, including McKesson, Amerisource Bergen, and Cardinal Health." Upon information and belief, Perrigo intends to sell the Perrigo ANDA product through these same retail outlets in Delaware, such as Walmart, Costco, CVS, Target, Walgreens, Dollar General, and Sam's Club.

15. Upon information and belief, Perrigo will market and distribute its Perrigo ANDA product in Delaware, and this product will be prescribed by physicians practicing in this state, and dispensed by pharmacies located in this state, all of which would have a substantial effect on commerce.

16. Upon information and belief, Perrigo is part of a corporate family that includes at least twenty-two Delaware entities, which are incorporated in Delaware. Upon information and belief, the Perrigo corporate family as a whole relies on Delaware for its successful business operations.

17. Upon information and belief, Perrigo Ireland works in concert with its subsidiary Perrigo Israel to sell, market, and distribute its generic drugs in the United States, including in this district.

18. Perrigo Ireland has previously been involved in litigations brought in this judicial district, for example, in *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc. et al.*, No. 18-cv-1673-RGA (D. Del.); and *In re: Kerydin (Tavaborole) Topical Solution 5% Patent Litigation*, No. 19-md-02884-RGA (D. Del.).

19. Perrigo Israel has previously consented to suit in this judicial district and has availed itself of a Delaware court through the assertion of counterclaims in lawsuits brought in Delaware, for example, in *Taro Pharmaceuticals U.S.A., Inc. et al. v. Perrigo Israel*

Pharmaceuticals Ltd., No. 14-cv-989-RGA (D. Del.); *Sun Pharmaceutical Industries, Inc. et al. v. Perrigo Company et al.*, No. 18-cv-703-CFC (D. Del.); *Stiefel Research Australia Pty. Ltd. v. Perrigo Co. & Perrigo Israel Pharmaceuticals, Ltd.*, No. 09-cv-758-JJF (D. Del.); *Stiefel Laboratories, Inc. et al. v. Perrigo Israel Pharmaceuticals Ltd. & Perrigo Co.*, No. 10-cv-592-GMS (D. Del.); and *Unimed Pharmaceuticals LLC et al. v. Perrigo Co. & Perrigo Israel Pharmaceuticals Ltd.*, No. 13-cv-236-LPS (D. Del.). Perrigo Israel has further been involved in several litigations in this judicial district, including, for example, *KV Pharmaceutical Co. et al. v. Perrigo Israel Pharmaceuticals Ltd. et al.*, No. 10-cv-641-SLR (D. Del.); *Unimed Pharmaceuticals, LLC et al. v. Perrigo Co. et al.*, No. 14-cv-985 (D. Del.); *Unimed Pharmaceuticals, LLC et al. v. Perrigo Co. et al.*, No. 14-cv-1003 (D. Del.).

20. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

21. Venue is also proper in this District under 28 U.S.C. § 1391(c)(3) because on information and belief, Perrigo Israel is an Israeli corporation and Perrigo Ireland is an Irish company and both are not residents in the United States.

THE PATENT-IN-SUIT

22. The '159 patent, titled "Halobetasol Foam Composition and Method of Use Thereof," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on December 8, 2020, to Robert T. Gauthier and James D. Hammer. Mayne Pharma, LLC, is listed as the assignee and is currently the sole assignee of the '159 patent.

23. A true and correct copy of the '159 patent is attached as Exhibit A.

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