

JUDGE PERMAN
IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

LEO PHARMA A/S,

Plaintiff,

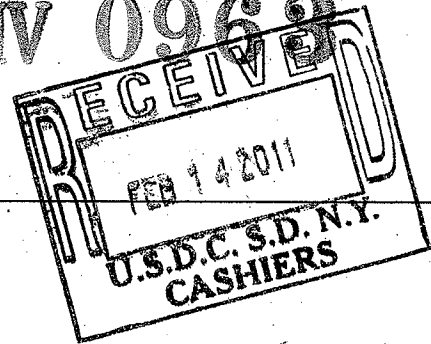
v.

PERRIGO ISRAEL PHARMA LTD.,

Defendant.

11 CIV 0963

C.A. No.



11-cv-0963 (RMB) ECF Case

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff LEO Pharma A/S (“LEO Pharma”) for its Complaint against Defendant Perrigo Israel Pharma Ltd. (“Perrigo Israel”), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Patent Laws of the United States, Title 35, United States Code.

THE PARTIES

2. Plaintiff LEO Pharma is a corporation organized and existing under the laws of Denmark with its corporate headquarters at Industriparken 55, DK-2750 Ballerup, Denmark.

3. Upon information and belief, Perrigo Israel is an Israeli corporation with its headquarters and corporate offices at 29 Lehi Street, Bnei Brak 51200, Israel.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

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

6. Upon information and belief, Perrigo Israel develops and manufactures pharmaceutical products for the U.S. market.

7. Upon information and belief, Perrigo Israel engages in the manufacture, importation and/or sale of a range of generic pharmaceutical products within the United States and the State of New York specifically by manufacturing its products for sale by a parent and/or affiliate to retail stores located within this jurisdiction, including, for example, to Wal-Mart, CVS, Dollar General, Sam's Club, Costco and Walgreens pharmacy stores.

8. Upon information and belief, pharmaceutical products developed and manufactured by Perrigo Israel for the U.S. market include cetirizine, clobetasol foam, halobetasol cream, imiquimod cream and mesalamine rectal suspension enema.

9. Upon information and belief, Perrigo Israel regularly transacts business within this judicial district, including but not limited to shipping generic pharmaceuticals to stores within the United States from locations outside the United States for sale within the United States generally, and within this judicial district specifically, including among others, generic cetirizine, clobetasol foam, halobetasol cream, imiquimod cream and mesalamine rectal suspension enema.

10. Perrigo Israel is subject to personal jurisdiction in this judicial district because, *inter alia*, upon information and belief, Perrigo Israel manufactures, sells, offers for sale, and causes to be supplied or sold throughout the United States various products, including prescription and over-the-counter pharmaceutical products. Perrigo Israel's products are sold by mass merchandisers, food stores, and drug stores throughout the United States, including within

this judicial district. Upon information and belief, Perrigo Israel derives substantial revenue from the sales of those products in this district.

11. Perrigo Israel has engaged in substantial and/or continuous and systematic contacts with the State of New York, which satisfy due process and confer personal jurisdiction over this defendant.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

12. LEO Pharma is the holder of New Drug Application (“NDA”) No. 21-852, which relates to ointments containing 0.064% betamethasone dipropionate and 0.005% calcipotriene monohydrate. On January 9, 2006, the United States Food and Drug Administration (“FDA”) approved the use of the ointments described in NDA No. 21-852 for the treatment of psoriasis vulgaris. These ointments are prescribed and sold in the United States under the trademark Taclonex®.

13. United States Patent No. 6,753,013 (the “’013 Patent,” copy attached as Exhibit A), “Pharmaceutical Composition,” was duly and legally issued by the United States Patent and Trademark Office on June 22, 2004. The ’013 Patent claims, *inter alia*, vitamin D or a vitamin D analogue in combination with a corticosteroid, which are the active ingredients in Taclonex® ointment. The ’013 Patent is currently listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “FDA Orange Book”) for Taclonex® ointment.

14. The named inventors on the ’013 Patent are Erik Didriksen and Gert Høy, who assigned their right in the ’013 Patent to LEO Pharmaceutical Products, Ltd. A/S. LEO Pharmaceutical Products, Ltd. A/S subsequently changed its name to LEO Pharma A/S.

15. Upon information and belief, Perrigo Israel submitted or caused to be submitted to the FDA an Abbreviated New Drug Application (“ANDA”), specifically ANDA

No. 20-0174, under the provisions of 21 U.S.C. §355(j), seeking approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing 0.064% betamethasone dipropionate and 0.005% calcipotriene monohydrate.

16. Upon information and belief, ANDA No. 20-0174 seeks approval to manufacture, use, sell and/or import calcipotriene monohydrate and ointments containing calcipotriene monohydrate and betamethasone dipropionate for the purpose of treating psoriasis vulgaris in humans.

COUNT 1
INFRINGEMENT OF U.S. PATENT NO. 6,753,013 (ANDA NO. 20-0174)

17. Plaintiff repeats and realleges paragraphs 1-16 above as if fully set forth herein.

18. By letter dated December 31, 2010 (the "December 31, 2010 Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Perrigo Israel notified LEO Pharma that it had submitted ANDA No. 20-0174 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing, upon information and belief, 0.005% calcipotriene monohydrate and 0.064% betamethasone dipropionate, prior to the expiration of the '013 Patent.

19. In its December 31, 2010 Notice Letter, Perrigo Israel notified LEO Pharma that, as a part of ANDA No. 20-0174, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") with respect to the '013 Patent. Upon information and belief, Perrigo Israel certified that, in its opinion and to the best of its knowledge, the '013 Patent is invalid.

20. By filing ANDA No. 20-0174 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of ointments containing, upon information and belief, 0.005% calcipotriene monohydrate and 0.064% betamethasone dipropionate, prior to the expiration of the '013 Patent, Perrigo Israel committed an act of infringement of the '013 Patent under 35 U.S.C. § 271(e)(2).

21. Upon information and belief, Perrigo Israel lacked a good faith basis for alleging invalidity when ANDA No. 20-0174 was filed and when the Paragraph IV certification was made. Perrigo Israel's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '013 Patent.

22. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation of ointments containing 0.005% calcipotriene monohydrate and 0.064% betamethasone dipropionate for the use for which Perrigo Israel seeks approval in ANDA No. 20-0174 will infringe, induce infringement and/or contributorily infringe one or more claims of the '013 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief.

(a) A judgment declaring that the effective date of any approval of Perrigo Israel's ANDA No. 20-0174 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the expiration date of the '013 Patent and any later date of exclusivity to which Plaintiff and/or the '013 Patent are or become entitled;

(b) A judgment declaring that the '013 Patent is valid, enforceable and has been infringed by Perrigo Israel;

(c) A permanent injunction against any infringement of the '013 Patent by Perrigo Israel, its officers, agents, attorneys and employees, and those acting in privity or contract with them;

(d) A judgment that this is an exceptional case, and that Plaintiff is entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(e) Costs and expenses in this action; and

(f) Such other relief as this Court may deem just and proper.



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