

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LEO PHARMA A/S, LEO PHARMA INC. and)	
FOAMIX PHARMACEUTICALS LTD.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 18-13 (CFC)
)	CONSOLIDATED
TEVA PHARMACEUTICALS USA, INC. and)	
PERRIGO UK FINCO LIMITED)	
PARTNERSHIP)	
)	
Defendants.)	
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LEO PHARMA A/S, LEO PHARMA INC. and)	
FOAMIX PHARMACEUTICALS LTD.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 18-1874 (CFC)
)	
PERRIGO UK FINCO LIMITED)	
PARTNERSHIP,)	
)	
Defendant.)	

FIRST AMENDED COMPLAINT

Plaintiffs LEO Pharma A/S, LEO Pharma Inc. (collectively, “LEO”), and Foamix Pharmaceuticals Ltd. (“Foamix”, and collectively with LEO, “Plaintiffs”), by their attorneys, for their Amended Complaint, amending D.I. 1 in C.A. 18-1874 (CFC), allege as follows:

THE PARTIES

1. Plaintiff LEO Pharma A/S is a corporation organized and existing under the laws of the Kingdom of Denmark, with a place of business at Industriparken 55, DK-2750,

Ballerup, Denmark. LEO Pharma A/S holds New Drug Application (“NDA”) No. 207071 on FINACEA[®] (active ingredient 15% azelaic acid) Foam.

2. Plaintiff LEO Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 7 Giralda Farms, 2nd Floor, Madison, NJ 07940.

3. Plaintiff Foamix Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the State of Israel, with a place of business at 2 Holzman Street, Weizmann Science Park, Rehovot 7670402, Israel.

4. Upon information and belief, defendant Perrigo UK FINCO Limited Partnership (“Perrigo”) is a limited partnership organized and existing under the laws of the United Kingdom, with a principal place of business at Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

5. Plaintiffs and Perrigo are currently parties to a related action pending in this district, LEO Pharma A/S, et al. v. Teva Pharmaceuticals USA, Inc., et al., C.A. No. 18-13-CFC (D. Del.) (“the Perrigo I Action”). The Perrigo I Action concerns, among other things, Plaintiffs’ assertion that Perrigo has infringed U.S. Patent No. 7,700,076 (“the ’076 patent”), U.S. Patent No. 8,435,498 (“the ’498 patent”), U.S. Patent No. 8,722,021 (“the ’021 patent”), U.S. Patent No. 8,900,554 (“the ’554 patent”), U.S. Patent No. 9,211,259 (“the ’259 patent”), and U.S. Patent No. 9,265,725 (“the ’725 patent”) (collectively, “the Related Patents”) through Perrigo’s submission to the U.S. Food and Drug Administration (“FDA”) and maintenance of Abbreviated New Drug Application (“ANDA”) No. 211077 (“Perrigo’s ANDA”) for an azelaic

acid foam, 15% (“ANDA Product”), for which Perrigo seeks approval prior to the expiration of the Related Patents. See generally D.I. 1, C.A. No. 18-261-CFC (D. Del.).¹

6. As set forth below, Plaintiffs now bring the instant action regarding Perrigo’s infringement of United States Patent No. 10,117,812 (“the ’812 patent”) (Exhibit A), arising from the same course of infringing conduct at issue in the *Perrigo I* Action.

NATURE OF THE ACTION

7. This is a civil action for patent infringement and declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq. It concerns the ’812 patent.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Perrigo by virtue of the fact that, inter alia, Perrigo has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. Upon information and belief, Perrigo intends to engage in the commercial manufacture, use, and/or sale under Perrigo’s ANDA of Perrigo’s ANDA Product, before the expiration of the ’812 patent, throughout the United States, including in the State of Delaware.

11. Upon information and belief, Perrigo is in the business of, inter alia, manufacturing and selling generic pharmaceutical products that are distributed throughout the

¹ C.A. 18-261-CFC is the action originally brought against Perrigo over the Related Patents. As explained *infra*, it was consolidated into C.A. No. 18-13-CFC on June 12, 2018.

United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, but not limited to Perrigo Co. and Perrigo Pharmaceuticals.

12. Perrigo's infringing activities with respect to its filing of ANDA No. 211077 and intent to commercialize Perrigo's ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware.

13. This Court also has personal jurisdiction over Perrigo by virtue of the fact that, upon information and belief, inter alia, Perrigo has availed itself of the rights and benefits of Delaware law, and has engaged in systematic and continuous contacts with the State of Delaware.

14. This Court also has personal jurisdiction over Perrigo because it has previously submitted to the jurisdiction of this Court and has asserted counterclaims in other civil actions initiated in this jurisdiction, including in the related *Perrigo I* Action pending before this Court. See *LEO Pharma A/S, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 18-13-CFC (D. Del.); see also *LEO Pharma, et al. v. Perrigo UK FINCO Limited Partnership, et al.*, No. 16-430-JFB (D. Del.) (unrelated case).

FINACEA[®] FOAM, THE *PERRIGO I* ACTION AND THE '812 PATENT ISSUANCE

15. FINACEA[®] (active ingredient 15% azelaic acid) Foam is a topical prescription medicine used to treat the inflammatory papules and pustules of mild to moderate rosacea.

16. The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations lists a number of patents in connection with FINACEA[®] Foam.

17. Those patents include the '812 patent and the Related Patents, each of which was issued to Foamix as assignee.

18. On December 8, 2006, Intendis GmbH (“Intendis”) was granted an exclusive license to the FINACEA[®] Foam Product covered by certain Foamix patents and patent applications, including those applications which ultimately led to the issuance of the '812 patent and the Related Patents. In December 2013, Intendis and Bayer Pharma AG, the parent of Intendis, entered into a business lease agreement providing, among other things, for the substitution of Intendis by Bayer Pharma AG in existing agreements. Thus, effective January 1, 2014, the exclusive license to the Foamix patents was assigned to Bayer Pharma AG. Thereafter, effective as of January 1, 2017, the exclusive license was assigned to Bayer AG, the parent of Bayer Pharma AG.

19. Perrigo submitted ANDA No. 211077 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (“Paragraph IV Certification”), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Perrigo’s ANDA Product prior to the expiration of patents listed in the Orange Book for FINACEA[®] Foam, which at that time included, among other things, the Related Patents.

20. By letter dated January 4, 2018, Perrigo advised Bayer HealthCare Pharmaceuticals Inc. (then the NDA holder), Bayer AG (collectively, “Bayer”), and Foamix that Perrigo had filed a Paragraph IV Certification in connection with ANDA No. 211077 with respect to the Related Patents and that Perrigo is seeking approval of its ANDA Product under ANDA No. 211077 prior to the expiration of those patents.

21. Bayer and Foamix commenced the Perrigo I Action against Perrigo with a Complaint filed in this Court on February 15, 2018. *See* D.I. 1, C.A. No. 18-261-CFC. In that case, Plaintiffs alleged that Perrigo had infringed the Related Patents.

22. Perrigo filed its Answer and Counterclaims in the Perrigo I Action on March 7, 2018, *see* D.I. 9, C.A. No. 18-261-CFC, and Plaintiffs filed their Answer to Perrigo's Counterclaims in the Perrigo I Action on March 28, 2018, *see* D.I. 15, C.A. No. 18-261-CFC. On June 12, 2018, the Perrigo I Action was consolidated with a similar ANDA litigation pending against Teva Pharmaceuticals USA, Inc. *See* D.I. (June 12, 2018), C.A. No. 18-261-CFC.

23. While that litigation was ongoing, Bayer AG sold its prescription dermatology business to LEO Pharma A/S. In connection with that sale, LEO Pharma A/S acquired Bayer AG's rights in the Foamix license agreement. On September 18, 2018, LEO Pharma A/S granted LEO Pharma Inc. a sublicense to the Foamix license.

24. Following this transaction, by order dated October 4, 2018, the Court substituted LEO for Bayer as plaintiffs in the Perrigo I action.

25. On November 6, 2018, the '812 patent, entitled "Foamable Composition Combining a Polar Solvent and a Hydrophobic Carrier," was duly and legally issued to Foamix as assignee.

26. The '812 patent is from the same patent family as the Related Patents. The '812 patent and the Related Patents each share at least two common inventors—Dov Tamarkin and Doron Friedman. LEO Pharma A/S is the exclusive licensee of the '812 patent and LEO Pharma Inc. has been granted a sublicense to the '812 patent.

27. LEO has caused the '812 patent to be listed in the Orange Book in connection with FINACEA® Foam.

28. On or around December 6, 2018, LEO and Foamix received a notice letter from Perrigo concerning its submission of ANDA No. 211077 to the FDA.

29. That notice letter indicated that Perrigo's ANDA had been amended to contain a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, sale, or importation of Perrigo's ANDA Product before the expiration of the '812 patent.

30. There is thus a dispute between Plaintiffs on the one hand and Perrigo on the other hand about whether Perrigo's proposed commercial manufacture, use, sale, offer for sale or importation of its ANDA Product infringes the '812 patent and/or whether the '812 patent is valid.

31. As of December 14, 2018, C.A. No. 18-1874 (CFC) concerning the '812 patent has been consolidated with *Perrigo I*.

COUNT I—INFRINGEMENT OF THE '812 PATENT

32. Plaintiffs fully incorporate each of the preceding paragraphs 1-31 as if fully set forth herein.

33. Upon information and belief, Perrigo's proposed commercial manufacture, use, sale, offer for sale or importation of its ANDA Product infringes one or more claims of the '812 patent either literally or under the doctrine of equivalents.

34. As an example, claim 1 of the '812 patent recites a foamable pharmaceutical vehicle or composition, comprising:

1. a liquid organic carrier, at a concentration of 10% to 70% by weight of the composition, wherein said organic carrier concurrently comprises:
 - (i) at least one hydrophobic organic carrier comprising a triglyceride, and

- (ii) at least one polar solvent comprising dimethyl isosorbide,
2. a surface-active agent selected from the group consisting of at least one non-ionic surface-active agent, and a mixture of a non-ionic surface-active agent and an ionic surface-active agent, wherein the ratio of non-ionic surface-active agent to ionic surface-active agent is greater than 14:1;
 3. water;
 4. at least one liquefied or compressed gas propellant at a concentration of 3% to 25% by weight of the total composition; and
 5. a polymeric agent selected from the group consisting of a locust bean gum, sodium caseinate, an egg albumin, a gelatin agar, a carrageenin gum, sodium alginate, a xanthan gum, a quince seed extract, a tragacanth gum, a guar gum, a starch, a chemically modified starch, a cellulose ether, an alkyl cellulose, a hydroxyalkyl cellulose, a hydroxyethyl cellulose, a hydroxypropyl cellulose, a methyl cellulose, a carboxymethyl cellulose, a methylhydroxyethylcellulose, a methylhydroxypropylcellulose, a hydroxypropylmethyl cellulose, a hydroxyethylcarboxymethylcellulose, a carboxymethylhydroxyethylcellulose, a hydroxypropyl guar gum, a soluble starch, a carboxyvinyl polymer, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyacrylic acid polymer, a polymethacrylic acid polymer, a polyvinyl acetate polymer, a polyvinyl chloride polymer, a polyvinylidene chloride polymer, an acrylic acid/ethyl acrylate

copolymer, a carboxyvinyl polymer, a silicone dioxide, a poly(acrylic)acid, a poly(methylvinyl ether/maleic anhydride) copolymer, a chitosan, an alginic acid, a hyaluronic acid, a pectin, a karaya gum, a cyclodextrin, a chemically modified cyclodextrin, hydroxypropyl- β -cyclodextrin, a poly(N-isopropylamide), a poloxamer, and mixtures of any two or more thereof; and

wherein the composition is provided in an aerosol container and upon release expands to form a breakable foam that collapses upon application of shear force.

35. Upon information and belief, Perrigo's proposed commercial manufacture, use, sale, offer for sale or importation of its ANDA Product infringes claim 1 of the '812 patent literally or under the doctrine of equivalents.

36. Perrigo's submission of ANDA No. 211077 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's ANDA Product prior to the expiration of the '812 patent was an act of infringement of the '812 patent under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, Perrigo intends to engage in the commercial manufacture, use, sale, offer for sale or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 211077, i.e., prior to the expiration of the '812 patent.

38. Upon information and belief, Perrigo has knowledge of the claims of the '812 patent. Notwithstanding this knowledge, Perrigo has continued to assert its intent to engage in the commercial manufacture, use, sale, offer for sale or importation of Perrigo's ANDA

Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 211077.

39. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '812 patent when ANDA No. 211077 is approved, and plans and intends to, and will, do so after approval.

40. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '812 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '812 patent immediately and imminently upon approval of ANDA No. 211077 by commercial manufacture, use, sale, offer for sale or importation of its ANDA Product.

41. The foregoing actions by Perrigo constitute infringement of the '812 patent. Additionally, Perrigo's commercial manufacture, use, sale, offer for sale or importation of its ANDA Product would constitute infringement of the '812 patent, active inducement of infringement of the '812 patent, and contributing to the infringement by others of the '812 patent.

42. Further, Plaintiffs are entitled to an order of this Court that the effective date of the approval of ANDA No. 211077 be a date that is not earlier than the expiration date of the '812 patent, or any later expiration of any patent term extension or exclusivity for the '812 patent to which Plaintiffs become entitled.

43. Plaintiffs will be irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '812 PATENT

44. Plaintiffs fully incorporate each of the preceding paragraphs 1-43 as if fully set forth herein.

45. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Perrigo on the other regarding Perrigo's infringement, active inducement of infringement, and contribution to the infringement by others of the '812 patent.

46. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Perrigo's ANDA Product, or any other drug product which is covered by or whose use is covered by the '812 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '812 patent.

* * *

47. Perrigo has proceeded with knowledge of the '812 patent and with no reasonable basis to believe that it has not infringed and will not infringe that patent. This is an exceptional case.

* * *

WHEREFORE, the Plaintiffs request the following relief:

- (a) A judgment that Perrigo has infringed the '812 patent;
- (b) A judgment ordering that the effective date of any FDA approval for Perrigo to make, use, offer for sale, sell, market, distribute, or import Perrigo's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '812 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Perrigo, and all persons acting in concert with Perrigo, from making, using, offering for sale, selling, marketing, distributing, or importing Perrigo's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '812 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, offering for sale, selling, marketing, distributing, or importing Perrigo's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the '812 patent will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '812 patent;

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

(f) An award of the Plaintiffs' costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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December 18, 2018

CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 18, 2018, upon the following in the manner indicated:

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