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. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

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 Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Teva Pharmaceuticals USA, Inc. ("Teva"), of Abbreviated New Drug Application ("ANDA") No. 210928 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Bayer's FINACEA® (azelaic acid) Foam ("FINACEA® Foam") prior to expiration of U.S. Patent No. 10,322,085 ("the '085 patent") (Exhibit A hereto).

THE PARTIES

2. 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.

3. 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.

4. 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.

5. Upon information and belief, defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

JURISDICTION AND VENUE

6. 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 '085 patent.

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

8. Upon information and belief, Teva is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates.

9. This Court has personal jurisdiction over Teva by virtue of the fact that, *inter alia*, Teva 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, Teva intends to engage in the commercial manufacture, use, offer for sale, and/or importation of Teva's ANDA Product, before the expiration of the '085 patent, throughout the United States, including in the State of Delaware.

10. Teva's infringing activities with respect to its filing of ANDA No. 210928 and intent to commercialize Teva's ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware.

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

12. This Court also has personal jurisdiction over Teva because it has previously submitted to the jurisdiction of this Court and has asserted counterclaims in other civil actions initiated in this jurisdiction. *In re Copaxone 775 Patent Litigation*, 16-1267-GMS (D. Del.); *Teva Pharmaceuticals USA, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, 17-249-GMS (D. Del.); and *Teva Pharmaceuticals USA, Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, 17-992-GMS (D. Del.). Teva has also submitted to the jurisdiction of this Court and has asserted counterclaims in a related case pending before this Court. *LEO Pharma A/S, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 18-13-CFC (D. Del.) (hereinafter "*Teva I* Action").

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

FINACEA® FOAM, THE *TEVA I* ACTION, AND THE '085 PATENT ISSUANCE

14. 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.

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

16. Those patents include U.S. Patent Nos. 7,700,076, 8,435,498, 8,722,021, 8,900,554, 9,211,259, and 9,265,725 (hereinafter, collectively, "Related Patents"). Each of these patents was issued to Foamix as assignee.

17. 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 the applications which ultimately led to the issuance of the '085 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.

18. Teva submitted ANDA No. 210928 to the FDA under Section 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 Teva's ANDA Product prior to the expiration of the Related Patents.

19. On or around November 21 and November 22, 2017, Bayer HealthCare Pharmaceuticals Inc. (then the NDA holder), Bayer AG (collectively, "Bayer"), and Foamix received a Notice Letter dated November 20, 2017, from Teva stating that Teva had submitted to

the FDA ANDA No. 210928 for an azelaic acid foam composition containing 15% azelaic acid. Teva's ANDA Product is a drug product that is a generic version of FINACEA® Foam.

20. The purpose of Teva's submission of ANDA No. 210928 was to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Teva's ANDA Product prior to the expiration of the Related Patents.

21. In its Notice Letter, Teva indicated that, in connection with its ANDA No. 210928, Teva had filed Paragraph IV Certifications with respect to each of the Related Patents.

22. Bayer and Foamix commenced an Action against Teva with a Complaint filed in this Court on January 3, 2018. *See* D.I. 1, C.A. No. 18-13-CFC. In that case, Plaintiffs alleged that Teva's proposed commercial manufacture, use, sale, offer for sale or importation of its ANDA Product infringes one or more claims of the Related Patents.

23. Teva filed its Answer and Counterclaims in the *Teva I* Action on February 26, 2018, *see* D.I. 10, C.A. No. 18-13-CFC, and Plaintiffs filed their Answer to Teva's Counterclaims in the *Teva I* Action on March 19, 2018, *see* D.I. 14, C.A. No. 18-13-CFC.

24. While that litigation was ongoing, in September 2018, 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.

25. Following this transaction, by order dated October 4, 2018, the Court substituted LEO for Bayer as plaintiffs in the *Teva I* Action.

26. On June 18, 2019, the '085 patent, entitled "Dicarboxylic Acid Foamable Vehicle and Pharmaceutical Compositions Thereof," was duly and legally issued to Foamix as assignee.

27. The ’085 patent issued from the same patent family as the Related Patents. The ’085 patent and the Related Patents each share at least two common inventors—Dov Tamarkin and Doron Friedman.

28. LEO Pharma A/S is the exclusive licensee of the ’085 patent, and LEO Pharma Inc. has been granted a sublicense to the ’085 patent.

29. The ’085 patent has been listed in connection with FINACEA® Foam in the Orange Book.

30. On information and belief, Teva continues to seek approval of its ANDA Product prior to the expiration of the patents covering FINACEA® Foam, despite the issuance of the ’085 patent and the listing of the ’085 patent in the Orange Book.

31. There is a dispute between Plaintiffs and Teva about whether Teva’s proposed commercial manufacture, use, sale, offer for sale or importation of its ANDA Product infringes the ’085 patent and/or whether the ’085 patent is valid.

COUNT I
INFRINGEMENT OF THE ’085 PATENT

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

33. Upon information and belief, Teva’s proposed commercial manufacture, use, sale, offer for sale or importation of its ANDA Product will infringe one or more claims of the ’085 patent either literally or under the doctrine of equivalents.

34. As an example, claim 1 of the ’085 patent recites a foamable composition comprising a carrier and a liquefied or compressed gas propellant, wherein the carrier comprising:

(a) about 15% by weight of the carrier of azelaic acid;

(b) about 2% to about 50% by weight of the carrier of a hydrophobic solvent;

(c) a polar solvent;

(d) a surface-active agent;

(e) a polymeric agent; and

(f) water; and

wherein the surface-active agent comprises a combination of at least two surface-active agents and wherein there is a difference of about 4 or more units between the HLB values of the at least two surface-active agents;

wherein combined amount of the polymeric agent and the surface-active agent is about 0.05% to about 10% by weight of the carrier; and

wherein the liquefied or compressed gas propellant is present at about 3% to about 25% by weight of the composition.

35. Upon information and belief, Teva's proposed commercial manufacture, use, sale, offer for sale or importation of its ANDA Product will infringe claim 1 of the '085 patent literally or under the doctrine of equivalents.

36. Teva's submission and continued effort to obtain FDA approval of ANDA No. 210928 to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product prior to the expiration of the '085 patent is an act of infringement of the '085 patent under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, Teva intends to engage in the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Product immediately and imminently upon approval of ANDA No. 210928, and prior to the expiration of the '085 patent.

38. Upon information and belief, Teva has knowledge of the claims of the ’085 patent. Notwithstanding this knowledge, Teva has continued to assert its intent to engage in the commercial manufacture, use, sale, offer for sale or importation of Teva’s ANDA Product with the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210928.

39. Upon information and belief, Teva plans and intends to, and will, actively induce infringement of the ’085 patent when ANDA No. 210928 is approved, and plans and intends to, and will, do so after approval.

40. Upon information and belief, Teva knows that its ANDA Product is especially made or adapted for use in infringing the ’085 patent, and is not suitable for substantial noninfringing use. Upon information and belief, Teva plans and intends to, and will, contribute to infringement of the ’085 patent immediately and imminently upon approval of ANDA No. 210928 by commercial manufacture, use, sale, offer for sale or importation of its ANDA Product.

41. The foregoing actions by Teva constitute infringement of the ’085 patent. Additionally, Teva’s commercial manufacture, use, sale, offer for sale or importation of its ANDA Product would constitute infringement of the ’085 patent, active inducement of infringement of the ’085 patent, and contributing to the infringement by others of the ’085 patent.

42. Further, Plaintiffs are entitled to an order of this Court that the effective date of the approval of ANDA No. 210928 be a date that is not earlier than the expiration date of the ’085 patent, or any later expiration of any patent term extension or exclusivity for the ’085 patent to which Plaintiffs become entitled.

43. Plaintiffs will be irreparably harmed by Teva'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 '085 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 Teva on the other regarding Teva's infringement, active inducement of infringement, and contribution to the infringement by others of the '085 patent.

46. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Product, or any other drug product which is covered by or whose use is covered by the '085 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '085 patent.

47. Teva has proceeded with knowledge of the '085 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 Teva has infringed the '085 patent;

(b) A judgment ordering that the effective date of any FDA approval for Teva to make, use, offer for sale, sell, market, distribute, or import Teva's ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation

of which infringes the ’085 patent, be not earlier than the expiration date of the ’085 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Teva, and all persons acting in concert with Teva, from making, using, offering for sale, selling, marketing, distributing, or importing Teva’s ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the ’085 patent, prior to the expiration date of the ’085 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 Teva’s ANDA Product, or any product or compound the making, use, offer for sale, sale, marketing, distribution, or importation of which infringes the ’085 patent prior to the expiration date of the ’085 patent, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the ’085 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.

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