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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED; BAUSCH HEALTH US, LLC; and BAUSCH HEALTH AMERICAS INC., Plaintiffs, v. PADAGIS ISRAEL PHARMACEUTICALS LTD.; PADAGIS US LLC; and PADAGIS LLC, Defendants.	Civil Action No. 22-4248 *Document Electronically Filed*

COMPLAINT

This is a patent infringement action brought by Plaintiffs Bausch Health Ireland Limited ("Bausch Ireland"), Bausch Health US, LLC ("Bausch US"), and Bausch Health Americas Inc. ("Bausch Americas") (collectively, "Bausch" or "Plaintiffs") for infringement of U.S. Patent No. 11,311,482 (the "'482 Patent" or the "Patent-In-Suit") by Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Padagis" or "Defendants"), through the filing of Abbreviated New Drug Application ("ANDA") No. 215393

for the approval of Defendant's generic version of Plaintiffs' Arazlo® product described therein. Plaintiffs hereby alleged as follows:

THE PARTIES

1. Plaintiff Bausch Ireland is a private company incorporated in Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Bausch US is a corporation organized and existing under the law of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

3. Plaintiff Bausch Americas is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

4. Upon information and belief, Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis Israel") is a corporation operating and existing under the laws of Israel, having a principal place of business at 1 Rakefet St., Shoham 608500, Israel. Upon information and belief, Padagis Israel is a wholly owned subsidiary of Padagis LLC.

5. Upon information and belief, Defendant Padagis US LLC ("Padagis US") is a corporation operating and existing under the laws of Delaware, having a principal place of business at 1251 Lincoln Road, Allegan, Michigan, 49010. Upon information and belief, Padagis US is a wholly owned subsidiary of Padagis LLC.

6. Upon information and belief, Defendant Padagis LLC ("Padagis LLC") is a corporation operating and existing under the laws of Delaware, having a principal place of business at 1251 Lincoln Road, Allegan, Michigan, 49010.

7. Upon information and belief, Padagis seeks to, sell, market, and distribute generic pharmaceutical products throughout the United States, including in this district.

NATURE OF THE ACTION

8. This is a civil action for infringement of the Patent-In-Suit. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

9. This action arises out of Padagis's filing of ANDA No. 215393 ("Padagis ANDA") including its Paragraph IV Certification (defined below) under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the Patent-In-Suit is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Padagis ANDA Product (defined below).

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201–02.

11. Upon information and belief, this Court has jurisdiction over Padagis Israel. Upon information and belief, Padagis Israel is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Padagis Israel directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Padagis ANDA Product. Upon information and belief, Padagis Israel purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Padagis Israel has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Padagis Israel has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drug—that will be purposefully directed at, upon information and belief, New Jersey and elsewhere. Padagis Israel's ANDA filing constitutes a formal act that reliably indicates plans to engage in marketing of the proposed generic drug. Upon information and belief, Padagis Israel intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Padagis Israel will engage in marketing of its proposed ANDA product in New Jersey upon approval of its ANDA.

13. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Padagis Israel pursuant to Federal Rule of Civil Procedure 4(k)(2)

because Padagis Israel has extensive contacts with the United States, including but not limited to the above-described commercial contact, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Padagis Israel is consistent with the laws of the United States and the United States Constitution.

14. Upon information and belief, this Court has jurisdiction over Padagis US. Upon information and belief, Padagis US is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and/or selling pharmaceutical products, including generic drug products. Upon information and belief, Padagis US directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for the Padagis ANDA Product. Upon information and belief, Padagis US purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Padagis US has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

15. Upon information and belief, this Court has jurisdiction over Padagis LLC. Upon information and belief, Padagis LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Padagis LLC directly, or indirectly, develops, manufactures, markets, and/or sells generic drug products throughout the United States and in this judicial district through its subsidiaries, and this judicial district is a likely destination for the Padagis ANDA Product. Upon information and belief, Padagis LLC purposefully has conducted and continues to conduct business in this judicial district, at least through its wholly owned subsidiaries Padagis Israel and Padagis US.

16. Upon information and belief, Padagis Israel, Padagis US, and Padagis LLC hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products. Upon information and belief, Padagis LLC exercises control over Padagis Israel and Padagis US.

17. In addition, jurisdiction is proper in this district with respect to Padagis Israel, Padagis US and Padagis LLC because, by stipulation dated June 24, 2022, to be filed concurrently herewith, these entities confirmed that they do not contest jurisdiction in the District of New Jersey for the purposes of this action, and thus have consented to jurisdiction in this District for the purposes of this action.

18. Upon information and belief, venue is proper in this district under 28 U.S.C. §§ 1391(c) and (d), and 1400(b).

19. Venue is further proper as to Padagis Israel, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district, and has previously consented to venue in this jurisdiction.

20. Venue is further proper as to Padagis US and Padagis LLC because both entities have previously consented to venue in this jurisdiction.

21. In addition, venue is proper in this district with respect to Padagis Israel, Padagis US, and Padagis LLC because, by stipulation dated June 24, 2022, to be filed concurrently herewith, these entities confirmed that they do not oppose venue in the District of New Jersey for the purposes of this action, and thus have consented to venue in this District for the purposes of this action.

THE PATENT-IN-SUIT

22. On April 26, 2022, the ’482 Patent entitled “Topical Compositions and Methods for Treating Skin Diseases” was duly and legally issued. A copy of the ’482 Patent is attached as Exhibit A.

23. The named inventors of the ’482 Patent are Arturo Angel and Radhakrishnan Pillai.

24. The FDA’s Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists the expiration of the ’482 Patent as May 11, 2038.

25. Bausch Ireland is the assignee of the ’482 Patent.

ACTS GIVING RISE TO THIS ACTION

26. Bausch US holds the approved New Drug Application ("NDA") No. 211882 for Arazlo® (tazarotene 0.045%) (the "Arazlo® NDA").

27. Arazlo® is indicated for the topical treatment of acne vulgaris in patients 9 years of age or older.

28. Pursuant to 21 U.S.C. § 355(b)(1), the '482 Patent is listed in Orange Book for Arazlo® (tazarotene 0.045%).

29. Upon information and belief, Padagis Israel submitted the Padagis ANDA to the FDA seeking approval to engage in the commercial manufacture, use or sale of a generic tazarotene (0.045%) lotion, referred to herein as the "Padagis ANDA Product."

30. Plaintiffs received from Padagis Israel a letter, dated May 12, 2022, (the "Padagis Notice Letter"), stating that Padagis Israel had included a certification in the Padagis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '482 Patent is invalid, or will not be infringed by the commercial manufacture, use, or sale of the Padagis ANDA Product (the "Paragraph IV Certification.")

31. The Padagis ANDA refers to and relies upon the Arazlo® NDA and contains data that, according to Padagis Israel, demonstrate the bioequivalence of the Padagis ANDA Product and Arazlo®.

32. This action was commenced by Plaintiffs within 45 days of the date of receipt of the Padagis Notice Letter.

CLAIMS FOR RELIEF

COUNT I (Infringement of the '482 Patent)

33. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

34. Upon information and belief, Padagis has infringed at least one claim of the '482 Patent, pursuant to 35 U.S.C. § 271(e)(2), by submitting the Padagis ANDA, by which Padagis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale

within the United States, or importation into the United States of the Padagis ANDA Product prior to the expiration of the '482 Patent.

35. Upon information and belief, the Padagis ANDA Product will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '482 Patent.

36. Upon information and belief, Padagis will, through the manufacture, use, import, offer for sale, and/or sale of the Padagis ANDA Product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '482 Patent.

37. If Padagis's marketing and sale of the Padagis ANDA Product prior to the expiration of the '482 Patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II (Declaratory Judgment of Infringement of the '482 Patent)

38. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

39. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

40. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

41. Padagis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Padagis ANDA Product before the expiration date of the '482 Patent, including Padagis's filing of ANDA No. 215393.

42. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '482 Patent.

43. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Padagis ANDA Product will constitute infringement of at least one claim of the ’482 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor against Padagis on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Padagis has infringed at least one claim of the ’482 Patent by submitting or causing to be submitted ANDA No. 215393 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Padagis ANDA Product before the expiration of the ’482 Patent;

2. order that that the effective date of any approval by the FDA of the Padagis ANDA Product be a date that is not earlier than the expiration of the Patent-In-Suit, or such later date as the Court may determine;

3. enjoin Padagis from the commercial manufacture, use, import, offer for sale, and/or sale of the Padagis ANDA Product until expiration of the Patent-In-Suit, or such later date as the Court may determine;

4. enjoin Padagis and all persons acting in concert with Padagis from seeking, obtaining, or maintaining approval of Padagis’s ANDA No. 215393 until expiration of the Patent-In-Suit;

5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney’s fees; and

9. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: June 24, 2022
Newark, New Jersey

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: June 24, 2022
Newark, New Jersey

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