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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH US, LLC f/k/a VALEANT
PHARMACEUTICALS NORTH AMERICA
LLC; BAUSCH HEALTH IRELAND LIMITED
f/k/a VALEANT PHARMACEUTICALS
IRELAND LTD.; BAUSCH HEALTH
AMERICAS, INC. f/k/a VALEANT
PHARMACEUTICALS INTERNATIONAL;
and KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.;
ZYDUS WORLDWIDE DMCC; and CADILA
HEALTHCARE LIMITED d/b/a ZYDUS
CADILA,

Defendants.

Civil Action No. 20-2748

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch Health US, LLC (“Bausch,” formerly known as Valeant Pharmaceuticals North America LLC), Bausch Pharmaceuticals Ireland Ltd. (“Bausch Ireland,” formerly known as Valeant Pharmaceuticals Ireland Ltd.), and Bausch Health Americas, Inc. (“Bausch Americas,” formerly known as Valeant Pharmaceuticals International), and Kaken Pharmaceutical Co., Ltd.

(“Kaken”) (collectively, “Plaintiffs”) by way of this Complaint against Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”), Zydus Worldwide DMCC (“Zydus Worldwide”), and Cadila Healthcare Limited d/b/a Zydus Cadila (“Zydus Cadila”) (collectively, “Zydus” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Bausch is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Bausch Ireland is a company existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Bausch Americas is a corporation organized and existing under the laws of Delaware, having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

4. Plaintiff Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

5. Upon information and belief, Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

6. Upon information and belief, Zydus Worldwide is a corporation organized and existing under the laws of United Arab Emirates, having a principal place of business at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Rashid, Dubai, United Arab Emirates.

7. Upon information and belief, Zydus Cadila is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad, 380015, Gujarat, India.

8. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Worldwide.

NATURE OF THE ACTION

9. This is an action for infringement of United States Patent Nos. 10,512,640 (“the ’640 patent”); 10,342,875 (“the ’875 patent”); and 10,478,601 (“the ’601 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Zydus’s filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic efinaconazole topical solution, 10% (“Zydus’s generic efinaconazole topical solution”).¹

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 Zydus Worldwide. Upon information and belief, Zydus Worldwide is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug

¹ A related action against Zydus for infringement of United States Patent Nos. 7,214,506 (“the ’506 patent”), 8,039,494 (“the ’494 patent”), 8,486,978 (“the ’978 patent”), 9,302,009 (“the ’009 patent”), 9,566,272 (“the ’272 patent”), 9,662,394 (“the ’394 patent”), 9,861,698 (“the ’698 patent”), 9,877,955 (“the ’955 patent”), and 10,105,444 (“the ’444 patent”) is pending in this District. *See* Nos. 3:18-cv-13635, 3:19-cv-05162 (consolidated into No. 3:18-cv-13635).

products. Upon information and belief, Zydus Worldwide 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 Zydus's generic efinaconazole topical solution. Upon information and belief, Zydus Worldwide purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Zydus Worldwide 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, including in actions related to the same ANDA at issue in this suit.

12. Upon information and belief, this court has jurisdiction over Zydus Cadila. Upon information and belief, Zydus Cadila is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Zydus Cadila 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 Zydus's generic efinaconazole topical solution. Upon information and belief, Zydus Cadila purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Zydus Cadila 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, including in actions related to the same ANDA at issue in this suit.

13. Upon information and belief, this Court has jurisdiction over Zydus USA. Upon information and belief, Zydus USA is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Zydus USA directly, or indirectly, develops, manufactures, markets, and

sells generic drug products manufactured by Zydus Worldwide and Zydus Cadila, throughout the United States and in this judicial district, and this judicial district is a likely destination for Zydus's generic efinaconazole topical solution. Upon information and belief, Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Zydus USA purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Zydus USA 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, including in actions related to the same ANDA at issue in this suit.

14. Zydus Worldwide has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. Zydus Worldwide's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Zydus Worldwide 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, Zydus Worldwide will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

15. Upon information and belief, Zydus Worldwide, Zydus Cadila, and Zydus USA operate as a single integrated business. Upon information and belief, Zydus Worldwide, Zydus Cadila, and Zydus USA each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

16. Zydus Worldwide, Zydus Cadila, and Zydus USA know or should know that Jublia® is manufactured for Bausch, formerly known as Valeant Pharmaceuticals North America LLC, in Bridgewater, NJ 08807 USA at least because that information is included in Jublia®'s label and prescribing information.

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

18. Venue is proper against Zydus Worldwide, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

19. Venue is proper against Zydus Cadila, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

20. Venue is proper against Zydus USA because it is incorporated in New Jersey and operates a principal place of business in this judicial district.

THE PATENTS IN SUIT

21. The United States Patent and Trademark Office ("PTO") issued the '640 patent on December 24, 2019. The '640 patent claims, generally speaking, *inter alia*, methods of treatment of onychomycosis comprising topically applying pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl lactate and a triazole antifungal agent. Plaintiffs hold all substantial rights in the '640 patent and have the right to sue for infringement thereof. The '640 patent is valid and enforceable. A copy of the '640 patent is attached hereto as Exhibit A.

22. The PTO issued the '875 patent on July 9, 2019. The '875 patent claims, generally speaking, *inter alia*, methods of treatment of onychomycosis comprising topically applying pharmaceutical formulations including ethanol, cyclomethicone, diisopropyl adipate, C12-15 alkyl

lactate, butylated hydroxytoluene (BHT), a salt of ethylenediaminetetraacetic acid (EDTA), citric acid and a triazole antifungal agent. Plaintiffs hold all substantial rights in the '875 patent and have the right to sue for infringement thereof. The '875 patent is valid and enforceable. A copy of the '875 patent is attached hereto as Exhibit B.

23. The PTO issued the '601 patent on November 19, 2019. The '601 patent claims, generally speaking, *inter alia*, drug applicators with specific physical characteristics, and methods of using said applicators to treat, among other diseases, tinea unguium (onychomycosis). Plaintiffs hold all substantial rights in the '601 patent and have the right to sue for infringement thereof. The '601 patent is valid and enforceable. A copy of the '601 patent is attached hereto as Exhibit C.

24. Bausch Americas is the holder of New Drug Application ("NDA") No. 203567 for Jublia[®], which the FDA approved on June 6, 2014. In conjunction with NDA No. 203567, the '640, '875 and '601 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

25. Efinaconazole topical solution, 10% is sold in the United States under the trademark Jublia[®].

ZYDUS'S INFRINGING ANDA SUBMISSION

26. Upon information and belief, Zydus filed or caused to be filed with the FDA ANDA No. 212178, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

27. Upon information and belief, Zydus's ANDA No. 212178 seeks FDA approval to sell in the United States Zydus's generic efinaconazole topical solution, intended to be a generic version of Jublia[®].

28. Upon information and belief, ANDA No. 212178 seeks approval of Zydus's generic efinaconazole topical solution that is the same, or substantially the same, as Jublia[®].

COUNT I AGAINST ZYDUS

Infringement of the '640 Patent under § 271(e)(2)

29. Paragraphs 1–28 are incorporated herein as set forth above.

30. Under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '640 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212178 seeking approval for the commercial marketing of Zydus's generic efinaconazole topical solution before the expiration date of the '640 patent.

31. Upon information and belief, Zydus's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '640 patent.

32. Upon information and belief, Zydus will, through the manufacture, use, import, offer for sale, and/or sale of Zydus's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '640 patent.

33. If Zydus's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '640 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II AGAINST ZYDUS

Declaratory Judgment of Infringement of the '640 Patent

34. Paragraphs 1–33 are incorporated herein as set forth above.

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

36. 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.

37. Zydus has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Zydus's generic efinaconazole topical solution before the expiration date of the '640 patent, including Zydus's filing of ANDA No. 212178.

38. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '640 patent.

39. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic efinaconazole topical solution will constitute infringement of at least one claim of the '640 patent.

COUNT III AGAINST ZYDUS

Infringement of the '875 Patent under § 271(e)(2)

40. Paragraphs 1–39 are incorporated herein as set forth above.

41. Under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '875 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212178 seeking approval for the commercial marketing of Zydus's generic efinaconazole topical solution before the expiration date of the '875 patent.

42. Upon information and belief, Zydus's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '875 patent.

43. Upon information and belief, Zydus will, through the manufacture, use, import, offer for sale, and/or sale of Zydus's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '875 patent.

44. If Zydus's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '875 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV AGAINST ZYDUS

Declaratory Judgment of Infringement of the '875 Patent

45. Paragraphs 1–44 are incorporated herein as set forth above.

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

47. 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.

48. Zydus has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Zydus's generic efinaconazole topical solution before the expiration date of the '875 patent, including Zydus's filing of ANDA No. 212178.

49. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '875 patent.

50. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic efinaconazole topical solution will constitute infringement of at least one claim of the '875 patent.

COUNT V AGAINST ZYDUS

Infringement of the '601 Patent under § 271(e)(2)

51. Paragraphs 1–50 are incorporated herein as set forth above.

52. Under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '601 patent by submitting, or causing to be submitted to the FDA, ANDA No. 212178 seeking approval for the commercial marketing of Zydus's generic efinaconazole topical solution before the expiration date of the '601 patent.

53. Upon information and belief, Zydus's generic efinaconazole topical solution will, if approved and marketed, infringe, either literally or under the doctrine of equivalents, at least one claim of the '601 patent.

54. Upon information and belief, Zydus will, through the manufacture, use, import, offer for sale, and/or sale of Zydus's generic efinaconazole topical solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '601 patent.

55. If Zydus's marketing and sale of its generic efinaconazole topical solution prior to the expiration of the '601 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI AGAINST ZYDUS

Declaratory Judgment of Infringement of the '601 Patent

56. Paragraphs 1-51 are incorporated herein as set forth above.

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

58. 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.

59. Zydus has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Zydus's generic efinaconazole topical solution before the expiration date of the '601 patent, including Zydus's filing of ANDA No. 203567.

60. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic efinaconazole topical solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '601 patent.

61. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's generic efinaconazole topical solution will constitute infringement of at least one claim of the '601 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Zydus 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), Zydus has infringed at least one claim of the '640 patent by submitting or causing to be submitted ANDA No. 203567 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus's generic efinaconazole topical solution before the expiration of the '640 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '875 patent by submitting or causing to be submitted ANDA No. 203567 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the

United States of Zydus's generic efinaconazole topical solution before the expiration of the '875 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Zydus has infringed at least one claim of the '601 patent by submitting or causing to be submitted ANDA No. 203567 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus's generic efinaconazole topical solution before the expiration of the '601 patent;

4. order that that the effective date of any approval by the FDA of Zydus's generic efinaconazole topical solution be a date that is not earlier than the expiration of the '640 patent, the '875 patent, and the '601 patent, or such later date as the Court may determine;

5. enjoin Zydus from the commercial manufacture, use, import, offer for sale, and/or sale of Zydus's generic efinaconazole topical solution until expiration of the '640 patent, the '875 patent, and the '601 patent, or such later date as the Court may determine;

6. enjoin Zydus and all persons acting in concert with Zydus from seeking, obtaining, or maintaining approval of Zydus's ANDA No. 203567 until expiration of the '640 patent, the '875 patent, and the '601 patent;

7. 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

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

Dated: March 12, 2020
Newark, New Jersey

Respectfully submitted,

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

Dated: March 12, 2020
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

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