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

BIOMARIN PHARMACEUTICAL INC.,

Plaintiff,

v.

ZYDUS LIFESCIENCES LIMITED, ZYDUS
LIFESCIENCES GLOBAL FZE, and ZYDUS
PHARMACEUTICALS (USA) INC.,

Defendants.

Civil Action No. 26-1005

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff BioMarin Pharmaceutical Inc. (“BioMarin”), by its attorneys, brings this Complaint against Defendants Zydus Lifesciences Limited (“Zydus Ltd.”), Zydus Lifesciences Global FZE (“Zydus FZE”), and Zydus Pharmaceuticals (USA) Inc. (“Zydus USA” and, collectively with Zydus Ltd. and Zydus FZE, “Defendants” or “Zydus”) and hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, and 21 U.S.C. § 355(j) (the “Hatch-Waxman Act”), arising from

Zydus's submission of an Abbreviated New Drug Application ("ANDA"), No. 220670 ("Zydus's ANDA"), with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a purported generic version of VOXZOGO[®] (vosoritide for injection, 0.4 mg/vial, 0.56 mg/vial, and 1.2 mg/vial), prior to the expiration of U.S. Patent No. 12,233,106 ("the '106 patent"). VOXZOGO[®] was the first drug to receive regulatory approval for treatment of achondroplasia in the United States.

PARTIES

2. Plaintiff BioMarin is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 770 Lindero Street, San Rafael, California 94901.

3. On information and belief, Defendant Zydus Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, Gujarat, India.

4. On information and belief, Defendant Zydus FZE is a corporation organized and existing under the laws of Dubai, United Arab Emirates, having a principal place of business at FZJO B2601, Jebel Ali Free Zone Dubai, Dubai, United Arab Emirates. On information and belief, Zydus FZE is a wholly owned subsidiary of Zydus Ltd. and is controlled by Zydus Ltd.

5. On information and belief, Defendant 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 N., Pennington, NJ 08534. On information and belief, Zydus USA is a wholly owned subsidiary of Zydus Ltd. and is controlled by Zydus Ltd.

6. On information and belief, Defendants are in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

7. By a letter dated January 5, 2026 (“Zydus Notice Letter”), Zydus notified BioMarin that Zydus had submitted to the FDA Zydus’s ANDA for approval to market and sell in the United States a purported generic version of VOXZOGO® (vosoritide for injection, 0.4 mg/vial, 0.56 mg/vial, and 1.2 mg/vial) (referred to herein as the “Zydus ANDA Product”), for use with *inter alia* children 2 years of age and younger, prior to the expiration of the ’106 patent.

8. On information and belief, Defendants have acted and continue to act in concert with respect to the preparation, submission, and prosecution of Zydus’s ANDA, as well as the preparation and submission of the Zydus Notice Letter.

9. On information and belief, Defendants know and intend that upon approval of Zydus’s ANDA, Defendants will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Zydus ANDA Product throughout the United States, including in New Jersey, for a use that is covered by the ’106 patent. On information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the Zydus ANDA Product, and enter into agreements that are nearer than arm’s length. On information and belief, Defendants participated, assisted, and cooperated in carrying out the acts detailed in this Complaint.

10. On information and belief, following any FDA approval of Zydus’s ANDA, Defendants will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Zydus ANDA Product throughout the United States, including in New Jersey, for a use that is covered by the ’106 patent.

JURISDICTION AND VENUE

11. Plaintiff incorporates each of the preceding paragraphs 1–10 as if fully set forth herein.

12. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the '106 patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 & 1338(a).

13. Zydus Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Zydus Ltd. itself, including by and through its agents Zydus FZE and Zydus USA, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Zydus Ltd. itself, and through its agents Zydus FZE and Zydus USA, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Zydus Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Zydus FZE and Zydus USA, and therefore the activities of Zydus FZE and Zydus USA in this jurisdiction are attributable to Zydus Ltd.

14. Zydus Ltd., in concert with Zydus FZE and Zydus USA, has committed an act of infringement in this judicial district by filing Zydus's ANDA with the intent to make, use, sell, offer for sale, and/or import the Zydus ANDA Product in or into this judicial district, prior to the expiration of the '106 patent, for a use that is covered by the '106 patent.

15. Additionally, this Court has personal jurisdiction over Zydus Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as: (a) Plaintiff's claims arise under federal law; (b) Zydus Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Ltd. has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Zydus's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Zydus Ltd. satisfies due process.

16. Zydus Ltd. has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g., Genentech, Inc. v. Natco Pharma Ltd.*, No. 2:25-cv-17100-BRM-JSA (D.N.J. Oct. 31, 2025).

17. Zydus FZE is subject to personal jurisdiction in New Jersey because, among other things, Zydus FZE itself, including by and through its affiliate Zydus USA, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Zydus FZE itself, and through its affiliate Zydus USA, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

18. Zydus FZE, in concert with Zydus USA, has committed an act of infringement in this judicial district by filing Zydus's ANDA with the intent to make, use, sell, offer for sale, and/or import the Zydus ANDA Product in or into this judicial district, prior to the expiration of the '106 patent, for a use that is covered by the '106 patent.

19. Additionally, this Court has personal jurisdiction over Zydus FZE because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as: (a) Plaintiff's claims arise under federal law; (b) Zydus FZE is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zydus FZE has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Zydus's ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, including in this judicial district, such that this Court's exercise of jurisdiction over Zydus FZE satisfies due process.

20. Zydus FZE has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g., Genentech, Inc. v. Natco Pharma Ltd.*, No. 2:25-cv-17100-BRM-JSA (D.N.J. Oct. 31, 2025).

21. This Court has personal jurisdiction over Zydus USA because Zydus USA is a corporation organized and existing under the laws of the State of New Jersey and having a principal place of business in New Jersey.

22. Zydus USA is also subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Zydus USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID. No. 0100915422. On information and belief, Zydus USA is registered with the New Jersey Department of Health as a drug manufacturer (Drug and Medical Device Certificate of Registration Number 5003171).

23. On information and belief, Zydus USA develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including

in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

24. Zydus USA has consented to jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g., Genentech, Inc. v. Natco Pharma Ltd.*, No. 2:25-cv-17100-BRM-JSA (D.N.J. Oct. 31, 2025).

25. Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Zydus ANDA Product for a use that is covered by the '106 patent, that will be purposefully directed at New Jersey and elsewhere in the United States.

26. On information and belief, Defendants have systematic and continuous contacts with New Jersey; have established distribution channels for drug products in New Jersey; regularly and continuously conduct business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in New Jersey; and derive substantial revenue from the sale of drug products in New Jersey.

27. On information and belief, if Zydus's ANDA is approved, Defendants will manufacture, market, promote, sell, offer for sale, import, use, and/or distribute the Zydus ANDA Product within the United States, including in New Jersey, for a use that is covered by the '106 patent and consistent with Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Defendants regularly do business in New Jersey, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in

New Jersey. On information and belief, Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On information and belief, the Zydus ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey, all for a use that is covered by the '106 patent. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the '106 patent in the event that the Zydus ANDA Product is approved before the '106 patent expires.

28. On information and belief, Defendants derive substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and that are manufactured by Defendants and/or for which Zydus Ltd., Zydus FZE, and/or Zydus USA is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Zydus Ltd., Zydus FZE, and/or Zydus USA is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in New Jersey.

29. Venue is proper in this Court as to Zydus Ltd. because Zydus Ltd. is a foreign entity that may be sued in any judicial district, including in the District of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

30. Venue is proper in this Court as to Zydus FZE because Zydus FZE is a foreign entity that may be sued in any judicial district, including in the District of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

31. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Zydus USA, because, on information and belief, Zydus USA is organized under the laws of the State of New Jersey, has a regular and established place of business in New Jersey, and because, on information and belief, Zydus USA has committed or aided, abetted, contributed to, and/or

participated in the commission of, acts of infringement of the '106 patent that will lead to foreseeable harm and injury to Plaintiff by preparing or assisting in preparing Zydus's ANDA in New Jersey and/or with the intention of seeking to market the Zydus ANDA Product nationwide, including within New Jersey, for a use that is covered by the '106 patent.

THE '106 PATENT

32. The '106 patent is entitled "Use of C-Type Natriuretic Peptide Variants to Treat Skeletal Dysplasia in Children" and is attached as Exhibit A.

33. The '106 patent was duly and legally issued on February 12, 2025.

34. BioMarin owns and has the right to enforce the '106 patent.

35. The '106 patent is directed generally to novel methods of treating skeletal dysplasias in children from birth to about two years of age, and improvement in one or more symptoms of skeletal dysplasia by administering variants of C-type natriuretic peptides.

36. FDA's List of Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") currently lists the expiration of the '106 patent as July 11, 2042.

THE VOXZOGO® DRUG PRODUCT

37. VOXZOGO® is a groundbreaking innovation for the treatment of achondroplasia, and the first drug to receive regulatory approval for treatment of achondroplasia – the most common type of dwarfism – in the United States. BioMarin is the holder of NDA No. 214938, under which the FDA approved the commercial marketing of VOXZOGO® (vosoritide for injection, 0.4 mg/vial, 0.56 mg/vial, and 1.2 mg/vial) on November 19, 2021, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a).

38. VOXZOGO® is a daily injection of vosoritide given under the skin, once a day at about the same time every day. A caregiver (or the patient) administers VOXZOGO® to the patient pursuant to instructions from a healthcare provider. VOXZOGO® increases linear growth plate

in children with achondroplasia and whose growth plates remain open. A healthcare provider will monitor patient growth on VOXZOGO® and stop treatment if they determine the patient is no longer able to grow. A true and correct copy of the current prescribing information for VOXZOGO® is attached as Exhibit B.

39. Approved methods of using VOXZOGO® are covered by one or more claims of the '106 patent. The '106 patent is listed with NDA No. 214938 in the FDA's Orange Book.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

40. Zydus has submitted, or caused the submission of, Zydus's ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Zydus ANDA Product, as a purported generic version of VOXZOGO®, prior to the expiration of the '106 patent.

41. On information and belief, the FDA has not yet approved Zydus's ANDA.

42. In the Zydus Notice Letter, Zydus notified Plaintiff that Zydus's ANDA had been submitted to the FDA, and that it contained a Paragraph IV certification directed to the '106 patent. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The purpose of this submission was to obtain approval under the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product prior to the expiration of the '106 patent, for a use that is covered by the '106 patent.

43. On information and belief, Zydus's ANDA contains a Paragraph III certification directed to BioMarin's U.S. Patent No. 8,198,242 (the "'242 patent"), which is listed in the Orange Book in conjunction with VOXZOGO®, meaning that Zydus has asked FDA not to finally approve the Zydus ANDA Product until after the '242 patent expires. 21 U.S.C. § 355(j)(2)(A)(vii)(III). The U.S. Patent and Trademark Office has recently awarded a patent term extension (PTE) for the '242 patent, meaning that it will not expire until June 11, 2035.

44. On information and belief, Zydus's ANDA also contains a Paragraph III certification directed to BioMarin's U.S. Reissued Patent No. RE48267, which is listed in the Orange Book in conjunction with VOXZOGO®, and which expires on May 20, 2030.

45. The Reference Listed Drug for Zydus's ANDA is VOXZOGO®. VOXZOGO® is indicated for use by pediatric patients with achondroplasia who have open epiphyses, or growth plates.

46. The Zydus ANDA Product is vosoritide for injection, 0.4 mg/vial, 0.56 mg/vial, and 1.2 mg/vial.

47. Zydus, through its own actions and through the actions of its agents, affiliates, and subsidiaries, prepared and submitted Zydus's ANDA, and intends to further prosecute Zydus's ANDA. On information and belief, if the FDA approves Zydus's ANDA, Zydus will manufacture, offer for sale, or sell the Zydus ANDA Product within the United States, or will import the Zydus ANDA Product into the United States. On information and belief, if the FDA approves Zydus's ANDA, Zydus will directly manufacture, use, offer for sale, sell, or import the Zydus ANDA and/or actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Zydus ANDA Product in or into the United States, for a use that is covered by the '106 patent.

48. Plaintiff brings this action within forty-five (45) days of receipt of the Zydus Notice Letter. Accordingly, Plaintiff is entitled to a stay of FDA approval of Zydus's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I

INFRINGEMENT OF THE '106 PATENT

49. Plaintiff incorporates each of the preceding paragraphs 1–48 as if fully set forth herein.

50. The intended use of the Zydus ANDA Product to treat skeletal dysplasia in children from birth to about 2 years of age is covered by one or more claims of the '106 patent including, but not limited to, claim 1 of the '106 patent.

51. In the Zydus Notice Letter, Zydus did not contest the infringement of claims 1–14 of the '106 patent. If Zydus had a factual or legal basis to contest infringement of those claims of the '106 patent, then it was required by applicable regulations to state such a basis in the Zydus Notice Letter. *See* 21 C.F.R. § 314.52 (requiring a Paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug as to which the applicant has submitted a Paragraph IV Certification). Thus, Zydus has conceded infringement of the '106 patent.

52. Zydus's submission of Zydus's ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Zydus ANDA Product in or into the United States before the expiration of the '106 patent is an act of infringement of the '106 patent under 35 U.S.C. § 271(e)(2)(A).

53. Zydus has full knowledge of the '106 patent and its claims, as evidenced *inter alia* by its submission of a Paragraph IV certification directed to that patent in Zydus's ANDA and its submission of a purported analysis of that patent as part of the Zydus Notice Letter.

54. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will infringe one or more claims of the '106 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Zydus ANDA Product in or into the United States for a use that is covered by the '106 patent.

55. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will induce infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Zydus ANDA Product in or into the United States for a use that is covered by the '106 patent. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will, through its own actions or through the actions of its agents, affiliates, and subsidiaries, market and/or distribute the Zydus ANDA Product to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Zydus will knowingly and intentionally accompany the Zydus ANDA Product with a product labeling or product insert that will include instructions for using or administering the Zydus ANDA Product, which are substantially similar to the instructions in the prescribing information for VOXZOGO[®], attached as Exhibit B, and which, if followed, will infringe the '106 patent. Accordingly, Zydus will induce healthcare professionals, caregivers, and/or other end users of the Zydus ANDA Product to directly infringe the '106 patent. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will intentionally encourage acts of direct infringement with knowledge of the '106 patent and knowledge that its acts are encouraging infringement.

56. On information and belief, upon FDA approval of Zydus's ANDA, Zydus will contributorily infringe one or more claims of the '106 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing the Zydus ANDA Product in or into the United States. On information and belief, Zydus has had and continues to have knowledge that the Zydus ANDA Product is especially adapted for a use that infringes one or more claims of the '106 patent, including at least claim 1, and that there is no substantial non-infringing use for the Zydus ANDA Product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

- a) A judgment that the '106 patent has been infringed under 35 U.S.C. § 271(e)(2) by Zydus's submission to the FDA of Zydus's ANDA;
- b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the Zydus ANDA Product, or any other drug product that infringes or the use of which infringes the '106 patent, be no earlier than the expiration date of the '106 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Federal Rule of Civil Procedure 65, enjoining Zydus, and all persons acting in concert with Zydus, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Zydus ANDA Product, or any other drug product covered by or whose use is covered by the '106 patent prior to the expiration of the '106 patent inclusive of any extension(s) and additional period(s) of exclusivity;
- d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Zydus ANDA Product, or any other drug product that is covered by or whose use is covered by the '106 patent, prior to the expiration of the '106 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement, and contribute to the infringement by others of the '106 patent;
- e) A judgment declaring that Zydus's commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Zydus ANDA

Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '106 patent by Zydus under one or more of 35 U.S.C. §§ 271(a), (b), and (c);

f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Zydus engages in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Zydus ANDA Product, or any product that infringes the '106 patent, or induces or contributes to such conduct, prior to the expiration of the '106 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

g) A judgment that Zydus willfully and deliberately induced infringement of the '106 patent;

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

i) Costs and expenses in this action; and such further and other relief as this Court may deem just and proper.

Dated: February 2, 2026
Newark, New Jersey

s/ William P. Deni, Jr.
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