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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GENENTECH, INC., HOFFMANN-LA ROCHE INC., and PTC THERAPEUTICS, INC.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 2:24-10567 (BRM)(JSA)
(Consolidated)

Document Electronically Filed

ZYDUS LIFESCIENCES GLOBAL FZE, ZYDUS LIFESCIENCES LIMITED, AND ZYDUS PHARMACEUTICALS (USA) INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendants Zydus Lifesciences Global FZE ("Zydus Global"), Zydus Lifesciences Limited ("Zydus Lifesciences"), and Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") (collectively, "Defendants"), for their Answer and Affirmative Defenses to the Complaint of Genentech, Inc. ("Genentech") and Hoffmann-La Roche, Inc. ("Roche") (collectively, "Plaintiffs"), state as follows:

All averments not expressly admitted are denied.

NATURE OF THE ACTION

1. This is an action for patent infringement under the laws of the United States, including 35 U.S.C. §§ 271(a), (b), (c), (e), and (f), arising from Zydus's Abbreviated New Drug Application No. 219902 (the "Zydus ANDA") to the United States Food and Drug Administration ("FDA"), by which Zydus seeks approval to market a generic version of Genentech and Roche's pharmaceutical product EVRYSDI® (risdiplam) prior to the expiration of United States Patent No. 12,122,789 (the "'789 Patent" or the "Asserted Patent"), which covers, *inter alia*, EVRYSDI®.

ANSWER: The allegations in paragraph 1 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs' Complaint purports to be a civil action alleging infringement of U.S. Patent No. 12,122,789 ("the '789 patent") under Title 35 of the United States Code. Defendants further admit that Zydus Global submitted Abbreviated New Drug Application ("ANDA") No. 219902 to the U.S. Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of risdiplam for oral solution, 0.75 mg/mL ("the Proposed ANDA Product") in or into the United States, that ANDA No. 219902 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '789 patent, and that ANDA No. 219902 identifies EVRYSDI® (risdiplam) for oral solution, 0.75 mg/mL as the Reference Listed Drug. Defendants lack knowledge or information sufficient to form a belief regarding the allegation that the '789 patent "covers, *inter alia*, EVRYSDI®" and therefore denies that allegation. Defendants deny that the Proposed ANDA Product infringes any valid and enforceable claim of the '789 patent. Defendants deny all other allegations in paragraph 1.

THE PARTIES

2. Plaintiff Roche is a New Jersey corporation with a principal place of business at 150 Clove Road, Little Falls, NJ 07424. Roche is a pharmaceutical company that researches, develops, and manufactures drugs to address unmet medical needs. Roche helped develop and obtained approval from FDA to market EVRYSDI®, the first and only therapy approved by FDA for treatment of spinal muscular atrophy ("SMA") in adults and children two months of age and older that can be administered orally at home.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore deny them.

3. Plaintiff Genentech is a Delaware corporation with a principal place of business at One DNA Way, South San Francisco, CA 94080. Genentech is a biotechnology company that develops, manufactures, and commercializes medicines to treat patients with serious and life-threatening medical conditions. Genentech holds the exclusive right to sell, distribute, and market EVRYSDI® in the United States.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore deny them.

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.

ANSWER: Defendants admit that Zydus Global is an entity organized and existing under the laws of Dubai, United Arab Emirates, and that Zydus Global has a principal place of business at FZJO B2601, Jebel Ali Free Zone Dubai, Dubai, United Arab Emirates. Defendants further admit that Zydus Global is a wholly owned subsidiary of Zydus Lifesciences. Defendants deny all other allegations in paragraph 4.

5. On information and belief, Defendant Zydus Ltd. is a corporation organized and existing under the laws of India, having its corporate offices and 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.

ANSWER: Defendants admit that Zydus Lifesciences is an entity organized and existing under the laws of India, and that Zydus Lifesciences has 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, India. Defendants deny all other allegations in paragraph 5.

6. On information and belief, Defendant Zydus Inc. is a corporation organized and existing under the laws of New Jersey, having a principal place of business located at 73 Route 31

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

ANSWER: Defendants admit that Zydus USA is an entity organized and existing under the laws of New Jersey, having a principal place of business located at 73 Route 31 N., Pennington, NJ 08534. Defendants further admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Defendants deny all other allegations in paragraph 6.

7. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc. acted in concert to prepare and file the Zydus ANDA.

ANSWER: The allegations in paragraph 7 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 219902. Defendants further admit that ANDA No. 219902 identifies Zydus Lifesciences as the manufacturer of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 7.

JURISDICTION

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in paragraph 8 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to the Proposed ANDA Product. Defendants deny all other allegations in paragraph 8.

9. This Court has personal jurisdiction over Zydus FZE and Zydus Ltd. under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Zydus FZE and Zydus Ltd. are organized under the laws of Dubai and India, respectively, and are not subject to jurisdiction in any State's courts of general jurisdiction and because exercising jurisdiction is consistent with the United States

Constitution and laws, including because Zydus FZE and Zydus Ltd. have sufficient contacts with the United States that relate to the claims in this case.

ANSWER: The allegations in paragraph 9 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Global and Zydus Lifesciences do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Global and Zydus Lifesciences and solely as they apply to the Proposed ANDA Product. Defendants admit that Zydus Global is an entity organized and existing under the laws of Dubai, United Arab Emirates and that Zydus Lifesciences is an entity organized and existing under the laws of India. Defendants deny all other allegations in paragraph 9.

10. On information and belief, Zydus FZE is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of New Jersey and throughout the United States.

ANSWER: Denied.

11. Zydus FZE has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, including Genentech, which sells EVRYSDI® for use throughout the United States, including in this judicial District. On information and belief, and as indicated by the Zydus Notice Letter (as further defined herein), Zydus FZE prepared and filed, or aided, abetted, contributed to, and/or participated in the preparation and filing of the Zydus ANDA with the intention of seeking to market generic risdiplam nationwide, including within this judicial District.

ANSWER: Defendants deny the allegations in the first sentence of paragraph 11. Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 11.

12. On information and belief, Zydus FZE plans to market and sell generic risdiplam in the State of New Jersey, list generic risdiplam on the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursement for sales of the ANDA products in the State of New Jersey, either directly or through one or more of Zydus FZE's wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 12.

13. On information and belief, Zydus FZE knows and intends that its proposed generic risdiplam product will be distributed and sold in New Jersey and will thereby displace sales of EVRYSDI®, causing injury to Plaintiffs. Zydus FZE intends to take advantage of its established channels of distribution in New Jersey for the sale of its proposed generic risdiplam product.

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 13.

14. This Court also has personal jurisdiction over Zydus Ltd. by virtue of, *inter alia*, its having engaged in systematic and continuous contacts with the State of New Jersey, including but not limited to through its United States subsidiary Zydus Inc., which has a principal place of business in Pennington, NJ; having previously admitted, consented to, or declined to contest the jurisdiction of this Court; and/or having availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, *AbbVie Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, Civ. No. 24-4603-ZNQ (D.N.J. Apr. 5, 2024); *Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, Civ. No. 22-2964-EP (D.N.J. Apr. 14, 2024).

ANSWER: The allegations in paragraph 14 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences and solely as they apply to the Proposed ANDA Product. Defendants admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences and that Zydus USA is a New Jersey corporation with a principal place of business in Pennington, New Jersey. Defendants further admit that in *AbbVie Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, C.A. No. 24-cv-4603 (D.N.J.), D.I. 24 at ¶ 17, Zydus Lifesciences stated "Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus

Lifesciences in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product"; and that in *Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 22-cv-2964 (D.N.J.), D.I. 25 at ¶ 23, Zydus Lifesciences stated "Zydus Lifesciences does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113." Defendants deny all other allegations in paragraph 14.

15. On information and belief, Zydus Ltd. is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of New Jersey and throughout the United States.

ANSWER: Defendants admit that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceutical products, sold in the United States. Defendants deny all other allegations in paragraph 15.

16. Zydus Ltd. has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, including Genentech, which sells EVRYSDI® for use throughout the United States, including in this judicial District. On information and belief, and as indicated by the Zydus Notice Letter (as further defined herein), Zydus Ltd. prepared and filed, or aided, abetted, contributed to, and/or participated in the preparation and filing of the Zydus ANDA with the intention of seeking to market generic risdiplam nationwide, including within this judicial District.

ANSWER: Defendants deny the allegations in the first sentence of paragraph 16. Defendants admit that ANDA No. 219902 identifies Zydus Lifesciences as the manufacturer of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 16.

17. On information and belief, Zydus Ltd. plans to market and sell generic risdiplam in the State of New Jersey, list generic risdiplam on the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursement for sales of the ANDA products in the State of New Jersey, either directly or through one or more of Zydus Ltd.'s wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States.

Defendants further admit that ANDA No. 219902 identifies Zydus Lifesciences as the manufacturer of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 17.

18. On information and belief, Zydus Ltd. knows and intends that its proposed generic risdiplam product will be distributed and sold in New Jersey and will thereby displace sales of EVRYSDI®, causing injury to Plaintiffs. Zydus Ltd. intends to take advantage of its established channels of distribution in New Jersey for the sale of its proposed generic risdiplam product.

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 219902 identifies Zydus Lifesciences as the manufacturer of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 18.

19. Although this court has personal jurisdiction over Zydus FZE and Zydus Ltd. for at least the reasons set forth above, in the absence of such personal jurisdiction in any single state, foreign entities such as Zydus FZE and Zydus Ltd. are subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2); *see, e.g.*, *Genetic Veterinary Scis.*, 933 F.3d at 1311–12; *M-I Drilling Fluids UK*, 890 F.3d at 1003.

ANSWER: The allegations in paragraph 19 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Global and Zydus Lifesciences do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Global and Zydus Lifesciences and solely as they apply to the Proposed ANDA Product. Defendants deny all other allegations in paragraph 19.

20. This Court has personal jurisdiction over Zydus Inc. by virtue of, *inter alia*, its being incorporated in the State of New Jersey and having a principal place of business in Pennington, NJ, and its having engaged in systematic and continuous contacts with the State of New Jersey; its having previously admitted, consented to, or declined to contest the jurisdiction of this Court; and/or its having availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, *AbbVie Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, Civ. No. 24-4603-ZNQ (D.N.J. Apr. 5, 2024); *Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, Civ. No. 22-2964-SRC (D.N.J. May 20,

2022); *Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*, Civ. No. 18-13635-PGS (D.N.J. Sept. 6, 2018); *Otsuka Pharm. Co. Ltd. v. Zydus Pharms. USA Inc. et al.*, Civ. No. 17-2754-JBS (D.N.J. Apr. 21, 2017).

ANSWER: The allegations in paragraph 20 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to the Proposed ANDA Product. Defendants admit that Zydus USA is a New Jersey corporation with a principal place of business in Pennington, New Jersey. Defendants further admit that in *AbbVie Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, C.A. No. 24-cv-4603 (D.N.J.), D.I. 24 at ¶ 16, Zydus USA stated "Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product"; that in *Aragon Pharms., Inc. et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 22-cv-2964 (D.N.J.), D.I. 25 at ¶ 32, Zydus USA stated "Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217113"; that in *Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*, C.A. No. 18-cv-13635 (D.N.J.), D.I. 20 at ¶ 13, Zydus USA stated "Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to the proposed product described in ANDA No. 212178"; and that in *Otsuka Pharm. Co. Ltd. v. Zydus Pharms. USA Inc. et al.*, C.A. No. 17-cv-2754 (D.N.J.), D.I. 12 at ¶ 6, Zydus USA stated "Defendants do not contest personal jurisdiction in this Court solely for purposes of Otsuka's claims against Defendants in this case." Defendants deny all other allegations in paragraph 20.

21. On information and belief, Zydus Inc. is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of New Jersey and throughout the United States.

ANSWER: Denied.

22. Zydus Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, including Genentech, which sells EVRYSDI® for use throughout the United States, including in this judicial District. On information and belief, and as indicated by the Zydus Notice Letter (as further defined herein), Zydus Inc. prepared and filed, or aided, abetted, contributed to, and/or participated in the preparation and filing of the Zydus ANDA with the intention of seeking to market generic risdiplam nationwide, including within this judicial District.

ANSWER: Defendants deny the allegations in the first sentence of paragraph 22. Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 219902. Defendants deny all other allegations in paragraph 22.

23. On information and belief, Zydus Inc. plans to market and sell generic risdiplam in the State of New Jersey, list generic risdiplam on the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursement for sales of the ANDA products in the State of New Jersey, either directly or through one or more of Zydus Inc.'s wholly owned subsidiaries, agents, and/or alter egos.

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 23.

24. On information and belief, Zydus Inc. knows and intends that its proposed generic risdiplam product will be distributed and sold in New Jersey and will thereby displace sales of EVRYSDI®, causing injury to Plaintiffs. Zydus Inc. intends to take advantage of its established channels of distribution in New Jersey for the sale of its proposed generic risdiplam product.

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use,

offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 24.

25. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc. collaborate with respect to the manufacture, regulatory approval, market, sale, and/or distribution of generic pharmaceutical products. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc. are agents of one another or operate in concert as integrated parts of the same business group. On information and belief, Zydus FZE, in collaboration with Zydus Ltd. and Zydus Inc., manufactures and distributes generic pharmaceutical products for sale in the State of New Jersey and throughout the United States.

ANSWER: Defendants admit that Zydus USA and Zydus Global file ANDAs seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of pharmaceutical products. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products developed and manufactured by Zydus Lifesciences, in the United States. Defendants further admit that Zydus USA and Zydus Global are wholly owned subsidiaries of Zydus Lifesciences. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 219902. Defendants deny all other allegations in paragraph 25.

26. Zydus FZE, Zydus Ltd., and Zydus Inc. have not contested jurisdiction in New Jersey in another action filed by Plaintiffs and have availed themselves of this Court's jurisdiction by asserting counterclaims. *See Genentech, Inc. et al. v. Natco Pharma Ltd. et al.*, Civ. No. 24-10567-BRM-JSA, D.I. 30 (D.N.J. Feb. 26, 2025).

ANSWER: The allegations in paragraph 26 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction and do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as they apply to the Proposed ANDA Product. Defendants admit that in *Genentech, Inc. et al. v. Natco Pharma Ltd. et al.*, C.A. No. 24-cv-10567 (D.N.J.), D.I. 30 at ¶ 10, Defendants stated "Zydus Defendants do not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus

Defendants in this case and solely as they apply to the Proposed ANDA Product"; at ¶ 18, Zydus Global and Zydus Lifesciences stated "Zydus Global and Zydus Lifesciences do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Global and Zydus Lifesciences and solely as they apply to the Proposed ANDA Product"; and at ¶ 29, Zydus USA stated "Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to the Proposed ANDA Product." Defendants deny all other allegations in paragraph 26.

VENUE

27. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) with respect to Plaintiffs' claims against Zydus FZE and Zydus Ltd. because, *inter alia*, Zydus FZE and Zydus Ltd. are foreign corporations that are incorporated in the United Arab Emirates and India, respectively, and may be deemed to reside and be sued in any judicial district in the United States in which Zydus FZE and Zydus Ltd., respectively, is subject to this Court's personal jurisdiction. *See In re HTC Corp.*, 889 F.3d at 1357.

ANSWER: The allegations in paragraph 27 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Global and Zydus Lifesciences do not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Global and Zydus Lifesciences and solely as they apply to the Proposed ANDA Product. Defendants admit that Zydus Global is an entity organized under the laws of the United Arab Emirates and that Zydus Lifesciences is an entity organized under the laws of India. Defendants deny all other allegations in paragraph 27.

28. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) with respect to Plaintiffs' claims against Zydus Inc. because, *inter alia*, Zydus Inc. resides in New Jersey by being incorporated in the State of New Jersey and by having a regular and established place of business in Pennington, NJ and, and has committed acts of infringement in the State of New Jersey including, *inter alia*, by participating in the submission of the Zydus ANDA in the State of New Jersey.

ANSWER: The allegations in paragraph 28 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest venue in this Court

solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to the Proposed ANDA Product. Defendants admit that Zydus USA is a New Jersey corporation with a principal place of business in Pennington, New Jersey. Defendants deny that they have or will infringe any valid and enforceable claim of the '789 patent. Defendants deny all other allegations in paragraph 28.

29. Zydus FZE, Zydus Ltd., and Zydus Inc. have not contested venue in New Jersey in another action filed by Plaintiffs. *See Genentech, Inc. et al. v. Natco Pharma Ltd. et al.*, Civ. No. 24-10567-BRM-JSA, D.I. 30 (D.N.J. Feb. 26, 2025).

ANSWER: The allegations in paragraph 29 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Defendants and solely as they apply to the Proposed ANDA Product. Defendants admit that in *Genentech, Inc. et al. v. Natco Pharma Ltd. et al.*, C.A. No. 24-cv-10567 (D.N.J.), D.I. 30 at ¶ 36, Zydus Global and Zydus Lifesciences stated "Zydus Global and Zydus Lifesciences do not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Global and Zydus Lifesciences and solely as they apply to the Proposed ANDA Product"; and at ¶ 37, Zydus USA stated "Zydus USA does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to the Proposed ANDA Product." Defendants deny all other allegations in paragraph 29.

EVRYSDI®

30. Genentech holds New Drug Application ("NDA") No. 213535 for EVRYSDI® (risdiplam) a survival of motor neuron 2 ("SMN2") splicing modifier indicated for the treatment of SMA in pediatric and adult patients, which Genentech sells under the trade name EVRYSDI®.

ANSWER: Defendants admit that the Orange Book lists "Genentech Inc" as Applicant Holder and "EVRYSDI" as Proprietary Name in connection with New Drug Application ("NDA") No. 213535. Defendants admit that that the prescribing information for EVRYSDI®, revised

02/2025, available at https://www.gene.com/download/pdf/evrysdi_prescribing.pdf (last accessed March 19, 2025), states in part:

---------- **INDICATIONS AND USAGE** ----------

EVRYSDI is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. (1)

Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 30 and therefore deny them.

31. The claims of the Asserted Patent cover, *inter alia*, EVRYSDI®.

ANSWER: The allegations in paragraph 31 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 31 and therefore deny them.

32. The active ingredient in EVRYSDI® is risdiplam.

ANSWER: Defendants admit that the Orange Book lists "RISDIPLAM" as Active Ingredient and "EVRYSDI" as Proprietary Name in connection with NDA No. 213535. Defendants deny all other allegations in paragraph 32.

33. The EVRYSDI® prescribing information label (the "EVRYSDI® Label") states that 60 milligrams of risdiplam is provided as a powder for constitution to provide 0.75 mg/mL solution. EVRYSDI® comprises risdiplam or a pharmaceutically acceptable salt thereof, a stabilizer, an antioxidant, an acidifier, and one or more pharmaceutically acceptable excipients.

ANSWER: Defendants admit that that the prescribing information for EVRYSDI®, revised 02/2025, available at https://www.gene.com/download/pdf/evrysdi_prescribing.pdf (last accessed March 19, 2025), states in part:

---------- **DOSAGE FORMS AND STRENGTHS** ----------

For Oral Solution: 60 mg of risdiplam as a powder for constitution to provide 0.75 mg/mL solution. (3)

Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 33 and therefore deny them.

34. The EVRYSDI® Label states that EVRYSDI® should be administered to a patient orally once daily and that the recommended dosage of EVRYSDI® is determined by age and body weight, as follows:

---------- **DOSAGE AND ADMINISTRATION** ----------

EVRYSDI must be constituted by a healthcare provider prior to dispensing.

Administer orally once daily after a meal using the provided oral syringe. (2.1, 2.4)

Age and Body Weight	Recommended Daily Dosage
Less than 2 months of age	0.15 mg kg
2 months to less than 2 years of age	0.2 mg kg
2 years of age and older weighing less than 20 kg	0.25 mg kg
2 years of age and older weighing 20 kg or more	5 mg

EVRYSDI® Label, Table 1.

ANSWER: Defendants admit that the prescribing information for EVRYSDI®, revised 02/2025, available at https://www.gene.com/download/pdf/evrysdi_prescribing.pdf (last accessed March 19, 2025), states in part:

---------- **DOSAGE AND ADMINISTRATION** ----------

- Administer once daily with or without food per the table below (2.1):

Age and Body Weight	Recommended Daily Dosage	Dosage Form
Less than 2 months of age	0.15 mg/kg	EVRYSDI for Oral Solution
2 months to less than 2 years of age	0.2 mg/kg	
2 years of age and older weighing less than 20 kg	0.25 mg/kg	
2 years of age and older weighing 20 kg or more	5 mg	EVRYSDI for Oral Solution or EVRYSDI Tablet

- Swallow EVRYSDI tablet whole with water or dispersed in non chlorinated drinking water (e.g., filtered water). (2.2)
- Administer EVRYSDI for oral solution with the provided oral syringe. (2.2)

- EVRYSDI for oral solution must be constituted by a healthcare provider prior to dispensing. (2.4)
- See Full Prescribing Information for important preparation and administration instructions. (2.2, 2.4)

Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 34 and therefore deny them.

35. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '789 Patent is listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "*Orange Book*") in connection with EVRYSDI® and the related NDA.

ANSWER: Defendants admit that the Orange Book lists the '789 patent and "EVRYSDI" as Proprietary Name in connection with NDA No. 213535. Defendants deny all other allegations in paragraph 35.

THE ZYDUS ANDA

36. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc. acted collaboratively and in concert to file the Zydus ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, sell and/or market a generic version of EVRYSDI® for oral solution (the "Zydus ANDA Product").

ANSWER: The allegations in paragraph 36 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 219902. Defendants further admit that ANDA No. 219902 identifies Zydus Lifesciences as the manufacturer of the Proposed ANDA Product. Defendants further admit that ANDA No. 219902 identifies EVRYSDI® (risdiplam) for oral solution, 0.75 mg/mL as the Reference Listed Drug. Defendants deny all other allegations in paragraph 36.

37. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc. acted collaboratively and in concert to prepare and submit the Zydus ANDA and continue to act collaboratively and in concert to pursue FDA approval of the Zydus ANDA and to seek to market the Zydus ANDA Product.

ANSWER: The allegations in paragraph 37 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 219902. Defendants further admit that ANDA No. 219902 identifies Zydus Lifesciences as the manufacturer of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 37.

38. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc. rely on material assistance from each other to manufacture, market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of New Jersey. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc. intend to act collaboratively and in concert to commercially manufacture, market, distribute, import into the United States, offer for sale, and/or sell the Zydus ANDA Product, in the event FDA approves the Zydus ANDA.

ANSWER: The allegations in paragraph 38 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants further admit that Zydus USA is the U.S. Agent for Zydus Global with respect to ANDA No. 219902. Defendants further admit that ANDA No. 219902 identifies Zydus Lifesciences as the manufacturer of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 38.

39. On information and belief, the Zydus ANDA refers to and relies upon the EVRYSDI® NDA and contains data that, according to Zydus, demonstrates the bioequivalence of the Zydus ANDA Product and EVRYSDI®.

ANSWER: Defendants admit that ANDA No. 219902 identifies EVRYSDI® (risdiplam) for oral solution, 0.75 mg/mL as the Reference Listed Drug. Defendants further admit that ANDA No. 219902 contains bioequivalence data required by applicable regulations. Defendants deny all other allegations in paragraph 39.

40. On information and belief, Zydus made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Zydus ANDA Product will not infringe any valid and enforceable claims of the '789 Patent.

ANSWER: Defendants admit that ANDA No. 219902 includes a Paragraph IV Certification in which Zydus Global certified pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4) that the '789 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 40.

41. Genentech and Roche received written notice of the Zydus ANDA and Paragraph IV Certification by letter dated January 14, 2025 (the "Zydus Notice Letter"), along with an enclosed statement (the "Zydus Detailed Statement") with Zydus's bases for stating that the Zydus ANDA Product will not infringe any valid and enforceable claims of the '789 Patent.

ANSWER: Defendants admit that Zydus Global sent a letter dated January 14, 2025 ("Zydus Global's Notice Letter") to Genentech and Roche pursuant to 21. U.S.C. § 355(j)(2)(B) of the Food, Drug, and Cosmetic Act notifying Genentech and Roche that Zydus Global submitted ANDA No. 219902 to FDA seeking approval to engage in the commercial manufacture, use, sale, or importation of the Proposed ANDA Product in or into the United States and that ANDA No. 219902 was amended to include a Paragraph IV Certification with respect to the '789 patent. Defendants further admit that Zydus Global's Notice Letter includes a Detailed Factual and Legal Bases in Support of Zydus Global's Paragraph IV Certification that, in its opinion and to the best of its knowledge, no valid and enforceable claim of the '789 patent will be infringed by the manufacture, use, sale, offer to sell within, or importation into, the United States of the Proposed ANDA Product. Defendants deny all other allegations in paragraph 41.

42. This action is being commenced within 45 days of receipt of the Zydus Notice Letter.

ANSWER: Admitted.

43. Zydus has infringed one or more claims of the '789 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Zydus ANDA with a Paragraph IV Certification and seeking FDA approval of the Zydus ANDA prior to the expiration of the '789 Patent or any extensions thereof.

ANSWER: Denied.

44. Zydus has infringed one or more claims of the '789 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of filing the Zydus ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States a generic version of EVRYSDI® prior to the expiration of the Asserted Patent or any extensions thereof. Zydus will infringe one or more claims of the Asserted Patent under 35 U.S.C. §§ 271(a), (b), (c), or (f) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of a generic version of EVRYSDI® prior to the expiration of the Asserted Patent or any extensions thereof.

ANSWER: Denied.

THE ASSERTED PATENT

U.S. Patent No. 12,122,789

45. The allegations above are incorporated herein by reference.

ANSWER: Defendants restate and reallege their answers to each of the preceding paragraphs 1-44 as if fully set forth herein.

46. Roche owns the '789 Patent entitled "Forms of Pyrido[1,2-a]pyrimidin-4-one Derivatives, Its Formulation and Its Process of Making." The USPTO duly and legally issued the '789 Patent on October 22, 2024. The '789 Patent names as inventors Roland Meier, Urs Schwitter, Anne De Paepe, Juergen Thun, and Frank Stowasser. Currently, the '789 Patent is duly assigned to Roche. Roche has licensed its rights under the '789 Patent to Genentech for the commercialization, manufacture, and sale of EVRYSDI® and any product containing risdiplam. Genentech and Roche have all necessary rights in and to the '789 Patent to assert infringement of, and seek relief for, infringement of the '789 Patent.

ANSWER: The allegations in paragraph 46 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '789 patent is entitled "Forms of Pyrido[1,2-a]pyrimidin-4-one Derivatives, Its Formulation and Its Process of Making."

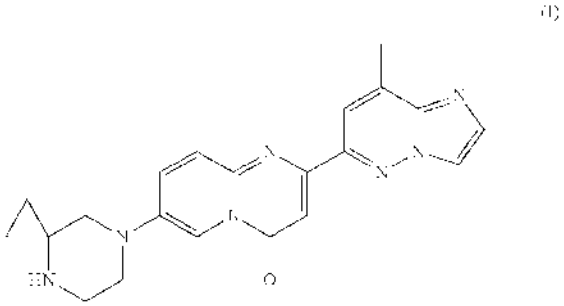
Defendants further admit that the ’789 patent lists October 22, 2024 as “Date of Patent” and lists Roland Meier, Urs Schwitter, Anne De Paepe, Juergen Thun, and Frank Stowasser as “Inventors” on the face of the ’789 patent. Defendants further admit that the ’789 patent lists “Hoffmann-La Roche Inc.” as “Assignee” on the face of the ’789 patent and that “Hoffmann-La Roche Inc.” is listed as “Assignee” according to the electronic patent assignment listings of the United States Patent and Trademark Office (“USPTO”) at Reel 062995, Frame 0595, and Reel 062995, Frame 0498. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 46 and therefore deny them.

47. A true and correct copy of the ’789 Patent is attached to this Complaint as Exhibit A.

ANSWER: Defendants admit that what purports to be a copy of the ’789 patent is attached to Plaintiffs’ Complaint as Exhibit A. Defendants deny all other allegations in paragraph 47.

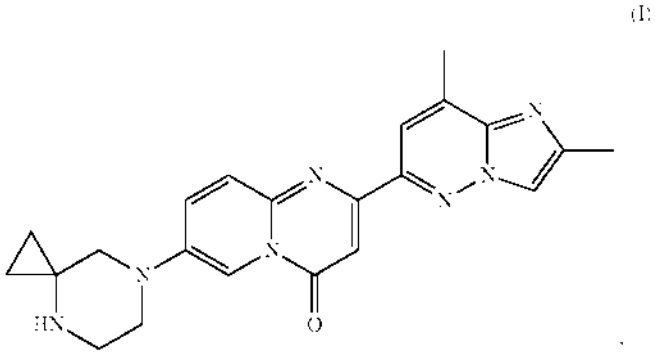
48. The ’789 Patent claims solid forms of risdiplam. For example, claim 1 of the ’789 Patent claims:

A solid form of a compound of formula (I)



Wherein the solid form is crystalline Form A having an x-ray powder diffraction (XRPD) pattern comprising at least two XRPD peaks selected from the group consisting of 8.3 (±0.2) degrees two-theta, 11.4 (±0.2) degrees two-theta, 15.1 (±0.2) degrees two-theta, 15.9 (±0.2) degrees two-theta, 17.0 (±0.2) degrees two-theta. 24.0 (±0.2) degrees two-theta, and 25.6 (±0.2) degrees two-theta angle of diffraction.

ANSWER: The allegations in paragraph 48 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that the allegations in the first sentence of paragraph 48 completely and accurately recite the claims of the '789 patent and therefore deny them. Defendants admit that claim 1 of the '789 patent states:

> **1**. A solid form of a compound of formula (I)
>
> 
>
>
> wherein the solid form is crystalline Form A having an x-ray powder diffraction (XRPD) pattern comprising at least two XRPD peaks selected from the group consisting of 8.3 (±0.2) degrees two-theta, 11.4 (±0.2) degrees two-theta, 15.1 (±0.2) degrees two-theta, 15.9 (±0.2) degrees two-theta, 17.0 (±0.2) degrees two-theta, 24.0 (±0.2) degrees two-theta, and 25.6 (±0.2) degrees two-theta angle of diffraction.

Defendants deny the remaining allegations in paragraph 48.

49. The '789 Patent claims formulations of pharmaceutical compositions comprising risdiplam. As an example, claim 9 of the '789 Patent claims:

> A pharmaceutical composition comprising the solid form of claim **1**, and a pharmaceutically acceptable excipient.

ANSWER: The allegations in paragraph 49 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that the allegations in the first sentence of paragraph 49 completely and accurately recite the claims of the '789 patent and therefore deny them. Defendants admit that claim 9 of the '789 patent states:

> 9. A pharmaceutical composition comprising the solid form of claim 1, and a pharmaceutically acceptable excipient.

Defendants deny the remaining allegations in paragraph 49.

50. The '789 Patent also claims kits for the preparation of pharmaceutical compositions comprising risdiplam. For example, claim 11 of the '789 Patent claims:

> A kit comprising the pharmaceutical composition of claim **9**, and water as solvent for constitution of said pharmaceutical composition into an oral aqueous solution.

ANSWER: The allegations in paragraph 50 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that the allegations in the first sentence of paragraph 50 completely and accurately recite the claims of the '789 patent and therefore deny them. Defendants admit that claim 11 of the '789 patent states:

> 11. A kit comprising the pharmaceutical composition of claim 9, and water as solvent for constitution of said pharmaceutical composition into an oral aqueous solution.

Defendants deny the remaining allegations in paragraph 50.

COUNT I
(INFRINGEMENT OF THE '789 PATENT)

51. The allegations above are incorporated herein by reference.

ANSWER: Defendants restate and reallege their answers to each of the preceding paragraphs 1-50 as if fully set forth herein.

52. On information and belief, Zydus submitted the Zydus ANDA to FDA, and thereby seeks FDA approval of the Zydus ANDA Product.

ANSWER: Defendants admit that Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 52.

53. Zydus has infringed at least claims 1, 9, and 11 of the '789 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Zydus ANDA with a Paragraph IV Certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale in the United States or importation into the United States of a generic version of EVRYSDI® prior to the expiration of the '789 Patent. At least claim 1 of the '789 Patent encompasses solid forms of risdiplam, at least claim 9 of the '789 Patent encompasses pharmaceutical compositions comprising risdiplam, and at least claim 11 of the '789 Patent encompasses a kit for the preparation of a pharmaceutical composition comprising risdiplam. In the Zydus Notice Letter, Zydus has not contested infringement of claims 1, 9, and 11—or any claim—of the '789 Patent.

ANSWER: Defendants deny the allegations in the first sentence of paragraph 53. Defendants deny that the allegations in the second sentence of paragraph 53 completely and accurately recite the claims of the '789 patent and therefore deny them. Defendants deny that the allegations in the third sentence of paragraph 53 completely and accurately recite the statements in Zydus Global's Notice Letter and therefore deny the allegations in the third sentence of paragraph 53. Defendants do not waive, and expressly reserve, the right to raise additional defenses and arguments concerning noninfringement, invalidity, and unenforceability of the '789 patent in this or any ensuing litigation or other proceeding. *See Abbott Labs., Inc. v. Apotex Inc.*, 725 F. Supp. 2d 724, 728 (N.D. Ill. 2010) (refusing to strike defense theories not raised in defendant's notice letter because an ANDA filer is "not limited to the invalidity and noninfringement theories raised in its paragraph IV [notice] letter"); *Astra Aktiebolag v. Kremers Urban Dev. Co.*, No. 99 Civ. 8928 (BSJ), 2000 WL 257125, at *1 (S.D.N.Y. Mar. 8, 2000) ("There is no language in the relevant statutory provisions, legislative history or cases barring [an ANDA filer] from raising defenses and counterclaims not noticed in [its] ANDA."). Defendants deny all other allegations in paragraph 53.

54. On information and belief, the Zydus ANDA essentially copies the EVRYSDI® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(8)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians and/or patients to infringe at least claim 11 of the '789 Patent.

ANSWER: Denied.

55. On information and belief, the Zydus ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 11 of the '789 Patent.

ANSWER: Denied.

56. Zydus's commercial manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Product before the expiration of the '789 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '789 Patent, including, but not limited to, claims 1, 9, and 11, under 35 U.S.C. § 271. Zydus's infringement of at least claims 1, 9, and 11 is either literal or under the doctrine of equivalents.

ANSWER: Denied.

57. Genentech and Roche will be harmed substantially and irreparably if Zydus is not enjoined from infringing the '789 Patent and/or if FDA is not enjoined from approving the Zydus ANDA before the '789 Patent expires.

ANSWER: Denied.

58. Genentech and Roche have no adequate remedy at law.

ANSWER: Denied.

59. Genentech and Roche are entitled to all relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for the Zydus ANDA to be a date which is not any earlier than the expiration date of the '789 Patent, including any extensions, adjustments, and exclusivities associated with the '789 Patent.

ANSWER: Denied.

60. Zydus was aware of the '789 Patent when it submitted its ANDA. On information and belief, Zydus's statement of the factual and legal basis regarding the invalidity of the '789 Patent is devoid of a good faith basis in either the facts or the law.

ANSWER: Defendants admit that ANDA No. 219902 was amended to include a Paragraph IV Certification with respect to the '789 patent. Defendants deny all other allegations in paragraph 60.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiffs are entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable

attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

JURY DEMAND

Defendants admit that Plaintiffs have demanded a trial by jury on all issues triable to a jury.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,122,789)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 219902 and/or the manufacture, use, sale, or offer to sell within, and or importation into, the United States of the Proposed ANDA Product will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '789 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,122,789)

Upon information and belief, the claims of the '789 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

COUNTERCLAIMS

Zydus Lifesciences Global FZE ("Zydus Global"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Counterclaimants"), by their attorneys, allege the following counterclaims against Plaintiffs/Counterclaim Defendants Genentech, Inc. ("Genentech") and Hoffmann-La Roche, Inc. ("Roche") (collectively, "Counterclaim Defendants").

PARTIES

1. Zydus Global is an entity 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.

2. Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

3. Zydus Lifesciences is an entity 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 382 481, India.

4. Upon information and belief, Genentech is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One DNA Way, South San Francisco, California 94080.

5. Upon information and belief, Roche is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 150 Clove Road, Little Falls, New Jersey 07424.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

7. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants commenced and continue to maintain this action against Counterclaimants in this judicial district.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II), and because Counterclaim Defendants commenced and continue to maintain this action against Counterclaimants in this judicial district.

REGULATORY FRAMEWORK

9. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

10. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the

manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ORANGE BOOK PATENTS LISTED FOR EVRYSDI®

11. Upon information and belief, Genentech is the holder of NDA No. 213535 for EVRYSDI® (risdiplam) for oral solution, 0.75 mg/mL.

12. United States Patent No. 12,122,789 ("the '789 patent"), titled "Forms of Pyrido[1,2-a]pyrimidin-4-one Derivatives, Its Formulation and Its Process of Making"—a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit A—was issued on October 22, 2024. According to the United States Patent and Trademark Office's ("USPTO") Patent Assignment Search database, Reel/Frame No. 062995/0595 and Reel/Frame No. 062995/0498, the '789 patent is assigned to Roche. FDA's Orange Book lists the expiration date of the '789 patent as April 15, 2041.

13. Upon information and belief, the '789 patent is owned by Roche.

14. Upon information and belief, Roche licensed its rights under the '789 patent to Genentech.

15. Upon information and belief, Genentech submitted the '789 patent to FDA for listing in the Orange Book in connection with NDA No. 213535 for EVRYSDI® (risdiplam) for oral solution, 0.75 mg/mL, on November 12, 2024. Accordingly, Genentech maintains and has affirmatively represented that the '789 patent claims the approved drug risdiplam or a method of using that drug. Therefore, any ANDA applicant, including Zydus Global, attempting to sell risdiplam for oral solution before the expiration of the '789 patent has a reasonable apprehension of suit with respect to the '789 patent.

ZYDUS GLOBAL'S ANDA

16. On August 7, 2024, Zydus Global submitted ANDA No. 219902 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, or sale of risdiplam for oral solution, 0.75 mg/mL ("the Proposed ANDA Product").

17. Because Zydus Global seeks FDA approval to engage in the commercial importation, manufacture, use, or sale of the Proposed ANDA Product before the expiration of the '789 patent, ANDA No. 219902 was amended to include a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '789 patent.

18. Zydus USA, as U.S. Agent for Zydus Global with respect to ANDA No. 219902, sent a letter dated January 14, 2025, notifying Genentech and Roche that Zydus Global submitted ANDA No. 219902 to FDA seeking approval to engage in the commercial importation, manufacture, use, or sale of the Proposed ANDA Product and that ANDA No. 219902 was amended to include a Paragraph IV Certification with respect to the '789 patent ("Zydus Global's Notice Letter").

19. Zydus Global's Notice Letter includes a detailed statement of the factual and legal bases in support of Zydus Global's Paragraph IV Certification for the '789 patent.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,122,789)

20. Counterclaimants repeat and reallege the allegations in paragraphs 1-19 above as though fully set forth herein.

21. By asserting their claim against Counterclaimants for infringement of the '789 patent, Genentech and Roche have created a case or controversy regarding the noninfringement of the '789 patent.

22. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of the Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '789 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,122,789)

23. Counterclaimants repeat and reallege the allegations in paragraphs 1-22 above as though fully set forth herein.

24. By asserting their claim against Counterclaimants for infringement of the '789 patent, Genentech and Roche have created a case or controversy regarding the validity of the '789 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

25. The claims of the '789 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimants respectfully request that the Court enter judgment against Counterclaim Defendants as follows:

A. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '789 patent;

B. A declaration that the claims of the '789 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

C. A declaration that Counterclaim Defendants take nothing by their Complaint;

D. A dismissal of Counterclaim Defendants' Complaint with prejudice;

E. An award to Counterclaimants of their reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

F. An award of any other and further relief that this Court may deem just and proper.

Dated: April 3, 2025

Respectfully submitted,

By: *s/ Theodora McCormick*

Theodora McCormick
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Alec Wong
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding.

Dated: April 3, 2025

By: *s/ Theodora McCormick*
Theodora McCormick

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

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

Dated: April 3, 2025

By: *s/ Theodora McCormick*
Theodora McCormick

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Defendants' Answer, Affirmative Defenses, and Counterclaims was filed and served on all counsel of record via ECF on April 3, 2025.

Dated: April 3, 2025

By: *s/ Theodora McCormick*
Theodora McCormick