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**Pro hac vice* application forthcoming

IN THE UNITED STATES DISTRICT COURT
FOR THE 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.

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Genentech, Inc. ("Genentech"), Hoffmann-La Roche, Inc. ("Roche"), and PTC Therapeutics, Inc. ("PTC"), for their Complaint against Defendants Natco Pharma Limited ("Natco"), Zydus Lifesciences Global FZE ("Zydus FZE"), Zydus Lifesciences Ltd. ("Zydus Ltd."), Zydus Pharmaceuticals (USA) Inc. ("Zydus Inc." and, collectively with Zydus FZE and Zydus Ltd., "Zydus"), allege as follows:

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 Natco's Abbreviated New Drug Application No. 219848 (the "Natco ANDA") and Zydus's Abbreviated New Drug Application No. 219902 (the "Zydus ANDA") to the United States Food and Drug Administration ("FDA"), by which Natco and Zydus each seek approval to market a generic version of Genentech and Roche's pharmaceutical product EVRYSDI® (risdiplam) prior to the expiration of one or more of United States Patent Nos. 9,586,955 (the "'955 Patent"), 9,969,754 (the "'754 Patent"), 11,534,444 (the "'444 Patent"), 11,827,646 (the "'646 Patent"), and 11,938,136 (the "'136 Patent" and, collectively with the '955 Patent, the '754 Patent, the '444 Patent, the '646 Patent, and the '136 Patent, the "Asserted Patents"), which cover, *inter alia*, EVRYSDI® and/or its use.

THE PARTIES

Plaintiffs

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.

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 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.

4. Plaintiff PTC is a Delaware corporation with a principal place of business at 500 Warren Corporate Center Drive, Warren, NJ 07059. PTC is a pharmaceutical company focused on the discovery, development, and commercialization of clinically differentiated medicines that provide benefits to patients living with rare disorders.

Natco

5. On information and belief, Defendant Natco is a corporation organized and existing under the laws of India, having its corporate offices and principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad-500 034, India.

Zydus

6. 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.

7. 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.

8. 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.

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

JURISDICTION

10. 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.

Natco

11. This Court has personal jurisdiction over Natco under Fed. R. Civ. P. 4(k)(2) because, on information and belief, Natco is organized under the laws of India and is 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 Natco has sufficient contacts with the United States that relate to the claims in this case.

12. This Court also has personal jurisdiction over Natco by virtue of, *inter alia*, 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.*, *Janssen Pharmaceutica NV v. Natco Pharma Ltd.*, Civ. No. 23-3959-JKS (D.N.J. July 25, 2023); *Shire Development LLC v. Natco Pharma Ltd.*, Civ. No. 14-7053-SRC (D.N.J. Nov. 10, 2014); *Celgene Corp. v. Natco Pharma Ltd. et al.*, Civ. No. 14-3126-SDW (D.N.J. May 15, 2014).

13. On information and belief, Natco 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.

14. Natco 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 Natco Notice Letter (as further defined herein), Natco prepared and filed, or aided, abetted, contributed to, and/or participated in the preparation and filing of the Natco ANDA with the intention of seeking to market generic risdiplam nationwide, including within this judicial District.

15. On information and belief, Natco 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 Natco's wholly owned subsidiaries, agents, and/or alter egos.

16. On information and belief, Natco 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. Natco intends to take advantage of its established channels of distribution in New Jersey for the sale of its proposed generic risdiplam product.

17. Although this Court has personal jurisdiction over Natco for at least the reasons set forth above, in the absence of such personal jurisdiction in any single state, a foreign entity such as Natco is subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2); *see,*

e.g., *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1311–12 (Fed. Cir. 2019); *M-I Drilling Fluids UK Ltd. v. Dynamic Air Ltda.*, 890 F.3d 995, 1003 (Fed. Cir. 2018).

Zydus

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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).

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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).

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

VENUE

Natco

35. 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 Natco because, *inter alia*, Natco is a foreign corporation that is incorporated in India and may be deemed to reside and be sued in any judicial district in the United States in which Natco is subject to the Court's personal jurisdiction. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

Zydus

36. 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.

37. 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.

EVRYSDI®

38. 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®.

39. The claims of the Asserted Patents cover, *inter alia*, EVRYSDI® and/or its use.

40. The active ingredient in EVRYSDI® is risdiplam.

41. The EVRYSDI® prescribing information label (the "EVRYSDI® Label") states that 60 grams 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.

42. 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.

43. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '955, '754, '444, '646, and '136 Patents are 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.

THE NATCO ANDA

44. On information and belief, Natco filed the Natco 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 "Natco ANDA Product").

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

46. On information and belief, Natco 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 Asserted Patents are invalid, unenforceable, and/or that certain claims will not be infringed by the Natco ANDA Product.

47. Genentech, Roche, and PTC received written notice of the Natco ANDA and Paragraph IV Certification by letter dated October 10, 2024 (the "Natco Notice Letter"), along with an enclosed statement (the "Natco Detailed Statement") of Natco's alleged factual and legal bases for stating that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the Natco ANDA Product.

48. The Natco Detailed Statement does not provide any factual bases for stating that the '754, '444, '646, and '136 Patents will not be infringed by the Natco ANDA Product.

49. The Natco Detailed Statement does not provide any factual bases for stating that the Asserted Patents are unenforceable.

50. This action is being commenced within 45 days of receipt of the Natco Notice Letter.

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

52. Natco has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by virtue of filing the Natco 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 Patents or any extensions thereof. Natco will infringe one or more claims of the Asserted Patents 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 Patents or any extensions thereof.

THE ZYDUS ANDA

53. 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").

54. 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.

55. 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.

56. 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®.

57. On information and belief, Zydus made and included in its ANDA a Paragraph IV Certification that, in its opinion and to the best of its knowledge, the ’444 and ’136 Patents are invalid, unenforceable, and/or that certain claims will not be infringed by the Zydus ANDA Product.

58. Genentech and Roche received written notice of the Zydus ANDA and Paragraph IV Certification by letter dated October 21, 2024 (the “Zydus Notice Letter”), along with an enclosed statement (the “Zydus Detailed Statement”) of Zydus’s alleged factual and legal bases for stating that the ’444 and ’136 Patents are invalid, unenforceable, and/or will not be infringed by the Zydus ANDA Product.

59. The Zydus Detailed Statement does not provide any factual bases for stating that the ’444 and ’136 Patents are unenforceable.

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

61. Zydus has infringed one or more claims of the '444 and '136 Patents 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 '444 and '136 Patents or any extensions thereof.

62. Zydus has infringed one or more claims of the '444 and '136 Patents 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 '444 and '136 Patents or any extensions thereof. Zydus will infringe one or more claims of the '444 and '136 Patents 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 '444 and '136 Patents or any extensions thereof.

THE ASSERTED PATENTS

U.S. Patent No. 9,586,955

63. The allegations above are incorporated herein by reference.

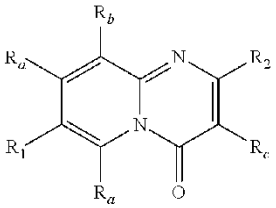
64. Roche and PTC jointly own the '955 Patent entitled "Compounds for Treating Spinal Muscular Atrophy." Genentech, Roche, and PTC have all necessary rights in and to the '955 Patent to assert infringement of, and seek relief for, infringement of the '955 Patent.

65. The United States Patent and Trademark Office ("USPTO") duly and legally issued the '955 Patent on March 7, 2017. The '955 Patent names as inventors Hongyan Qi, Soongyu Choi, Amal Dakka, Gary Mitchell Karp, Jana Narasimhan, Nikolai Naryshkin, Anthony A. Turpoff, Marla L. Weetall, Ellen Welch, Matthew G. Woll, Tianle Yang, Nanjing Zhang, Xiaoyan

Zhang, Xin Zhao, Luke Green, Emmanuel Pinard, and Hasane Ratni. Currently, the '955 Patent is duly assigned to Roche and PTC. Roche has licensed its rights under the '955 Patent to Genentech for the commercialization, manufacture, and sale of EVRYSDI® and any product containing risdiplam.

66. A true and correct copy of the '955 Patent is attached to this Complaint as Exhibit A.

67. The '955 Patent claims chemical compounds with a pyridopyrimidinone core. For example, claim 1 of the '955 Patent claims:

> A compound of Formula (IIa1):
>
> (IIa1)
>
> 
>
> or a form thereof, wherein:
>
> R_1 is heterocyclyl;
>
> wherein, heterocyclyl is optionally substituted with one, two or three R_3 substituents and optionally, with one additional R_4 substituent; or,
>
> wherein, heterocyclyl is optionally substituted with one, two, three or four R_3 substituents;
>
> R_2 is heteroaryl;
>
> wherein, heteroaryl is optionally substituted with one, two or three R_6 substituents and optionally, with one additional R_7 substituent;
>
> R_a is, in each instance, independently selected from hydrogen, halogen or $C_{1\text{-}8}$alkyl;
>
> R_b is hydrogen, halogen, $C_{1\text{-}8}$alkyl or $C_{1\text{-}8}$alkoxy;
>
> R_c is hydrogen, halogen or $C_{1\text{-}8}$alkyl;

R_3 is, in each instance, independently selected from cyano, halogen, hydroxy, oxo, C_{1-8}alkyl, halo-C_{1-8}alkyl, C_{1-8}alkyl-carbonyl, C_{1-8}alkoxy, halo-C_{1-8}alkoxy, C_{1-8}alkoxy-C_{1-8}alkyl, C_{1-8}alkoxy-carbonyl, amino, C_{1-8}alkyl-amino, (C_{1-8}alkyl)$_2$-amino, amino-C_{1-8}alkyl, C_{1-8}alkyl-amino-C_{1-8}alkyl, (C_{1-8}alkyl)$_2$-amino-C_{1-8}alkyl, amino-C_{1-8}alkyl-amino, C_{1-8}alkyl-amino-C_{1-8}alkyl-amino, (C_{1-8}alkyl-amino-C_{1-8}alkyl)2-amino, (C_{1-8}alkyl)$_2$-amino-C_{1-8}alkyl-amino, [(C_{1-8}alkyl)2-amino-C_{1-8}alkyl]$_z$-amino, (C_{1-8}alkyl-amino-C_{1-8}alkyl)(C_{1-8}alkyl)amino, [(C_{1-8}alkyl)$_2$-amino-C_{1-8}alkyl](C_{1-8}alkyl)amino, C_{1-8}alkoxy-C_{1-8}alkyl-amino, (C_{1-8}alkoxy-C_{1-8}alkyl)$_2$-amino, (C_{1-8}alkoxy-C_{1-8}alkyl)(C_{1-8}alkyl)amino, C_{1-8}alkyl-carbonyl-amino, C_{1-8}alkoxy-carbonyl-amino, hydroxy-C_{1-8}alkyl, hydroxy-C_{1-8}alkoxy-C_{1-8}alkyl, hydroxy-C_{1-8}alkyl-amino, (hydroxy-C_{1-8}alkyl)$_2$-amino or (hydroxy-C_{1-8}alkyl)(C_{1-8}alkyl)amino;

R_4 is C_{3-14}cycloalkyl, C_{3-14}cycloalkyl-C_{1-8}alkyl, C_{3-14}cycloalkyl-amino, aryl-C_{1-8}alkyl, aryl-C_{1-8}alkoxy-carbonyl, aryl-sulfonyloxy-C_{1-8}alkyl, heterocyclyl or heterocyclyl-C_{1-8}alkyl; wherein, each instance of C_{3-14}cycloalkyl, aryl and heterocyclyl is optionally substituted with one, two or three R_5 substituents;

R_5 is, in each instance, independently selected from halogen, hydroxy, cyano, nitro, C_{1-8}alkyl, halo-C_{1-8}alkyl, C_{1-8}alkoxy, halo-C_{1-8}alkoxy, amino, C_{1-8}alkyl-amino, (C_{1-8}alkyl)$_2$-amino or C_{1-8}alkyl-thio;

R_6 is, in each instance, independently selected from halogen, hydroxy, cyano, nitro, C_{1-8}alkyl, C_{2-8}alkenyl, halo-C_{1-8}alkyl, hydroxy-C_{1-8}alkyl, C_{1-8}alkoxy, halo-C_{1-8}alkoxy, C_{1-8}alkoxy-C_{1-8} alkyl, amino, C_{1-8}alkyl-amino, (C_{1-8}alkyl)$_2$-amino or C_{1-8}alkyl-thio; and,

R_7 is C_{3-14}cycloalkyl, C_{3-14}cycloalkyl-oxy, aryl, heterocyclyl or heteroaryl.

68. As a further example, claim 11 claims:

The compound of claim 1, wherein R_2 is heteroaryl selected from furo[3,2-b]pyridinyl, furo[3,2-c]pyridinyl, furo[2,3-c]pyridinyl, thieno[3,2-c]pyridinyl, thieno[2,3-d]pyrimidinyl, 1H-pyrrolo[2,3-b]pyridinyl, 1H-pyrrolo[2,3-c]pyridinyl, pyrrolo[1,2-a]pyrimidinyl, pyrrolo[1,2-a]pyrazinyl, pyrrolo[1,2-b]pyridazinyl, pyrazolo[1,5-a]pyridinyl, pyrazolo[1,5-a]pyrazinyl, imidazo[1,2-a]pyridinyl, imidazo[1,2-a]pyrimidinyl, imidazo[1,2-c]pyrimidinyl, imidazo[1,2-b]pyridazinyl, imidazo[1,2-a]pyrazinyl, imidazo[2,1-b][1,3]thiazolyl, imidazo[2,1-b][1,3,4]thiadiazolyl, [1,3]oxazolo[4,5-b]pyridinyl and quinoxalinyl; wherein, each

> instance of heteroaryl is optionally substituted with one, two or three R_6 substituents and optionally, with one additional R_7 substituent.

U.S. Patent No. 9,969,754

69. The allegations above are incorporated herein by reference.

70. Roche and PTC jointly own the '754 Patent entitled "Compounds for Treating Spinal Muscular Atrophy." The USPTO duly and legally issued the '754 Patent on May 15, 2018. The '754 Patent names as inventors Hasane Ratni, Luke Green, Marla L. Weetall, and Nikolai A. Naryshkin. Currently, the '754 Patent is duly assigned to Roche and PTC. Roche has licensed its rights under the '754 Patent to Genentech for the commercialization, manufacture, and sale of EVRYSDI® and any product containing risdiplam. Genentech, Roche, and PTC have all necessary rights in and to the '754 Patent to assert infringement of, and seek relief for, infringement of the '754 Patent.

71. A true and correct copy of the '754 Patent is attached to this Complaint as Exhibit B.

72. The '754 Patent claims chemical compounds with a pyridopyrimidinone core and an imidazopyridizine group. For example, claim 36 of the '754 Patent claims:

> A compound of claim 24, wherein the compound is 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b] pyridazine-6-yl)pyrido[1,2-a]pyrimidin-4-one.

73. The '754 Patent also claims a method of treating SMA in a human using chemical compounds with a pyridopyrimidinone core and an imidazopyridizine group. For example, claim 28 of the '754 Patent claims:

> A method for the treatment of spinal muscular atrophy in a human, which method comprises administering a therapeutically effective amount of a compound of formula (I) according to claim 1, or a pharmaceutically acceptable thereof, to a human in need of such treatment.

U.S. Patent No. 11,534,444

74. The allegations above are incorporated herein by reference.

75. Roche owns the ’444 Patent entitled “Treatment of SMA.” The USPTO duly and legally issued the ’444 Patent on December 27, 2022. The ’444 Patent names as inventors Jean-Paul Pfefen, Heidemarie Kletzl, and Lutz Mueller. Currently, the ’444 Patent is duly assigned to Roche. Roche has licensed its rights under the ’444 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 ’444 Patent to assert infringement of, and seek relief for, infringement of the ’444 Patent.

76. A true and correct copy of the ’444 Patent is attached to this Complaint as Exhibit C.

77. The ’444 Patent claims methods for treating SMA using specific amounts of risdiplam based on the patient’s body weight. For example, claim 1 of the ’444 Patent claims:

> A method of treating spinal muscular atrophy (SMA) in a subject in need thereof comprising administering to said subject 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido[1,2-a]pyrimidin-4-one or a pharmaceutically acceptable salt thereof, wherein the administered dose of 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido[1,2-a]pyrimidin-4-one or a pharmaceutically acceptable salt thereof is
>
> a. 0.25 mg/kg for a subject with a body weight of less than 20 kg, and
>
> b. 5 mg for a subject with a body weight of more than or equal to 20 kg.

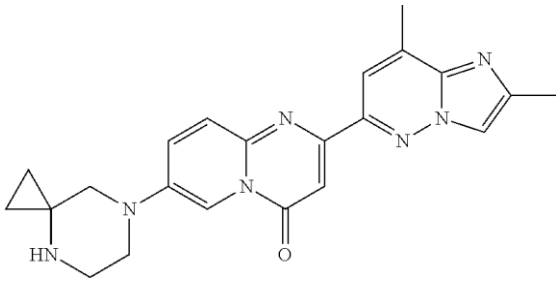
U.S. Patent No. 11,827,646

78. The allegations above are incorporated herein by reference.

79. Roche and PTC jointly own the ’646 Patent entitled “Compounds for Treating Spinal Muscular Atrophy.” The USPTO duly and legally issued the ’646 Patent on November 28, 2023. The ’646 Patent names as inventors Hasane Ratni, Luke Green, Marla L. Weetall, and Nikolai A. Naryshkin. Currently, the ’646 Patent is duly assigned to Roche and PTC. Roche has licensed its rights under the ’646 Patent to Genentech for the commercialization, manufacture, and sale of EVRYSDI® and any product containing risdiplam. Genentech, Roche, and PTC have all necessary rights in and to the ’646 Patent to assert infringement of, and seek relief for, infringement of the ’646 Patent.

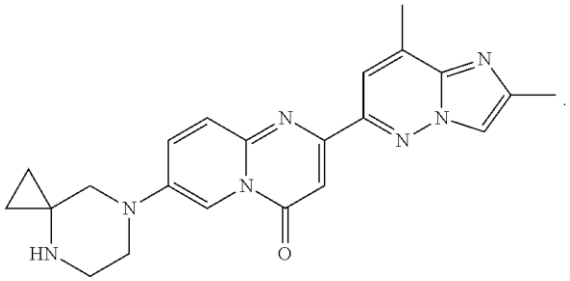
80. A true and correct copy of the ’646 Patent is attached to this Complaint as Exhibit D.

81. The ’646 Patent claims methods of treating SMA using risdiplam. For example, claim 1 of the ’646 Patent claims:

> A method for the treatment of spinal muscular atrophy in a human in need thereof, said method comprising administering to said human a therapeutically effective amount of
>
> 
>
>
> or a pharmaceutically acceptable salt thereof.

82. As another example, claim 11 of the ’646 Patent claims:

> A method for the treatment of spinal muscular atrophy in a human in need thereof, said method comprising administering to said human a therapeutically effective amount of



U.S. Patent No. 11,938,136

83. The allegations above are incorporated herein by reference.

84. Roche owns the ’136 Patent entitled “Compositions for Treating Spinal Muscular Atrophy.” The USPTO duly and legally issued the ’136 Patent on March 26, 2024. The ’136 Patent names as inventors Jochem Alsenz, Olaf Grassmann, Peter Kuehl, Friedrich Metzger, Kathleen Dorothy McCarthy, Eduardo Paulo Morawski Vianna, and Marvin Lloyd Woodhouse. Currently, the ’136 Patent is duly assigned to Roche. Roche has licensed its rights under the ’136 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 ’136 Patent to assert infringement of, and seek relief for, infringement of the ’136 Patent.

85. A true and correct copy of the ’136 Patent is attached to this Complaint as Exhibit E.

86. The ’136 Patent claims formulations of pharmaceutical compositions comprising risdiplam. As an example, claim 1 of the ’136 Patent claims:

> A dry granulated powder blend for an oral solution, said dry granulated powder blend comprising

> 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b] pyridazin-6-yl)pyrido[1,2-a]pyrimidin-4-one or a pharmaceutically acceptable salt thereof;
>
> a stabilizer comprising disodium ethylenediaminetetraacetate; an antioxidant comprising ascorbic acid; and
>
> an acidifier comprising tartaric acid.

87. The ’136 Patent also claims aqueous solutions comprising a dry granulated blend. For example, claim 35 of the ’136 Patent claims:

> An aqueous solution comprising the dry granulated blend of claim 24 constituted in said solution.

88. The ’136 Patent also claims kits for the preparation of pharmaceutical compositions comprising risdiplam. For example, claim 36 of the ’136 Patent claims:

> A kit for the preparation of a pharmaceutical composition comprising 7-(4,7-diazaspiro[2.5]octan-7-yl)-2-(2,8-dimethylimidazo[1,2-b]pyridazin-6-yl)pyrido[1,2-a]pyrimidin-4-one, or a pharmaceutically acceptable salt thereof, wherein the kit comprises the dry granulated powder blend of claim 1.

COUNT I
(BY ALL PLAINTIFFS)
(INFRINGEMENT OF THE ’955 PATENT BY NATCO)

89. The allegations above are incorporated herein by reference.

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

91. Natco has infringed at least claims 1 and 11 of the ’955 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Natco 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 ’955 Patent. At least claims 1 and 11 of the ’955 Patent encompass risdiplam. In

the Natco Notice Letter, Natco has not contested infringement of claims 1–8, 10, 11, or 20 of the '955 Patent.

92. Natco's commercial manufacture, use, offer to sell, sale, or importation of the Natco ANDA Product before the expiration of the '955 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '955 Patent, including, but not limited to, claims 1 and 11, under 35 U.S.C. § 271. Natco's infringement of at least claims 1 and 11 is either literal or under the doctrine of equivalents.

93. Plaintiffs will be harmed substantially and irreparably if Natco is not enjoined from infringing the '955 Patent and/or if FDA is not enjoined from approving the Natco ANDA before the '955 Patent expires.

94. Plaintiffs have no adequate remedy at law.

95. Plaintiffs 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 Natco ANDA to be a date which is not any earlier than the expiration date of the '955 Patent, including any extensions, adjustments, and exclusivities associated with the '955 Patent.

96. Natco was aware of the '955 Patent when it submitted its ANDA. On information and belief, Natco's statement of the factual and legal basis regarding the invalidity of the '955 Patent is devoid of a good faith basis in either the facts or the law.

COUNT II
(BY ALL PLAINTIFFS)
(INFRINGEMENT OF THE '754 PATENT BY NATCO)

97. The allegations above are incorporated herein by reference.

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

99. Natco has infringed at least claims 28 and 36 of the '754 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Natco 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 '754 Patent. At least claim 36 of the '754 Patent encompasses risdiplam and claim 28 of the '754 Patent encompasses treating SMA with a therapeutically effective amount of risdiplam. In the Natco Notice Letter, Natco has not contested infringement of claims 28 and 36—or any claim—of the '754 Patent.

100. On information and belief, the Natco 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 claim 28 of the '754 Patent.

101. On information and belief, the Natco ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claim 28 of the '754 Patent.

102. Natco's commercial manufacture, use, offer to sell, sale, or importation of the Natco ANDA Product before the expiration of the '754 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '754 Patent, including, but not limited to, claims 28 and 36, under 35 U.S.C. § 271. Natco's infringement of at least claims 28 and 36 is either literal or under the doctrine of equivalents.

103. Plaintiffs will be harmed substantially and irreparably if Natco is not enjoined from infringing the '754 Patent and/or if FDA is not enjoined from approving the Natco ANDA before the '754 Patent expires.

104. Plaintiffs have no adequate remedy at law.

105. Plaintiffs 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 Natco ANDA to be a date which is not any earlier than the expiration date of the '754 Patent, including any extensions, adjustments, and exclusivities associated with the '754 Patent.

106. Natco was aware of the '754 Patent when it submitted its ANDA. On information and belief, Natco's statement of the factual and legal basis regarding the invalidity of the '754 Patent is devoid of a good faith basis in either the facts or the law.

COUNT III
(BY GENENTECH AND ROCHE)
(INFRINGEMENT OF THE '444 PATENT BY NATCO)

107. The allegations above are incorporated herein by reference.

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

109. Natco has infringed at least claim 1 of the '444 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Natco 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 '444 Patent. At least claim 1 of the '444 Patent encompasses a method of treating SMA in a patient in need thereof with risdiplam according to specific weight-based dosing. In the Natco Notice Letter, Natco has not contested infringement of claim 1—or any claim—of the '444 Patent.

110. On information and belief, the Natco 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 1 of the '444 Patent.

111. On information and belief, the Natco ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 1 of the ’444 Patent.

112. Natco’s commercial manufacture, use, offer to sell, sale, or importation of the Natco ANDA Product before the expiration of the ’444 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the ’444 Patent, including, but not limited to, claim 1, under 35 U.S.C. § 271. Natco’s infringement of at least claim 1 is either literal or under the doctrine of equivalents.

113. Genentech and Roche will be harmed substantially and irreparably if Natco is not enjoined from infringing the ’444 Patent and/or if FDA is not enjoined from approving the Natco ANDA before the ’444 Patent expires.

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

115. 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 Natco ANDA to be a date which is not any earlier than the expiration date of the ’444 Patent, including any extensions, adjustments, and exclusivities associated with the ’444 Patent.

116. Natco was aware of the ’444 Patent when it submitted its ANDA. On information and belief, Natco’s statement of the factual and legal basis regarding the invalidity of the ’444 Patent is devoid of a good faith basis in either the facts or the law.

COUNT IV
(BY ALL PLAINTIFFS)
(INFRINGEMENT OF THE ’646 PATENT BY NATCO)

117. The allegations above are incorporated herein by reference.

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

119. Natco has infringed at least claims 1 and 11 of the '646 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Natco 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 '646 Patent. At least claims 1 and 11 of the '646 Patent encompasses treating SMA with a therapeutically effective amount of risdiplam. In the Natco Notice Letter, Natco has not contested infringement of claims 1 and 11—or any claim—of the '646 Patent.

120. On information and belief, the Natco 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 claims 1 and 11 of the '646 Patent.

121. On information and belief, the Natco ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1 and 11 of the '646 Patent.

122. Natco's commercial manufacture, use, offer to sell, sale, or importation of the Natco ANDA Product before the expiration of the '646 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '646 Patent, including, but not limited to, claims 1 and 11, under 35 U.S.C. § 271. Natco's infringement of at least claims 1 and 11 is either literal or under the doctrine of equivalents.

123. Plaintiffs will be harmed substantially and irreparably if Natco is not enjoined from infringing the '646 Patent and/or if FDA is not enjoined from approving the Natco ANDA before the '646 Patent expires.

124. Plaintiffs have no adequate remedy at law.

125. Plaintiffs 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 Natco ANDA to be a date which is not any earlier than the expiration date of the '646 Patent, including any extensions, adjustments, and exclusivities associated with the '646 Patent.

126. Natco was aware of the '646 Patent when it submitted its ANDA. On information and belief, Natco's statement of the factual and legal basis regarding the invalidity of the '646 Patent is devoid of a good faith basis in either the facts or the law.

COUNT V
(BY GENENTECH AND ROCHE)
(INFRINGEMENT OF THE '136 PATENT BY NATCO)

127. The allegations above are incorporated herein by reference.

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

129. Natco has infringed at least claims 1, 35, and 36 of the '136 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Natco 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 '136 Patent. At least claim 1 of the '136 Patent encompasses a dry granulated powder blend for an oral solution comprising, *inter alia*, risdiplam, at least claim 35 of the '136 Patent encompasses an aqueous solution comprising a dry granulated powder blend comprising risdiplam, and at least claim 36 of the '136 Patent encompasses a kit for the preparation of a pharmaceutical composition comprising risdiplam. In the Natco Notice Letter, Natco has not contested infringement of claims 1, 35, and 36—or any claim—of the '136 Patent.

130. On information and belief, the Natco 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 35 of the '136 Patent.

131. On information and belief, the Natco ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 35 and 36 of the '136 Patent.

132. Natco's commercial manufacture, use, offer to sell, sale, or importation of the Natco ANDA Product before the expiration of the '136 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '136 Patent, including, but not limited to, claims 1, 35, and 36, under 35 U.S.C. § 271. Natco's infringement of at least claims 1, 35, and 36 is either literal or under the doctrine of equivalents.

133. Genentech and Roche will be harmed substantially and irreparably if Natco is not enjoined from infringing the '136 Patent and/or if FDA is not enjoined from approving the Natco ANDA before the '136 Patent expires.

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

135. 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 Natco ANDA to be a date which is not any earlier than the expiration date of the '136 Patent, including any extensions, adjustments, and exclusivities associated with the '136 Patent.

136. Natco was aware of the '136 Patent when it submitted its ANDA. On information and belief, Natco's statement of the factual and legal basis regarding the invalidity of the '136 Patent is devoid of a good faith basis in either the facts or the law.

COUNT VI
(BY GENENTECH AND ROCHE)
(INFRINGEMENT OF THE '444 PATENT BY ZYDUS)

137. The allegations above are incorporated herein by reference.

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

139. Zydus has infringed at least claim 1 of the '444 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 '444 Patent. At least claim 1 of the '444 Patent encompasses a method of treating SMA in a patient in need thereof with risdiplam according to specific weight-based dosing. In the Zydus Notice Letter, Zydus has not contested infringement of claims 1–18 or claims 20–35 of the '444 Patent.

140. Zydus FZE, Zydus Ltd., and Zydus Inc. are jointly and severally liable for the infringement of one or more claims of the '444 Patent. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Zydus ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '444 Patent under 35 U.S.C. § 271(e)(2)(A).

141. 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 1 of the '444 Patent.

142. 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 1 of the ’444 Patent.

143. Zydus’s commercial manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Product before the expiration of the ’444 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the ’444 Patent, including, but not limited to, claim 1, under 35 U.S.C. § 271. Zydus’s infringement of at least claim 1 is either literal or under the doctrine of equivalents.

144. Genentech and Roche will be harmed substantially and irreparably if Zydus is not enjoined from infringing the ’444 Patent and/or if FDA is not enjoined from approving the Zydus ANDA before the ’444 Patent expires.

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

146. 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 ’444 Patent, including any extensions, adjustments, and exclusivities associated with the ’444 Patent.

147. Zydus was aware of the ’444 Patent when it submitted its ANDA. On information and belief, Zydus’s statement of the factual and legal basis regarding the invalidity and noninfringement of the ’444 Patent is devoid of a good faith basis in either the facts or the law.

COUNT VII
(BY GENENTECH AND ROCHE)
(INFRINGEMENT OF THE ’136 PATENT BY ZYDUS)

148. The allegations above are incorporated herein by reference.

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

150. Zydus has infringed at least claims 1, 35, and 36 of the '136 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® in the United States prior to the expiration of the '136 Patent. At least claim 1 of the '136 Patent encompasses a dry granulated powder blend for an oral solution comprising, *inter alia*, risdiplam, at least claim 35 of the '136 Patent encompasses an aqueous solution comprising a dry granulated powder blend comprising risdiplam, and at least claim 36 of the '136 Patent encompasses a kit for the preparation of a pharmaceutical composition comprising risdiplam.

151. Zydus FZE, Zydus Ltd., and Zydus Inc. are jointly and severally liable for the infringement of one or more claims of the '136 Patent. On information and belief, Zydus FZE, Zydus Ltd., and Zydus Inc.'s participation in, contribution to, inducement of, aiding or abetting the submission of the Zydus ANDA and its Paragraph IV Certification to FDA constitutes direct, contributory, or induced infringement of one or more claims of the '136 Patent under 35 U.S.C. § 271(e)(2)(A).

152. 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 35 of the '136 Patent.

153. 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 claims 35 and 36 of the '136 Patent.

154. Zydus's commercial manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Product before the expiration of the '136 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '136 Patent, including, but not limited to, claims 1, 35, and 36, under 35 U.S.C. § 271. Zydus's infringement of at least claims 1, 35, and 36, is either literal or under the doctrine of equivalents.

155. Genentech and Roche will be harmed substantially and irreparably if Zydus is not enjoined from infringing the '136 Patent and/or if FDA is not enjoined from approving the Zydus ANDA before the '136 Patent expires.

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

157. 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 '136 Patent, including any extensions, adjustments, and exclusivities associated with the '136 Patent.

158. Zydus was aware of the '136 Patent when it submitted its ANDA. On information and belief, Zydus's statement of the factual and legal basis regarding the invalidity and noninfringement of the '136 Patent is devoid of a good faith basis in either the facts or the law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Genentech, Roche, and PTC respectfully request that this Court enter judgment in its favor and grant the following relief:

A. A judgment that Natco has infringed directly, contributed to, or induced infringement of one or more claims of the '955 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Natco ANDA to FDA to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in,

or importation into the United States of the Natco ANDA Product before the expiration of the ’955 Patent;

B. A judgment that Natco has infringed directly, contributed to, or induced infringement of one or more claims of the ’754 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Natco ANDA to FDA to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in, or importation into the United States of the Natco ANDA Product before the expiration of the ’754 Patent;

C. A judgment that Natco has infringed directly, contributed to, or induced infringement of one or more claims of the ’444 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Natco ANDA to FDA to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in, or importation into the United States of the Natco ANDA Product before the expiration of the ’444 Patent;

D. A judgment that Natco has infringed directly, contributed to, or induced infringement of one or more claims of the ’646 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Natco ANDA to FDA to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in, or importation into the United States of the Natco ANDA Product before the expiration of the ’646 Patent;

E. A judgment that Natco has infringed directly, contributed to, or induced infringement of one or more claims of the ’136 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Natco ANDA to FDA

to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in, or importation into the United States of the Natco ANDA Product before the expiration of the ’136 Patent;

F. A judgment that Natco will infringe directly, contribute to, or induce the infringement of one more claims of the ’955 Patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Natco markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States the Natco ANDA Product before the expiration of the ’955 Patent;

G. A judgment that Natco will infringe directly, contribute to, or induce the infringement of one more claims of the ’754 Patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Natco markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States the Natco ANDA Product before the expiration of the ’754 Patent;

H. A judgment that Natco will infringe directly, contribute to, or induce the infringement of one more claims of the ’444 Patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Natco markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States the Natco ANDA Product before the expiration of the ’444 Patent;

I. A judgment that Natco will infringe directly, contribute to, or induce the infringement of one more claims of the ’646 Patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Natco markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States the Natco ANDA Product before the expiration of the ’646 Patent;

J. A judgment that Natco will infringe directly, contribute to, or induce the infringement of one more claims of the ’136 Patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Natco markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States the Natco ANDA Product before the expiration of the ’136 Patent;

K. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Natco ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the ’955, ’754, ’444, ’646, and ’136 Patents, including any extensions, adjustments, or exclusivities;

L. A judgment ordering that Natco amend its Paragraph IV Certification to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

M. Entry of preliminary and permanent injunctions pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Natco, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’955, ’754, ’444, ’646, and ’136 Patents, or contributing to or inducing the same, including the manufacture, use, offer to sell, sale, distribution or importation of any current or future versions of the Natco ANDA Product before the expiration of the ’955, ’754, ’444, ’646, and ’136 Patents, including any applicable extensions, adjustments, and exclusivities;

N. If Natco commercially manufactures, uses, offers to sell, or sells in the United States or imports into the United States the Natco ANDA Product prior to the expiration of the ’955, ’754, ’444, ’646, and ’136 Patents, including any extensions,

adjustments, or exclusivities, a judgment pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284 awarding Plaintiffs Genentech, Roche, and PTC monetary relief, together with interest;

O. A judgment that Zydus has infringed directly, contributed to, or induced infringement of one or more claims of the '444 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Zydus ANDA to FDA to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in, or importation into the United States of the Zydus ANDA Product before the expiration of the '444 Patent;

P. A judgment that Zydus has infringed directly, contributed to, or induced infringement of one or more claims of the '136 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Zydus ANDA to FDA to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in, or importation into the United States of the Zydus ANDA Product before the expiration of the '136 Patent;

Q. A judgment that Zydus will infringe directly, contribute to, or induce the infringement of one more claims of the '444 Patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Zydus markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States the Zydus ANDA Product before the expiration of the '444 Patent;

R. A judgment that Zydus will infringe directly, contribute to, or induce the infringement of one more claims of the '136 Patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Zydus markets, manufactures, uses, offers for sale,

sells, distributes in, or imports into the United States the Zydus ANDA Product before the expiration of the ’136 Patent;

S. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Zydus ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the ’444 and ’136 Patents, including any extensions, adjustments, or exclusivities;

T. A judgment ordering that Zydus amend its Paragraph IV Certification to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

U. Entry of preliminary and permanent injunctions pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Zydus, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’444 and ’136 Patents, or contributing to or inducing the same, including the manufacture, use, offer to sell, sale, distribution or importation of any current or future versions of the Zydus ANDA Product before the expiration of the ’444 and ’136 Patents, including any applicable extensions, adjustments, and exclusivities;

V. If Zydus commercially manufactures, uses, offers to sell, or sells in the United States or imports into the United States the Zydus ANDA Product prior to the expiration of the ’444 and ’136 Patents, including any extensions, adjustments, or exclusivities, a judgment pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284 awarding Plaintiffs Genentech and Roche monetary relief, together with interest;

W. An award to Plaintiffs of attorneys’ fees in this action as an exceptional case pursuant to 35 U.S.C. § 285; and

X. An award to Plaintiffs of costs and expenses in this action; and

Y. Such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury on all issues so triable, pursuant to Fed. R. Civ. P. 38.

s/ Keith J. Miller
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**Pro hac vice* application forthcoming