Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
Tel: (973) 690-5400

Attorneys for Plaintiffs
Genentech, Inc. and Hoffmann-La Roche Inc.

Eric Alan Stone
Daniel J. Klein*
Aileen Huang*
Eliza P. Strong*
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
565 Fifth Ave, Suite 2900
New York, New York 10017
Tel: (332) 269-0030

Philip S. May
Saurabh Gupta*
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP
801 17th Street NW, Suite 1050
Washington, D.C. 20006
Tel: (202) 505-5830

**Pro hac vice* application forthcoming

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

Plaintiffs,

v.

NATCO PHARMA LIMITED,

Defendant.

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Genentech, Inc. ("Genentech") and Hoffmann-La Roche, Inc. ("Roche") for their Complaint against Defendant Natco Pharma Limited ("Natco"), 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") to the United States Food and Drug Administration ("FDA"), by which Natco 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®.

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.

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.

4. 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.

JURISDICTION

5. 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.

6. 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.

7. 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).

8. 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.

9. 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® 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.

10. 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.

11. 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.

12. 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).

VENUE

13. 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).

EVRYSDI®

14. 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®.

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

16. The active ingredient in EVRYSDI® is risdiplam.

17. 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.

18. 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.

19. 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.

THE NATCO ANDA

20. 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").

21. 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®.

22. 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 '789 Patent is invalid, unenforceable, and/or that certain claims will not be infringed by the Natco ANDA Product.

23. Genentech and Roche received written notice of the Natco ANDA and a Paragraph IV Certification by letter dated November 20, 2024 (the "Natco Notice Letter"), along with an enclosed statement (the "Natco Detailed Statement") alleging that "the claims of the '789 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale in the United States or importation into the United States of Natco's ANDA product."

24. The Natco Detailed Statement does not provide any factual bases for stating that the '789 Patent will not be infringed by the Natco ANDA Product.

25. The Natco Detailed Statement does not provide any factual bases for stating that the '789 Patent is unenforceable.

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

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

28. Natco has infringed one or more claims of the Asserted Patent 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 Patent or any extensions thereof. Natco 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.

THE ASSERTED PATENT

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

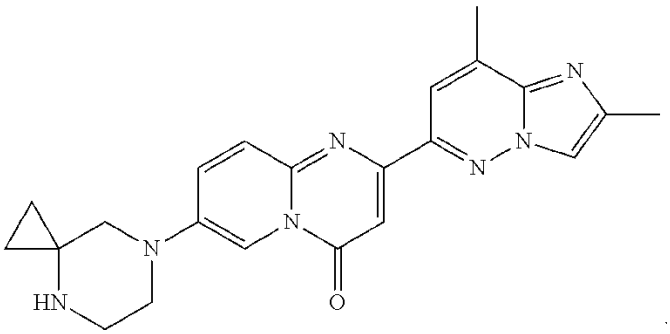
29. The allegations above are incorporated herein by reference.

30. 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.

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

32. 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)
>
> (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.

33. 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.

34. 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.

COUNT I
(INFRINGEMENT OF THE '789 PATENT)

35. The allegations above are incorporated herein by reference.

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

37. Natco 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 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 '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 Natco Notice Letter, Natco has not contested infringement of claims 1, 9, and 11—or any claim—of the '789 Patent.

38. 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 11 of the '789 Patent.

39. 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 11 of the '789 Patent.

40. Natco's commercial manufacture, use, offer to sell, sale, or importation of the Natco 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. Natco's infringement of at least claims 1, 9, and 11 is either literal or under the doctrine of equivalents.

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

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

43. 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 '789 Patent, including any extensions, adjustments, and exclusivities associated with the '789 Patent.

44. Natco was aware of the '789 Patent when it submitted its ANDA. On information and belief, Natco'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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Genentech and Roche 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 '789 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 '789 Patent;

B. A judgment that Natco will infringe directly, contribute to, or induce the infringement of one more claims of the '789 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 '789 Patent;

C. 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 '789 Patent, including any extensions, adjustments, or exclusivities;

D. 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);

E. 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 '789 Patent, 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'789 Patent, including any applicable extensions, adjustments, and exclusivities;

F. 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 '789 Patent, 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;

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

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

I. 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
Keith J. Miller
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, NJ 07102
kmiller@rwmlegal.com
Tel: (973) 690-5400

Attorneys for Plaintiffs
Genentech, Inc. and Hoffmann-La Roche Inc.

Of Counsel:

Eric Alan Stone
Daniel J. Klein*
Aileen Huang*
Eliza P. Strong*
GROOMBRIDGE, WU, BAUGHMAN
& STONE LLP
565 Fifth Ave
Suite 2900
New York, NY 10017
eric.stone@groombridgewu.com
dan.klein@groombridgewu.com
aileen.huang@groombridgewu.com
eliza.strong@groombridgewu.com
Tel: (332) 269-0030

Philip S. May
Saurabh Gupta*
GROOMBRIDGE, WU, BAUGHMAN
& STONE LLP
801 17th Street NW, Suite 1050
Washington, D.C. 20006
philip.may@groombridgewu.com
saurabh.gupta@groombridgewu.com
Tel: (202) 505-5830

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