

**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,
SUN PHARMACEUTICAL
INDUSTRIES LTD., SUN
PHARMACEUTICAL
INDUSTRIES INC., ZYDUS
LIFESCIENCES GLOBAL FZE,
ZYDUS LIFESCIENCES LTD.,
AND ZYDUS
PHARMACEUTICALS (USA)
INC.,**

Defendants.

Consol. Court No. 24-10567-JCG-JSA

ANDA CASE

OPINION AND ORDER

[Providing claim construction for the patents in suit.]

Dated: October 23, 2026

Bradley A. Suiters and Keith J. Miller, Robinson Miller LLC, of Newark, N.J.;
Eric Alan Stone, Daniel J. Klein, Aileen Huang, and Eliza P. O'Connor,
Groombridge, Wu, Baughman & Stone LLP, of New York, N.Y.; and Philip S.
May and Alyssa B. Ertel, Groombridge, Wu, Baughman & Stone LLP, of
Washington, D.C. Attorneys for Plaintiffs Genentech, Inc., Hoffmann-La Roche
Inc., and PTC Therapeutics, Inc.

Gregory D. Miller, Timothy P. Gonzalez, and Catherine Salerno, Rivkin Radler LLP, of Hackensack, N.J.; and C. Kyle Musgrove, Robert Cerwinski, Scott Cunning II, Netanel Finkelstein, and Zachary Travis, Gemini Law LLP, of New York, N.Y. Attorneys for Defendants Natco Pharma Limited, Sun Pharmaceutical Industries, Ltd., and Sun Pharmaceutical Industries, Inc.

Theodora McCormick, Lauren B. Cooper, and Alec Wong, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, of Princeton, N.J.; and Michael J. Gaertner, James T. Peterka, Jonathan B. Turpin, Leah M. Brackensick, and Scott P. Clark, Buchanan Ingersoll & Rooney PC, of Chicago, IL. Attorneys for Zydus Lifesciences Global FZE, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited.

Choe-Groves, Judge: This matter is before the Court for claim construction of a disputed term in U.S. Patent Number 12,122,789 (“the ’789 Patent”). See Joint Claim Construction & Prehearing Statement (“Joint Claim Chart”) (ECF No. 85-1); Pls.’ Opening Claim Construction Br., Ex. 1, U.S. Patent No. 12,122,789 (“’789 Patent”) (ECF No. 102-2). The Parties dispute construction of the term “crystalline Form A.”¹ Joint Claim Chart at 3–4. Upon consideration of the written and oral arguments of counsel, the Court resolves the claim term dispute as set forth below.

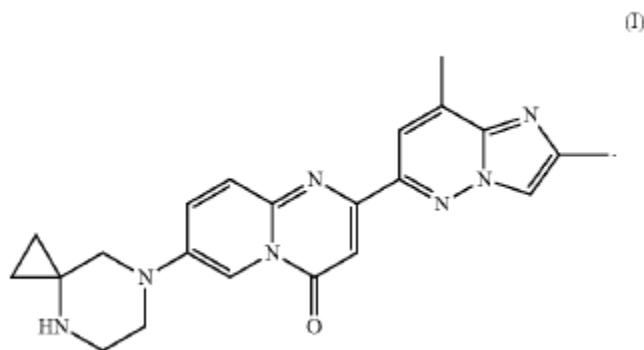
¹ The Parties proposed originally constructions for the disputed terms “effective amount” in U.S. Patent No. 9,586,955 and “therapeutically effective amount” in U.S. Patent Nos. 9,969,754 and 11,827,646, but the Parties reached agreement on the construction of both terms. See Joint Claim Chart; Order Adopting Constructions (Feb. 13, 2026) (ECF No. 105).

BACKGROUND

The drug at issue in this case is EVRYSDI® or risdiplam. See First Am. Compl. (Court No. 24-11308) (ECF No. 99). EVRYSDI® is an oral medication that treats spinal muscular atrophy. Id. at ¶ 2. Plaintiffs Genentech, Inc. (“Genentech”) and Hoffman-La Roche, Inc. (“Roche”) (collectively, “Plaintiffs”) filed suit against Defendants Natco Pharma Limited (“Natco”), Sun Pharmaceutical Industries Ltd. (“Sun Ltd.”), and Sun Pharmaceutical Industries, Inc. (“Sun Inc.”) (collectively, “Defendants”) for patent infringement arising from Natco’s Abbreviated New Drug Application (“ANDA”) to market a generic version of EVRYSDI®.² Id. at ¶ 1. This Opinion concerns the first step of the two-step infringement analysis, the construction of claims in the ’789 Patent. The ’789 Patent is titled “Forms of Pyrido[1,2-a]Pyrimidin-4-One Derivatives, Its Formulation and Its Process of Making.” ’789 Patent at [54]. The United States Patent and Trademark Office issued the ’789 Patent on October 22, 2024. Id. at [45].

² The Court consolidated Case Nos. 24-11308, 25-1521, and 24-10567 under Consol. Court No. 24-10567, and later also consolidated 25-17100 into Consol. Case No. 24-10567 for all pre-trial purposes. Stipulation & Order Consolidating Cases (ECF No. 104). Plaintiffs Genentech and Roche filed a First Amended Complaint against Defendants Natco, Sun Ltd., and Sun Inc. on February 12, 2026, alleging one count of infringement of the ’789 Patent. First Am. Compl. at ¶¶ 1, 42–51.

The '789 Patent is directed toward crystalline forms of compounds of formula (I):



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, and the crystalline forms' production process, composition, and use as pharmaceutically active compounds. Id. at 1:17–36. The claimed invention relates to crystalline polymorphic Form A and a crystalline hydrate Form D of a compound of formula (I). Id. at 2:34–50. Crystalline polymorphic Form A of a compound of formula (I) is the thermodynamic stable polymorph. Id. at 2:51–52.

This is a polymorphic form with properties advantageous for easy manufacturing and dosage form stability, which improves storage and packaging capabilities for the medication. Id. at 2:61–63. For example, Form A has improved filtration efficiency which allows “a faster isolation of the compound of interest resulting in [the] saving of solvents which may have a great impact on the environment.” Id. at 2:66–67, 3:1–3.

The Parties filed a joint claim construction chart and briefs in support of their respective positions on claim construction. Joint Claim Chart; Pls.’ Opening Claim Construction Br. (“Pls.’ Opening Br.”) (ECF No. 102); Defs.’ Opening Markman Br. (“Defs.’ Opening Br.”) (ECF No. 101); Pls.’ Resp. Claim Construction Br. (“Pls.’ Resp. Br.”) (ECF Nos. 161, 167); Defs.’ Resp. Markman Br. (“Defs.’ Resp. Br.”) (ECF No. 160); Defs.’ Supp. Markman Br. (“Defs.’ Supp. Br.”) (ECF No. 172). The Court held a claim construction hearing on September 17, 2026, and the Parties did not call expert witnesses. See Minutes of Proceeding (ECF No. 182).

CLAIM CONSTRUCTION STANDARD

When the meaning of a patent claim’s language is disputed, the Court must construe the claim as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996). “[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court.” Markman, 517 U.S. at 372. “The purpose of claim construction is to ‘determin[e] the meaning and scope of the patent claims asserted to be infringed.’” O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting Markman, 52 F.3d at 976).

“The patent is a fully integrated written instrument.” Markman, 52 F.3d at 978. For claim construction, “[a] court should look first to the intrinsic evidence of

record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history.” Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman, 52 F.3d at 979). “The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history.” Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

Limitations from dependent claims, the specification, and embodiments will not be read into the claims. “The doctrine of claim differentiation [] creates a presumption that [] dependent claim limitations are not included in the independent claim.” GE Lighting Sols., LLC v. AgiLight, Inc., 750 F.3d 1304, 1310 (Fed. Cir. 2014) (citation omitted). Limitations found in the specification are not imposed into the claims. Phillips, 415 F.3d at 1323–24. In the same vein, “[i]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.” GE Lighting Sols., LLC, 750 F.3d at 1309 (citation omitted) (discussing a figure as a “depicted embodiment”).

DISCUSSION

I. Undisputed Terms

The Parties reached agreement previously on the construction of the terms “effective amount” and “therapeutically effective amount,” and the Court adopted the Parties’ proposed constructions. Thus, “effective amount” shall have its “plain and ordinary meaning, which is: an amount that, when administered, has a therapeutic effect and/or beneficial effect,” and “therapeutically effective amount” shall have its “plain and ordinary meaning, which is an amount that, when administered to a subject, (i) treats or prevents spinal muscular atrophy, (ii) attenuates, ameliorates or eliminates one or more symptoms of spinal muscular atrophy, or (iii) prevents or delays the onset of one or more symptoms of spinal muscular atrophy.” Order Adopting Constructions at 2.

II. Disputed Term

The Parties disagree on one claim term, “crystalline Form A,” found in Claims 1, 2, 4–8, 12–21, 30, and 31 of the ’789 Patent. Joint Claim Chart at 3–4. Plaintiffs contend that the term does not require construction and initially proposed that the inventors defined the term accordingly:

“Form A” is a proper noun referring to a crystalline anhydrous polymorphic form 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 that is designated as “Form A.” The properties and characteristics of Form A are set forth in the claims.

Pls.’ Opening Br. at 10. Defendants propose construing the claim term as “[t]he risdiplam crystalline form described in the specification as Form A, having all of the characteristics assigned to Form A in the specification.” Defs.’ Opening Br. at 4.³ Plaintiffs later altered their proposal with what Plaintiffs described as “non-substantive, clarifying amendments.”⁴ Pls.’ Resp. Br. at 5. Plaintiffs revised their proposal to state:

No construction necessary. The ’789 Patent defines “Form A”: “Form A as used herein refers to the crystalline anhydrous polymorphic Form A 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”—i.e., risdiplam. Form A has the same meaning in each claim of the patent; each claim identifies properties and characteristics of Form A that must be observed for that specific claim to be infringed.

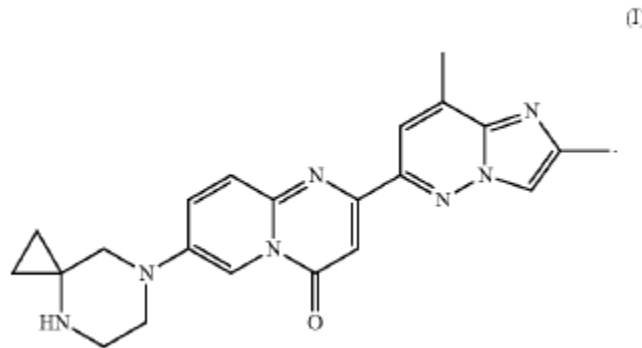
³ Defendants also raise invalidity arguments involving written description and enablement. Defs.’ Opening Br. at 9–10. The Court observes that Defendants reserved “all rights to assert all indefiniteness arguments under 35 U.S.C. § 112 for the Asserted Patents disclosed in their invalidity contentions dated August 7, 2025, or any later amended or supplemental invalidity contentions permitted by the Court, during summary judgment or trial.” Joint Claim Chart at 3 n.3. On May 4, 2026, the Court granted Defendants’ joint request to amend their joint invalidity contentions. See Oral Argument & Case Mgmt. Conf. Tr. at 4:9–12, 35:3–4 (May 4, 2026) (ECF No. 133).

⁴ Plaintiffs note that Defendants consented to Plaintiffs amending their initial proposal during the hearing to address case management and Defendants’ request to amend their invalidity contentions. Pls.’ Resp. Br. at 5 n.1; see Oral Argument & Case Mgmt. Conf. Tr. at 17:12–18 (“Now, if counsel is implying that plaintiffs would have proposed a different construction or would have changed their construction if only they had known that the construction they did propose had these flaws, they – you know, they certainly have the opportunity to rethink their claim construction position now if they are no longer are [sic] confident in that position.”).

Id. at 5–6.

The disputed claim term appears in Claim 1 of the '789 Patent, and Claim 1 recites:

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.

'789 Patent at 53:2–25. Dependent Claims 2, 4–8, 12–21, 30, and 31 refer to the solid form of “crystalline Form A” that is recited in Claim 1 but describe Form A with different “comprising” characteristics. Id. at 53:26–67, 54:14–67, 55:1–17, 56:15–24. The core dispute between the Parties is whether the definition of “crystalline Form A” should include all the exemplary characteristics described in the dependent claims and specification. See Pls.’ Opening Br. at 11; Defs.’ Opening Br. at 7.

Plaintiffs assert that the first clause of Defendants’ proposed construction,

“[t]he risdiplam crystalline form described in the specification as Form A,” is synonymous with Plaintiffs’ argument that the ’789 Patent itself defines “Form A.” Pls.’ Resp. Br. at 1. The Court should not depart from the plain meaning of the claims absent lexicography or disavowal, and “[t]o act as its own lexicographer, a patentee must ‘clearly set forth a definition of the disputed claim term,’ and ‘clearly express an intent to define the term.’” See Luminara Worldwide, LLC v. Liown Elecs. Co., 814 F.3d 1343, 1353 (Fed. Cir. 2016); GE Lighting Sols., 750 F.3d at 1309 (quoting Thorner, 669 F.3d at 1365). The ’789 Patent’s specification defines “Form A” as follows:

“Form A” as used herein refers to the crystalline anhydrous polymorphic Form A 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.

’789 Patent at 7:43–46. The ’789 Patent provides an explicit definition for “Form A” in the specification; however, whether “Form A” requires further construction given the way that the term is used throughout the patent is disputed amongst the Parties.

Defendants acknowledge that “Form A” is a singular, polymorphic form of risdiplam, and argue that a polymorph’s attributes are what distinguish polymorphs of the same compound from one another. Defs.’ Resp. Br. at 1–2. Because the dependent claims in the ’789 Patent recite various characteristics that comprise “crystalline Form A,” Defendants contend that if a crystalline form of risdiplam

does not exhibit any one of Form A’s given attributes, then it is not “Form A.” Id. at 2. Thus, “crystalline Form A” as the claimed polymorphic form “must exhibit all of the defined characteristics in the ’789 Patent.” Id.

Plaintiffs argue that Defendants’ request to import embodiments from the specification into the claim term is improper. Pls.’ Resp. Br. at 9. Although specifications often describe specific embodiments of inventions, the U.S. Court of Appeals for the Federal Circuit has warned repeatedly “against confining the claims to those embodiments.” Phillips, 415 F.3d at 1323 (“To avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so.”); Pfizer, Inc. v. Ranbaxy Lab’ys Ltd. (“Pfizer”), 457 F.3d 1284, 1290 (Fed. Cir. 2006); Cont’l Cirs. LLC v. Intel Corp., 915 F.3d 788, 797 (Fed. Cir. 2019) (“We acknowledge the difficulty in drawing the fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims.”) (internal quotation omitted); Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharms. Ltd., 887 F.3d 1153, 1158 (Fed. Cir. 2018) (“Appellants’ claim construction arguments conflict with Pfizer and other precedent because they seek to import limitations from the specification into the claim.”). Defendants purport that “crystalline Form A” is a distinct limitation

separate from the specific characteristics identified in each dependent claim.

Defs.’ Supp. Br. at 4. Defendants argue that confirming whether “Form A” is present is a “distinct and predicate step” that is evaluated in light of the specific characteristics identified in the specification. Id. at 5.

The ’789 Patent’s dependent claims refer to “[t]he solid form of [C]laim 1, wherein the solid form is crystalline Form A . . . ” which recognizes that the solid form being discussed in each claim is crystalline Form A. ’789 Patent at 53:1–67, 54:1–67, 55:1–18, 56:15–24. For example, Claim 4 recites the solid form of crystalline Form A that has an X-ray powder diffraction (“XRPD”) comprising many XRPD peaks within degrees two-theta angles of diffraction. Id. at 53:36–44. The specification describes many different embodiments of “Form A” comprising of different XRPD peaks. Id. at 3:4–67 (stating multiple different Form A embodiments that consist of different XRPD peaks and even noting that “[o]ptionally, all five peaks may be present.”).

To define the claim term with “all of the characteristics assigned to Form A in the specification,” as Defendants request, would lead to improperly importing embodiments from the specification into the claim language. See Defs.’ Opening Br. at 4. The Court will not adopt Defendants’ construction. One of ordinary skill in the art considering independent Claim 1, and the subsequent dependent claims, would understand that “crystalline Form A” is the polymorphic form defined in the

specification as: “the crystalline anhydrous polymorphic Form A 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.” ’789 Patent at 7:43–46; see Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1371–74 (Fed. Cir. 2014). Therefore, the term “crystalline Form A” shall mean “the crystalline anhydrous polymorphic Form A 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.”

CONCLUSION

For the foregoing reasons, the Court defines the disputed claim term from the ’789 Patent as follows:

1. “crystalline Form A” as “the crystalline anhydrous polymorphic Form A 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.”

IT IS SO ORDERED this 23rd day of October, 2026.

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves
U.S. District Court Judge*

*Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.