

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEUROCRINE BIOSCIENCES, INC.,
Petitioner,

v.

SPRUCE BIOSCIENCES, INC.,
Patent Owner.

PGR2026-00059
Patent 12,569,491

**PETITIONER'S PRELIMINARY REPLY TO
PATENT OWNER'S PRELIMINARY RESPONSE**

Spruce’s original claims do not provide adequate written-description support for the challenged claims. The written-description requirement applies to original claims, and *ipsis verbis* disclosure does not, by itself, demonstrate possession of the claimed invention. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc) (“while it is true that original claims are part of the original specification, that truism fails to address the question whether original claim language necessarily discloses the subject matter that it claims” (cleaned up)).

The Petition explained that the challenged claims lack written description *at least because* the ’491 patent fails to show possession for (i) a method of treating OARTs and (ii) crinecerfont. Pet. 18-19. As to (ii), the Petition addressed the original claims and explained that they do not disclose the chemical structure for crinecerfont. *Id.*, 46-49. Spruce cannot rely on originally filed claims that *do not* support crinecerfont *ipsis verbis* to argue that its issued claims have adequate written description. *Enanta Pharms., Inc. v. Pfizer Inc.*, 178 F.4th 1341, 1347-48 (Fed. Cir. 2026) (“a disclosure of one chemical compound...cannot necessarily be a disclosure of another, even one close by structurally”). Spruce’s reliance on Neurocrine’s post-critical-date crinecerfont studies (POPR 17) likewise fails because “it is the specification itself that must demonstrate possession.” *Ariad*, 598 F.3d at 1352.

As to (i), the claimed methods, the Petition explained that the ’491 patent fails to show possession of a method for treating OARTs at all. Pet. 19-24. Spruce’s

original claims do not compel a different result. Those claims (just like the issued claims) expressly recite a therapeutic result (treating OARTs) that is not “supported by adequate disclosure in the specification.” *Id.*, 25 (quoting *Nuvo Pharms. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1384 (Fed. Cir. 2019)). Spruce argues that the specification provides *ipsis verbis* support for treating OARTs while the original claims “provide literal support.” POPR 9-11. But “[a] claim does not become more descriptive by its repetition, or its longevity.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968–69 (Fed. Cir. 2002). Spruce’s argument that the ’491 patent need not provide “experimental verification of every claimed species” (POPR 13) is beside the point: the specification lacks disclosure for treating OARTs with **any species**—and that deficiency is particularly significant given unpredictability in the art. Pet. 20-23. Spruce’s argument that experimental data relating to TARTs provides written description for treating OARTs (POPR 14-15) is wrong. The Petition demonstrates that “a POSA would have understood that OARTs were very rare as of the priority date, more difficult to diagnose than TARTs, and more difficult to treat.” Pet. 21-23 (citing EX1038, e70, e72; EX1040, 146-47; EX1069, R91; EX1003, ¶¶38-40, 42, 101-102).

The cases Spruce cites (POPR 5-6) for arguing that “*ipsis verbis* support” necessarily satisfies the written-description requirement are distinguishable. The original claim in *Gardner* recited a subgenus of guanidinoalkyl-1:4-benzodioxan

derivatives having a specific chemical structure (480 F.2d 879), while the original claim in *Allergan* recited a tablet comprising eluxadoline and an inert ingredient (111 F.4th 1358, 1374). The claims here recite methods of treating OARTs, and there is insufficient disclosure demonstrating that the Spruce inventors actually possessed the claimed methods. Pet. 19-24. Spruce’s argument that the Petition’s written-description ground is inconsistent with its obviousness ground (POPR 16) fails because “a description that merely renders the invention obvious does not satisfy the [written description] requirement.” *Ariad*, 598 F.3d at 1352.

None of the Board decisions Spruce cites (POPR 6-7) establishes a *per se* rule that institution must be denied whenever a petition challenges written description without separately analyzing every originally filed claim. In *Neosales* (PGR2021-00058), the Board criticized petitioner’s failure to address the original claims *as well as* “the state of knowledge in the field” and “the predictability of using different shaped” devices. Paper 6, 26. By contrast, the Petition here detailed both the state of the art and unpredictability associated with treating OARTs. Pet. 21-23. *Emerson* (CBM2016-00095) involved a final written decision rather than an institution decision, and *L’Oréal* (PGR2018-00024) involved a claimed range that was expressly recited in an original claim (Paper 12, 17-18). Lastly, to the extent the original claims “are substantively identical to the challenged claims” (POPR 5), the Petition’s analysis of the challenged claims applies equally to the original claims.

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR § 42.6(e)(4), the undersigned certifies that on October 14, 2026, a complete and entire copy of this Petitioner's Preliminary Reply was provided via electronic mail on Patent Owner's lead and backup counsel listed below at the following email addresses:

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