

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NEUROCRINE BIOSCIENCES, INC.,  
Petitioner,

v.

SPRUCE BIOSCIENCES, INC.,  
Patent Owner.

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Case No. PGR2026-00061  
Patent No. 12,576,084

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**PATENT OWNER'S PRELIMINARY SUR-REPLY**

As the Reply confirms, the petition argued lack of written description support based on alleged failure to “disclose” the claimed method. *E.g.*, Paper 9, 1; Pet., 33. The Reply, however, does not dispute two critical deficiencies in the petition case. First, neither the petition nor Petitioner’s expert addressed the original claims, which themselves directly rebut virtually all written description allegations in the petition. POPR, 6-15 (citing, *inter alia*, *Allergan* and *Gardner*). Indeed, Petitioner’s Reply tacitly concedes as much by now arguing only a few points of dispute remain. Second, despite incorrectly demanding additional experimental verification using additional compounds, they failed to consider Petitioner’s own confirmatory studies. POPR, 24-25. In its Reply, Petitioner does not dispute any of this. Paper 9, 1-3. Each of these undisputed deficiencies illustrates Petitioner’s failure to satisfy its burden.

Petitioner asks the Board to excuse its admitted oversight simply because there is no *per se* requirement to deny institution where the petition failed to address original claims. Paper 9, 1-3. Petitioner, however, provides no good reason to ignore its deficiency, does not deny the original claims themselves rebut most of the petition argument, and cites no authority for any post-petition cure. Petitioner’s attempts to distinguish *Emerson* and *L’Oréal* also fail: it never disputes they demonstrate routine denial for failure to address original claims. POPR, 7-8. Petitioner’s new Reply argument that the petition analysis “applies equally to the

original claims” (Paper 9, 3) is impermissibly late and substantively deficient. The original claims here expressly recite ten compounds for the claimed methods.

At bottom, Petitioner’s allegation the “specification lacks disclosure for changing a metabolic parameter with any claimed species” (Paper 9, 2) now boils down to an unjustified demand for experimental verification for each species of the claims. Petitioner conflates the “disclosure” requirement as *per se* requiring experimental data. Paper 9, 2. But this applies an incorrect legal standard. POPR, 16 (discussing *Ariad* and *Falkner*). The Reply invokes *Nuvo* (at 2) but does not explain why a narrow exception should swallow the rule here. *Nuvo Pharms. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1376 (Fed. Cir. 2019). In *Nuvo*, the court noted the lack of “supporting experimental data” of what was claimed because of prior art teaching away, whereas the specification lacked any “theory or explanation of how or why a claimed composition will be effective.” *Id.*, 1376, 1380. *Nuvo* is inapposite here and Petitioner fails to show otherwise. Petitioner, for example, fails entirely to rebut specification disclosure and the explanation of how and why a claimed composition will be effective. POPR, 3-4.

Petitioner alleges that OARTs are less common and more difficult to diagnose than TARTs, but does not justify leaping to the unsupported conclusion that treatment is somehow uniquely unpredictable. Paper 9, 2. At most, Petitioner demonstrates adrenal rest tumors present on the ovaries are more difficult *to image*

(EX1040) than on testes. Petitioner disregards experimental verification (POPR, 16, 24-25) for treating adrenal rest tumors with recited compounds and identifies *no example* of any adrenal rest tumor medication failing to treat such tumors when located on the ovaries as compared to the same tumors located on the testes.

Furthermore, Petitioner does not dispute that its own data corroborates description of the original claims (POPR, 24-25). Petitioner erroneously argues that corroborating data should be disregarded simply as outside the four corners of the specification. Paper 9, 1. But Petitioner's request is misplaced both legally and factually. Petitioner's own publications undermine the petition argument, regardless of whether it is found within the four corners of the specification. Such evidence weighs against Petitioner's burden of proof. *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996); *Bd. of Trs. of the Leland Stanford Junior Univ. v. Chinese Univ. of H.K.*, 860 F.3d 1367, 1378 (Fed. Cir. 2017).

Regarding crinecerfont, the Office already determined correcting an unambiguous typo is supported by the specification. POPR, 19-22. This case is thus nothing like *Enanta Pharms., Inc. v. Pfizer Inc.*, in which claimed compounds (C1 alkyl) lacked any referent in the original specification. 178 F.4th 1341, 1345 (Fed. Cir. 2026). Petitioner failed to meet its burden to reopen the Office's (correct) decision. Paper 6, 13-19; POPR, 19-22. *See* 35 U.S.C. §325(d); *Advanced Bionics*, IPR2019-01469 Paper 6, at 9-11.

Respectfully submitted,

Date: October 19, 2026

/ Michael T. Rosato /  
Michael T. Rosato, Lead Counsel  
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## APPENDIX – EXHIBIT LIST

| Exhibit No. | Description                                                                                                                                                                                                                                  |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2001        | <i>Neurocrine Biosciences, Inc. v. Spruce Biosciences, Inc.</i> , No. 1:25-cv-00059 (D. Del. June 9, 2025), ECF No. 19 (Motion to Dismiss).                                                                                                  |
| 2002        | <i>Neurocrine Biosciences, Inc. v. Spruce Biosciences, Inc.</i> , No. 1:25-cv-00059 (D. Del. June 9, 2025), ECF No. 26 (Memorandum Opinion).                                                                                                 |
| 2003        | E-mail Letter from Mike Morin, Counsel representing Neurocrine Biosciences, to Dr. Javier Szwarcberg, CEO Spruce Biosciences Inc. (Dec. 10, 2024).                                                                                           |
| 2004        | E-mail from Mike Morin, Counsel representing Neurocrine Biosciences, to Michael Rosato, Counsel representing Spruce Biosciences Inc. (Jan. 11, 2025).                                                                                        |
| 2005        | E-mail Letter from Mike Morin, Counsel representing Neurocrine Biosciences, to Michael Rosato, Counsel representing Spruce Biosciences Inc. (Jan. 6, 2025).                                                                                  |
| 2006        | <i>Neurocrine Biosciences, Inc. v. Spruce Biosciences, Inc.</i> , No. 1:25-cv-00059 (D. Del. June 9, 2025), ECF No. 1 (Complaint).                                                                                                           |
| 2007        | <i>Neurocrine Biosciences, Inc. v. Spruce Biosciences, Inc.</i> , CASEBOARD (Jan. 30, 2025), <a href="https://caseboard.io/cases/ac09fc0e-6e6e-497b-adc5-4bc46d1541be">https://caseboard.io/cases/ac09fc0e-6e6e-497b-adc5-4bc46d1541be</a> . |
| 2008        | File History – US Pat. No. 12,569,491.                                                                                                                                                                                                       |
| 2009        | File History – US Pat. No. 12,569,490.                                                                                                                                                                                                       |
| 2010        | File History – US Pat. No. 12,576,084.                                                                                                                                                                                                       |
| 2011        | Danielle Gully et al., <i>4-(2-Chloro-4-methoxy-5-methylphenyl)-N-[(1S)-2-cyclopropyl-1-(3-fluoro-4-methylphenyl)ethyl]5-methyl-N-(2-propynyl)-1,3-thiazol-2-amine Hydrochloride (SSR125543A): A Potent and Selective Corticotrophin-</i>    |

| Exhibit No. | Description                                                                                                                                                            |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | <i>Releasing Factor1 Receptor Antagonist. I. Biochemical and Pharmacological Characterization</i> , 301(1) J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 322-332 (2002). |
| 2012        | Notice of Opposition Proceedings to EPO Pat. No. 3784233                                                                                                               |

**CERTIFICATE OF SERVICE**

I certify that the foregoing Patent Owner's Preliminary Sur-Reply was served on this 19th day of October, 2026, on Petitioner at the following electronic service addresses:

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Respectfully submitted,

Date: October 19, 2026

/ Michael T. Rosato /  
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