## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

NEUROCRINE BIOSCIENCES, INC., Petitioner,

v.

SPRUCE BIOSCIENCES, INC., Patent Owner.

> PGR2022-00025 Patent 11,007,201 B2

Before KATHERINE K. VIDAL, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

DECISION Vacating the Decision Denying Institution and Remanding to the Patent Trial and Appeal Board Panel for Further Proceedings

## PGR2022-00025 Patent 11,007,201 B2

Neurocrine Biosciences, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting a post-grant review of claims 1–19 of U.S. Patent No. 11,007,201 B2 (Ex. 1001, "the '201 patent").<sup>1</sup> Spruce Biosciences, Inc. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

On September 15, 2022, the Patent Trial and Appeal Board ("Board") denied institution of a post-grant review of the '201 patent. Paper 10 ("Decision" or "Dec."). In its Decision, the Board relied on the reasoning of its prior decision to deny institution in PGR2021-00088. *See, e.g.*, PGR2021-00088, Paper 11 at 17–19 (anticipation), 33–34 (written description).

On October 13, 2022, Petitioner filed a rehearing request and a request for Precedential Opinion Panel ("POP") review. *See* Paper 11; Ex. 3002. In the request for POP review, Petitioner argued that:

Precedential Opinion Panel review is warranted to ensure that a uniform legal standard is applied when assessing the patentability of method of treatment claims, and to correct the Board's repeated errors of law in analyzing anticipation and written description in this proceeding and in PGR2021-00088.

Ex. 3002, 2.

On July 20, 2023, I issued an order granting *sua sponte* Director Review (Paper 13) and the POP dismissed the request for POP review (Paper 14). I also issued an order granting *sua sponte* Director Review in PGR2021-00088 (*see* PGR2021-00088, Paper 14) and the POP dismissed the request for POP review in that case (*see* PGR2021-00088, Paper 15).

<sup>&</sup>lt;sup>1</sup> Petitioner previously filed a Petition requesting a post-grant review of claims 1–25 of U.S. Patent No. 10,849,908 ("the '908 patent"). *See* PGR2021-00088. The '201 is a continuation of the application that issued as the '908 patent. *See* Ex. 1001, code (63).

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On August 4, 2023, I issued a Director Review decision in PGR2021-00088, vacating the Board's Decision denying institution of post-grant review, and remanding to the Board for further proceedings. PGR2021-00088, Paper 16. My discussion in PGR2021-00088 applies similarly to this case. Accordingly, for the reasons set forth in my Director Review decision in PGR2021-00088, I vacate the Board's Decision and remand this case to the Board for further proceedings consistent with my Director Review decision in PGR2021-00088.

## I. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Board's Decision Denying Institution is vacated; and

FURTHER ORDERED that the case is remanded to the Board for further proceedings consistent with my Decision in PGR2021-00088.

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