

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 PGR2021-00088  
U.S. Patent 10,849,908

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**PETITIONER'S MOTION TO SEAL**

## I. Introduction

Pursuant to 37 CFR § 42.54, Petitioner, Neurocrine Biosciences, Inc. respectfully submits this Motion to Seal Exhibits 1005 and 1009, as well as the Petition for Post Grant Review. Below, Petitioner explains that Good Cause exists for placing these exhibits and the Petition for Post Grant Review under seal.

## II. Applicable Legal Principles for Sealing Confidential Information

There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an *inter partes* review which determines the patentability of claims in a patent and therefore affects the rights of the public. *St. Jude Medical, Cardiology Division, Inc. v. Volcano Corp.*, IPR2013-00258, Decision to Revised Motion to Seal 37 C.F.R. §§ 42.14 and 42.54, Paper 28 at 2. Under 35 U.S.C. § 316(a)(1), the default rule is that all papers filed in an *inter partes* review are open and available for access by the public; and a party may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion. *Id.*

It is, however, only “confidential information” that is protected from disclosure. 35 U.S.C. § 316(a)(7) (“The Director shall prescribe regulations -- ... providing for protective orders governing the exchange and submission of confidential information”). *Id.* In that regard, the *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48760 (Aug. 14, 2012), provides:

The rules aim to strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information.

\* \* \*

Confidential Information: The rules identify confidential information in a manner consistent with Federal Rule of Civil Procedure 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information. § 42.54.

The standard for granting a motion to seal is “for good cause.” 37 C.F.R. § 42.54. Patent Owner, as the moving party, has the burden of proof in showing entitlement to the requested relief. *Id.*

### **III. Good Cause Exists for Sealing Exhibits 1005 and 1009, and the Petition for Post Grant Review.**

**Exhibit 1009:** Exhibit 1009 is a manuscript that describes Petitioner's Phase II clinical study related to the use of crinecerfont to treat CAH. It was submitted confidentially for review to The Lancet scientific journal on April 30, 2021, and has not been published. The manuscript contains clinical study protocols and results that are proprietary to Neurocrine. Disclosing those protocols and results to the public while the manuscript is undergoing peer review could damage Neurocrine.

**Exhibit 1005:** Exhibit 1005 includes portions that refer to and discuss Exhibit 1009.

**Petition for Post Grant Review:** The Petition for Post Grant Review

includes portions that refer to and discuss Exhibit 1009.

**IV. Certification of Non-Publication**

On behalf of Petitioner, undersigned counsel certifies that as of this date, the information sought to be sealed has not been published or otherwise made public. Further, the confidentiality of this information has been consistently maintained by the Petitioner during this proceeding, and any related proceedings.

**V. Proposed Protective Order**

The Protective Order attached hereto as Appendix A corresponds to the default protective order set forth in the Office Patent Trial Practice Guide. Petitioner and Patent Owner have agreed to use the attached protective order to govern the handling of confidential information in this proceeding. Per agreement of the parties, confidential information will be designated “PGR Protective Order Material.” Accordingly, Petitioner respectfully requests entry of the Proposed Protective Order.

**VI. Confidential and Non-Confidential Versions**

Submitted herewith are non-confidential versions of the Petition for Post Grant review and Exhibit 1005. Confidential versions are being filed concurrently.

**VII. Conclusion**

For the above reasons, Petitioner, Neurocrine Biosciences Inc., respectfully requests Exhibit 1009, and the unredacted Petition for Post Grant Review and Exhibit 1005, to be treated as confidential information and be placed under seal.

Respectfully submitted,

Date: /May 28, 2021/

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