

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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APOTEX INC.,  
Petitioner

v.

NOVO NORDISK A/S,  
PATENT OWNER

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CASE IPR2024-00631  
U.S. PATENT NO. 10,335,462  
ISSUED: JULY 2, 2019

TITLE:  
USE OF LONG-ACTING GLP-1 PEPTIDES

**APOTEX'S MOTION TO SEAL AND FOR ENTRY OF A PROTECTIVE  
ORDER PURSUANT TO 37 C.F.R. § 42.54**

## I. INTROUCTION

Pursuant to 37 C.F.R. §§ 42.14, 42.54, and 42.55, Petitioner Apotex Inc. (“Apotex”) hereby moves for entry of the protective order (Appendix A below) and further moves to seal (1) its Motion for Joinder Under 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22 and 42.122(b) to inter partes review of IPR2023-00724 (the “joinder motion”) and (2) the Declaration of Robert Shapiro, Ex. 1507 (the “Shapiro declaration”). That order is the Board’s default protective order. Patent Owner Novo Nordisk A/S (“Novo”) has likewise moved for entry of the Board’s default protective order in *Mylan Pharms. Inc. v. Novo Nordisk A/S*, IPR2023-00724 (the “Mylan IPR proceeding”). Good cause exists for sealing those documents. That is because they contain Apotex’s confidential business information, which, if disclosed, would likely cause competitive harm to Apotex.

## II. ENTRY OF A PROTECTIVE ORDER

Apotex moves for entry of the Board’s default protective order, submitted here as Appendix A below. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide 117–22 (Nov. 2019). Novo has moved for entry of the same protective order in the Mylan IPR proceeding. *Mylan*, IPR2023-00724, Paper No. 28 (PTAB Jan. 17, 2024). The challenged patent in that proceeding is the same as in this proceeding: U.S. Patent No. 10,335,462. Apotex seeks joinder to that proceeding.

### III. GOOD CAUSE EXISTS TO SEAL APOTEX'S JOINDER MOTION AND THE DECLARATION OF ROBERT SHAPIRO

Pursuant to the protective order and 37 C.F.R. §§ 42.54 and 42.55, Apotex moves to seal its joinder motion and the Shapiro declaration (Ex. 1507). As the Board has found in similar cases, “good cause” exists to seal these documents because they contain Apotex’s non-public business information. *Celltrion, Inc., v. Genentech, Inc.*, IPR2016-01667, Paper No. 20 at 4 (PTAB Aug. 18, 2017) (granting motion to seal non-public business information, including information about drug development and regulatory strategies), Paper No. 31 at 4 (PTAB July 23, 2018) (granting motion to expunge that information from the record); *Unified Patents Inc. v. Dragon Intellectual Prop., LLC*, IPR2014-00216, Paper No. 40, 6-7 (PTAB Feb. 27, 2015) (granting motion to seal non-public business information, including information relating to business strategies); *see also* 37 C.F.R. § 42.54. Specifically, the entirety of the Shapiro declaration describes Apotex’s confidential drug development and regulatory approval strategies. Ex. 1507. Certain portions of Apotex’s joinder motion rely on the declaration and contain the same confidential information. If that confidential information were publicly disclosed, it would likely cause competitive business harm to Apotex.

Apotex has filed unredacted, nonpublic versions of its joinder motion and the Shapiro declaration concurrently with this motion and its petition for *inter*

*partes* review. Apotex has also concurrently filed a redacted version of its joinder motion redacting the limited portions of the motion that rely on the confidential Shapiro declaration. Because the entirety of the Shapiro declaration contains confidential information, Apotex has not filed a redacted version.

#### **IV. CONCLUSION**

For the foregoing reasons, Apotex respectfully requests that the Board grant this motion to seal and for entry of a protective order.

Dated: March 1, 2024

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