UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN INSTITUTIONAL LLC, Petitioner,

v.

NOVO NORDISK A/S, Patent Owner.

Case IPR2020-00324 Patent 8,114,833

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



Patent Owner Novo Nordisk A/S ("Novo Nordisk") hereby moves for entry of the Protective Order appended as Addendum A and further moves to seal its Patent Owner Response and certain Exhibits, including two declarations, submitted with its Patent Owner Response as described herein. Novo Nordisk and Petitioner Mylan Institutional LLC ("Mylan") have discussed this Motion, and Mylan does not oppose this Motion.

I. MOTION FOR ENTRY OF A PROTECTIVE ORDER

Pursuant to 37 CFR § 42.54(a), a motion to seal must be accompanied by a proposed protective order and a certification that the parties have met-and-conferred regarding the issue. On September 16, 2020 and September 18, 2020, Novo Nordisk emailed counsel for Mylan to notify Mylan of Novo Nordisk's intent to file the Motion and propose that the parties adopt the Board's default protective order (appended as Addendum A). Mylan had no objections to the requests made in this Motion. Novo Nordisk respectfully requests that the Board's default protective order be entered in this proceeding.

II. MOTION TO SEAL

Pursuant to the stipulated protective order and 37 C.F.R. §§ 42.54 and 42.55, Novo Nordisk moves to seal (i) its Patent Owner Response submitted concurrently with this motion; (ii) the Declarations of Peter M. Tessier, Ph.D. (Ex2022) and Dorthe Kot Engelund (Ex2023), submitted in support of its Patent Owner Response;



and (iii) the following additional Exhibits submitted in support of its Patent Owner Response:

- Exhibits 2050-53
- Exhibits 2055-60
- Exhibits 2062-75

Novo Nordisk has also concurrently with this Motion filed redacted, non-confidential versions of the Patent Owner Response (Paper 21) and the Declaration of Peter M. Tessier, Ph.D. (Ex2080), which Novo Nordisk consents may be made available on the public docket. The Declaration of Dorthe Kot Engelund (Ex2023) and Exhibits 2050-53, 2055-60, and 2062-75, however, are confidential in their entirety and are submitted to the Board with this motion for filing under seal. Novo Nordisk is serving Mylan, concurrently with this Motion, copies of all Papers and Exhibits being filed today, including those under seal, as well as redacted non-confidential versions of Paper 21 and Exhibit 2080.

The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54. Good cause exists here because the Patent Owner Response and Exhibits that are the subject of this Motion contain confidential, non-public research and development information in the form of proprietary clinical and scientific data. *See also, e.g.* Ex2024 at ¶¶ 7-16 (establishing Ex2051, Ex2055, Ex2057, Ex2058, Ex2059, Ex2060, Ex2064, Ex2068, and Ex2072 as Novo Nordisk business records);



Ex2025 at ¶¶ 7-9 (establishing Ex2068 as a Novo Nordisk business record). In other inter partes review proceedings, the Board has held that confidential information similar to the information in Novo Nordisk's Patent Owner Response and Exhibits thereto should remain under seal. See, e.g. Apotex Inc. v. Wyeth LLC, IPR2014-00115, Paper 93 (PTAB Apr. 20, 2015) (granting motion to seal with respect to confidential research and development documents that were not publicly available); Celltrion, Inc. v. Genentech, Inc., IPR2016-01667, Paper 20 (PTAB Aug. 18, 2017) (granting motion to seal with respect to "non-public research development information in the form of proprietary clinical and scientific data concerning rituximab, and confidential information about drug development and regulatory approval strategies"). Moreover, the public policy for making all information filed in *inter partes* review proceedings available to the public should not apply here because the information that Novo Nordisk requests to keep confidential does not affect the rights of the public.

III. CONCLUSION

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



Dated: September 18, 2020 Respectfully submitted,

/s/ Jeffrey J. Oelke (Electronically signed)
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