

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

Case IPR2022-01103
U.S. Patent No. 9,616,097

**PATENT OWNER'S MOTION TO SEAL AND
ENTER DEFAULT PROTECTIVE ORDER**

I. Introduction

Patent Owner Bausch Health Ireland Limited requests that the confidential versions of the Patent Owner's Preliminary Response and Exhibit 2013 be sealed under 37 C.F.R. § 42.54. Good cause to seal these documents exists because a public version of the Patent Owner's Preliminary Response has also been filed, and the redacted information, along with the entirety of the information in Exhibit 2013, is sensitive, non-public excerpts of Bausch's New Drug Application ("NDA") 208745. Petitioner does not oppose this motion to seal or the entry of the default protective order, provided that Petitioner may seek additional restrictions to the default order if Petitioner's confidential information is proposed to be submitted later.

II. Governing Rules and PTAB Guidance

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, but a party may file a concurrent motion to seal and the information at issue is sealed pending the outcome of the motion.

Similarly, 37 C.F.R. § 42.14 provides:

The record of a proceeding, including documents and things, shall be made available to the public, except as otherwise ordered. A party intending a document or thing to be sealed shall file a motion to seal concurrent with the filing of the document or thing to be sealed. The document or thing shall be

provisionally sealed on receipt of the motion and remain so pending the outcome of the decision on the motion.

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”). In that regard, the *Office 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.

III. Identification of Confidential Information

The confidential information consists of non-public excerpts of Bausch’s NDA 208745. This information is contained in the following documents:

- Patent Owner’s Preliminary Response in pages 10, 33, 36, 63, 64.
- Exhibit 2013

IV. Good Cause Exists for Sealing the Confidential Information

The Board's 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. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,760 (Aug. 14, 2012). Accordingly, the Board has recognized that New Drug Applications and Abbreviated New Drug Applications contain confidential commercial information that should be protected from public disclosure. *See Sandoz, Inc. v. EKR Therapeutics, LLC*, IPR2015-00005, paper 21. Here, the information that Patent Owner seeks to seal is information contained in Bausch's NDA 208745, which was filed confidentially with the Food and Drug Administration ("FDA") in order to obtain FDA approval to market its innovative pharmaceutical product. Specifically, Patent Owner seeks to seal the entirety of Exhibit 2013 because it is excerpts of the NDA, the entirety of which is confidential, and redaction would not be practical. In addition, Patent Owner seeks to seal the portions of the Patent Owner's Preliminary Response, pages 10, 33, 36, 63, 64, that cite or substantially describe the NDA. Accordingly, there is good cause to grant this motion to seal.

III. PROPOSED PROTECTIVE ORDER

Pursuant to 37 C.F.R. § 42.54(a), the parties propose that the default protective order found in Appendix B of the Trial Practice Guide be entered.

IV. CERTIFICATION OF NON-PUBLICATION

The undersigned counsel certifies the information sought to be sealed by this Motion to Seal has not, to their knowledge, been published or otherwise made public. Patent Owner has made efforts to maintain the confidentiality of this information in a related district court proceeding. In that district court proceeding, the information that Patent Owner presently moves to seal has been produced and designated “Highly Confidential Information.”

V. CONCLUSION

For the reasons set forth above, Patent Owner respectfully requests the Board grant this motion to seal and enter the default Protective Order.

Respectfully submitted,

Dated: October 7, 2022

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