

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
MSN LABORATORIES PRIVATE LTD.,
and MSN PHARMACEUTICALS INC.,

Petitioner,

v.

BAUSCH HEALTH IRELAND LIMITED,

Patent Owner.

Case IPR2022-00722¹
U.S. Patent No. 7,041,786

PATENT OWNER'S MOTION TO SEAL

¹ IPR2023-00016 has been joined with this proceeding.

I. Introduction

Patent Owner Bausch Health Ireland Limited requests that the confidential versions of Petitioner's Reply and Exhibits 1060, 1063 and 1064 be sealed under 37 C.F.R. § 42.54. Good cause to seal these documents exists because a public version of Petitioner's Reply and Exhibits 1060, 1063 and 1064 have also been filed, and the redacted information is sensitive, non-public excerpts of Bausch's New Drug Application ("NDA"). Petitioner indicated that it will reserve any position on the merits of this motion until it has an opportunity to review the motion.

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. This information is contained in the following documents:

- Petitioner’s Reply in pages 24-28
- Exhibit 1060 in pages 38-50, 53-61, and 63-85
- Exhibit 1063 in pages 80, 82-101, 110-111, 116-118, and 120-121
- Exhibit 1064 in page 23

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, 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 portions of the Petitioner's Reply, pages 24-28; Exhibit 1060 pages 38-50, 53-61, and 63-85; Exhibit 1063, pages 80, 82-101, 110-111, 116-118, and 120-121; and Exhibit 1064, page 23 that cite or substantially describe the NDA. Accordingly, there is good cause to grant this Motion to Seal.

III. Certification of Non-publication

The undersigned counsel certifies that 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.”

IV. Conclusion

For the reasons set forth above, Patent Owner respectfully requests the Board grant this Motion to Seal.

Respectfully submitted,

Date: May 10, 2023

By: / Justin J. Hasford /
Justin J. Hasford, Reg. No. 62,180
Lead Counsel
Bryan C. Diner, Reg. No. 32,409
Back-up Counsel
Joshua L. Goldberg, Reg. No. 59,369
Back-up Counsel
Kassandra M. Officer Reg. No. 74,083
Back-up Counsel
Lauren J. Robinson Reg. No. 74,100
Back-up Counsel
Caitlin E. O’Connell, Reg. No. 73,934
Back-up Counsel
Kyu Yun Kim, Reg. No. 72,783
Back-up Counsel

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Ave. NW
Washington, DC 20001-4413
(202) 408-4000

Counsel for Patent Owner

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