

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 IPR2022-00722
U.S. Patent No. 7,041,786

**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 Response and Exhibits 2023, 2024, 2025, 2027, and 2028 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 Response, Exhibits 2023, 2024 and 2025 have also been filed, and the redacted information, along with the entirety of the information in Exhibits 2027 and 2028, is sensitive, non-public excerpts of Bausch's New Drug Application ("NDA"). 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. This information is contained in the following documents:

- Patent Owner’s Response in pages 58-65
- Exhibit 2023 in pages 4-14

- Exhibit 2024 in pages 101, 102, 105-112, and 114-118
- Exhibit 2025 in pages 49-53 and 56-59
- Exhibit 2027
- Exhibit 2028

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 entirety of Exhibits 2027 and 2028 because they are 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 Response, pages 58-65, Exhibit 2023 pages 4-14, Exhibit 2024 pages 101, 102, 105-

112, and 114-118, and Exhibit 2025 pages 49-53 and 56-59 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,

Date: December 14, 2022

By: /Justin J. Hasford/
Justin J. Hasford, Reg. No. 62,180
Lead Counsel
Bryan C. Diner, Reg. No. 32,409
Back-up Counsel

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.