

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 IPR2022-01105

Patent No. 9,925,231

**PATENT OWNER'S MOTION TO EXPUNGE CONFIDENTIAL
INFORMATION**

I. Introduction

Pursuant to 37 C.F.R. § 42.56, Patent Owner, Bausch Health Ireland Limited (“Patent Owner” or “Bausch”), hereby requests that certain confidential information in the record be expunged for the reasons set forth below.

Specifically, Bausch respectfully requests that the following paper and document currently under seal be expunged from the record as this paper and document contain Bausch’s highly confidential information:

- Exhibit 2013: Final Clinical Study Report SP304101-08 (excerpt)
CONFIDENTIAL
- Paper 7: Patent Owner’s Preliminary Response (CONFIDENTIAL)

II. Applicable Legal Standards

37 C.F.R. § 42.56 provides that following “denial of a petition to institute a trial or after final judgment in a trial, a party may file a motion to expunge confidential information from the record.” Similarly, the Trial Practice Guide states “[t]here is an expectation that information will be made public where the existence of the information is referred to in a decision to grant or deny a request to institute a review or is identified in a final written decision following trial.” 2019 Office Consolidated Trial Practice Guide¹ at 21-22. However, the Trial Practice Guide also states that a party “seeking to maintain the confidentiality of information . . . may

¹ Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

file a motion to expunge the information from the record prior to the information becoming public.” *Id.* A party seeking expungement from the record must show good cause by demonstrating “that any information sought to be expunged constitutes confidential information, and that [a party’s] interest in expunging it outweighs the public’s interest in maintain a complete and understandable history of this *inter partes* review.” *Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.*, IPR2013-00453, Paper 97 at (P.T.A.B. Apr. 15, 2015).

III. Good Cause Exists to Expunge Exhibit 2013 and Paper 7 from the Record

In this proceeding, the Board granted Patent Owner’s Motion to Seal Exhibit 2013 (excerpts of Patent Owner’s New Drug Application 208745), and the portions of Patent Owner’s Preliminary Response (on pages 10, 32-34, and 60-61) “that cite or substantially describe” the content of Exhibit 2013. Paper 15 at 21. In its Order, the Board concluded “that Patent Owner has established good cause to seal its confidential information” and granted its Motion to Seal. Paper 15 at 19-20.

Redacted versions of the now-sealed Exhibit 2013 and Paper 7 were provided and are currently available to the public. Specifically, the following table summarizes the confidential, sealed documents (left column) and the corresponding redacted versions that are currently publicly available (right column):

Sealed Document	Redacted Version of Document
Ex. 2013: Final Clinical Study Report SP304101-08 (excerpt) CONFIDENTIAL	Ex. 2013: Final Clinical Study Report SP304101-08 (excerpt) PUBLIC
Paper 7: Patent Owner's Preliminary Response (CONFIDENTIAL)	Paper 8: Patent Owner's Preliminary Response (Public Version)

As set forth in Patent Owner's Motion to Seal, the highly confidential, now-sealed documents contain information from Bausch's NDA 208745, which was filed confidentially with the Food and Drug Administration ("FDA") in order to obtain FDA approval to market Bausch's Trulance[®] drug product. Further, 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. 2019 Office Consolidated Trial Practice Guide at 19. The Board has accordingly 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 (PTAB Apr. 24, 2014).

Patent Owner submits that it would be placed in a competitive and strategic disadvantage should the confidential information related to its New Drug

Application become public. Additionally, redacted versions of the highly confidential documents have been filed publicly in the present proceeding. These redacted versions “maintain the essence” of non-confidential material contained within the paper and document and thus allow the public to “maintain[] a complete and understandable history” of the present proceeding. *Atlanta Gas Light*, Paper 97 at 2-3. The Board also did not cite anything exclusively in the confidential documents in its decision denying institution of the *inter partes* review. See generally Paper 15. Accordingly, the public interest would be served by maintaining the confidentiality of this information.

Therefore, good cause exists to expunge Exhibit 2013 and Paper 7.

IV. Conclusion

For the above reasons, Patent Owner respectfully requests that the Board protect Patent Owner’s highly confidential information and expunge Exhibit 2013 and Paper 7 pursuant to 37 C.F.R. § 42.56.

V. Request for Call with the Board

Should the Board not be inclined to grant the present Motion to Expunge, Patent Owner hereby requests a conference call with the Board to discuss any concerns prior to the Board issuing a decision on the Motion.

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