

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

BAUSCH HEALTH IRELAND LIMITED,
Patent Owner.

Case IPR2022-00722¹
Patent 7,041,786

**MYLAN'S OPPOSITION TO
BAUSCH'S MOTIONS TO SEAL**

¹ IPR2023-00016 has been joined with this proceeding.

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I. INTRODUCTION

Petitioner Mylan opposes patentee Bausch’s motions to seal (inclusive of Papers 48 and 50) to the extent they seek to redact materials that are not confidential. Currently-redacted material includes materials that are already publicly available, including material publicly of record in this review. Bausch’s blanket redactions impose undue prejudice on the public, the Board, and Petitioner. That prejudice is quickly magnified as the parties prepare for oral argument, which should be open to the public. Bausch’s motions should be denied, or at least dismissed to require Bausch to provide an accurate accounting well before the oral argument of all material Bausch has purportedly maintained in confidence.

II. REASONS FOR OPPOSITION

A. Background

In Paper 26, Bausch moved to seal EX2023 (Shailubhai Decl.), EX2024 (Davies Decl.), EX2025 (Waldman Decl.), EX2027 (SP-PH-001), and EX2028 (SP-PH-004), which were filed with Bausch’s response, and portions of Bausch’s response discussing them. According to Bausch, EX2027 and EX2028—both of which Bausch redacts entirely—are “sensitive, non-public excerpts of Bausch’s New Drug Application (‘NDA’).” Paper 26, 1. The declarations and Patent Owner Response are redacted where they cited EX2027 and EX2028. Paper 26, 2-3 (“The confidential information consists of non-public excerpts of Bausch’s NDA.”).

Bausch counsel certified that the information “has not, to their knowledge, been

published or otherwise made public.” *Id.*, 4. Based on Bausch’s representations, Mylan did not oppose the first motion. *Id.*, 1.

Bausch’s two later motions to seal (Papers 48 and 50) are also based on the alleged confidentiality of EX2027 and EX2028. Because Mylan no longer believes Bausch’s certification, it opposes these latter motions. This opposition is timely under 37 C.F.R. §42.25(a)(1) for both motions.

Paper 48 seeks to seal redacted portions of EX1060 (Davies Depo.), EX1063 (2d Peterson Decl.), EX1064 (Epstein Decl.), and Petitioner’s Reply. Again, these redactions are predicated on the alleged confidentiality of EX2027 and EX2028. Paper 48, 2 (“The confidential information consists of non-public excerpts of Bausch’s NDA.”). Paper 50 similarly seeks to seal Bausch’s surreply (Paper 49) because it allegedly contains “non-public excerpts of Bausch’s NDA.” Paper 50, 2.

As the record developed, Mylan became concerned that Bausch’s certification for the NDA studies was not accurate. Significantly, EX1067 (Excerpts from File History of EP App. 02721604.3, retrieved from <https://register.epo.org/regviewer> (last visited March 23, 2023)), and EX1069 (Pharmacology Review(s), “TRULANCE (Plecanatide) Tablets”, Application No. 208745Orig1s000, Dec. 2, 2016, p. 1-322, retrieved from https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208745Orig1s000PharmRedt.pdf (last visited March 23, 2023)), are publicly available on

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