

Paper No. ____
Date Filed: July 16, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC.,
AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S
LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD.,
SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA
PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL
CORP., and HIKMA PHARMACEUTICALS, LLC,
Petitioners,

v.

JANSSEN ONCOLOGY, INC.
Patent Owner.

Case IPR2016-01332¹
Patent 8,822,438 B2

**PATENT OWNER'S MOTION TO EXPUNGE
UNDER 37 C.F.R. § 42.56**

¹ Case IPR2017-00853 was joined with this proceeding.

I. STATEMENT OF RELIEF REQUESTED

Pursuant to 37 C.F.R. § 42.56 and the Board’s email authorization of July 16, 2019, Patent Owner Janssen Oncology, Inc. (“Patent Owner”) respectfully requests that the Board expunge from the record Exhibits 1134, 1143, 2044, 2092, 2093, and 2118—all of which contain Patent Owner’s confidential information—for the reasons set forth below. Patent Owner certifies that the parties have conferred in good faith, and Petitioners do not oppose this motion.

II. PROCEDURAL BACKGROUND

On March 8, 2017, Patent Owner filed a motion to seal Exhibit 2044 (which is the confidential version of redacted Exhibit 2115), and Exhibits 2092, 2093, and 2118 (which are confidential in their entirety). *See* Paper 34. On April 19, 2017, Petitioners filed a motion to seal Exhibits 1134 and 1143 (which are the confidential versions of redacted Exhibits 1145 and 1144, respectively). *See* Paper 57.

All of the aforementioned exhibits contain Patent Owner’s confidential information. In the Final Written Decision, the Board granted Patent Owner’s and Petitioners’ motions to seal. *See* Paper 84 at 47-48. Furthermore, the Board found that “[i]n rendering [its] Final Written Decision, it was not necessary to identify, nor discuss in detail, any confidential information.” *Id.* at 47. The Board ordered

that the exhibits remain under seal until “the time period for filing a notice of appeal has expired or, if an appeal is taken, the appeal process has concluded.” *Id.*

On December 19, 2018, Patent Owner filed a Notice of Appeal. Paper 88. On May 14, 2019, the United States Court of Appeals for the Federal Circuit (the “Federal Circuit”) issued its opinion and judgment, and on June 20, 2019, the Federal Circuit issued its mandate.

III. APPLICABLE LEGAL STANDARDS

37 C.F.R. § 42.56 provides that “[a]fter 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.” The Board has previously explained that a party moving to expunge has to show that: i) “any information sought to be expunged constitutes confidential information[;]” and ii) the movant’s interest in expunging the information “outweighs the public’s interest in maintaining a complete and understandable file history.” *RPX Corp. v. VirnetX Inc.*, IPR 2014-00171, Paper 62 at 3 (P.T.A.B. Sept. 9, 2014). The regulations identify confidential information as “a trade secret or other confidential research, development, or commercial information.” 37 C.F.R. § 42.54(a)(7). The Board must 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.” 77 Fed. Reg. 48756, 48760 (Aug. 14, 2012).

IV. REASONS FOR THE RELIEF REQUESTED

In its Final Written Decision, the Board stated that “confidential information that is subject to a protective order ordinarily would become public 45 days after final judgment in a trial, unless a motion to expunge is granted.” Paper 84 at 47.

Accordingly, Patent Owner moves to expunge from the record the following sealed exhibits containing Patent Owner’s confidential information:

- Internal, non-public research summaries concerning the use of Patent Owner’s product: Exhibit 2092 (filed March 8, 2017); Exhibit 2093 (filed March 8, 2017).
- Internal, non-public technical research and development information concerning Patent Owner’s product: Exhibit 2118 (filed March 8, 2017).
- Expert declarations and deposition transcripts referring to Patent Owner’s confidential information: Reply Declaration of Ivan T. Hoffman, Exhibit 1134 (filed April 19, 2017); Deposition of Richard J. Auchus, M.D., Ph.D., Exhibit 1143 (filed April 19, 2017); Declaration of Christopher A. Velturo, Ph.D., Exhibit 2044 (filed March 8, 2017).

Patent Owner has already demonstrated, and the Board agreed, that Exhibits 1134, 1143, 2044, 2092, 2093, and 2118 contain confidential information. Paper 84 at 47. There has been no change in confidentiality of the information contained in these exhibits. Thus, Patent Owner has met its burden of showing that “any

information sought to be expunged constitutes confidential information.” *RPX*, IPR2014-00171, Paper 62 at 3.

In addition, Patent Owner’s interest in expunging the confidential information in Exhibits 1134, 1143, 2044, 2092, 2093, and 2118 “outweigh[s] the public’s interest in maintaining a complete and understandable file history.” *Id.* As stated in its Final Written Decision, the Board did not “identify, nor discuss in detail” the confidential information when rendering its decision.² Paper 84 at 47. The public, therefore, has access to all the materials relevant to the merits of this proceeding, either through publicly filed papers and exhibits or through redacted,

² The Final Written Decision cites paragraph 67 of Exhibit 2044, which contains confidential information redacted from the public version (Exhibit 2115). *See* Paper 84 at 40 (citing Exhibit 2044 ¶¶ 64-68). However, Patent Owner believes that this citation was made in error. The Final Written Decision refers to “evidence of market share” when referring to paragraph 67, but paragraphs 64-68 relate to product pricing. Instead, paragraphs 56-60 relate to market share. The error likely occurred because the Final Written Decision in IPR2016-01582 (involving the same patent) correctly refers to paragraphs 64-68 of Exhibit 2044 in that proceeding. *See* IPR2016-01582, Paper 72 at 40. In this proceeding, the corresponding paragraphs are 56-60.

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