UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC., Patent Owners.

U.S. Patent No. 9,326,945 to Patel et al.

Inter Partes Review IPR2018-00892

Before SHERIDAN K SNEDDEN, ZHENYU YANG, and KRISTI L. R. SAWERT, *Administrative Patent Judges*

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PETITIONER'S MOTION TO FILE SUPPLEMENTAL INFORMATION PURSUANT TO 37 C.F.R § 42.123(a)

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I. INTRODUCTION AND RELIEF REQUESTED

Pursuant to the Board's Order of November 20, 2018 (Paper No. 30), Petitioner moves to submit supplemental information pursuant to 37 C.F.R. § 42.123(a). In this proceeding, trial has been instituted for claims 1-38 of U.S. Patent No. 9,326,945 B2, based on, in part, Rudnic (Ex. 1010). In a Preliminary Response, Patent Owners challenged the admissibility and/or public availability of Rudnic and have maintained that position in Objections to Evidence. (See Paper No. 26). As detailed in Petitioner's Motion to Correct a Typographical or Clerical Mistake filed concurrently herewith, the Petition (Paper No. 2) and the Park Declaration (Ex. 1002) incorrectly referred to Rudnic as Chapter 10 of the fourth edition of the textbook *Modern Pharmaceutics* published in 2002, rather than from the third edition published in 1996, due to a third-party prior art search providing Petitioner with a copy of Chapter 10 of Modern Pharmaceutics from the third edition, but misidentifying that chapter as coming from the fourth edition. (See generally, Carroll Decl.). Petitioner seeks to replace Ex. 1010 submitted with the Petition with a clean copy of Rudnic (Ex. 1042), thereby removing the incorrect header pages (i.e., cover and publishing information) from the fourth edition with a new Ex. 1010 having the correct header pages.

II. DISCUSSION OF AUTHORITY AND MATERIAL FACTS

Petitioner first became aware of a possible error relating to Rudnic when

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Patent Owners challenged the admissibility and prior art status of Rudnic in a Preliminary Response (Paper No. 18, pp. 42-43) and submitted a table of contents purporting to be from the fourth edition of *Modern Pharmaceutics* (Ex. 2019). (*See* Carroll Decl., ¶ 7). Petitioner investigated further by obtaining a complete copy of the fourth edition of *Modern Pharmaceutics*, comparing Chapter 10 from both editions, and discovered the error necessitating this motion. (*See* Carroll Decl., ¶ 8). Patent Owners have maintained their assertions regarding the admissibility and prior art status of Rudnic, further necessitating this motion.

Within one month of the Board's institution decision, Petitioner timely requested authorization from the Board to file this motion¹ and the supplemental information is relevant to a claim for which the trial has been instituted as Rudnic was cited by Petitioner in support of Grounds 2 and 4 instituted by the Board. *See* 37 C.F.R. § 42.123(a); *Palo Alto Networks, Inc. v. Juniper Network, Inc.*, IPR2013–00369, Paper No. 37 at pp. 2-3; (Decision, Paper No. 24, pp. 2, 5-6, and 33); *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435 (Fed. Cir. 2015) (holding that supplemental information requests pursuant to 37 C.F.R.

¹ Pursuant to the Scheduling Order (Paper No. 25), the parties requested an initial conference call with the Board within one month of institution to discuss two proposed motions requested by Petitioner, including the present motion to file supplemental information pursuant to 37 C.F.R. § 42.123.

§ 42.123(a) are not automatically granted and the Board may discretionally consider additional information beyond timeliness and relevancy).² Here, Petitioner could not have anticipated that the citation to Rudnic contained a typographical error when the Petition was initially filed, nor that the copy of Rudnic originally filed contained incorrect header information, until Patent Owners questioned the same and submitted a copy of the table of contents from the fourth edition (Ex. 2019) along with Patent Owners' Preliminary Response.

The present situation is analogous to *Palo Alto Networks, Inc. v. Juniper Network, Inc.*, where the petitioner sought to submit supplemental information in the form of new exhibits that would establish that cited prior art within the Petition did in fact qualify as a prior art printed publication. IPR2013-00369, Paper No. 37, at p. 2-3 (Feb. 5, 2014) (finding that "Petitioner has met its burden because the supplemental information Petitioner seeks to submit does not change the grounds of unpatentability authorized in this proceeding, nor does it change the evidence initially presented in the Petition to support those grounds of

² See also 37 C.F.R. § 42.123(b) (requiring a showing "why the supplemental information reasonably could not have been obtained earlier, and that consideration of the supplemental information would be in the interests-of-justice" for requests made more than a month after institution). Petitioner has satisfied this additional burden despite the inapplicability of § 42.123(b).

unpatentability"). In particular, the Board found that Patent Owner would not be prejudiced because the "Patent Owner already [had] possession of the [identical] supplemental information" when it was served "in response to Patent Owner's objections" and allowing submission of the same into the record did not limit the Board's ability to timely complete the proceeding. (*Id.* at 4-5). The same is true here where Petitioner is only supplementing non-substantive information already in possession of, and considered by, Patent Owners.

The correct Chapter 10 from the third edition of *Modern Pharmaceutics* was filed along with the Petition as Ex. 1010 – only the header information from the fourth edition was incorrect. Moreover, the corrected version of Rudnic (with correct header information from the third edition), that Petitioner seeks to submit as a replacement for Ex 1010 was timely served on Patent Owners in response to their objections. Finally, as stated in Petitioner's Motion to Correct, Patent Owners already addressed the identical substance of Rudnic in their Preliminary Response (*see* Paper No. 18, p. 16 and 23; Paper No. 24, p. 8) and will also have an opportunity to further address it in their Response due on January 15, 2019 (*see* Paper No. 24, p. 34; Paper No. 25, p. 8). Patent Owners cannot credibly argue they will be prejudiced if Petitioner's motion is granted, and granting the motion will not interfere with the Board's ability to timely complete this proceeding.

The current situation is vastly distinguishable from cases where the Board

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