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Paper 22
Date: September 17, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

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

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Case IPR2018-00892
Patent 9,326,945 B2

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Before SHERIDAN K. SNEDDEN and ZHENYU YANG,
*Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

# ORDER
Conduct of the Proceeding
*37 C.F.R. § 42.5*

## I. INTRODUCTION

In an email sent to the Board on August 9, 2018, counsel for Petitioner requested a conference call seeking authorization to file a reply to Patent Owner's Preliminary Response (Paper 18, "Prelim. Resp.") to address arguments made by Patent Owners that: (a) the Board should exercise its discretion to deny the Petition pursuant to 35 U.S.C. § 325(d) (*id.* at 15–44); and (b) the Petition does not include any evidence to show that the references Carreiro,[1] FDA Dissolution Guidance,[2] and Rudnic[3] qualify as printed publications (*id.* at 42–45). Patent Owners oppose Petitioner's request.

A conference call was held between counsel for the parties and the Board on August 30, 2018, to discuss Petitioner's request. A transcript of the conference call has been entered by Petitioner as Ex. 1036.

Petitioner may seek authorization to file a reply to the preliminary response, but "must make a showing of good cause." 37 C.F.R. § 42.108(c) (revised April 1, 2016). For the reasons that follow, Petitioner's request for authorization is denied for lack of good cause.

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[1] Ex. 1004, Carreiro et al., *Apixaban, an oral direct Factor Xa inhibitor: awaiting the verdict*, 17(12) EXPERT OPIN. INVESTIG. DRUGS 1937–45 (2008).

[2] Ex. 1015, Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER) (Aug. 1997).

[3] Ex. 1010, Rudnic et al., "Tablet Dosage Forms," in *Modern Pharmaceutics*, 4th ed., G.S. Banker and C.T. Rhodes, eds., Taylor & Francis Group, Boca Raton, FL, pp. 333–59 (2002).

## II. ANALYSIS

### *A. Discretionary denial*

In its preliminary response, Patent Owners argue that Petitioner relies on the same or substantially the same references applied by the Examiner during prosecution. Prelim. Resp., 15. In particular, Patent Owners argued that "the portions of Wei relied upon by Petitioner are identical to the portions of Wei that were cited by the Examiner" and that "the portions of the Carreiro reference and the '208 Patent asserted in the Grounds are cumulative to the Nause reference cited by the Examiner for substantially the same information." *Id.* at 16.

On the call, Petitioner argued that the Patent Owner Preliminary Response omits material facts contained in the record, in particular, that there is no mention of the testimonial evidence from Dr. Park submitted in support of the Petition. Patent Owners argued that the Board is typically capable of evaluating whether there are factual inaccuracies in Patent Owner's Preliminary Response concerning the prosecution history without further briefing from Petitioner. Patent Owners further argued that Petitioner had the opportunity to address the issue in the Petition and that Petitioner was on notice that, by statute, consideration may be given to whether the prior art or arguments presented in the Petition are the same, or substantially the same, as those previously raised during prosecution.

In consideration of the arguments advanced during the teleconference by both parties, we determine that good cause for authorization to file the requested reply has not been shown for the reasons articulated by Patent Owners, summarized above. Furthermore, we are aware of Dr. Park's declaration and there is no indication that the record lacks sufficient

information hindering our ability to scrutinize Patent Owner's contentions regarding the prosecution history.

*B. Printed publication*

In its preliminary response, Patent Owners argued that "Petitioner has not met its burden of production to establish that Rudnic, FDA Guidance Document, and Carreiro are 'printed publications' under 35 U.S.C. §102(b)." Prelim. Resp. 42. In particular, Patent Owner argued that "Petitioner has not established that [Rudnic] is a 'printed publication,' or, if it is, that the version of Rudnic in Exhibit 1010 is authentic." *Id.* Patent Owner argued also that the Petition does not include any evidence supporting the public accessibility of FDA Guidance Document and that the copyright date of 2008 for Carreiro is not enough to establish that the document is a printed publication. *Id.* at 43–44.

On the call, Petitioner requested that it be given the opportunity to address factual and legal errors on the current record and to recite recent Federal Circuit case law related to the issue of public accessibility, namely *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347 (Fed. Cir. 2018) and *Gopro, Inc. v. Contour IP Holding LLC*, 898 F.3d 1170, 1176 (Fed. Cir. 2018). Patent Owners argued that the cases cited by Petitioner do not announce new law or modify existing law and, as such, Petitioner cannot rely on these cases to show good cause.

In consideration of the arguments advanced during the teleconference by both parties, we determine that good cause for authorization to file the requested reply has not been shown for the reasons articulated by Patent Owners, summarized above. Furthermore, we note that, if trial is instituted, Petitioner will have the opportunity at trial to respond to Patent Owner's

contentions with regard to sufficiency of evidence with supplemental information under § 42.123(a) and/or evidentiary objections with supplemental evidence under 37 C.F.R. § 42.64(b)(2). *See generally Groupon Inc. v. Blue Calypso, LLC*, Case CBM2013-00033, slip op. at 2-5 (PTAB May 12, 2013) (Paper 29) (distinguishing admissibility of evidence from sufficiency of evidence); *see also BioMarin Pharmaceutical Inc. v. Genzyme Therapeutic Products Limited Partnership*, IPR2013-00534, Paper 80, 5–6 (granting motion to submit supplemental information allegedly confirming the public accessibility of a prior art document); *cf. Illumina, Inc. v. The Trustees of Columbia Univ. in the City of New York*, IPR2012-00006, Paper 125, 3 (denying motion to submit supplemental information based on nineteen day delay in seeking relief and proximity to end of proceedings).

## III. ORDER

For the reasons given, it is hereby:

ORDERED that Petitioner's request to file a reply to Patent Owner's Preliminary Response is *denied*.

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