

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.

Case IPR2018-00892
Patent 9,326,945 B2

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

SNEDDEN, *Administrative Patent Judge.*

ORDER

Granting Petitioner's Motion to Submit Supplemental Information
37 C.F.R. § 42.123(a)

I. INTRODUCTION

Petitioner requested authorization to file a motion to submit supplemental information under 37 C.F.R. § 42.123(a) within one-month of our institution of trial. Paper 30. We authorized Petitioner to file the motion. *Id.* Petitioner filed a Motion to Submit Supplemental Information (Paper 32; “Mot.”) and Patent Owner filed an Opposition (Paper 36; “Opp.”).

In its motion, Petitioner proposes to submit, as supplemental information, a corrected version of Rudnic containing the correct header pages. Mot. 1. Rudnic is cited by Petitioner in support of Grounds 2 and 4 in the Petition as Exhibit 1010. *Id.* at 1–2. Petitioner explains that the substantive portion of Ex. 1010 is Chapter 10 of the third edition of the textbook *Modern Pharmaceutics* published in 1996, while the header pages were mistakenly taken out of the fourth edition of the textbook *Modern Pharmaceutics* published in 2002. *Id.* at 4. The corrected version of Rudnic that Petitioner requests be entered into the record, Exhibit 1042, contains the header pages and Chapter 10 from the third edition of the textbook *Modern Pharmaceutics*. *Id.* at 5. Petitioner contends that “the supplemental information does not change the substantive evidence provided in the original version of Rudnic; rather, it merely clarifies the edition of *Modern Pharmaceutics* from which the substance was obtained.” *Id.*

In its Opposition, Patent Owners first contend that Petitioner’s request should be denied because the proposed supplemental information does not sufficiently address the issue of establishing Rudnic (Ex. 1010) as a prior art reference and that it is “important for the Board to ensure that supplemental information is not used to edit them after the fact.” Opp. 3–4. Patent Owner

also contends that it has been prejudiced by Petitioner’s mistake because “Patent Owners prepared their Preliminary Response without knowing what reference Petitioner meant to refer to.” *Id.* at 4. “Patent Owners cannot effectively contest the public availability or substance of a reference that Petitioner has not adequately identified.” *Id.* at 4–5. Finally, Patent Owner argues that Petitioner could have discovered its mistake sooner, but “waited until after institution to explain it away.” *Id.* at 5.

Upon consideration of the documents and the parties’ arguments, and for the reasons stated below, Petitioner’s motion is granted.

II. ANALYSIS

As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). Here, because Petitioner seeks to submit supplemental information within one-month of institution, it must show that the information is “relevant to a claim for which the trial has been instituted.” 37 C.F.R. § 42.123(a). That said, however, section 123(a) “does not connote the PTAB must accept supplemental information so long as it is timely and relevant.” *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 445 (Fed. Cir. 2015) (citation omitted). In other words, satisfying the criteria of section 123(a) does not guarantee we will grant the motion and allow submission of the supplemental information.

Instead, our guiding principle in evaluating a motion to submit supplemental information is “to ensure the efficient administration of the Office and the ability of the Office to complete IPR proceedings in a timely manner.” *Redline Detection*, 811 F.3d at 445 (citations and internal quotations omitted). “Requiring admission of supplemental information so

long as it was timely submitted and relevant to the IPR proceeding would cut against this mandate and alter the intended purpose of IPR proceedings.” *Id.* That purpose is to “secure the just, speedy, and inexpensive resolution of every proceeding.” 37 C.F.R. § 42.1(b). Consistent with that purpose, we consider whether submission of the supplemental information would change the grounds initially presented in the petition or otherwise unfairly change the evidence underlying those grounds. We also consider whether the patent owner would be prejudiced in having to respond to the supplemental information if permitted.

Turning to the question of whether Petitioner’s supplemental information is “relevant to a claim for which the trial has been instituted,” 37 C.F.R. § 42.123(a), we determine that the supplemental information Petitioner seeks to admit generally relates to the public availability of Rudnic, which is a basis for grounds of unpatentability in this proceeding, and is therefore relevant to the claims of the ’945 patent for which this trial was instituted. We recognize that permitting a petitioner to supplement the record could potentially change the evidence supporting the grounds originally presented in a petition in a manner that is not in accord with the statutory requirement that the petition identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim,” including “affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions.” 35 U.S.C. § 312(a)(3)(B). Here, however, the supplemental information does not change the grounds of unpatentability authorized in this proceeding, nor does it change the evidence initially presented in the Petition to support the grounds of unpatentability. In our Decision to Institute, we addressed Patent Owners’

arguments concerning the status of Rudnic as a printed publication. Paper 24, 31–34. We noted that the factual dispute as to when Rudnic was published “may be resolved during trial.” *Id.* at 33. In that regard, Petitioner seeks to admit Ex. 1042 as evidence that Rudnic was published in the third edition of the textbook *Modern Pharmaceutics* published in 1996, thus allegedly confirming Rudnic as a printed publication. We see nothing wrong with Petitioner seeking to submit evidence on a dispositive issue at an early stage of trial so that Patent Owners may address the issue of whether Rudnic is a prior art publication in its Patent Owner Response, should it wish to do so.

We turn now to the question of whether granting the Motion is consistent with the efficient administration of this proceeding and the ability of the Board to ensure “the just, speedy, and inexpensive resolution of every proceeding.” 37 C.F.R. § 42.1(b). Here, we are not persuaded that the submission of the proposed supplemental information in this proceeding would limit our ability to satisfy that mandate. If we allow the supplemental information into the record at this juncture, Patent Owner will have sufficient time to address the supplemental information before filing the deadline of its Patent Owner Response, due January 15, 2019. Paper 25. Accordingly, we determine that admitting Exhibit 1042 as supplemental information will not inhibit the just, speedy, or efficient resolution of this proceeding, or our ability to complete it in a timely manner.

Moreover, because Patent Owners will have sufficient time to address the supplemental information, we are not persuaded that Patent Owners will be unduly prejudiced. Furthermore, in this regard, we note that Patent

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