Filed on behalf of Patent Owners Bristol-Myers Squibb Company and Pfizer Inc.

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.

IPR2018-00892

Patent No. 9,326,945

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

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I. INTRODUCTION

Petitioner's Ex. 1010 is not a prior-art reference, but a compilation consisting of the cover and publishing information of the fourth edition of *Modern Pharmaceutics* ("Rudnic") and pages from the third edition. Petitioner now seeks to replace Ex. 1010 with Ex. 1042, which is an excerpt solely from the third edition. Although Petitioner requests entry of a completely new reference, it ***still*** has not carried its burden to show that any edition of Rudnic is a prior-art printed publication. That behavior has prejudiced Patent Owners, who were forced to file their Preliminary Response without knowing what Petitioner meant to rely on and have been hampered in their ability to contest the public availability of Rudnic.

II. MATERIAL FACTS

Patent Owners were served with the Petition and the related exhibits on April 5, 2018. Among the exhibits was Exhibit 1010, identified as "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. 333-359 (2002)." Paper 2 at App. B. When Patent Owners obtained a copy of the fourth edition of *Modern Pharmaceutics*, it became clear that the pages referred to in the Petition and the Park Declaration did not correspond to the cited chapter. Although it was clear that something was wrong, Patent Owner had no way of knowing what. For example, the Petition and the Park Declaration may have correctly cited the fourth

edition but used the wrong page numbers, or they may have cited the proper page numbers of an unknown reference.

In their July 18, 2018 Preliminary Response, Patent Owners questioned the public availability and authenticity of Ex. 1010, pointing out that it appeared to be "a compilation of multiple documents pieced together by Petitioner." Paper 18 at 2-3, 13 & n.3, 26 n.10, 40-45; Ex. 2019. In the three months following that filing, Petitioner did not seek to correct the Petition.

After the Board instituted review on October 15, 2018, Patent Owners challenged the public availability of Rudnic in their Objections to Evidence. Petitioner served Patent Owners with supplemental evidence on November 9, 2018. In those materials, for the first time, Petitioner claimed that the information on which it was relying was actually from the third edition of Rudnic.

III. LEGAL AUTHORITY

37 C.F.R. § 42.123(a) provides that supplemental information may be filed (1) if authorization to do so is requested within a month of institution and (2) if the information is relevant to a claim for which trial has been instituted. The Board may also consider whether allowing the supplemental information would comport with its statutory mandate to consider "'the efficient administration of the Office[] and the ability of the Office to timely complete proceedings instituted under this chapter.'" *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 441-49

(Fed. Cir. 2015) (alteration in original) (quoting 35 U.S.C. § 316(b)). In particular, the Board can disallow submissions when the petitioner seeks to substantively change the grounds laid out in the petition after the preliminary response or the institution decision have pointed out weaknesses. Paper 22 at 7-9, *Western Digital Corp. v. Spex Techs., Inc.*, IPR2018-00082 (P.T.A.B. July 23, 2018).

IV. PETITIONER SHOULD NOT BE ALLOWED TO REPLACE A PRIOR-ART REFERENCE AFTER INSTITUTION

A. Petitioner's Mistake Should Not Be Correctable via Supplemental Information and Allowing Correction Would Reduce the Efficiency of the Proceeding

"The provision for submitting supplemental information is not intended to offer a petitioner a routine avenue for bolstering deficiencies in a petition raised by a patent owner in a preliminary response. Nor should the proposed supplemental information change any grounds of unpatentability that were authorized in [a] proceeding or change the type of evidence initially presented in the Petition to support those grounds of unpatentability." Paper 20 at 3, *Merck Sharp & Dohme Corp. v. Microspherix LLC*, IPR2018-00402 (P.T.A.B. Sept. 10, 2018).

Rather, § 42.123(a) is typically used to submit additional information to show that a reference relied on in the petition is a printed publication. *See, e.g.*, Paper 28 at 3-7, *Blue Coat Sys., Inc. v. Finjan, Inc.*, IPR2016-01444 (P.T.A.B. Oct. 23, 2017); Paper 37 at 2-3, *Palo Alto Networks, Inc. v. Juniper Networks, Inc.*, IPR2013-00369 (Feb. 5, 2014). The Board itself suggested that Petitioner use a

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