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Paper 23
Entered: August 1, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,
Patent Owner.

Case IPR2016-01565
Patent 8,853,156 B2

Before TONI R. SCHEINER, BRIAN P. MURPHY, and ZHENYU YANG, *Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1, 2, 4–8, 10–18, and 23–25 of U.S. Patent No. 8,853,156 B2 (Ex. 1001, "the '156 patent"). Paper 2 ("Pet."). Specifically, Petitioner challenged claims 1, 2, 4, 5, and 23 under 35 U.S.C. § 102(a) as anticipated by Mikhail,[1] and claims 1, 2, 4–8, 10–18, and 23–25 under 35 U.S.C. § 103(a) as obvious over the Januvia Label,[2] Huettner,[3] and Mikhail or the Knowledge of a POSA. Pet. 15–26. Boehringer Ingelheim International GmbH ("Patent Owner") filed a Preliminary Response to the Petition. Paper 11 ("Prelim. Resp.").

In our Decision on Institution (Paper 17, "Decision" or "Dec."), we determined that Petitioner had established a reasonable likelihood that it would prevail in its challenge to claims 1, 2, 4, 5, and 23 as anticipated by Mikhail, and instituted trial on that ground. Dec. 8–14. We further determined that Petitioner had established a reasonable likelihood that it would prevail in its challenge to claims 1, 2, 4, 5, and 23 as obvious over Mikhail and instituted trial on that ground as well (relying on the general principle that "anticipation is the epitome of obviousness" (*In re McDaniel*, 293 F.3d 1379, 1385 (Fed. Cir. 2002))). Dec. 14–21.

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[1] Nasser Mikhail, *Incretin mimetics and dipeptidyl peptidase 4 inhibitors in clinical trials for the treatment of type 2 diabetes*, 17 EXPERT. OPIN. INVESTIG. DRUGS 845–53 (2008) (Ex. 1003, "Mikhail").

[2] Januvia™ (sitagliptin phosphate tablets) Prescribing Information (2006) (Ex. 1006, "the Januvia Label").

[3] Silke Huettner et al., *BI 1356, a Novel and Selective Xanthine Based DPP-4 Inhibitor, Demonstrates Good Safety and Tolerability with a Wide Therapeutic Window*, Poster No. 0586P, ADA (June 22–25, 2007) (Ex. 1004, "Huettner").

Claims 6–8, 10–18, 24, and 25, however, are narrower than claims 1, 2, 4, 5, and 23. Pet. 27–30. Because we determined that Petitioner had not made a threshold showing that the Januvia Label and Huettner are printed publications within the meaning of 35 U.S.C. §§ 102 and 311(b), and because Petitioner's challenge to claims 6–8, 10–18, 24, and 25 relied on the Januvia Label and/or Huettner to meet the additional limitations of those claims, we declined to institute trial on those claims as obvious over the Januvia Label, Huettner, and Mikhail or the Knowledge of a POSA. Dec. 18–21.

Petitioner requested rehearing of our decision not to institute trial on claims 6–8, 10–18, 24, and 25. Paper 19 ("Rehearing Request" or "Req. Reh'g").

After considering Petitioner's Rehearing Request, our Decision, and the evidence of record, Petitioner's request is *denied*.

II. ANALYSIS

A party requesting rehearing bears the burden of showing that the decision should be modified. 37 C.F.R. § 42.71(d). The party "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." *Id.*

When reconsidering a decision on institution, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be determined if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold*

Partnership v. Dudas, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

A. The record evidence is insufficient to qualify the Januvia Label as a "printed publication" within the meaning of §§ 102 and 311(b)

In the Petition, page 1 of Exhibit 1006 was cited as evidence that "[t]he Januvia Label published in 2006" and, therefore, is "§ 102 prior art to the '156 patent." Pet. 19 (citing Ex. 1006, 1). In its Request for Rehearing, Petitioner contends that "the Januvia Label is conspicuously dated '2006' in at least two places on its face." Reh'g Req. 2. Petitioner argues that this "evidence should [have been] assessed while recognizing that this assessment is being done without the benefit of a fully developed record" (*id.* at 1), and should have been "sufficient for institution" (*id.* at 2). In other words, Petitioner argues that we "erred by imposing a greater evidentiary burden than required to establish that a reference is a printed publication at the institution stage." *Id.* at 1.

We are not persuaded that we erred. The decision whether to institute a trial is based on "the information presented in the petition." 35 U.S.C. § 314(a). Under 35 U.S.C. § 311(b), in an *inter partes* review, a petitioner may only challenge the claims of a patent based on "prior art consisting of patents or printed publications," and the petitioner has the initial burden of production to show that an asserted reference is prior art to the challenged claims under a relevant subsection of 35 U.S.C. § 102. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1379 (Fed. Cir. 2015); Dec. 16. As explained in our Decision, we have often required a petitioner to make a threshold showing that the reference relied upon was publicly accessible as a

printed publication prior to the effective filing date of a challenged patent to satisfy the initial burden of production. *See, e.g.*, *Apple Inc. v. DSS Tech. Mgmt., Inc.*, Case IPR2015-00369, slip op. at 5 (PTAB Aug. 12, 2015) (Paper 14) (noting that petitioner has the burden to make a threshold showing that a reference is "printed publication" prior art under 35 U.S.C. §§ 102 and 311(b)); *Frontier Therapeutics, LLC v. Medac Gesellschaft Für Klinische Spezialpräparate MBH*, Case IPR2016-00649, slip op. at 22 (PTAB September 1, 2016) (Paper 10). We further explained that "[a] given reference is 'publicly accessible' 'upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.'" *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 1378 (Fed. Cir. 2006) (citing *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)); Dec. 17.

In our Decision, we noted that Exhibit 1006 (termed the "Januvia Label" by Petitioner) relates to "prescribing information" for Januvia, and that page 1 of the exhibit bears two dates: "Initial U.S. Approval . . . 2006" and "Revised: 10/2006." Dec. 15. We explained that we agreed with Patent Owner that that neither of these dates is "synonymous with a publication date" (Dec. 20; Prelim. Resp. 14), and that Petitioner had "offer[ed] no evidence when (or even if) the [Januvia Label] was published and publically available" (Prelim. Resp. 13–15; Dec. 19–20). In other words, we agreed that Petitioner had provided no evidence that the revised prescribing information for Januvia became publicly available simultaneously with FDA approval of the revision and, therefore, had failed to make the requisite threshold showing that the Januvia Label was publicly accessible at the

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