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Paper 17
Entered: April 21, 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 IPR2016-01566
Patent 9,173,859 B2

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

YANG, *Administrative Patent Judge*.

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–22 of U.S. Patent No. 9,173,859 B2 ("the '859 patent," Ex. 1001). Paper 2 ("Pet."). We denied the Petition. Paper 15 ("Dec."). Petitioner filed a request for rehearing of the Decision. Paper 16 ("Reh'g Req.").

For the following reasons, we deny Petitioner's request.

II. STANDARD OF REVIEW

When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a "decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment." *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted). The request must identify, specifically, all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d).

III. DISCUSSION

In our Decision denying the Petition, we declined to institute *inter partes* review of (1) claims 14 and 20 as anticipated by the '510 publication, (2) claims 1–22 as obvious over the combination of the '510 publication and Glucophage® Label, and (3) claims 1–22 as obvious over the combination of the '510 publication and Ahrén, Hughes, and/or Brazg. Dec. 5–16. In its rehearing request, Petitioner only seeks redress on the third ground. Reh'g Req. 1 n.1.

According to Petitioner, we erred because we applied an "incorrect legal standard for obviousness." Reh'g Req. 1. Relying on *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013), Petitioner contends that the challenged claims "are presumed obvious because the claimed linagliptin dosages and dosage ranges fall squarely within the prior art range disclosed in the '510

Publication (Ex. 1003), and Patent Owner did not meet its burden to overcome this presumption." *Id.* We are not persuaded.

As a preliminary matter, we note that Petitioner did not argue in the Petition, as it argues now in its request for rehearing, that we should apply a legal presumption of obviousness. In fact, the Petition did not cite *Galderma*, or numerous other opinions of the Federal Circuit, district courts, and the Board, which Petitioner now relies on in its request for rehearing. The Board could not have misapprehended or overlooked an argument that was not made and case law that was not cited in the Petition.

In addition, we reiterate, as we stated in our Decision denying institution, in an *inter parte* review, Petitioner has the ultimate burden of persuasion to prove unpatentability. Dec. 8 (citing 35 U.S.C. § 316(e); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378–79 (Fed. Cir. 2015)). According to Petitioner, *Galderma* holds "Patent Owner has burden of overcoming obviousness presumption 'where there is a range disclosed in the prior art, and the claimed invention falls within that range.'" Req. Reh'g 1 (quoting *Galderma*, 737 F.3d at 737–38). To the extent Petitioner argues for a presumption of obviousness that shifts the burden of persuasion to Patent Owner, such an argument is misplaced. *See In re Magnum Oil Tools Int'l Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) (stating that the "burden-shifting framework does not apply in the adjudicatory context of an IPR").

In its request for rehearing, Petitioner relies heavily on *Galderma* and other newly cited cases to support its argument that we "should have presumed that the Challenged Claims are obvious, *as a matter of law*, because the '510 Publication's preferred dosage range encompasses the claimed linagliptin dosages." Req. Reh'g 3 (emphasis added). According to Petitioner, the Board "has routinely applied"

such a presumption "in finding claimed inventions *prima facie* obvious, even where the prior art range—when compared to the claim limitation at issue—is relatively much broader than the '510 Publication's range as compared to the claimed linagliptin dosages." *Id.* at 9. We decline to apply such a legal presumption in an analytical vacuum.

In *Galderma*, the claim recited a "topically applicable pharmaceutical composition comprising 0.3% by weight of [adapalene] . . . effective for the treatment of acne." *Galderma*, 737 F.3d at 734. The prior art Shroot patents taught topical adapalene compositions for treating acne "in a preferred range of 0.01%–1%," including exemplary formulations containing 0.001%, 0.1%, and 1%. *Id.* at 735–36. In addition, the Shroot patents were listed in the FDA's Orange Book for "prior art Differin® 0.1% Gel as well as Differin® Gel, 0.3%." *Id.* at 735. Furthermore, other prior art references taught the use of 0.3% adapalene in an animal model for treating acne and taught the use of 0.3% adapalene for other skin conditions "without intolerable irritability." *Id.* It was under these circumstances that the court framed the issue as "whether there was motivation to select the claimed 0.3% adapalene composition in the disclosed range." *Id.* at 737–38.

In contrast, here, Petitioner relies solely on the teachings of the '510 publication—a preferred dose of 1 to 100 mg administered "1 to 4 times a day"—to arrive at the claimed dosage of 2.5 mg or 5 mg. The Petition simply does not

provide the same type of evidence and context as those in *Galderma*, sufficient for us to apply the requested presumption.[1]

> Also in its request for rehearing, Petitioner asserts
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> > In fact, in the Companion IPR, this Board found, on the same evidence presented in this case, that Petitioner sufficiently established that the POSA would have been motivated to substitute the preferred linagliptin oral doses disclosed in the '510 Publication—"1 mg to 100 mg, in each case 1 to 4 times a day"—for the DPP-IV inhibitors in the prior art metformin combination therapies of Ahrén (Ex. 1005), Hughes (Ex. 1006), and Brazg (Ex. 1007). (*See* IPR2016-01563, Paper 16 at 20–21).
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> Req. Reh'g 2. Petitioner's representation is inaccurate.

In IPR2016-01563, we indeed instituted an *inter partes* review, but only with respect to claims 1 and 10 of U.S. Patent No. 8,673,927. *Mylan Pharms. Inc. v. Boehringer Ingelheim Int'l GMBH*, Case IPR2016-01563, slip op. 1 (PTAB Feb. 3, 2017) (Paper 16). That is because those claims recite "a pharmaceutically effective oral amount" or "a therapeutically effective oral dose" of linagliptin, and not any specific dose or dose range. *Id.* at 21. Petitioner fails to acknowledge that, for the same reason as we denied the Petition in this proceeding, we denied the petition in IPR2016-01563 with respect to the rest of the challenged claims, because each of those claims recites a particular dosage or dosage range for linagliptin. *Id.* at 22.

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[1] As explained in our Decision, Petitioner's argument regarding linagliptin dose is either conclusive or speculative. Dec. 16 (citing Pet. 36 ("The '510 Publication discloses the combination of metformin and the recited oral doses of a DPP-IV Inhibitor (linagliptin)."); *id.* at 41 ("As described in Table 1 above in Ground 1, the '510 Publication discloses linagliptin dosages of 2.5mg and 5mg."); *id.* at 38 ("Linagliptin's *purported* higher potency would have *potentially* allowed for smaller doses of DPP-IV inhibitor to be administered to the patient.") (emphases added)).

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