Trials@uspto.gov
571-272-7822

Paper 11
Date: October 24, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., BRECKENRIDGE PHARMACEUTICAL, INC., and ALEMBIC PHARMACEUTICALS, LTD.,[1]
Petitioners,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2016-01101, Case IPR2016-01242, Case IPR2016-01245
Patent RE38,551 E

Before FRANCISCO C. PRATS, JACQUELINE WRIGHT BONILLA, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Reviews and Motions for Joinder
35 U.S.C. § 314, 37 C.F.R. §§ 42.108 and 42.122

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[1] Mylan Pharmaceuticals Inc. is Petitioner in Case IPR2016-01101, Breckenridge Pharmaceutical, Inc. is Petitioner in Case IPR2016-01242, and Alembic Pharmaceuticals, Ltd. is Petitioner in Case IPR2016-01245.

I. INTRODUCTION

Three Petitioners in the above-captioned cases, Mylan Pharmaceuticals, Inc., Breckenridge Pharmaceutical, Inc., and Alembic Pharmaceuticals, Ltd. (collectively "the later Petitioners"), each filed a Petition requesting an *inter partes* review of claims 1–13 of U.S. Patent No. RE38,551 E (Ex. 1001, "the '551 patent"). Paper 2 ("Pet.").[2] Along with the Petitions, each of the later Petitioners filed a Motion for Joinder in the respective cases (*see supra* note 1) requesting that we join that Petitioner as a party to *Argentum Pharmaceuticals LLC v. Research Corporation Technologies, Inc.*, IPR2016-00204 ("Argentum IPR"). Paper 3 ("Joinder Mot.").

As stated in the Motions for Joinder, "Grounds 1–4 of the accompanying Petition are practical copies of the grounds presented in the petition in IPR2016-00204, including Grounds 3A–3B that were instituted by the Board, and challenge the same claims over the same prior art and using the same arguments and expert testimony." Joinder Mot. 1. The Motions for Joinder specify that "Petitioner requests joinder only as to Grounds 3A–3B, and not as to Grounds 1A–1B, 2A–2B, or 4A–4B" in the Petitions. *Id*. Thus, in all three cases, the Petitions only challenge claims based on grounds that "are practical copies of already instituted grounds" in the Argentum IPR. *Id*. at 1–2.

[2] Citations are to IPR2016-01101 as representative of corresponding papers in the three cases unless otherwise indicated.

II. DISCUSSION

A. The Petition

As authorized by the Board (Paper 7), Research Corporation Technologies, Inc. ("Patent Owner") filed an Abbreviated Preliminary Response and Opposition to Petitioner's Motion for Joinder. Paper 8. In that paper, Patent Owner contends that Petitions filed by all three later Petitioners should be denied as to asserted Grounds 1A, 1B, 2A, 2B, 4A, and 4B. *Id*. at 2–3. In view of our prior Decision to Institute in the Argentum IPR (IPR2016-00204, Paper 19, "Inst. Dec."), as well as statements by the later Petitioners that they each intend to pursue only Grounds 3A–3B as instituted in the Argentum IPR (Joinder Mot. 1–2), we agree. We deny the later Petitions as to those grounds.

In relation to Grounds 3A–3B, Patent Owner points to *In re Magnum Oil Tools* ("*Magnum Oil*"), an opinion by the Federal Circuit that issued after we instituted trial in the Argentum IPR. *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) ("In an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee." (quoting *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015))).

Citing *Magnum Oil*, Patent Owner argues that "the prior art on which Petitioner relies in Grounds 3A and 3B fails to disclose a 'therapeutic composition' as construed by the Board, and as required by claim 10 of the '551 patent." Paper 8, 5. According to Patent Owner, because the "burden of production never shifts from the Petitioner" and "Petitioner cannot cure its failure of proof in its Reply," Petitioner "has not—and cannot—meet its

burden of proving unpatentability of the claims." *Id*. at 5–6. Specifically, Patent Owner argues that the later Petitioners fail to establish sufficiently that an ordinary artisan "would have selected any functionalized amino acid ('FAA') as a lead compound, much less selected Compound 3l in Kohn 1991 over other FAAs, including similarly potent FAAs, given Compound 3l's 'synthetic and stability issues.'" *Id*. at 6 (footnote omitted).

We squarely addressed Patent Owner's position in this regard in our Decision to Institute in the Argentum IPR. Inst. Dec. 16–19. Patent Owner's citation to *Magnum Oil* does not persuade us to come to a different result now. When instituting trial in the Argentum IPR, we understood that Petitioner would have the ultimate burden of persuasion during the trial to show by a preponderance of the evidence that the challenged claims were unpatentable. Nonetheless, at the institution stage, we were persuaded that there was "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition," as required under 35 U.S.C. § 314(a). For the same reasons stated in our prior Institution Decision (Inst. Dec. 16–19), we are persuaded that there is a reasonable likelihood that the later Petitioners would prevail in their challenges of claims 1–9 as obvious over Kohn 1991 and Silverman.

In relation to claim 10, Patent Owner also points to where we adopt a district court's claim construction (Ex. 1007, 5) of the term "therapeutic composition" in the preamble, i.e., where we interpret the term to be limiting and to mean "suitable for use as a treatment regimen over an extended period of time (chronic administration)." Inst. Dec. 8; Paper 8, 8–9. Referring to that claim construction, Patent Owner argues that the later Petitioners fail to address this "key limitation of claim 10," and have not

shown that an ordinary artisan would have reasonably expected to achieve a therapeutic composition as claimed. Paper 8, 9–10. For instance, according to Patent Owner, "[n]o liver toxicity data, which would indicate to a [person of ordinary skill in the art] whether a composition is suitable for chronic administration, appeared in the prior art for any" relevant compound. *Id*. at 10.

As we stated in the Argentum IPR regarding claims 10–13, "[b]ased on the record before us, Petitioner provides adequate reasoning, with sufficient rational underpinning, for its contention that an ordinary artisan would have had reason to expect 'that compounds falling within claim 132 of the '729 patent—such as racemic lacosamide and R-lacosamide—would be useful for treating CNS disorders, and would have a reasonable expectation of success in using them for this purpose.'" Inst. Dec. 21 (quoting IPR2016-00204, Pet. 34 (citing Ex. 1002 ¶ 80; Ex. 1009, 3:9–17, claim 132)). The later Petitioners similarly argue that the '729 patent discloses pharmaceutical compositions "useful in the treatment of epilepsy and other CNS disorders." Pet. 31 (quoting Ex. 1009, 3:9–17); Inst. Dec. 20–21 (citing IPR2016-00204, Pet. 34).

Our rationale for including claim 10 in the instituted grounds in the Argentum IPR applies in these cases also. We are not persuaded otherwise by Patent Owner's suggestion that the absence of liver toxicity data is dispositive. We leave it for trial as to the ultimate determination whether a compound "useful in the treatment of epilepsy and other CNS disorders," as disclosed in the '729 patent (Ex. 1009, 3:9–17, claim 132), corresponds to a "therapeutic composition."

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