

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., BRECKENRIDGE  
PHARMACEUTICAL, INC., and ALEMBIC PHARMACEUTICALS,  
LTD.,<sup>1</sup>  
Petitioners,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,  
Patent Owner.

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

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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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<sup>1</sup> 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.”).<sup>2</sup> 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.

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<sup>2</sup> 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 31 in Kohn 1991 over other FAAs, including similarly potent FAAs, given Compound 31’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 Argentinum 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 Argentinum 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.”

We incorporate our previous analysis regarding Grounds 3A–3B in the Petitions in the above-captioned case, and conclude that the later Petitioners have demonstrated a reasonable likelihood of prevailing on those grounds asserted in the Petitions for the same reasons. *See* Inst. Dec. 12–24.

*B. Motions for Joinder*

Based on authority delegated to us by the Director, we have discretion to join a party to another *inter partes* review, subject to certain exceptions not present here. *See* 35 U.S.C. § 315(c); 37 C.F.R. § 42.122. As the moving party, Petitioner has the burden of proof in establishing entitlement to the requested relief. 37 C.F.R. §§ 42.20(c), 42.122(b). A motion for joinder should: (1) set forth the reasons why joinder is appropriate; (2) identify any new ground(s) of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address how briefing and/or discovery may be simplified to minimize schedule impact. *See* Joinder Mot. 3; *Kyocera Corp. v. SoftView LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15) (representative); Frequently Asked Question H5 on the Board’s website at <http://www.uspto.gov/ip/boards/bpai/prps.jsp>.

Here, the later Petitioners contend, and Patent Owner does not dispute, that the Petitions are “practical copies of the grounds presented in the petition in IPR2016-00204, . . . and challenge the same claims over the same prior art and using the same arguments and expert testimony.” Joinder Mot. 1, 4–6; Paper 8, 1. The later Petitioners further contend that they each intend to pursue only Grounds 3A–3B, as instituted in the Argentinum IPR. Joinder Mot. 1. In addition, they state that each later Petitioner will

participate “in the proceeding in a limited capacity as an understudy” to Petitioner in the Argentum IPR. *Id.* at 2.

Based on the above, the later Petitioners argue that joinder is “appropriate because it will promote the just, speedy, and inexpensive resolution of patentability issues, including the determination of validity of the challenged claims of the ’551 patent,” and potentially minimize issues and resolve any litigation regarding the challenged claims. *Id.* at 5. In addition, the later Petitioners contend no new grounds are presented, and granting joinder will not prejudice Patent Owner or Petitioner in IPR2016-00204, Argentum Pharmaceuticals LLC (“Argentum”), or significantly affect the trial schedule in the case. *Id.* at 4–7.

Lastly, the later Petitioners indicate that discovery and briefing can be simplified here because, in their understudy role, “as long as Argentum remains a party” (i.e., does not reach a settlement with Patent Owner), each of the later Petitioners “will not submit any separate filings unless it disagrees with Argentum’s position (which it is not anticipated), and in the event of such disagreement it will request authorization from the Board to submit a short separate filing directed only to points of disagreement with Argentum.” *Id.* at 7. As long as Argentum remains a party, the later Petitioners will not seek to submit any new declarations or request any additional depositions or time during depositions. *Id.* at 8.

Given that the later Petitioners agree to be limited to an “understudy” role, and limited to evidence and arguments presented in the Argentum Petition in relation to instituted Grounds 3A–3B, we conclude all later Petitioners have demonstrated that joinder will not unduly complicate or

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delay the Argentum IPR. Thus, we grant the later Petitioners' Motions for Joinder and, as a result, join those parties to the Argentum IPR.

### III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that *inter partes* reviews are instituted in Case IPR2016-01101, Case IPR2016-01242, and Case IPR2016-01245 as to claims 1–13 of the '551 patent, but only based on the same grounds instituted in Case IPR2016-00204;

FURTHER ORDERED that each of the later Petitioner's Motion for Joinder is *granted*, and the later Petitioners are joined as parties to Case IPR2016-00204;

FURTHER ORDERED that the grounds on which an *inter partes* review were instituted in Case IPR2016-00204 remain unchanged, and no other grounds are instituted in the joined proceedings;

FURTHER ORDERED that Case IPR2016-01101, Case IPR2016-01242, and Case IPR2016-01245 are instituted, joined, and terminated under 37 C.F.R. § 42.72, and all further filings in the joined proceedings shall be made in Case IPR2016-00204;

FURTHER ORDERED that the Scheduling Order entered in Case Case IPR2016-00204 (Paper 20) shall govern the schedules of the joined proceedings;

FURTHER ORDERED that the participation by the later Petitioners in the briefing, depositions, and oral argument of the joined proceedings shall be subject to Argentum's acquiescence to their participation and, absent our express authorization, the later Petitioners shall not file papers or exhibits apart from Argentum;

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FURTHER ORDERED that the case caption in Case IPR2016-00204 shall be changed to reflect the joinder with this proceeding in accordance with the attached example; and

FURTHER ORDERED that a copy of this Decision be entered into the files of Case IPR2016-00204, Case IPR2016-01101, Case IPR2016-01242, and Case IPR2016-01245.

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<sup>1</sup> Case IPR2016-01101, Case IPR2016-01242, and Case IPR2016-01245  
have been joined with this proceeding.