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Paper No. 85
Date Entered: March 22, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
MYLAN PHARMACEUTICALS INC.,
BRECKENRIDGE PHARMACEUTICAL, INC., and
ALEMBIC PHARMACEUTICALS, LTD.,
Petitioner,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2016-00204[1]
Patent RE38,551 E

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

PRATS, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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[1] Case IPR2016-01101, Case IPR2016-01242, and Case IPR2016-01245 have been joined with this proceeding.

I. INTRODUCTION

A. Statement of the Case

Argentum Pharmaceuticals LLC ("Argentum") 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."). Research Corporation Technologies, Inc. ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Upon review of those papers and cited information, we instituted trial as to claims 1–13 of the '551 patent in relation to the following two grounds of unpatentability (Paper 19, 23–24 ("Decision to Institute," or "Dec.")):

(1) Obviousness under 35 U.S.C. § 103(a) as to claims 1–9 over Kohn 1991[2] and Silverman[3]; and

(2) Obviousness under 35 U.S.C. § 103(a) as to claims 10–13 over Kohn 1991, Silverman, and the '729 patent.[4]

After the Decision to Institute, Mylan Pharmaceuticals, Inc. ("Mylan"), Breckenridge Pharmaceutical, Inc. ("Breckenridge"), and Alembic Pharmaceuticals, Ltd. ("Alembic"), were each joined as petitioners to the instant proceeding. *See* Case IPR2016-01101, Paper 12; Case IPR2016-01242, Paper 11; Case IPR2016-01245, Paper 12. Therefore, in

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[2] Kohn et al., *Preparation and Anticonvulsant Activity of a Series of Functionalized α-Heteroatom-Substituted Amino Acids*, 34 J. Med. Chem. 2444–52 (1991) ("Kohn 1991") (Ex. 1012).

[3] Richard B. Silverman, *The Organic Chemistry of Drug Design and Drug Action*, Academic Press (1992) ("Silverman") (Ex. 1013).

[4] Kohn et al., U.S. Patent No. 5,378,729, issued on Jan. 3, 1995 ("the '729 patent") (Ex. 1009).

the instant *inter partes* review, Argentum, Mylan, Breckenridge, and Alembic are, collectively, the "Petitioner."

Patent Owner filed a Response to the Petition (Paper 35; "PO Resp."), and Petitioner filed a Reply to the Patent Owner Response (Paper 52, "Pet. Reply").

Patent Owner filed a paper styled as "Patent Owner's Identification of Petitioners' Arguments and Evidence Outside the Scope of a Proper Reply and Improper Techniques that Circumvent Word Count." Paper 57.[5] Petitioner filed a response to that paper. Paper 63.

Both parties filed Motions to Exclude Evidence. Paper 72 ("Pet. Mot. to Exclude") and Paper 71 ("PO Mot. to Exclude").

Each party filed an Opposition to the other party's Motion to Exclude Evidence. Paper 78 ("Pet. Opp."); Paper 73 ("PO Opp."). Each party filed also a Reply to the other party's Opposition to the Motion to Exclude Evidence. Paper 81 ("Pet. Reply Opp."); Paper 80 ("PO Reply Opp.").

Patent Owner filed a Motion for Observations Regarding Cross-Examination as to each of Petitioner's three reply witnesses. Papers 65, 68, and 69. Petitioner filed responses to each of those motions. Papers 75–77.

An oral hearing was held on January 24, 2017, and the hearing transcript has been entered in the record. Paper 84 ("Tr.").[6]

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[5] The panel authorized this submission, and its response, by email. Ex. 2191.

[6] Patent Owner filed Objections to Petitioner's Demonstratives. Paper 82. In this Decision, we rely only on the arguments presented properly in the parties' briefs and the evidence of record. Our decision does not rely on any information presented solely in Petitioner's demonstrative exhibits. We, therefore, overrule Patent Owner's objections.

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a).

"In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e).

Based on the record developed in this proceeding, we conclude that Petitioner has not established by a preponderance of the evidence that claims 1–9 of the '551 patent are unpatentable for obviousness over Kohn 1991 and Silverman, nor has Petitioner established by a preponderance of the evidence that claims 10–13 of the '551 patent are unpatentable for obviousness over Kohn 1991, Silverman, and the '729 patent.

Petitioner's Motion to Exclude Evidence is *denied-in-part* and *dismissed-in-part* as moot. Patent Owner's Motion to Exclude Evidence is *denied-in-part* and *dismissed-in-part* as moot.

B. Related Proceedings

Patent Owner identifies multiple lawsuits it has filed against different defendants in relation to the '551 patent in several U.S. district courts. Paper 6, 2–3. Most of those cases have been consolidated with *UCB, Inc. v. Accord Healthcare Inc.*, 1:13-cv-01206 (D. Del.). *Id.*; Pet. 1.

The parties also identify as related IPR2014-01126, where a panel previously denied an *inter partes* review based on a petition filed by a different petitioner, challenging the same claims of the same patent at issue here. *Actavis, Inc., v. Research Corporation Technologies, Inc.*, Case No. IPR2014-01126, Paper 22 (PTAB Jan. 9, 2015). Pet. 1; Prelim. Resp. 2; PO Resp. 18, n.6.

II. PRELIMINARY MATTER—SCOPE OF PETITIONER'S REPLY

We address initially the parties' contentions concerning the scope of Petitioner's Reply. As noted above, we authorized by email separate briefing on this issue. Ex. 2191.

As provided in 37 C.F.R. § 42.23(b), a "reply may only respond to arguments raised in the corresponding opposition or patent owner response." Thus, "a reply that raises a new issue or belatedly presents evidence will not be considered and may be returned. The Board will not attempt to sort proper from improper portions of the reply." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012).

One indication that a new issue has been raised in a reply is where a petitioner submits "new evidence necessary to make out a *prima facie* case" of unpatentability of an original claim. *Id.; see also Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369–70 (Fed. Cir. 2016) (Board did not err or abuse its discretion in declining to consider new contentions and evidence in reply advanced to supplement unpatentability rationale presented in petition).

A. Arguments and Evidence Relating to the LeGall Thesis (Ex. 1008)

Having reviewed the parties' contentions (Paper 57, 1; Paper 63, 1), and the arguments at issue (Pet. Reply 28–29), we conclude that Petitioner's Reply exceeds the proper scope of a reply in relying on the LeGall Thesis, even as rebuttal. As Patent Owner notes, we concluded in our Decision to Institute that Petitioner failed to show that the LeGall Thesis constitutes prior art to the claims of the '551 patent and, therefore, declined to institute trial as to grounds relying on the LeGall Thesis. Dec. 8–12.

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