

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2016-00204
Patent RE38,551 E

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

BONILLA, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Argentum Pharmaceuticals LLC (“Petitioner”) 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.”). Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless it is determined that there is “a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Based on the information presented in the Petition and Preliminary Response, we are persuaded that there is a reasonable likelihood Petitioner would prevail with respect to the claims challenged in the Petition. We institute *inter partes* review of claims 1–13 of the ’551 patent.

A. 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 discuss 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.

B. Proposed Grounds of Unpatentability

Petitioner advances eight grounds of unpatentability under 35 U.S.C. § 102(b) or § 103(a) in relation to claims 1–13 of the '551 patent (Pet. 2):

References	Statutory Basis	Challenged Claims
The LeGall thesis ¹	§ 102(b)	1, 3–8
The LeGall thesis and the '729 patent ²	§ 103(a)	2, 9–13
Choi ³ and Kohn 1991 ⁴	§ 103(a)	1–9
Choi, Kohn 1991, and the '729 patent	§ 103(a)	10–13
Kohn 1991 and Silverman ⁵	§ 103(a)	1–9
Kohn 1991, Silverman, and the '729 patent	§ 103(a)	10–13

¹ Philippe LeGall, *2-Substituted-2-acetamido-N-benzylacetamides. Synthesis, Spectroscopic and Anticonvulsant Properties* (Dec. 1987) (“the LeGall thesis”) (Ex. 1008).

² Kohn et al., U.S. Patent No. 5,378,729, issued on Jan. 3, 1995 (“the '729 patent”) (Ex. 1009).

³ Choi et al., *Trimethylsilyl Halides: Effective Reagents for the Synthesis of β -Halo Amino Acid Derivatives*, 36(39) TETRAHEDRON. LETT. 7011–14 (1995) (“Choi”) (Ex. 1010).

⁴ 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).

⁵ Silverman, *The Organic Chemistry of Drug Design and Drug Action*, Academic Press (1992) (“Silverman”) (Ex. 1013).

References	Statutory Basis	Challenged Claims
Cortes ⁶ and Kohn 1991	§ 103(a)	1–9
Cortes, Kohn 1991, and '729 patent	§ 103(a)	10–13

In addition, Petitioner supports its challenges in the Petition with a Declaration by Dr. Binghe Wang (“Wang Decl.”) (Ex. 1002). Pet. 4–5.

C. The '551 Patent

The '551 patent relates to enantiomeric compounds and pharmaceutical compositions useful in the treatment of epilepsy and other central nervous system (“CNS”) disorders. Ex. 1001, 1:21–23. According to the '551 patent, at the time of the invention many anticonvulsant drugs were well known, but they exhibited liver toxicity over chronic administration. *Id.* at 1:45–47, 2:62–3:6. The '551 patent discloses “a group of compounds that is generally potent, exhibit minimal neurological toxicity, has a high protective index and is relatively non-toxic to the body organs, including the liver upon multiple dosing.” *Id.* at 3:56–60. One of those compounds is lacosamide, (R)-N-benzyl 2-acetamide 3-methoxypropionamide. *Id.* at claim 8.

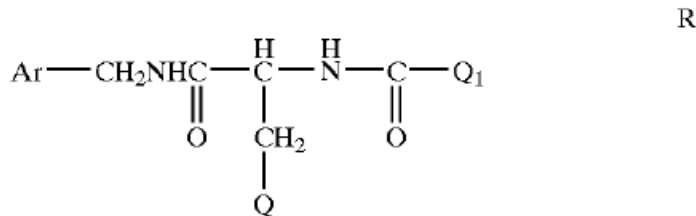
D. Claims

Among the challenged claims, claim 1 is the sole independent claim.

It reads:

⁶ Cortes et al., *Effect of Structural Modification of the Hydantoin Ring on Anticonvulsant Activity*, 28 J. MED. CHEM. 601–06 (1985) (“Cortes”) (Ex. 1015).

1. A compound in the R configuration having the formula:



wherein

Ar is phenyl which is unsubstituted or substituted with at least one halo group;

Q is lower alkoxy, and

Q₁ is methyl.

Claims 2–9 are compound claims that depend directly or indirectly from claim 1. Claim 8 is directed specifically to lacosamide. Claim 10 is directed to a therapeutic composition:

10. A therapeutic composition comprising an anticonvulsant effective amount of a compound according to any one of claims 1–9 and a pharmaceutical carrier therefor.

Claims 11–13 are method claims. Claim 11 reads:

11. A method of treating central nervous system disorders in an animal comprising administering to said animal in need thereof an anticonvulsant effective amount of a compound according to any one of claims 1–9.

II. ANALYSIS

A. Claim Construction

For *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted, sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S.Ct. 890 (2016) (No. 15-446). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary

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