

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS, INC., ACTAVIS LABORATORIES FL, INC.,
ACTAVIS PHARMA, INC., AMNEAL PHARMACEUTICALS, LLC,
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AUROBINDO
PHARMA LTD., AUROBINDO PHARMA USA, INC., BRECKENRIDGE
PHARMACEUTICAL, INC., VENNOOT PHARMACEUTICALS, LLC,
SANDOZ INC., SUN PHARMA GLOBAL FZE, and
SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Petitioner,

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2014-01126
Patent RE38,551 E

Before FRANCISCO C. PRATS, JACQUELINE WRIGHT BONILLA, and
ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review

37 C.F.R. §§ 42.108
INTRODUCTION

Actavis, Inc., Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Vennoot Pharmaceuticals, LLC, Sandoz Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Ltd. (collectively, “Petitioner”) filed a petition for an *inter partes* review of claims 1–13 of U.S. Patent No. RE38,551 E (Ex. 1001, “the ’551 patent”). Paper 6 (“Pet.”). Research Corporation Technologies, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 19 (“Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Because the Petition fails to meet the threshold requirement set forth in 35 U.S.C. § 314(a), we deny the Petition.

Related Proceedings

Parties state that Patent Owner previously filed multiple lawsuits, asserting the ’551 patent against several entities, including some of Petitioner. Pet. 5; Paper 10, 2–3. Most of these cases are consolidated with *UCB, Inc. v. Accord Healthcare Inc.*, 1:13-cv-01206 (D. Del.). See Pet. 5; Paper 10, 2–3.

The '551 Patent

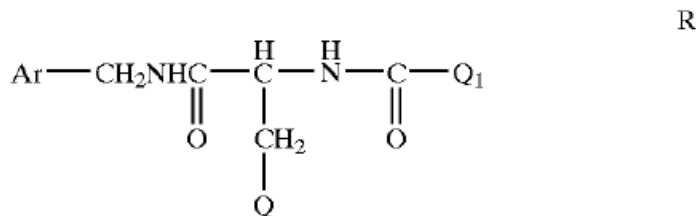
The '551 patent relates to enantiomeric compounds and pharmaceutical compositions useful in the treatment of epilepsy and other central nervous system (CNS) disorders. Ex. 1001, 1:21–23. According to the '551 patent, at the time of the invention, many anticonvulsant drugs were well known but they exhibited 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.

Illustrative Claim

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

It reads:

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.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds, each of which challenges the patentability of claims 1–13:

Basis	Reference(s)
§ 102(e)	The '301 patent ¹
§ 102(b)	The LeGall thesis ²
§ 103	The LeGall thesis and the '729 patent ³

¹ Kohn et al., U.S. Patent No. 5,654,301, issued on Aug. 5, 1997 (Ex. 1003) (“the '301 patent”).

² Philippe LeGall, 2-Substituted-2-acetamido-N-benzylacetamides. Synthesis, Spectroscopic and Anticonvulsant Properties (Ex. 1005) (“the LeGall thesis”).

³ Kohn et al., U.S. Patent No. 5,378,729, issued on Jan. 3, 1995 (Ex. 1008) (“the '729 patent”).

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner argues that the claim terms have no special meanings. Pet. 8. According to Petitioner, based on its ordinary meaning, the term “compound” as used in each challenged claim includes the compound known as lacosamide. *Id.* Patent Owner contends that Dr. Clayton H. Heathcock, Petitioner’s witness, correctly recognized the term that should be construed (i.e., “compound in the R configuration,” not “compound”), but incorrectly construed the term. Prelim. Resp. 12–13. Patent Owner also asks us to construe the term “therapeutic composition” as used in claim 10. *Id.* at 13–14.

We determine that, for purposes of this Decision, it is unnecessary, and thus, we decline, to expressly construe these terms at this time.

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