United States Court of Appeals for the Federal Circuit

MYLAN PHARMACEUTICALS INC., BRECKENRIDGE PHARMACEUTICAL, INC., ALEMBIC PHARMACEUTICALS LTD.,
Appellants

v.

RESEARCH CORPORATION TECHNOLOGIES, INC.,
Appellee

2017-2088, 2017-2089, 2017-2091

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-00204, IPR2016-01101, IPR2016-01242, IPR2016-01245.

Decided: February 1, 2019

STEVEN WILLIAM PARMELEE, Wilson, Sonsini, Goodrich & Rosati, PC, Seattle, WA, argued for all appellants. Appellant Mylan Pharmaceuticals Inc. also represented by MICHAEL T. ROSATO, JAD ALLEN MILLS; ADEN M. ALLEN, NICOLE W. STAFFORD, Austin, TX.

MATTHEW L. FEDOWITZ, Buchanan Ingersoll & Rooney PC, Alexandria, VA, for appellant Breckenridge Pharma-

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ceutical, Inc.

TODD S. WERNER, Carlson, Caspers, Vandenburgh, Lindquist & Schuman, PA, Minneapolis, MN, for appellant Alembic Pharmaceuticals Ltd. Also represented by SARAH STENSLAND, Patterson Thuente Pedersen, PA, Minneapolis, MN.

JACK B. BLUMENFELD, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE, argued for appellee. Also represented by ALEXA HANSEN, Covington & Burling LLP, San Francisco, CA; JENNIFER L. ROBBINS, New York, NY; BETH S. BRINKMANN, PRISCILLA GRACE DODSON, EVAN SMITH KRYGOWSKI, GEORGE FRANK PAPPAS, Washington, DC.

Before LOURIE, BRYSON, and WALLACH, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Mylan Pharmaceuticals Inc. ("Mylan"), Breckenridge Pharmaceutical, Inc. ("Breckenridge"), and Alembic Pharmaceuticals, Ltd. ("Alembic") (collectively, "Appellants") appeal from the final written decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("the Board") in an *inter partes* review concluding that claims 1–13 of U.S. Reissue Patent 38,551 ("the '551 patent") are not unpatentable. *See Argentum Pharm. LLC v. Research Corp. Techs.*, IPR 2016-00204, 2017 WL 1096590, at *1–2 (P.T.A.B. Mar. 22, 2017) ("*Decision*"). For the reasons detailed below, we affirm.

BACKGROUND

Epilepsy is a neurological disorder that affects about one percent of the human population. It is characterized by two or more unprovoked seizures occurring more than 24 hours apart. Epilepsy can be associated with conditions affecting the structure of the brain, but, for the vast

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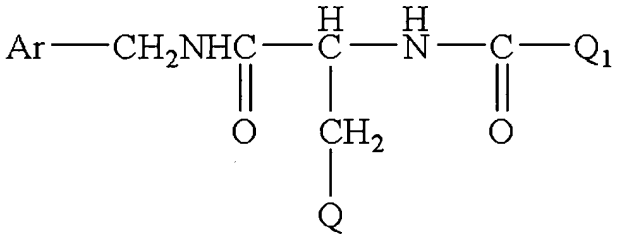
majority of affected individuals, no specific cause can be identified. While there is no known cure for epilepsy, treatment can include both drug therapy and surgery, and most patients are treated via long-term administration of anticonvulsant drugs to prevent seizures. The nature and severity of seizures varies considerably across the patient population, and treatment is typically tailored for each specific patient.

Research Corporation Technologies, Inc. ("RCT") owns the '551 patent, which discloses and claims enantiomeric compounds and pharmaceutical compositions useful in the treatment of epilepsy and other central nervous system ("CNS") disorders. Claim 1 recites:

> 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
>
> Q_1 is methyl.

'551 patent col. 38 ll. 8–23.

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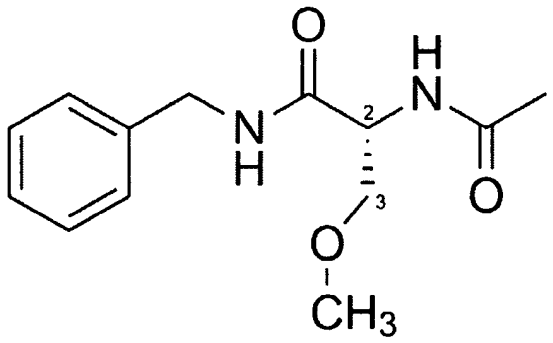
At issue here are claims 8–13.[1] Claim 8 depends from claim 1 and recites "[t]he compound according to claim 1 which is (R)-N-benzyl-2-acetamido-3-methoxypropionamide," referred to in the patent as "BAMP" and referred to herein as lacosamide:



Claim 9 claims lacosamide in 90 percent or greater purity, claim 10, therapeutic compositions comprising the claimed compounds, and claims 11–13, use of the compounds for treating central nervous system disorders. *Id.* col. 38 ll. 39–51. Because arguments have not been made concerning the separate claims, we will consider them together, as did the Board.

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[1] Before the Board, Appellants challenged claims 1–13, but, since this appeal was taken, claims 1–7 have been voluntarily cancelled in a separate, *ex parte* reexamination proceeding. *See* Citation of Supplemental Authority, *Mylan Pharm. Inc. v. Research Corp. Techs.*, No. 2017-2088 (Fed. Cir. Apr. 23, 2018), ECF No. 73. Because there is no case or controversy regarding the finally cancelled claims, we rule only on the still-existing claims 8–13. *See Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1347 (Fed. Cir. 2013) (litigation became moot because of the cancellation of claims).

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On November 23, 2015, Argentum Pharmaceuticals LLC ("Argentum") petitioned for *inter partes* review ("IPR") of the '551 patent. In its petition, Argentum challenged claims 1–13 on eight grounds. The Board only instituted on two grounds involving three references: (1) obviousness of claims 1–9 over Kohn 1991[2] and Silverman[3] and (2) obviousness of claims 10–13 over Kohn 1991, Silverman, and U.S. Patent 5,378,729 ("the '729 patent").[4] The instituted grounds appear in the petition as ground 3A and ground 3B.

In its argument, Argentum advanced a lead compound analysis. It relied on Kohn 1991 for disclosure of compound 3l, its proffered lead compound. Kohn 1991, authored by the named inventor of the '551 patent, Dr. Harold Kohn, discloses a series of functionalized amino acids ("FAAs") with anticonvulsant activity. Dr. Kohn observed that FAA racemates with N-benzylamide moieties and acetylated amino groups provided potent protection against seizures in mice. For his research presented in the 1991 paper, Dr. Kohn began with (R,S)-2-acetamido-*N*-benzyl-2-methylacetamide as a lead compound and replaced the α-methyl group, denoted in the structure below as "X," with functionalized nitrogen, oxygen, and sulfur substituents:

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[2] Harold Kohn et al., *Preparation and Anticonvulsant Activity of a Series of Functionalized α-Heteroatom-Substituted Amino Acids*, 34 J. Medicinal Chemistry 2444 (1991); J.A. 2404–12.

[3] Richard B. Silverman, *The Organic Chemistry of Drug Design and Drug Action* (1st ed. 1992); J.A. 2413–61.

[4] The application that led to the '551 patent was filed before March 16, 2013, and the pre-Leahy–Smith America Invents Act, Pub L. No. 112-29, 125 Stat. 284 (2011), version of § 103 applies.

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