

**United States Court of Appeals  
for the Federal Circuit**

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**UCB, INC., UCB BIOPHARMA SPRL, RESEARCH  
CORPORATION TECHNOLOGIES, INC., HARRIS  
FRC CORPORATION,  
*Plaintiffs-Appellees***

**v.**

**ACCORD HEALTHCARE, INC., INTAS  
PHARMACEUTICALS LTD., MYLAN  
PHARMACEUTICALS INC., MYLAN INC., ZYDUS  
PHARMACEUTICALS (USA) INC., CADILA  
HEALTHCARE LIMITED, AMNEAL  
PHARMACEUTICALS LLC, AMNEAL  
PHARMACEUTICALS OF NEW YORK, LLC,  
AUROBINDO PHARMA LTD., AUROBINDO  
PHARMA USA, INC., BRECKENRIDGE  
PHARMACEUTICAL, INC., SUN PHARMA GLOBAL  
FZE, SUN PHARMACEUTICAL INDUSTRIES, LTD.,  
WATSON LABORATORIES, INC. - FLORIDA, NKA  
ACTAVIS LABORATORIES FL, INC., WATSON  
PHARMA, INC., NKA ACTAVIS PHARMA, INC.,  
MSN LABORATORIES PVT. LTD., ALEMBIC  
PHARMACEUTICALS LTD., APOTEX CORP.,  
APOTEX INC.,  
*Defendants-Appellants***

**ALEMBIC PHARMA LIMITED, ACTAVIS, INC., NKA  
ALLERGAN FINANCE, LLC,  
*Defendants***

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2016-2610, 2016-2683, 2016-2685, 2016-2698, 2016-2710,  
2017-1001

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Appeals from the United States District Court for the District of Delaware in Nos. 1:13-cv-01206-LPS, 1:13-cv-01207-LPS, 1:13-cv-01208-LPS, 1:13-cv-01209-LPS, 1:13-cv-01210-LPS, 1:13-cv-01211-LPS, 1:13-cv-01212-LPS, 1:13-cv-01213-LPS, 1:13-cv-01214-LPS, 1:13-cv-01215-LPS, 1:13-cv-01216-LPS, 1:13-cv-01218-LPS, 1:13-cv-01219-LPS, 1:13-cv-01220-LPS, 1:14-cv-00834-LPS, Chief Judge Leonard P. Stark.

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Decided: May 23, 2018

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DIMITRIOS T. DRIVAS, White & Case LLP, New York, NY, argued for plaintiffs-appellees. Also represented by ADAM GAHTAN, CHRISTOPHER J. GLANCY, ERIC M. MAJCHRZAK, LAURA MORAN, JAMES TRAINOR; JACK B. BLUMENFELD, MEGAN DELLINGER, MARYELLEN NOREIKA, Morris, Nichols, Arsht & Tunnell LLP, Wilmington, DE; PRISCILLA GRACE DODSON, JEFFREY B. ELIKAN, GEORGE FRANK PAPPAS, Covington & Burling LLP, Washington, DC; ALEXA HANSEN, San Francisco, CA.

RICHARD G. GRECO, Albany, NY, argued for defendants-appellants Accord Healthcare, Inc., Intas Pharmaceuticals Ltd. Also represented by JOHN W. SHAW, Shaw Keller LLP, Wilmington, DE; GURPREET SINGH WALIA, Cohen & Gresser LLP, New York, NY.

MAUREEN L. RURKA, Winston & Strawn LLP, Chicago, IL, argued for defendants-appellants Alembic Pharmaceuticals Ltd., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Apotex Corp., Apotex Inc., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc.,

Breckenridge Pharmaceutical, Inc., Cadila Healthcare Limited, MSN Laboratories Pvt. Ltd., Mylan Inc., Mylan Pharmaceuticals Inc., Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd., Watson Laboratories, Inc. - Florida, Watson Pharma, Inc., Zydus Pharmaceuticals (USA) Inc. Defendants-appellants Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., MSN Laboratories Pvt. Ltd., Sun Pharma Global FZE, Sun Pharmaceutical Industries, Ltd., Watson Laboratories, Inc. – Florida, Watson Pharma, Inc., LLC, also represented by GEORGE C. LOMBARDI, JOHN REYNOLDS MCNAIR, SAMUEL S. PARK; CHARLES B. KLEIN, EIMERIC REIG-PLESSIS, Washington, DC.

M. JEFFER ALL, Carlson, Caspers, Vandenburg, Lindquist & Schuman, P.A., Minneapolis, MN, for defendant-appellant Alembic Pharmaceuticals Ltd. Also represented by SARAH STENSLAND, Patterson Thuent Pedersen, PA, Minneapolis, MN.

IAN SCOTT, Taft, Stettinius & Hollister, LLP, Chicago, IL, for defendants-appellants Apotex Corp., Apotex Inc. Also represented by STEPHEN AUTEN, RICHARD T. RUZICH.

NICOLE W. STAFFORD, Wilson, Sonsini, Goodrich & Rosati, PC, Austin, TX, for defendants-appellants Mylan Pharmaceuticals Inc., Mylan Inc. Also represented by ADEN M. ALLEN; ADAM WILLIAM BURROWBRIDGE, Washington, DC; JOSHUA B. KUSHNER, Los Angeles, CA; DAVID S. STEUER, Palo Alto, CA.

MICHAEL JOHN GAERTNER, Locke Lord LLP, Chicago, IL, for defendants-appellants Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Limited. Also represented by DAVID BRIAN ABRAMOWITZ, HUGH S. BALSAM, TIMOTHY FLYNN PETERSON; ANDREA LYNN WAYDA, New York, NY.

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Before PROST, *Chief Judge*, BRYSON and STOLL, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* STOLL.

Dissenting opinion filed by *Chief Judge* PROST.

STOLL, *Circuit Judge*.

This case arises under the Hatch-Waxman Act. Appellees UCB, Inc.; UCB BioPharma SPRL; Research Corp. Technologies, Inc.; and Harris FRC Corp. (collectively, “UCB”) own and/or license U.S. Patent No. RE38,551. The ’551 patent covers lacosamide, an anti-epileptic drug, which treats epilepsy and other central nervous system disorders. UCB holds New Drug Applications (“NDAs”) that cover its lacosamide anti-epileptic drug approved by the Food and Drug Administration (“FDA”) and marketed under the tradename Vimpat®. The ’551 patent is listed in the FDA’s *Approved Drug Products With Therapeutic Equivalence Evaluations* (“Orange Book”) as covering Vimpat®.

Appellants are generic drug manufacturers who filed Abbreviated New Drug Applications (“ANDAs”), seeking approval for generic versions of Vimpat®. Pursuant to the governing Hatch-Waxman provisions, Appellants certified in their ANDAs that the ’551 patent is invalid, unenforceable, or that their proposed generic lacosamide products will not infringe the ’551 patent. Consequently, UCB sued Appellants for patent infringement in the United States District Court for the District of Delaware. Appellants stipulated to infringement of claims 9, 10, and 13 of the ’551 patent but maintained that these claims are invalid for obviousness-type double patenting, obviousness, and anticipation.

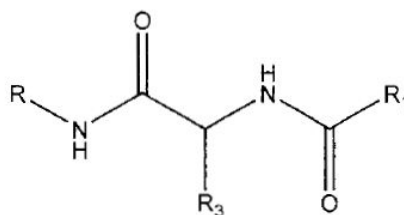
Following a bench trial, the district court made exhaustive fact findings based on the trial evidence and concluded that the asserted claims of the '551 patent are not invalid. Appellants appeal that decision, arguing that the district court misapplied the legal standards for obviousness-type double patenting, obviousness, and anticipation, and that the prior art anticipates and/or renders the '551 patent obvious.

As explained more fully below, we hold that the district court applied the correct legal standards in its obviousness-type double patenting, obviousness, and anticipation analyses. And because we discern no clear error in its underlying fact findings, we affirm the district court's ultimate conclusion that the asserted claims are not invalid.

## BACKGROUND

### A.

The '551 patent discloses and claims lacosamide, the active ingredient in Vimpat®. Lacosamide belongs to a class of compounds known as functionalized amino acids ("FAAs") having the following general structure:



The R, R<sub>1</sub>, and R<sub>3</sub> positions are variables, representing the many different chemical groups that can be placed at each position resulting in a vast number of possible FAA compounds. These groups may be aromatic, heteroaromatic, or nonaromatic. Aromatic groups have a two-dimensional structure, typically organized into rings, such as benzene. Heteroaromatic groups, such as oxygen

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