

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UCB, INC., UCB BIOPHARAMA SPRL, :
RESEARCH CORPORATION :
TECHNOLOGIES, INC. and :
HARRIS FRC CORPORATION, :

UNSEALED ON
AUGUST 15, 2016

Plaintiffs, :

v. :

Civil Action No. 13-1206-LPS
CONSOLIDATED

ACCORD HEATLHCARE, INC., et al., :

Defendants. :

Jack B. Blumenfeld, Maryellen Noreika, and Derek J. Fahnestock, MORRIS, NICHOLS,
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Attorney for Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.

OPINION

August 12, 2016
Wilmington, Delaware


STARK, U.S. District Judge:

Plaintiffs – UCB, Inc., UCB BioPharma SPRL, Research Corporation Technologies, Inc., and Harris FRC Corporation (collectively, “Plaintiffs”) – allege that Defendants – Accord Healthcare, Inc., Intas Pharmaceuticals Ltd., Alembic Pharmaceuticals, Ltd., 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 (n/k/a Actavis Laboratories FL, Inc.), Watson Pharma, Inc. (n/k/a Actavis Pharma, Inc), Actavis, Inc., Apotex Corp., Apotex, Inc., Mylan Pharmaceuticals Inc., Mylan, Inc., Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Limited (collectively, “Defendants”) – infringe United States patent No. RE38,551 (JTX-1 (“the ’551 patent” or “the patent-in-suit”)). (D.I. 1)

The ’551 patent generally relates to “anticonvulsant drugs,” which “control and prevent[] seizures associated with epilepsy or related central nervous system disorders.” (’551 patent at 1:26-29) Each of the Defendants has filed an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to market generic versions of Plaintiffs’ pharmaceutical product Vimpat®, which is an embodiment of claims of the patent-in-suit.

The Court construed the disputed claim terms in May 2015. (D.I. 240) In December 2015, the Court conducted a bench trial. (See D.I. 264-267 (“Tr.”)) The parties completed post-trial briefing on February 8, 2016. (D.I. 263, 271, 274, 277) In connection with the briefing, the parties submitted proposed findings of fact (D.I. 262, 270, 273) as well as a Stipulation of Uncontested Facts (“SUF”) (D.I. 272).

On May 23, 2016, the Patent Trial and Appeal Board (“PTAB”) instituted an *inter partes* review of the validity of claims 1-13 of the ’551 patent. (*See* D.I. 294, 294-1) On June 16, 2016, the U.S. Patent and Trademark Office (“PTO”) instituted an *ex parte* reexamination of the same claims. (*See* D.I. 300, 300-1)

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the Court concludes that: (1) Defendants have stipulated that their proposed products infringe claims 9, 10, and 13 of the ’551 patent, and (2) Defendants have failed to prove that any of claims 9, 10, and 13 of the ’551 patent are invalid for obviousness-type double patenting, obviousness, anticipation, indefiniteness, or improper reissue. The Court’s findings of fact and conclusions of law are set forth in detail below.

I. FINDINGS OF FACT

This section contains the Court’s findings of fact for issues raised by the parties during trial. Certain findings of fact are also provided in connection with the Court’s conclusions of law.

A. The Parties

1. Plaintiff UCB, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080. (SUF ¶ 1)

2. Plaintiff UCB BioPharma SPRL (together with UCB, Inc., “UCB”), is a corporation organized and existing under the laws of Belgium, having a principal place of business at Allée de la Recherche 60, Brussels, 1070, Belgium. (SUF ¶ 2)

3. Plaintiff Research Corporation Technologies, Inc. (“RCT”) is a corporation organized and existing under the laws of Delaware, having a principal place of business at 5210 East Williams Circle, Suite 240, Tucson, Arizona 85711-4410. (SUF ¶ 3)

4. Plaintiff Harris FRC Corporation (“Harris”) is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 2137 State Highway 35, Holmdel, New Jersey 07733. (SUF ¶ 4)

5. Defendant Accord Healthcare, Inc. is a corporation organized and existing under the laws of North Carolina, having a principal place of business at 1009 Slater Road, Ste. 210-B, Durham, North Carolina 27703. (SUF ¶ 5)

6. Defendant Intas Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Chinubhai Centre, off Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India. (SUF ¶ 6)

7. Defendant Alembic Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara-390 003, Gujarat, India. (SUF ¶ 7)

8. Defendant Amneal Pharmaceuticals, LLC is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. (SUF ¶ 8)

9. Defendant Amneal Pharmaceuticals of New York, LLC is a corporation organized and existing under the laws of Delaware, having a principal place of business at 85 Adams Avenue, Hauppauge, New York 11788. (SUF ¶ 9)

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