

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

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COSMO TECHNOLOGIES LIMITED,  
VALEANT PHARMACEUTICALS  
INTERNATIONAL, and VALEANT  
PHARMACEUTICALS LUXEMBOURG  
S.À R.L.,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC.,

Defendant.

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REDACTED PUBLIC VERSION

C.A. No. 15-164-LPS

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COSMO TECHNOLOGIES LIMITED,  
VALEANT PHARMACEUTICALS  
INTERNATIONAL, and VALEANT  
PHARMACEUTICALS LUXEMBOURG  
S.À R.L.,

Plaintiffs,

v.

ALVOGEN PINE BROOK, LLC,

Defendant.

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C.A. No. 15-193-LPS

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**MEMORANDUM OPINION**

October 27, 2017  
Wilmington, Delaware



**STARK, U.S. District Judge:**

Cosmo Technologies Limited, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals Luxembourg S.à r.l. (collectively, “Plaintiffs”) brought this patent infringement action under the Hatch-Waxman Act, 21 U.S.C. § 355(j), against Defendants Actavis Laboratories FL, Inc. (“Actavis”) and Alvogen Pine Brook, LLC (“Alvogen”), which each submitted an Abbreviated New Drug Application (“ANDA”) to market a generic version of Uceris®, which are oral tablets containing 9 mg of budesonide for treatment of mild to moderate ulcerative colitis. (C.A. No. 15-164-LPS D.I. 118 at ¶ 23; C.A. No. 15-193-LPS D.I. 116 at ¶ 20)<sup>1</sup> Plaintiffs assert Orange Book-listed U.S. Patent No. 8,784,888.<sup>2</sup> Specifically, Plaintiffs assert claim 9 against Actavis and claim 6 against Alvogen. (D.I. 221, 223) As relevant here, the ’888 patent generally claims budesonide tablets having a macroscopically homogenous composition.

The Court held a claim construction hearing on July 11, 2016 to construe disputed claim terms and issued a claim construction opinion and order on September 7, 2016. (D.I. 183, 184)

In May 2017, the Court held a bench trial. (*See* D.I. 241, 243 (“Tr.”)) At the close of Plaintiffs’ case-in-chief, both Defendants moved for partial judgment of non-infringement under Federal Rule of Civil Procedure 52(c). The Court granted Defendants’ motions from the bench.

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<sup>1</sup>All references to the Docket Index are to C.A. No. 15-164, unless otherwise noted.

<sup>2</sup>In their second amended complaint, Plaintiffs also asserted U.S. Patent Nos. 7,410,651; 8,293,273; RE 43,799; and 9,320,716 against Actavis (D.I. 118 at ¶ 5) and U.S. Patent Nos. 7,410,651; RE 43,799; and 9,320,716 against Alvogen (C.A. No. 15-193 D.I. 118 at ¶ 5), but they narrowed the asserted patents and claims before trial. (*See* D.I. 221) At trial, Plaintiffs also asserted claim 3 of the ’273 patent against Actavis. After trial, Plaintiffs dropped their allegations of infringement of the ’273 patent. (*See* D.I. 230 Ex. 1)

(See Tr. at 332) The Court subsequently allowed the parties to submit briefs to assist the Court in issuing written findings of fact and conclusions of law (D.I. 232, 234), and the parties also submitted a joint Statement of Uncontested Facts (“SUF”) (D.I. 233).

Pursuant to Rule 52(c), after having considered the entire record in this case and the applicable law, and consistent with the Court’s ruling after the close of Plaintiffs’ case, the Court concludes that Plaintiffs have failed to prove by a preponderance of the evidence that (1) Actavis infringes claim 9 of the ’888 patent and (2) Alvogen infringes claim 6 of the ’888 patent.

### FINDINGS OF FACT

This section contains the Court’s findings of fact (“FF”) on disputes raised by the parties during trial, as well as facts to which the parties have stipulated. Certain findings of fact are also provided in connection with the Court’s conclusions of law.

#### I. The Parties

1. Plaintiff Cosmo Technologies Limited (“Cosmo”) is an Irish corporation, having its principal place of business at Riverside II, Sir John Rogerson’s Quay, Dublin 2, Ireland. (SUF ¶ 1)
2. Plaintiff Valeant Pharmaceuticals International (“VPI”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. (SUF ¶ 2)
3. Plaintiff Valeant Pharmaceuticals Luxembourg S.à r.l. (“Valeant S.à r.l.”) is a Luxembourg corporation, having a principal place of business at 13-15 Avenue de la Liberté, L-1931 Luxembourg, Grand Duchy of Luxembourg. Valeant S.à r.l. is a wholly-owned subsidiary of VPI. (SUF ¶ 3)

4. Defendant Actavis Laboratories FL, Inc. (“Actavis”) is a corporation organized and existing under the laws of the State of Florida, having a place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. (SUF ¶ 4)

5. Defendant Alvogen Pine Brook, LLC (“Alvogen”) is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058. (SUF ¶ 5)

## II. Uceris®

6. VPI holds New Drug Application (“NDA”) No. 203634 for oral tablets containing 9 mg of the active ingredient budesonide, which are sold in the United States under the brand name Uceris®. (SUF ¶ 6)

7. Uceris® is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis. (SUF ¶ 7)

8. Uceris® was launched on February 14, 2013 by Santarus, Inc. (SUF ¶ 8)

## III. Defendants’ ANDAs

9. Actavis submitted ANDA No. 205457 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of extended release tablets containing 9 mg of budesonide (“Actavis ANDA product”) prior to the expiration of the patents-in-suit. The Actavis ANDA product is a pharmaceutical composition for oral administration. Actavis’ ANDA describes a manufacturing process for the production of the Actavis ANDA product. (SUF ¶¶ 21-23)

10. Alvogen submitted ANDA No. 205556 to the FDA under 21 U.S.C. § 355(j)

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