

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

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiffs,

v.

BRECKENRIDGE PHARMACEUTICAL, INC.,

Defendant.

C.A. No. 14-1043-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC.,

Defendant.

C.A. No. 14-1289-RGA
C.A. No. 14-1494-RGA
C.A. No. 15-78-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiffs,

v.

WEST-WARD PHARMACEUTICALS
INTERNATIONAL LIMITED,

Defendant.

C.A. No. 14-1196-RGA
C.A. No. 14-1508-RGA
C.A. No. 15-128-RGA

NOVARTIS'S OPENING BRIEF ON ESTOPPEL UNDER 35 U.S.C. § 315(e)(2)

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Pursuant to this Court’s February 28, 2019, order (C.A. No. 14-1043, D.I. 206), Novartis Pharmaceuticals Corporation and Novartis AG (collectively “Novartis”) file this brief explaining why the three Defendants¹ are estopped under 35 U.S.C. § 315(e)(2) from asserting their sole remaining invalidity defense against claims 1-3, 7 and 10 of U.S. Patent No. 5,665,772 (“the ’772 patent”).² That 35 U.S.C. § 103 defense is based on prior art that Defendants knew about and “raised or reasonably could have raised during” the ’772 patent IPR proceedings for which there is a final written decision (claims 1-3 and 8-10³) and *de facto* final written decision (claim 7) upholding patentability. Because Defendants are estopped, judgment for Novartis should be entered, disposing of the above-captioned litigations. Thus, this Court need not evaluate Defendants’ substantive § 103 defense.

I. PROCEDURAL BACKGROUND

Novartis sued Defendants for ’772 patent infringement based on their generic versions of Novartis’s Zortress® and Afinitor® products in multiple litigations.⁴ The parties agreed that the

¹ Breckenridge Pharmaceutical, Inc. (“Breckenridge”), Par Pharmaceutical Inc. (“Par”) and West-Ward Pharmaceuticals International-Limited (f/k/a Roxane Laboratories, Inc., n/k/a Hikma Pharmaceuticals International Limited) (“West-Ward”) (collectively “Defendants”).

² Unlike Par and Breckenridge who filed counterclaims, West-Ward can only challenge claim 10 of the ’772 patent as Novartis withdrew its infringement contentions against claims 1-3 at trial, and against claim 7 after trial. *See* C.A. No. 14-1043, D.I. 162 at 1 n.1, D.I. 205 at 2.

³ Although claims 8 and 9 are discussed in this brief as they were included in the ’772 patent IPRs and estoppel applies to those claims, no party presented evidence on claims 8 or 9 at the ’772 patent trial and this Court need not address whether estoppel applies to those claims.

⁴ The first ’772 patent suits were filed in August 2014 (Breckenridge, C.A. No. 14-1043), September 2014 (West-Ward, C.A. No. 14-1196), and October 2014 (Par, C.A. No. 14-1289) (collectively, “the Zortress® litigations”). Six additional suits were subsequently filed, C.A. Nos. 14-1494 and 15-0078 (Par); 14-1508 and 15-0128 (West-Ward); and C.A. Nos. 16-0431-RGA and 17-00420 (Breckenridge) (collectively, “the Afinitor® litigations”). The Breckenridge Afinitor® litigations were dismissed in August 2018. *See* C.A. No. 16-431, D.I. 99, 108.

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