

**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  
C.A. No. 16-431-RGA  
C.A. No. 17-420-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 OPPOSITION TO DEFENDANTS' MOTION  
FOR EXTENSION OF TIME TO SUBMIT JOINT STATUS REPORT**

Plaintiffs Novartis Pharmaceuticals and Novartis AG (collectively "Novartis") oppose the motion by Defendants Breckenridge Pharmaceutical, Inc., Par Pharmaceutical, Inc., and West-Ward Pharmaceuticals International Limited n/k/a Hikma Pharmaceuticals International Limited

(collectively, “Defendants”) for a 7 day extension to file a joint status report, *see, e.g.*, Case 1:14-cv-01043-RGA, D. I. 202. Defendants’ motion fails to provide any basis to grant the extension Defendants seek, and glaringly omits that there is an urgency to resolve the outstanding § 103 challenge to U.S. Patent No. 5,665,772 (“the ’772 patent”), as the 30-month stay has now expired, at least one Defendant has approval for its Zortress® generic product and will not agree to forgo an at-risk launch until the matter is resolved, and the other Defendants may obtain approval at any point.

Although the Mandate issued on February 15, 2019, the underlying decision on the merits issued on December 7, 2018, and Defendants’ request for rehearing was denied on February 8, 2019, so Defendants have known that remand was imminent. Novartis was preparing to contact the Court on the heels of the Mandate’s issuance when it received the Court’s Order directing the parties to file a joint status report within five (5) days.

In reliance on the Court’s Order, instead of filing its own submission, Novartis sent Defendants a draft of the joint status report on February 16, 2019, asking for comments by noon on Tuesday February 19, 2019 (Exhibit 1). Shortly before noon on Tuesday, the Defendants asked if Novartis would agree to a 7 day extension, citing the holiday weekend as the basis for the request (Exhibit 2 at 2). Novartis agreed subject to two straightforward conditions: (1) Defendants would agree not to launch while this Court considered the validity of the ’772 patent, and (2) Defendants would provide their comments on the joint letter by close of business on Friday February 22, 2019 (Exhibit 2 at 1-2). Defendants refused to agree to Novartis’s conditions, offered no counter-proposal and instead filed the instant motion (Exhibit 2 at 1).

Defendants’ motion fails to offer any explanation as to why any extension, let alone a 7 day extension, is necessary. The intervening 3 day weekend, which the Court presumably was

well-aware of when issuing its order, does not justify a 7 day extension. Novartis even suggested that Defendants could include as their position in the joint status report that Defendants were considering their options and would provide a further update later (Exhibit 3), but Defendants did not respond to that suggestion. This is not a matter of Novartis refusing to extend a courtesy; rather, Novartis believes this matter needs to be brought before the Court promptly to address (and preclude) any potential launch at risk. Thus far, none of the Defendants has agreed to not launch its respective Zortress® products before this Court issues a decision on the validity of the '772 patent, and accordingly, there is a need to quickly resolve the outstanding '772 patent issue. That issue can be quickly resolved because the Defendants are estopped from pursuing their § 103 obviousness challenge—the sole challenge remaining on remand—under 35 U.S.C. § 315(e)(2).

Accordingly, Novartis respectfully requests that this Court deny Defendants' motion and schedule an in person or telephonic status conference at the Court's earliest convenience.

Dated: February 21, 2019

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

Renaissance Centre

405 N. King Street, 8th Floor

Wilmington, Delaware 19801

(302) 984-6300

*dsilver@mccarter.com*

Of Counsel:

Nicholas N. Kallas

VENABLE FITZPATRICK

1290 Avenue of the Americas

New York, NY 10104-3800

(212) 218-2100

*nkallas@venable.com*

*Attorneys for Plaintiffs*