

NOTE: This order is nonprecedential.

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

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**BTG INTERNATIONAL LIMITED, JANSSEN  
BIOTECH, INC., JANSSEN ONCOLOGY, INC.,  
JANSSEN RESEARCH & DEVELOPMENT, LLC,**  
*Plaintiffs-Appellants*

v.

**AMNEAL PHARMACEUTICALS LLC, AMNEAL  
PHARMACEUTICALS OF NEW YORK, LLC, DR.  
REDDY'S LABORATORIES, INC., DR. REDDY'S  
LABORATORIES, LTD., WEST-WARD  
PHARMACEUTICALS CORP., nka Hikma Pharma-  
ceuticals USA Inc., HIKMA PHARMACEUTICALS  
LLC, WOCKHARDT BIO AG, WOCKHARDT USA  
LLC, WOCKHARDT LTD., TEVA  
PHARMACEUTICALS USA, INC.,**  
*Defendants-Appellees*

**MYLAN PHARMACEUTICALS INC., MYLAN, INC.,**  
*Defendants-Cross-Appellants*

**PAR PHARMACEUTICAL, INC., PAR  
PHARMACEUTICAL COMPANIES, INC., RISING  
PHARMACEUTICALS, INC.,**  
*Defendants*

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2019-1147, 2019-1167

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Appeals from the United States District Court for the District of New Jersey in Nos. 2:15-cv-05909-KM-JBC, 2:17-cv-06435-KM-JBC, Judge Kevin McNulty.

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**BTG INTERNATIONAL LIMITED, JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC,**  
*Plaintiffs-Appellants*

v.

**AMERIGEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS LIMITED,**  
*Defendants-Appellees*

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2019-1148

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Appeal from the United States District Court for the District of New Jersey in No. 2:16-cv-02449-KM-JBC, Judge Kevin McNulty.

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**ON MOTION**

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PER CURIAM.

**O R D E R**

Appellants move for an injunction, pending appeal, to prohibit Defendants from marketing, selling, offering to sell, or importing into the United States any generic version of ZYTIGA®. Appellees and Cross-Appellants oppose the motion. Appellants reply.

This court's evaluation of a motion for an injunction pending appeal is governed by four factors: (1) whether

the applicant had made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent an injunction; (3) whether issuance of the injunction will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987). Without prejudicing the ultimate disposition of these cases by a merits panel, we conclude based upon the papers submitted that Appellants have not established that an injunction is warranted here.

Accordingly,

IT IS ORDERED THAT:

(1) The motion for an injunction is denied. This court's temporary injunction is vacated.

(2) The merits briefing schedule is as follows: Appellants' principal brief is due no later than December 3, 2018; the response brief of Appellees and principal and response brief of Cross-Appellants is due no later than December 26, 2018; Appellants' response and reply brief is due no later than January 3, 2018; Cross-Appellants' reply brief is due no later than January 10, 2019. The joint appendix is due no later than January 11, 2019. Oral argument is scheduled for January 24, 2019 at 10:00 a.m.

(3) The parties notify the Court as soon as the Patent Trial and Appeal Board issues its reconsideration decisions in IPRs 2016-00286, 2016-01332, and 2016-01582, and whether any party intends to appeal those decisions.

(4) The court invites the Director of the United States Patent and Trademark Office for his views. We request that the Director address at least the following issues:

- (a) Whether a petitioner is estopped from challenging claims in district court under 35 U.S.C. § 315(e)(2) based on a ground that it brought in an *inter partes*

review, which resulted in a final written decision holding the claims unpatentable but which has a pending request for rehearing.

- (b) Whether a decision is a “final written decision” under 35 U.S.C. § 315(e)(2) if the period for rehearing under 37 C.F.R. § 42.71(d) has not yet expired.
- (c) Whether a PTAB decision on the pending requests for rehearing could moot the estoppel issue.
- (d) Whether a district court can stay a case pending the outcome of a request for rehearing of a final written decision and/or appeal from a final written decision.

The Director may file an amicus brief not to exceed 14,000 words by December 19, 2018 and will be given five minutes of oral argument time.

FOR THE COURT

November 20, 2018  
Date

/s/ Peter R. Marksteiner  
Peter R. Marksteiner  
Clerk of Court