2019-1147, -1148, -1323, -1324, -1325

#### UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

#### 2019-1147

#### 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., WOCKHARDT BIO AG, WOCKHARDT USA LLC, WOCKHARDT LTD., MYLAN PHARMACEUTICALS INC., MYLAN INC., WEST-WARD PHARMACEUTICALS CORP., NKA HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS LLC, TEVA PHARMACEUTICALS USA, INC., *Defendants-Appellees* 

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

Appeals from the United States District Court for the District of New Jersey in Nos. 2:15-cv-05909-KM-JBC, 2:16-cv-02449-KM-JBC, and 2:17-cv-06435-KM-JBC, Judge Kevin McNulty.

(Caption continued on next page)

**A** R M

#### 2019-1148

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

v.

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

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

-----

#### 2019-1323

#### JANSSEN ONCOLOGY, INC.,

Appellant

v.

#### AMERIGEN PHARMACEUTICALS LIMITED, ARGENTUM PHARMACEUTICALS LLC,

**Appellees** 

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-00286 and IPR2016-01317.

-----

(Caption continued on next page)

DOCKE

RM

#### 2019-1324

#### JANSSEN ONCOLOGY, INC.,

Appellant

v.

#### MYLAN PHARMACEUTICALS INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORPORATION, HIKMA PHARMACEUTICALS LLC,

Appellees

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-01332 and IPR2017-00853.

-----

#### 2019-1325

#### JANSSEN ONCOLOGY, INC.,

Appellant

v.

#### WOCKHARDT BIO AG,

Appellee

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-01582.

#### INVITED BRIEF FOR THE DIRECTOR – U.S. PATENT AND TRADEMARK OFFICE AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

Case: 19-1147 Document: 123 Page: 4 Filed: 02/01/2019

JENNIFER L. UTRECHT SCOTT R. MCINTOSH MARK R. FREEMAN *Of Counsel* 

Attorneys, Appellate Staff Civil Division U.S. Department of Justice THOMAS W. KRAUSE *Solicitor* 

FARHEENA Y. RASHEED Senior Counsel for Patent Law & Litigation

FRANCES M. LYNCH ROBERT J. MCMANUS JOSEPH MATAL Associate Solicitors

Attorneys for the Director of the U.S. Patent and Trademark Office

February 1, 2019

### TABLE OF CONTENTS

SUMMARY1
DETAILED RESPONSE TO ORDER
(1) 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
a. Section 315(e)(2) applies to both successful and unsuccessful petitioners
<ul> <li>b. Section 315(e)(2) estoppel attaches once the PTAB has issued a "final written decision" even if a party seeks rehearing of that decision</li></ul>
<ul> <li>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 expired15</li> </ul>
(3) Whether a PTAB decision on the pending requests for rehearing could moot the estoppel issue16
<ul><li>(4) 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</li></ul>
CONCLUSION

# DOCKET A L A R M



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

#### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

#### E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.