Paper No. ___
Date Filed: Nov. 16, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

WOCKHARDT BIO AG,

Petitioner

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner.

---

CASE IPR2016-01582

Patent 8,822,438

---

**JANSSEN ONCOLOGY INC.'S PRELIMINARY RESPONSE**

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

## TABLE OF CONTENTS

I. INTRODUCTION .......... 1

II. FACTUAL BACKGROUND .......... 2

III. THE WOCKHARDT PETITION SHOULD BE DENIED BECAUSE IT FAILS TO IDENTIFY AMERIGEN AS A REAL PARTY-IN-INTEREST PURSUANT TO SECTION 312(A)(2) .......... 7

- A. Disclosure Of All Real Parties-in-Interest Is A Mandatory Requirement .......... 8
- B. Wockhardt Was Required To Identify Amerigen As A Real Party-in-Interest .......... 10
- C. The Failure To Identify Amerigen As A Real Party-In-Interest Mandates Vacating The Wockhardt Petition Filing Date .......... 14

IV. THE WOCKHARDT PETITION SHOULD ALSO BE DENIED UNDER SECTION 325(D) .......... 15

- A. The Wockhardt Petition Uses the Same or Substantially the Same Prior Art and Arguments As Those Presented In Co-Pending IPRs .......... 15
- B. The Arguments Against Denial Based On Section 325(d) Made In The Wockhardt Petition Fail .......... 19

V. CONCLUSION .......... 22

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

## I. INTRODUCTION

The Petition filed by Wockhardt Bio AG ("the Wockhardt Petition") should be rejected for each of two independent reasons.

First, the Wockhardt Petition does not identify a real party-in-interest ("RPI")—Amerigen Pharmaceuticals Ltd. ("Amerigen"). Amerigen filed an *inter partes* review ("IPR") petition challenging the same claims of the '438 Patent on December 4, 2015 (the "Amerigen IPR") and has been coordinating closely with Petitioner Wockhardt in connection with each of these proceedings. Wockhardt's own statements confirm that Wockhardt and Amerigen are in effect jointly controlling these IPRs. Wockhardt has further admitted

The RPI disclosure requirement is intended "to assure proper application of the statutory estoppel provisions… [which] seek[] to protect patent owners from harassment via successive petitions by the same or related parties, to prevent parties from having a 'second bite at the apple.'" Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48759 (Aug. 14, 2012). The Wockhardt Petition seeks to do precisely what the RPI provisions are designed to prevent. Wockhardt's failure to disclose Amerigen as a RPI mandates dismissal of the Petition under 35 U.S.C. § 312(a)(2).

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Second, and independently, the Wockhardt Petition relies on "substantially the same prior art or arguments previously presented to the Office" in the Amerigen IPR. 35 U.S.C. § 325(d). Indeed, the Amerigen and Wockhardt IPR petitions are effectively the same in substance. Any differences in the art relied upon in the Wockhardt Petition are merely cosmetic—a fact that is underscored by verbatim identical experts' conclusions concerning what the new reference relied upon does and does not teach to those of ordinary skill. The Board should therefore exercise its sound discretion to dismiss the Wockhardt Petition under Section 325(d).

## II. FACTUAL BACKGROUND

Patent Owner's U.S. Patent No. 8,822,438 ("the '438 patent") claims a breakthrough discovery in cancer treatment, *i.e.*, that abiraterone acetate and prednisone can be used in combination to provide a dramatically more effective treatment for preventing or slowing the growth of castration resistant metastatic prostate cancer. This discovery, which is commercially embodied in the FDA approved uses of ZYTIGA®, has transformed doctors' ability to combat a deadly form of prostate cancer and extend patients' lives, in sharp contrast to earlier treatment options that were largely ineffective.

Numerous generic drug companies, each seeking to market generic versions of ZYTIGA®, have challenged the validity of '438 patent by providing the Patent

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Owner with "Paragraph IV" certifications under the Hatch-Waxman Act. On July 31, 2015, Patent Owner[1] sued twelve of these companies, including Petitioner Wockhardt and its subsidiaries, in the U.S. District Court for the District of New Jersey asserting infringement of the '438 patent. *See BTG Int'l Ltd. et al. v. Actavis Labs. Fl. Inc. et al.*, Case No. 2:15-cv-05909-KM-JBC (D.N.J.) (the "District Court Litigation").[2]

Although Amerigen was not one of the companies that originally submitted a "Paragraph IV" certification notice, and thus was not one that was originally sued, on December 4, 2015, Amerigen nonetheless filed an IPR petition challenging the patentability of claims of the '438 patent. *Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (the "Amerigen IPR").

Later, on March 24, 2016, Amerigen did serve the Patent Owner with a "Paragraph IV" certification for the '438 patent, whereupon, on May 2, 2016,

---

[1] In addition to Patent Owner, the District Court Litigation named as co-plaintiffs BTG International Limited, Janssen Biotech, Inc., and Janssen Research & Development, LLC (collectively, "co-plaintiffs"),

[2] Defendants, including Wockhardt, submitted Invalidity Contentions as required by the local patent rules in February 2016. Defendants' February 2016 Invalidity Contentions set forth each of the prior art references that Wockhardt relies upon as grounds in this IPR.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

# 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.

**WHAT WILL YOU BUILD?** | **sales@docketalarm.com** | **1-866-77-FASTCASE**

fastcase® Smarter legal research.