UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD. & ACRUX LIMITED Petitioners,

v.

KAKEN PHARMACEUTICAL CO., LTD. and

VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

Patent Owner and Licensee.

Case: IPR2017-00190

U.S. Patent No. 7,214,506

DECLARATION OF VINCENT A. THOMAS, CPA, CVA, CFF, ABV

Submitted August 1, 2017



# **TABLE OF CONTENTS**

I.	EXPERIENCE AND CREDENTIALS	.1
II.	SCOPE OF ASSIGNMENT	.2
III.	INFORMATION REVIEWED AND RELIED UPON	.3
IV.	SUMMARY OF OPINIONS	.4
V.	ANALYSIS OF JUBLIA®'S SUCCESS IN THE MARKETPLACE	6
A	ONYCHOMYCOSIS	6
B	. TREATING ONYCHOMYCOSIS	8
0	. THE '506 PATENT 1	10
Ľ	. JUBLIA®	1
E	. CAUSAL LINK OF JUBLIA®'S SUCCESS TO THE '506 PATENT 1	12



#### I. EXPERIENCE AND CREDENTIALS

1. I am a Senior Managing Director in the Forensic & Litigation Consulting ("FLC") practice of FTI Consulting, Inc. ("FTI"), a multidisciplinary international financial advisory and consulting firm. I am a Co-Leader of FTI's Dispute Advisory Practice and I also lead FTI's National Intellectual Property Practice. Before joining FTI, I was a partner with the international professional services firm, KPMG, LLP.

2. I have significant experience assisting companies and clients with complex accounting, corporate finance and litigation issues. I focus on the preparation of sophisticated economic analyses and the assessment of damages in various types of commercial disputes. Over the course of my career, I have analyzed economic and financial issues in more than one hundred commercial disputes, many of which involved patent, copyright, trade secret, and trademark infringement. Many of those assignments have also involved complex economic analysis of commercial success of various products, sophisticated valuation analysis, and damages in matters involving various pharmaceutical products, biotechnology, and drug technologies. For the past three years I have been named by *Intellectual Asset Management* magazine as one of the world's leading patent damages experts.

3. I also have significant experience in corporate, financial, and accounting management positions, including a role as an Analyst and Director as well as Chief Financial Officer for a high-tech company, where I was responsible for managing its intellectual property portfolio. In that capacity, as well as during my consulting career, I have been involved in license negotiations, performing

PAGE 1

royalty analysis, valuing intellectual property, and reviewing and analyzing license agreements.

4. I graduated *cum laude* from DePauw University with a Bachelor of Arts degree in Economics and I subsequently received a Masters of Business Administration degree from Indiana University. I am a Certified Public Accountant, Certified Valuation Analyst, and I am Certified in Financial Forensics and Accredited in Business Valuation. I am also a member of the American Institute of Certified Public Accountants and the National Association of Certified Valuation Analysts. **Appendix A** contains a summary of my education, experiences, prior testimony, and publications/seminars that I have authored. My business address is FTI Consulting, Inc., 227 W. Monroe Street, Suite 900, Chicago, Illinois 60606.

## II. SCOPE OF ASSIGNMENT

Page A of 35

5. On November 2, 2016, Acrux DDS PTY Ltd. and Acrux Limited (collectively, "Acrux" or "Petitioners") filed a petition with the Patent Trial and Appeal Board ("PTAB") to institute an *inter partes* review of patent number 7,214,506 (the "506 patent").<sup>1</sup> The '506 patent is owned by Kaken Pharmaceutical Co., Ltd. ("Kaken") and it is licensed to Valeant Pharmaceuticals International, Inc. ("Valeant") (collectively, "Patent Owners"). The PTAB instituted the *inter partes* review on May 1, 2017.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Paper 01, Petition submitted November 2, 2016.

<sup>&</sup>lt;sup>2</sup> Paper 12, Decision to Institute *Inter Partes* review, dated May 1, 2017.

6. It is my understanding that Acrux seeks to have the '506 patent invalidated as obvious over several combinations of alleged prior art references. I further understand that in the evaluation of obviousness, certain secondary considerations may be contemplated, such as commercial success, long-felt but unmet need, failure of others, and unexpected results. I have been retained by Finnegan Henderson Farabow Garret & Dunner, counsel for the Patent Owners ("Counsel"), to assess and provide opinions regarding secondary considerations relating to the '506 patent.

#### III. INFORMATION REVIEWED AND RELIED UPON

7. During the course of my work in this matter, I have examined documents provided to me by Counsel and other information I have obtained from public sources. This report and the opinions and conclusions reached herein are based on my review of these documents as well as my knowledge, education, experience, and training. A listing of the specific documents I considered and reviewed is contained in the attached **Appendix B**.

8. My opinions contained herein are the results of my investigations to date. They are to be used for the specific purposes of this proceeding and are not to be used for any other purpose without the express written consent of FTI. I reserve the right to supplement, amend, or alter these opinions based on information that hereafter becomes available, including information that becomes available prior to and during the time this proceeding.

PAGE 3



Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

# 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.