

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 No.: IPR2017-00190
Patent No. 7,214,506 B2

**REPLY DECLARATION OF KENNETH A. WALTERS, PH.D. IN SUPPORT
OF PETITION FOR *INTER PARTES* REVIEW OF PATENT NO. 7,214,506**

ACRUX DDS PTY LTD. et al.
EXHIBIT 1509

IPR Decision Set

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	SUMMARY	2
III.	ATTEMPTS TO NARROW CLAIM SCOPE LACK MERIT	3
IV.	DR. ELEWSKI MISCHARACTERIZES JP '639, THE '367 PATENT, AND HAY	16
A.	Dr. Elewski's Attacks on JP '639 are Baseless.....	18
B.	Dr. Elewski's Attacks on the '367 Patent are Baseless	20
C.	Dr. Elewski's Attacks on the Hay Reference are Baseless.....	23
V.	DR. ELEWSKI MISCHARACTERIZES THE KAKEN ABSTRACTS	30
VI.	DR. ELEWSKI MISCHARACTERIZES OGURA	43
VII.	TOPICAL ONYCHOMYCOSIS TREATMENTS WERE KNOWN.....	53
VIII.	DR. ELEWSKI'S ATTACKS ON THE MOLECULAR WEIGHT OF EFINACONAZOLE LACK MERIT	61
IX.	IT WAS KNOWN THAT KP-103 IS NOT INACTIVATED BY KERATIN UNLIKE OTHER TOPICAL ANTIFUNGAL AGENTS	69
X.	DR. ELEWSKI'S ARGUMENT THAT HYDROPHILIC MOLECULES WERE DISFAVORED LACKS MERIT	75
XI.	DR. ELEWSKI'S OTHER ARGUMENTS ARE ALSO CONTRADICTED BY THE PRIOR ART	77
XII.	EFINACONAZOLE WAS ALREADY A KNOWN POTENT TOPICAL ANTIFUNGAL COMPOUND BY 1999.....	81
XIII.	POSAS WERE MOTIVATED TO TREAT ONYCHOMYCOSIS TOPICALLY WITH POTENT ANTIFUNGAL AGENTS SUCH AS EFINACONAZOLE	88

..

XIV. PATENT OWNER’S ATTACKS ON MY EXPERTISE LACK MERIT	91
XV. CONCLUSIONS	93

I, Kenneth A. Walters, Ph.D., hereby state the following:

I. INTRODUCTION

1. In this declaration, I am providing my expert opinions in support of Petitioners' Petition for *Inter Partes* Review of Patent No. 7,214,506 (the "'506 patent") and in reply to Patent Owner's Response, including the Declaration of Boni E. Elewski, M.D., pursuant to 37 C.F.R. § 42.120.

2. I previously provided a declaration dated October 28, 2016, as part of the petition filed by Petitioners that led to this proceeding. My previous declaration is Ex. 1005. I am competent to make this declaration based upon my personal knowledge and technical expertise.

3. All of the exhibits I have considered and on which I have relied in this proceeding are the kinds of documents on which I typically rely when forming scientific opinions, including the opinions I have offered in this proceeding.

4. I reserve the right to supplement my opinions to address any information obtained, or positions taken, based on any new information that comes to light throughout this proceeding.

5. I have read the Declaration of Boni E. Elewski, M.D. (Ex. 2027). Her declaration does not change my previous opinions.

6. In forming my opinions, I considered and relied on my knowledge, education, experience, the references identified in Ex. 1005 and in this declaration.

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.