

PUBLIC VERSION

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 JOHN C. STAINES, JR. IN SUPPORT OF
PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

November 1, 2017

ACRUX DDS PTY LTD. et al.
EXHIBIT 1511
IPR Petition for

PROTECTIVE ORDER MATERIAL

I. QUALIFICATIONS

1. I am a Director and Principal in the Washington, DC office of Navigant Economics LLC (“Navigant Economics”), a subsidiary of Navigant Consulting, Inc., an international consulting firm. Navigant Economics provides expertise primarily in economics, finance, public policy, and business strategy. I am knowledgeable in the fields of microeconomics, industrial organization, financial economics, and statistics, and have particular expertise in applying the tools of these disciplines to legal disputes arising in the pharmaceutical and related industries.

2. My educational background includes a B.A. in Economics and M.P.M. in Public Policy from the University of Maryland and an M.B.A. in Business Economics and Finance from the University of Chicago. Since 1984, I have worked as a consultant on economic, financial, statistical, and general business issues arising in commercial litigation disputes. My work primarily has involved analyzing competitive issues and estimating commercial damages associated with various types of legal and regulatory disputes, most often relating to the pharmaceutical industry. I have been accepted in Federal Court as an expert witness to opine on economic issues arising in pharmaceutical-related patent and antitrust litigation. A copy of my curriculum vitae is included as Attachment A to this report.

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3. Navigant Economics is being compensated for the work I perform in connection with this case at my normal hourly rate of \$535. Part of the work underlying this report was performed by staff of Navigant Economics working under my direction. Payment of fees to Navigant Economics associated with work performed on this matter is not contingent upon or in any way affected by the nature of my opinions or the outcome of this litigation.

II. OBJECTIVES AND CONCLUSIONS

4. I have been retained by the Petitioners in this matter, Acrux DDS Pty, Ltd. and Acrux, Ltd. (collectively, “Acrux”) to render independent expert opinions concerning the existence and sources of any commercial success that may be associated with the fungal nail infection treatment, Jublia[®], as they may relate to the obviousness of U.S. Patent Number 7,214,506 (the “’506 patent”), entitled “Method for Treating Onychomycosis.”¹ Jublia[®] is marketed in the United States as a treatment for onychomycosis by Valeant Pharmaceuticals International, Inc. (“Valeant”).² The ’506 patent was issued to Kaken Pharmaceuticals Co., Ltd. (“Kaken”)

¹ U.S. Patent No. 7,214,506, May 8, 2007 (Exhibit 1001).

² Kaken Exhibit 2092.

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(Valeant and Kaken, collectively, “Patent Owners”) in 2007 and is exclusively licensed to Valeant.³ On November 6, 2016, Acrux petitioned the Patent Trial and Appeal Board (“PTAB”) to institute an *inter partes* review of the validity of claims 1 and 2 of the ’506 patent,⁴ which the PTAB did institute on May 1, 2017.⁵

5. I understand that the commercial success of a product allegedly containing technology claimed by an asserted patent may in some cases represent a secondary indicium that the patented technology was nonobvious. In this context, counsel for Acrux has asked me to evaluate the opinions and supporting evidence

³ *Id.*; Exhibit 1001.

⁴ Acrux DDS PTY, Ltd. & Acrux Limited v. Kaken Pharmaceutical Co., Ltd. and Valeant Pharmaceuticals International, Inc., U.S. Patent and Trademark Office, Patent Trial and Appeals Board, IPR2017-00190, Paper No. 1, Petition, filed on November 2, 2016, pp. 3-4.

⁵ Acrux DDS PTY, Ltd. & Acrux Limited v. Kaken Pharmaceutical Co., Ltd. and Valeant Pharmaceuticals International, Inc., U.S. Patent and Trademark Office, Patent Trial and Appeals Board, IPR2017-00190, Paper No. 12, Decision, Institution of *Inter Parties* Review, entered on May 1, 2017, p. 25.

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expressed in the Declaration of Vincent A. Thomas, CPA, CVA, CFF, ABV,⁶ which concluded that Jublia[®] is a commercial success due to its alleged embodiment of the method claimed in the '506 patent.⁷ My evaluation involves assessing whether there is sufficient evidence to conclude that Jublia[®] has achieved commercial success and assessing whether any such commercial success that may exist has a causal nexus to the alleged invention claimed by the '506 patent.

6. This evaluation, and specifically my review of Mr. Thomas' report, leads me to the opinion that there is insufficient evidence to conclude that Jublia[®] has achieved commercial success for the following reasons.

- The \$1 billion-plus cumulative gross sales revenue Mr. Thomas attributes to Jublia[®] by itself does not demonstrate commercial success in the context of gross sales revenues typically generated by prescription brand pharmaceutical drugs prior to the introduction of a generic equivalent, including, for example, the orally administered onychomycosis treatment Lamisil[®].

⁶ Declaration of Vincent A. Thomas, CPA, CVA, CFF, ABV, filed on August 1, 2017 as Kaken Exhibit 2028 ("Thomas Report") at ¶¶12, 79–83.

⁷ *Id.*, at ¶30.

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