#### UNITED STATES PATENT AND TRADEMARK OFFICE

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## ACRUX DDS PTY LTD. & ACRUX LIMITED Petitioners

V.

## KAKEN PHARMACEUTICAL CO., LTD. and VALEANT PHARMACEUTICALS INTERNATIONAL, INC. Patent Owner and Licensee

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Patent No. 7,214,506 Issue Date: May 8, 2007 Title: Method for Treating Onychomycosis

DECLARATION OF KENNETH A. WALTERS, PH.D.



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1. My name is Kenneth A. Walters. I was the Director of Research and Development and Business Development and am currently the Director of QA/QC at An-eX Analytical Services Limited in Cardiff, United Kingdom ("An-eX"). An-eX is an independent contract research and development company that offers a range of dermatological and transdermal services to the pharmaceutical, cosmetic, chemical and agrochemical industries. I understand that my declaration is being submitted in connection with a Petition for *Inter Partes* Review of U.S. Patent No. 7,214,506 (the "'506 patent") (Ex. 1001).

### I. Qualifications, Background, and Experience

- 2. I received CBiol and MIBiol degrees in physiology/pharmacology from Stockport Technical College (now Stockport College) in Stockport (United Kingdom) in 1973, a Ph.D. in Toxicology from University of Strathclyde in Glasgow (United Kingdom) in 1978. I held a post-doctoral position at the University of Michigan from 1978-1980 focusing on transungual delivery. I also held a post-doctoral position at the University of Bath (United Kingdom) from 1980-1981 focusing on pharmaceutical formulations. I am currently an elected Fellow of the Royal Society of Biology.
- 3. I have edited or co-edited 9 scientific and technical books and authored or co-authored over 100 scientific and technical journal articles and book



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