

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD., ACRUX LIMITED,
ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

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

Case IPR2017-00190¹
Patent 7,214,506 B2

**DECLARATION OF CAITLIN M. WILMOT IN SUPPORT OF
PETITIONER'S RESPONSE TO PATENT OWNER'S
OBJECTIONS TO EVIDENCE**

¹ Case IPR2017-01429 has been joined with the instant proceeding.

ACRUX DDS PTY LTD. et al.
EXHIBIT 1669
IPR Petition for

I, Caitlin M. Wilmot, declare and state as follows:

I am a law clerk with the firm Rothwell, Figg, Ernst & Manbeck, PC, attorneys for Acrux DDS Pty. Ltd. and Acrux Limited (“Petitioner”). I submit this declaration in support of the Response to Patent Owner’s Objections to Evidence. I have personal knowledge of the facts stated in this declaration and have personally reviewed each of the attached documents. If called upon to do so, I could, and would, competently testify on the matters set forth herein.

1. Attached hereto as **Exhibit 1513(a)** is a library-stamped, true and accurate copy of “Antibacterial activity of topical antifungal agent in the infected sites- study- skin permeability and absorption to horny materials,” Tadashi Arika et al., *Nishi Nihon Journal of Dermatology*, 52 (3): 545-549 (1990). Exhibit 1513(a) was obtained from the vendor Reprints Desk/Research Associates. The unnumbered pages between the journal cover and the article starting on page 545 of the journal, as well as pages 649-652 of the journal (understood to include the copyright and/or publication data, as well as a table of contents), have not been translated from Japanese into English, as they do not include the relevant portions of the exhibit cited by Petitioner. Exhibit 1513(a) is served in response to Patent Owner’s objections to Exhibit 1513.

2. Attached hereto as **Exhibit 1518(a)** is a library-stamped, true and accurate copy of “Risk factors and comorbidities for onychomycosis: implications

for treatment with topical therapy,” Boni E. Elewski et al., *Journal of Clinical Aesthetic Dermatology*, 8(11): 38-42 (2015), obtained from the National Library of Medicine. Exhibit 1518(a) is served in response to Patent Owner’s objections to Exhibit 1518.

3. Attached hereto as **Exhibit 1522(a)** is a true and accurate copy of “Antifungal drugs for onychomycosis: efficacy, safety, and mechanisms of action,” Theodore Rosen et al., *Seminars in Cutaneous Medicine and Surgery: Onychomycosis- Diagnosis, Treatment, and Prevention Strategies* (Supp. 3), 35 (3S): S51-S55 (2016), available at http://www.globalacademycme.com/fileadmin/images/supplement_image/onychomycosis16/SCMS_Onycho0316.pdf, accessed on November 16, 2017. I obtained this document by going to the homepage for the Global Academy for Medical Education at <https://www.globalacademycme.com/>; entering “onychomycosis” into the search prompt in the top right corner of the webpage and clicking “Search;” clicking on the link for “Onychomycosis: Diagnosis, Treatment, and Prevention Strategies;” and at the bottom of the right hand column on the webpage, under “Download PDF(s),” clicking the pdf link for “Seminars in Cutaneous Medicine and Surgery.” Exhibit 1522(a) is a true and accurate copy of the PDF at that link. Exhibit 1522(a) is served in response to Patent Owner’s objections to Exhibit 1522.

4. Attached hereto as **Exhibit 1561(a)** is a library-stamped, true and accurate copy of Durie, D. et al., *A Realistic Approach to the Obviousness of Inventions*, 50 (3) Wm. & Mary L. Rev. 989-1020 (2008), obtained from the University of California Berkeley, Law Library. Exhibit 1561(a) is served in response to Patent Owner's objections to Exhibit 1561.

5. Attached hereto as **Exhibit 1562(a)** is a library-stamped, true and accurate copy of "The Pharmaceutical Industry – Prices and Progress," F.M. Scherer, *The New England Journal of Medicine*, 351 (9):927-932 (August 26, 2004), obtained from the University of Minnesota Bio-Medical Library. Exhibit 1562(a) is served in response to Patent Owner's objections to Exhibit 1562.

6. Attached hereto as **Exhibit 1564(a)** are true and accurate copies of chapters 1 and 3 from the *Pharmaceutical Industry Antitrust Handbook*, American Bar Association Section of Antitrust Law, 2009. Exhibit 1564(a) is served in response to Patent Owner's objections to Exhibit 1564.

7. Attached hereto as **Exhibit 1565(a)** is a true and accurate copy of "Health Insurance and the Growth in Pharmaceutical Expenditures." P.M. Danzon and M.V. Pauly, *Journal of Law and Economics*, Vol. XLV: 587- 613 (October 2002), obtained from the vendor Reprints Desk/Research Associates. Exhibit 1565(a) is served in response to Patent Owner's objections to Exhibit 1565.

8. Attached hereto as **Exhibit 1567(a)** is a true and accurate copy of Chapter 3 (entitled “The Life Cycle of a Pharmaceutical Brand”) from T. Ellery and N. Hansen, *Pharmaceutical Lifecycle Management*, (Wiley: New Jersey), 2012. Exhibit 1567(a) is served in response to Patent Owner’s objections to Exhibit 1567.

9. Originally filed **Exhibit 1580** is a true and accurate copy of “Inside the Secret World of Drug Company Rebates,” M. Herper, *Forbes*, May 10, 2012, available at <https://www.forbes.com/sites/matthewherper/2012/05/10/why-astrazeneca-gives-insurers-60-discounts-on-nexiums-list-price/2/#7fd663de6ec5>, last accessed on October 30, 2017.

10. Attached hereto as **Exhibit 1589(a)** is a true and accurate copy of Chapter 16, entitled “Product Differentiation, Market Structure, and Competition,” pp. 572-611, from, F.M. Scherer and D. Ross, *Industrial Market Structure and Economic Performance*, (Houghton Mifflin: Boston) 1990. Exhibit 1589(a) is served in response to Patent Owner’s objections to Exhibit 1589.

11. Attached hereto as **Exhibit 1601(a)** is a library-stamped, true and accurate copy of “Returns on Research and Development for 1990s New Drug Introductions,” H. Grabowksi, J. Vernon, and J. A. DiMasi, *PharmacoEconomics*, 20 (Supp. 3): 11-29 (2002), obtained from the University of Wisconsin, Pharmacy

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