

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 LISA N. PHILLIPS 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 1672
IPR Petition for
U.S. Patent No. 7,214,506

I, Lisa N. Phillips, declare and state as follows:

I am a member of the Bar of the District of Columbia and a Partner 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. Originally filed **Exhibit 1515** is a true and accurate copy of Label for Kerydin[®] (tavaborole) topical solution, 5%, Anacor Pharmaceuticals, Inc., NDA 204-427, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/204427s000lbl.pdf, last accessed November 15, 2017. I obtained this document by going to the United States Food and Drug Administration (“FDA”) website at <https://www.fda.gov/>; clicking on the tab labeled “Drugs” at the top of the page; under “Spotlight” on the right side of the page, clicking “Search Drugs@FDA;” entering “Kerydin” into the search prompt and clicking “Search;” clicking on the drop-down tab labeled “Approval Date(s) and History, Letters, Labels, Reviews for NDA 203567;” and under “Original Approvals or Tentative Approvals,” clicking the link for “Label.”

Exhibit 1515 is a true and accurate copy of the PDF document that appeared at that link.

2. Originally filed **Exhibit 1516** is a true and accurate copy of Label for Diflucan[®] (fluconazole) tablets, Pfizer Inc., NDA 19-949, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/019949s041,019950s043,020090s0221bl.pdf, last accessed November 15, 2017. I obtained this document by going to the FDA website at <https://www.fda.gov/>; clicking on the tab labeled “Drugs” at the top of the page; under “Spotlight” on the right side of the page, clicking “Search Drugs@FDA;” entering “Diflucan” into the search prompt and clicking “Search;” clicking on “Diflucan” and then “Diflucan (FLUCONAZOLE)” for the oral tablet; clicking on the drop-down tab labeled “Approval Date(s) and History, Letters, Labels, Reviews for NDA 203567;” and in the line for “SUPPL-67” under “Supplements,” clicking the link for “Label.” Exhibit 1516 is a true and accurate copy of the PDF document that appeared at that link.

3. Originally filed **Exhibit 1517** is a true and accurate copy of Label for Sporanox[®] (itraconazole) capsules, Janssen Pharmaceutical Company, NDA 20-083, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020083s048s049s0501bl.pdf, last accessed November 15, 2017. I obtained this document by going to the FDA website at <https://www.fda.gov/>; clicking on the tab labeled “Drugs” at the

top of the page; under “Spotlight” on the right side of the page, clicking “Search Drugs@FDA;” entering “Sporanox” into the search prompt and clicking “Search;” clicking on “Sporanox” and then “SPORANOX (ITRACONAZOLE)” for the oral capsule, NDA 20083; clicking on the drop-down tab labeled “Approval Date(s) and History, Letters, Labels, Reviews for NDA 203567;” and in the line for “SUPPL-60” under “Supplements,” clicking the link for “Label.” Exhibit 1517 is a true and accurate copy of the PDF document that appeared at that link.

4. Originally filed **Exhibit 1523** is a true and accurate copy of Kaken Research & Development Division: R&D Pipeline, available at http://www.kaken.co.jp/english/business/rd_pipeline.html, last accessed on October 30, 2017. I obtained this document by going to the Kaken website at <http://www.kaken.co.jp/english/>; clicking on the tab labeled “Business” in the top right corner of the page; clicking on the tab labeled “Research & Development Division;” and then clicking on “R&D Pipeline.” Exhibit 1523 is a true and accurate copy of the webpage that appeared.

5. Originally filed **Exhibit 1524** is a true and accurate copy of “Leaked Documents Shed Light on the Defunct Pharmacy that Brought Valeant to its Knees.” M. Turner and L. Lopez, *Business Insider*, Nov. 8, 2016, available at <http://www.businessinsider.com/leaked-valeant-documents-show-phildor-strategy-2016-11>, last accessed on October 30, 2017.

6. Originally filed **Exhibit 1525** is a true and accurate copy of “Pharmacy’s Sales Tactics Disclosed,” J. Rockoff and J. Whalen, Oct. 28, 2015, available at <https://www.wsj.com/articles/pharmacys-sales-tactics-disclosed-1446075817>, last accessed on October 30, 2017.

7. Originally filed **Exhibit 1526** is a true and accurate copy of Valeant Pharmaceuticals International, Inc., Investor Conference Call Presentation, October 26, 2015, available at <http://ir.valeant.com/~media/Files/V/Valeant-IR/reports-and-presentations/10-26-15-investor-presentation.pdf>, last accessed on October 28, 2017. I obtained this document by going to the Valeant Investor Relations website at <http://ir.valeant.com/>; hovering the mouse over the tab on the top of the page labeled “Investor Relations” and then clicking the link below for “EVENTS AND PRESENTATIONS;” clicking on the tab for “2015” under the heading “Past Events;” and, finally, clicking the PDF link for “Valeant Investor Call” dated 10/26/2015. Exhibit 1526 is a true and accurate copy of the PDF that appeared at that link.

8. Originally filed **Exhibit 1527** is a true and accurate copy of “Valeant and Pharmacy More Intertwined than Thought.” J. Rockoff and J. Whalen, *Wall Street Journal*, October 25, 2015, available at <https://www.wsj.com/articles/valeants-ties-to-pharmacy-scrutinized-1445817449>, last accessed on October 30, 2017.

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