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 IPR2017-00190[1]
Patent 7,214,506 B2

DECLARATION OF AYDIN H. HARSTON IN SUPPORT OF PETITIONER'S RESPONSE TO PATENT OWNER'S OBJECTIONS TO EVIDENCE

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

I, Aydin H. Harston, declare and state as follows:

I am a member of the Bar of the District of Columbia and an attorney 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, served on November 8, 2017. 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 1504(a)** is a true and accurate copy of Administrative and Correspondence Documents, Application Number 203567Orig1s000, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/203567Orig1s000Admincorres.pdf, last accessed on 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 "Jublia" 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;" under "Original Approvals or Tentative Approvals," clicking the link for "Review;" and, finally, clicking "Administrative Document(s) &

Correspondence" at the bottom of the list on the final page. Exhibit 1504(a) is a true and accurate copy of the PDF document that appeared on the FDA's website. I note that these documents are communications between Dow Pharmaceutical Sciences (acquired by Valeant Pharmaceuticals International, Inc.) and the FDA and, presumably, are available to Patent Owners. Exhibit 1504(a) is served in response to Patent Owner's objections to Exhibit 1504. Exhibit 1504 is the Meeting Minutes for IND 77732, Division of Dermatology and Dental Products: Office of Drug Evaluation III (2012), which appears on pages 108-132 of Exhibit 1504(a). Originally filed Exhibit 1504 is a true and accurate copy of pages 108-132 of Exhibit 1504(a).

2. Originally filed **Exhibit 1512** is a true and accurate copy of "Dermatologic conditions of the foot," authored by Lucia Seminario-Vidal, Wendy Cantrell, DNP, and Boni E. Elewski, MD, *Orthopaedic Knowledge Online Journal 2014*, 12(8), located at https://www.aaos.org/OKOJ/vol12/issue8/FOO060/, last accessed October 31, 2017.

3. Attached hereto as **Exhibit 1514(a)** is a library-stamped copy of "Pharmacokinetics of antimycotics with emphasis on local treatment." Ulrich Tauber, in *Antifungal Drugs* (Vassil St. Georgiev ed.), 544: 414-426 (1988), obtained from the University of California at Berkeley. Exhibit 1514(a) is served in response to Patent Owner's objections to Exhibit 1514.

4. Originally filed **Exhibit 1519** is a true and accurate copy of Label for Lamisil® (terbinafine) DermGel™, 1% Gel, Jock Itch Product 6g Tube. Novartis Consumer Health, Inc., NDA 21-958, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021958lbl.pdf, last accessed on 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 "Lamisil" into the search prompt and clicking "Search;" clicking on "LAMISIL AT" and then "LAMISIL AT (TERBINAFINE) for the topical gel; 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 1519 is a true and accurate copy of the PDF document that appeared at that link on the FDA's website.

5. Attached hereto as **Exhibit 1520(a)** is a true and accurate copy of Approval Package for Application Number ANDA 77-511, dated July 2, 2007, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2007/077511Orig1Approv_Part1.pdf, last accessed Nov. 16, 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 "77511" into the search prompt and clicking "Search;" clicking on the drop-down tab labeled "Approval Date(s) and History, Letters, Labels, Reviews for ANDA 077511;" and under "Original Approvals or Tentative Approvals," clicking the link for "Review." Exhibit 1520(a) is a true and accurate copy of the PDF document that appeared at that link. Originally filed **Exhibit 1520** is the Label for Terbinafine Hydrochloride Cream, 1%, which displays labeling information similar to that on pages 15-22 of Exhibit 1520(a). Exhibit 1520(a) is served in response to Patent Owner's objections to Exhibit 1520.

6. Originally filed **Exhibit 1521** is a true and accurate copy of Final Printed Labeling for Center for Drug Evaluation and Research Application No. 21-022, Penlac™ Nail Lacquer (Ciclopirox) Topical Solution, 8%, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/99/21-022_Penlac%20Nail%20Lacquer%20Tropical%20Solution_prntlbl.pdf, last accessed on Nov. 16, 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 "Penlac" into the search prompt and clicking "Search;" clicking on the drop-down tab labeled "Approval Date(s) and History, Letters, Labels, Reviews for NDA 021022;" under "Original Approvals or Tentative Approvals," clicking the

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