

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<sup>1</sup>  
Patent 7,214,506 B2

---

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

<sup>1</sup> Case IPR2017-01429 has been joined with the instant proceeding.

ACRUX DDS PTY LTD. et al.  
EXHIBIT 1671  
IPR Petition for  
U.S. Patent No. 7,214,506

I, John C. Staines, Jr., declare and state as follows:

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. On November 1, 2017, I submitted a declaration (Exhibit 1511) that Petitioners in this matter, Acrux DDS Pty, Ltd. and Acrux, Ltd. (collectively, “Acrux”) retained me to prepare concerning whether or not the fungal toenail treatment, Jublia<sup>®</sup>, is a commercial success as that determination relates to the obviousness of U.S. Patent Number 7,214,506 (“the ’506 patent”), and the extent to which any such commercial success may have a causal nexus to the unique features claimed by the ’506 patent. A copy of my curriculum vitae has been submitted as Attachment A to Exhibit 1511.

2. I have been asked by Rothwell, Figg, Ernst & Manbeck PC, Acrux’s counsel, to provide further information relating to the exhibits I discussed and relied upon in my previous declaration to develop the opinions set forth in that declaration. These exhibits consist of several different types of documents I reviewed to inform those opinions. I make this present declaration based on my personal knowledge.

3. During the course of developing the opinions expressed in my previous declaration, I performed research into Valeant Pharmaceuticals

International Inc.'s ("Valeant") business practices as they related to the sales of Jublia<sup>®</sup>, which is relevant to the determination of whether or not Jublia<sup>®</sup> is a commercial success (both as to the significance of Jublia<sup>®</sup>'s sales and whether those sales have a nexus to the '506 patent). My research led me to several sources of information including online articles pertaining to the relevant time period that described, among other things, those business practices and their later consequences. Among these sources were articles written for and available from various business and financial websites (such as Business Insider, Reuters, Forbes, Fortune, Financial Times, Citron Research, and Bloomberg) as well as newspapers, such as The New York Times, The Wall Street Journal, The LA Times and the San Francisco Gate. *See* Exhibits 1524-1525, 1527-1528, 1530-1534, 1539-1549, 1555, 1557-1560, 1607, 1627, 1632-1634. As it is my understanding that Patent Owners did not provide materials regarding Valeant's relationship with its specialty pharmacy Philidor Rx Services, LLC, or with its current retail partner, Walgreens Co., I obtained this information from publicly-available sources to provide access to relevant facts I required to inform my opinions. In particular, the information relating to the business practices employed to sell Jublia<sup>®</sup> is, in my opinion, directly relevant to the determination of whether or not the drug was (or is) a commercial success. I, and others in the economic field, routinely use business and financial websites and publications as well as news outlet sources to

collect the relevant factual information necessary for reliable economic analysis and to inform the development of fact-based expert opinions.

4. In addition to the sources identified above, I also looked to Patent Owner's (Valeant's and Kaken Pharmaceuticals Co., Ltd. ("Kaken")) own public information to inform my opinions regarding, among other things, Jublia<sup>®</sup>'s quarterly net sales revenues, the Jublia<sup>®</sup> sales practices employed during the relevant time period, various expenditures made in support of those sales, and expenditures made to obtain approval of, and sales rights to, the product. Specifically, these corporate sources of public information included information available from Kaken's corporate website (*see*, Exhibits 1523, 1590, 1646-1651), Valeant's filings with the United States Securities and Exchange Commission ("SEC") (*see*, Exhibits 1553-1554, 1587-1588, 1603-1604, 1630), Valeant's investor and financial results presentations (*see*, Exhibits 1526, 1570-1575, 1578-1579, 1591-1593, 1608, 1610-1612, 1618), transcripts from various Valeant investor calls reporting its financial results (*see*, Exhibits 1529, 1569, 1576, 1582-1586, 1598, 1600, 1658-1660), Valeant's promotion of Jublia<sup>®</sup> (Exhibit 1631) and Valeant's press releases (*see*, Exhibits 1552, 1556). As both Kaken and Valeant are public companies, it is my experience that information relevant to company financials, updates on sales performance of various products and associated information are set forth in SEC filings and other publicly-available financial

statements and are discussed during financial results disclosure calls and presentations to investors and/or potential investors. It is my understanding that Patent Owners refused to provide information relating to, at least, the gross to net sales revenue adjustments applicable to Jublia<sup>®</sup> and the costs associated with Jublia<sup>®</sup>'s sales. To address these deficiencies, I sought out publicly available information originating from Patent Owners (as well as other information relevant to my opinions that Patent Owners had shared with the public) to inform my opinions. I typically rely on such information to inform my expert opinions.

5. I also sought publicly-available information from sources outside of Patent Owners to identify various facts relating to marketing expenditures committed in support of Jublia<sup>®</sup>. These included online articles and information from outlets that report and analyze marketing expenditures, including, specifically, direct-to-consumer marketing of branded pharmaceuticals. *See*, Exhibits 1594-1596, 1609. As this information was not provided by Patent Owners when requested, I obtained it through these public sources as well as through Patent Owner's own public information discussed above. I also typically rely on these types of information to inform my opinions.

6. In connection with my opinions I analyzed the information and testimony provided by Mr. Vincent A. Thomas, CPA, CVA, CFF, ABV, Patent Owner's witness regarding Jublia<sup>®</sup>'s alleged commercial success and its alleged

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.