Paper No. ___
Filed: December 22, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD., ACRUX LIMITED, and
ARGENTUM PHARMACEUTICALS LLC,
Petitioners,

v.

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

Case: IPR2017-00190[1]
U.S. Patent No. 7,214,506

PATENT OWNER'S MOTION FOR OBSERVATIONS ON THE CROSS-EXAMINATION OF JOHN C. STAINES, JR.

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

Pursuant to the Scheduling Order (Paper No. 13), Patent Owner submits this Motion for Observations on the Cross-Examination of Petitioner's expert John C. Staines, Jr.

Observation #1: In Exhibit 2116 at 15:21-20:1, particularly 18:12-19, Mr. Staines testified that the materials he cited to contend that Valeant secretly owned Philidor "does not say that." This is relevant to Mr. Staines's evaluation of Jublia's commercial success in his declaration, specifically his statements and conclusions regarding the effects of fulfillment practices through Philidor on Jublia's sales revenue. (Ex. 1511 at ¶¶ 12 and 20-54; *see also* Petitioner's Reply, Paper No. 37 ("Reply") at 21-22.) The testimony speaks to the weight and credibility the Board should afford to Mr. Staines's conclusions about Philidor's impact on revenue because it raises concerns about his source material.

Observation #2: In Exhibit 2116 at 20:7-21:11, Mr. Staines testified that his declaration cites to articles reporting on investigations into Philidor's fulfillment practices but he is not aware of an outcome from any investigation. This testimony is relevant to the statements in Mr. Staines's declaration and in the Reply regarding the commercial success of Jublia, specifically the impact of Philidor on Jublia's sales volumes. (Ex. 1511 at ¶¶ 7, 12-17, and 20-54; *see also* Reply at 21-22). The

testimony speaks to the weight and credibility the Board should afford to Mr. Staines's statements and conclusions about Philidor and its alleged conduct, as it raises concerns about whether those statements are speculative and unsubstantiated.

Observation #3: In Exhibit 2116 at 22:16-23:20, 27:12-29:22, and 142:2-7, Mr. Staines testified that fulfillment through Philidor involved actual supply of Jublia prescriptions to patients but it was appropriate to remove or discount those sales in his declaration even though he had "seen no document" showing Philidor sales were unprofitable. Mr. Staines also testified that he was not sure whether the sales and prescription data he evaluated in his declaration included or excluded fulfillment through Philidor. (*Id*. at 150:8-12.) This testimony is relevant to the statements in Mr. Staines's declaration regarding the commercial success of Jublia, specifically the impact of Philidor sales on revenue and profit. (Ex. 1511 at ¶ 53.) It speaks to the weight the Board should afford Mr. Staines's statements and conclusions about the number and profitability of Philidor sales to the extent he lacked supporting evidence for those statements.

Observation #4: Mr. Staines testified in Exhibit 2116 at 89:7-94:17 that he created Staines Exhibit 7a by assuming that the Jublia data he reviewed included

Philidor sales, estimating how much revenue those sales generated, and then replacing them with an average number generated from sales in other years. Using his estimated numbers, Mr. Staines testified that he calculated net sales of 343 million dollars. (*Id*. at 95:3-8 and 95:17-96:8.) This is relevant to statements and conclusions in Mr. Staines's declaration about commercial success, specifically Jublia's profitability with and without Philidor sales. (Ex. 1511 at ¶¶ 12, 15, 44, 53, Staines Exs. 7a, 7b, 9a and 9b; *see also* Reply at 21-22). The testimony speaks to the weight the Board should afford Mr. Staines's economic analysis because it is based on assumptions about the impact of Philidor sales on financial results.

Observation #5: In Exhibit 2116 at 98:18-100:14 and 102:12-21, Mr. Staines testified that a profit analysis was needed to evaluate the commercial success of Jublia. However, Mr. Staines also testified that he applied a commercial success test, looking at sales volume, in his declaration. Ex. 2116 at 32:3-33:3; *see also* 30:7-13. This is relevant to statements and conclusions in Mr. Staines's declaration explaining the tests he used to evaluate commercial success. (Ex. 1511 at ¶¶ 18, 25, and 36; *see also* Reply at 22). The testimony speaks to the weight and credibility the Board should afford to Mr. Staines's conclusions because it raises concerns about what legal standard should apply when evaluating commercial

success, or even which standard he chose to use at different points in his declaration.

Observation #6: In Exhibit 2116 at 34:13-38:3 and 79:2-80:2, Mr. Staines testified that generic and other competitor products were available when Jublia launched but he was not sure whether sales of 500 million dollars in a market facing generic competition was "significant" or "high." This is relevant to the statements and conclusions in Mr. Staines's declaration evaluating commercial success, specifically his assertion that Jublia benefited from a lack of competition in the onychomycosis market and did not produce high revenue. (Ex. 1511 at ¶¶ 21 and 22). The testimony speaks to the weight and credibility the Board should afford to Mr. Staines' conclusions about whether Jublia generated sufficient revenue to demonstrate commercial success, as it raises concern as to whether Mr. Staines provided a proper market comparison.

Observation #7: In Ex. 2116 at 41:10-46:2 and 60:5-17. Mr. Staines testified that among the competition Jublia faced was Kerydin, a drug which he stated did not have comparable sales revenue or market share despite offering similar sales discounts to Jublia. Mr. Staines also testified that he compared Jublia sales to those of another competitor, Lamisil, during a time period when that drug did not

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