

PUBLIC VERSION

Paper ___
Filed: December 22, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

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

Case IPR2017-00190¹
Patent 7,214,506 B2

**PETITIONERS' MOTION TO EXCLUDE EVIDENCE SUBMITTED
BY PATENT OWNER UNDER 37 C.F.R. § 42.64(c)**

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

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37 C.F.R. § 42.64(c).....1

I. INTRODUCTION

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c), Acrux DDS PTY Ltd., Acrux Limited, and Argentum Pharmaceuticals LLC (collectively, “Petitioners”) hereby submit this motion to exclude paragraphs 9-11 and 20-30 of the Declaration of Vincent A. Thomas, CPA, CVA, CFF, ABV (Exhibit 2028) and certain supporting evidence (Exhibits 2093, 2095, 2098, and 2099), filed by Kaken Pharmaceutical Co., Ltd. and Valeant Pharmaceuticals International, Inc. (collectively, “PO”) in support of the Patent Owner Response (“POR”).

II. PARAGRAPHS 9-11 AND 20-30 OF EXHIBIT 2028 SHOULD BE EXCLUDED

PO relied on Mr. Thomas’s declaration testimony in support of its assertion that Jublia[®] is a commercial success. POR, at 63-64. Petitioners timely objected to Exhibit 2028 as, *inter alia*, conclusory and unsupported by sufficient facts or data under Fed. R. Evid. 702. Paper 28, at 7.

Mr. Thomas relies on two alleged bases as support for his opinions that Jublia[®] is a commercial success. *First*, Mr. Thomas relies on alleged gross sales and gross sales market share of Jublia[®] to support his opinion. However, he was not provided with relevant facts regarding those sales, including, *inter alia*, any of the costs associated with those gross sales such as marketing and advertising costs, or the actual realized selling price of Jublia[®]. *Second*, Mr. Thomas asserts that

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Jublia[®] “shifted the market for onychomycosis treatment from oral to topical therapy, with only 19% of patients using topical treatments in 2013 to over 50% in 2015, Jublia[®]’s first full year on sale.” Exhibit 2028, ¶ 9. However, Mr. Thomas did not consider relevant factors that drove Jublia[®]’s total prescription numbers. *See* Section III.A., below.

Further, in rendering his opinions relating to the gross dollar sales and the market share and penetration of Jublia[®], Mr. Thomas did not collect or supervise the collection of the underlying data, but, instead, relied on information provided by PO’s counsel. Mr. Thomas has no idea how that data was collected or whether it is complete or even accurate and PO has provided no evidence to Petitioners that such information was supplied to him. Thus, his opinions are of no probative value. *See* Section III.B., below.

Finally, Mr. Thomas offers the conclusory opinion that the sales of Jublia[®] have a nexus to the ’506 patent and are not driven by marketing or advertising. Exhibit 2028, ¶¶ 23-30. However, Mr. Thomas admitted that, in forming that opinion, he was neither informed about, nor did he consider, the effect of PO’s blocking patents. Nor did Mr. Thomas consider – or even request – Jublia[®]’s marketing and advertising costs. His opinion that “the marketing spend for Jublia[®] is consistent with other companies’ advertising costs on comparable branded

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