

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: IPR2017-00190¹
U.S. Patent No. 7,214,506

PATENT OWNER'S MOTION TO STRIKE

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

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I. INTRODUCTION

In an end-run around the Office's Rules, Petitioner's Reply (Paper 37; "Reply") includes three new declarations, totaling nearly 50,000 additional words, and 162 further exhibits, amounting to over 5,000 new pages of information. The Reply does little to assist the Board in sifting through this data dump, because it improperly cites vast chunks of the declarations to support broad generalities rather than identifying specific arguments with particularity. In fact, large portions of the new declarations, and most of the new exhibits, are *never cited at all in the Reply*.

Not only is Petitioner's data dump prohibited by the Rules, it creates a misleading, bloated record that severely hinders the Board's and Patent Owner's ability to evaluate (or even discern) the arguments and evidence Petitioner intends to use in this proceeding. Petitioner relies on this evidence overload to raise a new legal theory that should have been in the Petition. If left in the record, the Federal Circuit will assume that the evidence was properly considered, when it had not, prejudicing Patent Owner.

II. BASES FOR STRIKING EXHIBITS AND ARGUMENTS

After the Board instituted trial, Patent Owner's Response demonstrated various fatal flaws in the Petition. These included objective, real-world evidence of non-obviousness and Petitioner's improper reliance on an expert lacking familiarity with methods of treating onychomycosis. In an attempt to overcome

these deficiencies, Petitioner improperly overwhelmed the record with new expert declarations, numerous new exhibits, and a new legal theory to which Patent Owner will not have any opportunity to respond.

To get this new material in the record, Petitioner's Reply circumvents the word limit by pushing most of its evidence and argument into declarations that are not cited with particularity. Rather, Petitioner incorporates by reference into the Reply large sections of its declarations without explaining their specific relevance. Such incorporation of large and non-specific sections of declarations is a particularly egregious and Board-recognized violation of the rules. 37 C.F.R. § 42.6(a)(3); *see Elec. Arts Inc. v. Terminal Reality, Inc.*, IPR2016-00929, IPR2016-00930, No. 50, at 37 (PTAB Oct. 19, 2017) (finding that the petitioner's citation of two expert declarations by citation to "Ex. 1003, 250-51; Ex. 1023 ¶¶ 4-22, 32," did not provide a persuasive argument in its Reply regardless of the additional detail in the cited declarations).

Petitioner's misuse of its new declarations does not stop there. Petitioner also uses the declarations as the sole vehicle for introducing most of its other new exhibits in violation of 37 C.F.R. § 42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another document."). This indirect incorporation of exhibits is clearly contrary to the requirement to identify "specific portions of the evidence that support the challenge" and explain their

relevance with particularity in the Reply. 37 C.F.R. § 42.104(b)(5). The Board may exclude or give no weight to such vaguely cited evidence. *Id.*

Moreover, a Reply may only respond to arguments raised in Patent Owner's Response and not include new evidence that could have been presented earlier. Office Patent Trial Practice Guide ("TPG"), 77 Fed. Reg. 48756, 48767 ("[A] reply that raises a new issue or belatedly presents evidence will not be considered and may be returned. The Board will not attempt to sort proper from improper portions of the reply."). Yet Petitioner raises a new legal theory and introduces a new supporting declaration to buttress the inadequacies of its original Petition.

Petitioner's failure to comply with the rules damages the efficiency and integrity of this proceeding, prejudicing both the Board and Patent Owner. Both must now approach the final stages of this proceeding without any clear sense of how Petitioner intends to use its vast array of new evidence. In fact, during the Parties' November 16 conference with the Board ("the Call"), Petitioner tacitly admitted as much, suggesting the Board should fill in the missing citations by lining up section headings between the Reply and corresponding, large sections of the declarations. Petitioner also suggested that the Board should determine the relevance of over a hundred vaguely or indirectly cited exhibits by reading all of them. That burden, however, rests with the Petitioner—not the Board or Patent Owner.

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