

Paper No. ____
Filed: November 8, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD. & ACRUX LIMITED
Petitioners,

v.

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

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

**PATENT OWNER'S OBJECTIONS
TO EVIDENCE SUBMITTED WITH PETITIONER'S REPLY
PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

Pursuant to 37 C.F.R. § 42.64(b)(1), Kaken Pharmaceutical Co., Ltd. and Valeant Pharmaceuticals International, Inc. (collectively “Patent Owner”) hereby object to the admissibility of the following evidence submitted by Acrux DDS PTY Ltd. and Acrux Limited (collectively “Petitioner”) with Petitioner’s Reply to Patent Owner’s Response (Paper No. 37) (“PR”).

In a clear end-run around the 5,600-word limit that 37 C.F.R. § 42.24 (c)(1) imposes, Petitioner’s Reply uses three new declarations, totaling nearly 50,000 additional words, to present new arguments and introduce new evidence in an improper attempt to cure deficiencies in the Petition. Petitioner’s efforts to undermine the regulations are most readily evidenced by one of its new declarations, Ex. 1510, which is from an entirely new expert declarant and attempts to fill the void created by Petitioner’s original declarant, Dr. Walters. Petitioner’s original declarant is clearly not one of skill in the art and is not qualified to opine on the claimed subject matter, as explained in Patent Owner’s Response.

Not only does Petitioner present three new declarations in an attempt to avoid the word limit, but the substance of those declarations is barely captured by Petitioner’s Reply and is almost never explained with any particularity. For example, Petitioner’s Reply commonly cites to large blocks of Dr. Walters’ new 20,000-word declaration without any specificity. *See, e.g.*, PR at 9 (citing Ex. 1509, §§ IV.C, XII-XIII (35 paragraphs)), 13 (citing Ex. 1509, §§ XIII-X (22

paragraphs)). In fact, only five out of 134 paragraphs are ever cited directly and more than forty are never cited at all (*i.e.*, §§ I-IV.A, XI, XIV, XV). Petitioner uses this same inappropriate bulk citation strategy for the other two declarations, Exhibits 1510 and 1511. *See, e.g.*, PR at 20 (citing Ex. 1510, § X (twelve paragraphs)), 21-22 (citing Ex. 1511, ¶¶ 20-54). Petitioner never cites significant portions of these additional declarations at all. *See generally* PR (never citing Ex. 1510 §§ I-V, VI.A, VI.C, VII-IX, XI; and never citing Ex. 1511 ¶¶ 1-19, 55-60, 72-77).

Petitioner's improper efforts do not end there. Petitioner also cites more than 150 *new* exhibits in its three new declarations, amounting to more than 5,000 additional pages of material. Almost none of these new exhibits are even cited in the Reply, much less described with any reasonable specificity. In large part, the new exhibits are also not actually relevant to any of the issues at bar. Tellingly, Petitioner fails to even cite most of them in their Reply, demonstrating either that they are trying to avoid the required word limit or that they have no bearing on the issues in this proceeding. In fact, Petitioner's Reply manages to cite just ten of the new exhibits. These exhibits are used to raise new arguments that could have been raised in the Petition or to introduce arguments that are not responsive to Patent Owner's Response. Patent Owner is therefore prejudiced by Petitioner's blatant attempt to avoid the limits set out in 37 C.F.R. § 42.24 (c)(1).

Accordingly, Petitioner's Reply and the evidence submitted therewith represent a flagrant effort to avoid the practice rules clearly limiting the scope of Petitioner's Reply.

Evidence Submitted by Petitioner	Patent Owner's Objection(s)
1500-1503	Exhibits were marked during the cross-examination of Dr. Boni Elewski, Patent Owner's declarant in this proceeding. Patent Owner's objections are already of record in the transcript.
1504	<p>Exhibit was marked during the cross-examination of Dr. Boni Elewski, Patent Owner's declarant in this proceeding. Patent Owner's objections are already of record in the transcript.</p> <p>Patent Owner notes that the pagination of Exhibit 1504 indicates that the document is incomplete (FRE 106). Specifically, pages 2, 24, and 25, are missing, as are all of attachment 1 and page 2 of attachment 2.</p>
1505	<p>Exhibit was marked during the cross-examination of Dr. Boni Elewski, Patent Owner's declarant in this proceeding. Patent Owner's objections are already of record in the transcript.</p> <p>Exhibit is inadmissible as not relevant and unfairly prejudicial (FRE 401, 402, 403) because it is used in the Reply brief to raise new arguments that could have been raised in the Petition and/or to introduce arguments that are not responsive to Patent Owner's Response. <i>See also</i>, 37 C.F.R. § 42.23(b).</p>
1506-1508	Exhibits are copies of the trial transcripts of the cross-examination of Yoshiyuki Tatsumi, Vincent Alexander Thomas, and Boni E. Elewski, Patent Owner's declarants in this proceeding. Patent Owner objections are already of record in the transcripts.
1509	Exhibit is inadmissible as lacking foundation, assuming facts not in evidence, conclusory, unsupported by sufficient facts or

Evidence Submitted by Petitioner	Patent Owner's Objection(s)
	<p>data, and containing testimony concerning several exhibits for which authentication is lacking.</p> <p>Exhibit is inadmissible under Rules 401/402 (lack of relevance) and Rule 403 (misleading, confusing, unfair prejudice, waste of time, needlessly cumulative) for providing opinions that Petitioner elected not to rely on in the Reply brief.</p> <p>Exhibit is inadmissible for reliance on hearsay documents (FRE 801, 802, 803, 805) to the extent the relied-upon documents are used to prove the truth of the matters asserted therein. Neither the Exhibit nor the underlying documents themselves qualify for any hearsay exception, including use by an expert.</p> <p>¶¶ 80,81, 86-90, 92-93, and 120-122 include conclusory statements and lack explanation for the bases of the stated opinions. There is inadequate information establishing that these statements / opinions rely on sufficient facts or data, that they are the product of reliable principles and methods, and/or that they reliably apply those principles and methods to the facts. FRE 702 and 703.</p> <p>¶¶ 24, 26, 65, 66, 69, 71, 73, 91, 98, and 115 provide improper opinions by raising new arguments and relying on exhibits in ways that do not appear in the Petition or Ex. 1005 and are not responsive to any positions raised in Patent Owner's Response. Thus, they are untimely and irrelevant to any issue in this IPR and are also inadmissible as unfairly prejudicial. They are used in Petitioner's Reply brief to raise new arguments that could have been raised in the Petition and/or to introduce arguments that are not responsive to Patent Owner's Response. Any future reliance on these opinions would be, among other things, unduly prejudicial, misleading, and a waste of the Board's time. FRE 401, 402, 403; 37 C.F.R. § 42.23(b); <i>see, e.g., In re NuVasive, Inc.</i>, 841 F.3d 966, 972-3 (Fed. Cir. 2016).</p>
1510	Exhibit is inadmissible as lacking foundation, assuming facts

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