

Filed on behalf of: Acrux DDS PTY LTD.
Acrux Limited

Paper _____
Filed: August 8, 2017

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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
Patent No. 7,214,506

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

Pursuant to 37 C.F.R. § 42.64(b)(1), Acrux DDS PTY Ltd. and Acrux Limited (collectively, “Petitioners”) hereby object to the admissibility of the following evidence submitted by Kaken Pharmaceutical Co., Ltd. and Valeant Pharmaceuticals International, Inc. (collectively, “Patent Owners”) with the Patent Owners’ Response (Paper No. 27) (“POR”).¹

| Evidence Submitted by Patent Owners | Petitioners’ Objection(s) |
|--|--|
| Exhibits 2001/2003 ² (Declaration of Yochiyuki Tatsumi, Ph.D.) | <p>Inadmissible as lacking foundation, assuming facts not in evidence, conclusory, and containing testimony concerning Exhibit 2004 for which authentication is lacking.</p> <p>Paragraph 8 is inadmissible as irrelevant (Fed. R. Evid. 402) to the extent it is not directed to the claimed subject matter and/or the prior art cited in the grounds on which the review was instituted.</p> <p>Paragraphs 9 through 12 are inadmissible as there is no indication that the declarant has personal knowledge of the alleged experiments described therein (Fed. R. Evid. 602) and as hearsay to the extent the testimony is being used to prove the truth of the matters asserted (Fed. R. Evid. 802).</p> |

¹ Petitioners have reasserted their Objections to Evidence Submitted with Patent Owners’ Preliminary Response (“POPR”) to preserve them.

² Petitioners list both exhibit numbers with respect to objections directed to the original Japanese language document and the corresponding English translation offered by Patent Owners.

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| | To the extent Patent Owners are introducing Dr. Tatsumi's testimony as expert opinion, it is unsupported by sufficient facts or data (Fed. R. Evid. 702). <i>See, e.g.,</i> POPR, at 19. |
| Exhibits 2002/2004 ³ | <p>Inadmissible as incomplete (Fed. R. Evid. 106) as it sets forth summaries of data allegedly obtained while not presenting all of the data obtained and its full underlying information in fairness to allow Petitioners to test its validity.</p> <p>Inadmissible as hearsay (Fed. R. Evid. 802) to the extent the document is being used to prove the truth of the matters asserted.</p> <p>Inadmissible as lacking authentication (Fed. R. Evid. 901). Patent Owner's declarant Dr. Tatsumi (Exhibit 2001/2003) does not provide sufficient</p> |

³ Although it appears Patent Owners have provided a "Corrected Research and Development Report" (Exhibit 2040, with corresponding Japanese language document at Exhibit 2039) Patent Owners have not specified what was corrected from the version filed previously as Exhibit 2004. Further, the POR cites to Exhibit 2004 and Dr. Tatsumi's Declaration in Support of the POR cites to Exhibit 2039. *Compare* POR, at 41 to Ex. 2025, at ¶¶ 14-15. To the extent Patent Owners have filed any exhibit in support of the POR in an attempt to cure the timely objections asserted in Petitioner's Objections to Evidence Submitted with the POPR, filed on May 15, 2017, they are untimely as supplemental evidence was due by or before May 30, 2017. 37 C.F.R. § 42.64(b)(2).

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| | evidence to establish that Exhibit 2004 is self-authenticating under Fed. R. Evid. 902 because there is no evidence presented to support his conclusory assertions tracking the requirements of FRE 803(6)(A)-(C). |
| Exhibits 2007, 2008, 2009, 2010 | <p>Inadmissible as unsupported expert testimony (Fed. R. Evid. 702). <i>See, e.g.</i>, POR, at 9-10, 13-16, 25-30.</p> <p>Inadmissible as hearsay (Fed. R. Evid. 802) to the extent the documents are being used to prove the truth of the matters asserted therein. <i>See, e.g.</i>, POR, at 9-10, 13-16, 25-30.</p> |
| Exhibit 2011 | <p>Inadmissible as unsupported expert testimony (Fed. R. Evid. 702). <i>See, e.g.</i>, POR, at 15, 25.</p> <p>Inadmissible as hearsay (Fed. R. Evid. 802) to the extent the document is being used to prove the truth of the matters asserted therein. <i>See, e.g.</i>, POR, at 15, 25.</p> <p>Inadmissible as lacking authentication (Fed. R. Evid. 901) as there is no indication of source accompanying the document, no witness testimony is offered to indicate its source and books are not self-authenticating under FRE 902.</p> |
| Exhibits 2012, 2013, 2014, 2015, 2016, 2017 | <p>Inadmissible as unsupported expert testimony (Fed. R. Evid. 702). <i>See, e.g.</i>, POR, at 11-13, 15-16, 23.</p> <p>Inadmissible as hearsay (Fed. R. Evid. 802) to the extent the documents are being used to prove the truth of the matters asserted therein. <i>See, e.g.</i>, POR, at 11-13, 15-16, 23.</p> |

| Evidence Submitted by Patent Owners | Petitioners' Objection(s) |
|---|---|
| Exhibit 2018 | <p>Inadmissible as unsupported expert testimony (Fed. R. Evid. 702). <i>See, e.g.</i>, POR, at 23-24.</p> <p>Inadmissible as hearsay (Fed. R. Evid. 802) to the extent the document is being used to prove the truth of the matters asserted therein. <i>See, e.g.</i>, POR, at 23-24.</p> <p>Inadmissible as lacking authentication (Fed. R. Evid. 901) as there is no indication of source accompanying the document, no witness testimony is offered to indicate its source and articles retrieved from the internet are not self-authenticating under FRE 902.</p> |
| Exhibits 2024/2025 (Declaration of Yochiyuki Tatsumi, Ph.D.) | <p>Inadmissible as lacking foundation, assuming facts not in evidence, conclusory, and containing testimony concerning several exhibits for which authentication is lacking.</p> <p>Paragraph 8 is inadmissible as there is no indication that the declarant has personal knowledge of the alleged experiments described therein (Fed. R. Evid. 602) and as hearsay to the extent the testimony is being used to prove the truth of the matters asserted (Fed. R. Evid. 802).</p> <p>Paragraphs 9, 10 and 13 are submitted in violation of 37 C.F.R. § 1.933. The information set forth in these paragraphs, as well as the Patent Owner's exhibits cited therein, should have been submitted both during prosecution of the '506 patent and earlier in this proceeding, <i>e.g.</i>, in connection with Dr. Tatsumi's Declaration submitted in support of the Patent Owner's Preliminary Response (Exhibit 2001/2003).</p> <p>Paragraph 17 is inadmissible as irrelevant (Fed. R. Evid. 402) to the extent it is not directed to the</p> |

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