

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEALS BOARD

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AMERIGEN PHARMACEUTICALS LIMITED,

Petitioner,

v.

SHIRE LLC,

Patent Owner

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Case No.: IPR2015-02009

Patent No. : Re 42,096

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**PETITIONER'S REQUEST FOR ORAL ARGUMENT**

Pursuant to the Paper #9, *Scheduling Order* at 4 and 37 C.F.R. § 42.70(a), *see also*, 35 U.S.C. 326(a)(10), Petitioner Amerigen Pharmaceuticals Limited submits this *Request for Oral Argument* on the following issues:

1. As presented in the Paper #8, *Decision, Institution of Inter Partes Review*, 37 C.F.R. § 42.108 (April 18, 2016) (“*Institution Decision*”):
  - a. Whether Claims 18–21 and 23 are invalid on the evidence of record on the basis of anticipation by Mehta<sup>1</sup>, from the Paper #8, *Institution Decision* at 25–28, 31; and
  - b. Whether Claims 18–21, 23, and 25 are invalid on the evidence of record on the basis of obviousness over Mehta and the Adderall PDR<sup>2</sup>, from the Paper #8, *Institution Decision* at 34–36
2. As presented in Paper #10, *Patent Owner’s Request for Reconsideration*, whether the *Institution Decision* instituted *inter partes* review of Claim 25 or instituted *inter partes* review of only some part less than the whole of Claim 25.
3. As presented by Petitioner’s Paper #11, *Motion Presenting Request for Rehearing Under 37 C.F.R. § 42.71(d) of Decision Denying-In-Part Institution*

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<sup>1</sup> U.S. Patent No. 5,837,284 (filed July 14, 1997) (“Mehta”) (Ex. 1003).

<sup>2</sup> PHYSICIANS’ DESK REFERENCE 331, 2209–11 (51st ed. 1997) (“Adderall PDR”) (Ex. 1004).

of *Inter Partes Review*, whether the claim language “essentially all . . . within about 60 minutes” is expressly disclosed and presumptively enabled by Mehta, without regard to inherency, as shown through the unrebutted testimony of Dr. Elder (Exhibit 1005 ¶ 283), such that the Board should reconsider (i) its denial of institution as to Claims 1–3, 5, 8–9, 11, and 25 on grounds of anticipation by Mehta, (ii) its denial of institution of Claims 1–3, 5, 8–9, and 11 on grounds of obviousness over Mehta and the Adderall PDR, and (iii) its denial of institution as to Claims 8, 9, and 11 on grounds of obviousness over Mehta, the 1997 Adderall ADR, and Rosen.

4. As presented by Paper #15, *Patent Owner’s Motion to Amend*; by Paper #17, *Petitioner’s Opposition to Motion to Amend*; and by Paper #21, *Patent Owner’s Reply to Petitioner’s Opposition to Motion to Amend*:

- a. Whether Patent Owner met its burden of showing that the proposed amended claim under its broadest reasonable interpretation would be valid over all art known to the Patent Owner, including, for example, but not limited to, art not cited in the Paper #1, *Petition for Inter Partes Review of USPN RE42,096 under 35 U.S.C. §§ 311–319 and 37 C.F.R. 42.1–42.80 and 42.100–42.123*, but otherwise disclosed to the Patent Owner in related litigation;

- b. Whether the proposed amended Claim 25 under its broadest reasonable interpretation would be valid in light of the unrebutted evidence of record teaching every limitation of proposed amended Claim 25 as it depends from Claim 2, including the claim language “essentially all . . . within about 60 minutes” as expressly disclosed and presumptively enabled by Mehta, without regard to inherency, as shown through the unrebutted testimony of Dr. Elder (*e.g.*, Exhibit 1005 ¶ 283); and
  - c. Whether the proposed amendment should be denied for Patent Owner’s failure to show good cause for its untimely filing.
5. Any issues presented in motions to exclude evidence filed in accordance with Paper #9, *Scheduling Order*.

Paper #9, *Scheduling Order*, at 6 has previously set oral argument (if requested) on the instituted claims for January 10, 2017. Petitioner requests that oral argument on all pending issues identified hereinabove be heard on that date, or at such other date and time as the Board may set.

Dated: December 9, 2016

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