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Paper No. 16
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,
Petitioners,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

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Case IPR2016-00829
Patent 9,095,559 B2

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Before TONI R. SCHEINER, DEBORAH KATZ, and
GRACE KARAFFA OBERMANN, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION
Denying Patent Owner's Request for Rehearing
37 C.F.R. § 42.71(d)

Patent Owner requests a rehearing of our decision to institute *inter partes* review of U.S. Patent 9,095,559 (Paper 13, "Decision"). Paper 15 ("Request"). When filing a request for rehearing, the challenging party bears the burden of showing the decision should be modified. 37 C.F.R.

§ 42.71(d). The request must specifically identify the matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a brief, in this case, Patent Owner's Preliminary Response. *Id*. "When rehearing a decision on petition, a panel will review the decision for an abuse of discretion." 37 C.F.R. § 42.71(c).

Patent Owner argues that we erroneously relied on the testimony of Petitioner's witness, Dr. Vaux, to supply an element of the challenged claims not otherwise taught in the prior art. Request 2. Specifically, Patent Owner argues that we improperly relied on Dr. Vaux's testimony as evidence that step (c) of its challenged claims[1] was known in the art. *Id*. 4-5. Patent Owner asserts that this is legal error, citing *Arendi S.A.R. v. Appel, Inc.*, 832 F.3d 1355 (Fed. Cir. 2016). *Arendi* warns that "references to 'common sense'—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing

[1] Claim 2 of patent 9,095,559, which Patent Owner asserts is representative, recites:

> A method of treating a subject with a urea cycle disorder who has previously been administered an initial dosage of glyceryl tri-[4-phenylbutyrate] and who has a fasting plasma ammonia level less than the upper limit of normal for plasma ammonia level, the method comprising:
>
> (a) measuring a fasting plasma ammonia level for the subject;
>
> (b) comparing the fasting plasma ammonia level to the upper limit of normal for plasma ammonia level; and
>
> (c) administering an adjusted dosage of glyceryl tri-[4-phenylbutyrate], that is greater than the initial dosage if the fasting plasma ammonia level is greater than half the upper limit of normal for plasma ammonia level.

from the prior art references specified." *Id.* at 1362.[2] In *Arendi*, the Board did not rely on any evidence to make its determination that searching for a telephone number would have been common sense. In contrast, we relied on the testimony of Dr. Vaux, who, at this point in the proceeding, we determined to be qualified to present opinions on the subject matter at issue. We did not rely on our own determination of what those of skill in the art would have considered to be common sense. We did credit Dr. Vaux's testimony and found it to be persuasive at this point in the proceeding because it seemed to be reasonable. *See* Decision 10, 11, and 15. Significantly, we relied on opinion testimony based not on any assertion of "common sense," but on a rational analysis of objective proof consisting of multiple printed publications. *See, e.g.*, Dec. 10 (citing Ex. 1002 ¶ 65 (citing printed publications, including Exs. 1006, 1012, and 1017)). Petitioner fails to cite to any place in our Decision where we relied on a determination of what is "common sense." Accordingly, we are not persuaded that we erroneously relied on Dr. Vaux's testimony or abused our discretion as Patent Owner argues.

Patent Owner also argues that the prior art of record fails to support Dr. Vaux's testimony. Request 5-6. Patent Owner argues that the prior art cited does not teach or suggest increasing the dosage or administering an initial dosage of a nitrogen scavenging drug to a patient having a fasting ammonia level below the upper limit of normal. *Id.* We stated in our Decision that we were persuaded, at this point in the proceeding, that the

[2] Patent Owner also cites *Cisco Systems Inc. v. C-CATION Techs., Inc.*, IPR2014- 00454, Paper 12, at 10-13 (PTAB Aug. 29, 2014). Because this is a non-precedential decision of the Board regarding a different patent, parties, and facts, its holding is not binding in this proceeding.

evidence cited by Dr. Vaux supports his testimony regarding variation of plasma ammonia levels at different times of the date and after eating. Decision 11, citing Ex. 1006, 1012 and 1017. We did not state that this evidence teaches increasing the dosage or administering nitrogen scavenging drugs to a patient with any particular ammonia level. Patent Owner does not argue that we misapprehended or overlooked anything about that evidence in regard to variations in plasma ammonia levels at different times of the day and after eating. Accordingly, we are not persuaded that we misapprehended or overlooked anything in our Decision.

## DECISION

For the reasons given, Patent Owner's Request for Rehearing is DENIED.

IPR2016-00829
Patent 9,095,559 B2

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