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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARAGEN BIOSCIENCE, INC.
AND
TRANSPOSAGEN BIOPHARMACEUTICALS, INC.,
Petitioner,

v.

KYOWA HAKKO KIRIN CO., LTD.,
Patent Owner.

Case IPR2017-01262
Patent 7,425,446 B2

Before JAMES T. MOORE, ERICA A. FRANKLIN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Aragen Bioscience, Inc. and Transposagen Biopharmaceuticals, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–6 of U.S. Patent No. 7,425,446 B2 (Ex. 1001, "the '446 Patent"). Paper 1. Kyowa Hakko Kirin Co., Ltd. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 8. In our Decision ("Dec.") dated October 23, 2017 (Paper 12), we determined that the information presented in the Petition and accompanying evidence did not establish a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one challenged claim of the '446 patent. Accordingly, we denied the Petition and did not institute an *inter partes* review of the '446 patent. *Id*. at 23.

Petitioner now requests rehearing of our decision not to institute trial on claims 1–6. Paper 13 ("Req. Reh'g"). For the following reasons, we deny Petitioner's Request for Rehearing.

II. STANDARD OF REVIEW

The applicable standard for a request for rehearing is set forth in 37 C.F.R. § 42.71(d), which provides in relevant part:

> A party dissatisfied with a decision may file a request for rehearing, without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

When reconsidering a decision on institution, we review the decision for an abuse of discretion. *See* 37 C.F.R. § 42.71(c). An abuse of discretion may be determined if a decision is based on an erroneous interpretation of

law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *See Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

III. ANALYSIS

As recited in independent claim 1, the challenged claims recite "[a]n isolated mammalian host cell" created "by deleting a gene encoding α1,6-fucosyltransferase or by adding a mutation to said gene to reduce or eliminate the α1,6-fucosyltransferase activity" In denying the Petition, we found that Petitioner did not establish that the prior art disclosed or rendered obvious the challenged claims because it failed to present sufficient evidence that one of ordinary skill in the art would have had access to the necessary genetic starting material. Dec. 16–21. In particular, we determined that "Petitioner fails to establish adequately that DNA encoding a mammalian α1,6-fucosyltransferase was either available, or could be routinely obtained by those of ordinary skill in the art." *Id.* at 20. According to Petitioner, our finding is "clearly erroneous" and based on "misunderstandings about the record evidence, as well as a failure to weigh, in full, unrebutted expert testimony before the Board." Req. Reh'g 1. We do not find Petitioner's argument persuasive.

First, pointing to "a critical portion of Example 12" of the Specification, Petitioner contends that we overlooked that the inventors cloned exon 2 of a mammalian FUT8 using "PCR primers based on 'a mouse FUT8 cDNA sequence (GenBank, AB025198).'" *Id.* at 4–5. (citing Ex. 1001 at 98:30–35; Dec. 4, 18–19) (emphasis omitted). Petitioner further

contends that, in light of this disclosure, the Board, in a parallel Institution Decision, "acknowledged that the FUT8 gene sequence was available as of the priority date." *Id.* We do not agree with Petitioner's characterization.

Nowhere does the Petition point us to GenBank entry AB025198—let alone suggest that it is prior art to the instant Specification. Only belatedly does Petitioner describe Exhibit 1039[1] as providing evidence that the GenBank entry relates to a genetic sequence of mouse α1,6-fucosyltransferase that was publically available prior to the earliest priority date of the '232 Patent. *Id.* at 4 & n. 3. Petitioner similarly argues that "the '446 patent specification also admits that 'human FUT8 cDNA' and 'swine FUT8 cDNA' were in the prior art," belatedly submitting Exhibits 1042[2] and 1043[3] in support of this new argument. *Id.* at 7–8 & n.5 (citing Ex. 1001, 79:53–56).

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). Because Petitioner raised none

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[1] Genbank entry AB025198.1. "Mus musculus mRNA for alpha-1,6-fucosyltransferase, complete cds," https://www.ncbi.nlm.nih.gov/nuccore/%20AB025198.

[2] Yanagidani et al., *Purification and cDNA Cloning of GDP-i-Fuc:N-acetyl-β-d-glucosaminyl fucosyltransferase (α1-6FucT) from Human Gastric CancerMKN45 Cells*, 121 J. Biol. Chem. 626-632 (1997).

[3] Naofumi Uozumi, *Purification and cDNA Cloning of Porcine Brain GDPL-Fuc:N-Acetyl-β-D-Glucosaminide α1→6Fucosyltransferase*, 271 J. Biol. Chem. 27810-27817 (1996).

of the above arguments in the Petition, nor timely submitted any of Exhibits 1038, 1041, and 1042, Petitioner has not established that we misapprehended or overlooked this evidence. *Cf. DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (Fed. Cir. 1999) ("A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record.").

Petitioner also contends that we overlooked the disclosures of Oriol (Ex. 1040) and Breton (Ex. 1041). Req. Reh'g 6. Petitioner correctly notes that "[t]he Board did not analyze these references" and that they were first submitted with Petitioner's Request for Rehearing. *Id.* at 10; *see id.* at 6, n.4. Petitioner asserts, however, that *Patent Owner* should have submitted them when it discussed Dr. Van Ness's testimony. *Id.* at 10–11.

We do not find this argument persuasive. "In an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) (quoting *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015)). Accordingly, it was Petitioner's responsibility, not Patent Owner's, to set forth arguments and submit evidence to support its Petition. And, in light of the arguments and evidence before us at the time of our Decision, Petitioner had not established that the prior art taught the availability of a mammalian FUT 8 gene sequence.

Petitioner further argues that we improperly discounted the testimony of Drs. Van Ness and Jefferis. Req. Reh'g 12–14 (citing Ex. 1007 ¶¶ 18–20, 40–43, 73; Ex. 1026 ¶¶ 38, 11–14). With respect to the latter, Petitioner points to Dr. Jefferis's statement that a person of ordinary skill in the art "would have had knowledge of the scientific literature no later than October

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