

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 IPR2017-01252  
Patent 6,946,292 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 1–12 of U.S. Patent No. 6,946,292 B2 (Ex. 1001, “the ’292 Patent”). Paper 1. Kyowa Hakko Kirin Co., Ltd. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 10. In our Decision (“Dec.”) dated October 23, 2017 (Paper 13), 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 ’292 patent. Accordingly, we denied the Petition and did not institute an *inter partes* review of the ’292 patent. *Id.* at 25.

Petitioner now requests rehearing of our decision not to institute trial on claims 1–12. Paper 14 (“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 fucosyltransferase knock-out host cell.” Consistent with Patent Owner’s position, we construed the fucosyltransferase knock-out as “a disruption of FUT8, the gene encoding  $\alpha$ 1,6-fucosyltransferase.” Dec. 13. 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. 19–24. In particular, we determined that “Petitioner fails to establish adequately that DNA encoding a mammalian  $\alpha$ 1,6-fucosyltransferase was either available, or could be routinely obtained by those of ordinary skill in the art.” *Id.* at 24. 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 portion of the Decision in which we note that the inventors cloned exon 2 of a mammalian FUT8 using “PCR primers based on ‘a mouse FUT8 cDNA sequence (GenBank, AB025198),’” Petitioner contends that “the Board acknowledged . . . the FUT8 gene sequence was

available . . . as of the priority date.” *Id.* at 4–5 (citing Dec. 5 & n.4 (citing Ex. 1001 at 97:15–20) (emphasis omitted)). 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 introduce Exhibit 1038<sup>1</sup> as evidence that the GenBank entry relates to a genetic sequence of mouse  $\alpha$ 1,6-fucosyltransferase that was publically available prior to the earliest priority date of the ’232 Patent. *Id.* Petitioner similarly argues that “the ’232 patent specification also admits that ‘human FUT8 cDNA’ and ‘swine FUT8 cDNA’ were in the prior art,” belatedly submitting Exhibits 1041<sup>2</sup> and 1042<sup>3</sup> in support of this new argument. *Id.* at 7–8 & n.4 (citing Ex. 1001, 79:62–65).

“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 of the above arguments in the Petition, nor timely submitted any of Exhibits

---

<sup>1</sup> Genbank entry AB025198.1. “Mus musculus mRNA for alpha-1,6-fucosyltransferase, complete cds,” <https://www.ncbi.nlm.nih.gov/nuccore/%20AB025198>.

<sup>2</sup> Yanagidani et al., *Purification and cDNA Cloning of GDP-i-Fuc:N-acetyl- $\beta$ -d-glucosaminyl fucosyltransferase ( $\alpha$ 1-6FucT) from Human Gastric CancerMKN45 Cells*, 121 J. Biol. Chem. 626-632 (1997).

<sup>3</sup> Naofumi Uozumi, *Purification and cDNA Cloning of Porcine Brain GDPL-Fuc:N-Acetyl- $\beta$ -D-Glucosaminide  $\alpha$ 1 $\rightarrow$ 6Fucosyltransferase*, 271 J. Biol. Chem. 27810-27817 (1996).

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. 1039) and Breton (Ex. 1040). Req. Reh’g 1. 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.3. 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, 77; Ex. 1026 ¶¶ 11–13). 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 6, 2000 concerning the means and methods for creating cells in which the gene for

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.