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Paper 48
Date: October 30, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORTE BIOSCIENCES, INC.,
Petitioner,

v.

UNIVERSITY OF MASSACHUSETTS,
Patent Owner.

PGR2023-00014
Patent 11,278,505 B2

Before GEORGIANNA W. BRADEN, ROBERT A. POLLOCK, and MICHAEL A. VALEK, *Administrative Patent Judges.*

BRADEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Procedural Background

The University of Massachusetts ("Patent Owner") timely filed a Request for Rehearing under 37 C.F.R. § 42.71(d) on July 24, 2024. Paper 46 ("Req. Reh'g"). Patent Owner's Request for Rehearing seeks reconsideration of our Final Written Decision (Paper 45, "Decision" or "Dec.") entered on June 24, 2024. Patent Owner disagrees with the Decision, alleging we overlooked that (1) Petitioner's Declarants were not competent to address § 112 compliance and (2) Petitioner failed to show a lack of written description and enablement. Patent Owner further alleges that the Board lacked authority to allow and rely upon Petitioner's Reply evidence.

For the reasons provided below, we *deny* Patent Owner's request.

II. ANALYSIS

A request for rehearing "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, a reply or sur-reply." 37 C.F.R. § 42.71(d). The party challenging a decision bears the burden of showing the decision should be modified. *Id.*

A. Petitioner's Declarants and the Evidence of Record

Patent Owner first contends the Decision overlooked "undisputed evidence" that Petitioner's Declarants (both Dr. Abbas and Dr. Plott) were not competent to address § 112 compliance because they failed to consider "more than a handful of the 300+ incorporated references or otherwise investigate[] the full state of the art with respect to the 350+ known IL-15/IL-15R inhibitors or their expected class effects." Reh'g Req. 2

(citing PO Response 30–32; Sur-Reply 7–10, 16–18; Hearing Transcript 59:1–60:7). According to Patent Owner, "[h]aving failed to consider 'existing knowledge in the particular field, the extent and content of the prior art' reflected in the art generally and the incorporated references specifically, the opinions of Drs. Abbas and Plott are not factually supported and not competent to address §112 compliance." *Id.* (citing e.g., *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)).

Patent Owner further contends the Decision overlooked the fact that Petitioner's experts did not provide testimony "from the perspective of a POSA who 'would have been familiar with well-known inhibitors of IL-15 and IL-15R as described in the '505 patent and as recognized in the art as of April 2017.'" Reh'g Req. 4 (citing Decision 7 (citing PO Response 26–27); Sur-Reply 7–10, 15–16). Patent Owner argues that "[n]either declarant addressed nor met the standard as they were not aware of and did not investigate the 350+ IL-15/IL-15R inhibitors described, collectively, in the '505 patent and in the art." *Id.* (citing PO Response 30–32; Sur-Reply 7–11; Hearing Transcript 27:4–28:11).

First, we are unpersuaded by Patent Owner's argument because Petitioner's Declarants provided testimony from the perspective of a person of ordinary skill in the art that is supported by underlying facts and data, and thus, are competent to address §112 issues. As stated in the Decision, we adopted Petitioner's level of ordinary skill in the art with Patent Owner's proposed modification because it appeared consistent with the problems addressed in the '505 patent and the prior art of record. Decision 7. Specifically, a person of ordinary skill in the art by April 24, 2017 would have had (1) an advanced degree (e.g., Ph.D., M.D., M.S., or equivalent), in a field related to medicine, immunology, molecular biology, cell biology,

microbiology, pathology, biochemistry, peptide chemistry, or a related field, (2) at least 3–5 years of experience in treating autoimmune diseases or researching cytokine signaling pathways relevant to treating autoimmune diseases, and (3) would have been familiar with well-known inhibitors of IL-15 and IL-15R as described in the '505 patent and recognized in the art as of April 2017. *Id.* Both Dr. Abbas and Dr. Plott meet these requirements. *See* Ex. 1002 ¶¶ 1–10; Ex. 1003; Ex. 1004 ¶¶ 1–8; Ex. 1005.

Second, our analysis was not premised solely on the testimonial evidence of Petitioner's Declarants. As explained in the Decision, the Board credited Petitioner's prior art evidence showing that the '505 patent lacks descriptive and enablement support for "a therapeutically effective amount of an inhibitor of IL-15 or the IL-15 receptor" as recited in claim 1 in light of: (1) the ineffective IL-15/IL-15R inhibitors identified by Petitioner in Patent Owner's own documents; (2) the unidentified structural features of the broad categories of potential IL-15/IL-15R inhibitors listed in the specification (e.g., small molecules, peptides, antibodies, or nucleic acids) necessary or sufficient to perform the claimed method; (3) the lack of information delineating how one of ordinary skill in the art would understand or determine whether any one of the cited individual inhibitors actually meets that functional requirement in the challenged claims; and (4) the unpredictability across the breadth of the claimed genera. *See* Decision 17–18 (citing Ex. 2013, 2:10–18; Ex. 2014, 2:12–20; Ex. 2015 ¶ 3; Ex. 2025, 2:10–18; Ex. 2078, 267).

That evidence directly undercuts Patent Owner's arguments regarding the alleged 350+ IL-15/IL-15R inhibitors known in the art because it demonstrates that several compounds identified by Patent Owner as inhibitors are actually ineffective and/or unpredictable in inhibiting

IL-15/IL-15R signaling. *See* Pet. 27–39 (citing Ex. 1002 ¶¶ 64–80; Ex. 1014, Abstr., 6; Ex. 1013, Abstr.; Ex. 1004 ¶¶ 43–45; Ex. 1008, 786). For example, contrary to Patent Owner's contentions, the prior art itself shows that soluble IL-15Rα molecules can inhibit IL-15 signaling and also can form complexes with IL-15, which induces a cellular response by *enhancing* IL-15 signaling (rather than inhibiting). Ex. 1047 ¶ 30; Ex. 1046, 256:15–258:4, 258:9–16; Ex. 2005 ¶ 163; Ex. 2079, 1, 5–6, 8. The enhanced IL-15 signaling limits the effectiveness of anti-IL-15 antibodies. *Id.*

Moreover, we credited Petitioner's prior art evidence that certain anti-IL-15 antibodies that inhibit IL-15 signaling *in vitro* have been shown to enhance IL-15 signaling, i.e., have the opposite effect, *in vivo*. Ex. 1047 ¶¶ 2–30; Ex. 1054, Abstr. (identifying an IL-15 antibody, DISCO280, with different responses and opposing cellular modes of actions depending on whether it was used *in vitro* or *in vivo*). All of the prior art evidence appears to support the testimonial evidence of Petitioner's Declarants. *See e.g.*, Ex. 1002 ¶¶ 29–33, 37, 54–55, 65, 68, 72–77, 86–87, 91; Ex. 1047 ¶¶ 10, 11, 19–23, 25–26, 29–30, 36, 45, 52, 54–55, 59–61, 71.

As stated in the Decision, Patent Owner's claims recite the administration of a "therapeutically effective amount" of inhibitor, but the various compounds identified in the '505 patent (as well as the additional inhibitor's Patent Owner points to in the prior art) do not exhibit a consistent, class-wide therapeutic efficacy for vitiligo treatment. *See* Dec. 18–21; Ex. 1001, 7:34–8:37; Ex. 1002 ¶¶ 67–69, 83–87, 91; Tr. 15:26–16:26. To the contrary, we explained previously, the evidence in the prior art suggests that different compounds have widely-varying and unpredictable effects on the different aspects of the pertinent biological

pathways. *See e.g.*, Ex. 1046, 256:15–258:4, 258:9–16; Ex. 2005 ¶ 163; Ex. 2079, 1, 5–6, 8. For example, administration of a particular IL-15 antibody to rhesus macaques was reported to significantly reduce tissue effector memory T cell populations but not recirculating memory T cell populations. *See* Ex. 1013, Abstr.

Accordingly, nothing presented in the Request for Rehearing persuasively cites to any misapprehended or overlooked arguments or evidence that demonstrates the opinions of Drs. Abbas and Plott are not factually supported or not competent to address §112 compliance and would warrant a different holding. Furthermore, we note that merely disagreeing with our analysis or conclusions does not serve as a proper basis for a rehearing, because it does not show an overlooked or misapprehended matter.

B. Lack of Written Description and Enablement

Patent Owner asserts a litany of contentions in an attempt to demonstrate that the Decision overlooked or misapprehended evidence showing the Petitioner failed to meet its burden in showing unpatentability under 35 U.S.C. § 112. Specifically, the Request for Rehearing argues that the Decision overlooked or misapprehended:

(1) the legal test by focusing on whether the specification discloses "a representative number of species" or "a sufficient correlation between structure and function" (Reh'g Req. 6 (citing Dec. 21–22));

(2) material differences in *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 926–27 (Fed. Cir. 2004) compared to the present case (Reh'g Req. 7 (citing Dec. 16–18));

(3) Petitioner's failure to establish the absence of a representative number of species in view of contrary evidence not considered by its declarants (*id.* at 7–8 (citing Dec. 14–22));

(4) the written description standard by relying on a few "outlier" compounds as "evidence of inconsistent and ineffective IL-15/ IL-15R inhibitors" when other compounds show otherwise (*id.* at 8 (citing Dec. 18–19));

(5) the teachings of the prior art, including Exhibits 1008, 1013, 1014, and the Petition's reliance on that art (*id.* at 9 (citing Dec. 18–21));

(6) that in finding that the "therapeutically effective" limitation lacks support, the Decision makes a new argument contradicted by the Petition (*id* at 10 (citing Dec. 17–18));

(7) Petitioner's burden to establish unpatentability (*id.* at 10 (citing Dec. 20–21));

(8) material factual distinctions (addressed above and below) to conclude that "[t]he facts of the present case are similar to the *Amgen* [*v. Sanofi*, 598 U.S. 594 (May 18, 2023)] case" because unlike the new class of compounds claimed in *Amgen* (and in *Rochester*), the claims here are directed to the use of a known class where hundreds were known, methods for making and identifying were known, and class-wide IL-15 efficacy was expected (Reh'g Req. 11 (citing Dec. 30);

(9) Petitioner's failure to rebut (i) Patent Owner's evidence of 350+ known inhibitors and their expected class effect, (ii) Patent Owner's *Wands* analysis that undue experimentation would not have been required, and (iii) the '505 patent's teachings of how to make, test, and screen compounds of the invention (*id.* at 11–12 (citing Dec. 35–36));

(10) improperly crediting incompetent testimony of Dr. Abbas and finding that IL-15/IL-15R inhibitors "are not part of a known or readily identifiable class" (*id.* at 12 (citing Dec. 34–35));

(11) the applicability of *Erfindergemeinschaft UroPep GbR v.Eli Lilly & Co.*, 276 F. Supp. 3d 629 (E.D. Tex. 2017), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018) (*UroPep* I) to the present case (*id.* at 12–13 (citing Dec. 35));

(12) Petitioner's failure to establish that the '505 patent specification does not teach how to make the IL-15/ IL-15R inhibitors in view of its disclosures that "[r]outine methods can be used to design an inhibitory nucleic acid that binds to the target sequence" and methods of screening for IL-15 inhibitors based on the known IL-15R structure (*id.* at 13–14 (citing Dec. 33));

(13) enablement does not require how to make "every inhibitor" or "every version of a compound" (*id.* at 14 (citing Dec. 32)); and

(14) that each anti-IL-15 antibody is an inhibitor of IL-15 or IL-15R, despite evidence to the contrary (*id.* at 14–15 (citing Dec. 32)).

As Patent Owner's citations to the Decision demonstrate, each of these issues was addressed and analyzed in the Decision. Nothing presented in the Request for Rehearing persuasively cites to any misapprehended or overlooked arguments or evidence that would warrant a different holding than that in our Decision. Furthermore, we note that merely disagreeing with our analysis or conclusions does not serve as a proper basis for a rehearing, because it does not show an overlooked or misapprehended matter.

C. Arguments Regarding Reply Evidence

Patent Owner argues that "affidavits or declarations" are authorized only for petitions and patent owner responses in Post Grant Review Proceedings ("PGRs") but are not allowed for petitioner's reply. Reh'g Req. 15 (citing 35 U.S.C. §§ 322(a)(3)(B), 326(a)(8), 326(a)(12)). Therefore, according to Patent Owner, the Board did not have authority to "allow and credit Petitioner's reply evidence (Ex. 1037–Ex. 1059), including Dr. Plott's declaration (Ex. 1047)." Reh'g Req. 15 (citing FWD, 18–21, 32–33, 35; *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024)).

We do not agree with Patent Owner. The Board's Consolidated Trial Practice Guide expressly provides, for example, that "Expert testimony may be submitted with the petition, preliminary response, and at other appropriate stages in a proceeding as ordered or allowed by the panel overseeing the trial." PTAB Consolidated Trial Practice Guide ("CTPG" 2019), 34 (https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL=TrialPracticeGuideConsolidated). Specifically, a petitioner may file a reply to a patent owner response and may submit directly responsive rebuttal evidence in support of its reply. 37 C.F.R. § 42.23; CTPG 73; *see Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015). If a party submits a new declaration with its reply, the opposing party may cross-examine the declarant, move to exclude the declaration, and comment on the declaration and cross-examination in any sur-reply. CTPG 73–74; *Belden Inc.* at 1081−82. Should a party believe that evidence exceeds the proper scope of a reply, it may request authorization to file a motion to strike. CTPG 80. Therefore, if Patent Owner believed Board did not have authority

to "allow and credit Petitioner's reply evidence," then the proper vehicle to challenge Petitioner's Reply Evidence would have been to request authorization to file a motion to strike such evidence. *Id.* at 78−79, 80−81. Patent Owner did not request a motion to strike, nor did it raise such a challenge during oral argument or at any time during the trial proceeding.

To the extent Patent Owner contends that the Board's rules and practice in this regard conflict with or are not premised on a reasonable interpretation of the statute, we disagree. Furthermore, as Patent Owner acknowledges, 35 U.S.C. § 326(a)(12) provides the Director authority to prescribe regulations "providing the petitioner with at least 1 opportunity to file written comments." Patent Owner points to nothing in the statute that excludes evidence from those "written comments" and the Office has consistently interpreted its authority to allow limited reply evidence, e.g., evidence that could not have been presented earlier because it is responsive to newly-raised arguments in the Patent Owner response. *See* CTPG 74–75. This was the nature of the reply evidence submitted here and, as noted above, Patent Owner had sufficient opportunity to respond—resulting in a fully-developed trial record and more accurate disposition of the patentability challenges in the Petition.

D. Summary

For the foregoing reasons, Patent Owner has not shown that the Board misapprehended or overlooked arguments or evidence in analyzing the competency of Petitioner's Declarants. For the same reasons as discussed in the Decision, Patent Owner's Request for Rehearing similarly is not persuasive as to Patent Owner's position during the trial phase of this case. Patent Owner's arguments regarding enablement or written description under 35 U.S.C. § 112(a) fail to identify what we misapprehended or

overlooked as required by 37 C.F.R. § 42.71(d). Thus, Patent Owner has not carried its burden of demonstrating that the Board's Decision should be modified. *See* 37 C.F.R. § 42.71(d).

III. ORDER

It is hereby ORDERED that Patent Owner's request for rehearing is *denied*.

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