

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.,

Petitioner,

v.

WYETH LLC,

Patent Owner.

Case IPR2017-01211
Patent 9,399,060 B2

Before TONI R. SCHEINER, GRACE K. OBERMANN, and
ULRIKE W. JENKS, Administrative Patent Judges.

OBERMANN, *Administrative Patent Judge*.

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

I. INTRODUCTION

On November 20, 2017, Petitioner filed a request for rehearing (Paper 10, “Req. Reh’g”) of our decision (Paper 9, “Dec.”) denying *inter partes* review of claims 1–13 of U.S. Patent No. 9,399,060 B2 (Ex. 1001, “the ’060 patent”). The request for rehearing is limited to our decision declining to institute review of claims 1 and 4–13. Req. Reh’g 1, n.1. Petitioner includes a request for panel expansion. *Id.* at 1.

For the reasons that follow, we deny the request for panel expansion and, further, deny the request for rehearing.

II. REQUEST FOR PANEL EXPANSION

Our governing statutes and regulations do not provide for parties to request, or panels to authorize, an expanded panel. *See generally* 35 U.S.C. § 6; 37 C.F.R. §§ 41.1–42.412. Our standard operating procedures, however, provide the Chief Judge with discretion to expand a panel to include more than three judges. PTAB SOP 1, 2–5 (§§ II, III) (Rev. 14); *see id.* at 2 (introductory language explaining that the Director has delegated to the Chief Judge the authority to designate panels under 35 U.S.C. § 6); *see also In re Alappat*, 33 F.3d 1526, 1532 (Fed. Cir. 1994) (providing that Congress “expressly granted the [Director] the authority to designate expanded Board panels made up of more than three Board members.”). The Chief Judge may consider panel expansions upon a “suggestion” from a judge, panel, or party. PTAB SOP 1, 3–4; *see also Apple Inc. v. Rensselaer Polytechnic Inst.*, Case IPR2014-00319, slip op. at 2 n.1 (PTAB Dec. 12, 2014) (Paper 20) (expanded panel) (per curiam).

The standard operating procedure exemplifies some of the reasons for which the Chief Judge may expand a panel. PTAB SOP 1, 3 (§ III.A). For

example, an expanded panel may be appropriate when “[t]he proceeding or AIA Review involves an issue of exceptional importance” or when “[c]onsideration by an expanded panel is necessary to secure and maintain uniformity of the Board’s decisions.” *Id.* (§ III.A.2, 3).

In this case, the Chief Judge has considered Petitioner’s request for an expanded panel, but has determined that an expanded panel is not warranted. Accordingly, Petitioner’s request for panel expansion is *denied*.

III. REQUEST FOR REHEARING

A. Legal Standard for Rehearing Requests

Upon a request for rehearing, we review a decision whether to institute trial for an abuse of discretion. 37 C.F.R. § 42.71(c). “The burden of showing a decision should be modified lies with the party challenging the decision.” 37 C.F.R. § 42.71(d). Further, “[t]he 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.” *Id.*

B. Effective Filing Date of the ’060 Patent

Petitioner avers that the request for rehearing “presents a narrow, but critical, issue” pertaining to whether claims 1 and 4–13 of the ’060 patent “should be afforded an effective filing date prior to the October 12, 2006 publication date of Petitioner’s asserted art.” Req. Reh’g 1. Specifically, Petitioner argues that the Board misapprehended or overlooked (1) controlling precedent bearing on the enablement standard; (2) substantial

evidence regarding the *Wands* factors¹ pertaining to enablement; and (3) alleged inconsistencies in our obviousness findings. *Id.* at i. We address each argument in turn below.

1. Application of the Correct Enablement Standard

Petitioner alleges that we erred by failing to address Federal Circuit cases that involved disparate facts surrounding the defense of enablement as asserted against open-ended claims in district court. Req. Reh’g 7–8. In that regard, the request for rehearing repeats argument, advanced unsuccessfully in the Petition, that the “claims at issue” are “open-ended” with respect to the number and identity of serotypes that fall within the scope of the claims. *Id.* at 4; *see* Dec. 12–16 (providing detailed reasons for rejecting the argument that claim 1 “is ‘open-ended’ and, therefore, embraces multivalent immunogenic compositions having any number of the ‘nearly 100 pneumococcal serotypes’ identified at the time of the invention” (Dec. 12 (quoting Pet. 37))).

We did not overlook or misapprehend those cases and were under no obligation to expressly address them, having determined that the Petition rests on a faulty assertion “that claim 1 ‘covers over **4 million** possible combinations,’ when one selects additional serotypes” over those

¹ As we explained in our decision declining to institute trial, the enablement inquiry focuses on whether the disclosure of the parent application would have enabled a person to practice the claimed invention by exercising no more than ordinary skill in the art, without resorting to “undue experimentation,” which “is analyzed by applying the factors set forth *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).” Dec. 12.

specifically identified in the claim and identified as 13vPnC.² Dec. 14 (quoting Pet. 37). Under these particular facts and circumstances, the request for rehearing does not establish that the Board applied an incorrect enablement standard in denying *inter partes* review of claims 1 and 4–13.

2. Evidence Pertaining to the *Wands* Factors

Petitioner also argues that “the Board overlooked Petitioner’s substantial evidence with respect to the enumerated *Wands* factors.” Req. Reh’g 7. In Petitioner’s view, the Board erroneously faulted the Petition for failing to set forth “a point-by-point analysis of the *Wands* factors.” *Id.* at 8 n.3. The Board, in fact, addressed “the ultimate inquiry” of whether a person of ordinary skill in the art at the time of the invention would have been equipped to “make and use the invention without undue experimentation.” *Id.* In an analysis tethered to the *Wands* factors (Dec. 12–16), we concluded that the information presented in the Petition and Preliminary Response supported a conclusion that “[t]he examples set forth in the ’060 parent applications provide adequate guidance enabling ‘the generation and characterization of a representative multivalent composition of the granted claims.’” *Id.* at 16.

Petitioner reasserts arguments, pertaining to undue experimentation, which were advanced unsuccessfully in the Petition. Req. Reh’g 9–14. In addition, Petitioner argues that the Board treated alleged “admissions” by Patent Owner “as not pertaining to enablement of the” challenged claims. *Id.* at 3. On the contrary, based on the totality of information contained in

² The parties and the Board refer to the 13-valent pneumococcal conjugate described in the ’024 patent as “13vPnC.”

the Petition and Preliminary Response, we held that the Petition did not “explain satisfactorily how” the identified statements “rise to the level of admissions” on the question of enablement. Dec. 13. Our decision on that point was informed by the content of the Preliminary Response, including Patent Owner’s argument that those statements “are taken out of context” in the Petition. *Id.* (quoting Paper 8, 27).

We did not overlook or misapprehend the Petition’s argument or evidence pertaining to undue experimentation. Instead, for reasons stated in our decision, we found that the Petition fails to direct us to information sufficient to make out the threshold for review. Dec. 7–16. Petitioner’s dissatisfaction with that outcome does not establish reversible error in our decision declining to institute trial with respect to claims 1 and 4–13.

3. Alleged Inconsistencies in Obviousness Findings

Lastly, Petitioner argues that the Board reached “inconsistent findings in the enablement and obviousness contexts.” Req. Reh’g 14. That argument is grounded in the faulty assumption that “the Board determined that the disclosure of [a] single embodiment sufficiently enabled the open-ended [c]laims covering potentially millions of immunogenic compositions.” *Id.* (citing Dec. 16). As explained above, however, the Board rejected that faulty assumption. *See supra* 4–5; Dec. 14–15 (explaining why “Dr. Kasper’s opinion that claim 1 ‘covers over **4 million** possible combinations,’ when one selects additional serotypes from among ‘the top 30 most prevalent serotypes,’ does not withstand scrutiny” (quoting Pet. 37 (citation omitted))).

IV. CONCLUSION

For the above reasons, we deny both Petitioner's request for panel expansion and Petitioner's request for rehearing of our decision declining to institute *inter partes* review of claims 1 and 4–13 of the '060 patent.

V. ORDER

It is

ORDERED that the Petitioner's request for an expanded panel is *denied*;

ORDERED that Petitioner's request for rehearing is *denied*.

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