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Paper 11
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.,

Petitioner,

v.

WYETH LLC,

Patent Owner.

Case IPR2017-01194
Patent 8,895,024 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 1–11 of U.S. Patent No. 8,895,024 B2 (Ex. 1001, "the '024 patent"). The request for rehearing is limited to our decision declining to institute review of claims 1–5. 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 '024 Patent

Petitioner avers that the request for rehearing "presents a narrow, but critical, issue" pertaining to whether claims 1–5 of the '024 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) the meaning of the claim phrase "consist essentially of" in claim 1; (2) controlling precedent bearing on the enablement standard; and (3) substantial evidence of non-enablement. *Id*. at i. The first three sections of our analysis below address those three arguments in turn. We include a fourth section devoted to the

second, independent rationale for denial (*see* Dec. 13–14) that is not addressed in the request for rehearing. *See generally* Req. Reh'g.

1. "Consist Essentially Of"

Petitioner alleges that the Board misapprehended or overlooked the meaning of the phrase "consist essentially of" in claim 1. *Id*. at 5–7. On that point, we applied Federal Circuit precedent explaining that, "[b]y using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." Dec. 12 (citing *PPG Indus. Inc. v. Guardian Indus. Corp*, 156 F.3d 1351, 1354 (Fed. Cir. 1998)).

Petitioner argues that the Board improperly engaged in "burden-shifting to Petitioner" on the question of whether "the inclusion of any additional serotype would not materially affect the basic and novel characteristics of the claimed invention." Req. Reh'g 7 (quoting Dec. 13). Petitioner provides no rationale, and cites no persuasive authority, supporting a conclusion that Patent Owner (instead of Petitioner) should have been tasked with coming forward with evidence on this factual issue "in its Preliminary Response" to the Petition (Paper 1, "Pet."). *Id*. On the contrary, our authorizing statute unambiguously requires Petitioner to prove all propositions of unpatentability in an *inter partes* review. 35 U.S.C. § 316(e). A patent owner's submission of a preliminary response is optional but never mandatory. *Id*. at § 313.

As we stated in our decision, the Petition "ignores express language in claim 1" (Dec. 12), which specifies "serotypes" that "consist essentially of 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F." Ex. 1001, 35:9–10.

Based on the particular facts and circumstances of this case, including the appearance of the term "consist essentially of" in claim 1 (upon which claims 2–5 depend), we properly placed on Petitioner an initial burden of producing evidence sufficient to support its broad assertion "that claim 1 covers '1.7×10^{12} possible combinations of serotypes' and, for that reason, is not enabled by the parent applications." Dec. 12–13 (quoting Pet. 40).

In that regard, Petitioner directs us to the same evidence of unpredictability advanced in the Petition, but the persuasiveness of that evidence is not improved by repetition in the request for rehearing. *See* Req. Reh'g 5–7, 10–15 (and evidence cited therein). As we explained in our decision (Dec. 12), the Petition does not adequately address the claim terms, which require "serotypes" that "consist essentially of" the 13 serotypes that characterize 13vPnC.[1] Ex. 1001, 35:9–10.

2. The Enablement Standard

Petitioner also argues that the Board erred by failing to address Federal Circuit cases that involve disparate facts regarding the enablement of open-ended claims. Req. Reh'g 7–8. The request for rehearing repeats argument, advanced unsuccessfully in the Petition, that the '024 patent concludes with "open-ended claims" with respect to the number and identity of serotypes that may be included in the composition. *Id*. at 7; *see* Dec. 12–14 (providing detailed reasons for rejecting the Petition's argument that independent claim 1 "is 'open-ended' and, therefore, embraces "1.7×10^{12} possible combinations of serotypes" (Dec. 12–13, quoting Pet. 40)).

[1] The parties and the Board refer to the 13-valent pneumococcal conjugate described in the '024 patent as "13vPnC."

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 'is open-ended with respect to the number and identity of serotypes added to 13vPnC.'" Dec. 12 (quoting Pet. 40). Under these particular facts and circumstances, the request for rehearing does not establish that the Board applied an incorrect enablement standard in reaching the decision to deny *inter partes* review of claims 1–5.

3. Evidence of Non-Enablement by the Parent Applications

In support of its position that claims 1–5 cannot claim priority based on any parent application filed before October 12, 2006, Petitioner repeats the Petition's arguments that the disclosures of those applications fail to enable claims 1–5. *Id*. Instead of pointing to any matter misapprehended or overlooked by the Board, Petitioner disagrees with our determination that the information advanced in the Petition is insufficient to support Petitioner's arguments pertaining to enablement. *Compare* Req. Reh'g 2–3, 5–6 *with* Dec. 11–13. The request for rehearing does not cure the Petition's lack of evidence adequate to establish "the effects of adding any unlisted serotype to 13vPnC." Dec. 13 (quoting Prelim. Resp. 24).

Petitioner reasserts arguments advanced unsuccessfully in the Petition. Req. Reh'g 2–3, 5–6, 10–15. We did not overlook or misapprehend those arguments—we found them insufficient to make out the threshold for *inter partes* review for reasons stated in our decision. Dec. 8–13. Petitioner's dissatisfaction with that outcome does not show reversible error in our decision declining to institute trial with respect to claims 1–5.

4. Second Independent Basis for Petition Denial

Our decision is supported by "a second independent" basis for finding the Petition "deficient" in establishing a reasonable likelihood of prevailing at trial with respect to claims 1–5. Dec. 13. Specifically, the Petition does not adequately analyze the level of ordinary skill in the art as of the filing date of each parent application through which priority is claimed. *Id*. at 13–14; *see In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) (enumerating factors that bear on enablement, including the level of ordinary skill in the art at the time of filing of the parent application at issue).

In that regard, Petitioner argues that "the Board overlooked the Petition's substantial evidence with respect to the enumerated *Wands* factors." Req. Reh'g 9. In our decision, however, we found significant that "[e]ven Petitioner acknowledges that the level of ordinary skill in this particular field of endeavor, including one's understanding of 'the universe of clinically relevant serotypes,' would not 'remain static' during the relevant span of time." Dec. 14 (citing Pet. 45 (quoting Ex. 1009 ¶ 129). "Yet the Petition does not clearly articulate the level of ordinary skill in the art applicable at the time of filing for each parent application. Instead, Petitioner focuses on the state of the art as of the earliest possible priority date of 'April 8, 2005.'" *Id*. (quoting Pet. 9 (heading "A").

Petitioner has not shown that the panel misapprehended or overlooked any evidence or argument directed to this "second, independent" rationale for denying the Petition. Dec. 13. Accordingly, Petitioner has not shown reversible error in our decision to deny institution of trial with respect to claims 1–5.

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 1–5 of the '024 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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