

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COHERUS BIOSCIENCES INC.,  
Petitioner,

v.

ABBVIE BIOTECHNOLOGY LTD.,  
Patent Owner.

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Case IPR2016-00172  
Patent 8,889,135 B2

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Before JACQUELINE WRIGHT BONILLA, SHERIDAN K. SNEDDEN,  
and MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

PER CURIAM.

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

On May 26, 2016, Patent Owner filed a Request for Rehearing (Paper 13, “Rehearing Request” or “Reh’g Req.”) of our Decision granting institution of an *inter partes* review (Paper 9, “Decision” or “Dec.”) of claims 1–5 of U.S. Patent No. 8,889,135 B2 (Ex. 1001, “the ’135 patent”). In the Decision, we determined that Petitioner had shown a reasonable likelihood of prevailing in showing the unpatentability of claims 1–5 of the ’135 patent, based on obviousness under 35 U.S.C. § 103(a) over Kempeni and van de Putte. Dec. 22.

We deny the Rehearing Request for the reasons set forth below.

#### ANALYSIS

When considering a request for rehearing, the Board reviews its decision for an abuse of discretion. 37 C.F.R. § 42.71(c). The party requesting rehearing bears the burden of showing that the decision should be modified, and “[t]he request must specifically identify all matters the party believes the Board misapprehended or overlooked.” 37 C.F.R. § 42.71(d).

Patent Owner asserts that, contrary to the applicable statutory and regulatory provisions, our Decision does not address explicitly and, therefore, misapprehended or overlooked, two arguments presented in the Preliminary Response: (1) the argument that Dr. Baughman’s testimony is conclusory and inconsistent with prior statements; and (2) the argument that no credible evidence supports Petitioner’s argument that minimizing drug dose was the skilled artisan’s goal. Reh’g Req. 1, 7. Patent Owner also “suggests rehearing by a newly composed panel,” arguing that rehearing by a new panel is appropriate because there exists “the mere appearance of possible impropriety.” *Id.* at 8–9. We address each of Patent Owner’s assertions below, beginning with the composition of the panel in this case.

*A. Panel Composition*

Patent Owner contends it learned after the entry of our Decision that the authoring administrative patent judge: (1) was a lawyer in the Wilmington, Delaware office of Petitioner’s counsel’s law firm, Fish & Richardson P.C. as of August 2014, (2) that office was the same office in which Petitioner’s back-up counsel, W. Chad Shear, also was located in August 2014, and (3) the authoring administrative patent judge and Mr. Shear appeared as co-counsel in two lawsuits “involving infringement of drug patents.” *Id.* at 8–9. Patent Owner contends that this information shows an appearance of impropriety “sufficient to justify reconsideration by a newly composed panel.” *Id.* at 9.

We disagree. Patent Owner argues that an appearance of impropriety exists based upon the above-described information, but fails to explain how that information shows such an appearance. Indeed, as explained below, the ethical rules governing the conduct of federal employees belie Patent Owner’s assertion.

We are guided by Subpart E of the Standards of Ethical Conduct for Employees of the Executive Branch (“Ethical Standards”), 5 C.F.R. Part 2635, which addresses the appearance of impartiality in performing official duties. The overview provides that the subpart “contains two provisions [ §§ 2635.502 and 2635.503 ] intended to ensure that an employee takes appropriate steps to avoid an appearance of loss of impartiality in the performance of his [ or her ] official duties.”<sup>1</sup> 5 C.F.R. § 2635.501(a). As is

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<sup>1</sup> Section 2635.503, which relates to extraordinary payments from former employers, is not applicable to Patent Owner’s arguments in the present case.

relevant to the facts of this case, the regulation governing personal and business relationships provides that an appearance of impropriety arises in a matter involving specific parties when two factors are met: (1) an employee knows that a person with whom he or she has a covered relationship represents a party to the matter, and (2) the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his or her impartiality in the matter, such that the employee should not participate in the matter without prior authorization by the agency designee. 5 C.F.R. § 2635.502(a). The provision further delineates the contours of a “covered relationship,” providing that “[a]n employee has a covered relationship with . . . any person for whom the employee has, *within the last year*, served as . . . employee.” 5 C.F.R. § 2635.502(b)(1)(iv) (emphasis added). In other words, after one year has passed, a federal employee, such as an administrative patent judge, no longer has a “covered relationship” with a former employer.

Turning to Patent Owner’s contentions, we find that they do not provide a sufficient basis for requesting a newly composed panel. First, we note that the Rehearing Request fails to address the Ethical Standards or explain why the information Patent Owner presents amounts to a “covered relationship” between any of the panel members and Petitioner’s counsel. Indeed, no “covered relationship” within the meaning of 5 C.F.R. § 2635.502 exists—or existed at any time during the pendency of this case—between the authoring administrative patent judge and counsel for any party in this case, because the authoring administrative patent judge had severed her relationship with Fish & Richardson P.C. more than a year and eight

months before participating in the present case (i.e., well past the one-year limitation for covered relationships provided in the Ethical Standards).

Patent Owner also fails to explain why having an office in the same location as and appearing as co-counsel with Petitioner's backup counsel in two litigation matters that involved neither the parties to this case nor the patent at issue here would "cause a reasonable person with knowledge of the relevant facts to question [the authoring judge's] impartiality." 5 C.F.R. § 2635.502(a). Taking Patent Owner's argument to its logical extension, an appearance of impropriety requiring recusal would arise in any case in which a judge previously was employed by (or a member of) the same law firm as counsel for a party, had an office in the same physical location as counsel for a party, and appeared as co-counsel with counsel for a party in unrelated litigation, no matter how long ago the business relationship was severed. That result, in addition to falling short of the criteria set forth in Ethical Standards, creates a potentially difficult and unnecessary burden that impacts efficiency at the Board. Accordingly, under the controlling regulation regarding covered relationships, Patent Owner fails to show an appearance of impropriety.

Patent Owner's cited cases also provide no basis for finding an appearance of impropriety sufficient to justify a newly composed panel in this proceeding. To the contrary, in *Aetna Life Ins. Co. v. Lavoie*, 475 U.S. 813 (1986) and *Caperton v. A.T. Massey Coal Co., Inc.*, 556 U.S. 868 (2009), the Supreme Court addressed "extraordinary situation[s]," *Caperton*, 556 U.S. at 887, in which recusal was required by the Due Process Clause of the Constitution because "experience teaches that the probability of actual bias on the part of the judge or decisionmaker is too high to be

constitutionally tolerable.’” *Id.* at 877 (quoting *Withrow v. Larkin*, 421 U.S. 35, 47 (1975)).

Specifically, in *Lavoie* and *Caperton*, respectively, the Court determined that: (1) cases in which the adjudicator has a pecuniary interest in the outcome, and (2) circumstances showing that “a person with a personal stake in a particular case had a significant and disproportionate influence in placing the judge on the case by raising funds or directing the judge’s election campaign when the case was pending or imminent” create “a serious risk of actual bias—based on objective and reasonable perceptions” that requires recusal under the Constitution. *Caperton*, 556 U.S. at 884; *Lavoie*, 475 U.S. at 822–25. That is, both cases addressed “extreme facts that created an unconstitutional probability of bias” not present here. *Caperton*, 556 U.S. at 887 (citing *Lavoie*, 475 U.S. at 822). Accordingly, we deny Patent Owner’s request for rehearing by a newly composed panel and turn to the merits of the Rehearing Request.

#### *B. Dr. Baughman’s Testimony*

Patent Owner argues that our Decision misapprehended or overlooked the argument that Dr. Baughman’s testimony is conclusory and inconsistent with prior statements. Reh’g Req. 1–6. In particular, Patent Owner contends our Decision observed that “Petitioner’s obviousness argument was ‘based primarily’ on” Dr. Baughman’s opinions concerning half-life data that were “‘unsupported by citation to any prior art publication, and are nothing more than conclusory.’” *Id.* at 2 (quoting Prelim. Resp. 39).

Patent Owner’s argument in this regard mischaracterizes Petitioner’s obviousness arguments and our Decision. As discussed in the Decision, Petitioner, with supporting testimony from Dr. Baughman, explained

sufficiently at this stage how the efficacy results disclosed in van de Putte for 20, 40, and 80 mg subcutaneous weekly doses of D2E7, in view of Kempeni’s teaching that D2E7 could be administered safely over a broad range of doses, would have led an ordinary artisan to reasonably expect a biweekly dosing of 40 mg to be efficacious and safe. Dec. 18. Thus, contrary to Patent Owner’s argument in the Rehearing Request, the Decision did not “observe[] that Petitioner’s obviousness argument was ‘based primarily’ on [Dr. Baughman’s] testimony” and we did institute a trial based primarily on Dr. Baughman’s “say-so.” Reh’g Req. 2, 5–6.

Patent Owner also repeats in the Rehearing Request essentially the same argument raised in the Preliminary Response. Specifically, Patent Owner contends that we overlooked the evidence it presented, which “shows that half-life is not a meaningful predictor of dosing interval for D2E7” in contrast to Petitioner’s “*expert say-so.*” Reh’g Req. 3–4.

We noted in the Decision that Patent Owner “dispute[d] Petitioner’s assertions regarding what knowledge of D2E7’s half-life would have conveyed to the skilled artisan about a dosing regimen” and pointed to “the expert declarations submitted during prosecution of the ’135 patent and dosing regimens for other FDA-approved antibodies.” Dec. 18 (citing Prelim. Resp. 35–38). Ultimately, we determined that Petitioner met its threshold burden of demonstrating a reasonable likelihood of prevailing at trial with respect to at least one claim. *Id.* at 19–20. Patent Owner’s disagreement with our analysis or that determination is not a proper basis for rehearing.

Patent Owner further contends that we overlooked the argument and evidence that Dr. Baughman's prior statements in her own patent application contradict her opinions. Reh'g Req. 4.

Although we did not address expressly Patent Owner's argument in this regard, we considered all arguments and evidence presented regarding the information before us. Dec. 1 ("upon consideration of the information presented in the Petition and the Preliminary Response"). Our review of Dr. Baughman's prior statement did not dissuade us from instituting a trial in this case. As explained in our Decision and above, we instituted trial based on information disclosed in the asserted prior art references, in view of the state of the art, and as supported by Petitioner's declaration testimony. *See* Dec. 19–20.

Moreover, as Patent Owner acknowledges in the Rehearing Request, it can use discovery during trial, including a deposition, to explore more fully Dr. Baughman's prior statement vis-à-vis her declaration testimony. Our determinations set forth in the Decision are preliminary in nature and may be revisited during trial when the record is fully developed. Patent Owner, therefore, may continue to press its arguments regarding Dr. Baughman's testimony in the Patent Owner Response. Indeed, our Decision instituting review expressly invited the parties to address in the Patent Owner Response and Petitioner Reply "whether a skilled artisan would have relied upon half-life or dose-stretching based on known half-life to establish a dosing regimen for D2E7." *Id.* at 19.

*C. Minimizing Drug Dose*

Patent Owner argues that the “Board’s determination that ‘a skilled artisan would have been led to optimize the dosing regimens disclosed in [the asserted] references in order to treat the patient with as little drug as possible’ was error,” as it is supported by conclusory evidence. Reh’g Req. 7. Patent Owner also points to Dr. O’Dell’s paper stating that “‘the fundamental goal’ of treating RA was to treat ‘disease activity to the fullest extent possible.’” *Id.* at 8. Patent Owner contends that this evidence demonstrates that the ordinarily skilled artisan would have focused efforts on “obtaining the most efficacious dose, not the lowest.” *Id.*

Here again, Patent Owner fails to point to any information that we misapprehended or overlooked. Rather, Patent Owner merely restates its argument from the Preliminary Response. We considered that argument and addressed it fully in the Decision. For example, as we pointed out, Patent Owner’s argument was based on a claim construction we did not adopt—that the claims required a particular level of efficacy not achieved by van de Putte’s 20 mg dose. Dec. 16. In addition, we explained that Patent Owner’s argument disregards van de Putte’s disclosure that “20, 40, and 80 mg D2E7 administered weekly were ‘nearly equally efficacious’ and ‘all statistically significantly superior to placebo’ for all efficacy parameters studied. *Id.* at 16–17 (quoting Ex. 1004, 1). As explained previously, Patent Owner’s disagreement with our analysis or determination in this regard is not a proper basis for rehearing. Accordingly, we are not persuaded we misapprehended or overlooked any of Patent Owner’s arguments or abused our discretion in instituting an *inter partes* review.

ORDER

It is

ORDERED that Patent Owner's request for a newly composed panel in this case is *denied*; and

FURTHER ORDERED that Patent Owner's request for rehearing of the Decision to institute *inter partes* review is *denied*.

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