

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOF CORPORATION,
Petitioner,

v.

NEKTAR THERAPEUTICS,
Patent Owner.

IPR2019-01396
Patent 8,809,453 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and
JON B. TORNQUIST, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION

Denying Petitioner's Request on Rehearing of Decision
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.71(d)

INTRODUCTION

NOF Corporation (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 8,809,453 B2 (Ex. 1004, “the ’453 patent”). We denied the Petition. Paper 19 (“Dec.”). Petitioner filed a request for rehearing of the Decision. Paper 21 (“Req. Reh’g”).

For the reasons discussed below, we deny Petitioner’s request for rehearing.

STANDARD OF REVIEW

When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a “decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted). A rehearing request “must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed.” 37 C.F.R. § 42.71(d).

DISCUSSION

The Decision addressed six grounds of unpatentability, four of which rely on Bentley (Ex. 1015) as the primary reference, and the other two rely on JP-542 (Ex. 1017) as the primary reference. Dec. 5. Petitioner requests rehearing of our decision not to institute review of the grounds related to Bentley. Req. Reh’g 1. According to Petitioner, “the Decision misapprehends and overlooks the disclosures of the prior art, as a whole, the proper level of skill, common knowledge and creativity to be applied by one

skilled in the art, and failed to resolve material factual disputes in a light most favorable to Petitioner.” *Id.* We are not persuaded.

Prior Art

Bentley relates to methods of coupling a PEG polymer to a biomaterial. Ex. 1015, 1:8–10. Bentley’s method “includes in situ preparation of PEG aldehyde hydrates, which can then be used in solution, without isolation, to form conjugates by reductive amination with a range of biologically active molecules.” *Id.* at 3:4–9.

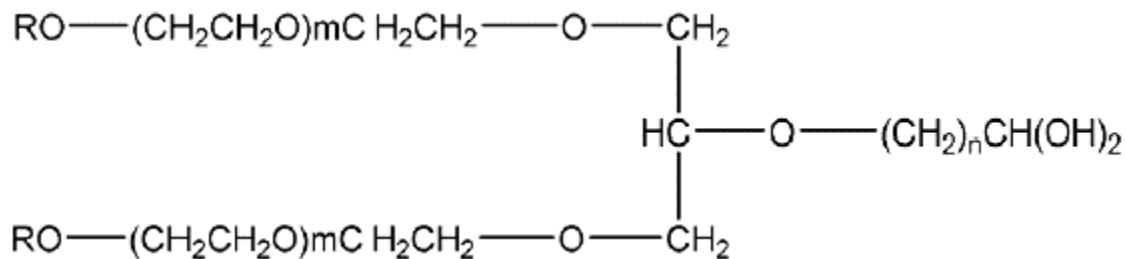
In the Decision, we found “Petitioner has not shown the Bentley polymer it relies on (depicted in the formula at lines 16–20 on column 7 of Bentley) is suitable for conjugating with a biologically active molecule.” Dec. 9. Petitioner contends that an ordinarily skilled artisan “would have understood Bentley to *expressly* teach and suggest that ***all activated PEGs*** thereof are for conjugation of biologically active molecules.” Req. Reh’g 8, *see also id.* at 9 (“Bentley’s statements of his *invention* apply to **ALL** Bentley activated PEG polymers.”). We disagree.

Bentley’s “invention provides a method for conjugating PEG and related polymers with substances including biomaterials and biologically active materials.” Ex. 1015, 3:2–4. For the polymers, Bentley teaches PEG as well as a broad variety of other polymers. *Id.* at 3:49–62. For the materials that can be conjugated to the polymers, Bentley teaches “any material having a reactive amine group accessible to the activated polymer having an aldehyde hydrate group can be used” in its invention. *Id.* at 6:15–18. In other words, Bentley teaches that the aldehyde hydrate moiety can be used to conjugate nearly any polymer to nearly any amine-containing substance.

As noted in the Decision, Bentley teaches that PEG aldehyde hydrate can be linked to either “a molecule or *surface* bearing one or more amine groups.” Dec. 6 (quoting Ex. 1015, 2:12–20, emphasis added); *see also id.* at 9 (quoting Ex. 1015, 7:44–46 (“PEG aldehyde hydrate and its derivatives can be used for attachment directly to *surfaces* and molecules having an amine moiety.” (emphasis added in the Decision))). We also observed that, in Bentley, “because biological properties may vary based on molecular weight and the degree of branching, ‘not all of these [disclosed] derivatives may be useful for biological or biotechnical applications.’” *Id.* (quoting Ex. 1015, 6:36–39).

In other words, Bentley does not teach that all of the PEG conjugates would be useful for all possible purposes. Nor does it describe how to determine which conjugates will be useful for any particular desired application. Instead, Bentley discloses a tool that can be used to conjugate a broad variety of polymers to nearly any amine-containing substance or surface. Petitioner does not persuasively explain why such a general disclosure teaches or suggests a conjugate of any particular PEG polymer to any particular type of amine-containing substance.

As noted by Petitioner, Bentley teaches a specific form of activated PEG polymer, the structure of which is reproduced below:



The figure above is Petitioner’s depiction of the chemical structure identified at column 7, lines 16–20 of Bentley. Pet. 28 (citing Ex. 1015, 7:12–20).

According to Petitioner, “one of ordinary skill would understand the ‘ $-\text{O}-(\text{CH}_2)_n\text{CH}(\text{OH})_2$ ’ of Bentley’s branched polymer would react with a protein, or other amine-containing substance, to form $-\text{O}-(\text{CH}_2)_n-\text{CH}_2-\text{NH}-\text{PROTEIN}$.” *Id.* at 30. We reiterate, as explained in the Decision, we disagree with Petitioner’s conclusion.

For the polymer the Petition relies on, Bentley does not provide any properties or explain how this molecule is to be used. Instead, Bentley states that this is a “star molecule” and that such molecules are generally described in Merrill (U.S. Patent No. 5,171,264), which is incorporated by reference in Bentley. Ex. 1015, 7:2–20. Merrill discloses that “star molecules” are useful for creating hydrogels for use in affinity columns. Ex. 2020, Abstract (“This invention pertains to a method for immobilizing polyethylene oxide (PEO) star molecules in the form of hydrogels.”).

The Petition does not address Bentley’s incorporation of Merrill or persuasively explain why an ordinarily skilled artisan would have understood that the disclosed activated PEG polymer would be useful when conjugated to a biologically active molecule, as opposed to a support surface of an affinity column. Petitioner relies instead on Bentley’s broad disclosure that an aldehyde hydrate moiety *could* be used to conjugate nearly any polymer to nearly any amine-containing substance, including biologically active molecules. Pet. 27–30. But, identifying a disclosure that something could be done is not sufficient to demonstrate a reason to do so in a particular instance or manner. *See Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1068 (Fed. Cir. 2018) (holding it is error to “focus[] on what a skilled artisan would have been *able* to do, rather than what a skilled artisan would have been *motivated* to do at the time of the invention”).

In view of the foregoing, Petitioner has not established that we overlooked Bentley's teachings or that we erred in concluding that Petitioner had not sufficiently demonstrated that Bentley teaches or suggests using the "star molecules" for biologic applications.

Expert Testimony

Petitioner refers to the expert declaration in support of the Petition, in which Dr. Yamamoto testifies that

. . . a POSA would appreciate that conjugation of the disclosed aldehyde hydrate polymers to biologically active molecules . . . is expressly disclosed . . . [and] [i]t would have been obvious to POSA to conjugate the branched PEG aldehyde hydrate disclosed by Bentley (Id. at 7:12-20) to a biologically active molecule . . . as disclosed by Bentley (Id. at 6:1-29).

Req. Reh'g 12 (quoting Ex. 1083 ¶ 286). Petitioner points out that Patent Owner did not provide any expert testimony. *Id.* at 13. According to Petitioner, we erred for "discounting Dr. Yamamoto's uncontroverted testimony in favor of PO's attorney argument." *Id.* We are not persuaded.

Dr. Yamamoto is an employee of Petitioner. Ex. 1083 ¶ 10. "While the opinion testimony of a party having a direct interest in the pending litigation is less persuasive than opinion testimony by a disinterested party, it cannot be disregarded for that reason alone and may be relied upon when sufficiently convincing." *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985).

How much we credit an expert's testimony, however, depends on whether the opinion adequately addresses the disclosures of a reference as a whole and adequately provides the justification for its conclusions. *See TQ Delta, LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1359–60 (Fed. Cir. 2019). Here, Dr. Yamamoto did not adequately explain why Bentley's disclosure of

being able to conjugate nearly any polymer to nearly any amine-containing material teaches or suggests the specific polymer identified at column 7, lines 14–20 of Bentley, would be useful when conjugated to biologically active molecules.

Moreover, Bentley generally teaches that activated PEG polymers can be conjugated to molecules or *surfaces* and specifically incorporates by reference Merrill, which discloses conjugating “star” molecules to the support *surface* of an affinity column. Ex. 1015, 6:12–13; Ex. 2020, 2:5–8. Dr. Yamamoto did not address these disclosures or explain adequately why one of ordinary skill in the art would have sought to conjugate the specific activated PEG molecule disclosed in Bentley (Ex. 1015, 7:14–20) to a biologically active molecule, as opposed to the support surface of an affinity column (Ex. 2020, 2:5–8). Indeed, Dr. Yamamoto did not persuasively identify any actual properties of the specific activated PEG molecule of Bentley relied upon in the Petition.

As a result, although we considered Dr. Yamamoto’s testimony, we accorded it proper weight. Petitioner has not established that we erred in doing so.

Level of Ordinary Skill in the Art

Petitioner asserts that “a POSA would have had a Ph.D. in chemistry, chemical engineering, materials science, or a related field and several years of experience working in the field of synthesis of active PEG polymers for PEGylation of biological molecules.” Pet. 24; Req. Reh’g 14. Petitioner contends we overlooked and misapplied the level of skill in the art when we declined to institute review in this case. Req. Reh’g 13–14.

The level of ordinary skill in the art asserted by Petitioner is high. A high level of skill in the art tends to favor an obviousness conclusion. *See Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011) (“A less sophisticated level of skill generally favors a determination of nonobviousness, and thus the patentee, while a higher level of skill favors the reverse.”). Despite so, to meet its burden for institution, Petitioner still must adequately explain why the art and such a high skill level would have led to the claimed invention. As noted above, we do not find that Petitioner and Dr. Yamamoto did so. Thus, Petitioner has not established that we overlooked its argument as to this issue.

Grounds Based on Bentley and Other References

Petitioner asserts three other grounds of unpatentability, relying on the combinations of Bentley with MDD (Ex. 1029), Harris (Ex. 1016), and Harris together with PSTT (Ex. 1030). Dec. 5. Petitioner contends that we overlooked the teachings of these additional references. Req. Reh’g 14–15. We, again, are not persuaded.

The Petition relies on the additional references for teaching the claim limitation of molecular weight. *See* Pet. 41–42 (“To the extent that more is need to show that POSA would arrive at the claimed molecular weight ranges of the ‘453 patent in connection with the branched polymers of Bentley, a POSA would have arrived at such ranges when considering Bentley in view of MDD.”), *id.* at 53 (“A POSA would be motivated to combine the teachings of the branched polymers of Bentley with the molecular weight teachings of Harris.”), *id.* at 60 (“A POSA would have been motivated to combine the teachings of Bentley and Harris with PSTT to optimize the molecular weight of branched polymers.”). In other words,

although certain teachings of the additional references may remedy the deficiencies of Bentley, the Petition does not rely on those teachings. And we could not have overlooked an argument that was not made in the Petition.

CONCLUSION

We have considered Petitioner's request for rehearing, but determine that Petitioner has not established that we misapprehended or overlooked any matter in declining to institute an *inter partes* review.

ORDER

In view of the foregoing, it is:

ORDERED that Petitioner's Requests for Rehearing is *denied*.

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