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Paper No. 12
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

BIOGEN, INC.,
Patent Owner.

Case IPR2017-01167
Patent 8,557,244 B1

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and JACQUELINE T. HARLOW, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

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

I. INTRODUCTION

Pfizer, Inc. ("Petitioner") requests a rehearing of the Decision Denying Institution of an *inter partes* review of claims 1 and 2 of U.S. Patent No. 8,557,244 B1 (Ex. 1001, "the '244 patent") entered on November 6, 2017 (Paper 8, "Dec."). Paper 9 ("Reh'g Req.").

Claims 1 and 2 of the '244 patent are reproduced below:

> 1. A method of treating a patient with diffuse large cell lymphoma, comprising administering an unlabeled chimeric anti-CD20 antibody and CHOP (cyclophosphamide, hydroxydaunorubicin/doxorubicin, vincristine, and prednisone/prednisolone) chemotherapy to the patient, wherein the patient is > 60 years old and has bulky disease (tumor >10 cm in diameter).
>
> 2. The method of claim 1, wherein the chimeric antibody is rituximab.

In the Petition (Paper 2, "Pet.") Petitioner raised the following challenges to those claims:

Claims	**Basis**	**References**
1 and 2	§ 103	Shipp, [1] Link,[2] and McNeil[3]

[1] Shipp et al., *High-Dose CHOP as Initial Therapy for Patients with Poor-Prognosis Aggressive Non-Hodgkin's Lymphoma: A Dose-Finding Pilot Study*, 13 J. CLIN. ONCOL. 2916–23 (1995) (Ex. 1009).
[2] Link et al., *Phase II Pilot Study of the Safety and Efficacy of Rituximab in Combination with CHOP Chemotherapy in Patients with Previously Untreated Intermediate- or High-Grade NHL, Program/Proceedings*, 17 AM. SOC. CLIN. ONCOL. 3a (Abstract 7) (1998) (Ex. 1005).
[3] McNeil, *Non-Hodgkin's Lymphoma Trials In Elderly Look Beyond CHOP*, 90 J. NAT. CANCER INST. 266–67 (1998) (Ex. 1003).

Claims	Basis	References
1 and 2	§ 103	Shipp and Coiffier[4]

Petitioner relied upon the Declarations of Howard Ozer, M.D., Ph.D. (Ex. 1002) and Scott Bennett, Ph.D. (Ex. 1016). Biogen, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

Upon consideration of the Petition, Preliminary Response, and evidence of record, we determined that Petitioner failed to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of challenged claims 1 and 2. Dec. 13. In the Rehearing Request, Petitioner seeks a reconsideration of that determination. Reh'g Req. 1.

II. ANALYSIS

"When rehearing a decision on petition, a panel will review the decision 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. The 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*. § 42.71(d). Because Petitioner has not met its burden, as discussed below, the Rehearing Request is *denied*.

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[4] Coiffier et al., *Rituximab (Anti-CD20 Monoclonal Antibody) for the Treatment of Patients with Relapsing or Refractory Aggressive Lymphoma: A Multicenter Phase II Study*, 92 BLOOD 1927–32 (1998) (Ex. 1006).

In the Decision, we determined that Petitioner had not shown a reasonable likelihood of prevailing in establishing that the challenged claims were obvious over the combination of Shipp, Link, and McNeil, or over the combination of Shipp and Coffier. Dec. 9–13. In particular, we explained that Petitioner had not supported its assertion that Shipp teaches all of the elements of independent claim 1, except for including rituximab in the treatment method. *Id*. at 10. For example, Petitioner asserted that "Shipp disclosed that CHOP therapy was the standard of care for DLCL patients with bulky disease, even for patients over 60 years old with intermediate-grade lymphomas such as DLCL accompanied by bulky disease." Pet. 39. In support of that assertion, Petitioner relied upon Shipp's disclosure of a pilot study designed to identify the maximum-tolerated dosage of cyclophosphamide and doxorubicin in a CHOP induction regiment for poor-prognosis patients, *see*, *e.g.*, Ex. 1009, 3–6, and the testimony of Petitioner's declarant, Dr. Ozer, Ex. 1002 ¶¶ 48–55.

Three patients in Shipp's study were over age 60. Ex. 1009, Table 1 (patients 2, 6, and 11). As we stated in the Decision, "Shipp does not disclose whether any of those elderly patients has DLCL. Rather, Shipp explains only that patients in the study have one of a variety of forms of aggressive NHL, i.e., 'diffuse mixed, diffuse large-cell, or large-cell immunoblastic lymphoma.'" Dec. 10 (quoting Ex. 1009, Table 1 "Characteristics of the Protocol Patients"). Dr. Ozer acknowledged that "Shipp does not say whether these elderly patients had 'diffuse,' 'diffuse large cell,' or 'immunoblastic large cell' lymphoma." Dec. 10 (quoting Ex. 1002 ¶ 52). In an attempt to fill that missing information, Dr. Ozer provided testimony that Shipp's failure to distinguish which patients had which

disease "reflects the understanding of those in the art that there were no significant distinctions in treating these three intermediate and high-grade lymphomas (types F, G, H), all of which are very similar." *Id*. (quoting Ex. 1002 ¶ 52). Noting that portion of Dr. Ozer's testimony did not include any citation to evidence, we explained:

> Dr. Ozer has not identified any discussion in Shipp to support that reasoning, or referred us to any other evidence to support that assertion. Without more, we do not accord persuasive weight to Dr. Ozer's opinion that the understanding of those in the art is that there are "no significant distinctions in treating" the three intermediate and high-grade lymphomas disclosed in Shipp.

Id. (quoting Ex. 1002 ¶ 52).

In the Rehearing Request, Petitioner asserts that the Board overlooked evidence supporting the testimony by Dr. Ozer that there were no significant distinctions in treating these three intermediate and high-grade lymphomas. Reh'g Req. 7; Ex. 1002 ¶ 52. Specifically, Petitioner draws our attention to the following assertion by Petitioner in the Petition,

> Lymphomas categorized as intermediate- or high-grade were often studied together, as treatments were considered to be the same. Ex. 1002 ¶ 37; *see also, e.g.*, Ex. 1009, Shipp at 2 (studying diffuse mixed, DLCL, and immunoblastic large cell lymphomas together); Ex. 1006, Coiffier at 2-3 (studying four types of intermediate- and high-grade lymphomas); Ex. 1005, Link at 5 (studying types D, G, and H together).

Pet. 9. Petitioner acknowledges that the Decision explains "Dr. Ozer has not identified any discussion in Shipp to support [his] reasoning" that there are "no significant distinctions in treating" the three intermediate and high-grade lymphomas." Reh'g Req. 7–8. However, Petitioner asserts that we "apparently overlooked" Petitioner's reference to Link and Coiffier as

support for that matter. *Id*. at 8. According to Petitioner, because Shipp, Link and Coiffier "all treated intermediate-grade NHL patients with the same therapy regardless of whether they had IWF Grades F, G, or H," those references, collectively, bolster Dr. Ozer's testimony. *Id*. at 9.

Significantly, Petitioner has not shown in its Rehearing Request that Dr. Ozer provided any evidentiary support for his conclusion that Shipp's failure to disclose whether any elderly patient had diffuse mixed, diffuse large cell, or immunoblastic large cell lymphoma "reflects the understanding of those in the art that there were no significant distinctions in treating these three intermediate and high-grade lymphomas (types F, G, H), all of which are very similar." Ex. 1002 ¶ 52; *see* Reh'g Req. 1–10. Thus, Petitioner has not shown that we overlooked any such evidence.

Insofar as Petitioner asserts in the Rehearing Request that its attorney argument and citation to Link and Coiffier "bolster" Dr. Ozer's opinion on the matter, Reh'g. Req. 9, we remain unpersuaded. Notably, Petitioner has not shown that those references provided an explanation, or otherwise would have prompted a person of skill in the art to infer, that there are no distinctions in treating intermediate and high-grade lymphomas, such that the artisan would have understood that Shipp's "treatment findings as to one of these types of NHL would apply equally to the others." *See id*. (quoting Ex. 1002 ¶ 52).

Nor are we persuaded that a rehearing is warranted based upon Petitioner's assertion that "Patent Owner never disputed that IWF Grades F, G, [and] H are treated the same way." Reh'g Req. 9. Patent Owner expressly challenged Dr. Ozer's testimony, stating, "[r]emarkably, Dr. Ozer tries to turn Shipp's silence regarding DLCL into an affirmative disclosure,

asserting that 'the very fact that Shipp does not distinguish among [types F, G, and H] reflects the understanding of those in the art that there were no significant distinctions in treating' different lymphoma subtypes." Prelim. Resp. 12.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has not shown that the Board abused its discretion in denying institution of the challenged claims. *See* 37 C.F.R. § 42.71(d).

ORDER

In consideration of the foregoing, it is hereby ordered that the Petitioner's Rehearing Request is *denied*.

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