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Paper No. 15
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

BIOGEN, INC.,
Patent Owner.

Case IPR2017-01094
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

Celltrion, 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 October 2, 2017 (Paper 12, "Dec."). Paper 13 ("Reh'g Req."). In the Petition (Paper 2, "Pet.") Petitioner raised the following challenges to the claims:

Claims	Basis	References
1 and 2	Pre-AIA § 103	Link,[1] McNeil,[2] and the FDA Transcript[3]
1 and 2	Pre-AIA § 103	Link, McNeil, and the Rituxan Label[4]
1 and 2	Pre-AIA § 103	The E4494 Patient Consent Form[5] and the FDA Transcript
1 and 2	Pre-AIA § 103	Sonneveld[6] and Link

[1] 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).
[2] McNeil, *Non-Hodgkin's Lymphoma Trials In Elderly Look Beyond CHOP*, 90 J. NAT. CANCER INST. 266–67 (1998) (Ex. 1006).
[3] Transcript of Proceedings, Nineteenth Meeting, Biological Response Modifiers Advisory Committee, Department of Health and Human Services, Food and Drug Administration (July 25, 1997) (Ex. 1010).
[4] IDEC Pharmaceuticals Corporation and Genentech, Inc., Product label for Rituxan (1997) (Ex. 1008).
[5] Eastern Cooperative Oncology Group E4494/Cancer and Leukemia Group B CALGB 9793, *Phase III Trial of CHOP versus CHOP and Chimeric Anti-CD20 Monoclonal Antibody (IDEC-C288) in Patients 60 Years or Older with Diffuse Mixed, Diffuse Large Cell and lmmunoblastic Large Cell Histology Non-Hodgkin's Lymphoma,* Appendix I: Suggested Patient Consent Form (undated) (Ex. 1007).

In the Petition, Petitioner also relied upon the Declarations of Izidore Lossos, M.D. (Ex. 1003) and Walter Longo, M.D. (Ex. 1004). Biogen, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("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 at least one challenged claim. Dec. 1. In the Rehearing Request, Petitioner seeks reconsideration of that determination only with respect to its contention that claims 1 and 2 would have been obvious over the combination of Sonneveld and Link. Reh'g Req. 1.

I. 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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[6] Sonneveld et al., *Comparison of Doxorubicin and Mitoxantrone in the Treatment of Elderly Patients With Advanced Diffuse Non-Hodgkin's Lymphoma Using CHOP Versus CNOP Chemotherapy*, 90 J. Clin. Oncol. 2530–2539 (1995) (Ex. 1009).

Petitioner asserts that the Board overlooked or misapprehended the arguments in the Petition that Sonneveld recommends CHOP for elderly DLCL patients, regardless of presence of bulky disease. Reh'g Req. 3–4. In particular, Petitioner asserts that, "[b]y narrowly focusing on the patient characteristics in Table 1 [of Sonneveld], the Board overlooked Sonneveld's conclusion that the superior efficacy of CHOP over CNOP is '*not affected* by any of the patient characteristics, such as . . . *bulky disease, age,* . . . *histopathology*." *Id*. at 1 (quoting Ex. 1009, 5) (emphasis added by Petitioner). Petitioner identifies pages 43, 57–58 of the Petition and paragraph 108 of Dr. Lossos' Declaration as the places where this matter was previously addressed. Reh'g Req. 1, 4. However, neither the cited pages of the Petition, nor the cited paragraph of Dr. Lossos' Declaration discuss the disclosure of Sonneveld upon which Petitioner now relies in the Rehearing Request.

Indeed, Petitioner does not discuss Sonneveld on page 43 of the Petition. On page 57–58 of the Petition, Petitioner supports an assertion that Sonneveld teaches the efficacy of CHOP in DLCL patients over age 60, including bulky disease, by quoting a portion of Sonneveld's Abstract, i.e., "CHOP is well tolerated in elderly patients with advanced intermediate- or high-grade NHL . . . . CHOP should be recommended for elderly patients with high risk NHL." Pet. 57–58 (quoting Ex. 1009, 3, Abstract). That disclosure does not explain, or specifically discuss patients with DLCL and bulky disease. Neither the Petition, nor any cited portions of Dr. Losso's declaration discuss the teaching in Sonneveld addressing study results with respect to specific histopathology and presence of bulky disease that Petitioner quotes and relies upon in the Rehearing Request. Thus, Petitioner

has not shown that we misapprehended or overlooked its argument relying on that teaching as that matter was not set forth in the Petition. As we explained in the Decision, in view of Table 1 only listing characteristics of trial patients separately, "[n]either Petitioner nor Dr. Lossos had explained how a person of skill in the art would understand whether Sonneveld's IWF grade F, G, and/or H NHL patients have bulky disease." Dec. 16. The Rehearing Request does not provide an opportunity to supplement the information set forth in the Petition.

Petitioner asserts also that "[t]he Board further made an incorrect factual determination that Sonneveld fails to disclose 'whether any patient having bulky disease also exhibits IWF grade F, G, or H NHL.'" Reh'g Req. 6 (quoting Dec. 16). According to Petitioner, "[a] closer look at Table 1 reveals that at least 11 patients in IWF grades F, G, and H had bulky disease." *Id*. Petitioner supports that assertion with a "mathematical exercise" to demonstrate that "11 bulky disease patients must have fallen within IWF grades F, G, and H." *Id*. at 6–7. Petitioner identifies pages 53–54 of the Petition as the place where this matter was previously addressed. However, Petitioner's calculation is not set forth on those pages of the Petition. Rather, with regard to Table 1, Petitioner asserts only that "Sonneveld shows that 44% of patients receiving CHOP treatment in the Sonneveld trial had bulky disease, defined as tumor mass ≥ 10 cm." Pet. 53.

Petitioner asserts further that its "mathematical exercise is not needed, given Sonneveld's teaching of CHOP's across-the-board superior efficacy irrespective of the patients' histopathology and presence of bulky disease, as discussed above." Reh'g Req. 8. However, as we discussed above, the disclosure in Sonneveld relied upon for Petitioner's contention was not set

forth in the Petition. Thus, Petitioner has not shown that we have misapprehended or overlooked its argument in this regard as it is missing in the Petition.

II. 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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