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Paper No. 25
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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 IPR2017-01095
Patent 9,296,821 B2

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, Paper 14 ("Reh'g Req."), of the Decision to Institute an *inter partes* review of claims 1–3, 5, and 6 of U.S. Patent No. 9,296,821 B2, Ex. 1001 ("the '821 patent"), insofar as the Decision involved a determination not to institute an *inter partes* review of claims 1–4 based upon an anticipation ground, Paper 12 ("Dec.").

In the Petition (Paper 2, "Pet.") Petitioner raised the following challenges to the claims 1–6:

Claims	**Basis**	**References**
1–6	Pre-AIA § 102	Marcus[1]
3 and 6	Pre-AIA § 103	Marcus and the '137 Patent[2]
1–3	Pre-AIA § 103	Czuczman,[3] IDEC 10-K/A,[4] Foon[5] and Dana[6]

[1] Marcus et al., *CVP chemotherapy plus rituximab compared with CVP as first-line treatment for advanced follicular lymphoma*, 105 BLOOD 1417–23 (2005) (Ex. 1005).
[2] U.S. Patent 5,736,137 issued to Anderson et al. on Apr. 7, 1998. (Ex. 1007).
[3] Czuczman et al., *IDEC-C2B8 and CHOP Chemoimmunotherapy of Low-Grade Lymphoma*, 86 BLOOD 10 Supp. 1:55a (Abstract 206) (1995) (Ex. 1011).
[4] IDEC Pharmaceuticals Corp., Form 10-K/A Annual Report for the Fiscal Year Ended Dec. 31, 1997, filed with the U.S. Securities and Exchange Comm. (Ex. 1006).
[5] Foon et al., Chapter 111: *Lymphomas,* Williams Hematology, 5th Ed. 1076–96 (1990) (Ex. 1008).
[6] Dana et al., *Long-Term Follow-Up of Patients with Low-Grade Malignant Lymphomas Treated with Doxorubicin-Based Chemotherapy or Chemoimmunotherapy*, 11 J. CLIN. ONCOL. 644–51 (1993) (Ex. 1009).

Claims	Basis	References
4–6	Pre-AIA § 103	Czuczman, IDEC 10-K/A, Foon, Dana, Link,[7] and Piro[8]
3 and 6	Pre-AIA § 103	Czuczman, IDEC 10-K/A, Foon, Dana, Link, Piro, and the '137 Patent

Petitioner also relied upon the Declarations of Izidore Lossos, M.D., Ex. 1002, and Walter Longo, M.D., Ex. 1003. 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 demonstrated a reasonable likelihood that it would prevail only in showing the unpatentability of claims 1–3, 5, and 6 on the following grounds:

> A. Claims 5 and 6 under 35 U.S.C. § 102(b) as anticipated by Marcus;
> B. Claim 6 under 35 U.S.C. § 103(a) as obvious over Marcus and the '137 patent;
> C. Claims 1–3 under 35 U.S.C. § 103(a) as obvious over Czuczman, Foon, and Dana; and
> D. Claim 3 under 35 U.S.C. § 103(a) as obvious over Czuczman, Foon, Dana, and the '137 patent.

Dec. 34. Thus, we instituted an *inter partes* review of only those claims, based upon only those grounds. *Id*. In the Rehearing Request, Petitioner

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[7] 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. 1010).
[8] Piro et al., *RITUXAN™ (rituximab, IDEC-C2B8): Interim analysis of a phase II study of once weekly times 8 dosing in patients with relapsed low-grade or follicular non-Hodgkin's lymphoma*, 90 BLOOD 10 Supp. 1:510a (Abstract 2272) (1997) (Ex. 1004).

seeks reconsideration of our determination not to institute an *inter partes* review of claims 1–4 as anticipated by Marcus. 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*.

Regarding claim 4, Petitioner takes issue with the Board's determination that Petitioner failed to address whether Marcus satisfies the "beneficial synergistic effect" claim limitation under the Board's construction of that claim term. Reh'g Req. 1. According to Petitioner, the Petition addresses that limitation by asserting that the Marcus teaches "more than doubled time to progression" resulting from the combination of rituximab and CVP. *Id*. (citing Pet. 38, 41). Petitioner asserts also that "the Board ignored record evidence showing Patent Owner's repeated admissions that Marcus teaches the 'beneficial synergistic effect' limitation," during prosecution and in Patent Owner's Preliminary Response. *Id*. at 2.

We disagree with Petitioner as to both points. As Petitioner notes in the Rehearing Request, Reh'g Req. 4–5, our Decision recognizes Petitioner's reliance on Marcus' teaching that "the addition of rituximab to a standard CVP regimen significantly lengthened [the] time to treatment failure and more than doubled time to progression, with significantly

improved response rates, duration of response, disease-free survival, and time to next antilymphoma treatment," for the "beneficial synergistic effect" limitation of claim 4. Dec. 15. However, as we explained in the Decision, Petitioner did not discuss or explain how that teaching demonstrates "a clinical outcome that reflects a greater beneficial effect than the additive effects of rituximab and CVP when administered alone," as required by our claim construction. Dec. 15–16. At most, the Petition explains that the combination therapy provided an improvement "compared with CVP" alone. Pet. 2, 41 (quoting Ex. 1005, 6).

Indeed, relying on Marcus' comparison of ritixumab and CVP with CVP alone, Petitioner summarily asserts in the Petition that "[b]ased on this reported improvement in clinical outcomes, Marcus accordingly reports a beneficial synergistic effect of the combination." Pet. 39 (citing Ex. 1002 95). Petitioner's declarant, Dr. Lossos, also relies on Marcus' "reported improvement in clinical outcomes" based upon "a clinical trial comparing CVP with CVP plus rituximab." Ex. 1002, 54–55. Petitioner has not shown, however, that the Petition or the declaration includes any discussion regarding a comparison of the combination therapy to rituximab alone, or, significantly, a comparison of the combination therapy to the additive effects of rituximab alone and CVP alone, as required to demonstrate a "beneficial synergistic effect."

Nor has Petitioner shown that the Petition cites to any portion of the prosecution history demonstrating synergistic data. Specifically, Petitioner refers to pages 31 and 65 of the Petition as places where it explained that "Patent Owner itself claimed that Marcus teaches 'beneficial synergistic effect' during prosecution of Application No. 13/524,896 ('the '896

[a]pplication')[9] which matured into the '821 patent." Reh'g Req. 5. Page 31 of the Petition sets forth Petitioner's proposed claim construction for the "beneficial synergistic effect" as meaning merely "an improvement in clinical outcome." Pet. 31. The prosecution history relied upon on that page is directed only to a comparison of combination rituximab-CVP therapy with CVP alone. *Id*. (citing Ex. 1069,[10] 120). According to Petitioner, Applicant argued that data showing an improvement provided by the combination therapy over CVP alone demonstrates a beneficial synergistic effect. *Id*. However, we explained in the Decision that a "beneficial synergistic effect" requires showing more than simply "an improvement in clinical outcome," but also that such improvement amounts to more than the additive effects of rituximab and CVP when administered alone. Dec. 7.

Page 65 of the Petition addresses Petitioner's assertion that there are no secondary indicia of non-obviousness and does not address its assertion that Marcus anticipates claim 4. Pet. 65. Petitioner's reference to the prosecution history on that page characterizes Applicant as having asserted that Marcus provided "an unexpected result because the art taught away from using CVP." Pet. 65 (citing 1069, 141). Neither the argument on that page, nor the information included on the cited portion of the prosecution

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[9] "The '821 patent issued from U.S. Application No. 13/524,896 ("the '896 application") filed on June 15, 2012. Exs. 1001 and 1069. The '896 application is a divisional of U.S. Application No. 11/840,956, which is a continuation of U.S. Application No. 10/196,732, which is in turn a continuation of U.S. Application No. 09/372,202 ("the '202 application") filed on August 11, 1999. Exs. 1001, 1034, 2003, 2004, and 2005." Dec. 8.

[10] "File history of the '821 patent (Application No. 13/524,896) (Ex. 1069)." Dec. 6 n.9.

history, address expected or unexpected additive effects of rituximab and CVP, as compared with the effects of rituximab alone and CVP alone. As set forth above, that discussion is precisely what we explained is missing from the Petition. Dec. 15–16.

Petitioner asserts that we "ignored" Patent Owner's discussion of the prosecution history in the Preliminary Response, Reh'g Req. 6–8. We disagree. In particular, Petitioner refers to page 11 of the Preliminary Response. *Id*. at 6. We address that specific page of the Preliminary Response and the discussion contained therein describing Patent Owner's proposed claim construction. Dec. 6 (citing Prelim. Resp. 11). Moreover, we note that the portion of the prosecution history referenced by Patent Owner on that page was not referred to, or otherwise relied upon, in the Petition. Instead, Petitioner seeks to set forth and rely upon such uncited information from the prosecution history in the Rehearing Request to supply the information we observed was missing in the Petition, i.e., demonstrating how the results in Marcus may be viewed as teaching that the combination of rituximab and CVP provides more than additive effects of offered by each component when used alone. However, a Rehearing Request does not provide an opportunity to supplement arguments or information set forth in the Petition.

Thus, Petitioner has not shown that we have misapprehended or overlooked matters raised in the Petition addressing whether the prior art disclosed that the combined rituximab-CVP therapy provides a "beneficial synergistic effect," as required by claim 4.

Regarding claims 1–3, Petitioner asserts that the Decision "improperly relied on disclosures of disconnected claim elements dispersed throughout the specification of the '202 application," to support finding that a person of skill in the art would have understood Applicant had possession of the claimed method. Reh'g Req. 9. We note that Petitioner does not contend that we misapprehended or overlooked this contention in the Decision. Indeed, we addressed this contention by Petitioner in the Decision and, thus, do not do so again here. *See* Dec. 10–11. Petitioner asserts further that the Decision "ignores" Dr. Lossos' testimony on this matter. *Id*. (citing Pet. 22–28; Ex. 1002 ¶¶ 22–25, 78–89). However, paragraphs 22–25 of Dr. Lossos' declaration do not address this matter, and paragraphs 78–89 do not offer any information in addition to the assertions made by Petitioner that we address in the Decision.

Petitioner asserts also that the Board misconstrued Petitioner's position regarding the disclosures of the '202 application by stating that "Petitioner acknowledges . . . the disclosure of CVP as a chemotherapeutic regimen used in combination with rituximab (375 mg/m^2) to treat low-grade NHL . . . ." Reh'g Req. 10 (citing Dec. 10). Petitioner asserts that it explained in the Petition that the '202 application discloses "a clinical trial that first administers standard CVP and *follows with* administration of rituximab maintenance therapy to Responders after a second randomization of the Responders," and, thus, did not acknowledge that the disclosure suggests "administering anti-CD20 antibody *during* CVP chemotherapy . . . ." *Id*. (citing Pet. 25–26). However, as the quoted portion of the Decision challenged by Petitioner reveals, we did not state that Petitioner acknowledged any disclosure of administering rituximab "during"

CVP. Rather, the Decision states that Petitioner acknowledges that the '202 application describes using rituximab "in combination" with CVP. Dec. 10. With regard to the timing for such combination, the Decision explains that original claim 17 of the '202 application expressly recites an option for administering rituximab "during" a chemotherapeutic regimen. Dec. 10–11.

Petitioner asserts that we abused our discretion by relying on that disclosure because it only serves to render the claimed invention obvious. Reh'g Req. 12 (citing Pet. 20). That argument was not raised on the cited page of the Petition, or at all with respect to arguments addressing the claim limitation for administering rituximab during CVP therapy. Moreover, as we stated in the Decision, the '202 application "expressly recited that option" in original claim 17, such that a person of skill in the art would have understood Applicants to have been in possession of the claimed method of administering rituximab during a chemotherapeutic regimen. Dec. 11. Petitioner has not explained persuasively otherwise, or at all, in the Petition or in the Rehearing Request.

Petitioner asserts further that we failed to consider that the sentence immediately following the disclosure of administering rituximab "during" a chemotherapeutic regimen states that such regimen "may be *selected from the group consisting of*, at the very least" a list of various chemotherapeutic regimens that did not include CVP. Reh'g Req. 11 (citing Pet. 22–23). According to Petitioner and Dr. Lossos, "the omission of CVP from this list means that this disclosure does not support CVP chemotherapy." *Id.* (quoting Ex. 1002 ¶ 81). This argument is not persuasive as it does not recognize that the phrase "consisting of" is modified by the phrase "at the very least." Ex. 1034, 9. The phrase "at the very least" communicates only

a lower limit to the group, i.e., the group is not to be intended to include any fewer items than those listed. The "at the very least" phrase does not confer an upper limit. In other words, taken together, the phrase "the group consisting of, at the very least" signals that the group listing is not intended to be exclusive. Petitioner has not explained persuasively otherwise in the Petition or in the Rehearing Request.

Thus, Petitioner has not shown that we have misapprehended or overlooked matters raised in the Petition addressing whether a person of skill in the art would have understood Applicants of the '202 application had possession of the inventions set forth in claims 1–3.

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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