

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2016-01667
Patent 7,976,838 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 of the Decision Denying Institution of an *inter partes* review of claims 1–14 of US 7,976,838 B2 (Ex. 1001; “the ’838 patent”) entered on March 2, 2017 (Paper 15, “Dec.”). Paper 16 (“Reh’g Req.”).¹ In the Petition (Paper 2; “Pet.”), Petitioner raised the following challenges to the claims:

Reference[s]	Basis	Claims challenged
Edwards ²	§ 102	1–5, 7–14
Edwards and Tuscano ³	§ 103(a)	1–14
Goldenberg, ⁴ Curd, ⁵ and De Vita ⁶	§ 103(a)	1–14

¹ Petitioner filed a Motion to Seal its Rehearing Request (Paper 17) and filed a Redacted Rehearing Request (Paper 18).

² JCW Edwards et al., *Efficacy and Safety of Rituximab, a B-Cell Targeted Chimeric Monoclonal Antibody: A Randomized, Placebo-Controlled Trial in Patients with Rheumatoid Arthritis*, Abstracts of the American College of Rheumatology 66th Annual Meeting, Oct. 24-29, 2002 (New Orleans, LA). Ex. 1033 (“Edwards”).

³ Joseph M. Tuscano, *Successful Treatment of Infliximab-Refractory Rheumatoid Arthritis with Rituximab*, 46 ARTHRITIS RHEUM 3420, LB11 (2002). Ex. 1034 (“Tuscano”).

⁴ Patent Application Publication No. WO 00/74718 A1 by David M. Goldenberg et al., published Dec. 14, 2000. Ex. 1038 (“Goldenberg”).

⁵ Patent Application Publication No. WO 00/67796 A1 by John G. Curd et al., published Nov. 16, 2000. Ex. 1031 (“Curd”).

⁶ S De Vita et al., *Ruolo Patogentico Dei Linfociti B Nella Sinovite Reumatoide: Il Blocco Selettivo B Cellulare Puo Indurre Risposta Clinica In Pazienti con Artrite Reumatoide Refrattaria*, OFFICIAL JOURNAL OF THE ITALIAN SOCIETY OF RHEUMATOLOGY, Vol. 53, No. 3 (Suppl. No. 4) (2001) [ENGLISH TRANSLATION]. Ex. 1051 (“De Vita”).

In the Petition, Petitioner also relied on the Declarations of Maarten Boers, M.D., Ph.D. (Ex. 1002), M. Laurentius Marais, Ph.D. (Ex. 1039), and Jack Goldberg, M.D. (Ex. 1036). Genentech, Inc. (“Patent Owner”) filed a Patent Owner Preliminary Response. Papers 10, 13⁷ (“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. 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*.

Petitioner asserts that “in construing ‘inadequate response to a TNF α -inhibitor,’ the Board erroneously required that the claimed patients be ones who had been subjected to prior treatment with TNF α -inhibitor and failed that treatment.” Reh’g Req. 1, 5–8. According to Petitioner, “the Board overlooked the crucial admission in the specification that ‘the invention is

⁷ Patent Owner filed a Motion to Seal its Patent Owner Preliminary Response and certain exhibits, and for Entry of a Protective Order. Paper 12.

not limited to a prior therapy step.” *Id.* at 1, 6 (citing Pet. 25). Petitioner asserts that the claim terms should have been construed “to include patients who are predisposed to an inadequate response to at least one TNF α -inhibitor, regardless of whether they have had prior treatment.” *Id.* at 1. Petitioner further asserts that a person of skill in the art would have known that certain patients are innately inadequate responders. *Id.* at 2, 7–8 (citing Pet. 25–26).

Although the Specification explains that the invention, as a whole, is not limited to treating patients who have had a prior treatment with a TNF α -inhibitor, the challenged claims are directed to such a population. Petitioner relies on a broader disclosure of the invention when referring to the Specification’s description of patients who “may be considered to be prone to experience a toxicity . . . with a TNF α -inhibitor before therapy therewith has begun, or the patient may be determined to be one who is unlikely to respond to therapy with a TNF α -inhibitor.” Ex. 1001, 28:55–61. The challenged claims are directed to methods of treating rheumatoid arthritis in a patient “who experiences an inadequate response to a TNF α -inhibitor,” and as we explained in the Decision, the Specification expressly defines the term “inadequate response to a TNF α -inhibitor” as “an inadequate response to previous or current treatment with a TNF α -inhibitor because of toxicity and/or inadequate efficacy.” Dec. 7 (quoting Ex. 1001, 5:25–28).

Next, acknowledging that Edwards “does not explicitly state that any of the patients in the study had already failed treatment with TNF α -inhibitor,” Petitioner asserts that, based upon its proposed construction, the claims do not require a prior therapy step. *Id.* at 2–3, 8–9. Petitioner asserts also that “statistics establish that Edwards necessarily and inevitably

practiced the claimed method” on at least one patient, based upon the testimony of Drs. Boers and Marais that many RA patients are inadequate responders. *Id.* at 3, 10–11. In the Decision, we squarely address this argument explaining that inherency may not be established by probabilities or possibilities. Dec. 7–9. Thus, Petitioner has not established that we overlooked or misapprehended its argument as to this issue. Petitioner’s assertions in the Rehearing Request concerning Patent Owner’s alleged admissions regarding the patient population in Edwards does not overcome the deficiency in the Petition insofar as it relies upon probabilities to establish inherency. *See* Reh’g Req. 3, 11 (citing Preliminary Resp. 24–25).

Regarding the combination of Edwards and Tuscano, Petitioner takes issue with the statement in the Decision that “Petitioner has not explained persuasively why a person of skill in the art would have expected the regimen that was effective in Edwards’s patients to be effective in Tuscano’s inadequate responders.” Reh’g Req. 3–4 (quoting Dec. 13). According to Petitioner, that issue “is not germane to obviousness,” as Edwards alone would have provided a person of ordinary skill in the art an expectation that Edwards’s regimen would be effective in inadequate responders. *Id.* at 4, 11–14 (citing Pet. 48). As discussed in the Decision, Petitioner has not established that fact. Dec. 13. Indeed, we explained, “[w]hat remains missing is some articulated reasoning why Edwards’ results would have provided a skilled artisan a reasonable expectation of successfully treating RA in inadequate responders with Edwards’ dosing regimen.” *Id.* Thus, Petitioner has not established that we overlooked or misapprehended its argument as to this issue.

With respect to the combination of Goldenberg, Curd, and De Vita, Petitioner asserts that “the Board erroneously found that a person of ordinary skill would not have known how to optimize the dose.” Reh’g Req. 4, 14–15. According to Petitioner, that “finding overlooks the patent itself, which states that a POSA was capable of determining the effective dosages via the exercise of therapeutic discretion.” *Id.* at 4–5 (citing Pet. 7). We do not agree that the Specification describes that a person of skill in the art “was capable of determining the effective dosages,” as asserted by Petitioner. Moreover, the Petitioner does not make that assertion. Rather, the Petitioner properly characterizes the Specification as providing suggested dosage amounts and explains that those suggested amounts “are subject to a great deal of therapeutic discretion.” Ex. 1001, 29:42–43; Pet. 7.

In the Petition, Petitioner relies on the teachings of the prior art as a basis for optimizing the dose of rituximab. Pet. 53. In response, we explained in the Decision that Petitioner’s argument was not sufficiently supported as the claimed dosing regimen involves a number of variables that differ from the cited prior art and Petitioner has not shown that each of those parameters represents a result-effective variable, such that a person of skill in the art would have had a reason to optimize those parameters. Dec. 17. Thus, Petitioner has not established that we overlooked or misapprehended its argument as to this issue.

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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