

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AJINOMOTO CO., INC.
Petitioner,

v.

ABTIS CO., LTD.
Patent Owner

Patent No. 11,896,675
Issue Date: February 13, 2024

Title: SITE-SPECIFIC ANTIBODY CONJUGATION AND ANTIBODY-
DRUG CONJUGATE AS SPECIFIC EMBODIMENT THEREOF

Inter Partes Review No. IPR2025-00283

**PETITIONER'S REQUEST FOR DIRECTOR REVIEW OF FINAL
WRITTEN DECISION**

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I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.75(c), Petitioner Ajinomoto Co., Inc. respectfully requests Director Review of the Board's Final Written Decision (Paper 46) granting Patent Owner's Motion to Amend and adding substitute claims 14–16 to U.S. Patent No. 11,896,675 B2. The Board's decision should be modified because the Board violated the Administrative Procedure Act ("APA") by implicitly construing the claim terms "antibody" and "modified lysine residue at 248 position" as limited to IgG1 antibodies in its Final Written Decision, despite expressly stating at institution that no claim construction was necessary and without providing the parties the requisite notice and opportunity to respond to the change in position.

As the Federal Circuit held in *Google LLC v. EcoFactor, Inc.*, 92 F.4th 1049, 1057 (Fed. Cir. 2024), the APA requires agencies to provide adequate notice and an opportunity to respond before changing positions on claim construction between institution and final decision. Here, the Board's Institution Decision stated that "we do not need to expressly construe any claim term to resolve any controversy at this stage of the proceeding." Paper 16, 12. Yet in its Final Written Decision, the Board for the first time implicitly adopted a limiting construction of "antibody" and the 248 position as applying only to IgG1 antibodies. Paper 46, 18-20, 27-28. The Board's analysis was outcome determinative to its written description and enablement decision, demonstrating that the Board engaged in claim construction despite stating

otherwise. Petitioner was denied adequate notice and opportunity to address this implicit construction, in violation of the APA.

II. LEGAL STANDARD FOR REHEARING

A party requesting rehearing 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).

The APA requires that “[p]ersons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.” 5 U.S.C. § 554(b)(3). The Board violates this requirement when it changes its claim construction position between institution and final decision without providing the parties adequate notice and opportunity to respond. *Google*, 92 F.4th at 1057. A statement by the Board “that it was not engaging in claim construction is not dispositive as to whether claim construction occurred.” *Id.* at 1056 (finding the Board implicitly engaged in claim construction where “the outcome of the Board’s assessment established the scope of the [] limitation”).

III. THE BOARD’S INSTITUTION DECISION STATED NO CLAIM CONSTRUCTION WAS NECESSARY AND ITS PRELIMINARY GUIDANCE DID NOT CHANGE THAT POSITION

In its Institution Decision, the Board addressed claim construction in Section III.C. Paper 16, 11-12. Although Petitioner proposed constructions for multiple claim terms, the Board declined to adopt any construction. The Board stated:

After reviewing Petitioner’s arguments and the evidence currently before us, we determine that we do not need to expressly construe any claim term to resolve any controversy at this stage of the proceeding.

Paper 16, 11-12 (Section III.C, Claim Construction). This statement established the baseline understanding for the proceeding, that the claims would be given their ordinary and customary meaning without any limiting construction.

Petitioner reasonably relied on this statement in developing its opposition to Patent Owner’s Motion to Amend. When the Board represents that no claim construction is necessary, parties are entitled to rely on that representation and to understand that the claims will be evaluated according to their ordinary meaning.

Subsequently, in its Preliminary Guidance on Patent Owner’s Motion to Amend, the Board did not address claim construction. Instead, the Board generally referenced the definition of “antibody” in the specification without providing any indication that it was contemplating a limiting construction. Paper 27, 6-7.

IV. THE FINAL WRITTEN DECISION IMPLICITLY CONSTRUED THE CLAIMS AS LIMITED TO IgG1 ANTIBODIES

Despite stating in Section III.E.2 of the Final Written Decision that “we do not need to expressly construe any claim term to resolve any controversy in the proceeding” (Paper 46, 22), the Board effectively adopted a limiting construction that was outcome determinative to its written description and enablement analyses. Throughout Sections III.D.4 and III.E.4, the Board effectively construed the claims

as limited to IgG1 antibodies, even though the claim language recites “antibody” without limitation to any particular species or isotype.

A. The Board’s Written Description Analysis Reveals an Implicit IgG1 Limitation

In addressing Petitioner’s written description arguments, the Board relied on an implicit construction limiting “antibody” to only those compatible with IgG1-specific technology. The Board stated:

Because Petitioner acknowledges that “[t]he disclosure of SSFI that only binds to IgG1 Fc domains (SEQ ID NO:1) is consistent with the limited scope of examples in the ’675 patent” (Sur-Reply 5) and because the scope of the antibody that claims 14–16 recite is limited by all claim elements beyond the recited “modified antibody” such as the lysine residue position 248, we are not persuaded by Petitioner’s argument that the full scope of claims 14–16 lacks written description support.

Paper 46, 17 (Section III.D.4). This reasoning necessarily depends on construing the claims as limited to antibodies compatible with the IgG1-specific SSFI disclosed in the specification. The Board’s analysis would be nonsensical if “antibody” were given its ordinary meaning encompassing all immunoglobulin isotypes (IgA, IgD, IgE, IgG, and IgM), as Petitioner argued and consistent with the definition in the specification.

While the Board pointed to Dr. Zhou’s testimony that “[a] POSA would understand the claim itself to limit the modified antibodies to those with lysine at

position 248” (Paper 46, 16), this was a single sentence provided in an expert declaration without any context or explanation (EX2008, ¶46). Dr. Zhou’s statement was also unrelated to any proposed construction advanced in Patent Owner’s papers (*see, e.g.*, Papers 8, 9, 23, 28, and 45). Nevertheless, the Board adopted this reasoning and the implicit construction that the 248 position (as determined by the EU numbering system) effectively limits the claims to IgG1 antibodies, which are the only antibodies for which the EU numbering system assigns position 248 to a lysine residue. The Board relied on this implicit construction to reject Petitioner’s arguments that the claims encompass other immunoglobulin isotypes that recite other sequences or lack lysine at position 248 under the EU numbering system.

B. The Board’s Enablement Analysis Confirms the Implicit IgG1 Limitation

The Board’s enablement analysis similarly reveals the same implicit IgG1 construction. The Board stated:

Petitioner’s claim scope argument is based on the false premise that the scope of claims 14–16 is as broad as the claim term “antibody” without taking into account all other claim elements.

Paper 46, 27 (Section III.E.4.b). And further:

Petitioner’s argument that the claims encompass proteins that lack a lysine residue at a 248 position improperly excludes from the claim language the “lysine residue at 248 position . . . [as] determined by the EU numbering system” that claims 14–16 require.

Id. The Board concluded that the 248 limitation (as determined by the EU numbering system) inherently limits the claims to IgG1 antibodies. This is precisely the type of claim construction dispute that the Board stated was unnecessary to resolve. If the Board believed that the 248 limitation narrowed the claim scope to only IgG1 antibodies, it was required to say so expressly and give the parties notice.

V. THE BOARD’S NEW CONSTRUCTION VIOLATES THE APA

In *Google*, 92 F.4th 1049, the Federal Circuit addressed a similar situation where the Board changed its position on claim construction between institution and final decision. The Federal Circuit held that the APA requires the Board to provide adequate notice when it intends to rely on a particular claim construction, even when that construction is not expressly stated. Further, the Board “cannot, without notice and opportunity for the parties to respond, change theories midstream by adopting a claim construction in its final written decision that neither party requested nor anticipated.” *Google*, 92 F.4th at 1057 (citing *SAS Institute, Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016), *rev’d on other grounds*, 584 U.S. 357 (2018)); *see also SAS Institute*, 825 F.3d at 1351 (“We have interpreted § 554(b)(3) in the context of IPR proceedings to mean that “an agency may not change theories in midstream without giving respondents reasonable notice of the change” and “the opportunity to present argument under the new theory.”” (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1080 (Fed. Cir. 2015))).

The Federal Circuit applied this principle to the Board’s new explicit claim construction in the earlier *SAS Institute* decision that *Google* cites. The Federal Circuit explained:

SAS focused its argument on the Board’s institution decision claim interpretation, a reasonable approach considering ComplementSoft agreed with this interpretation in its patent owner’s response and never suggested that the Board adopt the construction that eventually materialized in the final written decision. It is difficult to imagine either party anticipating that already-interpreted terms were actually moving targets, and it is thus unreasonable to expect that they would have briefed or argued, in the alternative, hypothetical constructions not asserted by their opponent.

825 F.3d at 1351. Critically, *Google* illustrates that implicit constructions are subject to the same notice requirements as express constructions. *See* 92 F.4th at 1056–57.

At institution, the Board stated unequivocally that “we do not need to expressly construe any claim term to resolve any controversy at this stage of the proceeding.” Paper 16, 12. This statement established the parties’ reasonable expectations for the remainder of the proceeding. The Board’s Preliminary Guidance did not change on this position.

In the Final Written Decision, however, the Board implicitly adopted a different, limiting construction that the 248 position limitation effectively restricts the claims to IgG1 antibodies. Paper 46, 16–17, 27–28. Importantly, “neither party requested nor anticipated” this implicit construction. *Google*, 92 F.4th at 1057.

Rather, Petitioner was the only party to advance specific constructions of “antibody” and “at 248 position of heavy chain amino acid sequence.” Petitioner’s construction relied on the express definitions of the ’675 patent to indicate that these terms are not confined to IgG1. Paper 1, 9-12. Patent Owner never countered this construction nor provided an alternative construction of its own, and the Board repeatedly indicated that no construction was needed. Yet, the Board relied on this implicit construction to reject Petitioner’s arguments that the claims lack written description support and enablement because they encompass antibodies beyond IgG1. Contrary to Petitioner’s construction—the only proposed construction in the record—the Board stated that “the scope of the antibody that claims 14–16 recite is limited by all claim elements beyond the recited ‘modified antibody’ such as the lysine residue position 248” Paper 46, 17.

Although the Board recited that no claim construction was necessary, its analysis necessarily depended on a construction limiting “antibody” and the 248 position to IgG1 antibodies. Without this limiting construction, the Board could not have rejected Petitioner’s arguments that the claims lack written description support and enablement for the full scope of antibodies recited in the claims.

VI. PETITIONER WAS PREJUDICED BY THE LACK OF NOTICE

Petitioner was prejudiced by the Board’s failure to provide notice of the implicit claim construction adopted in the Final Written Decision. Petitioner argued

throughout that the claims, as written, encompass all immunoglobulin isotypes (IgA, IgD, IgE, IgG, and IgM) and therefore lack written description support and enablement for the full claim scope. Paper 25, 2–5; Paper 33, 2–10.

The Board rejected Petitioner’s arguments in the Final Written Decision based on its implicit construction that the 248 limitation effectively restricts the claims to IgG1 antibodies. Had Petitioner been given adequate notice that the Board intended to adopt this construction, Petitioner could have addressed it directly, for example, by presenting evidence regarding the EU numbering system’s applicability to different immunoglobulin isotypes, or by arguing that the 248 limitation does not inherently restrict the claims to IgG1 antibodies.¹

Instead, Petitioner reasonably relied on the Board’s statement that no claim construction was necessary. The Board’s subsequent reliance on an implicit limiting construction to reject Petitioner’s arguments deprived Petitioner of a meaningful opportunity to respond, in violation of the APA.

VII. THE IMPLICIT CONSTRUCTION WAS OUTCOME DETERMINATIVE

The Board’s implicit construction was not merely incidental to its analysis, it was outcome determinative. The Board’s rejection of Petitioner’s written description

¹ To the extent the issue was raised at oral hearing, that does not constitute adequate notice. *See Dell Inc. v. Accelaron, LLC*, 818 F.3d 1293, 1300-01 (Fed. Cir. 2016).

and enablement arguments depended entirely on the implicit construction limiting the claims to IgG1 antibodies.

Petitioner argued that the claims, as written, encompass all immunoglobulin isotypes, including IgA, IgD, IgE, IgG, and IgM. Paper 25, 3; Paper 33, 2–3. The '675 patent specification only discloses examples and methods for modifying human IgG1 antibodies. Paper 33, 5-6, 9. If the claims were given their ordinary meaning encompassing all antibody isotypes, Petitioner's written description and enablement arguments would have substantial force because the specification does not teach how to modify IgA, IgM, or other non-IgG1 antibodies at position 248.

The Board avoided this result only by implicitly construing the claims as limited to antibodies compatible with the disclosed IgG1-specific technology. The Board repeatedly characterized Petitioner's arguments as improperly "excluding" claim limitations, when in fact Petitioner was arguing for the ordinary meaning of "antibody" as defined in the specification to include all immunoglobulin isotypes. Paper 46, 16–17, 27–28.

VIII. CONCLUSION AND REQUESTED RELIEF

For the reasons stated above, the Board's implicit construction was outcome determinative to the Board's rejection of Petitioner's written description and enablement arguments. Petitioner was denied adequate notice and an opportunity to

respond to this implicit construction, in violation of the APA's procedural requirements. Petitioner respectfully requests that the Board:

1. Grant rehearing of the Final Written Decision;
2. Provide Petitioner with notice and an opportunity to respond to any claim construction the Board intends to adopt, whether express or implicit;
3. Reconsider its written description and enablement analyses in light of the proper claim scope; and
4. Deny Patent Owner's Motion to Amend and find that proposed substitute claims 14–16 are unpatentable for lack of written description support and/or enablement.

Respectfully submitted,

Dated: August 31, 2026

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petitioner's Request for Rehearing of Final Written Decision was served August 31, 2026, by electronic mail to the attorneys of record for Patent Owner at the following address:

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