

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. IPR2025-0283

**OPPOSITION TO PATENT OWNER'S ARGUMENT FOR
DISCRETIONARY DENIAL**

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EXHIBIT LIST

Ex #	Exhibit Description
1001	U.S. Patent No. 11,896,675 (“the ’675 Patent”)
1002	Declaration of Dr. Lawrence Nathan Tumey
1005	CA 3132959A1 (Canadian National Stage of WO 2020/184944)
1006	Yamada et al., <i>Development of a Novel Chemical Site-Specific Conjugation Platform for ADCs – Ajicap™ Technology</i> , Poster Presentation from PEPTALK 2019, THE PROTEIN SCIENCE WEEK, Jan. 14-18, 2019 (“PepTalk Poster”)
1007	Okuzumi, <i>Technology of Site Specific Conjugation for Next Generation ADCs</i> , Luncheon Presentation from PEPTALK 2019, THE PROTEIN SCIENCE WEEK, Jan. 16, 2019 (“PepTalk Presentation”)
1008	WO 2018/199337 (“Yamada”)
1009	U.S. 2020/0190165 (U.S. National Stage of Yamada)
1010	WO 2019/240288 (“Matsuda”)
1011	U.S. 2021/0139541 (U.S. National Stage of Matsuda)
1035	Prosecution History for the ’675 Patent

I. INTRODUCTION

Petitioner, Ajinomoto Co., Inc. (“Ajinomoto” or “Petitioner”), submits this brief in opposition to the Patent Owner Discretionary Denial (“PODD”) brief submitted by AbTis Co., Ltd. pursuant to the Board’s “Interim Processes for PTAB Workload Management” (“Guidance”), dated March 26, 2025.

Petitioner challenged thirteen claims of U.S. Patent No. 11,896,675 (“the ’675 Patent”). In response to the merits of the Petition, Patent Owner has statutorily disclaimed twelve of the claims, leaving only Claim 11 at issue in this Petition. Patent Owner suggests that the narrowed scope of the Petition and the absence of co-pending district court litigation are reasons to deny the Petition altogether. The opposite is true. Because only Claim 11 remains, the *inter partes* review of the ’675 Patent will be far more efficient and expeditious. Likewise, because patentability will not otherwise be decided in another forum, both facts weigh *against* denial.

None of Patent Owner’s other arguments for discretionary denial have merit.

Patent Owner repeatedly invokes the presumption of validity that flows from 35 U.S.C. § 282 (PODD, 2, 9, 17), but as the Board is aware, that presumption does not apply during *inter partes* review. See *Celgene Corp. v. Peter*, 931 F.3d 1342, 1362 (Fed. Cir. 2019).

Patent Owner repeatedly mischaracterizes a single statement in the Petition about the Matsuda reference as an “intentional or negligent misrepresentation” in

the hope of biasing the Board against institution. Not only has Patent Owner misinterpreted the statement, but Patent Owner's ad hominin argument also ignores that Matsuda plays virtually no role in the remaining grounds, and therefore has little relevance to the discretionary denial analysis under *Advanced Bionics*.

Patent Owner argues that the Petition should be discretionarily denied because it relies on prior art previously considered by the Examiner, but multiple relevant references were not previously addressed during prosecution nor are they cumulative. PepTalk Presentation and PepTalk Poster were neither cited nor considered during prosecution by the Examiner, and Section XI shows how the Examiner materially erred in evaluating Yamada. Petition, 84-86.

As to Ground 1, Patent Owner's assertion of "legal error" in the Petition's anticipation theory and underlying priority date analysis is not only a *non-discretionary* consideration, but more importantly, is simply wrong. The lack of adequate written description support for Claim 1's Negative Limitation renders dependent Claim 11 equally unsupported, and the '959 Publication is therefore anticipating prior art to Claim 11 just as to Claim 1. Indeed, Patent Owner appears to acknowledge this via its stated intention to amend Claim 11 to omit the Negative Limitation. PODD, 19 n.4.

Finally, Patent Owner grossly mischaracterizes the nature and extent of the Petition's reliance on the expert testimony of Dr. Tumey. The Petition more than

satisfies the “reasonable likelihood of success” standard as to one or more grounds even in the absence of Dr. Tumey’s testimony. In any case, nothing in the Office’s Guidance suggests that the Petition’s reliance on Dr. Tumey favors discretionary denial.

In sum, Patent Owner fails to identify any valid basis for discretionary denial of the Petition, and many of Patent Owner’s arguments affirmatively support *institution*, not denial. After Patent Owner’s disclaimer, all that remains for the Board to decide is the patentability of Claim 11, and under only select grounds. There is no other co-pending proceeding in which Claim 11 will otherwise be adjudicated, and the Petition easily meets the reasonable likelihood of success standard for which an *inter partes* review should be instituted.

II. ANY MISIMPRESSION REGARDING MATSUDA WAS INADVERTENT AND IMMATERIAL

Patent Owner makes much of the fact that U.S. Patent Publication No. 2021/0139541 (“Matsuda ’541”) (EX1011) is listed on the face of the ’675 Patent. PODD, 7-8. That is accurate. As Patent Owner points out, Grounds 3, 5, and 7 of the Petition rely on International Publication WO 2019/240288 (“Matsuda”) (EX1010), of which Matsuda ’541 was the U.S. National Stage.

However, Petitioner did not misrepresent Matsuda. Patent Owner’s assertion that Petitioner did so is incorrect, and Patent Owner’s suggestion that Petitioner may have done so intentionally is inappropriate. PODD, 1-2. Patent Owner’s allegation

rests on a single statement in the Petition: “The PepTalk Poster, PepTalk Presentation, and Matsuda were not of record or considered by the Office during prosecution of the ’675 Patent.” Petition, 84. Petitioner here intended to convey that each of these three references was not of record, not considered (i.e., addressed in prosecution), or both. To the extent the Petition’s phrasing left any misimpression as to whether Matsuda was of record, it was inadvertent.

Moreover, Patent Owner’s focus on Matsuda is a red herring, as Matsuda plays little to no role in the Petition’s remaining Grounds as applied to Claim 11. Grounds 1, 3, 5, and 7 remain relevant, and only Grounds 3, 5, and 7 reference Matsuda at all. However, neither Ground 3 nor Ground 5 relies on Matsuda to challenge Claim 11 – these grounds rely on Matsuda only in connection with other claims. Specifically, Ground 3 relies on PepTalk Poster and Yamada (Petition, 45, 49-56), and Ground 5 relies on PepTalk Presentation and Yamada (Petition, 62, 65-68). Ground 7 cites Matsuda with respect to certain elements of Claim 1, from which Claim 11 depends, but only in the alternative to obviousness based on Yamada alone. Petition, 77-79, 80-83. Ground 7 makes clear that Yamada alone renders Claim 1 obvious for the reasons provided in Ground 6, and Ground 7 makes clear that Yamada alone discloses and renders obvious Claim 11. *Id.*

Because Matsuda is not necessary for any of the Petition’s challenges to Claim 11, whether Matsuda was of record during the ’675 Patent prosecution has little relevance to the Board’s institution decision.

III. THE *BECTON, DICKINSON* FACTORS DO NOT SUPPORT DISCRETIONARY DENIAL

Section 325(d) provides that, in determining whether to institute *inter partes* review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). As explained in the recent Director Review decision in *Ecto World*, the Board evaluates arguments for discretionary denial under § 325(d) using the two-part framework articulated in *Advanced Bionics*:

- (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
- (2) if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims.

Ecto World LLC v. Rai Strategic Holdings, Inc., IPR2024-01280, Paper 10 at 8 (PTAB Mar. 6, 2025) (precedential) (quoting *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”)) (“*Ecto World*”).

In applying *Advanced Bionics*, the Board considers the factors identified in *Becton, Dickinson*,¹ and under this framework, discretionary denial is not warranted in this case.

A. The Petition Presents Materially Different Art and Arguments than Were Involved During Examination – *BD* Factors (a), (b), (d)

Part one of the *Advanced Bionics* framework is guided by *Becton, Dickinson* factors (a), (b), and (d):

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art.

Ecto World, Paper 10 at 8-9.

First, there is no dispute that the Petition relies principally on prior art and arguments that were not presented to or considered by the Office during examination of the '675 Patent.

¹ *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”).

Ground 1 relies on the '959 Publication (EX1005), which is the publication of the Canadian national stage of PCT/KR2020/003282 to which the '675 Patent ultimately claims priority. The examiner never evaluated whether the claims in the application for the '675 Patent were in fact entitled to the benefit of priority earlier than the January 16, 2023 filing date. As a result, the examiner never considered whether a publication of any related application, including the '959 Publication, was invalidating prior art.

Ground 3 relies on PepTalk Poster as the primary reference. Petition, 46; EX1006. Patent Owner admits that PepTalk Poster was not of record during examination. PODD, 14. The Petition asserts, in Ground 2, that PepTalk Poster anticipates independent Claim 1. Petition, 37-43. As to Claim 11, Ground 3 asserts that the additional limitation of Claim 11 would have been obvious to a person of ordinary skill in the art. Petition, 50. In the alternative, Ground 3 asserts that the additional limitation of Claim 11 is disclosed by Yamada (EX1008), and that Claim 11 would be obvious over the combination of PepTalk Poster and Yamada. Petition, 50-55. While Yamada was evaluated by the examiner, the examiner materially erred in considering Yamada for the reasons discussed in the following section, and the Examiner did not consider Yamada in combination with PepTalk Poster. In any case, Yamada is not necessary for Claim 11, but serves as an alternative argument.

Ground 5 relies on PepTalk Presentation as the primary reference. Petition, 62; EX1007. Patent Owner admits that PepTalk Presentation was not of record during examination. PODD, 14. The Petition asserts, in Ground 4, that PepTalk Presentation anticipates independent Claim 1. Petition, 57-60. As to Claim 11, Ground 5 asserts that the additional limitation of Claim 11 would have been obvious to a person of ordinary skill in the art. Petition, 65. In the alternative, Ground 5 asserts that the additional limitation of Claim 11 is disclosed by Yamada, and that Claim 11 would be obvious over the combination of PepTalk Presentation and Yamada. Petition, 65-68. Similar to Ground 3, the Examiner did not consider PepTalk Presentation in combination with Yamada.

Ground 7 relies on Yamada as the primary reference. The examiner materially erred in evaluating Yamada for reasons discussed below and in the Petition. Ground 7 relies on Matsuda with respect to certain elements of Claim 11. Although Matsuda was identified on the face of the '675 Patent, Matsuda was never substantively discussed or evaluated during prosecution. In addition, Ground 7 cites Matsuda only in the alternative to obviousness based on Yamada alone. Petition, 77-79, 80-83. Ground 7 makes clear that Yamada alone renders Claim 1 obvious for the reasons provided in Ground 6, and Ground 7 makes clear that Yamada alone discloses and renders obvious Claim 11. *Id.*

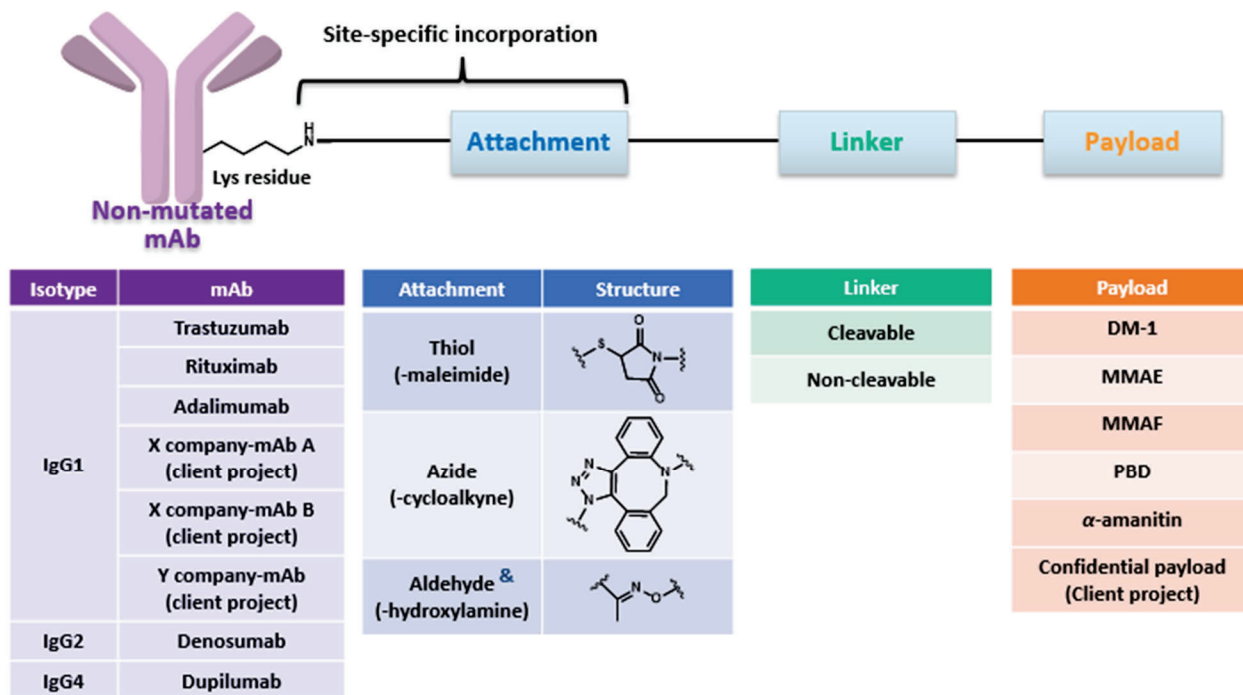
In sum, Grounds 1, 3, and 5 all rest on prior art that was not presented to or considered by the Office. To the extent they rely on Yamada, they do so only in the alternative. Ground 7 relies on Yamada, but the examiner erred in considering Yamada, and to the extent Ground 7 relies on Matsuda, it does so only in the alternative.

Unable to avoid the fact that the Petition relies primarily on art not presented to the Office, Patent Owner urges denial of the Petition on the basis that a “strong presumption” exists that “the PTO considered and approved the Challenged Claim over the art and arguments raised in the Petition” PODD, 9.

Patent Owner does not identify any purported legal basis for its “strong presumption” and offers no legal authority in support. To the extent Patent Owner means to invoke the “presumption” of the validity of issued patents that flows from 35 U.S.C. § 282, that presumption does not apply in the context of *inter partes* review. *See Celgene Corp. v. Peter*, 931 F.3d 1342, 1362 (Fed. Cir. 2019); *see also* 35 U.S.C. § 316(e) (“[T]he petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.”). Patent Owner’s claim of a “strong presumption” appears to be a mischaracterization of the discretionary denial analysis, under which, *if* the examiner considered the same art and arguments, the Board evaluates whether that consideration was erroneous or incomplete.

Patent Owner argues that both PepTalk Poster and PepTalk Presentation are cumulative of Yamada. PODD, 14-16. They are not. In making this argument, Patent Owner relies on the mere fact that these three references were created by Petitioner, have overlapping inventors and authors, and relate to Petitioner's AJICAP™ technology. PODD, 14-15. Patent Owner makes no attempt to substantively compare the disclosures of Yamada with those of PepTalk Poster or PepTalk Presentation. The general relatedness Patent Owner cites comes nowhere close to showing, as Patent Owner asserts, that “Yamada fully discloses all of the purported differences in the prior art asserted in this Petition, and the PepTalk References add nothing new that *Yamada* did not already disclose.” PODD, 14.

In fact, both PepTalk Poster and PepTalk Presentation disclose structures and information *not* found in Yamada, and therefore *not* previously presented to the examiner. For example, both PepTalk Poster and PepTalk Presentation provide the figure below which shows different combinations of antibodies, attachments, and linkers that are chemically similar to the modified lysine residues of Claim 11 and include an azide (i.e., N₃) attachment just like the first structure in Claim 11.



EX1006; EX1007.

Because Grounds 1, 3, and 5 do not require reliance on any art previously presented to the Office—i.e., Yamada or Matsuda—and because PepTalk Poster and PepTalk Presentation are not cumulative of Yamada, the first part of the *Advanced Bionics* framework is not satisfied as to these Grounds, and the Board’s analysis should end there. Discretionary denial is not warranted. Nevertheless, even under the second part of *Advanced Bionics*, discretionary denial is not warranted on any remaining Ground, because the examiner materially erred with respect to Yamada and Matsuda.

B. The Examiner Erred During Prosecution of the '675 Patent – *BD* Factors (c), (e), and (f)

Part two of the *Advanced Bionics* framework is guided by *Becton, Dickinson* factors (c), (e), and (f):

(c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

(f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Ecto World, Paper 10 at 9.

As discussed in the preceding section, Yamada and Matsuda are the only prior art references that the Petition relies on in challenging Claim 11 that were of record during examination.

Patent Owner argues that Yamada “was fully evaluated and distinguished during the prosecution of the '675 Patent.” PODD, 13. Patent Owner argues that the Petition merely “disagrees with” the examiner’s evaluation of Yamada, and invokes *Advanced Bionics*’ statement that, “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Advanced Bionics*, Paper 10 at 9; see PODD, 13-14.

That principle does not apply here, as the Petition does not merely “disagree regarding the purported treatment” of Yamada. Rather, the Petition points out that the examiner materially erred by overlooking that Yamada unambiguously discloses the “Negative Limitation” recited in claim 1 of the ’675 Patent:

[W]herein the modified lysine residue does not comprise a terminal bioreactive functional group selected from terminal hydroxy group, terminal carboxyl group, terminal thiol group, terminal amino group, and terminal aldehyde group.

EX1001, 179:13-17. *Advanced Bionics* made clear that “overlooking specific teachings of the relevant prior art where those teachings impact patentability” is “[a]n example of a material error.” *Advanced Bionics*, Paper 10 at 8 n.9.

Claims 1 and 11 of the ’675 Patent correspond to original Claims 54 and 66, respectively, in the application for the ’675 Patent. *See* EX1035, 104. The Negative Limitation of Claim 1 was originally recited only in dependent Claim 58. EX1035, 470-471. In the August 16, 2023, Office Action—the application’s only rejection—the examiner rejected original Claims 54 as anticipated by Yamada, and objected to Claims 58 and 66 as dependent on rejected Claim 54. EX1035, 326-27, 329. To overcome the rejection of independent claim 54, Patent Owner simply amended claim 54 to incorporate the Negative Limitation of Claim 58 and cancelled Claim 58. EX1035, 304. Patent Owner did not make any substantive arguments. EX1035, 312. The examiner then allowed Claims 54 and 66 to issue as Claims 1 and 11.

EX1035, 94-98. The examiner did not identify any Reasons for Allowance or otherwise discuss Patent Owner's amendment to Claim 54. EX1035, 94-98. The examiner did not even state that Yamada failed to disclose Claim 54 as amended. EX1035, 94-98. At no point during prosecution did the examiner ever discuss the Negative Limitation, whether recited in original Claim 58 or amended Claim 54, nor the additional limitation of Claim 66, nor address whether either limitation was disclosed in any prior art of record.

The examiner materially erred by allowing amended Claim 54 and original Claim 66 over each of Yamada and Matsuda, because both unambiguously disclosed the Negative Limitation. As explained throughout the Petition, Yamada discloses terminal bio-orthogonal click-chemistry functional groups that satisfy the Negative Limitation, i.e., are not excluded by it, including azide and norbornene groups. *E.g.*, Petition, 57, 69, 71-75. For example, Yamada discloses:

[A] divalent group comprising **a bioorthogonal functional group selected from the group consisting of consisting of an azide residue, ...**

EX1009, [0151] (emphasis added).

Similarly, Yamada discloses:

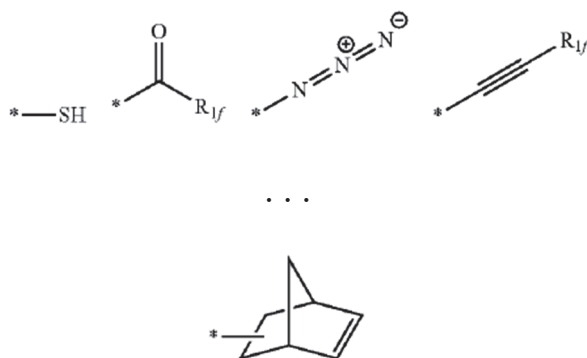
FIG. 18 is a diagram of amino acid sequences and modifications identified for modified trastuzumab (IgG1). The grey portions are the identified amino acid sequences. The identified modifications are expressed above the amino acid sequences. **Regioselective modification of an azide-introduced compound was determined only at**

the surrounded two lysine residues (positions 246 and 248 by EU numbering).

EX1009, [1037] (emphasis added).

Likewise, Yamada discloses and depicts both a terminal azide and terminal norbornene:

[0153] (30) The compound or salt thereof according to any one of (1) to (29), wherein the bioorthogonal functional group is any one represented by the following:



EX1009, [0153]; *see also* Petition, 71-72.

Patent Owner points out that the examiner relied on Yamada “for the disclosure of the bioorthogonal functional group is an azide residue (which is a group capable of participating cycloaddition reaction).” PODD, 13 (citing EX1035, 327). The examiner cited this disclosure in relation to then-pending Claims 64-65 (EX1035, 327), which recited:

64. The modified antibody of claim 54, wherein the bio-orthogonal click chemistry functional group is a group capable of participating in a click chemistry reaction selected from Huisgen 1,3-dipolar cycloaddition and Diels-Alder reaction.

65. The modified antibody of claim 54, wherein the bio-orthogonal click chemistry functional group is selected from azide group and norbornene group.

EX1035, 472.

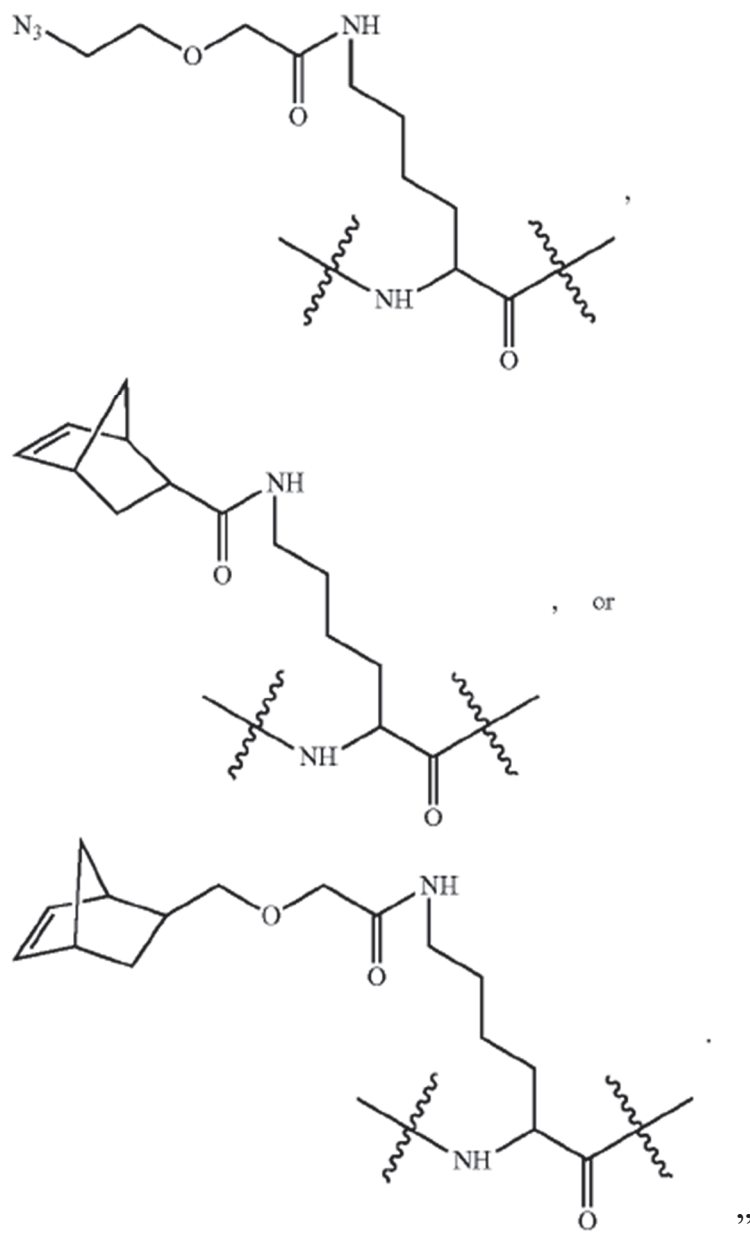
However, the examiner never cited any of Yamada's disclosures of an azide residue in relation to the Negative Limitation, either in original Claim 58 or amended Claim 54. This is not a case of "reasonable disagreement" over the examiner's treatment of Yamada. While the record indicates that the examiner was aware of at least some disclosure of an azide residue in Yamada, the examiner clearly overlooked that Yamada disclosed the Negative Limitation. On that basis, the examiner should have rejected amended Claim 54.

Matsuda was not substantively evaluated or discussed during examination. As already noted, only Ground 7 relies on Matsuda in challenging Claim 11. Ground 6 shows how Claim 1 is anticipated, and therefore necessarily rendered obvious, by Yamada alone. Petition, 69-76. Ground 7 shows how Claim 1 is further rendered obvious by combining Yamada with Matsuda. Petition, 77-79. Ground 7 then shows how the additional limitation of Claim 11 is disclosed by Yamada, such that Claim 11 is also obvious over a combination of Yamada and Matsuda. Petition, 80-83.

Because the Examiner never discussed Matsuda, there is no record as to which if any limitations of the pending claims the Examiner believed were disclosed by Matsuda, and why or why not. Nevertheless, as explained in the Petition, like

Yamada, Matsuda discloses regioselectively modifying an antibody with terminal bio-orthogonal functional groups. Petition, 78. Further, Matsuda specifically discloses Lysine 248 as one of only five preferred positions for such modification (*id.* (citing EX1011, [0329], [0431])), and specifically discloses an examples 5-2-1 and 5-2-2 where an azide is used as the terminal bio-orthogonal functional group (*id.* (citing EX1011, [1018]-[1029], [1289-1290], and [1296]-[1298])). Thus, to the extent Yamada could be deemed not to anticipate or render Claim 1 obvious with respect to Lysine 248 as the modification site or with respect to the Negative Limitation, Matsuda provides further motivation and a reasonable expectation of success as to both of these claim limitations. While there is no record that the Examiner concluded Matsuda failed to disclose the Negative Limitation, such a conclusion would have been material error for the same reasons as with Yamada. Both references disclose using an azide as the terminal bioreactive functional group and therefore disclose the modified antibody of Claim 1 where “the modified lysine residue does not comprise a terminal bioreactive functional group selected from terminal hydroxy group, terminal carboxyl group, terminal thiol group, terminal amino group, and terminal aldehyde group.”

With respect to Claim 11, there is no record that the Examiner even considered whether any art of record, including Yamada and Matsuda, disclosed the additional limitation that “the modified lysine residue has following structure:



EX1001, 180:11-48. The Examiner never issued a rejection against Claim 11, and never stated any finding that this limitation was not disclosed in the prior art of record.

Nevertheless, to the extent the Examiner could be deemed to have found that Yamada does not disclose or render obvious the limitation of Claim 11, such a

finding would have been material error. As explained in the Petition, Yamada discloses an antibody regioselectively modified with a bio-orthogonal functional group at position 248 Formula IV: L1-B-R'-T. Petition, 80. As also explained, selecting from among the substituents that Yamada discloses for the components for Formula IV yields the first and third structures recited in Claim 11. Petition, 81-82.

In sum, the Petition relies principally on prior art that was not presented to the Examiner, and the Examiner materially erred in evaluating the Yamada and Matsuda references that were of record. Accordingly, under *Advanced Bionics*, there is no basis for discretionary denial of the Petition.

IV. THERE IS NO BASIS FOR DISCRETIONARY DENIAL AS TO GROUND 1

Ground 1 of the Petition asserts that the '675 Patent is anticipated by the '959 Publication. Despite being a publication of an application in the same priority chain as the '675 Patent, the '959 Publication is nevertheless prior art because neither the '675 Patent nor any of the applications to which it claims priority provide adequate written description support for the Negative Limitation recited in Claim 1. See Petition, 13-19, 22.

Patent Owner argues that discretionary denial is further supported on the basis that Ground 1 is "legally erroneous." PODD, 18-19. As a threshold matter, Patent Owner fails to identify any authority in Title 35 or in the Board's precedent for considering the legal merits of a Petition as a basis for discretionary denial. Whether

Ground 1 rests on a correct view and application of the law governing priority dates and written description is properly considered in evaluating whether Petitioner has shown a reasonable likelihood of success, but it is not an appropriate basis for discretionary denial.

On the merits, Patent Owner's criticism of Ground 1 is mistaken. Patent Owner argues that Claim 11 has adequate written description support because the Negative Limitation of Claim 1 is itself "negated by the addition of the specific functional groups in Claim 11." PODD, 17. In support, Patent Owner again invokes Section 282's presumption of validity. PODD, 17 (quoting 35 U.S.C. § 282). Although not entirely clear, Patent Owner appears to rely on Section 282's statement that "dependent . . . claims shall be presumed valid even though dependent upon an invalid claim." *Id.* Thus, Patent Owner appears to suggest that even if Claim 1 is invalid for lack of written description due to the Negative Limitation, Claim 11 is still presumed valid. The problem with this argument is that, as already noted, the presumption of validity does not apply during *inter partes* review. *Neither* of Claims 1 and 11 are presumed valid. *See Celgene Corp. v. Peter*, 931 F.3d 1342, 1362 (Fed. Cir. 2019).

Furthermore, Patent Owner's assertion that the recitation of specific functional groups in Claim 11 "negates" the Negative Limitation is incorrect. Patent Owner offers no legal support for this proposition. Patent Owner's only legal

citation is to the Federal Circuit’s decision in *Novartis Pharmaceuticals v. Accord Healthcare*, and only for the general proposition that written description requires that the specification “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” PODD, 17 (quoting *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1020 (Fed. Cir. 2022)). In fact, *Novartis* supports Petitioner’s position, not Patent Owner’s. *Novartis* concerned a negative limitation, which the Federal Circuit held *lacked adequate written description support*. 38 F.4th at 1018-20. Nothing in the Federal Circuit’s opinion suggests that a negative limitation can itself be “negated” by a dependent claim such that written description support for the negative limitation becomes unnecessary. Indeed, such a holding would make little sense because in order for Claim 11 to be properly dependent under 35 U.S.C. § 112(d), it must necessarily incorporate and comply with the Negative Limitation.

In sum, Patent Owner’s argument contradicts two well-settled principles: (1) dependent claims include all of the limitations of their independent claims, and (2)

written description support must exist for all elements of a claim.² Patent Owner's argument lacks legal support and is not an appropriate basis for discretionary denial in any case. The Board should institute on Ground 1.

V. PATENT OWNER'S OTHER ARGUMENTS FOR DISCRETIONARY DENIAL LACK MERIT

A. The Petition Is Not Overly Reliant on Expert Testimony

Patent Owner argues that discretionary denial is favored because of the Petition's "overreliance on expert testimony and non-prior art references." PODD, 19. More specifically, Patent Owner alleges that the Petition "bases all remaining alleged Grounds of unpatentability of expert testimony" and that the relied-upon expert testimony is conclusory. Neither criticism has merit.

There is nothing improper about the Petition's reliance on expert testimony, and nothing in the Office's Guidance suggests otherwise. While the Guidance indicates only that consideration is given to "[t]he extent of the petition's reliance

² Patent Owner adds, in a footnote, that it intends to amend Claim 11 into independent form to remove the Negative Limitation, tacitly acknowledging that Claim 11 is equally impacted by the lack of written description support for the Negative Limitation. PODD, 19 n.4.

on expert testimony,”³ the USPTO’s “FAQs for Interim Processes for PTAB Workload Management,” specifically FAQ No. 21, addresses the issue of “How does the extent of the petition’s reliance on expert testimony bear on discretion to institute IPR or PGR?”⁴ There, the USPTO explains that:

While the Board may consider expert testimony, as a matter of efficiency, extensive reliance on expert testimony and/or reasonable disputes between experts on dispositive issues may suggest that the questions are better resolved in an Article III court. The statute and our reviewing court require that petitions be based on prior art patents and printed publications. As the judges have technical and legal expertise, it is not necessary for an expert to explain every aspect of the prior art. It is most helpful if an expert is providing focused testimony, for example to provide helpful context or to explain terms of art. The failure to provide focused expert testimony may weigh against institution.⁵

The Petition’s use of expert testimony is entirely consistent with this further guidance. For Claim 11, the Petition relies on Dr. Tumey to provide “focused expert testimony,” not to “explain every aspect of the prior art.” That is because the primary

³ <https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf>

⁴ <https://www.uspto.gov/patents/ptab/faqs/interim-processes-workload-management>

⁵ *Id.*

references of '959 Publication, PepTalk Poster, PepTalk Presentation, and Yamada largely speak for themselves. Ground 1 shows that structures recited in Claim 11 and their precursors are disclosed in the '959 Publication (Petition, 37 (citing EX1005, 5, 165-174, Figs. 17, 19, 22)), and Ground 7 shows that structures recited in Claim 11 are disclosed by Yamada (*see e.g.*, Petition, 80-82 (citing EX1009, [0222], [1037], [1109], [1114], [0584]-[0588], [0677], [0678], [0697], [0702]-[0705], [0708]-[0710])). Dr. Tumey only confirms these disclosures. This is equally true in Grounds 3 and 5, where the Petition relies on and principally cites Yamada's own disclosures as disclosing structures recited in Claim 11.⁶ Petition, 50-55 (Ground 3), 65-68 (Ground 5).

Patent Owner misleadingly implies that the Petition's arguments against Claim 11 rely crucially on the statement that "short alkyl or cycloalkyl linkers would be obvious to a POSA." PODD, 21 (quoting Petition, 50). While that statement is

⁶ Patent Owner insinuates that a typographical error in the Petition favors discretionary denial because it forces the Board to "excavate the actual grounds of the challenge." PODD, 22 n.6. This error notwithstanding, the Petition is quite clear that Ground 3 is based on the PepTalk Poster and Ground 5 on the PepTalk Presentation. The Board should ignore this strained effort by Patent Owner to avoid institution.

true, as Dr. Tumey opines, that is an argument that Claim 11 would be obvious over PepTalk Poster or PepTalk Presentation *themselves*, even without Yamada. Because the Petition also shows, as already noted, that Yamada discloses structures recited in Claim 11, there is no overreliance on Dr. Tumey's testimony relating to short alkyl or cycloalkyl linkers.

Patent Owner's suggestion that Dr. Tumey cites only primary and secondary references in support of his opinions is also false. Dr. Tumey's declaration cites numerous other background and supporting references as informing his opinions beyond the references cited in the Grounds. *See, e.g.*, EX1002, ¶13.

While the Office's answer to FAQ No. 21 suggests that "extensive reliance on expert testimony and/or reasonable disputes between experts on dispositive issues may suggest that the questions are better resolved in an Article III court," there is no such "extensive reliance" here. Nor are there any such disputes between experts at this stage in the proceeding, because Patent Owner has offered no expert testimony attempting to rebut Dr. Tumey. Further, the Office states only that disputes between experts "may suggest" that such questions are better resolved in an Article III court, not that such issues necessarily require denial of institution. Moreover, that alternative does not apply here because, as Patent Owner notes, there is no co-pending district court action.

B. The Lack of Co-Pending Litigation Favors Institution, Not Denial

Patent Owner asserts that “[t]he absence of a parallel district court proceeding strongly favors a discretionary denial.” PODD, 23. It is unclear why Patent Owner believes this fact favors denial—Patent Owner cites no authority—but common sense suggests just the opposite. Because there is no parallel district court proceeding, the patentability/validity of Claim 11 will not otherwise be adjudicated, and, therefore, contrary to Patent Owner’s assertion, the Board’s examination becomes *more* “necessary and compelling,” not less.

C. The New Focused Nature of the Proceeding Favors Institution, Not Denial

Patent Owner asserts that a trial on Claim 11 is “unnecessary and would not serve the interests” articulated in the Office’s new Guidance. PODD, 23-24. Patent Owner further suggests that its disclaimer of the other ’675 Patent claims, and the resulting narrowing of the dispute, somehow reduces the necessity of a trial and favors denial. On contrary, like the absence of co-pending litigation, the narrowed scope of the dispute weighs *against* denial, not in favor.

First, Patent Owner seems to suggest that its disclaimer of all other claims “underscores [its] commitment to resolving the central dispute efficiently,” as though the disclaimer was motivated primarily by concern for the PTAB’s workload. In reality, Patent Owner likely disclaimed all other claims out of recognition that it could not maintain their patentability.

Second, Patent Owner asserts that “[t]his narrowing reflects a deliberate decision to focus the proceeding on a single, dispositive claim that Patent Owner believes is valid and fully distinguishable over the asserted prior art.” PODD, 23. But a more focused proceeding would be meaningless if the Board did not institute that proceeding. In effect, Patent Owner argues that, because it has made the Board’s job easier, the Board should forgo doing that job. This makes no sense. As it stands, the Board need only consider a single claim and a fraction of the Grounds advanced in the Petition. This would not be a drain on Board resources or exacerbate its workload and, as such, would easily be completed within the statutory deadlines for AIA proceedings.

VI. CONCLUSION

For the reasons set forth above, the Petition should not be denied on a discretionary basis, and an *inter partes* review should be instituted as to Claim 11 of the ’675 Patent on each of Grounds 1, 3, 5, and 7.

Respectfully submitted,

Dated: June 11, 2025

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24, the undersigned certifies that this Opposition to Patent Owner's Argument for Discretionary Denial complies with the type-volume limitation of 37 C.F.R. § 42.24(c). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 5,505 words.

Respectfully submitted,

Dated: June 11, 2025

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Opposition to Patent Owner's Argument for Discretionary Denial was served on June 11, 2025, by electronic mail to the attorneys of record for Patent Owner at the following address:

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