

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 SUPPLEMENTAL LETTER BRIEF

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I. INTRODUCTION

In response to the Board’s May 11, 2026 communication, Petitioner Ajinomoto Co., Inc. (“Ajinomoto”) provides this letter brief addressing the lack of written description under 35 U.S.C. § 112 for amended claims 14-16 in light of *Teva Pharm. v. Eli Lilly & Co.*, 172 F.4th 1367 (Fed. Cir. 2026) (hereafter “*Teva*”).

Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. (collectively, “Teva”) sued Eli Lilly and Company (“Lilly”) for infringing U.S. Patent Nos. 8,586,045 (“the ’045 patent”), 9,884,907 (“the ’907 patent”), and 9,884,908 (“the ’908 patent”; collectively “the headache patents”). Unlike the present claims, which are product claims directed to purportedly novel antibody-modifications, the patent claims in *Teva* were methods of treating headaches with humanized anti-CGRP antibodies (a new use of a known product class).

II. *TEVA* AND ITS UNDERLYING PRECEDENT ESTABLISH LACK OF WRITTEN DESCRIPTION FOR PRODUCT CLAIMS 14-16

As noted in *Teva*, “[t]o satisfy the written-description requirement of § 112 ¶1, a patent’s specification must ‘reasonably convey[]’ that, as of the filing date, ‘the inventor[s] had possession of the claimed subject matter’—i.e., that they ‘actually invented the invention claimed.’” *Teva*, 172 F.4th at 1374 (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*)). For genus claims, adequate written description requires disclosure of “either a representative number of species falling within the scope of the genus or structural features

common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus.” *Id.* (citing *Ariad*, 598 F.3d at 1350).

Among the various underlying precedent cited by the *Teva* panel, *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021) is most relevant and therefore controlling in relation to the present product claims 14-16. Following *Ariad*’s structural-features analysis, the *Juno* panel held that the specification’s disclosure of two scFvs—one derived from the SJ25C1 antibody, one from the J591 antibody, with no amino acid sequences disclosed for either—failed to describe the vast structural diversity of the scFv genus encompassed by the “scFV” component of the combination product claims. *Juno*, 10 F.4th at 1341-42. In particular, the *Juno* panel stated, “[t]he test is the same whether the claim is to a novel compound or a novel combination of known elements.” *Id.* at 1341 (citing *Boston Scientific Corp. v. Johnson & Johnson, Inc.*, 647 F.3d 1353, 1365 (Fed. Cir. 2011)). Thus, present claims 14-16 relating to antibody-linker combinations are highly similar to the combination structures claimed in *Juno*, with the “scFV” component of the combination product claims in *Juno* being analogous to the “antibody” component of the combination product claims 14-16.

As Patent Owner tries to do here with the “antibody” element of its amended claims 14-16, the patent owner in *Juno* similarly argued for the “scFV” element of

its claims “that scFvs are interchangeable and have common structural features.” *Id.* at 1336. However, the *Juno* decision held as follows:

The '190 patent provides no amino acid sequences or other distinguishing characteristics of the scFvs that bind. Simply put, the '190 patent claims a “problem to be solved while claiming all solutions to it . . . cover[ing] any compound later actually invented and determined to fall within the claim’s functional boundaries,” *Ariad*, 598 F.3d at 1353, which fails to satisfy the written description requirement.

Id. at 1339. The *Juno* panel found additional support for its conclusion “in *AbbVie*, [where] we concluded that substantial evidence supported the jury’s verdict of inadequate written description when the patents described one species of structurally similar antibodies derived from only one lead antibody but the asserted claims covered ‘every fully human IL-12 [targeted] antibody that would achieve a desired result’ without an indication about an established correlation between the structure and the claimed function. *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301–02 (Fed. Cir. 2014).” *Id.* at 1339 (citing *AbbVie*) (emphasis added). With respect to proposed amended claims 14-16, even if Patent Owner’s disclosure of sequences 8-1, 8-2, and 8-3 is regarded as a common structural element of a structure-function relationship, Patent Owner and the Board’s construction of “antibody” (Paper No. 27 at 6-7) have made clear that claims 14-16 are not so limited and cover not just antibodies with sequences 8-1, 8-2 and 8-3, but that they cover any possible sequence without regard for the structure-function relationship set forth in the specification. *Juno* and *AbbVie* both

found similar generic product claims covering any “compound later actually invented and determined to fall within the claim’s functional boundaries” to violate the written description requirement in the absence of a common structural element.

The *Teva* panel expressly pointed out that *Juno* did not apply to the appealed method claims in *Teva* because Teva only argued lack of a “representative number” of examples – Teva presented no argument about a failure to claim structural features common to the members of that genus. *Teva*, 172 F.4th at 1374, FN8 & 1379, FN16. *Teva*’s decision about method of use claims and its express acknowledgement that its holding does not apply to product claims is consistent with *Juno*’s holding that product claims (whether they cover a novel compound or a novel combination of known elements) fail to satisfy the written description requirement when the specification does not describe the structural features common to the members of the genus that permit a skilled artisan to visualize or recognize members of the genus. Here, as in *Juno* and *AbbVie*, Patent Owner has not included in claims 14-16 what is acknowledged to be a common structural requirement—namely the 8-1, 8-2, and 8-3 sequences identified in the ‘675 specification—as the “acceptable” range of sequences for successful binding of the SSFI. EX1001, 28:27-37.

A. Pertinent Facts for the *Teva* Headache Patents

As explained above, the *Teva* decision is clearly not applicable to the proposed amended claims 14-16 because the appellant in *Teva* did not pursue any argument

about the absence of a common structural feature in the claims at issue that was required to support the genus, and so it only dealt with the representativeness issue. The particular facts of *Teva* involve further distinctions from the case at hand as shown below.

The *Teva* panel indicated that method claim 30 of the '045 patent was representative of the headache patents:

A method for reducing incidence of or treating headache in a human, comprising administering to the human an effective amount of an anti-CGRP antagonist antibody, wherein said anti-CGRP antagonist antibody is a . . . humanized monoclonal antibody.

Teva, 172 F.4th at 1372. The claims used humanized anti-CGRP antagonist antibodies, but “[t]he headache patents make clear that their claimed invention is the use of anti-CGRP antagonist antibodies, or humanized versions thereof, to treat headache—not such antibodies themselves.” *Id.*, at 1376.

To this end, the record in *Teva* and the specification of the headache patents showed “that anti-CGRP antagonist antibodies themselves and methods of making them were well known, replete, or extensively described in the prior art ... humanization was a well-established and routine procedure by the priority date ... [and] all humanized anti-CGRP antagonist antibodies treat headache.” *Id.*

More specifically, the specification of the headache patents “observes that anti-CGRP antagonist antibodies were ‘known in the art,’ and it cites prior art

regarding murine antibodies of this sort” (citing the ’405 patent at col. 25 ll. 59–63); “references murine anti-CGRP antagonist antibody ‘4901’ and cites a product catalog offering this antibody for sale” (citing the ’405 patent at col. 25 ll. 61–62) as well as other commercially available murine anti-CGRP antagonist antibodies (citing the ’405 patent at col. 51 ll. 5–27, col. 55 ll. 22–23); “states that “anti-CGRP antagonist antibodies may be made by any method known in the art” (citing the ’405 patent at col. 27 ll. 41–42); discloses “one *humanized* anti-CGRP antagonist antibody—‘G1,’ which is the active ingredient in Teva’s Ajovy product” (citing the ’405 patent at cols. 72–730; and “also disclosed prior-art methods of humanization” (citing the ’405 patent at col. 28 l. 55–col. 29 l. 28).

Notably, column 28, line 55 – column 29, line 28 of the ’045 patent, which the Federal Circuit cited to show humanization was an “established technique,” discloses (i) routine steps for humanization, (ii) twenty-four examples of references that disclose methods of humanization or related technology, and (iii) a discussion of how the established humanization technologies apply to the disclosed antibodies.

The court also found that “critically, a skilled artisan would have understood from the specification that *all* humanized anti-CGRP antagonist antibodies can be used treat headache.” *Teva*, 172 F.4th at 1376-77(emphasis original); *see also id.* at 1380. Thus, the elements needed to practice the claimed methods—humanized antagonist antibodies that bind CGRP—were known in the art and could be obtained

from commercial sources or made with routine, prior art technology.

B. Pertinent Facts for the Abtis '675 Patent

In contrast with the headache patents considered in *Teva*, the '675 patent at issue here describes the technology utilized for claims 14-16 as neither well-established, described in the prior art, nor routine. The '675 patent states, “[t]he present invention relates to a novel method of labeling an antibody” (EX1001, 1:53-54)” To create these labeled antibodies, the '675 patent explains that, “[t]he present invention discloses a novel compound capable of being used to label an antibody” (*id.*, 28:41-42) and “[a]ccording to the present invention, there is disclosed a novel peptide for bringing a molecule to be labeled into close contact with a certain site of an antibody ... referred to as a site-specific antibody interactome” or “SSAI” (*id.*, 33:19-24). The point of novelty clearly lies in the product and how it is made, unlike *Teva* where the claims related to a method of using a known class of antibodies.

The patentee-defined scope of claims 14-16 encompasses a broad range of modified antibodies across all “naturally occurring immunoglobulins” and “all recombinant proteins, fusion proteins, chimeric proteins, human immunoglobulins, non-human animal immunoglobulins ... which have the same or similar structures.” EX1001, 23:40-54. However, the '675 patent only discloses SSAI sequences that bind to a singular, specific region—corresponding SEQ ID NO: 1—of the human IgG1 Fc domain (*id.*, 33:36-38:34; also known as “site-specific Fc interactome” or

“SSFI”). Despite this broad scope, the ’675 patent discloses actual reduction to practice of only a single such SSFI (*id.*, 151:50-154:67). Notably, SSAI/SSFI for binding any other isotype of human antibody, any non-human antibody, and any other “recombinant proteins, fusion proteins, [and] chimeric proteins ... which have the same or similar structures” were not commercially available and there is zero evidence in the record that such SSAI/SSFI existed as of the time of filing of the application that issued as the ’675 patent or its earliest claimed priority date.

Similarly, the “labeling compounds” (or “Agent for transferring first chemical functional group to antibody”; *see* EX1001, 38:35-42:18) that are conjugated to the SSAI/SSFI to make the claimed modified antibodies were not commercially available and the ’675 patent itself argues that the chemistry of these compounds was unlike anything previously described in the art (*see e.g., id.*, 70:13-29; 71:36-51; 72:16-27).

Far from the commercially-available antibodies and routine methods of humanization present in *Teva*, making modified human IgG1 antibodies according to ’675 patent claims 14-16 requires SSAI/SSFI and labeling compounds that are allegedly novel. Making other versions of modified antibodies within the scope of the claims (e.g., human IgM, human IgA, or non-human antibodies) would require reagents that bind to and modify sequences distinct from SEQ ID NO: 1, and those reagents were not commercially available or even disclosed in the ’675 patent, let

alone “extensively described” in the prior art. Thus, a plain reading of the ’675 patent demonstrates that the technology underlying the claimed compositions was not routine or well-established.

C. *Teva* Does Not Apply to Claims 14-16, And Even If It Does, The ‘675 Patent’s Examples Are Not Representative

While the *Teva* panel found that Lilly had not established that the claims of the headache patents lacked written description under the clear and convincing evidentiary standard based only on the “representativeness” prong of the written description test (and not based on the common structural element prong which was not argued on appeal), the facts of the present case are distinguishable even as to the representativeness issue and show that the examples of the ‘675 specification are not representative of the genus claimed. As the *Teva* decision notes, “anti-CGRP antagonist antibodies themselves and methods of making them were well known, replete, or extensively described in the prior art ... humanization was a well-established and routine procedure by the priority date ... [and] all humanized anti-CGRP antagonist antibodies treat headache.” *Teva*, 172 F.4th at 1376.

This record fails to provide any evidence that the technology and reagents needed to make the full scope of the claimed modified antibodies (e.g., human IgM, human IgA, or non-human antibodies) were known at all, much less “extensively described,” “well-established,” or “routine.” While the ’675 patent’s discussion of designing SSFIs cites DeLano, W. L., et al., SCIENCE 2000, 287:1279-1283 as

alleged prior art guidance (EX1001, 34:5-6; 37:25-27; 37:50-51), this paper is merely a high-level discussion of protein binding interactions of one “selected 13-amino acid peptide” and “the Fc fragment of human immunoglobulin G.” It does not have any teachings involving SSAI/SSFI, specifically, and it relates only to human IgG1. The ’675 patent likewise cites Dias et al., JOURNAL OF THE AMERICAN CHEMICAL SOCIETY 2006, 128(8), 2726-2732 (*id.*, 34:1-4), but this paper is a high-level discussion of using phage display and synthetic chemistry to design ligands, in general, not SSAI/SSFI or antibody modification specifically. Neither paper evidences that the design or synthesis of SSAI/SSFI for modifying all antibodies within the scope of the claims was “well-established” or “routine” like humanization was in the context of the headache patents.

The court in *Teva* noted that Lilly argued “that, even if humanizing these antibodies might have been obvious in view of the specification, ‘a description that merely renders the invention obvious does not satisfy’ the written-description requirement.” *Teva*, 172 F.4th at 1377 (quoting *Ariad*, 598 F.3d at 1352). This argument was unsuccessful because “[t]he specification did not merely render humanizing these antibodies obvious; it explicitly disclosed as much, along with how to do it, via prior-art methods that a reasonable jury could have found were routine.” *Id.*

To the extent Patent Owner argues that designing new SSFI would have been “routine optimization” or otherwise within the skill of a POSA in view of the ’675 patent’s specification, such an argument should be equally unavailing because (i) the ’675 patent fails to describe specific prior art methods how a POSA would adapt existing technology to make SSAI/SSFI, and (ii) Patent Owner has argued on this record that such adaptation is not routine or obvious.

Like the ’675 patent, Yamada (EX1009) and the PepTalk References (EX1006, EX1007) disclose actual reduction to practice of modification of the same human IgG1 (i.e., trastuzumab) at lysine 248 using an “affinity peptide” (which is akin to the ’675 patent’s SSFI). Yet, Dr. Zhou stated that Yamada did not show possession beyond what was explicitly exemplified, noting “[a] POSA would ... understand Yamada’s disclosed compounds as limited to what can actually be synthesized using Yamada’s taught chemistry” because “importing chemistry from other sources would not be considered routine or obvious.” EX2008, ¶33. With respect to the PepTalk References, Dr. Zhou stated, “[r]eferences regarding broad applicability or ‘potential’ across antibody isotypes are merely aspirational” because “they do not disclose the chemistry-specific information necessary for a POSA to reasonably predict success for a particular modification.” *Id.*, ¶8.

Also in contrast to *Teva*, where “all humanized anti-CGRP antagonist antibodies treat headache,” the ’675 patent makes clear that not just any peptide

sequence can serve as an SSAI/SSFI. According to the '675 patent, a functional SSFI must “allow a nucleophilic substitution reaction with a linker” (EX1001, 34:11) and “be arranged with the Fc domain with a specific topology due to the interaction between amino acid residues” (*id.*, 37:15-17). The SSFI must bring the labeling compound in close proximity with Lys 248 (e.g., the only exemplified SSFI provided a “maximum distance” of 16.208 Å between the labeling compound and Lys 248 of a human IgG1). *Id.*, 38:24-30. Thus, SSFI for modifying antibodies that do not include SEQ ID NO: 1 would require specific properties and sequences that are not disclosed within the '675 patent and for which there is no evidence of possession.

Even Patent Owner's expert testified that adapting a technology like the one disclosed in the '675 patent to modified antibodies aside from human IgG1 was not “well-established” or “routine” in the art. Dr Zhou testified that “site-specific protein modification was ... exceptionally complex and unpredictable” (EX2004, ¶37) and “the field was inherently non-predictable” (*id.*, ¶40). Dr. Zhou further opined that “given the structural diversity and highly variable chemo-physical properties of antibodies, a POSA could not predict with confidence whether a modification that succeeded for one antibody would also succeed for another.” *Id.*, ¶40. This testimony is unequivocal: the technology and reagents needed to make the claimed modified antibodies of claims 14-16 were not “extensively described,” “well-established,” or “routine” as was the case in *Teva*.

D. Additional Precedent Cited in *Teva* Favors Finding a Lack of Written Description Here

In supporting its decision to reverse the lower court in *Teva*, the Federal Circuit cited earlier decisions “where a claim pertains to a well-known genus that is not, itself, the invention” (*Teva*, 172 F.4th at 1374), and these cases are distinguishable for the same reasons discussed above.

Briefly, *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1346–47 (Fed. Cir. 2019) involved a patent that “disclosed that enhancing the activity of a bacterium’s *yddG* gene would increase the bacterium’s production of particular amino acids” and “several ways of enhancing that activity, one of which was substituting a ‘more potent promoter’ in the bacterium’s DNA” where “enhancing promoter activity was well-known” and “‘the genus of more potent promoters was already well explored’ in the art by the time of the patent’s invention.” *Teva*, 172 F.4th at 1374-75. Here, SSAI/SSFI for modifying antibodies other than human IgG1 were not “well-known” nor “well explored in the art” as of the filing of the ’675 patent.

In re Herschler, 591 F.2d 693, 695 (CCPA 1979) involved a patent that claimed “a method of enhancing skin penetration of a ‘physiologically active steroidal agent’ by applying it together with DMSO.” *Teva*, 172 F.4th at 1375. In *Herschler*, “it acknowledged that while steroids ‘as drugs’ might vary broadly in their physiological activity, steroids ‘as a class of compounds carried through a layer of skin by DMSO’ appeared on the record to be ‘quite similar.’” *Id.* No evidence in this

record suggests that all SSAI/SSFI would look or behave similarly. Rather, Dr. Zhou has insisted that “given the structural diversity and highly variable chemo-physical properties of antibodies, a POSA could not predict with confidence whether a modification that succeeded for one antibody would also succeed for another” (EX2004, ¶40) because “chemistry-specific information [is] necessary for a POSA to reasonably predict success for a particular modification” (EX2008, ¶8).

While *Ajinomoto*, *Herschler*, and the *Teva* headache patents make clear that their claimed methods utilize a “well-known” genus that is not itself the invention, the genera of reagents and compounds needed to make the combination products of claims 14-16 were not “well-known” and the ’675 patent refers to these reagents and compounds as key aspects of the invention itself. EX1001, 28:41-42; 33:19-24.

E. Claims 14-16 Fundamentally Differ from the Claims in *Teva*

Claims 14-16 are fundamentally distinct from those at issue in *Teva*, *Ajinomoto*, and *Herschler* because claims 14-16 are directed to combination products that Patent Owner had not made, did not possess, and required technology that was neither described in the patent nor established in the art. The claims in *Teva*, *Ajinomoto*, and *Herschler* involved methods of using well-established technology that was readily available to a skilled artisan as of the priority date of those patents.

III. CONCLUSION

Proposed product claims 14-16 are controlled by *Juno* and were expressly

excluded by the *Teva* panel from the scope of the *Teva* decision, and therefore these claims are unpatentable for lack of sufficient written description under 35 U.S.C. § 112, including for failure to recite a necessary common structural element and due to lack of representative examples.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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