

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AJINOMOTO CO., INC.

Petitioner,

v.

ABTIS CO., LTD.

Patent Owner.

CASE: IPR2025-00283

U.S. PATENT NO. 11,896,675

PATENT OWNER’S SUPPLEMENTAL BRIEF REGARDING
TEVA PHARMACEUTICALS INTERNATIONAL GMBH V. ELI LILLY &
CO., 172 F.4TH 1367 (FED. CIR. 2026)

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	ARGUMENT	1
	A. Overview of <i>Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.</i>	1
	B. The Claims are Grounded In a Defined Structural Framework	3
	C. A POSA Would Understand The Specification Demonstrates That The Inventors Were In Possession of the Claims	3
III.	<i>Teva</i> Negates Petitioner’s “Full Scope” Arguments	6
IV.	CONCLUSION.....	9

I. INTRODUCTION

Patent Owner (“PO”) submits its supplemental briefing regarding the recent case, *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, 172 F.4th 1367 (Fed. Cir. 2026), and its impact on whether the proposed substitute Claims 14–16 of the ’675 Patent satisfy the written description requirement of 35 U.S.C. § 112.

Teva confirms that a single disclosed example provides sufficient written description and enablement of a genus where the claims are grounded in a known framework and a person of ordinary skill in the art (“POSA”) would understand the disclosed embodiments to be representative of the claimed scope. Applied here, the ’675 Patent’s disclosure satisfies the written description and enablement requirements for proposed substitute Claims 14–16 because it provides a working example of each claimed structural moiety attached at the Lysine-248 (“Lys-248”) site of a modified IgG-based antibody,¹ and a POSA would understand those examples to be representative of the claimed scope. *Teva*, 172 F.4th at 1374.

II. ARGUMENT

A. Overview of *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*

In *Teva*, the Federal Circuit addressed whether claims directed to a method of

¹ The ’675 patent discloses examples of each moiety attached to Trastuzumab, an IgG1 antibody.

treating headache using a genus of humanized anti-CGRP antagonist antibodies satisfied the written description and enablement requirements of 35 U.S.C. § 112. There, the patent disclosed that anti-CGRP antagonist antibodies were known in the art and described prior art methods for humanizing such antibodies, but identified only a single humanized² antibody example—an IgG2. *Teva*, 172 F.4th at 1371.

The Federal Circuit rejected Lilly’s argument that additional species were required to show possession of the claimed genus, explaining that the analysis must consider what a POSA would have understood from the specification. *Id.* at 1377. That is, in view of the specification and the state of the art, the court found that a POSA would recognize that humanized anti-CGRP antagonist antibodies as a class could perform the claimed method, and that the combination of disclosed antibodies and known humanization techniques was sufficient to demonstrate possession of the claimed invention. *Id.* at 1377–78. The court also rejected Lilly’s argument “that, because its product differs structurally and functionally from G1 (the sole humanized anti-CGRP antagonist antibody disclosed in the specification), written description must be inadequate” because “Lilly has not explained, nor do we see, why we should treat any of the alleged structural or functional differences between Lilly’s product

² *Teva* refers to the humanized antibody as “G1,” citing U.S. Patent No. 8,586,045 at columns 72-73. *Id.* at 1371. There, the ’045 patent identifies “G1” as an IgG2.

and G1 differently[.]”³ *Id.* at 1379–80. Because the specification and prior art established that such antibodies were known and that humanization was routine, the court held that the claims were enabled. *Id.* at 1380. That framework governs here.

B. The Claims are Grounded In a Defined Structural Framework

Written description is satisfied where the claims are within a known system such that a POSA can understand their scope without exhaustive disclosure. *Teva*, 172 F.4th at 1377–78. Proposed substitute Claims 14–16 are each anchored to a specific structural feature: a specific click-chemistry bioorthogonal group attached by a spacer to Lys-248 in the Fc region of an antibody. Ex. 2004, ¶ 48.

C. A POSA Would Understand The Specification Demonstrates That The Inventors Were In Possession of the Claims

While the specification defines “antibody” broadly (Ex. 1001, 23:40–54), the claims impose meaningful structural constraints. The requirement that Lys-248 be identified “by an EU numbering system” situates the invention within the Fc domain architecture of IgG antibodies. The EU numbering system is used for IgG—including natural and engineered IgGs—but not for structurally distinct non IgG isotypes (e.g., IgM, IgA, IgE, IgD). *See* Ex. 1001, 27:61-28:2. Thus, a POSA would understand the claims to correspond to antibodies having an IgG-like Fc-domain framework. SEQ ID NO:1 provides an example of the IgG-specific Fc-domain

³ The FDA label for Lilly’s Emgality product identifies it as an IgG4.

context in which Lys-248 resides, but does not define the invention.

The claims instead are defined by modification at Lys-248. A POSA would understand that Lys-248 occupies a conserved position within the Fc domain across IgG subclasses and can be preserved in engineered IgGs that retain the same structural framework, thereby providing a consistent structural anchor for the claimed modification across IgG-based antibodies. A POSA would understand that the disclosed IgG1 embodiments are representative of IgG-based antibodies sharing the same Fc-domain framework. Ex. 2012, ¶ 46; Ex. 2008, ¶ 46.

Further, because the claimed antibodies require modification at Lys-248, a POSA would understand that the Fc domain must retain a structure consistent with accomplishing the claimed modification at Lys-248, as described in the specification. Modifications that materially alter that structure would not be expected to permit selective modification at Lys-248 as claimed. A POSA would further understand that achieving selective modification at Lys-248 reflects the presence of the Fc-domain structural context required for that modification to occur.

Viewed together, the claims are directed to a defined structural framework: IgG-based antibodies (natural or engineered) that preserve the Fc-domain architecture necessary to support the claimed modification at Lys-248. The written description inquiry here turns not on enumerating every possible antibody variant, but on whether a POSA would understand the claims to operate within a defined and

well-understood structural framework, such that the claimed subject matter can be recognized without requiring disclosure of each possible species. The claims do not seek to define the universe of antibody structures, but instead operates within a known IgG structural framework while specifying a particular site-directed modification. Under *Teva*, the specification's disclosure—through representative IgG embodiments and the described interaction mechanism—provides written description support for the claimed subject matter.

Purporting to address “[t]he portions of the ’675 patent cited by the Preliminary Guidance,” Petitioner asserted that SEQ ID NO: 1 “is an essential element” that the claims “omit,” and that omission means the claims lack written description. Paper 33 at 8–9. That argument is misplaced because it assumes that a specific sequence defines the structural boundary of the claims, when the claims are instead defined by modification at Lys-248 as determined by the EU numbering system. A POSA would understand the claims to be limited with the Lys-248 limitations, which is adequately described in the specification. As PO’s expert explained, “[a] POSA would understand the claim itself to limit the modified antibodies to those with lysine at position 248. Therefore, there is no overbreadth problem.” Ex. 2012, ¶ 46; Ex. 2008, ¶ 46.

Petitioner’s expert did not opine that the claims were so unduly broad as to lack written description. PO’s expert offers the only evidence of a POSA on this

point. As in *Teva*, the proposed substitute claims are each directed to a well-defined structural framework that a POSA would readily understand the inventors to have possessed. *Teva*, 172 F.4th at 1377–78. Further, Petitioner’s expert similarly recognized that the claims are structurally confined and construed the “at 248 position” limitation to refer to a defined residue within the antibody heavy chain under the EU numbering system. Ex. 1002, ¶¶ 69–70. This confirms that the claims are anchored to a specific structural context, not an unbounded genus, and do not present overbreadth concerns asserted by Petitioner.

Petitioner’s suggestion that antibodies outside the disclosed example necessarily would not work is speculation, not evidence. At the hearing, Petitioner could not identify testing or record support establishing non-operability for other putative isotypes or engineered variants; the discussion instead emphasized that applicability is a determinable matter in that a POSA can readily assess, based on the structural context, whether a given antibody falls within the claimed scope. *See* Paper 43 at 53:11–64:10. In that setting, routine confirmation does not undermine written description under *Teva*.

III. *Teva* Negates Petitioner’s “Full Scope” Arguments

Petitioner argues that the claims are invalid because PO has not shown that all antibodies within the scope of the claims are supported by the ’675 Patent’s examples of the claimed moieties on human IgG1 examples. That argument is

inconsistent with *Teva*. *Teva* squarely rejects any rigid requirement that a patent disclose a particular number of species to support a genus. *Teva*, 172 F.4th at 1374 (“[T]he number of species that must be disclosed to describe a genus claim ... necessarily changes with each invention”). Instead, the question is whether the patent’s disclosures, viewed through the lens of a POSA, reasonably convey possession of the claimed invention. *Id.*

Consistent with *Teva*, the written description inquiry does not require a showing of operability across every conceivable embodiment within the full scope of the claims. Rather, where the claims are anchored to a defined structural framework and a POSA can determine their scope in a predictable manner, routine confirmation does not defeat written description. Here, the claims are anchored to modification at Lys-248 (EU numbering), and a POSA would recognize the structural context relevant to that modification, allowing a POSA to readily identify and confirm which antibodies fall within the claimed scope.

Teva discusses *Ajinomoto Co. v. ITC*, 932 F.3d 1342 (Fed. Cir. 2019), *In re Herschler*, 591 F.2d 693 (C.C.P.A. 1979), and *In re Fuetterer*, 319 F.2d 259 (C.C.P.A. 1963). These cases are “particularly instructive” where a claim pertains to a well-known framework that is not, itself, the point of novelty. *Teva*, 172 F.4th at 1374. That is the situation here. Proposed substitute Claims 14–16 do not claim a new genus of antibodies or new chemistries; rather they claim moieties substituted

at Lys-248 (EU numbering) within an established antibody framework. Ex. 2004, ¶ 48; Ex. 2012, ¶ 46; Ex. 2008, ¶ 46.

In *Ajinomoto*, the Federal Circuit held that written description was satisfied for a genus of “more potent promoters” because the genus was “well explored,” and the invention was not the well-known techniques, but the identified target and application. *Teva*, 172 F.4th at 1374–75 (quoting *Ajinomoto*, 932 F.3d at 1359). Here, the identity of individual antibody variants is not the invention; rather, the invention lies in the modification of antibodies at Lys-248 with defined moieties. Because the claims are structurally bounded in this way, a POSA would understand that the inventors had possession of the claimed invention without enumerating every antibody variant.

Similarly, *In re Herschler* involved using DMSO to enhance the tissue penetration of a known class of “steroidal agents,” and held that a single disclosed species can support such a genus where a POSA would understand that members of the genus would work in the claimed method. *Teva*, 172 F.4th at 1375. Here, the antibody framework is likewise well-known, and the claims use that framework to define a different invention—the modification of Lys-248 with specified substituents.

Finally, *Teva* discusses *In re Fuetterer*, 319 F.2d 259 (CCPA 1963), which involved claims to a rubber stock composition for producing tire treads that included

“an inorganic salt capable” of maintaining homogeneity of other components in the composition. *Fuetterer* confirms that a patent need not identify “which of all” possible species will work in a claimed combination to meet the written description requirement. *Teva*, 172 F.4th at 1375–76. That principle directly refutes Petitioner’s scope argument: predictable variation within a known framework does not require exhaustive disclosure.

IV. CONCLUSION

Under the guidance set forth in *Teva*, PO respectfully submits that proposed substitute Claims 14–16 satisfy 35 U.S.C. § 112.

Dated: May 26, 2026

Respectfully submitted,

By: /Peter L. Giunta/
Peter L. Giunta
Reg. No. 55,207
K&L GATES LLP
599 Lexington Avenue
New York, NY 10022
T: (212) 536-3910

Counsel for Patent Owner

CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2026, a true and correct copy of the foregoing was caused to be served on the following counsel of record for Petitioner by electronic mail at the following address:

Stephen Maebius
Jason N. Mock
FOLEY & LARDNER LLP
3000 K St. NW
Washington, D.C. 20008
Fax: 202-672-5399
Email: FOLEY_AJINOMOTO_IPR2025_0283@foley.com

By: /Peter L. Giunta/
Peter L. Giunta
Reg. No. 55,207

Counsel for Patent Owner