24-1094

United States Court of Appeals for the Federal Circuit

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs-Appellants,

– v. –

ELI LILLY AND COMPANY,

Defendant-Appellee.

On Appeal from the United States District Court for the District of Massachusetts in No. 1:18-cv-12029-ADB

BRIEF OF MERCK SHARP & DOHME LLC AND IPSEN BIOPHARMACEUTICALS, INC. AS *AMICI CURIAE* IN SUPPORT OF REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

Counsel for amici curiae Merck Sharpe & Dohme LLC and Ipsen Biopharmaceuticals, Inc. certifies the following:

1. **The full name of every party or amicus represented by me is:**

   Merck Sharpe & Dohme LLC

   Ipsen Biopharmaceuticals, Inc.

2. **The names of the real party in interest represented by me is:**

   Not applicable.

3. **All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amici curiae represented by me are:**

   For Merck Sharpe & Dohme LLC: Merck & Co., Inc.

   For Ipsen Biopharmaceuticals, Inc.: Ipsen S.A.

4. **The names of all law firms and the partners or associates that appeared for the party or amici now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:**

   None.

5. **The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:**

   Not applicable (amicus brief).

6. **Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).**

   None.

July 1, 2026

/s/ *Katherine A. Helm*
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I. STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are innovative biopharmaceutical companies that are among the most consequential producers of novel, life-changing therapeutics, including antibodies such as KEYTRUDA® (pembrolizumab) and ENFLONSIA® (clesrovimab), vaccines such as GARDASIL® and CAPVAXIVE®, and small molecules such as CABOMETYX® (cabozantinib). *Amici* support robust, predictable patent rights and recognize their essential role in innovation.

Teva affects *amici* directly. *Amici* now face the prospect of infringement liability after investing years to independently develop, characterize, and clinically validate structurally-distinct compositions simply because those products might target the same biochemical pathway claimed in a method patent whose specification never contemplated those structures. This is not a hypothetical concern. Although *Teva* relates to use of antibodies, it potentially impacts large and small molecules alike. Many of *amici*'s therapeutics provide patients with options that are structurally-distinct from (and often superior to) competitor therapeutics that treat the same indications. These options are predicated on the certainty that the scope of patent exclusivity is bounded by what was actually invented and disclosed. *Teva* inverts that bargain, harming innovation.

[1] Pursuant to Fed. Cir. R. 40(i)(1), this brief is accompanied by a motion for leave to file.

II. INTRODUCTION AND SUMMARY OF ARGUMENT

En banc review is warranted for the following reasons.

First, *Teva* creates a §112 claim-format distinction the Court previously disavowed—"[t]he test for written description is the same" regardless of "whether the claim element is essential or auxiliary to the invention." *Juno Therapeutics v. Kite Pharma*, 10 F.4th 1330, 1341 (Fed. Cir. 2021). Teva's method claim should fare no differently. Whether a claim recites a method of using a genus of antibodies or the genus itself, Teva must describe and enable the full scope of its claim—a method of treating headache with ***all*** humanized anti-CGRP antagonist antibodies. Teva did not do so, disclosing only one humanized antibody, a far cry from the representative species the Court has required for other genus claims previously considered.

Second, Teva's reliance on *Herschler* as precedent for a claim-format distinction is misplaced. Because the functionally-claimed genus of antibodies here are ***essential*** to the method, not ancillary like the genus in *Herschler*, the patentee must describe the full scope of ***all limitations*** consistent with *Ariad*. *Herschler* is thus distinguishable.

Third, *Teva*'s claim-format distinction harms innovation. Where, like here, there is only one therapeutic use associated with a mechanism of action, a claim

reciting a method of treatment using a genus of compositions is just as broad in its exclusionary effect as a composition claim to the genus itself.

Fourth, for a true invention encompassing a new method for a known class of compositions (which Teva's is not), *amici* offer the alternative solution of using means-plus-function language to invoke 35 U.S.C. § 112(f) and allow functional claiming commensurate in scope with what was actually invented.

III. ARGUMENT

A. *Teva* Creates Confusion and a Claim-Format Distinction that Contradicts Precedent

The Court has long held that claims directed to genera of compositions and claims directed to methods of using those compositions are held to the same disclosure requirements under §112. *See, e.g.*, *Univ. of Rochester v. G.D. Searle*, 358 F.3d 916, 926 (Fed. Cir. 2004). *Amici* have relied on this precedent when making their investments. As explained below, *Teva* improperly overturns this precedent to hold that §112 scrutiny is relaxed for claims reciting a method of using a genus of antibodies; and, even if *Herschler* supports some distinction in specific cases, it is inapposite because the claimed genus here is essential to the claimed method.

1. *Teva*'s claim-format distinction is contrary to precedent.

Teva's written description holding draws a distinction between "(1) claims to a method of using humanized anti-CGRP antagonist antibodies *to treat*

headache and (2) claims to such antibodies themselves." *Teva Pharms. v. Eli Lilly*, 172 F.4th 1367, 1377-78 (Fed. Cir. 2026). The Court effectively requires less disclosure in the headache patents because the antibody genus in the method claims was effectively "well known" enough. *Id.*

Specifically, *Teva* found sufficient written description for the humanized anti-CGRP antagonist antibody limitation because the specification disclosed ***one*** humanized antibody and a plan for obtaining more by disclosing murine versions and prior-art humanization methods. *Id.* at 1377. Such evidence cannot pass muster under the Court's precedent. A single species that binds only one of at least three possible CGRP binding domains (*Teva Pharms. v. Eli Lilly*, 2023 WL 6282898, at *6 (D. Mass. Sept. 26, 2023)) cannot be representative of the entire functional genus or demonstrate that the class is well known when 300 Joe-9 antibodies were found insufficient in *AbbVie Deutschland v. Janssen Biotech*, 759 F.3d 1285, 1300 (Fed. Cir. 2014).[2]

Moreover, murine antibodies outside the claimed genus and prior-art humanization methods cannot cure that deficiency. Such evidence amounts to "[a] 'mere wish or plan' for obtaining the claimed invention," which "is not adequate

[2] Teva did not argue and the Court did not address whether the specification disclosed common structural features. 172 F.4th at 1374 n.8. Nevertheless, the evidence here could not pass muster under either test.

written description." *Juno*, 10 F.4th at 1335. Yet, *Teva* found adequate written description based on the distinction that "[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." 172 F.4th at 1376.

The Court has previously disavowed this analytical framework, stating "the test for written description is the same" regardless of "whether the claim element is essential or ***auxiliary to the invention***." *Juno*, 10 F.4th at 1341. The patentee must describe the full scope of ***all limitations*** consistent with *Ariad*. *See id.* at 1341-42. Under *Teva*'s new rule, however, a patentee who claims "an anti-CGRP antagonist antibody" must adhere to *Ariad* and disclose that genus with structural breadth commensurate with the claim, while a patentee who claims "a method of treating headache by administering an anti-CGRP antibody" can do less vis-à-vis the same functionally-defined genus under the same facts.

Teva's enablement holding also turns on this improper distinction. Because the claims recite a method of treating headache, *Teva* cast the relevant "research assignment" as determining which antibodies treat headache and concluded that assignment was "completed" because all humanized antibodies that bind CGRP

would purportedly do so.[3] 172 F.4th at 1381. *Amici* believe this is an extraordinary proposition; nevertheless, the claims require undertaking several research assignments, not one. A skilled artisan must make antibodies in a non-human species, identify which of those binds and antagonizes CGRP, and humanize them in a way that preserves binding and antagonizing functions. Only then can one determine whether such humanized antibodies treat headache. If the former assignments are not complete, then adding another does not somehow resolve that shortcoming.

Indeed, the additional assignment of determining whether humanized anti-CGRP antibodies treat headache was never completed. Contrary to *Teva*'s finding, Lilly never admitted, nor did Teva allege Lilly admitted, that all antibodies that bind treat headache. Rather, the evidence the Court cited to support that finding was testimony from Teva's experts, not Lilly's. 172 F.4th at 1376 (citing J.A. 4174 (Teva's Dr. Hale); J.A. 4272 (Teva's Dr. Hill)). Moreover, key evidence on which a jury could have relied to reach that conclusion was only in evidence because

[3] *Amici* believe this proposition is scientifically unsound; even when a target is validated such that inhibiting it with a potential drug is known to impact a biological pathway and, in turn, treat a disease, a significant portion of potential drugs targeting that same pathway fail for efficacy reasons. Kozlowski, S., *Current and future issues in the manufacturing and development of monoclonal antibodies*, ADV. DRUG DELIVERY REV., 58(5-6):707-722, 709 (2006). https://www.sciencedirect.com/science/article/abs/pii/S0169409X06000901

Teva shifted its priority-date position. *Teva*, 2023 WL 6282898, at *19 n.23. In IPR, Teva asserted and benefited from a 2005 priority date to argue nonobviousness; in district court, Teva asserted a 2006 date and thereby benefited from an intervening publication and disclosure found only in its 2006 application to gap-fill §112 deficiencies. *Eli Lilly v. Teva Pharm.*, IPR2018-01710, Paper No. 69, at 67, 140 (PTAB Mar. 31, 2020); *Teva*, 2023 WL 6282898, at *19 n. 23. Such a record makes a poor vehicle for the significant doctrinal shift *Teva* represents.

Moreover, *Teva*'s purported distinction from *Amgen*—that Amgen's claims covered the "antibodies themselves" rather than "the use of such antibodies" (172 F.4th at 1381)—makes no difference. Amgen's claims recited the functions of binding a target (PCSK9) and blocking a harmful pathway (PCSK9 from binding LDL receptors). *Amgen Inc. v. Sanofi*, 598 U.S. 594, 598 (2023). Under *Teva*'s logic, *Amgen* would have had a different outcome on the same facts had the claims recited a "method of lowering LDL cholesterol by administering an antibody that binds and blocks PCSK9." The correct outcome cannot be to trivialize *Amgen* with grammatical semantics. *Teva*'s claim-format distinction is inconsistent with precedent and garners confusion.

2. Any claim-format distinction cannot apply here because anti-CGRP antibodies are essential to Teva's method.

Teva grounds its claim-format distinction on the Court's decision in *Herschler*. Even if *Herschler* supports some distinction in specific cases, it is

inapplicable here.[4] In *Herschler*, the claims were directed to a method of using a single compound, dimethylsulfoxide (DMSO), to enhance transdermal penetration of steroidal agents by topically administering them with DMSO. *In re Herschler*, 591 F.2d 693, 695 (CCPA 1979). *Herschler*'s application did not purport to have invented new steroidal agents or a new class of transdermal penetration enhancers, instead premising its invention on this new use for DMSO as applied to therapeutic agents, including steroids. *Id.* at 701. The Court found Herschler's claims satisfied §112 because the essential feature, DMSO, for performing the method was specified, the steroidal agents were "auxiliary to the invention" and were a "known" class, and the applicant had demonstrated utility of DMSO across the auxiliary class. *Id.* at 701-02.

In sharp contrast, the claimed "antibodies" here are not auxiliary to the invention, *i.e.*, are not analogous to the "steroidal agents" in *Herschler*. Rather, Teva's antibodies are analogous to DMSO as they are the critical feature through which the method is accomplished. How the genus is used in the claimed function is key—"[s]teroids, when considered as ***drugs***, have a broad scope of physiological activity," but they were not claimed in *Hershler* for their use as drugs but rather

[4] *UroPep v. Eli Lilly*, 276 F. Supp. 3d 629, 648 (E.D. Tex. 2017) is also distinguishable. There, unlike here, hundreds of species (including the accused product) were known, and UroPep presented unrebutted evidence that all species shared a common structural feature. *Id.*

"as a class of compounds carried through a layer of skin." *Id.* Here, the discovery that anti-CGRP antibodies could be used as drugs to treat headache is inseparable from the antibodies themselves (which Teva also alleged were part of its invention in the "headache patents"[5]) because without a described/enabled composition capable of antagonizing CGRP, there is no method at all. In other words, the antibodies are not a vehicle for some other inventive insight, but rather the underlying means for achieving the claimed single-step treatment method itself. And, unlike in *Herschler*, where the claim itself recited the specific structure (DMSO) for achieving the method of enhancing skin penetration, here, Teva chose to claim the key feature necessary to achieve the method of treating headache not by structure, but by their "anti-CGRP antagonist" function.

B. *Teva*'s Claim-Format Distinction Will Harm Innovation

If method claims directed to using a genus require less disclosure than composition claims to that same genus, patentees will respond accordingly. For example, inventors who have made a single promising antibody, and can describe a research project to discover others, will draft broad functional method claims extending reach across all structurally-distinct antibodies that might share the

[5] *See* Headache Patents ("The invention disclosed herein concerns ***anti-CGRP antagonist antibodies***…."); *see, e.g.*, U.S. Patent Nos. 8,597,649, 9,266,951 (related patents claiming antibodies themselves).

functional property. As a result, innovators like *amici* will either risk infringement liability for developing a structurally-distinct composition based on a method patent providing inadequate disclosure under *AbbVie* and/or *Amgen* or, more likely, forego the investment entirely.

For example, suppose a company discloses that a single novel composition X binds target Y and thereby treats disease Z. A claim directed to all compositions that bind Y regardless of structure would be invalid under §112 if that single disclosed species and known/described methods for making more compositions having that function do not satisfy the legal standards set out in *AbbVie* and *Amgen*.

But under *Teva*'s logic, the exact same facts that would fail under *AbbVie*/*Amgen* could still satisfy §112 if the claim instead recited a method of treating indication Z by administering any composition that binds Y. And, if Z is the only indication correlated with binding Y, the claim would foreclose development of all compositions in that functional class, including those structurally unrelated to composition X, those not yet discovered or characterized, and even those with dramatically improved binding, safety, or dosing.

Teva entrenches this dubious outcome by requiring less disclosure for method claims than composition claims. A court evaluating a method claim under *Teva*'s framework might reason that the claim is narrower than a composition

claim because it covers only the use of those antibodies for a different purpose and therefore requires less disclosure. But again, that reasoning misses the practical reality: there often may only be one therapeutic use for a given genus of compositions. Thus, a method claim using a functionally-defined genus to treat that indication is no narrower in its exclusionary effect than a composition claim covering the same genus. And, if a method claim recites using a functional genus to disrupt a biological mechanism in a pathway correlated with ***multiple indications***, then the exclusionary effect would be even broader still. *Teva*'s claim-format distinction thereby risks foreclosing entire fields of independent scientific development, chilling innovation precisely where it is needed most.

C. An Alternative Solution: 35 U.S.C. § 112(f)

The Supreme Court in *Halliburton Oil Well Cementing v. Walker* interpreted §112 to foreclose claims that "do not describe the invention but use conveniently functional language at the exact point of novelty." 329 U.S 1, 10 (1946). In response, Congress enacted §112(f) (formerly §112, ¶6) as an exception to *Halliburton*'s rule, but "limited the breadth of such claim language by restricting its scope to the structure disclosed in the specification and equivalents thereof." *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1582 (Fed. Cir. 1996). The Supreme Court has recognized that §112(f) is for combination claims—*i.e.*, claims that unite existing components (such as known compounds) in a novel way

(such as a new method of treatment)—limited by the "actual means" for performing the function that is "shown in the patent specification" and its equivalents. *Warner-Jenkinson v. Hilton Davis Chem.*, 520 US 17, 28 (1997).

This rule provides significant protection for innovation. Indeed, Teva's use of functional language cut off Lilly's access to using its own novel drug for a method of treatment Lilly pioneered and developed at great cost. Had Teva instead drafted its claims under §112(f), infringement liability would be reasonably limited to the disclosed structures, statutory equivalents known at the time of issuance, and after-arising technologies that satisfy the doctrine of equivalents. *See Ring & Pinion Serv. v. ARB Corp.*, 743 F.3d 831, 835 (Fed. Cir. 2014). This approach supports functional claiming at the point of novelty, but in a way that is limited to what was actually invented and known in the art.

IV. CONCLUSION

Amici request the Court grant rehearing *en banc*.

Date: July 1, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 29(b)(4). This brief contains 2589 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman.

Date: July 1, 2026

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