Cooley

What Teva v. Eli Lilly Means for Written Description and Enablement of Method-of-Use Patents

April 30, 2026

On April 16, 2026, the US Court of Appeals for the Federal Circuit issued a precedential decision in *Teva Pharmaceuticals International GmbH v. Eli Lilly and Company*, No. 2024-1094 (Fed. Cir. Apr. 16, 2026), reversing the district court's grant of judgment as a matter of law that the asserted claims lacked adequate written description and enablement under 35 USC § 112.[i] The Federal Circuit found that the district court applied an overly stringent standard that failed to account for the well-established background knowledge in the field and the specific nature of the claimed invention as a method of treatment.[ii] Previously, Lilly successfully challenged Teva's related composition of matter patents claiming the same genus of humanized anti-CGRP antibodies in inter partes review proceedings that were affirmed by the Federal Circuit.

The technology and patents at issue

Calcitonin gene-related peptide (CGRP) is a neuropeptide associated with migraines, and blocking CGRP signaling through antagonist antibodies has become an important therapeutic approach. Anti-CGRP antagonist antibodies can be made in mice, and "humanization" refers to the process of converting nonhuman antibodies into a form that the human immune system will not reject, resulting in "humanized" antibodies.[iii] Teva's patents (sometimes referred to as the "headache patents") claim a method for treating headaches by administering any humanized monoclonal anti-CGRP antibody.[iv] Expert testimony indicated that a very large number of antibodies would need to be screened in order to identify those that could antagonize CGRP.[v]

While there were no humanized versions of anti-CGRP antagonist antibodies in the prior art, it was undisputed that the prior art was "replete with exemplary disclosures of anti-CGRP antagonist antibodies," techniques for making such antibodies were "extensively described in the prior art," and humanization "was a well-established and routine procedure."[vi] Lilly itself made those same points in arguing obviousness during the earlier inter partes review proceedings against Teva's anti-CGRP antibody patents.

The Teva headache patents disclosed only one exemplary humanized anti-CGRP antagonist antibody, referred to as "G1," but also disclosed several mouse (murine) anti-CGRP antagonist antibodies. The specification also states that "anti-CGRP antagonist antibodies may be made by any method known in the art" and referenced established prior-art methods for humanizing antibodies."[vii] Based on the data in the specification and the testimony heard at trial, the district court acknowledged that a jury could have found "that a person of ordinary skill would have … understood from the specification that *all* humanized anti-CGRP antagonist antibodies would treat headache."[viii]

Written description: Using a well-known genus as part of a different invention

The written description requirement demands the specification demonstrate that the inventor was "in possession" of the claimed invention as of the filing date. According to the Federal Circuit's en banc decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co*,[ix] generally, a genus can be disclosed by 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."

In life sciences, where genus claims may encompass vast numbers of compounds, this can be a daunting standard. For example, the Federal Circuit invalidated genus claims for lack of written description in *AbbVie*

Deutschland GmbH v. Janssen Biotech, Inc.[x] (disclosing more than 300 exemplary antibodies) and *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*[xi] (disclosing two embodiments from a known class; "Even accepting that scFvs were known and that they were known to bind, the specification provides no means of distinguishing which scFvs will bind to which targets.").

In *Teva*, the court acknowledged the *Ariad* written description standard, but then pivoted to "analyzing written description in circumstances like those here—where a claim pertains to a well-known genus that is not, itself, the invention."[xii]

The court started with *Ajinomoto Co. v. International Trade Commission* – the only binding precedent in this part of the court's analysis that post-dates *Ariad* – for the proposition that the specification could be "read in light of the background knowledge in the art" to find a representative number of species, where the genus "was already well explored," techniques for producing the relevant functionality were "well known," and those "well-known techniques" were not the core invention."[xiii]

The court then turned to *In re Herschler*, a case from 1979 that in turn relied heavily on the reasoning from a 1963 plurality opinion from *In re Fuetterer* for the proposition that an inventor does not necessarily need to identify every member of a genus that is not, itself, the invention.[xiv] In a footnote, the court quoted a more recent case from the US District Court for the Eastern District of Texas, *Erfindergemeinschaft UroPep GbR v. Eli Lilly* & Co., to emphasize that "when a genus is well understood in the art and not itself the invention but is instead a component of the claim, background knowledge may provide the necessary support for the claim."[xv]

Applying those cases, the court concluded that a reasonable jury could find that:

1. The claimed invention was the **use** of anti-CGRP antagonist antibodies to treat headache, not the antibodies themselves.
2. Nonhumanized anti-CGRP antagonist antibodies and methods of humanization were well-established in the art.
3. The specification could have led a skilled artisan to understand that all humanized anti-CGRP antagonist antibodies would treat headache.[xvi]

Notably, the court found this conclusion was supported, in part, by Lilly's own statements during inter partes review proceedings in which it successfully challenged Teva's anti-CGRP antibody claims as unpatentable.[xvii]

Lilly argued that humanized anti-CGRP antibodies were not known in the prior art at all (much less well-known), and that murine antibodies could not be representatives of a humanized antibody genus.[xviii] In rejecting that argument, the court reasoned that the jury could find humanization was a routine step, and that the specification explicitly disclosed humanization and identified prior-art methods for accomplishing it.[xix] Thus, the court effectively accepted a single representative humanized antibody, combined with murine antibodies, and the "routine" process of humanization, as demonstrating possession of the entire genus of humanized anti-CGRP antibodies.

The court also rejected Lilly's reliance on *University of Rochester v. G.D. Searle* and *Ariad* because the patents in those cases did not disclose any compounds that could be used in the claimed methods, nor was there any evidence that such compounds were known.[xx] By contrast, the specification in *Teva* included one example that could be produced from a well-known class of antibodies using a routine procedure, along with data that a skilled artisan would understand to show that any humanized anti-CGRP antibody would be effective for the claimed method of treatment.[xxi]

Enablement: Claim scope defined by specific use

As with written description, the standard for enablement of genus claims in life sciences cases has been demanding. The US Supreme Court's unanimous decision in *Amgen Inc. v. Sanofi* reinforced that a patentee claiming an entire class of compositions "must enable a person skilled in the art to make and use the **entire class**" (emphasis added).[xxii] Applying this principle, the Federal Circuit found a lack of enablement for genus claims in *Baxalta Inc. v. Genentech, Inc.*[xxiii] and *Idenix Pharms. LLC v. Gilead Scis. Inc.*[xxiv]

The *Teva* court reiterated the foundational principle that the specification must teach persons of ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation, and that the scope of enablement must be commensurate with the scope of the claim.[xxv] However, the court went on to distinguish *Amgen* and *Baxalta* by characterizing Teva's claims as narrow in functional scope, as opposed to claiming the entire antibody genus "for any and all purposes."[xxvi] Rather, the Teva claims covered only the use of humanized anti-CGRP antagonist antibodies to treat headaches.[xxvii]

The court reasoned that, in light of the well-known status of anti-CGRP antibodies and the routine nature of humanization, the only determination a person of skill would need to make is which humanized anti-CGRP antagonist antibodies treat headache.[xxviii] That determination was already made, because a reasonable jury could have found that **all** humanized anti-CGRP antagonist antibodies work for that specific therapeutic purpose.[xxix] As a result, unlike *Amgen* and *Baxalta*, a practitioner did not need to identify and screen vast numbers of candidate antibodies to determine which ones are effective for treating headache, as the answer was effectively already known. In other words, even assuming in Lilly's favor that making all anti-CGRP antagonist antibodies would require screening a very large number of candidates, and that the time and expense of doing so could constitute undue experimentation, such experimentation would not be required.[xxx]

The court also distinguished *Idenix* on its record, noting that while the evidence in *Idenix* did not support a finding that all members of the claimed genus would be effective for the claimed therapeutic use, in the *Teva* case, Lilly did not dispute that the jury could have found that all humanized anti-CGRP antagonist antibodies treat headache.[xxxi]

Conclusion

The Federal Circuit's decision in *Teva v. Eli Lilly* introduces an important distinction between claims directed to a novel genus of compounds and claims directed to the use of a well-known genus for a specific therapeutic purpose. Practitioners should carefully consider how this framework may affect the drafting, defense and challenge of method-of-use and genus claims in the pharmaceutical and biotechnology space.

Notes

i. *Teva Pharms. Int'l GmbH v. Lilly*, No. 2024-1094, slip op. at 2 (Fed. Cir. Apr. 16, 2026).
ii. Id. at 13 – 14, 22 – 24.
iii. Id. at 2 – 3.
iv. Id. at 3 – 4 ("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.")
v. Memorandum and Order, *Teva Pharms. Int'l GMBH v. Eli Lilly and Co.*, 18-cv-12029-ADB, ECF No. 695 at 24 (D. Mass. Sept. 26, 2023) (hereinafter D.Ct. Order) ("[T]he jury could only have found that (1) there are a very large number of antibodies that would need to be screened in order to identify those that could antagonize CGRP, … and (2) the size of the genus, i.e., the number of anti-CGRP antagonist antibodies that could be humanized and treat headache, was "unknowable," and thus not necessarily very large or small.") (record citations omitted); see also *Teva Pharms.*, No. 2024-1094, slip op. at 21 – 22 (Federal Circuit assuming a "very large number of candidate antibodies").
vi. *Teva Pharms.*, No. 2024-1094, slip op. at 4, 13 – 14.
vii. Id. at 3, 13.
viii. Id. at 5 (see also D.Ct. Order at 25 ("That said, the jury could have credited testimony that a POSA would understand … that all humanized anti-CGRP antagonist antibodies would treat headache."))
ix. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010).
x. *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014).
xi. *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1336 (Fed. Cir. 2021).
xii. *Teva Pharms.,* No. 2024-1094, slip op. at 9.
xiii. Id. at 9 – 10 (citing *Ajinomoto Co. v. International Trade Commission*, 932 F.3d 1342, 1346-47 (Fed. Cir. 2019).
xiv. Id. at 10 – 11 (citing *In re Herschler,* 591 F.2d 693 (CCPA 1979) and *In re Fuetterer,* 319 F.2d 259 (CCPA 1963).
xv. Id. at 12 n.11 (citing *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 648 (E.D. Tex. 2017) (Bryson, J., sitting by designation), *aff'd*, 739 F. App'x 643 (Fed. Cir. 2018)) (nonprecedential).
xvi. Id. at 12 – 14.

xvii. Id. at 4, 12 – 13.
xviii. Id. at 14.
xix. Id. at 14 – 15.
xx. Id. at 16 – 17 (citing *University of Rochester v. G.D. Searle & Co*., 358 F.3d 916, 918 (Fed. Cir. 2004) and *Ariad*, 598 F.3d at 1341, 1355-58).
xxi. Id. at 16 – 17.
xxii. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023).
xxiii. *Baxalta Inc. v. Genentech, Inc*., 81 F.4th 1362 (Fed. Cir. 2023).
xxiv. *Idenix Pharms. LLC v. Gilead Scis. Inc.,* 941 F.3d 1149, 1153 (Fed. Cir. 2019).
xxv. *Teva Pharms*., No. 2024-1094, slip op. at 21.
xxvi. Id. at 22.
xxvii. Id.
xxviii. Id. at 23.
xxix. Id; see D.Ct. Order at 25.
xxx. Id. at 22 – 23.
xxxi. Id. at 24.

Key Contacts

Geoffrey Biegler **San Diego**	**gbiegler@cooley.com** **+1 858 550 6012**
John P. Rearick Boston	jrearick@cooley.com +1 617 937 2305
Dr. Daniel Knauss Palo Alto	dknauss@cooley.com +1 650 843 5287