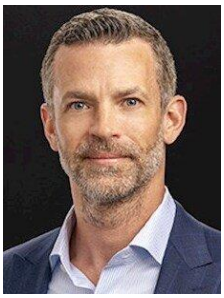
Teva Ruling Offers Patentees New Support For Genus Claims

By **Geoffrey Biegler, John Rearick and Dan Knauss** (May 29, 2026)



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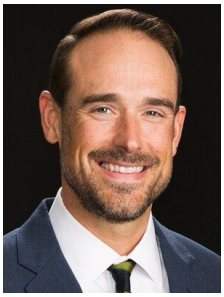

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On April 16, the U.S. Court of Appeals for the Federal Circuit **issued** a precedential decision in Teva Pharmaceuticals International GmbH v. Eli Lilly and Company, reversing the U.S. District Court for the District of Massachussetts' grant of judgment as a matter of law that the asserted claims lacked adequate written description and enablement under Title 35 of the U.S. Code, Section 112.[1]

As discussed below, the Federal Circuit found that the district court had applied an overly stringent Section 112 standard that failed to account for the well-established background knowledge in the field and that the claims' scope was limited to methods of treating a specific condition.

The decision is particularly interesting because it offers a counterexample against the recent trend of courts invalidating patents claiming a broad, functionally defined class, or genus, of compounds under Section 112.

The Technology and Patents at Issue

Calcitonin gene-related peptide is a neuropeptide associated with migraines. Teva's patents, sometimes referred to as the headache patents, claim a method for treating headaches by administering a humanized monoclonal anti-CGRP antibody, with the antibody identified only by the target.[2]

As is often true when an antibody is identified by its target, expert testimony at the district court indicated that a very large number of antibodies would need to be screened to identify those that could antagonize CGRP.[3]

The Teva headache patents disclosed only one exemplary humanized anti-CGRP antibody, referred to as G1, in addition to several mouse anti-CGRP antibodies.

However, according to the court, the prior art was replete with exemplary disclosures of

anti-CGRP antagonist antibodies, and techniques for making such antibodies were "extensively described in the prior art."[4] And, while no humanized anti-CGRP antibodies were disclosed in the prior art, the specification referenced methods for humanizing antibodies that the parties agreed were "well-established and routine."[5]

The district court further found 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."[6]

While making obviousness arguments during earlier inter partes review proceedings against Teva's anti-CGRP antibody compound patents, Lilly itself took many of the same positions regarding the knowledge in the art and disclosure of the specification.

Written Description: Using a Well Known Genus as Part of a Different Invention

To satisfy the written description requirement, the specification must 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. in 2010, generally, a genus can be supported 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."[7]

In the 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. in 2014, disclosing over 300 exemplary antibodies.[8]

The Federal Circuit also invalidated genus claims in Juno Therapeutics Inc. v. Kite Pharma Inc. in 2021,[9] disclosing two embodiments of known type of molecule. The court explained that 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 purported to apply the Ariad written description standard, but emphasized a line of cases "where a claim pertains to a well-known genus that is not, itself, the invention."[10]

The court started with Ajinomoto Co. v. International Trade Commission, in which the court found sufficient written description where the claimed genus "was already well explored," techniques for producing the claimed functionality were "well known," and those "well-known techniques" were not the core invention.[11]

The court then relied on In re: Herschler, from 1979, and In re: Fuetterer, from 1963 — older cases from the Federal Circuit's predecessor court — for the proposition that an inventor does not necessarily need to identify every member of a genus that is not, itself, the invention, particularly when the genus is well understood in the art and is merely a component of the claimed invention rather than the invention itself.[12]

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) non-humanized anti-CGRP antagonist antibodies and methods of humanization were well-established in the art, and (3) the specification could have led a skilled artisan to understand that all humanized anti-CGRP antagonist antibodies would treat headache.[13]

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.[14]

The court rejected Lilly's argument that murine antibodies known in the art could not be representative of a humanized antibody genus. Specifically, the court found that the single representative humanized antibody in the specification, combined with additional murine antibodies, and the routine process of humanization, was sufficient to establish possession of the claimed methods using the genus.[15]

The court also distinguished 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, whereas the Teva specification included one working example from a well known class of antibodies, 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.[16]

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 Supreme Court's unanimous decision in Amgen Inc. v. Sanofi in 2023 **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."[17]

Applying this principle, the Federal Circuit has found genus claims invalid for lack of enablement in numerous cases, including Baxalta Inc. v. Genentech Inc.[18] in 2023 and Idenix Pharmaceuticals LLC v. Gilead Sciences Inc. in 2019.[19]

Here, the court distinguished Amgen and Baxalta by characterizing Teva's claims as narrow in functional scope. Rather than claiming the antibody genus "for any and all purposes," the court characterized the claims as covering only the use of humanized anti-CGRP antagonist antibodies to treat headache.[20]

The court then reasoned that the relevant research assignment was not identifying and making all possible humanized anti-CGRP antibodies, but rather determining which ones would treat headache.[21]

The court believed that assignment was already completed because the evidence showed that all anti-CGRP antibodies would work to treat headache.[22]

Implications of the Decision Going Forward

The Teva v. Lilly decision is certain to be popular with patentees in future cases seeking to defend patent claims reciting a large genus of compounds. It stands among a relatively small number of recent cases upholding claims reciting a large genus of compounds as adequately described and enabled, particularly where the specification discloses few exemplary compounds.

On written description, patentees will cite Teva for the proposition that a patent disclosing a single species may satisfy Ariad if the genus was well known in the prior art and the genus itself is not the invention.

While it is not the first case to find sufficient description based on that theory, Teva arguably reaches that conclusion based on the slimmest disclosure in the specification relative to the scope of the claims. Moreover, there are few, if any, other cases finding

sufficient written description for a claim reciting a genus of antibodies identified by their target.

The Teva case also may fuel further debate about whether the written description standard differs when the claimed genus is not itself the invention. The Teva decision relies heavily on certain precedents for the proposition that the written description standard may be lower in that scenario, but cases such as Juno have specifically held that "[t]he test for written description ... is the same whether the claim element is essential or auxiliary to the invention."[23]

On the other hand, the Teva case involved a factual scenario unlikely to arise often in written description disputes. Because of positions taken in earlier inter partes review proceedings, Lilly effectively conceded that anti-CGRP antagonist antibodies were "well known" and "replete" in the prior art, and that humanization was "routine." Those concessions provided the Federal Circuit with sufficient evidence to support the jury's written description verdict.

In other notable written description cases, such as AbbVie and Juno, those same facts were hotly contested. Absent Lilly's factual concessions, Teva offers limited guidance on how courts will assess whether a genus was well known in the prior art or what constitutes sufficient evidence that all members of a genus will work for the claimed purpose.

On enablement, the court's analysis similarly turned on Lilly's apparent failure to dispute that all anti-CGRP antibodies would satisfy the claimed function. In the absence of such concessions, patentees in future cases will likely have a harder time making that showing and will need to adduce evidence showing that a skilled artisan would understand that the full scope of the claimed class of compounds would work in the claimed method.

Patentees may also argue that Teva makes method-of-treatment claims reciting a large genus of compounds more likely to survive an enablement challenge than composition-of-matter claims to the same genus.

However, the court's conclusion that a skilled artisan did not need to carry out the research assignment of identifying all anti-CGRP antibodies, because all of them would work to treat headache may be in tension with Amgen.

After all, there is a fine line between claiming a broad functional compound genus, as in Amgen, versus claiming the use of a broad compound genus, as in Teva.

And even if all anti-CGRP antibodies work for the claimed methods, the court did not explain how a skilled artisan would identify the full scope of antibodies that would antagonize CGRP without screening.

Thus, practitioners should watch carefully to see whether future decisions draw a meaningful distinction between method-of-treatment and composition-of-matter claims that recite the same genus.

In the meantime, those seeking to claim a new use of a broad class of compounds should consider including ample disclosure in the specification highlighting known examples of the class in conjunction with the new use.

Conclusion

The Federal Circuit's decision in Teva v. Eli Lilly reiterates 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.

In reaching its decision, the Federal Circuit suggested that claims for methods of treating specific conditions using a broad class of well known compounds may be more likely to survive a Section 112 challenge than composition of matter claims drawn to a similarly broad class of compounds.

However, the case presents unique circumstances in which the defendant was forced to concede many facts that supported the court's conclusion based on positions taken in previous proceedings.

Practitioners should carefully consider how this decision may affect the drafting, defense and challenge of method-of-use and genus claims in the pharmaceutical and biotechnology space.

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[1] Teva Pharms. Int'l GmbH v. Eli Lilly & Co. , No. 2024-1094, slip op. at 2 (Fed. Cir. Apr. 16, 2026).

[2] 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.")

[3] Memorandum and Order, Teva Pharms. Int'l GMBH v. Eli Lilly & 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.")

[4] Teva Pharms., No. 2024-1094, slip op. at 5, 12-13.

[5] Id. at 5, 13.

[6] 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."))

[7] Ariad Pharms., Inc. v. Eli Lilly & Co. , 598 F.3d 1336, 1350 (Fed. Cir. 2010).

[8] AbbVie Deutschland GmbH v. Janssen Biotech, Inc. , 759 F.3d 1285, 1298 (Fed. Cir. 2014).

[9] Juno Therapeutics, Inc. v. Kite Pharma, Inc. , 10 F.4th 1330, 1338 (Fed. Cir. 2021).

[10] Teva Pharms., No. 2024-1094, slip op. at 9-14.

[11] Id. at 9-10 (citing Ajinomoto Co. v. International Trade Commission , 932 F.3d 1342,

1346-47 (Fed. Cir. 2019).

[12] Id. at 10-12 (citing In re Herschler , 591 F.2d 693 (CCPA 1979) and In re Fuetterer , 319 F.2d 259 (CCPA 1963).

[13] Id. at 12–14.

[14] Id. at 12–13.

[15] Id. at 14–15.

[16] Id. at 16-17.

[17] Amgen Inc. v. Sanofi , 598 U.S. 594, 610 (2023).

[18] Baxalta Inc. v. Genentech, Inc. , 81 F.4th 1362, 1366-67 (Fed. Cir. 2023).

[19] Idenix Pharms. LLC v. Gilead Scis. Inc. , 941 F.3d 1149, 1153 (Fed. Cir. 2019).

[20] Teva Pharms., No. 2024-1094, slip op. at 22-23.

[21] Id. at 23.

[22] Id. at 21.

[23] Juno, 10 F.4th at 1341 (quoting Boston Sci. Corp. v. Johnson & Johnson , 647 F.3d 1353, 1365 (Fed. Cir. 2011)).