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

2024-1094

Appeal from the United States District Court for the District of Massachusetts in No. 1:18-cv-12029-ADB, Judge Allison Dale Burroughs.

ON PETITION FOR REHEARING EN BANC

JEFFREY A. LAMKEN, MoloLamken LLP, Washington, DC, filed a petition for rehearing en banc for appellee. Also represented by KAYVON GHAYOUMI; CHARLES COLLINS-CHASE, DANIELLE ANDREA DUSZCZYSZYN, J. MICHAEL JAKES, WILLIAM BARRETT RAICH, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC.

KEVIN P. MARTIN, Goodwin Procter LLP, Boston, MA,

filed a response for plaintiffs-appellants. Also represented by ELAINE BLAIS; GABRIEL FERRANTE, New York, NY.

Before MOORE, *Chief Judge*, LOURIE, DYK, PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL, CUNNINGHAM, and STARK, *Circuit Judges*,[1] and ANDREWS, *District Judge*.[2]

DYK, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

O R D E R

Eli Lilly and Company filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals International GmbH.

IPSEN Biopharmaceuticals, Inc., Merck Sharp & Dohme LLC, Amgen Inc., Sanofi S.A., Johnson & Johnson Nagra USA, Inc., Dennis Burton, David Manuta and Barbara Ruskin moved for leave to file briefs as amicus curiae, which the court granted.

The petition was first referred as a petition to the panel that heard the appeal, and thereafter the petition was referred to the circuit judges who are in regular active service. The court conducted a poll on request, and the poll failed.

Upon consideration thereof,

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[1] Circuit Judge Newman did not participate.

[2] Honorable Richard G. Andrews, District Judge, United States District Court for the District of Delaware, sitting by designation, participated only in the decision on the petition for panel rehearing.

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

FOR THE COURT

Jarrett B. Perlow
Clerk of Court

September 30, 2026
Date

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DYK, *Circuit Judge*, dissenting from denial of petition for rehearing en banc.

I respectfully dissent from the court's denial of en banc rehearing. This case presents important questions as to the scope of the enablement requirement for method claims. The panel's holding creates confusion as to the enablement standards for method claims, will undermine medical innovation by sustaining overly broad claims, and is contrary to Supreme Court enablement precedent.

I

The claims at issue are claim 30 of U.S. Patent No. 8,586,045 (the "'045 patent") and claims 5 and 6 of U.S.

Patent No. 9,884,907, of which claim 30 of the '045 patent is representative. *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 172 F.4th 1367, 1372 & n.3 (Fed. Cir. 2026). Claim 30 recites 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." *Id.* at 1372 (omission in original) (quoting '045 patent claims 17, 30).

Thus, the claim recites two functional limitations: (1) an antagonist limitation requiring a "humanized monoclonal antibody" that functions as an "anti-CGRP antagonist," and (2) a treatment limitation in which administering the antibody reduces or treats headache. '045 patent claims 17, 30. The difficulty of identifying the relevant compounds lies in the first limitation, not the second limitation. This is so because the second limitation adds nothing of substance to the first limitation. As the panel opinion recognizes, any member of the genus of humanized anti-CGRP antagonist antibodies would be effective for treating headache. *Teva*, 172 F.4th at 1381 ("[T]he specification disclosed that *all* such antibodies work for that purpose.").

At the same time, the undisputed record shows that the difficulty of identifying compounds with antagonist properties (the first limitation) was considerable. The evidence established that there were a large number of species with potential antagonist properties; that identification and humanization of anti-CGRP antibodies required laboratory benchtop and animal testing at substantial costs of time (months) and money (tens of thousands of dollars per antibody). *E.g.*, J.A. 1344, 4227.[1] The panel explicitly assumes

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[1] Citations to "J.A." refer to the Corrected Non-Confidential Joint Appendix filed by the parties in this appeal. Dkt. No. 36.

for this reason that the genus of anti-CGRP antagonist antibodies was *not* enabled. *Teva*, 172 F.4th at 1381 ("[W]e will assume that . . . the amount of time and expense required to make (and humanize) all anti-CGRP antagonist antibodies would have constituted undue experimentation . . . ."). A claim that requires undue experimentation is not enabled. *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988); *Wyeth & Cordis Corp. v. Abbott Lab'ys*, 720 F.3d 1380, 1384 (Fed. Cir. 2013).

The opinion indeed recognizes that "if the asserted claims were to the genus of humanized anti-CGRP antagonist antibodies themselves[,] . . . this case would resemble *Amgen* [*Inc. v. Sanofi*, 598 U.S. 594 (2023)]." *Teva*, 172 F.4th at 1381. In *Amgen*, the Supreme Court explained that to enable the full scope of a claimed genus of antibodies, a patentee must do more than define the screening process for identifying the antibody compositions that successfully bind to a target. 598 U.S. at 610, 614.

The panel nonetheless concludes that this case is different from *Amgen* for two reasons. First, because anti-CGRP antagonist antibodies were "well known"—even if not enabled—the panel holds that the specification enables the treatment of headache using such antibodies. *Teva*, 172 F.4th at 1380–82. It was only well known that such a genus exists, but as the panel recognizes, the genus is "not, itself, the invention." *Id.* at 1374. The invention required identification of the various antibody species with antagonist qualities. It was not well known which antibody species had such antagonist qualities. It is established that a genus may be well known but the specific embodiments with the desired qualities are not enabled by knowledge of the genus. *See Wyeth*, 720 F.3d at 1383–86 (concluding that a class of compounds effective for treatment was known but that undisclosed individual species of the claimed genus were not enabled).

Second, the panel opinion examines the scope of the asserted claims and concludes that they "do not claim humanized anti-CGRP antagonist antibodies *themselves*; instead, they claim only the use of such antibodies for the different, limited purpose of treating headache." *Teva*, 172 F.4th at 1381.

The panel thus treats the claimed headache-treatment method as narrower than a claim to the underlying genus of antibodies and requires correspondingly narrower enablement. This simply makes no sense. Where the record does not suggest uses for the underlying compounds other than to treat headache, *see* J.A. 16410, 16447, the practical scope of the method claim is equal to the scope of the compound. The method claim here is not effectively narrower than the compound claim. Even if it were, the compound still must be enabled since the compound is indisputably a claim limitation. A patent "must enable the full scope of the invention as defined by its claims." *Amgen*, 598 U.S. at 610. "This important doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012). "[A] patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Id.*

In order for a person of ordinary skill in the art to practice the whole claimed method, the patent would need to enable the recited anti-CGRP antagonist antibodies. Claiming a method of use that depends on a recited component cannot excuse the enablement requirement of the component. Both the antagonist limitation and the treatment limitation are defined functionally in claim 30. There is no support for the panel's approach, which concludes that the method claim is enabled because one functional limitation (treating headache) is enabled while the other functional limitation (the underlying compound) is not.

II

As amici note, the opinion creates an "end-run around *Amgen*" and has resulted in guidance urging patent practitioners to use "creative claim drafting to skirt the disclosure requirements of *Amgen*." Amicus Br. of Johnson & Johnson and Nagra USA LLC at 10–12, Dkt. No. 91. In *Amgen* itself, the principal use of the claimed PCSK9-blocking antibodies was to lower cholesterol. *Amgen*, 598 U.S. at 598–99. The Supreme Court held that the genus of PCSK9-blocking antibodies was not enabled. *Id.* at 613–14. Had Amgen simply claimed a cholesterol-lowering method using such antibodies, the scope of Amgen's patent would not have been meaningfully narrowed; the PCSK9-blocking antibodies were not useful if not used for treating cholesterol. Yet according to the panel opinion in this case, the patentee in *Amgen* could have evaded the enablement requirement by doing exactly that.

Amici representing the pharmaceutical industry, not known for urging onerous requirements for patentability, view the panel decision as confusing and erroneous. Amici predict that the result "risks foreclosing entire fields of independent scientific development, chilling innovation precisely where it is needed most," Amicus Br. of Merck Sharp & Dohme LLC & Ipsen Biopharmaceuticals, Inc. at 11, Dkt. No. 86, and that "[a]llowing this type of method claim to proliferate may block research programs for undeveloped treatments or disincentivize companies from investing in product development," Amicus Br. of Johnson & Johnson and Nagra USA LLC at 14. Amgen and Sanofi argue that "differing outcomes" between this case and *Amgen* "will create uncertainty for future decisionmakers, the USPTO, and the industry—ultimately harming patients." Amicus Br. of Amgen Inc. & Sanofi S.A. at 14, Dkt. No. 90.

I respectfully dissent from the denial of rehearing en banc.