Teva, Wyeth Show How Claimed Advances Shape Enablement

By **Kendall Gurule** (September 23, 2026)



Kendall Gurule

Two recent U.S. Court of Appeals for the Federal Circuit decisions involving method-of-treatment claims reached opposite enablement outcomes from strikingly similar procedural postures, underscoring how the claimed patentable advance can shape the enablement inquiry.

In Teva Pharmaceuticals International GmbH v. Eli Lilly & Co., a jury rejected Eli Lilly and Co.'s enablement challenge, the U.S. District Court for the District of Massachusetts granted judgment as a matter of law that the claims were invalid, and the Federal Circuit **reversed** on April 16.

In Wyeth LLC v. AstraZeneca Pharmaceuticals LP, a jury likewise rejected an enablement challenge and the district court again granted JMOL of invalidity. This time, however, the Federal Circuit **affirmed** on July 9.[1]

At first glance, the claimed subject matter looks similar. The claims in both cases recite methods of treating a condition by administering an "effective amount" (Teva), or a daily "unit dosage" (Wyeth), of a functionally defined genus of therapeutic agents.

However, the court's treatment of the two cases suggests an analytical framework that can reconcile the differing outcomes: First, identify the patentability-defining technical advance, and next, determine the size and character of the gap between that advance and what the patent — read with the knowledge and skill of a person of ordinary skill in the art, or POSA — teaches.

The claim is enabled if a skilled artisan can bridge that gap without undue experimentation. If not, the patent has supplied a research assignment rather than an enabling disclosure.

The Backdrop of Amgen: A New Therapeutic Class

The U.S. Supreme Court's 2023 decision in Amgen v. Sanofi provides the backdrop for this analysis.

In Amgen, the claimed advance was an entire functionally defined antibody genus. As the Supreme Court articulated, while the specification need not describe every embodiment

individually, "the more one claims, the more one must enable." [2]

Against a large claimed advance, the Supreme Court found that the specification merely directed scientists to generate candidates and test them to determine which possessed the claimed functional limitations. The court characterized those approaches as mere research assignments, rather than an enabling disclosure.

While Amgen involved claims to the antibody genus itself, Teva and Wyeth help provide insight into how the enablement inquiry should be applied to a claim that covers a treatment method using a functionally defined genus of therapeutic agents. Their differing outcomes illustrate why the nature of the claimed advance matters to that analysis.

Teva: A New Use of a Known Class

The representative Teva claim recited a method of treating headache by administering an effective amount of a humanized anti-calcitonin gene-related peptide, or anti-CGRP, antagonist antibody.

The specification disclosed one humanized anti-CGRP antagonist antibody, several murine anti-CGRP antagonist antibodies and prior art humanization methods. The record also permitted the jury to find that murine anti-CGRP antagonist antibodies and methods of making them were well known and that humanization was routine. Some of that evidence came from Lilly's own earlier statements to the U.S. Patent and Trademark Office.[3]

During oral argument, counsel for Teva framed the novel aspect as the use of the known antibody class to treat headache, rather than suggesting that the antibody class itself was novel.[4] The Federal Circuit's opinion appears to have concurred with that approach, recognizing that the claims did not cover the antibody class for all purposes, but instead only covered their use for the limited purpose of treating headache.

Thus, the relevant inquiry was what members of the class treated headache. The opinion noted that the specification itself provided the answer to that inquiry — teaching that all humanized anti-CGRP antagonist antibodies were effective to treat headache.

Lilly argued that the potential antibody genus was enormous and that making and screening its members would require undue experimentation. But given the limited scope of the claimed patentable advance — i.e., treating headaches — the court questioned the relevance of this argument and concluded that finding or making every possible member of

the class would be extra credit, rather than necessary work.[5]

Wyeth: Dosing Became Part of the Claimed Advance

Wyeth's prosecution history helps explain why its dosage language carried greater significance than the "effective amount" language in Teva.

The asserted Wyeth claims required treating gefitinib- or erlotinib-resistant nonsmall cell lung cancer in a patient by administering a daily unit dosage of an irreversible epidermal growth factor receptor inhibitor satisfying a functional binding limitation.

The specification expressly defined "unit dosage" as "a predetermined quantity of active material calculated to produce the desired therapeutic effect." The Federal Circuit held that the relevant inquiry was whether a POSA was enabled to arrive at a repeatable patient-level dosing regimen — not merely at identification of compounds that inhibited epidermal growth factor receptors or killed cancer cells in vitro. At the same time, the court rejected the idea that enablement required U.S. Food and Drug Administration-level safety, efficacy or approval.[6]

The patentee had added the "unit dosage" and "daily" limitations during prosecution and contrasted this with a dose of approximately 500 to 3,000 milligrams, administered as a bolus once or twice per week, disclosed in the prior art.[7] Daily therapeutic unit dosing was therefore not necessarily the patent's sole point of novelty, but the prosecution history made it a material part of the claimed patentable advance over the prior art.

Against this backdrop, the specification identified three exemplary inhibitors and reported in vitro results showing increased killing of cancer cells. It also disclosed broad "general" and "projected" in vivo dosage ranges. However, there was evidence in the record that dosages within the disclosed ranges could prove toxic, and that achieving an effective dose while avoiding toxicity was a difficult balancing act.

The specification also provided no working example of a unit dosage administered to a human patient; no explanation of how to extrapolate from the disclosed in vitro activity to a daily human dose; and no other teaching that permitted a skilled artisan to calculate the claimed dosage across the inhibitor class. The specification instead stated that dosing depended on the particular compound, the patient, the route of administration, the severity of the condition and the desired effect.

Noting the complexity and unpredictability of the technology at issue, the court found that the gap between the specification's guidance and the claimed technological advance — daily, effective dosing — was too great for enablement.

Teva and Wyeth Suggest an Advance-and-Gap Framework

While the Federal Circuit did not announce a new formal test, the two decisions can be reconciled using a practical three-step framework:

1. Identify the patentability-defining advance.

The first step is to identify the patentability-defining advance embodied in the claim as a whole. That inquiry should consider the claim as properly construed, the specification's description of the problem and solution, the prosecution history, and the relevant prior-art baseline.

In Amgen, this claimed contribution was the therapeutic class itself. In Teva, the contribution was a method of treating headaches, using a known therapeutic class. In Wyeth, the applicant's emphasis of dosing limitations to attain patentability revealed the relevant advance to be a daily effective dosage.

2. Establish the skilled artisan's starting point.

The second step is to determine what the disclosure, read in light of the skilled artisan's knowledge, already provides. As the Federal Circuit identified in Idenix Pharmaceuticals LLC v. Gilead Sciences Inc. in 2019, the specification, not the knowledge of one skilled in the art, must supply the novel aspects of an invention.[8]

But that does not eliminate the role of background knowledge; the specification is read through the knowledge and skill of the POSA rather than in isolation. The specification therefore does not have to close the entire gap, but it must provide enough of the claimed advance that a POSA can bridge the remainder without undue experimentation.

In Teva, the specification provided guidance that all of the claimed class treated headache, against the backdrop of known-in-the-art murine antibodies and routine humanization methods. In Wyeth, the specification provided in vitro data, broad prospective ranges, and an acknowledgement that appropriate dosage depends on numerous variables and is "peculiar to each individual."

3. Determine whether the remaining gap requires undue experimentation.

The final step is to assess whether bridging the gap between the starting point in the disclosure and the patentable advance requires undue experimentation. Relevant considerations include the breadth of the unresolved space, the predictability of the technology, the amount and quality of guidance, the representativeness of examples, and the prevalence of operative and inoperative embodiments.

In Teva, the gap was closed because the specification disclosed that all members of the known, routinely implemented class worked for the claimed treatment purpose. In Wyeth, the relationship between the disclosed in vitro activity and the claimed daily human dosing regimen was too great in light of the delicate balance between effectiveness and toxicity, and the complexity and unpredictability emphasized by the specification itself.

Practical Patent-Lifecycle Implications: What Teva and Wyeth Mean for Patent Strategy

For patent prosecutors, the cases illustrate that a narrowing amendment can change more than infringement scope. A dosage, frequency, route, patient population, biomarker or functional limitation added to distinguish the prior art may become a material part of the patentable advance — and therefore the focus of a later enablement challenge.

To the extent possible, applications should support foreseeable fallback positions, not merely the broad therapeutic concept initially contemplated. Where a treatment claim may ultimately require an in vivo dose or regimen, ideally, the disclosure should explain the bridge between experimental evidence and that limitation.

That may include why a laboratory or animal model predicts the claimed patient-level result, how a POSA selects within a disclosed range and which variables affect that selection. To the extent such explanation is not included, it is wise to avoid using the specification to emphasize the difficulty or unpredictability of the determination.

The decisions also underscore the balance between obviousness and enablement positions. A valid patent must claim an advance that was not within ordinary skill before the inventor's disclosure. Once that advance is claimed, however, the disclosure must provide enough of a leg up that a POSA can practice the claimed advance without undue experimentation.

Nonobviousness asks whether a POSA would have reached the claimed advance without the inventor's teaching; enablement asks whether a POSA can do the same after receiving that teaching. For a valid patent, the answer must be no to the former and yes to the latter.

Thus, arguments that the prior art supplied no reasonable expectation of success may support patentability if the specification supplies the missing insight. However, they can become dangerous when the specification does not.

For litigators, the first task should be to define the claimed advance consistently with the complete intrinsic record. Patent owners should identify the disclosure in the specification the provides enough instruction to a POSA to enable that which is nonobvious.

Challengers should develop evidence showing that the gap between disclosure and advance is no smaller than the gap between prior art and advance. A successful showing on this issue traps the patent between obviousness and enablement.

Kendall Gurule is a shareholder at Polsinelli.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of their employer, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] Teva Pharmaceuticals International GmbH v. Eli Lilly & Co. , 172 F.4th 1367, 1372-73, 1382 (Fed. Cir. 2026); Wyeth LLC v. AstraZeneca Pharmaceuticals LP , 180 F.4th 1371, 1373, 1383 (Fed. Cir. 2026).

[2] Amgen Inc. v. Sanofi , 598 U.S. 594, 610-15 (2023).

[3] Teva, 172 F.4th at 1372, 1376-77.

[4] Oral Argument at 8:02-9:30, Teva Pharmaceuticals International GmbH v. Eli Lilly & Co., No. 24-1094 (Fed. Cir. Sept. 5, 2025).

[5] Id. at 1380-82.

[6] Wyeth, 180 F.4th at 1374-75, 1377-82.

[7] Amendment and Response, U.S. Patent Application No. 11/883,474, at 2 (July 28, 2017); Amendment and Response, U.S. Patent Application No. 11/883,474, at 5-7 (Feb. 23, 2018); Office Action, U.S. Patent Application No. 11/883,474, at 6-9; Amendment and Response, U.S. Patent Application No. 11/883,474, at 2, 6-9 (Aug. 14, 2019).

[8] Idenix Pharmaceuticals LLC v. Gilead Sciences Inc. , 941 F.3d 1149, 1159 (Fed. Cir. 2019) (quoting Genentech Inc. v. Novo Nordisk A/S , 108 F.3d 1361, 1366 (Fed. Cir. 1997)).