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Enablement Risks for Method of Treatment Claims After Wyeth v. AstraZeneca

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On July 9, 2026, the US Court of Appeals for the Federal Circuit issued a precedential decision in *Wyeth LLC v. AstraZeneca Pharmaceuticals LP*, No. 2024-2325. The Federal Circuit affirmed the district court's holding that the asserted claims were invalid for lack of enablement and granting AstraZeneca judgment as a matter of law to set aside Wyeth's $107.5 million jury verdict. (Slip op. at 2, 19.)

Following the US Supreme Court's 2023 decision in *Amgen v. Sanofi*, the trend toward increased scrutiny for enablement for life sciences patents has continued. The *Wyeth* decision has implications for patents claiming methods of treatment, which are frequently sought prior to the availability of clinical data.

The patents at issue

The Wyeth patents claimed methods of treating non-small cell lung cancer (NSCLC) that has become resistant to standard drug therapies, using a class of drugs called irreversible epidermal growth factor receptor (EGFR) inhibitors. (Slip op. at 2-3.)

The specification described three candidate drugs and provided experimental cell assay data (not in patients) showing that these compounds could kill cancer cells (the "in vitro" testing). (Slip op. at 3-4). The specification also listed broad daily dose ranges of approximately 1 to 1,000 mg. However, the patents taught that "[p]recise amounts of active ingredient … depend on the judgment of the practitioner and are peculiar to each individual" but contained no examples of any of these drugs administered to human patients. (Id. at 4.)

Claim construction: 'Unit dosage' requires more than in vitro activity

An exemplary claim recited a method "comprising administering daily to the patient ... a pharmaceutical composition comprising a unit dosage" of the claimed drug. (Slip op. at 3 (quoting '314 patent 35:52-60).)

Before trial, the district court construed the term "unit dosage" according to the specification's own express definition as "physically discrete units suitable as unitary dosage for the subject, each unit containing a predetermined quantity of active material **calculated to produce the desired therapeutic effect** in association with the required diluents; i.e., carrier, or vehicle." (Slip op. at 5, citing *Claim Construction* Decision, 2023 WL 2683559, at *9 (emphasis added).) At the judgment as a matter of law (JMOL) stage, the district court explained the practical consequence of that construction in the context of the full claim was the requirement for an actual repeatable dosing regimen capable of producing a therapeutic effect in a human patient, not merely a compound shown to kill cancer cells in a laboratory setting. In other words, based on the claim language as construed by the court, the claimed dosage must work in a person, not just in the laboratory. (Id. at 6.)

Wyeth argued on appeal that the district court improperly imported clinical safety and efficacy requirements into the claims, contending the claims required nothing more than inhibiting EGFR activity and killing cancer cells in vitro. (Slip op. at 9.) The Federal Circuit disagreed because the claims, as construed, required the daily administration of a dosage "calculated to produce the desired therapeutic effect." (Id. at 10-11.) This construction drew in patient-level efficacy as a required part of the claim. (Id.) According to the Federal Circuit, however, this does not mean Wyeth's specification needed to demonstrate US Food and Drug Administration-approved safety or clinical optimality. Instead, the claim as construed required only that the claimed dosage be capable of producing a therapeutic effect when administered to a patient. (Id.)

The Federal Circuit also rejected Wyeth's argument that the district court had amended its claim construction post-verdict, finding that the district court's statements in its JMOL order were permissible clarifications of its original pre-trial construction. (Slip op. at 12.)

Enablement: The specification's in vitro data could not bridge the gap to patient dosing

The Federal Circuit identified several interconnected failures in the disclosure of Wyeth's specification:

- **No working patient examples.** The specification provided no examples of any irreversible EGFR inhibitor being given to a human patient at a dose that worked. (Slip op. at 14.) The three candidate drugs described in the patents were tested only in in vitro experiments on cancer cells, and the specification gave no guidance on how to convert those lab results into a dose that could safely and effectively be given to a real patient. (Id.)
- **Broad, unvalidated dose ranges.** The dose ranges disclosed in the specification – a per-body-weight range of approximately 0.5 to 1,000 mg/kg, and a total daily dosage range of 1 to 1,000 mg (preferably 2 to 500 mg), which the specification described as "general" and "projected" – came with no explanation of how those numbers were arrived at, how a skilled artisan would select among them for a given compound, or how they related to the claimed unit dosage calculated to produce a therapeutic effect in a (Slip op. at 15.)
- **Lab doses were toxic in humans.** Testimony from Wyeth's own experts and the inventors confirmed AstraZeneca's unrebutted evidence that the doses at which at least two of the three described drugs (HKI-272 and EKB-569) appeared to work in the lab exceeded the maximum dose a human patient could safely tolerate. (Slip op. at 15-16.) In other words, the "effective" in vitro dose indicated by the disclosure would translate to a dose that would be dangerous in a person. For example, one of the inventors confirmed that "[t]he concentrations in the test tube are higher than those you can give to patients." (Id. at 16.) The court acknowledged that the mere presence of nonworking examples in the specification will not always defeat a patent, citing *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984). (Id. at 16.) Here, however, the nonfunctionality of several of the drug dosages described in the specification played a direct evidentiary role, especially in the absence of any affirmative examples of doses that did work in human patients. The Federal Circuit concluded that the disclosed doses could not serve as a starting point for patient treatment across the claimed category. (Id.)
- **Specification acknowledges its own gaps.** Rather than providing a methodology for calculating a unit dosage, the specification stated that "[t]he skilled artisan is aware of the effective dose for each patient" and precise amounts "depend on the judgment of the practitioner and are peculiar to each individual." (Slip op. at 17.) The Federal Circuit held that relying on skilled artisan knowledge cannot substitute for the obligation to supply the novel aspects of the claimed invention in the specification. (Id.)

The Federal Circuit emphasized that, in a complex and unpredictable field, the specification must provide greater guidance. (Slip op. at 17.) Because the specification identified only a starting point for further research, leaving the skilled artisan to conduct an iterative, trial-and-error process to identify operative dosing regimens, practicing the claims would require undue experimentation, and therefore the claims were not enabled. (Id. at 17-18.)

Importantly for life sciences innovators, the Federal Circuit acknowledged the generally accepted practice of claiming a method of treatment with a range of doses without providing clinical data from large human trials. (Slip op. at 19.) But it distinguished this general trend from Wyeth's patents based on the specific facts relevant to those patents. For the court, the problem was not the absence of clinical data per se, but instead the specification's failure to disclose any actual dosages suitable for patient administration, combined with unrebutted evidence that at least two of the three disclosed compounds could not be administered to patients because all therapeutically effective dosage levels across the disclosed ranges would exceed the maximum tolerated dose in humans. (Id. at 15-16, 19.)

The outcome in Wyeth provides a noteworthy contrast to the Federal Circuit's recent opinion in *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, No. 24-1094 (Fed. Cir. Apr. 16, 2026), which also concerned method claims in which a class of compounds were defined by their function – a class of humanized antibodies (humanized anti-CGRP antagonist antibodies) to treat headache. Unlike the Wyeth case, in *Teva* the Federal Circuit held that the claimed antibody class was well known in the prior art, the specification disclosed that all antibodies would work for the claimed purpose (which was unrebutted at trial), and the point of novelty

was not the compounds themselves but the application of those compounds to treating headache. (*Teva Pharms.*, No. 24-1094, at 13, 22–23.)

The different outcome in *Wyeth* seems to have turned on the inventive concept captured by the claims and the state of the specification: The claims at issue in *Teva* were directed to a novel therapeutic use (treating headache) with a known class of compounds, and the specification directly addressed the novel aspect of the invention (the therapeutic use). In contrast, the claims at issue in *Wyeth* were directed to a dosing regimen, and the specification left the novel and critical element (a dosing regimen capable of producing a therapeutic effect in a patient) insufficiently addressed, with most of the disclosed compounds proving inoperative at some of the very doses the patents claimed.

Practical implications

For a variety of reasons, life sciences companies need to file patent applications covering methods of treatment before clinical data is available, including publications on clinical trial registries, scientific presentations and fundraising. Companies in this situation should consider two practical points following *Wyeth*:

1. **Be aware of how claim language and the specification can introduce unintended functional limitations.** In *Wyeth*, claim scope created an unexpected enablement problem through the construction of a single term. The term "unit dosage" appeared in every asserted claim, and the district court's construction – uncontested on appeal – required "a therapeutic effect." (Slip op. at 5, 10.)
2. **Avoid unnecessary language about uncertainty in the specification.** In *Wyeth*, the specification's own statements ("[p]recise amounts of active ingredient … depend on the judgment of the practitioner and are peculiar to each individual" and "[t]he skilled artisan is aware of the effective dose for each patient") were used by the court as evidence that determining the claimed unit dosage was a complex and individualized task that the specification failed to address. (Slip op. at 17.) Patent drafters should consider avoiding unnecessary language overemphasizing dosing unpredictability or patient-by-patient variability because it can become evidence against enablement when broad method claims are later asserted.

However, life sciences companies should also exercise caution in attempting to enable method-of-treatment applications with speculative and excessive disclosure around doses and dosing regimens. The safe and effective dosing regimen for a particular drug and indication will be discovered in clinical trials, which may occur several years after initial in vitro data. Filing applications for dosing claims contemporaneously with such clinical results can lead to additional – and often more defensible – patents with later expiration dates, potentially adding valuable exclusivity to the commercial product.

Conclusion

Wyeth v. AstraZeneca reinforces the principle the Supreme Court established in *Amgen v. Sanofi*: Where a claim limitation requires dosage form and/or patient-level efficacy, the specification must provide the guidance necessary to achieve that outcome across the full scope of the claimed compounds. In vitro data, broad projected dose ranges and reliance on skilled artisan knowledge may not suffice.

Key Contacts

Dr. Daniel Knauss Palo Alto	dknauss@cooley.com +1 650 843 5287
Dr. Jon Cousin Washington, DC	jcousin@cooley.com +1 202 728 7079
John P. Rearick Boston	jrearick@cooley.com +1 617 937 2305