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Federal Circuit Finds Method-of-Treatment Claims Including In Vivo Dosing Limitations Are Not Enabled By In Vitro Data

In *Wyeth LLC v. AstraZeneca Pharmaceuticals LP*, the Federal Circuit affirmed judgment as a matter of law that Wyeth's method-of-treatment claims were invalid for lack of enablement, wiping out a $107.5 million jury verdict over AstraZeneca's Tagrisso®. The ruling arrives three months after the same court, in *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, reversed the same kind of judgment in a mirror-image case. Read together, the two decisions illuminate the requirements for an enabling disclosure of method-of-treatment claims.

Key Takeaways

- **The claims' recitation of in vivo dosing limitations set the enablement burden.** The claims required "administering daily to the patient" a "unit dosage," a term the specification itself defined as a quantity "calculated to produce the desired therapeutic effect." That language obliged the disclosure to teach a real in-human dose.
- **In vitro data cannot enable a claim that requires dosing a patient.** Wyeth claimed a genus of irreversible epidermal growth factor receptor (EGFR) inhibitors, but the specification only described three species of the claimed genus, characterized only through in vitro experiments, and disclosed no working example of any unit dosage ever administered to a human.
- **Broadly disclosed dosing ranges may not be sufficient.** Disclosure of generalized dosing ranges was not sufficient for enablement where the specification never explained how they were derived, how a skilled artisan would select among them or how they related to the therapeutic effect the claims require.
- **Three months earlier, the Federal Circuit upheld a functionally-claimed treatment method in a mirror-image case.** In *Teva v. Lilly*, claims recited administering "an effective amount" of a humanized anti-CGRP antagonist antibody to treat headaches. The Federal Circuit reversed judgment as a matter of law of invalidity for lack of enablement, though the specification disclosed only one such antibody. The distinction between the decisions relates to the inquiry posed by the respective claims to a POSA: Teva's specification had answered the question posed by the claims, while Wyeth's had not.

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What Happened

Wyeth's U.S. Patent Nos. 10,603,314 and 10,596,162 claimed methods of treating "gefitinib and/or erlotinib resistant" non-small cell lung cancer (NSCLC) with irreversible inhibitors of the epidermal growth factor receptor. Exemplary claim 1 of the '314 patent recited "[a] method for treating gefitinib and/or erlotinib resistant non-small cell lung cancer in a patient in need thereof, comprising *administering daily to the patient* . . . a pharmaceutical composition comprising a *unit dosage* of an irreversible epidermal growth factor receptor (EGFR) inhibitor that covalently binds to cysteine 773 residue in the ligand-binding pocket of EGFR or cysteine 805 residue in the ligand-binding pocket of erb-B2."

In 2021, Wyeth sued in the District of Delaware, alleging that AstraZeneca induced infringement through the marketing, distribution, and sale of Tagrisso® (osimertinib, NDA 208065). After a five-day trial, the jury found the asserted claims not invalid, found induced infringement, and awarded Wyeth $107.5 million in damages. AstraZeneca renewed its motion for judgment as a matter of law, and Judge Matthew F. Kennelly granted it, holding the asserted claims invalid for failure to meet the enablement requirement of 35 U.S.C. § 112(a). The Federal Circuit affirmed.

Wyeth's Dosing Limitations Set the Bar for Enablement

Wyeth's lead argument was focused on claim construction: that the district court improperly imported clinical safety and efficacy requirements into claims that contained none. The Federal Circuit accepted the premise and rejected the conclusion, finding that while the claims do not require FDA-type clinical standards, Wyeth had also "fail[ed] to appreciate and give meaning to" certain dosing limitations — namely that the "unit dosage" must be "administer[ed] daily" to a "patient." The unchallenged pre-trial construction, drawn from the specification's own definition, made a "unit dosage" a "predetermined quantity of active material *calculated* to produce the desired *therapeutic effect*." Combining that definition with the recited daily administration to a patient, the court found that the claims "plainly require the daily administration of a unit dosage *to a patient* to achieve a therapeutic effect . . . not merely the identification of compounds capable of inhibiting EGFR activity *in vitro*." In essence, the Federal Circuit found that, due to these dosing limitations, the claims sit between two poles: they demand more than killing cancer cells in a dish, but less than a full FDA clinical showing.

With those claim construction determinations in mind, the Federal Circuit considered the enablement issues. The court explained that the specification must enable the full scope of these claims without undue experimentation, and, quoting *Amgen*, the court reiterated that "[t]he more one claims, the more one must enable." Notably, the court did not rely on or discuss the *Wands* factors for its enablement analysis, but focused on whether the specification provided guidance to allow a skilled artisan to practice the full scope of the claims without undue experimentation.

Here, the specification stated that the irreversible EGFR inhibitor "may be any compound" that binds to cysteine 773 of EGFR, but it identified only three exemplary compounds and relied on in vitro data showing increased killing of NSCLC cells harboring an EGFR mutation. The court found no working example of a daily unit dosage calculated to achieve therapeutic effect in a human patient. Although the specification provided information about the disclosed compounds' in vitro activity, it provided no basis for translating that into the claimed in vivo dosing regimen.

Finally, while the disclosure offered dose ranges, it hedged them as "general" and "projected," never explaining how they were derived, how a skilled artisan would select among them or how they related to the therapeutic effect the claims require. For these

reasons, the court found the disclosure inadequate to enable the recited dosing limitations.

The Counterpoint: Why *Teva's* Method-of-Treatment Claims Survived

Three months earlier, a different panel confronted a structurally similar case and came out the other way. In *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, Teva asserted its "headache patents," including U.S. Patent No. 8,586,045, against Lilly's Emgality®. Representative 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."

The procedural posture was a mirror image to Wyeth's. A jury found the claims willfully infringed and not proven invalid; the district court granted judgment as a matter of law of invalidity for, *inter alia*, lack of enablement. The Federal Circuit reversed and remanded.

On enablement, the court found that the claims required "only the use of such antibodies for the…limited purpose of treating headache." Because the specification taught that *all* of the recited genus of antibodies treat headache, the court found that JMOL of no enablement was improper.

Reading *Wyeth* and *Teva* Together

The two cases are close cousins. Both review judgment as a matter of law related to enablement method-of-treatment claims built on a functionally defined class of active agents — and they reach opposite results.

Initially, the different outcomes appear to hinge on the presence of specific dosing limitations, with the claims in *Wyeth* reciting a "unit dosage" and its daily administration to a patient to achieve a therapeutic effect. In contrast, the decision in *Teva* did not focus on dosing limitations and instead characterized the claims as simply being directed to the use of certain antibodies for treating headaches. But the two claim sets were not so different as this treatment might suggest. Both claim sets required administration to a person (i.e., "to a patient" in *Wyeth*, and "to a human" in *Teva*). Both claim sets also required an amount effective for the claimed treatment. In *Wyeth*, "unit dosage" meant a predetermined quantity "calculated to produce *the desired therapeutic effect*," and in *Teva*, the representative claim expressly recited an "*effective amount*."

The more distinct contrast is in how the two specifications characterized the subject matter of the claims. In *Wyeth*, the specification made dosing (and determination of effective amounts) look individualized and complex. The court emphasized the disclosure that determining the claimed unit dosage depended on the patient, the patient's capacity to use the active ingredient, the desired therapeutic effect, the compound used, route of administration and disease severity, and that "[p]recise amounts" were "peculiar to each individual." Against that record, the court concluded that the specification "itself demonstrates" that determining the claimed unit dosage was "a complex and highly individualized task," while failing to provide the guidance needed to perform that task without undue experimentation.

In *Teva*, the specification presented the opposite story. In that case, the court found the relevant question posed by the claims was which humanized anti-CGRP antagonist antibodies treat headaches — and "[t]hat assignment was completed; the specification disclosed that all such antibodies work for that purpose."

Why It Matters

For companies building life sciences portfolios, *Wyeth* and *Teva* together suggest that a claim set directed to a therapeutic concept and a claim set directed to a dosing regimen, may require different supporting disclosures. *Wyeth* makes clear that claims reciting dosing limitations (e.g., daily administration, a unit dosage, a particular patient population) should be drafted with support that goes beyond disclosing target activity and broad dose ranges to supply a clear bridge from mechanism or in vitro activity to patient administration. Disclosure emphasizing complexity or difficulty should also be treated with caution. While this type of disclosure can support a patentability story based on nonobviousness, it may have negative effects on 112 validity.

For challengers, *Wyeth* opens up enablement challenges where the asserted method claim requires a particular dose, schedule, unit dosage, formulation or patient subgroup. If the specification lacks corresponding or linking disclosure, there may be a route to invalidity for lack of enablement under *Wyeth*.

For more information, contact the alert authors or your preferred Polsinelli attorney.

1. *Wyeth LLC v. AstraZeneca Pharmaceuticals LP*, No. 2024-2325, slip op. (Fed. Cir. July 9, 2026) (precedential) (Lourie, J., joined by Linn and Hughes, JJ.) (affirming grant of judgment as a matter of law of invalidity), *appeal from* No. 1:21-cv-01338-MFK (D. Del.) (Kennelly, J.).
2. *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, No. 2024-1094, slip op. (Fed. Cir. Apr. 16, 2026) (precedential) (Prost, J., joined by Cunningham, J., and Andrews, District Judge, sitting by designation) (reversing and remanding), *appeal from* No. 1:18-cv-12029-ADB (D. Mass.) (Burroughs, J.).