Insights: Alerts

Federal Circuit Invalidated "Unit Dosage" Treatment Claims for Lack of Enablement

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On July 9, 2026, the U.S. Court of Appeals for the Federal Circuit affirmed a District of Delaware decision granting judgment as a matter of law (JMOL) in *Wyeth LLC v. AstraZeneca Pharmaceuticals LP*, __ F.4th __, 2026 WL 1981095 (Fed. Cir. 2026). The decision invalidates asserted claims in Wyeth's U.S. Patent Nos. 10,603,314 and 10,596,162 for failure to satisfy the enablement requirement.

Although a jury had previously awarded Wyeth §107.5M in induced infringement damages, the Federal Circuit held that Wyeth's patents failed to enable the claimed methods of treating gefitinib and/or erlotinib resistant non-small cell lung cancer ("NSCLC"). The Court's decision highlights the legal challenges of claiming in vivo human treatment methods where the corresponding disclosure relies on un-optimized in vitro data and where certain preferred embodiments are shown to be toxic at the specified dosage ranges.

The Disputed Claims

The technology at issue relates to methods of treating gefitinib and/or erlotinib (g/e) resistant non-small cell lung cancer (NSCLC) using "irreversible" EGFR inhibitors. Wyeth sued AstraZeneca, alleging that AstraZeneca induced infringement of its patents through the sale of the drug Tagrisso (osimertinib).

Claim 1 of the '314 patent is exemplary, reciting:

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....*

The district court construed "unit dosage" using the specification's own definition: "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...".[1]

The Court's Enablement Reasoning

1. The Mismatch Between In Vitro Data and In Vivo Claims

The Federal Circuit's enablement analysis focused on what it characterized as a mismatch between the scope of the claims and the guidance in the specification. While Wyeth's claims require daily administration of a unit dosage to a human patient to treat cancer (gefitinib and/or erlotinib (g/e) resistant NSCLC), the Court determined that the specification only provided disclosure sufficient for killing cancer cells in a test tube.[2]

Wyeth's specification described three compounds—EKB-569, HKI-357, and HKI-272. However, the data presented in the patents was limited strictly to in vitro cell line experimentation.

Citing its precedent in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1217 (Fed. Cir. 1991), the Federal Circuit reiterated that: “The district court erred in accepting the in vitro data as support for claims containing what has been found to be an in vivo limitation.”[3]

Because the claims specifically required administering a daily "unit dosage" to a patient to achieve a therapeutic effect, the Court concluded that the patent was required to provide the skilled artisan with a reliable method of translating in vitro data into safe and therapeutic in vivo clinical dosing. The specification offered no such guidance.

2. Shifting the Burden to the Skilled Artisan

In the Court's view, the specification attempted to bypass the lack of dosing guidance by stating: "The skilled artisan is aware of the effective dose for each patient." See the ‘162 patent. Col. 8, ll. 60-62. The Federal Circuit rejected this approach, holding that the specification itself must provide the essential teaching for the novel aspects of the invention rather than relying entirely on the background knowledge of the art. Citing *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1159 (Fed. Cir. 2019), the Court stated:

“It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.”[4]

By leaving the calculation of the therapeutic "unit dosage" entirely to the practitioner, the Court held that Wyeth's patents improperly forced the skilled artisan to perform the foundational research the patent itself should have provided.[5]

3. Toxic Preferred Embodiments and Inoperable Ranges

The Court considered the specification's generic "projected" daily dosage ranges—such as 1 to 1000 mg, 2 to 500 mg, and 0.5 to 1000 mg/kg of body weight—without critical teachings necessary to validate that projection, is insufficient to enable the claimed invention.

According to the Court's opinion, AstraZeneca presented uncontroverted trial testimony, confirmed by Wyeth's own co-inventor (Dr. Haber) and experts, showing that for at least two of the three preferred compounds (HKI-272 and EKB-569), any dosage within the disclosed ranges required to achieve a therapeutic effect would far exceed the Maximum Tolerated Dose (MTD) in humans. Dr. Haber admitted that the therapeutic concentrations

demonstrated in the test tube were "five times higher" than what could safely be administered to human patients without severe toxicity.[6]

While the court noted that the disclosure of some inoperative embodiments is not automatically fatal (citing Atlas Powder), the high proportion of toxic, inoperable combinations across the preferred embodiments forced the skilled artisan to conduct "undue experimentation" to find a safe, effective dose.[7]

4. The "Starting Point" Trap in Unpredictable Fields

Because the biological mechanisms of second-generation irreversible inhibitors are complex and highly unpredictable, the Federal Circuit concluded that Wyeth's patents provided only a starting point, a direction for future research that placed the burden on a skilled artisan to conduct an iterative trial and error approach to practice the claimed invention.

The Court held that because the specification provided no mechanism or screening guidelines to help the artisan reliably determine which compounds and doses were actually operable within the broad class, the disclosure failed to enable the full scope of the claimed methods.[8]

Impact On Patent Law & Clinical Method Claims

The Federal Circuit took care to distinguish *Wyeth* from cases where clinical trial data is not required to patent a treatment method (e.g., *United Therapeutics Corp. v. Liquidia Technologies, Inc.*).[9] The court recognized that a patentee may claim a therapeutic method and leave safety/efficacy testing to the FDA. However, if a patentee chooses to limit their claims to human dosage forms and patient administration, they cannot simply disclose a broad, uncalibrated range of doses—some of which are toxic— and rely exclusively on in vitro data, leaving the practitioner to do the trial-and-error work of discovering a safe, therapeutic window.

Footnotes

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[1] The ‘314 patent, col. 9 ll. 33-38.

[2] Wyeth LLC v. AstraZeneca Pharmaceuticals LP, __ F.4th __, 2026 WL 1981095, at *5,*7 (Fed. Cir. 2026).

[3] Id. at. *1, *7.

[4] Id. at *6.

[5] Id. at *7.

[6] Id.

[7] Id.

[8] Id. at *8.

[9] United Therapeutics Corp. v. Liquidia Techs., Inc., 74 F.4th 1360, 1369 (Fed. Cir. 2023), cert. denied, —– U.S. ——–,144 S. Ct. 873, 218 L.Ed.2d 59 (2024)

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