WYETH LLC v. ASTRAZENECA PHARMACEUTICALS LP, Appeal No. 2024-2325 (Fed. Cir. July 9, 2026). Before Lourie, Linn, and Hughes. Appealed from D. Del. (Judge Kennelly).

Background:

Both Wyeth and AstraZeneca (hereinafter "AZ") developed inhibitors for treating drug-resistant lung cancer. Wyeth holds two patents, both related to methods of using irreversible EGFR inhibitors to treat "gefitinib and/or erlotinib resistant" non-small cell lung cancer, wherein the methods comprise administering to a patient "a pharmaceutical composition comprising a unit dosage of [an irreversible EGFR inhibitor]". AZ manufactures the irreversible EGFR inhibitor Tagrisso (osimertinib). Wyeth sued AZ, alleging that the use of Tagrisso infringed upon both method patents.

The district court construed the term "unit dosage" as "[…] units suitable as unitary dosage for the subject, each unit containing a predetermined quantity of active material calculated to produce the desired therapeutic effect […]." AZ asserted that it was entitled to summary judgement because "the patents claim but do not enable treatment via a 'unit dosage' […]", as determining the "unit dosage" for even a single compound is unpredictable and involves excessive experimentation.

After Wyeth concluded its presentation of evidence, AZ moved for judgment as a matter of law, which was denied. The jury found that the asserted claims were not invalid and that AZ induced infringement of the asserted claims. AZ subsequently renewed its JMOL motion. The district court granted JMOL of invalidity for lack of enablement, determining that no reasonable jury could have found the asserted claims not invalid. Wyeth appealed.

Issues/Holdings:

(1) Was the district court's JMOL unsupported due to (a) incorrect construction of the term "unit dosage", or (b) changing its construction of "unit dosage" post-verdict? No, affirmed.
(2) Did the district court err in construing the term "unit dosage" by improperly importing clinical safety and efficacy requirements into the claims? No, affirmed.

Discussion:

Wyeth argued that because the claims do not include clinical-trial endpoints, grant of JMOL based on unclaimed clinical safety or efficacy standards is improper. The Federal Circuit disagreed, noting that the term "unit dosage" was defined in the specification in such a way that the claims clearly require daily administration of a unit dosage to a patient to achieve a therapeutic effect. The Federal Circuit held that the claims clearly require more than merely killing cancer cells or identification of compounds capable of inhibiting EGFR *in vitro*. The Federal Circuit further held that both before and after trial, the district court construed the claims to require daily administration of a "unit dosage" "to produce the desired therapeutic effect" in a patient.

Wyeth argued that a reasonable jury could have concluded that AZ failed to prove that the asserted claims require undue experimentation to determine a non-toxic or non-fatal unit dosage for daily administration to a patient. The Federal Circuit disagreed, noting that Wyeth's patents fail to disclose any basis for translating the exemplified *in vitro* activity into the claimed dosing regimen in a patient, leaving determination of the claimed "unit dosage" entirely to the knowledge of the skilled artisan.