Fed. Circ. In July: Meeting The Enablement Requirement

By **Jeremiah Helm and Sean Murray** (August 28, 2026)

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*This article is part of a **monthly column** that highlights an important recent patent appeal. In this installment, we examine the Federal Circuit's ruling in Wyeth LLC v. AstraZeneca Pharmaceuticals LP.*

The U.S. Court of Appeals for the Federal Circuit has, in recent months, issued several opinions emphasizing the role that a patent's disclosure plays in defining the appropriate scope of the claims. Many of these decisions have come in the context of the written-description requirement of Title 35 of the U.S. Code, Section 112(a), which requires that the patent's disclosure demonstrate the inventors possessed the idea of the claimed invention.

But Section 112(a) also includes the requirement that a patent's disclosure must enable a person of ordinary skill in the art to make and use the claimed invention without undue experimentation. This enablement requirement differs from the written description requirement in several ways, including its emphasis on providing sufficient detail so that others can take advantage of the invention described in the patent.

The Federal Circuit's July 9 **decision** in Wyeth LLC v. AstraZeneca Pharmaceuticals LP is an example of where the inventor's generalized conception of an invention did not enable the full scope of the asserted claims. The enablement requirement turns on the ability of a person of ordinary skill in the art to make and use the claimed invention, based on the disclosure.

Thus, the claim scope, the patent's specification and the knowledge of a skilled artisan will each influence the enablement analysis. Indeed, in Wyeth, each of these three factors contributed to the ultimate conclusion that the claims were invalid for failure to satisfy the enablement requirement.

In Wyeth, the patents at issue were directed to methods of treatment of cancer, in particular non-small cell lung cancer. One target for treatment was the epidermal growth factor receptor, or EGFR.

The asserted claims recited methods for treating certain non-small cell lung cancers by

administering, daily, a unit dosage of an irreversible inhibitor of EGFRs that binds to one of two potential amino acid sites on EGFRs. The claims thus identified how the inhibition would occur, by irreversibly binding at one of two specifically identified cysteine residues, but provided little additional detail.

The claims' generality does not necessarily mean there is an enablement problem, provided that the patent specification provides the missing details that a skilled artisan would have needed to make and use the claimed invention.

Unfortunately, at least for Wyeth, the patents' shared disclosure had few details about the unit dosage form. The patents disclosed only three example EGFR inhibitors and included only in vitro experiments, but no results from administering unit dosage forms to patients.

Although the disclosure provided broad example dosage ranges for the irreversible inhibitors, it did not provide details for how to go from in vitro laboratory testing to in vivo dosing of a patient.

Indeed, at trial, Wyeth's experts testified that a patient must avoid toxic doses, but conceded that, for at least two of the three disclosed compounds, the example dosage ranges exceeded the maximum tolerated dose in patients.

The broad functional claim language and lack of disclosure of in vivo therapeutic results proved to be the patents' undoing. The Federal Circuit emphasized that the method required administering daily, to a patient, a unit dosage of an irreversible EGFR inhibitor. As a result, merely identifying compounds with in vitro activity was insufficient because the patent failed to detail how to determine a unit dosage to be administered to patients.

The court explained that what was required, but missing, in the specification was a way to translate the disclosed in vitro result to the claimed in vivo daily dosing regimen. Although the patents disclosed three example compounds, they did not provide any working examples of a unit dosage that was both (1) calculated to achieve a therapeutic effect, and (2) suitable for daily administration to a human.

A skilled artisan's knowledge can sometimes bridge the gap between the disclosure and the claimed invention. But that was not the case here because the specification provided no guidance and, instead, required undue experimentation from the skilled artisan to figure out what claimed unit dosages would work in the claimed method.

The Federal Circuit illustrated this problem by pointing out that for at least two of the three example compounds, the broad example dosage ranges in the patents far exceeded the maximum tolerated dose in humans. Such inoperative embodiments, the court explained, weigh heavily in favor of nonenablement.

Finally, the Federal Circuit noted that the patents' disclosure emphasized the complexity and unpredictability of dosing. In particular, the court cited the patent's explanation that dosing depended on the subject treated, the capacity of the subject's system to use the active ingredient and the desired therapeutic effect. As such, according to the patent, the amount of drug administered depends on the practitioner's judgment and is "peculiar to each individual." That uncertainty further undermined the claims' enablement.

Wyeth is important because, as the Federal Circuit recognized, many pharmaceutical patents claim a method of treatment without including clinical data in the patent's disclosure.

Where there is close prior art, patentees typically emphasize the unpredictability in dosing and distinguish the prior art by pointing to the claimed method's use in human patients, just as the patents did in Wyeth. Such arguments are often successful in establishing that the claimed methods are nonobvious over the prior art.

But there is a tension between obviousness and enablement positions. A nonobviousness argument that downplays a skilled artisan's ability to move from what was known to what has been invented naturally conflicts with a pro-enablement argument that relies on the ability of a skilled artisan to use routine experimentation to implement a claimed invention based on a cursory disclosure.

Wyeth recognizes that tension, particularly in a field that is admittedly unpredictable.

Wyeth is likely to lead to more enablement challenges. But Wyeth may also cause patentees to carefully weigh their own patent's disclosure when devising nonobviousness positions, particularly whether to emphasize unpredictability and downplay a skilled artisan's ability to experiment.

Ultimately, Wyeth sets out a series of factual issues — close prior art, disclosure of broad dosage ranges that include toxic amounts, no actual dosages within the scope of the claims disclosed — that suggest practicing claims to in vivo methods of treatment may require undue experimentation and thus might not be enabled.

Moving forward, it will be interesting to see how litigants, especially in the pharmaceutical space, attempt to apply or distinguish Wyeth in their own enablement disputes.

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