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insights

TYPES NOT MAPPED YET January 10, 2024 | TTR not mapped yet | William A. Holtz Ph.D.

USPTO Says Wands is Still the Test Post-Amgen

The United States Patent and Trademark Office issued a notice in the Federal Register on January 10, 2024, providing guidelines to assist USPTO personnel in assessing enablement under 35 U.S.C. 112(a), in view of and consistent with the Supreme Court decision in *Amgen Inc. et al.* v. *Sanofi et al.,* 143 S. Ct. 1243 (2023) and post-*Amgen* Federal Circuit precedent.

In *Amgen,* the Supreme Court held that claims drawn to a genus of functionally claimed monoclonal antibodies were invalid due to a lack of enablement. While the Supreme Court emphasized the trial-and-error nature of experimentation that would be required to practice the invention in the absence of additional guidance, such as common structural characteristics, it maintained a patent specification may still require a reasonable amount of experimentation to make and use the invention. What is reasonable, it stated, will depend on the nature of the invention and the underlying art.

Patent practitioners will recognize that a "reasonable amount" or "reasonable degree" of experimentation is not the same wording as "undue experimentation" under the *Wands* factors (from *In re Wands,* 858 F.2d 731, 737 (Fed. Cir. 1988)) they are used to applying. The Supreme Court in *Amgen* did not address the *Wands* factors. The USPTO notice refers to the post-*Amgen* Federal Circuit holding in *Baxalta Inc. et al.* v. *Genentech Inc.,* 2023 U.S. App. LEXIS 24863 (Fed. Cir. 2023), in which the Federal Circuit stated, "[w]e do not interpret *Amgen* to have disturbed our prior enablement case law, including *Wands* and its factors," and "[w]e see no meaningful difference between *Wands'* `undue experimentation' and *Amgen's* `[un]reasonable experimentation' standards."

In its conclusion, the USPTO provides guidance that: "The *Wands* analysis should provide adequate explanation and reasoning for a lack of enablement finding in order to facilitate the USPTO's clarity of the record goals, as well as the USPTO's goals of providing consistency between examination and post-grant challenges."

Consistent with Amgen and the Federal Circuit's post- Amgen decisions of Baxalta, Medytox, and Starrett, when assessing whether the claims in a utility patent application or patent are enabled, regardless of the technology, USPTO personnel will continue to use the Wands factors to ascertain whether the experimentation required to enable the full scope of the claimed invention is reasonable.

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