Parsing The USPTO's Guidelines For Assessing Enablement

By **Ryan Hagglund** (January 24, 2024)

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The U.S. Patent and Trademark Office recently published the Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al. for ascertaining compliance with the enablement requirement of Title 35 of the U.S. Code, Section 112.

Published in the Federal Register on Jan. 10, the guidelines require that a patent specification enable a person of ordinary skill in the art to make and use the invention in light of the U.S. Supreme Court's 2023 decision in Amgen Inc. v. Sanofi.

In Amgen, the Supreme Court affirmed the U.S. Court of Appeals for the Federal Circuit's holding that claims directed to a genus of monoclonal antibodies that bind to specific amino acid residues on the PCSK9 protein and block the binding of PCSK9 to the LDLR receptor protein — i.e., a genus defined by function.

The court explained that the specification must enable the full scope of the claimed invention, but can call for a reasonable amount of experimentation.

Thus, the court found that the specification at issue, which disclosed sequences for 26 antibodies and three-dimensional structures for two of them, did not meet this standard with respect to the broad claims to a functionally defined genus.

Prior to Amgen, the Federal Circuit prescribed that enablement was to be assessed using a framework set forth in its 1988 decision In re: Wands. This analysis required the consideration of factors set forth in Wands, referred to as the Wands factors, in determining whether the specification allowed an invention to be made and used without undue experimentation.

While the Supreme Court did not expressly mention Wands or the Wands factor in Amgen, the guidelines point to several cases after Amgen in which the Federal Circuit applied or at least discussed the Wands factors in assessing enablement in its 2023 decisions in Baxalta Inc. v. Genentech Inc., Medytox Inc. v. Galderma SA and In re: Starrett.

Based on these cases, the guidelines explain that the Wands factors are probative of the essential inquiry in determining whether one must engage in more than a reasonable amount of experimentation under Amgen.

The USPTO explained that in Baxalta, the Federal Circuit found that it "d[id] not interpret Amgen 'to have disturbed [its] prior enablement case law, including Wands and its factors.'"

Accordingly, the guidelines confirm that after Amgen, the USPTO will continue to apply the Wands factors previously used by the Federal Circuit in assessing enablement.

In addition, the guidelines prescribe that there is no reason to treat the Amgen decision as limited to antibodies or biotechnology, and that the principles set forth in this decision regarding the enablement requirement apply to all fields of technology.

The USPTO's rationale is that the Supreme Court relied on precedent from a wide variety of technologies in Amgen.

Perhaps unsurprisingly given the Federal Circuit's findings concerning the continued vitality of the Wands factors after Amgen, the guidelines provide that the USPTO will continue to apply the Wands factors regardless of the technology at issue.

In Amgen, the Supreme Court explained that while a specification must enable the full scope of the invention, it may call for a reasonable amount of experimentation to make and use the claimed invention.

The guidelines also note that in Baxalta, the Federal Circuit found that there was no meaningful difference between the Federal Circuit's prior formulation of the standard as requiring the specification to enable the full scope of an invention without undue experimentation set forth in Wands and the reasonable-experimentation standard set forth by the Supreme Court in Amgen.

Given that the standard for the degree of experimentation that comports with enablement remains unchanged, the guidelines make clear that Federal Circuit precedent applying the Wands factors prior to Amgen is still informative as to how the Wands factors should be analyzed in different situations.

While the guidelines clearly provide for the continued vitality of the analysis and factors set forth in Wands, they provide little in terms of concrete guidance as to the application of the Wands factors and determination of whether more than a reasonable amount of experimentation would be required to make and use the full scope of the invention.

Rather, the guidelines focus on summarizing the reasoning in the Federal Circuit and Supreme Court decisions in Amgen, as well as the Federal Circuit cases applying Amgen discussed above.

The guidelines do recite several principles articulated by the Supreme Court in Amgen.

For instance, the guidelines explain that if a patent claims an entire class of processes, machines, manufactures or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class and quote the general principle that "[t]he more one claims, the more one must enable."

The guidelines also point to the Supreme Court's statement in Amgen that what is reasonable in terms of the degree of experimentation required will depend on the nature of the invention and the underlying art.

For example, disclosure of one example or a few examples may suffice if the specification also discloses some general quality running through the class that gives it a peculiar fitness for the particular purpose, and disclosing that general quality may reliably enable a person skilled in the art to make and use all of what is claimed, not merely a subset.

In addition, the guidelines state that in determining whether experimentation is reasonable, it is instructive to look at the Federal Circuit's 2021 decision in Amgen, which the Supreme Court affirmed, and the above-referenced post-Amgen Federal Circuit enablement decisions.

The guidelines explain that the Federal Circuit in Amgen weighed the Wands factors and found that the scope of the claims was far broader in functional diversity than the disclosed

examples, that the invention was in an unpredictable field of science with respect to satisfying the full scope of the functional limitations, and that there was not adequate guidance in the specification.

In finding a lack of enablement, the court relied on the evidence that showed that the scope of the claims encompassed millions of antibodies and that it was necessary to first generate and then screen each candidate to determine whether it met the functional limitations.

The guidelines explain that in Baxalta, the Federal Circuit found a situation where functional generic claims potentially encompassed millions of antibodies and the patent only disclosed 11 antibodies along with a method of producing and screening antibodies to determine whether they met the claimed functional limitations to be materially indistinguishable from Amgen.

Indeed, the USPTO pointed to the Federal Circuit's conclusion that the specification ''simply directs skilled artisans to engage in the same iterative, trial-and-error process the inventors followed to discover the eleven antibodies they elected to disclose'' and that "under Amgen, such random trial-and-error discovery, without more, constitutes unreasonable experimentation."

As noted in the guidelines, in Medytox, the Federal Circuit found claims invalid directed to a method of using an animal protein-free botulinum toxin formulation that exhibited a longer-lasting effect in the patient than an animal protein containing botulinum toxin composition and a responder rate limitation of 50% to 100%.

The Federal Circuit determined that there was no error in the finding that the specification would not have enabled a responder rate greater than 62% without undue experimentation and reasoned that the full scope of the claimed invention must be enabled.

The guidelines finally point to Starrett, in which the Federal Circuit affirmed a decision of lack of enablement of a claim to a computer-readable medium for maintaining augmented telepathic data for telepathic communication that contained 47 ''or'' clauses and potentially covered over 140 trillion embodiments.

The USPTO noted the court's reliance on Amgen for the proposition that the more one claims, the more one must enable, and finding that as in Amgen, much is claimed and little is enabled.

The guidelines dispel any residual doubt remaining after Baxalta that the USPTO would continue to apply the Wands factors and the framework set forth in earlier Federal Circuit cases after Amgen.

However, the guidelines offer little guidance as to how the Wands factors should be applied to novel sets of facts, as well as the line between reasonable and unreasonable levels of experimentation.

Thus, it remains to be seen how the USPTO will address the enablement outside of facts analogous to those of the cases discussed in the guidelines. In the past, the USPTO has often granted broad claims to genera defined by function in the biotechnology context, such as the generic antibody claims at issue in Amgen.

While the guidelines indicate that the Wands framework and factors still apply after Amgen, the guidelines make clear that under Amgen, the full scope of the claimed invention must be

enabled.

Thus, the guidelines stand for the proposition that broad functional genera relating to antibodies and the like are unlikely to meet the enablement requirement absent disclosure of some general quality running through the class that gives it a peculiar fitness for the particular purpose where such disclosure reliably enables a person skilled in the art to make and use all of what is claimed, not merely a subset.

In this respect, an examiner following the guidelines might apply the Wands factors in a more stringent manner than examiners ordinarily did prior to Amgen.

While the guidelines reaffirm the applicability of the Wands factors to all technology areas, based on the Federal Circuit opinion in Amgen, they indicate that an unpredictable field, such as biotechnology, weighs against enablement.

Thus, the guidelines do not resolve how the USPTO will apply the Wands factors outside of unpredictable fields.

Finally, the guidelines do not specifically address the role of Amgen in the assessment of enablement of structural — as opposed to functional — claims or the application of the Wands factors in this context.

The fact that the guidelines do not draw a distinction between structural and functional claims in terms of application of the Wands factors and the principles set forth in Amgen weighs in favor of applicability to structural as well as functional claims.

Nonetheless, it is not clear how the USPTO will address the enablement of structural generic claims after Amgen and apply its holding in this context.

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