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DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2023-0013]

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.*

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing guidelines for USPTO employees to use, regardless of the technology, for ascertaining compliance with the enablement requirement of the patent laws during the examination of utility patent applications and the review of utility patents in light of the recent U.S. Supreme Court decision in *Amgen Inc. et al. v. Sanofi et al*. These guidelines, which also inform the public of the USPTO's practices, provide that when considering whether claims in a utility patent application or patent are enabled, USPTO personnel will continue to use the *In re Wands* factors to ascertain whether the amount of experimentation required to enable the full scope of the claimed invention is reasonable. Publishing these guidelines will promote consistent analysis of the enablement requirement of the patent laws by USPTO employees and will result in clearer USPTO communications to applicants, patentees, and relevant third parties concerning any deficiencies in enablement compliance. These guidelines will also promote the consistent treatment of enablement, both by the patent examining corps in patent applications and reexamination proceedings and by the Patent Trial and Appeal Board (PTAB) in ex parte appeals and post-patent issuance proceedings.

DATES: These guidelines are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION: These guidelines are intended to inform USPTO personnel and the public on the USPTO's implementation of the Supreme Court decision in *Amgen Inc. et al. v. Sanofi et al.*, 143 S. Ct. 1243 (2023) (hereafter *Amgen*). These guidelines will assist USPTO personnel in assessing enablement under 35 U.S.C. 112(a) and, where a lack of enablement has been found, they will assist in providing appropriate supporting rationale in view of the *Amgen* decision. These guidelines are based on the USPTO's current understanding of the law, and are believed to be fully consistent with the binding precedent of the Federal Circuit and the Supreme Court.

These guidelines do not constitute substantive rulemaking and therefore do not have the force and effect of law. They have been developed as a matter of internal USPTO management and are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the USPTO. Rejections will continue to be based on the substantive law, and it is the rejections that are appealable. Consequently, any failure by USPTO personnel to follow the guidelines, by itself, does not create a new ground to appeal or petition.

These guidelines are not intended to announce any major changes to USPTO practice or procedure, and are incorporating guidance from the *Amgen* decision and several post-*Amgen* enablement court decisions that are consistent with current USPTO policy. If earlier guidance from the USPTO, including certain sections of the current

Manual of Patent Examining Procedure (9th ed., Rev. 07.2022, February 2023) (MPEP), is inconsistent with the guidance set forth in this notice, USPTO personnel are to follow these guidelines. The *Amgen* decision and the guidance in these guidelines will be incorporated into the MPEP in due course.

Enablement Requirement

The enablement requirement refers to the requirement of 35 U.S.C. 112(a) that the specification must describe the invention in such terms that one skilled in the art can make and use the claimed invention. As discussed in section 2164.01 of the MPEP, any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claim so as to enable one skilled in the pertinent art to make and use the claimed invention. In *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021) (hereafter *Sanofi-Aventisub*), the Federal Circuit applied the factors from *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (hereafter *Wands*), to assess whether the specification of Amgen's patent provided sufficient enablement, for purposes of 35 U.S.C. 112(a), to make and use the full scope of the claimed invention. The *Wands* factors include, but are not limited to: (A) the breadth of the claims, (B) the nature of the invention, (C) the state of the prior art, (D) the level of one of ordinary skill, (E) the level of predictability in the art, (F) the amount of direction provided by the inventor, (G) the existence of working examples, and (H) the quantity of experimentation needed to make and use the invention based on the content of the disclosure. MPEP 2164.01(a).

In *Amgen*, the Supreme Court, in a unanimous decision, affirmed *Sanofi-Aventisub* and held that claims drawn to a genus of monoclonal antibodies, which were functionally claimed, were invalid due to a lack of enablement. The patents at issue (U.S.

Patent Nos. 8,829,165 and 8,859,741) concerned a genus of monoclonal antibodies that bind to specific amino acid residues on the PCSK9 protein and block the binding of PCSK9 to a particular cholesterol receptor, LDLR. The claims at issue were functional in that they defined the genus by its function (the ability to bind to specific residues of PCSK9) as opposed to reciting a specific structure (the amino acid sequence of the antibodies in the genus). In affirming the Federal Circuit's decision, the Supreme Court concluded that the patents at issue failed to adequately enable the full scope of the genus of antibodies that performed the function of binding to specific amino acid residues on PCSK9 and blocking the binding of PCSK9 to the LDLR cholesterol receptor.

In *Sanofi-Aventisub*, the Federal Circuit relied on its prior precedential opinions when determining whether the full scope of a genus was enabled. These decisions included *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091 (Fed. Cir. 2020) (hereafter *McRO*); *Wyeth & Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013) (hereafter *Wyeth*); *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*, 928 F.3d 1340 (Fed. Cir. 2019) (hereafter *Enzo*); and *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019) (hereafter *Idenix*).

The Federal Circuit, citing *McRO*, provided guidance on the application of enablement to genus claims, holding that "[a]lthough a specification does not need to describe how to make and use every possible variant of the claimed invention, when a range is claimed, there must be reasonable enablement of the scope of the range." *Sanofi-Aventisub*, 987 F.3d at 1085 (internal quotations omitted). Additionally, the Federal Circuit characterized *Wyeth* as holding "that due to the large number of possible candidates within the scope of the claims and the specification's corresponding lack of structural guidance, it would have required undue experimentation to synthesize and screen each candidate to determine which compounds in the claimed class exhibited the claimed functionality." *Id.* at 1086. Similarly, the Federal Circuit characterized *Enzo* as

holding "that the specification failed to teach one of skill in the art whether the many embodiments of the broad claims would exhibit that required functionality." *Id.* Finally, the Federal Circuit characterized *Idenix* as affirming "the district court's determination that the claims had both structural and functional limitations, and that undue experimentation would have been required to synthesize and screen the billions of possible compounds because, given a lack of guidance across that full scope, finding functional compounds would be akin to finding a 'needle in a haystack.'" *Id.*

Turning to the claims at issue in *Sanofi-Aventisub*, the Federal Circuit analyzed the *Wands* factors and found that there was a lack of enablement for the broad functional genus claims. See *Sanofi-Aventisub*, 987 F.3d at 1087-1088. The court relied on evidence showing that the scope of the claims encompassed millions of antibodies and that it was necessary to screen each candidate antibody in order to determine whether it met the functional limitations of the claim. *Id.* at 1088. Consequently, the Federal Circuit concluded that there was a lack of enablement.

Thus, the Federal Circuit decision in *Sanofi-Aventisub* positioned the Supreme Court to answer the question of what is required to satisfy the enablement requirement for a patent claim directed to a functional genus. The Supreme Court held that "[i]f 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. . . . The more one claims, the more one must enable." *Amgen*, 143 S. Ct. at 1254. While the specification in *Amgen* identified 26 exemplary antibodies that performed the claimed function by their amino acid sequences, the claims at issue were directed to a class that included "a 'vast' number of additional antibodies" that Amgen had not described by their amino acid sequences. *Id.* at 1256. The Supreme Court found that Amgen sought to monopolize an entire class of antibodies by their function, which

was much broader than the 26 exemplary antibodies disclosed by their amino acid structure.

The Supreme Court clarified that the specification does not always need to "describe with particularity how to make and use every single embodiment within a claimed class." *Id.* at 1254. Rather, the specification may require a reasonable amount of experimentation to make and use the invention, and what is reasonable will depend on the nature of the invention and the underlying art. For example, "it may suffice to give an example (or a few examples) 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." *Id.* at 1254-1255 (internal quotations omitted). However, the Supreme Court found that Amgen failed to enable all that it claimed, even if allowing for a reasonable degree of experimentation.

The Supreme Court's conclusion rested on the examination of the particular claims in light of the Court's precedent, including *O'Reilly v. Morse*, 56 U.S. 62 (1854) (hereafter *Morse*); *The Incandescent Lamp Patent*, 159 U.S. 465 (1895) (hereafter *Incandescent Lamp*); and *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928) (hereafter *Holland Furniture*). While each of these decisions involved different technologies than *Amgen*, the Supreme Court stated that "these decisions are no less instructive for it." *Amgen*, 143 S. Ct. at 1252. The Supreme Court compared the claims in *Amgen* to the claims of *Morse*, *Incandescent Lamp*, and *Holland Furniture*. The Court found that "Amgen seeks to claim 'sovereignty over [an] entire kingdom' of antibodies," just as "Morse sought to claim all telegraphic forms of communication, Sawyer and Man sought to claim all fibrous and textile materials for incandescence, and Perkins sought to claim all starch glues that work as well as animal glue for wood veneering." *Id.* at 1256. The Supreme Court further stated that "if our cases teach anything, it is that the more a

party claims, the broader the monopoly it demands, the more it must enable. That holds true whether the case involves telegraphs devised in the 19th century, glues invented in the 20th, or antibody treatments developed in the 21st." *Id.* The Supreme Court emphasized that while *Amgen* involved a new technology, antibodies, the Court has applied the same legal principle for over 150 years for many different technologies. Thus, since the Supreme Court relied on precedent from a wide variety of technologies, there is no reason to treat the decision as limited to antibodies or biotechnology; the principles set forth in this decision regarding the enablement requirement apply to all fields of technology.

In reviewing the Federal Circuit's enablement determination, the Supreme Court stated that the specification is not necessarily inadequate just because it leaves the skilled artisan to perform some measure of adaptation or testing. The Supreme Court, citing *Wood v. Underhill*, 46 U.S. 1 (1846), and *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261 (1916) (hereafter *Minerals Separation*), stated that the specification may call for a reasonable amount of experimentation to make and use the claimed invention. *Amgen*, 143 S. Ct. at 1246. The Court in *Amgen*, citing to *Minerals Separation*, opined that "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art." *Id.* That reasonableness standard is still the one to be applied following the Supreme Court decision in *Amgen*.

Determining "Reasonableness of Experimentation"

To assess the amount of experimentation required by the specification so as to determine compliance with the enablement prong of 35 U.S.C. 112(a), the Federal Circuit developed a framework of factors in *Wands*, 858 F.2d at 737, referred to as the *Wands* factors. The Supreme Court did not explicitly address the *Wands* factors in *Amgen*; however, the Court emphasized that the specification may call for a reasonable amount of

experimentation to make and use the full scope of the claimed invention. The *Wands* factors are probative of the essential inquiry in determining whether one must engage in more than a reasonable amount of experimentation and were applied or at least discussed by the Federal Circuit in several post-*Amgen* enablement decisions. See *Baxalta Inc. et al. v. Genentech Inc.*, 2023 U.S. App. LEXIS 24863 (Fed. Cir. 2023) (hereafter *Baxalta*); *Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990 (Fed. Cir. 2023) (hereafter *Medytox*); and *In re Starrett*, 2023 WL 3881360 (Fed. Cir. 2023) (non-precedential) (hereafter *Starrett*). Therefore, consistent with the Federal Circuit in *Sanofi-Aventisub* and in post-*Amgen* enablement decisions, the *Wands* factors, which were used by the USPTO prior to *Amgen*, will continue to be used to assess whether the experimentation required by the specification to make and use the entire scope of the claimed invention is reasonable. See MPEP 2164.01(a). 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.

For more recent guidance on how to determine whether experimentation is reasonable, it is instructive to look at the *Sanofi-Aventisub* decision, which the Supreme Court affirmed, and the Federal Circuit's post-*Amgen* enablement decisions. In *Amgen*, 143 S. Ct. at 1256, the Supreme Court agreed with the Federal Circuit's determination, which the Federal Circuit rendered utilizing the *Wands* factors, that Amgen failed "to enable all that it has claimed, even allowing for a reasonable degree of experimentation." While both *Wands* and *Sanofi-Aventisub* are antibody cases, the Federal Circuit distinguished *Wands* based on the facts and evidence and stated in *Sanofi-Aventisub* that its decision was not inconsistent with *Wands*. 987 F.3d at 1088. The court 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. *Id.* at 1087-1088. While the Federal

Circuit did not hold "that the effort required to exhaust [i.e., make and use the full scope of] a genus is dispositive," 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. *Id.* at 1088. The Federal Circuit concluded that there was a lack of enablement, which was affirmed by the Supreme Court in *Amgen.*

In *Baxalta*, a post-*Amgen* enablement decision, the Federal Circuit affirmed a district court's grant of summary judgment that the claims of a patent directed to a functionally defined genus of antibodies were not enabled. *Baxalta*, 2023 U.S. App. LEXIS 24863 at *1. The court found that the "facts of this case are materially indistinguishable from those in *Amgen*." *Id.* at *9. Although the scope of the claims potentially encompassed millions of antibodies, the patent only disclosed 11 antibodies and a method of producing and screening antibodies to determine whether they met the claimed functional limitations. *Id.* at *10. The court found that, just like in *Amgen*, the method "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 "[u]nder *Amgen*, such random trial-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by § 112(a)." *Id.* at *8, *10. In response to an argument that the district court's enablement determination was inconsistent with *Wands*, 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." *Id.* at *10.

In *Medytox*, another post-*Amgen* enablement decision, the Federal Circuit affirmed a PTAB decision in a post-grant review proceeding using the *Wands* factors and found that the full scope of a substitute claim was not enabled. *Medytox*, 71 F.4th at 998-

999. The substitute claim was directed to a method of using an animal protein-free botulinum toxin composition that exhibited a longer-lasting effect in the patient than an animal protein-containing botulinum toxin composition, and included a responder rate limitation of 50% or greater. *Id.* at 993. The Federal Circuit interpreted the responder rate limitation as having an upper limit of 100%. *Id.* at 997. The specification contained, at most, three examples of responder rates above 50%. *Id.* at 998. Employing the *Wands* factors, the PTAB found that a skilled artisan, reading the specification, would not have been able to achieve higher than 62% for the responder rate limitation without undue experimentation. *Id.* at 998-99. Citing *Amgen*, the Federal Circuit stated that "[t]he more one claims, the more one must enable" and that although the specification does not need to always "describe with particularity how to make and use every single embodiment within a claimed class, it must nevertheless enable the full scope of the invention as defined by its claims, for example by disclosing [a] general quality of the class that may reliably enable a person skilled in the art to make and use all of what is claimed." *Id.* at 998 (internal quotations omitted). The Federal Circuit found that the PTAB provided an adequate explanation and reasoning for its enablement finding, which utilized the *Wands* factors, and found no error in the PTAB's determination of a lack of enablement. *Id.* at 999.

Finally, in *Starrett*, another post-*Amgen* enablement decision, the Federal Circuit affirmed a PTAB decision in an ex parte appeal upholding an examiner's rejection for a lack of enablement of a claim to a non-transitory computer readable medium for maintaining augmented telepathic data for telepathic communication. *Starrett*, 2023 WL 3881360 at 1. While reviewing the examiner's enablement rejection, the PTAB treated the claim as a genus claim because it contained 47 "or" clauses and potentially covered over 140 trillion embodiments. *Id.* at 2. The PTAB affirmed the examiner's determination of a lack of enablement and found that the examiner properly analyzed all the relevant

Wands factors when making the determination that the claim lacked enablement. *Id.* The Federal Circuit once again cited *Amgen* for the proposition that "the specification must enable the full scope of the invention as defined by its claims," and the "more one claims, the more one must enable." *Id.* at 4. The Federal Circuit found that, as in *Amgen*, "[h]ere, much is claimed, and little is enabled." *Id.* In reliance on *Amgen*, the Federal Circuit stated that "[a]lthough a finding of enablement is not precluded by a skilled artisan's need[] to engage in some measure of experimentation, the extent of that experimentation must be reasonable." *Id.* The Federal Circuit endorsed using the *Wands* factors to determine whether the amount of experimentation required in *Starrett* was reasonable when it stated that "[t]he determination as to whether the extent of experimentation is undue or reasonable is informed by the eight *Wands* factors." *Id.* In concluding that the claim lacked enablement, the Federal Circuit found that nothing in the specification or claims undermined the PTAB's reliance on the examiner's *Wands* factor analysis and that the examiner's discussion of the *Wands* factors "properly faulted the specification for failing to describe *how* the claim elements function," thereby indicating that the *Wands* factors should be used to determine whether the experimentation was reasonable. *Id.* at 4-5 (emphasis in original).

Conclusion

Therefore, 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. The explanation in an enablement rejection or in a PTAB determination that a claim is not enabled should focus on those factors and the reasons and evidence that led the examiner or decision-maker to arrive at their conclusion. See MPEP 2164.04. 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.

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Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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