Amgen v. Sanofi: Enabling the Enablement Requirement

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The Supreme Court of the United States will have the opportunity to review application of the enablement requirement in its upcoming term. In the case of *Amgen, Inc. v. Sanofi* (Appeal No. 2020-1074, Fed. Cir., Feb. 11, 2021), the Federal Circuit held that genus claims reciting functional chemical elements, in an unpredictable technology area, face a "high hurdle" erected by the Federal Circuit to satisfy the enablement requirement.[1] The enablement inquiry for such claims now focuses almost exclusively on the number of compounds that can be within the scope of the claim, making generic patent claims in chemical technology areas virtually impossible to defend.[2]

The district court for the District of Delaware held claims 19 and 29 of U.S. Patent No. 8,829,165, and claim 7 of U.S. Patent No. 8,859,741, invalid for lack of enablement. Claim 29 is representative of the problem:

> 29. A pharmaceutical composition comprising an isolated monoclonal antibody, wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO: 3 and blocks the binding of PCSK9 to LDLR by at least 80%.

As observed by the Federal Circuit, "the claimed antibodies are defined by their function."[3] Sanofi argued correctly that Federal Circuit precedent requires sufficient guidance in the specification of the patent for practicing the millions of candidate antibodies that fall within the scope of the claim. The Federal Circuit agreed that making and using the full scope of substances having the functions recited in the claims would require "undue experimentation."[4]

The enablement requirement is set forth in section 112(a) of Title 35 of the United States Code, as follows:

> "The specification shall contain a written description of the invention, and of the manner and process of making an using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...."

In cases like this where generic elements are recited in a claim, the enablement requirement is analyzed using the so-called Wands factors. In the case of *In re Wands*[5], the Federal Circuit considered a rejection in a patent application before the United States Patent and Trademark Office. Reviewing facts found by the Board of Patent Appeals and Interferences,[6] the Federal Circuit observed that to meet the enablement requirement a patent specification must enable a

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[1] *Id.* at *12.
[2] Amgen, Inc. v. Sanofi, case No. 2020-1074, Supreme Court of the United States. Brief amicus curiae of Intellectual Property Professors, December 22, 2021.
[3] Federal Circuit opinion, at *5.
[4] *Id.* at *12.
[5] 858 F.2d 731 (Fed. Cir. 1988).
[6] Now called the Patent Trials and Appeals Board after passage of the Leahy Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284, September 16, 2011.

person of ordinary skill in the art to practice the invention without "undue experimentation," where "[t]he key word is 'undue,' not 'experimentation."[7] In Wands, The Federal Circuit implemented a formulation first gathered from earlier cases by the Board in the case of *In re Forman*, 230 USPQ 546 (Bd. Pat. App. Int. 1986). The formulation grew into a fact-finding procedure the Federal Circuit has come to regard as required for analyzing whether a person of ordinary skill in the art would have to resort to undue experimentation to practice a claimed invention. The Wands factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.[8]

The *Wands* claims are not entirely dissimilar from the *Amgen* claims. The *Wands* claims recite monoclonal antibodies that have high-affinity binding with certain hepatitis viruses. The *Amgen* claims recite monoclonal antibodies with binding functions like those in claim 29, *supra*. The specification of the *Amgen* patent runs to 61 pages of dense text, with 152 sheets of figures and 151 pages of genetic sequence information, and presents 26 working examples. Although Wands presented only four examples of antibodies falling within the scope of the claims, the Federal Circuit held the claims enabled because: the disclosure in the patent provides considerable direction and guidance on how to practice the invention and presents working examples; there was a high level of skill in the art at the time when the application was filed; and all the methods needed to practice the invention were well known.[9] The court further observed that the nature of monoclonal antibody technology is that screening is employed to identify suitable antibodies, so the screening that would be employed in connection with practicing the claimed invention would not be "undue experimentation."[10]

The "undue experimentation" aspect seems to have arisen from the case of *In re Angstadt*.[11] In that case, the Court of Customs and Patent Appeals, predecessor to the Court of Appeals for the Federal Circuit, held that because there was no evidence that undue experimentation was required, the disclosure enabled practice of the claimed subject matter.[12] The *Angstadt* court declared that the specification is not required to disclose every species covered by the claims, even in an unpredictable art, because such a requirement would deter patenting.[13] The dissent in *Angstadt* argued that a patent specification must give guidance regarding what does *not* work, in addition to enabling the claimed subject matter, in order to meet the enablement requirement.[14] Such a requirement would clearly enlarge the amount of experimentation that must be dispelled by the description of the specification.

The Federal Circuit today seems to take an approach opposite to that in *Wands* and more aligned with the dissent in *Angstadt*. Although the *Amgen* patent is directed to monoclonal

[7] *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).
[8] *Ibid.*
[9] *Id.*, at 740.
[10] *Ibid.*
[11] 537 F.2d 498 (CCPA 1976).
[12] *Id.* at 504.
[13] *Id.* at 503.
[14] *Id.* at 507, Miller, Judge, dissenting.

antibody technology, the same technology field as in *Wands*, the screening that would be employed in connection with the *Amgen* claims now seems undue, chiefly because the Federal Circuit now holds that "practicing" the invention requires that the "full scope of the broad claims can be predictably generated by the described methods."[15] Tellingly, the opinion states,

> "even assuming that the patent's 'roadmap' provided guidance for making antibodies with binding properties similar to those of the working examples, no reasonable factfinder could conclude that there was adequate guidance beyond the narrow scope of the working examples that the patent's 'roadmap' produced."[16]

The *Wands* court thus equates "practicing the invention" with the need to "discover undisclosed claimed embodiments."

Amgen argues today that the experimentation required to "obtain antibodies fully within the scope of the claims" is not undue because their specification provides a "roadmap" based on known screening techniques, as set forth in 26 examples. Sanofi does not controvert the contentions advanced by Amgen, but argues that the mere multiplicity of possible embodiments that "must be made and tested to determine whether they satisfy the claimed function," alone, requires the claim be held invalid for lack of enablement. The Federal Circuit agreed with Sanofi, even though it did not take such an approach in *Wands.*

The *Wands* court stated that the level of skill in the art of monoclonal antibodies was high at the time the *Wands* application was filed. The *Amgen* court did not comment on the level of skill in the art at the time the application was filed, although that is one of the Wands factors. If the level of skill in the art of monoclonal antibodies was high in 1988, it does not seem incorrect to regard the level of skill in the art as high today, perhaps even as a matter of law. The *Wands* court saw no evidence in the record of that case regarding how much screening would be undue, but implied that the screening itself is but a small part of the overall preparation of antibodies. The *Amgen* court is not so sanguine.

The amici Professors (*supra* note 2) explain that this approach to enablement by the Federal Circuit "misunderstands the basic purpose" of the enablement requirement. A person of ordinary skill in the art will likely never undertake to identify all, or even a substantial portion, of embodiments that fall within the scope of a genus claim, and there is no reason, within the technology promotion mechanism of the patent system, for them to do so. As the court observed in *Wands*, "the sole issue is whether...it would require undue experimentation to produce" embodiments of the claims, not to identify a substantial portion of embodiments throughout the scope of the claims. Section 2 of the 1790 Patent Act expressly stated the point of the enablement requirement "to the end that the public may have the full benefit thereof, after the expiration of the patent term." Such objective would not seem to require the artisan to determine the covered embodiments a priori.

The scope analysis approach in this case is geared toward identifying embodiments that are within the scope of the claims, seemingly in order to understand the scope of the claims. In the case of *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014), the Supreme Court held

[15] *Amgen*, at *13.
[16] *Ibid.*

that understanding the scope of the claims, with "reasonable certainty," was part of the definiteness requirement of 35 U.S.C. § 112, paragraph 2 (now § 112(b)). Other Federal Circuit precedent allows some imperfection in the disclosure without violating the enablement requirement. For example, it is not necessary to enable one of ordinary skill to make and use a "perfected, commercially viable embodiment absent a claim limitation to that effect."[17] The presence of inoperative embodiments in the specification also does not necessarily violate the enablement requirement.[18] What is required is that the description "guide those skilled in the art to its successful application."[19] The *Amgen* court goes to great lengths to explain that the approach taken is not to be understood as precluding the use of functional limitations in genus claims. The amici Professors (*supra* note 2) observe that the effect is however to do exactly that.

Like the phrase "undue experimentation," the phrase "full scope" does not appear in the statute. Nonetheless, the "full scope" requirement has grown in importance recently in evaluating enablement of chemistry patents. The Federal Circuit, in *Amgen*, concluded that because it would take substantial time and effort to "reach the full scope of claimed embodiments," undue experimentation is required to "practice the full scope of these claims." The "full scope" requirement seems to be an outgrowth of language in earlier cases holding that the extent of enablement required must be "commensurate in scope" with the claims.[20]

The requirement that the description enable the "full scope" of the claims now regularly produces patents listing hundreds to thousands of chemical structures in the specification to ensure coverage of those structures. Patents in the technology areas of medical science routinely run to hundreds of pages of dense text because patent applicants understandably discern a requirement for herculean disclosure of every conceivable possibility in the hope of covering something valuable. The *Amgen* case cites *Wyeth & Cordis Corp. v. Abbott Laboratories*,[21] *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*,[22] and *Idenix Pharms. LLC v. Gilead Sciences Inc.*[23] as support for the stringent enablement requirement. In *Wyeth*, the Federal Circuit held, as a matter of law upon review of a summary judgment in the district court, that to "practice" the invention "it would be necessary to first synthesize and then screen *each* candidate compound using the assays disclosed in the specification to determine whether it has immunosuppressive and antirestenotic effects,"[24] observing that there are at least tens of thousands of such candidates. In *Enzo*, the Federal Circuit characterized its holding in *Wyeth* as finding a lack of enablement because "it would have required undue experimentation to determine which compounds in the claimed class would have the required functionality."[25] In *Idenix*, the Federal Circuit determined that the "quantity of experimentation required to determine which 2'-methyl-up nucleosides meet claim 1 is very high."[26] The requirement that the description enable the "full scope" of the claims

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[17] *CMFT, Inc. v. Yield up Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003).
[18] *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.,* 750 F.2d 1569 (Fed. Cir. 1984).
[19] *See Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 271 (1916).
[20] *See, e.g., In re Moore*, 439 F.2d 1235 (C.C.P.A. 1971); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970).
[21] 720 F.3d 1380 (Fed. Cir. 2013).
[22] 928 F.3d 1340 (Fed. Cir. 2019), *cert. denied* 140 S. Ct. 2634 (2020).
[23] 941 F.3d 1149 (Fed. Cir. 2019)
[24] *Wyeth*, 720 F.3d at 1385 (emphasis in original).
[25] *Enzo*, 829 F.3d at 1346.
[26] *Idenix*, 941 F.3d at 1156.

seems thus to have been realized as a requirement that the experimentation to determine a priori the chemical embodiments within the scope of a claim not be excessive. It is almost axiomatic, however, that experimentation is the quintessence of the chemical arts. It has been known since at least the time of *Wands* that determining which embodiments have a particular characteristic can only be done through experimentation, which is routine in the art of monoclonal antibodies. In an effort to comply with the present articulation of the enablement requirement, those with the means continually amplify their disclosures to extents that seem facially unreasonable, and certainly unobtainable for those with less means.

One more aspect that bears mentioning is the difference in posture of the *Wands* and *Amgen* cases. The *Wands* court reviewed the result of examination of a patent application in the United States Patent and Trademark Office. The *Amgen* court reviewed the validity of an issued patent. These two different postures, in theory, require two different levels of deference from a reviewing court. In the *Wands* case, the result in the Patent Office would be owed some deference under the standard of *Chevron U.S.A., Inc. v. Natural Resource Defense Council, Inc.*[27] In the *Amgen* case, the deference owed is defined by statute. Section 282 of Title 35, United States Code, flatly states, "A patent shall be presumed valid," and places the "burden" of proving otherwise on the party asserting invalidity. In theory, it seems the Federal Circuit should be more convinced of an erroneous result in the *Amgen* case than in the *Wands* case. Neither case contains any discussion of the standard of review, or explanation of how the analysis comports with the standard.

The Supreme Court has an opportunity,[28] in its next term, to review the evolution of the enablement requirement in the context of unpredictable technologies. The current trend toward requiring ever more disclosure to support broad claims worth patenting in a highly technical and advancing technology field is puzzling to many practitioners, and to some venerable law professors. As of this writing, the Justices have invited the Solicitor General to file a brief in the case expressing the views of the United States, indicating to some that the Court is initially in favor of hearing the case. The Justices should not miss this golden opportunity to review how the law has developed from the *Minerals Separation* requirement that the disclosure be "reasonable, having regard to [the] subject matter,"[29] and to perhaps enable more patenting in such technology areas.

[27] 468 U.S. 837 (1984).
[28] Docket No. 21-757, petition filed November 18, 2021.
[29] *Minerals Separation,* 242 U.S. at 262.