LAW360

Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

4 Potential Paths For High Court In Amgen Patent Case

By **Will Milliken** (March 31, 2023, 6:25 PM EDT)

Will Milliken

On March 27, the U.S. Supreme Court heard oral argument in Amgen v. Sanofi, a closely watched case concerning the appropriate legal standard for patent law's enablement requirement.

That requirement is found in Title 35 of the U.S. Code, Section 112(a), which provides that a patent must describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same."

The argument was as notable for what the parties appear to agree on as it was for what they dispute. Amgen Inc., Sanofi SA and the U.S. — appearing as amicus curiae — all appear to agree on the following propositions of law.

- The enablement inquiry should ask whether the specification enables a skilled artisan to make and use the invention without undue experimentation.

- In other words, it's okay for those in the field to have to do some experimentation to make and use certain embodiments of the claimed invention, so long as the amount of experimentation is not undue under the circumstances.

- The eight factors set forth in the U.S. Court of Appeals for the Federal Circuit''s seminal 1988 decision in In re: Wands provide a useful guide to determining whether the amount of experimentation required in a given case is undue.[1] Amgen says, however, that the Wands factors should not be viewed as a rigid checklist or a replacement for the ultimate statutory make and use standard.

- The specification need not necessarily enable skilled artisans to cumulatively identify and make every single claimed embodiment without substantial time and effort. Sanofi and the US. think the cumulative effort inquiry is relevant but not dispositive; Amgen thinks it is irrelevant.

- The proper inquiry is whether the patent enables the full scope of the claims — that is, it's not enough to merely enable some embodiments of the claims.

None of the justices seemed inclined to push back on any of these agreed-upon principles. So let us assume for argument's sake that the Supreme Court's ultimate decision will not disturb them.

And, while the parties vehemently disagree about how these principles should apply to the particular patents at issue in this case, that sort of factbound question is not the sort the Supreme Court typically addresses.

Given that, one might reasonably ask what there is left for the Supreme Court to do. In fact, Justice Neil Gorsuch asked just that.

What follows are some potential paths forward for the court, along with the practical implications that may flow from each.

1. The court holds that the Federal Circuit applied the correct legal standard and affirms.

An opinion along these lines would endorse the undue experimentation standard and the Wands factors and conclude that the Federal Circuit correctly applied that law to the facts here, or else indicate that the court will not disturb the Federal Circuit's application of the law because it depended on disputed questions of fact that the court is not inclined to revisit.

This outcome would — obviously — mean the governing legal standard remains in place and so would not result in a sea change in enablement law.

But the very fact that the Supreme Court endorsed the standard would have significant consequence in and of itself.

The law of enablement would be, in a sense, fixed at least until the next time the court takes up a Section 112 case: the Federal Circuit has significantly less freedom to modify its precedent once that precedent receives the Supreme Court's stamp of approval.

And it would be settled, as a judicial matter, that broad, functional genus claims like Amgen's are very hard to obtain. If the consequences of that are as dire as Amgen and its amici claim, that outcome might in turn prompt legislative intervention.

It also bears emphasis that a Supreme Court decision endorsing the Wands factors could have significant — and possibly unpredictable — ripple effects outside of the biotech and pharmaceutical space.

Wands itself involves antibody science, and, while the Wands factors' application is not limited to biotech and pharmaceutical inventions, as the law currently stands the Wands factors tend to play the largest role in those sorts of cases.

But, if the Supreme Court says Wands is the law, we can expect courts to begin rigorously applying Wands in all types of cases. And that could lead to an interesting evolution of enablement law outside of the life sciences.

To see what I mean by that, consider the analogy of subject matter eligibility. Alice Corp. v. CLS Bank International, in the Supreme Court in 2014, was nominally a case about business method patents.[2]

But the Alice two-step is now the law for all types of patents, and that has led to some very interesting results — like, for example, a holding that a patent on a digital camera is too abstract to be eligible for patenting.[3]

2. The Supreme Court clarifies the standard, vacates the Federal Circuit's decision and remands.

I'm using the word "clarify" here for a reason — given the significant agreement about the proper legal standard, discussed above, any new law the court sets down is going to be more in the nature of a clarification than an announcement of some wholesale new legal test.

What might the Supreme Court clarify? The oral argument presented the following, non-mutually exclusive, possibilities:

The court might agree with Amgen that the cumulative effort required to make and use all embodiments within the scope of a claim is legally irrelevant and remand for the Federal Circuit to do a new analysis that does not consider cumulative effort at all.

The court might reject the government's suggestion that genus claims need to have a unifying structure — thereby at least implicitly blessing the idea of functional genus claims — and remand for the Federal Circuit to consider whether Amgen's claims are enabled notwithstanding their functional nature.

The court might hold that a patentee alleging lack of enablement must at least prove the existence of one concrete embodiment that falls within the claims and yet could not be made without undue experimentation and remand for the Federal Circuit to determine if Sanofi made that showing.

The court might hold that the Wands factors, while a useful guide to the enablement analysis, should not be applied as a rigid checklist, analogous to the court's rejection of the teaching-suggestion-motivation test in KSR International Co. v. Teleflex Inc. in 2007, and remand for the Federal Circuit to perform a more holistic and flexible inquiry.[4]

An outcome like this would likely lead to a little more uncertainty than a simple affirmance. While we would have a definitive pronouncement on the law from the Supreme Court, the task of filling in the interstices of that pronouncement would be left to the Federal Circuit.

And whether functional genus claims like Amgen's are feasibly obtainable would remain unsettled, potentially meaning lesser incentives for a legislative solution.

The other consequence identified above, however — significant ripple effects outside the life sciences — would likely come to pass in this scenario as well.

3. The Supreme Court either endorses or clarifies the legal standard applied by the Federal Circuit, but holds the court of appeals erred in applying that standard to reverse the jury's verdict in Amgen's favor.

This version of the opinion would require the court — in addition to laying down the law of enablement — to actually wade into the facts and the underlying science and make a determination that a reasonable jury, faced with the trial evidence, could properly have found Amgen's claims enabled.

The Supreme Court typically resists doing fact-intensive analyses like this, so this outcome is somewhat unlikely, though certainly not impossible.

This would likely be the most patentee-friendly of the possible outcomes: after such a decision,

patentees would likely have a much easier time obtaining and enforcing broad functional genus claims than they do under current Federal Circuit law. And — if the result of that is as dire as Sanofi and its amici claim — that in turn might prompt legislative intervention.

This sort of decision could be important civil procedure precedent in addition to being an important patent law one.

Depending on how such an opinion were written, it could signal to lower courts deciding motions for judgment as a matter of law that they should be more deferential to jury findings.

4. The Supreme Court dismisses the case as improvidently granted.

Probably the most anticlimactic outcome would be a DIG — i.e., an order dismissing the case as improvidently granted.

DIGs are rare, but they sometimes happen in cases like this where the briefing and argument indicate that the question presented is factbound rather than a clean issue of law. Indeed, the prospect of a DIG came up explicitly at oral argument.

The consequence of a DIG would be, in effect, preservation of the status quo.

Patentees would continue to argue that the Federal Circuit is improperly raising the bar for enablement, continue to push that court to relax the standard, and continue to file cert petitions.

Patent challengers would continue to argue that broad, functional claims are harmful to innovation, continue to push the Federal Circuit to make it harder to obtain those sorts of claims, and continue to oppose cert petitions.

And the law would, for better or worse, remain relatively hostile to functional genus claims like Amgen's.

The Supreme Court's decision is expected by the end of June.

William H. Milliken is a director and co-chair of the appellate practice at Sterne Kessler Goldstein & Fox PLLC.

[1] 1 858 F.2d 731 (Fed. Cir. 1988).

[2] Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).

[3] Yu v. Apple, 1 F.4th 1040 (Fed. Cir. 2021).

[4] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).