Morton and Wolfson in Westlaw Today: Patent Enablement Following 'Amgen v. Sanofi'

August 5, 2024 Jeffrey Morton, Jeffrey Wolfson

PRACTICES Patents, Patent Litigation, Patent Office Trials

Haynes Boone Partners Jeff Morton and Jeff Wolfson authored an article for *Thomson Reuters* a year removed from the United States Supreme Court issuing a unanimous decision on patent enablement in *Amgen v. Sanofi*.

Read an excerpt below.

A little over one year ago, in May 2023, the United States Supreme Court issued the unanimous decision on patent enablement in *Amgen v. Sanofi* (hereinafter referred to as the "Amgen" decision). In Amgen, Justice Neil Gorsuch neatly summarized the statement on enablement as follows:

"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. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable."

This decision immediately sent shockwaves through the life sciences and chemical industries due to the legitimate concern that broad genus claims are now susceptible to being struck down in favor of narrower species claims. Indeed, in Amgen, the demonstrated efficacy of over 25 antibody species had been insufficient to maintain broad genus claims that arguably covered well over a million antibody variants.

In January 2024, the U.S. Patent and Trademark Office (USPTO) issued patent examiner guidance that addressed the implications of the Amgen decision. The guidance directed USPTO personnel to "continue to use the [circa 1988] In re Wands factors to ascertain whether the amount of experimentation required to enable the full scope of the claimed invention is reasonable." 858 F.2d 731 (Fed. Cir. 1988).

The Wands factors are fact-specific and 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.

While the implications of the USPTO guidance support the view that the Amgen decision may have a more muted impact on the examination of life science and chemical patent applications than originally anticipated, the fact remains that the Amgen decision bolsters a patent litigator's arsenal in invalidating an issued patent on the basis of lack of enablement.

Accordingly, patent practitioners in the life science and chemical industries have started to shift their approaches to patent drafting in order to minimize the future impact of Amgen in the event that the

ensuing patents are ultimately challenged for lack of enablement. A summary of a few of the more common patent drafting adjustments follows.

To read the full article from *Westlaw Today*, click here.