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The following remarks were delivered during a panel discussion on Amgen Inc. v. Sanofi at Chicago-Kent's 2023 Supreme Court Intellectual Property Review.

AMGEN V. SANOFI AND THE RETURN OF PATENT FORMALISM TO THE SUPREME COURT

LAURA PEDRAZA-FARIÑA

In *Amgen v. Sanofi*,¹ the Supreme Court's first engagement with the enablement doctrine since the 1800s, the Court solidifies the Federal Circuit's relatively recent expansion of the doctrine. Together with written description, enablement has emerged in Federal Circuit jurisprudence as a sword against broad genus claims in biotechnology, and in particular broad claims that use functional language. The Court's opinion can be boiled down to the following key concepts. Patentees must enable the "full scope of the invention as defined by its claims." The Court explains the "full scope" requirement as demanding broader claims to provide "more" enablement. In the words of the Court "The more one claims, the more one must enable." How much is needed for full scope enablement was never precisely clear in earlier Federal Circuit opinions, in part because these opinions tied enablement decisions to (changing) facts on the ground, including the knowledge of people having ordinary skill in the art (PHOSITA), and the nature of the patented technology. The Court in *Amgen*, however, provides a clearer doctrinal answer.

1. *Amgen Inc. v. Sanofi*, 142 S. Ct. 1243 (2023).

A patentee who, like *Amgen*, seeks to claim a large class of compounds by their function, must disclose representative species or identify specific structural characteristics that all members of the class have in common, and which make them suitable to perform the claimed function. This is an impossible task for antibody claiming, where the natural process of VDJ recombination produces large numbers of functionally equivalent candidate compounds with different structures that are unpredictable *ex ante*.²

This focus on structure represents a stark departure from earlier, and foundational, Federal Circuit enablement cases, such as *In re Wands*³ and *Hybritech Inc. v. Abbott Laboratories*.⁴ These cases focused more squarely on whether a PHOSITA, armed with the knowledge provided in the disclosure and their own tacit knowledge, could practice the invention (or, in this case, identify working antibodies encompassed by the functional claim) without “undue experimentation.” *In re Wands* tied “undue experimentation” to a “reasonableness” standard, which, in turn, depended upon facts on the ground.⁵ The opposite of “undue” experimentation was “routine” scientific research, which again was tied to the norms of science prevalent in the relevant PHOSITA community. Thus, in earlier cases, a claim was enabled if a PHOSITA need only engage in “routine experimentation” to practice the invention. It turns out, then, that the Court’s doctrinal guidance is clearer in large part because it is unconcerned with factual inquiries about how an actual scientific community would go about making and using the invention.⁶

The Court in *Amgen* does not use the canonical “undue experimentation” and “routine experimentation” language, framing the inquiry instead as one of a “reasonable amount of” experimentation. More specifically, the Court insists that, because the number of antibodies encompassed by the functional claim is potentially unfathomably large, disclosing the sequences of only twenty-six antibodies while providing a roadmap for further research, is not “reasonable” experimentation but rather simply asking the PHOSITA to engage in “the trial and error” process of discovery. For such a claim to be enabled, patentees must instead identify a structural feature that all members of that functional claim have in common. The curious thing about this holding, however, is that the work of a PHOSITA to isolate working antibodies would not be made easier by knowing a supposedly common structure

2. See, e.g., Ruffolo *et al*, *Fast, accurate antibody structure prediction from deep learning on massive set of natural antibodies*, 14 NATURE COMMUNICATIONS 2389 (2023) (“The binding of antibodies is facilitated by a set of six hypervariable loops that are diversified through genetic recombination and mutation. Even with recent advances, accurate structural prediction of these loops remains a challenge.”).

3. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

4. *Hybritech Inc. v. Abbott Lab’ys*, 849 F.2d 1446 (Fed. Cir. 1986).

5. *Wands*, 858 F.2d at 737 (“The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.”).

6. See Timothy Richard Holbrook & Mark David Janis, *How the Supreme Court Ghosted the PHOSITA: Amgen and Legal Constructs in Patent Law*, IOWA L. REV. ONLINE (Forthcoming 2023), <https://ssrn.com/abstract=4552342>.

of functional antibodies. Antibodies are not (or at least not yet) isolated like small peptides through controlled chemical reactions. Amgen's guidance is in fact more useful to a PHOSITA in making and using the invention than any structure could be.

Neither the Federal Circuit nor the Supreme Court acknowledge this sea change. Rather, the Supreme Court opinion is crafted as the logical extension of fundamental concepts present in its earlier opinions in *O'Reilly v. Morse*⁷ and *In re: Incandescent Lamp Patent*.⁸ And yet, as many have already pointed out, *Amgen v. Sanofi* significantly narrows the possible breadth of claims in antibody technology, making it all but impossible for functional claiming to succeed either in antibody technology or in biotechnology more broadly.

This case also represents a more subtle yet equally important departure, this time not so much from *precedent* but from the Supreme Court's attitude about how patent law should engage with the realities of on-the-ground scientific research. In an earlier article, I documented a trend in Supreme Court jurisprudence that, I argued, sought to counter the Federal Circuit's increasing formalism⁹ In a trio of Supreme Court decisions—*KSR International Co. v. Teleflex Inc.*,¹⁰ *Nautilus, Inc. v. Biosig Instruments, Inc.*,¹¹ and *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*¹²—the Court centers the obviousness, definiteness and claim construction inquiries, respectively, on understanding social and economic norms in scientific and technological communities. This trend seems to have come to a grinding halt. Justice Gorsuch's unanimous opinion stands out for how little it engages with the realities of antibody research, and for its lack of concern with tying concepts such as “reasonable” to what members in the antibody research community would think or expect.

7. *O'Reilly v. Morse*, 56 U.S. 62 (1853).

8. *The Incandescent Lamp Patent*, 159 U.S. 465 (1895).

9. Laura G. Pedraza-Fariña & Ryan Whalen, *The Ghost in the Patent System: An Empirical Study of Patent Law's Elusive "Skilled Artisan,"* 108 IOWA L. REV. 247, 256 (2022).

10. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402–03 (2007).

11. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

12. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318 (2015).