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Comments on Amgen v. Sanofi

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COMMENTS ON *AMGEN v. SANOFI*

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Thank you to Chicago-Kent Law and its excellent intellectual property faculty for the opportunity to discuss *Amgen v. Sanofi*.[1] I will begin with some more personal reflections on the case and then I will turn to thoughts as to its impact.

On the day it was released, I hurriedly downloaded and skimmed the opinion. My immediate reaction was deep relief. It had been nearly one hundred years since the Supreme Court had taken a significant Section 112(a) case and I felt that Amgen's position and those of their allied amici, if adopted by the Court, would have heralded a significant setback to the disclosure requirements in United States patent law. Luckily this did not happen.

Amgen v. Sanofi and indeed the whole subfield of monoclonal antibody patents has been an area of specific concern for me for some time. It combines two separate areas of interest, one scientific and one legal. As to the science of the *Amgen* case, I have spent considerable time studying protein structure and function. A particular challenge in this field is the high degree of unpredictability of the tertiary structure of a protein given its primary structure.[2] Advances in predictive protein folding will someday (maybe soon) start to reduce that unpredictability but we are certainly not there yet. Second, I've been interested in the case as a legal matter as well. I've spent a significant portion of my scholarly career exploring the 'invention' in

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1. Amgen Inc. v. Sanofi, 143 S. Ct. 1243 (2023).

2. My PhD work in biophysics focused on techniques for determining the three-dimensional structure of proteins.

patent law.[3] To summarize a bit, in my view the 'invention' is a well-defined concept that exists necessarily prior to a patent specification being written and certainly before any claims are written. It is a necessary pre-requisite input that starts the process of drafting a patent application. Roughly put, the invention is the set of solutions created by the inventor that solves some technical problem. If you care about the invention, then you care a lot about Section 112 and cases like *Ariad v. Lilly*,[4] *Centocor v. Abbott*,[5] *Abbvie v. Janssen*.[6] Accordingly, I cared a lot about *Amgen v. Sanofi*.

As mentioned, my first reaction was deep relief. I was relieved in large part because, up until oral arguments, there was a sense of impending doom building around the case especially as momentum for Amgen's position seemed to gain traction with some patent scholars. I felt those arguments misunderstood patent law and ignored or misunderstood relevant aspects of the technology. This worry reached a fever pitch once the Court granted certiorari in spite of the Solicitor General's recommendation to the contrary. At the time, it seemed that the only reason to grant the petition was to side with Amgen and its amici and to reverse the Federal Circuit. I was determined to write an amicus brief that explained as persuasively as possible that the District Court's grant of JMOL for lack of enablement and the Federal Circuit's affirmance all were squarely in line with the Court's foundational cases on Section 112, primarily *O'Reilly v. Morse*[7] and *The Incandescent Lamp Case*.[8] The brief that ultimately emerged from that concern was co-authored with Professor Arti Rai and Professor Sean Tu and was joined by seven other of our patent scholar colleagues.[9] It wasn't until oral arguments that glimmers of hope emerged. The questions from the Justices seemed to suggest that the Justices had serious doubts about all of Amgen's positions. Thankfully those glimmers of hope were realized, and the Court sided entirely with Sanofi. Amgen's overly broad genus claim was invalid under Section 112. That was a great relief. Of particular note was the Court's recognition of Amgen's roadmap as a trial-and-error method of inventing in the first place and not an enabling method of making the invention. Recognition of this scientific reality is central to the case and was either misunderstood or conveniently ignored by Amgen and their amici. Luckily our trial-and-error

3. Not as the pre-1952 usages of invention as exemplified by Justice Douglas in *Cuno Engineering v. Automatic Devices*, 314 U.S. 84 (1941) and the so-called requirement of invention but instead "the invention" as the solution actually conceived and described by the inventor.

4. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010).

5. Centocor Ortho Biotech, Inc. v. Abbott Lab'ys, 636 F.3d 1341 (Fed. Cir. 2011).

6. Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285 (Fed. Cir. 2014).

7. 56 U.S. 62 (1853).

8. 159 U.S. 465 (1895).

9. Brief of Intellectual Property Law Professors and Scholars as Amici Curiae in support of the Respondents, Amgen Inc. v. Sanofi, 143 S. Ct. 1243 (2023) (No. 21-757). Though my co-authors Prof. Arti Rai and Prof. Sean Tu and I wrote the brief together, the views and opinions expressed here are mine. In addition, I should note that, although Prof. Josh Sarnoff wrote and filed his own brief in the case, he contributed significant time and energy discussing the case and our arguments with us.

focus was also corroborated by the amicus brief written by Sir Gregory Winter, the person awarded the Nobel prize for his discoveries relating to monoclonal antibodies.[10] Furthermore, to my great satisfaction, the Court even extensively cited our brief's analogy to a combination lock as being central to explaining the deficits in Amgen's reasoning.

Moving on from those more personal aspects of the case, I'd like to spend the rest of my time discussing the case's impact moving forward. I will start with the most narrow and specific and I will end with the most general and high-level impacts. The narrowest, specific impacts deal with monoclonal patents and those impacts are fairly certain to be felt rather immediately. In contrast, the most general discussion is less concrete, less certain and its arc and direction are only hinted at and implied by the Court's opinion.

As to the patenting of monoclonal antibodies, there will be immediate impacts from *Amgen v. Sanofi*. First, the so-called 'antibody exception' has been finally and fully laid to rest.[11] Though relatively recent Federal Circuit decisions were certainly dismantling the antibody exception, this case presented an opportunity for the Supreme Court to upend and reverse those changes. Thankfully the Court did not resurrect it; rather the Court made clear that it is dead and gone. Detailed disclosures focused on the *antigen* of interest are just not going to be enough for claims covering *antibodies* that bind to that antigen. The Court reaffirmed the applicability of its own cases (like *The Incandescent Lamp Case*) to police overly broad claims in the antibody space.

Second, *Amgen v. Sanofi* widens the fronts on which patent defendants can attack broad antibody claims. The conventional wisdom had held that written description was the more stringent requirement. Enablement was thought to be an easier requirement to surmount, and the written description was the only real hurdle. *Amgen* has changed that. Defendants and the PTO are now armed with another avenue to invalidate overly broad claims.

Third, the Court made clear that Amgen's roadmap for trial-and-error hunting for new antibodies did not enable its broad claim. This remained true despite the fact that Amgen argued that their disclosed roadmap had been improved by the information they had gleaned from their earlier successes.[12] Even this updated roadmap was not enough. The Court also held that

10. Brief of Sir Gregory Paul Winter and Interested Scientists as Amici Curiae in Support of Respondents at 27, *Amgen*, 143 S. Ct. 1243 (No. 21-757).

11. *See generally* Oskar Liivak, *Centocor, the Antibody Exception, and Claiming Only What was Invented*, PATENTLY-O (Feb. 27, 2011), https://patentlyo.com/patent/2011/02/guest-post-centocor-the-antibody-exception-and-claiming-only-what-was-invented.html [https://perma.cc/26BU-SH87].

12. Amgen argued that their knowledge of the two fully characterized and disclosed antibodies allowed them to provide an updated roadmap where the disclosure of the two antibodies allowed an easier method for determining whether a target antibody competitively bound with the earlier antibody thus generally indicated that the newfound antibody likely bound at or near the so-called sweet spot of PCSK9.

Amgen's method for intelligent substitution was not enough to help enable the broad claim.

The Court, in my opinion, was correct in both of these conclusions, but I do have one quibble with the Court's analysis here. In my view, the roadmap and intelligent substitution are different in kind. The former really cannot ever enable while the latter might in other future cases. The former is always going to be telling persons of skill to go forth on a "research assignment." It is always going to be, using the combination lock analogy, like "telling others 'to randomly try a large set of combinations and then record the successful ones." The latter though is different. Intelligent substitution might well someday start to lead to broader inventions. I thought it would have been helpful to highlight this difference. And even if and when an inventor is able to disclose a set of related embodiments via intelligent substitution, it will still have to claim only the narrower genus of antibodies that are tethered to antibodies that have actually been found and sequenced. The claim at issue in Amgen had no such limitations that tethered its reach to antibodies that had originated with the twenty-six disclosed antibodies and accordingly neither disclosed method (the roadmap nor intelligent substitution) enabled the broad claim. I just wish that the Court would have noted the difference in kind between these two methods.

Moving beyond the confines of monoclonal antibody patenting, there will be impacts for enablement law more generally. Most clearly, the Court utterly rejected all of Amgen's and their amici's arguments. Amgen aimed to reverse the Federal Circuit arguing that their "Reach-the-Full-Scope Standard Finds No Support in § 112."[13] Amgen's arrayed amici argued that the Federal Circuit's full scope test is "at odds with this Court's long-standing precedent."[14] These arguments were clearly and emphatically rejected by the Supreme Court. The Court held that "the specification must enable the full scope of the invention . . . The more one claims, the more one must enable."[15] To boot, the Court ruled that this followed squarely from Section 112's "simple statutory command" and was reinforced by the Court's opinions in "*Morse, Incandescent Lamp*, and *Holland Furniture.*"[16]

Yet even with this full scope rule, the Court did not demand explicit disclosure of every embodiment in every possible case. The Court noted that a specification need not "always . . . describe with particularity how to make and use every single embodiment within a claimed class."[17] The Court explained that a broad claim may be merited even without explicit and particular description of each claim member when a specification discloses "'some

13. Brief for Petitioners at 22, *Amgen*, 143 S. Ct. 1243 (No. 21-757).

14. Brief of Intellectual Property Professors as Amici Curiae in Support of Petitioners at 9, *Amgen*, 143 S. Ct. 1243 (No. 21-757).

15. *Amgen*, 143 S. Ct. at 1254.

16. *Id.*

17. *Id.*

general quality . . . running through' the class that gives it 'a peculiar fitness for the particular purpose.'"[18]

In addition, the Court left room for its earlier decisions like *Wood v. Underhill*[19] and *Minerals Separation v. Hyde*[20] that allowed for some experimentation in the specification. Ultimately the Court held that "a specification may call for a reasonable amount of experimentation."[21] Here the Court refused to delineate in detail how much experimentation was allowable. The Court simply noted that "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art."[22]

But despite the lack of a bright line rule, one thing was made clear: the experimentation required by Amgen's patent was not the kind that could support Amgen's broad claim. "Amgen has failed to enable all that it has claimed, even allowing for a reasonable degree of experimentation."[23] From this holding some important conclusions can be gleaned. After all Amgen has argued that "[i]t was undisputed that, by following the patents' roadmap, skilled artisans can generate other claimed antibodies every time. The roadmap employed 'routine and well-known' methods, including 'automated high-throughput techniques' to generate additional antibodies 'quickly, efficiently, and cheaply.'"[24] And that characterization of their 'roadmap" is scientifically accurate. The roadmap would produce an antibody every time and their associated techniques were well known and routine. In one sense of the word then the type or amount experimentation required by the 'roadmap' was not particularly onerous. Yet this was not enough for the Court. Instead, there was something categorically defective about the type of experimentation that Amgen's patent required. The Court held that Amgen's roadmap was just a trial-and-error search for new antibodies. It did not matter that the method would produce result 'every time' nor that it was 'routine.' A trial-and-error method was different in kind from other allowable experimentation. To help highlight the difference the Court cited an analogy from our brief:

> Think about it this way. "Imagine a combination lock with 100 tumblers, each of which can be set to 20 different positions." Brief for Intellectual Property Law Professors and Scholars as Amici Curiae 20. "Through trial and error, imagine that an inventor finds and discloses 26 different successful lock combinations." *Ibid.* But imagine, too, "that the inventor tries to claim much more, namely all successful combinations," while instructing others "to randomly try a large set of combinations and then record the

18. *Id.* (quoting The Incandescent Lamp Patent, 159 U.S. 465, 475 (1895)).
19. Wood v. Underhill, 46 U.S. 1 (1846).
20. Minerals Separation v. Hyde, 242 U.S. 261 (1916).
21. *Amgen*, 143 S. Ct. at 1255.
22. *Id.*
23. *Id.* at 1256.
24. Brief for Petitioners at 49, *Amgen*, 143 S. Ct. 1243 (No. 21-757) (citations omitted).

> successful ones." *Id.*, at 21. Sure enough, that kind of "roadmap" would produce functional combinations. *Ibid.* But it would not enable others to make and use functional combinations; it would instead leave them to "random trial-and-error discovery." *Ibid.* Like many analogies, this one may oversimplify a bit, but it captures the gist of the problem.[25]

Though of course Amgen deals with monoclonal antibodies, trial and error techniques exist in many areas. And though it is a perfectly legitimate mode of finding inventions, it will always be a relatively narrow invention that supports only modest claims.[26] Throughout biochemistry, wherever screening techniques are being used or other such methods that can be seen as trial and error based, similarly broad, functional claims will not be supported by simply disclosing the trial-and-error technique without more. The key is that the enabling method should be instructing the person of ordinary skill to make something that has been described in the specification – the enabling method needs to be describing how to make something that has already been invented. In contrast, Amgen's roadmap taught how to invent new antibodies; it was not a method to make antibodies that were Amgen had already invented.

Beyond monoclonal antibodies and Section 112, the case may be significant even more broadly to the overall structure of patent law. When significant scholarly support emerged for Amgen's positions, I was surprised. In my view, Amgen's broad, functionally defined claims were wholly unsupported by Amgen's specification. A central feature of my view of patent law is that the claims cannot exceed the disclosed invention. Yet the scholars supporting Amgen argued for reversing the Federal Circuit and that invalidating Amgen's claim was some great disaster needing redress. I surmised that the only possible source for this sharply divergent take on the case must have its roots in some deep yet unspoken assumptions about the basic structure of the patent system. These scholars must have been seeing enablement, antibody science, and likely the whole patent system quite differently than I was. This section will try to understand what those two differing world views look like. And having outlined them, this section concludes by judging the continued viability of those worldviews in light of the Court opinion in *Amgen*. Though its reasoning is curt, this section concludes that the worldview that I believe was animating the support for petitioner is just no longer tenable.

As best as I can surmise, support for Amgen needed to understand enablement and the patent system with these tenets:

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25. *Amgen*, 143 S. Ct. at 1257.

26. *See generally* Oskar Liivak, *Finding Invention*, 40 FLA. ST. U. L. REV. 57 (2012) (arguing that inventions found by trial and error are inherently narrow inventions).

1) Claim scope exists as a continuously variable reward for the scientific contributions provided by the disclosure.

2) Enablement just requires the specification to teach how to make (and use) the embodiments of *the claimed subject matter* without undue experimentation.

3) The question of what specific things (antibodies in this case) were conceived by Amgen is just not central to the analysis. The invention is defined as whatever the specification would enable persons of skill to make and use it. It need not be limited to things conceived by the inventor.

In such a worldview, Amgen's patent claim could perhaps pass muster. After all, their "roadmap" was a way to make antibodies that meet the limitations of the claim. In fact, their "roadmap" is a rather easy, very nearly routine way to make such antibodies. It will consistently make such antibodies every time it is employed. That the "roadmap" could be seen as a trial-and-error search or as a research plan for future inventing was just irrelevant. And accordingly, Amgen's broad claim could be defensible *if that worldview were adopted*.

I think the above worldview is quite wrong and not supported at all by the statute and the history of patent law. I think about basic patent law and Section 112 quite differently:

1) The story begins prior to any patent lawyer's involvement. It begins with the inventor conceiving of a set of solutions to some problem: the invention.

2) Section 112 requires the patentee to document that conception in all its permutations.
    a. Written description requires a written description of the things the inventor conceived.
    b. Enablement requires a teaching of how to make and use the things the inventor conceived.

3) The claims can only cover an inventor's disclosed *invention*.

The focus of the specification and Section 112 is on the invention: the inventor's definite and permanent solution to the problem at hand. In this worldview, Amgen's "roadmap" cannot be used to support enablement because it is a method for finding the invention in the first place. It is not instructions for making or using antibodies that have already been found. This

distinction was the focus of the combination lock analogy from our brief that was adopted by and cited by the Court. A trial-and-error method for searching for a solution is critically different from the instructions you would give to someone if you were trying to teach them how to make or use a solution that you have already found. Accordingly, in a world where the disclosure requirements are centered on the things actually invented by the patent applicant, Amgen's "roadmap" categorically cannot enable as it does not teach how to make something that was already invented. The Court's opinion certainly does not explicitly decide any worldview, but I think it implicitly makes the world view supporting Amgen much harder to sustain. Thank you and I look forward to your questions.