

AI and Enablement After *Amgen v. Sanofi*: Implications for Life Sciences Patents

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Artificial intelligence (AI) is rapidly becoming a standard tool in life sciences research, from predicting new drug candidates to streamlining synthesis routes. At the same time, the Supreme Court's decision in *Amgen v. Sanofi* heightened scrutiny of the enablement requirement under 35 U.S.C. §112.

Together, these developments raise an emerging question: When AI assists in discovery, does it strengthen an inventor's case for enablement, or expose the patent to new validity challenges?

The Supreme Court's *Amgen* Decision: A Narrowing of Enablement for Genus Claims

The Supreme Court in *Amgen v. Sanofi* affirmed the invalidation of Amgen's antibody patents for lack of enablement. The patents at issue claimed "the entire genus" of antibodies capable of (1) binding specific amino acid residues on PCSK9 and (2) blocking PCSK9 from binding to LDL receptors.

Amgen disclosed the amino acid sequences of 26 such antibodies and described two methods that could, in theory, be used to identify other antibodies with the claimed functions. Sanofi argued that these methods amounted to little more than trial and error, leaving potentially millions of antibodies within the claimed genus undisclosed and unenabled. The district court and the federal circuit agreed, and the Supreme Court affirmed.

The Court emphasized several key points:

- **Breadth vs. Disclosure:** "The more a party claims...the more it must enable." A patent that seeks to monopolize a broad class of embodiments must provide a correspondingly robust disclosure
- **No "Research Assignments":** A specification cannot shift the burden to skilled artisans to engage in "painstaking" trial-and-error experimentation. The two methods Amgen described—screening antibodies and substituting amino acid components—were deemed little more than research assignments
- **Not a Bright-Line Rule:** The Court clarified that a specification need not always describe every embodiment in detail. General qualities may suffice if they reliably allow skilled artisans to make and use the full scope of what is claimed

In short, the Court reaffirmed that enablement is a fact-specific inquiry, but one where broad

functional genus claims face heightened scrutiny.

Where AI Fits In: A Double-Edged Sword for Enablement

Against this backdrop, AI raises novel questions for enablement. While the USPTO has ruled that AI cannot be named an inventor on a patent application, it has not yet addressed the use of AI in supporting enablement. Life sciences researchers can now use predictive AI systems to propose new compounds, optimize structures, and identify therapeutic candidates far more efficiently than traditional methods. These tools could reshape how courts evaluate whether a patent is enabling under §112.

- **AI as a Strength:** If AI allows skilled artisans to reliably predict and synthesize compounds within a claimed genus, patentees may argue that fewer concrete examples are needed in the specification. AI could effectively lower the threshold for "undue experimentation" by making discovery more predictable
- **AI as a Weakness:** On the other hand, if a patent disclosure omits critical details about the AI methods or data needed to practice the invention, challengers may argue that the patent fails to enable its full scope. Heavy reliance on proprietary AI models could suggest that the specification itself is insufficient, because only those with access to similar AI systems could reproduce the invention

For example, a patent claiming a broad genus of compounds identified through AI might face arguments that, without disclosure of the AI training data, algorithms, or methodology, the patent merely sets forth a functional goal, echoing the Court's concern in *Amgen* about research assignments.

In addition, patent applicants may want to consider including in the specification an example showing how AI was used to generate a molecule/compound that meets the functional limitations of the genus claim. Rather than just asserting (either in the specification or later in response to an enablement challenge to the patent) that AI can be used to create additional species within the scope of a functional genus, a concrete example showing that AI succeeded in doing so without undue experimentation could go a long way to supporting the functional breadth of the claim.

Litigation and Prosecution Implications

- **For patentees:** AI could be leveraged to argue that practicing the invention is less burdensome than in the past, supporting enablement. But patentees should anticipate scrutiny of whether their disclosure teaches the invention independent of the AI system
- **For challengers:** Defendants may argue that patents relying on undisclosed AI processes are non-enabled, particularly when claims encompass broad functional classes. Expect AI to feature in invalidity defenses alongside traditional enablement arguments

- **At the USPTO:** Examiners may begin probing whether claimed inventions can be practiced without reliance on undisclosed AI tools, especially for chemical and biotech applications

Practical Takeaways for Life Sciences Companies

1. **Reassess patent drafting strategies.** Consider whether to describe AI methods, inputs, or outputs in the specification, particularly when they are central to identifying or practicing the invention
2. **Document AI use internally.** Invention disclosure forms should capture whether and how AI was used in the discovery process. This can help clarify inventorship and support enablement
3. **Anticipate litigation arguments.** Be prepared for challengers to frame AI as evidence that a disclosure is incomplete or as a reason the patentee's claimed genus is overly broad
4. **Monitor evolving law.** Courts have not yet squarely addressed AI's role in enablement, but *Amgen* provides a framework challengers are likely to adapt to AI-driven discoveries

Conclusion

As AI becomes more deeply integrated into life sciences R&D, questions about its impact on patent law will only grow more pressing. Companies that proactively address how AI is used in their discovery and disclosure practices will be better positioned to defend their patents against enablement challenges and to adapt as courts and the USPTO develop guidance in this area. Careful coordination between R&D teams, in-house counsel, and outside IP advisors now can help ensure today's innovations remain enforceable tomorrow.