

Enablement Doctrine: Current Law and Best Practices

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What is Enablement?

35 U.S.C. § 112(a)

a patent's specification must describe the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art' to 'make and use' the invention

- Ensures the public can practice the invention without *undue* experimentation after the patent term
- Enables a *skilled person* in the art to make and use the claimed invention
- No need to disclose what is well-known in the art
- No need to hold the hand of a skilled artisan
- Some effort and experimentation is acceptable

Enablement vs. Written Description

- **Enablement:** Teaches others how to use the invention.
 - Test: Can the invention be practiced without undue experimentation?
- **Written Description:** Shows the inventor was in possession of the invention at filing.
 - Test: Is the claimed invention clearly described?
- Enablement failures involve lack of technical detail; written description failures involve unsupported claims

Amgen: Supreme Court (2023)

U.S. Patent No. 8,829,165:

- 1. An **isolated monoclonal antibody**, wherein, when bound to **PCSK9**, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and **wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.**

U.S. Patent No. 8,859,741:

- 1. An **isolated monoclonal antibody that binds to PCSK9**, wherein the isolated monoclonal antibody binds an epitope on PCSK9 comprising at least one of residues 237 or 238 of SEQ ID NO: 3, and **wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.**

Amgen: Supreme Court Takeaways

- **One enablement standard** for all technologies
- A “**reasonable amount**” of experimentation is permissible
- For claims covering a class/genus of compositions of matter, specification “must enable a [PHOSITA] to make and use the entire class”
 - Specification need not describe with particularity how to make and use every embodiment within the claimed class, but “research assignments” are not sufficient
 - Can give one, or a few, examples if specification also discloses a general quality/feature that gives the class of claimed matter a “peculiar fitness for the particular purpose”
- Court did not explicitly address **continued relevance of *Wands* factors**, but parties agreed during oral argument that this was not at issue

Amgen: Subsequent Cases and Updates

- *Baxalta v. Genentech*
- *In re Xencor (Chamberlain)*
- USPTO Enablement Guidance (January 2024)

Enablement of AI-Related Inventions

- Not talking about AI as an inventor (different discussion entirely)
- Is AI “unpredictable”
 - LLMs, math, computer science are all considered “predictable”
 - AI’s results are unpredictable
- It’s not just high-level GenAI
 - Autonomous vehicles
 - Drug discovery
 - Robotic surgery
 - Medical imaging/diagnosis
- PTO Request for comment
 - How can patent applications for AI inventions best comply with the enablement requirement, particularly given the degree of unpredictability of certain AI systems?
 - How, if at all, does the availability to a PHOSITA of AI as a tool impact the enablement determination under 35 U.S.C. 112(a)?

The Federal Circuit's Current View

- *In re Starrett* (post-Amgen) 2023 U.S.P.Q.2d 684. (Fed. Cir., Jun. 8, 2023)
 - Claims included elements related to machine learning tasks aimed at processing biological system data to recover various forms of representations, such as imagery, sounds, or feelings.
 - PTAB affirmed the Examiner's enablement rejection of all claims
 - The PTAB noted that claim 1 contained forty-seven “or” clauses, potentially covering over 140 trillion embodiments, insufficient specification guidance for a POSA to practice the full scope of the claimed invention without undue experimentation.
 - The Federal Circuit affirmed. The court found that the application's disclosure amounted to little more than a “research assignment,” requiring undue experimentation to implement the claimed invention.

Keys to AI Enablement

- For AI inventions, provide details about:
 - The specific AI algorithms or models used
 - The training data and processes
 - The hardware and software environment
 - Any specialized parameters or configurations
- The level of detail required depends on the complexity of the AI system and the state of the art
- Examiners and courts may require more extensive disclosure for cutting-edge AI technologies to ensure that the enablement requirement is met

What are the Examiners Saying?



hkb1130 • 7mo ago •

On the enablement side, I'd imagine that the expanding reliance on AI tools might increase the amount of experimentation required to reach the "undue" level.

↑ 6 ↓ Reply Award Share ...



SolderedBugle • 7mo ago •

Someone is paying the PTO money to get something with no value? Nice hypothetical.

The PTO recently sent out a reminder about the duty of candor with respect to AI.

↑ 7 ↓ Reply Award Share ...



ashakar • 7mo ago •

🏆 Top 5% Commenter

Well first, AI can't be inventors.

If the invention is the generative AI, most of those claims aren't enabled at all. If they don't include the trained model, the training data or even the hyperparameters we really should be rejecting them for lack of enablement or best mode. Unfortunately, ain't nobody got time for that.

↑ 3 ↓ Reply Award Share ...



PennyForever • 7mo ago •

We are expected to have at least a basic understanding of the physics/technology of our respective arts to be able to weed out the proverbial perpetual motion machines; so yes, if you really don't see how the claimed invention can function, as disclosed, then make all of the appropriate rejections, 112 and/or 101. Make the record clear, and provide Applicant the opportunity to clarify the record.

↑ 1 ↓ Reply Award Share ...



[deleted] • 7mo ago • Edited 7mo ago •

I'm not exactly sure what your question is (are you referring to generative AI models writing patent applications or actually inventing things from scratch?), but baked into the MPEP and the case law is a presumption that disclosures are enabled. In order to apply an enablement rejection the examiner must have a *reasonable basis* for questioning whether the invention is enabled. The burden is on the examiner to explain that basis.

By the way, I reckon that AI models cannot receive patents (as they are not people), so most likely such an application wouldn't make it past a 35 USC 101 rejection.

Tips for Successful Enforcement

- Ensure sufficient disclosure to avoid enablement problems – include all conceivable examples
- Claims must be fully supported to meet the written description requirement – don't go overbroad and/or carefully draft dependent claims
- Avoid claiming more than what was originally disclosed
- Litigation position needs to be realistic in terms of scope