When AI drives discovery — Patents and drug development

By Carla Kim, Esq., Sterne, Kessler, Goldstein & Fox PLLC

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The call comes late on a Friday. Your general counsel has just learned that the company's most important patent — the composition-of-matter patent covering its approved peptide drug for a metabolic disease — has been attacked in federal court. A generic manufacturer wants to clear the path for launch.

The theory is not that the claimed peptide was already known, or that the patent fails to enable the drug. It is more unsettling: The patent is invalid and unenforceable because no human being invented the claimed compound, and the company misled the U.S. Patent and Trademark Office (USPTO) by naming you, the CEO, and your co-founders as inventors.

The timing could not be worse. The drug was approved years ago, and regulatory exclusivity expires in about a year. The challenged patent, if it survives, could protect the product for another decade; if it falls, generic entry could arrive far earlier than expected, with the company's lead asset — and perhaps the company itself — turning on a question few boards were asking when the application was filed: Who, exactly, conceived the invention?

Then the facts get worse. The internal record will show that the claimed peptide was not conceived by any founder or scientist in the conventional sense. The AI platform generated the peptide's structure, identified its use, selected the target indication, designed the validation cascade, and specified the assays to confirm potency, selectivity, pharmacokinetics, and safety.

The research team followed the AI's instructions, ran the tests it directed, and confirmed the results it predicted. AI took the company from discovery to FDA approval in record time and appeared to secure a decade of additional exclusivity. But the same autonomy that made the program so fast now threatens the patent at the center of that strategy. What should the company have done differently?

Current patent law

Major patent systems, including the United States, require a human inventive contribution. The U.S. Court of Appeals for the Federal Circuit confirmed this in *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022), holding that only a natural person can be an "inventor" under the Patent Act, and the USPTO's 2025 inventorship guidance confirms that no separate or modified standard applies to AI-assisted inventions — the ordinary conception analysis governs regardless of whether AI tools were used. U.S. Patent & Trademark Office, Revised Inventorship Guidance for AI-Assisted Inventions (Nov. 26, 2025), https://bit.ly/4pb52tM.

> *Conception requires a definite and permanent idea of the complete invention in the mind of an inventor,* Burroughs Wellcome Co. v. Barr Labs., Inc., *40 F.3d 1223 (Fed. Cir. 1994); and to be named, the inventor under* Thaler v. Vidal *has to be human.*

The European Patent Office reached a similar result in the DABUS proceedings (J 8/20) — the exposure runs across a company's global portfolio, not just the United States.

Conception requires a definite and permanent idea of the complete invention in the mind of an inventor, *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223 (Fed. Cir. 1994); and to be named, the inventor under *Thaler v. Vidal* has to be human. If AI conceived the claimed peptide and the human team merely carried out the validation work it directed, the patent may lack a legally sufficient human inventor.

Section 256 can correct certain human inventorship errors, but it cannot supply a human inventor where none exists. And if the company understood the peptide's true AI origin but named human inventors anyway, the challenge may extend beyond invalidity to inequitable conduct.

Does this mean patent protection is unavailable for AI-discovered drugs? Not necessarily. Even if the AI-generated peptide is a problematic starting point for inventorship, the strategy does not have to end there. The focus should shift to the human-guided development work that turns the AI's output into a therapeutic product — selection, modification, formulation, clinical positioning, or other development choices that create protectable inventions beyond the raw AI output.

None of these approaches makes the underlying AI-generated peptide itself patentable — that inventorship problem does not go away. The goal is not to cure it, but to build a broader web of exclusivity around it, so the overall portfolio is stronger than the single vulnerable composition-of-matter claim.

Modifying AI-generated molecules

One way to reduce inventorship risk is to make the claimed invention reflect human-guided development rather than the AI's raw output. This assumes the AI-generated molecule was conceived without a legally sufficient human inventor. It also does not separately address whether AI itself can be named as an inventor.

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To build that human contribution into the claimed invention, researchers may take an AI-identified peptide and modify it to extend half-life — attaching a fatty acid, Fc domain, or albumin-binding moiety — or make structural changes to improve stability, manufacturability, or route of administration: substituting residues to reduce aggregation, enhance folding, or improve solubility. Patent counsel should work with scientists early to identify which changes were driven by human judgment and document the rationale behind them.

This is where patentability and inventorship diverge, and the distinction is the crux of the strategy. In that assumed posture, the question is not whether AI may be an inventor, but what protection remains available when the record does not support naming a human inventor for the AI-generated molecule itself.

Assume the AI-generated peptide is novel and non-obvious over the prior art. When human researchers deliberately modify that peptide, the resulting molecule may also be novel and non-obvious — because it incorporates the AI-generated peptide's patentable features — without the modification needing to be independently inventive in isolation. Novelty and non-obviousness can rest largely on the AI-generated peptide, while inventorship rests on the human contribution that turned it into the claimed form.

The point is not that the modification must itself be the breakthrough; under the current law, it is that researchers used the AI's output as a tool and then developed it into a therapeutically effective form selected for patent protection.

Combination and co-formulation strategies

The same principle applies whether the claimed molecule is the original AI-generated peptide or a human-modified version: Patentability can derive from the peptide while inventorship derives from human decisions about how to use it. Researchers may pair the peptide with a known biologic or small-molecule agent, select excipients that improve stability or bioavailability, or develop a co-formulation that improves tissue penetration or addresses dosing limitations. The stronger the record of those decisions, the easier it is to defend the claimed invention as more than the raw AI output.

That portfolio is narrower than a clean composition-of-matter claim, but it still carries real commercial value. Layered protection around human-developed combinations, formulations, and routes of administration can make generic or biosimilar entry more difficult and preserve leverage even where the original molecule presents inventorship risk.

Method-of-treatment and clinical innovation

The same logic extends downstream into clinical development. Patentable subject matter can arise from human decisions about dose ranges, dosing schedules, treatment durations, combination regimens, and responsive patient populations. Companies should structure development to capture those decisions as they are made and preserve them as sources of inventorship, rather than reconstructing the record later.

The business case for building in human inventorship

Some will ask why a company should slow down at all if AI can generate the structure, propose the use, and direct the validation work on its own. The answer is that patent strategy is not only about speed to discovery; it is about protecting the investment required to turn a promising molecule into an approved drug. Building human contribution into the program deliberately may add time up front, but it can secure a far stronger exclusivity position on the back end.

For a product requiring years of clinical development and substantial capital, that extra time can be the difference between a vulnerable AI-generated asset and a patent-protected drug with a meaningful 20-year exclusivity framework. (For guidance on building that record before an application is even filed, see Carla Kim and Dan Block, "When AI Is the Inventor, the Patent Problem Starts Before Filing," Law.com (June 18, 2026), https://bit.ly/4y7OgQn)

Conclusion

The central lesson is simple: Do not let AI alone define the invention. In the opening hypothetical, the risk turns not on whether the peptide lacked therapeutic promise, but on whether the company can point to a legally meaningful human inventive contribution when the patent comes under attack, just as regulatory exclusivity is nearing expiration.

AI may identify a novel and non-obvious molecule, but companies should deliberately build and document the researcher-driven work that turns that output into a therapeutically effective product selected for patent protection — structural modification, formulation, combination strategy, dosing, patient selection, clinical development decisions, or more likely some combination of them.

If the general counsel can show that the company made those human-driven choices, and has a contemporaneous record explaining who made them and why, the GC and CEO should have far less to worry about when the Friday-night litigation call comes. The goal is not to slow innovation for its own sake. It is to ensure that human researchers do more than confirm the AI's answer — they drive the development path that turns an AI-generated lead into the claimed drug.

About the author

Carla Kim is a director in **Sterne, Kessler, Goldstein & Fox's** biotechnology and chemical practice group and serves as a co-chair of the firm's patent prosecution practice. She advises a diverse group of biotechnology companies on building worldwide exclusivities around their products. She is based in Washington, D.C., and can be reached at ckim@sternekessler.com.

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