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AI IS INVENTING MOLECULES: WHY U.S. PATENT LAW MUST ALLOW OWNERS OF INVENTIONS TO FILE PATENT APPLICATIONS WITHOUT NAMING INVENTORS

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ABSTRACT

Artificial intelligence is already inventing or coinventing molecules. Whether identifying novel therapeutic uses for existing drugs, generating entirely new antibiotic structures, discovering first-in-class small molecules, or redesigning proteins with unprecedented properties, AI systems increasingly perform functions that closely resemble the inventive activities historically carried out by human researchers.

The USPTO's current approach, reflected in its 2025 Revised Inventorship Guidance on AI-Assisted Inventions, attempts to avoid this reality by treating AI as a mere laboratory tool. But legal fictions eventually collide with technological facts. The Revised Guidance obscures

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rather than resolves the central inventorship question. By declining to analyze AI contributions under the same standards applied to human contributors and by assuming that AI can never contribute to conception in a legally meaningful way, the Revised Guidance risks encouraging issuance of patents whose inventorship may ultimately prove incorrect and uncorrectable.

We propose that Congress should modernize the patent statutes so that patent applications may be filed by the legal or equitable owners of inventions without requiring identification of individual inventors. Such a framework would preserve the disclosure incentives that make the patent system valuable while avoiding increasingly artificial attempts to force AI-assisted innovation into doctrines developed for exclusively human inventors.

I. INTRODUCTION

Artificial intelligence ("AI") is no longer a speculative tool in drug discovery. It is already generating new molecular structures, identifying new therapeutic uses for existing drugs, and redesigning proteins with properties that exceed those achieved by human researchers. Yet the United States Patent and Trademark Office ("USPTO"), in its Revised Inventorship Guidance for AI-Assisted Inventions, has interpreted the Federal Circuit's decision in *Thaler v. Vidal*[1] to mean that AI should be treated merely as a sophisticated laboratory tool.[2] This legal fiction is becoming—and may soon become—untenable.

The Revised Guidance goes further than *Thaler*. It asserts that because AI cannot legally be a joint inventor,

[1] Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022) (holding only humans may be named as inventors), *cert. denied*, 143 S. Ct. 1783 (2023).
[2] Revised Inventorship Guidance for AI-Assisted Inventions, 90 Fed. Reg. 54636, 54636–37 (Nov. 28, 2025).

"there is no joint inventorship question to analyze."[3] This approach collapses two distinct inquiries into one: (1) who conceived the invention, and (2) who may legally be named as an inventor. The result is a structural trap.[4]

This article argues that the U.S. patent system is drifting toward a reckoning. The number of inventions generated wholly or partly by AI is increasing rapidly, particularly in pharmaceuticals and biotechnology. If AI provides a contribution that is "not insignificant in quality[] when . . . measured against the dimension of the full invention," as contemplated by *Pannu v. Iolab Corp.*,[5] the human participant's conception may be nonexistent or incomplete. In that circumstance, the patent may be filed and issued with incorrect inventorship. Because AI cannot be added as an inventor under current law, the error may be uncorrectable, and the patent would be invalid.

If the USPTO continues to insist that AI contributions should not be analyzed as part of inventorship and continues to treat AI as incapable of inventing or coinventing, the consequences will be severe: invalid patents, increased reliance on trade secrecy, reduced disclosure, and diminished investment in innovative drug research.

We propose a targeted statutory solution that fits well with the present U.S. patent statute. Several sections of

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[3] *Id.* at 54636.

[4] *See, e.g.,* Volpe Koenig, *If AI Can Be Rightfully Named As A Joint Inventor, Is The Patent Invalid*? JD SUPRA, (May 20, 2026), https://www.jdsupra.com/legalnews/if-ai-can-be-rightfully-named-as-a-6592719/, [https://perma.cc/JPP6-G5BE]; Brian Hausman, *Patent Invalidity Due to Incorrect Inventorship,* JD SUPRA, (June 2, 2026), https://www.jdsupra.com/legalnews/patent-invalidity-due-to-incorrect-1316391/ [https://perma.cc/N79P-MSSS] (demonstrating that commentators have recently noted potential problems with the proscription of naming AI as inventor or co-inventor).

[5] Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998).

the statute, such as the basic "Definitions" in 35 U.S.C. §§ 100(f), (g), and (h), already distinguish between the narrow term "individual," which refers to a human being, and the broader term "person," which includes both individuals and corporate entities.[6] Continuing with this statutory distinction, in Section VI(A) this article proposes amendments to (i) remove the requirement for human-only inventors by replacing the term "individual" with "inventive entity"; (ii) facilitate filing by legal or equitable owners—not just assignees; and (iii) remove the requirement for an oath in those Sections that require one. This approach preserves the constitutional structure of the patent system while aligning patent law with technological reality.

Before discussing the legal framework, it is useful to examine real-world examples of AI-assisted molecular inventions and to consider the relative conceptual contributions of humans and AI. In doing so, let us make clear at the outset that we do not—and cannot—provide legal opinions on the proper inventorship of the published instances of AI-assisted molecular inventions. We have neither a complete set of facts nor the human researchers' testimonies to reach anything approaching an informed opinion. At best, our analyses are a discussion on how one might apply the existing case law on inventorship to situations involving AI.

[6] *See* 35 U.S.C. §§ 100(f)–(h); *Thaler*, 43 F.4th at 1211 (noting that "'individual' . . . refers to human beings" and "'person' broadly include[s] . . . 'corporations . . . *as well as individuals*.'").

II. REAL-WORLD EVIDENCE THAT AI IS INVENTING OR COINVENTING MOLECULES

A. Drug Repurposing: Adalimumab for Castleman's Disease

A 2025 study published in the *New England Journal of Medicine* provides a compelling example.[7] Human researchers identified tumor necrosis factor ("TNF") signaling as a potential therapeutic target for idiopathic multicentric Castleman's disease ("iMCD").[8] In parallel, an AI system was prompted to evaluate the likelihood that each FDA-approved drug could successfully treat each disease.[9] The scale of that task is enormous. A rough estimate places the number of FDA-approved prescription drug products at approximately 24,000.[10] The total number of therapeutic indications is likely quite higher. AI ultimately identified adalimumab as its highest-ranked candidate for treatment of iMCD.[11] A patient suffering from treatment-refractory iMCD subsequently entered long-term remission after receiving adalimumab.[12]

Who conceived the new therapeutic use for adalimumab? Human researchers identified TNF signaling as a promising target.[13] Yet AI identified a specific therapeutic agent from among tens of thousands of

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[7] Melanie D. Mumau et al., *Identifying and Targeting TNF Signaling in Idiopathic Multicentric Castleman's Disease*, 392 NEW ENG. J. MED. 616 (2025), https://doi.org/10.1056/nejmc2412494.
[8] *Id.* at 618.
[9] *Id.*
[10] *FDA at a Glance*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/economics-staff/fda-glance [https://perma.cc/VDQ4-AAE8] (last visited June 14, 2026).
[11] Mumau, *supra* note 7, at 618.
[12] *Id.* at 618.
[13] *Id.*

possibilities.[14] Under the framework established in *Pannu*, whether AI's contribution was "not insignificant in quality" when measured against the invention as a whole is fundamentally a factual question.[15] It is precisely the type of inquiry routinely undertaken in disputes involving multiple human contributors. If the identifier of adalimumab was a human collaborator, would she legally be a co-inventor? Ignoring AI's contributions amounts to an anthropocentric approach to inventorship.

The USPTO's Revised Guidance nevertheless instructs examiners not to conduct a *Pannu* inquiry with respect to AI contributions.[16] Instead, AI contributions are to be treated as those of a laboratory tool, while human participants are presumed to be the sole inventors.[17] Although the Revised Guidance acknowledges that human inventors must still possess complete conception,[18] it leaves unanswered a critical question: what happens when the human participant lacks complete conception or lacks conception altogether?

B. De Novo Antibiotic Design

Aarti Krishnan and colleagues reported another striking example in 2025.[19] Using generative deep-learning models, researchers designed novel antibiotic compounds without supplying predefined chemical fragments.[20] The AI

[14] *Id. See also FDA at a Glance*, *supra* note 10 (stating there are approximately 24,000 FDA-approved prescription drug products).
[15] *See* Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998).
[16] Revised Inventorship Guidance for AI-Assisted Inventions, 90 Fed. Reg. 54636, 54636 (Nov. 28, 2025).
[17] *See id.* at 54637.
[18] *Id.*
[19] Aarti Krishnan et al., *A Generative Deep Learning Approach to De Novo Antibiotic Design*, 188 CELL 5962, 5963, 5975 (2025), https://doi.org/10.1016/j.cell.2025.07.033.
[20] *Id.* at 5971, 5975.

system generated nearly thirty million candidate structures, filtered those candidates according to predetermined criteria, and alone or with human collaborators ultimately selected twenty-two compounds for synthesis and testing.[21] One compound, designated DN1, demonstrated potent activity against *Staphylococcus aureus*.[22]

The human researchers did not know DN1's structure before the AI system generated it. Their contribution consisted of defining the problem, establishing evaluation criteria and—apparently—focusing the search on testable compounds. AI supplied the rest.

If the human contribution was limited to identifying the problem to be solved, existing inventorship doctrine suggests that the human participants may not qualify as inventors at all. Alternatively, if the invention emerged through an iterative back-and-forth conceptual interaction between humans and AI analogous to intellectual collaboration among human researchers, AI and humans may properly be viewed as coinventors.

The Revised Guidance largely sidesteps this issue by declining to analyze AI contributions under the standards traditionally applied in joint-inventorship analysis.[23]

C. First-in-Class Small Molecules: Rentosertib

In 2025, Insilico Medicine reported that it used AI to identify both a novel therapeutic target—a kinase known

[21] *Id.* at 5971.
[22] *Id.* at 5974.
[23] *See* Revised Inventorship Guidance for AI-Assisted Inventions, 90 Fed. Reg. 54636, 54637 (Nov. 28, 2025).

as TNIK—and a novel inhibitor of that target, rentosertib.[24] Remarkably, rentosertib entered Phase II clinical trials for idiopathic pulmonary fibrosis approximately eighteen months after target identification.[25]

Human researchers directed AI to search for molecules capable of binding to selected regions of TNIK.[26] AI-generated candidate structures optimized for binding affinity, novelty, and medicinal-chemistry characteristics.[27] Human researchers synthesized and tested those structures.[28]

Again, AI appears to have contributed more than routine experimentation. It generated candidate molecular structures that completed the inventive concept. Under traditional inventorship principles, the human researchers' conception may have been incomplete without those AI-generated contributions.

D. Protein Redesign: Thermostable Chitinase

In 2026, Tencent's Ontology Reinforcement Iteration ("ORI") system reportedly generated, synthesized, tested, and iteratively improved chitinase enzyme sequences.[29] Ultimately ORI produced a chitinase enzyme

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[24] Feng Ren et al., *A Small-Molecule TNIK Inhibitor Targets Fibrosis in Preclinical and Clinical Models*, NATURE BIOTECHNOLOGY, Jan. 2025, at 63, 63, https://doi.org/10.1038/s41587-024-02143-0.

[25] *See id.* at 63, 72. *See also* Vera Malherio et al., *The Potential of Artificial Intelligence in Pharmaceutical Innovation: From Drug Discovery to Clinical Trials*, 18 PHARM., May 2025, at 1, 20–21, https://doi.org/10.3390/ph18060788.

[26] Feng Ren, *supra* note 24, at 64.

[27] *Id.*

[28] *Id.*

[29] Bing He et al., *Functional Protein Design and Enhancement with Ontology Reinforcement Iteration,* NATURE COMMC'NS, May 2026, at 1, 1, https://doi.org/10.1038/s41467-026-69855-6. *See also Sino Biological's Cell-Free Protein Synthesis Supports Tencent AI for the Life Sciences Lab's Protein Design Study Published in Nature*

that remained active at approximately eighty-five degrees Celsius—far above the temperature tolerance of naturally occurring counterparts.[30]

ORI's generate/test/update cycle bears little resemblance to a microscope, chromatograph, or database. It is not merely collecting information. It is proposing solutions, evaluating outcomes, and refining future proposals based on prior results.[31]

Across all these examples, AI appears to be performing conceptual work that courts historically would have characterized as inventing or coinventing if performed by human researchers. The growing disconnect between technological reality and existing inventorship doctrine therefore warrants closer examination of the governing case law.

III. WHAT EXISTING HUMAN INVENTORSHIP CASE LAW TELLS US

Existing inventorship jurisprudence provides a useful framework for analyzing AI-assisted inventions.[32]

Communications, SINO BIOLOGICAL, (May 28, 2026), https://www.sinobiological.com/news/sino-biological-supports-ai-protein-design [https://perma.cc/UXR4-KT47].

[30] *Sino Biological's Cell-Free Protein Synthesis Supports Tencent AI for the Life Sciences Lab's Protein Design Study Published in Nature Communications*, *supra* note 29.

[31] Bing He et al., *supra* note 29, at 1.

[32] *See, e.g.,* Regents of the Univ. of Cal. v. Broad Inst., Inc. 136 F.4th 1367, 1378 (Fed. Cir. 2025) ("Conception is defined as 'the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice. Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.'" (quoting Burroughs Wellcome Co. v. Barr Lab'ys, Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994) (citation omitted))). *See also, e.g.,* Pannu v. Iolab Corp., 155 F.3d 1344, 1351

Our review of the case law reveals two recurring categories of inventorship disputes: (1) cases in which an alleged inventor lacked complete conception of the invention, and (2) cases in which the alleged contribution of an additional collaborator was deemed insignificant because the named inventor already possessed a complete conception. These two categories offer a useful lens through which to evaluate human-AI collaborations. They give us court-legitimized illustrations of what are "insignificant" or "not-insignificant" contributions to complete conceptions.

A. Human Conception Is Nonexistent or Incomplete

One of the most fundamental principles of inventorship law is that merely identifying a problem to be solved does not constitute conception of an invention.[33] In *Ex parte Smernoff*, the Board held that a person who merely proposes a problem is not necessarily an inventor.[34] Inventorship requires conception of the solution, not simply recognition of the need for one.

This principle appears in *University of Colorado Foundation, Inc. v. American Cyanamid Co.*[35] There, Ellenbogen was originally named as an inventor but was

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(Fed. Cir. 1998) (stating that when two or more inventors contribute to the conception, each joint inventor must "(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.").

[33] *See Ex parte* Smernoff, 215 U.S.P.Q. 545, 547 (Pat. & Tr. Office Bd. App. 1982).

[34] *Id.*

[35] *See* Univ. of Colo. Found., Inc. v. Am. Cyanamid Co., 342 F.3d 1298, 1308 (Fed. Cir. 2003).

subsequently removed by the district court because he had no role in conceiving any part of the claimed invention.[36] However, because the order of the lower court was based on fraud and unjust enrichment—both of which are state causes of action—the Federal Circuit vacated the order and remanded with instructions to base the decision on federal patent inventorship law.[37] There is no record that the inventorship was eventually changed, but after that the Cyanamid patent was never enforced.

The importance of complete conception arose again in *Board of Education ex rel. Board of Trustees of Florida State University v. American BioScience, Inc.*[38] The district court had removed two named coinventors, Soon-Shiong and Desai, on the theory that they lacked a conception-level contribution to the claimed compounds.[39] The Federal Circuit reversed.[40] The court emphasized that the record contained no evidence that the concept of creating the specifically claimed taxol analogs originated elsewhere.[41] Because conception of the claimed compounds remained attributable, at least in part, to Soon-Shiong and Desai, their inventorship status could not be eliminated.[42]

The Federal Circuit's analyses underscore an important point. Conception is not satisfied merely by preliminarily identifying a broad research objective. Rather, conception must extend to the specific subject matter ultimately claimed. Drug-discovery cases illustrate the same principle.

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[36] Univ. of Colo. Found., Inc. v. Am. Cyanamid Co., 105 F.Supp.2d 1164, 1181 (D. Colo. 2000).
[37] *Univ. of Colo. Found., Inc.,* 342 F.3d at 1306–07.
[38] *See* Bd. of Educ. *ex rel.* Bd. of Tr. of Fla. State Univ. v. Am. BioScience, Inc., 333 F.3d 1330, 1339 (Fed. Cir. 2003).
[39] *Id.* at 1337.
[40] *Id.* at 1344.
[41] *Id.* at 1339.
[42] *See id.*

In *MacMillan v. Moffett*, the court held that MacMillan, who screened and tested compounds and was the first to confirm the activity of a particular structure, was not the inventor of the structure.[43] Moffett had previously conceived the specific structure and therefore remained the true inventor.[44] The court distinguished between conception of a compound and subsequent confirmation of its utility.[45]

By contrast, in *Bergendahl v. Sasai*, the Patent Trial and Appeal Board concluded that where no prior conception of an active compound existed, the researcher who identified the specific active structure among several was the inventor.[46] Because the claimed compound itself had not previously been conceived, the later identification of that structure constituted conception rather than mere verification.[47]

The need for specificity in conceiving a claimed chemical structure finds an echo in decisions dealing with the conception of specific synthetic methods. In *Falana v. Kent State University*, the inventions were a set of specific compounds claimed by chemical formulae.[48] Challenger Falana's method of synthesizing the compounds was considered a not-insignificant contribution to the conception of the compounds themselves.[49] The court reasoned that Falana's synthetic methods were not "'general method'" contributions, but specific, inventive synthesis protocols that supplied part of the conception of the claimed compounds.[50]

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[43] MacMillan v. Moffett, 432 F.2d 1237, 1240 (C.C.P.A. 1970).
[44] *Id.*
[45] *Id.*
[46] Bergendahl v. Sasai, No. 106,009, WL 3564534 at *7 (P.T.A.B. June 29, 2016).
[47] *Id.* at *8–9.
[48] Falana v. Kent State Univ., 669 F.3d 1349, 1358–59 (Fed. Cir. 2012).
[49] *See id.*
[50] *Id.*

These decisions have significant implications for AI-assisted drug discovery. Suppose all a human researcher does is instruct an AI system to identify a small-molecule therapeutic for a particular disease. AI generates a finite collection of candidate compounds, one of which ultimately becomes the claimed invention. In that circumstance, the situation may be analogous to *Ex parte Smernoff* and *University of Colorado Foundation,* where the originally named inventors merely proposed problems to be solved.[51] Our human researcher instructing AI may have conceived neither the specific compound nor the inventive solution.

More commonly, however, human researchers do provide substantial scientific guidance. They may identify a biological target, define a binding site, establish design constraints, or specify medicinal-chemistry objectives. The AI system then generates structures that satisfy those constraints and, as in *Falana*, may propose specific synthetic methods for making the structures. In such circumstances, the relationship begins to resemble the collaborative inventorship scenarios addressed by the Federal Circuit in cases such as *Pannu*. The question is no longer whether the AI contributed, but whether that contribution was sufficiently significant to complete or materially shape the claimed invention.

B. Human Conception Is Complete and Additional Contributions Are Insignificant

The second category of inventorship cases involves circumstances in which the named inventor already possessed a complete conception, and the alleged

[51] *See Ex parte* Smernoff, 215 U.S.P.Q. 545, 547 (Pat. & Tr. Off. Bd. App. 1982); Univ. of Colo. Found., Inc. v. Am. Cyanamid Co., 342 F.3d 1298, 1308 (Fed. Cir. 2003).

contributions of others were insufficient to justify inventorship status.

An example is *Vanderbilt University v. ICOS Corp.*[52] Vanderbilt argued that several of its researchers should have been named as coinventors of the claimed compound tadalafil.[53] The Federal Circuit rejected that argument.[54] Although Vanderbilt scientists had performed research related to phosphodiesterase inhibitors, the evidence failed to establish that the inventors of tadalafil relied upon Vanderbilt's work in conceiving the specifically claimed compound.[55] The alleged contributions therefore were not sufficiently connected to the claimed invention to justify coinventorship.[56]

Similarly, in *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, the Federal Circuit held that the inventors of AZT for the treatment of HIV/AIDS possessed a complete conception of the invention even though they remained uncertain whether AZT would ultimately prove effective in humans.[57] Researchers at the National Institutes of Health later confirmed AZT's antiviral activity in a model system, but confirmation did not transform them into coinventors.[58] The court explained that uncertainty regarding whether an invention will work does not necessarily indicate incomplete conception.[59] Once the inventors had identified AZT and formulated the idea of using it to treat HIV infection, conception was complete.[60] Subsequent experimental verification did not create

[52] Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297 (Fed. Cir. 2010).
[53] *Id.* at 1305.
[54] *Id.*
[55] *Id.* at 1306.
[56] *Id.* at 1305.
[57] Burroughs Wellcome Co. v. Barr Lab'ys, Inc., 40 F.3d 1223, 1231 (Fed. Cir. 1994).
[58] *Id.* at 1230–31.
[59] *Id.* at 1231.
[60] *Id.*

inventorship rights in those who merely confirmed the invention's effectiveness.[61]

In 2025, the Federal Circuit reaffirmed this principle in *Regents of the University of California v. Broad Institute, Inc.*[62] Although one party harbored doubts about whether CRISPR-based gene editing would function in eukaryotic cells, those doubts did not render conception incomplete.[63] The existence of uncertainty regarding operability is not equivalent to a failure of conception.[64]

Together, *Burroughs Wellcome*, *Vanderbilt*, and *Regents* establish an important boundary. If a human inventor possesses a complete conception and AI merely verifies or confirms that conception, the human remains the sole inventor. In those circumstances, AI functions much like the sophisticated laboratory equipment of the Revised Guidance.

The difficult cases are those in which AI does more than verify. When AI supplies the very structure, composition, or elucidation that completes the inventive concept, the analogy to conventional laboratory tools breaks down. AI's contributions are then not-insignificant and since AI cannot be named, the human's conception is incomplete.

IV. THE STRUCTURAL TRAP: INCORRECT INVENTORSHIP THAT CANNOT BE CORRECTED

The USPTO's current approach creates a significant risk for patents that are both incorrectly issued and legally uncorrectable.

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[61] *See id.* at 1230–31.
[62] Regents of the Univ. of Cal. v. Broad Inst., Inc., 136 F.4th 1367, 1378 (Fed. Cir. 2025).
[63] *See id.* at 1372, 1381–82.
[64] *See id.* at 1381–82.

Under 35 U.S.C. § 256(b), a patent may be invalid if inventorship errors cannot be corrected.[65] Historically, this provision has served as a safety valve. If an inventor is omitted inadvertently, courts and the USPTO possess mechanisms to correct the inventorship record.[66]

The limits of that corrective framework, however, were recently illustrated in *Fortress Iron, LP v. Digger Specialties, Inc.*[67] There, a patent was held invalid because a missing inventor could not be located and therefore could not be added to the patent.[68] Because the inventorship defect could not be corrected, the patent could not be saved.[69]

AI presents an even more difficult problem. The missing inventor in *Fortress Iron* at least existed as a natural person capable of being added if located.[70] AI, by contrast, is categorically excluded from inventorship under current law.[71] Even if a court were to conclude that an AI system contributed to conception in a manner that would satisfy the standards traditionally applied to human coinventors, current law provides no mechanism for correcting the inventorship record.

The consequence is straightforward. If AI supplied a contribution that was significant enough to render the named human inventor's conception incomplete, the original inventorship would be incorrect. Because AI

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[65] *See* 35 U.S.C. § 256(b) (stating "[t]he error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section.").
[66] *See id.*
[67] Fortress Iron, LP v. Digger Specialties, Inc., 171 F.4th 1310 (Fed. Cir. 2026).
[68] *Id.* at 1313, 1317.
[69] *Id.* at 1317.
[70] *See id.* at 1313.
[71] *See* Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022) (holding only humans may be named as inventors).

cannot be added to the patent, the error could not be corrected. The patent would therefore face invalidity.

The Revised Guidance largely avoids confronting this problem. By instructing the public to treat AI as a laboratory tool and by declining to recommend a conventional inventorship analysis of AI contributions,[72] the Revised Guidance assumes away the very issue that threatens the validity of future patents. Yet administrative guidance cannot eliminate the underlying legal question. Indeed, the Revised Guidance itself lacks the force of law. Courts remain free to interpret inventorship statutes independently and to apply traditional inventorship principles to emerging technologies. As Judge Plager observed in his concurrence in *In re Packard*, agency guidance cannot displace statutory requirements or judicial interpretations of patent law.[73]

Accordingly, the risk is not merely theoretical. As AI-generated inventions become more common, litigants will inevitably challenge patents on inventorship grounds. Courts will then be forced to determine whether AI contributions should be evaluated under the same conception-based framework applied in human inventorship disputes. If courts conclude that AI-generated contributions satisfy traditional inventorship standards, the patent system may find itself having issued patents that were invalid from the moment they were granted because the inventive entity cannot later be corrected.

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[72] *See* Revised Inventorship Guidance for AI-Assisted Inventions, 90 Fed. Reg. 54636, 54636–37 (Nov. 28, 2025).

[73] *See In re* Packard*,* 751 F.3d 1307, 1324 (Fed. Cir. 2014) (Plager, J., concurring).

V. CONSEQUENCES FOR DRUG DISCOVERY AND INNOVATION

The legal fiction that AI is incapable of inventing or coinventing is not merely a doctrinal curiosity. If maintained, it will have significant practical consequences for pharmaceutical and biotechnology innovation.

A. Increased Reliance on Trade Secrecy

The first consequence is likely to be increased reliance on trade secrecy. The patent system operates as a bargain between inventors and society. Inventors disclose their inventions to the public, and in exchange receive a limited period of exclusivity.[74] If innovators cannot reliably obtain valid patents on AI-assisted inventions, that bargain begins to break down.

This concern is particularly acute in the pharmaceutical sector. Companies developing AI-generated compounds may conclude that public disclosure creates unacceptable legal risks if resulting patents can later be challenged as invalid for incorrect inventorship. The rational response will be to withhold information whenever possible and to rely more heavily on proprietary databases, confidential research programs, and trade-secret protection.

Although trade secrecy is not always feasible in pharmaceuticals, e.g., due to FDA disclosure requirements for drug approval, the incentive to avoid disclosure will nonetheless increase. The result would be less public dissemination of scientific knowledge and a diminished ability of subsequent researchers to build upon earlier discoveries.

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[74] *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989) (stating that patent law encourages disclosure by providing limited exclusivity).

B. Reduced Investment

A second consequence is reduced investment in drug development. Modern pharmaceutical development requires enormous financial commitments. Bringing a new therapeutic product to market frequently requires investments measured in hundreds of millions or even billions of dollars.[75] These investments are typically justified by the expectation that resulting intellectual property rights will provide meaningful exclusivity.

If AI-generated inventions are vulnerable to invalidity challenges because inventorship cannot be corrected, investors and companies will face increased uncertainty regarding the enforceability of their patent portfolios. Uncertainty concerning ownership and validity of foundational intellectual property inevitably increases risk and decreases investment.

This effect may be especially pronounced in emerging therapeutic areas where AI-generated inventions form the core of the innovation strategy. Investors are unlikely to commit substantial capital to programs whose principal assets may ultimately prove unenforceable.

C. Global Competitive Consequences

A third consequence is potential international competitive disadvantage. At this writing, most jurisdictions around the world have adopted the same position as the U.S.: AI cannot be a named as an inventor.[76]

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[75] *See, e.g.,* CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY, (2021), https://www.cbo.gov/publication/57126#_idTextAnchor000 [https://perma.cc/SYC9-NMWD] (stating that pharmaceutical companies spent $83 billion on research and development in 2019).

[76] *See*, *e.g.,* Alice Wang, *Specialist Chapter: Navigating AI Inventorship, Patentability and Disclosure Requirements in China,*

Certain patent regimes, such as South Africa's registration-based system or Germany's model registration system, have more flexible approaches to AI-assisted inventions.[77] When in the future, as other countries become aware of problems with side-stepping the role of AI in the conception of pharmaceutical or biotechnology inventions, they may, whether through legislation, administrative practice, or judicial interpretation, create pathways that better accommodate such inventions.

If the United States remains committed to a framework that treats AI-generated inventive contributions as legally irrelevant, innovators may then seek protection and commercialization opportunities elsewhere. Over time, this could erode the United States' historical leadership in pharmaceutical and biotechnology innovation.

The issue is therefore not merely one of doctrinal consistency. It is also one of national competitiveness and innovation policy. It is preferable to think ahead than to follow later.

Europe and the United States, IAM, (Aug. 18, 2025), https://www.iam-media.com/review/the-patent-prosecution-review/2026/article/specialist-chapter-navigating-ai-inventorship-patentability-and-disclosure-requirements-in-china-europe-and-the-united-states [https://perma.cc/R4JC-8PCK].

[77] *See* Brett J. Smith, *AI Inventorship and the Emerging Global Consensus*, JD SUPRA, (July 23, 2026); https://www.jdsupra.com/legalnews/ai-inventorship-and-the-emerging-global-5831834/?origin=CEG&utm_source=CEG&utm_medium=email&utm_campaign=CustomEmailDigest&utm_term=jds-article&utm_content=article-link [https://perma.cc/T2EH-R7GG].

VI. A TARGETED SOLUTION: CHANGE THE DEFINITION OF "INVENTORS" AND ALLOW FILING BY OWNERS WITHOUT NAMING INVENTORS

A. Proposed Statutory Changes

Congress should modernize the statutory framework governing patent applications while preserving the constitutional purposes of the patent system. Helpfully, several sections of the statute, such as the definitions in 35 U.S.C. §§ 100 (f), (g), and (h), already distinguish between the narrow term "individual," which refers to a human being, and the broader term "person," which includes both humans and corporate entities.[78] The terms "inventor" and "joint inventor" in 35 U.S.C. §§ 100(f) and (g) are defined as "individual," while the immediately following subsection § 100(h), which deals with joint research agreements, uses the term "person."[79] Thus, "person" in § 100(h) refers broadly to both individuals and corporate entities or universities.[80] While preserving and relying on this existing statutory distinction, the authors propose three main amendments.

First, Congress should amend 35 U.S.C. §§ 100(f) and (g) by replacing the term "individual" with the term "inventive entity." The proposed amendments would be as follows (changes crossed over or italicized):

> 35 U.S.C. § 100(f). The term "inventor" means the ~~individual~~ *inventive entity* or, if a joint invention, the ~~individuals~~ *inventive entities* collectively who invented or discovered the subject matter of the invention.

[78] *See* 35 U.S.C. §§ 100(f)–(h).
[79] *See id.*
[80] *See* 35 U.S.C. § 100(h).

> 35 U.S.C. § 100(g). The terms "joint inventor" and "coinventor" mean any 1 of the ~~individuals~~ *inventive entities* who invented or discovered the subject matter of a joint invention.

The term "individual" also appears in 35 U.S.C. § 135(a)(1) (Derivation Proceedings).[81] For consistency, this section of the statute should also be amended by replacing "individual," which appears twice, with "inventive entity." Replacing "individual" with "inventive entity" in both 35 U.S.C §§ 100 and 135 would eliminate the statutory barrier that currently excludes nonhuman contributors from inventorship analysis.

Second, Congress should repeal 35 U.S.C. § 115.[82] Section 115 requires identification of inventors and execution of inventor oaths or declarations.[83] 35 U.S.C. § 116(a) (Joint Inventions) also requires an oath by each of the joint inventors[84] and, while not to be repealed, should be amended to remove that condition. The requirements for oaths make sense in a system designed exclusively around human inventors. In a world where conceptual contributions may originate from AI systems, however, the

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[81] *See* 35 U.S.C. § 135(a)(1) ("An applicant for patent may file a petition with respect to an invention to institute a derivation proceeding in the Office. The petition shall set forth with particularity the basis for finding that an *individual* named in an earlier application as the inventor or a joint inventor derived such invention from an *individual* named in the petitioner's application as the inventor or a joint inventor and, without authorization, the earlier application claiming such invention was filed." (emphasis added)).

[82] *See generally* 35 U.S.C. § 115(a) (stating "[a]n application for patent . . . shall include, or be amended to include, the name of the inventor for any invention claimed in the application. Except as otherwise provided in this section, each individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application.").

[83] *See id.*

[84] *See* 35 U.S.C. § 116(a).

requirements become increasingly difficult to administer and increasingly disconnected from the purposes of the patent system.

Third, Congress should amend 35 U.S.C. § 118 to permit filing by any legal or equitable owner of an invention. The proposed amendment is as follows (additions italicized):

> 35 U.S.C. § 118. (Filing by other than inventor). A person *that is the legal or equitable owner of the invention, or a person* to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent. . . . If the Director grants a patent on an application filed under this section by a person other than the inventor, the patent shall be granted to the real party in interest and upon such notice to the inventor as the Director considers to be sufficient.

Current law allows filing by a "person" (such as a corporation or university) that has received assignment from the inventor, who is an individual.[85] The statute should be broadened to provide that in addition to assignees, the legal or equitable owner of an invention conceived solely or collaboratively by AI, may file a patent application regardless of whether the owner received title from a human inventor.

The proposed amendments carry forward and rely on the existing statutory distinction between broadly-defined "persons" and narrowly-defined "individuals."[86] After amendment, the distinction will persist. On the one hand, there will be "inventive entities," which will refer to human and AI inventors. On the other hand, there will be "persons," which will include inventive entities—by then human as well as AI inventors—in addition to corporations

[85] *See* 35 U.S.C. §§ 100(f)–(h), 118.
[86] *See* 35 U.S.C. § 100(f)–(h).

and universities. The latter do not invent but own inventions and file patent applications. Other sections of the statute can then be interpreted consistently without amendment.[87]

Our approach offers several advantages. Most importantly, it preserves the disclosure function of the patent system. The public will continue to receive detailed disclosures of new inventions. Ownership will remain identifiable. Patent rights will remain transferable and enforceable. At the same time, the system will avoid becoming trapped in increasingly artificial debates regarding whether a machine should be treated as a legal person.

The proposal will also eliminate the uncorrectable inventorship problem. Patent validity would no longer depend upon identifying and naming every conceptual contributor. Instead, the focus would shift to the ownership and disclosure of inventions.

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[87] For an example of how other sections would be interpreted, see 35 U.S.C. § 112(a). This Section requires that the inventor or joint inventor set forth the best mode they "contemplate." After the proposed amendment it will be the inventive entity that "contemplates" the best mode. AI may or may not be able to "contemplate" the way a human does. However, AI's proposed solutions may well include a best mode, which the IP owner would then ignore at its own risk. For another example, see 35 U.S.C. § 112(b). This section requires a claim to "the subject matter which the inventor or joint inventor regards as the invention." Again, this section may be interpreted to refer to what the inventive entity "regards" as the invention. AI may well describe the inventive solution in a manner analogous to a human, that is, how a human may "regard" it. For another example, see 35 U.S.C. § 116(a). After the proposed removal of the requirement for an oath in this Section, the remaining portions either use the term "person"—which term will now include inventive entities as well as corporate entities—or "inventor"—which term will now include human and AI inventors. For another example, see 35 U.S.C. §§ 256(a)–(b). These Sections use both "inventor" and "person." These existing subsections will readily incorporate the new definitions of these two terms.

B. Constitutional Considerations

The Patent and Copyright Clause of the U.S. Constitution authorizes Congress "[t]o promote the Progress of Science and Useful Arts" through limited exclusive rights.[88] The Clause does not expressly require inventors to be natural persons.

Some courts confronting the authorship of AI-generated works, however, have considered whether constitutional limitations require human creators for copyrightability. For example, in *Thaler v. Perlmutter*, the district court suggested that constitutional principles supported the Copyright Office's position regarding human-only authorship.[89] The decision of the lower court is based squarely on the words of James Madison in THE FEDERALIST NO. 43.[90] In writing about both copyrights and patent rights in the Copyrights and Patents Clause, he said: "[t]he copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals."[91] Madison uses the word "individuals," which by a strict 18th century interpretation—unburdened by the notion that machines would, 250 years in the future, be writing or inventing by themselves or in collaboration with humans—means "humans."

On appeal, and notwithstanding Madison, the D.C. Circuit affirmed purely on statutory grounds, and expressly avoided broad constitutional pronouncements concerning

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[88] U.S. CONST. art I, § 8, cl. 8.
[89] Thaler v. Perlmutter, 687 F.Supp.3d 140, 146 (D.D.C. 2023), *aff'd*, 130 F.4th 1039 (D.C. Cir. 2025).
[90] *Id.* at 147.
[91] THE FEDERALIST NO. 43. (James Madison).

the scope of the Copyright Clause.[92] The D.C. Circuit acknowledged the coming wave of AI creations and expressly recommended going to Congress to resolve the policy issue of non-human copyrightability.[93]

Patent law has followed a similar path as that of the D.C. Circuit. The Federal Circuit in *Thaler v. Vidal* rested its holding on statutory interpretation rather than constitutional command.[94] The court concluded that existing patent statutes require human inventors because Congress used language referring to "individuals," not because the Constitution independently mandates human inventorship.[95] The restraint of both courts of appeal may be a signal that they are not averse to letting the Congress intervene. The decisions at least do not represent an absolute constitutional ban to include AI as author or inventor.

Madison's comments in THE FEDERALIST NO. 43 stress that the rights of individuals to their intellectual creations coincide with the public good.[96] A credible argument can be made that Madison's "public good" is achieved by the availability of valid patents on drug-related inventions made in collaboration with AI. And that the right of humans to their intellectual creations can equally be achieved by allowing them (or their companies or universities) to own the collaboratively-conceived inventions. Our proposal therefore fits comfortably within existing jurisprudence. Congress would simply revise the statutory framework governing patent applications. Nothing in the Constitution appears to prohibit Congress from

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[92] Thaler v. Perlmutter, 130 F.4th 1039, 1044–45 (D.C. Cir. 2025), *cert. denied*, 146 S.Ct. 1777 (2026).
[93] *See id.* at 1050–51.
[94] *See* Thaler v. Vidal, 43 F.4th 1207, 1211 (Fed. Cir. 2022), *cert. denied*, 143 S. Ct. 1783 (2023).
[95] *Id.*
[96] THE FEDERALIST, *supra* note 91.

allowing patent rights to be sought and owned without requiring identification of individual inventors.

The constitutional objective remains unchanged: promoting scientific and technological progress through public disclosure and incentivization of innovation.

VII. CONCLUSION

The door to congressional amendment of the patent law is not constitutionally closed. Congress could amend Title 35 to override *Thaler's* statutory holding and permit naming a non-human inventor by using terms such as "inventive entity" in the inventorship statutes. It could enact owner filing without naming inventors or requiring assignments.

USPTO's current approach attempts to avoid inventorship issues in AI-human collaborations by treating AI as a mere laboratory tool.[97] But its Revised Guidance obscures rather than resolves the central inventorship question: what if the human's conception is incomplete? Doing nothing while AI increasingly provides not-insignificant contributions to complete a human's conception is not a viable posture in the long term. If nothing is done, our intellectual property system will become heavily tilted toward secrecy and generate patents vulnerable to challenge for uncorrectable inventorship errors. Worse, the patents issued may be based on intentionally—or, at best, wishfully—misleading information about the contributions of AI. Better to act, even in the shadow of unresolved constitutional questions.[98]

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[97] *See* Revised Inventorship Guidance for AI-Assisted Inventions, 90 Fed. Reg. 54636, 54636–37 (Nov. 28, 2025).

[98] We have considered alternative approaches to address the problems of AI as an inventor or coinventor. One might be for Congress to amend 35 U.S.C. § 282(b)(3) (Presumption of validity; defenses) by

Patent law has repeatedly adapted to transformative technologies. The rise of artificial intelligence presents the next challenge. If the United States wishes to remain a global leader in pharmaceutical and biotechnological innovation, it should address that challenge directly rather than pretending that AI is merely another piece of laboratory equipment like a pH meter or a spectrophotometer.

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adding a new subsection (D) that says, "failure to correct inventorship of any claim of a patent conceived in whole or in part by AI shall not be a basis on which such claim may be canceled or held invalid or otherwise unenforceable." Such an amendment mirrors 35 U.S.C. § 282 (b)(3)(A), which precludes a defense of invalidity based on failure to disclose the best mode. A similar amendment addressing inventorship by AI would restrain the courts from considering whether contributions by AI are insignificant or not insignificant. We do not favor this approach, however, in that it begs the same questions as those of the Revised Guidance: what if the conception by the human contributor(s) was incomplete? And worse, what if the conception by the human(s) was non-existent? Legally condoning the validity and enforceability of claims with incorrect inventorship may tempt human applicants with no claim to inventorship to exaggerate or even misrepresent their conceptual contributions. Such a result would be at cross-purposes with the idea of a transparent patent system. We believe that it is better to follow the approach we propose in this article: allow owner filing without naming inventors.