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Protecting AI-Driven Innovation In Life Sciences IP

By **Sandra Haberny** (June 10, 2026, 5:08 PM EDT)


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The legal landscape for artificial intelligence-driven innovation in the life sciences industry has reached a genuine inflection point.

In late April, the U.S. Patent and Trademark Office confirmed that its new subject matter eligibility declaration tool is already helping applicants overcome Section 101 patent eligibility rejections and appointed a dedicated deputy commissioner for patents for AI policy.

These developments follow the U.S. Court of Appeals for the Federal Circuit's February decision in Rensselaer Polytechnic Institute v. Amazon.com Inc., which further tightened the standard for AI patent claims, and the U.S. Supreme Court's March ruling in Thaler v. Perlmutter, which closed the door on AI holding intellectual property rights.

For life sciences companies, where the cost of bringing a therapeutic, diagnostic or device to market makes robust IP protection existential, these converging developments demand immediate strategic attention.

AI has become an indispensable engine of discovery in life sciences for screening molecular candidates, predicting protein structures, identifying biomarkers and personalizing treatment regimens. Yet these novel methods test a patent system built around human-driven invention, throwing into flux what can be patented, who qualifies as an inventor and what counts as prior art.

Proving Human Inventorship

An AI system cannot be a named inventor on a U.S. patent. This is the most settled question in AI patent law, but also one of the most practically consequential.

The Federal Circuit confirmed this in 2022 in Thaler v. Vidal,[1] and the USPTO's November 2025 inventorship guidance went further, establishing that AI is to be treated solely as an instrument, like a centrifuge or sequencing platform, regardless of how central its role was in generating the claimed innovation.[2]

The Pannu factors for evaluating joint inventorship,[3] established by the Federal Circuit in Pannu v. Iolab Corp. in 1998, while still applicable to human collaborators, have been explicitly rejected as a framework for assessing AI contributions.[4]

The human-element requirement has recently been reinforced at the highest judicial level in the copyright context. In March, the Supreme Court denied certiorari in Thaler, leaving intact the U.S. Court of Appeals for the District of Columbia Circuit's ruling that human authorship is a bedrock requirement of copyright law.[5]

Although not a patent decision, the denial eliminates any remaining uncertainty regarding whether the Thaler v. Vidal patent holding might eventually be revisited. It furthermore signals the court's unwillingness to disturb the broad legal consensus that AI systems cannot hold IP rights.

In the patent context, this means human inventors named on a patent involving AI must be able to demonstrate that they, not the AI, conceived the claimed invention.

Under U.S. patent law, conception is the formation in the inventor's mind of a definite and permanent idea of the complete and operative invention. In a world where AI can generate thousands of candidate compounds or suggest novel molecular targets, the human scientist's role may be concentrated in defining the problem, setting parameters, evaluating and selecting outputs, and recognizing utility — none of which is automatically captured in a standard lab notebook entry.

Life sciences companies should immediately implement protocols to document human decision-making separately from AI outputs. When AI screens a chemical library and a scientist selects a lead compound based on their scientific judgment, that selection and its underlying reasoning should be recorded contemporaneously.

The same applies to hypothesis formation, experimental design and interpretation of results. If a patent's inventorship is challenged in litigation or in a USPTO postgrant proceeding, that record's strength will be the patent owner's most critical asset. Companies should also proactively audit existing patents that have documented AI involvement to discover opportunities to correct inventorship before a challenger exploits the gap.

For Patent Eligibility, the Devil in the Details

Not every AI-assisted invention automatically qualifies for patent eligibility under Title 35 of the U.S. Code, Section 101.

The governing legal framework, built on the Supreme Court's decisions in Alice Corp. v. CLS Bank[6] in 2014 and Mayo Collaborative Services v. Prometheus Laboratories in 2012,[7] holds that patents cannot be granted for abstract ideas, laws of nature or natural phenomena unless the patent claims add something meaningfully concrete beyond the abstract concept itself.

For life sciences AI innovations, the current legal landscape is defined by a critical and widening tension between the USPTO and the Federal Circuit that companies must account for strategically.

On the restrictive side, the Federal Circuit in Recentive Analytics Inc. v. Fox Corp. held last year that claims that merely apply established machine learning methods to a new data environment are not patent eligible.[8]

That is, the novelty of the application field alone is insufficient. The court recently extended that logic in Rensselaer, invalidating a patent claiming case-based reasoning applied to natural language processing,

reiterating that using AI in a novel field does not supply an inventive concept at Step 2 of Alice.[9]

Together, these cases clarify that, at least as of now, the Federal Circuit's doctrinal floor has not shifted.

On the more permissive side, the U.S. District Court for the District of Delaware in Aon Re Inc. v. Zesty.AI Inc. last year **upheld** patent eligibility where the claims described a specific technical implementation — the how, not just the what — of a machine learning-based assessment system.[10]

And USPTO Director John Squires, in Ex Parte Desjardins last September, instructed that Section 101 should not be used to categorically exclude AI from protection, because doing so jeopardizes U.S. technological leadership.[11]

This divergence between the USPTO and the Federal Circuit is itself a portfolio risk. A patent that progresses smoothly through examination under Squires' more receptive environment may still face successful invalidity challenges in litigation governed by unchanged Federal Circuit precedent.

Companies should draft applications to satisfy the courts' standards, not just the USPTO's, from early on. Claims that describe the specific model architecture, nature and preprocessing of training data, the particular technical problems being solved, and the mechanisms by which the claimed approach improves on prior methods are substantially more durable than claims that simply recite "using machine learning to identify a drug candidate" or "applying an AI model to diagnose a condition."

Critically, the USPTO has just provided life sciences companies with a new and already-proven prosecution tool for responding to Section 101 rejections.

On April 30, Squires issued updated guidance on subject matter eligibility declarations, which are voluntary Rule 132 declarations through which applicants submit factual evidence demonstrating that a claimed invention constitutes a concrete technological improvement.[12]

The updated memo notably confirmed that early voluntary subject matter eligibility declaration submissions are already succeeding in overcoming Section 101 rejections.

This is a significant and timely development for life sciences companies with diagnostic methods and AI-driven therapeutic claims, which are among the most frequent targets of abstract-idea rejections.

Reinforcing this institutional commitment, the USPTO also recently created a new dedicated position of deputy commissioner for patents for AI policy, practice and operations.

A well-crafted subject matter eligibility declaration should establish a clear nexus between the patent claims and concrete technical improvements such as greater speed, accuracy or efficiency, which are precisely the kind of objective evidence that also strengthens a patent against future litigation challenges under Alice.

Importantly, the Patent Eligibility Restoration Act remains pending in Congress.[13]

If passed, PERA would overturn the Alice/Mayo framework, replacing judicial exceptions with narrow statutory exclusions and dramatically expanding the universe of patent-eligible AI-assisted inventions in life sciences, including diagnostic methods and AI-identified therapeutics currently vulnerable under Section 101.

Companies should monitor PERA's progress closely, while structuring pending applications to survive the existing judicial standard, regardless of PERA's ultimate fate.

The Growing Prior Art Problem

Perhaps the most underappreciated threat to life sciences IP portfolios is the proliferation of AI-generated prior art. AI systems are now capable of generating vast libraries of chemical structures, protein sequences and biological hypotheses at near-zero cost and publishing them publicly, potentially anticipating or rendering obvious innovations that human researchers have not yet patented.

Projects like All Prior Art deliberately exploit this dynamic, algorithmically creating and publishing combinations of existing disclosures to preempt future patents.[14]

The legal framework for evaluating AI-generated prior art under Title 35 of the U.S. Code, Section 102, is unsettled.

The text of Section 102(a)(1) makes any disclosure available to the public before a patent's effective filing date potentially qualify as prior art, without any requirement that it be authored by a human.

Various organizations have responded to the USPTO's April 2024 request for comments on this topic.[15]

The American Intellectual Property Law Association's position is that there is no recognized basis in current law for requiring human authorship of prior art.[16] Amgen Inc., by contrast, has argued that sufficient human action should be required to place AI-generated information in the public domain, and that AI-generated content should require indicia of reliability before presumptions of operability and enablement apply.[17]

The USPTO's request for comments acknowledged the problem, but has not yet produced definitive guidance.[18]

Existing legal tools may provide partial protection. The Federal Circuit in Acceleration Bay v. Activision Blizzard ruled in 2018 that a disclosure is only prior art if a person of ordinary skill exercising reasonable diligence could have found it, potentially excluding AI-generated content buried in enormous databases of nonsensical disclosures.[19]

The enablement doctrine may provide another filter. Algorithmically generated chemical structures ungrounded in chemical reality are unlikely to enable a person of skill in the art to practice a claimed invention without undue experimentation.

Life sciences companies should incorporate AI prior art surveillance into their prefiling due diligence processes, file provisionally as expeditiously as possible to minimize the prior art accumulation window and draft claims specific enough to distinguish AI-generated disclosures while preserving commercially meaningful scope.

The "Person of Ordinary Skill in the Art" and the Future of Obviousness

Patent law does not just ask whether your invention is novel. It also asks whether it would have been

obvious to a skilled researcher in the field. As AI tools become standard practice in drug discovery, the question of whether the hypothetical "person having ordinary skill in the art" should be assumed to routinely use AI is increasingly raised in prosecution and inter partes review proceedings.

If so, the bar for nonobviousness rises dramatically. Combinations of known compounds, targets or methods that might once have required genuine inventive insight may become obvious because a person of skill would routinely generate them with AI.

Life sciences companies should anticipate increases in the frequency and sophistication of AI-enabled obviousness arguments, and should invest in building secondary indicia of nonobviousness into their applications, including evidence of unexpected results, long-felt unmet need, failure of others and commercial success.

Clinical validation data, mechanistic insights and in vivo efficacy results that surpass what an AI screen alone would predict are particularly valuable in this regard.

A Strategic Framework for Life Sciences IP Leaders

The convergence of these developments, including evolving inventorship standards, Section 101 patent eligibility uncertainty, AI prior art proliferation and the shifting "person of ordinary skill in the art" standard, demands that life sciences companies elevate AI patent strategy to a board-level concern.

Companies best positioned to protect and monetize their AI-driven innovations will be those that immediately invest in documentation infrastructure, claim-drafting sophistication, portfolio auditing and proactive monitoring of a rapidly changing legal landscape.

This dynamic legal terrain extends beyond the U.S. patent laws.

For example, the U.K. Supreme Court's February 2026 decision in Emotional Perception AI Ltd. v. Comptroller General of Patents abandoned nearly two decades of restrictive precedent and aligned U.K. law with the European Patent Office's more permissive "any hardware" approach to AI patentability.[20] Consequently, the U.K. may now offer improved prospects for protecting AI-driven innovations for companies with global patent portfolios.

The fundamental principle underlying the U.S. patent system, enshrined in Article I, Section 8, of the U.S. Constitution as the power to promote the progress of science by securing to inventors the exclusive right to their discoveries, remains unchanged.

However, the definitions of what constitutes a patentable discovery or common knowledge and who or what qualifies as an inventor or prior art are rapidly evolving. Navigating these changes effectively will be the defining IP challenge for life sciences innovators in the years ahead.

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[1] Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022).

[2] https://www.federalregister.gov/documents/2025/11/28/2025-21457/revised-inventorship-guidance-for-ai-assisted-inventions.

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

[4] https://www.federalregister.gov/documents/2025/11/28/2025-21457/revised-inventorship-guidance-for-ai-assisted-inventions.

[5] Thaler v. Perlmutter, 130 F.4th 1039 (D.C. Cir. 2025); Thaler v. Perlmutter, No. 25-449 (2026) (cert. denied).

[6] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 134 S. Ct. 2347 (2014).

[7] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 132 S. Ct. 1289 (2012).

[8] Recentive Analytics, Inc. v. Fox Corp., 134 F.4th 1205 (Fed. Cir. 2025).

[9] Rensselaer Polytechnic Inst. v. Amazon.com, Inc., Nos. 2024-1725, 2024-1739, 2026 U.S. App. LEXIS 5361 (Fed. Cir. Feb. 24, 2026).

[10] Aon Re, Inc. v. Zesty.Ai, Inc., 791 F. Supp. 3d 531 (D. Del. 2025).

[11] Ex Parte Desjardins, Appeal 2024-000567 (PTAB Sept. 26, 2025) (Appeals Review Panel Decision).

[12] Memorandum, Best Practices for Submission of Rule 132 Subject Matter Eligibility Declarations (SMEDs) (Apr. 30, 2026) (superseding Dec. 4, 2025 Director's Best Practices Memo), available at https://www.uspto.gov/sites/default/files/documents/smeds-application-practitioners-4302026.pdf.

[13] Patent Eligibility Restoration Act, S. 1546, 119th Congress (2025-2026), H.R. 3152, 119th Congress (2025-2026).

[14] All Prior Art, https://areben.com/project/all-prior-art/.

[15] https://www.federalregister.gov/documents/2024/04/30/2024-08969/request-for-comments-regarding-the-impact-of-the-proliferation-of-artificial-intelligence-on-prior.

[16] https://www.aipla.org/docs/default-source/advocacy/aipla-comments-to-uspto-on-ai-generated-prior-art.pdf.

[17] https://www.regulations.gov/comment/PTO-P-2023-0044-0054.

[18] https://www.federalregister.gov/documents/2024/04/30/2024-08969/request-for-comments-regarding-the-impact-of-the-proliferation-of-artificial-intelligence-on-prior.

[19] Acceleration Bay, LLC v. Activision Blizzard, Inc., 908 F.3d 765, 774 (Fed. Cir. 2018).

[20] Emotional Perception AI Ltd v. Comptroller-General of Patents, [2026] UKSC 3.