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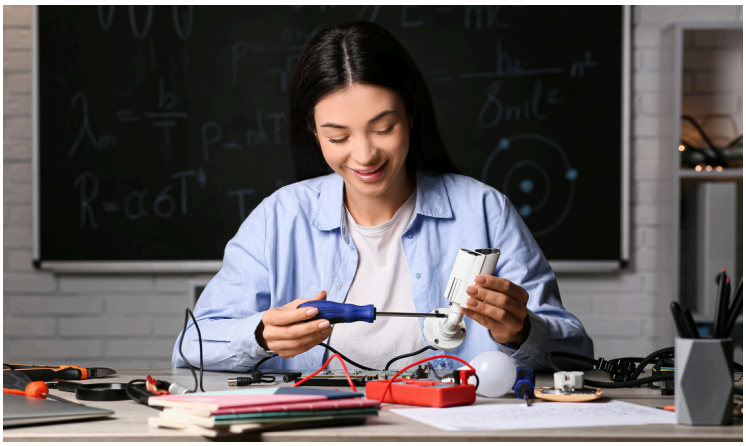
## More Strategic Filings will be Key Amid USPTO Changes



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The United States is one of the least expensive countries in the world, in which to file for patent protection. During my tenure on the Patent Public Advisory Committee (PPAC) I learned in great detail about the long-held mandate of the USPTO, that to encourage small business and independent inventors, filing costs are kept low. Indeed, the patent office does not break even on a patent until the second maintenance fee is paid, 7.5 years after the patent issues, and likely more than 10 years after the case was filed. The USPTO also offers discounted fees for small entity and micro entity status applicants. An initial provisional application can be filed in the U.S. for a small entity for as little as $130.00, with a later filed conversion case claiming priority thereto of about $1000 in fees.

This low threshold to entry to the patent system distinguishes the US system from other systems. The European Patent Office, for example, where filing fees, annuities, and excess claim fees (which begin above 15 claims), can make prosecution materially more expensive than in the U.S.This also contrasts with the USDA Plant Variety Protection system, where the current total cost of protection is $5,150, paid at filing. That lower entry cost reflects the USPTO's longstanding emphasis on broad access to the patent system.



This model is coming under increased pressure in recent years. Low filing costs also have the unintended consequence of increased questionable or fraudulent submissions; which has required the USPTO to expand efforts to identify and terminate patent applications involving rule violations and falsified signatures. Further pressure has come as the USPTO battles to recover from the backlog, which reached a record 837,928 unexamined applications in January 2025, attrition of Examiners lost during COVID, the federal government hiring freeze, and the mandatory return-to-office policy issued last year. These staffing constraints have further complicated efforts to reduce pendency. The increased pressure on the USPTO was no more apparent than in the House Intellectual Property Subcommittee's September 2, 2026, hearing on renewal of the USPTO's AIA fee-setting authority, which was scheduled to expire September 15, 2026, absent congressional action.

The USPTO is entirely funded by fees collected from its users and does not rely on the federal government's tax revenues. The patent office, once touted as the "only government agency that is self-sufficient" and where once political battles (and PPAC report urgings) centered around preventing fee diversion from the USPTO to other agencies, is now likely to become one of those agencies operating in need of taxpayer funding. Pressures are mounting, making fee-setting authority a focal point of broader congressional debate. Hence the September 2 hearing, where renewal of fee-setting authority became intertwined with broader debate over USPTO discretion under the AIA. Indeed, Congress only temporarily renewed the authority in an unprecedented short extension through December 12, 2026. The pressure continues.

My second year on the PPAC was a fee setting year and the fee increases the USPTO proposed had been working their way through the system for years.These fee proposals formed part of our hearing and 2023 public report to the President, as provided for in the Leahy-Smith America Invents Act of 2011 (AIA), where the USPTO was granted the authority to set its own fees, but only after following a structured process of collecting and considering public input. The last fee adjustment went into effect January 19, 2025 and included increases and new fees affecting continuing applications, design patents, PTAB proceedings, accelerated design examination, excess claims, IDS submissions, patent term adjustment, terminal disclaimers, and certain petitions. There was also a 10% across the inflation adjustment and general increase.



These USPTO increases are a drop in the bucket of what is needed to set the agency on a healthy fiscal path. The primary expense of the USPTO is examination of applications and the unexamined backlog remains at a historically high level and will be costly to work down.

This all means that massive USPTO fee increases will no doubt be coming. The USPTO is attempting to battle the backlog with programs like the newly Initiated (May 21, 2026), PCT Informed Examination Request (PIER) pilot program. The pilot requires selected national-stage applicants to respond before examination and allows them either to proceed or to delay examination for 12 months. No doubt the hope is that after the lengthy PCT process of 30 months and waiting in the queue at the patent office, Applicants will make a "reality check" and withdraw certain cases. This will result in earlier abandonment of cases, to help address the unexamined backlog. Useful, but modest compared with the scale of the backlog.

**What does all of this mean for Applicants?**

U.S. patent prosecution is likely to become more expensive and more fee sensitive. Even if the agency continues reducing its backlog, fee levels and fee structure will remain central to funding examination capacity. That makes filing strategy more important: applicants may need to be more selective about what they file, draft applications more deliberately at the outset, and rely less on repeated continuation filings or other later-course corrections. Those hurt most by these changes will be the many small entities and independent inventors that are the cornerstone of the US patent system. My patent-litigating father used to always say that the patent system is a great equalizer, a patent to IBM carries the same legal rights as a patent to Jane Smith, an independent inventor working in her basement. The commitment of the USPTO to this mandate is about to be seriously tested, as the challenges mount to preserve the mandate while making the system financially sustainable.

# Lexicography Traps in Chemical Patents: A Cautionary Case Study

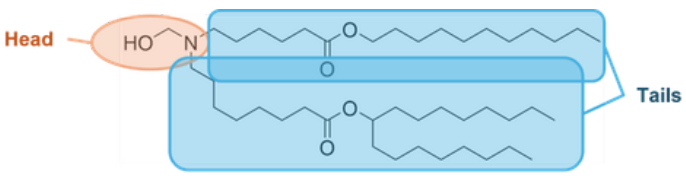


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Alnylam Pharmaceuticals lost their infringement case against Moderna last year. The U.S. Court of Appeals for the Federal Circuit affirmed the District of Delaware's earlier decision. Alnylam alleged that Moderna's COVID-19 vaccine included a compound covered by their patents U.S. Patent No. 11,246,933 ('993 patent) and U.S. Patent No. 11,382,979 ('979 patent). The compound in question is called SM-102, and the outcome of this case depended entirely on Alnylam's own definitions.

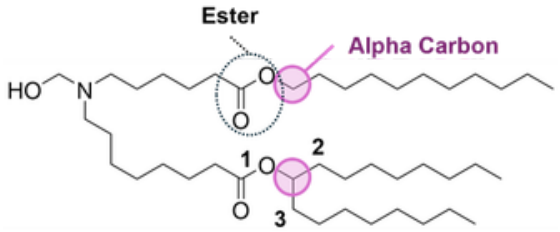
Alnylam's patents cover lipid molecules used to deliver mRNA. Lipid molecules are fatty substances that are difficult to dissolve in water. Without these fatty molecules for protection, mRNA would degrade in the bloodstream and get blocked from reaching the target cells. The fatty molecules form a spherical shell around the mRNA, allowing the vaccine to travel to its intended targets unscathed. Since mRNA molecules have a negative charge, lipids developed by Alnylam are positively charged to attract the mRNA around which the protective shell is formed.

The SM-102 lipids possess a charged head group and two tails. The long "tails" attached to the head comprise the fatty part of the molecule. The exact structure is shown below:




SM-102

The tails have ester groups made up of the carbon atom attached to two oxygen atoms. The carbon atoms adjacent to the esters are the alpha carbon atoms. The overall structure of the alpha carbons adjacent to ester groups is highlighted below:




SM-102

These alpha carbon atoms start the alkyl chains. In the illustration, the top alpha carbon is attached to just one alkyl chain. In contrast, the bottom alpha carbon is attached to two alkyl chains, forming a branched structure. In total, the bottom alpha carbon has just three attachments, including the ester. The entirety of the Alnylam v. Moderna case hinged on competing definitions of this "branched alkyl".

Alnylam filed their first lawsuit against Moderna in March 2022 related to the '993 patent. A second lawsuit related to the '979 patent followed in July 2022. During litigation, Alnylam argued that the term "branched alkyl" should be interpreted according to its normal meaning in chemistry. The ordinary meaning, according to Alnylam, is "a saturated hydrocarbon moiety that is not a straight chain". However, the specification of Alnylam's own patents contained the following "branched alkyl" definition: "alkyl in which one carbon atom in the group (1) is bound to at least three other carbon atoms, and (2) is not a ring atom of a cyclic group". As can be seen above, the bottom alpha carbon is only bound to two other carbon atoms.

Moderna argued before the District Court that the branched alkyl definition from the specification applies, as apposed to the much broader definition offered by Alnylam. The District Court agreed with Moderna, and, after appeal, the Federal Circuit also found that the specification represented a binding definition.

The Federal Circuit systematically addressed each of the arguments made by Alnylam. Alnylam pointed to prosecution history, unclaimed embodiments, the claim language in both patentes, and qualifying language in the "Definitions" section of the specification. Although the Federal Circuit admitted that the issue of prosecution history was the strongest argument, none of Alnylam's arguments rescued the branched alkyl definition from its overly narrow appearance in the specification.

For chemical patents, definitions of chemicals in the specification must exactly match what is found in the claims and examples. The power of acting as a lexicographer comes with great responsibility, and this responsibility encompasses the specification to the same degree as the claims. Sometimes the intent behind a definition is broader than what actually gets allowed, as in the Alnym v. Moderna case. Lexicographical mistakes cannot be easily undone.

References
1. https://www.cafc.uscourts.gov/opinions-orders/23-2357.OPINION.6-4-2025_2525006.pdf

## Biotech Patent Eligibility and the US Patent Eligibility Restoration Act



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When it comes to specifying what is eligible for patenting under US law, 35 USC §101 simply and briefly states that "(w)hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." While 35 USC §101 itself is remarkably expansive in setting forth what is patent-eligible, it does not explicitly call out what is not patent-eligible. It has thus fallen to the US Supreme Court in particular to identify what is not patent-eligible. Two key US Supreme Court decisions have limited patent-eligibility of some disease diagnosis methods and "products" of nature such as isolated DNA encoding a gene. These and other decisions of our highest Court have prompted the bipartisan Patent Eligibility Restoration Act (PERA) which would set forth clear boundaries on patent eligibility if enacted. To understand what has motivated PERA, we review these decisions as well as their impact on patent applicants and some key sectors of the biotech industry.

In Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012), the Supreme Court held that patent claims drawn to a method of predicting proper dosing of certain drugs to treat autoimmune disease were not patentable as the claims amounted to nothing more than "a drafting effort designed to monopolize the law of nature itself." In brief, Mayo held that claimed methods which simply apply a law of nature through routine and conventional steps are not patent-eligible. The routine and conventional steps were administering a drug and measuring levels of the drug in the patient's blood. Mayo thus required that the additional claim steps transform the unpatentable law of nature into an inventive application of the law for patent-eligibility. Mayo rejected the US Government's brief arguing that such "inventiveness" considerations be addressed through the sections of the US patent code for determining novelty (35 USC §102) and non-obviousness (35 USC §103).

In Association for Molecular Pathology v. Myriad Genetics, Inc. (2013), the Supreme Court unanimously held that naturally occurring DNA is not patent eligible merely because it has been isolated. This holding was quite remarkable as the long-standing position of the courts was that other isolated natural products such as Vitamin B12 were patent eligible (Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156 (4th Cir. 1958). Myriad did not explicitly opine on the patentability of isolated natural products in general but did state that "separating that gene from its surrounding genetic material is not an act of invention." The US Government's amicus brief also argued that isolated DNA was not patentable.

Since Mayo and Myriad, the USPTO has had seven different directors who have in turn provided at least 10 guidance memos to USPTO patent examiners on procedures for evaluating patent claims for eligibility over the past 14 years. Such guidance has had a direct and lasting impact on patent applicants whose patent claims are under evaluation for eligibility.

The initial USPTO guidance on Mayo in 2012 stated that the methods based on a natural principle must provide "additional elements or steps must relate to the natural principle in a significant way to impose a meaningful limit on the claim scope." Later USPTO Mayo guidance in 2014 instructed Examiners to determine if the claim as a whole recited "something significantly different" than a natural phenomenon by weighing six different factors that favor eligibility against six different factors that disfavor eligibility. In 2019, additional USPTO guidance to Examiners on Mayo pointed out that method of patient treatment claims that applied a natural phenomenon but were not directed to the phenomenon were patent eligible even if the treatment steps were routine. Adding a treatment step has since become an established path to patenting diagnostic methods based on natural phenomenon such as DNA sequences or metabolite levels but raises enforcement concerns over "divided infringement" as two parties (i.e., a diagnostic test provider and a physician) will typically perform different steps of the method.

USPTO's guidance on Myriad has similarly evolved over the past 13 years. The initial 2013 guidance limited ineligibility to "naturally occurring nucleic acids or fragments thereof, whether isolated or not,..." Just one year later, the USPTO guidance extended patent ineligibility to other isolated or purified products of nature including chemical compounds, proteins, unmodified bacteria, unmodified bacterial mixtures, cells, and certain foods. Significantly, eligibility for certain types of antibodies was preserved so long as the antibodies were not naturally occurring antibodies.

With such restrictions imposed by the Courts and implemented by the USPTO, robust patent protection is not available for a variety of quite useful biotech-related inventions. Methods for early diagnosis of diseases such as cancer and Alzheimer's disease must include additional treatment steps which can complicate enforcement or add "non-routine" steps in the method which allow easy "work arounds" which devalue the claims. Isolated natural products such as naturally occurring bacteria which are useful for promoting crop plant yield or pest tolerance are also ineligible. Several studies find that venture capital investment in biotech companies impacted by these decisions has decreased (see Taylor, D.O. "Patent Eligibility and Investment" and Schultz, M.F. "Declining Patent Reliability and Venture Capital Reallocation"). It has been estimated that investment in US diagnostics fell by more than $9 billion dollars following Mayo (Hoyt, A.S. The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S. Medical Diagnostic Technologies, 2022). In the meanwhile, Supreme Court has seemingly invited a legislative fix by consistently declining cases which might further clarify patent-eligibility.

To remedy the "extensive confusion and a lack of consistency" in determining patent eligibility, the bipartisan Patent Eligibility Restoration Act of 2025 (PERA) bill has been introduced in both the US Senate and the House of Representatives. The Senate bill adds a lengthy addendum to 35 USC §101 which would explicitly state what is and what is not patent-eligible. On the explicitly patent ineligible list are

mathematical formulae, “substantially economic, financial, business, social, cultural, or artistic” processes, a “mental process performed solely in the human mind,” an “unmodified human gene, as that gene exists in the human body,” and “unmodified natural material, as that material exists in nature.” However, a human gene would be patent eligible if it is “ purified, enriched, or otherwise altered by human activity” or “otherwise employed in a useful invention or discovery,” effectively negating some aspects of Myriad and related USPTO guidance. Similarly, a natural material would not be unmodified if “isolated, purified, enriched, or otherwise altered by human activity” or “otherwise employed in a useful invention or discovery.” The Senate bill further specifies that patent eligibility is determined “without regard to— the manner in which the claimed invention was made,” “whether a claim element is known, conventional, routine, or naturally occurring,” “the state of the applicable art, as of the date on which the claimed invention is invented,” or “any other consideration in section 102, 103, or 112.” Mayo and related USPTO guidance would also be negated by the Senate bill since most of the Mayo considerations such as being naturally-occurring, known, or conventional (i.e., not novel under section 102, obvious under section 103, or not enabled/described under section 112) would not be applicable to patent eligibility.

The full Senate Judiciary Committee held a earing entitled “From Genes to Machines: the Patent Eligibility Debate” on July 14 of this year. PERA proponent and former USPTO director Andrei Iancu testified that patent eligibility should be established by Congress rather than the Courts, that the legislation was needed to “replace today’s confusion with clear statutory rules” and to counteract current disincentives to investment in U.S. diagnostic technologies, disadvantage start-up companies, and disadvantage innovation in the US relative to China, Europe, and Japan. PERA opponent Dr. Debra G.B. Leonard (University of Vermont Molecular Pathologist; former Association for Molecular Pathology president) testified that licensing demands restricted her ability to serve patients, commenting that “(t)hanks to Supreme Court decisions such as Myriad, competition has increased, costs have fallen, and patients have greater access to high-quality testing than ever before.” According to one account, patentability of isolated human genes was one of the more divisive issues where the currently proposed amendments to section 101 would need to be revised for passage. The Association for Molecular Pathology, which opposes PERA in its current form, has indicated that they will “develop redline edits and will reach out to your committee staff with recommendations soon” (see Questions for the Record: Dr. Debra G.B. Leonard, M.D., Ph.D).



The future of PERA remains uncertain. It is likely that the PERA will not come to a vote before the 119th Congress ends in January 2027 and would then need to be reintroduced in the next Congress. Senator Tillis (R-NC), who co-sponsored the bill with Senator Chris Coons (D-Del.), will retire at the end of this term. Potential but by no means assured next steps would be an announced Judiciary Committee markup, followed by committee approval and a leadership commitment to floor consideration. Senator Grassley (R-IA) chairs the Judiciary Committee and opened the July 14 meeting to learn “how to strike this balance” between the maintaining both innovation and benefit to all Americans. Any path to patent eligibility reform through PERA will thus need to be built through a compromise which balances the interests of stakeholders ranging from innovators and investors to end-users such as physicians, patients, and growers.

# The Disappearing Invention Record: Proving Inventorship in the Age of Generative AI



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An engineer tasked with improving a consumer product turns to generative AI to explore possible solutions. She supplies technical constraints, rejects several AI-generated configurations, refines others, and ultimately modifies a promising approach that her team successfully prototypes. Months later, the company files a patent application covering the product.

Years later, in litigation, an accused infringer simply asks: Who conceived the claimed invention?

The question is no longer simply whether AI can be an inventor. Under U.S. patent law, it cannot. The more consequential question may be whether companies can prove what their human inventors conceived when AI participated in the inventive process.

As AI becomes more ingrained as a research and development tool, the legal rules governing inventorship may not change while the factual circumstances underlying inventorship become substantially more complicated. The result is an emerging evidentiary problem: invention-record practices designed for predominantly human-to-human innovation may be poorly suited to reconstructing conception in an era of human-AI collaboration.

**The Legal Rule Is More Familiar Than the Technology**

The starting point is relatively straightforward. U.S. patent law requires inventors to be natural persons. In Thaler v. Vidal, the Federal Circuit addressed whether an artificial intelligence system could itself be identified as an inventor. Looking to the Patent Act's use of the term "individual," the court concluded that an inventor must be a human being.

An important doctrine for AI-assisted inventions is therefore not Thaler's natural-person requirement, but the longstanding law of conception. More recently, the United States Patent and Trademark Office has confronted these questions through guidance published regarding AI-assisted inventions. The USPTO's November 2025 guidance largely embraces that conventional framework: AI-assisted inventions do not receive a separate inventorship test; AI is treated as a “tool”, and only natural persons may be named as inventors.

Thus, conception remains a central question. Inventorship generally turns on who conceived the claimed subject matter, and joint inventorship depends on the contributions made by the participating human inventors. AI does not become an inventor merely because its output was useful, sophisticated, or unexpected. Thus, saying that AI is a "tool" answers the legal-personhood question. It does not necessarily answer the question of what the human being using that tool actually conceived.

**AI Changes the Factual Anatomy of Conception**

Consider a general invention-development narrative:

Problem → Human Idea → Experimentation → Reduction to Practice

In this simplified description, an inventor recognizes a solution with sufficient definiteness, after which experimentation may confirm whether the solution works.

Use of AI can complicate that sequence:

Problem → Human Prompt → AI Output → Human Evaluation of Output → Revised Human Prompt → AI Variation on Output → Human Selection and Modification → Testing → Claimed Invention

Where, exactly, did conception occur?

Consider four increasingly difficult scenarios. First, a scientist conceives a complete mechanical arrangement and uses AI only to optimize dimensions. Here, the human conception is relatively easy to identify. Yet, what if the scientist conceives a general idea but asks AI to generate alternative implementations, one of which she materially modifies. Or, further, the scientist supplies only the technical problem and performance constraints, and the AI generates the architecture ultimately claimed. Finally, what happens when several scientists interact with the AI at different stages: one defines the problem, another prompts the system, another selects an output, and another modifies it into a workable design.

The governing inventorship principles have not necessarily changed. What has changed is the factual record that must be examined to apply them.

**A Prompt Is Not Necessarily an Invention**

One response to this problem might be to preserve AI prompts. But that solution cuts both ways.

A prompt could say: "Develop a closure that prevents leakage when this container is inverted."

Or it might say: "Develop a closure having concentric flexible sealing members positioned between these identified structures, with the inner member engaging the specified surface when the container is inverted."

Both are prompts, but they tell very different stories about the user's contribution.

The first primarily states a problem and desired result. If the AI independently proposes the structural arrangement ultimately claimed, the prompt may provide little evidence that the user had already conceived that arrangement. The second could contain substantial details of the eventual claimed invention and demonstrate that the human had formulated important aspects of the solution before receiving the AI output. Earlier USPTO guidance used similar hypotheticals to illustrate how the substance of a human's interaction with AI could matter to inventorship.

Preserving a prompt alone therefore may not establish inventorship. Nor does preserving the AI output necessarily resolve the question. What matters is the relationship among the human's existing knowledge, the instructions given to the system, the resulting output, and the human's subsequent contributions.

**The Evidence May Exist—Until It Doesn't**

Patent disputes frequently require reconstructing events that occurred years earlier. Yet, a generative AI conversation may contain timestamped prompts and responses showing the progression of an idea with extraordinary granularity. In theory, the development of an invention could be better documented than ever before.

Although, in practice, the opposite may occur. Employees may use different AI platforms. Some may use company-approved enterprise systems, while others may experiment with public services or personal accounts. Conversation histories may be subject to automatic deletion. Models and product features may change. Employees may leave. AI-generated outputs may be copied into another document without preserving their origin. Years later, an inventor's recollection may collapse a complex series of interactions into a simple narrative: "I developed the design using AI." That statement does little to answer the question patent law actually asks.

**The Disclosure Paradox**

The Office generally presumes that the inventors identified in a patent application are the actual inventors. Examiners typically do not investigate inventorship and that AI-assisted inventions do not create an additional duty requiring applicants to disclose the extent to which AI was used. Existing duties remain applicable, but the mere involvement of AI does not trigger a new disclosure requirement. The MPEP likewise states the Office's general presumption that the named inventor is the actual inventor. This avoids burdening applicants with reporting routine uses of AI. But it creates a potential disconnect between prosecution and later enforcement.

If the USPTO generally does not ask how AI was used, applicants may have little immediate incentive to develop a detailed record addressing the issue. An invention disclosure may identify the invention and the individuals believed to be inventors without documenting whether a particular claimed feature first arose from a human proposal, an AI output, or subsequent human modification.

Of course, an issued patent enjoys a statutory presumption of validity, and alleged incorrect inventorship does not automatically place a patent owner in the position of proving conception again. But where inventorship becomes genuinely disputed, evidence concerning the respective human contributions may become important, and may be far more reliable than recollections reconstructed years later.



**Document Contributions, Not Merely AI Usage**

Companies should therefore consider whether traditional invention-disclosure procedures remain adequate for AI-assisted R&D.

Adding "Was AI used?" to an invention disclosure form is unlikely to solve the problem. As AI becomes embedded in ordinary engineering software, an affirmative answer may become both commonplace and largely meaningless. Using AI to summarize test results is fundamentally different from asking it to generate the structure ultimately recited in claim 1.

The better question is whether AI generated or materially suggested technical subject matter potentially relevant to the claimed invention. If so, patent counsel can ask what the human contributors supplied before the output, what they selected or rejected, what they changed afterward, and what contemporaneous evidence reflects those contributions.

Inventorship remains a legal determination tied to the claimed invention, and claims may change substantially during prosecution. But asking contribution-focused questions early can preserve the facts from which that legal determination later can be made.

As for AI documentation, the answer should not be to preserve every AI interaction. Wholesale retention could create substantial volumes of irrelevant material, increase discovery and information-governance burdens, and preserve sensitive technical information without providing useful evidence of conception.

The objective should therefore be selective preservation. Not of AI activity generally, but of evidence sufficient to reconstruct material human contributions to potentially claimed subject matter.

**Updating the Invention Record for AI-Assisted R&D**

Companies incorporating generative AI into R&D should consider several modest changes to incorporate in their existing patent processes.

1. **Modify invention disclosures.** Ask whether AI generated or materially suggested technical subject matter potentially relevant to the invention, not simply whether AI was used.
2. **Investigate contribution, not usage.** Where AI played a material role, identify what each proposed inventor contributed before and after the relevant AI output.
3. **Create an escalation trigger.** Routine AI assistance does not require special review, but AI generation of potentially claimed features may trigger a focused inventorship inquiry.
4. **Preserve selectively.** Retain key prompts, outputs, drawings, modifications, or explanations where they help establish human conception rather than retaining every AI interaction.
5. **Revisit inventorship as claims change.** The relevant inquiry ultimately concerns claimed subject matter, so the inventorship analysis should evolve with the claims.
6. **Coordinate patent and AI-governance policies**. Ensure retention or deletion rules do not automatically destroy potentially important conception evidence.

**AI Doesn't Necessarily Change Inventorship—It Changes What We Need to Remember**

Generative AI does not necessarily require a new law of inventorship. In many cases, it will likely function exactly as the USPTO's current guidance contemplates: as another tool used by a readily identifiable human inventor. But treating AI as a tool does not eliminate the factual question of what the human using that tool actually conceived.

That question may become harder to answer as AI becomes more deeply integrated into ordinary R&D. AI can create an extraordinarily detailed record of inventive activity, such as prompts, outputs, revisions, selections, and timestamps, while making that same record remarkably easy to lose.

Companies therefore need not document AI merely because it was used. They should preserve enough of the development history to reconstruct human contribution when AI materially participates in generating potentially patentable subject matter.

The emerging challenge of AI-assisted invention may be less about redefining who can be an inventor than about ensuring that, years later, we can still prove who was.

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# Don’t Set It and Forget It: Why Trademark Licensors Must Maintain Quality Control



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When it comes to license agreements, signing the agreement can often feel like the end of the licensor’s involvement—grant the rights, collect the royalties, and let the licensee take it from there. When the licensed asset is a trademark though, “set it and forget it” can be a dangerous strategy.

This trademark-specific risk was recently illustrated in an order from the U.S. District Court for the Central District of California in Lagree Fitness, Inc. v. Studio Physique, LLC.

This case centered around Lagree Fitness and its licensing of several of its trademarks to a fitness studio named Studio Physique. After entering into a licensing agreement in 2015, Lagree effectively took the “set it and forget it” approach, exercising little ongoing oversight over Studio Physique’s operations. In particular, Lagree did not conduct any audits or regular inspections of Studio Physique’s equipment or premises, did not require routine equipment maintenance reports, did not inspect or manage Studio Physique’s marketing materials, and only visited the premises for the grand opening and three trainer certification programs. After approximately 10 years, Lagree attempted to terminate the agreement and sued for trademark infringement, seeking a preliminary injunction to stop Studio Physique’s continued use of its marks.

In order to obtain a preliminary injunction, Lagree needed to establish a likelihood of success on its trademark infringement claim. To do so, it needed to first show that it had a valid and protectable trademark. The court denied Lagree’s motion, finding that “Lagree has not demonstrated that it likely has a valid and protectable trademark to enforce against Studio Physique because it likely abandoned its trademark rights through naked licensing.”

"Naked licensing" is a trademark-specific risk that occurs when a licensor fails to exercise adequate quality control over a licensee's use of its trademarks. This concern is particularly important in trademark licensing because trademarks are intended to serve as indicators of source for given goods or services and are thus inextricably linked to the goodwill associated with those goods or services. Accordingly, when a trademark owner allows a licensee to use its marks without maintaining sufficient control over the quality of those goods or services, the marks may cease to serve that function, potentially resulting in abandonment of the owner's trademark rights.

With this in mind, the relevant question becomes what level of quality control is sufficient for trademark licensors to avoid naked licensing. The court here noted that the "requisite degree of control varies by situation," but identified three questions courts typically consider in this regard: (1) whether the licensing agreement gives the licensor a meaningful right to inspect and supervise the licensee; (2) whether the licensor actually exercises control over the licensee's operations; and (3) whether the licensor can reasonably rely on the licensee to maintain appropriate quality standards.

Applying those factors, the court found that Lagree fell short in each respect. The licensing agreement did not give Lagree meaningful rights to inspect or supervise Studio Physique's operations, and Lagree exercised little actual control over the course of the parties' ten-year relationship. The court also found that Lagree could not reasonably rely on Studio Physique to maintain quality on its own because Lagree had made little effort to familiarize itself with Studio Physique's quality-control practices. Taken together, these circumstances supported a finding that Lagree had likely engaged in naked licensing and had thus likely abandoned its trademarks.

For trademark owners, the court's order here underscores the importance of treating quality control as an ongoing obligation rather than a contractual formality. Trademark license agreements should provide the licensor with meaningful rights to monitor and enforce quality standards, whether through inspection rights, approval requirements, operating standards, or similar mechanisms. Just as importantly, licensors should actually exercise those rights and document their efforts to do so. Although the level of oversight required will vary depending on the circumstances, quality-control provisions should not simply sit unused in the agreement. Ongoing oversight can be critical to preserving the trademark rights the license is intended to monetize.

# MVS: *SUPPORTING INNOVATION EVENTS*

**LEGUS 2026 Fall Meeting**
November 5-7, 2026 - New York, NY
**Jill N. Link, Pharm.D., JD,** Partner and Patent Attorney in the Biotechnology/Technology Practice Group and Licensing Practice Group.

**LEGUS NextGen Summit**
November 4-5, 2026 - New York, NY
**Andrew J. Morgan,** Trademark Attorney and Co-Chair, MVS Trademark Practice Group

**American Institute of Chemical Engineers (AIChE) Conference**
November 6-10, 2026 - Minneapolis, MN
**Montana B. Minnis,** Patent Agent in the MVS BioChem Practice Group

**ASTA 2026 Field Crop Seed Convention**
December 7-10, 2026 - Chicago, IL
**Charles P. Romano, PhD,** Sr, Patent Agent in the MVS BioChem Practice Group

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