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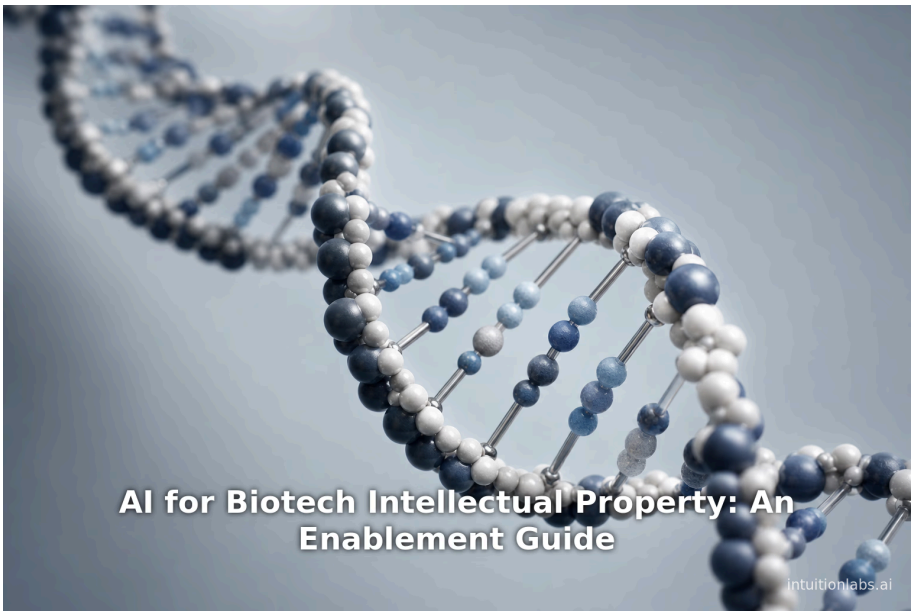
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AI for Biotech Intellectual Property: An Enablement Guide

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Published by IntuitionLabs · 2026-06-27 · ai for biotech intellectual property · biotech patent search ai · ai in life sciences legal departments · intellectual property management for biotech · generative ai for patent drafting · ai ip strategy for startups · legal tech for biotechnology companies · ai in drug discovery patenting

Original article: https://intuitionlabs.ai/articles/ai-for-biotech-intellectual-property



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Executive Summary

Artificial intelligence has moved from a peripheral research aid to a load-bearing component of biotech intellectual property (IP) practice, touching everything from prior art discovery to inventorship documentation to patent drafting. The global legal AI market was valued at $1.4 billion in 2024 and is projected to reach $3.9 billion by 2030 at a 17.3% compound annual growth rate (grandviewresearch.com), while narrower estimates of the AI-driven drug discovery segment put its value at $1.8 billion in 2024, rising to a projected $13.4 billion by 2035 (goodwinlaw.com). For biotech IP teams specifically, AI now performs three broad jobs: it searches and analyzes patent and scientific literature at a scale no human team can match, it assists with drafting and prosecution workflows, and it forces a reckoning with a legal question that remains unsettled: who, or what, counts as an inventor when a machine-learning model proposes the molecule.

That last question has a clear answer in the United States and Europe, even if its application to specific biotech workflows does not. Under U.S. patent law, only a natural person can be named as an inventor. The European Patent Office has likewise confirmed that an inventor designated on a European patent application "must be a human being" (epo.org). In November 2025, the United States Patent and Trademark Office (USPTO) issued revised inventorship guidance that rescinded its February 2024 framework "in its entirety," reaffirming that the same legal standard for determining inventorship applies to all inventions "regardless of whether AI systems were used in the inventive process" and that AI tools are treated as instruments akin to laboratory equipment rather than co-inventors (uspto.gov).

Despite that settled framework, the practical application to AI-driven drug discovery (AIDD) remains genuinely contested. More than 500 U.S. Food and Drug Administration (FDA) submissions between 2016 and 2023 included AI components (goodwinlaw.com) (fda.gov), yet courts have not clarified how much human contribution is legally sufficient when a generative model proposes the compound structure. A May 2025 study in *Science* by Freilich and Rai found that AI-derived drug patents involve less in-depth, in vivo testing before filing than conventional pharmaceutical patents, raising questions about premature patenting (pubmed.ncbi.nlm.nih.gov). This report examines the AI tools biotech IP teams actually use (patent search and analytics platforms such as PatSnap Eureka, IPRally, Boundly, and Cypris; drafting-focused tools such as DeepIP and Qthena), the legal and regulatory scaffolding that governs their outputs, the economics of deploying them against biotech's brutal patent-cost realities (a five-jurisdiction filing portfolio can run $150,000 to $400,000 over five years (iinvent.co)), and named case studies including Insilico Medicine, Recursion Pharmaceuticals, and Royal Philips.

The evidence points to a measured but real return on investment. According to a DeepIP-published (vendor) blog post, Philips' in-house IP team observed a conservative 20% efficiency gain in drafting and prosecution during its AI tool trial period, with vendor estimates of 3-10x return on investment depending on adoption depth (deepip.ai). A 2026 survey of 452 in-house legal professionals found 52% of teams already using or evaluating AI for contract review, with active usage nearly quadrupling since 2024 (legalontech.com), yet a separate March 2026 survey of 528 in-house legal leaders found only 7% of teams have actually scaled AI across their organization and 83% cannot measure whether their AI spending is working (axiomlaw.com). For biotech companies specifically, where an unclear title or a single missed prior art reference can derail a financing round or a licensing deal, the report concludes that AI tools are best understood as force multipliers for experienced IP counsel rather than replacements for them, and that governance, documentation, and human-contribution recordkeeping matter as much as the underlying model's accuracy.

Introduction and Background

Biotechnology occupies a peculiar position in intellectual property law: it is simultaneously one of the most patent-dependent industries and one of the most expensive to protect. Bringing a single therapeutic to market can take more than a decade and cost more than one billion dollars, and only about one in five drug candidates that enter clinical testing ever reaches approval (wipo.int). Because most biotech startups have no product revenue for years, their patent portfolio is often their primary balance-sheet asset and the chief signal investors use to gauge downside protection: Gilead's 2017 acquisition of Kite Pharma for nearly $12 billion rested heavily on Kite's chimeric antigen receptor (CAR)-T cell therapy patent portfolio, even though Kite carried more than $600 million in accumulated debt at the time of the deal(wipo.int). The subject matter this patent-dependent industry actually protects is unusually heterogeneous by patent-law standards, spanning proteins described by functional or structural properties, proteins described by amino acid sequence, plasmids, vectors, antibodies, antigens, hybridomas, and nucleic acids described by nucleotide sequence, which is precisely why keyword-based prior art search performs so poorly in this domain and why AI search tools built around semantic and sequence-aware matching have found a ready market among biotech IP teams (wipo.int).

Into this high-stakes environment, artificial intelligence has arrived from two directions simultaneously. First, AI is now embedded in the drug discovery process itself. One widely cited 2022 *Nature Reviews* analysis found that the number of startup drug-candidate pipelines employing AI was already roughly equivalent to 50% of the preclinical programs run by big pharmaceutical firms (fenwick.com). Generative chemistry models can propose tens of thousands of candidate molecular structures in hours, and Insilico Medicine's AI-designed TNIK inhibitor for idiopathic pulmonary fibrosis reached Phase II clinical trials with a preclinical-to-candidate timeline of roughly 18 months, versus a conventional expectation of five to six years (drugpatentwatch.com) (fenwick.com). Second, AI has arrived inside the patent function itself, in the form of software that searches prior art, drafts specifications and claims, monitors competitor filings, and triages invention disclosures. These two arrivals are related but distinct: the first raises questions about whether a discovery is patentable at all, while the second is a productivity and workflow question about how patent professionals do their jobs.

Patent filing activity reflects both. AI-related patent filings in the pharmaceutical sector grew at a compound annual rate of about 23% from 2020 to 2022, and by 2025, biotech innovators such as **Gritstone Bio** and **Guardant Health** had filed 33 and 26 AI-related patents respectively since 2020, with big pharma players **F. Hoffmann-La Roche** and **Amgen** filing 22 and 20 over the same period (per IntuitionLabs' own patent-analytics research, not independent evidence). In a single quarter, Roche filed 72 AI-themed patents (Q1 2024) and Bayer filed 44 (Q1 2024) and 35 (Q2 2024) (per IntuitionLabs' own patent-analytics research). The United States accounts for roughly half of global AI pharmaceutical patent filings since 2020, ahead of China and Japan (per IntuitionLabs' own patent-analytics research). This report addresses what AI can and cannot do for biotech IP teams today, as of July 2026: how AI patent search and drafting tools work, what the current inventorship and eligibility rules require, how much these tools cost and what returns they deliver, and how biotech-specific concerns (sequence claims, Markush structures, freedom-to-operate against the FDA's Orange and Purple Books) shape tool selection. IntuitionLabs' own patent-analytics research on pharmaceutical AI filings is cited in this report and should be read as the publisher's own analysis rather than independent evidence.

Biotech Patent Search: How AI Prior Art and Novelty Tools Work

The most mature application of AI in biotech IP is patent and prior art search. Traditional Boolean keyword search struggles with biotech's vocabulary problem: a single gene, protein, or compound may be described by dozens of synonymous names across patents filed in different languages and different eras, and biologics claims frequently hinge on sequence homology rather than exact string matches. AI search tools address this with two complementary techniques: semantic or "neural" search, which ranks documents by conceptual similarity rather than exact keyword overlap, and hybrid search, which layers semantic ranking on top of classification-code and citation-graph signals.

Boundly, for example, searches more than 96 million global patents and applications across major offices (USPTO, EPO, JPO, KIPO, CNIPA, WIPO), scoring each result by claim overlap, classification proximity, and citation depth, and surfacing foreign-language references in English (boundly.ai). For pharmaceutical and biologics work specifically, Boundly's search now extends to the FDA's Orange Book (approved small-molecule

drug products with therapeutic equivalence evaluations) and Purple Book (licensed biological products), so listed drug and biologic references surface alongside patent prior art (boundly.ai). This matters for biotech specifically because small-molecule freedom-to-operate (FTO) and invalidity work routinely needs to check against the regulatory exclusivity and patent-listing data the Orange and Purple Books contain, not just the patent corpus. Boundly also advertises a data-handling commitment relevant to any biotech evaluating a vendor's confidentiality posture: the vendor states that a user's search queries "are never used to train a model," a distinction that matters when the query itself may reveal an unfiled invention's technical scope (boundly.ai). The platform also collapses patent families "to a single result so you don't review the same disclosure across five jurisdictions," and lets a user set a priority date so that "the engine excludes anything published after," keeping a patentability search anchored to the correct legal cutoff without manual filtering (boundly.ai).

PatSnap Eureka publishes its own accuracy benchmark against generic large language models: an 81% hit rate on novelty search and a 77% hit rate on design freedom-to-operate search, with the vendor claiming its design FTO results are 83 times more accurate than unassisted ChatGPT output (patsnap.com). These are vendor-published figures rather than independent third-party benchmarks, and the report treats them accordingly: useful as an order-of-magnitude signal, not as a substitute for a buyer's own evaluation against a specific technology area. **IPRally** takes a "Graph AI" approach, representing patent claims and citations as a knowledge graph to support similarity search without requiring users to construct complex Boolean queries (iprally.com). **Cypris** takes a broader R&D-intelligence framing, unifying patents, scientific literature, and market data across a claimed 500 million-plus data point index, positioning itself for corporate R&D teams (including in life sciences and materials science) rather than IP departments alone (cypris.ai) (prnewswire.com). Cypris explicitly markets its life-sciences module around patents, scientific literature, and chemical compounds together, arguing that R&D teams "developing new compounds, formulations, and processes" need prior art search that spans both patent and non-patent scientific literature rather than a patent-only index (www.cypris.ai).

A specialized biotech IP intelligence vendor, **Fyled**, positions itself specifically against the search-versus-signal problem: it argues that biotech matters rarely suffer from a lack of documents but instead from an overwhelming volume of overlapping patents, publications, and conflicting scientific signals, where "the biggest risk isn't missing a patent. It's missing the signal" (fyled.ai). This framing captures a genuine biotech-specific problem: modern patent databases can return hundreds of patents, publications, citations, and inventors on a single search, and the analytical bottleneck has shifted from retrieval to triage (fyled.ai). The vendor pitches its approach as going beyond search and analytics toward understanding "the scientific meaning behind patents, publications, sequences, mechanisms, and competitive programs," positioning itself as a science-first layer on top of the patent-search tools already discussed above (fyled.ai). A life-science-specific invention-triage platform, **Patenter**, targets a related pain point for technology transfer offices (TTOs) and corporate IP teams: a typical TTO files only 30-40% of the disclosures it receives, and a typical corporate IP team ships more than 90% of its products without conducting a full infringement analysis, making triage itself "the most expensive decision in IP" given that a wasted $25,000 filing and a $50 million lawsuit sit on opposite ends of the same decision (patenter.io).

A further category serves combined patent-and-trademark IP departments rather than patent-only functions. **Qthena**, a Questel product built by ipQuants, positions itself as "the only IP Digital Assistant with a purpose-built workspace," bundling invention disclosure generation, patent search and review, trademark search and watch review, freedom-to-operate analysis, patent drafting, claim chart generation, and office action response inside one interface rather than requiring separate point tools for each task (www.questel.com). The vendor advertises that its out-of-the-box workflow automations "increase efficiency by up to 90%," a figure that, like other vendor-published efficiency claims in this market, should be read as a marketing claim pending independent verification rather than an audited benchmark (www.questel.com). For biotech IP departments that manage both patent portfolios and companion trademark portfolios (product and brand names for approved therapeutics, for example), this bundled approach can reduce the number of vendor relationships and associated data-security review cycles a legal department must maintain, though it also concentrates more sensitive IP data inside a single third-party platform.

Generative AI for Patent Drafting: Capabilities and Chemistry-Specific Limits

Patent drafting is the second major AI use case, and it is where biotech's technical specificity creates the sharpest divide between tools that work well and tools that do not. According to one industry survey, patent professionals report using AI for up to 50% of their work time in some functions, though a separate IPRally survey of its own admin users found the picture more measured: 78% of professionals use AI tools for 0-30% of their work time, while a smaller segment (22%) already use AI for 30-50% of their time (deepip.ai) (iprally.com). Within that same survey, patent search and review was the most established use case at roughly 85% adoption among respondent teams, followed by patent analytics at 50%, with patent classification, portfolio analysis, and drafting tied for third place at 17% each (iprally.com). The gap between search adoption (85%) and drafting adoption (17%) is itself informative: patent professionals trust AI more as a retrieval and triage aid than as an author of legal text, particularly in technical domains.

That caution is well founded in chemistry and biotech specifically. General-purpose large language model (LLM) drafting tools generate text probabilistically, which is a poor fit for chemical structures that must be deterministically valid. A 2024 study published in *Nature Machine Intelligence* documented that molecular-generation AI models routinely produce invalid chemical structures (incorrect connectivity, invalid valences, implausible scaffolds), and these same failure modes carry directly into AI-drafted chemical patent claims: a single invalid substituent, an unsupported genus, or a malformed Markush group (the standard patent-claim format for a chemical genus defined by variable substituents) can compromise an entire application (deepip.ai). The distinction the industry draws is between "language-first" tools, which are general LLMs adapted for legal drafting, and "structure-first, domain-specific" tools, which embed chemical logic (Markush-aware drafting rules, structure validation, audit trails linking each clause to its underlying input) directly into the workflow (deepip.ai).

Table 1 below summarizes the primary categories of AI IP tools relevant to biotech patent work, drawing on vendor documentation and independent practitioner commentary gathered during this research.

Tool category	Representative platforms	Primary biotech-relevant function	Reported pricing (as of July 2026)
Patent search and novelty/FTO analytics	PatSnap Eureka, IPRally, Boundly, Cypris	Prior art retrieval, freedom-to-operate scoring, cross-lingual and cross-database search including FDA Orange/Purple Book coverage	PatSnap Eureka Patent Searching: **$400/month**; PatSnap Eureka Free tier available (eureka.patsnap.com)
Patent drafting and prosecution	DeepIP, PatSnap Eureka Drafting, Qthena, Patlytics	Invention disclosure capture, first-draft specifications and claims, office action response drafting, chemical/Markush-aware drafting	PatSnap Eureka Patent Drafting: **$200/month** (eureka.patsnap.com)
Biotech-specific patent intelligence and triage	Fyled, Patenter	Signal extraction from overlapping scientific and patent literature; disclosure and product-launch triage against novelty and FTO risk	Custom/enterprise, not publicly listed
Life-science AI research and discovery search	PatSnap Eureka Life Sciences Agents	Lead compound search and pharma-specific analysis, SAR (structure-activity relationship) data extraction from patents	Eureka Life Sciences Pro reported at **$400/month** (pricingsaas.com)

The table shows a market segmented less by company size than by workflow stage: search tools compete on database breadth and semantic precision, while drafting tools compete on domain-specific structural validity, and the pricing spread ($200 to $400 per month at the individual-seat tier, before enterprise contracts) suggests these are being sold as productivity add-ons for individual practitioners as much as departmental platform purchases. Practitioner commentary on a patent-law discussion forum corroborates the market's own segmentation: one in-house team reported using PatSnap for "quick novelty searches, diligence, and FTO searches" while treating DeepIP as a slower-to-learn tool best suited to office-action review, and another reported that a competing drafting tool "doesn't hallucinate but it doesn't do a very good job," describing its tendency to reproduce inventor disclosure language verbatim rather than synthesizing a proper generic claim term (reddit.com). Such community sentiment should be read as anecdote, not a controlled evaluation, but it aligns with the vendor-side consensus that biotech and chemistry claims punish drafting tools that were built primarily for software or mechanical patents. On a separate patent-law discussion thread, one patent attorney who also builds drafting software estimated that AI-assisted drafting can already cut attorney hours "by two," with a longer-term trajectory toward roughly five hours per application instead of the conventional 20 to 25, for the time needed to understand the invention, feed it to the AI system, and review the output (reddit.com). That estimate comes from a vendor with a direct commercial interest in the answer and should be discounted accordingly, but directionally it is consistent with the roughly 20% efficiency improvement a Philips IP executive described in a DeepIP-published blog post (a self-reported figure relayed in vendor marketing content, not an independent benchmark), suggesting the true figure for chemistry-light patent work likely sits somewhere between the vendor's optimistic estimate and the more conservative in-house benchmark.

AI Inventorship, Eligibility, and the Unsettled Law of AI-Driven Discovery

No governance question looms larger over biotech AI-IP practice than inventorship: if a generative model proposes a novel therapeutic compound, who is legally entitled to be named as the inventor, and does the answer change what can be patented at all? The doctrinal starting point is the Patent Act's requirement that an inventor be a natural person, which forecloses AI systems from inventor status regardless of their actual contribution, and the European Patent Office applies the same human-inventor requirement to European applications.

What has genuinely shifted is the standard for evaluating *human* inventorship when AI assisted the process. In February 2024, the USPTO issued its first Inventorship Guidance for AI-Assisted Inventions, which applied the *Pannu* joint-inventorship factors to assess whether a human's contribution to an AI-assisted invention was significant enough to qualify for inventorship (pmc.ncbi.nlm.nih.gov). In November 2025, the USPTO rescinded that 2024 guidance in its entirety and issued revised guidance implementing Executive Order 14179, "Removing Barriers to American Leadership in Artificial Intelligence" (uspto.gov). The Federal Register notice itself explains the mechanics: the *Pannu* factors "only apply when determining whether multiple natural persons qualify as joint inventors," and are simply inapplicable when a single natural person develops an invention with AI assistance, because an AI system is not a person and so there is no joint-inventorship question to analyze in the first place (federalregister.gov). The key substantive change: the USPTO now treats AI systems as tools analogous to laboratory equipment, explicitly stepping away from a joint-inventorship framing that had implicitly analogized AI contributions to a second human collaborator's (sternekessler.com). The February 2024 guidance articulated several principles; this report does not assume they carried over unchanged into the November 2025 revision. Under the 2024 guidance, a natural person's use of an AI system does not by itself negate that person's status as an inventor; merely recognizing a problem or having a general research goal does not rise to the level of conception; and reducing an invention to practice alone, without more, is not a significant contribution (pmc.ncbi.nlm.nih.gov). The 2024 guidance also stated that merely maintaining "intellectual domination" over an AI system, that is, having the ability to control or direct it, does not on its own make a person an inventor of whatever the system produces, which, under that now-rescinded guidance, foreclosed a shortcut argument that simply owning or operating the AI platform is sufficient for inventorship (pmc.ncbi.nlm.nih.gov).

The European Patent Office's approach to AI patentability runs on a parallel but distinct track focused on technical character rather than inventorship. Under the EPO's Guidelines for Examination, AI and machine learning methods (neural networks, genetic algorithms, support vector machines, and similar computational models) are "per se of an abstract mathematical nature," but their use "does not by itself render inventions related to artificial intelligence or machine learning non-patentable" so long as the claim is directed to a method involving technical means or to a device with technical character as a whole (epo.org). Updated EPO examination guidelines effective April 1, 2025 clarified this framework specifically for AI inventions (secerna.com). In practice, EPO examiners apply a "two-hurdle approach" to any AI or software-related claim: the first, easier hurdle requires only that the invention be technical and not solely directed to excluded subject matter (reciting a computer or a computer-implemented method typically suffices), while the second and more

demanding hurdle applies the "COMVIK approach," established in decision T 641/00 (epo.org) and confirmed by the Enlarged Board of Appeal in G 1/19, under which only the claim features that contribute to a technical solution to a technical problem count toward inventive step (secerna.com). For biotech applicants drafting AI-related claims for European filing, this means the specification should identify, as filed, which specific technical problem the AI or machine learning component solves and should include a detailed disclosure of the training methods, datasets, and algorithms a skilled person would need to reproduce the invention, since non-technical features contribute nothing to inventive step under COMVIK even if they are central to the claim's commercial value (secerna.com). The EPO's own guidelines illustrate the point with a health-adjacent example directly relevant to biotech and medical device applicants: using a neural network inside a heart-monitoring apparatus to identify irregular heartbeats is treated as making a genuine technical contribution, because the classification task is tied to a specific technical application rather than claimed as an abstract algorithm in isolation (epo.org).

For biotech specifically, the stakes of the inventorship question are amplified by an economic and scientific problem the courts have not yet resolved: conception in drug discovery traditionally requires both an appreciation of a molecular structure and an understanding of how to make it, but when a generative model proposes a structure that satisfies preset constraints, courts have offered "little guidance" on whether the human team's problem-framing, constraint-setting, and candidate-selection choices amount to the "significant contribution" the law requires (goodwinlaw.com). Legal commentators recommend that biotech IP teams contemporaneously document how scientists framed the problem, why specific constraints and endpoints were chosen, how data was selected or excluded, and why some AI-generated candidates advanced while others were rejected, precisely because this record both establishes human contribution and builds credibility with examiners, investors, and partners well before any courtroom test (goodwinlaw.com). Insilico Medicine's general counsel, writing in the peer-reviewed *Journal of Law and the Biosciences*, similarly argues that while the Inventorship Guidance provides welcome clarity, "there remain concerns with the application of the framework," including the complex, real-world assessment of substantial human contributions across collaborative, multi-party AIDD partnerships (pmc.ncbi.nlm.nih.gov).

A related but analytically distinct question is whether AI-assisted compound discovery satisfies the separate, non-obviousness requirement even once inventorship is resolved. Patent counsel note that because machine learning algorithms can rapidly evaluate millions of molecular combinations, discoveries that would have taken a human medicinal chemist years to reach by trial and error can start to look "obvious to try" in hindsight, a legal standard that traditionally applies when there is a finite number of identified, predictable solutions and a reasonable expectation of success (sternekessler.com). Key factors examiners and courts are likely to weigh include the size and diversity of the chemical space an AI model actually explored, whether the model revealed a genuinely unexpected structure-function relationship, and the degree of human intervention in training and interpreting the model, meaning that documentation practices built for the inventorship question tend to double as evidence for the non-obviousness question as well (sternekessler.com).

AI in Life Sciences Legal Departments: Adoption, Budgets, and Governance

Biotech IP practice sits inside a broader in-house legal AI adoption trend that is accelerating unevenly. Deloitte's 2025 predictions noted that over two-thirds of organizations planned to increase generative AI investment entering 2025, with significant executive support flowing to legal departments as a downstream beneficiary (deloitte.com). By 2026, LegalOn and In-House Connect's survey of 452 in-house legal professionals found that 52% of teams were already using or evaluating AI for contract review, with active usage nearly quadrupling since 2024, and that 87% believed AI would benefit contract review and redlining given that legal teams spend an average of 3.1 hours reviewing a single contract (legalontech.com). Seventy-nine percent of respondents reported reduced time on routine legal tasks, and 80% were exploring or evaluating AI agents, though teams overwhelmingly preferred supervised, human-in-the-loop automation over full autonomy (legalontech.com).

That optimism should be read against a more sober counterpoint. A March 2026 survey of 528 in-house legal leaders across six countries, conducted by InsightDynamo for Axiom, found that only 7% of teams have actually scaled AI across their organization and that 83% cannot measure whether their AI spending is working, even as 100% of teams already using AI plan to raise their AI budget in the next cycle (axiomlaw.com). The same survey found that 98% of teams already using AI say outside guidance would help them use it more effectively, suggesting that the gap is less about willingness to invest and more about a shortage of proven implementation playbooks (axiomlaw.com). This gap between enthusiasm and measurable outcomes is the defining characteristic of AI adoption in legal departments broadly, and biotech legal and IP teams are not exempt from it: enthusiasm for AI's potential outpaces most departments' ability to prove that potential converted into value.

For life sciences and healthcare organizations specifically, security is a distinct governance concern given the sensitivity of chemical, formulation, sequence, and patient-adjacent data that flows through AI IP tools. A 2023 Deloitte UK survey found that third-party relationships and identity management are "top-level concerns" for life sciences and healthcare organizations, a concern that only intensifies when those third parties are AI vendors processing proprietary compound and sequence data (deepip.ai). The U.S. National Institute of Standards and Technology's (NIST) AI Risk Management Framework similarly flags a core risk of AI systems as their "lack of transparency and explainability," and emphasizes that users must be able to understand a system's limitations and the reasoning behind its outputs, a standard directly relevant to any AI tool whose output will ultimately support a patent claim or an FDA submission. NIST released the AI Risk Management Framework (AI RMF) on January 26, 2023, describing it as intended for voluntary use to help organizations incorporate trustworthiness considerations into the design, development, and evaluation of AI systems, and it followed that framework in July 2024 with a companion Generative Artificial Intelligence Profile addressing risks specific to generative models (www.nist.gov).

On the regulatory side specifically, the FDA's Center for Drug Evaluation and Research (CDER) established a dedicated CDER AI Council in 2024 to provide oversight, coordination, and consolidation of the agency's internal AI activities, replacing a patchwork of an AI Steering Committee, an AI Policy Working Group, and an

AI Community of Practice that had grown up around the issue piecemeal (www.fda.gov). FDA officials from CDER and the Center for Biologics Evaluation and Research (CBER) also collaborated directly with the European Medicines Agency (EMA) to develop 10 joint guiding principles for the use of AI in accelerating drug and biological product development, published in January 2026, giving biotech sponsors operating across both the U.S. and European Union a converging rather than diverging set of expectations on this point (www.fda.gov).

AI IP Strategy for Biotech Startups: Budget Realities and Practical Sequencing

Biotech startups face a distinct version of the AI-and-IP question: not whether to adopt AI tools, but how to sequence limited capital across search, drafting, and prosecution when the underlying patent budget itself is severely constrained. A full five-jurisdiction patent portfolio (United States, Europe, China, Japan, and Korea, the five jurisdictions most investors and acquirers consider essential) costs somewhere between $150,000 and $400,000 over a five-year period, a figure well beyond what most pre-seed and seed-stage biotech startups can commit (iinvent.co). A startup with as little as $15,000 to $30,000 in IP budget can, with the right sequencing, still establish patent-pending status, priority dates, and adequate early prosecution quality, while deferring the more expensive national-phase filings until capital allows (iinvent.co).

Against that backdrop, AI search and drafting tools function less as a luxury and more as a way to extend a constrained IP budget further. AI-assisted prior art search can substitute for some of the billable hours a firm would otherwise spend on manual novelty and FTO searches before a filing decision, and AI-assisted invention triage can help a resource-constrained team decide which of several competing disclosures actually merits the $8,000 to $15,000 it costs to prosecute a single U.S. non-provisional application to grant (iinvent.co). This is precisely the "triage" problem that platforms like Patenter and Fyled are built to address, since a poorly triaged decision (filing on a disclosure that will not survive novelty scrutiny, or failing to file on one that would have blocked a competitor) is far more expensive than the AI tool itself.

Startup patent strategy also intersects directly with AI licensing and deal structure in ways that did not exist five years ago. Because AI shatters the traditional linear model of "researcher invents, institution owns, licensee commercializes" by distributing inventive contributions across algorithms, datasets, and human researchers, ownership ambiguities now surface routinely during financing rounds, valuation negotiations, and post-acquisition integration (healthcarelawinsights.com). Legal commentary identifies three recurring gaps in licensing agreements drafted before AI became integral to a program: ambiguity over model-ownership versus output-ownership, unresolved training-data lineage and consent issues (particularly where genomic or patient data is involved), and a mismatch between FDA's expectation that sponsors be able to explain and validate AI-driven discoveries and many AI vendors' unwillingness to provide the underlying validation documentation (healthcarelawinsights.com). Where a university spins out a company built substantially on an AI platform's contribution, commentators note that platform's share of the underlying innovation can run in the range of 30% to 40%, leaving founder equity allocation genuinely unresolved and creating downstream dilution risk before the first institutional investor even arrives (healthcarelawinsights.com).

Practical sequencing for a resource-constrained biotech IP strategy therefore looks roughly as follows:

- **Adopt AI search before AI drafting.** Search tools have the highest measured adoption (roughly 85% among IPRally's surveyed teams) and the clearest return, since a missed prior art reference is categorically more expensive than a slightly-slower first draft (iprally.com).
- **Reserve chemistry-heavy drafting for structure-first tools**, not general-purpose LLMs, given documented failure modes around invalid Markush structures and unsupported genus claims (deepip.ai).
- **Document the human contribution contemporaneously** for every AI-assisted discovery, capturing problem framing, constraint selection, and candidate rejection rationale, in line with post-2025-guidance best practice.
- **Negotiate AI licensing terms explicitly**, specifying model-versus-output ownership, training-data lineage and consent chain-of-custody, and vendor cooperation obligations for FDA validation requests (healthcarelawinsights.com).
- **Budget for triage, not just filing.** An AI-assisted invention-disclosure triage step, even an inexpensive one, reduces the risk of both overspending on commercially irrelevant patents and underspending on the core moat (patenter.io).

A worked illustration from startup patent-strategy practice shows how this sequencing plays out in dollar terms over three years: one documented approach staged spending as a US non-provisional filing, then a Chinese utility model registration, then a Chinese invention patent and an EPO patent in prosecution, then a Korean patent and a continuation covering the first identified competitor, for a total spend of $44,000 across three years, with $6,000 remaining in the budget for the next prosecution round (iinvent.co). That is described in the source as "not the maximum portfolio," but as a purposeful, commercially grounded one that would satisfy Series A intellectual property due diligence at a startup of that stage, precisely the kind of disciplined sequencing that AI-assisted search and triage tools are designed to support at each decision point (iinvent.co).

Data Analysis and Evidence

Several independent market-sizing estimates place the broader legal AI market's 2024-2025 value between roughly $1.4 billion and $3.1 billion, depending on scope and methodology, with growth projections through 2030 ranging from a 17.3% CAGR (Grand View Research) to a more aggressive 28.3% CAGR (MarketsandMarkets). Grand View Research's estimate placed the global legal AI market at $1.4 billion in 2024, growing to $2.1 billion by 2026 and $3.9 billion by 2030 at a 17.3% CAGR, with North America accounting for 46.0% of 2024 revenue (grandviewresearch.com). A separate MarketsandMarkets estimate placed the narrower "legal AI software" segment at $3.11 billion in 2025, projected to reach $10.82 billion by 2030 at a 28.3% CAGR (prnewswire.com). The disparity between these estimates illustrates a persistent measurement problem in this space: "legal AI" and "legal technology" are not consistently scoped across research firms, and a biotech IP buyer should treat any single market-size figure as directional rather than precise. Within Grand View Research's segmentation, the solutions (software) segment accounted for the largest share of 2024 revenue, driven by growing adoption of legal AI software to automate routine, repetitive legal work, while the services segment (integration and consulting) is expected to post the fastest growth through 2030 as more organizations need help implementing rather than simply licensing these tools (grandviewresearch.com).

Table 2 below lines up the divergent market-size estimates gathered during this research side by side, so the scope and methodology differences behind each headline figure are visible rather than hidden inside a single cited number.

Source	Segment scoped	Base-year value	Projected value	CAGR
Grand View Research	Global legal AI market (software plus services)	$1.4 billion (2024)	$3.9 billion (2030)	17.3% (grandviewresearch.com)
MarketsandMarkets	"Legal AI software" (narrower software-only scope)	$3.11 billion (2025)	$10.82 billion (2030)	28.3% (prnewswire.com)
Goodwin (citing third-party projection)	AI-driven drug discovery specifically (a biotech-relevant subsegment, not general legal AI)	$1.8 billion (2024)	$13.4 billion (2035)	Not stated as a CAGR in source (goodwinlaw.com)

As *Table 2* shows, none of these figures are directly comparable: Grand View Research and MarketsandMarkets scope different slices of the same general "legal AI" category using different base years, while Goodwin's figure describes an entirely different market, AI-driven drug discovery, that overlaps only partially with legal AI spending. A biotech IP buyer reading vendor materials or press coverage that cite a single headline number should ask which of these scopes, if any, the cited figure actually describes before using it to justify a budget request.

For the AI-driven drug discovery segment specifically, discussed further in *Table 2* below, a narrower and more directly biotech-relevant estimate places 2024 revenue at $1.8 billion, projected to reach $13.4 billion by 2035. Patent filing data corroborates that this is a growing, not merely a hypothetical, market: AI-related pharmaceutical patent filings grew at roughly 23% CAGR between 2020 and 2022, and the top filers among biotech innovators (Gritstone Bio, Guardant Health) filed dozens of AI-related patents over a five-year window (per IntuitionLabs' own patent-analytics research).

On the regulatory side, the FDA's own account of its submission experience is instructive: the agency has reviewed more than 500 drug and biological product submissions containing AI components since 2016, and "the use of AI in drug development and in regulatory submissions has exponentially increased" over that period (fda.gov). Then-FDA Commissioner Robert M. Califf framed the agency's approach in explicitly enabling terms when the related AI credibility framework was proposed, stating that "with the appropriate safeguards in place, artificial intelligence has transformative potential to advance clinical research and accelerate medical product development to improve patient care" (fda.gov). On the patent office side, the USPTO's own modernization efforts reflect the same trend from the examiner's side of the desk: its Artificial Intelligence Search Automated Pilot Program (ASAP!), launched for applications filed between October 20, 2025 and April 20, 2026, tests an internal AI tool's ability to conduct automated pre-examination prior art searches, targeting at least 1,600 applications distributed across technology centers, with at least 200 applications accepted per technology center that examines utility applications (uspto.gov). This is a significant signal for biotech applicants specifically, since it indicates the same automated search technology increasingly used on the applicant side is

now being formally piloted on the examiner side as well, with the potential to compress the time between filing and the first substantive Office Action. Under the pilot's mechanics, the assigned examiner is instructed to consider the AI-surfaced documents "in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art," meaning the automated results become a genuine part of the examination record rather than an informational-only add-on (uspto.gov).

Independent scientific scrutiny of AI-derived drug patents has begun to surface tensions the market-size figures do not capture. Freilich and Rai's May 2025 Policy Forum article in *Science*, based on an analysis of granted drug compound patents from more than 100 AI-drug companies, found a pattern the authors characterized as concerning: less in-depth, in vivo testing occurs before patenting, potentially affecting overall research and development outcomes (pubmed.ncbi.nlm.nih.gov). This finding drew a direct rebuttal from IP commentators, who argued there is no legal requirement for drug compound patents to disclose the discovery process that led to a claimed compound, and that AI drug companies, being in the expensive drug-discovery business, have little incentive to pursue granted patents on molecules they do not believe are commercializable (ipkitten.blogspot.com). The disagreement between these two credible sources (a *Science* Policy Forum article and a widely read IP-practitioner rebuttal) is presented here as an open empirical and normative question rather than a settled fact, and biotech IP teams evaluating their own AI-assisted patenting practices should weigh both perspectives rather than assume either is dispositive.

Market segmentation data adds further texture to the growth figures above. Within the broader legal AI market, Grand View Research found that the legal research application segment dominated 2024 revenue, driven by AI-powered natural language processing (NLP) tools that interpret complex legal language and surface relevant case law and statutes, while the natural language processing technology segment overall is projected to post the fastest growth of any technology category, at a 17% CAGR from 2025 to 2030 (grandviewresearch.com). Regionally, Asia Pacific is projected to grow fastest among all regions, at a 20% CAGR through 2030, reflecting a supportive regulatory environment and expanding legal-tech ecosystems in markets including Japan (grandviewresearch.com).

The litigation-economics dimension of AI-accelerated drug discovery is likewise becoming more concrete. Because AI can compress the preclinical portion of a drug's development timeline, companies that file compound patents earlier retain more of the twenty-year patent term by the time of FDA approval, which directly increases the effective exclusivity window and the net present value of the asset, an effect that is more pronounced for small-molecule programs governed by the Hatch-Waxman framework and Orange Book listings than for biologics programs governed by the twelve-year reference-product exclusivity clock under the Biologics Price Competition and Innovation Act (BPCIA) (www.drugpatentwatch.com). At the same time, AI is being used on the challenger's side of the docket as well, to mine competitor patent portfolios for invalidity arguments and to support the kind of Paragraph IV Abbreviated New Drug Application (ANDA) challenges that trigger Hatch-Waxman litigation, meaning the same acceleration that helps an innovator file earlier also arms generic and biosimilar challengers with faster prior art analysis once that patent is asserted (www.drugpatentwatch.com).

Case Studies and Real-World Examples

Insilico Medicine: AI-Designed Compound to Phase II in 18 Months

Insilico Medicine, a clinical-stage AI-driven biotech, used generative chemistry models to identify **INS018_055**, a novel TNIK inhibitor for idiopathic pulmonary fibrosis, reaching Phase II clinical trials with a preclinical-to-candidate discovery timeline of approximately 18 months, compared with the conventional five-to-six-year expectation for that phase (drugpatentwatch.com). The company filed patents on both the compound itself and the underlying AI discovery platform (drugpatentwatch.com). Insilico's general counsel, writing in the peer-reviewed *Journal of Law and the Biosciences*, describes her role overseeing IP among a portfolio that included a drug R&D collaboration with Sanofi potentially worth up to $1.2 billion and a drug license-out with Exelixis involving an $80 million upfront payment, underscoring how directly IP strategy and AI-driven discovery outcomes are financially intertwined for AIDD-focused biotechs (pmc.ncbi.nlm.nih.gov).

Royal Philips: Measured, Trial-Based AI Adoption in an In-House IP Function

Royal Philips began evaluating AI tools for its in-house IP function in 2023 and, according to its Head of IP Data and AI Tom Tassignon, deliberately avoided treating AI as a replacement for patent attorneys: "the true value that can be determined from IP is still done by the patent attorney," with AI functioning as a tool to help extract value from the in-house counsel's existing strategic knowledge (deepip.ai). During its trial period, according to the same vendor-published post, Philips observed an approximately 20% efficiency improvement in drafting and prosecution work, a figure the company characterized as conservative (deepip.ai). Philips found AI particularly valuable for novelty searches, patent drafting support, and prosecution management, including generating a quick preliminary analysis of an Office Action that previously would have been immediately outsourced to external counsel. Vendor-reported ROI across DeepIP's broader client base runs 3-10x investment depending on adoption depth, a figure that should be read as a vendor claim rather than independently verified (deepip.ai).

Recursion Pharmaceuticals: Machine-Learning Patents on Biological Data Analysis

Recursion Pharmaceuticals runs phenotypic screens at scale using convolutional neural networks that process cellular imaging data to identify morphological signatures associated with disease states, and has built a discovery pipeline predicated on computational hits validated by automated wet-lab experiments (drugpatentwatch.com). Recursion has patented advanced AI methods, according to IntuitionLabs' own patent-analytics research.

USPTO's ASAP! Pilot: AI Search Moves to the Examiner's Desk (Hypothetical Example: Illustrative Biotech Applicant)

The USPTO's Artificial Intelligence Search Automated Pilot Program, running from October 20, 2025 through April 20, 2026, provides an early, concrete signal of how AI search will affect biotech patent prosecution timelines going forward. Under the program, an automated search is run prior to formal examination and an Automated Search Results Notice (ASRN) is sent to the applicant, giving earlier visibility into potential prior art issues; applicants are not required to respond, but may choose to file a preliminary amendment or request deferral in light of the notice (uspto.gov). (Hypothetical Example) Consider a hypothetical biotech applicant whose original, non-continuing utility application is accepted into the ASAP! pilot: an early ASRN flagging a closely related sequence patent could allow the applicant's IP team to file a narrowing preliminary amendment months before the assigned examiner would otherwise have surfaced the same reference, potentially avoiding a full rejection-and-response cycle and shortening the path to allowance. This illustrates the pilot's intended mechanism rather than a documented individual case, since the program accepted petitions only from October 2025 and is now closed, and no outcome data had been located as of this report's publication date.

Implications and Future Directions

Several structural trends are likely to shape how biotech IP teams use AI over the next 24 to 36 months. First, the inventorship question, while doctrinally settled at the level of "AI cannot be named as an inventor," remains operationally unsettled at the level of "how much human contribution is enough," and this ambiguity will likely be resolved case by case as AIDD-related patents reach litigation, rather than through a single clarifying guidance document. Companies that build a habit of contemporaneous human-contribution documentation now will be better positioned than those that treat it as a retroactive exercise once a dispute arises.

Second, the gap between search-tool adoption (approximately 85% among surveyed IP professionals) and drafting-tool adoption (approximately 17%) is likely to narrow, but probably not by drafting tools becoming trusted as fully autonomous authors. Instead, the more likely path is the one drafting-tool vendors describe as an evolution from "fast scribes" to "junior reviewers": agentic systems that iterate, self-validate, and flag uncertainty before a human ever sees the output, rather than systems that draft once and hand off a finished product.

Third, the examiner side of the patent system is catching up to the applicant side. The USPTO's ASAP! pilot is the clearest evidence that AI-assisted search is becoming institutionalized inside the patent office itself, not just among the law firms and corporate IP teams filing applications, and its outcome (the program is now closed to new petitions, and whether it is renewed or replaced remains to be seen) will be a useful signal for how much the agency trusts automated search against biotech's especially heterogeneous prior art landscape (uspto.gov).

Fourth, the licensing and deal-structure gaps identified in AI drug discovery partnerships are unlikely to resolve through litigation alone; they are more likely to resolve through standardized term-sheet practice as more deals close and more dealmakers encounter the same recurring issues (model-versus-output ownership, training-data lineage, spin-out equity allocation) repeatedly enough to develop market-standard contract language (healthcarelawinsights.com). Finally, the gap between AI adoption and measurable AI value, visible in the

Axiom survey's finding that 83% of legal teams cannot measure whether their AI spending works, is likely to become a governance priority in its own right, pushing biotech legal and IP departments toward more rigorous internal tracking of time saved, error rates, and outcomes attributable to specific AI tools before the next budget cycle's spending increase is approved (axiomlaw.com).

Frequently Asked Questions (FAQs)

Can an AI system be named as the inventor on a biotech patent? No. Under U.S. law, as reflected in the USPTO's revised November 2025 inventorship guidance, and under European law, only a natural person can be named as an inventor, regardless of how central an AI system's contribution was to the discovery (cafc.uscourts.gov) (epo.org).

Does using AI in drug discovery make an invention unpatentable? Not automatically. Both the USPTO's revised guidance and the EPO's examination guidelines treat AI as a tool, similar to laboratory equipment, that does not by itself preclude patentability so long as a natural person's contribution satisfies the ordinary inventorship and technical-character standards that apply to any invention (uspto.gov) (epo.org).

What is the difference between AI patent search tools and AI patent drafting tools? Search tools (PatSnap Eureka, IPRally, Boundly, Cypris) retrieve and rank prior art, patents, and scientific literature for novelty and freedom-to-operate analysis; drafting tools (DeepIP, Qthena, PatSnap Eureka's drafting agents) assist with generating invention disclosures, specifications, claims, and office action responses. Search tool adoption (about 85% among surveyed patent professionals) substantially outpaces drafting tool adoption (about 17%), reflecting greater practitioner trust in AI for retrieval than for legal authorship (iprally.com).

Are generic large language models like ChatGPT reliable for drafting biotech patent claims? Independent research on molecular-generation AI, including a 2024 *Nature Machine Intelligence* study, documents that generic language models routinely produce chemically invalid structures, and this same failure mode carries into claim drafting for Markush structures and chemical genus claims; domain-specific, structure-first tools built around chemical validation rules are considered materially more reliable for this use case, as discussed above.

How much do AI patent search and drafting tools cost? Individual-seat pricing observed as of July 2026 ranges roughly from $200 to $400 per month depending on the platform and module (for example, PatSnap Eureka's Patent Searching tier at $400/month and its Patent Drafting tier at $200/month), with enterprise and life-science-specific platforms generally priced on a custom basis (eureka.patsnap.com).

Conclusion

Artificial intelligence has become a genuine, load-bearing part of biotech intellectual property practice, but its role is bounded on both ends by law and by chemistry. On the legal end, courts and patent offices in both the United States and Europe have settled the threshold question, AI cannot be named as an inventor, while leaving the harder operational question, how much human contribution is enough when a model proposes the molecule, to be worked out case by case. On the technical end, generic AI drafting tools remain measurably unreliable for the deterministic structural demands of chemistry and biotech claims, which is why the market

has bifurcated into general-purpose drafting assistants and domain-specific, structure-first platforms built around chemical validation. Search and analytics tools have achieved far broader trust and adoption than drafting tools, and for good reason: the cost of a missed prior art reference or an unassessed freedom-to-operate risk dwarfs the cost of a slower first draft. For biotech companies operating under severe capital constraints, where a five-jurisdiction patent portfolio can cost $150,000 to $400,000 and a single lost or delayed patent can jeopardize a financing round or a licensing deal, AI tools offer a genuine way to extend limited legal budgets further, but only when paired with the kind of contemporaneous human-contribution documentation, licensing-term specificity, and governance discipline that the current unsettled legal landscape demands. The organizations that treat AI as a force multiplier for experienced IP counsel, rather than a replacement for their judgment, are the ones best positioned to capture its benefits while avoiding its clearest risks.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

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AI consulting and adoption

Our AI enablement services cover readiness assessments, use-case selection, governance and policies, team workshops, adoption measurement and ongoing advisory support. We help organizations structure the information layer behind AI: source material, context, permissions and maintained knowledge that make generated answers useful and reviewable. Private LLM inference and hosted AI options support teams evaluating how to operate AI with appropriate control over their data and infrastructure.

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IntuitionLabs develops custom software for pharma and biotech, integrates enterprise systems, and builds data engineering and business intelligence solutions. Areas of focus include AI agents, regulatory research, medical writing, medical affairs, CMC information, competitive intelligence and clinical-document workflows. Our eTMF intelligence work includes cross-system reconciliation and inspection-readiness support.

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