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Rethinking Inventorship In The Age Of Ai-Driven Drug Development

Author – Mahima Mahajan

Designation – Assistant Professor

Department – Law

Organization – National Law University Delhi

Abstract: *The overlap of artificial intelligence and pharmaceutical innovations is now a challenge to the intellectual property law on a level never seen before: when AI systems are heavily involved in discovering the drug, who can be called the legal inventor?*

This paper will thoroughly examine the doctrine of inventorship in key patent regimes and offer evidence-based reforms to accept AI-aided pharmaceutical discoveries. The study shows that although the world has solidified around human-only inventorship conditions as shown by rulings by the US Federal Circuit, European Patent Office, the UK Supreme Court, and courts in Japan and Canada. Existing frameworks are based on significant contribution standards which were established in ***Pannu v. Iolab Corp.*, 155 F. 3d 1344** which are challenging to implement in pharmaceutical situations where computational prediction and biological validation wipe out conventional lines of conception.

Comparing the US, European, Indian, and emerging frameworks, this paper has found five structural gaps: poor non-obviousness criteria of AI-enhanced settings, unfair patenting of technology before experiments, unclear data ownership division, insufficient disclosure mandates and mismatched regulatory monopoly timeframes. The paper states that pharmaceutical firms should enact stringent documentation procedures involving human inputs during the AI-aided discovery paths, whereas policymakers should pursue coherent reforms via international harmonization under the WIPO tagline.

The paper finds that the key issue is not that AI-aided patentability should be recognized in the law, but that operational boundaries that would strike a balance between innovation motives and publicly accessible information and competition as the crucial components of international pharmaceutical development.

Keywords: *Artificial Intelligence, Inventorship, Pharmaceutical, Patents, Discovery.*

INTRODUCTION

Background

Artificial intelligence has forever changed the pharmaceutical research. The old route, through target identification, initiated sequential development and enormous capital expenditure, towards completing drug approval, now follows at timescales shortened by factors five to ten, at costs a quarter, or less, of the former. Data is starting to prove that AI-based approaches could save about forty percent in development costs in addition to shortening pre-clinical timelines that used to take years down to months.[1]

[1] *AI Meets Drug Discovery – But Who Gets the Patent?*, DRUGPATENTWATCH (Dec. 3, 2024), accessed 13 December 2025, https://www.drugpatentwatch.com/blog/ai-meets-drug-discovery-but-who-gets-the-patent/

The example provided by *Insilico Medicine* typifies this pace of doing things; within forty-six days, the biotechnology company headquartered in Boston, Massachusetts identified, designed, synthesized and validated a novel therapeutic small-molecule idiopathic pulmonary fibrosis (IPF) , which would have taken the conventional methodologies years to accomplish.[2] It is not simply a matter of computational efficiency that is embodied in this technological revolution. Pharmaceutical companies have made a systemic deployment of machine learning architectures, neural networks, and generative models across the whole drug discovery value chain: initial target identification through congregation of disparate biological datasets, lead compound optimization through computer-based screening of billions of distinct molecular permutations, and compound manufacture direction through retrosynthetic analysis.

The integration is executed so deeply that today big pharmaceutical companies and AI-native drug discovery firms do not see AI as an optimization tool with peripheral parts but believe it is a core engine of innovation.

However, this techno change has exceeded legislative structures that are meant to regulate intellectual property rights. The human inventors who participate in the intentional act of innovating, the primary agent of exclusivity of any market, was conceptualized at the core of the patent system where pharmaceutical companies are involved. Formalized in the form of statutes written decades prior to the technological development of an artificial intelligence of a contemporary level, these frameworks assume that inventorship only attaches to human participants with the ability to make consciously creative decisions. The clash between the abilities of AI and the anthropomorphic premises of law, creates the foundational problematic animus of this analysis, namely, who qualifies as an inventor under the current patent law when artificial intelligence systems do a significant part of the work of pharmaceutical compound discovery?[3]

The economic implications of this uncertainty are massive. It is estimated that AI-mediated drug discovery worldwide will amount to 16.52 billion USD in 2034.[4] This amounts to the concentration of unusual capital resources into the area where clarity on intellectual property is in fact ambiguous. It is not rational that pharmaceutical firms cannot spend such resources without having knowledge about who would eventually own patent rights in the end. Without an understanding of ownership of AI-identified compounds, investors will not be able to do due diligence. Without a system through which inventorship is attributed, research institutions are unable to agree on any forms of collaboration. Any effort to defend the patent validity cannot be made by the Strategic IP without knowing in which inventorship standards should be applied. The uncertainties produce wholesome latent risk on all stakeholders involved in AI-enhanced pharmaceutical innovation.[5]

Research Questions and Scope of Research

The paper discusses an apparently simple question: under the existing systems of patent law, including the statutory law of the United States, the jurisprudence of the European Patent Office, the patent legislation of India and any growing international consensus, who is the inventor when artificial intelligence systems have a key role to play in the discovery of pharmaceutical compounds?

This primary inquiry logically subdivides into five subordinate research questions that structure the analysis. First, what do existing statutory frameworks define as “inventor” and “conception,” and how have courts conceptualized these foundational doctrines? Second, what operational threshold must human involvement satisfy, the “significant contribution” doctrine, and how have patent offices applied this standard to AI-assisted inventions? Third, do meaningful jurisdictional variations exist across major patent regimes, and what strategic implications follow for multinational pharmaceutical enterprises? Fourth, what practical challenges do pharmaceutical companies confront when demonstrating human inventive contribution amid AI-generated compound identification, and what documentation protocols mitigate these challenges? Fifth, what persistent

[2] Victoria Rees, *AI designed, synthesised and validated new drug in 46 days,* Drug Target Review, (Sep. 2 2019) accessed 13 December 2025, https://www.drugtargetreview.com/news/48404/ai-designed-synthesised-and-validated-new-drug-in-46-days/

[3] Joanna Wang, *Navigating the USPTO’s AI inventorship guidance in AI-driven drug discovery*, Journal of Law and the Biosciences, 12 (2), July-December 2025, lsaf014, https://doi.org/10.1093/jlb/lsaf014.

[4] Press Release, *Artificial Intelligence (AI) in Drug Discovery Market Size Expected to Reach USD 16.52 Billion by 2034,* BioSpace, (Nov. 20 2025), https://www.biospace.com/press-releases/artificial-intelligence-ai-in-drug-discovery-market-size-expected-to-reach-usd-16-52-billion-by-2034

[5] Federal Register, *Inventorship Guidance for AI-Assisted Inventions*, 89 Fed. Reg. 10043, 10044-46 (Feb. 13, 2024) https://www.federalregister.gov/documents/2024/02/13/2024-02623/inventorship-guidance-for-ai-assisted-inventions.

policy gaps remain inadequately addressed by current legal frameworks, and what evidence-based reforms might enhance both innovation incentives and public health objectives?

The geographic area includes comparative study of jurisprudence of patent law of the United States, the largest pharmaceutical market in the world and the most developed area of jurisprudence in the pharmaceutical industry, as well as European Patent Law and its member states, representing different approaches based on the tradition of a civil jurisdiction and an emphasis on the idea that the innovation requires human mental effort in order to be patented; and Indian Patents Act 1970 jurisprudence, chosen not only because India offers a rapidly emerging centre of pharmaceutic innovation and drug production, but also because The analysis reflects the developing global consensus on AI inventorship all along the way and it does so through World Intellectual Property Organization (WIPO) efforts to harmonize international policy responses towards artificial intelligence on the patent front.

FOUNDATIONAL LEGAL FRAMEWORK AND THE *DABUS* PRECEDENT

Statutory Foundations of Inventorship

The patent laws of large jurisdictions surprisingly neither formally define inventor nor specify it, leaving courts with the interpretive work of trying to derive meaning out of statutory language and by historical precedent. The United States Patent Act defines an "inventor" through 35 U.S.C. SS 100(f) as "the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention."[6] The statute does not explicitly define "individual," yet this seemingly laconic provision contains textual anchors suggesting human actors. The repeated use of personal pronouns, "himself" and "herself", throughout the Patent Act's treatment of inventors presupposes human participation. Moreover, 35 U.S.C. § 115 mandates that inventors submit sworn oaths or declarations, a requirement presupposing legal capacity and conscious belief, attributes artificial systems demonstrably lack.[7]

The Indian Patents Act 1970 approaches inventorship through the concept of "true and first inventor." Section 6 (1) (a) allows applications by any person who proposes to be the true and first inventor of the invention.[8] Section 2(1)(j) adopts and gives meaning to the term invention as a new product or process in which there is an inventive act and the product or process is industrial application. Indian jurisprudence thus has always given it meaning referring to a product or process that requires the human intellectual input.[9] The true and first inventor formula has specific implications, which suggest that the concept of invention is pursued down to the very birth of the inventive designs and not just to the point of identity or report.

The European Patent Convention (EPC) creates its requirement with Article 81 that states that an inventor has to be designated by the applicant.[10] Although the EPC does not clearly restrict inventors to natural persons, the designation component together with substantive limitations concerning the inventor leads to the assumption of human actors. These textual areas of establishing, which are located in different jurisdictions of the law, denote a shared assumption: inventorship involves human involvement.

In its 2020 Revised Issues Paper, WIPO has explicitly recognised this gap in doctrine whereby it posed eight foundational questions in regards to AI-generated inventions and the ability of current frameworks to accommodate autonomous systems.[11] This institutional acceptance gave an indication that an anthropomorphic assumption of patent law necessitated to be systematically investigated.

[6] *35 U.S.C.* § 100(f).
[7] *35 U.S.C.* § 115.
[8] *Patents Act, 1970,* § 6(1)(a).
[9] *Id.* § 2(1)(j).
[10] *European Patent Convention* art. 81.
[11] WIPO, *Revised Issues Paper on Artificial Intelligence and Intellectual Property Policy* (May 2020), accessed on 14 December 2025, https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=499504

The *DABUS* Case: Convergence Around Human Inventorship

The *DABUS* case dropped to legal concurrence worldwide that current laws do not cover machine inventors. Dr. Stephen Thaler submitted two patent applications with the pseudonym name "Device for the Autonomous Bootstrapping of Unified Science" (DABUS) as the sole inventor of two inventions labelled with "Neural Flame" and "Fractal Container".[12] The ensuing juridical journey gives truly impressive jurisprudential collusion. *Thaler v. Vidal,* 43 F.4th 1207 of the U.S. started with text of statutes. Court made a ruling that individual in 35 U.S.C. SS 100(f) connotes beyond reasonable doubt a natural person.[13]

The court noted that the Patent Act uses 'himself' and 'herself' instead of 'itself', showing that the Congress considered human inventors. This conclusion was also guided by the requirement of the oath that assumed conscious belief. Most importantly, the Federal Circuit admitted that it was only ruling on whether AI could independently claim inventorship, making no efforts to assess whether inventions that were created by human beings with the help of artificial intelligence are even patentable. The consequence of this was reduced to precisely this: human inventorship was now inaugurated as prerequisite, but operational considerations were not determined.

The European Patent Office Legal Board of Appeal in J 0008/20 (December 2021) reached parallel conclusions through treaty interpretation. The Board held that Articles 60 and 81 EPC presuppose "a person with legal capacity."[14] Significantly, the Board acknowledged that AI-generated inventions might satisfy Article 52(1) EPC's patentable subject matter requirement while simultaneously holding that Article 81's inventor designation requirement remained binding. This doctrinal split, permitting AI-created inventions as patentable subject matter while precluding AI from inventorship, would influence subsequent jurisprudence.

The UK Supreme Court (2023), Japanese Intellectual Property High Court (January 2025), and Canadian Patent Appeal Board (June 2025) reached identical substantive conclusions through divergent doctrinal pathways: existing statutory language requires natural person inventors.[15] The Canadian Board's invocation of the patent system's "quid pro quo", exclusive rights exchanged for inventive disclosure, proved particularly illuminating, suggesting that inventorship requirements reflect not merely formal classification but fundamental patent policy.[16] South Africa's grant of patent 2021/03242 listing *DABUS* as inventor stands anomalous. The grant reflects minimal substantive examination and contains formal defects regarding assignment of rights from non-legal-person AI to human patentee, rendering ultimate invalidation probable.[17]

Inventorship as Conception-Based Doctrine

Inventorship in the United States patent law is based on the "conception", which refers to the process by which a particular idea about the invention has been created in the mind of the inventor in a definite, permanent and complete way.[18] According to this criterion, no reduction of physical accomplishment is needed to practice, but rather conception is the point in time when creative ideas become clear enough to be implemented by highly qualified practitioners without deep study. For unpredictable arts, chemistry, pharmaceuticals, biotechnology, conception frequently coincides with or follows reduction to practice through experimental validation. Courts have recognized that "conception and reduction to practice may occur simultaneously" in these domains. This simultaneity reflects the nature of scientific inquiry: theoretical conception gains evidentiary force only through experimental proof that predictions correspond to physical reality.

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[12] Dennis Crouch, *Thaler v. Vidal: Will Patentability be Negated by the Manner of Invention?*, Patent LYO, (May 2022), https://patentlyo.com/patent/2022/05/patentability-negated-invention.html

[13] *Thaler v. Vidal*, 43 F.4th 1207, 1212-13 (Fed. Cir. 2022) (emphasizing statutory use of "himself" and "herself" as evidence Congress contemplated human inventors).

[14] *J 0008/20* (Designation of inventor/DABUS), EPO Legal Board of Appeal (Dec. 21, 2021), https://www.epo.org/en/boards-of-appeal/decisions/j200008eu1

[15] *AI as an Inventor of Patents? IP High Court Judgment and the 2025 IP Strategic Program*, AIPPI (Aug. 24, 2025), https://www.aippi.org/news/ai-as-an-inventor-of-patents-ip-high-court-judgment-and-the-2025-ip-strategic-program/

[16] *In Canada, AI Cannot Be An "Inventor"*, FIELD LAW (Dec. 2, 2025), https://www.fieldlaw.com/insights/publication/in-canada--ai-cannot-be-an--inventor

[17] Spoor & Fisher, *DABUS, the Rise of the Inventive Machines* (Apr. 3, 2025), https://spoor.com/dabus-the-rise-of-the-inventive-machines/

[18] LA Law, *Patent Inventorship Requires Conception*, (June 2024) https://www.lalaw.com/knowledge-center/article/ip-insights-the-u-s-patent-office-continues-to-clarify-that-patent-inventorship-requires-conception-despite-broader-language-used-by-courts/

This conception-based framework creates singular challenges for AI-assisted discoveries. When artificial systems generate molecular structures, predict biological properties, or identify drug targets at computational scales, has conception occurred? If a human scientist, then evaluates AI outputs, selects promising candidates, conducts experimental validation, and interprets results, did the human conceive the inventions, or merely discover pre-existing solutions the AI had generated?

The framework demands that inventorship attach to someone who possessed "a definite and permanent idea of the complete and operative invention" with clarity sufficient that skilled practitioners could execute it. Yet AI systems can generate millions of molecular permutations, ranking them computationally without conscious deliberation, intentional problem-solving, or the creative insight traditionally characterizing conception. This doctrinal tension, between statutory requirements for human inventors and technological realities of substantial machine contribution, animates the subsequent analytical chapters and demands resolution through clearer articulation of what constitutes the "significant contribution" to conception that existing frameworks presuppose.

THE SIGNIFICANT CONTRIBUTION TEST AND AI-ASSISTED PHARMACEUTICAL INVENTORSHIP

The Pannu Factors and USPTO 2024 Guidance

The preceding part established statutory requirements mandating human inventors across major jurisdictions. The operative question becomes: what quantum of human contribution satisfies these requirements? United States patent law addresses this through the "significant contribution" doctrine originating from ***Pannu v. Iolab Corp***., 155 F.3d 1344, 1351 (Fed. Cir. 1998). The Federal Circuit articulated a three-part test: an inventor must (1) contribute significantly to conception or reduction to practice; (2) make a contribution not insignificant in quality relative to the full invention; and (3) do more than merely explain well-known concepts or prior art.[19]

The United States Patent and Trademark Office's 2024 Inventorship Guidance operationalizes these factors for AI contexts with particular precision. The Guidance clarifies that "AI-assisted inventions are not categorically unpatentable" provided natural persons make "significant contributions" to each claim.[20] Five guiding principles establish operational boundaries.[21] First, using AI systems does not negate human inventorship claims. Second, merely recognizing problems and prompting AI proves insufficient. Third, persons refining AI outputs through significant improvements may qualify as inventors. Fourth, those designing, building, or training AI systems for specific problems may constitute inventors if their contribution proves significant to the ultimate invention. Fifth, maintaining "intellectual domination" over AI systems does not alone confer inventorship.

These principles form workable differences. A researcher simply telling a generic AI to "produce kinase inhibitors" is not enough, similar to implying one wishes something to happen, but does not describe how to do that.[22] On the other hand, scholars who set training datasets, hyperparameters to achieve binding profiles or optimizing AI results with experimental feedback would fulfil *Pannu* factors. The Guidance therefore maintains continuity of doctrines and the presence of technological realities.

Application to Pharmaceutical AI-Assisted Drug Discovery

Pharmaceutical contexts test these principles most acutely, where computational predictions confront biological unpredictability. *Insilico Medicine's* INS018_05 illustrates permissible inventorship through documented human-AI collaboration.[23] Researchers curated training datasets emphasizing fibrosis-associated pathways, directed AI toward protease inhibition profiles, iteratively refined outputs through medicinal chemistry expertise, and validated predictions experimentally. This documented collaboration demonstrates requisite inventorship: humans directed problem formulation and experimental validation while AI accelerated candidate generation.

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[19] *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998).
[20] *Supra note 5.*
[21] *Patent Inventorship Requires Significant Human Contribution*, NIXON PEABODY (Feb. 15, 2024), https://www.nixonpeabody.com/insights/alerts/2024/02/15/patent-inventorship-requires-significant-contribution-by-human (Guiding Principles).
[22] *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004).
[23] *Supra note 3.*

DrugPatentWatch case studies provide illustrative scenarios. Company X develops proprietary AI screening 10 million virtual compounds against protein targets within 48 hours, generating binding affinity predictions. Medicinal chemists then synthesize candidates, conduct wet-lab validation, and optimize structures based on experimental discrepancies from computational predictions.[24] This iterative process demonstrates "significant contribution": chemists actively directed AI outputs through independent scientific judgment distinguishing computational predictions from biological reality.

Insufficient contribution presents differently. A researcher recognizing a protease target, prompting generic AI to "generate inhibitors," and merely validating highest-ranked outputs without parameter modification or alternative screening criteria likely falls short. Such activity resembles routine tool application rather than inventive contribution. The distinction hinges on whether humans execute AI suggestions or actively shape investigation through scientific judgment.

The documents are important in a legal context. The current records on AI prompts, rationality of training data, parameter tuning, the anomalies in experimental validation, and human decision-making are the sources of evidences to the inventorship claims. Drug manufacturers more and more keep such records which acknowledge their two functional roles: documentation of scientific advances and provision of a legal defense against challenges of not having invented or invented.

Comparative Framework: Indian Patents Act and Joint Inventorship

The Indian Patents Act 1970 lacks explicit AI provisions, yet demonstrates administrative flexibility accommodating technological evolution. Section 6(1)(a) permits applications by "any person claiming to be the true and first inventor."[25] Section 2(1)(j) requires "inventive step", technical advance or economic significance rendering inventions non-obvious to skilled artisans. Indian jurisprudence, including ***Roche v. Cipla***[26] and ***Novartis v. Cipla***[27], emphasizes human intellectual contribution as foundational to inventorship determinations. The July 2025 Computational Research Invention Guidelines signal receptiveness to AI-assisted innovation through administrative interpretation rather than statutory amendment.[28]

The "person in the know" doctrine facilitates accommodation. Indian courts assess whether skilled artisans, equipped with contemporaneous knowledge, would find claimed inventions obvious. Applied to AI-assisted discoveries, this framework permits arguments that human-directed AI applications achieve non-obvious results unattainable through conventional methodologies. A compound exhibiting unexpected selectivity identified through human-curated AI training demonstrates inventive step satisfying Section 2(1)(j).

Joint inventorship adds complexity characteristic of pharmaceutical AI development. United States law requires collaboration toward shared inventive goals; contributors need not work contemporaneously or equally.[29] Pharmaceutical teams typically encompass medicinal chemists interpreting AI outputs, computational biologists curating training data, machine learning engineers designing architectures, and pharmacologists conducting validation assays. Each potentially qualifies if contributing significantly to conception.[30]

Determining which team members "contributed significantly to conception" versus performing routine tasks demands nuanced factual analysis. Data curators will have to show that AI outputs were materially guided by particles of datasets. Machine learning engineers have to demonstrate architectural choices based on the identification of particular compounds. The medicinal chemists would be required to record scientific considerations between AI recommendations and experimental reality. This multi-contributor fact necessitates

[24] *The New Prescription for IP: A Strategic Guide to Patenting AI-Derived Drugs*, DRUGPATENTWATCH (Dec. 3, 2024), https://www.drugpatentwatch.com/blog/the-new-prescription-for-ip-a-strategic-guide-to-patenting-ai-derived-drugs/
[25] *Supra note 8,* § 6(1)(a).
[26] 148 (2008) DLT 598.
[27] 2017 (70) PTC 80 (Del).
[28] *AI-Generated Drugs & Patentability in India: What the July 2025 Computational Research Invention Guidelines Mean*, LINKEDIN PULSE (Nov. 19, 2025), https://www.linkedin.com/pulse/ai-generated-drugs-patentability-india-what-july-2025-arya-qbn3f.
[29] *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 916-17 (Fed. Cir. 1992); Konski & Wu, supra note 1, at 3.
[30] *Blurring the Line Between the Dry and Wet Lab: Joint Inventorship in AI-Assisted Life Science Inventions*, JONES DAY (Apr. 2025), https://www.jonesday.com/en/insights/2025/04/blurring-the-line-between-the-dry-and-wet-lab-joint-inventorship-in-ai-assisted-life-science-inventions.

strict contemporaneous records differentiating inventive to technical performance especially in cases whereby partners work across organizations by way of licensing.

This framework is therefore open to AI-aided pharmaceutical invention and satisfies human inventorship specifications. The success of operations depends on whether or not pharmaceutical enterprises adopt systematic documentation procedures that control the involvement of human contribution throughout development pipelines.

PRACTICAL CHALLENGES IN PATENTING AI-ASSISTED PHARMACEUTICAL INVENTIONS

Disclosure Requirements and the "Black Box" Problem

The practical challenges of AI-assisted inventorship have daunting theoretical challenges with enablement requirements under 35 U.S.C. SS 112(a).[31] Written descriptions necessary to make and use claimed inventions should be included as patent specifications.[32] Drug discovery through neural networks produces intrinsic conflict: founders would have to reveal receiving training methodology, data, architecture enough to recreate an analog on the state of a trade secret proprietary AI models.[33]

The Board of Appeal of the European Patent Office in T 0161/18 (May 2020) set very strong standards. The Board denied an application as lacking an adequate disclosure of input data characteristics relevant to training artificial neural networks holding that a failure to specify data ranges and selection criteria breached Article 83 EPC in a similar manner as insufficient disclosure of neural network topology, activation functions and learning mechanisms and endpoint conditions as in Article 83 EPC.[34] These decisions crystallized the "black box" problem: the decision-making process of neural networks cannot be explained, and because they are required to be functional, they must be reproducible.[35]

Pharma companies also more often use provisional patent arrangements that obtain a priority date without disclosure followed by submission of continuation-in-part application with experimental validation.[36] This hybrid approach balances trade secret protection with enablement compliance. Yet pharmaceutical-specific challenges persist: AI-identified compounds demand correlation between computational predictions and experimental pharmacokinetic, toxicology, and efficacy data.[37]

Non-Obviousness Determination in AI-Augmented Prior Art

Non-obviousness under 35 U.S.C. SS 103 demands advancement beyond what persons having ordinary skill in the art (PHOSITA) would predictably achieve.[38] AI systems generating millions of molecular permutations challenge this framework fundamentally: if PHOSITA assumes access to generative chemistry tools, incremental structural modifications risk obviousness classification.[39]

The *Freilich and Rai* empirical analysis of 100+ AI-derived drug patents revealed only 23% included in vivo experimental data compared to 47% of traditional pharma patents, raising sufficiency questions regarding non-obviousness support.[40] Pharmaceutical applicants increasingly rely on "unexpected results" doctrine, providing experimental evidence of surprising efficacy, selectivity, or toxicity profiles not predictable from computational analysis. Indian law's Section 2(1)(j) "inventive step" requirement similarly demands technical

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[31] *35 U.S.C.* § 112(a) (2012).
[32] *'AISITAs' and Written Description Requirements: Considerations & Guidance for AI Patent Applications*, IPWATCHDOG (July 25, 2021), https://ipwatchdog.com/2021/07/25/aisitas-written-description-requirements-considerations-guidance-ai-patent-applications/.
[33] *Navigating AI Training Data Acquisition and IP Implications*, ARAPACKE LAW (Mar. 6, 2025), https://arapackelaw.com/patents/ai-training-data-acquisition-ip/.
[34] *European Patent Convention,* art. 84.
[35] F. Hagel, *T 0161/18 brings to the fore the requirement of disclosing training data in AI case,* EPI Information, accessed 14 Dec. 25, https://information.patentepi.org/issue-4-2020/t-0161/18.html
[36] *Supra note* 3.
[37] *Pharmaceutical Patents in an Age of AI Drug Development*, MEDICINES L. & POL'Y (Apr. 2025), https://medicineslawandpolicy.org/wp-content/uploads/2025/04/Pharmaceutical-Patents-in-an-Age-of-AI-Drug-Development.pdf.
[38] *35 U.S.C.* § 103.
[39] David H. Holman et al., *Top 5 Potential Implications of AI-Generated Prior Art on Patent Law*, REUTERS (Nov. 7, 2024), https://www.reuters.com/legal/legalindustry/top-5-potential-implications-ai-generated-prior-art-patent-law-2024-11-07/.
[40] *Are AI-Discovered Drug Patents Blocking Innovation? A Sceptical Kat Defends the Patent Office*, IPKITTEN (June 24, 2025), https://ipkitten.blogspot.com/2025/06/are-ai-discovered-drug-patents-blocking.html

advance beyond obvious modifications, potentially accommodating AI-assisted innovations demonstrating genuine unpredictability.

Data Ownership and Strategic Portfolio Management

Training data with multi-sources leads to the attribution complexity that must be managed. The *BioNTech-Nucleai case* in 2025 demonstrated the dangers of litigation in situations where tumour image data were used in training cancer therapeutics AI.[41] Copyright concerns compound difficulties: training on scientific literature without licensing risks infringement under precedents established through ***Getty Images v. Stability AI* [2025] EWHC 2863 (Ch)**. and ***New York Times v. OpenAI,* S.D.N.Y. Case No. 1:23-CV-11195**.[42] European firms navigate GDPR (General Data Protection Regulation) and EU AI Act transparency requirements complicating trade secret strategies. Blockchain provenance tracking emerges as best practice documenting data lineage across distributed teams.

Strategic responses emphasize portfolio diversification. *Insilico Medicine* pursues 45+ patents covering platforms, targets, compounds, formulations, and manufacturing processes. Patent Cooperation Treaty filings accommodate jurisdictional variations, enabling tailored prosecution strategies. AI-native firms increasingly avoid in silico-only claims, emphasizing experimentally-validated compounds demonstrating human-directed development. Dual protection prevails: patenting disclosed compounds while maintaining AI architectures as trade secrets.[43]

Market dynamics reflect heightened scrutiny. *Deloitte's* 2025 survey found 78% of pharmaceutical companies mandating AI project inventorship audits, reflecting heightened due diligence responding to legal uncertainty. FDA's 2024 approval of AI-developed *Humira* generic six months ahead of traditional schedule compresses exclusivity periods, affecting patent portfolio economics. *Merck's* $2.1 billion *Atomwise* acquisition (2025) included contractual human oversight clauses ensuring compliance with inventorship requirements. Under non-infringing analogue design, AI tools allow creating fast design that minimizes successful exclusivity within the market and strains overall coverage systems.[44]

These complex issues, disclosure rules, evidentiary rules, clarity of ownership, and positioning in the market require complex strategies that are adjusted to the changing standards of doctrinal principles and the reality of drug development.

CONCLUSION AND RECOMMENDATIONS

Synthesis of Current Legal Framework

The legal system that regulates the inventorship of pharmaceuticals supported by AI has reached an impressive level of convergence. Convergence to the same thresholds has been achieved by the Federal Circuit and European Patent Office Legal Board of Appeal, United Kingdom Supreme Court, Japan Intellectual Property High Court and the Canadian Patent Appeal Board: current laws put natural person inventors.

However, this agreement glosses over some underlying questions of implementation. Although AI cannot be the inventor, United States and emerging international practice does not rule out the fact that AI-assisted inventions can be patented provided there is a genuine contribution to invention, which humans have made. This framework is suited to fit technological reality without having to change laws, and this opens the ways to operational innovation in the pharmaceutical industry. Despite this similarity, there are still jurisdictional differences. The Indian Patents act 1970 does not specifically allow AI but it does allow administrative change by creating guidance similar to the approach of the USPTO 2024.

This carries with the Board jurisprudence of the EPO, because patentable subject matter (including possibly AI-generated inventions) and inventorship restrictions (including natural person requirement) differ. That is a doctrinal divide which makes it flexible and yet statutorily faithful. The South African anomalous *DABUS*

[41] *AI Meets Drug Discovery – But Who Gets the Patent?*, DRUGPATENTWATCH (Dec. 3, 2024), https://www.drugpatentwatch.com/blog/ai-meets-drug-discovery-but-who-gets-the-patent/.
[42] Adam Buick, *Copyright and AI Training Data—Transparency to the Rescue?*, 20 J. INTELL. PROP. L. & PRAC. 182, 186-89 (2025), https://academic.oup.com/jiplp/article/20/3/182/7922541.
[43] *Protecting Generative AI-Derived Inventions in the Pharmaceutical and Life Science Industry*, MAYNARD NEXSEN (Nov. 17, 2025), https://www.maynardnexsen.com/publication-protecting-generative-ai-derived-inventions-in-the-pharmaceutical-and-life-science-industry.
[44] *Role Of AI In Drug Discovery: A Case To Reconsider Pharmaceutical Regulatory Exclusivities*, SSRN (Sept. 8, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5126246.

patent grant is not an expression of principled legal stance but administrative laxity and has formal issues on the assignment of rights in AI as a non-legal person to human patentee which presents the risk of invalidation.

Policy Gaps and Evidence-Based Recommendations

Current frameworks leave five critical gaps. First, non-obviousness doctrine inadequately addresses AI-augmented PHOSITA scenarios where person having ordinary skill in the art assumes access to generative chemistry systems capable of producing millions of candidates. Second, AI companies may file premature patents on computationally-identified compounds lacking experimental validation, creating "blocking patents" without clinical development pathways. Third, international patent law insufficiently addresses allocation of inventorship rights when multi-source training datasets contribute to AI-identified innovations. Fourth, enablement standards may permit inadequate AI methodology disclosure, creating asymmetric information favouring patent holders. Fifth, regulatory exclusivity periods (FDA's five-year generic, twelve-year biologics exclusivity) were designed assuming lengthy development, yet AI acceleration may warrant recalibration to prevent indefinite monopolies on minimally-modified compounds. Six evidence-based reforms merit implementation.

Recommendation One: Establish explicit thresholds delineating insufficient (merely understanding AI output) from sufficient (designing AI systems, iteratively refining output, providing experimental validation) contributions. Safe harbours for documented activities, contemporaneous logs of AI prompts, parameter selections, experimental validation, and decision-making rationale, should create presumptions of significant contribution. The Indian Patent Office should issue formal guidelines explicitly addressing AI-assisted pharmaceutical inventions, providing domestic industry clarity.

Recommendation Two: Implement heightened disclosure requirements requiring patent applicants to disclose AI platform characteristics, training data sources and rationale, validation datasets, hyperparameters, and computational-experimental concordance. Pharmaceutical applications on novel compounds should include minimum experimental validation, binding affinity data, preliminary toxicology, pharmacokinetic parameters, to meet non-obviousness standards in AI-augmented environments. Phased disclosure through continuation-in-part applications should balance trade secret protection with public transparency.

Recommendation Three: Attempt to reach state presumptions that the AI-identified compounds are non-obvious only when they show some non-obvious behavior or reveal non-obvious AI usage (new training architecture, novel training architecture creativity). The burden to demonstrate that unexpected results were achieved by the applicant should be linked to have the experimental proof of the same instead of depending on the un-computational novelty. WIPO-coordinated advice ought to align the measures in the US, EPO, and India.

Recommendation Four: Add licensing best practice in which the rights to inventions are explicitly provided in case of multi-source datasets when AI innovations are based on them. It should record data provenance through blockchain-based provenance tracking through distributed teams. All training data sets of pharmaceutical companies should retain chain-of-title documentation.

Recommendation Five: Congress, EPO member states, and Indian Patent Office ought to weigh regulatory exclusivity periods on AI-discovered drugs, to take into account fewer durations in drug development, but leave robust protection on authentic therapeutic breakthroughs. The market-based solutions of authorized generics (therapeutic substitutes) may allow the premature competition of routine AIs-based variation.

Recommendation Six: WIPO ought to hold working groups to align AI inventorship guidelines, which come up with model patent law terms that could be embraced by national legislatures. Close attention should be paid to the pharmaceutical / biotechnology applications since the industry has been dependent on patents and is experiencing quicker AI implementation.

Conclusion and Implementation Imperatives

The legal landscape has adopted a consistent position requiring human inventorship under existing statutory and innovation standards, notwithstanding the use of AI-mediated technologies, so long as a significant human contribution to the invention can be demonstrated. Legal recognition of AI-assisted patentability is not the biggest challenge facing the pharmaceutical industry, but instead: standardization of threshold of significant contribution, augmented disclosure, non-obviousness re-adjustment of AI-enhanced setting, data location principles, and harmonization of jurisdictions to reduce compliance costs. Pharmaceutical firms need to

urgently adopt effective documentation guidelines that encompass human creative efforts at every AI-aided discovery phase.

Coordination of strategic IP counsel with research teams keeping contemporary records of AI prompts, parameter choices, experimental validation and human decision-making processes, records now forming significant legal evidence in the defense of patent claims, should occur. At the same time, policymakers can support evidence-based reforms that can specify the doctrine of significant contribution explaining AI and introduce standards of disclosures specific to AI-backed pharmaceutical innovation, as well as harmonize international processes (under the coordination of the WIPO). These reforms will facilitate the ongoing innovation of AI-based drug discovery and allow the transparency of the population to remain and sustain the market forces, which are critical in advancing pharmaceuticals and promoting global health.

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