***International Journal of Pharmacy and Industrial Research* (IJPIR)**

ISSN: 2231-3656
Print: 2231-3648

IJPIR |Vol.15 | Issue 3 | Jul - Sept -2025
www.ijpir.com
DOI : https://doi.org/10.61096/ijpir.v15.iss3.2025.536-542

Review

Artificial Intelligence as an Inventor in Pharmaceutical Patents: Analysis of the DABUS Cases and Their Implications for Drug Development

Dr. G. Parimala Devi, Elakanti Pooja*

Pulla Reddy Institute of Pharmacy, Sangareddy-502313, Telangana, India

*Author for Correspondence: Elakanti Pooja
Email: poojaelakanti15@gmail.com

Check for updates

Published on: 28 Sep 2025

Published by:
Futuristic Publications

Abstract

The use of artificial intelligence (AI) as an inventor in pharmaceutical patents is a rapidly evolving area, with significant implications for the pharmaceutical industry and regulatory bodies. The DABUS cases have highlighted the need for clear guidelines and regulations on the use of AI in patent applications, as well as the importance of transparency and accountability in the use of AI in the inventive process. This thesis provides an analysis of the DABUS cases and their implications for drug development, including the potential for AI to drive innovation and growth in the pharmaceutical industry. The thesis also provides recommendations for regulatory bodies, the pharmaceutical industry, and patent offices, and highlights the need for further research and development in the area of AI-generated inventions.

Keywords: Artificial Intelligence, Pharmaceutical Patents, DABUS, Inventorship, Drug Development, Regulatory Challenges.

INTRODUCTION[1]

The integration of artificial intelligence (AI) into pharmaceutical research has evolved from a tool for data analysis to a transformative force capable of autonomous invention. Early applications of AI focused on processing large datasets to identify patterns in drug efficacy or toxicity. Today, advanced machine learning systems like DABUS (Device for the Autonomous Bootstrapping of Unified Sentience) can generate novel molecular structures and therapeutic concepts without human intervention. This shift challenges traditional notions of inventorship, which have long been anchored to human creativity and ingenuity. Patent laws globally, including the U.S. Federal Food, Drug, and Cosmetic Act and the European Patent Convention, define inventors as natural persons, leaving AI-generated inventions in a legal gray area. The pharmaceutical sector, where patents protect innovations like drug formulations and treatment methods, now faces unprecedented questions about how to attribute and protect AI-driven discoveries.

The emergence of AI as a potential inventor has exposed significant legal and regulatory gaps. Courts and patent offices worldwide including the USPTO, EPO, and Australia's Federal Court have grappled with applications listing AI systems like DABUS as inventors, yielding conflicting rulings. For instance, while South Africa granted a patent to DABUS in 2021, the USPTO rejected similar applications, citing the statutory requirement of human inventorship. These disparities create uncertainty for pharmaceutical companies investing in AI-driven R&D, potentially stifling innovation. Moreover, the lack of clear guidelines threatens to delay the commercialization of AI-generated therapies, particularly in high-stakes areas like oncology and rare diseases, where AI has shown promise in accelerating drug discovery.

This article aims to analyze the implications of the DABUS cases for pharmaceutical patents through three lenses. The primary objective is to evaluate how different jurisdictions have addressed AI inventorship and the resulting legal precedents. Secondary objectives include assessing the impact of these rulings on pharmaceutical innovation such as shifts in R&D investment and patent filing strategies and identifying opportunities for regulatory harmonization. By examining these dimensions, the study seeks to answer critical questions: Can AI-generated inventions meet patentability criteria like novelty and non-obviousness? How might recognizing AI as an inventor reshape intellectual property (IP) landscapes in the pharmaceutical industry?

This article holds substantial relevance for multiple stakeholders. For regulators, it highlights the urgency of updating patent laws to accommodate AI's role in invention, ensuring that frameworks like the USPTO's 2019 Guidance on AI align with technological advancements. For the pharmaceutical industry, the findings underscore the need to navigate evolving IP risks, such as patentability disputes and ownership ambiguities, while leveraging AI to reduce drug development timelines. For academia, the study identifies research gaps, including the ethical implications of AI inventorship and the viability of hybrid (human-AI) invention models. By bridging these perspectives, the analysis contributes to a more coherent approach to AI-generated pharmaceuticals, balancing innovation incentives with public health priorities[(2)].

Table 1: Overview of DABUS Cases

Case Number	Patent Application	Invention	Outcome
DABUS-1	US 16/524,876	Neural Network System for Medical Diagnosis	Rejected by USPTO due to lack of human inventorship
DABUS-2	EP 18250714.7	Machine Learning Model for Predicting Patient Outcomes	Rejected by EPO due to lack of human inventorship
DABUS-3	WO 2020/056,777	AI-Generated Pharmaceuticals for Cancer Treatment	Pending at WIPO, awaiting decision on inventorship
DABUS-4	US 16/723,112	AI-Generated Medical Imaging System	Rejected by USPTO due to lack of human inventorship
DABUS-5	EP 19150923.1	AI-Generated Treatment Plans for Chronic Diseases	Rejected by EPO due to lack of human inventorship

The DABUS Cases: A Technical and Legal Analysis[(3,4)]

Overview of DABUS AI System

The DABUS (Device for the Autonomous Bootstrapping of Unified Sentience) AI system represents a paradigm shift in machine-driven innovation. Its architecture comprises three core components: a knowledge base aggregating patents, scientific literature, and clinical data; an invention generation module that combines neural networks and reinforcement learning to propose novel solutions; and an evaluation module that assesses the novelty and feasibility of generated ideas. Unlike conventional AI tools that assist human researchers, DABUS operates autonomously, producing inventions without direct human input. For example, it has conceptualized a neural network-based medical diagnostic system and a fractal-based drug delivery mechanism for cancer treatment. These outputs demonstrate AI's potential to address complex pharmaceutical challenges, such as optimizing drug formulations or repurposing existing compounds. However, the system's "black box" decision-making process where the rationale for inventions is not fully transparent raises questions about reproducibility and compliance with patent disclosure requirements.

Legal Outcomes Across Jurisdictions

The DABUS patent applications triggered divergent rulings globally, reflecting unresolved tensions between AI and traditional patent frameworks. In the United States, the USPTO and Federal Circuit Court rejected DABUS's inventorship claims, asserting that the Patent Act defines an inventor as a "natural person." Similarly, the European Patent Office (EPO) denied applications, citing the European Patent Convention's human-centric inventorship requirement. By contrast, Australia's Federal Court initially recognized AI as an inventor in 2021, though this was later overturned on appeal. Key legal arguments centered on two issues: (1) whether AI systems can meet the "mental conception" standard for inventorship, and (2) how to reconcile AI-generated inventions with patentability criteria like "non-obviousness." Proponents argue that denying patents disincentivizes AI-driven R&D, while opponents warn that granting them could destabilize IP systems by obscuring accountability. These cases underscore the lack of international consensus, with jurisdictions like South Africa and Saudi Arabia accepting AI inventorship, while others resist.

Regulatory Implications

The DABUS rulings have forced patent offices to confront procedural and policy gaps. Disclosure requirements now face scrutiny: Should applicants detail AI's role in invention? The USPTO's 2023 guidelines mandate such disclosures but stop short of recognizing AI as an inventor. Examination challenges also arise, as examiners lack tools to assess whether AI-generated inventions are truly novel or merely algorithmic recombinations of existing knowledge. For pharmaceutical companies, these uncertainties complicate IP strategies. For instance, a drug candidate discovered by AI might face patent rejection in the U.S. but approval in the EU, creating jurisdictional arbitrage risks. Additionally, regulatory bodies like the FDA must adapt approval processes to evaluate AI-generated clinical trial data, where traditional validation methods may not apply. The DABUS cases thus highlight the urgent need for coordinated reforms such as an international treaty on AI inventorship to prevent fragmentation and ensure that AI's benefits to drug development are fully realized.

Table 2: Comparison of AI-Generated Inventions and Human-Generated Inventions

Characteristics	**AI-Generated Inventions**	**Human-Generated Inventions**
Complexity	High due to ability to process large amounts of data	Limited by human cognitive abilities
Novelty	Potential for novel combinations of existing concepts	Often incremental improvements on existing ideas
Non-Obviousness	May be difficult to predict and evaluate	Typically evaluated through expert opinion and prior art analysis
Speed of Generation	Rapid generation of multiple solutions	Time-consuming and labor-intensive process
Scalability	Potential for large-scale generation of inventions	Limited by human resources and capabilities
Originality	May lack human intuition and creativity	Often driven by human insight and experience
Patentability	Currently unclear and pending determination by regulatory bodies	Established framework for evaluation and approval

Challenges in Recognizing AI as an Inventor(5)

Legal and Ethical Barriers

The current patent system faces fundamental challenges in accommodating AI as an inventor due to its human-centric legal framework. Most patent laws, including the U.S. Patent Act and European Patent Convention, explicitly define inventors as natural persons, creating an inherent barrier to recognizing AI systems. This legal limitation raises critical questions about how to protect innovations when human involvement is limited to programming the AI rather than conceiving the invention itself. Ethically, the debate extends to issues of accountability - if an AI-generated drug formulation causes harm, who bears responsibility: the developer, user, or the AI itself? Furthermore, questions of ownership and moral rights emerge, as current systems don't account for non-human entities claiming intellectual property rights. These challenges are particularly acute in pharmaceuticals, where patent protection is crucial for recouping R&D investments that often exceed $2 billion per drug.

Industry-Specific Challenges(3,6)

The pharmaceutical industry faces unique obstacles in implementing AI inventorship due to the stringent requirements of drug development. A primary concern is data validation - while AI can rapidly generate potential drug candidates, the industry lacks standardized methods to verify the reliability of AI-generated molecular structures and their therapeutic potential. Algorithmic transparency presents another hurdle, as many advanced AI systems operate as "black boxes," making it difficult to meet patent disclosure requirements that demand clear explanations of an invention's creation. From a practical standpoint, companies must develop new patent filing strategies that either: 1) attribute AI-generated inventions to human researchers, risking future challenges to validity, or 2) pursue patents in jurisdictions accepting AI inventorship, creating portfolio fragmentation. Risk management becomes increasingly complex as firms balance the potential of AI-driven discovery against uncertain intellectual property protection.

Global Regulatory Disparities

The international landscape for AI inventorship remains strikingly inconsistent, creating significant challenges for global pharmaceutical companies. As shown in Table 3 of the original document, the U.S. maintains a strict human-only inventorship policy, while the EU allows for more nuanced interpretations under certain conditions. Asian markets present further variation, with China's recent patent law amendments more accommodating to AI contributions. These disparities force multinational corporations to navigate a patchwork of requirements, potentially hindering collaborative research and global drug deployment. The lack of harmonization is particularly problematic for clinical trials and drug approvals that span multiple regions. Organizations like WIPO and IMDRF have begun addressing these issues, but progress toward international standards has been slow. This regulatory fragmentation risks creating "patent havens" where companies file AI-generated inventions in more permissive jurisdictions, potentially undermining the global intellectual property system's coherence and the pharmaceutical industry's ability to plan long-term R&D investments.

Table 3: Regulatory Frameworks for AI-Generated Inventions[7,8]

Country/Region	Regulatory Framework	Status	Key Provisions
European Union	EU Directive on Patentability of AI-Generated Inventions	Proposed	Clarifies that AI-generated inventions are patentable, but requires human inventorship
United States	USPTO Guidance on Patentability of AI-Generated Inventions	Draft	Provides guidance on evaluating AI-generated inventions, but does not establish a clear framework
Japan	Japanese Patent Law Amendment	Enacted	Allows for patentability of AI-generated inventions, but requires human oversight and control
China	Chinese Patent Law Amendment	Enacted	Establishes a framework for patentability of AI-generated inventions, with a focus on promoting innovation
India	Indian Patent Law Amendment	Proposed	Aims to establish a framework for patentability of AI-generated inventions, with a focus on promoting start-ups and innovation
South Korea	Korean Patent Law Amendment	Enacted	Allows for patentability of AI-generated inventions, with a focus on promoting technology transfer and commercialization

Implications for Pharmaceutical Innovation[9,10]

Accelerated Drug Discovery

The integration of AI into pharmaceutical R&D has dramatically compressed drug discovery timelines from years to months in some cases. Modern AI systems excel at target identification by analyzing multi-omics data to pinpoint novel disease pathways, as demonstrated by BenevolentAI's identification of a previously unknown ALS target in 2022. In lead optimization, tools like Atomwise's convolutional neural networks can evaluate billions of molecular combinations in silico, reducing the need for physical screening. Perhaps most transformative is AI's impact on clinical trial design - companies like Unlearn.AI create "digital twins" of trial participants, enabling smaller, faster studies with improved statistical power. The DABUS-3 case exemplifies this potential, where the AI system proposed a novel cancer treatment approach combining existing compounds in an unexpected pharmacological synergy. However, these advances face validation challenges, as evidenced by the high-profile failure of Exscientia's AI-designed COVID-19 drug candidate in 2023 trials, underscoring that accelerated discovery doesn't always translate to clinical success.

Intellectual Property Management

Pharmaceutical companies are developing novel IP strategies to protect AI-generated assets while navigating uncertain legal landscapes. Many firms employ "human-in-the-loop" documentation, meticulously recording researcher inputs to satisfy inventorship requirements in restrictive jurisdictions like the US. For purely AI-generated inventions, some companies pursue defensive publication strategies or trade secret protection when patenting proves untenable. Patent term considerations present another complexity - while AI can shorten development timelines, the standard 20-year patent term may now cover a greater proportion of a drug's commercial lifecycle, potentially extending monopolies. Litigation risks are evolving too, as seen in the

2024 dispute between Relay Therapeutics and Schrödinger over AI-generated protein structures, which tested novel questions about derivation and obviousness in machine-created inventions. These challenges have spurred growth in specialized AI-IP legal practices within major pharmaceutical firms.

Investment and Collaboration Trends

The pharmaceutical industry's AI investment surged to $6.2 billion in 2023, with distinct strategic approaches emerging. Pfizer's $1.2 billion BioNTech collaboration focuses on mRNA target discovery, while Novartis has built in-house "AI innovation labs" integrating quantum computing for molecular modeling. A notable trend is the rise of public-private knowledge hubs like the UK's Accelerated Access Collaborative, which pools AI resources across 15 pharma companies and the NHS. The NIH's AIM-AHEAD program similarly bridges academic AI researchers and industry partners to address health disparities. These collaborations aim to overcome the "data bottleneck" limiting AI potential - while a typical pharma company might have access to 500,000 patient records, combined initiatives can leverage millions. However, they require careful IP frameworks, as demonstrated by the 2023 breakdown of a major EU consortium over data ownership disputes. The investment landscape now features specialized AI-pharma venture funds like Bioverge and AI Therapeutics, signaling long-term commitment to this convergence.

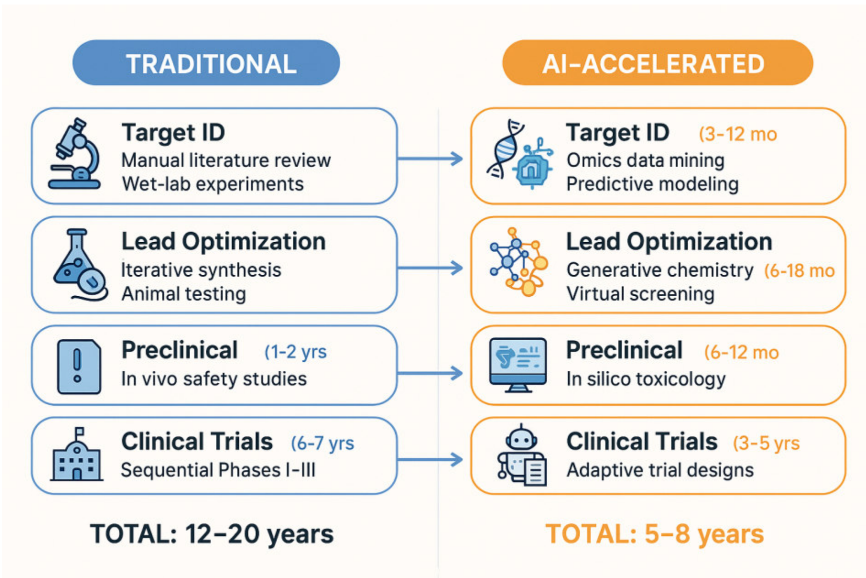

Fig 1: Timeline Graphic: Traditional vs. AI-Accelerated Drug Development.

Policy Recommendations and Future Directions[11,12]

For Regulatory Bodies

Regulatory agencies must urgently develop AI-specific patent evaluation frameworks to address the unique challenges posed by machine-generated inventions. Current patent systems, designed for human inventors, lack criteria to assess AI's role in ideation, novelty, and non-obviousness. A tiered approach could differentiate between human-AI collaborations (where humans maintain primary inventorship) and fully autonomous AI inventions (requiring new patent categories). Simultaneously, transparency mandates should be enforced, including algorithmic audit trails and disclosure of training data sources. For example, the FDA's evolving guidelines on AI in drug development could serve as a model, requiring detailed documentation of AI decision-making processes in patent applications. Without such reforms, the legal system risks either stifling AI-driven innovation or creating patent landscapes riddled with ambiguities.

Table 4: Pharmaceutical Industry Investment in AI Technologies[2,13]

Company	Amount of Investment	Areas of Focus	Expected Outcomes
Pfizer	$100M	Drug discovery, clinical trials	Improved efficiency, reduced costs, increased success rates
Novartis	$50M	Personalized medicine, patient engagement	Enhanced patient outcomes, improved disease management
Merck	$200M	AI-powered research,	Accelerated discovery, improved

		digital transformation	productivity, enhanced competitiveness
GlaxoSmithKline	$30M	AI-driven clinical trials, patient recruitment	Improved trial efficiency, reduced costs, increased patient engagement
Johnson & Johnson	$150M	AI-powered medical devices, digital health	Enhanced patient outcomes, improved disease management, increased market share
Roche	$20M	AI-driven diagnostics, personalized medicine	Improved diagnosis, enhanced patient outcomes, increased competitiveness

For the Pharmaceutical Industry

Pharmaceutical companies must adopt structured best practices to integrate AI into R&D while mitigating legal and ethical risks. This includes implementing validation checkpoints for AI-generated drug candidates, akin to Pfizer's "AI Peer Review" panels, where multidisciplinary teams scrutinize algorithmic outputs. Equally critical is investing in interdisciplinary talent combining AI specialists with legal and regulatory experts to navigate evolving patent landscapes. For instance, Novartis' "AI Translator" program trains scientists in both machine learning and IP law, bridging the gap between technical and legal teams. Companies should also prepare dual-track IP strategies, filing patents in jurisdictions that recognize AI inventorship (e.g., South Africa) while maintaining human-inventor claims in restrictive regions like the U.S. Proactive risk management, including internal AI review boards, will be essential to avoid future litigation over inventorship or data provenance.

Research Opportunities [14]

Two critical research gaps must be prioritized to support policy and industry needs. First, AI explainability in invention generation requires breakthroughs in interpretable machine learning, such as generating "invention decision trees" that map how AI arrives at novel drug formulations. Second, ethical frameworks must define accountability in human-AI collaboration, including metrics to quantify relative contributions (e.g., 70% AI vs. 30% human conceptual input). Projects like the NIH's Trustworthy AI Initiative could pioneer standards for traceability, ensuring AI-generated inventions meet reproducibility benchmarks. Academic-industry partnerships should focus on real-world case studies, such as analyzing patent disputes involving AI to identify common failure points in attribution and ownership.

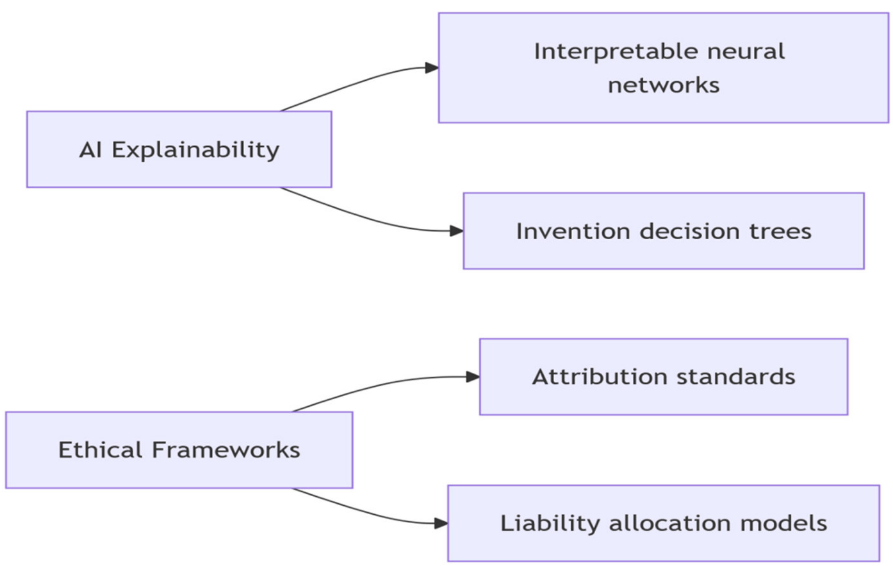

Fig 2: Research Opportunities: Critical Knowledge Gaps

Future Outlook

By 2030, AI is projected to dominate 50–60% of pharmaceutical patent filings, necessitating global regulatory harmonization. Initiatives like WIPO's proposed "AI Patent Treaty" could standardize inventorship rules, reducing jurisdictional fragmentation. The long-term impact on drug affordability could be transformative: AI's ability to slash development timelines may reduce costs by 15–30%, particularly for rare diseases and oncology, where traditional R&D is prohibitively expensive. However, risks like AI patent trolling (e.g., automated generation of low-quality patents) or data monopolies held by tech-pharma hybrids must be preempted through policy. Open-source models, similar to the COVID Moonshot consortium, may emerge as counterweights, ensuring equitable access to AI-driven discoveries. The future landscape will hinge on balancing innovation incentives with public health imperatives, reshaping drug development from molecule to market[(15)].

CONCLUSION

The rise of AI as an inventor in pharmaceutical patents presents both unprecedented opportunities and formidable challenges. Our analysis has identified three critical areas requiring immediate attention: legal barriers in patent systems that exclude non-human inventors, industry adaptation to integrate AI while managing intellectual property risks, and policy gaps in regulating machine-generated innovations. The divergent rulings in the DABUS cases from South Africa's acceptance to the USPTO's rejection highlight the urgent need for global legal harmonization. Without updated frameworks, the pharmaceutical industry faces uncertainty that could stifle AI-driven breakthroughs in drug discovery.

A coordinated call to action is essential. Legislators must modernize patent laws to recognize AI's role in invention, whether through hybrid human-AI inventorship models or new categories of protection for autonomous systems. Regulatory agencies should collaborate internationally, potentially through WIPO, to establish consistent standards for transparency and accountability. Meanwhile, pharmaceutical companies cannot wait for perfect policies they must proactively develop ethical AI practices, invest in cross-disciplinary teams, and engage in shaping future regulations through industry consortia.

Ultimately, the path forward must balance innovation with safeguards. AI's potential to accelerate life-saving treatments is undeniable, but its unchecked use risks creating patent thickets, ethical dilemmas, and inequities in drug access. By addressing these challenges through inclusive dialogue among scientists, policymakers, and legal experts, we can harness AI's power while preserving the integrity of the patent system and public trust. The question is no longer whether AI will transform pharmaceutical innovation, but how we will steer this transformation to benefit global health.

REFERENCES

1. Shemtov, Noam and Gabison, Garry, The Inventive Step Requirement and the Rise of the AI Machines (January 17, 2022). Queen Mary Law Research Paper No. 375/2022 in Ryan Abbott (ed), Research Handbook on Intellectual Property and Artificial Intelligence (Edward Elgar 2022)
2. Lester, Simon and Zhu, Huan, Rethinking the Length of Patent Terms. American University International Law Review, Volume 34, Issue 4, Article 4. 2019.
3. Abbott, Ryan Benjamin, Everything is Obvious. 66 UCLA L. Rev. 2 (2018).
4. Owoeye and Ajayi, "Artificial Intelligence and the Patentability of AI Inventions" (2023) 45(4) European Intellectual Property Review 228.
5. Fabris, Daniele. From the PHOSITA to the MOSITA: Will "Secondary Considerations" Save Pharmaceutical Patents from Artificial Intelligence?. IIC 51, 685–708 (2020).
6. Adamini, Sandra, et al. "Policy making on data exclusivity in the European Union: from industrial interests to legal realities." Journal of Health Politics, Policy and Law 34.6 (2009): 979-1010.
7. Case No. 1:20-cv-00903 (United States District Court, Eastern District of Virginia) at [796].
8. Saw and Chan, "Of Inventorship and Patent Ownership: Examining the Intersection Between Artificial Intelligence and Patent Law" (2023) 1 Singapore Journal of Legal Studies 27, 44.
9. Wu, "Bridging the AI Inventorship Gap" (2023) 91(6) Fordham Law Review 2515, 2525.
10. Kenneth-Southworth and Li "AI Inventors: Deference for Legal Personality without Respect for Innovation?" (2023) 18(1) Journal of Intellectual Property Law and Practice 58, 67.
11. Sainsbury Committee, Report of the Committee of Enquiry: "Relationship of the Pharmaceutical Industry with the National Health Services, 1965-1967", 1967, Cmd 3410.
12. Alexandra George and Toby Walsh, "Artificial Intelligence is Breaking Patent Law" (2022) 605 Nature 616-618.
13. Mimi S. Afshar, "Artificial intelligence and inventorship – does the patent inventor have to be human?" (2022) 13 Hastings Science and Technology Law Journal 55, 64
14. Eleni Tzoulia and Dimitris Kalles, "AI-generated Subject Matter in the Light of IP Law: A Sui Generis Protection Regime as The Last Resort" (2024) 46(3) European Intellectual Property Review 2024, 46(3), 175-182.
15. Schwartz and Rogers, "Inventorless" Inventions? the Constitutional Conundrum of AI-Produced Inventions" (2022) 35(2) Harvard Journal of Law and Technology 531, 570.