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A Legal Analysis of Patent Eligibility and Inventorship for AI-Generated Biotechnological Inventions

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Biotechnological inventions and Artificial Intelligence together have become a transformative and driving force for developments such as drug discovery, genomic prediction, agricultural biotechnology and molecular design. This paper critically examines whether the existing statutory provisions are equipped to address inventions that are substantially or autonomously generated by AI-driven systems in biotechnology. The research adopts a doctrinal and analytical methodology, examining statutory provisions, judicial precedents, patent office guidelines and data published by authorities, drawing on global data compiled by the World Intellectual Property Organisation (WIPO), the Organisation for Economic Co-operation and Development (OECD) and local statutes. According to the WIPO 'Generative AI Patent Landscape' report of 2024, the number of Generative AI patent categories has surged from 733 in 2014 to over 14,000 in 2023, reflecting an explosive growth rate in AI-based inventions. This paper reveals several key findings at the intersection of AI, biotechnology and patent law – global patent data from WIPO and OECD demonstrates a substantial rise in AI-related inventions, current interpretations of the statutes, which often fail to adequately distinguish and the vagueness of Indian jurisprudence to recognise AI as an inventor. The paper concludes by offering recommendations, advocating for defined and clearer statutory definitions, AI-specific guidelines, a balanced framework that justifies maintaining human accountability while supporting AI- generated developments, creating a fast-track examination route for AI-driven inventions, mandating disclosure of training data provision, encouraging open licensing models and establish post grant review mechanism.

Keywords: *artificial intelligence, biotechnological inventions, inventorship, patent eligibility, autonomous innovation.*

INTRODUCTION

The intersection of AI with biotechnology has transformed and reshaped the landscape of scientific research and development in the industry.[1] In biotechnology, AI systems are now being used to perform core inventive functions as well as managerial functions, once thought to require human capability, including protein structure prediction, genetic sequence analysis and molecular synthesis. These developments and innovations observed are not only accelerating the discovery but also fundamentally altering the notion of creativity and intellectual contribution issues within the patent law. This paradigm shift has created a legal and philosophical tension: Can an AI system that autonomously generates an output be said to have 'invented' it? If not, who is the rightful inventor - the programmer, the user or the data curator?[2]

BACKGROUND OF AI AND ITS ROLE IN INNOVATION

Artificial Intelligence has the capacity to process vast data sets, recognise complex patterns and algorithms, and generate productive insights, which enables it to perform traditional functions that previously required human creativity and intelligence. This transformation is made significant due to the changing relationship between humans and machines. What distinguishes AI – driven innovation from earlier technological revolutions is its capacity for autonomous learning. AI is an umbrella term which includes Deep Learning and Machine Learning, which help in these processes.

Being first discussed in the Dartmouth Summer Research Project, AI is defined as a field of research that 'proceeds based on the conjecture that every aspect of learning or any other feature of intelligence can in principle be so precisely described that a machine can be made to simulate it.'

[1] Munawar Ali et al., 'A New Era of Discovery: How Artificial Intelligence Has Revolutionised Biotechnology' (2024) 12(1) Nepal Journal of Biotechnology <https://www.researchgate.net/publication/389880050_A_New_Era_of_Discovery_How_Artificial_Intelligence_has_Revolutionized_the_Biotechnology> accessed 15 March 2026

[2] Md Amir Khusru Akhtar et al., 'ROLE OF ARTIFICIAL INTELLIGENCE IN BIOTECHNOLOGY' (2023) 5(2) Journal of Research Administration <https://journlra.org/index.php/jra/article/view/1747> accessed 15 March 2026

At a broader level, AI has deep social, economic and legal implications. It has not only contributed to productivity growth and global competitiveness, with governments and corporations highly investing in it, but has also reshaped markets and industries. Yet, this shift presents questions and challenges such as credit responsibility, owners and liabilities. These questions highlight that AI is not only reshaping innovations but also compelling society and legal systems to accept and analyse the fundamental relationship between human creativity and technological revolutions.

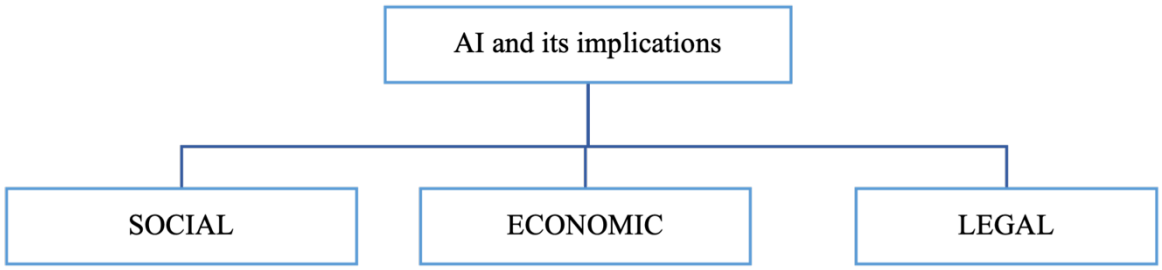

Figure 1: AI and Its Implications

The figure above illustrates the multi-dimensional implications of Artificial Intelligence across technological, economic and legal spheres. The chart highlights that AI is not merely a computational tool but a transformative framework influencing innovation structures, regulatory paradigms and institutional accountability. It demonstrates how AI intersects with productivity, governance, ownership and liability concerns. The chart explains that while AI enhances efficiency and accelerates research outcomes, it simultaneously creates doctrinal uncertainties regarding authorship, inventorship and responsibility. Thus, the figure visually captures AI as both an enabler of progress and a catalyst for regulatory recalibration.

INNOVATIONS – NOW POWERED BY ALGORITHMS

Meaning and Nature: Artificial Intelligence is a breakthrough of Industry 4.0 for scientific and technological milestones. It was originally proposed during the Dartmouth Summer Research Project, which defined AI as a field of research that 'proceeds based on the conjecture that every aspect of learning or any other feature of intelligence can in principle be so precisely described that a machine can be made to simulate it.'

Notably, while raising the questions of how patent law and policy should respond to 'autonomously generated' inventions, none of the reviewed policy documents provides a technical definition of such inventions. For instance, the WIPO draft issues paper states that 'it would now seem clear that inventions can be autonomously generated by AI'. [3] While no explicit reference is provided in support, it is worth noting that, only recently, this scenario was considered by WIPO to be 'a science fiction'. [4] The World Economic Forum white paper assumes that 'AI is no longer 'just crunching numbers' but is generating works of a sort that have historically been protected as 'creative' or as requiring human ingenuity'.[5] However, no technical literature but only legal sources are referenced. [6]

AI-generated Inventions in Biotechnology: Traditionally, biotechnological research and innovation were extensively based on experimentation and human interpretation of data. However, AI – driven systems, such as machine learning, neural networks and generative algorithms, now enable the automatic process of hypothesis generation, molecular designs and predictive modeling, transforming the innovation process. AI is now extensively used in biotechnology to solve various issues. These include - drug discovery, drug safety, functional and structural genomics, pharmacology and pharmacogenomics, among many others. [7]

AI has emerged as a transformative tool in agriculture offering solutions for food security challenges increasing due to climate change to data driven analysis, such as climate resilient crops, molecular biology tools including genetic manipulation and genomic breeding, integration of AI with tissue culture and optimization algorithms, enhancing production efficiency and biotechnology based farming, computer vision technologies which facilitates

[3] *BACKGROUND DOCUMENT ON PATENTS AND EMERGING TECHNOLOGIES* (WIPO, 2024)
[4] 'The WIPO Conversation on Intellectual Property and Artificial Intelligence' (*WIPO*) <https://www.wipo.int/en/web/frontier-technologies/artificial-intelligence/conversation> accessed 15 March 2026
[5] *Ibid*
[6] Liza Vertinsky & Todd M Rice, 'THINKING ABOUT THINKING MACHINES: IMPLICATIONS OF MACHINE INVENTORS FOR PATENT LAW' (2002) 8(2) Boston University Journal of Science and Technology Law <https://www.bu.edu/law/journals-archive/scitech/volume82/vertinsky%26rice.pdf> accessed 15 March 2026; Ben Hattenbach & Joshua Glucoft, 'PATENTS IN AN ERA OF INFINITE MONKEYS AND ARTIFICIAL INTELLIGENCE' (2015) 19 Stanford Technology Law Review <https://law.stanford.edu/wp-content/uploads/2017/10/PATENTS-IN-AN-ERA-OF-INFINITE-MONKEYS-AND-ARTIFICIAL-INTELLIGENCE.pdf> accessed 15 March 2026
[7] Andreas Holzinger et al., 'AI for life: Trends in artificial intelligence for biotechnology' (2023) 74 New Biotechnology <https://doi.org/10.1016/j.nbt.2023.02.001> accessed 15 March 2026

real time detection of plant disease and pesticide-fertilizer applications and digital agriculture supporting data collection on soil health and regenerative practices.

AI in forest biotechnology includes Predictive Modelling, Disease and Pest Management, Environmental Monitoring, resource management and inventory management. AI in medical biotechnology includes data analysis and decision making by many companies, drug screening, medical images such as CT scans and MRI images analysis, and analysing data from sources such as electronic health records and wearable devices.

There are many such instances to show various integrations of AI for biotechnological inventions. These inventions involve a unique intersection of law, science and ethics. Initially, this was a trial-and-error method and experimentation; now, with the inclusion of AI, it has created a paradigm shift in technological advancements.

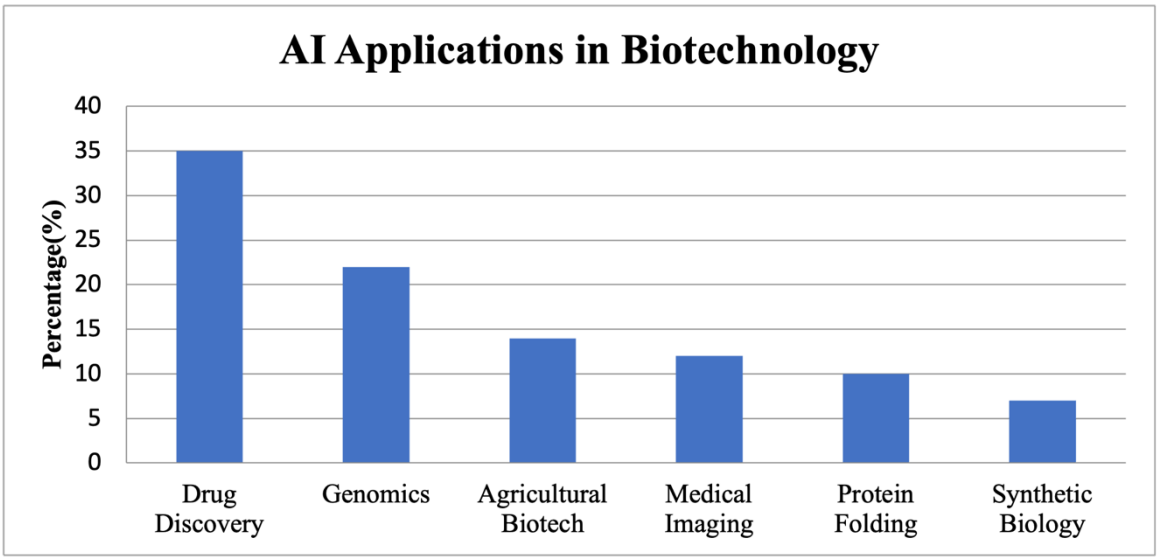

Figure 2: AI Applications in Different Sectors of Biotechnology

The figure above presents a sectoral mapping of AI applications within biotechnology, demonstrating and representing its extensive integration across drug discovery, genomics, agriculture, forestry and medical diagnostics. The graph reflects how AI systems facilitate predictive modeling, molecular simulations, crop optimisations, disease detection and clinical data analysis. By categorising AI use across these sub-domains, the figure underscores the shift from traditional experimental biotechnology toward data-driven and algorithm-assisted innovation. It also visually supports the argument that AI has transitioned from an assistive tool to an active contributor in inventive processes within biotechnology.

AI Inventions and Sustainable Development Goals – A Crossover: AI-generated biotechnological inventions have significant potential to advance the SDGs, particularly in sectors such as zero hunger (SDG 2), good health and well-being (SDG 3), and industry, innovation and infrastructure (SDG 9). In the context of SDG 2, AI-enabled agriculture biotechnology supports the creation of climate-resilient and high-yield crops, strengthening food security and reducing environmental stress. For SDG 3, AI-driven drug discovery and diagnostic tools significantly reduce development timelines and improve access to affordable treatments. Further, for SDG 9, these inventions contribute by fostering a data-driven research ecosystem and accelerating sustainable industrial biotechnology. However, the strict human inventor requirement may delay or limit patent protection for such AI-generated inventions, potentially discouraging investment and slowing their real-world deployment.

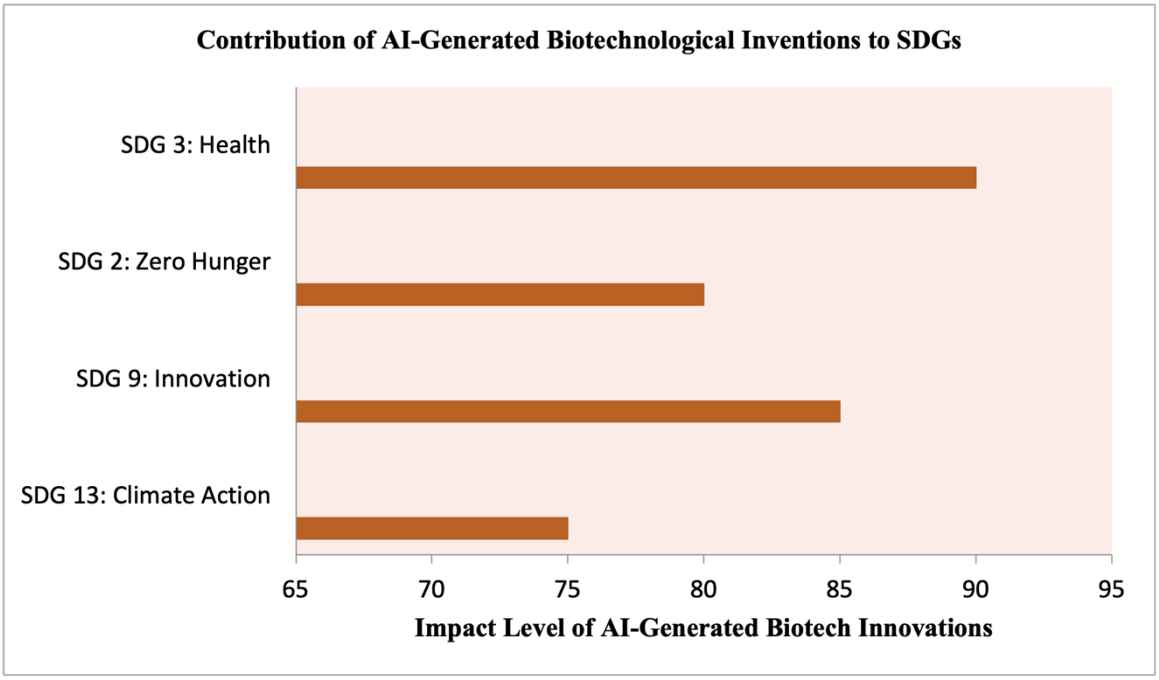

Figure 3: Contribution of AI-Generated Biotechnological Innovation to SDGs

The figure above depicts the correlation between AI-generated biotechnological inventions and selected Sustainable Development Goals (SDGs), particularly SDG 2 (Zero Hunger), SDG 3 (Good Health and Well-Being) and SDG 9 (Industry, Innovation and Infrastructure). The graph demonstrates how AI-enabled crop engineering enhances food security; AI-driven diagnostics improve healthcare accessibility, and an algorithmic research system fosters innovation ecosystems. The graph visually reinforces the policy argument that restrictive

patent frameworks may indirectly affect sustainable development by limiting incentives for AI-enabled solutions. Hence, the figure situates patent law reform within a broader developmental context.

PATENT ELIGIBILITY OF AI-GENERATED BIOTECHNOLOGIES

Criteria under the Indian Patents Act 1970: The Patents Act 1970 provides the well – defined criteria for patent eligibility under sections 2, 3 and 4. An invention must fulfil those defined criteria, which are primarily the core need for the qualification of patent protection. The criteria include: novelty - if it is new and not anticipated by any prior art and not any publicly available information before the filing date including earlier patents, pending application, publications or demonstrations; inventive step - when it shows a technical advance or economic significance and is not obvious to a person skilled in art; and industrial applicability - an invention have real-world practical use and be capable of being made or applied.

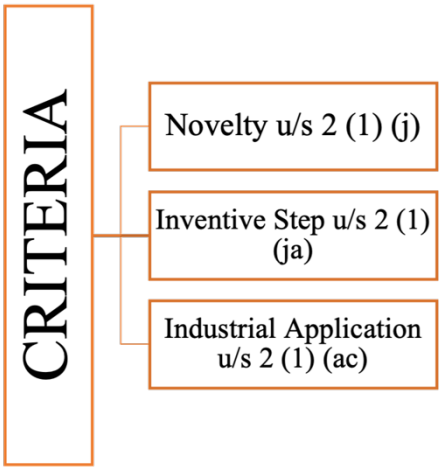

Figure 4: Criteria for Patent Eligibility

The figure above outlines the foundational statutory criteria for patent eligibility under the Patents Act, 1970 – comprising novelty, inventive step and industrial applicability. The chart visually organises these requirements to show their interdependence in determining patent validity. It emphasises that AI-generated biotechnological inventions must satisfy the same statutory thresholds as conventional inventions. However, the figure implicitly raises interpretative challenges regarding how novelty and inventive step are to be assessed when algorithmic systems contribute substantially to the inventive process.

Non-Obviousness Test (Person Skilled in the Art): The test forms the core element in assessing the presence of the inventive step. It examines whether the invention reflects the genuine creative element – an element which is not predictable or obvious to a person skilled in the field. There are certain factors to be considered in applying the test.

The elements of the test are:

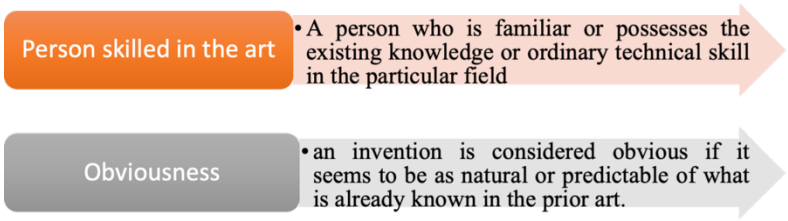

Figure 5: Non-Obviousness Test Elements

The above figure illustrates the components of the non-obviousness assessment, particularly the 'person skilled in the art' standard. The diagram highlights elements such as prior art comparison, technical advancement, economic significance and predictability. In the context of AI-generated inventions, this visual representation becomes especially significant, as it raises the doctrinal question whether the benchmark should account for the enhanced analytical capacity of AI systems. The chart, therefore, supports the discussion on whether the traditional human-centric standard remains adequate in the era of algorithm-driven innovation.

The 'Human Inventor' Requirement – A Necessity or a Bane: As per section 6(1) of the Patents Act, a patent application must be filed by a 'person' who is the true and first inventor or by the assignee of such inventor, while section 2 (1)(p) defines a patentee as a person entered on the register as the grantee or proprietor of the patent. Although these provisions are generally interpreted to mean a natural person. Section 2 (1) (s) of the Patents Act defines 'person' includes government, allowing for broader interpretation that may extend to non-human or artificial entities. Further, the term 'true and first inventor' under section 2 (1) (y) of The Patents Act is the exclusionary definition and states what may not be considered as the 'true and first inventor', thereby leaving scope for interpretative debate in the context of AI- generated inventions.

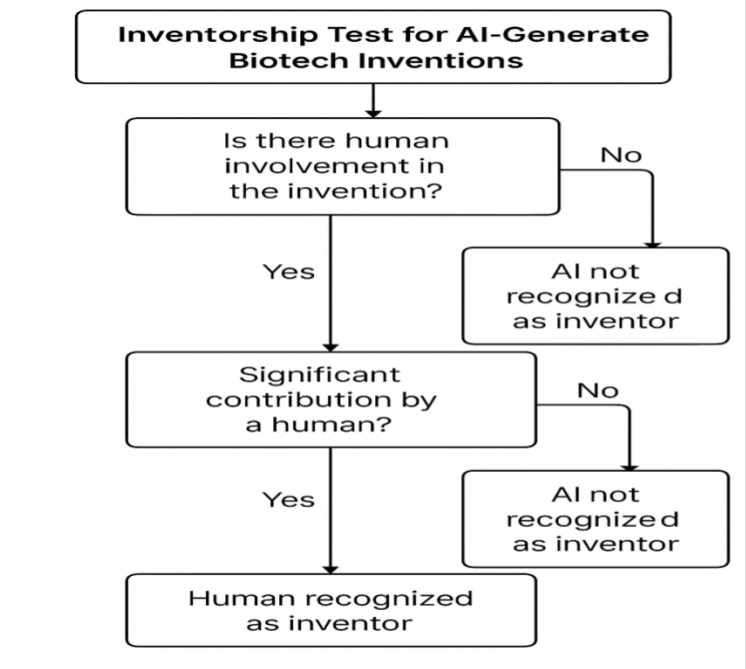

Figure 6: Inventorship Test for AI-generated Biotech Inventions Flowchart

Figure 6 presents a structured analytical framework for determining inventorship in cases where Artificial Intelligence systems are involved in biotechnological innovation. The flowchart visually captures the sequential legal inquiry that patent authorities are likely to undertake when examining whether an invention involving AI satisfies the 'true and first inventor' requirement under the Patents Act 1970. It illustrates that inventorship determination is not a single-step conclusion but a layered evaluative process grounded in statutory interpretation, judicial precedent and factual contribution.

The flowchart first assesses the extent of AI participation – whether AI functioned merely as a tool under human direction or autonomously generated the inventive output. It then evaluates the presence of human intellectual contribution, particularly whether a human conceived, selected, refined or validated the final invention. The diagram highlights that, under existing patent law, inventorship ultimately depends on identifying a natural person who made a material contribution to the inventive concept. Even when AI generates novel results, human supervision, interpretation or experimental verification becomes legally decisive. Thus, the figure demonstrates the current human-centric approach to patent law, where AI may assist or significantly contribute to innovation, but legal recognition of inventorship remains anchored in human accountability.

The Controller of Patents, in the case of National Institute of Virology v Mrs V.S. Bhide, has addressed the question 'who is the inventor', considering various factors such as –

'The person who has not contributed intellectually to the process of development is not considered;

In most jurisdictions, including the United States and Europe, inventions generated solely by Artificial Intelligence (AI) are not patent eligible because an inventor must be a natural person (human being). However, AI-assisted biotechnologies can be patented if a human inventor makes a 'significant contribution' to the invention.'[8]

The Sakata Seed Corporation case[9] has significantly broadened the importance and interpretation of 'human intervention' in Indian Patent laws.

The human requirement has long ensured legal accountability and clarity in patent rights. However, as AI systems increasingly perform inventive functions independently, this requirement risks excluding genuinely novel AI – generated inventions from protection. While retaining human inventor preserves responsibility and control, it may also hinder innovations, calling for a balanced approach that maintains human accountability while recognising AI's role in the process.

Are AI Inventions eligible for a Patent? Under section 3(k) and the 2017 CRI Guidelines, the Delhi High Court in 2019 gave a more liberal view, observing that the IPO's approach was too restrictive with respect to rapid technological progress as well as global practices being adopted worldwide. The court observed that: **'**The restriction applies only to 'computer programs per se' and not to every invention that uses computer programs. In the modern digital world, where most technologies rely on software, it would be unreasonable to claim that all such inventions are automatically non-patentable. Take any area, such as cars and other automobiles, microwave ovens, washing machines, refrigerators, all inherently have some sort of computer programs, which alone should not be the criteria to exclude them from

[8] *National Institute of Virology v Mrs Vandana S Bhide* Patent App No 581/BOM/1999
[9] *Sakata Seed Corporation, Rep by its Authorized Representative Mr Raghavan Ravindran Nair v The Controller of Patents and Designs, Government of India* (2024) SCC OnLine Mad 8398

patent protection. Therefore, for assessment of patentability, technical effects or contribution produced by the program should matter, particularly in digital and electronic inventions.'[10]

Due to massive advancements and changes in the technology sector, the draft guidelines for examination of Computer Related Inventions, 2025, came into light. The Office of the Controller General of Patents, Designs and Trade Marks issued certain guidelines in light of dealing with changes and advancements such as Artificial Intelligence, cloud computing, cyber space, jurisprudential development on patentability of CRIs and any such other with respect to CRIs.

The key features of Draft Guidelines, 2025 include an expanded definition of algorithm, which is protected under copyright laws. The guidelines clarify that algorithms are not patentable, but could be if such an algorithmic instruction results in a technical effect or contribution.[11]

Section 3(k) of the Patents (Amendment) Act 2002 states that a computer programme *per se* is not patentable, but the term *per se* implies that a computer programme is not patentable; however, if it contributes to another invention, it can be patentable. There are also various recent instances to clarify the same. In the case of Ferid Alliani v UOI & Ors, Hon'ble Delhi HC held that if the invention demonstrates a 'technical effect' or 'technical contribution', it is patentable if it is based on a computer programme.[12]

Draft Guidelines of 2025 also lays down one of the most important features, which is the introduction of patentability for AI-driven technologies and developments. The Hon'ble Madras High Court, in the case of Caleb Suresh Motupalli v Controller of Patents, analysed and highlighted 'the requirement of enablement to be fulfilled in AI-driven technologies, stating that the invention must disclose specific implementation elements critical to reproducing the AI model's functionality and any applied loss functions.'[13] There is also a graph below that represents the share of AI-based patent applications by countries.

[10] *Ferid Allani v Union of India & Ors* (2019) SCC OnLine Del 11867
[11] *Blackberry Ltd v Assistant Controller of Patents & Designs* (2024) 4 HCC (Del) 471
[12] *Ferid Allani v Union of India & Ors* (2019) SCC OnLine Del 11867
[13] *Caleb Suresh Motupalli v Controller of Patents* (2025) SCC OnLine Mad 20746

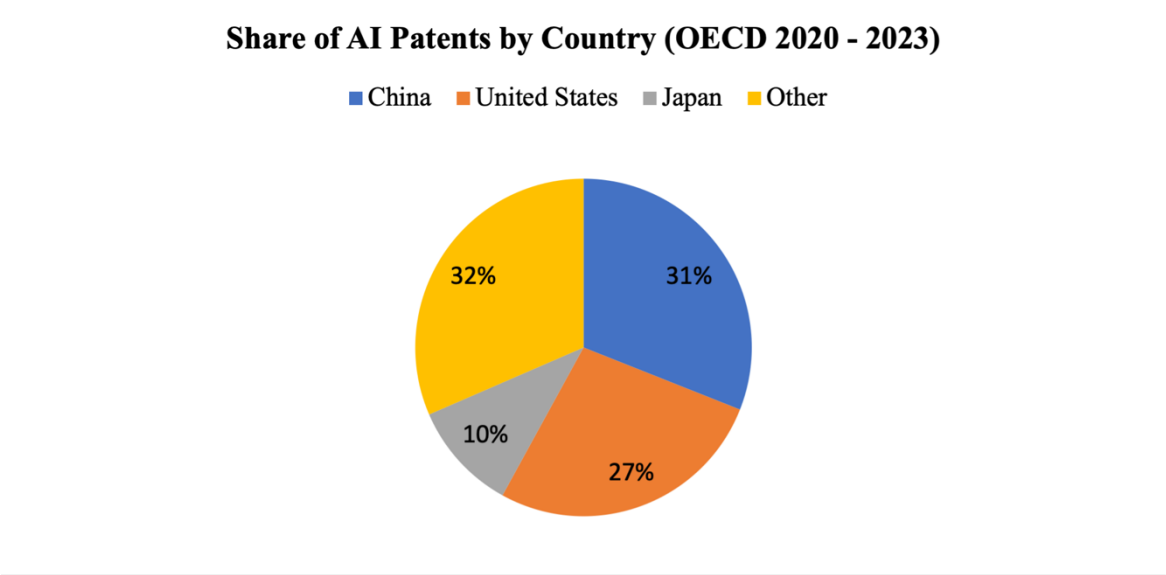

Figure 7: Share of global AI-based PCT patent filings between 2020-2023, as reported by OECD (2025)

The above figure provides a comparative graphical representation og global AI-based Patent Cooperation Treaty (PCT) filings across leading jurisdictions between 2020 and 2023. The chart highlights the concentration of AI patent activity in countries such as the United States, China and Japan, as reported by OECD data. The figure demonstrates the uneven global distribution of AI innovation and underscores the strategic importance of regulatory clarity in fostering competitive growth. It also conceptualises India's relative positions within the global AI patent ecosystem.

JUDICIAL DEVELOPMENTS AND INTERPRETATIONS

Thaler v Comptroller-General of Patents, Designs & Trade Marks:[14] This is one of the leading judgments on the inventorship of AI debate. UKSC held that an inventor must be a person and applications naming DABUS, where AI was considered as an inventor, were refused.

Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries:[15] The Supreme Court outlined standards of novelty, inventive step, and disclosure for patent applications. The judgment forms a foundational Indian precedent for patent validity.

[14] *Thaler v Comptroller-General of Patents, Designs & Trade Marks* [2023] UKSC 49
[15] *Bishwanath Prasad Radhey Shyam v Hindustan Metal Industries* (1979) 2 SCC 511

Ferid Allani v Union of India:[16] It is a landmark case holding that technical effect/technical contribution is key to patent eligibility for computer-related inventions. This reasoning will apply to AI-biotech inventions (e.g., AI-generated gene sequences).

Professor R. Sudharshan v The Controller of Patents: The case stressed that a true and first inventor must be clearly identifiable, and implies that an inventor must be a human who conceives the invention.

Association of Molecular Pathology v Myriad Genetics:[17] The court emphasised that a patentable biotech invention must have significant human modification or application beyond a natural product.

International Perspectives and Challenges –

TRIPS Agreement: does not define the term 'inventor' and leaves it up to State laws for interpretation. Also, does not give any detailed emphasis on AI-generated inventions.

Patent Cooperation Treaty 1970: The treaty provides for the unified filing of patent applications internationally. The requirement of naming an inventor has led to the rejection of AI applications such as DABUS.

International Union for the Protection of New Varieties of Plants, 1961 (revised in 1991): It indirectly covers and acknowledges AI-derived plant varieties. Use of AI generated and assistance may qualify for protection if a human is identified as supervising or directing the process.

Inventorship Debate in the Age of AI: Can a machine be recognised as an inventor? This question has created a storm of debates around. Present patent laws still lag in AI credibility. It is hard to analyse how and to what extent an AI can be recognised as an inventor. The US, UK and European nations have specifically denied the tag of inventor to any AI, for any AI inventions. With the tag of inventor comes along the credibility, accountability and liability, which is a challenge – modern laws are not prepared for. AI is no longer a mere tool for assistance; it is redefining innovation in its own ways. In certain European countries, with respect to biotechnology and AI, the innovation does not inherently become patentable or

[16] *Ferid Allani v Union of India & Ors* (2019) SCC OnLine Del 11867
[17] A*ssociation for Molecular Pathology v Myriad Genetics, Inc* [2013] 569 US 576

not; the usual assessment process takes place for each of such innovations. There might be challenges, but the grant of patents is not very difficult for such fields.

There is also the representation of the growth of AI-based biotechnology Patents given below:

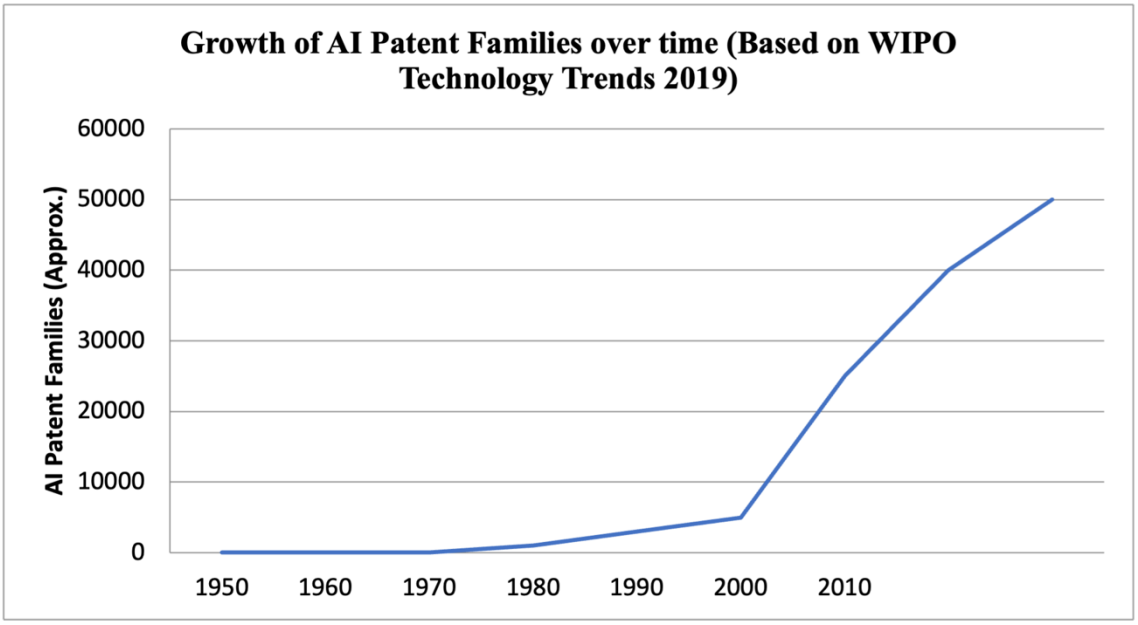

Figure 8: AIPLA 2024 Analysis Report on AI in Biotechnology (USPTO data)

Figure 8 reflects the upward trajectory of AI-based biotechnology patent filings, drawing on USPTO data and AIPLA analysis. The graph illustrates the exponential increase in filings over recent years, signifying accelerated technological integration between AI and life sciences. This visual trend substantiates the argument that while AI – driven innovation is expanding rapidly, legal reforms addressing inventorship and disclosure remains comparative slow. The figure thus reinforces the theme of regulatory lag and the need for adaptive patent frameworks.

REGULATORY GAPS AND THE FUTURE OF AI-DRIVEN BIOTECHNOLOGICAL PATENT GOVERNANCE

The rapid integration of Artificial Intelligence into biotechnology exposes a structural gap between technological capability and patent governance, while patent systems worldwide continue to rely on human-centric definitions of inventorship and conception, AI systems increasingly perform functions that resemble independent intellectual contribution. This

mismatch creates a 'regulatory latency gap', wherein innovation evolves faster than statutory interpretation.

One of the most significant concerns is the absence of standardised disclosure norms relating to AI involvement in the inventive process. Presently, patent applications are not uniformly required to disclose the extent to which AI systems contributed to hypothesis generation, molecular design or predictive modelling. This lack of transparency may affect both examination quality and post-grant validity challenges. A structure disclosure requirement would therefore enhance procedural fairness and doctrinal clarity.

Another emerging challenge relates to the recalibration of the non-obviousness standard. However, when AI systems are capable of processing millions of data points and generating optimised solutions within seconds, the baseline of what is obvious may shift. This raises an important question: Should patent law adapt the skilled-person standard to reflect AI-related capabilities, or should it preserve a purely human benchmark to protect innovation incentives? The future governance of AI-generated biotechnological inventions will likely evolve toward a hybrid accountability model. Under such a framework, AI would remain a non-legal entity, but the patent system would explicitly recognise varying degrees of AI contribution through structured disclosure, adjusted examination guidelines and refined inventorship standards. Additionally, the human inventor requirement, while preserving accountability, may lead to artificial attribution practices.

Ultimately, the challenge is not whether AI should replace human inventors, but how patent law can remain technologically neutral while ensuring fairness, transparency and innovation incentives. Addressing these regulatory gaps is essential for maintaining the legitimacy and effectiveness of the patent system in the age of autonomous biotechnology.

EMERGING PATTERN AND KEY FINDINGS

The rapid adoption of AI in biotechnology has produced remarkable changes and contributions to the inventions in various dimensions. The last decade has seen a remarkable surge in patent filings that either involve AI or protect AI technologies. WIPO's recent patent-structure work shows the documents on the diversification of GenAI patenting across industries and the rise of AI-related claims requiring interpretative approaches by examiners.

The OECD analysis of patent records corroborates that AI-related inventions have grown rapidly (roughly tripling as a share of PCT filings since 2015), with China, Japan and the USA forming the largest shares.

These shifts create two challenges for biotechnology:

1. How to apply traditional patentability tests when core inventive work is performed by machine learning or deep learning tools?
2. How to allocate inventorship and associated rights when the 'creative' act is automated?

The paper lays out the doctrinal tensions under Indian laws and international laws, along with judicial and administrative trends emphasising 'human contribution' as the decisive factor in awarding inventorship – a view similar in various jurisdictions.

Global datasets show a sharp rise in AI-based inventions concentrated in jurisdictions with high data accessibility, like the US, China and Europe; meanwhile, jurisdictions with strong capabilities but weaker institutional data ecosystems, such as India, show weaker growth. This suggests that patentability in the age of AI is not just dependent on inventive skill but also on data infrastructure.

- AI-generated biotechnology is creating a widening 'innovative asymmetry' between entities that possess proprietary datasets and compute infrastructure and those that do not. This imbalance could create a situation where a few powerful organisations with data sets and advanced technology will end up in a controlling position and lead major innovations.
- The paper also reflects on the examination pattern of the USPTO and EPO, which, despite rejecting AI as an inventor, has seen an increased number of applications based on AI-driven output being accepted, but the patentability is justified by the human curation or validation. This indicates that the shift has already begun towards hybrid responsibility, where humans become 'innovation supervisor' rather than 'innovation creation'.
- It can also be seen that countries with clear AI policies experience faster growth, as based on the database, which indicates that regulatory matters are more important than economic strength. India, as of now, stands at a decisive position. If it defines AI

involvement, standardised disclosures and clarifies inventorship, it can easily position itself on a global scale for AI- biotechnology patents. Technology, along with legal clarity, will determine who leads the innovation.

- AI-driven inventions are growing faster than legal adaptation: while global AI-related patent filings increased by over 300% in the last decade, statutory reforms addressing AI inventorship remain negligible, widening regulatory lag.
- Lack of AI disclosure correlated with examination inconsistency: Patent offices lack standardised AI disclosure norms, leading to non-uniform applications.
- Post-grant risk is increasing: without AI disclosure norms, AI-generated patents carry a higher probability of post-grant challenges.

CONCLUSION AND SUGGESTIONS

The AI-generated biotechnological inventions present a complex intersection of technology and laws in the present era. The Indian patent law, like all other nations, is grounded in the assumption that inventions originate from human intellect, but the expanding capability of AI is creating gaps and loopholes that go beyond the current laws. The growth and expansion of AI in any field is unstoppable, more than a helping hand – it is becoming the driving tool for innovations and discoveries. With time, it will be impossible to tackle modern problems and challenges with traditional laws and models. It is very important to clarify the role of AI to what extent it is acceptable and can contribute to developments, for which a new statutory development and framework is required, noting the increase in AI-driven inventions day-by-day. A few of the suggestions are:

Statutory Clarity: Provisions should be introduced to explicitly define various terms to help in distinction and determination.

Mandatory AI-disclosure Requirements: They should be incorporated into patent applications to ensure transparency regarding the role of AI in the inventive process.

Updated CRI and biotech-specific Patent Guidelines: They should be issued to reflect advancements in AI-driven technology.

A Specialised Regulatory-Patent Interface: It should be established for high-risk biotechnological inventions involving AI.

Policy focus should extend beyond Protection: To build a legally sound, technologically adaptive and socially responsible innovation environment.

Fast-Track Examination Route for AI-driven Inventions: Introducing this would incentivise innovation and reduce delays in protecting time-sensitive technologies.

Open and Responsible Licensing Models: Encouraging this for AI-generated inventions can promote wider access, especially for public-interest technologies.

Post-grant Review Mechanism: Establishing this for AI-related patents would help address errors, non-disclosure or evolving technological understanding.