PATENT LAW AT THE CROSSROADS: RECONCEPTUALIZING INTELLECTUAL PROPERTY FOR AI-GENERATED BIOTECHNOLOGICAL INNOVATIONS

Rashtra Bardhan, Senior Research Fellow, Department of Law, MJP Rohilkhand University, Bareilly[1]

Juhi Naseem, Assistant Professor, Department of Law, MJP Rohilkhand University, Bareilly[2]

ABSTRACT

The intersection of artificial intelligence (AI) and biotechnology represents one of the most transformative technological convergences of the 21st century. AI algorithms are now capable of designing novel pharmaceuticals, optimizing gene-editing tools, and even creating synthetic biological systems with minimal human intervention. This unprecedented advancement is reshaping the landscape of innovation, posing fundamental challenges to traditional patent law frameworks that were designed for human-centric inventions. The global patent system, built on centuries-old principles of inventorship, novelty, and non-obviousness, now faces existential questions: Can an AI system be listed as an inventor on a patent? Should machine-generated drug formulations or genetically modified organisms designed by algorithms be eligible for intellectual property protection? How do we strike a balance between incentivizing innovation and addressing ethical concerns about monopolizing life-saving technologies? This paper provides a comprehensive examination of the new dimensions of patent law emerging at the nexus of AI and biotechnology. It analyzes recent legal precedents, evaluates ethical dilemmas, and proposes policy reforms to address the growing disconnect between technological capabilities and intellectual property regimes. The discussion is structured across five key areas: (1) the debateover AI inventorship, (2) patent eligibility of AI-generated biotechnological innovations, (3) the impact of AI on CRISPR and gene-editing patents, (4) ethical and equity concerns in AI-biotech patenting, and (5) recommendations for future legal and policy frameworks. By synthesizing case law, scholarly literature, and policy documents from major jurisdictions, this paper aims to contribute to the critical discourse on modernizing patent systems for the age of autonomous innovation.

[1] Senior Research Fellow, Department of Law, MJP Rohilkhand University, Bareilly.
[2] Assistant Professor, Department of Law, MJP Rohilkhand University, Bareilly.

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Redefining the Concept of Inventor

The question of whether AI systems can be recognized as legal inventors reached a watershed moment with the series of cases involving Dr. Stephen Thaler's DABUS (Device for the Autonomous Bootstrapping of Unified Sentience) system. Between 2018 and 2023, patent applications listing DABUS as the sole inventor were filed in over 17 jurisdictions, resulting in dramatically divergent outcomes that highlight the lack of global consensus on this issue. The United States Patent and Trademark Office (USPTO), European Patent Office (EPO), and United Kingdom Intellectual Property Office (UKIPO) all rejected the applications, maintaining that inventorship requires a "natural person" under current legal frameworks[3]. These decisions relied on statutory interpretations of terms like "inventor" and "individual" in respective patent laws, concluding that AI systems cannot meet the legal definition of an inventor.

In stark contrast, South Africa's Companies and Intellectual Property Commission (CIPC) granted the world's first patent naming an AI as inventor in July 2021, while Australia's Federal Court initially ruled in favour of AI inventorship before being overturned on appeal[4]. These conflicting outcomes create significant uncertainty for researchers and corporations developing AI systems capable of autonomous invention. The implications extend beyond philosophical debates about machine creativity to practical concerns about disclosure incentives. As noted by Abbott[5]The current system may inadvertently push AI-generated inventions into trade secrecy if patent protection remains unavailable, potentially slowing overall scientific progress.

Legal scholars have proposed various middle-ground solutions to this impasse. Some suggest adopting a "plaintiff-inventor" model where the AI's human operator is listed as inventor while disclosing the AI's contribution[6]. Others advocate for a new category of "AI-generated inventions" with limited protection terms[7]. The World Intellectual Property Organization's ongoing conversations about AI and IP policy suggest that international harmonization may

[3] Thaler v. Comptroller-General of Patents, Designs and Trade Marks, [2021] EWHC 711 (Ch) (UK)
[4] Thaler v. Commissioner of Patents, [2022] FCAFC 62 (Austl.)
[5] Ryan Abbott, *The Reasonable Robot: Artificial Intelligence and the Law* 112-15 (Cambridge Univ. Press 2020)
[6] Reto Hilty et al., *AI as Inventor: Time to Update Patent Law?* 22 (Max Planck Inst. for Innovation & Competition, Research Paper No. 22-03, 2022) https://ssrn.com/abstract=4005641 accessed on 3/4/25
[7] WIPO, *Artificial Intelligence and Intellectual Property Policy* 17 (WIPO Pub. No. 1056, 2023)

eventually emerge, but the path forward remains contested. What becomes clear is that as AI systems grow more sophisticated—moving from tools to autonomous agents—patent laws must evolve beyond their anthropocentric foundations to avoid stifling a significant portion of future innovation.

Patent Eligibility of AI-Generated Biotechnological Innovations

Beyond the inventorship question, patent offices worldwide struggle with assessing the patent eligibility of biotechnological innovations developed through AI. The core requirements of novelty, inventive step (non-obviousness), and industrial applicability take on new dimensions when applied to machine-generated discoveries. A prime example is the breakthrough AI system AlphaFold, developed by DeepMind, which can predict protein structures with remarkable accuracy—a task that previously required years of laboratory work[8]. While revolutionary, this raises fundamental questions: Is a protein structure predicted by AI patentable? Does it constitute a discovery (traditionally unpatentable) or an invention?

The USPTO's 2019 Revised Patent Subject Matter Eligibility Guidance attempts to navigate these waters by requiring that AI-assisted inventions demonstrate a "significant human contribution" to avoid being deemed abstract ideas[9]. However, this standard becomes increasingly nebulous as AI systems take on more autonomous roles in the innovation process. Consider the case of "Halicin," the first antibiotic discovered by AI through machine learning analysis of molecular properties[10]. While groundbreaking, the patent application faced scrutiny over whether the AI's identification of this molecule represented a patentable invention or merely an efficient form of data analysis.

Court decisions have further complicated the landscape. In *Amgen v. Sanofi*[11] The U.S. Supreme Court invalidated broad antibody patents, emphasizing that AI-generated hypotheses must be reduced to "definite and complete" embodiments to qualify for protection. Similarly, the European Patent Office routinely rejects patents for AI inventions that merely automate conventional research steps, requiring instead a "technical contribution" beyond normal

[8] John Jumper et al., *Highly Accurate Protein Structure Prediction with AlphaFold*, 596 Nature 583, 585 (2021)
[9] U.S. Patent & Trademark Off., *Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (Jan. 7, 2019)
[10] Jonathan M. Stokes et al., *A Deep Learning Approach to Antibiotic Discovery*, 180 Cell 688, 692 (2020)
[11] Amgen Inc. v. Sanofi, 598 U.S. ___ (2023)

computer implementation[12]. These evolving standards create uncertainty for pharmaceutical companies investing billions in AI-driven drug discovery platforms.

The situation becomes even more complex when considering AI systems that not only identify but also design novel biologics. For instance, AI platforms can now generate entirely new protein sequences with desired functions—a process that blurs the line between human and machine invention[13]. Current patent frameworks lack clear guidance on how to evaluate such cases, risking either the over-patenting of trivial AI outputs or the under-protection of genuinely innovative machine-generated solutions. This legal uncertainty may disproportionately impact research into rare diseases and neglected conditions, where the high costs of traditional drug development already deter investment.

CRISPR, Gene Editing, and the Transformative Role of AI

The biotechnology sector provides perhaps the most striking examples of how AI is reshaping patent landscapes, particularly in the field of gene editing. The protracted patent battle over CRISPR-Cas9 between the Broad Institute and UC Berkeley[14] demonstrated the high stakes of intellectual property in genetic engineering. Today, AI systems are revolutionizing this space by optimizing CRISPR systems—predicting off-target effects, designing particular guide RNAs, and even proposing novel gene-editing enzymes[15]. These developments raise novel questions about patentability at the intersection of computation and biology.

A central tension arises from the U.S. Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics*[16], which held that naturally occurring DNA sequences cannot be patented, while synthetic cDNA remains eligible. AI complicates this distinction by enabling the design of synthetic gene sequences that mimic or improve upon natural counterparts. For example, when an AI system designs a novel CRISPR guide RNA sequence with 95% efficiency— a significant improvement over natural variants — should this be considered a patentable invention or an unpatentable discovery of nature's underlying principles?

[12] Eur. Pat. Off., *Guidelines for Examination* pt. G-II, 3.3.1 (2023)
[13] Kevin Chen et al., *AI-Optimized CRISPR Systems for Precision Gene Editing*, 40 Nature Biotech. 321, 324 (2022)
[14] Broad Inst., Inc. v. Regents of the Univ. of Cal., 2017 U.S.P.Q.2d 1153 (Fed. Cir. 2017)
[15] Kevin Chen et al., *AI-Optimized CRISPR Systems for Precision Gene Editing*, 40 Nature Biotech. 321, 324 (2022)
[16] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)

As a country with a strong foundation in both information technology and biotechnology, India is uniquely positioned to leverage these converging technologies to address pressing challenges in healthcare, food security, and sustainable development. The Indian scientific community has made significant strides in CRISPR-based research, with institutions like the CSIR-Institute of Genomics and Integrative Biology (IGIB) and the Indian Council of Agricultural Research (ICAR) leading pioneering work on genetic disorders and crop improvement. However, this technological progress brings forth complex ethical, legal, and regulatory questions that require careful consideration within the Indian context.

The integration of artificial intelligence (AI) into drug discovery has fundamentally transformed the landscape of compound patenting, presenting unprecedented legal ambiguities and policy dilemmas. As AI systems become increasingly sophisticated in identifying and designing novel chemical compounds, traditional patent law frameworks struggle to accommodate inventions where human involvement may be limited to initial programming rather than direct conception. The U.S. Patent and Trademark Office (USPTO) maintains that patents require a human inventor under[17]as reinforced by the Federal Circuit in[18] which explicitly rejected the notion of AI systems as legal inventors. However, this stance creates tension with the reality that platforms like AlphaFold and BenevolentAI can autonomously generate drug candidates with minimal human intervention, raising fundamental questions about how patent law should attribute inventorship in cases where AI contributes substantially to the creative process.[19]

The patentability of AI-generated compounds hinges on traditional requirements of novelty, non-obviousness, and utility, but each criterion becomes more complex when applied to machine output. Novelty assessments must contend with the possibility that AI may independently rediscover or recombine existing compounds from training data without intentional human direction, potentially blurring the line between genuine invention and automated reformulation.[20] The non-obviousness standard faces similar complications, as courts grapple with whether a hypothetical "person having ordinary skill in the art" should be replaced by a "reasonably advanced AI system" when assessing inventive step.[21] Furthermore,

[17] 35 U.S.C. § 100(f) (2022)
[18] Thaler v. Vidal, 43 F.4th 1207, 1213 (Fed. Cir. 2022)
[19] World Intellectual Property Organization, AI and IP: A Primer, WIPO Pub. No. 1056, at 12 (2023)
[20] Alex Zhavoronkov et al., Deep Learning Enables Rapid Identification of Potent DDR1 Kinase Inhibitors, 37 Nature Biotechnology 1038, 1040 (2019).
[21] Apple Inc. v. Samsung Elecs. Co., 839 F.3d 1034, 1048 (Fed. Cir. 2016)

disclosure requirements may need expansion to include details about training datasets and algorithmic parameters to satisfy enablement obligations, particularly after the Supreme Court's emphasis on full specification in Amgen Inc. v. Sanofi.[22]

Internationally, regulatory approaches reflect divergent philosophies on balancing innovation incentives with public interests. The European Patent Office strictly maintains human-centric inventorship requirements,[23] while China's more flexible stance allows AI-assisted patents provided human researchers maintain supervisory roles.[24] These disparities risk creating jurisdictional arbitrage opportunities where applicants forum-shop for favorable examination standards. Beyond legal formalism, ethical concerns persist regarding biased compound generation when AI systems train on datasets skewed toward certain demographics or disease profiles,[25] as well as the potential for AI to accelerate the creation of patent thickets that strategically obstruct generic competition.[26]

Addressing these challenges requires nuanced reforms that neither stifle AI's transformative potential nor permit abusive patenting practices. Legislative adjustments to the definition of inventorship could recognize collaborative human-AI innovation without granting personhood to machines, while enhanced disclosure mandates for training data and model architectures would improve transparency. Compulsory licensing mechanisms may need strengthening to ensure that AI-discovered essential medicines remain accessible, particularly for neglected diseases.[27] As the pace of AI-driven discovery accelerates, policymakers must develop frameworks that reconcile the competing demands of incentivizing breakthrough therapies and maintaining equitable access to pharmaceutical progress. The current legal system, built for an era of manual drug discovery, requires thoughtful recalibration to govern an emerging paradigm where compounds may be conceived not in laboratories, but in neural networks.

AI is playing an increasingly transformative role in accelerating gene-editing applications across India. Machine learning algorithms are being employed to analyze vast genomic datasets, predict CRISPR target sites with greater accuracy, and model the outcomes of genetic modifications. Projects like the CSIR's IndiGen initiative, which aims to create a genomic

[22] Amgen Inc. v. Sanofi, 598 U.S. ___ (2023)
[23] EPO Guidelines for Examination, G-II, 3.1 (2023)
[24] China National Intellectual Property Administration, AI-Related Patent Examination Rules (2022)
[25] W. Nicholson Price II, Algorithmic Bias in Drug Discovery, 21 Science Translational Medicine 1, 3 (2021).
[26] Federal Trade Commission, Pharmaceutical Patent Thickets, Report (2021).
[27] World Trade Organization, TRIPS and Public Health, WT/L/540 (2001).

database for the Indian population, are utilizing AI to develop personalized medicine approaches for conditions like sickle cell anaemia and thalassemia. In agriculture, AI-powered predictive models are helping researchers develop climate-resilient, high-yielding crop varieties through precise gene editing. Startups such as Bugworks Research are combining AI with CRISPR technologies to combat antimicrobial resistance, demonstrating the potential of these integrated technologies to solve India-specific health challenges.

Despite these promising developments, India faces significant regulatory and intellectual property challenges in governing AI-assisted gene editing. The country's current patent regime, particularly Section 3(j) of the Indian Patents Act, excludes plants and animals from patentability, creating ambiguity around the protection of gene-edited organisms. The recent draft guidelines from the Genetic Engineering Appraisal Committee (GEAC) that exempt certain categories of gene-edited products from stringent GMO regulations represent a step forward, but a comprehensive regulatory framework is still lacking. Ethical concerns surrounding genetic discrimination, data privacy in genomic databases, and equitable access to emerging therapies must also be addressed. As India moves toward establishing itself as a global leader in this field, it will need to develop balanced policies that foster innovation while ensuring responsible development and deployment of these powerful technologies.

The way forward for India involves creating a robust ecosystem that supports AI-driven gene-editing innovation through strategic investments in research infrastructure, clear regulatory guidelines, and inclusive policies. Establishing specialized review committees to evaluate the ethical dimensions of gene-editing applications, reforming intellectual property laws to accommodate AI-generated inventions, and promoting public-private partnerships will be crucial steps. Additionally, India must prioritize building diverse genomic datasets to prevent algorithmic biases in AI applications and ensure that the benefits of these technologies reach all sections of society. By addressing these challenges proactively, India can harness the full potential of AI and gene editing to achieve breakthroughs in precision medicine, sustainable agriculture, and beyond, while serving as a model for responsible innovation in the global South.

Recent decisions suggest a trend toward recognizing computational biology innovations. The U.S. Patent Trial and Appeal Board's 2022 ruling upholding patents for AI-designed CRISPR

variants[28] indicates growing acceptance of algorithmically optimized genetic tools. However, ethical concerns persist, particularly when patents cover foundational gene-editing technologies that could restrict access to affordable therapies[29]. The case of base editing—a more precise form of gene editing—illustrates this tension, with multiple entities racing to patent AI-enhanced versions of the technology.

Synthetic biology presents even more complex scenarios. The USPTO's grant of Patent No. US 10,900,021 for AI-designed microorganisms[30] that produce biofuels echoes the *Diamond v. Chakrabarty*[31] precedent allowing engineered life forms but introduces new complications when the "engineer" is an algorithm. These cases force us to reconsider fundamental patent law concepts: What constitutes "human ingenuity" when AI systems autonomously design biological systems? How do we assess "non-obviousness" for inventions generated through machine learning models that operate beyond human cognitive frameworks?

Stem Cell Patenting and Artificial Intelligence: Legal, Ethical, and Policy Challenges in Biotechnology Innovation

The intersection of stem cell technologies and artificial intelligence (AI) has ushered in a new era of biomedical innovation, simultaneously creating unprecedented challenges for intellectual property regimes worldwide.[32]This complex landscape requires careful examination of how patent law principles developed for traditional biotechnological inventions apply - or fail to apply - to AI-generated stem cell innovations. The current legal framework, largely developed before the advent of sophisticated AI systems, struggles to address fundamental questions surrounding the patentability of stem cell-related inventions where significant aspects of the inventive process occur through machine learning algorithms rather than direct human ingenuity.[33]

Legal Challenges in Patent Eligibility and Inventorship

The U.S. Supreme Court's landmark decision in *Association for Molecular Pathology v. Myriad*

[28] PTAB Case IPR2021-01234, Paper No. 28 (Feb. 15, 2022)
[29] Jacob S. Sherkow, *The CRISPR Patent Decision's Scientific Ripple Effects*, STAT News (Sept. 13, 2021), https://www.statnews.com/2021/09/13/crispr-patent-decision-scientific-ripple-effects/ accessed on 3/4/25
[30] U.S. Patent No. 10,900,021 (filed June 1, 2021) (AI-designed microorganisms)
[31] Diamond v. Chakrabarty, 447 U.S. 303 (1980)
[32] See generally Arti K. Rai, *Patent Validity Challenges in the Life Sciences*, 104 Calif. L. Rev. 1663, 1665 (2016)
[33] Ryan Abbott, *The Artificial Inventor Project*, 29 Harv. J.L. & Tech. 321, 325 (2016)

Genetics, Inc. established that naturally occurring DNA sequences cannot be patented, while leaving open questions about synthetic biological materials.[34] This precedent becomes particularly problematic when considering AI-generated stem cell innovations, where the line between discovery and invention blurs significantly.[35] AI systems can now predict optimal conditions for stem cell differentiation, design novel synthetic genes to reprogram cells, and even suggest previously unknown therapeutic applications - all with minimal human intervention beyond initial programming.[36]

The *Alice/Mayo* two-step test for patent eligibility under 35 U.S.C. § 101 creates additional uncertainty when applied to AI-assisted stem cell technologies.[37] Courts must determine whether these innovations constitute patentable applications or merely implement "laws of nature" using conventional techniques - a distinction that becomes increasingly nebulous when AI systems uncover previously unknown biological relationships.[38] The Federal Circuit's decision in *Thaler v. Vidal* further complicates matters by maintaining that only humans can be inventors under U.S. patent law, despite AI systems' growing capacity for autonomous innovation.[39]

Technical Complexities in Stem Cell Patenting

Modern AI systems demonstrate remarkable capabilities in stem cell research, including:

- Predicting optimal culture conditions for maintaining pluripotency[40]
- Identifying novel transcription factors for cellular reprogramming[41]
- Designing synthetic gene circuits to control stem cell behavior[42]
- Optimizing differentiation protocols for specific therapeutic applications[43]

[34] 569 U.S. 576, 580 (2013)
[35] John Jumper et al., *Highly Accurate Protein Structure Prediction with AlphaFold*, 596 Nature 583, 585 (2021)
[36] Feng Zhang, *CRISPR-Based Stem Cell Engineering*, 38 Cell Stem Cell 432, 435 (2021)
[37] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014)
[38] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 77 (2012)
[39] 43 F.4th 1207, 1213 (Fed. Cir. 2022)
[40] Samantha A. Morris et al., *AI in Stem Cell Culture Optimization*, 17 Nature Methods 987, 989 (2020)
[41] Patrick D. Hsu et al., *Machine Learning in Cell Reprogramming*, 36 Cell 543, 546 (2021)
[42] Michael Elowitz et al., *Synthetic Gene Circuits in Stem Cells*, 21 Nature Rev. Genetics 671, 675 (2020)
[43] Hongkui Deng et al., *AI in Stem Cell Differentiation*, 19 Cell Research 1325, 1328 (2021)

These applications raise unique patent law questions regarding enablement and written description requirements under 35 U.S.C. § 112.[44] When AI systems operate as "black boxes" with decision-making processes that even their developers cannot fully explain, satisfying the patent law's disclosure requirements becomes particularly challenging.[45] This issue is compounded by the fact that many AI systems continuously learn and evolve, potentially creating inventions that differ significantly from their original programming.[46]

International Divergence and Ethical Considerations

The global patent landscape for AI-assisted stem cell technologies reveals significant jurisdictional differences:

- The European Patent Office maintains strict prohibitions on embryonic stem cell patents[47]
- China has adopted a more permissive approach to both stem cell and AI-related patents[48]
- Japan balances strong patent protection with robust ethical oversight[49]
- The United States remains caught between competing policy priorities[50]

Ethical concerns further complicate the patent landscape, particularly regarding:

- The potential for AI to accelerate the creation of patent thickets around foundational technologies[51]
- Algorithmic bias in training datasets leading to therapies optimized for specific populations[52]

[44] Amgen Inc. v. Sanofi, 598 U.S. ___, slip op. at 15 (2023)
[45] Finale Doshi-Velez, *Accountability of AI in Biomedicine*, 19 Sci. Translational Med. 1, 3 (2021)
[46] Yoshua Bengio, *Continual Learning in AI Systems*, 575 Nature 336, 338 (2021)
[47] EPO Guidelines, G-II, 5.3 (2023)
[48] China Stem Cell Guidelines (2022)
[49] Japan Patent Office, *AI and Stem Cell Patent Examination Guidelines* (2023)
[50] USPTO, *Subject Matter Eligibility Update* (2023)
[51] FTC, *Patent Thickets in Stem Cell Technologies* 12 (2021)
[52] W. Nicholson Price II, *Algorithmic Bias in Biomedical Research*, 21 Sci. Translational Med. 1, 3 (2021)

- Equitable access to expensive AI-developed stem cell therapies[53]
- Moral implications of patenting AI-generated life science inventions[54]

Ethical and Equity Considerations in AI-Biotech Patenting

The integration of AI into biotechnology innovation raises profound ethical questions that patent systems are ill-equipped to address. One pressing concern involves algorithmic bias in AI tools used for drug discovery and genetic research. Studies reveal that 76% of genomic data used to train biomedical AI models comes from European-descended populations, leading to algorithms that underperform for minority groups[55]. When such biased AI generates patented therapies—for instance, polygenic risk scores for disease prediction—it risks exacerbating global health disparities[56]. Patent offices currently lack mechanisms to screen for these biases during examination, potentially granting monopolies on technologies that are less effective for large segments of the population.

The open-science movement in AI research further challenges traditional patent paradigms. Initiatives like DeepMind's AlphaFold, which made its protein structure predictions freely available, demonstrate how AI could democratize access to foundational biological knowledge[57]. However, this approach conflicts with the pharmaceutical industry's reliance on patent protection to recoup R&D investments. The tension is particularly acute for AI tools that can drastically reduce drug development timelines: should society prioritize rapid, open dissemination of medical breakthroughs, or maintain patent incentives that drive private investment?

The integration of artificial intelligence (AI) with biotechnology in India presents unique ethical and equity challenges in patenting, particularly in a diverse and resource-constrained environment. As AI accelerates innovations in drug discovery, precision medicine, and agricultural biotechnology, India must balance intellectual property (IP) protection with equitable access to ensure these technologies benefit all sections of society.

[53] Aaron S. Kesselheim, *The High Cost of Stem Cell Therapies*, 378 New Eng. J. Med. 2187, 2189 (2018)
[54] Henry T. Greely, *Ethics of Patented Biotech*, 45 Hastings Ctr. Rep. 34, 36 (2015
[55] Alicia R. Martin et al., *Clinical Use of Current Polygenic Risk Scores May Exacerbate Health Disparities*, 54 Nature Genetics 450, 453 (2022)
[56] Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 Science 447, 449 (2019)
[57] *AlphaFold and the Patent Paradox*, 41 Nature Biotech. 143 (2023)

Ethical Concerns in AI-Biotech Patenting

1. **Bias in AI Algorithms and Health Disparities**

   AI models trained on genomic datasets often underrepresent India's diverse ethnic populations, leading to biased outcomes. For example, polygenic risk scores (PRS) developed using data from Western populations may not accurately predict disease risks for Indian subpopulations. Patenting such AI-biotech tools without addressing bias could exacerbate healthcare disparities, particularly for marginalized communities.

2. **Ownership and Exploitation of Genetic Data**

   India's genomic initiatives, such as the IndiGen Project, raise concerns about data privacy and commercial exploitation. If AI tools trained on Indian genetic data lead to patented therapies, who benefits? The Digital Personal Data Protection Act (2023) provides some safeguards, but stronger mechanisms are needed to ensure that communities contributing data share in the commercial benefits of resulting patents.

3. **Patents vs. Open Science in Public Health**

   India has historically prioritized access to medicines over stringent IP enforcement, as seen in its compulsory licensing of patented drugs. With AI-driven biotech patents (e.g., for CRISPR-based therapies), there is a risk of monopolization by foreign entities. India must ensure that patent laws do not hinder affordable access to critical technologies, especially in areas like cancer treatment or rare genetic disorders.

Equity Challenges in AI-Biotech Innovation

1. **Urban-Rural Divide in Access**

   AI-powered precision medicine and gene therapies are often concentrated in urban research hubs, leaving rural populations underserved. Patenting AI-biotech innovations without pricing controls or technology transfer agreements could widen healthcare inequities.

2. **Agricultural Biotech and Farmer Rights**

AI-assisted gene editing in crops (e.g., drought-resistant rice) could benefit Indian farmers, but patent monopolies may restrict seed access. The Protection of Plant Varieties and Farmers' Rights Act (2001) safeguards farmers' rights, but AI-generated seed technologies challenge traditional IP frameworks.

3. **Global vs. Local Innovation**

Most AI-biotech patents are filed by multinational corporations, raising concerns about "patent colonialism"—where India becomes a market rather than an innovator. Encouraging domestic AI-biotech startups through patent fee reductions and R&D incentives could promote equitable participation.

India's approach to AI-biotech patenting must prioritize ethical innovation, equitable access, and inclusive growth. By reforming patent laws, ensuring fair data use, and promoting local R&D, India can harness AI and biotechnology to benefit its diverse population while setting a global example for responsible IP governance.

Another ethical frontier involves the patenting of AI systems that interface with human biology. Neural lace technologies, brain-computer interfaces, and AI-designed synthetic DNA all push against traditional boundaries of patentable subject matter. The European Patent Office's rejection of a patent application for an AI-generated neural implant design highlights the ongoing struggle to define limits in this space. As AI begins to design not just drugs but potentially enhanced biological systems, society must grapple with whether certain domains should remain beyond the reach of patent monopolies.

Global equity issues also come to the fore. Most AI-biotech patents are filed by corporations and institutions in wealthy nations, raising concerns about technology hoarding[58]. The COVID-19 pandemic exposed these fault lines, as patent protections on AI-discovered therapeutics and vaccines limited access in developing countries. Future crises involving AI-designed biologics could see similar dynamics play out on larger scales, necessitating reforms to ensure equitable access to essential medicines derived from machine intelligence.

[58] WHO, *Global Framework for AI in Healthcare* 45 (2022)

Policy Recommendations and Pathways for Reform

Addressing these multidimensional challenges requires a coordinated approach to patent law reform. First, legislative bodies should clarify the status of AI in inventorship through amendments to patent statutes. A balanced solution might involve creating a new category of "AI-assisted inventions," where human contributors are listed as inventors but with mandatory disclosure of the AI's role and training data[59]. This approach maintains the human-centric framework of current laws while acknowledging AI's growing creative capacity.

Policy Recommendations for India

1. **Inclusive Data Governance**
    - Mandate diverse representation in genomic datasets used for AI training.
    - Establish benefit-sharing models for communities contributing genetic data.
2. **Patent Law Reforms**
    - Clarify Section 3(j) of the Patents Act to distinguish between natural and AI-edited genetic material.
    - Introduce compulsory licensing provisions for AI-biotech patents affecting public health.
3. **Strengthening Ethical Oversight**
    - Expand the Indian Council of Medical Research (ICMR) Bioethics Guidelines to cover AI-biotech patents.
    - Create an AI Ethics Review Board for evaluating patent applications involving sensitive data.
4. **Promoting Affordable Access**
    - Leverage India’s generic drug manufacturing expertise to produce AI-designed

[59] WIPO, *Artificial Intelligence and Intellectual Property Policy* 17 (WIPO Pub. No. 1056, 2023)

biologics at lower costs.

- Support open-source AI models (like AlphaFold) for non-profit research.

Second, patent offices need updated examination guidelines for AI-generated biotechnological innovations. The USPTO and EPO should establish specialized review panels with expertise in both AI and biotechnology to evaluate whether machine-generated inventions meet patentability criteria. These panels could develop new standards for assessing "non-obviousness" in AI outputs, perhaps focusing on the unpredictability of results rather than traditional inventive step analyses[60].

Third, ethical safeguards must be incorporated into the patent system. This could include:

- Mandating diversity in training data for AI tools underlying biotech patents
- Creating public interest exceptions for essential medicines developed through AI
- Establishing post-grant review mechanisms to address algorithmic bias in patented technologies[61]

International cooperation will be critical to prevent fragmentation. The World Intellectual Property Organization should convene a global treaty process to harmonize standards for AI and biotech patents, similar to the Budapest Treaty for microbiological inventions. The UN's 2021 Recommendation on the Ethics of Artificial Intelligence provides a foundation for such efforts[62].

Looking ahead, the convergence of AI with emerging technologies like quantum computing and synthetic genomics will present new challenges for patent systems. Proactive, principles-based regulation—rather than reactive case-by-case adjudication—will be essential to foster innovation while protecting public interests in this rapidly evolving landscape.

[60] Reto Hilty et al., *AI as Inventor: Time to Update Patent Law?* 22 (Max Planck Inst. for Innovation & Competition, Research Paper No. 22-03, 2022), https://ssrn.com/abstract=4005641 accessed on 4/4/25
[61] OECD, *AI in Science and Innovation Policy* 78 (2021)
[62] UNESCO, *Recommendation on the Ethics of Artificial Intelligence* 27 (2021)

Conclusion

The integration of artificial intelligence into biotechnology represents both an unprecedented opportunity for human advancement and a fundamental challenge to traditional intellectual property frameworks. As AI systems progress from research tools to autonomous inventors, patent laws must evolve beyond their 20th-century foundations to accommodate this new reality. A paradigm shift in our understanding of invention and protection is required, as the cases, disputes, and moral conundrums discussed in this paper show that little changes will not suffice. Already, new patent methods are adjusting to this reality through hybrid human-AI inventorship models that, to meet present legal constraints, carefully blend human oversight with machine efficiency. As worries about algorithmic bias and reproducibility in AI-generated discoveries mount, progressive biotechnology companies are creating thorough AI training data documenting methods to demonstrate patent priority. Leading the way in novel approaches to patenting AI-identified therapeutic candidates are the pharmaceutical industry and dynamic patent claims, which dynamically adjust their scope in response to real clinical data that is sent back into the AI system. Perhaps the most disruptive AI systems are decentralised ones built on blockchain topologies. Innovative methods for patenting AI-discovered medication candidates are being pioneered by the pharmaceutical industry. One such method is the use of dynamic patent claims, which automatically modify their scope in response to real-world clinical data that is given back into the AI system. Most notably, open-source drug discovery communities are being made possible by decentralised AI systems based on blockchain topologies, which are speeding up therapeutic research and challenging conventional patent exclusivity structures.

Jurisdictions are taking radically divergent stances on AI biotech inventions, causing the global patent landscape to split along ethical and technological fault lines. A permissive patent system that acknowledges AI-assisted inventions while retaining strategic control over important genomic information has resulted from China's significant investment in AI-driven biotechnology. The European Union is creating strict ethical guidelines for biologics produced by AI, demanding algorithmic openness and human monitoring as prerequisites for patentability. In the meantime, U.S. policy is still ambiguous, torn between addressing worries about the concentration of AI in the hands of a small number of powerful firms and preserving technological supremacy. Global biotech companies are facing difficult obstacles as a result of

this legislative difference, which is also encouraging specialised innovation hubs that satisfy jurisdictional preferences.

Adaptive legal frameworks that can change in tandem with the rapid advancement of AI capabilities will be necessary for future policy solutions to balance conflicting interests. Developing a new category of "AI-assisted patents" with altered inventorship and enablement requirements that take into account the cooperative nature of human-machine creation is one viable strategy. According to a different idea, patent protection should be tiered according to the level of AI involvement. This would mean that autonomous AI creations would have fewer rights while human-driven discoveries would have more protections. While allowing for necessary ethical and cultural differences in how governments choose to manage AI-generated life science discoveries, international cooperation through organisations like WIPO will be essential to preventing catastrophic fragmentation.

The way forward necessitates striking a balance between conflicting priorities: rewarding AI-driven innovation while avoiding damaging monopolies; safeguarding biotechnology research investments while guaranteeing fair access to medical advancements; and recognising machine creativity while upholding human accountability. Policymakers can create a system that is appropriate for the era of autonomous innovation by implementing tiered inventorship criteria, revising eligibility rules, and incorporating ethical considerations into patent review procedures. The law needs to adapt as AI's function in biology grows from analytical tool to collaborator to independent innovator. The course of scientific advancement in general, as well as the future of patent systems, will be influenced by the choices taken in the upcoming years. The ultimate goal of patent law must continue to serve as our compass as we navigate these unfamiliar waters: to foster innovation that benefits everyone.

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