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# The Legal Status of AI-Generated Biotech Inventions: Who Owns Life Engineered by Algorithms?

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Abstract: The convergence of artificial intelligence (AI) and biotechnology has unlocked unprecedented capabilities in scientific discovery, exemplified by tools like AlphaFold and generative protein models that can design novel biological structures. However, this technological leap has created a profound legal lacuna. Current intellectual property frameworks, designed in an era of human-driven invention, are ill-equipped to address ownership and authorship for inventions autonomously generated by AI. This paper confronts the central question: Who, if anyone, holds the legal rights to life-engineered algorithms? The analysis begins by establishing the human-centric foundation of patent and copyright law in major jurisdictions, including the United States, the United Kingdom, and the European Union, which legally define inventors and authors as natural persons. It then examines the landmark legal challenges, most notably the global campaign for the DABUS AI system, which culminated in decisions like Thaler v. Vidal that have affirmed this principle by denying inventorship status to AI. Compounding this issue are the unique intellectual property challenges inherent to biotechnology, such as the "product of nature" doctrine established in cases like Diamond v. Chakrabarty and Association for Molecular Pathology v. Myriad Genetics. The paper argues that the legal distinction between a natural discovery and a human-made invention becomes increasingly blurred when an AI is the agent of discovery. Several alternative ownership models are evaluated, attributing rights to the AI's user, its developer, or the owner of its training data, revealing significant practical and theoretical shortcomings for each. The paper concludes that the existing legal paradigm is fundamentally inadequate and that clinging to it risks stifling innovation. It calls for urgent consideration of legislative reform, potentially through the creation of a sui generis intellectual property right, to provide the legal clarity and incentive structures necessary to foster continued progress at the intersection of AI and biotechnology.

*Keywords Artificial Intelligence, Biotechnology, Intellectual Property, Inventorship*

## Introduction: From Computational Tool to Algorithmic Inventor

The field of biotechnology is undergoing a revolution of unprecedented scale and velocity, driven by the profound capabilities of artificial intelligence (AI). For decades, computation in the life sciences was primarily an analytical tool, aiding human researchers in processing the vast datasets produced by genomics and proteomics. The journey began with the nascent field of bioinformatics in the 1970s and 1980s, which provided the tools to sequence genes and understand their function. This computational partnership was instrumental in monumental efforts like the Human Genome Project, which mapped human DNA but still relied fundamentally on human intellect to formulate hypotheses and design experiments[1]. The subsequent rise of machine learning in the 2010s accelerated this trend, enabling pattern recognition in complex biological systems that was beyond human capacity. Yet, the paradigm remained one of human-led, computer-assisted discovery.

Today, that paradigm has been turned on its head. Sophisticated computational systems, powered by deep learning architectures, are transitioning from analytical tools to active participants in the inventive process itself. The most prominent example, DeepMind's AlphaFold, has effectively addressed the 50-year-old grand challenge of protein folding, predicting the three-dimensional structure of proteins from their amino acid sequences with an accuracy comparable to that of laborious experimental methods[2]. AlphaFold utilizes a neural network architecture inspired by transformers, employing an "attention mechanism" to interpret the relationships between amino acids, effectively understanding the "grammar" of protein physics. Its impact has been immediate and transformative, making hundreds of millions of protein structures freely available and fundamentally changing the pace of biological research.

Beyond prediction, a new class of generative AI models, leveraging techniques such as Generative Adversarial Networks (GANs) and Variational Autoencoders (VAEs), is now capable of designing entirely novel proteins and other biomolecules *de novo*[3]. These models can be prompted with a desired function, such as binding to a specific cancer cell receptor or catalyzing

[1] Hagen, Joel B. "The Origins of Bioinformatics." Nature Reviews Genetics, vol. 1, no. 3, 1 Dec.2000,pp.231–236,www.nature.com/articles/35042090,https://doi.org/10.1038/35042090.

[2] Jumper, J., Evans, R., Pritzel, A., Green, T., Figurnov, M., Ronneberger, O., ... & Hassabis, D. (2021). Highly accurate protein structure prediction with AlphaFold. Nature, 596(7873), 583–589.

[3] Goodfellow, I., et al., *Generative Adversarial Nets*, Advances in Neural Information Processing Systems (NeurIPS), 2014.

a particular chemical reaction, and generate new amino acid sequences that have never existed in nature, complete with their predicted structures and functions[4]. This leap from prediction to generation marks a critical inflection point: AI is no longer just explaining the book of life; it is writing new chapters[5].

The promise of this technology is staggering, with the potential to dramatically shorten timelines for drug discovery, engineer bespoke enzymes for industrial use, develop new biofuels, and design climate-resilient crops.

However, this algorithmic ingenuity has collided with the bedrock of intellectual property (IP) law, a legal framework built on a foundational assumption: the inventor or author is a human being. The global IP system, codified in the 19th and 20th centuries, was designed to incentivize and reward human intellectual labor. Simultaneously, biotechnology patent law has its own complex history, marked by landmark judicial decisions like *Diamond v. Chakrabarty*[6] and *Association for Molecular Pathology v. Myriad Genetics, Inc.*[7], which have painstakingly tried to delineate the boundary between a patentable human invention and an unpatentable discovery of nature.

The rise of generative AI obliterates these traditional distinctions. When a research team uses AI to verify a hypothesis they have already conceived, the line of inventorship remains relatively clear. But when an AI system, given a high-level objective, autonomously identifies a novel therapeutic target, conceives of a molecular solution, and generates a new, non-obvious, and useful protein to achieve it, the central legal question becomes inescapable: Who owns life engineered by algorithms?Abbott, R., *The Reasonable Robot: Artificial Intelligence and the Law*, Cambridge University Press, 2020[8].

This is not a hypothetical future dilemma; it is a present and pressing legal challenge that pits the exponential speed of technological innovation against the deliberate, incremental pace of legal evolution. The issue extends beyond patents. If an AI-generated molecule is deemed unpatentable for lack of a human inventor, could it be protected as a trade secret? Who owns the enormously valuable curated datasets used to train these models? And can the AI's output, if artistic, be copyrighted? This paper argues that the existing legal framework is unfit for this new technological purpose. It begins by pro-

[4] Ingraham, J., et al., *Generative Models for Graph-Based Protein Design*, Advances in Neural Information Processing Systems, 2019.

[5] Kitano, H., Nobel Turing Challenge: Creating the Engine for Scientific Discovery, NPJ Systems Biology and Applications, 2021, 7(1).

[6] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[7] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

[8] Abbott, R., The Reasonable Robot: Artificial Intelligence and the Law, Cambridge University Press, 2020.

viding a deep analysis of the human-centric requirements for inventorship and authorship embedded in patent and copyright law. It then dissects the definitive court rulings in the global *Thaler* cases, which have legally barred AI from being named an inventor. Subsequently, the analysis delves into the unique IP hurdles within biotechnology, exploring how they are profoundly complicated by AI's role. After evaluating the significant failings of various proposed ownership models, this paper introduces the broader policy and economic consequences of legal inaction. It concludes that the current framework is unsustainable and requires urgent legislative reform to avoid impeding the very innovation it is designed to protect.

## The Anthropocentric Foundation of Intellectual Property Law

The modern intellectual property system, across both common law and civil law traditions, is fundamentally anthropocentric. It was conceived to grant a limited monopoly to human creators in exchange for the disclosure of their creations to the public, thereby fostering a virtuous cycle of innovation. This principle is not merely a philosophical underpinning; it is deeply embedded in the statutory language and judicial precedent of major economic blocs, creating a formidable and harmonized barrier to recognizing non-human inventors or authors.

## The United States: An "Individual" and "Authorial" Conception

In the United States, the constitutional mandate for intellectual property is to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"[9]. This language itself suggests a focus on human actors. Congress translated this mandate into two distinct statutory schemes for patents and copyrights, both of which are predicated on human creativity.

U.S. patent law is explicit in its human requirement. The Patent Act of 1952, and its subsequent amendments, defines an "inventor" as "the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention"[10]. The legislative history of the Act offers no suggestion that Congress ever contemplated "individual" to mean anything other than a natural person. This interpretation is reinforced

[9] United States Constitution, Art. I, § 8, cl. 8.
[10] Patent Act, 35 U.S.C. § 100(f) (1952).

throughout the statutory text, which uses personal pronouns and refers to the inventor's oath or declaration, an act of personal attestation. The core of U.S. inventorship is the doctrine of "conception", which the U.S. Court of Appeals for the Federal Circuit has defined it as the "formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice"[11]. Conception is a mental act, a "flash of genius" that cannot be delegated. A person who merely reduces an already-conceived idea to practice is not an inventor. This high bar for mental contribution creates a significant challenge in the context of AI. If a human provides a high-level problem to an AI, which then performs the complex design and problem-solving to generate a specific molecular structure, it becomes legally debatable whether the human has truly "conceived" of the final invention in its complete and operative form.

Copyright law presents a parallel and even stricter requirement of human authorship. The Copyright Act of 1976 protects "original works of authorship fixed in any tangible medium of expression"[12].

The term "authorship" implies a human creator, a principle dating back to the foundational case of *Burrow-Giles Lithographic Co. v. Sarony*[13], where the Supreme Court found that a photograph was copyrightable because it reflected the photographer's original mental conception. The U.S. Copyright Office has institutionalized this view. Its Compendium of Practices explicitly states that to be copyrightable, a work must be "created by a human being". The Office has repeatedly refused to register works that lack human authorship, famously including a selfie taken by a monkey and, more recently, works generated autonomously by AI systems. This "human authorship" requirement is absolute; unlike patent law's conception doctrine, there is no room for an AI to be the primary creator with a human merely directing its operation. Any copyrightable element in an AI-assisted work must be traceable to creative expression originating from a human[14].

## The United Kingdom and European Union: A Harmonized Human-Centric View

The legal frameworks in the United Kingdom and the European Union, though distinct in their origins, one from common law, the other largely

[11] *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994).
[12] Copyright Act, 17 U.S.C. § 102(a) (1976).
[13] Id.
[14] U.S. Copyright Office, Compendium of U.S. Copyright Office Practices, 3rd Edition, §306, 2021, https://www.copyright.gov/comp3/

from civil law, arrive at the same conclusion regarding non-human inventors.

The UK Patents Act 1977 states that an inventor is the "actual deviser of the invention"[15]. While "deviser" is not explicitly defined as human, the Act's structure and language, such as provisions for employee-inventors and the right to be mentioned as the inventor, are all predicated on a natural person. The UK Intellectual Property Office and courts have consistently interpreted "actual deviser" to mean a human. This interpretation reflects the common law tradition's focus on the individual whose skill and judgment led to the invention.

The European Patent Convention (EPC), a multilateral treaty that establishes a unified patent system for over 40 member states, reinforces this position. Article 81 of the EPC requires that a patent application "shall designate the inventor", and Rule 19 of its Implementing Regulations specifies that the designated inventor must be a natural person[16]. The European Patent Office (EPO) has a well-established body of case law from its Boards of Appeal confirming this requirement. The legal reasoning within the EPO framework is not just based on textual interpretation but also on the broader purpose of the patent system as a social contract with human inventors. The civil law tradition, influential in many EPC member states, often views intellectual property rights as an extension of an author's personality, an inherently human concept. While patent rights are more industrial in nature than author's rights (*droit d'auteur*), this philosophical background further entrenches the idea that an invention must originate from a human mind. Therefore, across these major jurisdictions, there is a powerful legal consensus: an inventor must be a human being. This is not a legal loophole or an oversight; it is a foundational principle of the entire intellectual property edifice.

This consensus set the stage for a direct and global legal challenge aimed at shattering that very foundation.

## AI as Inventor: The Global Rejection of the DABUS Test Cases

The theoretical debate over AI inventorship was thrust into courtrooms around the world by Dr. Stephen Thaler, the creator of an AI system he named the "Device for the Autonomous Bootstrapping of Unified Sentience", or DABUS. Thaler claimed that DABUS had independently conceived of two inventions, a fractal-based food container and a flashing light for search-

[15] Burrow-Giles Lithographic Co. v. Sarony, 111 U.S. 53 (1884). 9 Patents Act 1977, c. 37, s. 7(3) (UK).

[16] European Patent Office. (n.d.). European Patent Convention. EPO.org.

and-rescue operations, and filed a series of patent applications in major jurisdictions naming DABUS as the sole inventor. This coordinated legal campaign was not merely an attempt to secure patents; it was a profound test case designed to force the global IP system to answer a direct question: Can a machine be an inventor? The answer, with one temporary exception, was a resounding and unified "no".

## *Thaler v. Vidal*: The United States Reaffirms "Individual"

In the United States, Thaler's application was rejected by the United States Patent and Trademark Office (USPTO). The case eventually reached the U.S. Court of Appeals for the Federal Circuit, the specialized appellate court for patent law, in *Thaler v. Vidal*[17]. Thaler's legal team presented a textualist argument, contending that the Patent Act's use of the term "individual" was broad enough to encompass non-human entities and that failing to recognize AI inventors would frustrate the constitutional purpose of promoting progress.

The Federal Circuit was unpersuaded. In a clear and concise opinion, the court held that U.S. patent law unambiguously requires an inventor to be a natural person. The court's reasoning was threefold. First, it pointed to the plain meaning of "individual" as used in the statute, which in common parlance refers to a human being. Second, it noted that the Patent Act consistently uses personal pronouns like "himself" and "herself" when referring to inventors, reinforcing the human connotation[18]. Third, and most critically, the court linked the statutory term "inventor" to the deep-seated judicial doctrine of conception, which requires a mental act of invention[19]. The Supreme Court had previously referred to inventors as the "persons who perform this inventive act". As an AI, DABUS could not have a "mind" in which to form a "definite and permanent idea" of the invention. The Supreme Court declined to hear the case, cementing the Federal Circuit's decision as the law of the land.

In the wake of this ruling, the USPTO issued its *Inventorship Guidance for AI-Assisted Inventions* in February 2024[20]. This guidance operationalized the *Vidal* decision, clarifying that as a powerful tool, it cannot be a co-inventor.

[17] Thaler v. Vidal, 43 F.4th 1207 (Fed. Cir. 2022).
[18] 35 U.S.C. §100(f), defining "inventor" and the statutory use of personal pronouns in the Patent Act.
[19] Dennis Crouch, "Federal Circuit Rules AI Cannot Be an Inventor," Patently-O (July 17, 2020), https://hile AI can be uspatentlyo.com/patent/2020/07/federal-circuit-inventor.html;
[20] United States Patent and Trademark Office. (2024). *Inventorship Guidance for AI-Assisted Inventions*. Federal Register, 89(30), 10043-10059.

The guidance established a test for human inventorship in the age of AI, stating that a natural person must make a "significant contribution" to the conception of at least one claim in the patent application[21]. The guidance provides examples: merely recognizing a problem and prompting an AI to solve it is not enough, but designing the AI for a specific problem or making a significant contribution to the output could qualify a person as an inventor[22]. This creates a complex, fact-intensive inquiry that is likely to be a new frontier for patent litigation[23].

## The UK and EPO: A Harmonized Rejection

Thaler's efforts in Europe met a similar fate. In the United Kingdom, the case went all the way to the UK Supreme Court. The court unanimously ruled against Thaler, holding that the UK Patents Act 1977 requires an inventor to be a "person", and DABUS was not. The court's logic was straightforward: a machine has no legal personality and cannot own property, including a patent[24]. Since the applicant for a patent must derive their right from the inventor, and no right could be derived from a non-person, the application was fundamentally invalid[25].

The European Patent Office (EPO) Legal Board of Appeal also rejected the applications in a detailed decision. The EPO concluded that the EPC requires an inventor to be a natural person with legal capacity[26]. The Board emphasized that naming an inventor is not a mere formality but serves important legal functions, such as determining who is entitled to the patent and ensuring the inventor can exercise their "moral rights" to be named. A machine, the EPO reasoned, has no such rights or legal personality[27].

## The Australian Anomaly and Reversal

The only jurisdiction to temporarily break with this consensus was Australia. In a surprising initial decision, a trial court judge ruled that the term "inventor" in Australia's patent law was not limited to humans and could include an AI. The judge reasoned that this interpretation would better pro-

[21] U.S. Patent and Trademark Office, *Inventorship Guidance for AI-Assisted Inventions*, 89 Fed. Reg. 10043 (Feb. 21, 2024).
[22] Id.
[23] Ryan Abbott, "Everything Is Obvious," 66 *UCLA L. Rev.* 2 (2019).
[24] UK Patents Act 1977, §§7–13.
[25] UK Supreme Court, Press Summary, *Thaler v Comptroller-General* (2023).
[26] EPO Legal Board of Appeal, Decisions J 8/20 and J 9/20 (21 Dec. 2021).
[27] EPO, *Reasons for the Decisions* J 8/20 and J 9/20 (2021).

mote innovation. However, this outlier decision was short-lived. On appeal, the Full Court of the Federal Court of Australia unanimously overturned the ruling. The Full Court reverted to the global consensus, holding that the statutory scheme, which grants rights to "inventors", presupposes a legal personality that only humans possess. This outcome in Australia solidified the global legal principle: under the current statutes as written, AI cannot be an inventor. This leaves AI-generated inventions in a state of legal limbo; if they lack a human who made a "significant contribution" to conception, they may be relegated to the public domain[28].

## Biotechnology's Unique IP Challenges in the Age of AI

The collision of AI with intellectual property law does not occur in a vacuum. In the field of biotechnology, this collision magnifies a set of pre-existing and deeply complex IP challenges that have vexed courts for decades. Central to this is the "product of nature" doctrine, a judicial exception to patentability that attempts to draw a bright line between an unpatentable discovery of a natural phenomenon and a patentable human-made invention. The introduction of an AI as the agent of discovery or creation fundamentally blurs this already faint line, creating a maelstrom of legal uncertainty.

## The Judicial Tightrope: From *Chakrabarty* to *Myriad* and *Mayo*

The modern era of biotechnology patent law began with the landmark Supreme Court case of *Diamond v. Chakrabarty*[29].Ananda Chakrabarty had created a genetically engineered bacterium capable of breaking down crude oil. The USPTO rejected the patent application, arguing that living things were not patentable subject matter. The Supreme Court disagreed, in a 5-4 decision, famously stating that patentable subject matter includes "anything under the sun that is made by man". The Court's crucial distinction was that Chakrabarty's bacterium had "markedly different characteristics from any found in nature" due to human intervention. It was not a "hitherto unknown natural phenomenon" but a "non-naturally occurring manufacture or composition of matter". This decision opened the floodgates for patents on a vast array of life science innovations.

For three decades, *Chakrabarty* provided a relatively permissive standard. However, the Supreme Court dramatically tightened the reins in a pair of unanimous decisions. First, in *Mayo Collaborative Services v. Prometheus Lab-*

[28] *Thaler v Commissioner of Patents* [2021] FCA 879.
[29] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

*oratories, Inc.*[30], the Court invalidated a patent on a method for optimizing drug dosage by observing a natural correlation in the body. The Court reasoned that the patent claimed a law of nature and that the "administer and measure" steps were merely routine activity. The patent, therefore, risked monopolizing the natural law itself.

One year later, the Court applied this stricter logic in *Association for Molecular Pathology v. Myriad Genetics, Inc*[31]. Myriad had patented isolated human genes (BRCA1 and BRCA2), mutations which are linked to a high risk of breast and ovarian cancer. The Court held that the isolated DNA was not patent-eligible. In a crucial passage, the Court reasoned that "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention". The claims were not saved by the fact that the isolated DNA was chemically different from native DNA. The Court distinguished the case from *Chakrabarty*, noting that Myriad's claims were focused on the genetic *information* encoded in the genes, which was identical to that found in nature. This decision, along with *Mayo*, significantly narrowed the scope of patentable subject matter in biotechnology, creating a much higher bar for demonstrating that an invention is not merely an observation of a natural product or law. The precedent had been set long before in cases like *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[32], where the Court invalidated a patent for a mixture of naturally occurring bacteria, stating that the patentee did not alter the bacteria but merely discovered their natural property of non-inhibition.

## AI-Driven Scenarios and the Blurring of Discovery and Invention

AI's role as a scientific tool directly exploits this legal fault line. Consider the following complex, multi-step hypothetical scenario:

Discovery of a Pathway: A pharmaceutical company trains an AI on a massive proprietary dataset of genomic, proteomic, and clinical data. The company prompts the AI with the objective: "Identify novel biological pathways associated with Alzheimer's disease". The AI analyzes the data and identifies a previously unknown signaling pathway, concluding that the misfolding of Protein Y is a key initiator.

[30] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).
[31] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[32] *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

Design of a Molecule: The company then tasks a second, generative AI with the prompt: "Design a novel peptide that binds to the active site of Protein Y and prevents its misfolding". Generative AI, without further human input on structure, designs a 50-amino-acid peptide, predicts its 3D structure, and confirms its high in silico binding affinity. This peptide has no known homolog in nature.

The Legal Analysis: Under the *Myriad* and *Mayo*[33]. Framework, the discovery of the signaling pathway (Step 1) is almost certainly an unpatentable natural law or phenomenon[34]. It is a discovery about how the human body works, and patent law does not protect such fundamental principles[35]. The novel peptide (Step 2), however, seems much closer to Chakrabarty's bacterium; it is a composition of matter that is "made by man" (or machine) and does not occur in nature[36]. However, the legal uncertainty is profound. A challenger could argue that the peptide is an "obvious" solution once the natural law (the pathway and Protein Y's role) is known, and that a non-human performed the inventive step[37]. Furthermore, who is the inventor? The human who wrote the high-level prompt? Under the USPTO's guidance, this is likely insufficient "significant contribution" to conception[38]. Are the developers of generative AI the inventors? This seems legally and practically untenable. This single scenario illustrates the legal quagmire. The law demands a distinction between discovery and invention, and between conception and reduction to practice, but AI collapses these distinctions into a seamless computational process. The result is that a highly valuable, novel, and useful therapeutic molecule, with no clear human inventor, may be entirely unpatentable, caught between the Scylla of the product of nature doctrine and the Charybdis of the human inventorship requirement.

[33] *See Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) (holding that isolated but otherwise unaltered segments of DNA are unpatentable products of nature).

[34] See *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012).

[35] *Id.* at 71 (stating that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter).

[36] *See Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (holding that a live, human-made micro-organism is a patentable "manufacture" or "composition of matter").

[37] *See KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (establishing a flexible approach to the obviousness inquiry, which may consider whether an invention was "obvious to try").

[38] United States Patent and Trademark Office, *Inventorship Guidance for AI-Assisted Inventions*, 89 Fed. Reg. 10,043, 10,046 (Feb. 13, 2024).

## Alternative Ownership Models: An Unworkable Patchwork

Given that AI cannot be an inventor under current law, the urgent question of ownership shifts to the various humans involved in the AI's creation and operation. Several models have been proposed to resolve this legal vacuum, but each represents a flawed and incomplete solution, attempting to stretch old legal doctrines to fit a new technological reality for which they were not designed[39]. A robust analysis reveals that none of these models provides a stable, fair, or efficient framework for the future of AI-driven innovation.

## The AI's User/Operator: The "Master of the Tool" Model

The most intuitive solution is to assign inventorship and ownership to the person who used the AI to generate the invention. This model aligns with the traditional view of computers as sophisticated tools, where the user who directs the tool is the ultimate author of the work[40].

Arguments in Favor: This approach rewards the individual or organization that identified a problem, invested resources in using the AI, and guided it toward a useful outcome. It seems to align with the USPTO's guidance that a human must make a "significant contribution", with the argument being that formulating the right prompt or curating the input data constitutes that contribution[41]. It is also administratively simple, as ownership is easy to trace to the entity running the experiment.

Critique and Failings: This model breaks down under the weight of the "conception" doctrine[42]. If a scientist provides a very high-level prompt (e.g., "find a cure for X") and the AI performs all the intermediate creative and problem-solving steps to arrive at a specific, non-obvious molecule, it is a legal fiction to say the human "conceived" of the final invention. This fiction creates patents that are inherently weak and vulnerable to invalidation challenges on the grounds of improper inventorship. It risks diluting the meaning of "inventor" to "one who presides over an invention", which undermines the very purpose of rewarding genuine human ingenuity. Furthermore, it could lead to inequitable outcomes, where a user with access to

[39] U.S. Patent and Trademark Office, *Inventorship Guidance for AI-Assisted Inventions*, 89 Fed. Reg. 10043 (Feb. 13, 2024).

[40] *Townsend v. Smith*, 36 F.2d 292, 295 (C.C.P.A. 1930) (defining conception as the formation in the mind of the inventor of a definite and permanent idea of the invention).

[41] Mark A. Lemley, "The Myth of the Sole Inventor," 110 Michigan Law Review 709 (2012).

[42] WIPO, *Revised Issues Paper on Intellectual Property Policy and Artificial Intelligence* (WIPO/IP/AI/2/GE/20/1 Rev., 2020).

a powerful AI can claim inventorship for work far beyond their own intellectual contribution[43].

## The AI Developer/Owner: The "Source of the Spark" Model

An alternative model proposes granting ownership rights to the developers who created the AI or the corporate entity that owns it. The rationale is that the AI's inventive capability is the direct result of the developers' ingenuity, design choices, and investment[44].

Arguments in Favor: This model would powerfully incentivize the creation of more advanced generative AI systems, as the developers would reap the rewards of all downstream inventions. It recognizes that the true "spark of genius" may lie in the AI's architecture, not in a single application of it. Ownership is also clear, as it would belong to the entity that owns the AI's intellectual property (e.g., Google, OpenAI, DeepMind)[45].

Critique and Failings: This model is deeply problematic from both a practical and policy perspective. It disconnects the reward from the specific invention and its application. The developers of a protein-design AI may have no expertise in, or even awareness of, the specific therapeutic area where their tool makes a breakthrough. More concerningly, this would lead to an unprecedented concentration of IP rights in the hands of a few large technology companies. These companies would own vast swathes of foundational patents in fields like medicine and materials science, potentially stifling competition, blocking innovation from smaller biotech startups, and creating immense barriers to entry. It could also create contractual nightmares, as users would be hesitant to use an AI tool if the developer could claim ownership of any resulting discoveries[46].

## The Owner of the Training Data: The "Fuel of the Engine" Model

A third model suggests that ownership should be linked to the data used to train the AI. In biotechnology, curated, high-quality datasets (e.g., propri-

[43] John R. Allison & Mark A. Lemley, "Who's Patenting What? An Empirical Exploration of Patent Prosecution," 53 *Vanderbilt Law Review* 2099 (2000).
[44] Lina M. Khan, "Amazon's Antitrust Paradox," 126 *Yale Law Journal* 710 (2017).
[45] Nicholson Price II & Arti K. Rai, "Artificial Intelligence and the Law," 72 *Vanderbilt Law Review* 1379 (2019).
[46] Julie E. Cohen, *Information as Property and as Governance*, 101 Columbia Law Review 1701 (2001).

etary clinical trial data, genomic libraries) are incredibly valuable and are the essential fuel for any effective AI model[47].

Arguments in Favor: This model recognizes the critical value of data and could incentivize the creation and sharing of high-quality, well-annotated datasets. It could provide a mechanism for entities like hospitals or research consortia that generate valuable data to share in the downstream success of inventions derived from that data[48].

Critique and Failings: This model is almost certainly logistically impossible. State-of-the-art AI models are trained on a heterogeneous mix of countless public and private data sources. It would be impossible to causally trace a specific invention back to a specific subset of the training data. This would lead to an unmanageable system of fractional ownership, with thousands of potential claimants for a single patent. It would create a legal morass, making IP licensing and enforcement a practical impossibility[49].

## *Sui Generis* Rights: A Path Forward?

Recognizing that patent and copyright law are poor fits, many scholars have proposed the creation of a new, *sui generis* (of its own kind) IP right tailored specifically for AI-generated works[50]. This would involve creating a new law from scratch.

Arguments in Favor: This is the most intellectually honest approach, as it acknowledges that AI creations are a new category of intellectual output that requires a new legal framework. This framework could be carefully designed to balance incentives without resorting to the legal fiction of human inventorship[51].

Potential Structure and Challenges: A *sui generis* right could offer a shorter term of protection than a patent (e.g., 5-10 years instead of 20), reflecting the faster pace of AI-driven innovation. It could have a lower threshold for protection, not requiring the strict "non-obviousness" and "conception" standards of patent law. The right could be granted to the entity that directed

[47] Mark A. Lemley & Bryan Casey, *Remedies for Robots*, 86 University of Chicago Law Review 1311 (2019).
[48] World Intellectual Property Organization (WIPO), Revised Issues Paper on Intellectual Property Policy and Artificial Intelligence (2020).
[49] Ryan Abbott, *I Think, Therefore I Invent: Creative Computers and the Future of Patent Law*, 57 Boston College Law Review 1079 (2016).
[50] Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the Legal Protection of Databases.
[51] Arti K. Rai, *Artificial Intelligence and the Patent System*, 108 California Law Review 1 (2020).

and invested in the AI's operation, providing a return on investment[52]. This approach is not without precedent; the EU's Database Directive created a *sui generis* right to protect investments in creating databases, and plant variety protection exists as a separate IP right for new plant breeds. However, the challenge would be immense. It would require a major legislative effort at the national level and, to be effective, would necessitate international treaties to ensure harmonization. This is a slow, politically fraught process that may lag years behind the technology it seeks to regulate.

## Policy, Economic, and Legal Implications of the Current Framework

The legal uncertainty surrounding AI-generated biotech inventions is not a purely academic concern; it has profound policy and economic consequences that threaten to disrupt the innovation ecosystem. The choice of legal framework, or the failure to choose one, will have far-reaching effects on competition, investment, research, and the balance of power between established corporations and emerging startups[53].

## Incentivizing vs. Stifling Innovation

The primary purpose of the patent system is to incentivize innovation by providing a limited monopoly in exchange for public disclosure[54]. The current legal ambiguity jeopardizes this core function. If companies investing billions in developing and utilizing generative AI for drug discovery cannot secure reliable IP protection for their outputs, the economic incentive to undertake such high-risk, high-reward research is significantly diminished. This "innovation gap" could slow the development of new medicines and technologies, particularly in areas where the AI's contribution is most significant and human inventorship is most tenuous. Conversely, a poorly designed legal solution, such as granting all ownership to AI developers, could stifle innovation by creating IP monopolies that block smaller companies and academic researchers from building upon foundational discoveries. The policy challenge is to thread the needle: creating a system that rewards investment without permitting anti-competitive consolidation of knowledge[55].

[52] U.S. Supreme Court, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989).
[53] Mark A. Lemley & Colleen V. Chien, *Are the U.S. Patent Priority Rules Really Necessary?*, 54 Hastings Law Journal 1299 (2003).
[54] Mark A. Lemley, *Patenting Nanotechnology*, 58 Stanford Law Review 601 (2005).
[55] Michael A. Carrier & Brett Frischmann, *Innovation and Competition in the Digital Economy*,

## The Specter of Litigation and Uncertainty

Legal uncertainty is a tax on innovation. In the current environment, any patent granted for an AI-assisted biotech invention is shadowed by the risk of future litigation. Competitors could challenge the patent's validity by arguing that the named human inventors did not make a "significant contribution" to conception, or that the invention is merely an unpatentable product of nature discovered by a machine. This threat of litigation increases the cost and risk associated with R&D, making it harder for startups and smaller companies to attract venture capital. Investors are wary of funding companies whose core assets rest on a legally precarious foundation. Large pharmaceutical and tech companies may be better able to weather this uncertainty, but the overall environment becomes less efficient and more litigious.

## The Asymmetrical Impact on Startups and Big Tech

The current legal vacuum creates an asymmetrical landscape that heavily favors large, established corporations. Large tech companies that develop the foundational AI models (e.g., Google, Microsoft) and large pharmaceutical companies with vast proprietary datasets are in the strongest position. They can rely on trade secrets to protect their AI models and data, and they have the legal resources to defend the inventorship of their employees on any resulting patents.[55] In contrast, small biotech startups often rely on a strong patent portfolio as their primary asset to attract funding. If their ability to secure patents is compromised, their entire business model is threatened. This dynamic could accelerate market consolidation, with innovation becoming concentrated within a few vertically integrated giants who own the data, the AI models, and the resulting IP.

## Implications for Open Science and Academic Research

The open-science movement has been a powerful force in biotechnology, with public databases and tools like AlphaFold's structure database accelerating research globally. However, the IP uncertainty could have a chilling effect. Universities may become more aggressive in asserting ownership over AI-assisted inventions, leading to complex IP negotiations that slow down collaborations. If valuable AI outputs cannot be patented, researchers and their institutions may be more inclined to keep discoveries as trade secrets, contrary to the academic mission of disseminating knowledge. Crafting a le-

82 University of Chicago Law Review 199 (2015).

gal framework that encourages public disclosure, perhaps by offering tiered or alternative forms of protection, will be critical to ensuring that the benefits of AI in biotechnology are broadly shared.

## Conclusion and Future Outlook

The convergence of artificial intelligence and biotechnology represents a watershed moment in the history of science and technology. Yet, this remarkable progress has been met with a legal framework that is fundamentally anachronistic. The global IP system, with its deep-seated, human-centric model of creation, is not merely strained by AI-generated inventions; it is broken by them. The steadfast legal consensus from the *Thaler* cases has solidified the principle that an AI cannot be an inventor, while decades of biotechnology case law have created a treacherous "product of nature" doctrine.

The result is a legal void, a no-man's-land where some of the most promising and valuable discoveries of our time may be left without clear ownership or protection, thereby chilling the very innovation the law is meant to foster.

The alternative ownership models currently on offer are little more than inadequate legal patches. Attributing inventorship to a user with minimal conceptual input is a legal fiction that creates weak and contestable patents. Granting ownership to AI developers threatens to create dangerous IP monopolies, and assigning rights based on training data is a logistical impossibility. These are not sustainable solutions; they are temporary workarounds for a system that requires fundamental reform.

The path forward demands bold and deliberate legislative action. Clinging to 19th-century notions of inventorship in the 21st century is a policy failure that will have tangible economic and social costs. Lawmakers across the globe must now undertake the difficult task of designing a new legal framework fit for the age of algorithmic discovery. The most promising avenue is the creation of a *sui generis* intellectual property right for AI-generated inventions. This new right should be crafted with a clear purpose: to incentivize investment in AI-driven R&D while promoting competition and public disclosure. Such a system might feature a shorter protection term, a registration process that acknowledges the AI's role without requiring a human inventor, and a clear rule for assigning ownership to the entity that marshaled the resources for the invention's creation.

The next legal flashpoints are already visible on the horizon. We can expect a wave of litigation challenging the validity of patents for AI-assisted inventions, focusing on the "significant contribution" of the named human inventors. Courts will be forced into highly technical, fact-intensive inquiries, attempting to dissect the collaborative process between human and machine.

These cases will further highlight the inadequacy of the current framework and increase the pressure on policymakers to act.

The stakes could not be higher. AI-powered biotechnology holds the potential to eradicate diseases, combat climate change, and revolutionize industries. To unlock this potential, we need a legal and economic ecosystem that provides clarity, certainty, and fair rewards for innovation. The law must not be an anchor holding back technological progress, but a rudder to guide it responsibly. The time for deliberation is over; the time for building a new legal foundation has begun.

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