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Lauren Schultz, J.D. Candidate, 2025

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LEGAL AND POLICY ISSUES SURROUNDING AI-ASSISTED CHEMISTRY AND DRUG DISCOVERY

Lauren Schultz[1]

I. Abstract

Artificial intelligence (AI) has forever shaped our society and the ways in which individuals synthesize and utilize information. In particular, AI has revolutionized scientific research and the identification of potential disease therapeutics. It is no secret that developing a new drug is expensive and takes years. Luckily, AI has implications that would help expedite the process and make drug development more cost-effective. Yet, a major point of debate has been whether AI-assisted discoveries qualify for patent protection. Recent court decisions have overwhelmingly asserted that only human beings qualify as inventors on patent applications. However, with the rapid advancements of AI, the interpretation of what it means to be an inventor will likely need to be re-evaluated by the legal system. Moreover, courts should consider specifically examining AI inventorship related to AI-assisted chemistry and drug development. Additionally, potential solutions should be surveyed to help aid the integration of AI inventorship with patent law.

II. Introduction

Artificial intelligence (AI) systems have undoubtedly become a hot topic of conversation. Two months after ChatGPT's launch in December 2022, ChatGPT became the fastest app on record to reach 100 million active users.[2] It is undeniable that AI is quickly becoming integrated in nearly all aspects of everyday life and will have a substantial impact on society. One instance of this is how AI systems have forever changed the way new drug candidates are identified.[3] AI systems like AlphaFold, DeepAffinity, and DeepBAR, among several others, have caught the interest of the scientific research community because of their potential to rapidly analyze large-scale data sets, design new molecules, and predict the efficacy of potential drug candidates.[4] Pharmaceutical companies have started to integrate AI into their research and development pipelines, with some AI-generated drugs already in clinical trials.[5]

[1] J.D. Candidate, University of Arizona James E. Rogers College of Law, 2025

[2] David Curry, *ChatGPT Revenue and Usage Statistics (2024)*, BUSINESS OF APPS, https://www.businessofapps.com /data/chatgpt-statistics/ (July 2, 2024).

[3] William Douglas Heaven, *AI Is Dreaming Up Drugs that No One Has Ever Seen. Now We've Got to See if They Work.*, MIT TECH. REV. (Feb. 15, 2023), https://www.technologyreview.com/2023/02/15/1067904/ai-automation-drug-development/.

[4] Rizwan Qureshi et al., *AI in Drug Discovery and Its Clinical Relevance*, HELIYON, July 2023, at 1, 5.

[5] Willow Shah-Neville, *How AI Is Shaping Clinical Research and Trials*, LABIOTECH, https://www.labiotech.eu/in-depth/ai-clinical-research/ (Feb. 19, 2024).

However, the rise of AI-assisted chemistry and drug development systems has brought about an abundance of legal issues particularly related to patent inventorship.[6]

In April 2023, the United States Supreme Court denied certiorari in *Thaler v. Vidal*, which addressed the issue of whether AI could be considered an inventor on patent applications.[7] Thus, the United States Court of Appeals for the Federal Circuit decision, that interpreted the Patent Act to require a human inventor for purposes of obtaining a patent, was not re-evaluated.[8] Almost all other countries, except for South Africa, have followed suit and deny patent applications that do not list a human inventor.[9] This Note analyzes why courts should and will inevitably need to re-evaluate the definition of an inventor, specifically in patents related to AI-assisted chemistry and drug development. Additionally, this Note examines various regulations that could be enacted to help aid the integration of AI inventorship with patent law.

III. Current AI-assisted Chemistry and Drug Development Systems

On average it takes 10–15 years and roughly USD $2.6 billion to develop a new drug.[10] To fully appreciate why drug development is such a long and expensive process, it is important to provide a brief overview of how a drug is made from its inception to its final product.[11] Before a drug candidate is even identified, several years of academic and/or commercial research, known as "pre-discovery," is conducted to understand the underlying mechanism of a particular disease.[12] From this basic research, scientists hope to identify therapeutic agents that could potentially ameliorate disease symptoms.[13] These therapeutic agents usually target a macromolecule (typically a protein).[14] Pre-discovery is then followed by a "preclinical phase" in which the identified therapeutic agents or potential drugs are validated.[15] The next step is to conduct human clinical trials, which are broken up into three phases.[16] A drug may be submitted to the United States Food and Drug Administration (FDA) for approval when it has

[6] Ben Hsing, *Artificial Intelligence in Drug Development: Patent Considerations*, IPWATCHDOG (Sept. 25, 2023, 8:15 AM), https://ipwatchdog.com/2023/09/25/artificial-intelligence-drug-development-patent-considerations/.
[7] Patrick Muffo, *SCOTUS Denies Cert in Thaler – The Thorny Issue of AI Inventorship*, JD SUPRA (April 25, 2023), https://www.jdsupra.com/legalnews/scotus-denies-cert-in-thaler-the-thorny-1401757/.
[8] *See* i*d.*
[9] John Villasenor, *Patents and AI Inventions: Recent Court Rulings and Broader Policy Questions*, BROOKINGS (Aug. 25, 2022), https://www.brookings.edu/articles/patents-and-ai-inventions-recent-court-rulings-and-broader-policy-questions/.
[10] Maxime Derep, *What's the Average Time to Bring a Drug to Market in 2022?*, N-SIDE (Nov. 5, 2022), https://lifesciences.n-side.com/blog/what-is-the-average-time-to-bring-a-drug-to-market-in-2022.
[11] JP Hughes et al., *Principles of Early Drug Discovery*, 162 BRIT. J. PHARMACOLOGY 1239, 1240 (2011).
[12] Natesh Singh et al., *Drug Discovery and Development: Introduction to the General Public and Patient Groups*, FRONTIERS DRUG DISCOVERY, May 24, 2023, at 1, 2.
[13] *Id.*
[14] *See id.* at 2, 4.
[15] *Id.* at 2.
[16] *Id.* at 2–3.

successfully passed the three phases of clinical trials.[17] Once a drug is approved, follow-up studies, referred to as "Phase IV," are conducted to monitor the side effects of the new drug over time.[18] Taking all these steps into account, it is easy to see how much time, effort, and money is needed to develop a new drug.

AI can be very influential in the pre-discovery stage by analyzing large data sets and narrowing down potential therapeutic targets.[19] Deep learning (DL), a subset of AI, has been shown to be particularly advantageous for expediting drug development.[20] DL algorithms teach computers to process data in a way that mimics the human brain by identifying complex patterns, sounds, and text, among other data, to make predictions and insights.[21] In relation to drug development, DL is especially useful for computer-assisted discovery in molecular design, chemical synthesis planning, protein structure prediction, and macromolecular target identification.[22] Additionally, DL can also likely aid in the prediction of drug-target interactions, drug-drug similarity interactions, drug sensitivity and responsiveness, and drug side effects.[23] Furthermore, AI's ability to recognize patterns from large sets of data is especially useful for drug repurposing, which is a method for developing new targets from existing drugs that have already been shown to be efficacious and safe in humans.[24] Drug repurposing or drug repositioning allows for certain compounds to skip Phase I of clinical trials, thereby saving development costs and time.[25] Drug repurposing thus leads to direct preclinical and clinical testing compared to traditional *de novo* drug development, where novel compounds have not yet been subjected to *in vitro* and *in vivo* screening, chemical optimization, toxicology, mass production, and clinical trials.[26] Perhaps a recent and well-known instance has been the AI-based drug repurposing efforts for development of COVID-19 therapies.[27] The need to immediately develop a COVID-19 therapeutic led researchers all over the world to examine whether an existing drug could be used to target COVID-19. For example, in BenevolentAI's search for approved drugs that could

[17] Sharoon David & Peggy Y. Kim, *Drug Trials,* STATPEARLS, https://www.ncbi.nlm.nih.gov/books/NBK546595/ (June 20, 2023).
[18] Singh et al., *supra* note 12, at 7.
[19] *See* Heba Askr et al., *Deep Learning in Drug Discovery: An Integrative Review and Future Challenges*, 56 A.I. REV. 5975, 5976 (2023).
[20] *See* i*d.*
[21] *What is Deep Learning?* AWS, https://aws.amazon.com/what-is/deep-learning/ (last visited Sep. 27, 2024).
[22] José Jiménez-Luna et. al., *Drug Discovery with Explainable Artificial Intelligence*, 2 NATURE MACH. INTELL. 573, 573 (2020).
[23] Askr et al., *supra* note 19, at 5982.
[24] Yi Cong et al., *A New Approach to Drug Repurposing with Two-Stage Prediction, Machine Learning, and Unsupervised Clustering of Gene Expression*, 26 OMICS 339, 340 (2022).
[25] *See* Yi Hua et. al., *Drug Repositioning: Progress and Challenges in Drug Discovery for Various Diseases*, EUR. J. MED. CHEMISTRY, April 15, 2022, at 1, 2.
[26] *See id.*
[27] *See generally* Zhichao Liu et al., *AI-Powered Drug Repurposing for Developing COVID-19 Treatments*, 1 COMPREHENSIVE PRECISION MED. 144 (2024).

block the SARS-CoV-2 viral infection process they identified *baricitinib*,[28] a drug used to treat rheumatoid arthritis.[29]

Understanding protein structure is essential for drug development for many reasons such as predicting how disease-linked mutations potentially affect normal protein function as well as synthesizing drugs that will bind specifically to certain protein structures.[30] By the early 2010s, computer scientists and computational chemists had developed prototypes of AI systems, like RoseTTAFold and DeepMind's AlphaFold, that were designed to predict protein structures.[31] In 2020, DeepMind utilized their AlphaFold system in the biennial protein-structure prediction challenge called the Critical Assessment of Structure Prediction (CASP).[32] CASP was created in 1994 by Professors John Moult and Krzysztof Fidelis as a way to incentivize scientific breakthroughs related to protein structure predictions.[33] The challenge is for individuals to try and predict the protein structures which have been solved experimentally but are not yet publicly released.[34] DeepMind's AlphaFold amazingly won the 14th CASP challenge, outperforming 100 teams of independent scientists.[35]

Since the first prototypes, several other AI-assisted chemistry and drug discovery systems have been created. Some examples include DeepAffinity and DeepBar, which assess the efficacy of a drug by evaluating its binding affinity with its targets.[36] Another example is DeepTox, which is a DL model used for predicting the toxicity of certain chemical compounds.[37] The list of these AI-assisted chemistry and drug discovery systems only continues to expand, which has led to questions about AI's role in inventorship. The United States Patent Act defines an inventor as "the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention."[38] However, the application of AI has recently called the

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[28] Peter Richardson et al., *Baricitinib As Potential Treatment for 2019-nCoV Acute Respiratory Disease*, 395 LANCET e30, e30 (2020).
[29] Liu et al., *supra* note 27, at 151.
[30] *See* Ammar Ammar et al., *PSnpBind-ML: Predicting the Effect of Binding Site Mutations on Protein-Ligand Binding Affinity*, J. CHEMINFORMATICS, March 2, 2023, at 1, 2.
[31] Carrie Arnold, *Inside the Nascent Industry of AI-Designed Drugs*, 29 NATURE MED. 1292, 1294 (2023).
[32] Ewen Callaway, *'It Will Change Everything': DeepMind's AI Makes Gigantic Leap in Solving Protein Structures*, 588 NATURE 203, 203 (2020).
[33] *AlphaFold: A Solution to a 50-Year-Old Grand Challenge in Biology*, GOOGLE DEEPMIND (Nov. 30, 2020), https://www.deepmind.com/blog/alphafold-a-solution-to-a-50-year-old-grand-challenge-in-biology/.
[34] Carlos Outeiral Rubiera, *CASP14: What Google DeepMind's AlphaFold 2 Really Achieved, and What It Means for Protein Folding, Biology and Bioinformatics*, OPIG (Dec. 3, 2020), https://www.blopig.com/blog/2020/12/casp14-what-google-deepminds-alphafold-2-really-achieved-and-what-it-means-for-protein-folding-biology-and-bioinformatics/.
[35] Callaway, *supra* note 32, at 203–04.
[36] Mostafa Karimi et al., *DeepAffinity: Interpretable Deep Learning of Compound–Protein Affinity Through Unified Recurrent and Convolutional Neural Networks*, 35 BIOINFORMATICS 3329, 3329 (2019); Daisy Ireland, *DeepBAR: Calculating Binding Free Energy*, FRONT LINE GENOMICS (Mar. 19, 2021), https://d4-pharma.com/deepbar-calculating-binding-free-energy/.
[37] *DeepTox: Deep Learning for Toxicity Prediction*, INSTITUTE OF BIOINFORMATICS, JOHANNES KEPLER UNIVERSITY LINZ, http://www.bioinf.jku.at/research/DeepTox/ (last visited Sep. 27, 2024).
[38] 35 U.S.C. § 100(f).

interpretation of "individual" into question.[39] Specifically, is AI capable of formulating ideas sufficient to qualify as an inventor and, even if AI is not sentient, could its output rise to the level of warranting inventorship?[40] Additionally, if the definition of inventor is not broadly interpreted to include AI, should there be an exception for patent applications involving AI-assisted chemistry and drug discovery to incentivize investment in scientific research and reduce the cost and time of the drug development process?

Thaler v. Vidal elucidates the current legality of whether AI can be an inventor, however the case does not resolve many unexplored arguments and unanswered questions.[41] Despite denying certiorari in *Thaler v. Vidal*, the United States Supreme Court will inevitably need to address several of the issues the case poses, especially as AI continues to become more advanced. Moreover, it may eventually be necessary for the World Intellectual Property Organization (WIPO) to provide global guidelines on the issue of AI and inventorship.[42] But first, it is necessary to explore the decisions in *Thaler v Vidal* and how the decisions shaped the current landscape of AI inventorship in patent law.

IV. The Latest Decision on AI Inventorship — *Thaler v. Vidal*

Thaler v. Vidal is the most recent and arguably the most influential court case which has examined whether AI can be listed as an inventor on a patent application.[43] The plaintiff, Dr. Stephen Thaler, has long championed the AI industry.[44] In 1995, he founded Imagination Engines Incorporated, which is the company behind the recently developed AI system known as DABUS (Device for the Autonomous Bootstrapping of Unified Sentience).[45] According to Imagination Engines Incorporated, DABUS departs from nascent AI systems and is revolutionary for its human "brain-like functions" by continuously generating thought processes and memories.[46] DABUS's supposed ability

[39] Sean Flood, *Patents in the AI Era: Navigating the Complexities of AI Inventorship*, ICEMILLER (Mar. 10, 2023), https://www.icemiller.com/ice-on-fire-insights/publications/patents-in-the-ai-era-navigating-the-complexities/.

[40] Suzi Morales, *Can Artificial Intelligence Invent Things? A Curious Legal Case Could Have Big Implications for Business*, OBSERVER (Sept. 21, 2022, 5:30 AM), https://observer.com/2022/09/can-artificial-intelligence-invent-things-a-curious-legal-case-could-have-big-implications-for-business/.

[41] Fariba Sirjani et al., *A Failure of Fact: What Has Been Missing from the Arguments in* Thaler v. Vidal, IPWATCHDOG (Mar. 16, 2023, 4:15 PM), https://ipwatchdog.com/2023/03/16/failure-fact-missing-arguments-thaler-v-vidal/.

[42] *AI and IP Policy: The WIPO Conversation*, WIPO, https://www.wipo.int/about-ip/en/frontier_technologies/ai_and_ip_policy.html (last visited Sep. 27, 2024).

[43] Thaler v. Vidal, 43 F.4th 1207, 1210 (Fed. Cir. 2022).

[44] David Cassel, *Stephen Thaler Claims He's Built a Sentient AI*, THE NEW STACK (Mar. 16, 2023, 8:10 AM), https://thenewstack.io/stephen-thaler-claims-hes-built-a-sentient-ai/.

[45] *Id*.

[46] *DABUS Described*, NAV, https://imagination-engines.com/dabus.html (last visited Sep. 27, 2024); *DABUS Accepted As First AI Inventor*, MINESOFT, https://minesoft.com/dabus-accepted-as-first-ai-inventor/ (last visited Sep. 27, 2024).

to mimic human thinking has led Thaler to claim that it is sentient and capable of idea formation.[47]

Assertions of DABUS's sentience led to Thaler filing a patent application in which Thaler was listed as the patentee and DABUS was listed as the inventor.[48] This application entitled, "FOOD CONTAINER AND DEVICES AND METHODS FOR ATTRACTING ENHANCED ATTENTION" describes inventions that were proposed to be autonomously invented by DABUS.[49] The first invention listed describes a beverage container with alleged better grip and heat transfer regulation, referred to as a "Fractal Container."[50] The second invention describes an emergency beacon that flashes light in varying patterns to attract rescuer attention, known as a "Neural Flame."[51]

Thaler sought patent protection for these inventions in several jurisdictions including South Africa, the United States, the European Patent Office (EPO), the United Kingdom (UK), Germany, New Zealand, Taiwan, India, Korea, Israel, and Australia.[52] Thaler's patent application was rejected in every country, except for South Africa, on the basis that an inventor listed on a patent application must be a human being.[53] South Africa is the first and currently the only country to grant a patent application in which AI is listed as an inventor.[54] Thaler's patent was published in South Africa's Patent Journal in July of 2021.[55] Many critics of South Africa's decision to grant Thaler's patent application suggest that the decision was based on a technicality because South Africa does not actually define the term inventor.[56] Section 27(1) of South Africa's Patent Act merely states that a patent application may be made by "'an inventor or any other person acquiring from him the right to apply[.]'"[57] Although South Africa remains the only country to date to acknowledge AI as an inventor, this decision has opened the door to conversation about AI inventorship around the world.[58]

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[47] Cassel, *supra* note 44.
[48] Christopher Mhangwane & David Cochrane, *DABUS, the Rise of the Inventive Machines*, SPOOR FISHER (Jan. 19, 2023), https://spoor.com/dabus-the-rise-of-the-inventive-machines/.
[49] *See generally* International Publication No. WO2020079499A1 (filed Sept. 17, 2019).
[50] Aaron Gin, *Petition for Writ of Certiorari Filed in DABUS AI-as-Inventor Case*, PATENT DOCS (Apr. 6, 2023), https://www.patentdocs.org/2023/04/petition-for-writ-of-certiorari-filed-in-dabus-ai-as-inventor-case.html.
[51] *Id.*
[52] Mhangwane & Cochrane, *supra* note 48.
[53] *Id.*
[54] Ed Conlon, *DABUS: South Africa Issues First-Ever Patent with AI Inventor*, MANAGING IP (July 29, 2021), https://www.managingip.com/article/2a5czh91g6c8zwxjcpla8/dabus-south-africa-issues-first-ever-patent-with-ai-inventor.
[55] *Id.*
[56] Milon Gupta, *Roundtables About Uses Cases and Network Slicing*, EURESCOM, https://www.eurescom.eu/eurescom-messages/winter-2021/invented-by-dabus/ (last visited Sep. 27, 2024); Daniel Schwartz, *South Africa and Australia Break From U.S. and U.K. to Give DABUS Its First IP Breaks*, NIXON PEABODY (Aug. 10, 2021), https://www.nixonpeabody.com/insights/articles/2021/08/10/south-africa-and-australia-break-from-u-s-and-u-k-to-give-dabus-its-first-ip-breaks.
[57] Chijioke Okorie, *Artificial Intelligence System as Inventor in South African Patent Application: The Case of DABUS*, THE IPKAT (Aug. 16, 2021), https://ipkitten.blogspot.com/2021/08/artificial-intelligence-system-as.html.
[58] Mhangwane & Cochrane, *supra* note 48.

In 2019, the United States Patent and Trademark Office (USPTO) issued a Notice to File Missing Parts to amend the Application Data Sheet (ADS) in response to Thaler's patent application.[59] The USPTO explained that Thaler's application failed to identify a "natural person" as the inventor in accordance with Title 35 of the United States Codes (U.S.C.).[60] The USPTO also supported its position that an inventor must be a natural person by citing to the U.S. Court of Appeals for the Federal Circuit decision *Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V.*[61] In *Univ. of Utah* the Federal Circuit held that "inventors must be natural persons and cannot be corporations or sovereigns[,]" reasoning that only natural persons are capable of the mental act of "conception."[62] Conception is considered to be the "touchstone of inventorship."[63] Thaler challenged the USPTO's decision, but summary judgment was eventually granted by the District Court for the Eastern District of Virginia.[64] Thaler then appealed the case to the Federal Circuit.[65]

In 2022, the Federal Circuit upheld the District Court's ruling and concluded that "the Patent Act requires that inventors must be natural persons; that is, human beings[,]" which essentially rejected Thaler's argument that the definition of inventor should be broadly interpreted to include AI.[66] To support its reasoning, the Federal Circuit relied on the statutory language within 35 U.S.C. § 100(f) which defines an inventor as "'the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.'"[67]

While the Federal Circuit acknowledged that the Patent Act does not define the term "individual," it asserted that the Supreme Court has historically explained that "when used '[a]s a noun, "individual" ordinarily means a human being, a person.'"[68] Thaler proceeded to petition the United States Supreme Court for certiorari, however this request was denied in April 2023.[69] While this may have settled the matter for the time-being, this case has sparked debate for circumstances in which AI could, or should, be listed as an inventor such as in the areas of AI-assisted drug development.[70]

[59] *In re* Application of No.: 16/524,350, 2020 Apr. Comm'n Pat.
[60] *Id.*
[61] Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V., 734 F.3d 1315, 1323 (Fed. Cir. 2013).
[62] *Id.*
[63] Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227 (Fed. Cir. 1994).
[64] Aaron Gin, *Petition for Writ of Certiorari Filed in DABUS AI-as-Inventor Case*, PATENT DOCS (Apr. 6, 2023), https://www.patentdocs.org/2023/04/petition-for-writ-of-certiorari-filed-in-dabus-ai-as-inventor-case.html.
[65] *Id.*
[66] Thaler v. Vidal, 43 F.4th 1207, 1210 (Fed. Cir. 2022).
[67] *Id.* at 1211.
[68] *Id.* (citing Mohamad v. Palestinian Auth., 566 U.S. 449, 454 (2012)).
[69] Pamela M. Deese et al., *Federal Circuit Holds that AI Cannot Be an "Inventor" Under the Patent Act-Only Humans Can Get Patents*, ARENTFOX SCHIFF (May 5, 2023), https://www.afslaw.com/perspectives/alerts/federal-circuit-holds-ai-cannot-be-inventor-under-the-patent-act-only-humans.
[70] Ryan Abbott, *Allow Patents on AI-Generated Inventions—For the Good of Science*, NATURE (Aug. 22, 2023), https://www.nature.com/articles/d41586-023-02598-2.

Arguments for AI being listed as an inventor and against AI being listed as an inventor are discussed below in this Note.

V. Overview of AI Within the Scope of Drug Discovery

As previously mentioned, the crux of the argument for denying AI-inventorship on patents stems from the fundamental belief that only humans are capable of the conception of ideas.[71] To analyze this argument more thoroughly, it is necessary to examine the role humans play in AI-assisted drug discovery.

The consensus right now is that AI is "merely a tool" for innovation and that human involvement is still essential and prominent.[72] Currently humans are responsible for identifying a drug target, developing the AI parameters, and ultimately analyzing the AI output based on the parameters they have set.[73] However, "[i]f the AI conceives of a new chemical compound, for example, and no natural person made sufficient contributions to qualify as an inventor, it is unclear who, if anyone, may apply for a patent on the compound."[74] As AI systems become more advanced and the human role lessens, patent protection for AI-assisted discoveries becomes increasingly important and any drug candidates that an AI program could potentially invent would be unpatentable under the current system. [75] This raises an issue for how pharmaceutical companies would recoup their investment in AI drug development.[76]

Recall that bringing a new drug to market on average takes between 10–15 years and costs USD $2.6 billion.[77] A recent study projected that utilizing AI could reduce drug discovery costs upwards of 70% by saving pharmaceutical companies USD $54 billion annually on research and development as well as USD $28 billion annually on clinical research, all while performing drug screening and synthesizing in about half the amount of time.[78] Moreover, the global AI in the pharmaceutical market is expected to grow at a compound annual growth rate (CAGR) of 29.30% from 2023 to 2032.[79] With these

[71] Univ. of Utah v. Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V., 734 F.3d 1315, 1323 (Fed. Cir. 2013).
[72] Alexander Kersten, *Assessing the Patent and Trademark Office's Inventorship Guidance for AI-Assisted Inventions*, CSIS (June 3, 2024), https://www.csis.org/analysis/assessing-patent-and-trademark-offices-inventorship-guidance-ai-assisted-inventions.
[73] David McCombs et al., *How to Navigate the Patenting Challenges of AI-Assisted Drug Discovery*, PHARMACEUTICAL ONLINE (June 17, 2022), https://www.pharmaceuticalonline.com/doc/how-to-navigate-the-patenting-challenges-of-ai-assisted-drug-discovery-0001.
[74] Christopher Haley, *Who Gets the Patent When AI Is the Inventor?* GOODWIN (Sept. 5, 2023), https://www.goodwinlaw.com/en/insights/publications/2023/09/insights-technology-aiml-who-gets-the-patent-when-ai.
[75] McCombs et. al., *supra* note 73.
[76] *Id.*
[77] Derep, *supra* note 10.
[78] Nadejda Alkhaldi, *Why Use AI in Pharma, and How to Get It Right*, ITREX GROUP (Apr. 19, 2023), https://itrexgroup.com/blog/why-use-ai-in-pharma-and-how-to-get-it-right/.
[79] *AI in Pharmaceutical Market*, PRECEDENCE RSCH., https://www.precedenceresearch.com/ai-in-pharmaceutical-market (Oct. 2023).

statistics in mind, it is easy to see why pharmaceutical companies are incentivized to invest in AI-assisted drug development systems.

According to CB Insights's Pharma AI Readiness Index, Roche and Bayer hold the top two spots for pharmaceutical companies best equipped in their ability to attract top AI talent, execute AI projects, and innovate through R&D and investments.[80] In addition to Roche and Bayer, many other pharmaceutical companies are well into integrating AI systems in their drug development process and/or have made announcements related to their AI investments—the three frontrunners in 2023 were Schrödinger, Recursion Pharmaceuticals, and Exscientia.[81] Of recent note, Recursion Pharmaceuticals received a USD $50 million investment to aid in the development of its AI models for drug discovery.[82] Recursion has utilized its proprietary AI-powered drug discovery platform, Recursion OS,[83] to discover several AI-generative drugs that are either about to or have already entered clinical trials.[84] These AI-generative drugs are designed to target diseases, among which include familial adenomatous polyposis, cerebral cavernous malformation, neurofibromatosis type 2, and ovarian cancer.[85] Other companies, like Exscientia, Relay Therapeutics, and BenevolentAI have also invested in generative AI to develop therapeutics.[86] Exscientia has roughly eighteen AI-designed drugs in research and development which are designed to treat various diseases, such as COVID-19, tuberculosis, malaria, and hypophosphatasia.[87] Among Exscientia's AI-developed drug candidates, the most notable would arguably be EXS4318, a small molecule inhibitor used to treat inflammatory and autoimmune diseases which Exscientia licensed to Bristol Myers Squibb in a partnership valued at nearly USD $1.2 billion.[88] In 2021, Relay Therapeutics acquired the startup company, ZebiAI, for USD $85 million in order to expand their AI-drug discovery technology.[89] Relay Therapeutics is currently testing the AI-designed small molecule inhibitor, RLY–4008, for the treatment of certain cancers, such as intrahepatic cholangiocarcinoma.[90] Another example of AI-generative drug discovery would be BenevolentAI's small molecule inhibitors, BEN–2293 and

[80] *Pharma AI Readiness Index: Who's Best-Positioned for the AI Boom?* CBINSIGHTS (Aug. 8, 2023), https://www.cbinsights.com/research/ai-readiness-index-pharma/.
[81] Jim Halley, *3 AI Drug Discovery Stocks to Watch*, THE MOTLEY FOOL (Sept. 15, 2023, 8:45 AM), https://www.fool.com/investing/2023/09/15/3-ai-drug-discovery-stocks-to-watch/.
[82] Annika Kim Constantino, *Nvidia Invests $50 Million in Biotech Company Recursion for A.I. Drug Discovery*, CNBC (July 12, 2023, 5:22 PM), https://www.cnbc.com/2023/07/12/nvidia-invests-in-biotech-company-recursion-for-ai-drug-discovery-.html.
[83] *Recursion Announces Initiation of Phase 2/3 Trial for the Treatment of NF2-Mutated Meningiomas at Children's Tumor Foundation NF Conference*, RECURSION (June 20, 2022, 8:00 AM), https://ir.recursion.com/news-releases/news-release-details/recursion-announces-initiation-phase-23-trial-treatment-nf2.
[84] Arnold, *supra* note 31, at 1293.
[85] *Id.*
[86] Arnold, *supra* note 31, at 1293.
[87] *Id.*
[88] *Id.*
[89] Frank Vinluan, *Relay Therapeutics Pays $85M for Startup With a New AI Tech for Drug Discovery*, MEDCITY NEWS (Apr. 16, 2021), https://medcitynews.com/2021/04/relay-therapeutics-pays-85m-for-startup-with-a-new-ai-tech-for-drug-discovery/.
[90] Arnold, *supra* note 31, at 1293.

BEN–8744, which are in clinical trials to treat atopic dermatitis and ulcerative colitis, respectively.[91]

Meanwhile, Eli Lilly and XtalPi have collaborated on a USD $250 million project, which seeks to combine Eli Lilly's clinical and commercial development prowess with XtalPi's AI and robotics system for the *de novo* design and delivery of drug candidates.[92] A final example of pharmaceutical companies' extensive investment in AI technology would be Sanofi's collaboration with Atomwise to streamline drug screening.[93] Sanofi's initial investment into this collaboration was roughly USD $20 million and could potentially lead to additional payments related to critical research, development, sales milestones, as well as tiered royalties, which taken together would likely surpass USD $1 billion.[94]

In addition to the incentive to research more common diseases, the emergence of AI has also brought about an incentive for pharmaceutical companies to invest in research identifying therapeutics for rare diseases. Rare diseases, also known as orphan diseases, are those classified as affecting less than 200,000 Americans.[95] There have been more than 7,000 rare diseases identified to date in the United States, some of which include cystic fibrosis, Lou Gehrig's disease, and Tourette's syndrome.[96] These diseases are difficult to diagnose and treat because there is usually little research devoted to studying their underlying mechanisms, partly due to funding constraints; funding by the National Institutes of Health (NIH) is oftentimes proportional to the supposed "burden of the disease."[97] For example, in 2019 only 0.1% of the NIH's USD $39 billion fiscal year budget was allocated to rare disease studies.[98] Since any one rare disease only affects a few individuals, pharmaceutical companies are generally disincentivized to invest in drugs to treat rare diseases.[99] In order to try and incentivize companies to invest in drug development for rare diseases, the United States Congress passed the Orphan Drug Act (ODA) in 1983.[100] While the ODA has led to a lot of advancement, there is still a need for greater research and therapeutic development dedicated to rare diseases not only within the United States but across the globe.[101]

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[91] *Id.* at 1293–94.
[92] Andrea Park, *Eli Lilly, XtalPi Ink $250M Deal for AI-Powered Drug Discovery*, FIERCE BIOTECH (May 30, 2023, 10:30 AM), https://www.fiercebiotech.com/medtech/eli-lilly-xtalpi-ink-250m-deal-ai-powered-drug-discovery.
[93] James Waldron, *Sanofi Signs $1.2B Pact with Atomwise in Latest High-Value AI Drug Discovery Deal*, FIERCE BIOTECH (Aug. 17, 2022 8:24 AM), https://www.fiercebiotech.com/biotech/sanofi-signs-12b-pact-atomwise-latest-high-value-ai-drug-discovery-deal.
[94] *Id.*
[95] *Rare and Orphan Diseases*, NCSL (May 26, 2023), https://www.ncsl.org/health/rare-and-orphan-diseases.
[96] *Id.*
[97] Qian Zhu et al., *Scientific Evidence Based Rare Disease Research Discovery with Research Funding Data In Knowledge Graph*, ORPHANET J. RARE DIS., Nov. 18, 2021, at 1, 2, 6.
[98] *Id.* at 2.
[99] *See* Caroline Pearson et al., *The Next Generation of Rare Disease Drug Policy: Ensuring Both Innovation and Affordability*, 11 J. COMPARATIVE. EFFECTIVENESS. RSCH. 999, 999 (2022).
[100] *Id.*
[101] *Id.* at 1007.

One of the challenges with studying rare diseases is the fact that there is a limited amount of input data since only a small amount of the population is affected.[102] AI helps to circumvent this issue through data augmentation, which is a process where the algorithm can be trained and learn patterns from smaller amounts of data.[103] For example, recent DL algorithms spot commonly overlooked clinical indications to promote the early diagnosis of rare diseases.[104] Moreover, AI tools like Phenix and Xrare can assess patients' gene pathogenicity and discover molecular markers of rare diseases, allowing for a more tailored therapeutic approach.[105] Since rare diseases affect a proportionally smaller number of the population, it is difficult to garner sufficient participation in clinical trials for orphan drugs.[106] However, data mining computable phenotype algorithms have been shown to help effectively identify patients with rare diseases and aid in their recruitment for clinical trials.[107]

In February 2023, the FDA approved the first AI-generated candidate for orphan drug designation.[108] Insilico Medicine, a Hong Kong-based biotech startup with more than $400 million in funding, was granted FDA approval for their drug, INS018_055.[109] INS018_055 is a small molecule inhibitor used to treat idiopathic pulmonary fibrosis (IPF), a chronic lung disease.[110] It was designed by Insilico Medicine's AI platform, Pharma.AI.[111] According to Insilico Medicine's founder and CEO, Alex Zhavoronkov, INS018_055 is the first drug with both a novel AI-discovered target and a novel AI-generated design and has entered Phase II clinical trials.[112] Moreover, Insilico Medicine has two other AI-generative drugs that have received FDA approval to begin clinical trials; one to treat COVID-19 and the other to treat solid cancerous tumors.[113]

A phenomenon that threatens pharmaceutical companies' long-term profits on their drug discovery investments for both common and rare diseases is known as the "patent cliff."[114] The patent cliff denotes the impending sharp decline in revenues for

[102] Magda Wojtara et al., *Artificial Intelligence in Rare Disease Diagnosis and Treatment*, 16 CLINICAL TRANSLATIONAL SCI. 2106, 2107 (2023).
[103] *Id.*
[104] *Id.* at 2108.
[105] *Id.*
[106] Lawrence Ganti, *Why AI and Blockchain Are the Solutions to Developing Orphan Drug*, PHARMAPHORUM (Aug. 8, 2018), https://pharmaphorum.com/views-analysis-digital/blockchain-solution-developing-orphan-drug.
[107] Wojtara, *supra* note 102, at 2110.
[108] *Insilico Gains FDA's First Orphan Drug Designation for AI Candidate*, GENETIC ENG'G & BIOTECHNOLOGY NEWS (Feb. 10, 2023), https://www.genengnews.com/news/insilico-gains-fdas-first-orphan-drug-designation-for-ai-candidate/.
[109] Hayden Field, *The First Fully A.I.-Generated Drug Enters Clinical Trials in Human Patients*, CNBC (June 29, 2023, 3:51 PM), https://www.cnbc.com/2023/06/29/ai-generated-drug-begins-clinical-trials-in-human-patients.html.
[110] *Insilico Gains FDA's First Orphan Drug Designation for AI Candidate*, *supra* note 108.
[111] *Id.*
[112] Field, *supra* note 109.
[113] *Id.*
[114] Adam Hayes, *Patent Cliff: What It Means, How It Works*, INVESTOPEDIA, https://www.investopedia.com/terms/p/patent-cliff.asp (Oct. 15, 2022).

pharmaceutical companies upon the patent expiry of their leading products.[115] The term of patent protection for drugs is 20 years.[116] During this time frame, pharmaceutical companies are granted market exclusivity and can ward off generic competition while obtaining substantial revenue with some gross profit margins exceeding 90%.[117] On one hand, this exorbitant profitability enables pharmaceutical companies to recoup their time and monetary investments into the drug development process as well as incentivize them to continue doing so in the future—promoting a high risk, high reward mentality.[118] On the other hand, it is clear that the monopoly patent protection provides can lead to an abuse of power by many pharmaceutical companies wherein they set drug prices significantly higher than the overall costs to maximize profit.[119] However, the production and distribution of generic drugs is fair game once the patents for "brand-name" drugs expire after their 20-year term.[120]

To encourage generic drug competition, Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, in 1984.[121] Generic drugs are "created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use."[122] Generic drugs must undergo approval by the FDA and demonstrate that they function the same as their respective brand-name drug.[123] Generic drug applicants are approved by the FDA via an abbreviated new drug application (ANDA) and typically do not need to repeat animal and/or human clinical trials.[124] Instead, generic drug applicants rely on the safety and effectiveness studies of brand companies, thereby significantly lowering the upfront research costs.[125] According to the FDA, generic drugs are typically sold at substantial discounts—an estimated 80% to 85% less—compared with the price of their brand-name counterparts.[126] In fact, generic drugs reportedly saved the U.S. healthcare system approximately USD $2.2 trillion from 2009 to 2019.[127]

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[115] *Id.*
[116] Himanshu Gupta et al., *Patent Protection Strategies*, 2 J PHARMACY & BIOALLIED SCI. 2, 2 (2010).
[117] Jack DeRuiter & Pamela L. Holston, *Drug Patent Expirations and the "Patent Cliff,"* U.S. PHARMACIST (June 20, 2012), https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff.
[118] Chunming Xu & Debao Zhu, *On Conflicts Between Pharmaceutical Patent Protection and the Right to Life and Health Based on a Stackelberg Game*, 18 INT'L J. ENV'T RSCH. & PUB. HEALTH 1119, 1119 (2021).
[119] *Id.*
[120] Hayes, *supra* note 114.
[121] Gregory H. Jones et al., *Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 1398, 1398 (2016).
[122] *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (Mar. 16, 2021), https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers.
[123] *Id.*
[124] *Id.*
[125] Jones et al., *supra* note 121.
[126] *Generic Drugs: Questions & Answers*, *supra* note 122.
[127] *Id.*

Biosimilars are another example of a substantially cheaper version of a brand-name drug.[128] While generics are typically small molecules, biosimilars are large molecules that are initially more expensive and complex to manufacture.[129] However, biosimilars still offer a more cost-effective alternative to the brand-name drug.[130] Unlike generics, biosimilars are not completely identical to the chemical composition of the brand-name drug but are similar enough to provide the same therapeutic effect.[131] As of August 2022, 38 biosimilars have been approved by the FDA.[132] Uptake of biosimilars can offer an estimated savings for the U.S. of roughly USD $38.4 billion from 2021 to 2025.[133]

Brand-name drug patent expiration coupled with generic and biosimilar competition pose some of the biggest threats to big pharma's revenue and lead to the aforementioned patent cliff. Around 190 drugs will lose their patent exclusivity by 2030, accounting for an estimated USD $236 billion loss in pharmaceutical sales between now and then.[134] Up until now, pharmaceutical companies have come up with ways to try and delay the patent cliff phenomenon.[135] For example, they will sometimes negotiate what are known as "pay-for-delay" settlements with competing generic companies in which the company with the brand-name drug pays the generic drug applicant to delay their entry into the market.[136] Under the Hatch-Waxman Act, pharmaceutical companies are also the only ones permitted to produce their own authorized generics (AGs) of their brand-name drug within the first 180 days of filing, which can also prevent the entry of other generics onto the market.[137] Another strategy, known as "product hopping," involves pharmaceutical companies reformulating their brand-name drug prior to its patent expiry date, convincing physicians to prescribe this reformulated version, and consequently boxing out a generic due to specific state drug substitution laws.[138]

Given that the above strategies are not foolproof and arguably mere delay tactics, pharmaceutical companies are looking for other ways in which to stave off the dreaded patent cliff.[139] Recently, the CEO and founder of the pharmaceutical company, Eularis, published an article detailing ideas in which to leverage AI to lessen the blow of

[128] *Biosimilars vs. Generics: What's the Difference?,* PFIZER, https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2018/our-innovation/progressing-our-science/biosimilars-vs-generics/index.html (last visited Sept. 27, 2024).
[129] *Id.*
[130] *What's the Difference? Biosimilar and Generic Drugs*, CITY OF HOPE (July 9, 2024), https://www.cancercenter.com/community/blog/2024/07/biosimilars-generic-drugs-cancer.
[131] *Id.*
[132] *How Access to Biosimilar Drugs Could Boost Healthcare Equity*, PFIZER (Sept. 28, 2022), https://www.pfizer.com/news/articles/how_access_to_biosimilar_drugs_could_boost_healthcare_equity.
[133] Andrew Mulcahy et al., *Projected US Savings from Biosimilars, 2021-2025*, 28 AM. J. MANAGED CARE 329, 332 (2022).
[134] Meagan Parrish, *How Steep is Pharma's Patent Cliff?*, PHARMAVOICE (June 14, 2023), https://www.pharmavoice.com/news/pharma-patent-cliff-Merck-Keytruda-Pfizer-Seagen-Humira/652914.
[135] Jones et al., *supra* note 121.
[136] *Id.*
[137] *Id.* at 1399.
[138] *Id.*
[139] Andree Bates, *How to Leverage AI to Stave off the Impact of the Patent Cliff*, EULARIS, https://eularis.com/how-to-leverage-ai-to-stave-off-the-impact-of-the-patent-cliff/ (last visited Sept. 27, 2024).

impending patent expirations.[140] One idea involves using AI algorithms to identify potential patent violations early by "tracking mentions of drug compounds, formulations, and manufacturing methods across databases and social media . . . ."[141] Additionally, big pharma companies, like Pfizer, are utilizing AI to alert them of any new patent applications for competing products.[142] Furthermore, companies are trying to get ahead by using AI to analyze their own research and development and prior art before the competition does.[143] By doing this, pharmaceutical companies producing brand-name drugs are hoping to strengthen their IP protection and mitigate any potential revenue loss with patent expiration.[144]

With enormous amounts of money and effort being invested into AI drug discovery for both common and rare diseases, how do inventors navigate the current patent review process to ensure that their AI-assisted technologies are protected? Moreover, could the prohibition of AI-inventorship eventually threaten the investments made by pharmaceutical companies? The fact that AI cannot be listed as an inventor on a patent application has inarguably shaped the way in which inventors strategize how they draft claims to preempt inventorship issues.[145] As is, AI technologies have been subjected to high scrutiny under the patent eligibility process because they "often blur[ ] the line between abstract and concrete."[146] In other words, "patent applications that use AI may face patent eligibility challenges as being directed to unpatentable subject matter including abstract ideas or laws of nature."[147] This in turn has deterred some inventors from pursuing patents on AI technologies due to the unpredictable outcomes.[148] Those who decide to proceed with the process have the burden of crafting exceptionally nuanced patent claims to circumvent rejection.[149] The nuances and ways in which inventors currently strategize patent applications to include AI under the current U.S. patent law system is explored next.

VI. Patent Law Requirements

It is important to review the current U.S. patent law system in order to examine ways in which AI might be integrated. To begin, the idea of protecting intellectual property has been embedded in the fabric of American society and the legal system since its founding days. The U.S. Constitution itself states: "The Congress shall have Power . . . 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 .

[140] *Id.*
[141] *Id.*
[142] *Id.*
[143] *Id.*
[144] *Id.*
[145] McCombs et. al., *supra* note 73.
[146] Anup Iyer et al., *Drafting Patent Claims for AI-Based Inventions: Navigating Eligibility and Precision,* WESTLAW J. INTELL. PROP., Sep. 18, 2023, at 1, 2.
[147] McCombs et. al, *supra* note 73.
[148] Iyer et al., *supra* note 146.
[149] *Id.* at 3–4.

. . .”[150] Congress passed the first patent statute in April 1790 and the landscape of the patent law system in the U.S. has since undergone various changes over time.[151] Title 35 of the U.S.C. outlines the current statutory requirements for obtaining a patent.[152] First, to qualify under 35 U.S.C. § 101, a claimed invention must be eligible subject matter, meaning the invention must be a process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.[153] Over time, courts have interpreted this statute to disqualify abstract ideas, natural phenomena, and laws of nature from patent protection.[154]

In addition to being eligible subject matter, a claimed invention must also be novel and non-obvious.[155] Under 35 U.S.C. § 102, a claimed invention is considered to be novel if it has not been previously described or disclosed in what is known as “prior art.”[156] Prior art is any publicly known information before the effective filing date of a patent application.[157] A claimed invention may be rejected under § 102 as not novel if it is “anticipated” by a prior art reference, meaning that a single prior art reference already claims or discloses the invention.[158]

The Leahy-Smith America Invents Act (AIA), which was signed by President Barack Obama in 2011, was arguably the most substantial change in US patent law since the Patent Act of 1952.[159] It represented the U.S.’s transition from a first-to-invent system to a first-to-file system.[160] This had a significant impact on what constitutes prior art under 35 U.S.C. § 102, most notably by removing geographical limitations that were imposed under the pre-AIA statute.[161] Additionally, an inventor is no longer able to sidestep certain prior art by “swearing behind” an earlier date of conception.[162] The AIA also provides a one-year grace period for certain inventor-related public disclosures.[163]

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[150] U.S. CONST. art. I, § 8, cl. 1.
[151] *Milestones in U.S. Patenting*, USPTO, https://www.uspto.gov/patents/milestones (last visited Sep. 27, 2024).
[152] *See generally* 35 U.S.C. §§ 101–103, 112.
[153] 35 U.S.C. § 101.
[154] *See generally* Alice Corp. v. CLS Bank Int'l*,* 573 U.S. 208 (2014); Mayo v. Prometheus, 566 U.S. 66 (2012); Ass’n Molecular Pathology v. Myriad Genetics, Inc. 569 U.S. 576 (2013).
[155] 35 U.S.C. §§ 102, 103.
[156] 35 U.S.C. § 102.
[157] *Id.*
[158] MPEP (9th ed. Rev. 7, Feb. 2023) § 2131.
[159] Bryan L. Basinger & Seth L. Hudson, *America Invents Act, Ten Years After Enactment*, MAYNARDNEXSEN (Sept. 10, 2021), https://www.maynardnexsen.com/publication-america-invents-act-ten-years-after-enactment.
[160] Gene Quinn, *Patentability: The Novelty Requirement of 35 U.S.C. 102*, IPWATCHDOG (June 10, 2017, 09:45 AM), https://ipwatchdog.com/2017/06/10/patentability-novelty-requirement-102/.
[161] Matthew Warenzak & Gregory Kirsch, *Important Changes to U.S. Patent Law Under the AIA*, SMITH, GAMBRELL & RUSSELL (Feb. 19, 2013), https://www.sgrlaw.com/client-alerts/important-changes-to-u-s-patent-law-under-the-aia/.
[162] *Id.*
[163] Matthew Kitces & Angelo Christopher, *Understanding Global Grace Periods to Avoid Missing Patent Opportunities*, NIXON PEABODY (Sept. 29, 2021), https://www.nixonpeabody.com/insights/alerts/2021/09/29/worldwide-patent-grace-periods.

The grace period is an important distinction between the U.S.'s patent law system and other countries' patent law systems.[164]

In addition to being novel, a claimed invention must also be non-obvious under 35 U.S.C. § 103.[165] Under the AIA, 35 U.S.C. § 103 determines obviousness before the effective filing date of the claimed invention, instead of when the claimed invention was made as the pre-AIA statute indicated.[166] The following factors are assessed when determining if a claimed invention is obvious: 1) scope and content of the prior art; 2) differences between the putative prior art and the claimed invention; 3) the level of ordinary skill in the relevant art; and 4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved needs, and failure of others.[167] A claimed invention is deemed obvious when the existing prior art would lead a person having ordinary skill in the art (PHOSITA) to make the invention with a reasonable expectation of success.[168] The use of AI has raised some concerns regarding how obviousness should be assessed.[169] More specifically, it has been argued that the standard for obviousness will need to be raised if one is to assume that a PHOSITA has access to AI.[170]

If a claimed invention qualifies under the statutory provisions of Title 35 of the U.S.C., it may be eligible for a patent. Patents are in essence a property right which can be assigned.[171] There is a notable distinction between inventorship and ownership of a patent. Naming inventorship is the process of identifying the party or parties responsible for the conception of the subject matter described in at least one claim in the patent application.[172] On the other hand, ownership of a patent refers to the right of a patent owner to exclude others from making, using, offering for sale, selling, or importing into the U.S. the invention claimed in the patent.[173] An inventor is not necessarily the owner of the patent and vice versa.[174]

Much of the debate surrounding AI's role in the patent system hinges on the definition of inventorship compared to ownership.[175] The court in *Thaler v. Vidal* concluded that AI cannot be considered an inventor for purposes of patent applications, relying on the

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[164] Vic Lin, *What Are the Patent Grace Periods to File in the US and Foreign Countries?* PATENTTRADEMARKBLOG, https://www.patenttrademarkblog.com/patent-grace-periods/ (last visited Sept. 27, 2024).
[165] 35 U.S.C. § 103.
[166] MPEP (9th ed. Rev. 7, Feb. 2023) § 2158.
[167] Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966).
[168] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 402–03 (2007).
[169] *AI Raises the Obviousness Bar for Patents*, BLUESHIFTIP (Feb. 23, 2022), https://blueshiftip.com/ai-raises-the-obviousness-bar-for-patents/.
[170] *See, e.g., id.*
[171] 35 U.S.C. § 261.
[172] Michael K. Henry, *Patent Ownership vs. Inventorship: Who Really Controls the Rights to a Patent?,* HENRY PATENT LAW FIRM (Oct. 23, 2023), https://henry.law/blog/patent-ownership-vs-inventorship/.
[173] 35 U.S.C. § 154(a)(1).
[174] Henry, *supra* note 172.
[175] *See* Flood, *supra* note 39.

United States' Patent Act definition that an inventor is an "individual" and construing the meaning of individual to be a human being.[176] Perhaps an even more pressing issue implicated in *Thaler v. Vidal* is the ownership of an invention and the right to license or sell the patent if AI systems were to be recognized as inventors.[177] While Thaler himself of course claimed ownership and merely sought to credit DABUS as an inventor, this case does raise a few philosophical questions about AI and patent ownership. For example, would any consent to a patent assignment or license be coerced or involuntary if given by an AI that has been trained to give it?[178] Should the individual or company that owns the AI system or the developers who created the system possess ownership of the patent?[179] Moreover, who should be liable in the event AI makes mistakes?[180] As AI systems become more advanced questions like these will likely continue to be at the forefront of inventorship and patent ownership.

Given that patent applications that use AI may face patent eligibility challenges, many inventors are apprehensive in how they describe and incorporate AI-assisted technologies in their patent applications.[181] In order to try and address this, the USPTO released a document titled *Inventorship Guidance for AI-assisted Inventions* in February 2024.[182] The USPTO states in the guidance that "while AI-assisted inventions are not categorically unpatentable, the inventorship analysis should focus on human contributions, as patents function to incentivize and reward human ingenuity."[183] The USPTO elaborated that "[p]atent protection may be sought for inventions for which a natural person provided a significant contribution to the invention . . . ."[184] To assess what constitutes a "significant contribution" made by a natural person, the USPTO states it will examine the factors laid out in the 1998 case *Pannu v. Iolab Corp.*[185] These factors detail that an inventor must: "(1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art."[186] To try and provide more clarity, in *Inventorship Guidance for AI-assisted Inventions* the USPTO described hypothetical scenarios in which AI was used in the invention process, and the implications for the ability to get a patent.[187] The USPTO also stresses in *Inventorship*

[176] Inventorship Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10043 (Feb. 13, 2024).
[177] *See* Flood, *supra* note 39.
[178] *Id.*
[179] *Id.*
[180] Robayet Syed, *So Sue Me: Who Should be Held Liable when AI Makes Mistakes?,* MONASH UNIV. (Mar. 29, 2023), https://lens.monash.edu/@politics-society/2023/03/29/1385545/so-sue-me-wholl-be-held-liable-when-ai-makes-mistakes.
[181] *See* Iyer et al., *supra* note 146.
[182] Inventorship Guidance for AI-Assisted Inventions, *supra* note 176.
[183] *Id.* at 10044.
[184] *Id.*
[185] *Id.* at 10047–48.
[186] Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998).
[187] Ryan Davis, *4 Takeaways from USPTO Guidance on AI and Patents*, LAW360 (Feb. 13, 2024, 9:03 PM), https://www.law360.com/articles/1796918/4-takeaways-from-uspto-guidance-on-ai-and-patents.

Guidance for AI-assisted Inventions that "the significant contribution determination is made on a claim-by-claim and case-by-case basis, in each instance turning on its own set of facts."[188] However, the USPTO admits in *Inventorship Guidance for AI-assisted Inventions* that there remains "'no bright-line test'" for determining whether a person's contribution to an AI-assisted invention is significant.[189] Since this standard remains largely uncertain and despite the USPTO's list of non-exhaustive principles for applying the *Pannu* factors in AI-assisted inventions, many feel that litigation will inevitably result in the future when patents related to AI systems are asserted.[190]

Moreover, the USPTO did not address specific guidance for the use of AI-assisted drug discovery and development in their latest release. One can clearly surmise that the USPTO intends that the "substantial contribution" standard should apply to all AI-assisted inventions. However, should that always be the case? Should the "substantial contribution" standard be more clearly defined for AI-assisted drug discovery and development, especially given the amount of time and money involved in its investment and the potential betterment of public health at stake? Are there other potential solutions for defining AI's role in patent law? The answers to some of these questions will be explored in the following section of this Note.

VII. Other Potential Solutions

The emergence of AI has brought about quite the legal quandary—how can new technology be accommodated by increasingly antiquated patent laws?[191] Moreover, in what ways is it possible to preserve existing laws that still reflect the issues of modern society? There have been several propositions for how to best integrate AI into the legal system, particularly within patent law.[192] While some are seemingly more drastic than others, the proposed solutions provide fodder for discussion about how to address the growing use of AI in general as well as in the drug discovery and development space specifically.

Given that patent laws can vary from country to country, one proposition to strengthen patent protection of AI-assisted inventions would be to have nations create an international treaty to ensure that these laws follow standardized principles and that any disputes can be resolved efficiently.[193] While a rather ambitious and long-term plan,

[188] Erin Hanson & Sahra Nizipli, *USPTO Provides Guidance on the Patentability of AI-Assisted Inventions*, WHITE & CASE (Feb. 15, 2024), https://www.whitecase.com/insight-alert/uspto-provides-guidance-patentability-ai-assisted-inventions.
[189] *Id.*
[190] Davis, *supra* note 187.
[191] Alexandra George & Toby Walsh, *Artificial Intelligence is Breaking Patent Law*, NATURE (May 24, 2022), https://www.nature.com/articles/d41586-022-01391-x.
[192] *Drafting Patent Applications for AI Innovations: Navigating Challenges and Finding Solutions*, TTCONSULTANTS (Sept. 25, 2023), https://ttconsultants.com/drafting-patent-applications-for-ai-innovations-navigating-challenges-and-finding-solutions/.
[193] George & Walsh, *supra* note 191.

proponents of an international treaty being implemented argue that it would be a worthwhile investment with massive global benefits that could be accomplished by either negotiating a new treaty or adding those rules into an existing international IP agreement.[194] On the other hand, those that push back on this proposal object to nations giving up their autonomy to devise domestic policy about AI-generated inventions, especially when the full potential of AI has yet to be explored.[195]

Some also argue that "[t]inkering with existing legal protections risks leaving grey areas, so more comprehensive law reform is preferable[,]" and governments should instead model IP as a sort of *sui generis* law.[196] *Sui generis* law denotes essentially a "custom-built law" for creative outputs that do not classically fall under the types of traditional IP.[197] For example, computer software and databases/programs oftentimes fall under the protection of *sui generis* law.[198] Advocates of adopting *sui generis* protection for AI-assisted inventions maintain that this approach provides more legal stability and clears up several ambiguities of the current system.[199] Proponents of this approach emphasize that there would no longer be a need to identify inventorship of a claimed invention because the *sui generis* system would only apply to AI-generated outputs.[200] Another advantage of a *sui generis* system that only applied to systems developed by AI would be that no moral rights or attribution rights would need to be assigned.[201] It is important to keep in mind that adopting a *sui generis* system would likely reduce the term of protection for inventions to account for the fast pace at which AI advances.[202] A *sui generis* system may provide the most legally stable solution for AI-assisted inventions.[203]

Another proposed solution would be to keep AI-created inventions as trade secrets.[204] This may be an attractive option for pharmaceutical companies as they could instead protect their inventions by restricting public disclosure.[205] Trade secrets in theory can be protected indefinitely so long as the secret is not publicly disclosed.[206] In the realm of pharmaceuticals, however, drug information will need to be disclosed to the public after

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[194] *Id.*
[195] *Id.*
[196] *Id.*
[197] *Id.*
[198] *Copyright Protection of Computer Software*, WIPO, https://www.wipo.int/copyright/en/activities/software.html (last visited Sept. 27, 2024).
[199] *See* Isabella Lorenzoni, *Artificial Intelligence Creates, Invents … and Challenges Intellectual Property Law*, 3 STOCKHOLM INTELL. PROP. L. REV. 26, 31 (2020).
[200] *Id.* at 33.
[201] *Id.* at 34.
[202] See i*d.* at 34–35.
[203] *Id.* at 35.
[204] David McCombs et al., *Protecting Artificial Intelligence Inventions in Drug Development*, BIOPROCESS INT'l (Dec. 16, 2021), https://www.bioprocessintl.com/information-technology/protecting-artificial-intelligence-inventions-in-drug-development.
[205] *Id.*
[206] *Frequently Asked Questions: Trade Secrets*, WIPO, https://www.wipo.int/tradesecrets/en/tradesecrets_faqs.html (last visited Oct. 3, 2024).

testing and FDA approval, which can last on average between 7–12 years.[207] Therefore, the term of trade secret protection will eventually be limited if this approach is followed.[208]

In summary, it seems necessary and inevitable that the current patent law system must be reformed to better integrate AI-assisted inventions, especially those inventions that are related to drug discovery and development. From a public policy perspective, it is important to update laws so that they reflect the issues of modern society. Since there is currently no bright-line test for determining whether a person's contribution to an AI-assisted invention is significant, there is undoubtedly groundbreaking case law on the horizon that will help shape the future of patent law in the U.S. and abroad.

[207] McCombs et. al., *supra* note 204.
[208] *Id.*