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Inventing the Right Drug: Artificial Intelligence May Just be the Cure for an Antiquated Patent System

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Cover Page Footnote

J.D. Candidate, 2024, University of Georgia School of Law, M.B.A. Candidate, University of Georgia, Terry College of Business, 2024. I would like to dedicate this Note to my family. Thank you for your unwavering support and encouragement.

INVENTING THE RIGHT DRUG: ARTIFICIAL INTELLIGENCE MAY JUST BE THE CURE FOR AN ANTIQUATED PATENT SYSTEM

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I. INTRODUCTION

Artificial Intelligence, also known as "AI," is a revolutionary technology that makes it possible for machines to learn from experience, adjust to new inputs, and perform human-like tasks.[1] AI has the power to reshape how society innovates, integrates information, analyzes data, and generates solutions.[2] In particular, AI has begun to play a critical role in the pharmaceutical industry by transforming drug discovery, manufacturing, diagnostics, and treatment.[3] But this technological revolution also comes with inherent uncertainty under the current United States patent system, especially about the patentability of inventions created by AI.[4] Although the purpose behind United States patent law is to encourage innovation, patent protection currently cannot be obtained for inventions created by AI.[5] Accordingly, industries such as the pharmaceutical industry, which require incentives to innovate, cannot realize these incentives without patent protection for inventions created by AI.[6] Therefore, to satisfy the need regarding incentives to innovate in the pharmaceutical industry, Congress must consider reforming the scope of patent protection to sufficiently encompass inventions created by AI.

This Note will focus on the current scope of patent protection under the U.S. patent system and issues of patentability for the pharmaceutical industry in the era of AI technology. The Note will first provide a background on AI technology and its application in the pharmaceutical industry. The background section of this Note will then discuss the brief history behind the U.S. patent law system and its development through legislation over time. This section further details

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[1] *Artificial Intelligence What it is and why it matters*, SAS, https://www.sas.com/en_us/insights/analytics/what-is-artificial-intelligence.html (last visited Oct. 27, 2021).

[2] Darrell M. West & John R. Allen, *How artificial intelligence is transforming the world*, BROOKINGS (Apr. 24, 2018), https://www.brookings.edu/research/how-artificial-intelligence-is-transforming-the-world/.

[3] Samantha McGrail, *AI in the Pharma Industry: Current Uses, Best Cases, Digital Future*, PHARMANEWSINTEL. (Apr. 30, 2021), https://pharmanewsintel.com/news/ai-in-the-pharma-industry-current-uses-best-cases-digital-future.

[4] Susan Decker, *One Man's Quest to Get an AI Machine a Patent Gathers Momentum*, BLOOMBERG L. NEWS (Aug. 8, 2021, 9:19 AM), https://www.bloomberg.com/news/articles/2021-08-21/one-man-s-quest-to-get-an-ai-machine-a-patent-gathers-momentum.

[5] *Id.*; Elif Kavusturan, *Reforming U.S. Patent Law to Enable Access to Essential Medicines in the Era of Artificial Intelligence*, 18 NW. J. TECH. & INTELL. PROP. 51, 78-79 (2020); U.S. CONST. art. I, § 8.

[6] Richard D. Nelson & Roberto Mazzoleni, *Intellectual Property Rights and the Dissemination Of Research Tools In Molecular Biology*, NCBI 17 (1996), https://www.ncbi.nlm.nih.gov/books/NBK233537/pdf/Bookshelf_NBK233537.pdf.

the current state of patent law on who may seek patent protection, which types of intellectual property are covered by patents, and the process of obtaining patent protection. This section concludes with a discussion of how inventions created by AI are classified and the limited patent protection currently offered for AI under the U.S. patent system. Section III of this Note analyzes the beneficial impact of AI in the pharmaceutical industry and calls for patent law reform to protect drugs invented by AI. In addition, Section III considers and rebuts potential arguments in resistance to AI patent protection. Section III further proposes reforms and solutions that Congress should consider to ensure that patent law will encompass and protect drug inventions created by AI. Finally, this Note concludes with a discussion of how expanding patent protection for AI in the pharmaceutical industry will efficiently incentivize innovation and promote public health.

II. BACKGROUND

A. NATURAL INTELLIGENCE VS. ARTIFICIAL INTELLIGENCE

Human beings are widely considered to hold the highest level of biological intelligence ever observed.[7] As rational beings, humans can solve various complex issues through experience and intuition, supplemented by rules of logic, decision analysis, and statistics.[8] This sort of biological or "natural" intelligence encompasses the ability to autonomously and efficiently accomplish complex goals that are restricted to "things that only humans can do."[9]

Natural intelligence is generated through biological neural networks of flesh and blood, which make up the human brain.[10] Unlike other forms of intelligence, natural intelligence has given humans the ability to learn, multitask, and combat various multifaceted situations over time.[11] Due to such an immense cognitive capacity, the human brain can solve various arithmetic, conceptual, spatial, economic, socio-organizational, and political problems.[12] Even though the natural intelligence of humans is high compared to other animal species, "in

[7] J.E.H. Korteling et al., *Human- versus Artificial Intelligence*, FRONTIERS A.I. (Mar. 25, 2021), https://doi.org/10.3389/frai.2021.622364.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] Shivangi Sinha & Anwesha Pathak, *Artificial Intelligence Vs Natural (Human) Intelligence-Global Challenge for Human Rights*, 14 INT'L J. APPLIED ENG'G RSCH. 18, 19 (2019), https://www.ripublication.com/ijaerspl2019/ijaerv14n7spl_05.pdf.
[12] Korteling et al., *supra* note 7.

absolute terms[,] it may be very limited in its physical computing capacity."[13] On the other hand, machine learning or AI has become the cornerstone of innovation and has built upon natural intelligence to replicate and exceed how humans perceive and react to the world.[14]

AI refers to systems or machines that mimic natural intelligence to perform tasks and can iteratively enhance themselves based on the information and data collected.[15] AI systems generally consist of several databases, operations, and control modules interacting in a complex fashion to form an automatic problem-solving system.[16]

AI systems may either be categorized as weak or strong AI.[17] Weak AI is designed to perform a single or "narrow" task and cannot solve other problems outside of its specific field.[18] Strong AI, on the contrary, is programmed to think and reason autonomously.[19] The quintessential form, or "holy grail," of AI technology is General AI, capable of solving issues and achieving goals just as well as humans through comparable cognitive, emotional and social behavior.[20]

Although many believe AI refers to human-like robots and machines, AI systems are not intended to replace the natural intelligence of human beings.[21] Conversely, the underlying purpose behind AI technology is to "significantly enhance human capabilities and contributions."[22] AI has significant advantages given its ability to solve problems at significant speeds, its ability to work 24/7, and its ability to collect information and formulate solutions without bias.[23] In particular, the development of machine learning technology has drastically transformed the effectiveness of AI systems.[24]

Machine learning is an analytical process in which an AI system autonomously derives rules and procedures from patterns within a data set and creates explanations or predictions.[25] These rules and patterns derived through

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[13] *Id.*
[14] *What is AI? Learn About Artificial Intelligence*, ORACLE CLOUD INFRASTRUCTURE (Oct. 1, 2021), https://www.oracle.com/artificial-intelligence/what-is-ai/.
[15] *Id.*
[16] NILS J. NILSSON, PRINCIPLES OF ARTIFICIAL INTELLIGENCE (SYMBOLIC COMPUTATION) 17 (Springer-Verlag eds., 1982).
[17] Kavusturan, *supra* note 5, at 57.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *What is AI? Learn About Artificial Intelligence*, *supra* note 14.
[22] *Id.*
[23] Sinha & Pathak, *supra* note 11, at 19.
[24] *See* Kavusturan, *supra* note 5, at 58 (outlining the use of machine learning technology, which has helped minimize expenses and increase efficiency).
[25] *Id.*

the machine learning process are then used to formulate and test hypotheses and solutions for an issue.[26] The capabilities of machine learning technology can significantly benefit researchers through AI technology's ability to focus on specific problems and offer solutions to various problems based on available data.[27]

The many advantages of AI technology and machine learning allow society to transform numerous industries, from autonomous cars to drug discovery.[28] In particular, the pharmaceutical industry has taken great interest in AI and its potential to drastically impact the field of medicine.[29] Traditionally, developing and discovering a novel targeted drug is a costly and long-term process, costing billions of dollars, with a development process exceeding ten years.[30] Discovering new drugs is extremely complex, as "[i]t requires navigating a combinatorial space of more than 10^{60} molecules [in order] to find a suitable drug candidate."[31] Despite such challenges, the digitization and advancement of AI technology—especially through machine learning—has considerably increased the potential of discovering new drugs.[32]

Implementing AI to aid in drug development, for instance, has allowed specialists to find a novel antibiotic, Halicin, and various other drug candidates, out of more than 100 million molecules, in a fraction of the time required by traditional methods.[33] In addition to antibiotics, AI has also been implemented to accelerate the search for the COVID-19 vaccine.[34] Therefore, AI technology has been proven to identify new drug molecules or new uses for old drugs.[35] The current advancements in AI technology have unquestionably boosted target drug discovery at an unprecedented speed, leading AI to be recognized as one of the "must-win technologies of the future."[36]

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[26] *Id.*
[27] *Id.*
[28] Decker, *supra* note 4.
[29] *See generally Augmented intelligence in health care*, AM. MED. ASS'N (2018), https://www.ama-assn.org/system/files/2019-01/augmented-intelligence-policy-report.pdf (discussing the potential effects of AI in healthcare).
[30] Benquan Liu et al., *Artificial intelligence and big data facilitated targeted drug discovery*, STROKE & VASCULAR NEUROLOGY 206 (Nov. 7, 2019), https://svn.bmj.com/content/svnbmj/4/4/206.full.pdf.
[31] Bowen Lou & Lynn Wu, *AI on Drugs: Can Artificial Intelligence Accelerate Drug Development? Evidence from a Large-Scale Examination of Bio-Pharma Firms*, MIS Q. 2 (citations omitted), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3524985 (last updated June 6, 2022).
[32] *Id.*
[33] *Id.*
[34] *Id.* at 3.
[35] Decker, *supra* note 4.
[36] *Id.*; *see also* Liu et al., *supra* note 30, at 212 (demonstrating how the integration of artificial

B. HISTORY OF PATENT LAW

The purpose of a patent is to offer protection to an inventor of "any new and useful process, machine, manufacture or composition of matter."[37] Holding a patent provides an owner of an invention with "the right to exclude others from making, using, offering for sale, or selling" the owner's invention in the U.S. or importing the owner's invention into the U.S.[38]

The foundation of U.S. patent law dates back to the medieval era in England, where kings and queens would grant exclusive rights, or monopolies, called "letters patents" over everyday goods.[39] These letters patents allowed the holders to possess exclusive control over the market for a particular good.[40] The holders of the letters patents had the power to search stores and houses of suspected infringers and collect penalties from any person caught selling goods in competition with the exclusive holder.[41] Nevertheless, in 1642, the English Parliament's enactment of the Statute of Monopolies effectively restricted the King from granting letters patents for common everyday goods.[42] But the statute allowed for monopolies over certain goods, particularly products that were new to England.[43] The Statute allowed holders to maintain their monopolies for 14 years to encourage merchants to invest in new products and inventions.[44]

In the late 1700s, during the drafting of the United States Constitution, English patent law became the accepted model for encouraging invention.[45] Under the accepted English model, the Framers of the Constitution vested Congress with the power "[t]o promote the progress and Science of useful Arts, by securing, for limited Times, to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[46] Authorized with this power, Congress enacted a sequence of comprehensive patent statutes in response to

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intelligence and big data has made a large impact in the discovery process of novel targeted drugs).

[37] 35 U.S.C. § 101.

[38] *General information concerning patents*, USPTO, https://www.uspto.gov/patents/basics/general-information-patents (last visited Oct. 26, 2021).

[39] Maurice M. Klee, *Where Did the U.S. Patent Laws Come From?*, 17 IEEE ENG'R MED. & BIOLOGY 135 (1998), https://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=646231.

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.* (quoting U.S. CONST. art. I, § 8).

the U.S.'s continued efforts and perceived need to encourage and foster innovation.[47]

Before 1836, patents in the U.S. could be granted to inventors without review or examination.[48] This practice proved to be noticeably ineffective, as the issue of patentability was left solely in the hands of the courts.[49] To address this issue, Congress established the Patent Office in 1836, vesting it with the power to conduct thorough examinations of proposed inventions and review "prior art" before a patent could be issued.[50] Congress also authorized the Patent Office to resolve disputes among inventors and disseminate technical information contained in patents to the public.[51]

In 1836, Congress mandated that all patent applications include a claim pinpointing exactly what the inventor considers to be their invention.[52] The examination procedures established by Congress created a "presumption of validity" for all issued patents, entitling patent owners to damages for infringement suits absent "any satisfactory proof to the contrary."[53] The presumption of validity was later codified in 1952 in the Patent Statute.[54] Despite the various developments and changes to patent law over time, inventors continue to take advantage of the patent system and undoubtedly use patent law as a catalyst for technological innovation.[55]

C. PATENT LAW TODAY

There is a recognized concern that inventors will lose motivation to innovate and invent without legal protection afforded by patent rights since any invention would be free to copy.[56] The American patent law system has long been hailed as a key to national innovation and a crucial incentive for inventors to create new inventions.[57] Under current U.S. patent law, a patent for an invention is generally considered to be a grant of a property right that is issued by the United States

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[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] *Id.* (citing 35 U.S.C. § 282).
[54] *Id.*
[55] *Id.*
[56] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS (2020).
[57] *Id.*

Patent and Trademark Office ("USPTO").[58] An inventor who successfully obtains patent protection is "[granted] 'the right to exclude others from making, using, offering for sale, or selling' the invention in the United States or 'importing' the invention into the United States."[59] Patent protection, however, does not include positive rights, but only the negative right to exclude others from copying a patented invention.[60]

Patent protection spans twenty years from the date the patent application was filed and is only applicable within the U.S. and U.S. territories.[61] Patent rights bear similar characteristics to rights in personal property and thus can be assigned or sold to others.[62] Patent rights are also commonly transferred to other parties through contractual agreements, known as license agreements.[63]

Obtaining patent protection begins with filing an application with the USPTO.[64] Upon filing an application with the USPTO, a patent examiner reviews the application to determine if the invention meets the requirements for patentability.[65] If a patent application meets all the requirements for patentability, then a patent may be issued to the inventor.[66] On the other hand, if an application fails to meet any of the requirements, then the application must be rejected.[67] When an examiner rejects a patent application, an inventor can amend their patent application to overcome the rejection.[68]

To obtain patent protection, an invention must satisfy specific requirements, including patentable subject matter, novelty, usefulness, and non-obviousness.[69]

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[58] *General Information Concerning Patents, supra* note 38.
[59] *Id.* (citation omitted).
[60] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 7 (2020).
[61] *General Information Concerning Patents, supra* note 38.
[62] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 7 (2020); *see, e.g.*, Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993) (articulating the principle that an inventor, who is initially vested with the patent rights of an invention, may transfer such patent rights to another, barring any restrictions to the contrary).
[63] *See* KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 7-8 (2020) (Licensing agreements involve a contractual agreement where a patent owner permits another party "to make, use, import or sell" their patented invention in exchange for payment).
[64] 35 U.S.C. § 111; *see* also *id.* (discussing the process of filing a patent application with the USPTO).
[65] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 9 (2020).
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Patentability Requirements*, JUSTIA, https://www.justia.com/intellectual-property/patents/patentability-requirements/ (last visited Oct. 27, 2021).

For an invention to be considered patentable subject matter, it must fall within one of the statutorily defined categories of subject matter under Section 101 of the Patent Act.[70] As specified under Section 101, an inventor may obtain a patent for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[71] But even with such a seemingly vast scope of patentable subject matter, "the Supreme Court 'has long held that this provision contains an implicit exception[].'"[72] That exception is that subject matter pertaining to "[l]aws of nature, natural phenomena, and abstract ideas are not patentable."[73]

Courts will therefore apply a two-part test to determine if the subject matter of a proposed invention falls under one of the Supreme Court's listed exceptions.[74] Under the first prong of the test, a court will decide whether the claimed invention is directed to one of the proscribed exceptions.[75] If so, the court must then move to the second prong of the test to discern whether the claimed invention includes an "inventive concept."[76] An inventive concept makes a claimed invention more than a mere patent based on a law of nature, natural phenomenon, or an abstract idea.[77] Examples of non-patentable subject matter include "books or music, electromagnetic signals, laws of nature, and other abstract ideas."[78] Additionally, patent protection is only granted to novel or new inventions. A claimed invention must meet the novelty requirement prescribed under Section 102 of the Patent Act.[79] In general, "[a] person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention . . . ."[80] A patent,

[70] 35 U.S.C. § 101.
[71] *Id.*
[72] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 14 (2020) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 70 (2012)).
[73] *Mayo Collaborative Servs.*, 566 U.S. at 70 (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981)).
[74] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 14 (2020) (citing ChargePoint, Inc. v. SemaConnect, Inc., 920 F.3d 759, 765 (Fed. Cir. 2019)).
[75] *Id.* (citing Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014)).
[76] *Id.*
[77] *Id.*
[78] *Patentability Requirements*, *supra* note 69.
[79] 35 U.S.C. § 102.
[80] 35 U.S.C. § 102(a)(1).

therefore, will be rejected for lack of novelty if all features of an invention can be found within a single earlier patent.[81]

A USPTO examiner will determine the lack of novelty for a claimed invention by relying on "prior art" to establish what was known at the time of the applicant's claimed invention.[82] For an examiner to sufficiently show a lack of novelty, or patent "anticipation," it must point to a single reference that discloses all the limitations in a patent claim.[83] Markedly, an exception may be employed if a disclosure is made one year or less prior to the effective filing date of the claimed invention.[84] Although, such exceptions apply only if "the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed . . . from the inventor or a joint inventor."[85] Ultimately, the dispositive question about the anticipation of a claimed patent "[i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference's] teaching that every claim element was disclosed in that single reference."[86] The USPTO examiner, thus, has the burden of proving that a claimed invention lacks novelty; however, it is the inventor's responsibility to search prior patents before filing with the USPTO.[87] The fundamental purpose underlying the novelty requirement is to prevent prior art from becoming patented again and preserve the rights of prior patent holders.[88]

Furthermore, to receive a patent, the subject matter of a claimed invention must be useful.[89] Although the question of beneficial or moral use has not typically barred patent applications, logic and facts must support the claimed utility of an invention.[90] Generally, a claimed process, machine, or composition must achieve an intended purpose in the real world to satisfy the usefulness requirement.[91] Principally, the utility of a claimed invention cannot apply to a broad class of inventions but must instead apply specifically to the subject matter

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[81] *Patentability Requirements*, *supra* note 69.
[82] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 15 (2020) (citing 35 U.S.C. § 102).
[83] *Id.* (citing Acoustic Tech., Inc. v. Itron Networked Sols., Inc., 949 F.3d 1366, 1373 (Fed. Cir. 2020)).
[84] *General Information Concerning Patents, supra* note 38.
[85] 35 U.S.C. § 102(b)(1)(A).
[86] Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1368 (Fed. Cir. 2003) (citations omitted).
[87] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 15 (2020); *Patentability Requirements*, *supra* note 69.
[88] *Patentability Requirements*, *supra* note 69.
[89] *Id.*
[90] *Id.; Patent*, *Legal Information Institute*, CORNELL L. SCH., https://www.law.cornell.edu/wex/patent (last visited on Oct. 27, 2021).
[91] *Patent*, *supra* note 90.

of the claimed invention.[92] An alleged utility that allows a researcher to discover further or identify the real-world use of the claimed invention is not sufficient.[93] To satisfy the utility requirement, an inventor must ultimately show a specifically defined real-world use of their invention.[94]

Lastly, a claimed invention must satisfy the requirement of non-obviousness to qualify as patentable.[95] Section 103 of the Patent Act outlines the non-obviousness requirement, which provides that a patent cannot be granted for inventions that are "obvious extension[s] of the prior art."[96] The Supreme Court has dictated four factors that must be considered in deciding whether prior art renders a claimed invention as obvious.[97] The first factor considered is the scope and content of the prior art.[98] Next, an examiner will consider any differences between the prior art and the claimed invention.[99] Third, an examiner will then consider the level of ordinary skill of a person in the art.[100] Finally, an examiner must account for any secondary considerations of non-obviousness.[101] Secondary considerations may include commercial success, long-felt but unsolved needs, and the failure of others to create the invention, which may provide evidence of whether the claimed invention would have been obvious at the time of invention.[102] A claimed invention will fail to meet the requirement of non-obviousness if "someone knowledgeable about the area would look at [the claimed] invention and consider it to be already known; not exactly but rather known if one were to combine several references."[103]

AI has become an increasingly robust tool of innovation within modern industries.[104] Some analysts suspect it will only be a short time until AI is responsible for most inventions.[105] Yet under current patent law in the U.S., only

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[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 16 (2020) (citing Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966)).
[96] *Id.* (citing 35 U.S.C. § 103).
[97] *Id.* (citing *Graham*, 383 U.S. at 1, holding that the non-obviousness of a claimed invention may be determined through four basic factual inquiries).
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*
[103] Gene Quinn, *Patentability: The Nonobviousness Requirement of 35 U.S.C. 103*, IP WATCHDOG (June 17, 2017, 10:00 AM), https://www.ipwatchdog.com/2017/06/17/patentability-nonobviousness-35-usc-103/id=84716/.
[104] W. Michael Schuster, *Artificial Intelligence and Patent Ownership*, 75 WASH. & LEE L. REV. 1945, 1947 (2018).
[105] *Id.*

a "natural person" may be listed as the inventor or joint inventor when obtaining patent protection.[106] Given these inventorship requirements, the question has emerged of whether AI-created machines may qualify as an inventor of a patent.[107] Congress has yet to address this looming question of whether and to whom patent protection can be granted for AI inventions.[108] Furthermore, the USPTO has not provided any internal guidelines regarding domestic policy on AI inventions.[109] The patentability of AI-created inventions has thus become a pressing issue for U.S. Courts.[110]

The U.S. District Court for the Eastern District of Virginia issued an opinion—*Thaler v. Hirshfeld*—on September 2, 2021, regarding the patentability of inventions created by AI.[111] The court held that AI-created machines could not be considered an "inventor" under current U.S. patent law.[112] The court specified that the definitions of "inventor" and "joint inventor" under the Patent Act reference an "individual" or "individuals."[113] The court expressed that whether AI-created machines could classify as an inventor depends on the plain meaning of the statutory term "individual."[114] The court ultimately determined that Congress was clearly referencing natural persons through the use of personal pronouns when discussing the term "individual" under the Patent Act.[115] Despite the court holding that an "inventor" for a patent must be a natural person, it expressed that "there may come a time when artificial intelligence reaches a level of sophistication such that it might satisfy accepted meanings of inventorship . . . and, if it does, it will be up to Congress to decide how . . . it wants to expand the scope of patent law."[116]

The U.S. Court of Appeals for the Federal Circuit affirmed the Eastern District of Virginia's decision in *Thaler*, holding that "[t]he Patent Act requires that inventors must be natural persons . . . ."[117] The Federal Circuit further reasoned that the Patent Act unambiguously uses personal pronouns, such as

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[106] *See* KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 10 (2020) (citing Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. Cir. 1993), specifying that only natural persons may be declared inventors).
[107] *Id.*
[108] Schuster, *supra* note 104, at 1948.
[109] *Id.*
[110] *Id.* (discussing Thaler v. Hirshfeld, 558 F. Supp. 3d 238 (E.D. Va. 2021), *aff'd*, Thaler v. Vidal, 43 F.4th 1207 (Fed Cir. 2022)).
[111] *Thaler*, 558 F. Supp. 3d at 238.
[112] *Id.* at 247.
[113] *Id.* at 246 (citing 35 U.S.C. § 100(f)-(g)).
[114] *Id.* at 245.
[115] *Id.* at 246 (citing 35 U.S.C. § 100(f)).
[116] *Id.* at 249.
[117] Thaler v. Vidal, 43 F.4th 1207, 1210 (Fed. Cir. 2022).

"himself" and "herself," to refer to an "individual" and does not include pronouns such as "itself," which Congress would have used if it intended to permit non-human inventors.[118]

III. ANALYSIS

A. SAVING LIVES THROUGH ARTIFICIAL INTELLIGENCE

Discovering new drugs is daunting and largely considered to be the most challenging part of drug research and development ("R&D").[119] Despite such challenges, AI and machine learning can help address the intractable search problem in discovering new drug candidates.[120] AI excels at automating projections and identifying hidden patterns or trends in data sets.[121] AI can also facilitate recombination, which helps accelerate the discovery of novel chemical compounds under certain conditions.[122] These capabilities allow AI to screen compounds 100 times faster than humans using conventional approaches.[123] AI technology has become a versatile tool that can be applied ubiquitously during the different stages of drug development.[124] AI has proven beneficial in identifying and validating drug targets, designing new drugs, repurposing drugs, and improving R&D efficiency.[125] AI is helping to counter the inefficiencies and uncertainties that arise when applying classical drug development methods.[126]

Developing new drugs or drug compounds is an exceedingly complex and expensive process.[127] It is estimated that developing new drugs costs about 2.6 billion USD and takes an average of 12 years.[128] As a result, reducing costs and

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[118] *Id.* at 1211.
[119] Kit-Kay Mak & Mallikarjuna R. Pichika, *Artificial intelligence in drug development: present status and future prospects*, 24 DRUG DISCOVERY TODAY 773, 775 (2019), https://reader.elsevier.com/reader/sd/pii/S1359644618300916?token=D33D9690225DD4AC9E3681459EC322F573B94D6891A148E0EE722E9191A6BE8C9D7F16717907B1604010927E1CFE8E98&originRegion=us-east-1&originCreation=20221023154127.
[120] Lou & Wu, *supra* note 31, at 1452.
[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] Mak & Pichika, *supra* note 119, at 773.
[125] *Id.*
[126] *Id.* at 776.
[127] *Id.*
[128] H.C. Stephen Chan et al., *Advancing Drug Discovery via Artificial Intelligence*, 40 TRENDS IN PHARMACOLOGICAL SCIS. 592 (2019), https://reader.elsevier.com/reader/sd/pii/S016561471930135X?token=F069E912D747036E100481B4BBD5FD76D58B7CD9181619C8C52E9B168E139D9028CCA322688581730BC15C14556CBF18&originRegion=us-east-1&originCreation=20221010221649.

speeding up R&D are currently central concerns for nearly all pharmaceutical companies.[129] Researchers have found that implementing AI can reduce the time of the clinical research phase by 40% to 50% and reduce costs for U.S. pharmaceutical companies by as much as $54 billion in R&D costs annually.[130] AI has the potential to transform drug discovery by accelerating the R&D timeline in an attempt to make drugs more affordable and increase the probability of obtaining Food and Drug Administration approval.[131] The increasing application of AI in the pharmaceutical industry will reduce costs and enable faster development of more effective drugs.[132] Accordingly, improvements in the pharmaceutical industry will help lead to better accessibility to drug innovations for consumers and an overall healthier world.[133]

B. DEMAND FOR REFORM

AI has become a fundamental part of society, especially in the pharmaceutical industry.[134] In particular, AI technology has become essential in developing new drugs, vaccines, and forecasting programs.[135] Therefore, obtaining patent protection for these non-obvious solutions is a critical step in fostering R&D, large investments, and the commercial process of pharmaceuticals.[136] As U.S. patent law currently stands, only human inventors are eligible for patent ownership.[137] AI inventions pose challenges for the current patent law regime, which was established in an era prior to the creation of AI technology.[138] For this reason, U.S. patent law reform is needed to make pharmaceutical inventions created by AI patentable. Allowing AI to seek patent protection for inventions will therefore incentivize pharmaceutical companies and encourage investments in AI technology for drug R&D.[139]

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[129] *Id.*
[130] Kevin Gawora, *Fact of the Week: Artificial Intelligence Can Save Pharmaceutical Companies Almost $54 Billion in R&D Costs Each Year*, INFO. TECH. & INNOVATION FOUND. (Dec. 7, 2020), https://itif.org/publications/2020/12/07/fact-week-artificial-intelligence-can-save-pharmaceutical-companies-almost/.
[131] McGrail, *supra* note 3.
[132] Gawora, *supra* note 130.
[133] *Id.*
[134] Decker, *supra* note 4.
[135] Shlomit Yanisky-Ravid & Regina Jin, *Summoning a New Artificial Intelligence Patent Model: In the Age Of Crisis*, 2021 MICH. ST. L. REV. 811, 814 (2021).
[136] *Id.* at 816.
[137] *Id.*
[138] *Id.* at 818.
[139] *Id.* at 821.

C. RESISTANCE TO ARTIFICIAL INTELLIGENCE PATENT PROTECTION

Despite the growing application of AI technology, there is still resistance against allowing AI to obtain patents for inventions, given the view that AI does not fit within the purposes of U.S. patent law.[140] The first common point of resistance against expanding the patent system to encompass AI is the argument that AI patents may prevent latecomers from using or improving upon such patented inventions.[141] Despite the concern of exclusivity through patent protection, "the patent right is not equal to the monopoly in an antitrust sense."[142] The demand for incentives to promote new drug inventions through patent protection is essential in some instances, such as during a health crisis when no other efficient alternatives are available.[143] Moreover, patenting AI inventions will not necessarily prevent pharmaceutical companies from licensing out the rights to inventions created by AI to other pharmaceutical manufacturers and researchers.[144] The licensing of AI patents can effectively accommodate public interests—depending on the urgency and necessity of the invention's purported use—to ensure public access to life-saving pharmaceuticals.[145]

Another common point of resistance against patent law expansion is the question of whether patents actually incentivize innovation in today's society.[146] Executives within the pharmaceutical industry have reported that 60% of new pharmaceuticals would not have been developed without patent protection.[147] The balancing of access and incentivization is essential in the pharmaceutical industry.[148] Therefore, pharmaceutical companies need patent incentives to induce R&D activities, especially with the growing application of AI technology.[149]

Another common sentiment in resistance to the expansion of patent law is the fear that encouraging patent protection of pharmaceuticals invented by AI will, in turn, boost price gouging and hinder further innovation by latecomers.[150]

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[140] *See* Thaler v. Hirshfeld, 558 F. Supp. 3d 238, 249 ("[P]laintiff's policy arguments do not override the overwhelming evidence that Congress intended to limit the definition of 'inventor' to natural persons.").
[141] Yanisky-Ravid & Jin, *supra* note 135, at 854-55.
[142] *Id.* at 855.
[143] *Id.*
[144] *Id.*
[145] *Id.*
[146] *Id.* at 857.
[147] Nelson & Mazzoleni, *supra* note 6, at 20.
[148] Kavusturan, *supra* note 5, at 79.
[149] Yanisky-Ravid & Jin, *supra* note 135, at 857.
[150] *Id.* at 859.

On the contrary, the prohibition of AI patentability would hinder innovation and drug R&D, as it would prevent pharmaceutical companies from earning sufficient profits and recouping decade-long R&D costs through patent protection.[151] In addition, prohibiting patent protection for inventions created by AI would divest pharmaceutical companies of necessary incentives to innovate with such pivotal technology.[152] Conversely, some argue that other types of intellectual property rights, such as trade secrets, are better alternatives within AI.[153] Patent protection, however, remains the most exclusive, definite, and encompassing form of intellectual property protection.[154] Trade secrets do not present incentives to innovate, nor do they induce the dissemination of information, as patent disclosure offers through licensing or upon patent expiration.[155] Therefore, patent protection is the best method for incentivizing innovation while allowing public access to patented information.[156]

D. Future Development: Protecting Artificial Intelligence Inventions

The goal of patent law is to provide incentives for innovation and benefits for the public.[157] Nevertheless, the current uncertainty and lack of comprehensive policies regarding patentability in the era of AI have made the reform of U.S. patent law inevitable.[158] That being said, Congress must adhere to the U.S. Constitution in deciding patent protection.[159] Furthermore, any patent law reform must comply with the Agreement on the Trade-Related Aspects of Intellectual Property Rights ("TRIPS").[160] Congress, however, remains free to amend the scope and breadth of patent rights.[161] Congress can, for example, impose conditions on patent rights, limit duration, refuse to grant

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[151] *Id.*
[152] *Id.*
[153] *Id.* at 857.
[154] *Id.*
[155] *Id.* at 858.
[156] *Id.*
[157] Kavusturan, *supra* note 5, at 78.
[158] Decker, *supra* note 4, at 5.
[159] Kavusturan, *supra* note 5, at 81.
[160] *Id.*; *see also Overview: the TRIPS Agreement*, World Trade Org., https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#patents (last visited Oct. 16, 2022) (illustrating how "[t]he TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability").
[161] Kavusturan, *supra* note 5, at 81.

privileges or only grant rights for specific industries.[162] There are several proposals, described in the following sections, that Congress may consider regarding the standard of patentability and patent exclusivity in the context of AI technology.

1. Standard of Patentability

Given the current standards of U.S. patent law, only "natural persons" may be listed as the inventor or joint inventor when seeking or obtaining patent protection.[163] Congress should consider redefining the inventorship standard to sufficiently allow AI to be encompassed under U.S. patent law. Under the proposed reform, U.S. patent law would be expanded to include any inventor or joint inventor who is a natural person or AI system with the capacity to make decisions and mimic natural intelligence autonomously. If Congress deems the proposed patent inventorship requirement to be excessively broad, it may limit the inventorship standard to encompass only AI systems in the pharmaceutical industry. Redefining the inventorship standard will incentivize pharmaceutical companies to innovate and promote access to life-saving pharmaceuticals.[164]

2. Patent Exclusivity

Under U.S. patent law, an inventor may enjoy the exclusivity of patent protection for 20 years.[165] If patent law is reformed to extend patent protection to AI, Congress may express concerns about price gouging and stifling innovation of latecomers who may attempt to develop similar drugs.[166] Given the concerns of price gouging and hindered innovation, the exclusivity period for drugs invented by AI could be limited to 10 to 12 years. While a shortened exclusivity period will allow for quicker information dissemination of life-saving drugs, the proposed patent lifetime is long enough to allow pharmaceutical companies to recoup their decade-long R&D costs.[167]

Furthermore, under the proposed reforms, Congress will be provided with the option to implement compulsory licensing for essential, life-saving drugs invented by AI. Compulsory licensing occurs when the government licenses the rights of a patent to other companies or individuals without the patent owner's

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[162] *Id.*
[163] KEVIN T. RICHARDS, CONG. RSCH. SERV., R46525, PATENT LAW: A HANDBOOK FOR CONGRESS 10 (2020).
[164] Yanisky-Ravid & Jin, *supra* note 135, at 859.
[165] *General Information Concerning Patents, supra*, note 38.
[166] Yanisky-Ravid & Jin, *supra* note 135, at 859.
[167] *Id.*

permission.[168] Although the U.S. patent system has generally taken a hostile approach to compulsory licensing, pharmaceutical-specific price regulations have been previously contemplated.[169] Thus, compulsory licensing of essential medicines patented by AI may assist with public access to essential drugs and mitigate risks of inflated prices and price gouging.[170]

IV. CONCLUSION

AI technology can significantly enhance the capability of human beings, and countless industries have begun to implement AI to help advance innovation.[171] The pharmaceutical industry, in particular, has taken a significant interest in AI because of its potential to drastically improve the field of medicine through R&D, large investments, and the commercial process.[172] This increased application of AI, however, comes with the issue of whether inventions created by AI may obtain patent protection under the U.S. patent system.[173] Congress has not yet addressed this issue, and the USPTO has no internal guidelines regarding domestic policy on AI inventions.[174] The U.S. District Court for the Easter District of Virginia and the U.S. Court of Appeals of the Federal Circuit are the only U.S. Courts to address the issue of AI patentability in the recent ruling of *Thaler v. Hirshfeld*.[175] While both the Eastern District of Virginia and the Federal Circuit ultimately held that AI-created machines could not be considered an "inventor" under U.S. patent law, these holdings seemingly leave the door open for Congress to decide how it wants to amend or expand the scope of patent protection in the era of AI.[176]

Reforming the scope of the patent system will give Congress the authority it needs to properly incentivize the innovation and development of novel drugs

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168 William A. Reinsch, *Compulsory Licensing: A Cure for Distributing the Cure?*, CTR. FOR STRATEGIC & INT'L. STUD. (May 8, 2020), https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure.
169 Justin Culbertson & Jason J. Jardine, *Compulsory patent licensing in the era of pandemic*, INT'L BAR ASS'N, https://www.ibanet.org/article/36A60309-5A33-4891-8624-86A6D89A251E (last visited Nov. 26, 2021).
170 Reinsch, *supra* note 168.
171 *What is AI? Learn About Artificial Intelligence*, supra note 14.
172 *Augmented intelligence in health care*, *supra* note 29; Yanisky-Ravid & Jin, *supra* note 135, at 811.
173 Schuster, *supra* note 104, at 1948.
174 *Id.*
175 Thaler v. Hirshfeld, 558 F. Supp. 3d 238 (E.D. Va. 2021), *aff'd*, Thaler v. Vidal, 43 F.4th 1207 (Fed Cir. 2022) (holding that AI-created machines cannot be an "inventor" under current U.S. patent law).
176 *Id.* at 238, 43 F.4th at 1207.

and medicines. The demand for incentives to innovate in the pharmaceutical industry is evident, and Congress must address this demand by expanding patent protection to sufficiently encompass AI technology.