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Patenting Artificial Intelligence: Issues of Obviousness, Inventorship, and Patent Eligibility

Susan Y. Tull and Paula E. Miller*

Patent protection must keep pace with the growing applications of artificial intelligence in medical and pharmaceutical technologies. The rise of "thinking machines" raises questions regarding the application of personhood to patent law, including the definition of a "person" of skill in the art, predictability, inventorship, and subject matter eligibility. This article will address these questions in light of the recent technological advances.

Artificial intelligence ("AI") is rapidly transforming the world of medicine, as the recent decades have marked a surge in the development of medical AI.¹ These thinking machines are now used in diagnosis, treatment, and drug development. As the technology advances, so too must our understanding of patent law and patent protection. The use of AI in these fields raises several issues, all hinging on the question of personhood and human contributions, affecting both inventorship (and ownership) and patentability (including subject matter eligibility and predictability). This article addresses these questions in turn after addressing the recent advances in medical AI.

Artificial Intelligence in Medicine

AI techniques utilized in medicine include artificial neural networks, fuzzy expert systems, evolutionary computation, and hybrid intelligent systems.²

Artificial neural networks are used extensively in clinical diagnosis and image analysis because of the parallel processing power that allows the networks to learn from historical examples and known patterns.³ Artificial neural networks have been used for diagnosing prostates as benign or malignant, cervical screening, and imaging analysis (including radiographs, ultrasounds, CTs, and MRIs), as well as for analyzing heart waveforms to diagnose conditions such as atrial fibrillation and ventricular arrhythmias.⁴

For example, researchers at Stanford University trained a deep convolutional neural network to classify skin lesions into either benign or malignant groupings based on known images, using only pixels and disease labels as inputs.⁵ The researchers started with an algorithm developed by Google to perform image recognition⁶ and then trained their neural network to recognize skin cancer using 129,450 clinical images of 2,032 different diseases.⁷ The neural network was then tested against board-certified dermatologists on clinical images that had been confirmed through biopsy.⁸ The AI performed on par with the certified dermatologists, demonstrating that the AI was capable of classifying skin cancer with the same level of competence as the trained dermatologists.⁹

As yet another example, medical chatbots utilize neural networks to learn from medical textbooks, scientific research, patient records, and messages between actual patients and doctors.¹⁰ The AI chatbot is constantly learning and can be kept up to date on the latest medical research.¹¹ Baidu, a Chinese search engine, utilizes a chatbot named Melody within its Baidu Doctor app.¹² When a patient asks a question to the doctor, the chatbot asks appropriate follow-up questions to help learn more about the patient's symptoms so the doctor can make a more informed decision on treatment.¹³ Interventional radiologists at the University of California at Los Angeles have developed a chatbot to assist physicians in providing real-time evidence-based answers to the patient about the next phase of treatment, or information about their interventional radiology treatment.¹⁴

Fuzzy logic AI is applicable in medicine because diseases, symptoms, and diagnoses are described in imprecise and terms.¹⁵ Because fuzzy logic rests on the premise that everything is a matter of degree, it can recognize "partial truth logics," beyond just the true and false values applied in traditional programming.¹⁶ Fuzzy logic AI has been applied to cancer diagnosis for lung cancer, acute leukemia, breast cancer, and pancreatic cancer.¹⁷ Fuzzy logic has been applied to diagnosis of other conditions, including tuberculosis, aphasia, arthritis, and hypothyroidism.¹⁸

"Evolutionary computation is the general term for several computational techniques based on natural evolution process that imitates the mechanism of natural selection and survival of the fittest in solving real-world problems."¹⁹ Genetic algorithms are the

most widely used form of evolutionary computation in medicine, creating numerous solutions to a single problem, and then evolving those solutions from one generation to the next to arrive at the best solution.²⁰ Evolutionary computation has been used in diagnosis, prognosis, imaging, and signal processing.²¹

Combining these AI techniques generates hybrid intelligent systems that incorporate the advantages of each technology.²² For example, the combination of neural networks and fuzzy logic or "neuro-fuzzy" systems have become popular because they can absorb some of the "noise" generally present in the neural network.²³

Uncertainties in Patenting Al—Subject Matter Eligibility

As the use of AI in medicine becomes ever more prevalent, the patent system must answer increasingly difficult questions regarding the protection afforded these technologies. Perhaps the most significant question is that of subject matter eligibility. With the Supreme Court decisions in *Alice* and *Mayo*, the hurdle to meet subject matter eligibility has grown ever higher.²⁴

Subject matter eligibility is one of the core criteria for receiving a patent, in addition to novelty and nonobviousness. An invention must contain patent-eligible subject matter in order to receive patent protection. 35 U.S.C. § 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." Abstract ideas, laws of nature, and natural phenomena are excluded from patentable subject matter.²⁵ The U.S. Supreme Court has further enunciated the requirement for subject matter eligibility, ultimately laying out a two-part test that must be met by any claimed invention.

In *Mayo*, the Supreme Court invalidated issued patent claims directed to the relationship between the concentrations of certain metabolites in the blood and the likelihood that a drug dosage would prove ineffective or cause harm for failing to meet this requirement.²⁶ The Supreme Court held that the claims were not subject matter eligible under 35 U.S.C. § 101 because the claims provided "instructions [that] add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field."²⁷ According to

the Court, the dosage limits at which a drug would prove ineffective or cause harm was a law of nature that was unpatentable, and the claims merely instructed doctors to apply this law of nature using techniques that were already known.

Alice addressed the holding in *Mayo*, further enunciating a two-step test for subject matter patent eligibility: (1) determine whether the claims are directed to a patent-ineligible concept (laws of nature, abstract ideas, and natural phenomena); and (2) determine whether the claim's elements, considered both individually and as an ordered combination, transform the nature of the claims into a patent-eligible application.²⁸ If a claim is directed to a patent-ineligible concept and the claim's elements do not transform the nature of the claim, then it will fail to meet § 101.

These two Supreme Court cases present a hurdle that medical AI inventions will have to overcome in order to receive patent protection. Current AI medical device/system patents can be directed to both the methods and apparatuses that perform the abovedescribed analyses. Many AI medical patents are directed to the AI algorithms and the machines used to generate those algorithms.²⁹ As described above, AI has been found to be extremely successful in diagnosis and prognosis, relating known images to new cases and extrapolating based on the similarities or differences between the two. In some instances, this is the same process followed by a doctor or medical expert, just with greater efficiency or accuracy. The steps for diagnosis struck down in Mayo echo the steps taken in many medical AI algorithms. Practitioners and inventors alike will need to carefully consider the full scope of eligible subject matter in order to ensure that a patent can be obtained from the U.S. Patent and Trademark Office ("PTO") and maintained through any subsequent challenges.

Indeed, the Federal Circuit has already found revolutionary diagnostic technology to be patent-ineligible subject matter under the *Mayo/Alice* framework. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the court concluded that a novel method of prenatal diagnosis of fetal DNA was not directed to patent-eligible subject matter, despite agreeing that the claimed method "reflects a significant human contribution ... that revolutionized prenatal care."³⁰ The patent claims were generally directed to detecting the presence of cell-free fetal DNA was a natural phenomenon, the court turned to the second step in the *Mayo/Alice* framework—whether the claim

contained an inventive concept sufficient to transform the naturally occurring phenomenon into patent-eligible subject matter.³¹ The court found that the second step was not met because the method steps "were well-understood, conventional, and routine," despite acknowledging their breakthrough nature.³²

More recently, the Federal Circuit found methods for detecting myeloperoxidase ("MPO") in blood, and correlating the results to cardiovascular risk, to be directed to patent-ineligible subject matter in *Cleveland Clinic Foundation v. True Health Diagnostics LLC.*³³ Although Cleveland Clinic argued that the discovery of the correlation was groundbreaking, the Federal Circuit affirmed the district court's decision that the correlation between MPO levels in blood and cardiovascular disease was a law of nature.³⁴ The court noted that Cleveland Clinic had not invented any new and useful laboratory technique to detect MPO levels.³⁵ In the second step, the court found the claims applied well-known techniques to determine the level of MPO and applied established statistical methods to make the correlation.³⁶

Although the Supreme Court cautioned against construing the exclusionary principle of § 101 overbroadly, "lest it swallow all of patent law,"³⁷ many believe it has done just that in the life sciences and medical spaces.³⁸ The concurring opinion in *Ariosa* echoed these concerns, stating that "[b]ut for the sweeping language in the Supreme Court's *Mayo* opinion, [there was] no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible."³⁹ The same reasoning could well curtail the patent protections afforded medical AI absent a change in Supreme Court precedent or statute. Until such a change occurs, AI inventors and owners must draft their patents with an eye to this two-step test, including features related to the AI in the claims, such as detailing the computing or mathematical techniques applied by the system or describing how the computer interacts with other components to drive the AI processing.

Uncertainties in Patenting Al—Inventorship/ Ownership

Patenting AI also raises questions of inventorship and ownership. The U.S. patent system only recognizes individuals as inventors,⁴⁰ not companies⁴¹ or machines.⁴² Inventorship is determined by conception, or "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention."⁴³ The use of AI, particularly deep machine learning or self-evolving and coding AI, raises questions as to who (or what) conceived of the invention and should thus be named as an inventor.

Indeed, AI has already advanced to the point where the AI itself is generating new inventions, as opposed to a human programmer or logic developer.⁴⁴ This can especially be the case where AI systems develop their own code as a result of the system's training.⁴⁵ Recently, both Google and Facebook have seen their respective AI systems develop new languages to perform the assigned tasks, eschewing known human languages in favor of a more efficient means of communication.⁴⁶ As the use of AI grows in medicine and the life sciences, it is more and more likely that the AI will be the entity taking the inventive step, drawing new conclusions between the observed and the unknown, and creating new programming to further identify and exploit those connections.⁴⁷

As AI continues to advance, the PTO will receive more patent applications in which AI could be considered the inventor, or at least a co-inventor. The PTO and the courts will have to decide whether the current Patent Act encompasses computer-based inventors. Some have already advocated that computers should qualify as legal inventor.⁴⁸ Some have argued that AI will soon "displace humans from the inventive process altogether"⁴⁹ and thus no patent protection should be given unless a human provides a material contribution to the conception of an invention.⁵⁰ Of note, in copyright law, regulation prevents copyright protection being granted to works produced solely by a machine "without any creative input or intervention from a human author."⁵¹ It remains to be seen whether the PTO will adopt this strict requirement of human intervention or collaboration.

If the PTO and courts determine that patent protection will not be granted to an AI, then who among the humans responsible for the AI should be considered an inventor?⁵² The list of possible human inventors includes the AI software and hardware developers, the medical professionals or experts who provided the data set with known values or otherwise provided input into the development of the AI, and/or those who reviewed the AI results and recognized that an invention had been made. The predictability of the inventive concept may also be a factor. If the programmer developed an AI with a specific goal in mind, and it was predictable that the AI would generate the result, then the person is likely to have had the inventive concept, using the AI as a tool to reduce the idea to practice.⁵³ If the result is not predictable, the question remains if it is sufficient for inventorship that the person recognized the significance of the result and recognized it as novel and patentable.

Similarly, AI may confuse the question of ownership for medical inventions generated by the AI itself. Patent ownership often turns on the question of inventorship⁵⁴ (followed by assignment), and thus will be equally complicated when AI develops its own code and conceives its own inventions. One approach would be to allow AI-inventors to be designated as the first owner, requiring assignment and licensing of all inventions.⁵⁵ Another approach would be to allow the computer's owner or the algorithm's owner to be the first owner, separating inventorship from ownership from the beginning.⁵⁶

Given that AI can continue to advance after its initial programming, the question of inventorship and ownership may have to be answered years after the initial system programming. Development, assignment, and employment contracts will have to account for this possibility of continued and ongoing AI invention and thus ownership.

Uncertainties in Patenting Al—Who is the Person of Skill in the Art?

One additional question that must be answered in patenting AI is who is the person of ordinary skill in the art, the programmer, the AI, or some other human contributor? The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention and is a construct applied to multiple patentability analyses, including obviousness and enablement.⁵⁷

This hypothetical person is not deemed to have the knowledge level of the inventor, just the ordinary knowledge of a person skilled in the field or technology of the subject matter of the patent. Although the concept of a person of ordinary skill in the art knowing all the relevant art was always a legal fiction, as AI systems become more prevalent, this fiction may approach the realm of fact. AI is capable of sorting and storing vast databases of knowledge and accessing that information at speeds far outside the realm of human capabilities. At some point, AI may become the "person" of skill in the art, possessing actual knowledge of all known publications, patents, and prior art, transforming the hypothetical construct into reality.⁵⁸ If the AI alone is not determined to be the person of ordinary skill in the art, it may also be determined that the hypothetical skilled person should be elevated to a person equipped with an AI system.⁵⁹ Thus, the ability and knowledge of a person of skill in the art may be elevated to match the sophistication of the AI.

Elevating the standard of a person of ordinary skill in the art could impact multiple doctrines within patent law, including novelty, obviousness, and enablement, which are all determined from the perspective of a person of ordinary skill in the art. The test for non-obviousness takes into account the level of skill of the person of ordinary skill in the art and applies that perspective to determine if the difference between the invention and the prior art is obvious. If the person of ordinary skill in the art has a greater skill level and knowledge of prior art, it would be more difficult to argue that an invention was non-obvious over the prior art.⁶⁰ For more predictable areas of technology, modifications over the prior art that work in predictable way are already considered obvious. If it becomes predictable that an AI can generate inventive results, such as through brute force trial-and-error, it will be more difficult to argue that the invention is non-obvious, even where the "finite number of identified, predictable solutions" is beyond that of human calculation.⁶¹

In addition, this question as to the person of ordinary skill in the art implicates the requirement that a patent claim be enabled. To satisfy enablement, a patent's specification must disclose the invention in sufficient detail to enable a person of ordinary skill in the art to make it without undue experimentation. If the AI can predict a result without experimentation using less information than it would take a human being, then significantly less information may be required in a disclosure to enable the claims, compared to today's standard.

Conclusion

As the use of AI in medicine grows ever more prevalent and sophisticated, it is becoming inevitable that these questions will have to be answered by Congress, the PTO, or the courts.

In developing new applications, patent drafters should keep in mind the ideas surrounding subject matter eligibility, inventorship, ownership, as well as the skill level of the person of ordinary skill in the art. The most pressing question to be resolved is that of subject matter eligibility, so that innovation in this burgeoning field is not stifled. From there, the definitions of "person," "inventor," and "individual" will have to be revisited, so that our understanding of inventorship and ownership evolves with this rapidly advancing technology. Also, the question of the skill level of the person of ordinary skill in the art may have to be answered irrespective of whether an AI is recognized as an inventor or not. Early recognition and resolution of these thinking machines.

Notes

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3. *Id.*

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20. Id.

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22. Id. at 337.

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24. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

25. Alice, 134 S. Ct. at 2354.

26. Mayo, 566 U.S. at 69.

27. *Id.; see also id.* at 82 (noting that "[b]eyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law").

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30. 788 F.3d 1371, 1376, 1379 (Fed. Cir. 2015).

31. Id.

32. Id. at 1377.

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39. Ariosa, 788 F.3d at 1381 (Linn, J., concurring).

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42. Ben Hattenback & Joshua Glucoft, *Patents in an Era of Infinite Monkeys and Artificial Intelligence*, 19 STAN. TECH. L. REV. 32, 46 (2015).

43. *Townsend v. Smith*, 36 F.2d 292, 295 (C.C.P.A. 1929); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson on Patents 532 (1890)).

44. See Hattenback & Glucoft, *supra* note 42, at 35, 43 (describing inventions conceived by machines such as proportional-integrative-derivative

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51. Copyright Office, Compendium of U.S. Copyright Office Practices (3d ed. 2014) § 313.2.

52. Hattenback & Glucoft, *supra* note 42, at 46.

53. Abbott, *supra* note 47, at 1095.

54. Id.

55. Fraser, *supra* note 49, at 331. Companies creating AIs have started including ownership provisions in the licensing agreements to account for this possibility. *See e.g.*, Cloudera Licensing Agreement, Section 5 Ownership, http://www.cloudera.com/legal/terms-and-conditions/cloudera-standard-license-v2-2015-11-04.html ("Cloudera owns all right, title and interest in and to ... all ideas, inventions, discoveries, improvements, information, creative works and any other works discovered, prepared or developed by Cloudera").

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57. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986); see Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985).

58. George Dyson, *Turning's Cathedral*, EDGE (Oct. 23, 2005), https:// www.edge.org/conversation/george_dyson-turings-cathedral (quoting an unidentified Google employee as stating "[w]e are not scanning all those books to be read by people. We are scanning them to be read by an AI," in referring to the Google Books Library Project).

59. Liza Vertinsky & Todd M. Rice, *Thinking About Thinking Machines: Implications of Machine Inventors for Patent Law*, 8 B.U. J. Sci. & Tec. L. 574, 595 (2002); Abbott, *supra* note 47, at 1125-26.

60. Abbott, *supra* note 47, at 1124-25.

61. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007); Vertinsky & Rice, *supra* note 59, at 595-596.