

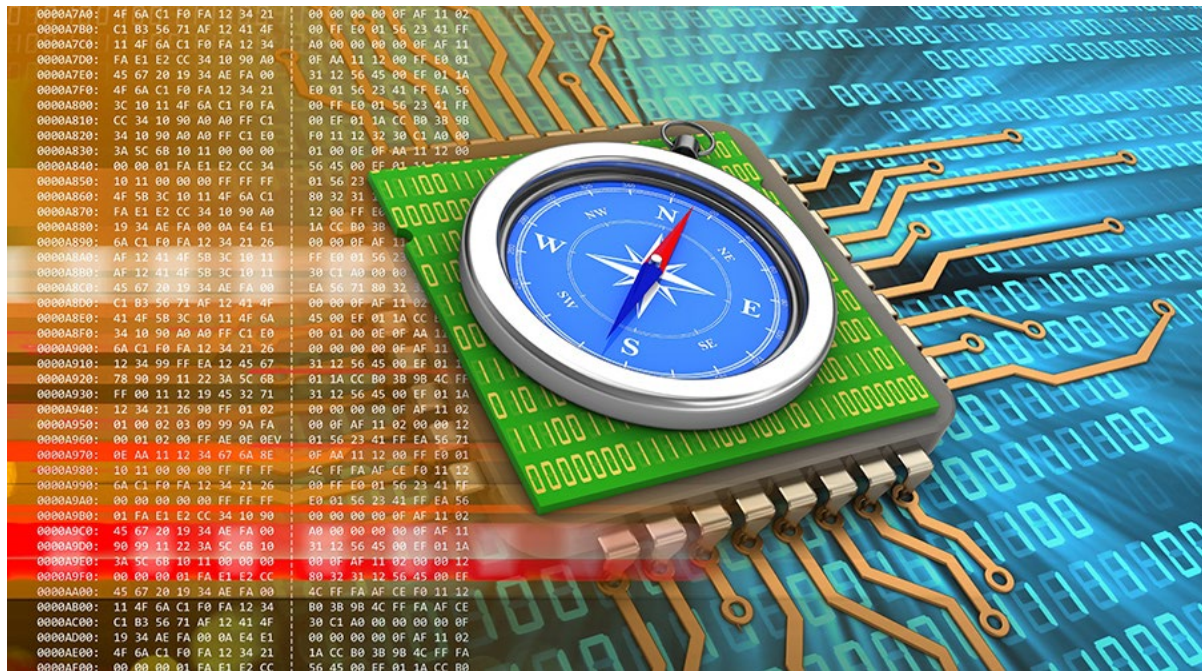
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Patents and Trade Secrets: IP Protection of AI in Digital Health and Wearable Devices

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Artificial Intelligence (AI) has expanded rapidly in many industries, particularly health care, ranging from radiological imaging, clinical diagnosis, drug discovery, and cardiac software that uses AI to guide users, to fitness training and equipment. Consistent with this trend, the World Intellectual Property Organization reported that the number of AI-related patent applications filed each year increased by a factor of 6.5 between 2011 and 2017.^[1] The COVID pandemic has accelerated the transition to digital health, and the use of wearable devices in telemedicine has become more prevalent. In an October 19, 2023 update, the Food and Drug Administration (FDA) projected a 30+% increase of Artificial Intelligence/Machine Learning (AI/ML)-enabled medical devices in 2023 (compared to 2022).^[2]

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Trade Secret vs. Patent Protection

Organizations want to find the appropriate IP strategy to protect their AI technologies. Generally, trade secret protection is better suited to the source code, training data set, and internal database structure of an AI system, while patent protection may be better suited to the user interface and the complex algorithm underlying the AI system.

Other factors, such as the nature, use, and control of the AI technology, may also determine the appropriate IP regime. For example, if technology is non-public facing, used only in-house, difficult to reverse engineer, and there is a well-controlled plan in place to keep the information secret, such technology may be kept as a trade secret. In contrast, if the technology is public facing, susceptible to reverse engineering, requires data sharing, or the technology is to be licensed out or offered as Software as a Service (SAAS), then the technology is probably better protected under the patent regime.

Notably, if the technology pertains to an industry that is subject to a public disclosure requirement, patent protection may be the better choice. For example, the FDA discusses a proposed framework that would require manufacturers to provide descriptions in premarket submissions for what aspects of their products they intend to change through learning algorithms and how the algorithms will remain safe and effective as the Software as a Medical Device (SaMD) and its associated algorithms learn and change over time.^[3] Accordingly, organizations should consider filing a patent application to cover the novel aspects of their AI/ML systems before they are made public to comply with regulatory requirements.

Patent Protection Hurdles

In the event that an organization decides to file a patent application to protect its AI/ML-based inventions, it will need to overcome hurdles, particularly in the area of subject matter eligibility under the *Alice* test,^[4] as illustrated in recent court cases.

First, the claimed invention cannot merely recite black box terminologies. Courts have invalidated AI/ML-related patents where the claims and specification lack sufficient specificity regarding the invention. In *PurePredictive*, the court invalidated a patent that merely recited the concept of predictive analytics performed on a generic computer without more.^[5] The claimed invention used AI to “generate a predictive ensemble in an automated manner with little or no input from a user or expert.”^[6] The court reasoned that the patent simply recited an abstract idea, a patent-ineligible concept, and lacked sufficient specificity to meet the second step of the *Alice* test because its claims and specification only described “generic ‘modules’” rather than specific system architecture.^[7]

In *Vehicle Intelligence*, the Federal Circuit similarly invalidated a patent for lack of implementation details. The patent claimed systems and methods that screened equipment operators for impairment, selectively tested those operators, and controlled the equipment

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if an impairment was detected.^[8] The specification provided examples of such equipment, which included a wide range of vehicles and machinery, as well as examples of impairments, which included intoxication, physical impairments, medical impairments, and emotional impairment.^[9] The court found that the claims were directed to the abstract idea of testing operators for impairments because the claims were not “limited to a particular kind of impairment” and did not “explain how to perform either screening or testing for any impairment, specify how to program the [system] to perform any screening or testing, or explain” how to control the equipment if the system detected an impairment.^[10] As such, the court found that the claims did not provide a redeeming inventive concept because the patent’s specification and claims did not explain how the system worked or how it achieved its supposed advantages over the prior art.^[11]

Additionally, patent applicants should show how their invention makes an improvement in the technological field and take care to distinguish it from mental processes, generic methods, and other abstract ideas. In the Federal Circuit case, *Braemar*, a patent involved AI technology in an electrocardiographic telemetry device that would monitor a patient’s cardiac activity, transmit information of cardiac events meeting the certain criterion to a remote medical receiver, and discard events that do not meet the criterion.^[12] The district court found that the claims in the ‘237 patent are directed to the patent ineligible abstract idea of “collecting, classifying, and selectively transmitting relevant data” although the technology enables “accurate, automatic review of a large volume of cardiac monitoring data that was previously reviewed manually by trained technicians.” The court also held the claims recite performing the abstract idea with conventional technology and fail to provide any specific, inventive technological improvement, as opposed to generic gathering and processing activities that can be carried out manually. On appeal, CardioNet attempted to argue that the claims are directed to “improved electrocardiographic monitoring systems” and “the claimed methods increase the relevance of data presented to physicians by automatically identifying and discarding less clinically-significant events.”^[13] However, the Federal Circuit stated that the purported improvement is the abstract idea of classification and filtering of data, not an improvement in the functioning of computer capabilities. The Federal Circuit then found the claims to be invalid because they did not describe an inventive concept; instead, they merely recited mental processes and routine data manipulation, which are “abstract ideas with conventional techniques.”^[14]

Likewise, the Federal Circuit recently invalidated a university’s patent application directed to a computerized statistical method for haplotype phasing, which has the potential to revolutionize personalized health care and tailor treatment according to a patient’s genetic background.^[15] The court found that the invention covered “abstract mathematical calculations and statistical modeling,” and that “practical, technological improvements” must extend “beyond improving the accuracy” of a mathematical calculation to demonstrate patent eligibility.^[16] The court emphasized that a “claim for a new abstract idea is still an abstract idea” and that “patent law does not protect such claims, without more, no matter how groundbreaking the advance.”^[17]

Conclusion

Trade secrets and patents can protect different parts of AI systems. Together, they afford more robust protections for AI/ML-based inventions. When patenting AI-related inventions, applicants should avoid using black box terminologies and instead define the technological improvements with sufficient specificity to set the invention apart from abstract ideas and generic techniques.

Chief Technology Officer Checklist for Protecting Digital Health and Wearable Devices

Factors to Weigh	Trade Secret	Patent
Using AI simulation result for the actual treatment and diagnosis of disease		X
User interface of the AI system		X
Source code of the AI system	X	
Internal database structure of the AI system	X	
Training data set (raw data, query, extracted data)	X	
Mathematical aspect of the statistical or mechanical models	X	
Public-facing technology		X
Development and use of the technology in-house	X	
Joint development, use of third-party contractor		X
Plan to license the technology or offer as a SAAS		X
Feasibility of reverse engineering the AI model		X
Key competitors hold a substantial patent portfolio		X
Contain complex algorithm that causes technology improvement		X
Controls in place to keep info. secret (NDA, data security, & employment agreement)	X	
Subject to public disclosure requirement (e.g., FDA submission)		X

About the Authors

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^[1] WORLD INTELLECTUAL PROPERTY ORG., WIPO TECHNOLOGY TRENDS 2019: ARTIFICIAL INTELLIGENCE 39 (2019).

^[2] U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING (AI/ML)-ENABLED MEDICAL DEVICES (Oct. 19, 2023 update).

^[3] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING (AI/ML) SOFTWARE AS A MEDICAL DEVICE ACTION PLAN pages 1, 3.

^[4] Under the Supreme Court’s two-step framework for determining patent eligibility, courts should first determine whether claims are directed to a law of nature, natural phenomena, or abstract idea. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014). If the claims are not directed to any of those enumerated categories, then the claims are patent eligible. If the claims are directed to one of those categories, the court should move to step 2 and determine whether the claims include an “inventive concept” sufficient to “transform” the invention into a patent eligible application. *Id.*

^[5] *PurePredictive, Inc. v. H2O.AI, Inc.*, No. 17-CV-03049-WHO, 2017 WL 3721480, at *7 (N.D. Cal. Aug. 29, 2017), *aff’d sub nom. PurePredictive, Inc. v. H2O.AI, Inc.*, 741 F. App’x 802 (Fed. Cir. 2018).

^[6] *Id.* at *6.

^[7] *Id.* at *7.

^[8] *Vehicle Intel. & Safety LLC v. Mercedes-Benz USA, LLC*, 635 F. App’x 914, 916 (Fed. Cir. 2015).

^[9] *Id.*

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[\[10\]](#) *Id.* at 917.

[\[11\]](#) *Id.* at 920.

[\[12\]](#) *Braemar Mfg., LLC v. ScottCare Corp.*, 816 F. App'x 465, 469 (Fed. Cir. 2020).

[\[13\]](#) *Id.* at 8.

[\[14\]](#) *Id.*

[\[15\]](#) *In re Bd. of Trustees of Leland Stanford Junior Univ.*, 991 F.3d 1245, 1247 (Fed. Cir. 2021).

[\[16\]](#) *Id.* at 1250–51.

[\[17\]](#) *Id.* at 1251 (citing *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016)).