THE
NATIONAL LAW REVIEW

Strategies to Unlock AI's Potential in Health Care, Part 1: Common Pitfalls to Avoid When Getting a Patent

Thursday, October 11, 2018

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Communications, Media & Internet
Health Law & Managed Care
Intellectual Property
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As in any area of technology, it is important to consider patent protection early in the development of an AI-related invention. However, AI and other digital health inventions raise a number of particular issues that, if not addressed fully or at the right time, could be fatal to securing U.S. patent protection that would otherwise be available to prevent others from making, using, selling, or importing the invention. This article identifies common pitfalls in getting a patent for AI and other digital health inventions, and provides insights on how to avoid them.

Timing the Patent Application Filing

AI and digital health inventions can fluctuate more during development than other types of inventions since they often undergo numerous iterations and alterations over a short period of time. This fluctuation is positive for experimentation, education, and innovation, but it can complicate the decision of when to first file a patent application.

Patent rights in the U.S. (and in other jurisdictions worldwide) are based on who files first for a patent, so time is of the essence to help ensure that someone else does not file a patent application for an idea that you actually invented first. Timing is also important because once a patentable idea is publicly disclosed, including any non-confidential disclosures to potential customers, to software developers, to friends or family, at trade shows, online, or elsewhere, the ability to get patent protection for that idea is lost forever in almost every country. The U.S. has a grace period for patent filing after a public disclosure, but it is a limited grace period.

It is almost never too early to start thinking about patent protection and consulting with a patent practitioner to start the patent application process and decide the right timing for your specific innovation. Filing for patent protection too soon may result in a patent application that is too sparse to meet various patent rules, such as the enablement requirement of 35 U.S.C. § 112 which requires that the application must enable a person skilled in the art to make and use the invention. Conversely, filing for patent protection too late may result in a complete loss of ever securing patent protection due to another party's prior patent application or public disclosure.

Enforcement Considerations

Enforcing a U.S. patent requires determining who is infringing the patent and, thus, who to enforce the patent against. For AI inventions, this potential infringer question can be complicated by the involvement of machine learning since machines themselves cannot be sued parties.

It is therefore important for AI patent claims to be pursued during the patent procurement process with an eye towards who potential infringers may be. This will ensure that the eventual patent has enforcement value for the

patentee. For example, would a manufacturer be a potential infringer? A distributor? An end user? A developer? For another example, are multiple parties required to carry out a claimed process? If so, complicated questions of induced infringement or contributory infringement may arise that could have been easily avoided if potential patent infringers had been more carefully considered during the patent application process.

Inventorship may also complicate enforcement of patents for AI inventions. A patent application must name all inventors of the claimed invention. Named inventors are "individuals" who invent or discover the invention, per 35 U.S.C. § 100. Machines that perform machine learning in an AI context may generate data or processes that are used with or help to define an invention. However, it has not been definitively decided under U.S. law whether machines can be "individuals" contributing to invention conception or whether individuals that develop programming for machine learning are inventors as opposed to the machines that perform the learning over time. Given this uncertainty, it can be helpful to avoid this issue by crafting patent claims to cover inventive ideas that are clearly conceived by one or more people.

Subject Matter Eligibility Under 35 U.S.C. § 101

Subject matter eligibility for patent under 35 U.S.C. § 101 has been a particularly hot topic since the 2014 Supreme Court decision in Alice Corp. v. CLS Bank Int'l. Section 101 patent eligibility has particular relevance to AI and digital health since they often involve computers and/or data processing whose mere presence, reference, or implication in claims frequently give rise to subject matter eligibility questions during patent prosecution as well as during litigation after patent issuance.

The breadth and gravity of current § 101 issues has been explored elsewhere and is beyond the scope of this article. In general, *Alice* and subsequent lower court decisions have made it more difficult to get patents issued with claims involving computers and/or data processing. It is therefore important to consider potential patent eligibility concerns under § 101 during the patent application drafting process in order to preemptively address these concerns as much as possible before the application faces any challenges during prosecution or during litigation as an issued patent. Some ways to do this include:

- Describing in text and illustrations all physical elements involved in implementing the AI and the specific role each physical element plays in the system or process;
- Providing as much detail as possible about any algorithm that is or may be claimed;
- Identifying specific industries or applications where the AI may be particularly useful and explaining the AI's advantages over existing systems and processes in each industry or application; and
- Indicating any improvements to computer functionality achieved by the claimed invention.

Design Patents

There are two types of patents available in the U.S.: utility patents and design patents. Utility patents cover new and useful products and processes and are typically the focus of patent protection for any invention. However, it is important to not forget about the availability of design patents in AI as well as in the broader digital health context.

A design patent protects a "look" or ornamental design. If a utility patent cannot be obtained for an AI or digital health invention for any of the reasons discussed above or otherwise, or if the invention's development does not have any inventive idea that may be eligible for a utility patent, many such inventions will have a unique design interface eligible for design patent protection. The idea may therefore be protected under robust patent law when it would not otherwise be protected if only utility patent protection is pursued.

Additionally, design patents are attractive because they typically cost much less to prepare, file, and prosecute as compared to utility patent applications. Design patents are also typically issued much faster than utility patents, which can make them useful in the fast-moving, continually-developing world of digital health and AI.

Read Part 2, Part 3 Part 4 and Part 5.