Professional Perspective

Covid Testing and Patentability

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In September 2020, a team of MIT researchers published a paper in the IEEE Open Journal of Engineering in Medicine and Biology, testing the hypothesis that coronavirus carriers—even asymptomatic ones—could be accurately detected using artificial intelligence (AI) based on only a phone recording of a forced cough.

If this hypothesis is correct, the Covid-19 test can be accessible to people worldwide. This is because it can be programmed into a mobile application, which can then be installed by millions of people on their smartphones. Once installed, people can use their smartphones to take a test from the comfort of their home and quickly determine whether they are likely to test positive or negative for the virus. There is no doubt that this invention is valuable, accessible, and easy to use. But is this invention patentable?

MIT Study

In the MIT study, a convolutional neural network (CNN) model was used to develop a process for predicting whether the cough came from a Covid-19 or non-Covid-19 carrier. First, an audio of a person's cough is recorded. The recorded audio is then divided into chunks and analyzed for indicative points or biomarkers in the audio spectrum. The biomarkers are subsequently passed to three different pre-trained 50-layer residual CNN (ResNet50) networks, each designed to analyze a different biomarker: one for the vocal cords, one for the lungs and respiratory tract, and one for sentiment or mood. The outputs of the ResNet50 networks are aggregated and a binary Covid/No-Covid decision is generated.

The key feature of the MIT study's model is its use of the ResNet50 networks. These networks are pre-trained to analyze voice recordings to detect Alzheimer's disease. Importing the pre-trained networks into the Covid-19 detection model provides several benefits. First, using a pre-trained model means that the Covid-19 detection already has a heuristic for decision-making, meaning the Covid-19 detection model requires less training and only fine-tuning. Second, using a pre-trained model can help the accuracy of the new network by increasing the saliency of information that may have not been apparent in the novel use. Think of it as the new model saying, "Oh! I never would have thought of it like that."

The MIT team's Covid-19 study demonstrates remarkable results. The sensitivity of the algorithm—a measure of false negatives or, in other words, how good the test is at accurately detecting real cases—is 98.5% and the specificity of the algorithm—a measure of false positives or, in other words, how good the test is at not over-diagnosing—is 94.2%. For asymptomatic subjects, the sensitivity rose to 100% and the specificity fell to 83.2%.

Figure 1: MIT COVID-19 prescreening study CNN model (from IEEE Publication)

Because the Covid-19 study results are promising, the MIT team is now working to incorporate their Covid-19 model into a mobile application and seeking FDA approval for its use. The Covid-19 mobile application has the potential to be an effective pre-screening tool for Covid-19 by helping to detect asymptomatic carriers, encouraging the general public to check their health more often, and simply giving peace of mind to those who suspect having been exposed to Covid-19.

The benefits of this mobile application are a double-edged sword for the MIT team: because of its imminent success, the Covid-19 mobile application will draw not only attention but also competition. To protect their investment and invention, the MIT team may, and should, apply for a patent covering the Covid-19 mobile application. However, is the Covid-19 mobile application patentable?

Patenting the Covid-19 Mobile Application

The U.S. Supreme Court's 2014 decision in *Alice Corp. v. CLS Bank International* clarified the subject-matter eligibility test for patent claims and this, in turn, led to the invalidation of numerous patents. 134 S. Ct 2347 (2014). Even now, after numerous interpretive decisions and guidance, the operating subject-matter eligibility test still leaves patent prosecutors uncertain of whether their patent applications will issue as patents and owners of issued patents uncertain of whether their patents will withstand scrutiny in court.

The subject-matter eligibility test involves a two-step analysis. Step 1 asks if a claim is directed to a process, machine, manufacture, or composition of matter. Step 2 is broken down further into two sub-steps, where Step 2A asks if the claim is directed to a judicially recognized exception and, if so, Step 2B asks if the claim recites additional elements that amount to significantly more than the judicial exception. We will take each of these steps in turn and consider how the MIT team may address each step, should they choose to pursue patent protection for their invention.

Step 1 is relatively straightforward. Both neural networks and mobile phone applications can be patented as processes or machines, and the Covid-19 mobile application is unlikely to stumble at this step of the test.

At this point, the team will have an important decision to make regarding the scope of their claims. The team could elect to patent the underlying neural network, rather than the Covid-19 mobile application. While this may produce less valuable IP, it may offer a more certain path towards patentability. The team could, on the other hand, direct their claims to the Covid-19 mobile application itself. If allowed, these claims could produce fairly valuable IP. Such IP could preempt other applications that aim to diagnose Covid through audio recordings. The team could also attempt an even broader patent, claiming the entire process of diagnosing a variety of diseases or conditions via forced cough recording through a mobile application. The potential value of this IP, especially as biomarker analysis accuracy for diseases continues to grow, is phenomenal.

Depending on how the claims are drafted, Step 2A may be the first point of difficulty for patenting the Covid-19 mobile application. If the MIT team claims the invention as a mobile application that uses the neural network as a black box decision mechanism—that is, without claims directed to the neural network's specific operation—the patent application may be rejected on grounds of being "a certain method of organizing human activity."

This description is potentially fatal to the application because it is one of the four main types of abstract ideas in Step 2A. The USPTO gives the example of "a method of anonymous loan shopping that person conducts using a mobile phone" as one such patent-ineligible method of organizing human activity in its subject matter eligibility guidance. Claiming the Covid-19 mobile application as "a method of diagnosing Covid-19 by receiving a cough at a mobile phone" may be too similar to distinguish.

However, careful claim drafting can help the Covid-19 mobile application from falling into the "black hole" of Step 2B, from which relatively few patent applications return. Foremost, claiming their invention in terms of a neural network structure can help the MIT team provide more fodder for argument that the invention is not directed to an abstract idea. The USPTO provides a list of patent eligibility examples with example 39 describing a claim for training a neural network for facial detection that passes Step 2A, i.e., by not being directed to a judicially recognized exception.

Accordingly, a patent application with claims directed to training a neural network for prescreening for Covid-19 is more likely to pass muster under Step 2A than one with claims directed to simply using the Covid-19 mobile application as a black box.

Generally, to pass Step 2A, the claims should avoid terminology clearly within an abstract-idea category. By tying the claims to more concrete, functional, and technological applications, patent applicants can increase their chances of getting a patent granted. Another good practice is to include a description of the technical problem in the art and emphasize in the specification the technical solution provided by the claimed invention, making sure to include technical steps, i.e., a neural network structure, that overcome the specific technological problem.

Step 2A is a critical juncture in the patent-eligibility test because failing Step 2A would take the patent application to Step 2B—often a graveyard for patent applications. The analysis is that the claims must amount to significantly more than the judicial exception by adding specific limitations other than what is well-understood, routine, or conventional in the field or arranging conventional pieces in a non-conventional way. A CNN of relatively basic form and lacking much in the way of revolutionary improvements to the processing of information is unlikely to demonstrate the requisite features to satisfy Step 2B. Accordingly, it is important for the team to draft their claims in such a way as to avoid Step 2B, even if it may come at the cost of the overall long-term value of the IP generated.

Policy Considerations for Granting the Patent

The U.S. Constitution proclaims that the purpose for granting a patent is "to promote the progress of science and useful arts." U.S. Const. art. I, § 8, cl. 8. Although it is unlikely that this nebulous purpose is running through the mind of an

individual patent examiner at the USPTO who is in the process of reviewing an application, it does underscore some of the tradeoffs made when a patent is accepted or rejected.

Granting the patent would disclose a novel method for using soundbites to detect physical ailments. This disclosure has great potential to drive further innovation in the field because it would reveal the techniques the MIT team leveraged to achieve their high success numbers. Other researchers or inventors could then build on the disclosed information. Giving the MIT team patent rights could also incentivize investment in their continued research, leading to increased funding for technology with a potential to save countless lives.

Denying the patent application, on the other hand, might incentivize the MIT team to keep the research a trade secret. Withholding this information could impede subsequent inventions and make the U.S. less competitive than other countries in the field of auditory biomarker analysis.

Conclusion

The MIT team's research paper outlines a largely successful method of using a pre-trained CNN model to pre-screen for Covid-19, even among asymptomatic carriers. Should the MIT team seek to patent their invention, they could pursue a patent application with claims directed toward training or structure of a neural network that analyzes forced-cough input for biomarkers of Covid-19.

Alternatively, the claims can be directed to a Covid-19 mobile application with a forced-cough input and a binary affirmative or negative prescreening output. Although the latter may be more valuable IP, due to its broader scope, it will undoubtedly be more difficult to prosecute. Conversely, the former may be more limited in scope, but it is much more likely to satisfy the patent-eligibility test's Step 2A requirements and thus avoid Step 2B.

Even if the Covid-19 application overcomes the subject matter eligibility hurtle, there are no guarantees that the Covid-19 application is patentable. To determine patentability, the USPTO would examine the claims of the Covid-19 application against the prior art, including existing patents, patent applications, and non-patent literature. At the very least, the claims of the Covid-19 application must be novel and non-obvious over the mobile application and the neural networks that MIT created to detect Alzheimer's disease on which the COVID-19 application is based.

To overcome potential novelty and non-obviousness issues, the specification of the Covid-19 application should be replete with implementation details that explain why the Covid-19 application design and its ResNet50 neural networks are novel and not obvious to a person of ordinary skill in the art.

One hurdle that the Covid-19 application is unlikely to experience is inventorship. Under current U.S. law and the USPTO ruling, only natural persons and not AI can be inventors. Because the ResNet50 neural networks in the Covid-19 application only determine whether a person tests positive or negative for Covid-19, and do not themselves invent the Covid-19 application, the AI does not appear to be an inventor of the Covid-19 application itself.

Regardless of whether the Covid-19 application is patentable and can be protected by a patent, today the Covid-19 application is valuable technology which may give people peace of mind.

