NOVEMBER/DECEMBER 2019

DEVOTED TO LEADERS IN THE INTELLECTUAL PROPERTY AND ENTERTAINMENT COMMUNITY

VOLUME 39 NUMBER 10

THE Licensing Journal®

Edited by Gregory J. Battersby and Charles W. Grimes

Wolters Kluwer

Technology Licensing

Emily J. Gardel PhD and Daniel G. Rudoy PhD

Strategies for Patenting Artificial Intelligence Innovations in the Life Sciences

Today, companies are developing artificial intelligence (AI) systems to meaningfully analyze the deluge of biomedical data. A substantial investment in building and deploying machine learning (ML) technology—the most active area of AI technology being developed today—warrants carefully considering how to protect the resulting intellectual property (IP), but there are challenges to doing so. In this article, we explore strategies of protecting IP for ML technology, including what aspects to consider patenting given current and ongoing changes to U.S. patent law, and when to consider trade secret protection.

What Is Machine Learning?

Generally, developing an ML system involves creating and deploying a computer program having a model whose performance on some task improves as additional data is used to train the model. In the life sciences, such data can include medical images, genomic data, and electronic health records.

For example, an ML model may be trained on magnetic resonance (MR) images to recognize whether a previously unseen MR image of a patient's brain shows a hemorrhage. As another example, an ML model may be trained on genomic data for individuals with a particular cancer to predict whether a patient's genome has features indicative of the cancer.

Today, neural networks are a popular class of ML models widely used, and are often referred to as "deep learning" in a nod to their multi-layer (deep) structure. Other ML models include Bayesian models, decision trees, random forests, and graphical models. Indeed, rapid development of various ML tools has led to an explosion of activity in applying them to new problems across diverse fields.

Machine Learning IP—Patent Protection

Deploying an ML system typically involves: (1) selecting/designing an ML model, (2) training the ML model using data, and (3) deploying and using the trained ML model in an application. Valuable IP may be generated at each of these stages, and it's worth considering protecting it through patents. There, however, are a number of challenges in patenting ML systems.

Novelty and Obviousness

An invention must be new and non-obvious to be patented. This makes it difficult to patent the use of off-the-shelf ML technology even if in the context of a new application. Simply downloading freely available ML software, providing it with data, and displaying the results (*e.g.*, to a doctor or researcher) may be viewed by the U.S. Patent and Trademark Office (USPTO) as failing to clear the non-obviousness hurdle. After all, the freely available ML software is distributed precisely so that people can perform this exact process—why, then, would it not be obvious to do so?

But in reality, building and deploying ML systems requires more work beyond simply downloading and running software. Focusing patent claims on the results of such efforts will lead to greater success. Here are three examples of potentially patentable aspects of an ML system:

1. *New ML model.* In deploying ML technology, a new model may have been developed (*e.g.*, new neural network architecture). Claiming novel aspects of the model will help to address novelty and non-obviousness challenges.
2. *Training an ML model.* Innovative ways of generating training data and/or a new training algorithm may be claimed. For example, when there is insufficient training data, it may be augmented by synthesizing new training data from old training data or other sources, and such data augmentation techniques may be innovative and the focus of patent claims.
3. *Deploying an ML model.* How an ML model is integrated into an application may provide a novelty and non-obviousness hook. Claims focusing on integration and deployment should go beyond merely displaying the model's output and focus on what

the output is used to achieve. For example, applying an ML system to medical images may result in instructions to take more images with different settings because the ones obtained are unsatisfactory. Other examples include choosing among different next steps in a control system, customizing a patient's treatment, or updating a clinical trial. When an ML system is deployed in conjunction with a specialized device (*e.g.*, an imaging device, a sequencing device), rather than merely a computer, claims could focus on how the ML system is integrated with the device.

Patent Eligibility

The law on whether it's possible to patent software innovations remains unsettled and unclear. Unhelpfully, this lack of clarity subsumes aspects of ML technology. The USPTO takes the position that a claim could be ineligible for patenting when it recites math, and USPTO examiners often take the position that ML technology claims do recite math since they may refer to ML models, which are mathematical in nature.

Recent guidance from the USPTO in the form of its "2019 Revised Patent Subject Matter Eligibility Guidance", however, has been more friendly to patent applicants, indicating that claims reciting mathematical concepts (as the case may be for ML claims) are patent eligible if they integrate the math concepts into a practical application. (See *https://www.federalregister.gov/documents/2019/01/07/2018-28282/2019-revised-patent-subject-matter-eligibility-guidance*). Drafting patent applications to explain the technical problem that the ML system addresses and claiming aspects of the solution to the technical problem can—and in our experience has—overcome patent eligibility challenges.

Obsolescence

ML is a hot area, with new technology being developed at a rapid pace. Given that the patenting process often takes years, it is possible that an ML innovation is obsolete by the time a patent is granted. As such, it is advisable to focus on patenting only those features of ML technology that will likely have relevance in the future to your products or those of your competitors.

Patent vs. Trade Secret Protection

Patenting is not always the right approach, and for ML innovations it is worth considering trade secret protection as an alternative. These are very different mechanisms—a patent provides the right to exclude others from practicing your invention for 20 years, even if they arrived at the invention independently, so long as you disclose the details to the public. By contrast, there is no time limit on trade secret protection so long as the subject matter is kept secret, and there are no eligibility, novelty, or obviousness bars to clear. There, however, is no recourse for independent discovery by a competitor.

Two important factors to consider when weighing trade secret and patent protection include:

1. *Detectability*. If detecting when a competitor uses an invention is hard, then the value of patenting that invention is diminished because it will be difficult to know that the patent is being infringed. This may be the case with innovative training algorithms for ML systems—it's perhaps possible to detect that the ML system is being used, but hard to detect how it was trained, potentially suggesting the trade secret route for such technology.
2. *Reverse Engineering*. If it is easy to reverse engineer the invention or hard to keep it secret (*e.g.*, due to desire to publish, visibility of the invention in the product), then the patent route may be preferable.

It's possible to delay deciding between patent and trade secret protection by filing a U.S. patent application with a non-publication request, which prevents your invention from becoming public unless and until you get a patent. If during prosecution it turns out that the patent is difficult to obtain or the allowed claims are so narrow that they have little value, the patent application can be abandoned without becoming public, thereby maintaining secrecy. This approach strikes a balance between secrecy and patentability, but unfortunately eliminates the possibility of getting foreign patent protection.

Takeaways

Many companies make a substantial investment in developing ML technology, and should consider protecting their IP through patenting. It is important to choose the right strategies to protect your investment because, without careful planning, you may obtain patents that do not meaningfully protect your technology. Focusing patent claims on the innovative technical aspects of how an ML system is built or deployed can not only address

novelty, obviousness, and eligibility challenges, but also create valuable patents. Trade secrets offer a degree of protection in circumstances where patenting is not the best approach.

Dan Rudoy is an associate in the Electrical & Computer Technologies Group at Wolf Greenfield. He focuses his practice on patent prosecution in the areas of artificial intelligence, speech and image processing, software, medical devices, computer security, networking, radar systems, and electronics. He is particularly skilled in technologies related to machine learning, including deep learning, signal processing, big data, data science and bioinformatics.

Emily Gardel is an associate in the Electrical & Computer Technologies Group at Wolf Greenfield. She focuses her practice on patent prosecution in areas where electronic devices and software overlap with biotechnology. She has worked with technologies related to single molecule detection, imaging systems, medical devices, microfluidics, biosensors, diagnostic devices and software, bioinformatics, and data processing, including technologies implementing machine learning.