

NOVEMBER/DECEMBER 2022

DEVOTED TO
LEADERS IN THE
INTELLECTUAL
PROPERTY AND
ENTERTAINMENT
COMMUNITY

VOLUME 42 NUMBER 10

THE *Licensing*
Journal®

Edited by Gregory J. Battersby and Charles W. Grimes



Patent Licensing

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The Importance of Patents for ML-Based Medical Device Inventions

The use of machine learning (ML) in the medical device field has greatly expanded in recent years, becoming increasingly important to the product offerings of many medical device companies. The benefits provided by ML are wide-ranging and include providing earlier and more accurate diagnoses by detecting patterns in clinical data associated with disease, improving surgical outcomes through preoperative and intraoperative surgical guidance, and enabling the development of personalized diagnostics and therapeutics.

Medical device companies should look to build a robust patent portfolio for their ML inventions. This raises the question of how to build a patent portfolio for ML inventions in the medical device field. ML involves the training of mathematical models to draw conclusions from data, such as medical images or other clinically relevant data. While mathematical models by themselves are not eligible for patenting, their application to achieve practical results is patentable. Broadly speaking, patents for ML-based inventions fit into three broad categories.

- **Applications of ML.** This category includes patents directed to novel results achieved using ML. Examples of ML applications in the

medical device field include automatic identification of anatomical structures in imaging, automatic diagnoses from patient data, and patient recovery tracking. Patents in this category are often the most valuable, both because of their breadth of coverage and because infringing activity can be readily detected, often from advertising materials and use of the product.

- **Structure of the ML model.** The structure of the ML model refers to the structure of the mathematical algorithm itself and how it processes data. Although mathematical algorithms by themselves are not eligible for patenting, the application of a novel ML model to a practical application can be patented. Patents in this category are often less valuable because their scope is narrower and detection of infringement is more difficult.
- **ML model training.** This category includes patents directed to the process for training an ML model to achieve its purpose. Training of an ML model is critical to how well it performs and thus can be one of the most important aspects of developing an ML solution. However, infringement of patents in this category is often very difficult to detect because the process for training is typically not advertised or apparent from the use of the product.

Although patents directed to the applications of ML are typically

the most valuable, medical device companies should also pursue patents to ML model structure and training because these patents contribute to the benefits that a robust patent portfolio provides, including:

- **Detering others from practicing the invention.** Patents, of course, can be used to prevent others from making and using an invention. However, patents that are unlikely to ever be asserted still serve as a deterrent from copying and as a roadblock to the ability of competitors to innovate their own products.
- **Providing freedom to operate.** Filing a patent application ensures that an invention is in the public space and thereby cannot be patented by anyone that invents the same thing later. Preventing others that create the same invention at a later date from patenting the invention ensures a company's ability to practice its own technology. This is an important countervailing consideration to keeping an ML invention as a trade secret since trade secret protections do not protect against independent invention and patenting.
- **Advertising to investors.** This benefit is most relevant to emerging companies looking for investments or acquisitions. Patents can serve as advertisements of the technical capabilities and sophistication of a company. They provide investors with the ability to "look under the hood" and make their own independent assessment of the value of the underlying ML technology.

Given the increasing importance of ML in the medical device market, robust patent portfolios protecting ML innovations can help ensure that medical device companies reap the benefits of their valuable innovations.

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industries. Mr. Gloria has drafted and prosecuted patents in numerous technology areas including medical devices, user interfaces, autonomous devices, image analysis, machine learning, and consumer products.

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