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Artificial Intelligence

AI in diagnosis – patent protection

In this article, we take a closer look at patent protection in Europe for developments of AI in diagnostic applications. There is enormous potential for the use of AI in diagnosis and this is reflected in the increasing number of regulatory approvals being granted.

Predicting outcomes

Many diagnostic approaches are based on "deep learning" which is inspired by the human brain and uses algorithms to train neural networks to recognise patterns. Generally speaking, a neural network is trained using historical patient data for which patient outcomes are known. Once the neural network has been trained it is able to generalise its knowledge so that when presented with a new example of patient data it has not seen before, it is able to compute a prediction of the patient outcome.

Recently a deep-learning algorithm that analyses images to detect potential strokes achieved regulatory approval in both Europe and the US. Viz.ai developed a computer-aided image software system designed to identify suspected large vessel occlusion strokes. The system sends a text message to specialists, who can view the results on their phone and decide if emergency treatment is necessary. According to Viz.ai, a study involving 300 CT scans comparing the performance of the software with that of neuroimaging specialists resulted in faster detection by the software in more than 95% of cases and saved an average of 52 minutes. A crucial 52 minutes when a patient is facing the potentially fatal and often debilitating affects of a stroke.

Another FDA approved diagnostic tool is QuantX, which combines machine learning and advanced image analysis with a deep database of historical cases to assist radiologists with diagnosing breast cancer. Imaging features are processed by an algorithm into a single value, the QI score, which is analysed relative to a database of reference abnormalities with a known ground truth. This has achieved a 39% reduction in overlooked cancers and a 20% overall improvement in diagnosis.

Patentability

These types of technologies are potentially patentable at the European Patent Office (EPO). However, it is necessary to navigate the "excluded subject matter" rules. Mathematical methods and computer programs – and nothing more – are not patentable, and neither are diagnostic methods conducted on a human or animal body.

Regarding the first exclusion, the EPO takes a two-step approach. First, it must be determined if the subject matter in question is directed to technical subject matter or not. This first hurdle is straightforward to overcome where the patent claim includes apparatus features such as a computer server, or where a method claim is directed to a "computer-implemented method". Second, the invention must be directed towards a non-obvious technical

solution of a technical problem. In this respect, only features which contribute to the technical character of the invention are taken into account, so that the second hurdle is difficult to pass where many of the features of the patent claim relate to features which are considered to be non-technical, such as administrative features, or business method features.

The EPO's guidance is that AI-related innovations should be described and claimed as being developed for a specific implementation (technical purpose), as this will assist in overcoming these two hurdles. It is generally more straightforward to avoid the bar on patentability of diagnostic methods by ensuring that at least one technical step of the method is carried out in the absence of a human or animal body (for example, on a computer).

DeepMind Technologies is currently seeking patent protection for a system developed as part of its high profile collaboration with Moorfields Eye Hospital, where software was trained to diagnose a range of ocular conditions from digitised retinal scans. The AI system has been shown to recommend the correct referral decision for over 50 eye diseases with 94% accuracy, matching the performance of top medical experts. The EPO has issued their first opinion on the claims of DeepMind's patent application, and appears to consider that the subject matter is eligible for patent protection (there are no objections regarding excluded subject matter). The objections that have been raised by the EPO relate to traditional lack of inventive step in view of technology known at the filing date of the application. It should be noted that where AI technology involves processing of medical images, generally speaking, there are strong arguments the subject matter is eligible for patent protection (i.e. not excluded) because of existing EPO case law concerning image processing.

Another AI company, Cognetivity, has already successfully achieved grant of a patent from the European Patent Office to protect their system for early detection of dementia. Using AI, Cognetivity has developed a simple screen-based test that it believes could transform diagnosis of the disease. Cognetivity's test involves subjects being shown approximately 100 images in five minutes, with each image flashed by for just 150 milliseconds. Subjects must then indicate immediately if they have seen an animal or not. The responses are then compared with historical data and the AI system compares the results with those from healthy people and people with the condition.

Transparency and trust

When deciding whether to proceed with patent protection clients can take into account ethical benefits which AI patents can bring in this field. Generally speaking, patent applications are published at around 18 months from filing an initial patent application. The patent application publication includes detailed information about the AI algorithm with enough detail to enable the reader to implement the invention. Thus full transparency is given regarding the technology. Regulators and the public are able to access the information and be assured they know how the technology works and how it reaches decisions.

Since AI technology in the field of diagnosis necessarily uses confidential patient data and makes predictions which significantly impact how a patient is treated, transparency is essential to facilitate trust by patients and medical staff and to aid in accountability in situations where AI results in harm. Because patent protection is a strong monopoly right the patent owner still retains the monopoly rights whilst being able to give the full transparency needed for AI ethics reasons.

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