

Protecting Digital Medtech Innovation

Author: Alex Bone

For many years the medical technology (medtech) sector has been at the forefront of innovation and the pandemic has not slowed it down, with new technology quickly being developed to test for, prevent and treat the virus.

Protecting medtech innovations can be crucial to the commercial viability of a new development project. A protection strategy that indicates the potential for securing patents can drive investment because patents can help to secure a market position and / or can be licensed for use by others to provide additional revenue.

The most recent data from the European Patent Office shows that the top ten technical fields for patent filings by number in 2020 include “medical technology” at number one, “pharmaceuticals” at six and “biotechnology” at eight, with each showing an increase in filings from the previous year. Some of this increase may have been due to the crisis, but it seems likely that the upward trend for this sector will continue, particularly in the digital space.

Digital technology is already well integrated into medtech, with electronic delivery, testing, diagnostic and monitoring devices improving all the time. Digital technology also facilitates the analysis of images and data, identifying trends and spotting abnormalities.

Incorporating Artificial Intelligence (AI) is becoming more common as it is hoped that this will result in systems that are faster and more accurate than digital, but non-AI, versions. The recent data already shows a significant increase in FDA approvals for AI algorithms with medical applications.

During the pandemic AI has also proven that it can help with drug discovery. In early 2020 an AI tool was used review data (including patents, papers and the like) and predicted that an existing drug for rheumatoid arthritis, baricitinib, might be beneficial in treating critically ill Covid-19 patients. That prediction was tested and ultimately resulted in some emergency regulatory approvals of the drug to treat that patient population.

Traditional developments continue, but the additional focus on digital innovation means that protection strategies need to evolve. Patent applicants for medical technology have always had to deal with the exclusion from patentability in some territories for methods of medical treatment or diagnosis carried out on the human body. Since many digital and AI medtech innovations involve software, and software “as such” is excluded from patentability in some territories, they must now deal with an additional exclusion. Given these exclusions, can these innovations be patented, and is it worth it when the actual software code is automatically protected by copyright?

Given the limited protection afforded by copyright, and the potential importance of protection for such innovations, the good news is that, “YES”, in many cases, patent protection can be obtained.

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However, AI is a new and fast evolving technology and the potential for obtaining patent protection is not always clear.

The major patent offices have, over recent years, worked with applicants and attorneys to understand the needs of industry and to issue guidance on protecting AI inventions. The general guidance is that a non-obvious technical solution to a technical problem should be patentable. AI and software inventions may be considered technical as a result of their technical application, or their technical implementation on a computer system, for example, improving that computer system.

Patents are not the only form of protection available for AI or software. Some technical aspects of an innovation may not be visible to an end user. A user may interact with a graphical user interface to access a cloud based AI, or they may interact only with an end product which has been developed using input from an AI device. In such cases end users do not gain direct access to, and cannot easily analyse, the AI or software. The disclosure required to obtain a patent may not be an attractive option.

Protecting such innovations using trade secrets may be a commercially appropriate option. A trade secret is information that (a) is not generally known, (b) has commercial value and (iii) is treated by its holder as secret. A trade secret should be known to as few people as possible and, preferably, only to those who need to know it.

There is no single IP right that is best for protecting digital innovations in the medtech field. It is important to have a flexible strategy that can take advantage of the benefits of different rights for aspects of the innovation.

If you have any queries regarding this topic, or other pharmaceutical or biotechnological matters, please contact Alex Bone at amtb@aathornton.com or visit aathornton.com.