Artificial
Intelligence

AI & patient compliance

This article looks at technology in the area of patient compliance, an area where AI is having a huge impact on the life sciences industry. Technologies facilitating patient compliance raise a host of intellectual property considerations in Europe.

What is patient compliance and why is it important?

Patient compliance or adherence refers to the extent to which patients take medications as prescribed by healthcare providers. Compliance is essential to ensure that medicines work properly and to track the safety and efficacy profiles of a medication during clinical trials and for long-term pharmacovigilance once a medication reaches the marketplace.

Non-compliance causes thousands of medication-related hospital admissions every year, issues with drug-resistance, difficulties in clinical trial data collection, wasted medicine and high medical costs. It is a widespread problem that particularly effects medications for chronic illnesses.

Historically, patient self-reporting or pill counts have been used as compliance measures, but these measures are unreliable, and now healthcare providers are turning to alternative solutions.

Could AI be the answer?

A number of new companies are developing AI-driven technologies to facilitate patient compliance. Companies are developing platforms that use software algorithms on smartphones to visually and automatically confirm patient identity, medication and ingestion, send ingestion/dose reminders, and adapt based on the unique patient behavioural profile. Some platforms have already been shown to increase adherence by over 50%.

As a result, more patients benefit from the full efficacy of their medication. Clinicians will have access to real-time data and more complete and accurate data collection from their patients. The knock-on effect of this should be faster and more successful clinical trials, safer medication on the marketplace, and less medical wastage.

Who are the current players?

Some of the bigger companies in the market at the moment who are providing these technologies include:

— *AiCure:* AI-based patient monitoring platform, for facial recognition to confirm that patients have ingested their medicine. Partners include AbbVie and NeuroBo.
— *Brite Health:* Adaptive personalised patient engagement platform, which personalises engagement strategies based on the unique behavioural profile of the user.
— *Medisafe:* Personalised medication management platform. Partners include Boehringer Ingelheim and Apple Health Records.
— *Proteus Digital Health:* develop smart-pills (ingestible digital sensors) with built-in machine learning capabilities that track medication adherence. Partners include Novartis and Otsuka.

It is likely that hospitals and the NHS will be key players in development and use of machine learning to facilitate patient compliance. An example is the machine learning system, developed by University College London Hospital, that was trained to predict the likelihood that individual patients will arrive on time for their MRI scan appointment and was found to be very accurate. The recently established NHSX includes in its mission "Improving NHS productivity with digital technology" and was announced to have £1bn in funding per year.

IP considerations

Patents

AI-driven technology is potentially patentable provided there is a technical problem solved by a new and inventive technical solution. In Europe, an AI invention is generally treated as a computer-implemented invention and to be patentable it must solve a technical problem using a new and inventive technical solution.

In the context of patient compliance platforms, inventions will most likely exist around the process of receiving personal patient data, learning from the data using machine learning, and then using the trained machine learning system to predict the likelihood a patient will not take their medication at the correct time. Patent claims may be directed to 'a computer-implemented method for providing a health assistant system' or 'a system for medication adherence management'.

A challenge with these types of inventions in Europe may relate to their 'technical purpose'. How many different technical effects and technical purposes could these platforms be addressing? Trade secrets could be used as an alternative form of protection. However, there are significant drawbacks to using trade secret protection in the field of patient compliance technology due to the ethical reasons around making the technology transparent and explainable to patients and medical staff. In addition, NHSX states on its web site that "all source code is open by default so that anyone who wants to write code for the NHS can see what we need". Where source code of an AI invention is open it is not possible to use trade secret protection.

Another consideration is how to assert AI algorithm patents for patient compliance inventions. Because patents are territorial, there is a need to identify the territory where technology is being exploited when thinking about asserting a patent. It can be difficult to identify where a patented AI process is occurring or where a result of a patented AI process is stored if the process can be implemented in the cloud or across a distributed computing system as the infringement is very often not in the same jurisdiction as the user who supplied the initial data. Having said that, there are often ways to overcome these issues and successfully assert patents. Regulatory requirements (such as from the GDPR) around the storage and handling of personalised patient data could mean more transparency in this area, which may make it easier to determine patent infringements if patient data, a patented process and resulting data must be contained within a single jurisdiction.

It may also be difficult to "detect infringement"; that is, identify if a patented AI process is being used by a competitor who deploys the technology as a black box cloud service. However, where AI software is part of a medical device, regulatory requirements can force competitors to disclose their technology. In addition, provisions of the GDPR may force competitors to disclose information about how AI algorithms work where those algorithms are used in automated decision making.

Trademarks

Brand protection of word marks, logos and App icons is extremely important for AI brand holders because of the reputational risk associated with AI. In the case of patient compliance, the reputational risk is extreme, because of the use of patient data in the AI algorithms used for patient compliance. AI brand holders need to consider strong brand protection and brand enforcement policies.

Copyright

Software source code in AI patient compliance algorithms will benefit from copyright protection. Copyright protection arises automatically and generally lasts for many decades. However, it does not protect against competitors independently developing similar technology. In order to enforce copyright, it is generally necessary to obtain evidence of the source code being copied. This can be difficult where AI is provided as a cloud service or using executable code.

Design rights

It is possible to gain protection for surface decoration i.e. the look of a smartphone App using UK Registered Design and/or Community Registered and Unregistered Designs. Generally speaking, design protection protects the appearance of a product, not the way the AI algorithm works.

Database rights

UK and EU database rights may exist for the databases that store the information processed by the AI and where skill and effort has been spent collating the data in the database.

Contacts

Frances Denney
Associate
T +44 20 7067 3261
E frances.denney@cms-cmno.com

Dr Rachel Free
Partner
T +44 20 7067 3286
E rachel.free@cms-cmno.com

Further reading: AI in life sciences
Please join our seminar on Harnessing Digital Health in London on 8 October in London.