GNP 18 The Impact of Artificial Intelligence and Machine Learning on Pharmaceutical Patents

Artificial Intelligence (AI) and Machine Learning (ML) have seen a surge in interest in recent years, with many sectors harnessing its power to accelerate innovation. Here, we examine the impact of AI and ML on the pharmaceutical sector, and its influence on patent strategies.

There is a great expectation that AI and ML will deliver new pharmaceuticals to the market in the near future. With an unparalleled ability to consume, recall and process data at rates beyond human capability, many believe that AI and ML will reverse the decline in drug development that has been experienced over the last decade.

AI and ML have the potential to impact many aspects of drug development. When it comes to Intellectual Property its main challenges are in the area of plausibility, inventorship, and inventiveness. Each of these will be explored in this guidance note, but before we start, a quick note on semantics. From here on, we will refer to AI and ML together as ML as it more accurately reflects the technology being used within the pharmaceutical sector at this time.

Plausibility

A patent application may be granted only if it is plausible that that invention can be put into practice, and that it has an unexpected advantage or "technical effect". Plausibility is based upon the information in the application as filed, in combination with the common general knowledge at the time. We refer to the separate guidance note explaining the plausibility assessment used by patent offices.

For pharmaceutical patents, satisfying the plausibility requirements usually means that applications should contain data, backed up by a sound scientific theory, which together makes credible the treatment of specific diseases. Data is typically in the form of established in vitro or in vivo models. For instance, efficacy data in the CFA-induced rat model of arthritis may render plausible the use of prospective drugs against heat hyperalgesia or tactile allodynia in humans as there is sufficient evidence in the literature to support the feasibility of a positive result in a rat translating into human treatment.

Unlike in vitro or in vivo models, in silico studies (those carried out by ML algorithms) are yet to earn the trust of the community or regulators. Currently, it appears that there is not enough evidence in the literature to convincingly support the translation of in silico results into real human treatments without additional support from in vitro or in vivo models.

Patent law relating to ML-derived innovation, particularly within the pharmaceutical sector, is in its infancy. At present, it is unlikely that patent offices will grant a patent based solely on in silico data. One would, however, expect this to change as ML models gain acceptance.

Inventorship

After recent consideration by various patent offices around the world, patent law still requires inventors to be human. In the short-term there appears to be no indication that computers will be recognised as being capable of "inventiveness". Patent law usually struggles to adapt with emergent technology in a timely manner. We may see this area of law develop but this is not expected for years to come.

In view of current research methods in the pharmaceutical sector, denying ML-algorithms inventorship appears to be an acceptable approach. People responsible for establishing the underlying inventive concept of a particular innovation are typically named correctly as inventors. In any case, it is strongly recommended that at least one human inventor is included on a patent application.

One particular case that has piqued the interest of the community is an AI system called DABUS (Device for the Autonomous Bootstrapping of Unified Sentience). Developed as part of "The Artificial Inventor Project", it has been listed as an inventor on two different patent application families. The examination of those applications by national patent offices will be keenly watched by those looking to protect and monetise their ML algorithms.

We do not yet have access to Artificial General Intelligence (AGI) – the intelligence of a machine that can understand and learn any intellectual task that a human being can. With the advent of such systems we may once again open the question of the legitimacy of computer programs as inventors. Until that time, ML algorithms continue to provide results for a very specific, clearly-defined problem, within a specific range of variables set and coordinated by a human operator. As such, current ML algorithms are unlikely to be capable of inventiveness.

Inventiveness

The journey to the creation of an invention is immaterial to its inventiveness as far as patent offices are concerned. Instead, an objective test for assessing inventive step is used, which is based upon the disclosure of the prior art and common general knowledge. The test does not consider how the invention was made. As computers cannot be inventors, and therefore cannot be responsible for the inventive concept underlying the technology, it is questionable whether anything that they produce can be inventive. This has led to a growing concern that the patent system may begin to consider the tools used in the innovation process, which could result in a higher inventiveness threshold being required for ML-derived innovation. There is, however, currently no indication that this is happening.

There is no requirement to disclose the process by which an invention is devised, and therefore one option may be not to disclosure the use of ML in a patent application. For instance, if you are using ML to design new agonists of a specific kinase receptor to treat a certain disease, then the inventive concept may lie in the structure of the agonist compounds and their ability it elicit a biological response. One may only need to disclose in a patent application their structure, their synthetic route, and in vitro data demonstrating their agonistic behaviour (assuming there is a known link between inhibition of the kinase and the disease to be treated). No information on the use of a ML algorithm to derive the structures would typically be required. Current thinking is that such uses of ML are not disclosed in patent applications.

The take-home message is that while ML may have a huge impact on pharmaceutical research, its influence does not currently extend beyond that of a tool used to increase research efficiency. Patent applicants should be mindful of the issues mentioned above, and seek help from a qualified patent attorney to navigate the potential patentability problems inherent in the use of ML technology in driving innovation.