Future Care Capital

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Impact of artificial intelligence on UK trade secret law

Introduction to Future Care Capital

Future Care Capital (FCC) is a charity which undertakes research and engages in practical projects to advance ideas that will help shape future health and social care policy and deliver better outcomes for individuals living in the UK. Beginning life as the National Nursery Examination Board in 1945, the charity has evolved throughout its 70-year history and we continue to have Her Majesty the Queen as our Royal Patron. Future Care Capital is a registered charity, charity no. 036232.

Our work

FCC has produced several publications which explore how the UK might better harness the value of healthcare data, as well as legal and regulatory considerations for data and data driven technology in healthcare, including: Taking Next Steps to Harness the Value of Health and Care Data (2019)[1]; Research and Commercial Use of Healthcare Data (2020)[2]; Parliamentary briefing for the Medicine and Medical Devices Bill (2020)[3].

1 https://futurecarecapital.org.uk/research/22nd-may-2019-taking-next-steps-to-harness-the-value-of-health-and-care-data/
2 https://futurecarecapital.org.uk/research/research-and-commercial-use-of-healthcare-data/
3 https://futurecarecapital.org.uk/policy/medicines-and-medical-devices-bill/

Summary

In recent years we have seen a proliferation of Artificial Intelligence (AI) technology, primarily driven by the advancement of Neural Network technology, with several technical competitions in 2012 and a subsequent “boom” in academic publications and commercial exploitation from 2016 onwards. Progress in the field continues at a rapid pace, with AI techniques such as reinforcement learning and generative models presenting opportunities for discovery as well as regulatory and ethical concerns. The current series of Intellectual Property (IP) consultation requests by the government are part of a landscape of important issues to be considered for the ongoing development and adoption of AI. In the response presented here, we focus on trade secret laws and AI, drawing on examples from healthcare to demonstrate considerations where exceptions to trade secret law should be maintained, namely where patient and clinical safety is of the greatest importance. We recommend taking inspiration from, and improving on, the drug approval processes currently in place in the UK. We recommend the following approaches related to AI and UK trade secret law in healthcare:

1. Work with AI developers, the healthcare industry, and its regulators, to develop adequate protection for trade secrets, while preserving patient safety
2. Draw on existing approaches to drug discovery and market entry when considering AI in healthcare
3. Communicate clearly with developers to address concerns over revealing trade secrets for the purpose of regulatory approval

Context

As the UK transitions from the European Union (EU), policymakers, regulators and legislators need to consider the consequences of continuation agreements, new trade clauses and incoming legislation which would otherwise have relied on EU rules, for example the Medicines and Medical Devices Bill. Such change represents an opportunity to create an environment which benefits the UK, its ability to research, innovate and develop pertinent technologies. The governing decisions related to AI are still being considered by government departments and regulators, where in some instances AI is an independent sector whereas in other scenarios, specific industries will require tailored AI legislation. Certain industries have made large steps in the adoption of data-driven technology and AI already - for example, financial regulatory initiatives such as PSD2 in the EU and the approach to Open Banking standardisation in the UK. This has been instrumental in start-ups and challenger banks flourishing as well as in driving the application of novel machine learning and AI techniques for a broad range of functions, from fraud detection to credit scoring.

The pharmaceutical industry has also started to explore different approaches to AI and machine learning, with the MELLODDY consortium[4] providing an exploration of Federated Learning approaches to derive mutual value for industry players, without exposing vast amounts of IP, trade secrets or proprietary datasets. The COVID-19 pandemic has, similarly, pushed forward the used of different analytic approaches and an emphasis has been placed upon data, scientific discovery, and analysis. There has been a rapid surge in intellectual property developed as a result of rapid funding allocation, data sharing and changes in policy to enable the modelling of scenarios and the development of vaccines, treatments and solutions to different problems arising from the pandemic. Indeed, there have been instances of individuals and organisations volunteering their IP to help rapidly develop solutions in this context[5]. The Medicines and Medical Devices Bill is currently making its way through parliament and the appropriate regulators are beginning to consider how AI should be accounted for in legislation and practice. This consultation is a useful one and the topic is of great importance for the healthcare sector which we specifically focus on here.

Response to questions:

1. Is trade secret protection important for the AI sector? Does the nature of AI technologies and business influence your answer?

This is an important topic which is relevant to all sectors adopting AI in the UK. The concerns highlighted through this consultation process will not be straightforward to address, and different sectors and specific cases of AI will require different approaches. It is essential that there is an ongoing dialogue with AI practitioners as well as the sectors those practitioners are deploying products, solutions, and services in. In this consultation response, we focus on AI developed and deployed in healthcare settings, however many of the concerns here would be prominent in other sectors and, in particular, where use of the technology would affect personal security and safety.

Developers of technology seek to protect their IP in relation to many different elements of AI development because it provides a competitive advantage in a given market niche. When discussing AI and any associated IP, It is not purely algorithm selection and model development which are apposite, as there are areas of AI tooling, such as overall software architecture, approaches for data curation, labelling, pre-processing, and the assembly of "AI plumbing" which could all be considered as either a trade secret, or the IP of a company or individual. Indeed, as novel AI techniques, for example Generative Adversarial Networks (GANs), progress, the outputs of AI models are increasingly considered to be unique, with interesting developments where researchers have attempted to make an "AI inventor" the patent holder, such as the DABUS case with the EU Patent office[6].

4 https://www.melloddy.eu/
5 https://www.nature.com/articles/s41587-020-0682-1
6 https://www.epo.org/news-events/news/2019/20191220.html

With this context in mind, we need to carefully consider how AI is potentially going to be deployed in healthcare, as well as academic transfer from the life sciences research sector. The following areas of the healthcare sector are already incorporating AI techniques which, alongside many others not listed, will require regulatory approval and medical device registration with the Medicines and Healthcare products Regulatory Authority (MHRA), or another appropriate body: drug discovery/development[7], clinical triage[8] and diagnostics/ biomarkers[9]. In all of these instances, patient safety is paramount, and where devices are deemed to have a medical purpose, the MHRA needs to be able to sufficiently audit and scrutinise the process and safe functioning of any tools being used. It is important that AI developers and IP owners should feel confident in the protection of trade secrets and their commercial advantages, however at no point should this be prioritised over patient safety; and, these considerations are inextricably linked to the extent that public trust in the deployment of new technologies in healthcare settings is vitally important to the growth of the AI sector over time. In response to Question 3., we explore where this has been effectively implemented for the pharmaceutical industry in relation to drug discovery, as well as looking at examples of where regulators (including the MHRA) have operated to protect trade secrets from wider visibility through certain public disclosure exemptions, while maintaining a rigorous approach to regulation and patient safety.

2. Does the nature of AI pose any problems if UK trade secret protection is required? Does UK trade secret law give adequate protection to aspects of AI technology where no other intellectual property rights are available?

There are certain sectors and scenarios where trade secret protection is either essential (for example, defence modelling systems and cyber resilience) or, equally, full protections are wholly unfeasible (as is the focus of this consultation response in healthcare and instances of patient safety). Other submissions will no doubt cover many of the essential needs for trade secret protections. The requirement for trade secret protection in healthcare would pose a problem if, as a result, an appropriate body would not be able to secure access to product features for the purpose of scrutiny and audit. AI is in and of itself difficult to audit and scrutinise, particularly in Deep Neural Network (DNN) approaches[10], however trade secret law should not prohibit such scrutiny when adequate methodology and tooling is developed from a regulatory perspective. Indeed, recent efforts by the MHRA and academic partners are starting to provide potential methods to be deployed in practice, however significant progress in this domain is needed for patient safety to be upheld[11]. The NHS AI lab has been launched to accelerate the development and deployment of AI products in the healthcare sector and will need to work with the regulator to ensure a smooth transition from development to deployment in the sector. From inception, the programme has aimed to address audit and inspection in an environment which prioritises safety and efficacy[12] and trade secrets should not hinder such efforts.

7 https://www.sciencedirect.com/science/article/pii/S1359644620304256
8 https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30199-0/fulltext
9 https://www.nature.com/articles/s41591-020-0942-0
10https://www.nature.com/articles/s41599-020-0501-9
11 https://www.nature.com/articles/s41746-020-00353-9
12 https://healthtech.blog.gov.uk/2019/10/30/the-nhs-artificial-intelligence-lab-how-to-get-it-right/

3. What are the advantages and disadvantages of using trade secrets in the AI sector? Could information that is not shared inhibit AI development?

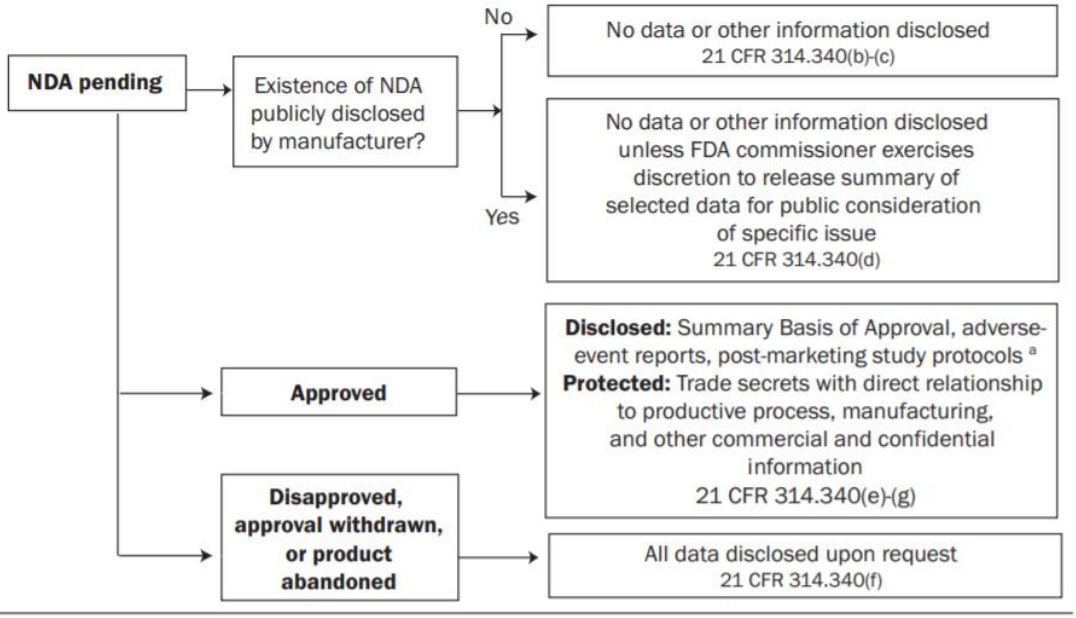
The AI sector has in part grown out of an academic field which has embraced open source approaches, whether publishing full datasets on GitHub, linked to pre-print arXiv papers, or indeed community-driven approaches to Kaggle competitions. However, this is not always the approach preferred by industry. The Alan Turing Institute has pioneered "Data Study Group" explorations of commercial data[13] and sits between the two extremes, with insights and findings published for wider consumption, whilst commercially sensitive information is redacted. All three approaches, in their own way, have pushed the field of AI forward rapidly. This progress is exceptional, and, in our recommendations, we do not seek to inhibit such progress.

From a regulatory perspective, trade secret laws should not pose a threat to audit, scrutiny or patient safety, as the regulator has long been able to protect IP and trade secrets as with drug approval processes, where clinical trial data and related information is considered to be a trade secret. This will certainly still be a concern for businesses and individuals developing AI, but clearly communicated examples from healthcare industry regulation as well as Food and Drug Administration (FDA) and MHRA approvals should help assuage such concerns[14]. Where the MHRA is able to regulate medicines and medical devices at present, trade secrets are protected by the regulator because the regulator is exempt from trade secret laws, on condition of protecting commercially sensitive information, as is the case for the FDA[10]. An increasing proportion of international trade is related to digital products and services, and AI products comprise a growing portion of this trade[15]. The Government should act to ensure that the products entering the UK market are reliable and of a high quality. The Financial Conduct Authority (FCA) has previously deployed regulatory sandboxes to trial Open Banking and PSD2[16] and similar initiatives may be useful where AI and healthcare is concerned.

Exhibit 1 below, adapted from the FDA regulatory pathway guidance on clinical trial data disclosures relating to new drugs[17], demonstrates how pharmaceutical companies approach trade secret law with the regulator in the United States of America. A similar approach, potentially more tailored in terms of the pathway for disapproved, withdrawn or abandoned products, would be suitable for AI in healthcare applications:

13 https://www.turing.ac.uk/collaborate-turing/data-study-groups
14 https://www.fda.gov/international-programs/confidentiality-commitments/united-kingdom-medicines-and-healthcare-products-regulatory-agency-fda-confidentiality-commitment
15 https://technation.io/unlocking-global-tech-report/
16 https://www.fca.org.uk/firms/innovation/regulatory-sandbox
17 https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.26.2.483 (accessed: 26.11.2020)

EXHIBIT 1
Food And Drug Administration (FDA) Disclosure Regulations Regarding New Drug Applications (NDAs)



SOURCE: Code of Federal Regulations (CFR).
[a] Information discussed by advisory committees may be subject to disclosure (21 CFR 14.75).

4. Do trade secrets cause problems for the ethical oversight of AI inventions?

Much of the time, a robust and reliable prediction, decision or recommendation is the required output of an AI system. Whether an autonomous vehicle (AV) or a medical diagnostic tool, these can have significant human costs in the event of a malfunction or misclassification of a scenario[18]. In a healthcare setting, if something goes wrong, an inquest needs to be held and an inquiry needs to examine and interpret the steps leading up to the incident. There is as much a requirement for accountability and justice for those harmed as there is for ensuring future adverse events do not occur. If being kept a trade secret prevents audit or interrogation for the sake of patient safety, then that is not acceptable ethical oversight. Academia and industry are both working together as well as with government to develop processes and tools to enable the ethical oversight of AI interventions in healthcare[19]; and, from our perspective, there is much to commend the idea of establishing a 'digital accident investigation unit' in healthcare.

18 https://www.nytimes.com/2018/03/19/technology/uber-driverless-fatality.html
19 https://pubmed.ncbi.nlm.nih.gov/31982053/