Abstracts for „Legal Issues Arising from AI and Big Data in the Health and Life Sciences”

Iain Mitchell QC, Tanfield Chambers - Robot Doctors? - Some legal and ethical issues of using Artificial Intelligence in medicine

Iain G. Mitchell QC will consider the use in medicine of medical algorithms generally, and AI systems in particular. As well as looking at black letter law questions of regulation, data protection and the assigning of legal responsibility where there are multiple authors (as in Open Source Software) and where there are none (as in AI systems), he looks more broadly at deeper questions such as the nature of Intelligence, and the role of ethics in AI systems.

Dr. Rachel Sachs, Washington University School of Law – Regulating Intermediate Technologies

Over the last several years, scholars studying health innovation policy have carefully considered the ways in which administrative agencies do and should regulate different types of technologies to encourage their development and dissemination. Scholars have examined a range of legal incentives, including patents, Food and Drug Administration (FDA) exclusivity periods, taxes, grants, health insurance reimbursement, and other tools to promote socially valuable innovations that our current system has structurally disfavored. This research has considered broad categories of technologies, including drugs, devices, and diagnostics.

However, this research has neglected an important dimension of the issue: the temporal one. Specifically, a large set of innovations in the life sciences may be considered to be intermediate innovations. Scientists and physicians continue to improve these technologies over time, even as the initial products are made available to patients. Yet the relevant innovation policy levers are not set up to consider whether intermediate technologies ought to be regulated differently than technologies which are further along in the development process.

Whether our existing intellectual property and regulatory frameworks are cognizant of an innovation’s stage of development matters. In many cases, if the regulatory structure is not appropriately calibrated, the technology will be frozen in time such that future development does not occur. The essential concern is that if the regulation around the intermediate technology is not appropriately calibrated, the later-stage technology will not be developed at all. This failure would be harmful for public health and for societal welfare. Policy levers which may facially appear to be targeted at early-stage technologies are not driven by this policy question, and lack a fit with this type of consideration.

This Article articulates the problem of regulating intermediate technologies in the life sciences and considers how existing laws might be altered to accommodate the situation. Although patent law scholarship has considered questions regarding technological improvement and sequential
innovation, it has not considered how patent law may interact with other areas of law to exacerbate these concerns. As such, this Article looks to FDA regulation and health law to address these issues. At present, some of the FDA’s existing regulatory approaches around devices or biologic products are already capable of addressing the problem (even if they were designed for other purposes), and others can be altered to do so. Other solutions may lie in the realm of reimbursement, in which the stage of a technology could play into the payments made by insurers for that technology.

Dr. Helen Yu, CeBIL - The European Open Science Cloud: What about Other Stakeholders’ Interests?

The goal of the European Science Cloud Declaration (EOSC) is to support knowledge creation by fostering open science, open innovation, and open dissemination to ensure knowledge and scientific data can circulate more freely for innovation and educational purposes. Conspicuously absent from the EOSC discussion of “inclusive stakeholder participation and engagement” is the role of industry in the innovation ecosystem. In this context, the EOSC’s ‘open access by default’ principle risks becoming a blunt policy instrument because a ‘by default’ position does not encourage relevant stakeholders to exercise the necessary care and consideration on how their actions impact the innovation ecosystem.