

Biomedical research, participants and access to innovation: Patents and the protection of the public interest

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Abstract:

Biomedical research infrastructures, such as biobanks, built on patient data, are a lynchpin in modern biomedical research. Such resources have been fundamental to research advances against Covid-19, and they are vital for modern biomedical research, especially in genomics and personalised medicine. These research infrastructures represent a significant public investment, both in terms of public and charitable research funding, as well as participant contributions in the form of samples and data.

The protection of participants and the public interest is core to the establishment and operation of these research infrastructures, and their regulation and governance is founded around this aim. However, that fundamental focus on the participants and public, whose continuing involvement is essential to the existence of these infrastructures, effectively evaporates when research begins to have translational outcomes, that is, becomes clinically relevant or results in a diagnostic or therapeutic innovation. At this point, the private rights of patent holders become key, and the rights of the participants are effectively removed from consideration – they have no legal rights because they are not the patent holder, and the legal framework becomes the private law framework of patent law, with its quite different focus.

This paper argues that intellectual property rights can and should better protect the public investment in biomedical research. It draws together arguments from the regulation of biomedical research, with its focus on the protection of participants, with intellectual property law scholarship, and argues that participants and the public, including appropriate access to the benefits of research, need to be more carefully considered throughout the translational research pathway. IP rights which arise from research on biomedical research infrastructure need not only be a tool for private gain for commercial patent holders, but instead may offer a means to ensure the better protection of the public interest, allowing improved recognition of the public investment in research. The importance of these large infrastructures in the biomedical research space should not be overlooked; they can leverage their power to drive change, such that IP rights can be used to enhance public access to innovation on reasonable terms.