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Contracts and intellectual property rights in translational R&D – furthering safeguards in the public interest

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The importance of IP safeguards

Intellectual property (IP) rights play a central role in debates around access to new technologies. The challenge of balancing private innovation incentives such as patents with public access to the fruits of innovation is particularly acute in the healthcare field.

Healthcare innovation is a field where IP rights proliferate. New biomedical products (e.g. therapies, vaccines and diagnostic products) are the subject matter of patent applications filed at patent offices around the world. Additional IP protection may be given to background technologies (e.g. assay methodologies) along with developments in manufacturing, transportation and storage of healthcare products. These different technologies may be protected by patent rights or as 'know-how' under trade secret laws.(1)(2) A healthcare innovator is typically unwilling to invest in developing a new technology in the absence of such protection.

IP rights, by their very nature, restrict public access by reserving monopoly control to the rights holder. Those wishing to access the technology, either as an end product user or for the purposes of manufacture, are required to contract with the owners of the IP rights. These exclusionary rights exists because they are thought to serve the public interest overall – through incentivising innovation, increasing disclosure and ensuring wider access overall to the fruits of inventive activity. Nevertheless, the system depends on a series of checks and balances to ensure that the pendulum does not swing too far in favour of rights holders, and away from the public interest. When it comes to the development and commercialisation of IP protected healthcare innovations, policymakers, advocacy organisations, practitioners and academics have explored multiple different avenues on how best to preserve a fair balance of private and public interests. These issues and concerns are not new, although they have been drawn into sharper relief, and have reached new audiences, in light of the Covid-19 pandemic and concerns over fair access to vaccines and treatments.

How publicly funded innovation fits into the patent system is also a relevant and contentious aspect of this debate. There has been a long and controversial history, particularly in the USA, over the patenting of publicly-funded and publicly-conducted research. Nevertheless, it is also widely accepted that patents and licensing are extremely important for facilitating technology transfer in many cases.(3) While we do not seek directly to enter into this discussion, we note that, for better or for worse, the privatisation of publicly-funded and publicly-conducted research is a key element driving innovation strategies in many western nations.(4) Instead, our objective here is to propose how changes within the current system of privatisation and exploitation can better acknowledge and protect the wider public interest throughout the process of translating innovative research into useful outcomes.

We argue that an under-explored potential means of addressing these issues is through the bilateral contracts which underpin the translational R&D process. Contracts underpin the entire innovation chain, and they are a valuable and direct means by which a policy balance within the IP system can be achieved.(5) IP safeguards can, and should, in our view, be more widely incorporated into those contracts, to preserve the interests of those not directly party to them, i.e. the public, especially where public funds and resources have spearheaded the innovation process.

Some efforts in this respect have previously been made. As discussed below, funder agreements usually express some, albeit inconsistent, level of control over IP and its exploitation. Furthermore, in 2007, the Association of University Technology Managers Board of Directors made the clearest attempt at the higher education level when it endorsed the Nine Points to Consider in Licensing University Technology.(6) These principles are widely referred to and have been endorsed by universities both within and outside of the USA. While not stated to be binding on universities, or

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even agreed as best practice to be adopted by signatories, this document sought to make some concrete suggestions on how to operationalise its conception of the way universities should protect the public interest in their contracting. However, recent research indicates that, despite the positives in the Nine Points document, relatively few changes in US university licensing agreements in relation to the promotion of public health or access to medical technologies can be seen.(3) More, therefore, remains to be done.

Greater attention to the contractual terms in research and commercialisation agreements *throughout* the translational development chain is a necessary and practically realisable way to achieve the fair balance discussed above. This approach complements current efforts, such as, for example, the adoption, adaptation or amendment of international legal instruments, including the WTO TRIPS Agreement. That being said, our proposal has the potential to be adopted without global agreement or even any changes to national legislation. Together, key stakeholders in the translational research chain, including public and charitable funders, universities, and commercial companies, have the ability to make important changes to policies and practices and to reflect them in contractual arrangements in order to enhance the wider public interest.

Contractual IP safeguards

Contracts are integral to all phases of the translational research chain. For example, the process of translation or commercialisation of biomedical research ranges from relatively early-stage research with the potential for clinical benefit, to the later stages which are much closer to the clinic.(3) It is rare, however, for a single institution to both fund and undertake the research and development across all stages of the translational research chain.(7) It is usual for several bodies, both public and private, to be involved at key points in the process and at each stage the relationship is governed by contracts. Although each contract stands on its own, a commercially useful product will be developed using a web of contractual arrangements. These agreements, beyond other matters, seek to define IP and each parties' rights and obligations in relation to that IP.(8)(9) It is, therefore, important to investigate the ways in which these contracts can be utilised as a tool for enhancing the balance in IP.

Contracts do, however, give rise to some key problems. First, contracts, are bilateral (and usually binding only on the parties) and, in most common law jurisdictions, rest on a fundamental principle of freedom of contract, such that the parties decide the terms subject to minimal external controls. Second, there is no single or standard contract governing the funding, research, and commercialisation process. There are many stages and many contracts between the initial funding of the first research through to its translation into a useful product, resulting in a chain (or in most cases a complex mesh) of contracts relating to a single innovative product. Finally, and as will be discussed in more detail below, the contractual obligations that exist as part of the translational research chain, and the interests that they seek to preserve, are, at present, not perfectly aligned. For example, research funders impose obligations, through contracts, on the parties that they fund to protect the public purse and to secure the overarching aims of the specific funding call; universities seek to preserve their own educational and research interests; and businesses impose terms to preserve their commercial objectives. While each may seek indirectly to advance the public interest through, for example, the provision of a new therapy, other issues such as the wider availability of innovations are regularly not addressed. Consequently, these private contractual arrangements seem, at first sight, to be an inapposite mechanism for the imposition of policy objectives around ensuring the maintenance of the wider public good.

Yet, contracts, at each stage, are a negotiated outcome that should reflect the objectives of the relevant parties. If suitably drafted, they are the main means by which the common charitable and statutory obligations of parties such as universities or public/charitable funders can be secured. These contracts should, therefore, reflect the general approach, policy and ethos of the parties, and can operate to constrain the freedom of other parties further down the translational research chain. On this basis, it is our contention that the use of contracts is a means by which IP safeguards can be embedded and traced through all stages of translational research. Against this background, we propose that it is useful to consider the contractual arrangements at three key stages of the translational pathway:

1. Funding agreements - between funding organisation and Research Practising Organisations (RPOs)(10)
2. Technology transfer and collaboration agreements – between RPOs other parties (including other RPOs and commercial entities)

3. Supply/procurement agreements.

Current approach to contractual IP safeguards

With the above typology in mind, we turn to consider existing contractual practice at each stage of the translational research chain. Our objective here is to demonstrate, first, the scope that exists for including consistent and robust IP safeguards in contractual arrangements and, second, the problems that arise in not doing so. Before embarking on this analysis, it is worth noting that the veil of agreements being declared 'commercial and in confidence' results in a widespread lack of transparency. This limits detailed, vigorous and reliable empirical understanding of the extent of the issue. Stage 1 on funding agreements has some degree of transparency, but even here detail on specific clauses is not shared publicly. Stages 2 and 3 are even more concealed from public oversight. However, the Covid-19 pandemic has resulted in improved availability of key documents and greater public scrutiny. Continued calls for enhanced transparency in relation to medicine are to be supported,(11)(12) because increased transparency enables increased academic scrutiny and analysis.

Stage 1: Funder Agreements

There are strong arguments for including IP safeguards in funder agreements. Key in this regard is the notion that IP rights derived from publicly funded research, and any financial returns arising from their exploitation, should be managed for public benefit on fair terms. There is long established practice of most government and charitable funders including contractual provisions within their funding agreements that control the ownership and exploitation of IP rights arising from research they have funded.(13)(14) These provisions may include the imposition of conditions on the downstream commercialisation or licensing agreement between the RPO and industry. However, there is little consistency between funders and across sectors, and these provisions vary significantly in their strength and their breadth.

Such IP safeguards are seen to have both positive and negative impacts further down the translational research chain. Positive aspects include the express acknowledgment and protection of the public or charitable contribution to the generation of useful knowledge. While many of these provisions tend to be aspirational in nature, they provide important guidance for the future management of research outputs.

At the same time, these clauses have negative impacts, especially for the RPO that will be tasked with commercialising the resulting innovation. Such terms inevitably increase the complexity of the contractual arrangements underpinning the research. In situations where there are multiple funding agreements, the IP safeguard obligations introduced by funders can be overlapping, contradictory or conflicting. This increases the workload and risk for the RPO and can result in situations where different agreements may be impossible to reconcile. Therefore, these terms can, if not well designed, increase the difficulty of future commercialisation or even prevent it in extreme cases.

Stage 2: Commercialisation agreements

Most RPOs, such as universities, have commercialisation or technology transfer departments (or, in some cases, subsidiary companies) to aid in translating academic research into products or processes that can be of practical benefit to society. This process of technology transfer often arises through the acquisition of IP rights over the outputs of funded research and the exploitation of that IP via licensing agreements to industry or as a basis for 'spin-out' companies. The link between the public interest missions of universities and the commercialisation of academic research has long been the subject of debate.(3)(15)(16) Several attempts have been made over the years to streamline and/or guide the commercialisation process to promote the wider public good.(6)(17)(18) Yet, these guidelines and principles have received limited attention and have not been always effectively deployed in practice.(19)(3)

There are several possible reasons why documents that seek to guide the RPO commercialisation process have not achieved their potential. First, broad aspirational provisions to promote the wider public good often fail to define which interests are to be prioritised and are easily technically satisfied whilst being largely ignored in substance. All stakeholders will agree that there is an obligation to work for the benefit of the public and will claim that their activities and contractual agreements are structured with that objective in mind. Yet, individual conceptions of the public

interest/benefit can vary considerably. Patient benefit, for example, can be understood from an individual patient perspective where the measure of success is the effective treatment of a single patient. In contrast, many working in public health would define public interest in terms of its global impact.(20)

Second, guidelines or standard form templates structured for commercialisation at the university or RPO level can conflict with the contractual obligations to funders discussed above. While commitments to the funder can operate as a 'shield' in negotiations with a potential commercialisation partner, they can also conflict with principles set out to guide the RPO processes. The commercialisation team is then placed in the unenviable position of trying to reconcile funder commitments, commercial partners' demands, and the principles or standard forms meant to guide the whole process. Almost inevitably, where conflict arises, it is the latter that is the first to succumb to the pressure.

Third, there can also be disparity between the public interest objectives contained within guidance documents and the management and internal processes of the organisations involved. For example, RPO priorities can vary considerably between universities and between departments within universities. Commitments to the local community can, for example, trump national and global objectives. Also, senior management's financial objectives can cause uncertainty on how best to transfer the technology to achieve the widest impact possible. Similarly, the approach of businesses that are involved in the commercialisation process, as well as their commitment to public interest objectives, varies depending, in part, on the priorities of their shareholders, managers and other stakeholders.

Finally, any guiding principles that seek to place controls or safeguards over IP and its exploitation generally adopt a very narrow definition of intellectual property, being limited to core IP rights – patents, trade marks, copyright, designs and specific know-how. In the biomedical context, however, 'related' IP, such as test data and market exclusivity, may be equally important in facilitating greater access to the end product and in enabling follow-on research and development of the underlying technology. Yet, this aspect of IP is dealt with inconsistently and is often overlooked or excluded in contract negotiations to commercialise funded technology.

Stage 3: Supply or (advanced) procurement agreements

This category of agreements, while it may include 'boilerplate' IP clauses, often lacks sophisticated IP terms that focus on public benefits. It is true that 'off the shelf' procurement agreements for a completed product would be unlikely to include IP safeguards (except perhaps in relation to redistribution of a product and the related exhaustion of IP rights) and we do not include such agreements in this discussion. However, where there is an advanced purchase agreement, such as is relatively common in relation to the procurement of innovative treatments for emerging healthcare needs in an emergency, then such IP safeguards can, and we argue, should, feature in these agreements.

APAs can be utilised to incentivise technological development by contractually securing the market for a future product, serving to increase the incentive to develop and commercialise a product, and to increase manufacturing capacity.(21) They act as an additional 'pull' incentive – a reward for those who successfully bring a product to clinical use by increasing or ensuring future revenues, on top of the existing 'pull' incentive of IP rights.

In the Covid-19 context, APAs were used extensively to support the later stages of vaccine development and to accelerate their path to market, with notable success. Some aspects of the process (such as the single focus on a sole objective by all parties, the extensive funding and the bespoke nature of the agreements generated with extensive expert involvement) are unlikely to be replicated in future situations, absent another crisis on the same scale. However, even when such 'ideal' circumstances for agreements existed, our research indicates that minimal IP safeguards were included in the APAs.(21) While this may be explained by other concerns, such as questions of both financial and reputational risk resulting in IP safeguards being watered down or removed, the fact remains that they were not prioritised in the vaccine agreements, with resulting impacts longer term.

Key practical questions remain about what types of IP safeguards can and should be implemented at this stage in the translation or commercialisation of a product. In some sense, because the product is so close to market, there is greater certainty in relation the likely generation of a useful product, as compared to stage 1 of the typology, which makes the terms easier to envisage. At the same time, the power balance in negotiations between the parties is different, and the likely impact of the terms is clearer – with the resultant commercial risks and benefits also more

tangible. How IP provisions, and more specifically IP safeguards, can best be implemented at stage 3 of our typology, whether and how they can have a positive impact, and what are the risks of their inclusion, remain to be determined.

A call to expand IP safeguards across the translational research chain

Existing practice demonstrates that it is possible to include IP safeguards in contracts for translational research and commercialisation. However, all too often, commercial parties are able to successfully reserve strong IP protections and avoid all but generally weak safeguards for the public interest. The inequity of access to Covid-19 vaccines globally has highlighted once again the importance of attention to the role that better controls on IP can play in addressing the public interest. We argue that IP safeguards in contracts have an important role to play in this respect. Moreover, it is vital that IP safeguards are traced through all stages of the translational research process, to ensure that the safeguards funders put in place at the outset do not evaporate by the time that research reaches the public. The state's investment must be recognised in a way that is meaningful and beneficial to public welfare.

Further research is needed to understand some of the key issues that are relevant. For example, how can we map the results of well-intentioned policies to understand whether it ultimately improves public access? How do we understand the lost opportunities/valley of death problem that some of these policies can unwittingly result in? How can we understand the competing interests and priorities of key stakeholders? And how should different conceptions of the public interest, with commercial, national and global interests, be accommodated?

There are multiple stakeholders involved in the transactions across the translational research chain, and even more when we consider the wider stakeholders who have interests in this area. Any proposal will need to have regard to the interests of all of these groups, including for example funders, RPOs, individual researchers, government, industry, investors, insurers and the public. It is vital that the interests of all stakeholders are balanced appropriately, in order to ensure that there is buy in and adoption of solutions devised.

Overlapping, inconsistent or conflicting contract terms increases complexity and represents a bar to development of innovation in the public interest. Efforts to reduce this complexity are welcome. At the very least, a more coordinated approach to IP contracting (or even contracting generally), with increased interoperability of terms, would be beneficial. In the short term therefore, research funders and other key stakeholders such as RPOs should seek to work towards formulating and implementing guiding principles which will enable IP safeguards to be embedded throughout the translational contract chain. Longer term, attempts to further develop and amend template agreements (such as the Lambert Agreements, Brunswick Agreements and USIT templates) and to encourage their more widespread use, to improve consistency and interoperability, and to embed IP safeguards may be beneficial. Such attempts will need to recognise the importance of sufficient flexibility, the significant variation in the types of agreements, and the need to engage all relevant stakeholders (including funders, universities, the public, industry and those involved in the financing of innovation) in order to avoid significant resistance or low uptake.

Finally, greater attention to the nature of the problem, and a deeper understanding of the need for contractual IP safeguards, is important. Government parties need to recognise their power to negotiate relevant terms and must leverage that power where possible to safeguard the rights of the public.

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