The Role of Patenting in the Valuation of Biomedical Innovation

Michael Morrison
University of Oxford

Corresponding author
Michael Morrison
HeLEX - Centre for Health, Law and Emerging Technologies
Faculty of Law, University of Oxford
Room 201, St Cross Building, St Cross Road, Oxford OX1 3UL, UK
michael.morrison@law.ox.ac.uk

Submitted: March 21, 2023
Accepted: November 18, 2023

Abstract
Intellectual property rights (IPR), and patents in particular, play a central role the commercialisation of new knowledge and techniques in the life sciences. In this paper I examine the shaping effect of patents and patenting on the innovation trajectories of three emerging biotechnologies: gene editing, induced pluripotent stem cells, and 3D bioprinting. All three are examples of "biomodifying technologies", that is, tools and techniques that permit human intervention in, and modification of, fundamental biological processes, and each has been subject to varying degrees of patenting activity. The analysis draws on the sociology of valuation to position patents as both the outcome of particular practices of valuation and as entities that are themselves folded into other practices for calculating value in the life sciences economy. Drawing on qualitative interviews with a range of stakeholders including academic and clinical scientists, representatives of companies whose commercial activity incorporates one or more of these technologies, and actors involved in other ways with the governance of these technologies such as intellectual property experts and employees of university Technology Transfer Offices (TTOs), I show how "upstream" market considerations inform strategic assessments of what is worth patenting and how patent claims should be drafted.

Keywords
patents; value; valuation; biotechnology; innovation.

1. Introduction

The concept of "biomodifying technologies" was developed to account for particular type of technique, developed through life sciences research, that enables scientists to modify living biological tissue in a directed fashion (Morrison et al. 2019). Historical examples include cell culture, recombinant DNA (rDNA), the polymerase chain reaction (PCR), hybridoma technology for creating monoclonal antibodies, and somatic cell nuclear transfer ("cloning"). Biomodifying technologies typically arise from molecular and developmental biology; fields dedicated to exploring the "plasticity of biological life" (Landecker 2010). They are at once "transformative" in that they extend and enhance scientists' capacity to manipulate and alter living biological

material, and simultaneously "domesticated" in that they belong to a familiar "genre of technique" (*ibid.*) within the life sciences (c.f. Martin et al. 2020). Unlike the early caution attending biomodifying technologies like rDNA, contemporary biomodifying technologies are subject to rapid commercialisation and efforts to "translate" them into new products and services, as is now common for life sciences research (Maienschein et al. 2008; Morrison and Bartlett 2022).

The project "Biomodifying technologies and experimental space: Organisational and regulatory implications for the translation and valuation of health research" examined three contemporary biomodifying technologies: induced pluripotent stem cells (iPSC), gene editing, and 3D printing of biological material. "IPSC technology" refers both to the method of producing the cells by chemically "reprogramming" adult somatic cells to an embryo-like, pluripotent state, and to the iPS cells themselves, which can be chemically induced to become many different types of body cell (lung cell, nerve cell, heart muscle cell et cetera). Gene editing tools, of which CRISPR/cas9[1] is currently the most prominent example, contain a programmable "targeting" domain that can be designed by scientists to find and attach itself to a particular sequence of genetic material in a living cell, and an enzyme that can cut out that particular piece of the DNA, replace it, or change its content (for example, changing an "A" to a "T" in the genetic code). 3D bioprinting is a manufacturing technique which can be applied to many different cell types, including iPSCs. It is a form of additive manufacture where complex three-dimensional constructs are produced via deposition of fine layers of material one on top of the other (Mironov et al. 2008). Bioprinting adapts additive manufacture techniques by replacing plastic or metal as the material to be 3D printed with gel-like suspensions containing living cells, known as "bioinks". The goal is to "[...] transfer the precision, flexibility, speed and agility offered by 3D printers to clinical applications in order to recreate highly complex and heterogeneous structures" (Lafontaine et al. 2021, 557).

To keep the project manageable and coherent over the three case study technologies, the project team (see *Acknowledgements*) opted to focus exclusively on attempts to develop these technologies for human biomedical application. The project, and this paper, do not consider the various plant or animal related applications of gene editing, bioprinting or iPSC. Our investigation of biomodifying technologies was structured around three questions:

- RQ1) How can the "experimental space" which these technologies currently occupy be characterised and what does this mean for translational health research and its likely trajectories?
- RQ 2) What are the challenges and risks posed by these technologies for existing, legal, regulatory and governance regimes?
- RQ3) What is defined as their benefit or value and how is benefit and/or value assessed?

My focus here is the project's first and third research questions[2], which are connected. The "experimental space" for each of the three case study biomodifying technologies maps, to a greater or lesser extent, onto the existing socio-technical system (Geels 2002) or techno-economic network (Callon 1990) of (medical) biotechnology. It is within this space that technology development occurs and innovation trajectories are shaped:

> Research is conducted by public laboratories, universities, private firms (small, medium and multinational), non-profit organizations and health-care facilities (public and private).

> It is funded by taxpayers, philanthropic foundations, private investors, companies and patients. And it is shaped by public policies and agencies, such as those for intellectual property (IP), regulatory standards, procurement, treatment guidelines and reimbursement. (Swaminathan et al. 2022, 207).

The connection between this understanding of the experimental space for biomodifying technologies, and the issue of how they are given value (and for and by whom) lies in the contention that the shaping of the innovation trajectories of biomodifying technologies, by the institutions, markets regulations, laws et cetera described above, can be understood and analysed through the lens of valuation.

Specifically, this strand of the project (RQ3) draws on work in Valuation Studies which treats value not as an inherent property of things, nor as a mere signifier of, e.g., social class, but *as the outcome of practices of valuation* (Muniesa 2011; Dussauge, Helgesson and Lee 2015). "Value" here is also understood in the sense of "worth": what is worth doing, having, being, knowing, et cetera. This encompasses multiple forms of merit (moral, cultural, epistemic and so on) and is not limited to economic value or cost. Contemporary biomedical innovation is subject to a plethora of assessments and valuations, including, but not limited to, those listed by Swaminathan et al. (2022) above. Many, though not all of these nodes use institutionally-embedded, formal tools and methods for calculating value or worth, which Valuation Studies describes as "devices". Translational research with biomodifying technologies may be animated by promise (Borup et al. 2006), but I argue that its trajectories and outcomes are steered by the cumulative (inter)actions of these disparate, but durable, practices and devices for valuing innovation.

Considering the "experimental space" in its entirety and all the forms of valuation it contains cannot be reasonably set out within the confines of a single paper. Elsewhere, project members have analysed how academic and commercial researchers working with biomodifying technologies identify what makes a "good target" for translational life sciences research (Morrison and Bartlett 2022). That analysis concluded that "translational" scientists anticipate the ways in which the value of their proposed work will be assessed by a variety of audiences (peers, funders, managers, journal editors, regulators, clinicians etc.), each deploying their own criteria and metrics of worth. Scientists' choices of which research is worth pursuing results from attempts steer a course that is likely to demonstrate at least adequate merit to each of these different groups. In other words, embedded practices for valuing translational science shape what comes to count as "good" or worthwhile research. In this paper, I extend this frame of analysis by examining patenting as another node within the experimental space for biomodifying technologies where they are subject to a particular form of assessment or valuation (the patent application) and where the outcome of that valuation in turn shapes the innovation trajectories of each technology. None of this is meant to imply that patenting is the only, or even the most important, site at which such technologies are valued. A granted patent cannot be taken as a measure of economic value or indeed of societal need for an invention. For example, Lehoux et al. (2014, 1026) report that in the medical devices sector almost half of all patent filings do not lead to any marketed product. Nonetheless, each of the three biomodifying technologies studied here has been subject of considerable patent activity

(Bicudo et al. 2022; Bicudo et al. 2021a) and it remains an important part of the story of how biomodifying technologies are valued and how their development is steered.

2. Patent examination as valuation

What does it mean to view patents and patenting through a lens of valuation, and can such an approach be justified? Valuation refers to "any social practice where the value or values of something are established, assessed, negotiated, provoked, maintained, constructed and/or contested" (Doganova et al. 2014, 87). This encompasses all forms of examination, testing and assessment as well as judgements and calculations. Importantly, "value" in Valuation Studies is not limited to economic value or price. Focusing on how people calculate and justify what is worth doing, having, being, knowing and so on, provides a way to consider economic value (usually considered quantitatively) alongside cultural and moral etc. values (usually considered qualitatively). This is not to imply that economic value in some way "is" cultural or vice versa. Rather, both "value" and "values" "denote the desirability of certain acts over others, and both refer to the collective production of that desirability and its governing effect on individual actions" (Dussauge et al. 2015, 9). This approach allows "valuation"-based analyses to consider multiple registers or grammars of worth, which can intersect, combine or oppose one another, without reducing one kind of value to another.

From this perspective, even an uncritical "face value" account of patent filing and examination shows that it clearly entails valuation. National patent offices form an obligatory passage point for anyone seeking a patent, and constitute an institutional site of valuation. The United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO) are the most globally significant patent offices (Parthasarathy 2017)[3]. In order to transform a piece of scientific knowledge or know-how, it must first be parcelled out and transformed into a set of one or more claimed "inventions". This is the task of patent attorneys who write patent applications, known as filings. The key criteria for assessment are: novelty (is the "invention" in some way distinct from what is already known), non-obviousness (did it require an "inventive step" to produce), and that it has utility or "industrial application". Patent offices also operate on the principle of "priority"; that is the first party to file a claim has the right to intellectual property rights on that invention, even if they were not necessarily the first to identify or produce what is being claimed. In addition, many types of "invention" are excluded from patentability such as varieties of animals and plants, computer software, the human body, and any elements of the human body derived from "simple discoveries". The EPC also contains prohibitions on granting patents in inventions whose exploitation is deemed to be contrary to morality or "ordre public"[4].

Lamont (2012) identifies several sub-practices that can go into making a valuation including classification, comparison and ranking of entities. In the process of examination, patent filings *are* ranked (who filed first and thus has priority?) classified (do the claims made fall into the acceptable or prohibited categories of invention?) *and* compared (is the claimed invention suitably distinct from what has gone before?), and therefore evaluated. This kind of institutionally embedded, standardised rules for *what* should (and should not) count and

be counted, *how* worth should be calculated or judgements reached, and often what format *outcomes* should follow can be considered as a "mode of valuation": "a particular manner of assessing and attributing the value of something" that is both adaptable and situated in concrete practices, metrics, categories and reference points (Hauge 2016, 127).

Scholars in STS and elsewhere have produced more detailed, more critical accounts of patenting, which recognise that patenting a piece of scientific knowledge or know-how is an act of translation, in the sense envisioned by Callon (1984). It is an attempt to impose a particular order and meaning on events (usually experimental findings and artefacts) by enrolling disparate human and non-human actors into a particular set of roles. In this case, this ordering partly takes place via the construction of texts in the form of patent filings which:

> [G]ive internalist and Whig accounts of the development of the process or apparatus that they describe, and as legal instruments they attempt to impose that interpretation on the material world. (Bowker 1992, 53)

As with any attempt at translation, a patent filing can fail, and even "success" is only a temporary stabilisation that can be undone by subsequent litigation. Bowker's (1992) account of patent litigation makes clear that criteria such as "priority" and "novelty" are produced by considerable behind-the-scenes work that is rendered invisible in formal patent filings or court battles, and that their validity is not inherent, but a local and contingent achievement. However, while these critical accounts add further layers of nuance and complexity to our understanding of the processes involved, they do not invalidate the fundamental idea of patent assessment as a series of formalised, institutionally-embedded valuations.

3. Folded valuations and the many uses of patents

Patents may be the outcomes of a process of valuation, but once granted they are themselves valued, and of value, in a number of different ways. This recursiveness is a repeated motif of valuation; for example, Helgesson and Lee note that "[a]ll experimental designs can be seen as both the outcome of valuations and as devices for performing valuations" (2017, 9). The idea that different valuation practices can be interrelated, and that what counts in one case can impinge on or drive what is counted, or how value is calculated in another setting is known as "folding" (Helgesson 2016). Patents confer a monopoly right, granted by the state, to exclude others from using an invention or to set the terms, via a licence, on which that invention may be used. Many arguments have been put forward about the justification and purpose of patents; that is about why such a monopoly right is *worth* permitting. These include the idea that they are "natural rights" resulting from the labour of an inventor, that they facilitate a right to self-development through creativity, that they act as a "just reward" and thereby a stimulus for innovation, that they provide a method of maximising utility of inventions, or that patents minimise wasteful duplication of effort by assigning control of the future development of a technology to a single party (Papaioannou 2006; Panagopoulos and Sideri 2021). STS scholars have also considered the value of patents as rent generating

assets (Birch 2020), as tools that facilitate their holders to secure entry to markets and send positive signals to capital investors (Lehoux et al. 2016), and as a means to shape the wider socio-technical systems through which new technologies develop (Hilgartner 2009). These are all examples of folded valuation practices; what is of analytical interest is not merely that they happen but their effects and consequences. For example, in the case of patents, we can ask whether anticipation of market valuations folds into decisions about what gets patented in the first place or how the claims in patent filings are drafted, and if so with what effects?

This understanding of patents as both the outcome of valuation practices and as entities folded into other practices of valuation within the experimental space, provides a conceptual framework for interrogating the shaping effect of patents and patenting on the innovation trajectories of biomodifying technologies, which is the overarching aim of this paper.

4. Methodology

The Biomodifying technologies project ("BioMOD") ran from 2017-2021 and employed a range of methods: review of academic and grey literature (government reports, company websites etc.), legal and regulatory analysis, quantitative data collection and qualitative interviews. The legal and regulatory analysis was partly supported by a separate grant from the Leverhulme Trust and has been presented elsewhere (Mahalatchimy et al. 2021; Mourby et al. 2022; Lim and Li 2022). This second project, "Governing biomodification in the life sciences" ("BioGOV") ran from 2018 to 2022. Both projects were collaborations between the universities of Oxford, Sussex and York in the UK and both examined the same three "biomodifying technologies". Mapping the experimental space was an iterative process of identifying key actors from the literature, conducting qualitative interviews, and often identifying further documents, events and actors from information provided by interviewees. Based on the project team's prior knowledge of biotechnology, it was recognised at the outset that this would include actors such as university Technology Transfer Offices (TTOs) and patent attorneys. It is important to note that a comparative analysis of the overall patent landscape of patenting for the three case study biomodifying technologies, which presented both qualitative and quantitative data, has already been published elsewhere (Bicudo et al. 2022), as has a more detailed look at the specific case of IP in bioprinting (Bicudo et al. 2021a). Equally, this was not a project exclusively, or even mainly, about intellectual property *per se*, so interviewees were selected to cover a range of stakeholders including academic and clinical scientists working on translational research with one or more case study technologies, representatives of companies whose commercial activity incorporates one or more of these technologies, representatives of UK regulatory agencies, and intellectual property experts and representatives of university. This reflects our framing of the experimental space, and while most interviewees were asked about their activity in relation to patents, questions about patents were only a limited part of a larger set of interview questions designed to get interviewees discussing the ways they evaluate their work and the ways in which they, and their work, is in turn evaluated, justified and measured.

Interview questions were tailored to different types of interviewees and patent professionals were included as part of the subset of interviews with questions designed for regulatory

and regulatory-adjacent actors. The number of interviewees of different types is summarised in Table 1 below. The full set of question schedules for BioMOD interviewees is available from the UK Data Service (study number 855143). The DOI is linked at the end of the manuscript. Patent attorneys, like most other regulatory interviewees were reluctant to discuss specific instances of regulating particular biomodifying technologies, usually because such details are confidential. As a result they tended to respond to questions with illustrative generalisations or examples from other well-known technology fields taken. However, this does not necessarily limit the validity of the data presented here because most systems for regulating biomedical innovation are themselves technologies of commensuration that act to make a wide range of technology-based products amenable to valuation through a single set of devices. Medicinal products regulation is a partial exemption as special regulatory categories already exist for cell or gene based therapeutics, but Health Technology Assessment and Intellectual Property Rights both aspire to fit biomodifying technologies into the remit of their existing categories, standards, and methods of assessment and valuation. Rather than regarding this as a limitation, it arguably increases the legitimacy of treating the analysis of biomodifying technologies a window into wider processes of patenting in biotechnology.

The majority of interviews were conducted in the UK by members of both project teams. The full list of project members who contributed interviews is given in the *Acknowledgements*.

Interview type	Number of interviews	Source Project
Academic or clinical scientists working with gene editing	9	BioMod
Companies involved with gene editing	7	BioMod
Academic or clinical scientists working with iPSC	9	BioMod
Companies involved with iPSC	7	BioMod
Academic or clinical scientists working with 3D bioprinting	16	BioMod BioGov
Companies involved with 3D bioprinting	9	BioMod BioGov
Representatives of regulatory bodies	13	BioMod BioGov
Other governance actors including intellectual property experts and representatives of university TTOs	14	BioMod BioGov
TOTAL	84	

Table 1.
Number of interviews per category.

Research ethics approval for the UK interviews on both projects was obtained from the University of Oxford Social Sciences and Humanities InterDivisional Research Ethics Committee. For BioMod, additional approval was obtained from the University of York ELMPS Ethics Committee. For BioGOV, a preliminary set of interviews with 3 academic and 3 commercial

3D bioprinting developers was conducted in Brazil as a way to supplement the limited number of bioprinting interviewees identified in the UK. Research ethics approval for these six interviews was obtained from the Research Ethics Committee of King's College London, as this was the institutional location of the project member conducting these interviews at the time.

Written informed consent was obtained from all participants prior to the interviews. Interviews were a mixture of in-person, online and telephone interviews and typically lasted between 40 minutes and 1 hour although a few were longer. All interviews were audio recorded except in a small number of cases (n = 3) where interviewees declined permission to be recorded and in one instance the digital recording function failed. These interviews produced only notes made during and immediately after the interview. Audio recordings were transcribed using a professional transcription service operating under a confidentiality agreement. Text from each interview transcript was assigned to broad codes based on pre-determined areas of interest defined by the projects' aims such as commercialisation of each case study technology, business models, patenting practices, and experiences of securing investment et cetera. Within these broad codes, data was inductively analysed to identify themes and patterns in interviewees' responses, in particular those relating to justifications for particular choices and courses of action, and accounts of which activities or entities were worth pursuing, owning, doing, having et cetera. The results reported below mainly derive from material at the intersections of the codes "patents and patenting" and "value and valuation" as assembled by the author.

5. Results

5.1 Characteristics of patenting in the experimental space for biomodifying technologies

Induced pluripotent stem cells, and gene editing, which in our study included tools such as Zinc Finger Proteins (ZFN), TALENS, and CRISPR/cas9, hew most closely to the established socio-technical system of biotechnology innovation. In each case there is a "foundational" new technical capacity – either a method of modifying DNA like CRISPR or the method for chemically "reprograming" isolated skin or hair cells to an embryo-like pluripotent state which is patented. Each initial patent was followed by a rapid growth in the number of filings and the number of applicants. Of the three biomodifying technologies, gene editing has by far the largest total number of patent filings and the fastest growth in number of filings (Bicudo et al. 2022). This is largely propelled by the vast popularity of CRISPR compared to other methods such as ZFN or TALENS (Bicudo et al. 2022; Zhou et al. 2021)[5]. IPSC exhibit a more modest patent estate and the slowest rate of new filings of the three technologies. This, Bicudo et al. suggest "is arguably signalling greater anticipated difficulty in commercialising applications of iPSC technology beyond its current use as a tool in preclinical drug screening" (2022, 6). 3D bioprinting is the most unique of the three biomodifying technologies. Bioprinting necessarily involves a range of elements: a bioprinter, bioinks, Computer Aided Design (CAD) software, Computer-aided manufacture (CAM) software (which translates CAD design files into printer instructions), and biomaterials to provide structural and chemical support for printed con-

structs (Bicudo et al. 2021b). There is no obvious "foundational" patent since the techniques of additive manufacturing originated in other sectors, initially for use with plastic or metal. Bioprinting has the fewest filed patents of the three biomodifying technologies but the number of filings is growing faster than that for iPSC suggesting a growing market (Bicudo et al. 2022).

Regardless of whether "foundational" patents derived from public or private sector research, as the number of patents in each field of biomodifying technology R&D increases so does the predominance of private sector patent holders:

> In the three domains, companies hold over 50% of the patents, a proportion that reaches around 65% for bioprinting. (Bicudo et al. 2022)

Despite being heavily commercialised, bioprinting also has a greater geographic diversity of small start-up bioprinting companies compared to the gene editing which tends to be dominated by US and European firms including many large incumbent companies holding large patent estates (Bicudo et al. 2022; Bicudo et al. 2021b) The situation with iPSC is similar but with a higher proportion of patents held by Japanese universities and firms, as iPS has been the subject of considerable national investment in Japan (Mikami 2015). While provision of gene editing and iPSC tools, equipment and reagents has been largely the province of incumbent life sciences supply firms, there is also a flourishing academic community using "open source" software for bioprinting and in many cases also building or modifying "in-house" bioprinters rather than buying "off the shelf" commercial products (Bicudo et al. 2021b). This however, is something of an exception.

5.2 The mode of valuation in patent assessment and its effects

The key to understanding this pattern of patenting is to recognise biomodifying technologies as platform technologies. While the promise around biomodifying technologies tends to emphasise the potential for new therapies, the first and largest market is as tools to be used in further research and development. To develop clinical applications of each biomodifying technology requires significant additional technological development, refinement, and advances in supporting technologies (e.g., cell culture media with no animal by-products, bioreactors etc). This in turn creates significant scope for patenting each of these subsequent steps and developments, as both novel and having their own, additive "technical effects". One IP expert explained the relevance of how the "utility" requirement is interpreted by patent examiners in the following way:

> The way the European Patent Office has evolved its law and its practice over the years is to interpret that as requiring some form of technical effect that can, at least in principle, be translated into something useful. The US law uses the concept of usefulness a little bit more but I think it comes to the same sort of thing. (Intellectual property expert interview 3#)

This "technical effect" approach to utility constitutes part of a particular "mode of valuation" practiced by examiners in patent offices. The traditional scientific metric of evidence,

here experimental evidence for what is being claimed, is translated into a legal one, in this case the "reasonable expectation" of a future application. The particular configurations of valuation practices matter because they have consequences. The ways in which the "novelty" and "technical effect" criteria are defined and assessed facilitate, and arguably help to incentivise, the fragmentation of a particular piece of research into multiple separate claims and patents. Specifically, the idea of "technical effect" frames the "patentable matter" as any functional element, rather than as a fully-operational device or process. What is patented is not for example "an iPS-derived neuronal cell therapy for Parkinson's disease" but the design for the functioning of a particular component within one of these devices. This allows complex devices and procedures to be broken down into multiple patentable elements, even if the utility of the device in the everyday world derives from the whole product not its isolated components:

> You've got a mobile phone sitting there or your recorder that's sitting there and you've probably got dozens of patents, if not sometimes hundreds of patents, that are involved in... [...] you can't make a mobile phone out of just one of those patents [...]. You've got lots of different aspects of it, each one of which could be separately patented, I suppose, as long as it fulfils that requirement of having something about it that's technical and not just abstract. (Intellectual property expert interview 2#)

With platform technologies like iPSC gene editing and bioprinting all being enrolled into translational endeavours to develop them as components of future complex products and services, this fragmentation has the twin effects of giving "upstream" patents with broad product claims such as those the main gene editing tools or on induced pluripotent stem cells significant value, whilst leaving considerable space for further innovation, which in turn leaves room for new patent applications and thereby new actors to enter the market for developing these technologies. The multiple ways in which patents are valued, and the way these practices fold back into decisions about what to patent are explored in the next section.

5.3 How patent valuation criteria drive strategic behaviour in patent filing

As the total number of patents relating to each biomodifying technology, and subject matter for each they cover, accumulates in a particular technology field, new prospective patent applicants and market entrants must also take care not only to identify and protect what is novel to their own attempt to commercialise some aspect of the technology, but also to check whether, and to what extent what they want to do is covered by intellectual property rights already held by other parties. In patent practice, securing a proposed area of activity that does not fall under the remit of one or more existing patent holders is known as "freedom to operate" (FTO). This is a direct consequence of the fragmentation of complex products into many patent claims facilitated by the mode of valuation of patent offices, but it also fosters a range of modes of valuation treat patent filing as an instrument for strategic gain (rather than, for example, a "just reward" for innovation or a mode of personal expression[6]).

Consider the practices of patent attorneys in writing filings; construction of these texts is part of the attempted translation of experimental data and artefacts into a particular order

and meaning (Callon 1984) but they are also actions in a particular mode of valuation (Hauge 2016). Patent attorneys make choices and write patent claims in a particular way in response to, and as a way of enacting, particular value imperatives that are part of their professional role. Importantly, the judgements they are making are less about a "naïve" consideration of whether or not the scientific subject matter meets the criteria of novelty, non-obviousness or utility and instead revolve around calculations of future markets and strategic advantage over competitors.

> [I]n general, the job of the patent attorney is to get as many different types of claim as possible so that one way or another you are going to be able to trap an infringer or encourage people to stay off the market. (Intellectual property expert interview 1#)

Some of the "value maximising" techniques are discussed in the following quotes from current or former patent attorneys:

> If we get somebody in who say "I've done this, 'A', and I think we could do 'B' as well but we're not sure, we haven't done it yet", what you can do is file twice, "A", one specification with what you know is right and another specification on the same day which has some extra information that you're not sure about. Then at 12 months you can say which one shall I take. I'll take "B". You can do the same if you're not sure about... you can file two [...]". (PAT02- patent attorney from European law firm with UK offices)

> [T]here are going to bells and whistles that you add later. You can do that either in the same patent or in a different patent. You've got something that is a development of it that's incorporating other aspects which are separately patentable, probably best putting that on a separate patent. (Intellectual property expert interview 3#)

These quotes capture the "inside" manoeuvring and negotiation that goes into constructing an "outside" official account of scientific discovery presented in a patent document (Bowker 1992). In the first quote, the patent attorney explains how patent filings can accommodate, and even leverage, scientific uncertainty by allowing a particular piece of research to be translated into multiple claims, some more expansive than others. Because patent applications take time to review and examine, the applicants can conduct further scientific work to support – or refute – their more expansive suite of claims, before deciding which version to proceed with. In the interim, both filings will count as "prior art" for anyone else trying to file a claim on an overlapping area, even if the first set of claimants are still waiting to see if their wider set of claims can be supported. In the second quote, the interviewee explains how a set of research findings can be converted into multiple claims and even multiple patents by considering the "bells and whistles" of extra or additional claims about, for example, different areas of (potential) application.

Patents give the holders what Hilgartner (2018, 64) terms "configurational power": the "capacity to influence the specific arrangements of technical components, humans and organisations, and social roles and relationships that make up socio-technical systems". Legal scholars have similarly noted the suite of "private governance" functions conferred on patent holders:

> [P]atent holders can place conditions on use, such as clauses prohibiting use of the invention for particular contexts. They can also limit use by charging high costs for access to the technology, or as noted, they can refuse to license the invention thereby becoming the sole provider. Furthermore, how the patent is licensed can impact other technologies because some technologies require the use of existing patented technologies to operate. Thus, patent holder decisions have the potential to have significant knock-on effects for uses of other technologies, and for research and development within a field of technologies (McMahon 2021, 143).

These strategic ways in which patents are considered useful, or valuable in the context of competitive markets for innovations, including biomedical innovations has in turn a shaping effect on what is considered worth patenting and why.

Patents on "upstream" aspects of complex technology development that cannot be invented around are especially valuable because they create obligatory passage points for anyone wanting to work on a certain area of application. This is true for "foundational" patents such as those on iPSC (held by iPS Academia Japan a private entity spun out from University of Kyoto) and on CRISPR, but new "blocking patents" also emerge from subsequent R&D:

> So, the way you make dopamine cells is you have to use a particular thing called dual SMAD and that is currently patented only in the States by Sloan Kettering. But, that is a... no-one has got round that yet. So, there's going to be that plus the patent here on how you make dopamine cells. So, this, I think, is going to prove to be quite a thorny issue going forward, will be these critical IPs. (Academic stem cell scientist 2#)

This example concerns attempts to develop dopamine-producing neurons from iPSC as a possible therapy for Parkinson's disease. Anyone wanting to make this particular type of neurons from iPSC needs specific pieces of technology that is covered by patents in the US and UK, and which appear essential to the process.

For universities, the value of "critical IP" of this kind lies mainly in the potential of the patent to generate income, especially through exclusive licensing of the right to exploit the patented technology:

> [U]niversity tech transfer offices need to earn money to commercialise the technology and most of the large companies coming to them want exclusive licences. So, it's easier to do a deal where you give an exclusive licence. If they refuse to give an exclusive licence, then the licence fee will generally be much smaller. (Intellectual property expert interview 1#)

This valuation of patents based on anticipated future markets and revenue streams echoes the findings of Miller et al. (2009) in their study of Canadian TTOs, where they observed that TTO staff conduct their own valuations of scientific knowledge by anticipating the industries and applications that might be prepared to pay for licencing a piece of knowledge:

> For TTOs, the immediate user of early health innovations is a commercial partner. End users are imagined relative to this immediate user, with the nature, size and salience of the

> imagined needs of end users informing predictions about the likely interest of commercial partners. (2009, 1484)

Companies prefer exclusive licences, especially of "foundational" patents because this grants them a monopoly on an entire segment of a future market. For example, The Broad Institute has licenced its CRISPR patents exclusively to Editas medicine with the proviso that Editas can decide which targets it wishes to pursue and which to out-licence to other developers (Feeney et al. 2018). This means, for example, that Editas can retain exclusivity over applications it prefers, such as gene editing therapeutics for sickle cell disease or cancer, while also generating revenue from granting other firms a licence to develop CRISPR for other medical domains such as heart disease. In this way what matters to companies, becomes valuable to TTOs who make their decisions about which patents to support and which types of licencing to negotiate based on the value preferences and valuation practices of (biotechnology) firms. The revenue generating potential of the foundational patents on CRISPR/cas9, which in turn derives from the anticipated future markets for gene editing based therapies, is such that it has resulted in a protracted and expensive patent dispute between rival claimants at The Broad Institute and the University of California, Berkley (Panagopoulos and Sideri 2021; Feeney et al. 2018).

There are also other reasons why TTOs file patents: numbers of successful patent filings can increase their own reputation and status, and can also signal to other players in the innovation space that there may be gaps in their own knowledge represented by the claimed invention[7]. This illustrates the ways in which multiple different valuations (of anticipated revenue and future markets, of reputations and standing etc) are folded into TTOs' calculation of what science is worth patenting.

For companies, the picture is more complex. Start-up or small biotechnology firms are typically dependent on attracting investment from Venture Capital firms and other investors. One of the (multiple) metrics that investors use to assess firms as an investment opportunity is the size and extent of their patent holdings One UK academic who was involved in two stem-cell related university spin-out firms, explained: "you need to protect that IP so you can get interest from investors." (Academic stem cell scientist 6#). When patents become a metric, the internal content of each patent becomes less relevant. An intellectual property expert explained:

> [T]here is a bit of tension between patent filings and venture capital. Where venture capital people don't understand IP, they just look at numbers, so some [Senior company personnel] are very worried about giving up some of their portfolio, losing some patents. A lot of companies just want numbers for their venture capital people and they're no good to them. (PAT02)

When a number of filed or granted patents becomes a metric for assessing value (whether the value of a firm as an investment as here or a way of measuring the performance of a researcher or a TTO), the value of patent holdings is quantified and abstracted. In simple terms, the number of patents is more valuable than the content of those patents. This can explain how the current valuation practices in innovation systems incentivise and give value to patents that may never give rise to a practical product or service.

Equally, anticipating the need to get the licences in order to secure FTO in a complex technology field with proliferating numbers of patents can also inform a company's calculations about which patents are worth filing and how best to translate experimental data and artefacts into suites of patent claims. This situation is not unique to biotechnology. One IP expert explained the point of using an account of a former client that wanted to use a particular industrial catalyst, only to find there were fully 800 already-granted patents relating to its use. With no way to pay so many royalties or litigate against so many patents, only one further solution presented itself:

> Eventually, we got a licence, basically by developing technology that the various different patentees would, themselves, want to take a licence on. Otherwise, no access. (Intellectual property expert interview 1#)

They went on to explain:

> It's always important to advise the small companies, and large companies, don't just develop and patent the technology you want to use, develop and patent technology that your competitors may want to use so that you have a bargaining point." (*ibid.*)

This quote explains how companies can use the patents they hold to negotiate with other IP holders for mutual access, where both, or all, parties have rights over some steps or components needed to develop a complex product such as a cell or gene therapy. Thus, it can also be strategically valuable for a company to file patent claims on things they think their competitors' might want to access in future, even if these are not of core interest to the firm's own product(s).

These examples of TTOs and companies both illustrate Helgesson and Lee's claim that "examining the configuration of valuation practices is a useful tactic for examining the complex links between the scientific, technical, and market poles" (2017, 3). In that study, Helgesson and Lee demonstrated how "ideas about markets for pharmaceuticals can be folded onto ideas about how to design trials and how to select candidates to introduce in said markets" (2017, 2) showing how, in contrast to "linear" models of innovation, markets and market assumptions do not only appear at the "downstream" end of the R&D process but are folded in to earlier "upstream" valuations of what is worth doing in product development. Here we have seen a similar folding in of different anticipatory calculations of valuations about "upstream" markets and competitive advantage in innovation trajectories for biomodifying technologies. Assessments of the size of patent estate as a means to attract and impress investors, the licencing and revenue generating potential for key patents, the potential utility of patents as tools to leverage negotiation with competitors and secure market segments (also reassuring to investors and shareholders) and so on have all been shown to be folded into, and informing, judgements about what is worth patenting and about how patents should be constructed as sets of claims in the domains of gene editing, iPSC and bioprinting.

6. Conclusions

As previous work from the project team has demonstrated (Bicudo et al. 2022; Bicudo et al. 2021a; Bicudo et al. 2021b), the development of biomodifying technologies into biomedical products and services involves a progressive transfer of control of each technology and its trajectories from public sector institutions to private ones. This is not to imply that all biomodifying technologies arise directly from public sector research. Zinc Finger Nucleases for gene editing, for example, are owned, patented and out licenced by Sangamo Therapeutics a California-based biotechnology firm. However, CRISPR/cas9 and cellular reprograming to make iPSC did originate from academic work, and a lot of bioprinting techniques developed in a similar fashion. Moreover, as most biomodifying technologies are commercialised as tools and reagents sold (back) to public sector laboratories for the purposes of conducting further research, which then generates more patentable knowledge that in turn is often transferred to university spin-outs and small biotech start-ups there are repeating cycles of privatisation not merely a single event.

Publicly funded research may be conceived of as a "public good". However, contemporary governments often view the public good as being best (or even exclusively) served by economic growth through commercial innovation. Innovation policy, especially in High Income Countries, is often guided by the belief that private control of innovation will ultimately be guided to serve (this version of) the public interest by the "invisible hand" of market forces. Patents prove an important practical mechanism for effecting this transfer of control due to the "private governance" functions (McMahon 2021) they confer and the "configurational power" (Hilgartner 2009) this enables. This power is further amplified when powerful players consolidate extensive patent suites and claims on multiple aspects of a technology field.

The limits of this model, and the impact of patents on biomedical innovation, are well documented. Both the proliferation of patents and the extensive private governance functions conveyed by intellectual property rights have been associated with high prices and uneven and unequal access to medicines within countries and between High Income Countries and Low and Middle Income Countries. These problems are not novel, but were made starkly visible during the Covid-19 pandemic (McMahon 2021; Walsh et al. 2021) and have led to calls to change global systems of biomedical innovation to ensure greater public benefit (Swaminathan et al. 2022; Torreele et al. 2021). Biomodifying technologies are not vaccines, but there are important similarities. Like vaccines, cell and gene based therapeutics, which includes those based on biomodifying technologies, are very hard to reverse engineer or mimic without detailed knowledge of specific manufacturing processes (McMahon 2021). The small number of cell and gene therapies that have reached the market have very high market prices and have raised concerns about health systems can pay for them (Jørgensen and Kefalas 2017; Devlin 2022). What the above analysis adds is to show that these outcomes are neither inevitable nor purely the result of individual choices or some notion of "the market" as an ineffable force acting on the world at large.

Instead, as with our previous study of translational scientists, durable institutional practices of valuation act to shape and incentivise behaviours in relation to patents and patenting even before any formal period of assessment is encountered. This illustrates performative nature of valuation:

> The act of measuring, ranking or rating not only affects how the value of something is established *but also affects what is considered valuable – or what "counts"*. (Hauge 2016, 126, *emphasis added*)

The formalised criteria of patent examination and the particular mode of valuation through which examiners enact their assessments create the possibility of fragmentation of complex inventions into multiple different patents held by different parties. The stable, embedded nature of these valuations means their operation can be anticipated and responded to in a strategic manner. In the context of a competitive, commercial global market for innovation, anticipatory valuations of this "downstream" market become folded into assessments of what is worth patenting and how patent claims should be drafted, augmented (the "bells and whistles") and multiplied to secure future advantage. This creates a chain of value, where what matters to investors and shareholders influences what matters to companies, which in turn informs the decisions of university TTOs, all of which must be considered by patent attorneys and their clients. It is important to stress here that this is neither a deterministic nor a linear relationship. At every stage multiple valuations must be considered – scientists and TTO staff must consider how any decision about patenting in light of the various different ways their own performance is metricised and evaluated by employers, by peers, and indeed in terms of their own career and personal priorities. Companies must consider the cost of filing and maintaining patents and which of the hundreds of national patent offices to file with, against the potential strategic value of each patent, how their patent portfolio will look to investors, what rival companies are doing, potential future revenue streams from licensing versus excluding competitors from key market segments and so on. Nonetheless, the general pattern of bringing market considerations into supposedly "pre-market" phases of R&D is evident.

This analysis shows that rather than constituting a malfunction of the system, the outcomes here are fostered by the valuation practices embedded in the patent system as they encounter the nature of life sciences innovation. Valuation is an analytic approach, not a legal remedy to IP problems, but it does provide a new way of understanding and mapping the way innovation is steered. In light of proposals to reconfigure global biomedical innovation to give greater weight to the public good (Swaminathan et al. 2022), I argue that in order to change what is valued, it is necessary to change how value is understood, measured and calculated. Changing investor proprieties may be difficult to achieve without significant regulatory reform, but universities have a clearer mandate to serve the public good, and for example TTOs could be encouraged to rethink the priority of patenting in their mission. Some technologies may be worth patenting (for example CRISPR "gene drive" technology was patented by academics as a way to try and ensure more responsible oversight of its use [Scheinerman and Sherkow 2021]) but others might deliver greater public benefit if they were more open and accessible. Both open source software and open hardware movements provide evidence of alternative innovation models that rely less on private governance and monopoly rights. The international open-source movement in bioprinting, which aims to develop and share projects for affordable bioprinters to be used in various laboratories, including those lacking resources to buy the most sophisticated scientific equipment demonstrates that this is possible. This movement has been underpinned by the initiative of individual academic researchers, but there is noth-

ing to suggest that it cannot gain, at some point, some form of institutional recognition and support. Alternatively, if bioprinting products and services get closer to clinical application, incumbent commercial interests could use patents and configurational power to squeeze out open source developers and create a centralised market dominated by a few big firms.

Understanding patents as (part of) the ecosystem that shapes emerging technologies also illuminates the wider web of folded, nested valuations that feeds into the whole system, from institutional incentives for university TTOs to the norms and duties of a patent attorney to their client. Any potential remedies for the deleterious effects of the patent system must look beyond the formal description of patents to consider their impact on this wider domain.

Acknowledgements

Andrew Bartlett, Edison Bicudo, Alex Faulkner, Phoebe Li and Andrew Webster all contributed to the generation of the qualitative interview data analysed here and to the development of a coding scheme for the interview data as described in the methods section of this paper. All of these project members, with further input from Jane Kaye, Miranda Mourby and Jessica Bell, contributed to our analysis of the governance frameworks for biomodifying technologies.

On behalf of the whole team I would particularly like to acknowledge the contribution of the late Professor Andrew Webster (SATSU, University of York), who had significant intellectual input into the entire project. Andrew sadly passed away before this paper was finished and will be deeply missed by all his colleagues on the "Biomodifying technologies" project.

Data Availability

Morrison, Michael, Bartlett, Andrew, Faulkner, Alex and Li, Phoebe (2022) Qualitative Interviews From the Biomodifying Technologies Project, 2017-2020 [data collection]. UK Data Service. SN: 855143, DOI: 10.5255/UKDA-SN-855143.

Funding

This work was supported by the UK Economic and Social Research Council through grant number ES/P002943/1 and the Leverhulme Trust through grant number RPG-2017-330.

Declaration of competing interests

I declare that I have no competing interests, whether financial, personal, or otherwise relevant to the content or choice of journal for this manuscript.

Notes

[1] CRISPR stands for "Clustered Regularly Interspaced Short Palindromic Repeats" in reference to the characteristic sequence of the RNA "targeting domain".

[2] For a publication dealing with RQ2 in detail see Mourby et al 2022.

[3] The EPO is not a national office *per se* but acts as a central examining body capable of awarding a "bundle" of patent rights valid in all countries that have signed up to the European Patent Convention (EPC).

[4] Specific prohibitions include examples include, cloning human beings, modifying the germ line genetic identity of human beings, commercial uses of human embryos, or modifying the genetic identity of animals and causing them suffering without substantial benefit to man or animals.

[5] For a discussion of why CRISPR has proven so widely adopted compared to other gene editing tools see Martin et al. 2020.

[6] For a review and critique of a broader range of philosophical justifications of patent right see Papaioannou 2006.

[7] My thanks to an anonymous reviewer for bringing this point to my attention.

References

Bicudo, Edison, Morrison, Michael, Li, Phoebe, Faulkner, Alex, Webster, Andrew, Mourby, Miranda and Kaye Jane (2022) *Patent Power in Biomedical Innovation: Technology Governance in Biomodifying Technologies*, in "The Journal of World Intellectual Property", 25, pp. 473-494.

Bicudo, Edison, Faulkner, Alex and Li, Phoebe (2021a) *Patents and the Experimental Space: Social, Legal and Geographical Dimensions of 3D Bioprinting*, in "International Review of Law, Computers and Technology", 35(1), pp. 2-23.

Bicudo, Edison, Faulkner, Alex and Li, Phoebe (2021b) *Sociotechnical Alignment in Biomedicine: The 3D Bioprinting Market beyond Technology Convergence*, in "Technology in Society", 66, p. 101668.

Birch, Kean (2020) *Technoscience Rent: Toward a Theory of* Rentiership *for Technoscientific Capitalism*, in "Science, Technology, & Human Values", 45(1), pp. 3-33.

Borup, Mads, Brown, Nik, Konrad, Kornelia and Van Lente, Harro (2006) *The Sociology of Expectations in Science and Technology*, in "Technology Analysis & Strategic Management", 18(3-4), pp. 285-298.

Bowker, Geoffrey C. (1992) *What's in a Patent?*, in Wiebe E. Bijker and John Law (eds.), *Shaping Technology/Building Society: Studies in Sociotechnical Change*, Cambridge (MA), The MIT Press, pp. 53-74.

Callon, Michel (1984) *Some Elements of a Sociology of Translation: Domestication of the Scallops and the Fishermen of St Brieuc Bay*, in "The Sociological Review", 32(1_suppl.), pp. 196-233.

Callon, Michel (1990) *Techno-Economic Networks and Irreversibility*, in "The Sociological Review", 38(1_suppl.), pp. 132-161.

Devlin, Hannah (March 5, 2022) *It's a real-life Hunger Games': A lifesaving drug costs $2m, but not every child can get it*. The Guardian. Available at: https://www.theguardian.com/business/2022/mar/05/real-life-hunger-games-lifesaving-drug-costs-2m-dollars (retrieved September 19, 2023).

Doganova, Liliana, Giraudeau, Martin, Helgesson, Claes-Fredrik, Kjellberg, Hans, Lee, Francis, Mallard, Alexandre, Mennicken, Andrea, Muniesa, Fabian, Sjögren, Ebba and Zuiderent-Jerak, Teun (2014) *Valuation Studies and the Critique of Valuation*, in "Valuation Studies", 2(2), pp. 87-96.

Dussauge, Isabelle, Helgesson, Claes-Fredrik and Lee, Francis (2015) *Value Practices in the Life Sciences and Medicine*, Oxford, Oxford University Press.

Dussauge, Isabelle, Helgesson, Claes-Fredrik, Lee, Francis and Woolgar, Steve (2015) *On the Omnipresence, Diversity, and Elusiveness of Values in the Life Sciences and Medicine*, in Isabelle Dussauge, Claes-Fredrik Helgesson and Francis Lee (eds.), *Value Practices in the Life Sciences and Medicine*, Oxford, Oxford University Press, pp. 1-28.

Feeney, Oliver, Cockbain, Julian, Morrison, Michael, Diependaele, Lisa, Van Assche, Kristof and Sterckx, Sigrid (2018) *Patenting Foundational Technologies: Lessons From CRISPR and Other Core Biotechnologies*, in "American Journal of Bioethics", 18(12), pp. 36-48.

Geels, Frank W. (2002) *Technological Transitions as Evolutionary Reconfiguration Processes: A Multi-Level Perspective and a Case-Study*, in "Research Policy", 31(8-9), pp. 1257-1274.

Hauge, Amalie M. (2016) *The Organizational Valuation of Valuation Devices: Putting Lean Whiteboard Management to Work in a Hospital Department*, in "Valuation Studies", 4(2), pp. 125-151.

Helgesson, Claes-Fredrik (2016) *Folded Valuations?*, in "Valuation Studies", 4(2), pp. 93-102.

Helgesson, Claes-Fredrik and Lee, Francis (2017) *Valuations as Mediators Between Science and the Market: How Economic Assumptions Shape Pharmaceutical Trial Designs*, in "Science as Culture", 26(4), pp. 529-554.

Hilgartner, Stephen (2009) *Intellectual Property and the Politics of Emerging Technology: Inventors, Citizens, and Powers to Shape the Future*, in "Chicago-Kent Law Review", 84(1), pp. 197-226.

Hilgartner, Stephen (2018) *Foundational Technologies and Accountability*, in "American Journal of Bioethics", 18(12), pp. 63-65.

Jørgensen, Jesper and Kefalas, Panos (2017) *Annuity Payments Can Increase Patient Access to Innovative Cell and Gene Therapies under England's Net Budget Impact Test*, in "Journal of Market Access & Health Policy", 5(1), 1355203.

Lafontaine, Céline, Wolfe, Maxime, Gagné, Janie and Abergel, Elisabeth (2021) *Bioprinting as a Sociotechnical Project: Imaginaries, Promises and Futures*, in "Science as Culture", 30(4), pp. 556-580.

Lamont, Michèle (2012) *Toward a Comparative Sociology of Valuation and Evaluation*, in "Annual Review of Sociology", 38, pp. 201-221.

Landecker, Hannah (2010) *Culturing Life: How Cells Became Technologies*, Cambridge (MA), Harvard University Press.

Lehoux, Pascale, Daudelin, Geneviève, Williams-Jones, Bryn, Denis, Jean-Louis and Longo, Christopher J. (2014) *How do business model and health technology design influence each other? Insights from a longitudinal case study of three academic spin-offs*, in "Research Policy", 43(6), pp. 1025-1038.

Lehoux, Pascale, Miller, Fiona A., Daudelin, Geneviève and Urbach, David, R. (2016) *How Venture Capitalists Decide Which New Medical Technologies Come to Exist*, in "Science and Public Policy", 43(3), pp. 375-385.

Lim, Pheh H. and Li, Phoebe (2022) *Patentability of Biofabricated Human Organs: "Products of Nature" or "Products Derived from Nature" Revisited*, in Naomi Hawkins (ed.), *Patenting Biotechnical Innovation: Eligibility, Ethics and Public Interest*, Cheltenham, Edward Elgar, pp. 69-89.

Mahalatchimy, Aurélie, Lau, Pin L., Li, Phoebe and Flear, Mark L. (2021) *Framing and Legitimating EU Legal Regulation of Human Gene-Editing Technologies: Key Facets and Functions of an Imaginary*, in "Journal of Law and the Biosciences", 8(2), pp. 1-30.

Maienschein, Jane, Sunderland, Mary, Ankeny, Rachel A. and Robert, Jason S. (2008) *The Ethos and Ethics of Translational Research*, in "American Journal of Bioethics", 8(3), pp. 43-51.

Martin, Paul, Morrison, Michael, Turkmendag, Ilke, Nerlich, Brigitte, McMahon, Aisling, De Saille, Stevienna and Bartlett, Andrew (2020) *Genome Editing: The Dynamics of Continuity, Convergence, and Change in the Engineering of Life*, in "New Genetics and Society", 39(2), pp. 219-242.

McMahon, Aisling (2021) *Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance*, in "Journal of Medical Ethics", 47(3), pp. 142-48.

Mikami, Koichi (2015) *State-Supported Science and Imaginary Lock-in: The Case of Regenerative Medicine in Japan*, in "Science as Culture", 24(2), pp. 183-204.

Miller, Fiona A., Sanders, Carrie B. and Lehoux, Pascale (2009) *Imagining Value, Imagining Users: Academic Technology Transfer for Health Innovation*, in "Social Science and Medicine", 68(8), pp. 1481-1488.

Mironov, Vladimir, Kasyanov, Vladimir, Drake, Christopher and Markwald, Roger R. (2008) *Organ Printing: Promises and Challenges*, in "Regenerative Medicine", 3(1), pp. 93-103.

Morrison, Michael and Bartlett, Andrew (2022) *Making Translational Value: Identifying "Good Targets" for Clinical Research on Gene Editing and Induced Pluripotent Stem Cell Technologies*, in "SSM – Qualitative Research in Health", 2, 100131.

Morrison, Michael, Mourby, Miranda, Bartlett, Andrew and Bicudo, Edison (2019) *Biomodifying Technologies and Experimental Space: Organisational and Regulatory Implications for the Translation and Valuation of Health Research. – ESRC*, in "Impact", 2019(1), pp. 63-65.

Mourby, Miranda, Bell, Jessica, Morrison, Michael, Faulkner, Alex, Li, Phoebe, Bicudo, Edison, Webster, Andrew and Kaye, Jane (2022) *Biomodifying the "Natural": From Adaptive Regulation to Adaptive Societal Governance*, in "Journal of Law and the Biosciences", 9(1).

Muniesa, Fabian (2011) *A Flank Movement in the Understanding of Valuation*, in "Sociological Review", 59(2_suppl.), pp. 24-38.

Panagopoulos, Andreas and Sideri, Katerina (2021) *Prospect Patents and CRISPR; Rivalry and Ethical Licensing in a Semi-Commons Environment*, in "Journal of Law and the Biosciences", 8(2), pp. 1-24.

Papaioannou, Theodoros (2006) *Towards a Critique of the Moral Foundations of Intellectual Property Rights*, in "Journal of Global Ethics", 2(1), pp. 67-90.

Parthasarathy, Shobita (2017) *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe*, Chicago, University of Chicago Press.

Scheinerman, Naomi and Sherkow, Jacob S. (2021) *Governance Choices of Genome Editing Patents*, in "Frontiers in Political Science", 3.

Swaminathan, Soumya, Pécoul, Bernard, Abdullah, Hisham, Christou, Christos, Gray, Glenda, IJsselmuiden, Carel, Kieny, Marie P., Mazzucato, Mariana, von Messling, Veronika, Ogutu, Bernhards, Reeder, John, Røttingen, John-Arne, Swarup, Renu, Tanner, Marcel, Lima, Nísia T., Childs, Michelle, Harris, Alex, Torreele, Els and Torreele, Suerie (2022) *Reboot Biomedical R&D in the Global Public Interest*, in "Nature (Comment)", 602, pp. 207-210.

Torreele, Els, Mazzucato, Mariana and Li, Henry L. (2021) *Delivering the People's Vaccine: Challenges and Proposals for the Biopharmaceutical Innovation System*, in "UCL Institute for Innovation and Public Purpose – Policy Brief series (IIPP PB 12)", pp. 1-10.

Walsh, Karen, Wallace, Andrea, Pavis, Mathilde, Olszowy, Natalie, Griffin, James and Hawkins, Naomi (2021) *Intellectual property rights and access in crisis*, in "IIC – International Review of Intellectual Property and Competition Law", 52(4), pp. 379-416.

Zhou, Wuyuan, and Wang, Xiang (2021) *Human Gene Therapy: A Scientometric Analysis*, in "Biomedicine and Pharmacotherapy", 138, 111510.