Producing Value or Responding to Valuation?
SMEs' Strategies for Commercialising Induced Pluripotent Stem Cell and Bioprinting Technology

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Abstract

This paper examines how small and medium-sized enterprises (SMEs) commercialise contemporary biomodifying technologies, focusing on induced pluripotent stem cells (iPSC) and 3D bioprinting. Drawing on qualitative interviews and desk-based mapping of the commercial landscapes surrounding these technologies, we analyse what is being commercialised, in what forms, and how firms justify their strategic choices. Combining insights from STS debates on value in the bioeconomy with concepts from valuation studies, we show that commercial value is rarely realised through anticipated therapeutic applications. Instead, it emerges through nearer-term markets for research tools, services, and platforms embedded within existing biomedical and pharmaceutical infrastructures. Our comparative analysis highlights how firms mobilise knowledge, expertise, and networks as assets, and how strategies of enclosure—through intellectual property, secrecy, and proprietary know-how—are shaped by anticipated evaluations from investors, customers, and regulators. We argue that embedded valuation practices play a constitutive role in directing innovation trajectories, favouring centralised control and constraining alternative, more open models of biomedical innovation.

Keywords: Valuation Practices, Biomodifying Technologies, Induced Pluripotent Stem Cells (iPSC), 3D Bioprinting, Bioeconomy

Introduction

'Biomodifying technologies' are tools and techniques from life sciences research that enable the modification and customisation of living biological material in novel ways (Morrison et al., 2019; Hansson, 2021). They are versatile, accessible tools for use in experimental settings, offering advances over existing practices, with a wide range of potential applications. This paper examines the commercialisation of contemporary biomodifying technologies, drawing on two case study

technologies: induced pluripotent stem cells (iPSC) and 3D bioprinting, which will be described below. Our aim is to characterise the current market in each of these technology areas, asking what exactly is being commercialised and what form(s) this takes. For pragmatic reasons, our analysis is limited to biomedical applications of each technology while the empirical work prioritised small to medium sized firms operating in the iPSC and bioprinting space. Most but not all of the firms in our study were based in the UK, albeit with a commitment to situating the findings within the wider global landscape for each technology. This bounded case study approach affords a particular lens to reflect on issues of value in the bioeconomy[1], particularly in relation to long running debates about the primacy of commodities or assets in understanding the intersections of capitalism and the life sciences (Waldby, 2002; Sunder Rajan, 2006; Helmreich, 2008; Birch and Tyfield, 2013). This focus is complemented by approaches from valuation studies which emphasise that the practical work of 'making things valuable' can be understood in terms of judgements about what is (or is not) worth doing, and that where actors are dependent on others (for example to access material resources or finance) they must also take into account how those third parties understand and assess value (Felt, 2017; Fochler, 2016; De Rijcke et al., 2016).

The paper will proceed by describing our two case study technologies, induced pluripotent stem cells and 3D bioprinting, in more detail, before setting out a fuller account of the theoretical framework underpinning our approach. The methods section will explain the rationale behind our choice of case studies and the reasons for the limited scope of our approach, as well as detailing our empirical work, characterising the firms in this study, and explaining our approach to analysing the qualitative and textual data sources. The results section then presents an account of the commercial landscape for each case study technology in turn. The analysis reports on how small-to-medium sized firms in this space generate revenue (or plan to do so) and whether commercial activity involves goods and commodities, services, access to specialist knowledge or proprietary datasets, novel platforms, rents on intellectual property, such as patents, or mixtures of these elements. As part of this analysis, we are also interested in understanding how commercial actors in our study justified their various strategies (in terms of what they considered worth doing or not worth doing), and whether they took into account the ways in which they, their firms or their products or services were (likely to be) evaluated by external audiences such as investors or customers. Our discussion reflects on the way in which a range of embedded valuation practices favours centralised control and enclosure of knowledge and technology in the bioeconomy, while the different cases of iPSC and bioprinting offer insights into how commercialisation plays out in fields at different stages of technological and commercial maturity.

Case studies and background

The decision to focus on iPSC and bioprinting in this paper stems from a mixture of theoretical and practical considerations. The cases of iPSC and bioprinting both involve, in different ways, living cells and tissues which offers a ready-made connection to prior STS debates on the nature of value in the life sciences (Waldby, 2002; Birch and Tyfield, 2013). Both technologies have also been enrolled in familiar promissory narratives of innovation yielding future 'health and wealth' benefits (Borup et al., 2006; Delvecchio Good, 2001). As with many biotechnologies, the formation of start-ups or university 'spin-out' companies to commercialise a specific piece of knowledge or technique from life sciences research is commonplace for iPS and bioprinting. This does not necessarily mean developing therapeutic products (which are in fact as yet rare for these technologies) but includes tools and services related to drug discovery, health research, and even testing cosmetic products. Typically, the basis for commercialisation is novel findings or techniques from publicly funded academic research, although small companies are also 'spun-out' from existing firms, to develop new products or services which arise from in-house research, but diverge from the core business of the original firm. In both cases, firms are mainly small-to medium sized entities[2] (SMEs). Intellectual property rights, primarily pat-

ents, are at the heart of the commodification of biological knowledge and its transfer from one entity (a university or parent company) to another (Hilgartner, 2009). This is supported by our own prior work that identifies our case study technologies as domains of increasing patent filing activity (Bicudo et al., 2021a; Bicudo et al., 2022). Beyond this, there are some important differences in the cases of iPSC and 3D bioprinting that make for a fruitful comparative analysis.

Induced pluripotent stem cells are, as the name suggests a type of stem cell, made through artificial reprogramming technology. IPSC are pluripotent[3], meaning that the cells in culture can be 'directed' through chemical prompts to become most other types of cells found in the adult body. In our study we are primarily concerned with human iPSC (although murine and other species of iPSC are also used in research) as human cell lines are most closely associated with biomedical translation. The property of pluripotency is something iPSC share with human embryonic stem cells (hESC), and in many ways iPSC are considered a successor technology to hESC when it comes to commercialisation. This is in large measure because human iPSC are seen by actors in the field to avoid the 'ethical issues' associated with using human embryonic material, resulting in iPSC something being framed as 'ethical stem cells' (Morrison, 2019). While this framing is problematic, not least for the implication that the only real 'ethical issue' raised by the stem cell field is the destruction of human embryos, the absence of certain regulatory restrictions associated with hESC- especially on patenting[4] –makes iPSC by far the more commercially attractive option. As a result, iPSC have taken on many of the translational expectations previously associated with hESC, especially cell therapy and screening prospective pharmaceutical compounds in drug discovery (see Wainwright et al., 2008). In this sense iPSC embody many of the longstanding aims, expectations, and organisational practices associated with human cell technology as documented by prior STS scholarship (Hauskeller and Weber, 2011). They are, if such a term is not an oxymoron, 'conventional stem cells' and provide an example of a technology and a translational pathway that is normalised in light of what has gone before.

By contrast, 3D bioprinting is not a new source or form of stem cell, it is a manufacturing technology. Although the field has inherited some promissory narratives from the older domain of tissue engineering, it draws more on the existing use of 3D printing of plastics and metal, also known as 'additive manufacturing', which is used, for example, to rapidly prototype new designs in various industry sectors. Bioprinting adapts additive manufacturing techniques by replacing plastic or metal as the material to be 3D printed with gel-like suspensions containing living cells, known as "bioinks". In this, it is agnostic with regards to cell type or source- human or animal, pluripotent or differentiated. The technology of 3D bioprinting incorporates a greater diversity of components than iPSC. Bioprinting requires a physical machine, the bioprinter, bioinks, cells, materials that are compatible with supporting the adhesion and growth of living biological material (biomaterials) and software. Computer Aided Design (CAD) programmes are needed to allow engineers to design the shape of the three dimensional construct to be printed, while Computer Aided Manufacture (CAM) software then translates the digitally manipulated design files into instructions for the 3D printer itself (Bicudo et al., 2021b). Of course, stem cell science (and manufacturing) use many digital technologies, for example to analyse gene expression patterns, but the difference is that while these are useful adjuncts for all cell-based science, it is possible to grow iPSC or other cells in culture without digital tools whereas bioprinting is not possible without its software components. Nonetheless the combination of physical, digital and biological components, and its use as a method of manufacturing, put 3D bioprinting on a potentially very different commercial trajectory to iPSC whilst still falling within the domain of biotechnology.

Theoretical framework

There is a long history of debates within STS and adjacent fields on how to theorise value generation in the bioeconomy (Waldby, 2002; Sunder Rajan, 2006; Waldby and Mitchell, 2006; Helmreich, 2008; Birch and Tyfield, 2013; Dussauge et

al., 2015a). Theories such as biovalue' (Waldby, 2002; Waldby and Mitchel, 2006) and 'biocapital' (Sunder Rajan, 2006) emphasise private sector attempts to capture the 'surplus value' produced by the control and reproduction of living biological matter in the form of commodified biomaterials. By contrast, accounts such as Birch and Tyfield (2013) and Birch (2017a; 2017b), emphasise the importance of assets, patenting, rent generation, and financialization in the economic strategies of biotechnology firms. In particular these accounts view the use of assets to generate income in the form of rents as the key driver of value in the bioeconomy, and are part of a wider turn emphasising the importance of assets and assetization as an economic form in late capitalism (Birch and Muniesa, 2020).

Pinel (2021) following Mazzucato (2018) makes a critical distinction between the use of assets to create value versus their use for value extraction:

> An asset is a tradable resource that an actor owns or controls with the expectation that it will provide a future benefit. There are two main ways in which assets can be mobilized to produce value […] In the value creation case, assets are used as resources to produce commodities, whereas in the value extraction case actors have control of assets, which can grant them a rent. (Pinel, 2021:279-280).

Thinking with these distinctions leads us to enquire what resources the SMEs in our study transform into assets and how they then employ those assets. For example, are they used to produce commodities, and if so, what form do these commodities take? Do they involve living cell-based products, or is commoditisation (if any) mainly restricted to reagents, equipment and similar items? Alternatively, if assets are mainly or entirely used to extract value, (e.g. as rents), what strategies are employed?

Focusing on the different ways in which digital assets are configured and made in educational platforms, Birch et al (2025: 18) proposed the related concept of rentiership to "distinguish between different social practices for making something valuable (as an asset) through the identification and constitution of new revenues streams"). As part of that work, Birch and colleagues identify four modes of rentiership; exaction (the introduction of new tolls to extract rent), extraction (redirecting existing revenues or resources from one party to another), enclosure (extending private property rights to cover previously common or collective resources), and externalities (shifting costs unto another party). This typology can be used to further characterise how (if at all) SMEs working in the iPSC or bioprinting spaces might generate revenues through their commercial offerings (e.g. generating 'passive' income from patent licensing or crating proprietary databases). Therefore, in addition to looking at the balance of assets and commodities, our characterisation of the iPSC and bioprinting markets pays attention to how firms configure their assets and how they employ them to generate income.

This approach is complemented by insights from the field of valuation studies (Helgesson and Muniesa, 2013; Doganova et al., 2014), and specifically the conceptualisation of 'value' in the sense of 'worth'. Focus on what actors consider *worth* doing, having, being, knowing et cetera allows us to consider economic value (usually considered quantitatively) alongside cultural, epistemic or moral values (usually considered qualitatively).[5] 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" (Dussauge et al., 2015b: 9). There is therefore an avenue to assess how valuation practices conducted in various different registers of worth can be folded[6] (Helgesson, 2016) into overall calculations of commercial value. The advantage of doing this is that we are not limited to looking at the formal economic valuation of biotechnology companies such as stock pricing and market capitalisation, but can look at a more granular level at how our respondents present and valorise their products, services and strategies. For example, a representative of an SME might highlight how their offering is fast, or robust, or especially novel to explain why it has value. Looking at what staff working for companies commercialising induced pluripotent stem cell or bioprinting technology consider worth doing and why, offers us an insight into how they justify particular strategies, including strategies of revenue generation such as producing

assets or commodities, or employing particular models of rent-seeking.

Within the broad range of work looking at valuation and assessments of worth, we also draw on one particular strand looking at the impact of performance metrics and assessment criteria, and specifically studies that have looked at how these indicators operated within academia itself (Felt, 2017; Fochler, 2016; De Rijcke et al., 2016). The key insight from this work is that when people are subject to assessments, this can shape their choices. This is especially the case when those being assessed depend on the outcomes of that assessment for access to resources, finance, or career prospects. They have an incentive to pursue courses of action that align with the anticipated assessment criteria (e.g. for academics it could be prioritising publications to improve the chances of promotion) and neglect less rewarded courses of action (for example choosing not to pursue 'unfashionable' research topics to improve chances of funding success). In our own prior work on biomodifying technologies, we examined how academic and clinical researchers selected particular disease areas for translational research projects with our case study technologies (Morrison and Bartlett, 2022) and found that they often justified their choices by highlighting how their chosen strategy could align with criteria of value utilised by regulators, funding agencies, commercial developers, or the market. This suggests that academic and clinical researchers also anticipate future assessments of their work by external (i.e. in this case non-academic) audiences when considering which possible areas of research to pursue.

SMEs commercialising iPSC and 3D bioprinting technology are similarly dependent on the appraisal of external actors- especially customers, investors and regulators - for success, so it made sense to extend this line of enquiry to our analysis of commercial actors. In practice this means that, as part of how we analysed commercial actors' accounts of what was worth doing and why, we looked at whether they made references to what external parties like customers or investors might consider worthwhile as part of the justification offered for choosing, or declining, a particular strategy. In this regard we were interested both in appraisals of the technology itself, such as patent filings (Morrison, 2024) marketing authorisation applications, and sales, and assessments of value of the company such as share prices, investment decisions, market capitalisation, and industry awards. Both aspects are important, and indeed connected, because of the aforementioned resource dependence of SMEs: "[b]y controlling when money is made available and for what types of design priorities, capital investors influence the level of refinement of the technology being developed" (Lehoux et al., 2016: 6).

In one sense, this approach is more closely aligned to the work of Birch and colleagues who consider that value in the commercial life sciences sector "is constituted primarily by the social *practices* of the political-economic actors who configure the financial value and valuation of firms" (Birch, 2017a: 3 emphasis added). However, where Birch is primarily concerned with the valuation of the biotech firms themselves, we are more interested in how those firms' own strategies to commercialise our case study technologies play out and how these choices are justified and shaped. Ultimately, we do not see this as a rejection of prior approaches such as Birch and colleagues (Birch and Tyfeld, 2013; Birch, 2017a; 2017b) but as a different (though potentially additive or complementary) strand of work.

Methodology

This paper draws on findings from two interrelated research projects: 'Biomodifying technologies' (2017-2021) and 'Governing biomodification' (2018-2022), which both involved collaboration between researchers at the Universities of Oxford, Sussex and York in the UK. The aim of these projects was i) to characterise the landscape for each case study technology, with a view to understanding what types of applications were being developed and what their proposed translational trajectories looked like, ii) to assess the interactions of these technologies with existing regulatory and governance regimes[7], and iii) to interrogate how different stakeholders in the translational pathway for each technology understood and assessed their value. In order to keep the work manageable within the available time, personnel and resource limits, research was limited to biomedical applica-

tions of each technology. We considered the perspectives of actors including academic and clinical researchers (Morrison and Bartlett, 2022), representatives of patient groups, regulators, patent attorneys and technology transfer offices (Morrison, 2024), and representatives of companies working with each of our case study technologies. The latter group are the focus here, as we consider how firms, primarily small biotech firms in the UK, engage with and try to commercialise biomodifying technologies.

Research material included empirical data in the form of qualitative semi-structured interviews, and information collected as part of the desk-based mapping of the commercial landscapes of each technology. The latter focused on the UK but also took into account global developments which provide a backdrop and context for UK-based efforts at commercialisation. Mapping and characterisation research included identifying potential firms working with iPSC and bioprinting (see below) and collecting information from their websites, reading academic and grey literature, such as industry reports, newsletters, and business news articles about cell therapy or bioprinting, blogs, and other materials. We also attended conferences in the field with a strong translational focus and significant numbers of industry participants and/or presentations, and collected additional data on firms in our study from the commercial database Crunchbase. While this database has limitations, for example out of date information, it is widely used in academic research on innovation (Ferrati and Muffatto, 2020). Where possible, information was correlated with information reported on company websites, press releases, company house filings, et cetera.

The interview material draws from a pooled subset of data from the two projects, comprising interviews with academic and clinical scientists working with iPSC and/or bioprinting and employees of biotechnology companies whose product or service relates to one of our two case study technologies. For most of the firms in this study we interviewed a single representative. This is because these firms are often very small, with only a few staff and we decided to concentrate limited resources on getting enough interviews with each type of actor rather than multiple interviews with any single entity. This yields a pool of 47 interviews in total. Table 1 describes the number of interviews in each category.

While this is not an especially large number of interviews, it is only a portion of the total number of interviews conducted for this project. The BioMOD and BioGOV projects included a third case study on gene editing, as well as interviews with patient group representatives, patent attorneys, tech transfer offices and regulators, which are not utilised here. Investors were not included as potential interviewees because we had concerns about getting access, especially since the UK iPSC and 3DP sectors are small and it would be hard to guarantee discussions of investment decisions in this sector could be kept confidential.

In deciding what counted as an 'iPSC company' or a 'bioprinting company' we took a pragmatic stance, mainly out of necessity. Potential firms that could be contacted to request an interview were identified through desk based research, searching the freely accessible parts (mainly 'table of contents') of industry outlook reports, translation-orientated regenerative medicine fora such as *Cell and Gene Therapy Insights* (Bioinsights Publishing Ltd) and RegMedNet, the online forum linked to

Table 1. Summary of interviews.

Interview type	Number of interviews	Project
Academic or clinical scientists working with iPSC	10	Biomodifying technologies
Companies involved with iPSC	6	Biomodifying technologies
Academic or clinical scientists working with 3D bioprinting	23	Biomodifying technologies & Governing Biomodification
Companies involved with 3D bioprinting	8	Biomodifying technologies & Governing Biomodification
TOTAL	**47**	

the journal *Regenerative Medicine* (Future Science Group), which also publishes a recurring industry roundup feature (see e.g. Ilic and Lovic, 2020), and similar sources. From initial lists of potential company interviewees, invitations were sent out and interviews were scheduled with respondents who agreed to be interviewed. Firms did not have to be working exclusively on iPSC or bioprinting to be considered. In addition, for iPSC, UK firms working in adjacent domains, such as supply chain logistics for cell therapies were considered as these firms play an important role in the emerging regenerative medicine economy that future iPSC based cell therapies would expect to enter. For 3D bioprinting there was still a paucity of UK firms available for interview so we leveraged the networks and contacts of project members to include SMEs working on bioprinting from outside the UK as a way to get an adequate number of interviews. Bioprinting company interviews were conducted with interviewees based in various countries, including the UK, Spain, France, Italy, Spain, and an Eastern European country.[8] Many of the academics interviewed were also involved with one or more spin-out companies developing our case study technologies, so the total pool of expertise relating to the commercial sector for iPSC and bioprinting is larger than the number of company interviews listed in Table 1. The identification of academic participants is described in Morrison and Bartlett (2022). Expanded information on the profile of each firm included in this data set is provided in Table 2.0 in the supplementary material. Interviewees from the 'Biomodifying technologies' project are assigned descriptors such as "UK academic bioprinting scientist 1" while interviewees from the 'Governing biomodification' project are assigned identifying codes such as "BP06" to signify 'bioprinting interview no 6'.

Research ethics approval for the study was obtained from the University of Oxford Social Sciences and Humanities Inter-Divisional Research Ethics Committee (SSH IDREC approval no R55654/RE001) and the University of York ELMPS Ethics Committee prior to any contact being made with potential interviewees. Written informed consent was obtained from all participants prior to the commencement of interviews. We used a mixture of in-person, online, and telephone interviews. The latter two categories were necessitated by the advent of Covid-19 preventing face-to-face meetings. All interviews were audio recorded except in three cases. Audio recordings were transcribed using a professional transcription service operating under a confidentiality agreement.

Interview transcripts were uploaded to NVIVO 12 (Lumivero) for coding and analysis. An initial round of broad coding was conducted using core themes of the project including 'value and valuation', 'regulation', 'intellectual property' and 'experimental space' (our term for the landscape of each technology). Following this there were further iterative rounds of inductive analysis. One project member took a lead on reading the material captured under broad codes for each case study technology. They then selected a limited number of transcripts (3-4) and performed a preliminary sub-coding exercise (i.e. proposing themes and codes within each broad category of responses). This was then shared with the wider team (including the authors) for review. Within the material coded under 'value and valuation', our theoretical framework directed us to consider identifying reports of specific valuation practices in respondents' accounts. These could include valuations of the technology or the company and included respondents' own valuations but also valuations that were applied by third parties. We were also sensitised by the prior debate within STS about the nature of value in the life sciences industry to consider mention of assets or commodities, or analogous terms such as discussion of patents (which can serve as rent generating assets (Birch, 2017a) or of sales of goods versus services. However, it is important to state that it was not our intention to try and make a specific argument about the current economic functioning of the bioeconomy. That would have required a dataset with a greater number, and more diverse types, of SMEs and was not compatible with our focus on three biomodifying technologies. The different potential subcodes were discussed by email and digital video calls among the group, and assessed in light of the project aims, the background literature, and the information presented in the transcripts themselves. Following this collective evaluation, a revised set of subcodes was devised and applied to the quali-

tative dataset, with further collective discussion of any new issues taking place as needed.

Results

Commercialisation of Induced pluripotent stem cells

Most of the promissory hype around iPSC and bioprinting emphasises their therapeutic potential. Human iPSC revisit a familiar and longstanding expectation associated with stem cells and regenerative medicine; to provide a source of biological material for "the repair, replacement or regeneration of cells, tissues or organs to restore impaired function resulting from any cause, including congenital defects, disease, trauma and ageing" (Daar and Greenwood, 2007: 181). Globally, there are firms developing iPSC-derived cell therapies although these are mainly based in the US and Japan (Ilic, 2016; Yamanaka, 2020) and there were none that we could identify in the UK. At the time of writing, no iPSC-derived cell therapies have secured regulatory approval in any territory in the world. Within this global landscape, the main commercial strategies that we identified for UK SMEs commercialising iPSC lie with what Banda et al (2019) describe as the 'materials and service provision business model' and in utilising human cells and tissues for upstream screening of prospective small molecule drug compounds, a business model that ultimately feeds into the conventional pharmaceutical value chain rather than that of cell and gene therapies.

For many life sciences technologies, the first market to emerge is for the materials, reagents and equipment needed to conduct further research and development. This type of market is also known as the 'picks and shovels' market, by way of analogy with the popular wisdom that entrepreneurs selling picks and shovels to miners during the California 'gold rush' of the 1840s were guaranteed a more reliable income, even with small profit margins on each item sold, compared to the high-risk strategy of hoping to strike gold which rewarded only a few lucky or skilled individuals. For iPSC the 'picks and shovels' include cellular reprogramming kits for making iPSC, pluripotency assays and specialised media for pluripotent cell culture. Since a lot of this was adaptable from what was already available for human embryonic stem cells, most iPSC equipment and reagents have been incorporated into the product ranges of large and medium sized incumbent life sciences supply companies like *Thermo Fisher Scientific* and *Sigma Aldrich*. An important exception is in the production of human iPSC lines. One option is the production of so-called 'clinical grade' human iPSC (hiPSC) lines. These require a significant investment of time, skill, labour and finances to manufacture as they must be made to a high standard of quality and produced under 'Good Manufacturing Practice' (GMP) conditions, because they form the potential starting material for human therapeutic products. At least one UK-based firm is currently producing GMP hiPSC lines as a commercial service for academic or commercial developers planning to develop iPSC cell therapies:

> 'I would say the likelihood is that someone wouldn't come to us and say 'we've got a clinical grade iPS cell' because there's not that many sources. Likely chance would be that we would do the primary tissue procurement, or work with them to do it. And, if that was the case, we know the challenges of patient consenting and getting patients to be comfortable with it (IPS Company Interview 1).

As this quote illustrates, although kits to make iPSC by reprograming human blood or skin cells are widely available, the resource and skill intensive nature of producing clinical grade iPSC make it something that cell therapy developers, in both the public and private sector, would be prepared to outsource to an SME. The stringent regulatory requirements for living material that will form the basis of medicines (themselves the result of prior value judgements about acceptable levels of risk) form a barrier to entry that creates a market for the specialist division of labour within the overall innovation process that these SMEs can address. The service provided is not only manufacturing the clinical grade cell line itself, but the knowledge base and networks needed to identify, recruit and screen suitable potential donors. As the quote from IPS Company Interview 1 suggests it is this mixture of 'hard' technical knowledge and 'soft' skills of 'getting patients to be comfortable

with it' that clients are willing to pay to access (i.e. which are valued).

'Research grade' human iPSC lines still require effort and specialist knowledge to produce but are never intended to be used in a medicinal product. The regulatory requirements, and hence costs, of production are lower than for a clinical grade cell line. Unlike hESC, iPSC can be created from any willing human donor and are therefore used to 'stand in for' particular *types* of donors, especially donors with diagnosed medical conditions (Morrison, 2019). Research grade iPSC lines are widely employed as tools to model human diseases and to conduct preclinical research and development on novel small molecule drug compounds (Hauskeller and Weber, 2011). Sourcing donors for 'disease-specific' research grade lines is thus another avenue where UK firms can provide a service offering:

> As a business we have got clients who are commissioning us to find tissue from people with particular genotypes or with particular clinical backgrounds, and to procure tissue from them so that we can make iPSCs, which our clients can then use in… these are commercial clients and could use for commercial research (iPS Company Interview 2).

In the account of iPS Company interview 2, what is valued by customers is again the capability to find and access appropriate donors and to secure legally compliant ethics approval and proof of consent. In this way SMEs can convert expertise (a resource) in recruiting cell donors and securing ethical approval, and privileged access to networks, knowledge, and locations (medical records, genetic characterisations)[9], into assets by managing these relationships and know-how and mobilising them through services than can be offered for sale as part of a productive system (Pinel, 2021). As the interviewee notes, this is mainly a service provided to commercial clients. Academics commonly use iPSC for disease modelling studies but typically need smaller volumes of material compared to commercial providers and academics often have alternative access to patient-derived biological material for research, including creating bespoke research grade iPSC, through direct clinical connections or through collaborating with colleagues (Morrison, 2017).

This service also feeds into the other notable market opportunity for UK firms commercialising human iPSC: using iPSC-derived cells or bioprinted constructs as a platform to model human diseases in vitro and screen small molecule drugs for potentially desirable or undesirable interactions with specific tissue types.[10] The perceived utility of the drug candidate screening approach lies in the way that iPSC can generate large amounts of genetically comparable cells and that these cells are seen as more accurate than animal models at predicting the effects of small molecule drugs on the human body (Avior et al., 2016). Here, what is valued is a combination of genetic knowledge and the (anticipated) predictive power derived from incorporating human tissues into systems for evaluating the properties of small molecule drug candidates (Morrison, 2019). Several UK firms directly provide iPSC-based drug candidate screening services, with each firm typically focusing on a narrow range of tissue types derived from iPSC:

> just do a web search there's a lot of companies who are doing neuronal, a lot of companies are doing cardiomyocytes. Less still are doing hepatocyte because it's quite hard; less still are doing hepatocytes and pancreatic and intestinal, for example. So we're doing all three (iPS Company Interview 4).

As this interviewee explains, focusing on a specific area is way for firms to distinguish themselves from rival firms offering iPSC-based drug candidate screening services. Part of the firm's value proposition is their claim to be able to differentiate iPSC into three tissue types that are 'quite hard' and not available from their competitors. Technical knowledge barriers to producing certain cell types create an exclusivity that is part of the firm's value offering. The claim that there are 'lots of companies' in this space also shows that UK firms are considering their position in relation to a global marketplace for this type of service. Again, a notable distinction from the tools and reagents market is that the main customers here are other companies. Although knowledge on how to 'nudge' iPSC to become different types of

human tissue, known as differentiation, is readily available in the academic literature, the firms in our study all claimed to have invested in proprietary methods that improved upon the published protocols:

> what we find is that compared to what is published in the literature for a given differentiation pathway, we can frequently better that in terms of yield, efficiency, certainly cost and very importantly also the length of time that is required to differentiate these cells into mature phenotypes. To give you an example, for instance we've been able to take protocols that might take three months in the literature and we can shave them down to two weeks to four weeks (iPS Company Interview 5).

This reinforces the idea that what is of value here is not just technical control but claims to exclusive proprietary (i.e. enclosed) knowledge. The variety of tissue types and methods explains why there can be multiple competing SMEs in the global market. Each one focuses on producing a few tissue types such as neural or cardiac cells from iPSC via proprietary methods that claim advantages in terms of speed, cost and reliability of results. IPS Company Interview 4 further elaborated on the nature of this market:

> …because of the venture capital situation out in Boston and San Francisco and San Diego; you've got a lot of well funded biotechs who have a lot of money. They don't have a lot of time and they're in a race to get therapies to market. Because they're young companies they can be far more dynamic than pharma. So they're willing to invest and develop the best pre-clinical models that they think will give them an edge in terms of developing their drugs. So that's where we've found our niche (iPS Company Interview 4).

Here we see how the drug candidate screening market not only feeds into the global pharmaceutical value chain, but into a specific segment of smaller, mainly American firms trying to commercialise a limited portfolio of drug candidates for specific diseases (which will target specific tissue types offered by one or more screening firms), rather than, for example large multinational pharmaceutical firms which typically have their own in house stem cell expertise. IPS Company Interview 4 characterises these clients as 'cash-rich, time-poor' due to the combination of accessible venture capital and strong competition in the US, and therefore willing to pay for the information generated by screening their lead candidate molecules against panels of human tissues derived from iPSC. Similar dynamics were also observed in the early years of the commercialisation of genetic and genomic data (Rothman and Kraft, 2006). This echoes the assertion of Lehoux et al that, "rather than challenging the power and position of the established companies, the technological discontinuities brought to the industry by the emerging firms reinforce the hegemony of the large incumbents" (Lehoux et al., 2014: 1036).

Commercialisation of bioprinting

Bioprinting, with its aspiration to enable precise manufacturing of three-dimensional biological constructs has been positioned as a future source of replacement human organs and addressing the long waiting list for transplant patients in many parts of the world (Vermeulen et al., 2017). There is a global commercial bioprinting sector, but unlike iPSC, medical bioprinting research is almost entirely preclinical and largely conducted by academic researchers. To date no bioprinted tissue implants or replacement organs have secured a marketing authorisation and approval in any territory in the world, nor were we able to confirm any approved clinical trials although we did hear anecdotally of one planned bioprinting trial abandoned before commencement. The leading bioprinting firms are those with a dominant position in bioink manufacture or in providing 'off-the-shelf' bioprinters (Bicudo et al., 2021a; 2021c). Fusing as it does cell biology, engineering technology, and data modelling techniques, bioprinting is significantly different from 'conventional' cellular technologies. As such, it has given rise to a range of new small firms specialising in its more niche 'picks and shovels': bioinks, biomaterials and bioprinters (Bicudo et al., 2021c). Given its largely preclinical status, a significant part of the market for materials and equipment involves academic and other public sector laboratories:

> And these bioprinting products don't yet have actual therapeutic applications. They're devices,

> hydrogels, and fibre matrices. What happens? They end up being products that go to a specific niche, which are researchers – researchers in universities, in research institutes, in companies, in industries… (BP24).

> Because it's such a long term process, that whole drug development process, it's something that we will adapt to as opposed to making massive investments at the moment. Our strategy, today, is to get the material into the hands of people that, potentially, would do that research and ultimately it's up to our clients to decide what applications they want to research (BP01).

Bioprinting, as these representatives of bioprinting firms attest, is still primarily a research activity. Almost all bioprinting activity is still at an experimental stage. As BP01 explains, the near-term business strategy is providing materials (in this case a bioink) to researchers whether in the public or private sector whilst being prepared to adjust the firm's offerings, if and when the sector develops further towards application. Most bioprinting equipment can be used for developing therapeutic tissue implants, disease modelling, 3D printing tissues for drug candidate screening or any other potential areas of application. However, none of these applications are on, or close to, market yet. This is distinct from iPSC where, although there are no iPSC cell therapies on the market, the protocols to make iPSC and to differentiate them into different tissue types are well enough established to form the basis of commercial services discussed above. Indeed, several of the iPSC firms we spoke with had investigated bioprinting technology, but mainly through academic collaborations:

> …am I racing to develop 3D disease models? No. I'm racing to get the early adopter clients working with us and then maybe in two or three years' time between us they'll come round and say "actually can you do this in 3D" or whatever (iPS Company Interview 2).

This quote reflects the consensus amongst firms that we spoke with that were offering drug candidate screening services. Using three dimensional tissue models (produced by bioprinting or otherwise) was seen as a likely future development but it was not yet ready to be deployed as a commercial service. Collaborating with academic bioprinting groups is a way not only to access knowledge about the current state of the technology, but a strategy to build relationships that could be leveraged in future to allow established stem cell based drug screening firms to adopt bioprinting technology to update their service offering rather than face competition from a future generation of new bioprinting based drug screening firms.

Also largely unlike iPSC, there is a tension between SMEs providing ready-made standardised bioprinting machines, bioinks and biomaterials (mainly three dimensional scaffolds for cells to grow on) and academic groups developing their own versions as part of their research activity. Bioprinters are large and expensive. One UK academic bioprinting researcher explained:

> There is much of a limitation in terms of the hardware development because hardware are, basically you can customise, but everything is based on the same design […] There are a few groups possibly exploring in hardware, not many, only a few of them […] I would say the hardware mainly comes from the commercial sector […] So, ideally speaking, I'm actually in between there. I'm not going completely independent but, at the same time, I'm using the best of what is on offer but then we are then customising it (Academic Bioprinting Interview 3).

Here, the interviewee explains that most bioprinting devices- 'the hardware' –that academics are using comes from the commercial sector as only a few research groups have the engineering expertise to build an in-house bioprinter from scratch. At the same time, the interviewee expressed their frustration with the homogeneity of commercial bioprinters- "everything is based on the same design" - and notes that they, like other academic groups in the UK, customise and adapt the standard commercial bioprinters to their own specifications. This illustrates the 'in-between' status of bioprinters as both tools to conduct scientific research and the subjects of research themselves. In Rheinberger's terms (1997) they flip between being technical objects and epistemic things. While this is not uncommon in life sciences research, the tension arises when the standardisation and black-boxing associated with commer-

cial products encounters academics' desire for novelty.

Some academics have denounced the 'closed', proprietary nature of many bioprinters and software packages being used in this field. An international open-source bioprinting movement has been created, opposing the unwillingness of some bioprinting companies to share information with which they claim the field could evolve more rapidly (Darwish et al., 2021; Garciamendez-Mijares et al., 2021). One of the main initiatives of this movement has been the circulation of scientific information on online platforms. For example, the open project developed by Lanaro and colleagues (2021: 2540) was described as follows: "The system is open source, with detailed diagrams, parts lists, computer-aided design (CAD) models, standard operating procedures (SOPs) and cost breakdowns on each subsection freely available […]."

This movement has been underpinned by the initiative of individual academics and while these researchers make up an important part of the potential client base for bioprinting firms, the commercial bioprinting sector has not embraced open source ideas. As with iPSC firms, for bioprinting (and indeed other life sciences) businesses, enclosure of knowledge through secrecy, black-boxing of technologies and intellectual property rights are a key part of protecting the exclusivity of the given niche in the distributed landscape of innovation that each firm seeks to occupy. Although patents must be published, thus nominally disclosing their contents, they are still an effective way of enclosing and restricting usable access to selected knowledge. With complex technologies such as bioprinting, the knowledge disclosed in patent filings is often only useful in the context of additional 'know-how' and equipment which may be protected by trade secrets, further proprietary rights or both (Geiger and Gross, 2024; McMahon, 2021). Indeed proprietary knowledge, rather than IP, was preferred by some firms in our sample:

> No it's more to be described as the secret sauce, so you know, we've been doing this for 50 years; we know which airlines are best, we know which flights are most reliable for what products. We know which ports of entry are easiest, what paperwork needs to be completed, so you overlay all of that with sort of the regulatory stuff that we spoke about. So there's not really IP as more formalised IP; it's knowhow (iPS Company Interview 6).

> It's confidential know-how, basically. For me it's not a problem if someone starts copying it because we are thinking about the same generation. So, by the time they find that our product works and they find how it works, hopefully we've moved on and I'm getting closer to retirement anyway! (UK academic bioprinting interview 4).

In these examples, iPS Company Interview 6, which provides specialist courier services for cell and gene therapies, explained how the firm relies on extensive knowledge resources to provide a service that competitors cannot, while one of the spin off firms founded by UK academic bioprinting interview 4 did not feel the need to patent the company's biomaterials, instead relying on the rapid pace of refinement of their product to ensure that competitors would not be able to bridge the knowledge gap and produce a rival biomaterial with comparable performance. The need for protection of knowledge is not only central to firm's business strategies, it is also valued by relevant third parties, especially investors. Prior to any investment, analysts are engaged to conduct a valuation of the company seeking financing. These valuations are important because they help investors decide whether or not to invest in a particular firm, and how much to pay for their particular ownership stake. As the following quotes from Academic stem cell scientist 6 (who was involved in two stem-cell related university spin-out firms) and BP01 illustrate, protection of knowledge is especially valued by investors, partly as evidence of a firm's ability to control information and exert a monopoly right to the technology underpinning their business model.

> You need to do the Coca-Cola, or take the Coca-Cola approach, you need to stick something in a safe and not tell anyone about it, but there's also other areas that you need to protect that IP so you can get interest from investors (Academic stem cell scientist 6).

> The IP is really important. It's not just about demonstrating something, but can you protect it? What's to stop somebody else coming in and replicating what you're doing, so what level of protection and differentiation do you have and how long is that for? (BP01).

As these quotes illustrate investors particularly value patents as quantifiable markers of the degree to which a firm can exclude competitors from its designated niche. Moreover, in this type of valuation, the number of patents held is often more important than the details of their content (Morrison, 2024). Of course, firms file patents for multiple reasons: to impress investors, to secure revenue streams, to inhibit competitors who need to licence the patented technology for their own endeavours, and to negotiate with rivals who hold other patented technologies the SME may in turn need to licence (Hilgartner, 2009; McMahon, 2021). Nonetheless, it is clear that the demands of clients, the priorities of investors and the potential for competitors to claim part of their market share all incentivise enclosure of knowledge, through secrecy, intellectual property rights and a mixture of the two. As such, it can be considered that these examples illustrate how staff of SMEs must always consider a variety of ways in which the firm, or its technology platform, will be evaluated by third parties when considering their business strategies.

Discussion

Commercialisation of induced pluripotent stem cell technology follows a relatively familiar and well characterised trajectory for life sciences technologies. In the clinical and disease-specific research grade cell lines made to order by some of the SMEs in our study we can clearly see an assetisation based process at work. Firms mobilise resources such as their knowledge of how to reliably recruit cell donors (including the soft skills of 'making donors comfortable') and how to secure legally valid consent, as well as how to reprogram donated tissues into iPSC lines of either research or clinical grade quality. These resources require labour to maintain (e.g. maintaining good relationships and privileged access to clinical sites for donor biopsies) and are made alienable and valuable by configuring them as services that can be accessed for a fee. At the same time, these assets are mobilised to produce a particular commodity, the custom iPSC lines that clients pay for. This can be understood as value creation where "assets are used as resources to produce commodities" (Pinel, 2021: 280) and is distinct from the use of assets purely as a source of rents (although that does not mean firms did not also extract rents for licencing IP they held etc). Control of resources is also maintained through a mixture of intellectual property rights and knowledge specialisation. Here the distribution of innovation activities is underpinned by the high knowledge, time and resource barriers needed to enter complex technical areas. This is a pattern we see in biomaterials and devices for bioprinting as well as in the use of iPSC for drug candidate screening. While 'big pharma' usually have in-house stem cell research groups, smaller pharmaceutical and biopharmaceutical firms often find it more efficient to pay specialised firms like those in our study to create specific iPSC to order or to have large, quality-assured supplies of tissues derived from iPSC to screen small molecule pharmaceuticals, than to invest in the expertise and material resources themselves. Similarly, only a few research groups have the time and expertise to build *de novo* bioprinters or to produce biomaterials or bioinks from scratch in the consistent batches needed for reliable experimentation.

However, while bioinks and biomaterials are also clearly commodities, the iPSC (or indeed tissues derived from them) are not positioned as commodities in the drug candidate screening business. The cell banks are clearly assets, requiring labour of tending and maintenance, with the protocols to differentiate them into particular tissue types protected by intellectual property rights and proprietary knowledge which erect an exclusionary 'moat' around the firm's core assets (Birch et al., 2025). They are assets used to generate rent in the form of the fees clients pay for the information produced by screening their candidate drugs against the various tissue types, where the iPSC derived tissues do not physically leave the firm that controls them. Unlike digital platform businesses, stem cell based drug screening firms- and indeed cell therapy courier / supply chain management firms – do not extract

value from the aggregation of users' data. Indeed, the firms in our study were at pains to point out that clients' data is entirely confidential and not used by the service-providing firm in any fashion. In terms of models of rentiership then, these service provision businesses seem closest to 'exaction' whereby a toll[11] is imposed to exact rent from a beneficial resource (Birch et al., 2025) rather than pure extraction.

The existing bioprinting market is largely commodity based, although it should be noted many firms also offer services such as consultancy or contract research and non-bioprinting related product lines to generate additional revenue. Again, firms marshal resources of expertise into valuable assets that underpin their ability to produce bioprinters, bioinks, biomaterials and related goods. Here it is important to note that although bioprinting is a cell based technology with applications in tissue engineering, none of the firms in our study, and indeed no bioprinting firm that we are aware of, positions cells or tissues *per se* as a commodity. This is partly because bioprinting is a manufacturing technology not a technology based on making or extracting a particular type of cell like iPSC or hESC and partly because the field is still largely experimental so both public and private research teams use the cheapest most readily available cellular materials since they are largely conducting proof of concept studies where the cells do not need to be the grade (or even species) of material that would eventually be used in human medical applications. Where the bioprinting case study provides a fruitful comparison with iPSC commercialisation is in the difference in their relative stages of development and commercialisation.

While there are no iPSC cell therapies currently in the market, there are now other approved cell therapies, and thus a pathway to market for potential future iPSC-based cell therapies. The US-based Alliance for Regenerative Medicine (ARM) lists 36 cell-based medicinal products that have secured regulatory approval in at least one territory worldwide (of which 15 are immunotherapies that use white blood cells as the basis for the medicinal product) (ARM, N.D.) By contrast, although there are 18 approved or clinically accepted tissue engineered medicines listed, most of which are products for cartilage or skin repair which first emerged in the late 1980s, none of them are 3D printed. iPSC firms thus have established business models providing "working examples that entrepreneurs can copy and that investors can use as benchmarks to assess the propositions submitted to them" (Doganova and Muniesa, 2015: 115). The field of iPSC technology is also more stabilised in one key respect: academic and private sector scientists certainly conduct experiments with iPSC but they do so with largely 'off the shelf', standardised equipment and reagents. By contrast bioprinting remains more experimental. While there are standardised bioprinters, bioinks and biomaterials sold as commodities, the design and composition of all of these materials are also still the subject of ongoing tinkering and customisation by research groups, especially in the university sector. The future applications, and thus the future commercial trajectories of bioprinting are still being worked out. Disease modelling, tissue engineered implants and organs, or drug and cosmetic testing are all possible avenues that might come to fruition but there is as yet no established pathway to technical, much less financial viability. The firms in our study are aware of this uncertainty. In the present they aim to 'go where the value is', by selling reagents and equipment, while also keeping one eye on what might be valuable in future. This is true for bioprinting and also for the iPS firms who were themselves exploring bioprinting through academic collaborations to be ready to exploit the technology if and when new applications become feasible.

As Birch explains "the 'firm' ends up where most value is realized" (Birch, 2017a: 3). What our contrasting case studies help illustrate is that this value proposition is not framed by firms alone nor in a vacuum. The resource dependence of SMEs mean that they are shaping their commercial offerings and business strategies in response to the ways in which they are evaluated by a variety of third parties. All the firms in our study are all aiming to find particular niches where their product or service will be seen as worth paying for by potential clients. This entails paying attention to what clients, whether researchers or biopharmaceutical firms consider valuable, which may be

speed, efficiency, access to proprietary know-how and expertise, or standardised equipment that can be used to conduct new experiments and generate new knowledge. It can also entail enclosing knowledge and knowhow to render it scarce and exclusive and this capable of being subject to tolls and fees. The bioprinting firms in our study relied much less often on venture capital than the iPSC firms we analysed (see Table 2.0 in the Supplementary material). Whereas all the iPSC firms in our study had utilised at least one round of venture capital financing, the bioprinting firms were much more likely to rely on a mixture of grant and other state funding, offering contract research services to generate revenue, and seed funding for university spin out firms. With fewer VC investors, it might be expected that would be less pressure or less incentive for bioprinting firms to protect knowledge. However, enclosure of knowledge was just as important to our bioprinting interviewees as those commercialising iPSC. Our interpretation of this situation is that the experimental and uncertain trajectory of bioprinting, coupled with its status as (material and digital) hardware afforded a space in the academic research community where an ethos of open-source activity could emerge, even as this was and is inimical to the strategies of commercial development pursued by bioprinting SMEs. In the iPSC field by contrast, the secrecy and IP-based business models and commercialisation pathways inherited from established stem cell technologies, and indeed from older biotechnologies, were so entrenched as to be taken as inevitable and we were unable to detect any discussion of open-source innovation as ever having being mooted with iPSCs.

Assessments and valuations by third parties constrain and direct the strategic behaviour of SMEs commercialising biomodifying technologies and can ultimately shape the technology offerings they produce. It is not just that firms are subject to these valuations but that they must *anticipate* how different external actors will calculate value- of the firm or its technology offering – and plan their actions accordingly. Innovation in iPSC and bioprinting may be animated by promise (Delvecchio Good, 2001; Borup et al., 2006), but our results strongly suggest that its trajectories and outcomes are steered by the cumulative (inter)actions of disparate, but durable, practices and devices by which life sciences innovation is valued. Many of these embedded, durable assessments of worth involve considerations other than the clinical value of the technology or its value to patients. They tend to promote centralised and exclusive control of flows of knowledge, and mitigate against local, public or open models of innovation. Looking at who enacts which valuation practices and what metrics and criteria they employ reveals the extent to which biomedical innovation is subject to "private governance," that is by decisions and value criteria that are not transparent or amenable to scrutiny by public bodies (c.f. McMahon, 2021). In this respect our paper can only make a small contribution to the bigger picture by highlighting this issue as one that warrants further research and consideration by STS scholars.

Conclusion

This paper has explored how UK-based SMEs attempt to commercialise induced pluripotent stem cells (iPSC) and 3D bioprinting, technologies that have been heavily enrolled in promissory discourses of biomedical transformation. Our analysis shows that, in practice, the commercial value of these technologies is not primarily located in the anticipated therapeutic applications that dominate such narratives, but in nearer-term markets for research tools, disease models, and services embedded in existing pharmaceutical pipelines. By situating these commercial activities within the wider landscape of valuation, we have highlighted the range of practices through which firms seek to configure both their technologies and themselves as valuable.

Theoretically, this analysis contributes to ongoing debates in STS around how value in the life sciences is constituted. Our empirical findings highlight that firms derive value from the direct commodification of cells and tissues only in a few limited cases, and that the mobilisation of knowledge, expertise, and networks as assets that can be enclosed, leveraged, and monetised is much more important. At the same time, while the formal economic calculation of firm value

clearly remains pertinent, our findings support that contention that the valuation of emerging biotechnologies cannot be understood solely in terms of formal economic instruments such as stock prices. Rather, firms rely on a variety of registers of worth: the technical credibility of differentiation protocols, the practical expertise of recruiting and consenting donors, the ability to enclose knowledge through secrecy or intellectual property, and the evidence of market traction sought by investors. These are assessed through a diverse array of embedded valuation practices, which together fold into calculative regimes that shape firms' survival and strategic trajectories, and shape what counts as commercially viable innovation.

This social shaping of innovation amounts to what Van Lente and Rip (2017) have termed 'governance through the pattern'. It is not top-down ('command and control') or deterministic but operates through a range of institutionally embedded valuation practices distributed across public and private sector organisations. These embedded, durable assessments of worth, whether of life sciences firms or their products or services, tend to promote enclosure and protection of knowledge and resources. Companies anticipate and try to meet these value criteria by adopting intellectual property rights, trade secrets, tolls, contracts and other devices to produce scarcity and enable control. As seen in our comparison of the iPSC and bioprinting domains this acts to inhibit or restrict more open, 'commons' type approaches to biomedical innovation. This is not to say that the current innovation model does not produce medically useful products and services (it clearly does). However, it is equally clear that not every innovative technology that could address patient needs is considered valuable according to hegemonic criteria, leading to gaps in treatment of disease and compounding health inequalities. In any strategy that aims to change the outcomes of innovation ecosystems, a critical first step is to challenge and potentially rethink the embedded and dominant practices of valuation within those systems. This means looking not only at the obvious and overt processes of assessment but also recognising that the standards applied in embedded assessments of value are themselves the results of prior judgements about what ought to count and be counted. This nesting or 'folding' of valuations into subsequent valuation devices is a common feature of complex interactions between science, technology and markets (Helgesson, 2016), and one that is useful in unpacking their effects - especially with a view to considering which interests are prioritised and what might be changed to ensure innovation is better aligned with the public interest (Geiger and Gross, 2024).

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References

Alliance for Regenerative Medicine (nd) Available products. Available at: https://alliancerm.org/available-products/ (accessed 28.08.2025).

Avior Y, Sagi, I and Benvenisty N (2016) Pluripotent stem cells in disease modelling and drug discovery. *Nature Reviews Molecular Cell Biology* 17(3): 170–182.

Banda G, Mittra J, Tait J, Watkins A and Omidvar O (2019) Understanding the emergence and evolution of new business models in the UK regenerative medicine sector. *Technology Analysis and Strategic Management* 0(0): 1–14.

Bicudo E, Faulkner A and Li P (2021a) Patents and the experimental space: social, legal and geographical dimensions of 3D bioprinting. *International Review of Law, Computers and Technology* 35(1): 2–23. https://doi.org/10.1080/13600869.2020.1785066

Bicudo E, Faulkner A and Li P (2021b) Software, risks, and liabilities: ongoing and emergent issues in 3D bioprinting. *Journal of Risk Research* 24(10): 1319-1334.

Bicudo E, Faulkner A and Li P (2021c) Sociotechnical alignment in biomedicine: The 3D bioprinting market beyond technology convergence. *Technology in Society* (66): 101668.

Bicudo E, Morrison M, Li P et al. (2022) Patent power in biomedical innovation: technology governance in biomodifying technologies. *The Journal of World Intellectual Property*: 1–22.

Birch K (2017a) Rethinking Value in the Bio-economy: Finance, Assetization, and the Management of Value. *Science Technology and Human Values* 42(3): 460–490.

Birch K (2017b) The problem of bio-concepts: biopolitics, bio-economy and the political economy of nothing. *Cultural Studies of Science Education* 12(4): 915-927.

Birch K and Muniesa F (eds) (2020) *Assetization: Turning things into assets in technoscientific capitalism*. Cambridge, MA: MIT press.

Birch K, Komljenovic J, Sellar S and Hansen M (2025) Data as asset, data as rent? Rentiership practices in EdTech startups. *Learning, Media and Technology* 50(1): 15-28.

Birch K and Tyfield D (2013) Theorizing the bioeconomy: biovalue, biocapital, bioeconomics or... what? *Science, Technology, & Human Values* 38(3): 299-327.

Borup M, Brown N, Konrad K and Van Lente H (2006) The sociology of expectations in science and technology. *Technology analysis & strategic management* 18(3-4): 285-298.

Daar AS and Greenwood HL (2007) A proposed definition of regenerative medicine. *Journal of tissue engineering and regenerative medicine 1*(3): 179-184.

Darwish LR, EL-Wakad MT and Farag MM (2021) Towards an ultra-affordable three-dimensional bioprinter: a heated inductive-enabled syringe pump extrusion multifunction module for open-source fused deposition modelling three-dimensional printers. *Journal of Manufacturing Science and Engineering* 43: 1–10.

Dussauge I, Helgesson C-F and Lee F (2015a) *Value practices in the life sciences and medicine*. Oxford: Oxford University Press

Dussauge I, Helgesson C-F, Lee F and Woolgar S (2015b) On the Omnipresence, Diversity, and Elusiveness of Values in the Life Sciences and Medicine. In: Dussauge I, Helgesson C-F and Lee F (eds) *Value Practices in the Life Sciences and Medicine*. Oxford: Oxford University Press, pp. 1–28.

DelVecchio Good MJ (2001) The biotechnical embrace. *Culture, medicine and psychiatry* 25(4): 395-410.

De Rijcke S, Wouters PF, Rushforth AD, Franssen TP and Hammarfelt B (2016) Evaluation practices and effects of indicator use—a literature review. *Research evaluation* 25(2): 161-169.

Doganova L et al (2014) Valuation Studies and the Critique of Valuation. *Valuation Studies* 2(2): 87–96.

Doganova L and Muniesa F (2015) Chapter 5. Capitalization devices: Business models and the renewal of markets. In: Kornberger M, Justesen L and Madsen AK (eds) *Making things valuable.* Oxford: Oxford University Press, pp. 109-125.

Eriksson L (2012) Pluripotent promises: configurations of a bio-object. In: Webster A, Vermeulen N and Tamminen S (eds) *Bio-Objects: Life in the Twenty-first century*. London: Ashgate, pp. 27-42.

European Commission (2003) *Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (Text with EEA relevance) (notified under document number C (2003) 1422)*. Luxembourg: Office for Official Publications of the European Communities.

Felt U (2017) Under the shadow of time: Where indicators and academic values meet. *Engaging Science, Technology, and Society* 3: 53-63.

Ferrati F and Muffatto M (2020) Using Crunchbase for research in Entrepreneurship: data content and structure. In: M Au-Yong-Oliveira M and Costa C (eds) *19th European Conference on Research Methodology for Business and Management Studies (ECRM)*, Aveiro, Portugal, 18-19 June 2020. Reading, UK: Academic Conferences and Publishing International Limited, pp. 342-351.

Fochler M (2016) Variants of Epistemic Capitalism: Knowledge Production and the Accumulation of Worth in Commercial Biotechnology and the Academic Life Sciences. *Science Technology and Human Values* 41(5): 922–948.

Garciamendez-Mijares CE, Agrawal P, García Martínez G, Cervantes Juarez E and Zhang YS (2021) State-of-art affordable bioprinters: a guide for the DIY community. *Applied Physics Reviews* 8: 1–13.

Geiger and Gross N (2024) Tech sharing, not tech hoarding: Covid-19, global solidarity, and the failed responsibility of the pharmaceutical industry. *Organization* 31(3): 567–582.

Hansson K (2021) New biomodifying technologies and near future alignment work. In: *Nordic Science and Technology Studies Conference 2021: STS and the future as a matter of collective concern,* Copenhagen, Denmark, 20-21 May 2021. Copenhagen: Danish Association for Science and Technology Studies, pp. 66.

Hauskeller C and Weber S (2011) Framing pluripotency: iPS cells and the shaping of stem cell science. *New Genetics and Society* 30(4): 415-431.

Helgesson C-F (2016) Folded Valuations? *Valuation Studies* 4(2): 93–102.

Helgesson C-F and Muniesa F (2013) For What It's Worth: An Introduction to Valuation Studies. *Valuation Studies* 1(1): 1–10.

Helmreich S (2008) Species of biocapital. *Science as Culture* 17(4): 463–478.

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

Ilic D (2016) iPSC in the past decade: the Japanese dominance. *Regenerative Medicine* 11(8): 747–749.

Ilic D and Liovic M (2020) Industry updates from the field of stem cell research and regenerative medicine in December 2019. *Regenerative medicine* 15(4): 1499-1507.

Lanaro M, Luu A, Lightbody-Gee A, Hedger D et al. (2021) Systematic design of an advanced open-source 3D bioprinter for extrusion and electrohydrodynamic-based processes. *International Journal of Advanced Manufacturing Technology* 113: 2539–2554

Lehoux P, Daudelin G, Williams-Jones B, Denis JL and Longo C (2014) How do business model and health technology design influence each other? Insights from a longitudinal case study of three academic spin-offs. *Research Policy* 43(6): 1025–1038.

Lehoux P, Miller FA, Daudelin G and Urbach DR (2016) How venture capitalists decide which new medical technologies come to exist. *Science and Public Policy* 43(3): 375–385.

Li P, Faulkner A and Medcalf N (2020) 3D bioprinting in a 2D regulatory landscape: gaps, uncertainties, and problems. *Law, Innovation and Technology* 12(1): 1-29

McMahon A (2021) Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance. *Journal of Medical Ethics* 47(3): 142–148.

Mazzucato M (2018) *The Value of Everything: Making and Taking in the Global Economy*. London, UK: Allen Lane.

Mittra J and Zoukas G (2020) Unpacking the concept of bioeconomy: Problems of definition, measurement, and value. *Science & Technology Studies* 33(1): 2-21.

Molnar-Gabor F (2019) Chapter 4: Science, ethics, and patents. Ethically-motivated barriers to the patenting of the results of human embryonic stem cell research. In: Hauskeller C, Manzeschke A and Pichl A (eds)*The Matrix of Stem Cell Research*. London: Routledge, pp 50-67.

Morrison M (2017) "A good collaboration is based on unique contributions from each side": assessing the dynamics of collaboration in stem cell science. *Life Sciences, Society and Policy* 13(1). https://doi.org/10.1186/s40504-017-0053-y

Morrison M (2019) Making cells worthwhile: calculations of value in a European consortium for induced pluripotent stem cell banking. *Science as Culture* 28(1): 46-69.

Morrison M (2024) The role of patenting in the valuation of biomedical innovation. *Tecnoscienza–Italian Journal of Science & Technology Studies* 14(2): 7-26.

Morrison M and Bartlett A (2022) Making translational value : Identifying 'good targets' for clinical research on gene editing and induced pluripotent stem cell technologies. *SSM - Qualitative Research in Health* 2: 100131. https://doi.org/10.1016/j.ssmqr.2022.100131

Morrison M, Mourby M, Bartlett A and Bicudo E (2019) Biomodifying technologies and experimental space: Organisational and regulatory implications for the translation and valuation of health research - ESRC. *Impact* (1): 63–65. https://doi.org/10.21820/23987073.2019.1.63, 2019.

Mourby M, Bell J, Morrison M et al. (2022) "Biomodifying the 'natural': from Adaptive Regulation to Adaptive Societal Governance" *Journal of Law and the Biosciences* 9(1). https://doi.org/10.1093/jlb/lsac018

Pichl A (2019) Chapter 9: What Keeps an Outdated Stem Cell Concept Alive? A search for traces in science and society. In: Hauskeller C, Manzeschke A and Pichl A (eds)*The Matrix of Stem Cell Research*. London: Routledge, pp. 131-148.

Pinel C (2021) Renting valuable assets: Knowledge and value production in academic science. *Science, Technology, & Human Values* 46(2): 275-297.

Rheinberger H-J (1997) *Toward a History of Epistemic Things: Synthesizing Proteins in the Test*

Tube. Stanford, CA: Stanford University Press.

Rose N (2007) *The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century*. Princeton, N.J: Princeton University Press.

Rothman H and Kraft A (2006) Downstream and into deep biology: Evolving business models in "top tier" genomics companies. *Journal of Commercial Biotechnology* 12(2). https://doi.org/10.1057/palgrave.jcb.3040154

Sunder Rajan K (2006) *Biocapital: The constitution of postgenomic life*. Durham, NC: Duke University Press.

Van Lente H and Rip A (2017) Chapter 2: Reflexive Co-Evolution and Governance Patterns. In: Bowman DM, Stokes E and Rip A (eds) *Embedding New Technologies into Society: A Regulatory, Ethical and Societal Perspective* (1st Ed.). New York: Jenny Stanford Publishing, pp. 16-33.

Vermeulen N, Haddow G, Seymour T, Faulkner-Jones A and Shu W (2017) 3D bioprint me: a socioethical view of bioprinting human organs and tissues. *Journal of Medical Ethics* 43(9): 618-624.

Waldby C (2002) Stem cells, tissue cultures and the production of biovalue. *Health* 6(3): 305-323.

Waldby C and Mitchell R (2006) *Tissue Economies: Blood, Organs and Cell Lines in Late*

Capitalism. Durham, NC: Duke University Press.

Wainwright SP, Michael M and Williams C (2008) Shifting paradigms? Reflections on regenerative medicine, embryonic stem cells and pharmaceuticals. *Sociology of Health & Illness* 30(6): 959-974.

Yamanaka S (2020) Pluripotent stem cell-based cell therapy—promise and challenges. *Cell Stem Cell* 27(4): 523-531.

Notes

1 The notion of the bioeconomy is subject to multiple, competing attempts to define, delimit and measure it as a phenomenon (Mittra and Zoukas, 2020). Here we are exclusively concerned with 'red' or human, medical areas of application.

2 By this we mean companies that would qualify as micro (<10 employees and annual turnover of less than 2 million Euro), small (<50 employees and ≤ €10 million annual turnover) or medium sized (<250 employees, ≤ €50 million annual turnover) using the current European classification (European Commission, 2003).

3 'Pluripotency' while often uncritically used in scientific and commercial accounts is not an unproblematic- or indeed necessarily coherent - term (Pichl, 2019). For a review of the history of the term and how its boundaries provided a strategic advantage to certain communities of stem cell scientists see Eriksson (2012)

4 See Molnar-Gabor (2019) for a recent account of restrictions to patents on human embryonic material in the European Union.

5 This displaces the primacy of economic value, albeit in a rather different way to the fusion of economic value and moral values described by authors such as Rose (2007) and Waldby (2002), and subsequently critiqued by Birch and Tyfield (2013: 304-305).

6 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 in Valuation Studies as 'folding' (Helgesson, 2016) and is a common feature of valuation.

7 The regulatory strand of work has been detailed elsewhere (Li et al., 2020; Mourby et al., 2022) and will not be discussed further here.

8 The specific country in Eastern Europe is not named because it has only ever had one bioprinting firm. That firm had a small number of employees and a founder who was very visible on social media discussing bioprinting. Naming the country would make it easy to identify which firm, and probably which specific person, we interviewed.

9 Which in turn, reflect prior value judgements that genetic and molecular traits are key factors in most diseases and easier to measure than social or environmental causes, as well as the role of existing infrastructure and previous organising work in making clinical and genetic data searchable (Morrison, 2019).

10 For example, during their interview, iPS Company 2 discussed an ongoing contract with a German company offering a platform of iPS-derived cells for drug candidate screening who outsourced the sourcing of their cell types to the UK firm.

11 Birch et al (2025: 18) define a toll as "a techno-economic configuration of claims, devices, and relations" that limits access to a useful resource.