Policy support for disruptive innovation in the life sciences

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Abstract

This paper focuses on business models and value chains to analyse sectoral innovation systems involving synthetic biology and gene editing, as potentially disruptive platform technologies in the life sciences. In the context of industrial biotechnology, we propose that the extent to which an innovation is expected to be disruptive, and the location of that disruption in existing value chains, are relevant to policy decision making on how to govern innovative technologies. Policy decisions on how to regulate or support an innovative technology will be among the most important factors determining the extent to which it is able to deliver its disruptive potential, leading to sectoral transformations through new business models and value chains. This mode of thinking about disruption and innovation could be incorporated in standard procedures for policy makers to guide decisions designed to support translation from basic scientific research to societally useful products and processes.

1. Introduction

A useful understanding of innovation in the life sciences can be built (Wield et al., 2017) on integrating the perspectives of:

- Scientists and innovators, working in universities, public and private research institutes, large and small companies, often involving networks and partnerships;
- Policy makers and regulators at national and international levels; and
- Citizens and stakeholders (the latter including patient interest groups and other advocacy organisations).

This triangular relationship has formed the basis of the research programme of the Innogen Institute, as reflected in several of the articles in this issue. It has evolved since 2002 to become an interdisciplinary methodology designed to support better translation of basic scientific research to societally and economically valuable innovation, by identifying enablers and blockers of effective translation and key pressure points where specific actions can be most effective (Chataway et al., 2006; Milne and Tait, 2009; Mittra, 2015; Tait, et al., 2002; Tait, 2007). The approaches and tools developed as part of this overall methodology, and the foundational research itself, are important to, and cited by, an unusually wide range of disciplines (Rafols and Costas, 2012) and this body of work has been influential on innovation and regulatory policy making for new technologies, particularly in life sciences (Mittra et al., 2015; Omidvar et al. 2014; Tait et al. 2017; Tait, 2016; Tait et al. 2014).

Among the tools and approaches developed as part of the Innogen methodology[1], this paper concentrates on Strategic Planning for Advanced Technology Innovation Systems (STRATIS) (Wield et al. 2017) which focuses on business models and value chains, as components of company innovation strategies and related support policies, particularly for disruptive innovations. Illustrative points are taken from industrial biotechnology and innovations arising from basic research on synthetic biology and gene editing.

Governments are increasingly concerned to reap the benefits of the basic research that they fund, particularly the highly significant benefits that can emerge from successful translation of a disruptive innovation, and for that to succeed they will need to have a better understanding of the nature of disruptive innovation itself, the circumstances that can stop it in its tracks or lead companies to migrate to another government's jurisdiction, and where in an overall value chain to focus policy attention.

This paper considers the influence of potentially disruptive discoveries in life sciences on specific business sectors involved in an overall value chain. It aims to help policy makers to predict when, how and where scientific discoveries could potentially have a disruptive influence and how specific policies could support or inhibit such outcomes. Other factors that can influence these processes, such as regulatory systems, stakeholder preferences and market influences are dealt with in other publications (Banda et al. 2019 (in press) (this journal issue); Mastroeni et al. 2019 (in press) (this journal issue); Mittra and Tait 2012; Mittra et al. 2015; Scannell et al 2019 (in press) (this journal issue); Tait et al. 2017).

Section 2 introduces our approach to sectoral innovation systems as applied to potentially disruptive technologies in the life sciences whilst section 3 emphasises the need to differentiate between incremental and disruptive technologies in policy making. Section 4 focuses on the sectoral location of disruption and in section 5 we illustrate some of the challenges that disruptive innovation may face based on the analysis of two potentially disruptive technologies – synthetic biology and gene editing. Section 6 describes how a better understanding of the processes of disruptive innovation can be applied to improve policy making for innovation support.

2. Sectoral Innovation Systems

Several systemic forms of innovation analysis have been developed (Tait, 2007), and STRATIS (Figure 1) relates most closely to Malerba's (2004) 'sectoral innovation systems' approach. It uses three levels of analysis: (i) sector-specific business models and value chains, (ii) the innovation ecosystem within which the value chains are embedded, and (iii) future interactions that will determine the success or failure of innovative developments (Wield et al. 2017). We define the key elements of this form of analysis as follows.

Business model.

The business model represents the processes by which firms within a common sector create, capture and deliver value from a set of

[1] https://www.innogen.ac.uk/downloads/Innogen-Institute-Research-Outline.pdf

technological opportunities. Within a sector or sub-sector there will be a generic business model, or models, designed around a common set of innovative developments, shaped by similar factors within the innovation ecosystem.

Value chain.

Most advanced technological innovation takes place through a value chain that requires carefully orchestrated collaboration of several companies with different business models, in parallel and/or in sequence to take an innovative development from conception to market. In some cases, a significant portion of the value chain can be located within a large multinational company with a single complex business model.

Innovation ecosystem.

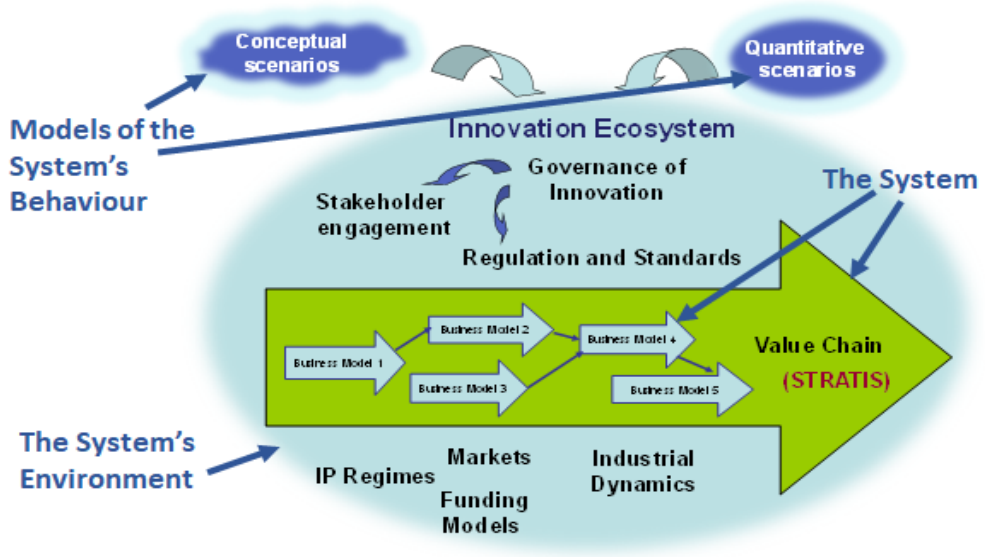
The innovation ecosystem encompasses the wider economic, regulatory, societal and political context within which a value chain is embedded. It includes the external factors that will either enable or constrain the ability of companies involved in the value chain to implement their business models and to cooperate nationally and internationally to create and deliver value.

The large arrows in Figure 1, indicating the system, the system's environment and models of the system's behaviour, relate to a systemic analysis that identifies the system of interest as the business models and value chain that are part of the STRATIS analysis and are largely under the strategic control of the companies developing an innovation, and the factors in the system's environment (the innovation ecosystem) that will affect companies' decision making, over which they can have very little influence (e.g. regulatory or patent systems). At the highest level of analysis, qualitative or quantitative scenarios can be used to model the behaviour of the system under the influence of different internal company decisions and external ecosystem influences.

STRATIS is designed to support decision making at various levels: (i) individual companies developing a business model for a specific innovation; (ii)groups of firms involved in strategy development for a sectoral value chain; (iii) analysts evaluating the impact of ecosystem factors such as markets, regulations or stakeholder actions as enablers or constraints on innovation trajectories (Mittra and Tait, 2012; Mittra et al, 2015); (iv) policy makers concerned to support disruptive innovation that can contribute to societal needs and wants and national economic prosperity (HM Government 2017; Tait et al. 2017); and (v) venture capitalists and others seeking information relevant to their investment decisions.

The focus on a sectoral innovation system approach is relevant here because of the importance of a common set of business models as the defining characteristic of a sector, whereby incumbent company business models and value chains act as a welcoming environment for incremental innovations and an often-hostile one for a disruptive innovation that would potentially make them redundant.

Figure 1. STRATIS approach



3. The disruptive–incremental distinction as a basis for innovation policy decision making

3.1 Defining and analysing disruptive innovation

The UK Industrial Strategy White Paper (HM Government 2017) recognises the need to support new industry sectors that will be disruptive of established ways of working and will ensure that the innovations on which these sectors will be based are not unnecessarily inhibited. It also recognises the important role played by incremental innovations that will improve our international competitiveness in existing industry sectors. Incremental and disruptive innovation are defined here as follows:

> *Incremental innovation* fits well with the current business model of a firm. It generates competitive advantage and contributes to the economy through more efficient use of resources, or elimination of wasteful or environmentally damaging practices, but will not lead to sectoral transformations.
>
> *Disruptive innovation* involves discontinuities in innovation pathways, requires new areas of research and development (R&D), creation of new modes of production and/or new markets. It can lead to sectoral transformations and the displacement of incumbent companies, or the creation of entirely new sectors, all with significant societal and economic benefits. There is often no pre-existing business model on which to build a strategy for disruptive innovation and there may also be a need to create a new value chain, or a new role for the emerging technology in an existing value chain.

The concept of disruptive innovation relates to the observation that innovation arises from new scientific or engineering discoveries and progresses through periodic Schumpeterian waves of creative destruction, involving discontinuities

in innovation pathways which are regarded as the driving force behind the market system (Rothaermel 2000). Against this background, the paper by Tait (2007) analysed the disruptive potential of life science-related innovations in three sectors, agro-biotechnology, pharmaceuticals and stem cell therapies. In each case, rather than experiencing the expected disruption, incumbent multinational companies had demonstrated surprising resilience in the face of several waves of potentially disruptive scientific discoveries. This is in sharp contrast to the experience of the information and communication technologies (ICT) sector which has experienced several such waves of disruption arising from hardware and software innovations over the same timescale.

The most influential exponent of the Theory of Disruptive Innovation, Clayton Christensen, has described it as starting from two market-related footholds: (i) *low end footholds* which exist because incumbents try to provide their most demanding customers with ever-improving products, opening the door to disrupters with a 'good enough' product to satisfy low-end customers; and (ii) *new-market footholds* where disrupters find a way to turn non-consumers into consumers (Christensen et al. 2015). Christensen's analyses have been almost entirely in industry sectors that do not, as in life sciences, experience onerous and time consuming regulatory regimes. King and Baatartogtokh (2015) found 77 cases of disruptive innovation described by Christensen and his co-workers, only two of which (endoscopic surgery and portable blood glucose meters) were related to life science innovation.

Although Christensen's theory has been extremely influential it has also had its critics. King and Baatartogtokh (2015) found that the theory of disruptive innovation has had only limited predictive power. Indeed Christensen et al. (2017) observed "Nearly a decade ago, *The Innovator's Prescription* showed how disruption could transform healthcare. Yet unlike other industries, healthcare has been largely immune to the forces of disruptive innovation." In a scenario analysis of the future of the pharmaceutical sector in 2030, Tait et al. (2007) predicted that disruption was eventually likely to come to the pharmaceutical sector through close interaction and possibly integration with major companies in the ICT sector, including the application of ICT sectoral business models to current challenges in the delivery of health care. This is now being realised as Apple, Google, Amazon and Facebook are disruptively entering the space of health research and delivery, offering new methods for collecting, storing and analysing health data (Sharon 2016). This reinforces our observation on the non-applicability of much of the writing on disruptive innovation to life science-related sectors and reinforces the case for a new approach to analysis of this phenomenon in such cases.

Tait (2007) attributed this resilience of the business models of multinational companies in life science-related areas largely to the existence of time-consuming and expensive regulatory systems acting as a barrier to entry for small companies with disruptively innovative ideas, and more recent evidence has supported this view (Tait et al. 2017). Another important set of insights, as discussed in this paper, relates to the need to think constructively about which sectors are most likely to be disrupted by a particular innovation and to consider the location of the disruptive impact across an entire value chain which may involve several industry sub-sectors with different business models.

The above definitions of the terms 'business model', 'value chain', 'innovation ecosystem', 'disruptive innovation' and 'incremental innovation' clarify how we are interpreting them and how we link them systemically in this new form of analysis to understand both the factors that drive innovation in different directions and how innovation can be influenced by, and contribute to, government policy agendas.

The definitions imply that incremental innovation should find an easy route to uptake in the companies whose business models it supports, while disruptive innovation faces many challenges but is also seen as an important part of the solution to greater national prosperity and international competitiveness (HM Government 2017). For these reasons, disruptive innovation is, or should be, the main focus of publicly-funded innovation support initiatives.

3.2 Disruptive innovation is a slippery concept

From the above discussion of the work of Christensen and others, it is clear that the concept of disruptive innovation cannot be straightforwardly extended to areas beyond ICT-like sectors in a way that would contribute to its status as a formal theory. However, it is a concept that is widely used in innovation and policy circles and there is a need to enrich it to support our understanding of how basic scientific research can most effectively be translated to innovative outcomes. The following two sector-related insights are important contributions to this enriched field of application of the disruptive innovation concept.

(i) An innovation that is disruptive of the business model of one industry sector can be incremental for another.

In the early stages of development of a disruptive innovation, as defined here, there will be no clear, pre-existing business model, and several existing sectors may have an interest in it. For example, when genetically modified (GM) crops were in the early stages of development in the 1980s, companies interested in the technology included many of the agrochemical companies then in business, Shell (interested in GM trees), Unilever (interested in cloned oil palm trees), and several large seed companies. GM technologies were most disruptive of the agrochemical company business model, across all stages of development from basic research, through later translational stages to manufacture, distribution and marketing. For most of the other companies in the mix, GM-related innovation would have had a relatively incremental impact on their pre-existing business models. The agrochemical companies faced another seriously disruptive challenge in the potential of GM crops to lead to significant reductions in the use of pesticides, the foundation of their business model at the time (Tait 2007). The agrochemical industry sector thus had a greater incentive than any of the others to gain control of this important, potentially disruptive innovation and they did so through the regulatory system, with the support of the policy community at the time (Tait and Levidow 1992, Tait 2007).

(ii) An innovation can be disruptive for some of the sectors/business models contributing to an overall value chain, and neutral or incremental for others

To understand fully how to manage a disruptive innovation, it is important to consider its impact across an entire value chain and this element is also lacking in the disruptive innovation literature. The point is elaborated more fully in Section 4, but it can also be illustrated through the above GM crops example. In developing its new business models to incorporate this disruptive innovation, the agrochemical industry sector assumed that its value chain ended at the farm level (Tait and Chataway 2007). They failed to follow it through from the farm level to the food producers and distributors and eventually to citizens as consumers, and the fact that the technology proved to be so disruptive at this level was a major factor in the failure of this technology to achieve its disruptive potential in Europe.

4. Contribution of synthetic biology and gene editing to innovation in industrial biotechnology.

Synthetic biology and gene editing are frequently described as *disruptive* platform technologies that are expected to form the future basis of the bioeconomy and to transform production processes across a number of sectors (Datta 2016; Law 2015; Talbot 2016; Synthetic Biology Leadership Council (SBLC) 2016). However there are no examples yet where the concept of disruptive innovation has been applied to examples of such innovation in practice.

The value of the UK bioeconomy was estimated recently to be £150 bn GVA, increasing by another £40 bn over the next decade and UK public investment in synthetic biology to date is over £300 million, supplemented by substantial private investment (Chambers et al. 2015; SBLC 2016). Continuing this trend, the 2018 bioeconomy strategy paper projected a doubling of the impact of the bioeconomy to £440 bn by 2030, much of it expected to be delivered through industrial biotechnology (HM Government 2018).

In the current chemicals manufacturing sector, a broad range of chemical intermediates (ethylene, propylene, butadiene, benzene, toluene, xylenes) is manufactured on a very large scale by petro-chemicals based companies and sold further along the value chain to companies in sectors developing drugs, detergents, polymers, synthetic fabrics, flavours, fragrances, enzymes and food ingredients. The final products then reach market end-users via supermarket chains and other consumer outlets. These established value chains have evolved over a number of decades and encompass companies with different business models operating in parallel or in sequence (Figure 1).

This is the value chain that is claimed to be open to disruption by innovations based on synthetic biology and gene editing, modifying micro-organisms and enabling fermentation-based production of high value chemical intermediates (Tait 2016). There are also longer-term prospects to develop chemicals that cannot currently be made at scale, or to build new classes of feedstock for fermentation-based processes.

Driven by the impacts of climate change, many countries now have policies designed to minimise the use of fossil fuels by supporting the development of biologically sourced chemical intermediates (the bio-economy) and eliminating waste (the circular economy) (Tait 2016). In the short term, industrial

biotechnology production of chemical intermediates is unlikely to be competitive with the low cost, large scale manufacture of products such as butadiene and toluene from fossil fuels, but new market niches are emerging, for example in the production of more specialised and higher value intermediates such as industrial enzymes, lactic acid, 1,3-propanediol, and isoprenoids (US National Research Council (US NRC) 2015).

Fermentation-based biofuel production is already in place on a significant scale. In 2016, global biofuel production amounted to approximately 82 bn metric tons oil equivalent, 70% of this in the USA and Brazil[2]. Further developments in this area are likely to arise using synthetic biology and gene editing to break down cellulose and lignin-based waste products to produce sugars as feedstock, among other things for biofuel production, contributing to the circular economy. Despite these impressive numbers, this level of biofuel production is still very far from beginning to disrupt the business models of the current producers of petrochemical based fuels for transport. It is an example of the use of government policy to support innovation that would otherwise be uncompetitive, to meet political and societal objectives (Nuffield Council on Bioethics 2011), in these cases based on the use of a carbon source that is surplus to requirements in the country concerned (corn in the USA and sugar in Brazil).

The US NRC Report (2015) identifies four different business models/value chains likely to be involved in the future development of industrial biotechnology:

(i) *Vertically integrated business model:* Research and design for bio-manufacturing is performed by corporations that develop the entire process from feedstock sourcing to organism engineering to manufacturing and sales, e.g. bio-pharmaceuticals.

(ii) *Centralised production business model:* Bio-manufacturing occurs in a small number of very large facilities that take advantage of economies of scale to deliver products with thin margins at large volumes to meet world demand, e.g. international scale brewers.

(iii) *Horizontally stratified value chain:* Research and design for bio-manufacturing is performed by different companies, each specialising in a different step along the production process, e.g. small and medium sized bio-based manufacturers of specialty chemical feedstocks (now emerging in the USA).

(iv) *Distributed production value chain:* Bio-manufacturing occurs in many small scale facilities, using geographically co-located feedstocks and delivering products to meet local or niche markets, equivalent to micro-breweries.

Predictions of the disruptive impact of synthetic biology and gene editing platform technologies on innovation in industrial biotechnology have so far been too vague to be of value in projecting future technology outcomes or in

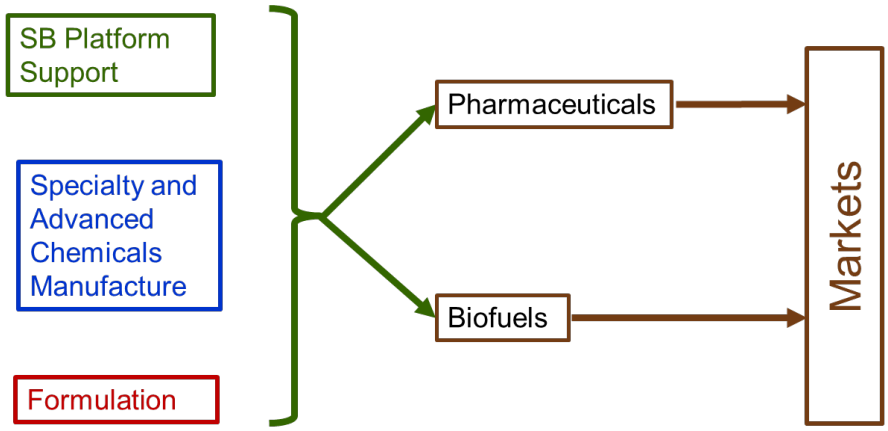
[2] https://www.statista.com/statistics/274168/biofuel-production-in-leading-countries-in-oil-equivalent/

guiding policies to support innovation. This section applies the concepts outlined above to these NRC categories of business model or value chain. The key points here are that: for vertically integrated or centralised production, one company is in control of all stages of production, from the initial innovation platform through to formulation and marketing, based on a single overarching business model; whereas for horizontally stratified or distributed production, the focus is on an integrated value chain incorporating several different business models pertaining to the different types of company involved in the value chain.

4.1 Business models - vertically integrated or centralised production

These two types of business model are considered together because of the potential for overlap between them. Vertically integrated company business models are likely to be based on centralised production facilities and vice versa (Figure 2).

Figure 2. Industrial Biotechnology Business Models – Vertically Integrated and Centralised Production



Many pharmaceutical companies already use modified micro-organisms to manufacture complex bio-pharmaceuticals, using a *vertically integrated* business model. Synthetic biology and gene editing will enable these companies to continue with the same business model, but to use a modified organism to improve the efficiency and reliability of the biology-based process, and hence the affordability or the quality of the drug produced. The innovation process will be able to build on the skills already available within the company to produce high value biopharmaceutical products for existing high value global markets. The likely impact of synthetic biology or gene editing on these business models thus fits with the above definition of incremental innovation in the context of that type of company and business model. This is valid for pharmaceutical companies that have already faced the disruptive transition to fermentation-based manufacturing processes[3]. Where a pharmaceutical

[3] This point could be seen as contradicting the observation below that chemical/fossil fuel-based manufacturers are unlikely to make the disruptive transition to fermentation based production methods. The incentive for the pharmaceutical companies to face this disruption lies in the very high

company still uses thermo-chemical manufacturing processes to produce its drugs, conversion to fermentation-based technology would of course be significantly disruptive.

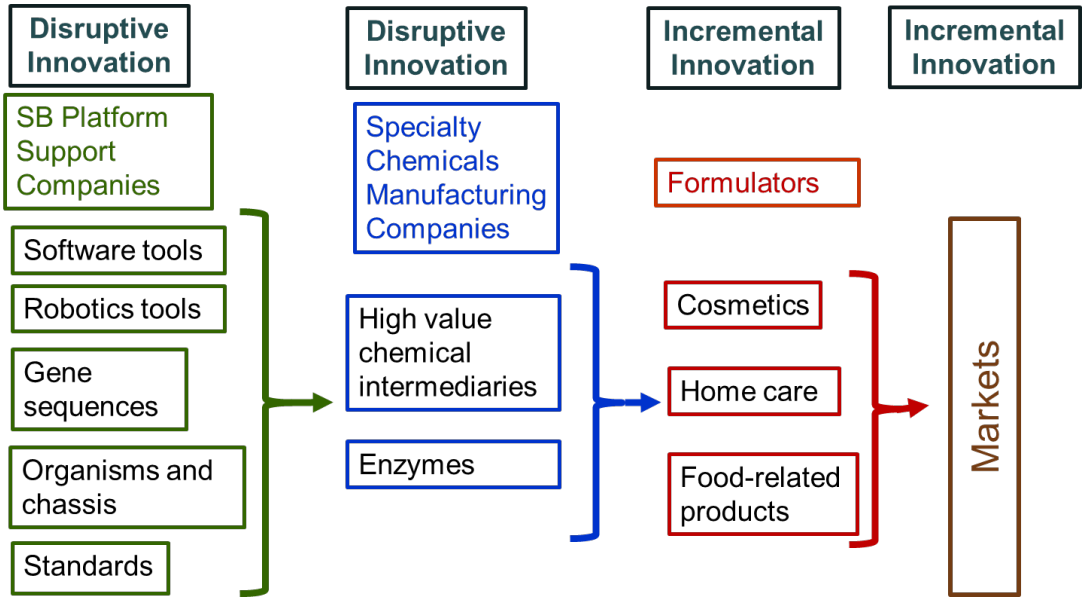
There are also large, centralised, vertically integrated companies in the US developing biofuel (ethanol) from maize with the support of government subsidies to encourage the use of this agricultural feedstock. Synthetic biology and gene editing will offer improvements in these processes through the re-design of the organisms involved in fermentation in a way that will again be incremental in their impact on company business models.

4.2 Value chains: Horizontally stratified or distributed production

Figure 3 describes the value chains that are the target for innovation in industrial biotechnology, based on synthetic biology and gene editing, with different impacts, disruptive or incremental, in different locations across the value chain.

Feeding in at the beginning of these value chains, a new type of SME has emerged, designing and delivering the novel engineered micro-organisms needed for fermentation-based manufacturing processes. These *synthetic biology platform support companies* are disruptively innovative in that there are no pre-existing business models that they can adopt – they are inventing new 'design and build' approaches that have not existed on any scale until the past few years. As implied in Figure 1, they will either need to find a role for their business model in existing value chains or (more uncertain) collaborate with other companies in the design of entirely new value chains.

Figure 3. Industrial Biotechnology Value Chains – Horizontally Stratified or Distributed Production



value of the bio-pharmaceutical products being developed and often the lack of any viable alternative manufacturing process.

Growth (or even viability) in this early platform support sector will depend on whether the next companies along the value chain (Figure 3), the incumbent specialty chemicals manufacturing companies with business models currently based on petrochemical raw materials are willing to take up the disruptive challenge of using synthetic biology and gene editing to develop the chemical feedstocks and advanced biological products of the future. The formulators, at the next stage of the value chain, will continue to base their production on small molecule intermediates and the novel source of these molecules is unlikely to have any disruptive impact on their business models so the result of innovation based on synthetic biology and gene editing for these companies will be incremental (Figure 3). They will also continue to produce similar (but better) products for the same consumer markets as before, so again there may be no overall market disruption.

4.3 A reality check

Sections 4.1 and 4.2 describe the expected context for incorporation of innovation based on synthetic biology and gene editing into industrial biotechnology value chains. However, the future shape of this industry and its potential contributions to the bioeconomy and the circular economy will depend on the resultant of the factors outlined above and will inevitably be more messy than expected. We suggested (Section 3.2) that an innovation can be disruptive for one industry sector within a value chain (Figure 3) but neutral or incremental for another, and Tait et al. (2017) have observed that the smoothest route to market for a potentially disruptive technology is likely to be through the incumbent industry sector for which it will be least disruptive.

For large scale petrochemicals-based producers of chemical intermediates, converting from fossil fuel based production to biotechnology based production, as projected in policy documents on the bioeconomy, would be seriously disruptive of their current business model, requiring new equipment, new staff skills and compliance with a new set of regulatory requirements. It is unlikely that the companies currently managing oil refineries would be willing or able to replace them with facilities based on bio-digesters and fermenters. The economics of production are also not conducive to such a change, given the current relatively low price of oil and some of the difficulties still to be overcome in achieving reliable fermentation-based manufacture of chemical intermediates (Cambridge Consultants 2018). There is thus unlikely to be any shift towards the bio-based direction from fossil fuel based manufacture in the foreseeable future and any policy initiative designed to support such an outcome is unlikely to succeed.

The observation, that the smoothest route to market for a potentially disruptive technology is likely to be through the incumbent industry sector for which it will be least disruptive, would point to companies with business models currently based on large scale fermentation and brewing, producing enzymes and drinks for human consumption. All other things being equal, this would be the most logical sector to take up the innovation potential for the bioeconomy arising from synthetic biology and gene editing. However, for these companies there is potential *market* disruption, given that they would be serving very different markets from their current focus on the food and drink sector, and the

potential for consumer-generated reputational risk will discourage such a move by these companies.

So there is a gap in the bio-based value chain that represents a new disruptive business niche for *specialty chemicals manufacturing companies* to begin developing moderate to high value chemical intermediates based on fermentation production processes using synthetic biology and gene editing-enhanced micro-organisms. These new business models are likely to be SME-based to begin with, with the potential for the companies to grow rapidly, to create an industrial biotechnology sector building on synthetic biology and gene editing. This trajectory is already well under way in the USA (US NRC 2015). One example of such a company with an intriguing business model, Intrexon[4], describes itself as "committed to a better world through better DNA"™, with initiatives in food, environment, drugs/health, GM insects, energy products and consumer products, " … designing and constructing . … single and multi-gene programs with predictable outcomes providing our collaborators a wealth of capabilities."

If investors understand the factors that will determine the success of different types of company planning to operate in industrial biotechnology value chains, these SMEs will benefit from the expectation that the occupants of the incumbent business sectors (petrochemicals and large scale brewing) have good reasons *not* to be planning to invest in this new, potentially disruptive technology. The new entrants will then be the next step along the value chain, using the products of the synthetic biology and gene editing platform support companies, and feeding their outputs either to the existing formulators or straight to an end-user market. In the longer run, depending on future oil prices and government policies to support non-fossil fuel based production, they may also be able to compete disruptively with the very large petrochemicals based producers by developing superior products (e.g. according to future climate change related criteria).

If the gap identified here is not filled, past public and commercial investment in synthetic biology platform support companies will not deliver the expected returns, these companies could go out of business and there may be a risk that public sector investment in their early development will have been wasted.

5. Conclusions

Disruptive innovation is usually regarded as a rare, desirable, but ill-defined outcome of basic scientific research, distinguished from the much more common, also societally beneficial incremental innovation. Because of the potential gains for a national economy that hosts the next generation of disruptive innovations, many governments, including the UK, now have policies designed to support this outcome (HM Government 2017). This paper is seen as a contribution to future policy making, intended to improve the extent to which a nation is able to capitalise on any potentially disruptive outcomes from basic scientific research.

[4] https://www.dna.com/

The approach to understanding disruptive innovation introduced here focuses on the interactions among innovative technology developments, the business models of incumbent companies and of potential future companies, and the value chains to which they contribute. It attempts to foresight future company behaviour and innovation outcomes based on knowledge of these elements of the innovation ecosystem within which they are embedded.

There is a common perception in policy circles that it is not possible to tell in the early stages of its development whether an innovative technology will be disruptive or incremental. This can be seen partly as a lack of recognition by policy makers of the extent to which their decisions are a determining factor in the future trajectory of an innovative technology platform (examples could be synthetic biology and gene editing as discussed in this paper or, in the ICT area, blockchain). Policy decisions on: what regulatory system to adopt for an innovative technology (Tait et al. 2017); which innovation support mechanisms to put in place; or how to measure success of a policy initiative and the timescale over which to monitor that success; will all contribute to the eventual innovation outcome and the extent of the disruption experienced.

This is a question of intelligent foresight, with all the usual caveats about human foresighting capabilities. However, such predictions can be more accurate if based on an intimate knowledge of the technology itself and of the collaborating or competing industry sectors that could take on the role of developing and marketing it (Mittra et al. 2015; Tait 1993; Tait et al 2007). As indicated in Figure 1, a scenario analysis that incorporated all these factors to model the future behaviour of specific sectors of the economy under the impact of a disruptive innovation could guide policy makers on where to focus their attention to inform future policies.

When a set of new technology developments is considered to be potentially disruptive, the above analysis leads to the following general recommendations for policy makers:

i. Identify the target areas where the innovation concerned is expected to have a disruptive impact and the high-level policies to which it is relevant (e.g. the bioeconomy or the circular economy);

ii. Map the relevant value chains, noting the sectors, the types of companies and the scale of the companies involved in the value chain, as for example in Figure 3;

iii. Consider the extent to which the expected innovations will be disruptive or incremental for the companies involved in the current value chain, whether they will be willing to incorporate the innovation into their current business models or to displace their current business models with a new one, and what is likely to be the innovation outcome of these decisions;

iv. Identify any gaps in future value chains that are likely to restrict the future operation of that value chain with the potential to stop development of the innovation concerned or to divert activity to a different value chain;

v. Consider what sectoral-level policies can support the value chain as a whole in delivering the higher level policies.

Such questions could form the basis of a dialogue between policy makers, innovators and incumbent companies as part of the planning process for future innovation support policies.

Considering these recommendations in the context of industrial biotechnology and its future development based on synthetic biology and gene editing, until recently innovation support initiatives have been largely targeted towards synthetic biology platform support companies, at the beginning of the value chain described in Figure 3. However, as noted in Section 4.3, a gap has been emerging in the part of the value chain that is currently occupied by petrochemicals-based specialty chemicals manufacturing companies with no clear candidates from that sector being willing to build disruptively innovative business models based on alternatives to fossil fuels. The logical policy conclusion would be that there is a need for policy initiatives to foster the emergence of new fermentation-based companies willing to fill the gap identified in the next generation value chain for industrial biotechnology.

Relevant to this need the UK government, through initiatives set up under its Industrial Strategy and Bioeconomy Strategy (HM Government 2017, 2018) has announced investments of £125 million in initiatives to reduce plastic waste and support the development of biodegradable plastics. These initiatives could help to fill the gap identified in some industrial biotechnology value chains, albeit in one specific area of the much broader bioeconomy. However, there is no evidence that these funding decisions were based on any formal consideration of the support needs of disruptive innovative technologies in general or in the specific case of industrial biotechnology.

The mode of thinking about innovation support policies introduced here could supplement current policy approaches and contribute to more creative policy dialogue between the key industry and policy players. It could lead to targeted cross-sectoral strategies that will deliver the necessary innovation support in a timely manner to the appropriate point in relevant value chains and enable the UK to retain more effectively the 'first mover' advantage it often has, arising from the high quality basic scientific research that it funds.

References

Banda, G., J. Tait, A. Watkins and O. Omidvar 2019, in press. "Business modelling and value chains". *Technology Analysis and Strategic Management (this issue)*

Cambridge Consultants 2018. *Building the Business of Biodesign: the synthetic biology industry is ready to change gear.* Workshop Report. https://www.cambridgeconsultants.com/synbio/building-business-biodesign

Chataway, J., J. Tait, and D. Wield. 2006. "The governance of agro- and pharmaceutical biotechnology innovation: public policy and industrial strategy". *Technology Analysis and Strategic Management,* 18(2): 1-17.

Chambers, G., A. Dreisin and M. Pragnell, 2015. *The British bioeconomy: an assessment of the impact of the bioeconomy on the UK economy.* Capital

Economics, Report to BBSRC. http://www.bbsrc.ac.uk/documents/capital-economics-british-bioeconomy-report-11-june-2015/

Christensen, C.M., M. Raynor and R. McDonald 2015. "What is Disruptive Innovation?" *Harvard Business Review,* Dec. 2015, Reprint R1512B https://hbr.org/2015/12/what-is-disruptive-innovation

Christensen, C., A. Waldeck and R. Fogg 2017. "How disruptive innovation can finally revolutionise healthcare" *Industry Horizons*, 1-28. https://www.christenseninstitute.org/wp-content/uploads/2017/06/How-Disruption-Can-Finally-Revolutionize-Healthcare.pdf

Datta, P. 2016. *Is synthetic biology a game-changing technology? Disruptive potential exceeds 3D printing and autonomous vehicles.* GEN Exclusives, July, 2016. http://www.genengnews.com/gen-exclusives/is-synthetic-biology-a-game-changing-technology/77900693

HM Government 2017. *Industrial Strategy: building a Britain fit for the future*. Nov. 2017, Cm 9528. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/662541/industrial-strategy-white-paper-print-version.pdf

HM Government 2018. *Growing the Bioeconomy: a national bioeconomy strategy to 2030.* Department for Business, Energy and Industrial Strategy, 5th Dec., 2018, p35. https://www.gov.uk/government/publications/bioeconomy-strategy-2018-to-2030

King, A.A. and B. Baatartogtokh 2015. "How useful is the theory of disruptive innovation? MIT Sloan Management Review, 57(1) https://sloanreview.mit.edu/article/how-useful-is-the-theory-of-disruptive-innovation/

Law, C. 2015. *Could CRISPR gene technology be a disruptive innovation?* 3 Dec, 2015. https://www.linkedin.com/pulse/why-crispr-cas9-gene-editing-technology-may-disruptive-robert-law

Malerba, F. Ed. 2004. *Sectoral Systems of Innovation: Concepts, Issues and Analysis of Six Major Sectors in Europe.* Cambridge: Cambridge University Press.

M. Mastroeni, J. Mittra and J. Tait 2019, in press "Political Influences on Biotechnology-based Innovation for European Agriculture: Risk-Assessment and Risk Management" *Technology Analysis and Strategic Management* (this issue, to be confirmed)

Milne, C.P. and J. Tait. 2009 "Evolution along the Government-Governance Continuum: FDA's Orphan Products and Fast Track Programs as Exemplars of 'What Works' for Innovation and Regulation". *Food and Drug Law Journal*, 64(4): 733-753.

Mittra, J., J. Tait, M. Mastroeni, M.Turner, J. Mountford, and K. Bruce. 2015 "Identifying Viable Regulatory and Innovation Pathways for Regenerative Medicine: A Case Study of Cultured Red Blood Cells", *New Biotechnology* 32(1): 180-190. http://www.sciencedirect.com/science/article/pii/S1871678414021293#

Mittra, J. 2015. *The New Health Bioeconomy: R&D Policy and Innovation for the Twenty-first Century.* Palgrave Macmillan US.

Mittra, J. and J. Tait. 2012. "Analysing Stratified Medicine Business Models and Value Systems: Innovation-Regulation Interactions". *New Biotechnology,* 29(6): 709-719.

Nuffield Council on Bioethics 2011. *Biofuels: Ethical Issues.* http://nuffieldbioethics.org/wp-content/uploads/2014/07/Biofuels_ethical_issues_FULL-REPORT_0.pdf

Omidvar, O., M. de Grijs, , D. Castle, J. Mittra, A. Rosiello, and J. Tait. 2014. *Regenerative Medicine: Business Models, Venture Capital and the Funding Gap.* Report to ESRC and InnovateUK, 30th Oct, 2014. http://www.innogen.ac.uk/downloads/RegenerativeMedicine-BusinessModels-VentureCapital-and-theFundingGap-Oct14.pdf

Rafols, I. and R. Costas. 2012. *Report on the Bibliometric Indicators of Innogen (2002-2010).* https://www.innogen.ac.uk/reports/703.

Rothaermel, F.T. 2000. "Technological Discontinuities and the Nature of Competition", *Technology Analysis and Strategic Management*, 12(2), 149-160

SBLC 2016. *Biodesign for the Bioeconomy: UK synthetic biology strategic plan, 2016.* https://connect.innovateuk.org/documents/2826135/31405930/BioDesign+for+the+Bioeconomy+2016+-+DIGITAL.pdf/0a4feff9-c359-40a2-bc93-b653c21c1586

Scannell, J., A. Bruce and J. Mittra. 2019, in press "Antibiotic Microbial Resistance" *Technology Analysis and Strategic Management* (this issue)

Sharon, T. 2016. "The Googlization of health research: from disruptive innovation to disruptive ethics". *Personalized medicine, 13(6*) https://doi.org/10.2217/pme-2016-0057.

Tait, J. and L. Levidow. 1992 "Proactive and Reactive Approaches to Risk Regulation: the Case of Biotechnology", *Futures*, *April, 1992*, 219-231.

Tait, J. 1993. Written evidence on behalf of ESRC to Report of House of Lords Select Committee on Science and Technology, *Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness*, 7th Report, Session 1992/93. London: HMSO HL Paper 80-I, pp187-196.

Tait, J., J. Chataway and D. Wield 2002. "The Life Science Industry Sector: Evolution of Agro-Biotechnology in Europe". *Science and Public Policy* 29(4): 253-258.

Tait, J. 2007. "Systemic Interactions in Life Science Innovation". *Technology Analysis and Strategic Management* 19(3): 257-277.

Tait, J. and J. Chataway 2007. The governance of corporations, technological change and risk: examining industrial perspectives in the development of genetically modified crops. *Environment and Planning C: Government and Policy, 25,* 21-37.

Tait, J. with D. Wield, J. Chataway, and A. Bruce 2007. "Health Biotechnology to 2030". Report to OECD International Futures Project, *The Bio-Economy to 2030: Designing a Policy Agenda*, OECD, Paris, pp 51. https://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40922867.pdf

Tait, J., A. Bruce, J. Mittra, J. Purves and J. Scannell. 2014. *Independent review on anti-microbial resistance regulation/innovation interactions and the development of antimicrobial drugs and diagnostics for human and animal diseases: Main Report*. 14th Dec., 2014. Report to ESRC for the O'Neill Commission on Antimicrobial Resistance http://www.innogen.ac.uk/reports/946

Tait, J. 2016. *Environmental Regulation of Advanced Innovative Biotechnologies: Anticipating future regulatory oversight.* Report to ShARE Group of Environment Agencies of the UK and Republic of Ireland. http://www.sepa.org.uk/media/219333/environmental-regulation-of-advanced-innovative-biotechnologies-anticipating-future-regulatory-oversight.pdf

Tait, J., G. Banda and A. Watkins. 2017. *Proportionate and Adaptive Governance of Innovative Technologies: a framework to guide policy and regulatory decision making.* Innogen Institute Report to the British Standards Institution. https://www.innogen.ac.uk/reports/1222

Talbot, D. 2016. *10 Breakthrough Technologies: precise gene editing in plants.* MIT Technology Review, March/April 2016. https://www.technologyreview.com/s/600765/10-breakthrough-technologies-2016-precise-gene-editing-in-plants/

US NRC 2015. *Industrialisation of Biology: a roadmap to accelerate the advanced manufacturing of chemicals.* Washington DC: National Academies Press. http://www.nap.edu/catalog/19001/industrialization-of-biology-a-roadmap-to-accelerate-the-advanced-manufacturing.

Wield, D., J. Tait, J. Chataway, J. Mittra, and M. Mastroeni. 2017. Conceptualising and practising multiple knowledge interactions in the life sciences. *Technological Forecasting and Social Change, 116, 3,* 308-315. http://dx.doi.org/10.1016/j.techfore.2016.09.025.