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From my perspective

Conceptualising and practising multiple knowledge interactions in the life sciences

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ABSTRACT

This paper presents an approach developed by the Innogen Centre for the analysis of systems of innovation. The approach, developed through the study of innovation in the life sciences, is unique in that it features a triangular view, alongside consideration of the behaviours and interactions between innovators, regulators and policymakers, and advocacy and public interest groups. Furthermore, while the approach can be characterised as co-evolutionary and system-based, it also allows for the user to shift from the macro to micro — considering the impact of institutions on actors and innovation within an institutional milieu, but also considering the individual behaviours and business plans or actions of the actors involved. This paper presents both the approach itself and how the approach was developed.

1. Introduction

This paper describes the development and use of a new methodological tool and analytical approach to the study of the life sciences that is rooted in interdisciplinarity. This, we argue, is needed to capture the complexity and interconnectedness of the sector's knowledge production and product development processes that constitute the life science innovation system. Our focus on life science sectors where regulatory and public interests play a key role builds on recent complementary work (Crespi and Quatraro, 2013; Kerr et al., 2013). The approach presented here is unique in that it features a triangular view, and equitable consideration, of the behaviours and interactions between innovators, regulators and policymakers, and advocacy and interest groups. Furthermore, while a co-evolutionary system-based view, the approach also allows for the user to shift from the macro to micro — considering the impact of institutions on actors and innovation within an institutional milieu, but also considering the individual behaviours and business plans or actions of the actors involved.

Understanding of innovation in the life sciences depends on pulling together three dimensions: first, a sense of the intradisciplinary and interdisciplinary complexity of the different disciplines that generate knowledge in the life sciences; second, an understanding of the wide range of science-industrial sectors that translate this knowledge into new products and processes; and thirdly, the social science disciplines needed to understand the social relations of these activities, and to build an integrated overview and effective decision- and policy-making for life sciences. By integrating these three dimensions, and treating the opportunities and challenges of life science innovation as inherently systemic in nature, we developed a novel set of methodological and conceptual tools. These tools better capture and understand the significant changes in the life sciences that are emerging from interactions between three key sets of actors:

- The innovators, the broad group of actors involved in the production of science, technology and product innovations. They may be located in public or private sector research settings, small and large companies, and within new networks and partnerships.
- Policy makers and regulators ranging from narrowly organised regulatory bodies for sub-parts of the innovation system, to those responsible for bridging boundaries and proposing new policy and regulatory innovations to ensure appropriate governance of the sector.
- Citizens and other users (such as patient interest groups and advocacy organizations) who provide an important public 'check', but also informed pressure on the other two sets of stakeholders, concerning for example improved food quality and new drugs for rare diseases.

It is the ability to look at the interaction between these three sets of actors, in breadth and depth, and without bias, that provides the value added to Innogen's approach.

We introduce a selection of the tools we have built, which provide a means of conceptualising and analysing the interactions among the actors with the aim of identifying gaps, weaknesses and opportunities

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to improve scientific and technological foresighting. We argue that foresight will be more accurate, and therefore have far greater and positive impact on policy, innovation and society, if it is based on a formal integrative approach such as the one we present. The methods section (Section 2) describes the evolution of our approach from the late 1980s to date. In Section 3 we provide the theoretical underpinnings of the approach. Section 4 shows how we apply the approach to the analysis of innovation in the life sciences, and in Section 5 we give a sense of how the approach works in detail with the case of regenerative medicine. We present our conclusions in Section 6.

2. Method

Our initial framework was developed over more than a decade from the late 1980s. As early as 1990, Tait suggested that misgivings would grow about the safety of new technologies in agriculture, especially those based on genetic modification (GM). She suggested that the outcome of these concerns would depend on complex interactions between industrial innovation, government policy, risk regulation and public attitudes: 'In the resulting system, perturbations in any one factor will have a major impact on the others, through a set of feedback loops' (Tait, 1990, p. 1).

Tait's concern, as expressed in evidence she gave for the UK Economic and Social Research Council (ESRC) to a UK parliamentary committee, was that industrial lobbying would destabilise existing risk regulation:

'[Industrial] lobbying activity … is also likely to diminish industry's perceived trustworthiness, and hence reinforce adverse public attitudes. The latter would then feed back, directly and through pressure to increase the level of risk regulation, to cut back on industry investment' (Tait, 1992, p. 192).

She went on to describe the results of a public attitude survey she had conducted concerning new biotechnologies, particularly genetic modification of plants and micro-organisms:

'The overall levels of concern expressed, among all groups, were high. This leads us to the tentative conclusion, a worrying one from industry's perspective, that these negative attitudes may be triggered into overt expression in behaviour by some relatively minor event'.

Tait, then, picked up these concerns, and the need for systemic integrated analysis, well before GM became a public issue and before GM products went onto the market. At the time her suggestion that concerns might arise was not taken seriously. Policy makers and regulators did not sense the growing public concerns about new agricultural technologies. Within a few years, however, the GM 'debate' had exploded and was to fundamentally change the nature of European approaches to food production. We decided to focus on analysing these issues. A range of research projects from the mid-1990s to the early 2000s focused on agricultural processes and practices (Chataway et al., 2004, 2006).

This research was consolidated by the establishment of the UK Innogen research centre (the ESRC Centre for Social and Economic Research on Innovation in Genomics — Innogen) in 2002 to study the new science and technologies emerging in the life science industries — human health, crop and animal. Our approach used and further developed the tools we had applied in the previous decade (Tait, 2007; Wield, 2008). We based the tools on a triangular framework based on the view that the major changes, and potential surprises that could destabilise innovation policy, would come from crucial systemic interactions between the three main sets of actors. Our research has shown that the interactions and collaborations of the three sets of actors with each other, and not simply their individual characteristics and actions, are important.

For example, our research with drug regulators and producers suggested that the weakening of drug industry innovation models could be reappraised as a mismatch between: the nature of new life science innovations, the nature of the companies that could best exploit these innovations, public and private expectation of new drugs and treatments, and regulatory systems that were designed around twentieth century models of drug development (Tait et al., 2008a, 2008b; Wield et al., 2013). Such a research approach involves: knowledge generation from multiple sources in a more 'open' way including from users of knowledge, such as patients with rare diseases and their organizations; the sharing and combination of ideas in an interdisciplinary way; and the contextualisation of these triadic interactions in particular situations — each with different and evolving routines.

The evolution of our approach has allowed development of a framework and empirical tools. In this paper we introduce one of these, the Strategic Analysis of Advanced Technology Innovation Systems (STRATIS) approach. The methodology provides an overarching framework that acts as a basis for interdisciplinary integration across academic disciplines, actor perspectives and across a wide range of areas of application.

3. Theoretical underpinnings

Our early research on the life sciences made it clear that simple analysis of the relationship between science and industry did not pick up the reasons why innovation was taking place in the life science sectors. Similarly, a focus on public attitudes alone, or only on regulators, did not allow rigorous analysis of the changing regulatory environment. A focus on both 'policy' and 'public' interests was necessary (Burawoy, 2005; Mastroeni et al., 2012). In order to pull together analysis of the various scientific disciplines and the complex social interactions, our approach to theory building began by working from in-depth analysis of our empirical data on complex situations. It was informed by four theoretical underpinnings: (1) specificity of the life sciences, emphasising the complex role of multi interest stakeholders; (2) how this specificity influences the sectoral nature of the life sciences; (3) its co-evolutionary approaches; and (4) its systemic characteristics.

3.1. Specificity of the life sciences

Our theoretical approach acknowledges and classifies the multi-stakeholder nature of the life science sector in order to capture its specificity and its strongly value-oriented environment.

The stakeholders include important non-market actors (such as universities, public sector research institutes, as well as patients, consumers, and health services). Even the nature of science is different. For example, Dupre (1995) argues that biological knowledge differs in its complexity and scientific disunity from sciences such as physics and chemistry. It does not appear to have the methodological unity or underlying theory to link its disparate fields. Such analyses may lead to a new unity of knowledge that is more complex and involves a wider range of actors (Wield et al., 2013). If we take the science and innovation together with the complex governance systems and public and non-market actors, we have a sector with complex knowledge interactions.

We add out triadic approach to a systems perspective to deal with complexity. Historically, the first category, 'innovator', has been treated as a firm-based activity with markets as the main testing ground for innovation success or failure. However, in the life sciences, innovation happens in a wide range of social and economic activities, many beyond that of the single firm. Life science innovation increasingly involves 'a wide range of external actors and sources to help them achieve and sustain innovation' (Laursen and Slater, 2006, p. 131). Although pharmaceutical companies are still the dominant actors in health, and agro-chemical and seed companies in agro systems, innovation in the life sciences includes a relatively higher degree of non-firm and non-market actors and interactions. Scientific labs in universities and large public research institutes are major actors, as are public health systems. There are a range of complex institutional arrangements such as public-private partnerships for rare and neglected diseases and patient-induced research networks. Our research on innovation dynamics