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Regulatory policy as innovation: Constructing rules of engagement for a technological zone of tissue engineering in the European Union

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ABSTRACT

This paper addresses the question of the part that regulation plays in processes of innovation in sectors of technology. The politico-economic phenomenon of 'Europe' is partly constituted by regulatory regime-building, and new technologies are one of the major sites of regime-building. A constructionist social theory perspective shows that study of the conflictual processes of regulatory policymaking affords insights into the formation of the rules of engagement that constitute technology domains. Adopting the concept of emergent 'technological zone' in preference to industrial 'sector' or technoscientific network, the paper presents, using empirical research, a detailed account of the case of the debate and development of regulatory policy for therapeutic tissue engineering in the European Union's policy institutions and stakeholder networks. It describes how the jurisdiction of an emergent zone has been formed through such negotiations, providing a counter-example to the common view that regulation 'lags behind' innovation. The analysis takes account particularly of the part played by the malleability of the definition of the material technology itself in such constructive governance processes, and it also suggests various consequences for the array of producers of the technology, for market structuring and for the innovation pathways taken by tissue engineering technology. Concluding, the paper argues that there is conceptual advance to be made by bringing together constructionist social theory with innovation studies approaches that highlight the part played by non-firm, public institutions in shaping innovation ecologies.

1. Introduction: innovative technology, regulation, technological zones

The political and economic phenomenon of 'Europe' can be regarded as in part constituted by regulatory policymaking work. Links between regulatory policy and scientific, technological and industrial innovation are regarded as poorly understood within the European institutions (EC, 2002, p. 24). A social theory perspective supports the insight that regulatory policymaking contributes to the defining of the boundaries of scientific and technological jurisdictions which can be supported, funded, structured, organised, standardised, contested and governed: the 'EU's governance blend. . . requires European domains to be constituted in order that they may be governed' (Delanty and Rumford, 2005, p. 146). Typically, economic and political interests are involved in the formation of such domains and are likely to be the object of conflict: 'Disputes over jurisdictional authority are high-stakes games' (Sharp, 2002, p. 373). Thus a study of the conflictual processes of negotiation of regulatory policy can afford insights into the formation of the rules of engagement for emerging technology domains.

This paper addresses the relatively neglected question of the part that regulation plays in processes of innovation in fields of technology. It aims to provide a vocabulary and conceptual analysis that begins to describe how regulatory policymaking contributes to the constitution of a new technological domain. More specifically, by examining in detail a case study of the development of regulatory policy for one potentially emerging field of therapeutic technology, the paper describes how the jurisdiction of a technological 'zone' is formed, and thus how the rules of engagement for transnational industrial R&D and healthcare technology within a variable global political economy are being negotiated.[1] The analysis takes account of the part played by the scope of the material technology itself in such processes, and it aims also to suggest various consequences for the array of producers of the technology, for market structuring and for the innovation pathways taken by the technology.

The case study is of the field of tissue engineering, which promises a range of novel medical therapies as part of the new 'regenerative medicine', some products of which are already avail-

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[1] The paper focuses on transnational, European-level developments. The part played by national political and regulatory in European negotiations is important, of course, and is mentioned in relation to some proposals for regulation based on national subsidiarity, but is otherwise beyond the scope and intentions of this paper.

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able in healthcare systems internationally. The paper begins by developing the theoretical approach to be tested in analysing the case study.

2. Theoretical approach

Technological innovation is conventionally seen as outpacing regulation—regulation usually 'lags behind' innovation. New regulatory arrangements are seen as responses to the composition and material qualities of novel technologies and practices. In more commonsensical terms, furthermore, regulation is seen as surveillance, policing, approving or disapproving, accrediting and so on. Thus regulation is not only seen as following innovation, but it is also seen as a socio-political force that is external to technological innovation and acts on it from a socio-political, non-technological realm of society. This paper develops an alternative view to these innovation-first/regulation-after, and regulation-as-external control conceptualisations. To do so the paper draws upon a variety of theoretical resources primarily from sociology and science and technology studies (STS). More specifically, in examining the co-development of a regulatory arena and novel technology, I draw upon a broadly social constructionist approach which sees regulation and regulatory policymaking as more active forces than implied by the conceptualisation of responses to technological innovation processes seen as autonomously motivating society to make organisational and political adjustments to *faits accomplis*. Thus it is argued that 'regulatory' policymaking and regime-building 'construct' as well as control emerging technology. In discussing innovation, the paper is concerned not only with development of innovative therapeutic products, but also with innovation into healthcare systems and the healthcare technology marketplace (it does not discuss technical process innovation, for example via development of safety testing regimes—cf. Abraham and Reed, 2002).

Whilst the primary raison d'être of the European Union lies in issues of political economy, the domain of public health and safety is becoming an increasingly important arena for regulatory decision-making. The BSE crisis and public controversy around genetically modified products in the late 1990s massively heightened awareness about public health risks of disease transmission. Whilst traditionally under national competence, regulation in this domain is moving beyond the nation state and has become part of a broader Europeanisation process (Vos, 1999; Abraham and Lewis, 2000; Steffen, 2005). Thus the domain of public health risk is being constituted increasingly alongside the domains of 'enterprise and industry' and 'research', for which the European Commission has separate institutions in the form of Directorates-General (DGs).

It has been stated that at the beginning of the 21st century Europe faces a general shift toward more risk averse and more stringent regulatory policies (Vogel, 2001), enshrined in policy movements such as the precautionary principle. The persistence of technocratic risk-oriented policy narratives in Europe during the 1980s and 1990s and the shattering effect of the BSE crisis, the HIV blood contamination scandal in France, and other controversies, have been noted elsewhere in this volume (Millstone, 2009). In the European Union in particular the BSE case provoked a seismic shift in thinking and theorising about modes of European governance of science that it is difficult to underestimate. However, it is likely that such a shift is not being reproduced across all sectors, and not even all health-related sectors. For example, there is strong evidence that recent trends in technical harmonisation of pharmaceutical regulatory standards are toward reduced stringency in terms of technical testing regimes (Abraham and Davis, 2007). Thus it is important to assess regulatory trends on a technology-specific and sector-specific basis. Nevertheless, the repercussions of the crises related to disease transmission have challenged technocratic approaches to risk assessment (Funtowicz et al., 2000; Levidow et al., 2007), and extend beyond issues affecting human health in the European political sphere. The political aftermath of public health crises has thus been crucial to a rapprochement of technoscientific R&D and risk regulation, and, as Millstone (2009) notes, to the adoption of a model of science policymaking that separates risk assessment from risk management, a key movement away from the integrationist technocratic and related approaches.

Innovation occurs at the limits of conventional organisational domains (Gibbons et al., 1994; Nowotny et al., 2001) challenging the taken for granted and presenting novel social, economic and health risks and opportunities. Regulatory governance of innovation exhibits, *par excellence*, societies' attempts to establish links between innovative technologies and the social and economic management of their opportunities and risks. Jurisdictional boundaries, such as define the scope of a technology (e.g. 'pharmaceuticals') or a governance domain (e.g. 'enterprise' or 'public health') are 'meant to invoke order and to demarcate boundaries' (Hogle, 2002, p. 243), but can be difficult to establish in political processes of regulatory ordering. Novel, hybrid and combinatorial technologies apparently present regulation with the need to alter the boundaries between existing institutional arrangements and devise new administrative units. But this formulation smacks of technological determinism. Regulation is innovative. Regulatory work, as is argued in this paper, should also be seen as a powerful force in the very conception and conceptualisation of innovative technology (Bud, 1999, p. 297). Here, therefore, I elaborate on the concept of the 'regulatory order' (Faulkner et al., 2004, 2006) and 'regulatory ordering' (Brown et al., 2006) to draw together strands of theory relevant to the innovativeness of regulatory policymaking. Processes of regulatory ordering, this paper will show, constructively stitch together a fluid patchwork—a web of interlinked laws, regulations, guidance, technical standards, surveillance and organising principles.

The jurisdictional fields of technology, knowledge and productiveness that regulation attempts to define can usefully be conceptualised as 'zones' (following Barry, 2001) or 'territories' (Sharp, 2002). In this paper I explore the use of the concept of 'technological zone' (Barry, 2001). The fluid patchwork of regulation interacts with the negotiation of technological zones, driven by various interests. Europe as a trade area itself is partly constituted by regulatory and standard-setting activity: '. . .technological zones are the objects of developing forms of transnational regulation' (Barry, 2001, p. 61). 'Europe' should be regarded as a site of the construction and negotiation of zones in which scientific and technological knowledge, processes and goods may circulate. Such zones themselves are partly the product of the work of regulatory policymaking and the active application of regulatory standards. Policy for technical standardisation is a *sine qua non* of the formation of technological zones (Callon, 2004).

The definition of a technological zone has some flexibility—for example, it may or may not be commensurate with a political territory. The zone of high-energy physics, for example, is located in a small number of organisations—it is at once highly dispersed geographically and highly concentrated in terms of organisations, expertise and technologies (Barry, 2001, p. 52). Zones have entry points whose definition allows participation, and boundaries which define participants from non-participants; they make association between participants possible but also create new distinctions and separations. In Barry's (2001, p. 122) terms they are 'spaces of circulation in which technologies take more or less standardised forms', and in which intellectual property implies new 'objects of technical practice'. In a subsequent elaboration of the concept, Barry (2006, p. 239) notes its applicability to emergent technologies, where technological zones 'imply particular demands on the identity of objects