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# Bioethical ambition, political opportunity and the European governance of patenting: The case of human embryonic stem cell science

Brian Salter [a,*], Charlotte Salter [b]

[a] Department of Political Economy, King's College London, Strand Campus, London WC2R 2LS, UK
[b] Norwich Medical School, University of East Anglia, UK

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ABSTRACT

Scientific progress in the life sciences is dependent on the governance of tensions between the economic potential of the innovation and the cultural response from society. Ownership of the scientific innovation through patenting is a necessary part of the realization of its economic value yet, in the case of human embryonic stem cell (hESC) science, ownership of the human body and human life may offend fundamental cultural values. In the case of transnational patenting governance by the European Patent Office (EPO) and the European Union (EU), cross-national cultural conflict in the field of hESC science has produced a political demand for a form of governance that can incorporate ethical as well as economic judgements in its decision making. This paper explores how bioethics has responded to this opportunity to establish itself as a form of expert authority for the negotiation and resolution of the cultural conflict. In so doing, it shows how the political struggle that has accompanied this bid for new governance territory has been influenced both by the political tensions between the EPO and EU systems of patenting governance and the resistance of competing experts in law and science to a bioethical presence.



## Introduction

As a means for knowledge ownership and the realisation of knowledge value, patenting is an important legal vehicle for the pursuit of market position and economic advantage. Yet at the same time, the definitions of ownership that patenting allows and facilitates for economic purposes may conflict with a society's cultural understanding of what may, and may not be owned – particularly with regard to the human body and human life. Out of this tension has arisen the political demand for a form of patenting governance capable of dealing with the negotiation of economic and cultural values. What forms of governance are capable of translating the separate languages of economics and culture into a common discourse where negotiation is possible and agreement achievable? Importantly, who controls this new governance territory and how welcome is their new found power to their competitors?

This paper uses human embryonic stem cell (hESC) science as a case study to show how bioethics has expanded its transnational governance territory by exploiting the political opportunities created by the tensions within European patenting policy.

Of itself, the demand for the 'co-production' of new forms of governance in parallel to novel forms of scientific research is a recognised feature of the political landscape (Jasanoff, 2004). What the engagement between patenting and hESC science creates is an intense focussing of the co-production process. Through its use of the human embryo, hESC research raises fundamental cultural issues about the relationship between ownership and the human body and human life: issues that collide with the economic imperative that without ownership no market can operate, or only imperfectly, and little value can be created. For European patenting governance, the question is how this cultural collision is to be negotiated and resolved, and by whom? For bioethical ambition, the question is how to provide answers that expand its governance territory.

The approach is as follows. First, the paper examines the nature of the collision between economic and cultural imperatives, the governance problem thus generated and the international contribution to that problem. Why is patenting economically important and how can we best understand its relationship to its cultural context? Second, it explores the role of the epistemic community of 'public' or 'formal' bioethics in the governance response to contentious scientific developments. Third, focussing on the European Patent Office (EPO) and the European Union's (EU's) Biotech Directive, it examines the attempt by bioethics to expand its governance territory through its contribution to the development of European patenting policy in response to the issues posed by hESC science.

* Corresponding author. Tel.: +44 2078482300.
*E-mail address:* brian.g.salter@kcl.ac.uk (B. Salter).

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## Governance problem: the economic and cultural imperatives

The political demand for a form of patenting governance that facilitates the operation of the global knowledge bioeconomy is summarised in a 2005 report from the EPO and the Organisation for Economic Cooperation and Development (OECD) *Intellectual property as an economic asset: key areas in valuation and exploitation* where it is argued that an increasing share of the market value of firms derives from their intellectual assets:

> As firms shift to more open models of innovation based on collaboration and external sourcing of knowledge, they are exploiting patents not only by incorporating protected inventions into new products, process and services, but also by licensing them to other firms or public research organisations (PROs). Moreover, they are using patents as bargaining chips in negotiations and as a means of attracting external financing from banks, venture capitalists and other sources. (EPO & OECD, 2005, p. 3)

In the science fuelled knowledge economies such as those of biomedicine, patents are units of biovalue that facilitate the operation of the market through their commodification of the intangible capital of knowledge and their consequent ability to be traded in many and various ways (Etzkowitz & Webster, 1995; Waldby, 2002). Without IPR, and in particular patent protection, emerging markets would find it difficult to develop since the tangible product has yet to appear and economic value is embedded in the potential application of the knowledge. This problem is particularly acute in high-tech and research based Small to Medium Enterprises (SMEs) for whom their IPR is their main asset.

The economic significance of patents is further enhanced by the need for new forms of knowledge to compete for attention in an increasingly global venture capital market with its own clear demands: investors, often institutional investors, make their decisions in the light of the patents held by companies (Florida & Samber, 1999; Haemmig, 2003). For capitalisation of a new knowledge market to occur, then, investors need to be reassured that the value of the knowledge, as opposed to the value of the eventual product, is in the hands of the company concerned. (Evidence of the relationship between patents and financial markets is shown in the responsiveness of stock prices to both the issuing of new patents and the number of patents owned by a company (Coriat & Orsi, 2002, p. 1501; Zeller, 2005, p. 17).) Investors are likely to be particularly sensitive to the patenting issue in high risk areas such as the early stage development of health biotechnologies where the science is very new and the potential therapies very distant. Indeed, it can be argued that the highly speculative nature of investment in the life sciences renders its aggressive patenting strategies a distinctive characteristic of the bioeconomy and, inevitably, a challenge to the robustness of patenting governance (Cooper, 2008; Waldby & Mitchell, 2006).

At the same time, the political imperative embedded in the cultural reservations society may have regarding the ownership and commodification of the human body is no less significant. It is not, as Scheper-Hughes (2001, p. 3) points out, a new issue but one 'continuous with earlier discourses on the desire, need and scarcity of human bodies and body parts for religious education, edification, healing, dissection, recreation and sports, and for medical experimentation and practice'. In response, considerable boundary work has been conducted which demonstrates the problematic and shifting relationship between the concepts of personhood, commodity and morality in this field (Hoeyer, Nexoe, Hartlev, & Koch, 2009; Wilkinson, 2003). Empirical studies, likewise, have revealed the strength and plurality of public attitudes on ownership of the human body and the consequent implications for the inclusion of the public in the formation of policies in this domain (Andreasen, 2010; Gold & Gallochat, 2001). Given this context it can be seen that, as Jasanoff observes, patents order the process of invention in ways that are 'intrinsically political' because their extension 'to new domains alters basic notions of what is a commodity and who can assert ownership over it.' In biotechnology, she notes, patents 'have the effect of removing the thing being patented from the category of nature to the category of artifice – a profound metaphysical shift' (Jasanoff, 2005, p. 204). Where the patenting object involves the human embryo either directly or indirectly, this metaphysical shift can generate considerable political emotion through its engagement with a fundamental cultural symbol of human life.

Patenting governance has traditionally dealt with cultural issues through the recognition of *ordre public* and morality concerns, usually known as morality exclusions, now incorporated into most national and international patenting law. Strongly influenced in Europe by the 1963 Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, morality exclusions ensure that a country, or other jurisdiction, will not provide protection for an invention that offends its cultural values (Moufang, 1998). For example, drawing on this tradition, Article 27 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) states:

> Members may exclude from patentability, inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law. (World Trade Organisation, 1994, Article 27, para 2)

Other permitted exclusions include 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals and plants and animals other than micro-organisms' (para 3). In applying their patenting morality exclusions, legal authorities need to know which set of values to apply, where they may be found and with what authority they are supported. Where the patenting law is specific in its exclusion this is relatively straightforward. Where the values addressed are more general, it may not be because there is then the question of who has the authority to interpret and apply the general values in practice. Accepted ways of dealing with this problem of interpretation is to draw on ethical principles and/or codes of practice that are formally embodied in professional and industrial guidance or in related bodies of law (Schatz, 1997).

However, a key governance problem is that a society's cultural values are not static. Over time these values evolve in response to national and international pressures and such changes must necessarily be incorporated into the process of patenting governance if the validity of the morality exclusions is to be maintained (Plomer, 2008). Furthermore, no two societies have the same cultural values, though there will be overlap and similarities. So where the patenting jurisdiction spans a number of states the governance problem is compounded because there is no obvious method for the authoritative identification of the value basis for morality exclusions across several states.

At a general ideological level, international pressure for the activation of these exclusions has emerged through a challenge to the assumption of the economic approach to patenting that knowledge is a private rather than a public good. Here the function of patenting is construed as the facilitation of the individual's ability to maximise the economic benefits of knowledge ownership. Against this has developed the alternative view that knowledge is a public or communal good and that the use of patenting as a market mechanism is less important than its contribution to the achievement of certain human and cultural rights (for example,