Patents and morality: governing human embryonic stem cell science in Europe

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Introduction

Innovation in biomedical science is characterized by a continuing engagement between the knowledge production process itself and the social context within which that production takes place. Although the response of society is often sympathetic because it can see the therapeutic advantages of a novel science, at times it is less so because aspects of the science may conflict with particular cultural values. It is in the interest of both science and society that such a situation is politically managed, or governed, by the state and that forms of governance are created to enable the science-culture collision to be regulated and negotiated. Once constituted, governance then places its own demands on the future development of biomedical science. As a result, to use Jasanoff's term, governance and science are 'co-produced' (Jasanoff, 2004).

It is inevitable that the co-production of science and governance has to be politically negotiated given the array of interests that surround their mutual genesis. Different groups, and in the case of transnational governance different states, may bring quite different cultural values to the policy making table. Nowhere is this more apparent than in the governance domain of intellectual property rights where the definition of knowledge ownership has the power both to facilitate or inhibit the development of a particular area of biomedical science and to challenge core cultural values. Such a power provokes intense political competition for control of this particular governance agenda, the policy formation to which it gives rise, the precise details of its legal manifestation and the implementation of the policy once agreed. Given the intensity of the commitment to the cultural positions that are engaged with the IP field, it is perfectly possible for the political competition to be continuous and cyclical rather than finite and linear.

In the case of the transnational governance of human embryonic stem cell (hESC) science patenting in Europe, the form of the competition has been strongly influenced by two dominating structural features: the separate and distinct legal structures of the European Patent Convention (EPC) and the European Union (EU), and the politics of multi-level governance (MLG) in the EU. When combined, these two features produce a political environment wherein the negotiation and resolution of cultural tensions over patenting governance are bound to be lengthy. Thus, when on 27th November 2008 the Enlarged Board of Appeal (EBoA) of the European Patent Office (EPO) ruled that the creation of human embryonic stem cells whose derivation requires the destruction of a human embryo cannot be patented, its decision brought closure to a 13 year debate over a patent application from the Wisconsin Alumni Research Foundation (WARF) for a method to derive stem cells from the undifferentiated cells of human embryos.

This paper employs the case of hESC science in Europe as a vehicle to explore the politics of innovation that have shaped the co-production of science and patenting governance. 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 patenting governance, the question is how this collision can be negotiated and resolved, not simply in terms of the legal components of patenting policy but also in terms of the way in which the policy is constructed, the authorities on which it draws for legitimacy in its consideration of the science-culture conflict, and the sustainability of the policy outcome given the range of institutional actors involved. In dealing with this question, the paper is organised as follows. Firstly, it addresses the political nature of the governance problem in patenting: what are the sources of political conflict,

in what ways do they place competing demands on the governance apparatus of patenting and what are the main points of difference? Secondly, what is the nature of the patenting governance response and, in particular, to what extent has bioethics emerged as an authoritative expert capable of dealing with the competing political demands in this policy arena?

The governance problem: patenting, culture and morality

The political demand for a form of patenting governance that facilitates the operation of the global knowledge bioeconomy is neatly summarised in a 2005 report from the EPO and the Organisation for Economic Cooperation and Development (OECD) 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 and OECD, 2005: 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 and 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 patents may be their main asset.

The economic significance of patents is further enhanced by the need for new forms of knowledge to compete for attention in a 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 and Smith, 1990; Florida and 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 and Orsi, 2002: 1501; Zeller, 2005: 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.

Although it is in the interest of science to promote the economic value of its knowledge products, a countervailing value is that scientists should have open access to the knowledge produced by their colleagues unfettered by the limits imposed by the patenting of those products. International science in particular has been less than enamoured with an economic justification of a form of patenting that in its view has the effect of either restricting the free flow of scientific information or restricting that information to those prepared to purchase the appropriate license from the patent holder. The Human Genome Programme, for example, strongly promoted the open science model and the Royal Society of Great Britain has registered its scepticism on the restrictive effects of IPR (HUGO, 1995; Royal Society, 2003).

In this context, the issuing of patents on research tools such the oncomouse granted to Harvard University (subsequently handed over to Dupont Corporation as part of an exclusive licensing arrangement) and the breast and ovarian cancer gene to the University of Utah, the National Institute of Health (NIH) and Myriad Genetics (which enjoys exclusive rights to the exploitation of all of the benefits that can be derived from diagnosing the gene) created the strong suspicion among some scientists that, as the report *Intellectual property rights and genetics* to the UK Department of Health observed, 'disproportionate and overlapping patent grants [were] gluing up the research world' as a result of an undue emphasis on commercial considerations (Cornish *et al*, 2003: 19).

In the case of biomedicine, the tension between the demands of open science and the economic imperative of knowledge ownership is often resolved through governance arrangements expressed in legislation incorporating patenting exclusions with special privileges for medical research. Diagnostic, therapeutic and surgical methods are usually excluded from patenting in order to facilitate the sharing of medical knowledge and European countries allow an academic exemption if the research is not commercial. However, less easy to deal with are the cultural reservations society may have regarding the ownership and commodification of the human body. Jasanoff suggests that 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 observes, 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: 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. It is also capable of reactivating, or redirecting, the 'culture wars' that have surrounded the scientific contribution to the creation of human life (IVF) and its termination (abortion) (McConkey, 2001; Minkenberg, 2002; Mulkay, 1997). As the recent tortuous Parliamentary debates over the UK's Human Embryology and Fertilisation Act 2008 clearly show, achieving a governance solution in the face of these cultural pressures is not straightforward.

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, paragraph 2).

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 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, 2004: 95). 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. The consequent political difficulties become part of the frequent tensions and negotiations that characterise all systems of multi-level governance (MLG) (Hooghe and Marks, 2001 and 2003; Jordan, 2001). How has patenting governance in Europe dealt with these MLG tensions in the provocative case of human embryonic stem cell science, what new forms of governance have emerged as a result and with what kind of authority have they been endowed? In particular, what has been the contribution of bioethics to the development of patenting governance?

Multi-level governance and patenting

The ability of patenting governance in Europe to construct a solution to the value conflicts surrounding the use of the human embryo in hESC science is complicated by virtue of the fact that it is composed of not one system of MLG but two quite separate ones with their own distinct legal identities and administrative systems: the European Patent Organisation (EPO) and the arrangements contained within the EU's 1998 Directive on the legal protection of biotechnological inventions (Directive 98/44/EC – commonly known as the Biotech Directive). Established in 1977 on the basis of the European Patent Convention (EPC) signed in Munich in 1973, the EPO is an intergovernmental organisation currently with 35 member states (EPO, 2009). The Directive, meanwhile, applies to the 27 member states of the European Union, all of whom are also signatories to the EPC, and acts within the legal system of the EU with the European Court of Justice (ECJ) as the final arbiter. However, although the EPO and the Directive operate through separate governance systems they are linked by the transposition in June 1999 of the provisions of the Directive into amendments to the EPC Implementing Regulations. This, as we shall see, has had a lasting impact on the way in which the 'cross-MLG' politics of European patenting governance has developed.

As the cultural questions surrounding human ESC science have increased, so the EPO has found itself subject to the implications of those questions for its governance procedures. Initially, the primary focus for the cultural pressures was Article 53 of the EPC, Exceptions to Patentability, which states that:

> European patents shall not be granted in respect of:
> (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

> (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods. (EPO, 2000)

As cases have arisen that have activated cultural opposition on the basis of 'ordre public' and morality, so the EPO has sought to refine its interpretation of these concepts on a case by case basis. Prior to the transposition of the Biotech Directive conditions into the Implementing Regulations of the EPC, the leading EPO Board of Appeal decision in this respect relates to a dispute in 1995 between Plant Genetic Systems (PGS) and Greenpeace where the Board reached the following conclusion.

> In the opinion of the Board the concept of morality is related to the belief that some behaviour is right and acceptable, where other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, inventions the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to this culture, are to be excluded from patentability as being contrary to morality. (EPO, 1995)

Although this judgement made it explicit that the inclusion of cultural norms in decisions about what knowledge can be patented and what not is a legitimate part of patenting governance, what it did not, and probably could not do was to identify precisely how this was to be achieved by the EPO. As Plomer observes, 'EPO examiners look out to a patchwork of moral perspectives in Europe, particularly reflected in the widespread differences in the [national] regulatory criteria for research on human embryos' (Plomer, 2006: 114). Given the absence of a procedure for negotiating those differences, the EPO found itself in a governance cul-de-sac.

Even prior to the hESC patenting issue, the governance limitations of the EPO had already been illuminated by two patenting applications with strong cultural overtones: the Harvard Oncomouse (transgenic-produced mice whose germ and somatic cells contained an activated onco-gene sequence introduced into the mouse at its embryonic stage) and the Myriad Genetics test for the cancer genes BRCA1 and BRCA2. Originally submitted in 1989, after 15 years of dispute centred on Articles 53(a) and 53(b) the Oncomouse case was finally resolved in 2004 (EPO, 2004a). Reflecting on the EPO's ability to deal with the ethical issues involved in the case, the UK Nuffield Council on Bioethics commented that 'the scrutiny of patent applications by reference to their being contrary to morality or "ordre public" requires expertise in areas that may not be represented in patent offices' such as moral philosophy, environmental ethics and public policy' (Nuffield Council on Bioethics, 2002: 35). However, it did not explain how such expertise might be incorporated into patenting governance procedures. In a similarly contentious case, for a decade from 1995 onwards, Myriad Genetics was involved in a dispute that severely tested the EPO's ability to handle culturally contentious patent applications (Rimmer, 2003; see also Cornish *et al*: Appendix 8).

At the same time as the MLG system of the EPO was struggling with the patenting governance implications of conflicting cultural values, the MLG system of the EU was engaged in the prolonged and arduous gestation of its own policy on intellectual property

rights. Both experiences reveal the extent of the political need for a new form of governance capable of dealing with the cultural intricacies stimulated by ownership of the human body and human life. Commencing in October 1988, the Commission's bid to harmonise Member States' legislations with regard to the patentability of inventions which make use of biological material as a measure in support of the single market took nearly 10 years to reach fruition, arriving on the statute books on 6th July 1998 as Directive 98/44/EC. During the intervening decade, the formal and informal position of ethics as a contributor to the debate surrounding the cultural dimensions of patenting governance matured considerably. Its emergence was strongly influenced by the fact that as the first international text to deal specifically with biotechnological inventions, the Directive was also the first to engage systematically the range of possible European cultural responses.

Formal recognition of the need for the policy making process to address the cultural implications of the Directive through a separate expert contribution came in 1993 with the request from the European Commission for a report from the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (set up by the Commission in November 1991) on the ethical questions arising from the proposed Directive. In producing its *Opinion on ethical questions arising from the Commission proposal for a Council Directive on legal protection for biotechnological inventions*, the Group rather optimistically observed that 'in the discussions on the Directive, ethical considerations now outweigh the purely legal and economic concerns' (Group of Advisers, 1993: para 1.4). Nonetheless, the felt political need for a separate ethics input to the highly technical governance territory of patenting marks the beginnings of a routinising of the ethics contribution to this arena of EU policy formation.

Not that its contribution resolved the tensions between Member States. Concerned about the ethical implications of the proposed Directive, the European Parliament rejected it in March 1995. No doubt in response to that debacle, the Group of Advisers was asked by the Commission to produce two further Opinions: the first, on the genetic modification of animals (Opinion 7) and, the second, on the patenting of inventions involving elements of human origin (Opinion 8) (Group of Advisers, 1996a and 1996b). In the latter, the Group took the opportunity to lobby strongly for a definition of patenting that contained an ethical dimension. The Directive, it maintained,

> must give sufficient guarantee so that refusal to grant a patent on an invention in so far as it infringes the rights of the person and the respect of human dignity should be legally founded. Consequently, the consideration of patentability criteria resulting from the usual technical requirements of novelty, inventive step and industrial application, *must also take into account consideration of these ethical principles*. (Group of Advisers, 1996b: para 2.1., emphasis added)

An immediate consequence of this redefinition was the Group's proposal that the exclusion of patents on the human body should be decided not only on the basis of the usual conditions of patentability but also on the basis of the ethical principle of non-commercialisation of the human body, a principle that was subsequently to be incorporated into the Directive (Group of Advisers, 1996b: para 2.3.).

The political rise of ethics as a legitimate part of patenting policy formation found expression in the subsequent 1998 Directive in several ways. First, the role of the European Group on Ethics in Science and New Technologies (EGE – established as successor to the Group of

Advisers in November 1997) was formally incorporated into the Directive as both recital and article. Thus Recital 19 notes that account has been take of Opinion No 8 of the Group of Advisers (*Opinion on ethical aspects of patenting inventions involving elements of human origin*) and Recital 44 and Article 7 state that the EGE 'evaluates all aspects of biotechnology….including where it is consulted on patent law' (European Parliament and Council of Ministers, 1998). Second, the importance of ordre public and morality as an integral part of patenting decisions is reiterated at several points including Recital 36 (incorporating Article 27 from TRIPS) and Recital 39 which states that

> 'ordre public' and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their relationship to living matter. Such ethical or moral principles shall supplement the standard legal examination under patent law regardless of the technical field of invention.

Ordre public and morality then form the basis for Article 6 and the consequent exclusion of:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identify of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from this process.

Finally, the Commission is required by Article 16 to produce a five yearly report 'on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which Member States have acceded'.

Inter-MLG tensions and expert rivalry

In June 1999 the transposition of the provisions of the Directive into amendments to the EPC Implementing Regulations brought together two MLG systems, the EPC and the EU, underpinned by two different sets of assumptions regarding the handling of cultural conflict. Whereas the EPO worked on the principle that patenting is essentially a legal-technical exercise within which the consideration of morality exclusions can be readily situated, the experience of the EU (Commission, Parliament and Council) in the genesis of the Biotech Directive had accustomed it to the continuing and problematic presence of ethical debate in the construction and implementation of patenting policy.

The formal linkage of the two MLGs on patenting governance through the importation of Article 6 of the Directive into Rule 23 [now Rule 28] of the Implementing Regulations was to have profound implications for two hESC related inventions, the Edinburgh case and the WARF case, that starkly illuminated the difficulties of cross-MLG governance. In early 2000 the EPO granted the University of Edinburgh Patent No. EP 0695351 entitled 'Isolation, selection and propagation of animal transgenic stem cells' (EPO, 2003). Although the patent claims were exemplified with mouse embryonic cells, the patent was challenged on the basis that its claims extended to a method of somatic cell nuclear transfer in 'animals' and that this included 'humans'. Opposition came from the governments of Italy, Germany, the Netherlands, the European Parliament and Greenpeace on the grounds that the patent was

contrary to 'ordre public' and morality according to Article 53(a) and not in compliance with Rule 23d(c) [now Rule 28(c)] of the Implementing Regulations which stipulates that the human embryo shall not be used for commercial or industrial purposes (the imported Article 6(c) from the Directive).

Equally significant was the reaction of the European Parliament, indicating that although in juridical terms the MLGs of EPO and EU were separate legal entities linked by the common acceptance of Rule 23 [now Rule 28] of the Implementing Regulations, in political terms they were now joined by the cultural conflict over hESC science. Events in one MLG would inevitably impact on the other. Thus, on 30th March 2000 the European Parliament passed a resolution stating that it was 'deeply shocked' at the granting of a patent that included techniques which allowed the genetic modification of the germ line of human embryos and which could be used for the cloning of human beings (European Parliament, 2000). It called on the EPO 'to ensure that all….patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural environment…'. Furthermore, demonstrating that it was prepared to enlarge the terms of the conflict to include the role of the EPO itself, it observed that the EPO is 'a body acting as both judge and jury whose powers and procedures must be reviewed'. As a result of the decade long gestation of the biotechnology Directive and its formal incorporation into EPO decision making, Parliament had an established interest in the way in which ethics was to be incorporated into patenting governance. For Parliament, the Edinburgh case was not a one off. Eighteen months after the Edinburgh resolution Parliament again took the EPO to task in a resolution opposing the granting of a patent to Myriad Genetics for the BRCA1 and BRCA2 breast cancer genes and again called for a review of the operations of the EPO (European Parliament, 2001). So far as the politics of the European Parliament are concerned, then, ethics and biological patenting are inextricably intertwined.

However, the subsequent rejection of the Edinburgh patent by the Opposition Division Decision of 21 July 2003 also shows the independence of the EPO procedures from EU influence (EPO, 2003). Responding to the EU's concern regarding this case, in May 2002 the EGE had published its Opinion 16 on *Ethical aspects of patenting inventions involving human stem cells* thus pursuing its mandate under the terms of the Directive to issue guidance on applicable ethical principles ((EGE, 2002). In rejecting the Edinburgh patent the Opposition Division also rejected the advice of the EGE which recommended in its Opinion that a distinction be drawn between modified isolated hESC, which it advised should not be patentable, from modified hESC which should. The Opposition Division may perhaps have been influenced, negatively, by other parts of the Opinion which argued that modern patent law has always had an ethical dimension since its inception at the end of the 18th century (EGE, 2002). Underpinning that dimension, the EGE maintains, is the negotiation of a 'social contract' between inventors and society at large where it is 'necessary to secure the right balance between the inventor's interests and the society's interests – in the sense that one task for the community is to secure ethical principles and values in the context of possible conflicting interests of stakeholders' (EGE, 2002: para 2.2). Having thus provided a general justification for the inclusion of ethical principles it is then but a small step for the EGE to recommend that ethical evaluations be included in the examination of patent applications by national patent offices and the EPO through the use of advisory panels of independent experts (EGE, 2002: para 2.10). In terms of ambition at least, ethical power has here assumed a potential bureaucratic dimension.

It is not a recommendation that resonates comfortably with the epistemic membership of the EPO's decision making machinery: primarily lawyers, patenting experts and scientists. No epistemic group likes its governance power base threatened by a rival group of experts and the sphere of patenting is no exception. In this respect it is interesting to note that, responding to the sensitivity of the patenting of biotechnological inventions, Directive 98/44 had included an Article 16c that requires the Commission to establish an Expert Group on Biotechnological Inventions with the brief to monitor 'the impact of patent law on biotechnology and genetic engineering' and provide regular reports. In its first report, the Expert Group identifies the patentability of human stem cells and of cell lines obtained from them as a particularly difficult issue (European Commission, 2002). In its second 2005 report, a difficult issue had become an intransigent one because, in the Group's view, the question of patenting was closely linked to the definition of what constitutes an embryo, and the scope of research allowed as determined by national legislation. It continued:

> In the light of the clear divergencies which currently exist between Member States as regards the acceptability of research relating to embryonic stem cells, the continuing and rapid developments in this field, and the fact that the Directive itself provides for Member States to refuse patents on grounds of ordre public or morality under Article 6(1) [of the biotechnology Directive], the Commission considers that it is premature to give further definition or provide further harmonisation in this area. At the same time the Commission will monitor developments taking into account *both the ethical aspects and the potential impact on competitiveness*. (European Commission, 2005: para 2.2, emphasis added)

However, although the governance tensions between the economic and cultural dimensions of patenting are here recognised, the ability to specify a governance solution that includes the ethical dimension is limited by the Group's composition: experts from the patent profession, patent practitioners (from the private sector, big business and a small biotech), three legal experts, two scientists and representatives from the EPO and the WIPO - but no bioethicists (European Commission, 2004: v).

One possible governance solution is that adopted by the EU's Clinical Trials Directive (CTD) 2001/20/EC for the further harmonisation of the regulatory framework for the European pharmaceutical industry that came into force in May 2003. In its Article 3(2)a-d the CTD contains provision for the introduction of ethical review in all clinical trials and in particular those that relate to human biological or genetic material: an evaluation to be carried out by an independent ethics committee; membership of the committee to include non-professionals; ethical acceptability of proposed trials to be considered on an individual basis; with the committee's decision being binding not advisory. However, there is no indication that such a governance method is readily transferable from the EU MLG system to that of the EPO.

In its absence, the WARF case posed very similar governance problems to the Edinburgh case. Originally lodged by WARF in 1995, the European Patent Application No. 96903521.1 was based on the work of James Thomson in describing how to culture primate (including human) embryonic stem cells in the laboratory for a long period of time without sacrificing their potential to differentiate and develop into any other cell type in the body. Its commercial significance was, and is, that it forms the basis for potential clinical applications and would have covered some of the most commonly used human embryonic stem-cell lines - hence the political interest in the decision. It has already been granted by the US Patent and Trademark Office. In July 2004, the Examining Division following the decision of the

Opposition division in the Edinburgh case, judged that the WARF application failed to comply with the requirements of Article 53(a) in conjunction with Rule 23d(c) [now Rule 28(c)], and referred it to the Enlarged Board of Appeal for a final decision (EPO, 2004b). On 1st June 2005, this then prompted Alain Pompidou, the then new President of the EPO, to announce a halt on human ESC patents because, as he put it, 'there are too many ethical aspects that have not been resolved at the political level' (Schubert, 2005: 720). In the event, on 25th November 2008 the EBoA upheld the decision of the Examining Board on the WARF case with the consequence that the EPO policy is that it will not award patents to applications related to embryonic-derived stem cells that require the destruction of a human embryo (Nettleton, 2009).

Conclusions

The European case demonstrates with revealing clarity the political complexities of constructing a governance response to the conflicting economic and cultural priorities generated by the question of ownership in the field of human embryonic stem cell science. The global experience is that there is an inherent tension between the individual ownership rights necessary for the operation of international markets in biotechnology and the communal values of the many cultures in which such markets operate. Which values should take precedence and why? In this context, the specific governance issue then centres on the means that could be used to negotiate the inevitable plurality of economic and cultural moralities that may shape policy on patenting. A new type of expertise and authority may be required capable of ordering, reconciling and, ideally, resolving the sensitive ownership disputes inherent in the development and application of the life sciences.

The EPO's experience of hESC science underlines the difficulty of finding a governance mechanism that effectively marries technical and ethical concerns in the absence of any legal EPO authority to determine what are, and what are not, the core 'European' values that should guide its decision making when there is no moral consensus in Europe on human embryo research (Plomer, 2006: 55). As an MLG system in its own right, the EPO does not incorporate a means for considering ethical conflict. Nor can it impose its authority. If members of the EPC disagree with an EPO decision, as in the case of hESC science many do, then they will simply develop and apply their own patenting rules within their national jurisdictions. For the MLG system of the EU the situation is different. Although the genesis of the Biotech Directive was long and ethically contentious, often fuelled by the conflicting national views channelled through the Parliament and Council, it did help to produce governance adaptations. Thus the creation of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission in 1991 and its successor body the European Group on Ethics in Science and New Technologies in 1997, their statutory incorporation as the EU's ethical experts and their formal contribution to the debate on patenting governance shows a recognition that at the European level cultural concerns have to be explicitly addressed. Not addressing them merely provides the provocation for prolonged political conflict. Yet at the same time the EPO has resisted suggestions that it should formally include bioethicists in its examining and review procedures, being content to rely on its existing definition of relevant 'experts'. Hence we find the European Parliament in 2005 obliged to reiterate its previous request that the EPO set up a body which 'checks patents that are sensitive from an ethical point of view before they are granted' (European Parliament, 2005).

The linking of the two MLG systems through the importation of Article 6 of the Directive into Rule 23d(c) [now 28(c)] of the EPC increased the exposure of the EPO to cultural sensitivities through the inclusion of a specific list of patenting exclusions relating to cloning, reproduction, the human embryo and genetic identify. Having already experienced difficulties with the Harvard Oncomouse and Myriad Genetics applications in terms of its existing morality exclusions, the EPO found the governance implications of the new exclusions difficult to deal with. As the Edinburgh and WARF cases clearly demonstrated, the cultural sensitivity of the hESC field meant that a technical decision by the EPO was likely to be construed as a political act by European governments, the European Parliament and interest groups such as Greenpeace. In the absence of a mechanism capable of addressing the ethical dimension of a patent application, the EPO discovered that purely legal arguments lacked the flexibility to deal with the political pressures surrounding hESC patents and lacked the authority to endow its decisions with lasting legitimacy.

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