Patenting, morality and human embryonic stem cell science: bioethics and cultural politics in Europe

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As the recent experience of the European Patent Office graphically demonstrates, there is an inherent political tension between the individual ownership rights necessary for the operation of an international market in human embryonic stem cell science and the communal values of the many cultures in which such markets operate. This report examines the basis of the conflict between patenting and morality at national and international levels, the manifestation of those tensions in European patenting policy, and the contribution of bioethics to the attempt by European institutions to develop a governance response.

On June 1 2005, the new President of the European Patent Office (EPO), Alain Pompidou, announced a halt on human embryonic stem cell (ESC) patents because, as he put it, "there are too many ethical aspects that have not been resolved at the political level" [1]. Nor, since then, has the EPO found the means to resolve these 'ethical aspects'. In November 2005, the EPO’s Technical Board of Appeal – to which the problem was referred – was also unable to determine to what extent inventions concerning human ESCs and their uses can be patented. Instead, the Board decided that it needed guidance from the EPO’s Enlarged Board of Appeal on the European Patent Convention’s (EPC’s) exclusion from patenting of inventions concerning ‘uses of human embryos for industrial or commercial purposes’ (Rule 23d[c]). And there the matter uneasily rests for the time being.

Behind the present impasse at the EPO lies a complex tale illustrative of the increasingly intense politics of patenting in a global knowledge economy, where the imperative of economic interest regularly collides with the priorities of cultural values. As a means for knowledge, ownership and, hence, the realization of knowledge value, patenting is an important legal vehicle for the pursuit of market position and economic advantage. Yet, at the same time, the definition of ownership that patenting allows and facilitates for economic purposes may well 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. It is out of the tension between the economic and cultural dynamics that the politics of patenting are created. For, as a consequence, patenting laws and agencies become the natural destination for the twin pressures of economic ambition and cultural concerns. They are the sites where often conflicting political demands are registered, insistent that resolution be found.

How should governments and other political authorities respond to these demands? What forms of governance are capable of translating the separate languages of economics and culture, when addressing human ESC science and its potential therapies into a common discourse, where negotiation is possible and agreement achievable? At the national level, bioethics committees have, to varying degrees and with variable powers, sought to deal with this issue by translating the arguments into the familiar précis of formal ethical discussion. However, at the transnational level, the situation is much more diffuse, with numerous political loci, where economic and cultural pressures can be brought to bear. Given the international nature of human ESC science and its potential global market, it is precisely in this more fluid environment that the political heat is developing most rapidly.

Given this context, the objective of this report is to analyze the political negotiations in the EPO and European Union (EU) arenas that have accompanied the engagement between, on the one hand, the conflicting pressures surrounding the patenting of human ESCs and, on the other, the governance response to those pressures from the range of European institutions with a direct and indirect responsibility for patenting policy formation and implementation. First, I examine the nature of the collision between economic and cultural pressures. Why is patenting economically important? How can we best understand its relationship to its cultural context?
Second, I explore the transnational governance response to the economics–culture tension and the contribution of bioethics to that response. Third, how has the relationship between pressures and response been handled in the case of the EPO and the EU? What is the position of bioethics within that relationship and how has its governance contribution changed over time?

Patenting, culture & morality
In their 2005 report, Intellectual Property as an Economic Asset: Key Areas in Valuation and Exploitation, the EPO and the Organization for Economic Cooperation and Development (OECD) argue that, in the global knowledge economy, an increasing share of the market value of firms derives from their intellectual assets. They continue [2]:

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 organizations (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."

Pursuing this economic logic, intellectual property rights (IPR) are regarded as an essential component of this kind of economy because they commodify the intangible capital of knowledge, generate value and facilitate trading. Without IPR, and in particular patent protection, emerging markets would find it difficult (or more 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, 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 light of the patents held by companies [3–5]. For capitalization of a new knowledge market to occur, investors must 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 [6,7]. 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 are very distant.

In a perfectly rational world, where economic arguments dominate, the political implication of this logic is that states will seek to adjust their patenting policies to enable more knowledge to be patented more efficiently with the intention of maximizing their capacity to compete effectively in the global knowledge economy. Patenting policy will be harnessed to the national interest. Furthermore, having made the domestic policy adjustment themselves, they will then apply international pressure for the harmonization of interstate patenting policies, along lines consonant with their national approach. While perhaps not perfectly rational, we can see that, in the important case of the USA, for example, an early adjustment was made to accommodate this logic in the field of health biotechnology. In its 1980 decision on *Diamond versus Chakrabarty* [8], the US Supreme Court ruled that a living organism (in this case a bacterium of the genus pseudomonas modified using molecular techniques) could be patented. In general, it commented, patents could be granted for "anything under the sun that is made by man" and in this respect, living organisms are not exceptional [9], a generous view of intellectual ownership. Other states have been less persuaded that the knowledge property generated by the life sciences should be so broadly interpreted. In 2002, Canada's Supreme Court rejected Harvard University's application for a patent on its Oncor-Mouse (a mouse with a cancer-promoting gene) on the grounds that higher life forms are distinctive and transcend the patenting definition of 'composition of matter' [10].

Although individual states may resist the economic logic of patenting so comprehensively embraced by the USA, the national level is not the only, nor necessarily the most critical, political site where the conflict over the appropriate definitions of ownership of the products of the life sciences takes place. Three international bodies have provided a continuing target for political pressure through their attempts to promote the international harmonization of patenting rules: the UN's World
Intellectual Property Organization (WIPO, established in 1967), the World Trade Organization’s (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the EPO (of which more later). The creation of TRIPS in 1994 by the Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade was, in large part, a response by developed countries, and in particular the USA, to the manoeuvrings of developing countries within the WIPO during the 1970s and 1980s seeking to resist international encroachments on their sovereign IPRs. TRIPS drastically limited their political space in two ways. First, it tied membership of the WTO (which most developing countries wanted and needed) to agreement on TRIPS (currently, 144 states are members of the WTO and therefore signed up to TRIPS). Second, it set detailed and mandatory harmonizing standards of intellectual property law on the ownership of two major technologies: digital technology and, importantly, biotechnology [11].

The struggle over the TRIPS agenda illustrates that even the economic logic of patenting regulation is less than neutral when political interest is included in the equation: a country’s approach to the global harmonization of patenting will be influenced by the strength or weakness of its competitive position in the international economy. For example, at the insistence of India, Argentina, Brazil and Turkey, all of whom sought to protect their own industries, TRIPS contains a 10-year delay for the institution of pharmaceutical and agricultural chemical patent protection in developing countries. At the same time, international science was becoming less enamored 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. It should be remembered that the TRIPS agreement was signed at a time in the mid-1990s when the Human Genome Project was strongly promoting the open science model [12.101]. In this context, the issuing of patents on research tools, such as the OncorMouse 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 US 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 that “disproportionate and crippling patent grants [were] gutting research work” [113]. In their report, In. Property Rights and Genetics to the UK Ministry of Health, the authors expressed that, as a result of the US-style of approach-patenting in the knowledge market of health technologies [13]:

“The cost of care will increase; that patients will be deprived of access to new techniques and drugs; that research and testing tools will be withheld; that researchers and carers will not share information; that research will become too complicated to enter upon (perhaps because of the so-called ‘anti-commons effect’ if there being too many right holders); and equally there could be premature commercialization in the race to get ahead.”

Here, we can see that the debate regarding the relationship between patents and economic advance is emphasizing important factors other than those that contribute to the efficiency of the patents–innovation linkage. Perhaps unsurprisingly, the political agenda of patenting harmonization is broadening as the pure economic arguments (contented though they may be) are supplemented by cross-cutting discourses regarding rights (e.g., who should have access to the new health technologies) and, as we shall see, ethics (what is the moral basis of patenting?). The future global politics of this field were to be greatly influenced by the extent to which these broader, cultural factors were able to penetrate the key decision and policy-making arenas.

Within the TRIPS agreement, the recognition that noneconomic factors may have a proper role to play in patenting policy finds expression in its Article 27, where the Agreement states (paragraph 2) [114]:

‘Members may exclude from patentability, inventions, the prevention within their territory of the commercial exploitation of which it is necessary to protect order 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.’

Other permitted exclusions include ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals and plants and
animals other than micro-organisms' (paragraph 3). For these exclusions to have international political impact there would need to be sustained pressure for their activation.

That pressure has emerged in large part through a challenge to the assumption behind the economic approach to patenting that knowledge is a private rather than a public good. In this context, the function of patenting is to facilitate the ability of the individual to maximize 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 (e.g., health, human dignity and cultural identity) (15,16). For the supporters of TRIPS and the US style of patenting (bearing in mind that US patent law has no morality clause), it has been important to limit the strength of this challenge by trying to keep human rights and its associated ethical arguments contained in a separate policy silo. To bring the two policy streams together at the international level, it was believed, would undermine the principles of the global knowledge economy that TRIPS was set up to protect by rendering the application of those principles relative to other, ethical priorities. However, the HIV/AIDS epidemic, and the imperative for developing countries to ensure their population’s right of access to medicines by resisting the anticipated rise in drug prices that it was believed would accompany the implementation of TRIPS, forced a reappraisal of this separatist approach (17). Nor is it simply an issue for developing countries. Citizens in developed countries are likely to be equally energized if they see patenting laws as depriving them of what they consider to be their healthcare rights.

In addition, the Universal Declaration on the Human Genome and Human Rights, in 1997, by the International Bioethics Committee (IBC) of the UN Educational and Cultural Organization, initiated a global debate regarding the moral status of the human body and human life and their relationship to the market that is still gathering political speed in both bioethical and policy-making circles worldwide (102). At the conclusion of its 8th Session on September 14, 2001, the IBC adopted by consensus an Advice on the Patentability of the Human Genome, which states that 'there are strong ethical grounds for excluding the human genome from patentability' and further recommends (103):

that the WTO, in its review of the TRIPS Agreement, clarify that, in accordance with the provision of Article 27(3)1 (the morality clause), the human genome is not patentable on the basis of the public interest considerations set out therein, in particular, 'ordre public, morality and the protection of human life and health'.

Ethical discussions regarding the status of DNA, the human embryo, human dignity and the commercialization of the human body — often subsequently enshrined in national legislation and, in the case of the Council of Europe’s Convention on Human Rights and Biomedicine, in a protective international agreement — now form an internationally salient discourse with which patenting policy and practice is obliged to engage.

Given this context, the governance problem can be seen as one centered on the construction of procedures that would enable productive engagement between the plurality of moralities accompanying the economic and cultural arguments surrounding patenting at the international and national levels. In her study of the problematic treatment of biotechnology in the UK, USA and Germany, Jauernig notes the dawning recognition in all three political systems that some of the risks and promises engendered by the multifaceted advances in genetics and biotechnology (particularly those associated with fears of 'playing God') (9):

'called for a new language of deliberation, geared to the analysis of human values rather than the benefits of the market, the facts of science, or the norms of law. The language that actors seized on for this purpose was a branch of moral philosophy, specifically, bioethics.

Combining life (bios) and moral concern (ethos) in a single portmanteau word, bioethics offered the promise of bringing order and principle to domains previously governed by irrational, emotive and unanalysed reactions.'

What we have here is the identification of the political need for a new form of expert, the bioethicist, able to deal with the novel governance problems posed by biotechnology.

Studies on the role of expertise in policy making, particularly in the fluid political environment of the EU, have shown how knowledge can
shape policy formation [18]. The EU’s decision-making system relies extensively on a plethora of working groups, standardization bodies and committees that draw on the knowledge of experts [18]. However, these ‘technocrats’, as they have become known, have their political limitations. Radaelli observes that ‘the technocrat believes that rational analysis and scientific examination of the facts will bring about unanimous consensus on policy solutions’ [19]. But this confidence assumes a high degree of certainty in the knowledge situation. ‘By contrast’, Radaelli continues, ‘the technocrat feels uneasy under conditions of political conflict, ideological debates, and controversies on the distributive issues of justice’, which are precisely the conditions of uncertainty prevailing in the interaction between biotechnology and its cultural locale.

So, is the bioethicist a new kind of expert, one able to deal with ethical uncertainty and offer advice but not an expert who is yet a fully fledged technocrat in the sense of being routinely integrated into the machinery of the EU’s transnational government?

Cultural politics of stem cell patenting in Europe
In Europe, the transnational governance challenge created by the clash between, on the one hand, the private ownership requirements of an unrestricted global knowledge economy of human ESC science and, on the other, the communal values of local cultures, has been manifested through the continuing political negotiations surrounding the two international agreements for the regulation of patenting in this field: the Council of Europe’s 1973 EPC and the EU’s 1998 Directive on the legal protection of biotechnological inventions [21]. The relationship between the two is an interesting compound of legal and political elements.

Neither the EPC nor its administrative arm, the EPO, are EU institutions, but have a quite separate legal identity. However, all EU Member States have ratified the EPC (as have several non-EU states, notably Switzerland). In addition, in 1999, the EPO stated that it would use the Directive as a supplement to interpretation of the EPC and included it in its Implementing Regulations [22]. In any case, regardless of the legal niceties, the institutions of the EU, particularly the European Parliament, have always treated the EPO as the inhabitants of a common political territory. If a political point needs to be made and pushed on patenting, the Parliament has never been inhibited by the technical limits of its jurisdiction.

As the cultural questions surrounding human ESC science have increased, so has the EPO become a target for these pressures and has found it difficult to maintain its direction as an impartial regulatory body concerned with purely technical patenting issues. As with the TRIPS agreement, the EPC contains a clause designed to allow the expression of arguments regarding values within the patenting decision-making process. Article 53(a) states that European patents shall not be granted in respect of [104]:

‘Inventions the publication or exploitation of which would be contrary to ordre public or morality, provided that the 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.’

Specifically excluded by Article 53(b) are ‘plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof’ [104]. As cases have arisen that have activated opposition on the basis of ‘ordre public’, so the EPO has attempted to refine its interpretation of this concept on a case-by-case basis. 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 [23]:

‘In the opinion of the Board the concept of morality is related to the belief that same 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.’

Unsurprisingly, perhaps, the explicit inclusion of cultural norms as a legitimate part of decisions regarding what knowledge can be patented and what not, opened the way for a further political debate regarding how you decide what cultural norms are relevant and what not: essentially ethical questions. By this action, the EPO enlarged its governance role in an area with which it was ill-equipped to deal.
Prior to the arrival of the human ESC patenting issue, the governance limitations of the EPO were starkly revealed by two patenting applications with strong cultural overtones: the Harvard OnceMouse and Myriad Genetics and its genetic test for the cancer genes BRCA1 and BRCA2. After 7 years of dispute centered around Articles 53(a) and 53(b), Harvard University was granted a patent for its transgenic mouse in 1992. However, there was no commitment to the patenting of transgenic animals in general, but rather the creation of a precedent for the case-by-case review of the ethical issues surrounding animal patenting [9]. Reflecting on the EPO's ability to deal with the ethical issues involved in the case, the Nuffield Council on Bioethics noted 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' [14]. For a decade from 1995 onwards, Myriad Genetics was involved in a similarly contentious dispute that severely tested the EPO's procedures [13,23].

Paralleling the politicization of patenting at the EPO was the long and arduous gestation of the directive on the legal protection of biotechnological inventions. Both experiences reveal the extent of the political need for a new form of governance capable of dealing with the cultural intricacies stimulated by any attempt at ownership of the human body and human life. Commencing in October 1988, the Commission's bid to harmonize Member States' legislations with regard to the patentability of inventions that 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 8th July 1998 as Directive 98/44/EC. During the intervening decade, the formal and informal position of ethics in the debate surrounding patenting policy matured considerably. 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 to address the ethical content of the debate through a separate governance initiative came in 1993 with the request from the 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, the Group observed that 'in the discussions on the Directive, ethical considerations now outweigh the purely legal and economic concerns' [10]. Within the governance machinery of the EU, ethics had taken its first small step to becoming institutionalised. Its effect was to begin a slow process of routinizing the inclusion of a new form of expertise in the process of EU policy formation. Perhaps unsurprisingly, in this early Opinion of the Group, there is a degree of self-consciousness regarding the significance of the shift that is taking place as it points out that the concept of 'human dignity' appears for the first time in Community law in the Directive drafts, observing that this 'is an indication of the concern aroused by certain developments in the fields of human genetics and medicine' [10].

That concern was such that the European Parliament rejected the proposal 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 modifications of animals and, the second, on the patenting of inventions involving elements of human origin [106,107]. In the latter, the Group effectively redefined the concept of patenting, insisting that it must contain an ethical dimension. The Directive, it maintained [107]:

"Must give sufficient guarantees 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 the ethical principles."

An immediate consequence of this redefinition was the exclusion of patents on the human body on the basis of not only the usual conditions of patentability but also the ethical principle of noncommercialization of the human body [107].

The political rise of ethics as a legitimate part of the policy discourse regarding patenting found expression in the subsequent 1998 Directive in several ways. First, the role of the European Group on Ethics (EGE) in Science and New Technologies (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 taken of Opinion No. 8
of the Group of Advisers and Recital 44 and Article 7 state that the EGE 'evaluates all aspects of biotechnology ... including where it is consulted on patent law' [21]. 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 (the significance of 'ordre public' and morality as defined by Member States). 'Ordre public' and morality then form the basis for Article 6 and the consequent exclusion of:

- Processes for cloning human beings
- Processes for modifying the germ-line genetic identity of human beings
- Uses of human embryos for industrial or commercial purposes
- Processes for modifying the genetic identity of animals that 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 report every 5 years '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'.

The agreement on the biotechnology Directive and its incorporation into the Implementing Regulations of the EPO not only consolidated the general position of ethics as a factor in European patenting decisions but also provided specific guidance on the treatment of patent applications involving the human body, gene sequences, cloning, human embryos and genetic modification. It is therefore no coincidence that, 5 months later, the University of Edinburgh ran into a considerable political storm when Patent No. EP 0695351 entitled 'Isolation, selection and propagation of animal transgenic stem cells' was granted to it by the EPO. 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'. Unusually, 14 different opponents registered their objection to the patent on the grounds of ordre public (Article 53a of the EPC), including the governments of The Netherlands and Italy. Demonstrations by Greenpeace, coupled with national and international press coverage, rapidly politicized this part of the stem cell field.

Equally significant was the reaction of the European Parliament. On 30th March 2000, it passed a resolution stating that it was 'deeply shocked' at the granting of a patent that included techniques that allowed the genetic modification of the germ line of human embryos and that could be used for the cloning of human beings [108]. It called on the EPO 'to ensure that all ... patent applications in Europe do not violate the principle of nonpatentability 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'.

Parliament's response to the EPO's decision is not unexpected when seen in the context of its ethically based policy narratives on biotechnology, particularly with regard to the human embryo. For example, in 1993, 1997 and 1998, Parliament had passed resolutions opposing cloning of the human embryo, supporting the Convention on Human Rights and Biomedicine and calling on Member States to introduce a legally binding ban on the cloning of human beings [25-27]. Another Parliamentary measure, Directive 98/79/EC, on in vitro diagnostic medical devices, makes it clear that 'the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine' [108]. In addition, the decade-long gestation of the biotechnology Directive and its formal incorporation into EPO decision making had ensured a continuing Parliamentary interest in the particular ethics of the patenting of the human body. The Edinburgh case was not a one off. A total of 18 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 [108]. So far as the politics of the European Parliament are concerned, ethics and biological patenting are inextricably intertwined. Moreover, in the case of human ESC science, the power of the relationship is multiplied where the ethics of ownership combine with the ethics of the human embryo to produce a potent political brew.
Although the reality of cultural conflict between the values of the Member States had, with the able assistance of the European Parliament, ensured the engagement between ethics and patenting in practice, a further political step was required by an authoritative body to explain and formally legitimize the link between ethics and patenting in principle. In May 2002, the EGE, the body charged by the biotechnology Directive to evaluate ‘all ethical aspects of biotechnology’, published its Ethical Aspects of Patenting Inventions Involving Human Stem Cells, where it argues that modern patent law has always had an ethical dimension since its inception at the end of the 18th century [23]. 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’ (including patients associations and industry but not, interestingly, religion) [24]. 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 [23]. In terms of ambition at least, ethical power has here assumed a bureaucratic dimension.

However, others were less convinced that bioethics, and bioethicists as an expert group, should form an integral part of the governance arrangements of the patenting field. Given the sensitivity of the patenting of biotechnological inventions, Directive 98/44 had included an Article 16(c), which 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 [118]. 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 [111]:

‘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 order public or morality under Article 8(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’.

Yet, its capacity to extend its governance function to include the ethical dimension is limited by its 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 [112].

The formal linkage between the EU’s biotechnology Directive and the EPC’s Implementing Regulations ensures that they share governance concerns (whether they like it or not) when interpreting the relationship between patenting and ethics. Returning now to the Edinburgh case, it is therefore apparent that decisions regarding the patentability of human ESCs and ESC lines were bound to be influenced by the ethical discussions taking place elsewhere in the Commission, Parliament and the EGE. Politically speaking, this is a highly permeable as well as highly charged field. Thus, when the EPO Opposition Division ruled on the University of Edinburgh patent application in July 2002, it asserted that any claims involving human ESCs violated the European Patent Convention’s rule 23(d)(c), which excludes uses of human embryos for industrial and commercial purposes from patentability [113]. The knock-on effect was immediate, with patent examiners using the decision as a precedent to reject an application concerning James Thomson’s technique for deriving primate ESCs from the Wisconsin Alumni Research Foundation [29]. Other applications from the California Institute of Technology on a method to isolate neural stem cells from embryonic tissue and from the University of Bonn on a method to differentiate neural cells from mammalian ESCs also remain unresolved. As a result of appeals from the University of
Edinburgh, the decision on the principle of human ESC patenting now rests with the EPO's final authority, the Enlarged Board of Appeal, a process that may take several years. As a consequence, the future value of human ESC science remains an unknown and the potential market in which biotechs and venture capitalists might invest, an unreality.

Conclusion
The European case demonstrates with revealing clarity the political complexities of constructing, knowingly or otherwise, a governance response to the conflicting economic and cultural priorities generated by the question of ownership in the field of human ESC 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 centers 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 is required capable of ordering, reconciling and, ideally, resolving the sensitive ownership disputes inherent in the development and application of the life sciences.

The convenient emergence of bioethics as a claimant for this new governance territory seemed to promise a way forward. Although the national philosophical traditions and origins of bioethics may vary, there is a common utilitarian emphasis on the identification of ethical procedures that may be used to address conflicting moral positions. Furthermore, as a transnational network, the ascent of bioethics has been marked by the emergence of a global infrastructure: high-profile ethical statements launched from the platform of established international bodies, an awareness of the need to translate these statements into legal/bureaucratic form and the proliferation of horizontal and vertical networks linking international and national levels of ethical governance [102].

However, the European experience of patenting policy in the field of human ESC science shows that the political advancement of bioethics is dependent on the extent to which it can consolidate its bureaucratic power and institutionalize its influence. Advances have undoubtedly been made. Recognition of the need for a routinization of the ethical conflict over the patenting of biotechnological inventions in general, and human ESCs and cell lines in particular, became unavoidable with the decade-long debate over Directive 98/44/EC and the long-running disputes resulting from the activation of the EPC’s public order Article 53(a) and its Rule 32d(c) on the 'uses of human embryos for industrial or commercial purposes'. The creation of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission in 1991 and its successor body, the EGE 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 shows the initiation of a bioethical bureaucratic presence.

Yet, at the same time, the EPO has resisted suggestions that it should formally include bioethicists in its examination and review procedures.

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<tr>
<th>Executive summary</th>
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<td>The ownership of the processes and products of human embryonic stem cell science is both economically necessary and culturally contentious.</td>
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<td>As a result, there are continuing political negotiations at national and international levels over the definition and scope of patenting law and the status of moral values within it.</td>
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<td>In this politically charged context, bioethics has emerged as both a vehicle for the expression of cultural concerns and, to an extent, a novel form of governance for the resolution of conflict.</td>
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<td>At the European level, the close relationship between the European Patent Office’s procedures and the EU Directive 98/44/EC on the legal protection of biotechnological inventions has generated a complex set of political tensions within the European Patent Office’s human embryonic stem cell science patenting policy.</td>
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<td>The rise of bioethics in the politics of European patenting is based on its ability to formulate a governance response to these tensions.</td>
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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 that 'checks patents that are sensitive from an ethical point of view before they are granted' [11]. As a form of governance without government in the arena of European patenting policy, therefore, bioethics can best be described as a horizontal network, exercising a form of steerable through rule setting, and drawing for its authority on the claim that it is using an 'objective' set of procedures in reviewing ethical arguments. If, in the future, the bioethics network can achieve a bureaucratic presence in the EPO's decision-making process as well as that of the EU, then its legitimacy, and its power, will be considerably enhanced. It will, of course, encounter opposition from the resident technocrats of the EPO; however, their inability to resolve the present stalemate and uncertainty over the patenting of human ESCs and cell lines renders them politically exposed to pressures from scientists, industry and venture capitalists.

Bibliography


Websites

http://ec.europa.eu/european_group_ethics/docs/opinion3_en.pdf

http://ec.europa.eu/european_group_ethics/docs/opinion7_en.pdf

http://ec.europa.eu/european_group_ethics/docs/opinion8_en.pdf


