Human Embryonic Stem Cells and Patent Law in the EU and China: - Convergence in Standards through Divergence in Institutions

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Abstract

While socio-cultural and historical differences in the EU Member States and China have resulted in two distinct regimes for human embryonic stem cell research, with the EU considered somewhat conservative and China significantly liberal in approach, the laws governing patenting of innovations derived from stem cell research in both legal regimes appear to be remarkably similar. How is it that two divergent systems have nevertheless converged on a restrictive approach to patenting in this field of research? This article will demonstrate the way in which different institutional pressures and objectives have resulted in similar practices: - while deliberative decision-making within the context of representative liberal democracy resulted in the EU placing morality-based limitations on economically-driven hESC patenting, China's elite-driven processes within the context of 'authoritarian deliberation' instead adopted morality-based limitations both as an indicator of demonstrating standards of best practice as a means of encouraging research and investment, and as the result of institutional learning. Therefore, despite different institutional designs and policy-making approaches, the EU and China have converged on remarkably similar hESC patent regimes.

Keywords: - patents, stem-cells, China, EU, institutions, biotechnology, bioethics

Introduction

Human embryonic stem cell (hereafter hESC) research is considered as having the potential to revolutionise medical science. However, hESC-related research is often an area of contestation, due to the potential destruction of the human embryo as a result. The EU

and China are regions with distinct religious, historical and social perspectives that directly impact upon official views of the status of the embryo and the acceptability of research involving human embryos. Nevertheless, it would appear that despite these significant differences, the patenting regimes for inventions resulting from hESC-related research have converged, rather than diverging as may be expected. The purpose of this article is to explore this phenomenon further, demonstrating how a combination of divergent socio-cultural factors and institutional pressures has actually resulted in two patent systems that share similar traits when considering the patenting of biotechnological inventions. The paper will begin with an overview of stem cell research in the EU and China, identifying key socio-cultural concepts that have contributed to the establishment of the position of the embryo in each system, and the resultant frameworks for hESC research, before entering into a comparison of the patent regimes for biotechnological inventions in the EU and China. This comparison will demonstrate that despite being separately achieved in time and space, the principles for the patenting of hESC-derived inventions are very similar, despite significant differences regarding the 'moral status' of an embryo in each jurisdiction. Finally, the paper will consider how the similarities found in the two systems can be understood in terms of 'institutional path-dependence', in which decisions being made through very different processes with different underlying 'logics of appropriateness' nevertheless arrived at similar results. Whereas in the EU, the system of patenting of hESC-related innovations has been the result of interest group advocacy within a framework of representative and participatory democracy, the results in China have instead been achieved through expert-governance by the identification of best practices through a process of 'authoritarian deliberation'. In order to provide legitimacy to biomedical research conducted in China, as well as to encourage both investment and repatriation of biomedical experts, China has sought to demonstrate compliance with 'Western' standards of best practice in its biotechnology patenting regime.

Stem cell research in the EU and China

In order to more effectively discuss the patentability of hESC-related research in the EU and China, this section of the article will provide a brief definition of this form of stem cell research and an overview of these forms of research in the two regions. It must be stated at the outset that it would not be correct to refer to one general approach to stem cell

research in the EU (as opposed to the harmonising legislation laying down the requirements for the patenting of biotechnological inventions), as no harmonised regime exists, and to describe a 'European' approach would neither be nuanced nor correct. After discussing the regimes, this section will then seek to explain divergences in approach between the regions based on differing constructions of the moral status of the human embryo, in order to apply this understanding to the patentability requirements for biotechnological inventions.

Human embryonic stem cells are cells that are pluripotent, which means they have the potential to develop into different types of specialised cell or tissue[1]. These cells are seen as particularly useful in medical research, due to their abilities of self-renewal and to develop into any type of cell found in the human body[2]. Salter argues that 'it is the promise of the scientists engaged in the HESC field that their work will lead to therapies capable of dealing with one of the major problems of modern medicine: irreversible organ and tissue failure'[3]. Stem cells are therefore seen as having the potential to revolutionise the field of 'regenerative' medicine, allowing for damaged organs to be regrown or repaired, rather than individuals waiting for kidney transplants or undergoing complicated, time-consuming and unpleasant dialysis treatments, for example. Similarly, stem cells have been indicated as a potential treatment for degenerative neurological conditions such as Alzheimer's or Parkinson's disease. For this reason, hESC-related research is perceived as being of considerable scientific and economic importance[4]. Yet despite this, research involving the use of hESCs is seen as politically controversial, particularly as in the process of manipulation and extraction of hESCs the embryo itself is destroyed. One branch of this controversy relates to the issue of human cloning, which, while interesting, thought provoking and worthy of debate, is ultimately outside the remit of this paper[5]. The other branch relates to the *moral status* of the embryo that is used in this research. According to Neal (née Ford), embryos exist as liminal entities, at the boundary between the categories

[1] Rosario M Isasi and others, 'Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa' (2004) 32 The Journal of Law, Medicine & Ethics 626, 628.
[2] Ibid
[3] Brian Salter, 'The Global Politics of Human Embryonic Stem Cell Science' (2007) 13 Global Governance 277, 279.
[4] Ibid
[5] However, for more on these issues, see Isasi and others (n 1) 626–640; Marie Fox, 'Legislating Interspecies Embryos' in Stephen W Smith and Ronan Deazley (eds), *The Legal, Medical and Cultural Regulation of the Body* (Ashgate 2009) 95–99.

of human and not human (or, rather lacking in identifiable human qualities) – entities capable of life, but not yet recognisable as such[6]. This complex and contentious position has meant that different regions and countries have regulated the use of hESCs in medical research differently. While it would be incorrect to state that the Member States of the EU have taken a common position on their use, it can be stated that the majority of EU Member States regulate the use of hESCs conservatively, with the exception of the UK, Sweden and Belgium, which have taken more liberal approaches[7]. The UK, for example, specifically allows for the creation of embryos specifically for research purposes, and is the only country in the EU to do so[8]. The Netherlands, in comparison, does not allow for the creation of embryos for research purposes, but 'leftover' embryos from fertility treatments may be used for research[9]. Germany and France, at the opposite end of the spectrum, take very strict and conservative approaches to the use of hESCs in medical research, and Germany in particular prohibits all instrumental uses of the embryo and forbids the creation of embryos for research[10]. China, particularly in light of approaches in Europe, is considered to have one of the most liberal and permissive regimes for stem cell research in the world[11]. China permits research on human embryos for a maximum period of 14 days, and allows for the sourcing of embryos from, for example, 'leftover' embryos after IVF treatment, the use of foetal cells subsequent to the performance of an abortion, and germ cells voluntarily donated[12]. Why then, given the potential uses for hESCs, is the permissibility of their use so varied in different states?

The moral status of the human embryo, and by extension, stem cell research using this biological material, is socially constructed. Social constructivism is a theoretical framework that maintains that 'people do one thing and not another due to the presence of

[6] Mary Ford, 'Nothing and Not-Nothing: Law's Ambivalent Response to Transformation and Transgression at the Beginning of Life' in Stephen W Smith and Ronan Deazley (eds), *The Legal, Medical and Cultural Regulation of the Body* (Ashgate 2009) 21–22.
[7] Mette N Svendsen and Lene Koch, 'Unpacking the "Spare Embryo" Facilitating Stem Cell Research in a Moral Landscape' (2008) 38 Social Studies of Science 93, 93.
[8] Samantha Halliday, 'A Comparative Approach To The Regulation Of Human Embryonic Stem Cell Research In Europe' (2004) 12 Medical Law Review 40, 44.
[9] ibid 55; On the topic of 'waste' or 'leftover' embryos, see Charis Cussins, 'Ontological Choreography: Agency through Objectification in Infertility Clinics' (1996) 26 Social Studies of Science 575, 575–610.
[10] Halliday (n 8) 57.
[11] Isasi and others (n 1) 633; Aaron D Levine, 'Science Policy and the Geographic Preferences of Stem Cell Scientists: Understanding the Appeal of China and Singapore' (2010) 29 New Genetics and Society 187, 192; Kerstin Klein, 'Illiberal Biopolitics and "Embryonic Life": The Governance of Human Embryonic Stem Cell Research in China' in Jon Yorke (ed), *The Right to Life and the Value of Life* (Ashgate 2010) 400.
[12] Isasi and others (n 1) 634.

certain 'social constructs': ideas, beliefs, norms, identities or some other interpretive filter through which people perceive the world'[13]. Through better understanding these norms, ideas or beliefs through which decision-making occurs, we are better able to understand how or why institutional actors take the particular policy decisions they do. As Hay argues, change occurs within institutions 'in the context which is structured (not least by institutions and ideas about institutions) in constantly changing ways which facilitate certain forms of intervention whilst militating against others'[14]. Hay states that taking a constructivist institutional perspective allows us to see how 'ideas' inform the development of institutions and their approaches to issues, including their political and normative constraints[15]. In other words, the dominant ideas and beliefs within a social and/or cultural area will have an impact on what is and is not possible within that area's political and legal institutions, in what is known as 'institutional path-dependency'[16]. Salter and Salter state that 'no two societies have the same cultural values, though there will be overlap and similarities'[17]. 'Morality', a concept that can be categorised as a normative construct, is an example of an idea that can have an impact on institutional structures and the policy decisions of institutional actors, be they governmental executives or the judiciary.

Medical research, and indeed, discussions concerning morality and ethics in medical research in the EU take place within the context of Western liberal democracy[18]. Within this framework, 'the freedom of individuals is regarded as a critical yardstick for governmental action'[19]. With this in mind, Blackford argues that in liberal democracies, individual behaviour should only be restrained when that behaviour results in direct harm to another[20]. In the EU, the status of the human embryo has been influenced by both religious and secular beliefs, and the exchange of views that has fed into the policy and

[13] Craig Parsons, 'Constructivism and Interpretive Theory' in David Marsh and Gerry Stoker (eds), *Theory and Methods in Political Science* (3rd edition edition, Palgrave Macmillan 2010) 80.
[14] Colin Hay, 'Constructivist Institutionalism' in RAW Rhodes, Sarah A Binder and Bert A Rockman (eds), *The Oxford Handbook of Political Institutions* (OUP Oxford 2006) 65.
[15] Ibid
[16] Ibid
[17] Brian Salter and Charlotte Salter, 'Bioethical Ambition, Political Opportunity and the European Governance of Patenting: The Case of Human Embryonic Stem Cell Science' (2013) 98 Social Science & Medicine 286, 287.
[18] Benjamin Farrand, 'Conceptualising Conscientious Objection as Resistance' [2014] Journal of Medical Law and Ethics 69, 75.
[19] Thomas Lemke, *Foucault, Governmentality, and Critique* (Paradigm 2011) 15.
[20] See Russell Blackford, *Humanity Enhanced: Genetic Choice and the Challenge for Liberal Democracies* (MIT Press 2014) 15–30 in particular for the application of the harm principle to genetic enhancement.

legal processes. Religious arguments based in Christian values, but particularly Roman Catholic doctrine, see life as beginning with conception. A human embryo, according to the Vatican, is considered human life, and that the 'fact that the process of *in vitro* fertilization very frequently involves the deliberate destruction of embryos […we must reiterate] the sacred and inviolable character of every human life from its conception until its natural end'[21]. Indeed, secular views in Europe also focus on the inviolability of the embryo as a form of human life, associated with conceptions of dignity[22]. Authors in this vein point towards the atrocities of the Second World War as a turning point in the way that human life is considered in Europe, with the concept of humanity imbuing the individual with an innate sense of dignity worthy of respect, and from which rights derive their source[23]. In his powerful work *The Future of Human Nature*, Habermas argues that the increased usage of the human embryo for scientific research 'instrumentalises' life, and constitutes an affront to dignity; there is a potential risk that 'with research involving the destruction of human embryos, a practice will come to prevail for which the protection of human life is secondary to "other ends", even if these other ends consisted in nothing more than the prospect of developing high ranking collective goods'[24]. In other words, arguments against hESC research centred on dignity are concerned that 'life' may increasingly be regarded as just another means to an end, rather than having its own intrinsic value. Another concern is with the *commodification* of the individual, in addition to an instrumentalisation of the individual, in which the human becomes a business asset, and life's 'value' takes on an economic nature[25]. Yet arguments also exist in favour of hESC research in Europe – for example, the above mentioned statements concerning the potential value of this research for the treatment of those currently suffering from serious and degenerative conditions. A counter argument was made by embryo researcher Johnson, who sought to free researchers from the 'tyranny of the embryo', allowing for useful medical research to be possible[26]. Others such as Savulescu have argued that if we ascribe these characteristics to the human embryo because of its potential to develop into a reasoning, thinking and feeling

[21] Lavada WC, Congregation of the Doctrine of the Faith, 'Instruction *Dignitas Personae* on Certain Bioethical Questions', Rome, 8 September 2008
[22] Ford (n 6) 29.
[23] See for example Jürgen Habermas, 'The Concept of Human Dignity and the Realistic Utopia of Human Rights' (2010) 41 Metaphilosophy 464, 66; Halliday (n 8) 57.
[24] Jürgen Habermas, *The Future of Human Nature* (Polity Press 2003) 71.
[25] Klein (n 11) 403.
[26] See John Gillott, 'The Changing Governance of Embryo Research?' (2013) 32 New Genetics and Society 190, 194.

human being, then we would also have to ascribe the same moral status to potentially trillions of cells that share this potential[27]. The development and contestation of the position of the human embryo in the Western liberal democracy tradition can be considered as the result of participative deliberation, with interaction between policy makers, scientific researchers, and activist organisations, both in favour of and against hESC research, based on the belief that a plurality of views is important in both policy making and legislating[28].

In China, we also see the influence of cultural norms upon the understanding of the human embryo, and what may be permissible in patenting. In comparison to ideals represented by secular humanism and Christian conceptualisations of life, Chinese conceptualisations have different sources. According to Sleeboom-Faulkner, Confucianism is one school of thought that has influenced understanding of the human embryo in China[29]. While acknowledging that Confucianism does not represent a unified school of philosophical thought, Zhen Cai, in a commentary reproduced in Degeling et al., argues that from the perspective of Mencius' Confucianism, 'being human' is about the formation of societal relationships, rather than being a universal quality or characteristic[30]. Confucianism in the Mencius tradition does not associate the 'human' with innate qualities, such as the possession of a soul, or being able to experience emotions or suffering, but with socialisation, and the forming of bonds with family and society[31]. Human embryos, being biological matter composed of human cells, are ultimately not considered as 'human life' in such a way that research involving hESC, and the subsequent patenting of those inventions, would necessarily be considered immoral[32]. A Chinese bioethicist discussed in Sleeboom-Faulkner reiterates this understanding, arguing that 'as embryos […] are not social human beings but biological human beings […] spare embryos after in vitro fertilisation (IVF) can be used in research'[33]. Tsai assumes a more moderate position, instead stating that from a Mencius Confucian perspective, the approach to the status of the human embryo is more 'gradualist' – while it

[27] See Julian Savulescu, 'Should We Clone Human Beings? Cloning as a Source of Tissue for Transplantation' (1999) 25 Journal of Medical Ethics 87, 87–95.
[28] Ibid, p. 195-196
[29] Margaret Sleeboom-Faulkner, *Global Morality and Life Science Practices in Asia: Assemblages of Life* (Palgrave Macmillan 2014) 120.
[30] Chris Degeling, Rob Irvine and Ian Kerridge, 'Faith-Based Perspectives on the Use of Chimeric Organisms for Medical Research' (2014) 23 Transgenic Research 265, 271.
[31] Ibid
[32] Ibid
[33] Sleeboom-Faulkner (n 29) 120.

may have value, it possesses *less* value than the later developed foetus, child or adult human, particularly insofar as the use of the stem cells derived from that embryo may treat sufferers of debilitating conditions in those children or adults, to whom we owe a greater respect and care as a result of strongly established social ties[34].

Interestingly, even amongst Chinese bioethicist resources consulted by Sleeboom-Faulkner where Confucianism was not part of the theoretical frame for discussions of hESC-related research, discussions relating to pre-birth attachment to life and trade in embryos were 'mainly defined as problems belonging to foreign, Western, feminist or Christian worlds'[35]. Klein states that in China, the 'One Child' policy means that successful IVF treatment leaves 'leftover' embryos as their use for the conception of additional children is prohibited[36]. IVF patients can then either choose to have the leftover embryos disposed of as waste, or donated for medical research, such as their use for the derivation of stem cells[37]. According to Salter, it is 'commonly supposed […] that the population, accustomed as it is to state population control […] places little value on the human embryo'[38]. While Salter[39] and Nie Jing-Bao[40] consider that such an assumption is not necessarily representative of the feelings of individuals on the topic, Salter nevertheless states that 'the political manifestation of such cultural attitudes is limited by the absence of formal mechanisms for the public discussion of scientific advance and most debate takes place in the confined professional realms of scientists and bioethicists'[41] (which will be returned to when discussing institutional design and its impact upon patent regimes). While Sleeboom-Faulkner states that there is an active debate on the moral status of the human embryo within this context, there is little consensus, with bioethicists' views ranging from the embryo being considered as constituting precious life, through to them having little-to-no intrinsic worth; 'official policies seem to support the latter fully, and the former

[34] DFC Tsai, 'Human Embryonic Stem Cell Research Debates: A Confucian Argument' (2005) 31 Journal of Medical Ethics 635, 639.
[35] Sleeboom-Faulkner (n 29) 120.
[36] Klein (n 11) 412.
[37] Ibid, p. 413
[38] Brian Salter, 'Governing Stem Cell Science in China and India: Emerging Economies and the Global Politics of Innovation' (2008) 27 New Genetics and Society 145, 151–152.
[39] Ibid
[40] See in particular Nie Jing-Bao, *Behind the Silence: Chinese Voices on Abortion* (Rowman & Littlefield Publishers 2005) for a sometimes harrowing account of the personal and social impact of the One Child policy upon women.
[41] Salter (n 38) 152.

indirectly'[42]. Nevertheless, what debate exists appears contradictory, and discourses concerning the status of embryos limited to an elite body of professionals, which as will be expanded upon in the fourth section of this article, has significant implications for the institutional approaches to the patenting of inventions resulting from hESC-related research.

Biotechnological patents in comparative perspective – innovation for economic development

Despite considerable differences in approach to the issue of medical research involving hESC, the approach to biotechnology-related patents in the EU and China demonstrate a significant level of commonality, particularly in terms of the drivers of biotechnology policies. In the EU, policy documents published in advance of the adoption of the Biotechnology Directive (which shall be discussed in more detail in the next sub-section) demonstrated the European Commission's perception that biotechnology was a priority area for legal reform in order to pursue economic ends. A 1994 Green Paper[43] on biotechnology stated that biotechnology was acknowledged to be 'one of the fields offering the greatest potential for innovation and growth…a key technology for the future competitive development of the Community'[44]. In the resultant Action Plan published in 1996, the Commission reiterated that there were considerable economic imperatives for speedy action in the field of biotechnology regulation, so as to 'maintain the ability for relevant research in Europe and stimulate the creation of new enterprises and the marketing of results'[45]. Creating a clear framework for the patenting of biotechnological inventions, therefore, was considered vital in improving Europe's innovation environment[46]. Schneider argues that this understanding of biotechnology as being essential for economic growth had been developing since the 1980s in the European

[42] Sleeboom-Faulkner (n 29) 121.
[43] Communication from the Commission of the European Communities, Biotechnology and the White Paper on Growth, Competitiveness and Employment: Preparing the Next Stage, COM(94) 219 final, Brussels 01/06/1994
[44] Ibid, p. 1
[45] Commission of the European Communities, The First Action Plan for Innovation in Europe: Innovation for growth and employment, COM(96) 589 final, Brussels 20/11/1996, p. 32
[46] Ibid, p. 14

Community[47], an understanding consistent with the drive for increased privatisation, market liberalisation and sector deregulation that had begun with cases such as *Cassis de Dijon*[48] and continued in the Single European Act and 'constitutionalisation' of principles of competition [49]. This instrumental view of patent law continues to the time of writing, with recent policy documents released by the Commission reiterating the importance of innovation, and by extension the incentivisation of innovation through patent protection, as a driver for economic growth and development in the EU[50].

In China, economic growth is also a driver of patent policies generally, as well as biotechnology policies specifically. Zhu Chen et al. argue that in China, biotechnology and life sciences have become an issue of national importance, with former President Hu Jintao stating that 'biotechnology is the priority of high-tech industries by which China will try to catch up with the developed countries'[51]. This has resulted in the establishment of 24 institutes with 13 research centres, and an increase in funding for life sciences and biotechnology from 50.92 billion RMB (0.64% of GDP) in 1997 to 184.3 billion RMB in 2004 (1.35% of GDP)[52]. Klein states that this investment is seen as a means of ensuring social and economic development[53], with the Chinese Government making clear its desire to develop an innovation and knowledge-based economy[54]. Former Premier Wen Jibao made a statement in 2009 that intellectual property protection formed part of this economic strategy; 'in the new era, global science and technology competition, as well as economic competition, is primarily a competition of IP rights. Promoting IP rights

[47] Ingrid Schneider, 'Can Patent Legislation Make a Difference? Bringing Parliaments and Civil Society into Patent Governance' in Sebastian Haunss and Kenneth C Shadlen (eds), *Politics of intellectual property: contestation over the ownership, use, and control of knowledge and information* (Edward Elgar 2009) 134.
[48] Case 120/78 *Cassis de Dijon* [1979] EU:C:1979:42, for more on this topic, see Mark Thatcher, 'Supranational Neo-Liberalisation: The EU's Regulatory Model of Economic Markets' in Vivien A Schmidt and Mark Thatcher (eds), *Resilient Liberalism in Europe's Political Economy* (Cambridge University Press 2013) 177–179.
[49] Fritz Scharpf, *Governing in Europe: Effective and Democratic?* (OUP Oxford 1999) 55.
[50] See, for example, European Commission Communication, A Single Market for Intellectual Property Rights: Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe, COM(2011) 287 final, Brussels 24/05/2011
[51] Zhu Chen and others, 'Life Sciences and Biotechnology in China' (2007) 362 Philosophical Transactions of the Royal Society of London B: Biological Sciences 947, 951.
[52] Ibid, p. 953
[53] Klein (n 11) 399.
[54] Peter K Yu, 'Building the Ladder: Three Decades of Development of the Chinese Patent System' (2013) 5 WIPO Journal 1, 12.

therefore promotes and inspires innovation'[55]. As in the EU, patenting and by extension patent protection is seen by Chinese policy-makers as a means of ensuring innovation, and by extension economic development as the result of the manufacturing of marketable products and processes. Indeed, as Wechsler states, China's approach to patent law 'demonstrates its determination to proactively resort to IP policies as an economic policy tool to promote innovation and economic development'[56]. For both China and the EU, biotechnological inventions would appear to play a major part in their respective innovation policies. For this reason, and before continuing to analyse the importance of the socially constructed nature of 'morality' for those patent regimes, it is necessary to consider the patentability requirements for biotechnological inventions in both regimes in more detail.

Biotechnological invention eligibility requirements in EU law

In the European Union, the European Patent Convention (hereafter EPC)[57], a multilateral treaty that is in force for 38 European states, serves as a significant part of the framework for the 'European' patenting of inventions. The EPC established the European Patent Organisation under Article 4, comprising the European Patent Office (EPO), which assesses the eligibility of patent applications and grants European Patents to successful claimants, and the Administrative Council, which oversees the work of the EPO. However, it is important to state that the European Patent Organisation *does not* constitute a supranational EU institution, but an international organisation to which EU Member States are party. The European patent is often referred to as constituting a 'bundle of national patents'[58], insofar as a patent awarded by the EPO will be subject to national validation by the courts in the contracting states in order to be enforceable in that state. Nevertheless, as stated by Luginbhuel, the situation is actually more nuanced, as the patentability

[55] Jibao, speech reproduced at State Intellectual Property Office of the People's Republic of China, 'China's Intellectual Property Protection in 2008', 27/04/2009 accessible at http://english.sipo.gov.cn/laws/whitepapers/200904/t20090427_457167.html (accessed 1 February 2015)
[56] Andrea Wechsler, 'Intellectual Property Law in the People's Republic of China: A Powerful Economic Tool for Innovation and Development' (2011) 1 China-EU Law Journal 3, 43.
[57] Convention on the Grant of European Patents (European Patent Convention, hereafter EPC) of 5 October 1973, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000
[58] See for example Zofia Zawadska, 'The Unitary Patent Protection - a Voice in the Discussion from the Polish Perspective' (2014) 45 International Review of Intellectual Property and Competition Law 383, 386; Ceyhun Necati Pehlivan, 'The Creation of a Single European Patent System: From Dream to (almost) Reality' (2012) 34 European Intellectual Property Review 453, 455.

requirements used by those national courts are set by the EPC[59]. Of particular relevance for this paper is Part II of the EPC, which concerns the substance of patent applications. Article 52(1) states that 'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application'.

How does this apply to biotechnological inventions? The EU has sought to harmonise the approach of the EU Member States to patenting in this field, with the introduction of the Biotechnology Directive[60]. This Directive states at Article 1(1) that Member States should protect biotechnological inventions under national patent law, with biological material being defined as 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'[61]. They can be patented so long as they are:

> 'inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used'[62].

Novelty requires that the invention does not constitute part of the 'state of the art' at the time that the application is made[63]. As specifically applied to biotechnological inventions, Article 3(2) of the Directive states that even if the biological material previously occurs in nature, if it is isolated from its natural environment or produced by means of a technical process, it can still be patented. Perhaps a better way of referring to this approach is the distinction between 'discovery' and 'invention'. Article 5(1) states that the human body, or the 'simple discovery of one of its elements', including complete or partial gene sequences, cannot constitute a patentable invention. Instead, there needs to be demonstration of the isolation of an element of the human body by way of a technical process[64], with the

[59] Stefan Luginbuehl, *European Patent Law: Towards a Uniform Interpretation* (Edward Elgar 2011) 1–2.
[60] Directive 98/44/EC on the legal protection of biotechnological inventions (hereafter the Biotechnology Directive)
[61] Ibid, Article 2(1)(a)
[62] Ibid, Article 3(1)
[63] EPC Article 54(1)
[64] Biotechnology Directive Article 5(2)

industrial application 'of a sequence or a partial sequence of a gene' made clear in the patent application[65]. Odell-West argues that the 'isolation and function' requirement constitutes the key requirement for patentability under the Directive[66], following the *Monsanto* case[67]. In the Opinion[68] written by Advocate General Mengozzi, it was stated that 'the isolation of a DNA sequence without any indication of a function constitutes a mere discovery and as such is not patentable'[69]. Indeed, Mengozzi continues, it is the 'indication of a function that it performs'[70] that transforms a mere biological discovery into an invention, reading Article 5 in line with Article 9, which states that the patent containing or consisting of genetic information material will extend to all material in which 'product in incorporated and in which the genetic information is contained and performs its *function*'[71]. Confirming the Advocate General's Opinion, the Court of Justice reiterates that an isolation of a DNA sequence without providing a function for that sequence cannot be patented[72]. Whereas Carpenter argues that this decision significantly restricts the scope of patent protection available for biological inventions in the EU[73] and Odell-West the case represents a significant development in EU patent law[74], Paton and Denoon see the case as one of fact, stressing Monsanto's lack of function-related information in their patent application, and the decision of the Court as confirming what was already stated in Articles 5 and 9 of the Biotechnology Directive[75]. At the level of the EPO, the *Icos Decision*[76] demonstrates that even where an element already exists in nature, the purification and isolation of that element (in this case, a nucleic acid), could in theory be patented as an invention rather than a discovery[77]. Nevertheless, even if an invention, if no function is provided in the patent application or the nature of the described function is speculative

[65] Ibid Article 5(3)
[66] Amanda Odell-West, '"Gene"-Uinely Patentable? The Distinction in Biotechnology between Discovery and Invention in US and EU Patent Law' [2011] Intellectual Property Quarterly 304, 305, although for her criticisms of this approach, see p.321.
[67] Case C-428/08 *Monsanto v Cefetra* EU:C:2010:402
[68] Case C-428/08 *Monsanto v Cefetra* EU:C:2010:128
[69] Ibid, para.31
[70] Ibid
[71] Emphasis added
[72] Case C-428/08 *Monsanto v Cefetra* EU:C:2010:402, para.45
[73] Craig C Carpenter, 'Seeds of Doubt: The European Court of Justice's Decision in Monsanto v. Cefetra and the Effect on European Biotechnology Patent Law' (2010) 44 The International Lawyer 1189, 1189.
[74] Odell-West (n 66) 320; see also Sven JR Bostyn, 'A Decade after the Birth of the Biotech Directive: Was It Worth the Trouble?' in Emanuela Arezzo and Gustavo Ghidini (eds), *Biotechnology and Software Patent Law* (Edward Elgar 2011) 233–234.
[75] Mark Paton and Alex Denoon, 'The Ramifications of the Advocate General's Opinion in the Oliver Brüstle Case' (2011) 33 European Intellectual Property Review 590, 593.
[76] *Icos Decision* [2002] OJEPO 293
[77] Ibid, p. 307

only, then the application will fail[78]. Interestingly, the EPO Guidelines for patent examination[79] draw directly from the Biotechnology Directive for its rules on novelty, inventive step and industrial application for biotechnological inventions, and state that it 'is to be used as a supplementary means of interpretation'[80]. For this reason, it may be concluded that biotechnological inventions may, at least in theory, be patentable in the EU. However, as will be demonstrated in in the following sections of this article, conceptualisations of morality may play a part in preventing the patenting of otherwise eligible inventions.

Biotechnological invention eligibility requirements in Chinese law

China, according to Qiongdi Chen[81], has formal patentability requirements that closely resemble those of the EPC. This is not particularly surprising – as Ping-Hsun Chen states, many of the early reforms to Chinese patent law were as a response to external pressures[82]. In particular, China's accession to the World Trade Organisation in 2001 necessitated the ratification of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and by extension the requirements of the Paris Convention on the Protection of Industrial Property. During the negotiations under the auspices of the Uruguay Round, China along with India tried to mediate between the interests of development in developing economies and the desire to ensure high levels of protection and substantive harmonisation in the industrialised economies, albeit unsuccessfully[83]. Whereas the Patent Law (1984) was significantly restrictive in its requirements for patentability, specifically excluding pharmaceutical products and plant and animal varieties (albeit allowing for patenting of the processes)[84], later iterations of the law represented a liberalisation of the eligibility requirements in line with international

[78] Ibid, p. 304
[79] Guidelines for Examination in the European Patent Office, November 2014
[80] Ibid, Part G-Chapter II-16 at para.5.2
[81] Qiongdi Chen, 'Patent Biotechnology Invention in China' (2010) 32 European Intellectual Property Review 9, 10.
[82] Ping-Hsun Chen, 'China as a Technology Exporter: A Question Mark after the Third Amendment of the China Patent Law in 2009' (2012) 34 European Intellectual Property Review 853, 853.
[83] Joseph Straus and Nina-Sophie Klunker, 'Harmonisation of International Patent Law' (2007) 38 International Review of Intellectual Property and Competition Law 907, 911–912.
[84] Patent Law of the People's Republic of China (1984) Article 25

requirements[85], with the exclusion of pharmaceutical products from patent protection being absent from the Patent Law (2008)[86]. According to Handong Wu, this was the result of internal pressures *in addition to* external pressures – in particular, the desire to stimulate the domestic economy as well as promote science and technology-related development[87].

In theory, biotechnological inventions can be patented under the 2008 Act, with Article 26 stating that for 'invention-creation accomplished by relying on genetic resources, the applicant shall, in the patent application documents, indicate the direct and original source of the genetic resources'. In general, however, a patent is subject to eligibility requirements under Article 22 that require the invention to be 'novel, creative and of practical use'. While the wording of this Article is significantly different to that of the EPC Article 52(1), the subsequent explanation in Article 22 helps to demonstrate the similarity in technical requirements. Novelty means that the invention is 'not an existing technology', creativity that the invention 'possesses prominent substantive features and indicates remarkable advancements' (indicating similarity with the 'inventive step' requirement under the EPC), and practical use that the invention 'can be used for production or be utilized, and may produce positive results' (i.e., that is possesses an industrial application). Furthermore, Article 22 states that 'scientific discoveries' are not patentable, indicating that the Chinese approach closely mirrors that of the EU under the EPC[88].

In determining the eligibility of biotechnological inventions for patent protection in China, it is particularly useful to refer to the English-language translation of the 2010 Guidelines on the Examination of Patents[89]. However, it must be explicitly stated that the Guidelines are considered in China as an agency manual, intended to assist the Chinese patent officials of the State Intellectual Property Office (SIPO) in assessing applications, and do not have

[85] Chen (n 81) 9; see also Xiang Yu, 'The Impact of the Amendments of the Chinese Patent System on the Technological and Economic Progress in China' in Wolrad Prinz zu Waldeck und Pyrmont and others (eds), *Patents and Technological Progress in a Globalized World* (Springer 2009) 877.
[86] Patent Law of the People's Republic of China (2008) Article 25
[87] Handong Wu, 'One Hundred Years of Progress: The Development of the Intellectual Property System in China' (2009) 1 WIPO Journal 117, 119.
[88] An assessment in line with that of Li Xiang and others, 'A Comparative Analysis of the Inventive Step Standard in the EPO, SIPO and USPTO' (2013) 8 Journal of Intellectual Property Law & Practice 539, 540.
[89] Guidelines of 1 February 2010, on Examination of Patents (promulgated by Order No. 55 of the State Intellectual Property Office, accessible at http://www.wipo.int/wipolex/en/details.jsp?id=6511 Accessed 1 February 2015

any legally binding force[90]. For this reason, any patent granted that appears to be in conflict with the Guidelines will not be considered invalid[91]. By way of explanation, the Guidelines state that 'scientific discoveries' refers to 'revelations of substances, phenomena, transformation processes and their features and laws, which objectively exist in the nature'[92]. Expanding upon the Patent Law (2008), the Guidelines provide for the consideration of biotechnological inventions, including a definition of biological material almost identical to that found in the Biotechnology Directive, namely 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system, such as a gene, plasmid, microorganism…and so on'[93]. Furthermore, the Guidelines state that a gene or DNA fragment may be patentable where it and the process to obtain it are 'isolated or extracted for the first time from the nature, its base sequence is unknown in the prior art and can definitely be characterised, and it can be exploited industrially'[94]. It would subsequently appear that on the face of it, the basic eligibility requirements for biotechnological patents are, if not identical, at least very similar in both the EU and China. Nevertheless, this may not be the case when assessing barriers to patenting on the basis of morality.

What cannot be patented – the *ordre public* and public morality

While in principle biotechnological inventions may be patented in the EU and China, even where those inventions may contain naturally occurring biological material, in both systems the granting of a patent will be subject to consideration of the *morality* of the invention. In the EU, the Biotechnology Directive states at Article 6(1) that inventions will not be granted patent protection where their commercial exploitation would be considered contrary to *ordre public* or morality. In particular, Article 6(2) states that any processes for the cloning of human beings, or the use of human embryos for industrial or commercial purposes, will also be deemed ineligible for patent protection. Preamble paragraph 42 states, however, that 'such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it'. This

[90] Huan Zhu, 'A Comparative Study on Human Embryonic Stem Cell's Patent-Eligibility in the United States, the European Patent Organization and China' [2012] ExpressO 1, 19.
[91] Ibid
[92] Guidelines at p. 134
[93] Ibid, p.346
[94] Ibid, p.347

would appear to indicate that whereas the patenting of the human embryo itself, or processes involving the use of human embryos may not be patentable, this does not in itself mean that patents involving hESC-related research are also prohibited under Article 6. As with Article 5 of the Directive, the EPO has also incorporated Article 6 into its own rules[95], with Article 53(a) of the EPC stating that 'inventions the commercial exploitation of which would be contrary to "ordre public" or morality' cannot be patented'. The application of this principle to hESC-research related inventions was considered in the *WARF* case heard before the EPO's Enlarged Board of Appeal[96]. In this case, the Wisconsin Alumni Research Foundation, or WARF, sought a patent for a cell culture comprising embryonic stem cells that could be grown in vitro. The appellants claimed that this was an exciting and promising invention[97], that the prior method of extraction of stem cells from a pre-14 day embryo does not constitute 'in any real sense performing an industrial or commercial act'[98], and that if Article 6 of the Directive intended to 'exclude from patentability products derived from human embryos it would have explicitly said so'[99]. The appellants maintained that the concern was with the commercialisation of embryos themselves, rather than tissues or cells derived from embryos[100]. Nevertheless, the Board found that the invention was not patentable. The stem cells derived in the technique described in the patent application could not occur without the destruction of the embryo itself, meaning that the use of the embryo involved destruction constituted 'an integral and essential part of the industrial or commercial exploitation of the claimed invention'[101]. Reference was specifically made to preamble paragraph 42 of the Biotechnology Directive, in determining that patentability was only possible where the invention was of therapeutic or diagnostic benefit to the embryo itself, which could not be the case if the embryo was destroyed[102].

While Torremans explicitly states (and has been discussed above) that there is no such thing as a common standard of morality in the EU that can be simply used in assessing

[95] See Paul Torremans, 'Patentability of Human Stem Cells or Synthetic Biology Based Inventions' in Emanuela Arezzo and Gustavo Ghidini (eds), *Biotechnology and Software Patent Law* (Edward Elgar 2011) 298.
[96] G 002/06 Use of embryos/*WARF* [2009] OJEPO 5 306
[97] Ibid, p. 310
[98] Ibid, p. 312
[99] Ibid, p. 313
[100] Ibid
[101] Ibid, p.328
[102] Ibid

patent claims[103], the Court of Justice nevertheless appears to have created something of a morality 'threshold' that patent claims involving hESCs must meet in order to be successful. *Brüstle v Greenpeace[104]* concerned a German patent held by Brüstle for the production of isolated and purified neural precursor cells obtained from hESCs for use in treating neural defects[105]. In Advocate General Bot's Opinion[106], the requirements of patentability should be consistent with the Directive, yet with a 'view to harmonisation which integrates ethical considerations so as to prevent the economic functioning of the market giving rise to competition at the cost of sacrificing the fundamental values of the Union'[107]. Bot however stated that taking a position on the definition of the human embryo based in philosophical or religious conceptualisations would be impossible to formulate in a way acceptable to everyone[108], and would therefore take a scientific approach, classifying embryos as the totipotent cells (those cells that can develop into any other cell, including placental cells) with the capacity to develop into a human being[109]. Pluripotent cells in comparison, which formed the basis of the patent, cannot develop individually into a human being, and in Bot's opinion could not be considered as an embryo in itself[110], with the result that hESCs would be considered as 'as elements isolated from the human body'[111], and subsequently not necessarily excluded from enjoying patent protection. However, as with the *WARF* decision, the cells in the patent claim could only be obtained through the destruction of the embryo, meaning that regardless of the fact that the claim did not make reference to the *use* of human embryos, the invention could not be patented as it would be contrary to the *ordre public[112]*. The Court concurred with the Opinion, stating that hESC-related inventions could not be patented where the material covered under the patent was extracted through the destruction of the embryo[113]. This decision caused considerable consternation on the part of certain academics, due to what has been seen as a deliberate sidestepping of deliberation

[103] Torremans (n 95) 298; see also Enrico Bonadio, 'Biotech Patents and Morality after Brustle' (2012) 34 European Intellectual Property Review 433, 438–440.
[104] C-34/10 *Brüstle v Greenpeace* EU:C:2011:669
[105] Ibid, para.15
[106] C-34/10 *Brüstle v Greenpeace* EU:C:2011:138
[107] Ibid, para.44
[108] Ibid, para.82
[109] Ibid, paras.84-85.
[110] Ibid, para.98
[111] Ibid, para.101
[112] Ibid, para.117
[113] C-34/10 *Brüstle v Greenpeace* EU:C:2011:669, paras.47-49

upon moral and philosophical issues[114], disagreements regarding the definition of a human embryo used by the Court[115], and the risk of the EU falling behind its competitors with regard to stem-cell research as a result of the restrictions placed on patentability[116].

However, *Brüstle* has been followed by the recent *ISCO* decision[117], which has considerably widened the scope for patenting relating to pluripotent stem cells, mitigating some of the above-stated criticisms. The Court had to determine whether an invention producing pluripotent human stem cell lines from parthenogenetically-activated oocytes could be patented[118]. According to Advocate General Villalón[119], scientists have discovered ways of initiating cell division that does not require an ovum to be fertilised; the unfertilised oocyte is 'activated' by a variety of chemical and electrical techniques allowing for the extraction of stem cells (parthenogenesis), but the oocyte cannot develop into a human being[120]. For Villalón, this could only mean 'that unfertilised human ova whose division and further development have been stimulated by parthenogenesis as described by the referring court are not included in the term "human embryos"'[121], with the result that hESCs obtained from them does not result in the destruction of human life. For this reason, such inventions are capable of being patented. The Court concurred with Villalón that the invention would not involve the use of a human embryo, with the caveat that 'if, in the light of current scientific knowledge, that ovum does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine'[122]. It may be concluded therefore that while in principle inventions containing hESCs may be patented in the EU under the Biotechnology Directive, a particularly restrictive approach has been taken – if the embryo is destroyed in the process of obtaining that material, it cannot be

[114] Shawn HE Harmon and Graham Laurie, 'Dignity, Plurality and Patentability: The Unfinished Story of Brustle v Greenpeace' (2013) 38 European Law Review 92, 97–98; Kathleen Liddell, 'Immorality and Patents', *New Frontiers in the Philosophy of Intellectual Property* (Cambridge University Press 2012) 167.
[115] Hubertus Schacht, 'Commencement or Completion: What Constitutes a "Human Embryo" within the Meaning of the EU Biotechnology-Directive ?' (2014) 36 European Intellectual Property Review 66, 71.
[116] Charles Brabin, 'Intellectual Property Law in the Realm of Biology - Striking the Right Balance' (2014) 36 European Intellectual Property Review 687, 691–692.
[117] Case C-364/13 International Stem Cell Corporation (ISCO) v Comptroller General of Patents, Designs and Trade Marks EU:C:2014:2451
[118] Ibid, para.10
[119] Case C-364/13 International Stem Cell Corporation (ISCO) v Comptroller General of Patents, Designs and Trade Marks EU:C:2014:2104
[120] Ibid, paras.29-30
[121] Ibid, para.75
[122] Case C-364/13 International Stem Cell Corporation (ISCO) v Comptroller General of Patents, Designs and Trade Marks EU:C:2014:2451, para.38

patented. Alternative means of obtaining such material, such as through artificial stimulation of a non-fertilised ova that cannot develop into a human being (and thereby does not constitute a human embryo) will be permitted, and the subsequent invention not excluded from patentability due to being contrary to the *ordre public*.

We must now turn to consideration of the morality principle in China. It may be concluded that the patenting of stem cells derived from human embryos would be subject to a much less restrictive approach, given the more liberal regime for hESC-related research. However, such a finding is not supported upon a reading of the Chinese Patent Act and accompanying Guidelines. According to Article 5 of the Patent Act, 'patent rights shall not be granted for invention-creations that violate the law or social ethics, or harm public interests'. According to Li Jiang, the Commission on Legislative Affairs has stated that 'the social morality standard depends on public acceptability'[123]. As the Guidelines state, '"social morality" refers to ethical or moral norms and rules generally recognised as justifiable and acceptable by the public'[124]. On this basis, the use of human embryos for industrial or commercial purposes is considered contrary to public morality and derived-inventions not granted patent rights[125]. How this has been interpreted in practice is not entirely clear – while Huan Zhu states that methods of producing non-modified pluripotent hESCs are patentable in practice, contrary to the Guidelines[126], Qiongdi Chen argues that the interpretation of this principle is closely in line with that of the EPO[127]. This argument would appear to be supported by an analysis of patent application appeals performed by Li Jiang. In one case, involving the Shanghai Genon Biological Products Company, an application was made for an invention that involved mixing a donor nuclear cell and non-mammalian cytoplasm, which would then be stimulated and transplanted into non-human mammals[128]. Li Jiang states that the application was rejected by SIPO, and the appeal subsequently rejected by the patent review committee, on the grounds that it was not

[123] Li Jiang, 'Between Scylla and Charybdis: Patentability and Morality Related to Human Embryonic Stem Cells' (2015) 6 Intellectual Property Brief 53, 75.
[124] Guidelines at p. 131
[125] Ibid
[126] Zhu (n 90) 19.
[127] Chen (n 81) 10.
[128] Jiang (n 123) 77.

precluded that the early embryos that provided the nuclear cells involved in the transfer could not develop into a human being[129].

A further development came with an application for a patent by the Regents of the University of California for the use of hESCs for the treatment of spinal cord injuries. The patent review committee appears to have concluded that where the use of hESCs relies upon the destruction of a human embryo, that invention cannot be patented[130]. This would appear to be reflective of the approach taken by the CJEU in the *Brüstle* and *ISCO* decisions. Whereas genetic information and material could be patented in principle, including information or material derived from hESC-related research, where that extraction involves use resulting in the destruction of an embryo, the invention cannot be patented. Caution must be exercised, however, in interpreting these decisions. As Huan Zhu states, the decisions of the SIPO patent office and its review committees are administrative rules only, and as such have no legal force in the courts, and cannot influence the decisions of the Supreme People's Court or the Standing Committee, which have the final say on the patentability (or not) of inventions involving the use of hESCs[131]. Therefore, to conclude that an established and binding precedent has been set on these matters in China would be both overreaching and premature. Nevertheless, empirical evidence would appear to suggest that while hESC-related innovations are granted patents in China, this is at a comparatively low level when compared to both the US and EU, with the US being responsible for 21% of all stem-cell related patents, the EPO for 14% and China for 2% respectively[132]. This may be explained by China adopting a more restrictive approach to patenting in this field, which according to Jiang, creates a paradox where human embryos have low moral status in practical scientific application, but high moral status in patent law[133]. If this is the case, then how may it be explained?

Institutional design and the impact upon legislative development

[129] Ibid, p. 78
[130] Ibid, p. 80
[131] Zhu (n 90) 22.
[132] Karl Bergman and Gregory D Graff, 'The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development' (2007) 25 Nature Biotechnology 419, 420 - however, it must be stated that this study does not specifically distinguish between 'embyronic' and 'adult' stem cells.
[133] Jiang (n 123) 81–82.

As discussed in the previous section, in theory at least, biotechnological inventions can be patented in both the EU and China, and the substance of the eligibility requirements analysed thus far is remarkably similar. While it would appear that the moral objection formalised in law to the patents related to hESC-related research is similar in the EU and China, these formalistic similarities are somewhat surprising and serve to conceal differing norms attached to human embryos that are reflective of different socio-cultural and historical traditions. How, then, can the similarities in the Biotechnology Directive and subsequent case law, and the Patent Act and associated Guidelines in China be explained? It is submitted that whereas substantially different institutional pressures have been exerted in both the EU and the China, these pressures have resulted in a convergence of *patenting* regulation, even if the regulation of stem cell research itself diverges substantially in the two regions.

It is important to consider that decisions taken by law-making bodies are not random or without underlying logic. Instead, decision-making exhibits 'path-dependence'[134], in which institutions, namely the rules, norms and 'standard operating procedures' of a particular organisation or state influence how decisions are made[135], which serves to constrain some actions or ways of formulating law, while facilitating others. These 'rules of appropriateness' are then transmitted between actors in a particular institution or organisation through 'socialisation [… and…] followed because they are seen as natural, rightful, expected and legitimate'[136]. As stated in the second section of this article, the regulation of medical technologies in the EU has occurred within the frame and discourses of Western liberal democracy, hinging upon such concepts as freedom of choice and representative democracy. Within this framework, the European Parliament ostensibly serves as a body representing the interests of European Union citizens, able in part to take an impartial stance against decision-making in the Commission[137], even prior to the establishment of the ordinary legislative procedure under the Treaty of Lisbon. While it

[134] As coined by Kathleen Thelen and Sven Steinmo, 'Historical Institutionalism in Comparative Politics' in Sven Steinmo, Kathleen Thelen and Frank Longstreth (eds), *Structuring Politics: Historical Institutionalism in Comparative Analysis* (Cambridge University Press 1992) 2.
[135] See generally Daniel Beland and Robert Henry Cox, 'Introduction: Ideas and Politics' in Daniel Beland and Robert Henry Cox (eds), *Ideas and Politics in Social Science Research* (Oxford University Press 2010).
[136] James G March and Johan P Olsen, 'Elaborating the "New Institutionalism"' in RAW Rhodes, Sarah A Binder and Bert A Rockman (eds), *The Oxford Handbook of Political Institutions* (OUP 2006) 7.
[137] Frank Decker, 'Governance beyond the Nation-State. Reflections on the Democratic Deficit of the European Union' (2002) 9 Journal of European Public Policy 256, 260–261.

may be accepted that the *participatory* element of citizens in the election of the European Parliament is relatively weak, with citizens considering national elections as more important than those at the EU level[138], the involvement of citizens in the political and law-making processes, and indeed interest group participation, is nevertheless understood within this framework as legitimate[139]. Schmidt refers to this involvement as being government 'for and with the people'[140], in which advocacy coalitions or organised interest groups can be involved in decision-making through a form of 'consultative democracy'[141]. With regard to the negotiation of the Biotechnology Directive, which subsequently influenced the EPO Guidelines, participatory activism by interest groups helped to shape the substance of the law. The Biotechnology Directive as originally envisaged was in essence an economic document[142], and a first Commission Proposal for a Directive published in 1988[143] made no mention whatsoever of issues of morality or ethics in biotechnology research, only laying out the various types of biotechnological invention that could be patented. Articles 5 and 6 of the Biotechnology Directive, concerned with the patenting of living material and inventions contrary to public morality respectively, did not exist in this first Proposal.

However, the fact that such a Directive was being considered, with no concern expressed regarding the possible commodification or private ownership of life forms, mobilised both secular and religious groups to engage in lobbying of the European Parliament[144]. Those with an outsider perspective, i.e. those not involved in the drafting and development of the legislation, saw the Directive as ignoring serious moral quandaries, with the experts involved in biotechnology-related innovation as ignoring or neglecting socio-cultural concerns[145]. Sustained lobbying pressures on the European Parliament by these outsider

[138] On the nature of European Parliament elections as 'second order' elections, see Julie Smith, 'How European Are the European Elections?' in John Gaffney (ed), *Political Parties and the European Union* (Routledge 1996).
[139] Sabine Saurugger, 'Interest Groups and Democracy in the European Union' (2008) 31 West European Politics 1274, 1280–1281; see also Stijn Smismans, 'European Civil Society: Shaped by Discourses and Institutional Interests' (2003) 9 European Law Journal 473.
[140] Vivien A Schmidt, 'The European Union: Democratic Legitimacy in a Regional State?*' (2004) 42 JCMS: Journal of Common Market Studies 975, 977.
[141] ibid 985.
[142] Schneider (n 47) 134.
[143] Commission Proposal for a Council Directive on the legal protection of biotechnological inventions COM(88) 496 final
[144] Schneider (n 47) 135–137.
[145] See for example Julia Black, 'Regulation as Facilitation: Negotiating the Genetic Revolution' (1998) 61 The Modern Law Review 621, 647–649.

activist groups ultimately saw the Proposal rejected in 1995 by the European Parliament on the 3rd reading, with 240 voting against acceptance of a conciliatory text as opposed to 188 in favour[146]. In the revised Proposal published at the end of 1995[147], the Commission acknowledged the failing of the first Proposal, stating however that it considered it to be largely technical in character;

> 'not that the ethical dimension was ignored but, at that time, it appeared that the exclusion from patentability of inventions the publication or exploitation of which would be contrary to public policy or morality [...already provided for in national legislation and the EPC] met the need to take into account the ethical dimension of biotechnological inventions'.[148]

The new text was a compromise version, incorporating the Articles on excluding living creatures from patentability and the clause on the *ordre public*[149]. Industry representatives in favour of the earlier draft lobbied intensely for the passing of the new draft of the Directive, alongside campaigners (both independent and financed by actors within the biotechnology industry) arguing *for* the inherent morality of biotechnology patents as a means of making the treatment of debilitating and/or degenerative conditions possible[150]. This compromise version of the Biotechnology Directive was ultimately approved by the European Parliament. The development of the EU approach to the patenting of hESC-related inventions is reflective of an institutional tension between experts and citizens[151], in which industry representatives and biotechnology experts framed their arguments in terms of sound academic science, rationality and scepticism of decisions made on the basis of emotions rather than facts[152] and citizen and activist organisations instead framing the discussion in terms of the need for consideration of moral issues[153]. This deliberation between competing viewpoints in a form of deliberative and participative democratic

[146] European Parliament, Minutes of Proceedings of the Sitting of Wednesday, 1 March 1995 [OJ] 95 C 68/12 at C 68/16
[147] Commission Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions COM(95) 661 final
[148] Ibid, p. 5
[149] Ibid, p. 14
[150] Schneider (n 47) 140–141.
[151] See Susana Borrás, 'Three Tensions in the Governance of Science and Technology' in David Levi-Faur (ed), *The Oxford Handbook of Governance* (Oxford University Press 2014) 434.
[152] Steve Emmott, 'No Patents on Life' in Brian Tokar (ed), *Redesigning Life: The Worldwide Challenge to Genetic Engineering* (Zed Books Ltd 2001) 377.
[153] Black (n 145) 649.

action ultimately led to a compromise between these views, in which the economic and scientific drivers of the Biotechnology Directive remained dominant, and in principle allowed for the patenting of hESC-related innovations, while nevertheless acknowledging the contested, and indeed contestable nature of a Directive with bioethical implications[154]. Subsequent jurisprudence then sought to mediate between these competing interests, reinforcing a scientific-rationalist view of the embryo, with a definition based on scientific principles and the distinction made between an embryo and its composite cells, while nevertheless reinforcing the destruction of the embryo as an affront to morality, albeit through the use of Article 6 of the Biotechnology Directive rather than reaffirmation of a more universal principle of dignity. Ultimately, it may be concluded that the current design of the Biotechnology Directive, and the subsequent consideration of how, if at all, hESC-related innovations can be patented are the result of an institutional framework in which citizen and/or interest group participation in the decision-making process is accepted as a legitimate form of law-making.

As stated in the above sections, and by way of comparison, the debate concerning the status of human embryos in China has largely been held amongst professional groups rather than with the participation of the general public. Biotechnology patent regulation has therefore been an elite-driven process rather than one that has hallmarks of representative or participatory democratic action on the part of individual citizens. Again, institutional path-dependence can help to explain this variation; whereas the law-making processes of the EU function in such a way as to give legitimacy to the involvement of interest groups, within the Chinese system, this type of involvement would not be consistent with its 'logic of appropriateness'. Weatherley states that legitimacy of law-making within the one-party state as led by Mao Zedong was based in a 'charismatic' legitimacy based upon his perception as a revered revolutionary leader[155]. In the post-1997 era, represented by the leadership of Jiang Zemin (and of particular relevance to patent laws) Hu Jinato, legitimacy has instead been based in reliance upon 'institutions and procedures as a means of augmenting their political power'[156]. In particular, the Chinese law-making system can be

[154] Schneider (n 47) 142.
[155] Robert Weatherley, *Politics in China Since 1949: Legitimizing Authoritarian Rule* (Routledge 2007) 7–8.
[156] ibid 8.

viewed as one of 'authoritarian deliberation'[157], where political leaders take guidance from experts upon strictly limited issues of governance, and which they then rely upon to uphold the legitimacy of their decisions[158]. While occasionally involving ordinary citizens, these processes more often include expert committees and think-tanks[159]. As applied to biotechnology research, this deliberation in China can most effectively be categorised as a form of 'expert governance', in which the Ministry of Health and the Ministry of Science and Technology work with technical experts, generally behind closed doors. It must be stated that as of 2013 this appears to have begun to change, with plans for the Ministry of Health's Ethics Committee to publish its findings publicly as a means of generating debates regarding bioethics[160]. Nevertheless, with regard to the regulation of stem-cell technologies, laws governing the patentability of resulting innovations have been an elite-driven process. As Sleeboom-Faulker states, interviews with 60 stem cell scientists in China indicated that they were opposed to general public engagement and debate on hESC-related research, as they were worried it would turn debate against such research[161]. They instead believed that their own involvement in the institutionalisation of review boards and ethical guidelines would help to safeguard against concerns regarding ethics and public morality[162]. In this respect, the means by which biotechnology regulation was developed in China stands in stark contrast to the more deliberative dimension of the passing of the Biotechnology Directive in the EU. Yet if this is the case, why do the standards demonstrated in the Patent Act and Guidelines in China appear so similar to those of the EU Biotechnology Directive and EPO standards?

It is submitted that this is the result of a combination of internal and external institutional pressures that have led to Chinese officials consciously adopting the standards of 'Western' bioethical standards in its biotechnology patent regulations. Internally, Sleeboom-Faulker indicates that the interviews with stem cell scientists and policy-makers view compliance with 'Western' standards of bioethics with 'advanced' practice and 'good science'[163], and

[157] Baogang He and Mark E Warren, 'Authoritarian Deliberation: The Deliberative Turn in Chinese Political Development' (2011) 9 Perspectives on Politics 269.
[158] ibid 269.
[159] ibid 283.
[160] Ayo Wahlberg and others, 'From Global Bioethics to Ethical Governance of Biomedical Research Collaborations' (2013) 98 Social Science & Medicine 293, 296.
[161] Sleeboom-Faulkner (n 29) 201.
[162] Ibid
[163] Ibid, pp. 128-129

that the use of international standards as a benchmark domestically promote an 'international aura of reliability and exude authority'[164]. This is related to the interaction between internal and external drivers, as these practices and approaches are introduced and promoted by Chinese scholars that have returned to China after experience in universities and scientific research institutions in other countries[165] - a form of institutional learning. In this form of institutional learning, the knowledge and experience developed by researchers and biotechnology experts in other countries becomes internalised within their home institutions, which then use this knowledge to revise policy positions[166]. This 'diaspora' of scientists is encouraged to return to China to provide their expertise, both in conducting research but also in establishing principles of best practice, in exchange for salaries often double those of Chinese scientists not trained abroad[167] in a form of 'reverse brain drain'[168]. With them, they 'bring back' internalised standards and guidelines for hESC research and patenting, and with it an air of international respectability that feeds into expert policy-making processes at home.

Finally, given the desire to become a major player in biotechnology research, an ostensible adherence to international standards, both in terms of research ethics and the subsequent patenting of that research serves China's international objectives as well as its internal ones. As already mentioned, developments in Chinese Patent law have in part been a response to international legal pressures[169]. However, compliance with international standards is also motivated by the above-stated economic pressures, where compliance is seen as a signal for foreign investment[170] as well as encouraging more stem cell scientists (both Chinese and non-Chinese nationals) to conduct research in China, something that has been considered historically difficult[171]. Furthermore, as global biomedical research with teams in multiple jurisdictions become more common, adherence to stricter ethical

[164] Ibid, p. 197
[165] Salter (n 38) 149.
[166] Paul A Sabatier, 'The Advocacy Coalition Framework: Revisions and Relevance for Europe' (1998) 5 Journal of European Public Policy 98, 104.
[167] Brian Salter, Melinda Cooper and Amanda Dickins, 'China and the Global Stem Cell Bioeconomy: An Emerging Political Strategy?' (2006) 1 Regenerative Medicine 671, 675.
[168] Levine (n 11) 204.
[169] Chen (n 82) 853; Yu (n 85) 877.
[170] Salter (n 38) 155; Weiping Yuan and others, 'Stem Cell Science On the Rise in China' (2012) 10 Cell Stem Cell 12, 13–14.
[171] Ibid, p. 154

conduct guidelines often becomes part of the collaborative agreement[172]. By demonstrating that Chinese Patent laws are in line with the EPC and EU approach to biotechnology innovation, including hESC-related inventions, it is intended that this will send a positive message to potential investors and researchers that China is a responsible and legitimate hub for biotechnology research. This highlights the fact that although the regulatory standards for patenting of hESC-related inventions has significantly converged upon similar conceptions of morality, this has been achieved through very different institutional processes, in which law-makers are bound by institutional path-dependencies that serve to render actions 'legitimate' or 'illegitimate' – whereas the EU's standards were developed through interest group interaction and public engagement within a system of representative and participatory democracy, the similar standards developed in China through expert-led governance based in a tradition of authoritarian deliberation, with policies being established as the result of 'learned' standards.

Concluding remarks

As this paper has demonstrated, the approaches to hESC-related research vary significantly even within the EU, let alone in comparison with China. Despite these substantial differences however, with one region ostensibly granting the human embryo high moral status and another that officially appears to grant it low social status, the position of the embryo within both systems is treated by their respective patent systems as being of high moral status, despite the significant differences in history, socio-cultural factors and institutional design. This is indicative of the fact that even regions that appear to differ substantially on the inherent values of the embryo may converge on a similar approach to patenting as the result of differing institutional pressures. In the EU, the approach has been formed as the result of participatory deliberation involving different stakeholders both aligned in favour and against hESC-related patents. In China, in comparison, a similar result has been achieved through elite policy-making decisions designed to facilitate research internally while encouraging human and capital investment externally through signalling compliance with international best practices. For this reason, the 'paradox' of the 'low moral status embryo' being afforded high moral status in the patenting regime may not be so paradoxical.

[172] Wahlberg and others (n 160) 297.