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Will Diversity Regulations disadvantage Human Embryonic Stem Cell Research: A Comparison Between EU and US

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ABSTRACT

The regulatory regime in HESC is a mixed landscape. Areas differ significantly in issues such as moral standards and patents. There is growing concern that "inconsistent regimes within legal jurisdictions have the potential to put researchers in unusually precarious positions with respect to their research methodology and output."[2] *However, it is worth considering whether inconsistent regulations truly hamper technological advances. The diversity may have costs but can also "enable systems to find novel and breakthrough solutions, and it can add to their value and robustness."*[3] *This article provides a succinct review of two major jurisdictions, the US and the EU, to address the issue of inconsistent HESC regulations. By comparing the EU's restrictive environment with the US's liberal environment, it concludes that adequate flexibility and diversity in the field of HESC regulation are beneficial to HESC research.*

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[2] C J Murdoch, *intraoperability problems: inconsistent stem cell IP and Research regimes within nations* 3 Stanford Journal of Law Science & Policy 49-55 (2011).

[3] Owen C.B. Hughes, Alan L.Jakimo and Michael J. Malinowski, *United States Regulation of Stem cell research: recasting government's role and questions to be resolved* 37 Hofstra law review 383-443 (2008):

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INTRODUCTION

Biotechnology raises many controversies particularly in the area of HESC research.[4] As one of the most fascinating developments in the biomedical area over the past decade, HESC research holds various potential in tissue engineering, genetic engineering and other regenerating technology. With the huge scientific, medical and commercial interest behind it, most countries commit to securing a competitive position among the human embryonic stem cell research, transplantation and regeneration medicine. Tremendous money was spent in human embryonic stem cell

[4] See Denis Schertenleib, *The patentability and protection of DNA based inventions in the EPO and the European Union*, 25 Eur. Intell. Prop. Rev. 125-138 (2003) (observing that we are faced with a new technology. Its complexity, however, poses problems which could never have been envisaged when patent law developed.); see also Graeme Laurie, *Patenting stem cells of human origin,* 26 Eur. Intell. Prop. Rev. 59-66 (2004) (stating that inventions involving embryonic stem cells are but the first in a long line of controversial patent applications that are set to beleaguer the patent offices of Europe.); see also Stephen R Crespi, *The human embryo and patent law-a major challenge ahead*, 28 Eur. Intell. Prop. Rev. 569-575 (2006) (pointing out that beginning with the oncecontroversial issue of micro-organsim patenting, the debate soon extended into the sphere of higher life forms, including cell-lines, plants, and animals and then even more controversially into the fundamental issue of gene patents, which may still need to achieve its final settlement.)

research, for instance in the US[5]. However, although a bright future of human embryonic stem cell research in conquering incurable diseases has been mirrored, its development face many legal and ethical challenges.[6] The complexity of human embryonic stem cell research creates most unusual and fraught situations for the regulators.

Considering the morality and patentability of HESC research, interoperability and intraoperability problems occur within and across nations.[7] The HESC regulation is divergent both within EU and US. These internal and external inconsistencies of HESC regulation continue to hurtle around biotechnology advance. The nature of HESC research highlights the difficulties lawmakers and scientists face with international collaborations that involve various researchers under conflicting policy regimes. Although HESC technology is young, the intrinsic nature of this area has generated a high level of international collaboration from the beginning.[8] It is argued that "variance within a jurisdiction seems much more likely to produce confusion and inefficiency."[9] The diversity of regulations and policies in this area often confusedly impact research and its outcome.[10]

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[5] In fiscal 2010, National Institute of Health (government funding) spent about $200 million to fund more than 200 human embryo research grants, accessed April 4th, 2011 http://www.bloomberg.com/news/2011-04-29/stem-cell-research-funding-can-continue-during-legal-case-u-s-court-says.html

[6] *Supra* note 3.

[7] *Supra* note 1.

[8] Jingyuan luo, Jesse M Flynn, Rachel E Solnick, Elaine Howard Ecklund and Kirstin R W Matthews, *international collaboration: how disparate policies between the United States and the United Kingdom impact research* 6 Plos One 1-7 (2011). (The study examined the impact of collaboration on pulication significance in the US and UK and reviewed publications by US and UK authors from 2008 along with their citation rates and the political factors that may have contributed to the number of international collaboration. The results shows that the UK exhibited a higher proportion of international publications than the US, this difference was consistent with overall trends in international scinece collaboration. The result shows tht the characteristics of a successful collaboration is crucial to maximizing the resources available for stem cell research and advancing this scientific field.)

[9] *Supra* note 1.

[10] Denise Stevens, *embryonic stem cell research: will president bush's limitation on federal funding put the United States at a disadvantage? A Compasion between US and Internation law*, 25 Hous. J. Int'l L. 623-654 (2003). (observing that the disparities among the laws of the various countries could have a profound impact on embryonic stem cell research; the Disparities between countries in stem cell laws could put the United States at a

However, this article argues the diversity can be hope for the improvement of HESC regulation. Part I of the article will examine the EU and its member state HESC regulations. It argues that even if member states reach the compromise in the EU level, inevitably they interpret diversely in national jurisdiction. The harmonisation attempt in the EU level remains the divergent interpretations in member sates. In the context of comparative law, Part II of this article will explore current federal and state HESC regulations in US. It argues that the diversity regulations in the states level alternatively fit it the absence of uniform regulations in federal level. Through comparing the restrictive legal framework in the EU with the liberal legal framework in the US, it finally concludes that the diversity toward HESC regulation is inevitable in the state level. Legal reconciliation is essential, whereas legal diversity is inevitable.

I. EU: RESTRICTIVE LEGAL FRAMEWORK WITH VARIOUS REGULATION IN MEMBER STATES

The margin of appreciation principle, which was developed in case *Vo v France*[11], allows different interpretations of human embryo based on various cultural, philosophical and cultural circumstance.[12] However, Member States do not have power to define the embryo.[13] Moreover, in case *Evans v United Kingdom*[14], the decision clarifies no uniform legal status for human embryos in EU. The lack of

technological and Economic disadvantage.)

[11] Case *Vo v France*, (Application No 53924/00) GC, 2004, at para. 83 and 40

[12] Yuval Shany, *Toward a General Margin of Appreciation Doctrine in International Law? 16* Eur. J. Inter'l L. 907 (2006).

[13] Recital 14 of the Directive provides that "whereas, consequently, substantive patent law cannot serve to place or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards."

[14] Case *Evans v UK* (Application No 6339/05) the European Court of Human Rights, 2006.

uniform moral definition and legal status of human embryos results that member states doubt whether the organism is a human embryo.[15]

A. European Patent Convention (EPC) and the Directive 98/44/EC of the European Parliament and of the Council (the Directive): harmonisation attempt

The EPC and the Directive is seen as an attempt to harmonising biotechnology patent. The patent protection of HESC research also stemmed from the EPC, which is an intergovernmental agreement between 38 European states for the purpose of harmonising patent law throughout the EU. Notably, the members of EPC not only include EU member but also non-EU member.[16] The European Patent Office established by the EPC is responsible for granting the European patent. However, the EPC is only limited to the grant of patent, not extend to the legal effect of a patent.[17] The European patent is 'a bundle of national patent' which is valid among the countries where patent application is sought.[18]

Unlike the patent laws in the US, the EPC contains a clause related to the morality of the claimed invention.[19] Under this provision, even if an invention fulfills the requirements of novelty, inventiveness and sufficient disclosure, a patent can still not

[15] Aurora Plomer, *Stem cell patents: European Patent law and Ethics Report*, reports for FP6 'life sciences, genomics and biotechnology for health 89 (2006).
[16] The European Patent Convention, http://www.epo.org/law-practice/legal-texts/epc.html.
[17] *Supra* note 14.
[18] Article 64(1) of the EPC provides that 'a European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date on which the mention of its grant is published in the European Patent Bulletin, in each contracting state in respect of which it is granted, the same rights as would be conferred by a national patent granted in that state'.
[19] Article 53(a) of the EPC provides that: European patents shall not be granted for: (a) inventions the publication or exploitation of which would be contrary to 'order public' or morality, provided that 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.

be granted if it is contrary to the "order public" or morality. This moral exclusion is often utilized by animal rights campaigners, Greenpeace or other similar institutions to oppose certain Biotechnology patents granted by the EPO.[20]

To harmonize the patentability of biotechnological products and processes throughout Europe, the Directive 98/44/EC of the European Parliament of 6 July 1998 on the legal protection of biotechnological inventions (the Directive) was enacted, establishing morality as an evaluative criterion in the granting of patents. The Directive was the result of 10 years of difficult negotiations, providing the general principles of biotechnological patents.[21] In 1988, the European Parliament rejected an earlier proposed Directive as lacking moral aspects, particularly in its provision on the patentability of materials derived from human beings.[22] But the purpose of the Directive, stated by the European Commission, is "foster the overall innovatory potential and competitiveness of Community science and industry in this important field of modern technology."[23]

The EU Commission believed that the Directive, as a uniform biotechnology regulation, was important to the development of biotechnology in the common market.[24] The commission also recognized that harmonization of biotechnology patenting is not confined to the technical dimension but also presents ethical concerns.[25] Therefore, from 1989-1995, the draft Directive introduced ethical elements,

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[20] See for example, case Howard Florey/Relaxin, EPO 6/1995 388, case HARVARD/Onco-mouse, T19/90, [1990]; see also Stephen Crespi, *supra* note 3.
[21] PLOMER AUROAR & PAUL TORREMANS, EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 16-124 (1st ed., Oxford University Press 2009).
[22] Proposal for a Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, COM(88),17 October 1988.
[23] *Id.*
[24] *Id.*
[25] *Id.*

such as respect for animal suffering, the non-patentability of human beings, and the safety of genetically engineered products.[26] Among these ethical elements, Parliament was particularly concerned about the patentability of the human body and its components. An amendment was added to exclusively prohibit granting patents to the human body or its components.[27] In the face of competition from the US and Japan, the Directive was finally sent to the Council and the Parliament in 1996.[28]

The Parliament reviewed the amended Directive and affirmed its amendments. The Directive was eventually approved in 1998.[29] The Directive stressed the importance of both patents and morality.[30] This provision is similar to Article 53(a) of EPC. After the Directive was issued, the EPC introduced a new chapter to accord with the Directive.[31] Rule 23(d) EPC stated that "under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: uses of human embryos for industrial or commercial purposes."[32]

The Directive first excluded 'uses of human embryos for industrial or commercial

[26] Richard E Gold and Alain Gallochat, *The European Biotech Directive: Past as Prologue*, 7 Eur. L. J. 331-366 (2007).
[27] *Id.*
[28] European Commission, Opinion of the Economic and Social Committee on the Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, [1996] OJ C295/1.
[29] Press Release, Environmental Council, 2106th session (16 June 1998) available at http://europa.eu/rapid/press-release_PRES-98-205_en.htm
[30] Article 6(1) of the Directive provides that inventions shall be considered unpatentable when their commercial exploitation would be contrary to public order or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
[31] Rule 23(b) of EPC provides that 'for European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this chapter. Directive 98/44/EC of 6 July 1998 on the legal protection for biotechnological inventions shall be used as supplementary means of interpretation'.
accordance with the provisions of this chapter.
[32] Rule 23 of the EPC. Article 23(e) EPC provides that:(1) The human body, at the various stages of its formation and development ... cannot constitute patentable inventions. (2) An element isolated from the human body or otherwise produced by means of a technical process ... may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

purposes' from patenting.[33] Although the original intention of listing unpatentable inventions is to clarify the regulation[34], its practical ramifications are ambiguous and misleading.[35] The moral provisions set out in the Directive also created some discomfort among member states, for example, in the case *The Netherlands (Italy and Norway, intervening) v. European Parliament and E.U. Council (E.C. Commission, intervening)*.[36] The Netherlands presented six arguments to revoke the Directive.[37] The ECJ stated that member states are responsible for assessing the morality of patents in the terms of "the ethical, sociological, or philosophical context of each country."[38] The court also affirmed that the directive is a necessary harmonization measure to eliminate biotechnology regulation disparities among member states. However, the intention of the EPC and the Directive is merely to make the uniform pre-grant phase.[39] No formal harmonization of regulations is achieved by the EPC and the Directive.[40]

B. Member States: divergent interpratations and disparties policies

Based on their different scientific, economic and moral ambitions, Member states have adopted different approaches in interpreting Article 53(a) of the EPC. In the plurality view, some states have more moral concerns, while others focus on the

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[33] Article 6(2) of the Directive.
[34] The EPO guidelines state that the purpose of this provision is to 'deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour', EPO Guidelines C-IV. 4.1.
[35] Amina Agovic, *stem cell patents on a knife edge*, 3 J. Intell. Prop. L. & Practice 718 (2008).
[36] *The Netherlands (Italy and Norway, intervening) v. European Parliament and E.U. Council (E.C. Commission, intervening)*, C-377/98, [2001] 3 C.M.L.R.49.
[37] *Id.* Six pleas includes: (1) that it is incorrectly based on Article 100a (now Article 95) of the Treaty; (2) that it is contrary to the principle of subsidiarity; (3) that it infringes the principle of legal certainty; (4) that it is incompatible with international obligations; (5) that it breaches fundamental rights; and (6) that the procedure for its adoption was incorrect.
[38] *Supra note 21*.
[39] *Supra* note 14 (pointing out that the objectives of the EPC and the EPO indicate clearly that the intent of the founders has been to achieve uniformity only in the pre-grant phase, whereas to limit the influence of the EPC in the post-grant phase only to certain standard rules, leaving the rest to the national patent law of the contracting states.)
[40] *Id.*

commercial applications. Member states such as France, Italy and the UK use the same wording in their own laws as the Directive.[41] However, some states use the wording to broaden the moral exclusion.[42] Nevertheless, the overview of policies in member states reveals a patchwork of disparate regulations on the patentability of HESC.

1. Permissive policy: UK approach

The rational reason for permissive policy is about advancing scientific and conquering disease that is beneficial to human.[43] In EU, Swede, Spain, Belgium, Denmark and so on all adopted the liberal policy towards HESC research. Despite their permissive policies, some core ethic principles such as human cloning is not allowed and human reproductive materials should not be commercialised are all agreed in these countries. As I will analyze in the following section, the liberal policy is well articulated in the UK's regulations and in funds for and the permitted range of stem cell research.

From Warnock report to Human Fertilisation and Embryology Act 1990: license up to the formation of the primitive streak (14 days after the mixing of the gametes)

The UK's regulatory system on HESC research is considered one of the best in the world.[44] Professor Anne Mclaren of the Wellcome Trust Gurdon Institute remarked

[41] Åsa Hellstadius, *A comparative analysis of the National implementation of the Directive's Morality Clause*, in PLOMER AUROAR & PAUL TORREMANS, EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 96-148 (1st ed., Oxford University Press 2009).
[42] *Ibid.*
[43] Bartha Maria Knopper, *Genetic Technologies: Commercialization of Genetic Research and Public Policy* 286 Sci. 2277-2278 (1999).
[44] UK Government proposals for the regulation of hybrid and chimera embryos, House of Commons Science and Technology Committee, March 2007, accessed January 19, 2012 http://www.publications.parliament.uk/pa/cm200607/cmselect/cmsctech/272/27202.htm.

that the "UK has a sensible and scientifically based regulatory system that has functioned with few major problems for the past 16 years."[45] Although both the US and the UK adopt permissive regulatory approaches to HESC research, the US mode does not seem appropriate for the UK's moral atmosphere.[46] Within Europe, the UK's liberal approach was strongly criticized by opponents.[47]

The Warnock report widely discussed two extreme views, one from religious members of the Catholic Church who believe that the human embryo has human status and the other from utilitarians who insist that the human embryo has no moral status.[48] Bypassing the fundamental question of whether an embryo is a human being, the highlight of the Warnock report is its endorsement of the view that a human embryo has a special moral status and that its particular status depends on its stage of development.[49] The Warnock report suggests that HESC research should be prohibited when cell differentiation has occurred after 14 days and the appearance of the primitive streak.[50] The UK legislature generally accepted HESC research using either embryos created for research or IVF waste embryos[51] and agreed that embryos used in research should be no older than 14 days.[52]

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[45] *Id.*

[46] Aurora Plomer, *Beyond the HFE Act 1990:the regulation of stem cell research in the UK,* 10 Med. L. Rev. 132-164 (2002) (stating that in the absence of a clear parliamentary intent by the UK parliament in 1990 to adopt moral principles endorsing the use of cloning techniques in embryo research, it is unclear how a judge can reach out into the past to identify all-embracing moral principles which could extend to novel and morally conested issues without inviting criticisms of abuse of judicial process and usurpation of the legislative fuction.)

[47] Jan Deckers, *Why Eberl is Wrong: reflections on the Beginning of Personhood*, 21 Bioethics 270 (2007).

[48] *Supra note 3.*

[49] Warnock Report 1984, accessed January 19, 2012, http://www.hfea.gov.uk/2068.html.

[50] *Supra note 3.*

[51] Because the proportion of successful IVF is normally at best 20-25%, doctors must produce many surplus embryos. These embryos are byproducts of IVF and are usually discarded or destroyed.

[52] There are four main views accepted by UK legislators: "argument from suffering justifies embryo research because of its potential to assist the development of treatments for disease"; "argument from twinning asserts that early embryos cannot be considered human individuals because blastocysts can develop into two human beings"; "the argument from capacities suggests that since embryos lack the ability to think, act and

Based on the Warnock report, the Human Fertilisation and Embryology Act (HFE Act) was passed in 1990. Because the huge potential of HESC was not foreseen at the time of passage of the HFE Act, it could be judged as accidental rather than by design that embryo research is permitted under the Act.[53] According to Schedule 2, section 3 (1), the legitimate purposes for which research could be licensed:

> (a) promoting advances in the treatment of infertility, (b) increasing knowledge about the causes of congenital disease, (c) increasing knowledge about the causes of miscarriages, (d) developing more effective techniques of contraception, or (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.[54]

The Human Fertilisation and Embryology Authority (HFEA) was created by the HFE Act.[55] HFEA is one of five critical regulatory bodies that make up the integral HESC regulatory framework in the UK.[56] HFEA licenses and regulates embryo research and UK fertility clinics.[57] Additionally, the Human Tissue Authority (HTA) and UKSCB are mainly responsible for overseeing the deposit and use of embryos and stem cell lines.[58] GTAC and MHRA are in charge of conducting clinical trials and

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communicate they cannot be accorded full status as human beings"; "argument from potentiality accepts that though the embryo has the potential to develop into a human being, this can only occur under specific circumstances and therefore it cannot be considered a human being in itself". Erica Haimes, Rouven Porz, Jackie Scully and Christoph Rehmann Sutter, "So what is an embryo? A comparative study of the views of those asked to donate embryos for hESC research in the UK and Switzerland," New Genetics and Society 27 (2008): 113.

[53] Ryan Morgan, *A tight fit? Deficiencies in the Human Fertilisation and Embryology Regulations 2001*, 28 Statute L. Rev. 199-217 (2007).

[54] Schedule 2, section 3 (1) of Human Fertilisation and Embryology Act 1990.

[55] Human Fertilisation and Embryology Act 1990, available at http://www.legislation.gov.uk/ukpga/1990/37/contents.

[56] Human Fertilisation and Embryology Authority (HFEA), Human Tissue Authority (HTA), Medicines and Healthcare Products Regulatory Agency (MHRA), Gene Therapy Advisory Committee (GTAC) and UK Stem Cell Bank Steering Committee (UKSCB).

[57] Human Fertilisation and Embryology Authority, available at http://www.hfea.gov.uk/.

[58] Human Tissue Authority, available at http://www.hta.gov.uk/; UK Stem Cell Bank, available at http://www.ukstemcellbank.org.uk/

investigating harmful accidents.[59] In light of the HFE Act of 1990, the UK is the only country in Europe that allows embryos to be created for research purposes.

Whether human embryo created by Cell Nuclear Replacement (CNR) is the embryo defined by the HFE Act 1990?

The HFE Act of 1990 was initially passed to settle the dispute over In Vitro Fertilization (IVF). However, Dolly's birth prompted questions about whether HESC research in Cell Nuclear Replacement (CNR) fell within the scope of the HFE Act.[60] Faced with the possibilities of human cloning and tissue factories, the HFEA collaborated with the Human Genetics Advisory Commission (HGAC) to address these questions. A joint report by the two organizations stated that the HFE Act of 1990 was effective in research involving NCR.[61] Because nuclear replacement of eggs is not listed in the HFE Act, it is permitted, and monitoring of NCR is under the jurisdiction of the HFEA.[62] During the same period, Chief Medical Officer Professor Donaldson, commissioned by the government, also reported beyond the legal scope of the HFE Act of 1990. In the Donaldson Report, research involving NCR is allowed under the HFE Act of 1990 provided that "it is for one of the existing specified research purpose."[63] Compared with the joint report, the Donaldson report indicated that embryos created

[59] Gene Therapy Advisory Committee, available at http://www.dh.gov.uk/ab/GTAC/index.htm; Medicines and Healthcare Products Regulatory Agency, available at http://www.mhra.gov.uk/#page=DynamicListMedicines.
[60] *Supra note 9.*
[61] Cloning issues in reproduction, science and medicine, available at http://www.dh.gov.uk/ab/Archive/HGAC/index.htm.
[62] *Id.*
[63] Stem Cell Research: Medical Progress with Responsibility, a report from the Chief Medical Officer's Expert Group reviewing the potential of developments in stem cell research and cell nuclear replacement to benefit human health, Department of Health (June 2000) available at http://www.lifecellinternational.com/downloads/whitepapers/stemcell_research_22.pdf.

for research generate more moral objections than spare embryos.[64] The report further proposed to "enact new legislation to ban CNR for reproductive purposes."[65]

Following these reports, Parliament approved the 2001 Human Fertilisation and Embryology (Research Purpose) Regulations to extend the legitimate purposes under Schedule 2, Section 3(1) of the HFE Act. Three conditions were added to obtain a license for research: "(a) increasing knowledge about the development of embryos; (b) increasing knowledge about serious disease; or (c) enabling any such knowledge to be applied in developing treatments for serious disease."[66] The regulation presents two clear deficiencies. First, according to the HFE Act of 1990, human cloning could potentially be permitted in the UK.[67] The public is uneasy about cloning humans and believes that it should have been strictly banned by regulation.[68] However, the 2001 regulation does not clearly outlaw the cloning of human embryos. Second, the definition of "serious disease" under Section 2(2)(c) might be narrowly read to preclude conditions such as injury or trauma.[69] Thus, some important therapeutic cloning, such as production of skin tissue, brain trauma or spinal cord injury, would not be allowed to develop in the UK.

Because the 2001 Regulation only extended the legitimate license purposes and did not answer the question of whether human embryos created by CNR fell within the definition of "embryo" under the HFE Act of 1990, the group Pro-life Alliance brought

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[64] *Id.*
[65] CNR for reproductive purposes means that a cloned embryo could be implanted in a womb and cloned fetus allowed to be born.
[66] Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (S.I. 2001 No. 188), accessed January 22, 2012, http://www.legislation.gov.uk/uksi/2001/188/contents/made.
[67] Wellcome Trust, Public Perspective on human cloning, available at http://www.wellcome.ac.uk/About-us/Publications/Reports/Public-engagement/wtd003422.htm.
[68] *Id.*
[69] Roger Brownsword, *Stem Cells, Superman, and the Report of the Select Committee*, 65 Modern L. Rev. 568-587 (2002).

a claim for judicial review.[70] In *Quintavalle v. Secretary of State for Health,* Crane J of the High Court held that fertilization is essential to the definition of an embryo[71] and that an organism produced by CNR does not have complete fertilization; therefore, the creation of human embryos through CNR falls outside the meaning of embryo in section 1 of the HFE Act of 1990.[72] Crane J also denied that section 3(3)(d) is effective in licensing of CNR by reason of fertilization.[73]

Although this narrow interpretation of the HFE Act of 1990 seemed to be an exemplary judgment, it was reversed by the Court of Appeal.[74] First, the lords explained the consistency between the rules that "statutory language retain the meaning" and that "a statute is always speaking" through the analogy that "If Parliament, passed an Act applicable to dogs, it could not properly be interpreted to apply to cats; but it could properly be held to apply to animals which were not regarded as dogs when the Act was passed but are so regarded now."[75] Additionally, the lords referred to the ruling in *Royal College of Nursing v. Department of Health and Social Security* that 'when a new state of affairs, or a fresh set of facts bearing on policy, comes into existence, the courts have to consider whether they fall within the Parliamentary intention'.[76] The lords also noted that the HFE Act was passed when embryos could only be created by fertilization and that the definition of embryo should be extended with the advance of technology. Finally, the court of appeal held that

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[70] LEE ROBERT GREGORY, HUMAN FERTILISATION AND EMBRYOLOGY: REGULATING THE REPRODUCTIVE REVOLUTION 2-345(1ST edn, Blackstone Press 2001).

[71] Section 1(1)(b) of the HFE Act of 1990 provides that: "the meaning of embryo, gamete and associated expressions in this Act, expect where otherwise stated, references to an embryo include an egg in the process of fertilisation".

[72] *Quintavalle v. Secretary of State for Health* [2001] 4 All E.R. 1013.

[73] Section 3(3)(d) of HFE Act of 1990 provides that: "a license cannot authorise replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person embryo or subsequent development of an embryo".

[74] *Quintavalle v. Secretary of State for health* [2003] UKHL 13.

[75] *Id.*

[76] *Royal College of Nursing of the United Kingdom v. Department of Health and Social Secutity* [1981] AC 800.

embryos created by CNR were within the ambit of the HFE Act. Aurora Plomer concluded that the judicial attempts to control HESC research under the HFE Act of 1990 exhibit "the weaknesses and deficiencies of precipitated legal intervention."[77] She suggested that the government rather than the court should be responsible for reviewing the HFE Act. Her opinion was cited in the legal challenge to the patentability of research involved human embryos.

Inventions related HESC: patentable or non-patentable?

One main difficulty faced by the UK is to create a rule regarding the patentability of inventions involving HESC. The UK Patent Act of 1977 was amended in 2000 to implement Article 1-11 of the Directive.[78] The 1995 Patent Rule and Plant Variety rights regulation was also changed to accord with Article 12-14 of the Directive.[79] In terms of HESC research, the question of how to interpret Article 6(2) of the Directive was left to the legislators. However, the 2000 patent regulation simply copied the wording of Article 6(2) of the Directive and did not expressly list the patentable inventions related to HESC. In 2003, the United Kingdom Intellectual Property Office (UKIPO) issued a practice statement to clarify this Article, prohibiting patents on human embryos or processes for deriving stem cells from a human being.[80]

Additionally, the approach adopted by the UKIPO is to exclude totipotent cells

[77] *Supra* note 45.
[78] The Patent Regulation 2000 (SI 2000/2037).
[79] The Patent Amendment Rules 2001 (SI 2001/1412) related to the deposit of, access to and re-deposit of biological material. Article 13-14 of the EU Directive; The Patents and Plant Variety Rights Regulations 2002 (SI2002/247) implemented Article 12 of the EU Directive.
[80] Inventions involving human embryonic stem cells, the United Kingdom Intellectual Property Office, available at http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm.

from patenting but to allow pluripotent cells to be patented.[81] The UKIPO noted that pluripotent cells have no potential to develop into human beings; therefore, inventions involving these cells are not within the scope of moral violation.[82] Aided by this narrow interpretation of the Directive, many inventions related to HESC were granted patents in the UK. According to a survey, the UKIPO played a pioneering role in granting downstream HESC derivatives.[83] Considering the permissive moral and legal culture in the UK, the UKIPO's interpretation of Article 6(2)(c) seems proper and effective.

Prohibition policy: German approach

Countries that adopted policies of prohibition often hold the opinion that human embryos have the status of human beings, conveying their skepticism toward biotechnology development through strict regulations. However, these strict regulations do not necessarily prevent all HESC research in these countries. In countries adopting restrictive policies, inconsistency between regulations and moral objectives might occur.[84] In the EU, this approach is widely accepted by Austria, Ireland, Italy and Germany. Among these countries, Germany offers a specific example of the prohibitive approach. Influenced by the devaluation of life during the Nazi era, the German constitution contains two provisions expressing the importance of human dignity.[85] These provisions could be viewed as the moral basis of the restrictive policy

[81] *Id.*
[82] Paragraph 3 (a) of Schedule A2 to the Patent Act 1977.
[83] A 2009 survey by A Plomer showed that almost 100 patents were granted to UK or non-UK residents by UKIPO. See *supra* note 40.
[84] For example, scientists in Italy are allowed to use cell lines obtained from abroad, which is against its moral value of the human embryo.
[85] The protection of human dignity and the right to life.

in Germany.

Protect the human embryo but allow importing embryo stem cell from abroad

German law is extremely restrictive of HESC research, as demonstrated by the definition of embryo in the German Embryo Protection Act (ESchG), which provides that "the fertilized human ovum which is capable of development after the nuclei have merged, also any totipotent cell extracted from an embryo capable – under the right circumstances – of dividing and developing into an individual."[86]

According to the ESchG, to protect human embryos, egg donation, pre-implantation genetic diagnosis (PGD)[87] and cultivation of more than 3 embryos are all prohibited.[88] However, the ESchG does not prohibit research on already harvested HESC because it is pluripotent. Because embryo stem cells can only be obtained by destroying embryos, it is paradoxical that the destruction of embryos is ethically forbidden whereas embryo stem cells are legal. Therefore, the German Research Foundation (DFG) recommended importing pluripotent embryonic stem cells from abroad. The DFG believes that doing so is "in principle admissible" because German constitutional law has no legal force outside of Germany.[89]

The main remaining dispute concerns whether importing HESC from abroad could be allowed. A report by the Parliamentary Study Commission on the Law and

[86] Section 8 of the German Embryo Protection Act.
[87] Pre-implantation genetic diagnosis (PGD) is "a technique that enables people with a specific inherited condition in their family to avoid passing it on to their children. It involves checking the genes of embryos created through IVF for this genetic condition". See PGD on Human Fertilisation and Embryology authority.
[88] The German embryo protection act, Federal Law Gazette, December 1990.
[89] Jan P Beckmann, *On the German debate on Human Embryonic Stem Cell research,* 29 J. Med. & Phil. 603-621 (2004).

Ethics of Modern Medicine suggested that embryonic stem cells should be completely prohibited even if they are imported from abroad.[90] However, the National Ethics Council proposed that imports of embryonic stem cells should be permitted for a period of three years under the condition that they are strictly regulated.[91]

In 2002, the legislature passed the Stem Cell Act (StZG) to "ensure the protection of embryos in connection with the importation and use of human embryonic stem cells."[92] StZG provides the basic principle that importation and use of embryonic stem cells is forbidden. However, StZG also decreed that imported stem cells meeting the following conditions could be licensed: (1) The lines were extracted from surplus embryos from in vitro fertilisations in the country of origin before 1 January 2002; (2) the persons entitled to disposal under the law of the country of origin have properly consented to the extraction of stem cells; (3) no remuneration or benefit in kind has been granted; (4) no other regulations, especially those of the ESchG, are violated.[93]

Without a license, importation or use of embryonic stem cells could be treated as a criminal offense.[94] Through setting limitations with the ban on importation and use of embryonic stem cells, German HESC research can be conducted without the destruction of embryos. German scientists need not move abroad to conduct their research, and German companies can invest money in this research. It is noteworthy

[90] Parliamentary Study Commission on the law and Ethics of Modern Medicine's report (n.103) at 102.
[91] National Ethics Council's Opinion at 17.
[92] The official title of the Stem Cell Act is "Act to Secure the Protection of Embryos in Connection with the Importing and Use of Human Embryonic Stem Cells". See Jan P Beckmann, *supra* note 88.
[93] Section 4, Para 2 of the Stem Cell Act.
[94] Section 13 of the Stem Cell Act provides that 'any person who imports or uses embryonic stem cells without having obtained approved pursuant to para 1 of section 6 above shall be punished with imprisonment of up to three years or shall be fined'.

that President Bush also borrowed this regulatory mode in his policy.[95] Nevertheless, StZG was criticized as adding problems in practice rather than resolving the controversy over HESC research.[96] One problem is that the difference in policy within and without Germany's geographical boundaries could be viewed as a double standard. Importing HESC might be viewed as "a convenient solution - the protection of the life of German embryos remains undiminished, but German scientists are enabled to act in an opportunistic manner, profiting from the destruction of embryos in other countries."[97] Another problem is that the rule that embryonic stem cells must have been extracted before January 2002 added the risk of contamination with mouse viruses.[98] Additionally, allowing derivation of imported HESC is to some extent condoning the destruction of the embryos.[99] Considering these restrictive clauses, StZG could merely be a temporary buffer in this scientific and moral conflict.

Case Oliver Brustle v Greenpeace - the patentability of Neuronal Precursor Cells

The case *Oliver Brustle v. Greenpeace* involved the validity of a patent regarding the Neuronal Precursor Cell.[100] In 1997, the patent granted to German neuroscientist Brustle claimed that the invention "isolated and purified neural precursor cells,

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[95] On August 9, 2001, President Bush announced that federal funds could only be used in the following circumstances: 'the derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 P.M. EDT on August 9, 2001; the stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed; Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements', human embryonic stem cell policy under former President Bush, available at http://stemcells.nih.gov/policy/2001policy.htm.

[96] Minou Bernadette Friele, *The case of German Stem Cell Laws' (2005) Transnational cooperation and national legislation*, available at http://www.hinxtongroup.org/au_trans_refs.html.

[97] Samantha Halliday, *a comparative approach to the regulation of human embryonic stem cell research in Europe, 12* Med. L. Rev. 40-69 (2004).

[98] Because successful culturing of human stem cells without mouse contamination is in 2003, but German scientists are only allowed to use human stem cells that were created before 2002. See Minou Bernadette Friele, The case of German Stem Cell Laws, Transnational cooperation and national legislation (2005).

[99] *Supra note 55.*

[100] Defined by Mr. Brustle in written observation, Neuronal Precursor Cells are 'immature cells which are capable of forming mature nervous system cells, such as neurons', see case *Oliver Brustle v. Greenpeace* C-34/10.

processes for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects."[101] After the Directive was issued, in 2004, Greenpeace sued for the revocation of the patent for the reason that neural precursor cells are harvested from human embryonic stem cells and that based on section 2 of the German Patent Law (GPL), the patent should be withdrawn.[102] In 2005, German patent law was changed to maintain consistency with the Directive. Thus, the core issue of this case changed to clearly elucidate Article 6(2) of the Directive in the German jurisdiction. The German Federal Patent Court (GFPC) ruled that the national patent conflicted with Article 6(2)(c) of the Directive, which prohibited patents on human embryos for industrial or commercial use.[103] Notably, the corresponding patent filed in the EU was granted by the EPO before this ruling.[104] The German patent was dismissed, and Mr. Brustle then appealed to the German Federal High Court of Justice (GFHCJ).

The GFHCJ decided to submit the case to the European Court of Justice (ECJ) and specifically asked for an interpretation of Article 6 of the Directive:

> 1.What is meant by the term "human embryos" in Article 6(2)(c) of Directive 98/44...? 2.What is meant by the expression "uses of human embryos for industrial or commercial purposes"? Does it include any commercial

[101] The German Patent DE 197 56 864; *Oliver Brustle v. Greenpeace* C-34/10.
[102] Section 2(2) of German Patent Act provides that 'patents are especially not granted for…the use of human embryos for industrial or commercial purposed'. This provision is transferred from Article 6(2)(c) of EU Directive.
[103] Martin Grund, Erik Richly and Stacey J Farmer, *the German Federal Patent Court Confronts the patentability of Human Embryonic Stem Cells,* 8 Bioscience law review 1-4 (2007) (Stating that the court has essentially rewritten the existing law to thereby impose a more stringent standard on patentability on embryonic stem cell technology than is actually required. In essence, by invoking the principles of ordre public, the GFPC has wrongfully excluded subject matter from patent protection that could otherwise be legitimately exploited under German Law.)
[104] Schneider Ingrid, *the ECJ judgment"bruestle v Greenpeace" (C-34/10). Importance and implications for Europe,* 3 Intell. Prop. J. 475-510 (2011)

> exploitation within the meaning of Article 6(1) of [Directive 98/44], especially use for the purposes of scientific research? 3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching.[105]

Answering the first question, the ECJ, referring to the preceding case *Monsanto v. Cefetra*[106], held that the Directive left almost no room for the discretion of national law. According to Recital 16 of the Directive[107], "human embryos" cover all stages "from the fertilisation stage to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body."[108] The blastocyst and unfertilized ova are both included in the concept of "human embryos".[109] However, pluripotent embryonic stem cells, with no potential to become human beings, are excluded from the definition of "human embryos" under Article 6(2)(c).[110] In terms of the second question, in accordance with the human dignity principle of the Directive, therapeutic or diagnostic uses are legitimate exceptions to non-patentable "uses of human embryos for industrial or commercial purposes".[111] With regard to the last question, the ECJ took the view that the description should be treated as an integral part. When obtaining neuron precursor cells entails the inevitable destruction of human embryos, patents

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105 Case *Oliver Brustle v Greenpeace* C-34/10, at 35.

106 Case *Monsanto v. Cefetra* C-428/08, para. 48 (providing that the body of rules laid down in Directive 98/44 is not complete, but must be deemed to be exhaustive in the area with which it deals: the corollary being that, in those areas, national legislation cannot provide for a level of patent protection which is wider than that provided for under the directive.)

107 Recital 16 of the Directive provides that 'it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented'.

108 *Supra note 62*, at 119.

109 *Id.*

110 *Id.*

111 *Id.*

must not be granted to the invention even if its claims do not contain any use of human embryos.[112]

As discussed in the previous case studies, the ECJ's ruling is undeniably similar to that of the EBA in terms of problems with patentability. Christopher Heath provided an explanation that if the ECJ has a different interpretation from that of the EBA, this would bring an uncomfortable situation: "the national courts would be bound by the ECJ in interpreting the patentability of national patents, whilst EBA would be bound by the EBA decision in determining patentability of a European patent application or European patent in appeal proceedings."[113]

2. Intermediate approach: Netherland policy

An intermediate approach between permissiveness and prohibition is usually the result of political and commercial balancing. One significant characteristic of this approach is that while embryos created for research are forbidden, surplus embryos from IVF are allowed. This approach to some extent has the effects of protecting human dignity and providing a safe environment for HESC research. Therefore, most European countries have formally adopted this approach.[114] However, policies made through this approach are "at risk of being ambiguous and internally inconsistent."[115]

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[112] *Id.*

[113] Christopher Heath, *case comment Germany: German Patent Act, sec.2; European Directive on the legal protection of biotechnological inventions, art.6(2)(c)-"Neural Precursor Cells/Brustle's Patent" (Neurale Vorlauferzellen),* 41 International Review of Intellectual Property and Competition Law 853-857 (2010).

[114] Charles Kessler, *European Policies and Priorities for stem cell research*, Remedie Project 2009, available at http://www.york.ac.uk/res/sci/events/FinalConfPres/Kessler.pdf.

[115] Rosario M Isasi and Bartha M Knoppers, *towards commonality? Policy approaches to human embryonic stem*

This approach is well developed in the Netherlands.

From Health Council report to the Dutch embryo Act: embryo created for research was not allowed

Similar to the Warnock report in the UK, a report by the Health Council provided advice on emerging IVF. Compared with the Warnock report, the Council agreed with the 14-day limit on permissible embryos in research.[116] However, the Council distinguished "the spare embryo" from IVF with embryos created for research.[117] Then, in a discussion about instrumental and non-instrumental uses of human embryos[118], the council expressed the view that human embryos could not be used or created for research.[119] The Christian Democratic Party (CDA) published a report titled "meaningful life" that opposed any instrumental uses of human embryos.[120] The report stated that "respect and protection of human life, irrespective of its developmental stage or manifestation, should be the cornerstone of our [Dutch] legal order."[121]

After this issue was hotly debated, the Dutch Embryos Act was finally passed in 2002. In the Act, the research use of supernumerary embryos is permitted within a three- to five-year moratorium.[122] As with the new technology CNR, an embryo is

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cell research in Europe in PLOMER AUROAR & PAUL TORREMANS, EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS (1st ed., Oxford University Press 2009).

[116] Gezondheidsraad (The Health Council), Interimadviesinzake IVF (s'-Gravenhage: Gezondheldsraad, 1984).

[117] *Id.*

[118] In this debate, instrumental use referred to use for research, whereas non-instrumental use was use for reproductive aims (such as IVF).

[119] Marta Kirejczyk, *Parliamentary Cultures and human embryos: the Dutch and British debates compared* 29 Soc. Stud. Sci. 889-912 (1999).

[120] The Christian Democratic Party, available at http://jonjayray.110mb.com/apr05.html

[121] *Id.*

[122] Section 32 of the Dutch Embryo Act 2002 provides that 'within three years of this Act entering into force, and every four years there-after, our Minister shall send a report to Parliament concerning its effectiveness and impact in practice'.

described as "a cell or a complex of cells with the capacity to develop into a human being."[123] Due to a declaration that only cloning of a person is forbidden, CNR was permitted by the Dutch Embryos Act provided that it satisfied all other provisions in the Act.[124] Additionally, the Dutch Embryos Act specifically listed legitimate purposes for research involving human embryos.[125] The Dutch Embryos Act was viewed as a compromise between moral objections to creating embryos for research use and potential benefits to certain categories of research.[126]

II. US: LIBERAL LEGAL FRAMEWORK WITH VARIOUS REGULATION IN THE STATES

Regulation of HESC operates at the federal and state levels of government. In general, the US has a liberal environment and has no uniform HESC regulation at the federal level.[127] Because the federal government has precluded coordinated efforts in this area, each state has developed its own regulations.[128] The HESC legal framework varies on one fundamental dimension: whether to permit or prohibit HESC research.[129] Some states widely permit HESC research, including somatic cell transfer.[130] Others do not explicitly prohibit reproductive cloning.[131] A small handful of states have

[123] Section 1 of the Dutch Embryo Act 2002.
[124] *Supra note 76*.
[125] Section 8 of the Dutch Embryo Act 2002.
[126] *Supra note 76.*
[127] Arif Jamil, *human stem cell research in Europe and the USA: post Brustle and Sherley, ethics issues and patent quagmire,* 2 NTUT J. of Intell. Prop. L. & Mgmt 145-166 (2013).
[128] Geoffrey P Lomax, Erik J Forsberg, Dan Gincel, Debra S Grega, Melissa J Lopes, Caroline J Marshall, Stefan Winkler and Warren Wollschlager, *policy harmonization through collaboration: The Interstate Alliance on Stem Cell Research* World Stem Cell Report 100-105 (2010), available at http://nas-sites.org/iascr/files/2013/01/Lomax_IASCR_2010_publication.pdf
[129] *Supra* note 2.
[130] E.g., New Jersey, California, Illinois.
[131] E.g., Arkansas, Virginia.

restrictive policies on HESC research.[132] Therefore, harmonizing the divergent HESC laws among the federal and state governments became important.

A. Regulation vacuum at the federal level

To pursue a competitive position in the HESC market, the legislation at the federal level in US is a vacuum in fact.[133] Moral opposition seems to have little impact on patenting inventions related to HESC research in the US. In light of prior rulings, HESC could not be patented due to morality issues; however, in 1980, the Supreme Court of the US opened the door to granting patents on "non-naturally occurring living substances" in *Diamond v. Chakrabarty.*[134] Since then, thousands of genes, animals and living materials have been granted patents. In 1987, the US Patent Office issued a notice clarifying that living organisms are patentable subject matter.[135]

The US Patent and Trademark Office Board (USPTO) of Patent Appeals and Interferences (BPAI) then shed further light on patenting human beings, explaining that "a claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C § 101."[136] The rationale behind this explanation is that patenting human life is similar to slavery. In 1998, the first human embryonic stem cell patent was granted with little moral objection.[137] Nevertheless, the

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[132] E.g., Oklahoma.
[133] *Supra* note 126 (concluding that the US does not have uniform state level laws and policies for human stem cell research and patent, but there are fewer complexities than in Europe).
[134] *Diamond v. Chakrabarty*, 447 US 303 (1980).
[135] US Patent and Trademark office Notice: Animals Patentability, reprinted in 1077 Official Gazette Patent and Trademark Office (7 April 1987) avaiable at http://www.uspto.gov/
[136] *Id.*
[137] David B Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15 Health Care Anal 211-222 (2007).

USPTO declared in a statement that "inventions directed towards human/non-human chimeras could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement."[138] According to *Juicy Whip, Inc. v. Orange Bang*, the United States Court of Appeals for the Federal Circuit held that the Patent Office should not play a role in determining whether an invention is moral.[139]

Adopted in 1980, the Bayh-Dole Act addressed the low utilization rate of government-owned patents.[140] This Act, sponsored by two senators, Birch Bayh of Indiana and Bob Dole of Kansas, was codified at 35 U.S.C. § 200-212.[141] The Bayh-Dole Act contains march-in provisions that could assure the commercial rights of grantees.[142] Aided by the Bayh-Dole Act, universities and small businesses rapidly established technology transfer groups and introduced experts in patenting

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[138] Media Advisory, US Patent and Trademark Office, Facts on Patenting Life Forms Having a relationship to Human, April 1 1998.

[139] Juicy Whip, Inc. v. Orange Bang, 185 F.3d 1364 (Fed. Cir.1999) (involving with a dispute on a patent. This patent owner is a beverage dispenser called post-mix beverage dispenser with an associated simulated display of beverage, Juicy Whip sued Orange Bang for patent infringement. The court held that patent lacked utility and was therefore unpatentable.)

[140] Wendy H. Schacht, *The Bayh-Dole Act: selected issues in patent policy and the commercialization of Technology* CRS Report for Congress Order Code 1-25 (2005) available at http://fas.org/sgp/crs/misc/RL32076.pdf.

[141] The Bayh-Dole Act, P.L.96-517, Section 200. The aim of this Act is to use "the patent system to promote the utilization of inventions arising from federally supported research or development, ...and to promote collaboration between commercial concerns and non-profit organizations, including universities..."

[142] 35 U.S.C. §203(a) states that "With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees; (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or (4) action is necessary because the agreement required by section has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section."

inventions.[143] The Bayh-Dole Act was widely viewed as achieving success in bringing new technologies to the public.[144] It aims to "give grantee inventors and those with whom they contract a reasonable degree of certainty."[145] In terms of HESC research, a system based on the "Bayh-Dole model" was created following the successes of California and Wisconsin.[146] In this system, stem cell lines were attempted to be placed in the public domain, which made them accessible to stem cell repositories or banks.

Based on the "Bayh Dole Model", there was patent inflation in the HESC area. In a 2002 speech, President Bush conveyed the worry of "human embryo farms"[147] and urged the US Senate to approve a total ban on the cloning of human embryos.[148] When the USPTO faced an application for a patent on a cloned or genetically modified human embryo, it applied the substantive part of the US Patent law, Title 35 of the United State Code, under which an invention is patentable if it satisfies patentable subject matter, novel, non-obvious and utility criteria.[149] In 1980, however, the United States Supreme Court opened the door to granting patents on "non-naturally occurring living substances" in *Diamond v. Chakrabarty.*[150] Since then, thousands of genes, animals and other living materials have been the subjects of patent protection. Some scientists hope that patents will be permitted on human embryos so that the scientists will have

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[143] Michael S Mireles, *states as innovation system laboratories: California, patents and stem cell technology,* 28 Cardozo L. REV. 1133-1159 (2006).

[144] See Ann L. Gisolfi and Anthony M. Insogna, *States fund stem cell research*, the national law journal, 13 June 2005, available at http://www.jonesday.com/files/Publication/3d2ce75f-3c86-4df2-976e-731d78366ece/Presentation/PublicationAttachment/00f6d721-ba2c-4178-bd0e-7995ef146491/stemcell_05132005.pdf; see also *supra* note 18.

[145] *Supra* note 2.

[146] *Id*.

[147] Using cloning technology, scientists could create billions of unfertilized human embryos for research or therapeutic use, called "human embryo farms".

[148] Bush backs ban on human cloning, 30 July 2002, available at http://abcnews.go.com/Politics/story?id=121416&page=1.

[149] Sections 101, 102, 103 of Title 35 of the United State Code.

[150] Diamond v. Chakrabarty, 447 US 303 (1980). (The application asserted 36 claims related to Chakrabarty's invention of a bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids. The patent examiner allowed the claims falling into the first two categories but rejected claims for the bacteria. His decision rested on two grounds: (1) that micro-organisms are products of nature and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101.)

the exclusive right to license others and collect royalty fees. Alta Charo, a support of human embryo patent from University of Wisconsin, pointed out that "investors hope for a return on their original investment with the basic research, but with no patent, there is no return."[151]

However, other experts hold different views. Congressman Dave Weldon, for example, believes that "no one should be able to own a human being at any stage of development."[152] Additionally, National Right to Life Committee (NRLC) chairman Douglas Johnson commented that "a member of the human family can never be regarded as a mere invention, or as intellectual property."[153] With their support, in 2004, the Weldon Amendment, contained in annual Commerce, Justice and Science Appropriation bills, was enacted, banning patents on human embryos for the first time. Section 518 of the Weldon Amendment states "None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism."[154] On September 16, 2011, the Weldon Amendment contained in the America Invents Act became an integral part of US patent law.[155] Granting a patent for a human embryo was permanently prohibited in the US under section 33 of this new law limiting the issuance of patents, which states that 'no patent may issue on a claim directed to or encompassing a human organism'.[156]

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[151] Congress bans patents on human embryos NRLC-backed Weldon Amendment survive BIO attacks, NRLC Federal legislation 2004, available at http://www.nrlc.org/killing_embryos/Human_Patenting/WeldonAmendmentEnacted.pdf .

[152] *Id.*

[153] *Id.*

[154] Alan Fram, *Panel Oks Anti-Abortion Provision* (the Washington post, July 14 2004) available at http://www.washingtonpost.com/wp-dyn/articles/A49778-2004Jul14.html.

[155] Jeremy Kryn, *amendment banning human embryo patents becomes permanent US law* (LifeSiteNews.com, September 20 2011) available at http://www.lifesitenews.com/news/congress-makes-amendment-banning-human-embryo-patents-permanent/

[156] America Invents Act of 2011, available at http://judiciary.house.gov/issues/issues_patentreformact2011.html

HESC regulation at the federal level remains a vacuum under the Bayh-Dole regime and the Weldon Amendment. The US position toward HESC is the liberal position on patent protection. There is no uniform regulation of procurement of embryos and the use of HESC lines at the federal level. A vacuum in HESC funding is also noticeable at the federal level.

B. Fill the vacuum in the state level-the example of California

Considering the sizeable tax and other benefits from the HESC industry, some states have stepped in to fill the vacuum. In the US, each state can have its own sets of definitions, rules, and regulations.[157] Certain states draw distinctions based on the source of the stem cells or add restrictions based on the purpose for which the research is conducted, while other states have yet to decide which research involving HESC to allow and which to restrict. New regulations are being proposed in many states. However, in those states that appear to have already settled on a position, HESC policies are still in considerable flux.

In 2004, 59.1 per cent of the California electorate endorsed Proposition 71, also known as the *Stem Cell Research and Cures Act* 2004 (California). This Act seemed to be a victory for scientists and research funding.[158] Proposition 71 was proposed as a

[157] For example, Massachusetts, Mass. Gen. Laws ch. 112 § 12 J (a) I; Michigan, Mich. Comp. Laws § 333.2685 (1); Minnesota, Min. Stat. § 145.422; North Dakota, N.D.Cent. Code § 14-02.2-01 (1); Pennsylvania, Pa. Cons. Stat. tit 18. § 3216 (a); Rhode Island, R.J.Gen. Laws § 11-54-1(a); South Dakota, S.D.Codified Laws §§ 34-14-16, 34-14-17.

[158] Elle Dolgin, *Stem cells: The impatient advocate* 468 Nature 620-623 (2010). (The approval of proposition 71 was mainly due to the efforts of Robert Klein, a California real estate developer whose son had juvenile diabetes. Klein used his huge wealth to underwrite Proposition 71's campaign and made a tremendous contribution to drafting and financing Proposition 71.)

response to the Bush administration's restrictive policy on HESC research. Based on this Act, a new state medical research institute, the Californian Institute for Regenerative Medicine, was established and the issuance of $3 billion in state general obligation bonds authorized to fund stem cell research and research facilities in California.[159]

The California Stem Cell Research and Cures Bond Act of 2004 (Proposition is worth reading closely, not only because California was the world's largest single backer of HESC research but also because it received strong moral opposition from religious Christian representatives.[160] This new legal model challenged the standard way in which public policy was formulated in federal level. It warranted a close examination and enabled voters to amend the law directly. Although many people believe that more direct democracy always leads to better policy, Proposition 71 not support that belief.[161] There are many lessons that could be learned from Proposition 71.[162] For example, it resulted in the circumvention of critical basic processes and the balkanization of research. It also concentrated too much power in a small group.[163]

The lack of federal funding has discouraged scientists from entering HESC research. Proposition 71 successfully fills the gap left by the lack of US federal funding.

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[159] MATTHEW RIMMER, INTELLECTUAL PROPERTY AND BIOTECHNOLOGY BIOLOGICAL INVENTIONS 360-390(Edward Elgar, Gheltenham 2007) (observing that Californian voters were upset that such funding of stem cell research could be hampered by patents)

[160] On November 2, 2004, California voters passed the California Stem Cell Research and Cures Bond Act of 2004

[161] Eileen Burgin, *embryonic stem cell research and Proposition 71*, 29 Pol. & Life Sci. 73 (2010). (noting that Proposition 71 is the outcome of direct democracy that was supported by 59% of voters.)

[162] Donna Gerardi Riordan, *Research funding via direct democracy: is it good for science?* Issues in science and technology (27 November 2013) available at http://www.issues.org/24.4/p_riordan.html.

[163] *Id.*

It uses an approach called obligation bonds, which are normally used in funding brick and mortar projects, to finance the research. HESC research is supported through a right under the state constitution through Proposition 71.[164] Proposition 71 created the California Institute for Regenerative Medicine (CIRM).[165] CIRM expanded the licensing authority under the Bayh-Dole regime, which is limited to "any contractor who is a non-profit research institution or a small business."[166] Based on Bayh-Dole, CIRM reserved the right of the funding agency and the march-in right. This new method has attracted both national and international researchers.

Although Proposition 71 is a huge success, it has significant deficiencies, especially its lack of clarity. For example, it does not state an adequate return on investment for taxpayers. It does not specify any social benefit for the citizens and public from the research.[167] What is worse, it authorizes the spending of 3 million dollars but does not specify any evaluation system. There is also growing concern about the conflict between the licensing regime under Bayh-Dole and CIRM regulations.

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[164] Proposition 71, California Stem Cell Research and Cures Initiative, Section 3, available at http://www.assembly.ca.gov/acs/committee/c15/Publications/Stem%20Cell%20background.doc. (stating that Proposition 71 is part of the state constitution rather than the state law and that the purpose of Proposition 71 is to protect and benefit the California budget by funding scientific medical research that will significantly reduce future state health care costs and provide an opportunity for the state to benefit from royalties, patents and licensing fees that result from the research. Proposition 71 has four key provisions: (1) The California Institute for Regenerative Medicine (CIRM) was established to regulate stem cell research and funding, and the Independent Citizen's Oversight Committee (ICOC) was established to govern CIRM; (2) Loans of up to 3 million dollars were provided for CIRM's initial administration and implementation costs, and bonds to annually finance CIRM were authorized (an annual limit of 350 million dollars up to a total of 3 billion; (3) A constitutional right to conduct stem cell research but one that prohibits funding of human reproductive cloning was established; (4) No amendments are allowed to statutes for the first three years and any repeal or amendment thereafter requires a legislative supermajority (70%).)

[165] The California Institute for Regenerative Medicine, available ata http://www.cirm.ca.gov/ (providing grants and loads for stem cell research, research facilities, and other vital research opportunities to realize therapies and establishing the appropriate regulatory standards of oversight bodies for research and facilities development.)

[166] See Bayh-Dole Act , NO. 96-1307, pt. 1, at 5 (1980).

[167] *Supra* note 36.

Moreover, the federal restrictions in the United States on funding HESC research led to inconsistent and perhaps unduly costly state funding mechanisms for HESC research.

However, Proposition 71 is California's answer to the federal restriction, developing policies to ensure that HESC research is conducted under the highest medical and moral standards.[168] An economic analysis concluded that Proposition 71 could generate economic benefits for California and the global society.[169] In the context of the vacuum at the federal level, Proposition 71 attempts to fill the gap between science and politics at the state level.

C. The Interstate Alliance on Stem Cell Research (IASCR): a venue for the states to cooperate

The varying policies on the derivation and use HESC lines threaten the cooperative attempt between states. In order to "advance stem cell research by fostering effective interstate collaboration, by assisting states in developing research programs, and by promoting efficient and responsible use of public funds has achieved important milestones", the IASCR was established.[170] The IASCR aims to "identify and increase opportunities for interstate collaboration; identify and decrease obstacles

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[168] Zach W Hall, *stem cell research in California: the intersection of science, politics, culture and law*, 10 MINN. J. L. SCI. & TECH. 1-18 (2008).

[169] Laurence Baker and Bruce Deal, Economic Impact Analysis Proposition 71 California Stem Cell Research and Cures Initiative, analysis group economic financial and strategy consultants (2004), available at http://www.analysisgroup.com/uploadedFiles/News_and_Events/News/Proposition_71_report.pdf.

[170] Geoffrey P Lomax, Erik J Forsberg, Dan Gincel, Debra S Grega, Melissa J Lopes, Caroline J Marshall, Stefan Winkler and Warren Wollschlager, *policy harmonization through collaboration: the Interstate Alliance on Stem Cell Research*, World Stem Cell Report 2010, available at http://www.iascr.org/about.shtml

to collaborative research across state lines; and assist state that wish to develop or improve upon public funding programs in this area."[171]

Efforts by the IASCR center on two areas: to "identify policies that spur economic development" and to "facilitate inter-jurisdictional collaborative partnerships".[172] As described, the IASCR may vertically integrate relevant regulations and blunt some sharp differences in research policies.[173] For example, the IASCR is crucial to the cooperation of Ohio and Maryland.[174] The IASCR also supports the development of private-public partnerships, such as the New York Stem Cell Foundation (NYSCF).[175]

Moreover, the IASCR promotes state investment in HESC research. State policy makers in Connecticut, for example, approved a 10-year, 100 million dollar funding program in June 2005, and lawmakers in New Jersey, Illinois, and Maryland have allocated state funds to support research in the field. Altogether, policy makers from at least 15 states have expressed interest in supporting stem cell research.[176]

CONCLUSIONS

As discussed, in HESC, hundreds of flowers bloom on multiple jurisdictional levels. This article observed that the EU patent regulations contain moral opposition

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171 *Id.*
172 *Id.*
173 Insoo Hyun, *the bioethics of stem cell research and therapy* 120 J. Clinical Investigation 71-75 (2010).
174 *Supra* note 64.
175 *Id.*
176 *Supra* note 67.

to HESC, while the US has no such clause. The EU tradition values bioethics and is rooted in moral values,[177] whereas the US tradition does not share these characteristics.[178] The moral-exclusion-fits-all approach of the EU Directive is not likely to yield the best result in the member states, which differ widely in social and cultural realities. The US position toward HESC is the liberal position on patent protection. There is no uniform regulation of procurement of embryos and the use of HESC lines at the federal level. A vacuum in HESC funding is also noticeable at the federal level.

The comparison of these areas also demonstrates that legal reconciliation is essential, whereas legal diversity is inevitable. To ensure efficiency and effectiveness, cultural, ethical and legal harmonization is indispensable. The restrictive legal framework cannot conclusively determine the adoption mode of member states. Continuing diversity at the national level will promote research and development in the field of HESC. A case in point is the US. The diverse regulations at the state level fill the vacuum at the federal level.

[177] Brian Salter, *Bioethics, politics and the moral economy of human embryonic stem cell science: the case of the European Union's Sixth Framework Programme*, 26 New Genetics & Soc'y 269-288 (2007). (indicating that the EU modes of ethics engagement become a political technology that constitutes a permanent feature of the new cultural politics as mechanisms are sought that will enable the refining, manipulating, resolving and legitimating of cultural differences.)

[178] David B Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15 Health Care Anal 211-222 (2007). (observing that patent examiners focus on technical questions concerning novelty, non-obviousness, utility, and disclosure, while the courts focus on policy questions related to economic development, competition, and scientific and technical innovation.)