

The Possible Impact of Legal Globalization on the ECJ Decision on Human Embryonic Stem Cell Patents and its Implications

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I. Introduction: From *Brüstle* to ISCC

On December 18, 2014, the Grand Chamber of the Court of Justice of the European Union (ECJ) lifted part of its more general 2011 ban on obtaining patents for human embryonic stem cells (hESCs), by ruling in *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks (ISCC)* that hESCs made from unfertilized eggs can be patented.¹ In this landmark case, the ECJ held that the moral exclusion of industrial and commercial uses of “human embryos” in Article 6(2)(c) in Directive 98/44/EC on the legal protection of biotechnological inventions, or the Biotech Directive, does not cover “parthenotes,” the unfertilized human eggs produced by parthenogenesis.²

This case arose when the United Kingdom’s Intellectual Property Office (UKIPO) refused to grant two national patents to International Stem Cell Corporation (ISCC), a California-based publicly traded biotech company. The UKIPO stated that these two patents growing out of parthenogenesis fell within the definition of the term “human embryo” adopted by the Grand Chamber in *Brüstle v. Greenpeace*.³ ISCC appealed, arguing that *Brüstle* did not apply because mammalian parthenotes can never develop to term due to a lack of paternal DNA.⁴ ISCC cited specific language in *Brüstle* that determines what might constitute a human embryo: “capable of

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1. Case C-364/13, *Int’l Stem Cell Corp. v. Comptroller Gen. of Patents, Designs, and Trade Marks*, EU:C:2014:2451 (Dec. 18, 2014).

2. *Id.* “Parthenogenesis” is a term describing the reproduction from an ovum without fertilization, a normal process in some invertebrates and lower plants.

3. “The first patent, GB0621068.6, entitled ‘Parthenogenetic activation of oocytes for the production of human embryonic stem cells,’ covered both the methods for producing pluripotent human stem cell lines from parthenogenetically-activated oocytes and the stem cell lines. The second application GB0621069.4, entitled ‘Synthetic cornea from retinal stem cells,’ included claims to methods and ‘product-by-process.’” Aurora Plomer, *Case C-364/13 – Patentability of Embryonic Stem Cells and Parthenotes: Inherently Uncertain?*, EUTOPIA LAW (Dec. 19, 2014), <https://eutopialaw.com/2014/12/19/case-c-36413-patentability-of-embryonic-stem-cells-and-parthenotes-inherently-uncertain/>.

4. *Id.* More specifically, ISCC argued that the parthenogenetically-activated oocytes are incapable of initiating the process of development of a human being due to the phenomenon of genomic imprinting. *Id.* Confronted with research suggesting that these hurdles could be successfully overcome by genetic engineering, ISCC amended the claims by introducing the

commencing the process of development of a human being,” to argue for a narrow interpretation including only those organisms capable of leading to a full human being, rather than a broad one which would also include organisms capable of commencing such process but incapable of leading to a full human being.⁵ The Chancery Division (Patents Court) of the High Court of Justice (England & Wales) decided that the appeal “raised a question of considerable importance” with regard to the meaning of the term “human embryos” in the Biotech Directive.⁶ Finally, the ECJ held that in order to be classified as a “human embryo,” a non-fertilized human ovum must have the “inherent capacity” of developing into a human being.⁷ Because an unfertilized human ovum whose division and further development have been stimulated by parthenogenesis lacks the “inherent capacity” to develop into a human being, it is not a “human embryo” within the meaning of the Directive, and stem cells derived from it are therefore patentable.⁸ Reasoning that the issues at stake are questions of fact answerable with reference to the state of scientific knowledge at the time of the decision, the ECJ allowed national courts to decide, on a case-by-case basis, whether parthenotes, in the light of “current scientific knowledge,” have the “inherent capacity” of developing into a human being and qualify for patent protection.⁹

While some may attribute the *ISCC* ruling to economic globalization or a fear of “brain drain,” it may be understood in the context of the globalization of law. This possibility raises two questions. First, did American laws and policies on hESC research and patents have any impact on the ECJ’s decision? Second, how might legal globalization affect the Court’s application of the “inherency” test to unexamined or new biotech inventions in the future?

Part II of this article will examine why American laws and policies on hESC research and patents may have had an impact on the ECJ decision, despite the lack of direct evidence of this impact. While the decision does not fully converge with American policy and rulings with regard to hESC research and patents, its partial lifting of the general ban on hESC patents signals a progression towards the American jurisprudence on these matters. Moreover, as Part II will explain, the possible impact of legal globalization coincided with the ECJ’s activist role to promote human rights in the EU by paying equal regards to all provisions of the Charter of Fundamental

word “pluripotent” before “human stem cell line” to exclude any possibility of genetic manipulation. *Id.*

5. Case C-34/10, *Oliver Brüstle v. Greenpeace e.V.*, 2011 E.C.R. I-09821 (Oct. 18, 2011).

6. *Int’l Stem Cell Corp v. Comptroller General of Patents* [2013] EWHC 807 (Ch) (17 April 2013) at para 5.

7. Case C-364/13, *Int’l Stem Cell Corp. v. Comptroller Gen. of Patents, Designs, and Trade Marks*, EU:C:2014:2451 (Dec. 18, 2014).

8. *Id.*

9. *Id.*

Freedoms for the European Union and the European Convention on Human Rights.

Part III will look towards the future by predicting how courts of various EU member states will apply the “inherency test” to determine the patentability of hESCs, and how the ECJ, in the era of legal globalization, may apply this test to unexamined or new biotechnological inventions. Although the ECJ does not dictate how its member states should apply the test, how various states, including Sweden, Germany, and Austria, will approach and apply it is very predictable. This Part will also explain why the 2014 decision may have revealed an interaction between civil law and common law features in the era of globalization, and how the ECJ may balance the interests of different parties as it applies the law to unexamined or new biotech inventions.

II. ISCC in the Context of Legal Globalization

The 2014 decision may be regarded as the result of economic globalization or more specifically, the fear of brain drain on the part of the EU. Indeed, the topic of brain drain emerged repeatedly as the EU and the U.S. revised their policies and laws with regard to stem cell research. For example, the 2006 agreement among science ministers to allow part of the Union’s expanded budget to be spent on hESC research led to the prediction that American scientists, dissatisfied with President George W. Bush’s restrictive policy on hESC research, would flock to Europe.¹⁰ President Obama’s 2009 Executive Order boosting domestic stem cell research funding likewise sparked fears among the European research community of a possible brain drain across the Atlantic in the opposite direction.¹¹ Reactions among European scientists to the *Brüstle* ruling were especially gloomy.¹²

The impacts of these policies and laws nonetheless have been overestimated. Critics noted that the interpretation of *Brüstle* was unnecessarily gloomy.¹³ First, because the Directive did not prohibit all stem cell research, it neither “prevented European firms developing technology platforms based on non-embryonic human stem cells nor has it precipitated a ‘brain-drain’ of European stem cell expertise to the US or Asia.”¹⁴ In addition, despite prior patent restrictions, firms that develop and sell human embryonic stem cell lines and their accompanying technology

10. Nicholas Watt, *US Faces Science Brain Drain After Europe Backs Stem Cell Funding*, THE GUARDIAN (July 25, 2009), <https://www.theguardian.com/world/2006/jul/25/eu.genetics>.

11. Ian Sample, *Obama to Lift Restrictions on Funding Stem Cell Research*, THE GUARDIAN (Mar. 8, 2009), <https://www.theguardian.com/science/2009/mar/09/stem-cell-research-lift-us-ban>.

12. Emma, *European Court Bans Stem Cell Patents*, EUROSTEMCELL (Oct. 18, 2011), <http://www.eurostemcell.org/story/european-court-bans-stem-cell-patents>.

13. Watt, *supra* note 10.

14. Michael Morrison, *The Patenting of Human Embryonic Stem Cells*, ESRC GENOMICS NETWORK (Nov. 21, 2011), <http://www.genomicsnetwork.ac.uk/egenis/news/25326>.

platforms have flourished and remained competitive.¹⁵ Without denying the role of economics, this article examines whether legal globalization may also have played a role in the *ISCC* ruling.

A. WHAT IS LEGAL/JUDICIAL GLOBALIZATION?

Because of globalization, legal problems tend to arise in similar ways, especially in advanced societies and economies, including the U.S., the EU, Canada, and Japan.¹⁶ National governments frequently look to their peers for solutions to these problems, leading to the convergence of national laws.¹⁷ Judicial globalization, or judicial interaction across borders, is one source of this convergence.¹⁸ It takes place either “vertically” between national and international tribunals, or “horizontally” across national boundaries, as the need for judicial cooperation in resolving transnational disputes has become more common.¹⁹

While processes like dispute resolution represent the most active types of judicial interaction, “cross-fertilization” of national judicial decisions is a common, more passive form of judicial globalization.²⁰ Judges use foreign law to support their arguments or legal reasoning, often without citation.²¹ The U.S. Supreme Court in particular, which almost never quotes other courts, is itself the most quoted among foreign courts due to its rich supply of ideas.²² Because “[c]ourts don’t do what they say and they don’t say what they do,” the use of foreign case law in different ways—both direct and more subtle—is likely more frequent than it seems to be.²³

B. THE AMERICAN JURISPRUDENCE ON HESC RESEARCH AND PATENT

American law and its judiciary possibly had an impact on the ECJ’s decision. One should note that hESC research and patentability in the U.S. were first approved through legislation. The U.S. Patent Act holds that

15. *Id.*

16. *See, e.g.,* Ralf Michaels, *Globalization and Law: Law Beyond the State*, DUKE LAW SCHOLARSHIP REPOSITORY (Jan. 2013), http://scholarship.law.duke.edu/faculty_scholarship/2862.

17. *See, e.g., id.*

18. Anne-Marie Slaughter, *Judicial Globalization*, 40 VA. J. INT’L L. 1103, 1103-04 (2000).

19. *Id.* at 1112.

20. *Id.* at 1116-19.

21. Marta Cartabia & Sabino Cassese, *How Judges Think in a Globalised World? European and American Perspectives*, GLOBAL GOVERNANCE PROGRAMME, at 1, 3 (Dec. 2013). Judicial networks have been established by the European legislature (EJN – European Judicial Network) as well as by judiciaries themselves, such as the conference of European Constitutional Courts and the International Association of Supreme Administrative Jurisdictions. *Id.* at 4-5. Academic institutions also set up forums where judges and academics meet in order to create bridges between research and practice. *Id.*

22. *Id.*

23. *Id.* at 4.

“[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”²⁴ This broad grant was limited by a few judicially recognized exceptions, namely, “laws of nature, natural phenomena, and abstract ideas.”²⁵ Later, the Supreme Court in *Diamond v. Chakrabarty* ruled that bioengineered living organisms were altered enough to deserve patent protection.²⁶ Following the *Chakrabarty* decision, the U.S. Patent and Trademark Office (USPTO) wrestled with the question of the patentability of other emerging forms of biotechnology, including those that are human-related. Its 1987 “Quigg Memo” considers that “[a] claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 USC 101.”²⁷ Notwithstanding this longstanding policy against the patenting of “entire” or “complete” human beings, the USPTO has allowed for patents on “living tissue, genetically modified cells, and other emerging forms of biotechnology,” such as isolated human genes.²⁸

With regard to hESC research, Congress banned the creation or destruction of human embryos for research purposes in 1996, and President George Bush signed an order in 2001 barring the National Institutes of Health from funding research on embryonic stem cells beyond using the sixty cell lines already in existence.²⁹ Nevertheless, President Obama’s Executive Order 13,505 (2009), entitled “Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,” repealed Bush’s order by casting such research as not ethically problematic.³⁰ More recently, the America Invents Act (AIA) of 2011 imposes a statutory limitation on patentable subject matter through its § 33(a), stating that “no patent may issue on a claim directed to or encompassing a human organism.”³¹ The

24. 35 U.S.C. § 101.

25. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l et al.*, 134 S.Ct. 2347, 2354-55 (2014).

26. *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

27. Jonathan R. K. Stroud, *Is Congress Politicizing Patents? Patenting Biotechnology in the Wake of Section 33, Prometheus, and CLS Bank*, FOOD & DRUG POL’Y F. at 4 (July 25, 2012).

28. *Id.* at 2-3. “This policy was put to test in 1997, when scientist Stuart Newman sought to obtain a patent for a human/non-human chimera,” in part to force the USPTO to clarify its policy regarding the patent eligibility of human organisms. Ava Caffarini, *Directed to or Encompassing a Human Organism: How Section 33 of the America Invents Act May Threaten the Future of Biotechnology*, 12 J. MARSHALL REV. INTELL. PROP. L. 768, 776 (2013). Although the USPTO rejected Newman’s patent application, stating that it would violate the Thirteenth Amendment’s ban on slavery and thus fail to meet the moral utility requirement under § 101, it did not deal with the issue of the percentage of genetic material required to make a patent application human-related.

29. *Timeline of Major Events in Stem Cell Research Policy*, RESEARCH AMERICA, <http://www.researchamerica.org/advocacy-action/issues-researchamerica-advocates/stem-cell-research/timeline-major-events-stem-cell> (last visited Aug. 14, 2015).

30. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

31. Leahy-Smith America Invents Act, PUB. L. NO. 112-29 §33(a), 125 STAT. 284, 340 (codified as amended at 35 U.S.C. §101 (2011)).

Congressional Record states that this amendment “simply reaffirms current U.S. patent policy,” that it “would not interfere in any way with any existing patents with respect to stem cells,” and that it would “not forbid funding research on embryonic stem cells, because a human embryo is an ‘organism’ but a stem cell clearly is not.”³² The USPTO also issued a memorandum stating that it viewed the amendment as “fully consistent with USPTO’s policy on the non-patentability of human life-forms.”³³ Hence, § 33(a) codifies the already existing policy by narrowly tailoring the patent exception to only very rare circumstances, such as attempts to patent entire human clones or human offspring for unethical, unsafe, or unconstitutional purposes.

The legality of hESC research and patents has not been challenged by the judiciary. In early 2013, the Supreme Court refused to step into the heated debate over hESC research by declining to hear *Sherley v. Sebelius*, in which two scientists challenged Obama’s 2009 order.³⁴ This lawsuit first arose in 2010, when James Sherley of the Boston Biomedical Research Institute and Theresa Deisher of Sound Choice Pharmaceutical Institute sued on behalf of “plaintiff embryos,” alleging that Congress had forbidden hESC research in 1996.³⁵ When the Court of Appeals for the Federal Circuit upheld the lower court’s decision ruling that the National Institutes of Health could legally fund hESC research, plaintiffs appealed to the Supreme Court.³⁶ The Supreme Court’s refusal to hear the case, though cannot be taken as its support for Obama’s order, allowed hESC research and patents to stay ethical. Most recently, in *Consumer Watchdog vs. Wisconsin Alumni Research Foundation* (2014), the Federal Circuit rejected Consumer Watchdog’s attempt to strike down a long-contested hESC patent held by the Wisconsin Alumni Research Foundation, by holding that Consumer Watchdog lacked standing to challenge the patent.³⁷ In February 2015, the Supreme Court

32. Stroud, *supra* note 27, at 4 (quoting 157 CONG. REC. E1, 177-80 (daily ed. June 23, 2011) (statement of Rep. Smith)).

33. *Id.* (quoting Memorandum from Robert W. Bahr, Senior Patent Counsel & Acting Assoc. Comm’r for Patent Examination Policy to Patent Examining Corps (Sept. 20, 2011), available at http://www.uspto.gov/aia_implementation/human-organism-memo.pdf).

34. Terry Baynes, *U.S. High Court Won’t Review Federal Embryonic Stem Cell Funds*, REUTERS (Jan. 7, 2013), <http://www.reuters.com/article/us-usa-court-stemcell-idUSBRE906IQ20130107>.

35. *Id.*

36. *Id.*

37. *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1263 (Fed. Cir. 2014); see Donald Zuhn, *Consumer Watchdog v. Wisconsin Alumni Research Foundation* (Fed. Cir. 2014), PATENTDOCS.ORG (June 5, 2014), <http://www.patentdocs.org/2014/06/consumer-watchdog-v-wisconsin-alumni-research-foundation-fed-cir-2014.html>. This case lasted for over eight years. In July 2006, Consumer Watchdog (CW) (then known as the Foundation for Taxpayer and Consumer Rights), along with the Public Patent Foundation, filed formal requests with the USPTO to revoke three patents held by Wisconsin Alumni Research Foundation (WARF), on the grounds that they are overreaching and “significantly undermine research and waste taxpayer money.” When the USPTO upheld the challenges for all three stem cell patents in 2007, agreeing with CW’s claim that WARF’s work was “obvious in light of previous scientific

denied Consumer Watchdog's petition to overturn the circuit ruling.³⁸ This decision, which does not examine whether hESCs are patentable, similarly left the legality of hESC research and patent intact. Meanwhile, although human stem cell patents in general do not go unchallenged, their patentability has earned support from the USPTO and the judiciary where the products are not naturally occurring.³⁹

C. THE ECJ, JUDICIAL ACTIVISM, AND HUMAN RIGHTS

Decisions of the ECJ in general “[o]ffer no direct clue as to whether they have been influenced by decisions of the U.S. Supreme Court” or any other foreign court.⁴⁰ Nevertheless, in certain important cases, the opinions of the Advocates General have made references to the Supreme Court, which then bore direct relevance to the ECJ decisions; alternatively, these references may have a dialectic function where the ECJ did not follow the AG's opinions.⁴¹ For example, in *Netherlands v. Parliament & Council*, the Netherlands brought an action for annulment of the Biotech Directive.⁴² AG Francis Jacobs cited *Diamond v. Chakrabarty* to assure that the Biotech Directive would “leave untouched” the “[c]lassic requirements for a patent of novelty, inventive step, and industrial application,” thus quenching the anxiety that “[a]ny gene or gene sequence, or even the entire human genome” would “automatically be patented.”⁴³ This opinion likely had a heavy influence on the ECJ, which finally ruled in favor of the defendant by

research,” WARF narrowed its patent claims to only include stem cells derived from “pre-implantation embryos,” which were eventually granted by USPTO in 2008 for all three patents. In 2008, CW filed an appeal to the USPTO regarding the '913 patent. In 2013, it further filed an appeal with the U.S. Federal Circuit to overturn USPTO's decision to uphold the '913 patent. On January 17, 2014, the USPTO responded to a request by the Federal Circuit panel concerning CW's standing, arguing that CW had no actual standing to appeal its decision to uphold WARF's patent as CW lacked any “concrete or particularized interest” in the issue at hand and failed to show any “injury or harm” to justify an appeal. Further, CW argued that the federal court did not satisfy the requirements for jurisdiction as specified by Article III of the U.S. Constitution and therefore had no judicial power to render judgment.

38. David Jensen, *California's Consumer Watchdog Loses U.S. Supreme Court Challenge to WARF Stem Cell Patents*, CAL. STEM CELL REP. (Feb. 24, 2015), <http://californiastemcellreport.blog.spot.ca/2015/02/californias-consumer-watchdog-loses-us.html>.

39. For example, in *Association of Molecular Pathology v. Myriad Genetics*, the Supreme Court, through a unanimous decision, held that while a naturally occurring DNA segment is a product of nature and not patent eligible, a complementary DNA, or cDNA, which corresponds to the naturally occurring DNA sequences except that certain of its non-coding sequences (“introns”) are removed, is not naturally occurring and therefore is patent eligible. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013).

40. Carl Baudenbacer, *Judicial Globalization: New Development or Old Wine in New Bottles?*, 38 TEX. INT'L L.J. 505, 516 (2003); see also Peter Herzog, *United States Supreme Court Cases in the Court of Justice of the European Communities*, 21 HASTINGS INT'L & COMP. L. REV. 903 (1998).

41. See Baudenbacer, *supra* note 40, at 516.

42. *Id.* at 513.

43. *Id.*

holding that the Directive was correctly adopted under Article 100a of the E.C. Treaty (now Article 95 E.C.).⁴⁴

Admittedly, there is no direct evidence as to whether the 2014 ruling was influenced by American law. Moreover, AG Cruz Villalón did not mention any American cases or statutes at all in his opinion. On the other hand, the fact that the ECJ was heavily influenced by AGs' references to American law in past decisions indicates that it may have considered American law and court cases like *Sherley*. Although the ECJ decision does not fully converge with American policy and rulings, its partial lifting of the general ban on hESC patents indicates its progression towards the American jurisprudence on hESC research and patents.

Yet judicial globalization may have had a more indirect impact on the ECJ decision, which went hand in hand with its effort to further its role in championing human rights in the EU. Scholars have noted how the ECJ has embraced the Supreme Court's role in the nationalization of American politics in its own contribution to the EU's integration through judicial activism. For example, Elizabeth F. Defeis notes that throughout its fifty year history, the ECJ has held in a series of cases that fundamental rights of individuals such as non-discrimination, freedom of religion, association, and expression, were enshrined in the general principles of its Community law.⁴⁵ It has also incorporated provisions of the European Convention on Human Rights (ECHR), decisions of the European Court of Human Rights, and the Charter of Fundamental Rights of the European Union into its human rights jurisprudence, noting that the principle aim of the Charter is to reaffirm rights as they result from constitutional traditions and international obligations common to Member States, the Treaty on the European Union, and the ECHR.⁴⁶

Whether in the U.S. or in Europe, hESC research and biotechnology in general have sparked fears that such innovations violate the sanctity of human life.⁴⁷ Further, hESC patents raise concerns that patients' access to the patented inventions will be limited by high costs as a consequence of monopolies.⁴⁸ But the right to conduct research and intellectual property rights are also derived from basic human rights. The American legislature and courts, by allowing patents except those encompassing human organisms, have striven to balance the right to conduct research and to own intellectual property with the sanctity of human rights and the right to

44. *Id.*

45. Elizabeth F. Defeis, *Human Rights and the European Court of Justice: An Appraisal*, 31 *FORDHAM INT'L L.J.* 1104, 1110 (2008).

46. *Id.* at 1110-11; see also Case C-540/3, *European Parliament v. Council of the European Union*, 2006 E.C.R I-5769.

47. See, e.g., Jessica Reaves, *The Great Debate Over Stem Cell Research*, *TIME* (July 11, 2001), <http://content.time.com/time/nation/article/0,8599,167245,00.html>; *Human Embryonic Stem Cell Research and Ethics*, *EUROSTEMCELL* (Mar. 4, 2011), http://www.eurostemcell.org/files/Human_ES_ethics_1.pdf.

48. See, e.g., Reaves, *supra* note 47.

access patented inventions. In contrast, until its 2014 ruling, the ECJ had not struck a similar balance. While the ECHR mentions neither human dignity nor intellectual property, Article 1 of its Protocol states that “[e]very natural or legal person is entitled to the peaceful enjoyment of his possessions.”⁴⁹ The Charter more directly addresses these issues. Although Article 1 states that human dignity is to be safeguarded, and Article 3 prohibits eugenic practices and human cloning, Article 17 safeguards the right to intellectual property.⁵⁰ By lifting part of its general ban on obtaining patents for hESCs in *ISCC*, the ECJ thus addressed and accommodated the right to conduct hECS research and patenting the products of such research by balancing it with the right to access new inventions and the dignity of human life.

III. Legal Globalization and the Likely Applications of the “Inherency” Test

Critics predict that national patent offices and courts will react differently to the ECJ decision.⁵¹ Although it empowered national courts to decide whether parthenotes have the “inherent capacity to develop into a human being,” it did not provide proper guidelines for the “inherency” test. As AG Villalón stated, Member States might still decide to ban the patenting of hESCs derived from human parthenotes in accordance with the more general exclusion in Article 6 (1) of the Biotech Directive on the grounds of public order and morality.⁵² In light of the different positions of Member States regarding the definitions of embryo and stem cell research, this discretion may lead to uncertainty. Further, one wonders whether a stored frozen human embryo has the inherent capacity to become a human being if it is never going to be implanted.⁵³ This section thus predicts how courts of various Member States will apply the “inherency test,” and how the ECJ may apply this test to unexamined or new biotech inventions.

49. *European Convention on Human Rights*, art. 1, Sept. 3, 1953, E.T.S. No. 005.

50. *Charter of Fundamental Rights of the European Union* art. 1, 3, 17, 2010 O.J. C 83/02.

51. Timo Minssen & AnaNordberg, *The Evolution of the CJEU's Case Law on Stem Cell Patents: Context, Outcome and Implications of Case C364/13 International Stem Cell Corporation*, 5 NORDIC INTEL. PROP. L. J. 493, 502 (2015). First, it remains unclear how the European Patent Office will react and how national patent offices will interpret the present decision in practice. The EPO, which is not an EU institution, is not formally bound by the Biotech Directive, nor is it obliged to accept the decisions of the CJEU. But, its Administrative Council introduced in September 1999 several of the relevant provisions of the Biotech Directive into the Implementing Regulations to the EPC (the “Rules”). For the sake of harmonization, it will likely mirror the *ISCC* decision in its guidelines for examination and implemented in its practice, which was the approach taken following the *Brüstle* decision.

52. Opinion of Advocate General Villalón, Case C-364/13, Int'l Stem Cell Corp. v. Comptroller Gen. of Patents, Designs, and Trade Marks, EU:C:2014:2014 (Dec. 18, 2014).

53. Aurora Plomer, *Case C-364/13 – Patentability of Embryonic Stem Cells and Parthenotes: Inherently Uncertain?*, EUTOPIA LAW (Dec. 19, 2014), <https://eutopalaw.com/2014/12/19/case-c-36413-patentability-of-embryonic-stem-cells-and-parthenotes-inherently-uncertain/>.

A. PREDICTING MEMBER STATES' NEW POLICIES ON hESC PATENTING

The hESC regulatory regimes in the EU countries are highly disparate. On the restrictive end, Germany prohibits embryo research and makes the importation of stem cell lines from other nations subject to a cut-off date.⁵⁴ Austria prohibits the procurement of cells from a human embryo for research purposes, but allows the use of pluripotent embryonic stem cells (which are capable of developing into any type of cell or tissue except those that form a placenta or embryo) that have already been established in a lawful manner, for example, in other nations, or outside the territorial scope of its law.⁵⁵ Similarly, Italy bans the derivation of hESC lines, but permits the use of imported ones for research.⁵⁶ On the more permissive end, France allows hESC research so long as specific conditions are met.⁵⁷ Portugal allows stem cell research and permits the use of frozen or surplus embryos created in-vitro for the derivation of hESC lines that would bring therapeutic and medical benefits to the community.⁵⁸ The U.K. and Sweden have remained the most aggressive promoters of hESC research: while forbidding reproductive cloning, both have comprehensive and well-established regulatory frameworks for stem cell research, and allow the use of IVF embryos, the destruction of these embryos to find new stem lines, and the creation of embryos through somatic cell nuclear transfer.⁵⁹

The responses of national courts to the *ISCC* ruling are not difficult to predict. Because Germany permits no hESC research at all, it will not allow the patenting of hESCs, including those derived from parthenotes. Austria and Italy, which permit the use of imported hESC lines for research, will more likely than not permit the patenting of hESC research output derived from parthenotes. First, parthenotes lack the “inherent capacity” to develop into a human being according to current scientific knowledge in these two

54. *Regulation of Stem Cell Research in Germany*, EUROSTEMCELL (Mar. 1, 2012), <http://www.eurostemcell.org/regulations/regulation-stem-cell-research-germany>.

55. *Regulation of Stem Cell Research in Austria*, EUROSTEMCELL (June 18, 2013), <http://www.eurostemcell.org/regulations/regulation-stem-cell-research-austria>.

56. *Regulation of Stem Cell Research in Italy*, EUROSTEMCELL (Mar. 1, 2012), <http://www.eurostemcell.org/regulations/regulation-stem-cell-research-italy>.

57. *Regulation of Stem Cell Research in France*, EUROSTEMCELL (Mar. 1, 2012), <http://www.eurostemcell.org/regulations/regulation-stem-cell-research-france>. The research must meet all four conditions: it is scientifically relevant; it is likely to allow major medical advances; it cannot be performed unless cells derived from embryos are used; it respects French ethical principles for research on embryos and embryonic stem cell lines. Embryos used for research must come from the assisted reproduction process (IVF) and informed consent must be obtained from the donors. *Id.*

58. *Regulation of Stem Cell Research in Portugal*, EUROSTEMCELL (Dec. 1, 2011), <http://www.eurostemcell.org/regulations/regulation-stem-cell-research-portugal>.

59. *Regulation of Stem Cell Research in the United Kingdom*, EUROSTEMCELL (Dec. 14, 2011), <http://www.eurostemcell.org/regulations/regulation-stem-cell-research-united-kingdom>; *Regulation of Stem Cell Research in Sweden*, EUROSTEMCELL (Mar. 1, 2012), <http://www.eurostemcell.org/regulations/regulation-stem-cell-research-united-kingdom>.

nations. Second, these two nations have legalized abortion since 1974 and 1978 respectively,⁶⁰ and therefore have little reason to prohibit, on the grounds of public order and morality, patenting hESCs made from unfertilized cells that have not even achieved the “embryo” status. Because France and Portugal allow hESC research under certain conditions, they will likely allow the patenting of parthenote-derived hESCs that are lawfully produced under these conditions. Finally, the U.K. and Sweden, both with progressive policies, will find no justification in banning hESC research and patents.

B. THE “INHERENCY” TEST AND UNEXAMINED AND NEW BIOTECH INVENTIONS

The question concerning the application of the “inherency” test to unexamined and new biotech inventions is more difficult to answer. Because the 2014 decision possibly revealed an interaction between civil and common law features in the era of globalization, legal globalization provides a framework for predicting how the ECJ may apply the “inherency” test to these inventions.

Scholars have attempted to lay out the major aspects of civil law and common law models as reflected in the EU and the U.S. legal systems respectively. For example, Charles H. Koch points out that the EU legal principles are largely founded upon the civil law model, the codes of which are the product of the “Age of Reason” and premised on the belief that life has an order.⁶¹ The drive for certainty and stability “emphasizes systemic values focusing on definitions and categorizations.”⁶² Such an emphasis on categorization is often criticized as “insensitive” and “static” by U.S. commentators whose modern jurisprudence focuses on balancing rather than categorization: “Balancing requires the explicit articulation and comparison of rights or structural provisions, modes of infringement, and government interests.”⁶³ Nevertheless, one needs to consider that the principle of proportionality originated in continental Europe and is one of the fundamental principles of the jurisprudence developed by the ECJ.⁶⁴ In

60. See Bundesgesetz vom 23. Jänner 1974 über die mit gerichtlicher Strafe bedrohten Handlungen (Strafgesetzbuch [StGB]) [Federal Law of 23 January 1974 on Punishable Acts (Penal Code [StGB])] (in force on Jan. 1, 1975, as last amended by Bundesgesetzblatt [BGBl] I No. 106/214, Dec. 29, 2014, Part I, No. 1974/60, Stück 21, pp. 641–92 (Austria) (available in English at <http://www.hsph.harvard.edu/population/abortion/Austria.abo.htm>); *Termination of Pregnancy and Abortion in Italy*, ANGLINFO, http://rome.angloinfo.com/information/health_care/pregnancy-birth/termination

61. Charles H. Koch, Jr., *Envisioning a Global Legal Culture*, 25 MICH. J. INT’L L. 1, 10 (2003).
62. *Id.* at 17–18.

63. *Id.* at 44.

64. The proportionality principle, according to which a public authority may not impose obligations on a citizen except to the extent to which they are strictly necessary in the public interest to attain the purpose of the measure, is the preferred procedure for managing disputes involving an alleged conflict between two rights claims, between a rights provision and a state or

addition, because the civil system by no means prohibits change, its categorization is an applied—not extreme—formalism that allows for certain degrees of creativity in interpretations and applications, especially in the age of globalization.⁶⁵

Despite using the case law method, the ECJ was established in principle on civil law principles. Hence its rulings resemble interpretative decisions by civil law courts more than creative ones by common law courts.⁶⁶ Because the *ISCC* ruling made no reference to the proportionality principle, it arguably contained an implicit balancing of rights and interests that possibly revealed the influences of the common law principles. By tapping into the ambiguity of *Brüstle*'s criterion of a human embryo as one that is “[c]apable of commencing the process of development of a human being,” *ISCC* pointed out, first, that there exist two interpretations, and second, that its narrow interpretation is preferable to its broad interpretation.⁶⁷ AG Villalón and the ECJ did not expressly conduct such a comparison. But AG Villalón impliedly endorsed *ISCC*'s logic and argument for the narrow interpretation by redefining “human embryo” as necessarily containing the “inherent capacity” of developing into a human being.⁶⁸ The ECJ did the same by following the AG's opinion. By refusing to strictly adhere to the definition in *Brüstle*, and by implicitly assessing two interpretations, the ECJ balanced the rights to intellectual property and to conduct research with respect for human dignity and the right to access inventions.

Recent technological advances may complicate the application of the “inherency” test. Scholars have mentioned, for example, the generation of hESCs from “non-viable”⁶⁹ “triploid zygotes”:⁷⁰ arising in approximately 5% of in-vitro fertilizations (IVF), these contain an extra set of haploid chromosomes of which prevent them from developing to term.⁷¹ Another example would be the patentability of blastocysts created by abnormal nuclear transfer, which cannot be implanted into the uterus but are capable

public interest (constitutional law), or between a private interest and a state or public interest (administrative law). This principle originated in continental (in particular German) administrative law, but is also connected to the new wave of (liberal) constitutionalism that has spread worldwide since the Second World War. Tor-Inge Harbo, *The Function of the Proportionality Principle in EU Law*, 16 *EUROPEAN L. J.* 158, 158 (2010).

65. See Koch, *supra* note 61, at 18.

66. See, e.g., *id.* at 38; Anita Frohlich, *The European Union as a Mixed Legal System*, *COMPARELEX* (June 5, 2014), <https://comparelex.org/2014/06/05/the-european-union-as-a-mixed-legal-sytem/>.

67. Case C-34/10, *Oliver Brüstle v. Greenpeace e.V.*, 2011 E.C.R. I-09821 (Oct. 18, 2011).

68. See Opinion of Advocate General Villalón, Case C-364/13, *Int'l Stem Cell Corp. v. Comptroller Gen. of Patents, Designs, and Trade Marks*, EU:C:2014:2014 (Dec. 18, 2014).

69. “Viability” refers to the potential to develop through gestation to birth.

70. Organisms whose cells contain a distinct membrane-bound nucleus, and are formed by fertilization between two gametes and containing three homologous sets of chromosomes.

71. Gerard Porter, Chris Denning, Aurora Plomer, John Sinden & Paul Torremans, *The Patentability of Human Embryonic Stem Cells in Europe*, 24 *NATURE BIOTECHNOLOGY* 653, 655 (2006).

of generating customized embryonic stem cells.⁷² One further example would be hESCs created by using a discarded IVF supernumerary, which is a fertilized egg.⁷³

How would the ECJ apply the “inherency” test to unexamined or new biotech inventions? Where fertilized cells, such as non-viable triploid zygotes and blastocysts are involved, the European Patent Office and the ECJ would need to consider whether viability is a necessary condition for the cells to be classified as an “embryo.” This leads to two options: Either viability is a necessary condition for the inherency test, or it is not. Given current scientific development—neither non-viable triploid zygotes nor blastocysts created by abnormal nuclear transfer can develop into human beings—the ECJ would likely consider viability to be a necessary condition for the “inherency” test. Thus, it would likely consider hESCs derived from both types of cells to be patentable. The ECJ could also achieve this result by assessing and balancing the rights of different parties: because the fertilized cells cannot develop into human beings and therefore cannot be said to have human dignity, the right to claim property in hESCs derived from these new inventions would win the balance of these rights.

What about the use of a discarded IVF (in vitro-fertilized) supernumerary—a fertilized egg—to create hESCs?⁷⁴ Because this method involves a viable fertilized egg, which would pass the inherency test, hESCs created through this method should not be patentable. Yet a further complication may occur because among these fertilized eggs, or pre-embryos that are in deep freeze, some of the post-thaw pre-embryos may be deemed “unviable” and thus lacking the inherent capacity of developing into a human being.⁷⁵ The ECJ may then consider the interests of various parties and adjust the balance as it applies the law to different scenarios.

IV. Conclusion

This article has explained how legal globalization provides a framework to understand the ECJ ruling in *ISCC*. America’s laws and policies on hESC research and patents may have had some impact on the ECJ decision, an impact that went hand in hand with the Court’s activist role in its promotion of human rights in the EU. In the future, the ECJ may need to apply the “inherency” test to unexamined or new biotech inventions. It would likely

72. *Id.* Blastocysts are structures formed in the early development of mammals. They possess an inner cell mass that subsequently becomes the embryo.

73. *E.g.*, Anna Nordberg & Timo Minssen, *A “Ray of Hope” for European Stem Cell Patents or “Out of the Smog into the Fog”? An Analysis of Recent European Case Law and How It Compares to the US*, 47 INT’L REV. INTELL. PROP. AND COMPETITION L. 138, 138 n. 24 (2016).

74. *E.g.*, *Stem Cell Research*, UNIV. OF MICH., <http://www.stemcellresearch.umich.edu/overview/faq.html> (last visited Oct. 7, 2016).

75. *E.g.*, *Embryo & Blastocyst Grading: Which to Transfer, Which to Discard*, SHER FERTILITY, <http://haveababy.com/fertility-information/ivf-authority/embryo-blastocyst-grading-which-to-transfer-which-to-discard> (last visited Oct. 7, 2016).

adopt a mixed, creative approach towards these inventions, which may reveal the influences of common law influences upon civil law traditions in the era of globalization.