PATENTABILITY AND REGULATION OF STEM CELLS – THE NEED FOR AN EU-WIDE COMPROMISE ON MORALITY

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Abstract

Today, stem cell research is a swiftly growing area of medical research, with significant projected growth in the global stem cell market due to their diverse applications and increased funding and development efforts. Stem cells have a unique ability to self-renew and recreate functional tissues, receiving warranted attention from the public and the bio-pharmaceutical industry. However, with this great potential, there are also profound moral dilemmas as it relates to the use and destruction of human embryos. In the context of international patent law, the regulation and management of stem cell research presents a critical challenge in balancing the promotion of innovation with these ethical considerations, raising questions on the ethical boundaries of innovation and how each society places morally relevant status on the human embryo process.

This Note draws attention to the conflict between having a globally impactful research paradigm within an infrastructure that is designed to operate on a national basis. Due to this conflict, each territory can use "morality clauses", utilizing vague allusions to morally relevant status of the human embryo in law and practice, to establish confusing and albeit contradictory regulations and policies that are impacting human embryonic stem cell research and its patentability outcome. It recognizes that, although the E.U. and North America on its face have different patterns of regulation, patent law needs to adopt a form of standardization in their respective territories. Because of such, it highlights the need for a more coherent and navigable system to acknowledge and encourage legitimate

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research, reduce discrepancies between countries, and enable policy guidance to supervise and monitor the implementation within each country to have positive effects on the international research field.

I. INTRODUCTION

Stem cell research is widely known for its positive influence on regenerative medicine and changing the way modern medicine approaches treating blood disorders, combating neurodegenerative diseases, drug development, and tissue engineering.[1] The research has rightfully received significant public attention because of its ability to revolutionize medicine through new perspectives, and with this heightened attention, it also emphasizes the profound moral dilemmas as it relates to the use of human embryos and the broader discourse of abortion.[2]

In the United States ("U.S."), patents are an exclusive right granted for invention, this right aims to promote innovation and development of new

1. *Stem Cells: What They Are and What They Do*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stem-cells/art-20048117 (last visited Feb. 2, 2024).

2. *See generally* Rebecca Dresser, *Stem Cell Research as Innovation: Expanding the Ethical and Policy Conversation*, 38 J. LAW, MED. & ETHICS 332 (2010).

products in our society through the protection of individual creations and intellectual property.[3] On the contrary, in Europe, patents are a privilege granted by the governments in pursuit of specific economic or technological objectives.[4] Each country independently governs patent law, and there is no single international patent that applies universally.[5] This allows each country to establish its own criteria for what it will grant patent protection over.[6] Due to the countries' different influences and motivations by seeing one as a fundamental right and the other as a privilege, there are naturally different approaches to the regulation of patents.

In the context of international patent law, the regulation and management of emerging technology, like stem cell research, presents a critical challenge in balancing the promotion of innovation with ethical considerations. As science and medicine have progressed, stem cell research has developed into a highly controversial method of innovation by extracting a human embryo at an early stage of development.[7] Because of stem cells' ability to self-renew and recreate functional tissues,[8] stem cells have gotten the attention of the public and the bio-pharmaceutical industry, raising questions on the ethical boundaries of innovation and how each society places morally relevant status on the human embryo process.[9]

This article does not aim to argue the morally relevant status of the human embryo, rather it argues that such vague allusions to it in law and practice often create confusing and diverse regulations and policies that impact human embryonic stem cell research and its patentability outcome. Unclear standards, especially within the E.U., should not create the precedent for this emerging and influential field because the protection of intellectual property is a field that encourages growth.

Therefore, although the E.U. and North America on its face have different patterns of regulating, patent laws, especially within the E.U., should adopt a form of standardization to modify patent law in their respective territories to have a more coherent and navigable system by: (1) acknowledging legitimate research, (2) reducing discrepancies between countries, and (3) enabling policy guidance to supervise and monitor the

3. *See Patents*, WIPO, https://www.wipo.int/patents/en/ (last visited Feb. 25, 2025).

4. COUNCIL OF THE ROYAL SOCIETY, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE 7-8 (The Royal Society 2003).

5. WIPO, *supra* note 3.

6. *Id.*

7. *See generally* Deitmar Mieth, *Going to the Roots of the Stem Cell Debate*, 1 EMBO REP. 4 (2000).

8. *Stem Cell Basics*, NAT'L INSTS. OF HEALTH (NIH), https://stemcells.nih.gov/info/basics/stc-basics (last visited Feb. 2, 2024).

9. *See* Mieth, *supra* note 7.

implementation within each country to have positive effects on the international research field.

Section II will create a foundational understanding of stem cells. Following this, Section III will discuss the North American regulations of current federal and state embryonic stem cell patents. Section IV will then address the European Union's stem cell regulation through the E.U. Biotechnology Directive ("Directive") and European Patent Convention ("EPC") and how the E.U. should have harmonized their patent system. Lastly, Sections V through VII will address why the current practices in the U.S. and the E.U. fall short and thus do not reap the three benefits of standardization. This note will argue that by adopting a standard process, both the U.S. and the E.U. would benefit from the goals of patent law, which is progress and innovation.

II. STEM CELLS

Stem cells are cells that all other specialized cells in the body generate from.[10] Stem cells divide, either in the body or the laboratory, to form more cells.[11] These cells would then either be specialized cells or new stem cells.[12] Specialized cells have more specific functions in the body, such as blood, brain, liver, heart, or bone cells.[13] This is the only cell type capable of generating new cell types.[14]

Typically, there are two types of stem cells: embryonic and adult stem cells.[15] Embryonic stem cells come from embryos that are three to five days old when an embryo is a blastocyst made up of 150 cells.[16] These 150 cells are pluripotent, meaning that they can divide into more stem cells or into specialized cells.[17] This unique trait is what makes research with them so special and versatile. The versatility at this early stage of stem cell development allows for regeneration and or repairability of diseased tissue and organs.[18]

10. MAYO CLINIC, *supra* note 1.
11. *Id*.
12. *Id*.
13. *Id.*
14. *Id.*
15. *Id.*
16. *Id*.
17. *Id.*
18. *Id.*

Adult stem cells are undifferentiated cells that are essential for healing, growth, and replacement of lost cells.[19] Although these undifferentiated cells may be useful for specific areas of the body, they do not have the capability of differentiating into any cell type unless they have been genetically reprogrammed to act as embryonic stem cells.[20] Additionally, due to the artificial nature of reprogramming, there are unclear effects in humans and the cells are more susceptible to immune rejection.[21] This is a major disadvantage to researchers and often leads researchers to try to avoid them, even though it is the less controversial alternative because the use of them does not involve creating, using, or destroying human embryos.[22]

Opponents of embryonic stem cell research typically do not encourage patents because of ethical reasoning.[23] The reasoning is deeply rooted in public policy motivations, such as the argument against creating, using, or destroying human embryos.[24] However, allowing embryonic stem cell research does not mean disrespecting ethical and legal principles. There is a way to engage public policy and influence the opponents of stem cell research, while still encouraging legitimate research practices and reducing discrepancies between territories and nations.

III. HISTORY AND DEVELOPMENT OF UNITED STATES STEM CELL REGULATION

The history of United States stem cell regulation is marked by evolving policies shaped by scientific advancements. The United States Patent and Trademark Office ("USPTO") provides the statutory framework for the field and case law interprets such regulations and has recently developed to reflect the ethical considerations and societal concerns regarding the scope of stem cell patents.[25]

19. Wojciech Zakrzewski, Maciej Dobrzyński, Maria Szymonowicz & Zbigniew Rybak, *Stem Cells: Past, Present, and Future*, STEM CELL RSCH. THERAPY 10, 68, 3 (2019).

20. *Id.*

21. *Id.* at 16.

22. *Id.*

23. *See generally* Dresser, *supra* note 2.

24. *Id.*

25. Sarah E. Fendrick & Donald L. Zuhn Jr., *Patentability of Stem Cells in the United States*, 5(12) COLD SPRING HARBOR PERSPECTIVES IN MED. 1, 2 (2015).

A. United States Legal Framework

The USPTO shapes stem cell innovation because it provides the statutory framework that delineates the parameters for patentability.[26] Title 35 of the United States Code, titled "Patents," provides the USPTO the authority to perform its functions in examining applications, determining patentability, and issuing patents.[27] Additionally, Title 35 sets forth the comprehensive U.S. legal framework for the USPTO to enforce and define the rights and obligations of patent holders and the public. Specifically, section 101 defines what constitutes patentable subject matter, stating "Whoever invents or discovers any new and useful process, machine, manufacturer, 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."[28]

The Leahy–Smith America Invents Act ("AIA")[29] addresses the patentability of stem cells. AIA states that a claim directed to or encompassing a human organism is not patentable.[30] Through its legislative history, the AIA further acknowledges that the "U.S. Patent Office has already issued patents on genes, stem cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses."[31] This has allowed the Supreme Court to distinguish exceptions to section 101's broad patent-eligibility principles but statutorily establishes that stem cells are patent-eligible.[32]

B. Case Law

United States stem cell regulation has recently evolved through Supreme Court case law. A patent applicant who is dissatisfied with the final decision in an appeal to the Patent Trial and Appeal Board may appeal the Board's decision to the United States Court of Appeals for the Federal Circuit.[33] The

26. *Id.*

27. 35 U.S.C. § 1-390 (2018).

28. 35 U.S.C. § 101 (2018).

29. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

30. *Id.*

31. MPEP § 2105, at 2100-12 (9th ed. Rev. March 2014); 157 CONG. REC. E2417-01, at E1179 (daily ed. 2011) (statement of Rep. Dave Weldon, previously presented in connection with the CONSOLIDATED APPROPRIATIONS ACT, 2004, Pub. L. No. 108-199, § 634, 118 STAT. 3, 101, and later resubmitted regarding the AIA).

32. *Id.*

33. 35 U.S.C. § 141(a) (2018).

Supreme Court may also issue decisions that may narrow the patentability of the subject matter and even can impose new limitations.[34] *Funk Bros. Seed Co. v. Kalo Inoculant Co.* identifies three exceptions to the USPTO statutory framework.[35] This case establishes that laws of nature, physical phenomena, and abstract ideas are not patent-eligible.[36]

Previously, the USPTO had consistently accepted the patentability of stem cells or their related technologies.[37] In both *Chakrabarty*[38] and *In re Bergy*,[39] the USPTO and the United States Court of Customs and Patent Appeals ("CCPA"), respectively, facilitated a path and provided guidance for securing patent protection for innovations in the biotech industry.

The claims at issue in *Chakrabarty* was a genetically engineered *Pseudomonas aeruginosa* bacterium, which was determined to be patent-eligible because it had markedly different characteristics from any bacterium found in nature.[40] In claims at issue in *In re Bergy* related to the "biologically pure culture" of the microorganism *Streptomyces vellosus*, the CCPA held that the biologically pure culture was not a product of nature and patentability is not affected by the microorganism being alive.[41] Following the precedent and legal framework provided by these two cases stem cells were then found to be patent-eligible.[42] The first human embryonic stem cell patents were issued to James Thomson of the University of Wisconsin, nearly twenty-years after the rulings in *Chakrabarty* and *In re Bergy*.[43]

The United States Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[44] and *Association for Molecular Pathology v. Myriad Genetics, Inc.*[45] further defined the bounds of patent-eligible subject matter under 35 U.S.C. Section 101. These recent decisions resulted in the USPTO issuing the *Myriad-Mayo* Guidance, implementing a new procedure involving a three-step analysis: (1) Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories:

34. 35 U.S.C. § 144 (2018).

35. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

36. *Id.*; *see also* Diamond v. Diehr*,* 450 U.S. 175, 185 (1981).

37. Yvonne Shyntum & Edward Kalkreuter, *Stem Cell Patents—Reexamination/Litigation—The Last 5 Years*, 15 TISSUE ENG. PART B REV. 87, 87-88 (2009).

38. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

39. *In re* Bergy, 596 F.2d 952 (C.C.P.A. 1979).

40. *See* Diamond, 447 U.S. at 310.

41. *Bergy*, 596 F.2d at 975.

42. *See id.*; *See* Diamond v. Chakrabarty, 447 U.S. 303.

43. U.S. Patent No. 5,843,780 (filed Jan. 18, 1996); U.S. Patent No. 6,200,806 (filed June 26, 1998); U.S. Patent No. 7,029,913 (filed Oct. 18, 2001).

44. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

45. Ass'n. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

process, machine, manufacture, or composition of matter?[46] (2) Does the claim recite or involve one or more judicial exceptions identified by the Supreme Court in *Diehr* (i.e., laws of nature, physical phenomena, or abstract ideas)?[47] (3) Does the claim as a whole recite something *significantly different* than the judicial exceptions?[48]

The first major challenge to the patentability of stem cells came when the USPTO initially rejected the Wisconsin Alumni Research Foundation ("WARF") matters because independent inventors had already patented the embryonic stem cells.[49] Upon reexamination, the USPTO granted all three requests based on a "substantial new question of patentability" and subsequently rejected them as anticipated and/or obvious.[50] WARF then narrowed its patent claims to only include stem cells derived from preimplantation embryos and those were determined to be patentable subject matter.[51]

These matters were all independently viewed by the USPTO and decisions could not be appealed because they were ex parte reexaminations, which are final decisions.[52] During the reexamination period, the patents are presumed valid, allowing research to continue, and "increase its IP estate" by continuing to file follow-on inventions that further define the field, needing each one to strengthen the next.[53] Therefore, although public interest groups challenged stem cell patents, the three original WARF patents have been upheld.[54] By allowing follow-on patents, original, or base patents, may emerge in a stronger position if challenged within the USPTO because they are secured with additional patent protection resting on it.[55] However, the issue of patentability of stem cells has yet to be addressed in federal courts.[56]

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46. U.S. PATENT & TRADEMARK OFFICE, GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENON & NATURAL PRODUCTS (2014).

47. *Id.*

48. *Id.*

49. Robert Williams and Bridget Hogan had already patented stem cells in 1992 or at least described them on applications in 1992 and 1994, respectively. Katja Triller Vrtovec & Christopher Thomas Scott, *Patenting Pluripotence: The Next Battle for Stem Cell Intellectual Property*, 26 NAT. BIOTECHNOLOGY 393, 393 (2008) (referencing U.S. Patent No. 5,166,065 (filed Aug. 3, 1989); U.S. Patent No. 5,453,357 (filed Oct. 8, 1992); U.S. Patent No. 5,690,926 (filed Mar. 25, 1994)).

50. Fendrick & Zuhn, *supra* note 25, at 5.

51. *Id.*

52. *Id.*

53. Vrtovec & Scott, *supra* note 49, at 394.

54. *Id.* (referencing Plomer, A., Taymor, K. & Scott, *Challenges to Human Embryonic Stem Cell Patents* C.T. STEM CELL 2, 13 (2008)).

55. *Id.*

56. *See generally Consumer Watchdog v. Wisconsin Alumni Research Foundation*, 753 F.3d 1258 (2014) (showing the issue of the patentability of stem cells is yet to be addressed when

As seen through the development of case law and the statutory regulations, the USPTO seems to have fewer issues with the flow of information when deciding the patentability and reexamination. Coordination within the 50 states is less important in patent law because it does not respond to independent territorial court systems and is instead handled federally by the USPTO and the designated federal courts for appeal. This creates a unitary court procedure, bypassing the need for coordination with individual state law. This also allows states to create whatever restrictions on the research of embryonic stem cells they may choose, but the research is still capable of being done in another state and deemed patent-eligible by the same federally organized system in the U.S.[57]

IV. EUROPEAN UNION

The European Union's ("E.U.") patent system represents an attempt to harmonize intellectual property protection across member states.[58] Although it attempts to streamline and foster innovation and economic growth, the framework instead relies on loose morality clauses to define patent rights across the E.U.[59]

The legal guidance that governs patents on biotechnological inventions in Europe is the European Patent Convention and the E.U. Biotechnology Directive 98/44/EC on the legal protection of biotechnological inventions.[60] The European Patent Convention ("EPC")[61] is a multinational treaty protecting thirty-nine Member States of the European Patent Organization and providing an autonomous legal system for European patents to be

Consumer Watchdog appealed the *inter partes* reexamination decision to the United States Court of Appeals for the Federal Circuit because the '913 patent was ineligible subject matter as it fell within the "product of nature" exception, drawing similarities to *Myriad* and that WARF did not create or alter the properties of the claimed stem cells. The Federal Circuit dismissed the appeal for lack of Article III standing because it was not engaged in any activity involving human embryonic stem cells that could form the basis for an infringement claim, did not allege that it intended to engage in such activity, and did not allege that it was an actual or prospective licensee or that it had any other connection to the '913 patent or the claimed subject matter. In its decision, the question of stem cell patentability was not addressed); *see* U.S. Patent No. 7,029,913 (filed Oct. 18, 2001).

57. C.J. Murdoch, *Intraoperability Problems: Inconsistent Stem Cell IP and Research Regimes Within Nations*, 3 STAN. J. L. SCI. & POL'Y 49, 53 (2011).

58. *Id.* at 50.

59. *Id.* at 51.

60. Convention on the Grant of European Patents (European Patent Convention) art. 63, Oct. 5, 1973, 13 INT'L LEGAL MATS. 268 (1974), revised by Act Revising Article 63 EPC of Dec. 17, 1991, and Act Revising the EPC of Nov. 29, 2000 [hereinafter EPC]; Council Directive 98/44, Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 (EC) [hereinafter Biotech Directive].

61. *See* EPC, *supra* note 60.

granted.[62] It serves as the E.U.'s attempt to harmonize patent law using transnational treaties to regulate the patentability of stem cells.[63] The most relevant sections to patent-eligibility of stem cells within the EPC are Rules 26[64] to 29, and so long as applications are in accordance, biotechnological inventions are typically patentable.[65] The Directive is used as a supplement for the interpretation of these rules.[66]

The Directive, implemented on July 6, 1998, was intended to systematize the laws of member states regarding the patentability of biotechnological inventions.[67] It also includes exceptions from patentability, stating that patents contrary to *ordre public* and morality are excluded from patentability.[68] In full it states:

> (1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so merely because it is prohibited by law or regulation.
>
> (2) On the basis of [the above] paragraph 1, the following, in particular, shall be considered unpatentable:
>
> (a) processes for cloning human beings;
>
> (b) processes for modifying the germ line genetic identity of human beings;
>
> (c) uses of human embryos for industrial or commercial purposes;
>
> (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.[69]

Relevant to stem cell research, Article 6, subsection 2(c) states that "uses of human embryos for industrial or commercial purposes" are excluded from patentability.[70] The intent at the time was to prohibit patents claiming techniques for the cloning of human beings, faced with intense political pressure from animal welfare activists and environmentalists in 1995 when

62. Member States of the European Patent Organization, EUROPEAN PATENT OFFICE, https://www.epo.org/en/about-us/foundation/member-states (last visited Feb. 16, 2025).

63. Murdoch, *supra* note 57, at 50.

64. EPC, *supra* note 60, at 348-50.

65. EPC, *supra* note 60, at 348-54.

66. Biotech Directive, *supra* note 60.

67. *Id.*

68. *Id*. at art. 6(1).

69. *Id.* at art. 6.

70. *Id*. at art. 6(2)(c).

it was first put before the European Parliament.[71] However, as stem cell research has increased, this article is now being used to exclude stem cell patents.[72]

All E.U. Member States also did not fully implement the Directive into national law until 2007.[73] This was because some Member States were not as keen to allow patents for biotech innovations.[74] The lack of uniformity among the Member States is due to different interpretations based on cultural and philosophical circumstances.[75]

Importantly, there is a morality clause included in Article 6, subsection 1 that makes it even more difficult to identify a uniform understanding of "*ordre* public" and "morality" across different jurisdictions because its interpretation varies from country to country.[76]

Brüstle vs. Greenpeace Case, Docket No. X ZR 58/07 is an important application of Article 6, subsection 2(c).[77] The German Patent Act adopted the Article 6, paragraph 2 directive of 98//44/EC on the legal protection of biotechnological inventions and the German Federal Supreme Court interpreted the directive in *Greenpeace* in 2012 when deciding whether neural precursor cells, originating from human stem cells, are patentable.[78] Brüstle filed for a patent in 1997 and received one in April 1999 from the German Patent and Trademark Office ("DPMA").[79] The patent was specific to the protection of neural precursor cells, which is a procedure to cultivate the cells and use them in therapies for neural defects in humans and animals.[80] According to the patent, the neural precursor cells were derived from embryonic stem cells and those could be obtained from an embryo at an early stage of development, resulting in the destruction of the embryo.[81] Greenpeace filed a nullity action against the patent based on public policy and common moral principles.[82] The German Federal Supreme Court on

71. Duncan Curley, *Stem Cell Patenting in Europe – the Twilight Zone*, 4 GENOMICS, SOC'Y & POL'Y 1, 2 (2008).

72. *See id.* at 5-6.

73. Murdoch, *supra* note 57, at 51 (citing Robert Fitt, *New Guidance on the Patentability of Embryonic Stem Cell Patents in Europe,* 27 NAT. BIOTECHNOLOGY 338, 338 (2009)).

74. *Id*.

75. *Id*. at 50.

76. *Id*. at 51 (citing Biotech Directive, *supra* note 59, at art 6).

77. Entscheidungen des Bundespatentgerichts [BPatGE] [Federal Patent Court] Dec. 17, 2009, X ZR 58/07 [hereinafter Brüstle Case] (Ger.).

78. Nicholas A. Zachariades, *Stem Cells: Intellectual Property Issues in Regenerative Medicine*, 22 (Suppl. 1) STEM CELLS & DEV. 59, 61 (2013).

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

appeal requested a preliminary ruling by the Court of Justice of the European Union ("CJEU") on the interpretation of the terms "human embryo" and "use of human embryos for industrial or commercial purposes."[83]

The CJEU arrived at three conclusions regarding the "human embryo."[84] The first is that a "human embryo" is any ovum[85] once fertilized, including creation by transfer of a nucleus from another mature cell or stimulated to cell division by parthenogenesis.[86] The Court also held that harvesting cells from embryos that have fully and finally ceased to develop further is not what the directive targeted, and so they are patent-eligible.[87] Finally, the court concluded that human stem cells that are harvested without destroying an embryo are not embryos themselves because they lack the potential to develop a human being, and thus patent-eligible.[88]

However, in *International Stem Cell Corporation v. Comptroller General of Patents*, the European court said "in order to be classified as a 'human embryo,' a non-fertilized human ovum must necessarily have the inherent capacity of developing into a human being" and that "[t]he mere fact that [parthenogenetically-activated human ovum] commences a process of development is not sufficient for it to be regarded as a human embryo."[89] In effect, the press release differs from the decision in the Greenpeace case because the process of parthenogenesis was seen as a sufficient process of development to be sufficient to be regarded as a human embryo.[90] The ruling

83. *Id.*; BGH, Dec. 17, 2009, Xa ZR 58/07, (Ger.) https://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=2009-12&Seite=1&nr=50583&anz=288&pos=52&Frame=4&.pdf.

84. Zachariades, *supra* note 78, at 61.

85. *See* The Editors of Encyclopedia Britannica, *Ovum*, ENCYCLOPEDIA BRITANNICA (last updated Dec. 9, 2023), https://www.britannica.com/science/ovum (Ovum is a single cell released from either of the female ovaries that can develop into a new organism when fertilized with a sperm cell).

86. *See* The Editors of Encyclopedia Britannica, *Parthenogenesis*, ENCYCLOPEDIA BRITANNICA (last updated Nov. 13, 2023), https://www.britannica.com/science/parthenogenesis; Zachariades, *supra* note 78, at 61.

87. Zachariades, *supra* note 78, at 61-62.

88. *Id.*

89. Int'l Stem Cell Corp. v. Comptroller Gen. of Patents, Designs & Trade Marks, Case C-364/13, ECLI:EU:C:2014:2451, ¶ 28 (CJEU Dec. 18, 2014), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62013CJ0364.

90. Court of Justice of the European Union, Press Release No. 181/14, Judgment in Case C-364/13, *Int'l Stem Cell Corp. v. Comptroller General of Patents, Designs and Trademarks* (Dec. 18, 2014), available at https://curia.europa.eu/jcms/upload/docs/application/pdf/2014-12/cp140181en.pdf.

lifts the ban on obtaining patents for embryonic stem cells, as established in the 2011 judgement in *Brüstle vs. Greenpeace*.[91]

Other significant case law has established that patents are not permitted for stem cells that can only be obtained through the destruction of an embryo. In November 2008, a ruling by the EPO's highest appeal board, the Enlarged Board of Appeal ("EBA"), rejected an application from the Wisconsin Alumni Research Foundation ("WARF") for a patent of five stem cell lines.[92] Further, this decision makes clear that research on embryos or downward variants resulting from the destruction of embryos that carry the potential to develop into a human being is morally wrong and should not be protected.[93] Despite this decision coming directly from the EPO, there is no indication of whether derivative products originally derived from destructed embryos may be patent-eligible.

A. United Kingdom

Contrary to the E.U., the United Kingdom (U.K.) is more permissive with its patent laws and regulation of research. The U.K. Intellectual Property Office ("UKIPO") updated its policy in February 2009 to harmonize with the European Patent Office EBA's WARF decision, that no stem cells or procedures that come about exclusively by the destruction of embryos or that are derived therefrom may be patented.[94] The UKIPO also includes distinctions between totipotent and pluripotent stem cells.[95] Human stem cells not derived from human embryos, such as pluripotent cells and adult stem cells, are patent-eligible.[96] Meanwhile, because totipotent cells have the potential to develop into an entire human body, they are not patent-eligible.[97]

91. Ewen Callaway & Alison Abbott, *European Court Clears Way for Stem-Cell Patents*, 516 NATURE (2014), https://www.nature.com/articles/nature.2014.16610.

92. EUROPEAN PATENT OFFICE, ENLARGED BOARD OF APPEAL, Decision G 2/06 of 25 Nov. 2008, 2009 O.J. EPO 306, at 2 (EUR. PAT. OFF.), https://www.epo.org/boards-of-appeal/decisions/pdf/g060002ep1.pdf (citing Mats G. Hansson et al., *Isolated Stem Cells—Patentable as Cultural Artifacts?*, 25 STEM CELLS 1507, 1507 (2007), https://academic.oup.com/stmcls/article/25/6/1507/6402321).

93. Hansson, *supra* note 92, at 1508.

94. UK Intellectual Property Office, *Statutory Guidance: Inventions Involving Human Embryonic Stem Cells* (Mar. 25, 2015), https://www.gov.uk/government/publications/inventions-involving-human-embryonic-stem-cells-25-march-2015/inventions-involving-human-embryonic-stem-cells-25-march-2015.

95. Murdoch, *supra* note 57, at 52.

96. Aurora Plomer, *Stem Cell Patents: European Patent Law and Ethics Report*, 69 (July 28, 2006), https://www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf.

97. UKIPO, *supra* note 94.

V. STEM CELL PATENT REGULATION NEEDS TO ENCOURAGE LEGITIMATE RESEARCH PRACTICES

Stem cell patents are important for the future of medicine and if countries block those patents, they will also block research and find themselves left further behind in medical technology and lose out on economic opportunities.[98] Through recent years, the global healthcare innovation landscape has evolved, with the U.S. and Asia setting the pace by implementing policies that encourage innovative thinking by adopting a unitary patent system.[99] However, the E.U. relies on the UPC, adding another judicial layer,[100] encouraging the protection of what they deem to be a fundamental right, focused on the destruction or lack of, a human embryo.[101]

While fundamental rights are important, the balance between dignity and innovation is creating less than earnest research practices. The innovation is continuing, whether a country wants to protect it or not, because the funding and researchers are going to where it is allowed, creating monopolies.[102] The prevalence of patent restrictions not only undermines the intended incentives for innovation but also contributes to the creation of unjustified monopolies, posing a serious challenge to fair competition.[103]

Countries need to consider their statutory interpretations while acknowledging and considering the promotion of legitimate research practices. Legitimate research practices, including objectivity and respect for patents, can foster innovation and streamline the intellectual property landscape. Antitrust law seeks to promote and maintain market competition and if stem cell patents can further create monopolies, then competition will dwindle transnationally.[104] Patent and antitrust law must work together to achieve the proper balance to achieve stability in the field and become

98. COUNCIL OF THE ROYAL SOCIETY, *supra* note 4, at v.

99. Aurora Plomer, *The Unified Patent Court and the Transformation of the European Patent System*, 51 INT'L REV. INTELL. PROP. & COMPETITION L. 791, 795 (2020), https://doi.org/10.1007/s40319-020-00963-6 (citing European Patent Office, *EPO 2018 Statistics*, EUROPEAN PATENT OFFICE, https://www.epo.org/about-us/annual-reports-statistics/annual-report/2018/statistics/granted-patents.html (last visited Feb. 3, 2025); World Intellectual Property Organization, *WIPO Facts and Figures 2019: International Patent Applications* (2019), https://www.wipo.int/edocs/infogdocs/en/ipfactsandfigures2019/).

100. Plomer, *supra* note 99, at 796.

101. Myrthe G. Nielen, Sybe A. de Vries & Niels Geijsen, *European Stem Cell Research in Legal Shackles*, 32(24) EMBO J. 3107, 3108 (2013), https://www.embopress.org/doi/epdf/10.1038/emboj.2013.249.

102. *See* Plomer, *supra* note 99, at 794-95.

103. *Id.*

104. *See id.* at 796.

complementary, as both are aimed at encouraging innovation, industry, and competition.[105]

This balance is already inherent in the basic structure of the United States patent system by limiting the duration of the patent. "[T]he Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any accompanying advance in the 'Progress of Science and useful Arts.'"[106] According to a report by the United States Federal Trade Commission, questionable patents are a significant competitive concern and are ones that can harm innovation.[107] The high level of controversy surrounding stem cell patents makes this subject-matter contentious. Its validity is already in doubt as case law has been developing in both the U.S. and the E.U., creating reasonable doubt in the path forward for the field.

Additionally, poor-quality patents can harm innovation and competition by deterring rival groups from entering or continuing research within specific areas.[108] Although the patent system in the United States appears to be self-correcting and the U.S. Patent and Trademark Office is responsive to concerns raised in the industry, frequently updating guidelines and resources in the biotech field, adverse impacts of questionable patents are still developing.[109]

Alternatively, scholars have also argued that the development of anticommons can harm innovation.[110] Anticommons is when too many people own pieces of one thing, such that nobody can use it.[111] There is also the possibility of underuse when governments allow too many people the rights to exclude others through privatization.[112]

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105. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf (quoting Atari Games Corp. v. Nintendo of Am., 897 F.2d 1572, 1576 (Fed. Cir. 1990)).

106. FTC, *supra* note 105, at 3, note 9; *see* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 147 (1989) (explaining that federal patent laws embody "a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy").

107. *See* FTC, *supra* note 105, at 5.

108. *Id.*

109. *Id.*

110. *Id.*

111. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998), https://www.science.org/doi/epdf/10.1126/science.280.5364.698.

112. *Id.* (citing Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets,* 111 HARV. L. REV. 621, 624 (1998)).

Biomedical privatization can lead to an increase in intellectual property rights leading to a stifling of life-saving innovation further downstream in the course of research and product development.[113] As the United States patent system has shifted, large research institutions, such as the National Institute of Health, and commercial biotechnological firms have the resources to privatize their research and heavily restrict their use.[114] The problem then forms when a user needs access to multiple patented inputs to create a single useful treatment or product.[115] This would also create monopolies, increase prices, and restrict the use at the top, not allowing others to benefit on the way down.[116]

The natural production of monopolies is possibly a side effect of patent law. By nature, it is more restricted in its ability to create a network to bundle multiple licenses compared to other fields of intellectual property, building corporate value in the 'knowledge economy.'[117] Patent law is more prevalent in the pharmaceutical and biotechnology industries, and these are also the industries that are worried about competitors undermining the gains from exclusivity and have a lack of substitutes for their biomedical discoveries.[118]

This creates diverging interests based on how the money is being distributed and the interests it carries. As Heller and Eisenberg note, a public and/or politically accountable government agency would want to use their intellectual property rights to ensure widespread availability and engage in transactions relevant to their ultimate governmental purpose.[119] By contrast, private dollars drive private institutions and firms and are more likely to use intellectual property to maintain a product monopoly to further block the strategies of others.[120] U.S. legislation has attempted to mitigate the stark differences we see between the two driving forces through the Bayh-Doyle Act.[121] The Act enables universities, small businesses, and non-profit

113. Heller & Eisenberg, *supra* note 111, at 698.

114. *Id*. (citing Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 82 VA. L. REV. 1663 (1996), https://repository.law.umich.edu/cgi/viewcontent.cgi?article=2223&context=articles; Martin Kenney, *Biotechnology: The University-Industrial Complex* 198–99 (Yale Univ. Press 1986)).

115. Heller & Eisenberg, *supra* note 111, at 699.

116. *Id.*

117. COUNCIL OF THE ROYAL SOCIETY, *supra* note 4, at 7 ¶ 3.1.

118. Heller & Eisenberg, *supra* note 111, at 700 (citing Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson & Sidney G. Winter, *Appropriating the Returns from Industrial Research and Development*, BROOKINGS PAPERS ON ECON. ACTIVITY, at 783-84 (1987), https://www.brookings.edu/wp-content/uploads/1987/12/1987c_bpea_levin_klevorick_nelson_winter_gilbert_griliches.pdf).

119. Heller & Eisenberg, *supra* note 111, at 700.

120. *See id.* at 698.

121. *See* Bayh-Dole Act, 35 U.S.C. §§ 200-212.

research institutions and organizations to pursue ownership of their inventions that are developed under federally funded research.[122] This was very difficult to do beforehand and by mitigating the diversion of money interest, the U.S. has created a more equitable research practice.

The E.U.'s response to the threat of monopolies is the Directive.[123] The Directive is derived from European patent law aimed at preventing the grant of patent monopolies for inventions that would be morally repugnant to the public if exploited by the patentee.[124] The English Statute of Monopolies of 1624 declared all monopolies to be contrary to law and that any exceptions would be a privilege and determined by the common law.[125] As a general prohibition, patents serving a term of fourteen years or under were not to be prejudiced.[126] With the root of the Directive being in protecting against monopolies, the goal was to protect innovative interests but to balance against the possibility of over-protection and the creation of monopolies and unwanted side effects.

The creation and management of monopolies can also be rooted in the US and E.U.'s differing understanding of the purpose of a patent. In the United States, inventors generally view patents as an almost absolute or natural right.[127] On the contrary, in Europe, patents are a privilege granted by governments in pursuit of specific economic or technological objectives. Naturally, this makes the U.S. more patent-friendly than the E.U.[128]

When a country has stricter patent regulations on stem cell-based inventions, it reduces the country's competitive position against other economies that may more liberally apply morality exclusions. Researchers are then driven to apply for patents in the region that is the most flexible and liberal about their morality exclusions.[129] Countries, then that are losing prominent research, are bound to find ways to move around the laws and regulations.[130] For example, Japan includes a morality exclusion on patents but seems to not adhere to it when it comes to the patenting of human embryonic stem cell ("ESC") related inventions.[131] Similarly, the Court of

122. *See id.*

123. *See* Duncan Curley, *Stem Cell Patenting in Europe – the Twilight Zone*, 4(3) GENOMICS, SOC'Y & POL'Y Apr. 2008, at 2, 3.

124. *Id.* at 3.

125. *See* English Statute of Monopolies, 1624, 21 Jac.I, c.3.

126. Ronan Deazley, *Commentary on the Statute of Monopolies 1624*, in PRIMARY SOURCES ON COPYRIGHT (1450-1900) (Univ. of Birmingham, UK 2008), https://www.copyrighthistory.org.

127. COUNCIL OF THE ROYAL SOCIETY, *supra* note 4, at 7 ¶ 3.4.

128. *Id.* at 7-8 ¶ 3.4.

129. *See* Nielen et al., *supra* note 101, at 3109.

130. *Id.*

131. *See id.*

Justice of the European Union is being asked to clarify its decision to prevent the patenting of stem cell research involving the use and destruction of human embryos because the ban is claimed to be deterring investment in Europe, while competitors in Asia and the U.S. can continue unhindered research using embryonic stem cells.[132]

By driving the majority of patents in this area to centralized locations, innovative thinking is driven to be centered in these areas as well.[133] This creates future roadblocks for the ways our pharmaceutical industry interacts with different academic and research-based institutions.[134] Industries that exist in the international specter are lured by a level playing field with uniform standards of patentability between European and U.S. industries. However, one of the main differences preventing harmony is the fundamental importance that each assigns to patents, creating different priorities.

The monopolistic nature of patents means that patent holders are typically trying to capitalize off limiting the rest of the market's access to insulate the patent owners from competition, which with such sensitive subject matter, may result in unethical practice.[135] If stem cell regulation encouraged patent stability and rather encouraged competition and equitable research practices, stem cell patents would be part of a more standardized patent system because it would put more control in the government's hands, as "custodians of the public interest" to monitor the activities and utilize the licensing and competition law to engage in a moral approach from the beginning.[136] Additionally, it would create an environment for governments to work more closely together, not relying on individualized approaches to achieve responsible use of stem cells.[137]

Therefore, the E.U. should balance its morality clauses more leniently to be cautious of creating monopolies within the patent system. There are more flexible approaches, as seen in China and Japan to mitigate the morality clauses and embrace innovative thinking to still have the E.U. be another epicenter of innovation on the stem cell patent front.

132. *See* Zachariades, *supra* note 78, at 62.
133. *See* Nielen et al., *supra* note 101, at 3109.
134. *Id.*
135. *See* COUNCIL OF THE ROYAL SOCIETY, *supra* note 4, at 10 ¶ 3.19.
136. *Id.*
137. *See id.*

VI. THE E.U. SHOULD CREATE A MORE ACCESSIBLE PATENT SYSTEM TO AVOID CONFUSION BETWEEN COUNTRIES, RESEARCHERS, AND BIOPHARMACEUTICAL COMPANIES

The accessibility of the patent system is a frequent source of confusion between countries, researchers, and companies regarding the enforcement of such patents. The lack of a universal patent system results in non-harmonized laws that rely on individual countries engaging in patent disputes and accepting judgments from other nations' courts, particularly within the E.U. By creating a practice that encourages harmonizing protocols, patent applications, and patent disputes would be a more efficient, cheaper, and more realistic option for parties, leading to more consistency throughout governments.[138] Although this issue may be present in all areas of patent law, it is especially prevalent in matters concerning stem cell patentability because of the wide array of morality exclusions and application of the law that exists in the E.U.

The Patent Cooperation Treaty[139] ("PCT") is an attempt at addressing this problem.[140] The PCT allows for one patent application to apply simultaneously to several countries instead of filing separate national or regional patent applications.[141] The patents granted remain under the control of the national or regional patent offices and this is frequently referred to as the "national phase."[142] This saves time, work, and money for any person or firm seeking to protect an invention in more than one country.[143]

Despite the attempt to ease and regulate the application process, patent holders only have patent rights in the markets in which they have achieved territorial rights.[144] The complexity of regulation arises from companies in different countries adhering to specific territorial rights and having to know other nations' patent laws that will be regulating their valid patent.[145]

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138. *See id.* at 13 ¶ 3.37 (Stem cells and DNA sequences frequently face similar debates because of their morality implications and heavy morality concerns. Although this researcher recommends them in turn, they are similar enough to discuss together attempting to clarify an approach to patenting in the bioscience field).

139. As of December 1, 2023, there were 157 PCT contracting states. *See* WIPO, *PCT System*, https://www.wipo.int/pct/en/pct_contracting_states.html.

140. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 reprinted in 9 I.L.M. 978 (1970).

141. *See* WIPO, *PCT FAQs*, https://www.wipo.int/pct/en/faqs/faqs.html#:~:text=155%20Contracting%20States.-,1,pay%20one%20set%20of%20fees; *see* Patent Cooperation Treaty, *supra* note 140, at art. 4.

142. *See* WIPO, *supra* note 141.

143. *See id.*

144. *See id.* at ¶¶ 8(c), 10.

145. *See id.* at ¶ 2.

Companies in different countries can follow specific territorial rights linked to the country or region where they filed and granted the patent.[146]

The patent system in the E.U. and the U.S. present different legal challenges, as seen through the developing case law. Through the E.U. Directive on Biotechnological Inventions, the E.U. was attempting to harmonize patent laws with its member states, illustrative of the existing consensus on the types of inventions that were morally unpatentable at the time.[147] Unfortunately, this attempt to harmonize has instead generated legal uncertainty and obscured the patenting process because of the fragmentation of national and European courts' jurisdiction.[148]

A. European Patent System Challenges

Within the E.U. alone, there is confusion as to the interpretation and implementation among E.U. member states. The judgments of the Court of Justice of the European Union ("CJEU") on the interpretation of Directive 98/44/EC are not binding on the European Patent Office ("EPO").[149] The EPO member states and the E.U. member states serve different populations, as the EPO is an independent organization from the E.U., with thirty-nine EPO Contracting States and the European Commission as observers.[150]

Although there is separation, the judgments may still be considered persuasive.[151] Mere persuasion provides that success under the national laws of individual European nations is not guaranteed, and instead, judgments on stem cells are dependent on how each nation understands these terms. Europe does not have a consistent understanding of biotechnology patents, exemplified by the 1998 Directive not fully implemented into national law by all E.U. members until 2007.[152] The interpretation continues to vary and change across nations and with it, the weight of the EPO patent can yield heterogeneous results across national IP landscapes.[153]

146. *See id.*

147. Aurora Plomer, Kenneth S. Taymor & Christopher Thomas Scott, *Challenges to Human Embryonic Stem Cell Patents*, 2 CELL STEM CELL 13, 15 (2008).

148. *Id.*

149. European Patent Office, *Guidelines for Examination in the European Patent Office* (Dir. 5.3.1 – Patent Law & Processes, EPO 2024) (ISBN 978-3-89605-361-9).

150. *See id.* ¶ 6.

151. EPC, *supra* note 60.

152. *See* Murdoch, *supra* note 57, at 51.

153. *Id.* at 50.

In *International Stem Cell Corporation v. Comptroller General of Patents*, the CJEU held three conclusions regarding the "human embryo."[154] The CJEU defined "human embryo", clarified that the directive did not target harvesting cells from embryos that have fully and finally ceased to develop further, and concluded they are not embryos when human stem cells are harvested without destroying an embryo.[155]

Although these were the assigned meanings by the CJEU, they only act as persuasive to the European Patent Office. The Unified Patent Court Agreement ("UPCA") is a treaty creating an "international" court that obeys European Union law exclusively for the enforcement of ''European Patents with Unitary Effect'' ("EUPE"), created by E.U. legislation but granted and administered by the EPO and is an autonomous and international organization existing outside the E.U.[156] This approach is to facilitate European patent integration into a single market[157] but fails to do so because it simultaneously fractures the E.U. market between the twenty-five participating states.[158] Aurora Plomer, the Director of the Sheffield Institute of Biotechnology, Law and Ethics at the University of Sheffield, asserts that the attempt to integrate "has since proved stubbornly resistant to integration within the E.U. legal order, whilst implementing E.U. law (notably the Biotech Directive)."[159] The EPO has developed into a quasi-judicial body, interpreting eligibility requirements and patent exclusions, including stem cells.[160]

The E.U. attempted to remove confusion within its nations and territories and instead resulted in a complex judicial system exacerbating the fragmentation and creating an uncertain legal environment.[161] The Directive is responsible for governing the patent law in all territories and court systems within the E.U., but when individual national and territorial courts attempt to define the terms important in the stem cell patent process, the result is a lack

154. Int'l Stem Cell Corp. v. Comptroller Gen. of Patents, Designs & Trade Marks, Case C-364/13, ECLI:EU:C:2014:245 1, ¶ 28 (CJEU Dec. 18, 2014), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62013CJ0364.

155. Parthenogenesis, *supra* note 86; *see* Zachariades, *supra* note 78, at 61-2.

156. *See* Plomer, *supra* note 99, at 794.

157. The value of the UPC is largely dependent on the UK's continued participation. *See* Matthias Lamping & Hanns Ullrich, *General Introduction*, in *The Impact of Brexit on Unitary Patent Protection and Its Court*, MAX PLANCK INSTITUTE FOR INNOVATION & COMPETITION RESEARCH PAPER NO. 18-20, at 18-20 (2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3232627.

158. *See generally* Ritu Padmakant Pandey & Samantha Marzullo, *The Unitary Patent System Sparking Innovation & Collaboration*, UPPSALA UNIVERSITET, 2, 31 (2024).

159. Plomer, *supra* note 147, at 795.

160. *Id.*

161. *Id.* at 796.

of cohesion. Valid patents need to be respected on a global scale and not consistently under threat, so researchers and patent holders are engaging with a more simple and comprehensible patent system, allowing parties to engage with and expand on research, rather than stifle it in the legal process.

B. United States Patent System Challenges

The United States has been more consistent and clearer than the E.U. regarding stem cell patents. They include basic criteria that must be met for patentability. Patents are exclusive to eligible subject-matter, new, useful, and nonobvious inventions.[162] Eligible subject-matter does not include laws of nature, natural phenomena, and abstract ideas.[163] The United States Patent and Trademark Office has frequently recognized inventions including stem cells.[164] However, patents protecting discoveries related to stem cells are now in question. On June 13, 2013, the Supreme Court issued a landmark decision in *Association for Molecular Pathology, et al., Petitioners v. Myriad Genetics, Inc., et al*.,[165] addressing whether DNA is patent-eligible.[166] In *Myriad Genetics*, the Supreme Court further defined the scope of the subject matter eligibility requirement of 35 U.S.C. Section 101, and held that naturally occurring DNA is not patent-eligible, but cDNA is, because it is not naturally occurring.[167]

Further defining subject matter eligibility, in *Mayo Collaborative Services v. Prometheus Laboratories Inc*,[168] decided the year before *Myriad Genetics*, the United States Supreme Court's decision stressed the need to "balance access to research tools for innovation versus innovation itself" and held that the steps of testing for proper drug treatments are unpatentable laws of nature.[169] The Court's concern was that allowing patents of laws of nature would unnecessarily inhibit further discovery.[170] Although this case involved isolated nucleic acids and not stem cells, the standard would still apply.[171] To surpass the standard manifested from this case, it is theorized that a stem cells

162. *See* 35 U.S.C. § 101 (2022).

163. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., et al., 569 U.S. 576 (2013).

164. *See* Zachariades, *supra* note 78, at 60.

165. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., et al., 569 U.S. 576 (2013).

166. *Id.* at 1. There are four statutory categories of invention that are interpreted by the courts: process, machine, manufacture, or composition of matter and improvements thereof. 35 U.S.C. § 101 (2022).

167. *Id.*

168. Mayo Collaborative Services v. Prometheus Laboratories Inc., 566 U.S. 66 (2012).

169. *See generally id.*; Zachariades, *supra* note 78, at 60.

170. Zachariades, *supra* note 78, at 60.

171. *Id.*

patentability will depend on the extent of human manipulation of the stem cell in the laboratory to fit within the subject matter and not as the exclusion of being more analogous to a product of nature.[172]

Although case law is still developing, there is not as much confusion in the U.S. regarding when certain standards apply. Naturally, there are continuing statutory interpretation challenges regarding the patent eligibility of stem cells. The Leahy–Smith America Invents Act does offer some clarifications, which can then be used in tandem with the USPTO regulations and standards.[173] Further, the AIA legislative history acknowledges USPTO patent precedent and does not aim to conflict with that but is clear in its language to serve as a supplement.[174]

VII. CLEAR MORALITY CLAUSES ALLOW FOR POLICY GUIDANCE IN SUPPORT OF STEM CELL PATENT LAW

The central argument against the existence of stem cell patents comes from the ethical concerns surrounding the destruction of human embryos.[175] The response to this issue varies, with nations adopting diverse approaches to morality exclusion clauses. This introduces a difficulty in interpretations as it deviates across cultures. Despite the variability that exists, the need for certainty is essential in demanding policy guidance to shape directives and statutes.[176] Contributing largely to the complex interplay between patent systems, ethical considerations, and the global landscape of stem cell research, is that the E.U. has a stance against patents involving the destruction of human embryos, which contrasts with the diverse approaches taken by individual European countries.[177] The governing patent law needs to have a more cohesive approach to applying over EPO and E.U. countries.

172. *Id.*

173. *See generally* Jacob S. Sherkow & Christopher Thomas Scott, *Stem Cell Patents after the America Invents Act*, 16 CELL STEM CELL 461, 461 (2015).

174. "U.S. Patent Office has already issued patents on genes, *stem cells,* animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses." 157 Cong. Rec. E1177-04 (testimony of Representative Dave Weldon previously presented in connection with the Consolidated Appropriations Act, 2004, Pub. L. 108-199, 634, 118 Stat. 3, 101, and later resubmitted with regard to the AIA; see 149 Cong. Rec. E2417-01).

175. Bernard Lo & Lindsay Parham, *Ethical Issues in Stem Cell Research*, 30 ENDOCR. REV. 204 (2009), https://pmc.ncbi.nlm.nih.gov/articles/PMC2726839/.

176. *See generally* Zachariades, *supra* note 78, at 59.

177. *See generally* Andrew Sheard, *Patenting Stem Cell Technologies in Europe*, 5 COLD SPRING HARBOR PERSPECTIVES IN MED. 1, 10 (2014).

The primary argument for why stem cell research patents should not exist is that it is unethical to destroy a human embryo.[178] Countries have taken unique and individualized approaches to this issue, creating a wide range of moral exclusion clauses, some with no moral exclusions.[179] In this context, individuals exclude others from their moral community through a moral exclusion clause, perceiving them as outside the realm of accepted moral values, rules, and considerations of fairness.[180] Because these clauses can be interpreted differently based on different cultures, the results of a singular invention with multiple patent applications in various territories or countries may yield a different patent status in different areas. However, despite this difference, there is still a need for certainty, while still respecting other countries' will. Policy guidance is what shapes the directives and statutes' meaning.[181] Yet, this guidance by policymakers and lawmakers around the world is what has created the highly variable and confusing governance of stem cell research.[182] Morality and patentability of human embryonic stem cell research operate at an interoperable and intraoperable level, with individual territories and national governance over the issue. Legal diversity is inevitable with embryonic stem cell regulation at the state and territorial level, but legal reconciliation is essential.[183]

When it comes to the weight different cultures put on the morality of a human embryo, there are different moral concerns that each group considers when creating their individual laws and practices. Although the rules of reciprocity require a country that issues a patent to provide the foreign national with the same rights as a patent owner that is a citizen of that country,

178. *See Stem Cell Research*, THE CENTER FOR BIOETHICS & HUMAN DIGNITY, https://www.cbhd.org/issues/stem-cell-research (last visited Feb. 22, 2025).

179. Moral exclusion clauses are more specific in declaring unpatentable moral grounds when it comes to this work versus previous international law. *See generally* Plomer, *supra* note 98, at note 4.

180. In a study, researchers examined how people perceive AI's action in moral dilemmas, finding a tendency to lean more towards utilitarian choices, which prioritize practicality and emphasize the consequences of actions and decisions. According to this study of how people perceive AI, which is another example of advancements in technology akin to stem cell patents and research accompanied by moral dilemmas and conflict, how people interact and perceive the work has important implications. If people tend to lean towards utilitarian choices, there should be a utilitarian approach to the patentability of stem cells. Zaixuan Zhang, Zhansheng Chen, & Liying Xu, *Artificial Intelligence and Moral Dilemmas: Perception of Ethical Decision-Making in AI*, 101 J. EXPERIMENTAL SOC. PSYCH. 1 (2022).

181. *See generally* Dan L. Burk & Mark A. Lemley, *The Patent Crisis and How Courts Can Solve It* (2009); Murdoch, *supra* note 57, at 50.

182. Li Jiang, *Will Diversity Regulations Disadvantage Human Embryonic Stem Cell Research: A Comparison between the European Union and the United States*, 25 DEPAUL J. ART, TECH. & INTELL. PROP L. 53, 55-6 (2014).

183. *Id.* at 56, 90.

there is no guarantee that each researcher will be granted that right if their application does not abide by the morality clause. Because of this, there is growing concern that inconsistent authority within legal jurisdictions can potentially put researchers work in a perilous position.[184] By having statutory support as to the lines drawn by public policy, the laws governing stem cell patents would most accurately reflect the public opinion for each territory and should be respected.

In the United States, the WARF patents have raised concerns more to do with scientific and economic issues. The WARF patents involve claims on embryonic stem cells and processes to make such cells and competitors are concerned with the broadness of their patents keeping competitors out of the U.S. market.[185] There is clear precedent from the USPTO that patents on embryonic stem cells or the processes for isolating, purifying, or culturing embryonic stem cells are all patent eligible.[186]

However, in the E.U., the primary source of issues and controversies in Europe is regarding these morality clauses. According to *Brüstle vs. Greenpeace* (CJEU C-34/10), it established that the EPO will not be issuing patents for stem cells that have been obtained through the destruction of human embryos, irrespective of whether that is relevant to the patent.[187] Despite the clarity to that issue, there is no clear answer as to whether or not this moral exclusion will extend to downstream derivative products. The E.U. allows anything to be patented so long as a human embryo is not destroyed at any point in the process.[188] The Directive includes a clause protecting against patents that are contrary to public morality, such as those that offend human dignity.[189] The result of such a clause allows the government to refuse to issue patents on moral grounds, without providing further clarification as to what those moral grounds will consistently be.

Further, because of the patent system design in Europe, not all European countries are following the EPO's moratorium.[190] Researchers have begun filing applications directly to national patent offices, hoping to bypass the

184. *Id.* at 54 (citing Murdoch, *supra* note 57, at 55).

185. David B. Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15 HEALTH CARE ANALYSIS 211, 211 (2007).

186. *See* Fendrick & Zuhn, *supra* note 25, at 2; Resnik, *supra* note 185, at 211.

187. Case C-34/10, *Oliver Brüstle v. Greenplace eV*, 2011 E.C.R.

188. This is like the Canadian approach, allowing for research on stem cells that cannot develop further into an entire animal, however Canada does not include any morality provision. Case C-34/10, *Brüstle v. Greenpeace* eV, 2011 E.C.R. I-9821, ¶ 20.

189. *See generally* Resnik, *supra* note 185, at 212.

190. For example, the U.K. will grant patents on pluripotent and multipotent embryonic stem cells but not on totipotent embryonic stem cells, which have the potential to develop into human beings and Sweden, which has some of the most liberal embryonic stem cell research laws in Europe, also allows patents on human embryonic stem cells. Resnik, *supra* note 185, at 212.

EPO, which may not reflect their own national moral beliefs.[191] These secretive filings are trying to protect research, but ultimately pushing research into only favorable environments.[192]

VIII. CONCLUSION

As medical advancements continue to thrive with new developments in technology and medicine, protection of innovation should always be at the forefront. The E.U. should modify their patent laws to be more standardized in their respective territories to encourage a coherent and competitive system. It is important that Member States are represented by national system of regulation, so the field continues to encourage innovation and a greater understanding of diseases and illnesses. This would reduce discrepancies between Member States and countries and allow for policy guidance to supervise and monitor the implementation within each country guided by clear principles rather than loose phrasing to leave up to independent national and transnational organizations interpretations.

191. *See generally* Nayana Siva, *Stem Cells Caught in Morality Clause*, 27(2) NATURE BIOTECHNOLOGY 1, 109 (2009).

192. *See id.* As a way of keeping up, China has also shifted from strict moral standards to an ethically neutral approach to allow for limited recognition of hESCs' patentability.