Brüstle v. Greenpeace: The Court of Justice of the European Union Interprets the Term "Human Embryo" Widely, Restricting Member States' Discretion To Pass National Patent Legislation for Biotechnological Inventions

I. OVERVIEW

Oliver Brüstle obtained a German patent in 1997 for a process that treats neurological defects by transplanting neural precursor cells (that have been extracted from embryonic stem cells) into the nervous system.[1] The necessary precursor cells must be immature and obtained during the brain's development phase; the ethical issues surrounding the extraction of cerebral tissue from human embryos make it impossible to produce the needed amount from that source, and therefore, Brüstle's process must instead generate the necessary precursor cells from pluripotent embryonic stem cells.[2] The use of these cells also raises an issue under paragraph two of the *Patentgesetz* (Patent Act), which prohibits the grant of patents for processes that use human embryos for industrial or commercial purposes.[3] Greenpeace brought suit for the annulment of Brüstle's patent to the *Bundespatentgericht*,[4] and the court invalidated his

1. Case C-34/10, Brüstle v. Greenpeace, paras. 15-16 (Oct. 18, 2011), http://curia.europa.eu/jcms/jcms/j_6/ (search Case Number C-34/10; select "C-34/10: Judgment" hyperlink). Parkinson's disease is one of the neural disorders at present for which clinical application of this process has been developed. *Id.* para. 16.

2. *Id.* paras. 17-18. Pluripotent embryonic stem cells are capable of developing into different types of cells and tissues and "can be conserved during many passages in the state of pluripotentiality and can multiply"; therefore, using them allows the production of the "unlimited quantity of isolated and purified precursor cells having neural or glial properties" required for Brüstle's process. *Id.* para. 18.

3. *Id.* para. 8.

4. The *Bundespatentgericht* is the German Federal Patent Court.

patent on the grounds that its use of human embryonic stem cells indeed violated the provisions of paragraph two.[5]

Brüstle then filed an appeal with the *Bundesgerichtshof*[6] on the question of whether his patent's technical teaching, which only uses human embryonic stem cells in its process, is unpatentable under the Patent Act.[7] The court stayed its conclusions pending a ruling from the Court of Justice of the European Union (CJEU) on its interpretation of article 6(2)(c) of the 1998 European Parliament and Council Directive (Biotech Directive), which also prohibits patents for the industrial or commercial use of human embryos.[8] The lower court requested the following article 6(2)(c) clarifications: the definition of "human embryo"; whether or not scientific research is included in the article's prohibition; and if technical teaching is unpatentable when the destruction of human embryos is a precondition to the process and not its intended purpose.[9] The CJEU *held*: (1) a human embryo is classified as any fertilized *or* nonfertilized human ovum that has been stimulated into further development by parthenogenesis or contains the transplanted cell nucleus of a mature human cell; (2) human embryos used for scientific research are excluded from patentability; and (3) if the technical teaching requires the destruction or use of human embryos, then it is also unpatentable. Case C-34/10, Brüstle v. Greenpeace, para. 53 (Oct. 18, 2011).

II. BACKGROUND

A. International Agreements Binding the European Union

Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) states that an invention in any field of technology qualifies for a European patent if it is "new, involve[s] an inventive step and [is] capable of industrial application."[10]

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5. Case C-34/10, *Brüstle*, paras. 2, 19.

6. The *Bundesgerichtshof* is Germany's Federal Court of Justice.

7. Case C-34/10, *Brüstle*, paras. 19-20.

8. *Id.* paras. 1, 7, 20. The lower court sought interpretation of article 6(2) because, for purposes of uniformity across the European Union (EU), the Directive does not allow Member States discretionary judgment over patentability. Therefore, even though the *Patentgesetz* explicitly defines what constitutes a human embryo while the 1998 European Parliament and Council Directive (Biotech Directive) does not, Germany's national court is not at liberty to interpret the term differently than article 6(2) and requires clarification from the CJEU. *Id.* paras. 21, 25-26.

9. *Id.* para. 23.

10. Marrakesh Agreement Establishing the World Trade Organization art. 27, Apr. 15, 1994, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 U.N.T.S. 229, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement].

However, because the grant of a patent on a process extends exclusive rights over its use, sale, and importation, the myriad inconsistent legislations governing patent procedures among the Member States create trade barriers.[11] The result is an ineffectual internal market.[12] The TRIPs Agreement codified the provisions and enforcements governing intellectual property rights law in order to reduce this friction and improve international trade.[13] Although the TRIPs Agreement binds its signatories to its provisions, it extends to each nation the discretion to declare unpatentable those inventions whose commercial exploitation is contrary to their nation's sense of *ordre public* or morality.[14]

The Council of the European Union approved the TRIPs Agreement on December 22, 1994, making it legally binding across the European Union (EU).[15] Accepting the provisions of the TRIPs Agreement altered European patent law because it required Member States to amend their legislation pursuant to its terms.[16] It also required amending legislation binding on the entire EU: the Convention on the Grant of European Patents (EPC), which created a common system of law governing the grant of patents among the contracting states in 1973, was amended in 2000 to reflect the language of the TRIPs Agreement.[17] It adopted article 27 of the TRIPs Agreement, which includes the definition of a patentable invention to include inventions "[in] all fields of technology" in addition to the "commercial exploitation" clause that governs unpatentable inventions.[18] This is significant because the original text of article 53 allowed rejection of a patent if either its "exploitation" or "publication" offended a nation's principles of morality or *ordre public*; the adoption of the TRIPs Agreement's "commercial exploitation" requirement is a less strict standard.[19]

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11. *Id.* art. 28(1)(b).
12. *See id.* pmbl.
13. *Id.*
14. *See id.* art. 27.
15. Council Decision 94/800, Concerning the Conclusion on Behalf of the European Community, as Regards Matters Within Its Competence, of the Agreements Reached in the Uruguay Round Multilateral Negotiations (1986-1994) art. 1, 1994 O.J. (L 336) 1, 2.
16. *See* David Vaver & Shamnad Basheer, *Popping Patented Pills: Europe and a Decade's Dose of TRIPs*, 28 EUR. INTELL. PROP. REV. 282, 283 (2006).
17. Convention on the Grant of European Patents art. 1, Oct. 5, 1973, 1065 U.N.T.S. 255, 259 (as amended Nov. 29, 2000) [hereinafter European Patent Convention].
18. Vaver & Busheer, *supra* note 16, at 285 (citing European Patent Convention, *supra* note 17, art. 53).
19. *Id.*

B. European Union Legislation

The European Parliament and the Council of the EU issued its 1998 Biotech Directive to achieve harmonization of the legal protections governing biotechnological inventions among its Member States.[20] It emphasized the need for a unified system of patent law among Member States on the grounds that the discrepancies among the Member States' national patent legislation created barriers to trade and impeded the effectiveness of the internal market.[21] Although the Biotech Directive designates national patent law as the governing legal basis for each Member State, it requires all national legislation to be amended in accordance with its provisions.[22]

The Biotech Directive codifies what makes inventions unpatentable. Article 6(1) adopts the language of the TRIPs Agreement to declare: "Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality."[23] This provision allows each Member State the right to determine whether a patent violates this principle within the context of its own national conceptions of morality and order.[24] Article 6(2) restricts this discretion by explicitly stating that the industrial or commercial use of human embryos is unpatentable, but it provides no clear definition as to what this entails.[25] In *Netherlands v. Parliament*, the CJEU affirmed that article 6(2) gives Member States no discretion on the grounds that its provisions specifically identify what is and is not patentable and held that Member States are bound by its exclusions.[26]

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20. Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, pmbl., 1998 O.J. (L 213) 13, 13 [hereinafter Biotech Directive]. The Directive explicitly states in article 1 that the provisions therein do not effect Member States' obligations under international agreements. *Id.* art. 1.

21. *Id.* pmbl., paras. 5-7; *see also* Case C-377/98, Netherlands v. Parliament, 2001 E.C.R. I-7149, I-7155-56, paras. 16, 20 (finding that even though most Member States' national patent legislation already reflects the provisions of the EPC, it is the differing interpretations of these provisions that disrupts the functioning internal market).

22. Biotech Directive, *supra* note 20, art. 1.

23. Biotech Directive, *supra* note 20, art. 6(1); *see, e.g.*, TRIPs Agreement, *supra* note 10, art. 27.

24. Case C-377/98, *Netherlands*, 2001 E.C.R. I-7149, I-7161, para. 38; Case C-456/03, Comm'n v. Italy, 2005 E.C.R. I-5355, I-5386, para. 78.

25. Biotech Directive, *supra* note 20, art. 6(2). Article 6(2) also explicitly makes unpatentable "(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings . . . (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." *Id.*

26. Case C-377/98, *Netherlands*, 2001 E.C.R. I-7149, I-7170, para. 39; Case 456/03, *Italy*, 2005 E.C.R. I-5355, I-5356-57, paras. 78-79.

The Biotech Directive was met with immediate opposition from the Member States. On October 19, 1998, representatives from the Netherlands, Italy, and Norway filed claims with the CJEU requesting its annulment.[27] The CJEU rejected their claims and dismissed the case, thereby ensuring the Biotech Directive's validity as binding EU legislation.[28] However, this ruling did not resolve the issue of noncompliance: the deadline for Member States to implement the policies of the Biotech Directive into their national laws was July 30, 2000, but three years later, the European Commission faced the potential necessity of referring eight Member States to the CJEU for failure to implement.[29] Regardless of Member State noncompliance since the Biotech Directive's inception, the CJEU has consistently upheld the validity of its objectives on the grounds that its provisions for uniform interpretation of patent law effectively encourage market stability and promote biotechnological research.[30]

C. German Domestic Law

German patent law, as defined in the 2005 amended Patent Act, prohibits the patenting of inventions whose commercial exploitation contravenes *ordre public* and morality or requires the use of human embryos for "industrial or commercial purposes."[31] The Patent Act stipulates that a patent can be revoked if the invention is determined to violate these provisions, which are governed under the *Embryonenschutzgesetz* (Embryo Protection Act).[32] The Embryo

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27. Case C-377/98, *Netherlands*, 2001 E.C.R. I-7149, I-7152, I-7154, I-7158, paras. 1, 9, 26.

28. *Id.* at I-7173. The representatives of the Netherlands, et al., put forward six pleas for the Directive's annulment, but the most relevant here are the claims that the Directive breached both international law obligations and the "fundamental right to respect for human dignity." The remaining four pleas included the complaint that the Biotech Directive's legal basis was incorrectly founded, that it breached the principle of subsidiarity and of legal certainty, and that it was adopted in breach of procedural rules. *Id.* at I-7154, para. 12.

29. Press Release, Eur. Comm'n, Industrial Property: Eight Member States Referred to Court for Failure To Implement Directive on Legal Protection of Biotechnological Inventions (July 10, 2003). All Member States ultimately complied with the Biotech Directive and implemented its provisions into their national laws. *State of Play of the Implementation of Directive 98/44/EC*, EUR. COMM'N, http://www.ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf (last updated Jan. 15, 2007) (listing the dates of Member State implementation of the Directive into their national laws).

30. Press Release, *supra* note 29; Case C-377/98, *Netherlands*, 2001 E.C.R. I-7149, I-7155-58, paras. 16, 21, 27; *see, e.g.*, Case C-428/08, Monsanto Tech., LLC v. Cefetra BV, 2010 E.C.R. I-06761, paras. 55-57, 59.

31. Case C-34/10, Brüstle v. Greenpeace, paras. 8-9, http://curia.europa.eu/jcms/jcms/j_6/ (search case number C-34/10; select "C-34/10: Judgment" hyperlink).

32. *Id.*

Protection Act criminalizes (1) the fertilization of an ova or *in vitro* development of human embryos when pregnancy is not the intent; (2) selling human embryos conceived *in vitro* or removed before the end of the nidation process; and (3) transferring, acquiring, or using these embryos for nonpreservation purposes.[33] Paragraph eight of the Embryo Protection Act states:

> For the purpose of this Act, an embryo already means the human egg cell, fertilised and capable of developing, from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual under the appropriate conditions for that.[34]

Under the Embryo Protection Act, the *importation* of pluripotent cells is not forbidden, and this gap in legislation led to the push for amending the laws to allow the importation of human embryonic stem cells as well.[35]

Two of Germany's "high-priority principles," as codified in its constitution, are competing goals: to protect human embryos and to allow freedom of research.[36] Both remained at the forefront of German consciousness, especially as the *Deutsche Forschungsgemeinschaft* (DFG)[37] pushed for legislation allowing greater freedom in importing human embryonic stem cells in order to better facilitate biotechnological research.[38] This led to great parliamentary debates that allowed input from the DFG as well as reports on the ethics of stem cell research from a parliamentary Inquest-Commission.[39] In their reports, the Inquest-Commission argued that the question on the importation of stem cells should take into account an ethical analysis that respects human dignity and integrity.[40] The Inquest-Commission remained divided on the

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33. Embryonenschutzgesetz [ESchG] [Embryo Protection Act], Dec. 13, 1990, BUNDESGESETZBLATT, Teil I [BGBL. I] at 2747, §§ 1-2 (Ger.) [hereinafter Embryo Protection Act].

34. *Id.* § 8.

35. Jan P. Beckmann, *On the German Debate on Human Embryonic Stem Cell Research*, 29 J. MED. & PHIL. 603, 605 (2004).

36. *Id.*; *see, e.g.*, GRUNDGESETZ FÜR DIE BUNDESREPUBLIK DEUTSCHLAND [GRUNDGESETZ] [GG] [BASIC LAW], May 23, 1949, BGBL. I, arts. 2, 5 (Ger.).

37. The *Deutsche Forschungsgemeinschaft* (DFG) is the German Research Foundation.

38. *See* Beckmann, *supra* note 35, at 605-07.

39. *Id.* at 607. There was much debate on the ethics of expanding the reach and availability of human embryonic stem cells with dissents and concurrences from all levels: Germany's President publicly pronounced his belief that human embryonic stem cell research "would transgress ethical limits." *Id.*

40. *Id.*

question—for ethical reasons and on constitutional grounds—and submitted final reports both for and against stem cell importation.[41]

This national discussion resulted in the 2002 legislation on the importation of human embryonic stem cells: the *Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen* (Stem Cell Act).[42] The Stem Cell Act prohibits the importation of human embryonic stem cells, but allows for exceptions for research that "pursues high-level research aims for the increase of scientific knowledge . . . or serves to extend medical knowledge in connection with the development of diagnostic, preventative or therapeutic procedures for human use."[43] This exception represents a compromise between the constitutional principles requiring freedom of research and the respect for human dignity.[44]

III. THE COURT'S DECISION

In the noted case, the CJEU upheld the objectives of the Biotech Directive and gave a strict interpretation of its article 6(2)(c) provision on human embryos.[45] First, the CJEU acknowledged that the Biotech Directive primarily aimed to encourage investment in biotechnology, while, at the same time, "respect[ing] the fundamental principles safeguarding the dignity and integrity of the person."[46] The CJEU held that achieving these stated goals therefore required a wide definition as to what constitutes a "human embryo."[47] Using this understanding of the

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41. *Id.* at 607-08. The National Council on Ethics was similarly split and worried that any absolute protection of the human embryo's right to life would violate the guaranteed right to research under Germany's constitution. *Id.* at 608.

42. *See id.* at 607-09. The *Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen* is the Act To Secure the Protection of Embryos in Connection with the Importing and Use of Human Embryonic Stem Cells.

43. *See* Case C-34/10, Brüstle v. Greenpeace, para. 14, http://curia.europa.eu/jcms/jcms/j_6/ (search Case Number C-34/10; select "C-34/10: Judgment" hyperlink) (internal quotation marks omitted).

44. *See* Beckmann, *supra* note 35, at 608-09.

45. Case C-34/10, *Brüstle*, paras. 38, 46.

46. *Id.* para. 32.

47. *Id.* para. 34. The specific requests of the referring court in regards to question one on the definition of "human embryos" include:

> a) Does [the term human embryo] include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?
>
> b) Are the following organisms also included:
>
> 1) unfertilised human ova into which a cell nucleus from a mature cell has been transplanted;

Biotech Directive's stated prohibitions against patenting inventions that offend human dignity, the CJEU determined inventions that require the use of human embryos for scientific research are unpatentable under article (6)(2)(c).[48] Further still, the CJEU interpreted article 6(2)(c) to mean that any invention requiring the destruction of a human embryos is unpatentable as well, regardless of whether or not that is the process' intended purpose.[49]

To address the referring court's first question—how does the Biotech Directive interpret the term "human embryo?"—the CJEU first turned to the basis for the necessity of a uniform definition.[50] The CJEU reaffirmed its mandate to provide uniform application of EU law by citing that its history has consistently upheld that the driving principles of equality require an "independent and uniform interpretation throughout the European Union" in cases where the provision at issue makes no direct reference to a particular Member State's laws.[51] Taking this into consideration, the CJEU then looked at the Biotech Directive's stated belief that harmonizing patent law governing biotechnological inventions had the effect of removing trade barriers and encouraging scientific research and development.[52] Concerned that conflicting definitions of the term "human embryo" throughout the Member States' legislation

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2) unfertilised human ova whose division and further development have been stimulated by parthenogenesis?

c) Are stem cells obtained from human embryos at the blastocyst stage also included?

Case C-34/10, Reference for a Preliminary Ruling from the Bundesgerichtshof (Ger.), 2010 O.J. (C 100) 19, 19 [hereinafter Reference for a Preliminary Ruling].

48. *See* Case C-34/10, *Brüstle*, paras. 33, 46; *e.g.*, Biotech Directive, *supra* note 20, pmbl., para. 38.

49. Case C-34/10, *Brüstle*, para. 49. The specific request of the lower court regarding question three is as follows:

3) Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching,

a) because the patent concerns a product whose production necessitates the prior destruction of human embryos,

b) or because the patent concerns a process for which such a product is needed as base material?

Reference for a Preliminary Ruling, *supra* note 47, at 19.

50. Case C-34/10, *Brüstle*, paras. 24-25.

51. *Id.* para. 25; Case C-287/98, Luxemburg v. Linster, 2000 E.C.R. I-6949, I-6965, para. 43; Case C-5/08, Infopaq Int'l A/S v. Danske Dagblades Forening, 2009 E.C.R. I-6569, para. 27; Case C-467/08, Padawan SL v. Sociedad General de Autores y Editores de España, para. 32, http://curia.europa.eu/jcms/jcms/j_6/ (search Case Number C-467/08; select "C-467/08: Judgment" hyperlink).

52. Case C-34/10, *Brüstle*, paras. 26-27.

would subvert the Biotech Directive's intentions (because this would allow inventors to use the differing regulations to gain patents on processes prohibited in their own nations under the more lenient legislation of other Member States), the CJEU reasoned that a uniform definition must be established in order to fulfill the Biotech Directive's purpose.[53]

Article 6(2)(c) explicitly states that inventions requiring the use of human embryos for industrial or commercial purposes are unpatentable, and the CJEU held that this removes from Member States the discretion to derogate from this prohibition.[54] The Biotech Directive does not in itself define what is or is not a human embryo, and in situations where the law does not provide a clear definition for a term in its provisions, the CJEU must define the term within the context and purpose of the rules from which it comes.[55] Taking these above factors into account, CJEU interpreted article 6(2)(c)'s "human embryo" to refer to "any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis."[56] The CJEU reasoned that because both fertilized and unfertilized ova are capable of beginning the process of human development, their use must be taken to equate an offense against dignity.[57]

The CJEU then turns to the referring court's second question: whether or not article 6(2)(c)'s prohibition on patenting inventions involving "uses of human embryos for industrial or commercial purposes" includes scientific research requiring the use of human embryos.[58] The CJEU addresses this question by first looking at the Biotech Directive, which defines the right a patent grants as the right to exclude others from accessing the process or product's industrial or commercial use.[59] Therefore, the CJEU finds that the mere grant of a patent "implies, in principle, its industrial or commercial application."[60] The CJEU recognizes that the nature of scientific research is different

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53. *Id.* paras. 27-28.

54. *Id.* para. 29; *e.g.*, Case C-456/03, Comm'n v. Italy, 2005 E.C.R. I-5355, I-5386, paras. 78-79.

55. Case C-34/10, *Brüstle*, paras. 26, 31; Case C-549/07, Wallentin-Hermann v. Alitalia, 2008 E.C.R. I-11061, para. 17, http://curia.europa.eu/jcms/jcms/j_6 (search Case Number C-549/07; select "C-549/07: Judgment" hyperlink).

56. Case C-34/10, *Brüstle*, para. 38.

57. *See id.* paras. 35-38.

58. *Id.* para. 39 (internal quotation marks omitted).

59. *Id.* para. 42; *e.g.*, Biotech Directive, *supra* note 20, pmbl., para. 14.

60. Case C-34/10, *Brüstle*, para. 41.

than traditional industrial or commercial purposes, but because the right to exclude is a commercial right, any process whose patent application includes scientific research that requires use of human embryos is included in the article 6(2)(c) prohibition.[61]

The third question posed sought clarity on whether an invention whose process requires material obtained by destroying human embryos, or a product whose production requires the destruction of human embryos, can be patented.[62] First, looking at information presented on the process of extraction, the CJEU determined that removing stem cells at the blastocyst stage results in the destruction of the human embryo.[63] The CJEU, once again, looked to the Biotech Directive and its mandate that no patent be granted for inventions that are offensive to human dignity.[64] The CJEU therefore interpreted that any process requiring the destruction of human embryos—regardless of the process' purpose—offends human dignity, and that its patentability would undermine the purpose of the Biotech Directive.[65]

IV. ANALYSIS

The CJEU's interpretation of article 6(2)(c) is significant because, by defining the term "human embryo" widely, it places strict limitations on Member States' ability to pass domestic legislation reflecting their own national consensuses.[66] The CJEU's reasoning on the intended meaning of the Biotech Directive's article 6(2)(c) terms relied on the supposition that fulfilling the Biotech Directive's aim of creating a harmonized system of patent law required a strict definition of "human embryo."[67] By restricting the definition, the CJEU upheld the principle belief that disunity among the varying national laws governing the patent

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61. *Id.* paras. 42-43.
62. *Id.* para. 47.
63. *Id.* para. 48.
64. *Id.* paras. 32-35, 49.
65. *See id.* paras. 49, 52.
66. *See id.* paras. 26, 28-29. In a 2008 case, the Enlarged Board of Appeal of the European Patent Office confirmed that the use of human embryos was commercial in nature (unless used for therapeutic purposes), and processes requiring the destruction of human embryos are unpatentable. This ruling was made based on the post-Biotech Directive provisions of the Implementing Regulations to the EPC, and the CJEU pointed out that its rulings on the second and third question are in accord with this previous holding (under which the Member States were already bound). Therefore, the latitude afforded to Member States in creating national patent legislation hinged the CJEU interpretation of the Biotech Directive's meaning of the term "human embryo," because most were already bound under their EPC obligations for the first two issues. *See* Case G 2/06, Decision of the Enlarged Board of Appeal of 25 Nov. 2008, OFFICIAL J. EUR. PAT. OFF 306, paras. 22, 25-27 (2009).
67. *See* Case C-34/10, *Brüstle*, paras. 26-28.

process for biotechnological inventions contributes to trade barriers.[68] The intended result of harmonization is the fulfillment of the Biotech Directive's objective to facilitate trade and stabilize the internal market.[69] Even though the CJEU acknowledged that it cannot make decisions regarding "questions of a medical or ethical nature" and can only provide a legal interpretation of article 6(2)(c), ethical considerations cannot be easily distinguished from the proceedings.[70] As a matter of process, ethical issues arose during the balancing of factors undertaken by the CJEU to define the Biotech Directive's meaning of "human embryo."

Article 6(1) of the Biotech Directive gives Member States the discretion over whether or not inventions whose commercial exploitation compromises the nation's sense of morality or *ordre public* are patentable.[71] The CJEU's interpretation of article 6(2), as working to intentionally limit the specific rights afforded Member States in defining their own conception of morality, is contradictory in purpose.[72] Also, it represents a moral ruling, which is what the CJEU professed to avoid, because it establishes an overbroad standard of morality that binds all Member States, regardless of their individual findings. The issue therefore becomes: how can a nation legislate its own terms of morality—a right granted by the Biotech Directive, the TRIPs Agreement, and the EPC[73]—when the CJEU provides such a wide definition of the terms governing the explicit prohibitions and limitations placed on that right?

Germany's Embryo Protection Act worked within the language of the Biotech Directive to place stringent restrictions on the use of embryos.[74] When it became apparent that such provisions compromised Germany's founding principles by inhibiting freedom of research, a national debate over the ethical implications behind using human embryonic stem cells divided the country.[75] Exercising its right to determine on its own whether or not an invention's grant of a patent resulted in commercial exploitation that contravened *ordre public* and morality, the German Parliament passed the Stem Cell Act in 2002,

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68. *See id.* para. 27; Biotech Directive, *supra* note 20, pmbl., paras. 5-8.
69. *See* Case C-34/10, *Brüstle*, paras. 26-29.
70. *See id.* para. 30.
71. Biotech Directive, *supra* note 20, art. 6(1).
72. *See* Case C-34/10, *Brüstle*, para. 29; *see also* Case C-456/03, Comm'n v. Italy, 2005 E.C.R. I-5355, I-5386, paras. 78-79 (upholding here also that the purpose of Biotech Directive article 6(2) is to limit discretion granted under article 6(1)).
73. Biotech Directive, *supra* note 20, art. 6(1); TRIPs Agreement, *supra* note 10, art. 27; European Patent Convention, *supra* note 17, art. 53.
74. Embryo Protection Act, *supra* note 33, paras. 1-2.
75. Beckmann, *supra* note 35, at 605-08.

which set out provisions for the importation of human embryonic stem cells.[76] Of note here is the provision in the Stem Cell Act that required the importation of the human embryonic stem cells only under the condition that doing so would not go against the founding principles of the German legal order.[77] The provisions of the Stem Cell Act reflected Germany's consensus on legislation in a manner that both showed great respect for human dignity and integrity, and, at the same time, allowed for greater opportunities and progression within the field of biotechnological research.[78]

Germany's national moral calculus, however, is found to be irrelevant by the CJEU.[79] The CJEU's interpretation of the Biotech Directive's goal of respecting human life requires a much wider expansion of what constitutes "human dignity" than that taken by Germany.[80] The CJEU's basis and justifying principle behind its interpretation is the need for harmonization of the laws of the EU, where the intended effect is the removal of trade barriers, the encouragement of biotechnological research, and the improvement of the internal market.[81] To enable this end, the CJEU interprets the term "human embryo" widely so as to create as broad and uniform a working definition as possible.[82] However, in light of the fact that encouragement of biotechnological research was the driving force behind Germany's passage of the Stem Cell Act, the CJEU's reading of the article 6(2)(c) ultimately defeats its own purpose.

The uniform interpretation of law across the EU is a valid—and important—objective. Both the Biotech Directive and the CJEU have upheld the belief that the harmonization of law across the EU effectively increases the functionality of its internal market.[83] However, when the effect of that uniform interpretation serves to negate the legislation's intended purpose, the CJEU should reconsider its assessment of this principle. In *Brüstle*, the CJEU's wide interpretation of the term "human embryo" within the means of the Biotech Directive is flawed logic because such an interpretation allows the CJEU to overlook the

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76. *Id.* at 608-09.

77. *Id.*

78. *Id.*

79. Case C-34/10, Brüstle v. Greenpeace, para. 25, http://curia.europa.eu/jcms/jcms/j_6/ (search Case Number C-34/10; select "C-34/10: Judgment" hyperlink).

80. *See id.* paras. 33-34.

81. *Id.* paras. 25-26.

82. *See id.* paras. 26-27.

83. Biotech Directive, *supra* note 20, pmbl., paras. 507; Case C-377/98, Netherlands v. Parliament, 2001 E.C.R. I-7149, I-7155, I-7158, paras. 16, 27.

necessary discretion afforded to Member States to determine their own conceptions of morality and fails to take into account individual state assessment as to what inhibits trade.

The effects of the CJEU's interpretation of the Biotech Directive's are, as yet, hard to ascertain; however, it is certain that the CJEU's broad definition of a "human embryo" will significantly alter the landscape of biotechnological research in the EU.[84] This ruling calls into question the status of current patents whose processes involve the use of human embryonic stem cells but were obtained under provisions of their national legislation prior to this expansively defined interpretation of the term "human embryos." Whether or not these patents will be found to be in contravention to the Biotech Directive's article 6(2)(c) exclusions, and now therefore subject to revocation, will remain unclear until all the Member States amend their national legislations to reflect this ruling.[85] The invalidation of these patents would, in any case, have a detrimental effect on the EU's scientific community and on investment in biotechnology: there is little incentive for investors to fund scientific research involving human embryonic stem cells in the EU when the end result cannot be patented.[86]

V. CONCLUSION

The conclusions reached by the CJEU preserve its mandate to ensure uniformity of law throughout the EU; however, doing so required interpreting the provisions governing the exclusion of certain biotechnological inventions from patentability, as set out in article 6(2) of the Biotech Directive, in broad terms. This interpretation unfairly removes from Member States the right to pass legislation reflecting their own morality. Although it is a valid assumption that discord among the Member States' competing patent laws poses barriers to trade by allowing the subversion of the internal market, this is just one of the

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84. Sophie Mosca, *Biotechnology: Court's Human Embryo Ruling Sparks Flood of Reactions*, EUROPOLITICS (Oct. 20, 2011), http://www.europolitics.info/court-s-human-embryo-ruling-sparks-flood-of-reactions-artr316130-10.html (subscription required). Plaintiff Olivier Brüstle remarked that this is an "unfortunate decision that wipes out in one blow the results of years of transnational research by European scientists, and places them in the hands of the United States or Asia, which will reap the benefits of European advances in this area." *Id.* (internal quotation marks omitted).

85. *See* Karl M. Nobert, Daniela Bohn & Markus Brock, *Stem Cell Patentability in Europe: Are Patents Relying on Human Embryonic Stem Cells at Risk of Invalidation?*, INTELL. PROP. TODAY (June 2011), http://www.iptoday.com/issues/2011/06/stem-cell-patentability-in-europe-are-patents-relying-human-embryonic-stem-cells-at-risk-invalidation.asp. The number of patents that would qualify for disqualification is also, as yet, uncertain.

86. *Id.*

objectives behind the Biotech Directive and similar EU-wide legislations. The CJEU failed to take into account the Biotech Directive's other stated goal: to increase and promote biotechnological research.

The Biotech Directive's preamble directly acknowledges both the need to protect the future of biotechnological research and the realization that adequate legal protection is necessary to ensure continuing investment in the field. Germany's patent laws, especially those enumerated in its Stem Cell Act, fell within the bounds of respect for the dignity and integrity of the person as stated in the Biotech Directive. The development of this legislation took into account the provisions of the Biotech Directive, and yielded a result that reflected a national consensus on the necessity for law both to protect human life *and* encourage biotechnological investment. The CJEU's ruling in *Brüstle* denies Germany—and other Member States—this right to take into account its own moral and ethical calculus in determining how to best encourage the promotion of biotechnological research. In light of these considerations, it seems highly contradictory to the purpose of the Biotech Directive to expand the definition of "human embryo" so widely as to inhibit scientific research.

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