

STEM CELL AND BIOTECHNOLOGICAL PATENTABILITY AND  
RESEARCH IN THE EUROPEAN UNION: AN  
INTERDISCIPLINARY APPROACH

Jacqueline Hill Tudor\* and Jarrod Tudor†

ABSTRACT

*Stem cell and biotechnological research is a flourishing industry around the globe. The growth of the industry can be attributed to its promise to lead to a cure for numerous human diseases that are currently considered unconquered. Within this industry, the patentability of researched innovations has been a hot topic in the past decade. Through the patenting process, the industry itself can be a source of economic opportunity for countries willing to extend patent protection for the inventions produced by stem cell and biotechnological research.*

*Because it takes significant resources for research to produce a patentable invention, investors desire assurances that their time and money will head a result from which they can benefit, whether that be a financial benefit, a status benefit, or some other benefit. Despite the medical promises of stem cell and biotechnological research, there are concerns in some places around the world such as the European Union about potential policy implications that would stem from patenting innovations in this industry. These concerns are displayed in the two leading sources of law governing stem cell and biotechnological research: the European Union's Directive 98/44/EC and the European Patent Convention.*

*This Article discusses the patentability of stem cell and biotechnological inventions under both European Union law and the European Patent Convention. The Article continues by discussing several other topics that a practitioner must be familiar with when analyzing a patentability issue. A few of these topics include the morality debate, the promise of stem cell and biotechnological research, taxation of stem cell-related products, access to records, legal notice, research funding, and the free movement of goods. This Article also examines the key case law from both the European Court of Justice as well as the two judicial organs of the European Patent Office, the Board of Appeal and the Enlarged Board of Appeal, that provide insight into this area of law. Additionally, this Article identifies the discrepancies between the law governing stem cell research and biotechnological research within the European*

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\*Ohio University.

†The University of Akron.

*continent and provides recommendations for greater harmonization within these two areas of law.*

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## I. INTRODUCTION.

A. *The stem cell research industry.*

With robust investment at play, the stem cell and biotechnology industry is a thriving global phenomenon.<sup>1</sup> For those participating in this industry, it can be an incredibly lucrative opportunity.<sup>2</sup> In addition to basic research, the industry includes advanced segments such as services for storing body tissues, organs, and cells.<sup>3</sup> In recent years, human cells have become global commodities and the industry has grown exponentially. However, increased regulation in certain areas of the globe has created a shortage of supply which in turn has created a lucrative market for these cells; a market that is largely composed of wealthy individuals and satisfied using cells from countries with less regulation. Within this market, certain types of cells and human tissue are more easily transferred. For example, unfertilized ova are more easily traded across countries while oocytes are scarcely traded.<sup>4</sup> There is evidence that a gap in the human tissue economy exists and that experimental therapies involving stem cell technology could lead to a solution to filling this gap.<sup>5</sup>

Stem cell research is a segment of biotechnological research that promises to lead to cures for some of the world's most damaging and most expensive human diseases, such as cancer and cardiovascular diseases, that are currently considered either incurable or untreatable.<sup>6</sup> The market for stem cell technologies is expected to grow quickly over the next several years with one estimate forecasting \$7.3 billion in additional investment.<sup>7</sup> This industry has provided large economic opportunities for players choosing to participate. Being that the European Union offers protection of inventions through the European intellectual property laws, the stem cell industry has experienced a large increase in the number of participating players within Europe.<sup>8</sup> As more and more patents are issued for stem cell research based inventions, investment in the industry will become more enticing because of the potential revenue streams for the

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1. SARAH DEVANY, *STEM CELL RESEARCH AND THE COLLABORATIVE REGULATION OF INNOVATION* 55 (2014); *see also id.* at 87.

2. *Id.* at 22.

3. Maria Fannin, *Personal Stem Cell Banking and the Problem with Property*, 12 *SOCIAL & CULTURAL GEOGRAPHY* 342-343 (2011).

4. GOTTWEIS, ET. AL, *supra* note 5, at 46.

5. *Id.* at 4.

6. GOTTWEIS, ET. AL, *supra* note 5, at 7. *See also* Eneda Hoxha, *Stemming the Tide: Stem Cell Innovation in the Myriad-Mayo-Roslin Era*, 30 *BERKELEY TECH. L.J.* t 567-568 (2015).

7. ANDREAS HUBEL, ULRICH STORZ, & ALOYS HUTTERMAN, *LIMITS OF PATENTABILITY: PLANT SCIENCES, STEM CELLS AND NUCLEIC ACIDS* 9 (2013).

8. JUSTINE PILA & PAUL TORREMANS, *EUROPEAN INTELLECTUAL PROPERTY LAW* 3 (2016).

investors.<sup>9</sup>

According to Margarit, Levy, and Loike, stem cell technologies are believed to be in an infancy stage.<sup>10</sup> Many factors contribute to the obstacles in the way of the growth of stem cell research. First, stem cell research firms and other players in the industry will always be competing for capital with one another because of the limited number of potential investors.<sup>11</sup> Furthermore, stem cell research is subject to heavy regulation, both in regard to the use of stem cells in research as well as the patents derived from said research.<sup>12</sup> The patenting process of stem cell research discoveries is one of the most controversial topics in intellectual property law.<sup>13</sup> The controversy stems from the diverse view as to what constitutes a human embryo.<sup>14</sup>

Much of the current investment in stem cell research is comprised of public funds with the investing country trying to increase its strength in a knowledge-based economy.<sup>15</sup> In 2005, South Korea created the World Stem Cell Hub so that it could advance its position in the knowledge-based economy.<sup>16</sup> On the other side of the world, the U.S. has successfully used its intellectual property law to aggressively progress the biotechnology industry.<sup>17</sup>

While many countries around the globe have heavily invested in stem cell research, there are risks involved in this form of research. For example, biomedical research can be more costly in comparison to other scientific fields due to the need for specialized laboratories and scientists.<sup>18</sup> Further, biomedical research is also riskier in comparison to other scientific fields because firms and inventors must spend significant resources on trials to protect public health and safety.<sup>19</sup> Despite these realities, countries are pushing money into the field with the hopes of finding cures for previously untreatable human diseases.

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9. Hoxha, *supra* note 10, at 569.

10. Yehezkel Margarit, Orrie Levy, & John Loike, *The New Frontier of Advanced Reproductive Technology: Reevaluating Modern Legal Parenthood*, 37 HARV. J.L. & GENDER 138 (2014).

11. GOTTWEIS, *supra* note 5, at 19.

12. HUBEL, *supra* note 9.

13. PILA, *supra* note 16, at 101.

14. AURORA PLOMER & PAUL TORREMANS, EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 30 (2009).

15. GOTTWEIS ET. AL, *supra* note 5, at 22.

16. *Id.* at 1.

17. *Id.* at 179.

18. RAVEESHA GUPTA, HUMAN EMBRYONIC STEM CELLS PATENTING: INNOVATION VS MORALITY 16 (2016).

19. *Id.* at 16.

*B. International variations.*

There is much debate as to the legal status of the components within the human body, including tissues, organs, and cells.<sup>20</sup> There is also debate as to what constitutes something such as a human embryo.<sup>21</sup> This debate regarding stem cell research is global in scope with various sides including industry players, state interests, consumer advocates, and ethical opponents competing for dominance.<sup>22</sup> The international framework for stem cell research contains much diversity in regard to what is considered permissible research activity.<sup>23</sup> The International Stem Cell Initiative is a global organization charged with standardizing and harmonizing the area of stem cell research across the globe.<sup>24</sup> Countries have responded to the Initiative's efforts at international harmonization in various ways. Responses range from complete prohibitions against all research on embryos all the way to explicit endorsement and public funding of such research.<sup>25</sup>

Comparing Japanese law and European law provides a glance at the varying sides of the aforementioned spectrum. The Japanese law has a strong concern for the morality of what can potentially be patented; as a result, it elects to place limitations on the research it endorses. On the other hand, the European law endorses more methods of stem cell research.<sup>26</sup>

Canada allows for stem cell research to be conducted so long as certain requirements are met by the researcher including that the research has potential health benefits, there is a system of free and informed consent based on full disclosure for donation purposes, respect exists for privacy and confidentiality, payment is not made for donation, embryos are not created merely for science, and there is respect for human dignity as well as physical, spiritual, and cultural dignity.<sup>27</sup> Despite these restrictions, some major breakthroughs in the field of stem cell research have come out of Canada.<sup>28</sup>

In China, stem cell research can be performed on spare embryos

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20. Fannin, *supra* note 4, at 340

21. Francoise Baylis & Timothy Krahn, *The Trouble with Embryos*, 22 *SOCIAL STUDIES* 32 (2009).

22. GOTTWEIS ET. AL., *supra* note 5, at 4.

23. Carl E. Gulbrandsen, Michael Falk, Elizabeth Donley, David Kettner, & Lissa Koop, *Legal Framework Pertaining to Research Creating or Using Human Embryonic Stem Cells*, in *HUMAN EMBRYONIC STEM CELLS* 328 (J. Ororico, S.-C. Zhang, & R. Pedersen eds. 2005).

24. DEVANEY, *supra* note 1, at 22.

25. *Appendix E: Overview of International Human Embryonic Stem Cell Laws*, 34 *THE NEW ATLANTIS* 129 (2012).

26. Plomer at 5.

27. *Appendix E: Overview of International Human Embryonic Stem Cell Laws*, 34 *THE NEW ATLANTIS* 130 (2012).

28. *Id.*

originally designated for in vitro fertilization, donated gametes, fetal cells from abortion, and embryos created by somatic cell nuclear transfer.<sup>29</sup> Stem cell research in Israel is conducted without much controversy and the country has a very successful industry.<sup>30</sup>

One of the most difficult ethical issues within stem cell research is how to compensate those who have made physical donations to the research and, if so, to make sure the donations are equal and that donations are never made as the result of coercion.<sup>31</sup> One approach to compensation is an equity-based solution whereby the donor gets a share of the proceeds obtained from the successful research project.<sup>32</sup> Problematically, women who are not in a country with a reliable legal structure, are not covered by bioethics laws, not living in a country reflective of a feminist-influenced society, and/or lack adequate income could be taken advantage of in these donor transactions.<sup>33</sup>

Perhaps one international legal and social standard that exists is the prohibition against the development, implantation, and research on human embryos 14 days after fertilization. Most European countries, as well as Region X, and countries Y and Z, follow this standard.<sup>34</sup> However, although this 14-day rule has been followed since human embryological research began in earnest in the 1970s, there is now pressure to move to a 28-day rule allowing embryos to be kept alive for a longer period of time given that the research has advanced with much support from some bioethicists.<sup>35</sup> Regardless, despite this one example, the variety of cultures and social, historical, and religious differences have made it difficult to adopt a common set of ethics within the EU to guide biomedical research.<sup>36</sup>

Being that thirty-five percent of all patent applications with stem cell technology as the subject matter are filed with the European Patent Office (“EPO”) or the United States Patent and Trademark, it is important to understand the EU’s and U.S.’s stances on the morality debate.<sup>37</sup>

### *C. The Morality Debate in the EU.*

The moral status of the human embryo is a constant source of debate

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29. *Id.* at 131.

30. GOTTWEIS ET. AL, *supra* note 5, at 45.

31. DEVANEY, *supra* note 1, at 57.

32. *Id.* at 107.

33. GOTTWEIS ET. AL, *supra* note 5, at 49.

34. GUPTA, *supra* note 21, at 27.

35. *A Debate is Needed over Embryo Research Limits*, FINANCIAL TIMES (August 8, 2018), <https://www.ft.com/content/40f521ac-9ef0-11e8-85da-eeb7a9ce36e4>.

36. GUPTA, *supra* note 21, at 26.

37. Hoxha, *supra* note 10, at 603-604.

among politicians, philosophers, theologians, as well as the average citizen.<sup>38</sup> Within the EU, the European Group on Ethics, an advisory board to the European Commission on matters of science and new technologies, is one of the main sources of authority that has spoken to the controversy of the morality of patenting stem cell research.<sup>39</sup> The Group suggests that the moral debate is not just about what is a human life, but also about the application of the research and resulting therapies.<sup>40</sup> Much of the controversy is one of ethics; it is questioned whether stem cell research should be conducted when some consider it immoral to engage in an activity that leads to the destruction of a human embryo.<sup>41</sup>

The moral status of the human embryo is a constant source of debate among politicians, philosophers, theologians, as well as the average citizen.<sup>42</sup> The issue of morality in biotech research in Europe likely began in the 1980s.<sup>43</sup> The debate began focusing on stem cell research conducted in Europe at roughly the same time.<sup>44</sup> The debate was further stoked in 1996 when stem cell-related research led to the cloning of Dolly the sheep in the United Kingdom.<sup>45</sup> There is some evidence that the media continues to shape biomedical research policy as such news affects politicians, religious representatives, and researchers.<sup>46</sup>

Controversy has surrounded human embryonic stem cell research since the first scientists extracted an embryo from a human body.<sup>47</sup> Many unanswered questions remain in this area of research including the definitions of “human embryo” and “life.”<sup>48</sup> The social construction of the human embryo sets the stage for the debate on research and funding for stem cell-related activities.<sup>49</sup> The fundamental question of whether the human embryo *could* become a person does not have a simple answer, yet the answer is crucial because it plays a role in determining the human

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38. R. Alta Charo, *Ethical and Policy Considerations in Embryonic Stem Cell Research*, in HUMAN EMBRYONIC STEM CELLS 312 (J. Ororico, S.-C. Zhang, & R. Pedersen eds. 2005).

39. GUPTA, *supra* note 21, at 23.

40. GOTTWEIS ET. AL., *supra* note 5, at 4.

41. GUPTA, *supra* note 21, at 5.

42. R. Alta Charo, *Ethical and Policy Considerations in Embryonic Stem Cell Research*, in HUMAN EMBRYONIC STEM CELLS 312 (J. Ororico, S.-C. Zhang, & R. Pedersen eds. 2005).

43. GUPTA, *supra* note 21, at 28-29.

44. Laura Palazzani, *Embryo Research in Italy: The Bioethical and Biojuridical Debate*, 17 HUMAN REPRODUCTION AND GENETIC ETHICS 28 (2012).

45. GOTTWEIS ET. AL., *supra* note 21, at 61.

46. Cristina Rodriguez Luque, *Framing Bioethics: A Decade of Controversy over Stem Cell Research in the Spanish Press—El Pais and ABC (1996-2006)*, 3 THE INTERNATIONAL JOURNAL OF SCIENCE IN SOCIETY 79 (2012).

47. GUPTA, *supra* note 21, at 5.

48. *Id.* at 5.

49. PLOMER, *supra* note 17, at 32.

embryo's legal status.<sup>50</sup> Although the assumption is that humans have greater value than other living organisms, the potential destruction of a human embryo may be justified to help those suffering from a disease.<sup>51</sup>

In Europe, the debate is often solved through a balancing test of the usefulness of what may be developed from stem cell research on the one hand and the severity of the violation of public order on the other.<sup>52</sup> In an attempt to reduce the controversy associated with stem cell research, governments and non-governmental organizations have attempted to develop uniform standards for research activities so that scientists are better equipped to make personal and professional choices as to what type of research should be pursued, where it should be pursued, and how the research should be funded.<sup>53</sup>

The approach to establishing rights for human embryos has ranged from assigning embryos full rights as if it is a human all the way to virtually no rights such that it is treated no different than any other cell.<sup>54</sup> In a majority of EU member-states, a human embryo has a unique status which exists somewhere between that of less than a full human but more than just a cluster of cells.<sup>55</sup> Regardless of the different perspectives across the EU, the competing ethical views find their way into the law of the member-states and therefore the law serves as a reflection of societal viewpoints.<sup>56</sup>

When a product or process involves the use of internal human material, ethical questions arise.<sup>57</sup> Critics of biomedical research fear that a living organism could be commercialized and seen as a profit opportunity, such that health and safety risks are set aside which consequently could cause harm to humans.<sup>58</sup> By extension, if stem cell research is considered immoral, then it would likewise be immoral to patent a resulting technology.<sup>59</sup> Regardless of the immorality concern, as an example, the exclusion of patentability due to a violation of public order or based on morality in Europe is rare.<sup>60</sup>

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50. *Id.* at 33.

51. DEVANEY, *supra* note 1, at 26.

52. HUBEL, *supra* note 9, at 11.

53. Baylis, *supra* note 25, at 31.

54. DEVANEY, *supra* note 1, at 25.

55. PLOMER, *supra* note 17, at 33.

56. Baylis, *supra* note 25, at 33.

57. Tamera Hervey, *EU Health Law*, in *EUROPEAN UNION LAW 642* (Catherine Barnard & Steve Peers, eds., 2014).

58. GUPTA, *supra* note 21, at 20.

59. *Id.* at 6.

60. HOFFMANN EITLE, *THE EUROPEAN PATENT CONVENTION FOR FOREIGN PRACTITIONERS* 58 (2017).

*D. The Morality Debate in the U.S.*

What is patentable subject matter is a sign of societal approval.<sup>61</sup> Within stem cell research, morality has been a bigger issue in Europe than in the United States, where patents are routinely granted for innovations resulting from stem cell research without a concern for morality.<sup>62</sup> In contrast to European law, U.S. law does not have a specific prohibition on stem cell-related patents.<sup>63</sup> In fact, isolated stem cells have been considered patentable subject matter in the U.S. for many years.<sup>64</sup> Some believe that since U.S. law is so permissive on the subject of biotechnology, U.S. law suggests that life itself may be patentable.<sup>65</sup>

Thirty-five percent of all patent applications with stem cell technology as the subject matter are filed in the United States Patent and Trademark Office and the European Patent Office (“EPO”).<sup>66</sup> It should also be noted that in the U.S., access to embryonic stem cells is federally monitored while extraction of adult stem cells from a patient’s body remains unregulated.<sup>67</sup> Within the federal regulation, stem cell research is more likely to be regulated while the resulting therapies are not subject to strict regulation.<sup>68</sup>

*E. The promise of stem cell research.*

Stem cell research is not only a scientific endeavor. The manner of performing such research also reflects what is acceptable within the political and social realm of a country’s culture.<sup>69</sup> What is patentable drives scientific research in a particular direction and patent law itself serves as a form of encouragement or discouragement.<sup>70</sup> Taken together, the subject matter that is patentable by a country’s intellectual property law is not only designed to promote innovation but also to foster social participation and market growth in a particular field.<sup>71</sup>

The promise of stem cell research begins with the estimate that

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61. Christopher J. Asakiewicz, *Separation of Church and State While Promoting the Progress of Biotechnology and Modern Science: Does Morality Have Its Place in United States Patents?*, 7 J. INT. COMM. LAW TECHNOL 81 (2012).

62. GUPTA, *supra* note 21, at 5-6.

63. HUBEL, *supra* note 9, at 12.

64. ANTOINETTE F. KONSKI, PATENTING STEM CELL TECHNOLOGIES: MAKING A CLAIM 31 (2013).

65. Asakiewicz, *supra* note 63, at 83.

67. Jeneen Interlandi, *Could This Cell Save Your Life?*, 83 CONSUMER REPORTS 38 (2018).

68. *Id.* at 40.

69. GOTTSWEIS ET. AL, *supra* note 5, at 11.

70. BARNARD & PEERS, *supra* note 59, at 643.

71. PILA, *supra* note 16, at 3.

therapies resulting from such research could help 300 million people in the United States, Japan, and the European Union.<sup>72</sup> Countries that choose to encourage stem cell research by offering patents for its innovations often see stem cell research as an avenue that will address problems felt by its aging population.<sup>73</sup> Stem cell therapies have also been used in clinical settings to successfully attack diseases already impacting the patient.<sup>74</sup>

The biggest promise of stem cell research is that it could lead to organ regenerating technologies that can cure damaged or diseased cells in humans.<sup>75</sup> Both adult and embryonic stem cells can contribute to this big promise.<sup>76</sup> Besides the ability to attack many diseases, stem cell technology can also be used to test and screen certain pharmaceuticals.<sup>77</sup> Thus, using stem cell testing can be an avenue through which a country can discourage pharmaceutical testing on animals and humans.<sup>78</sup>

The challenge of determining patentability of stem cell research and biotechnology, and thus its utility, partially rests on separating what is considered nature and what is produced separately by way of human invention.<sup>79</sup> Specifically, the promise of stem cell technology lies partially in the debate between whether biotechnology can produce something that is patentable and the uncertain implications of patentability.<sup>80</sup> The discussion as to whether stem cell research activities can lead to patentable inventions also involves weighing the ethical concerns associated with commercialization and the potential for life-saving therapies.<sup>81</sup> What has helped both quell the debate on stem cell research, and thus, improve the prospects of stem cell therapies is the fact that other, new methods to obtain stem cells for research purposes now exist such as obtaining them through somatic cell nuclear transfer, parthenogenesis, and/or the inducement of pluripotent stem cells.<sup>82</sup>

#### *F. The mechanics of patenting stem cell research innovations in Europe.*

The purpose of a patent is to provide the inventor with exclusive rights

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72. GOTTWEIS ET. AL, *supra* note 5, at 32.

73. *Id.* at 14-15.

74. DEVANEY, *supra* note 1, at 7.

75. *Id.* at 7.

76. PILA, *supra* note 16, at 101.

77. DEVANEY, *supra* note 1, at 9.

78. *Id.* at 5.

79. PILA, *supra* note 16, at 123.

80. *Id.* at 101-102.

81. HUBEL, *supra* note 9, at 10.

82. *Id.* at 26-28.

to the patented subject matter for a limited time period.<sup>83</sup> Like elsewhere, patents issued in Europe are limited-term monopoly rights for an invention whereby the rights are granted by each individual member-state.<sup>84</sup> An inventor seeking a patent in an EU member-state may apply to the EPO or to that member-state's patent office, directly.<sup>85</sup> There are currently 38 member-states that are a party to the European Patent Convention ("EPC").<sup>86</sup>

The first step to achieving a patent is making sure the invention is patentable subject matter.<sup>87</sup> The EPC created the EPO and also created the substantive law as to what is patentable in the EU.<sup>88</sup> Where the inventor meets the criteria subject to the EPC, the EPO may issue a "European Patent" that provides patent rights in the 38 member-states.<sup>89</sup>

Some of the Rules that the EPC stated are relevant to the patentability of stem cell research. Article 53(a) of the EPC prohibits patenting inventions where the commercial exploitation of the subject matter would be contrary to public order or morality.<sup>90</sup> Rule 28 of the EPC prohibits patenting the process for cloning humans and processes for modifying the germ line genetic identify of humans.<sup>91</sup> Rule 29 of the EPC prohibits the patentability of the human body, internal human material at the various stages of development of the human body, the simple discovery of an element of the human body, gene sequences, and partial gene sequences.<sup>92</sup>

The TRIPS Agreement also disallows patentability for inventions that may infringe upon public order or morality grounds.<sup>93</sup> The TRIPS Agreement defines public order and morality in a way that a party to the TRIPS Agreement may rely on this provision to protect human life and/or other concerns.<sup>94</sup>

Patent law in the EU is complex in that the EPC works alongside the

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83. BARNARD & PEERS, *supra* note 59, at 643.

84. PILA, *supra* note 16, at 113.

85. PLOMER, *supra* note 17, at 6.

86. These member-states include the 28 EU member-states as well as Albania, Iceland, Liechtenstein, Macedonia, Monaco, Norway, San Marino, Serbia, Switzerland, and Turkey. PLOMER, *supra* note 17, at 6.

87. Hoxha, *supra* note 10, at 590.

88. PLOMER, *supra* note 17, at 6.

89. *Id.*

90. Convention on the Grant of European Patents [hereinafter "EPC"] of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, Art. 53(a).

91. EPC, Rule 28.

92. EPC, Rule 29.

93. HUBEL, *supra* note 9, at 25. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

94. GUPTA, *supra* note 21, at 21. TRIPS Agreement.

patent regimes in each member-state.<sup>95</sup> Even in cases where stem cell research cannot be patented, EU law generally allows the marketing and commercialization of such products and processes developed from research.<sup>96</sup>

Article 168 (ex 152, 129) of the Treaty on the Functioning of the European Union (hereinafter “TFEU”) provides EU governing bodies with the ability to regulate the derivatives of human blood and organs but also allows member-states to impose more stringent protections.<sup>97</sup> The

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95. EITLE, *supra* note 62, at 13.

96. PLOMER, *supra* note 17, at 180.

97. Consolidated Version of the Treaty on the Functioning of the European Union art. 168, Oct. 26, 2012 O.J. (C326) 47 [hereinafter TFEU]. Article 168 (ex 152, 129) of the TFEU reads:

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention. 2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed. 3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health. 4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns: (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures; (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; (c) measures setting high standards of quality and safety for medicinal products and devices for medical use. 5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States. 6. The Council, on a proposal from the Commission, may also adopt recommendations for

Directive on the Legal Protection of Biotechnological Inventions of 6 July 1998 (the “Biotech Directive” or “Directive 98/44/EC”), despite its controversial evolution, was necessary because it provided a pathway for the EU member-states could compete with the U.S. and other countries.<sup>98</sup> Using their powers, some individual member-states took action to develop the stem cell research industry. For example, the United Kingdom’s Stem Cell Initiative was designed to foster investment by large pharmaceutical firms.<sup>99</sup>

The Biotech Directive was one of the most controversial and politicized pieces of EU legislation ever, taking ten years to complete.<sup>100</sup> The Biotech Directive should be viewed as a political compromise among many points of view on the subject.<sup>101</sup> The compromise was necessary due to the cultural, religious, economic, and historical diversity across the EU.<sup>102</sup> For example, German constitutional law provides a right to science and research but stem cell research in Germany also competes with other constitutional rights such as the rights to personality, life, and personal integrity.<sup>103</sup> In effect, the Biotech Directive reproduces provisions of the EPC, codifies the EPC case law, and clarifies ambiguities within the EPC.<sup>104</sup> The Biotech Directive remains the only substantive patent legislation on the subject matter at the EU level.<sup>105</sup> Although it is not an organization of the EU, the EPO uses the Biotech Directive in matters of patentability which in theory should allow for greater harmonization of law across Europe.<sup>106</sup> However, the EPO does not take direction from the European Court of Justice (“ECJ”) which could threaten harmonization if the EPO at any time decided that its jurisprudence should separate.<sup>107</sup> Regardless, the ECJ is the de facto authority on both individual EU member-state patents and European patents if the litigation in question

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the purposes set out in this Article. 7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

98. PLOMER, *supra* note 17, at 8.

99. DEVANEY, *supra* note 1, at 9.

100. PLOMER, *supra* note 17, at 3-4.

101. *Id.* at 26.

102. PLOMER, *supra* note 17, at 29.

103. Barbara Advena-Regnery, Hans-Georg Dederer, Franziska Enghofer, Tobias Cantz, & Thomas Heinemann, *Framing the Ethical and Legal Issues of Human Artificial Gametes in Research, Therapy, and Assisted Reproduction: A German Perspective*, 32 *BIOETHICS* 317 (2018).

104. PILA, *supra* note 16, at 129.

105. *Id.*

106. HUBEL, *supra* note 9, at 35.

107. *Id.*

begins in an EU member-state.<sup>108</sup>

Despite efforts at creating a fully harmonized body of patent law in the EU, a unitary body of patent law does not yet exist. Consequently, higher costs exist for inventors attempting to secure and enforce patent rights on the European continent.<sup>109</sup> However, over the years, the ECJ has drawn the European continent closer to a unified body of patent law through its harmonizing decisions.<sup>110</sup>

A natural tension still exists in European patent law between the right to prohibit others from copying the technology and a purchaser's right to resell the patented product purchased by that consumer.<sup>111</sup> This tension is somewhat resolved by EU law which allows a purchaser to sell the purchased personal property as the owner sees fit.<sup>112</sup> Therefore, the patent granted in Europe only extends to the prohibition of bringing the technology to the marketplace without permission.<sup>113</sup> This exhaustion of rights doctrine does not allow a patent holder to block the entry of a patented good into another member-state once it has been freely and legally available in another member-state.<sup>114</sup> The regulation of the sale of non-patented human tissue research is covered by Directive 2004/23/EC.<sup>115</sup>

EU law, generally, does regulate blood, organs, and human tissue through both regulations and patent law.<sup>116</sup> The protection of human dignity and integrity is considered to be a guiding principle of the Directive 98/44/EC.<sup>117</sup> However, human dignity is rarely mentioned in member-state constitutions despite the use of the phrase in many international documents.<sup>118</sup> The definition of a human embryo becomes crucial in European patent law so that patentability can be established.<sup>119</sup>

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108. *Id.*

109. PILA, *supra* note 16, at 113.

110. *Id.*

111. *Id.* at 210.

112. *Id.*

113. *Id.*

114. *Id.*

115. Directive 2004/23/EC of March 31, 2004, on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage, and Distribution of Human Tissues and Cells.

116. BARNARD & PEERS, *supra* note 59, at 642.

117. GUPTA, *supra* note 21, at 23.

118. PLOMER, *supra* note 17, at 217.

119. GUPTA, *supra* note 21, at 29-30.

## II. THE SCIENCE OF STEM CELLS.

### *A. Application.*

Scientists first discovered stem cells in the 1950s in the marrow of long bones.<sup>120</sup> Scientists then discovered the high levels of plasticity of embryonic stem cells in the 1980s largely by studying mice.<sup>121</sup> By the 1990s, scientists proposed that stem cells could regenerate organs such as the heart, liver, and nervous system.<sup>122</sup> Human stem cells were first collected in 1998 by two research teams working independently—one team discovered the presence of stem cells from five-day-old blastocysts (a mammalian embryo in its early stages of development) and the second team discovered the presence of stem cells in two- to four-month old fetuses garnered from elective abortions.<sup>123</sup>

The goal of most stem cell therapies is to produce new cells to replace cells that have died, as well as delivering new cells to parts of the body that need but lack them.<sup>124</sup> Stem cell therapies require the cells to be injected into a patient akin to an organ transplant.<sup>125</sup> Examples of stem cell therapy include injecting new muscle cells into a failing heart or neurons into a brain affected by a stroke.<sup>126</sup>

Because stem cells are unspecialized, they hold the potential to grow bone tissue, cartilage, nerves, organs, and even breast tissue.<sup>127</sup> Embryonic stem cells, because of their plasticity, have a greater ability to differentiate compared to adult stem cells.<sup>128</sup> Cells from embryos can create all of a human's structures, including specialized cells, tissues, and organs.<sup>129</sup> On the other hand, stem cells that replace lost cells in specific organs have limited plasticity, having only the ability to produce cells of specific tissue.<sup>130</sup> However, these tissue-specific cells which can only be harvested post-natal could still be used to renew or repair existing tissue.<sup>131</sup> For example, stem cells collected from umbilical cords are uniquely capable of treating a multitude of blood diseases such as

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120. LYGIA V. PEREIRA, *STEM CELLS: PROMISE AND REALITY* 15 (2017).

121. JOSEPH PANNO, *STEM CELL RESEARCH: MEDICAL APPLICATIONS & ETHICAL CONTROVERSY* 5 (2006).

122. PEREIRA, *supra* note 124, at 17.

123. PANNO, *supra* note 125, at 18-19.

124. JONATHAN SLACK, *STEM CELLS: A VERY SHORT INTRODUCTION* 10 (2012).

125. PANNO, *supra* note 125, at 59.

126. SLACK, *supra* note 128, at 10-11.

127. JOSEPH CHRISTIANO, *STEM CELL REVOLUTION* 14 (2018).

128. PANNO, *supra* note 125, at 1.

129. PEREIRA, *supra* note 124, at 2-3.

130. *Id.* at 11.

131. SLACK, *supra* note 128, at 70.

leukemia, lymphoma, anemia, and human immune diseases.<sup>132</sup>

*B. Garnering stem cells.*

A stem cell is a cell that can reproduce itself and also general offspring of different functional cell types.<sup>133</sup> There are five types of stem cells: embryonic stem cells (garnered from an early developmental stage or embryo), fetal (garnered from a fetus), amniotic (garnered from amniotic fluid garnered from a routine amniocentesis procedure), post-natal (garnered from an umbilical cord or tissue from a healthy, live birth), and adult stem cells (garnered from a living human).<sup>134</sup>

Despite these five categories, stem cells are usually divided into two groups: embryonic stem cells and adult stem cells.<sup>135</sup> Embryonic stem cells originate from cells associated with the early embryo.<sup>136</sup> They are generally derived from a pre-implantation embryo.<sup>137</sup> Embryonic stem cells of a mammal are obtained exclusively from the inner cell mass of a blastocyst and when placed in a culture, can transform into many types of cells.<sup>138</sup> The stem cells with the most therapeutic potential are the cells derived from a fertilized egg which can transform into an entire organism because they are totipotent—meaning they have almost unlimited potential for development.<sup>139</sup>

The therapeutic advantage of embryonic stem cells is that they can become any type of cell, meaning they are pluripotent, while adult stem cells can give rise to just a limited number of types of cells.<sup>140</sup> Adult stem cells are harvested post-birth from umbilical cords and/or placentas.<sup>141</sup> The types of proteins embedded in the membrane of an embryonic stem are different than those of an adult stem cell.<sup>142</sup>

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132. PEREIRA, *supra* note 124, at 26.

133. *Id.* at 2.

134. NEIL H. RIORDAN, *STEM CELL THERAPY: A RISING TIDE* 37 (2017).

135. PEREIRA, *supra* note 124, at 12-13.

136. SLACK, *supra* note 128, at 5.

137. CHRISTIANO, *supra* note 131, at 9.

138. PANNO, *supra* note 125, at 5.

139. *Id.* at 5.

140. PEREIRA, *supra* note 124, at 43. MARK BERMAN & ELLIOT LANDER, *THE STEM CELL REVOLUTION* 1 (2015).

141. *Id.* at 13.

142. PANNO, *supra* note 125, at 1.

143. PEREIRA, *supra* note 124, at 43. MARK BERMAN & ELLIOT LANDER, *THE STEM CELL REVOLUTION* 1 (2015).

Cell differentiation is the process by which the genes of a cell and the external environment interact to produce specialized cells such as liver cells, heart cells, and bone cells.<sup>144</sup> Cell differentiation can occur in one of three ways: spontaneously, through a process called directed differentiation which allows cells to contact each other, or when the culture medium is provided with certain growth factors.<sup>145</sup> Stimulating the cell cultures using growth factors will focus the differentiation toward a particular type of cell.<sup>146</sup> The first stage of differentiation divides the embryo into four groups of cells, all of which become progressively differentiated and specialized into various tissues and organs.<sup>147</sup> Scientists consider embryonic stem cells to be “undifferentiated” because they can divide without limit and, most likely, become all of the various cell types found in the human body.”<sup>148</sup> Stem cells can also divide and regenerate for an indefinite period of time after they are harvested.<sup>149</sup> Similar to embryonic cells, stem cells can also differentiate into more than one type of cell.<sup>150</sup> Cell differentiation, when taking place in the embryo, allows cells to take on specific forms and functions.<sup>151</sup> In a laboratory, embryonic stem cells can respond to various forms of stimuli.<sup>152</sup>

Embryonic stem cells can be extracted from embryos beginning in the third day of development when an embryo is made up of 100 cells. These 100 cells can be divided into placenta cells or those developing into all adult tissues.<sup>153</sup> During extraction, the inner cell mass is removed from the blastocyst and multiplied in a way that embryonic stem cells are produced in large quantities and perhaps can serve as an unlimited source for transplants.<sup>154</sup> If the association between the inner cell mass and the trophoblast is disrupted, the embryonic stem cell cannot develop into an embryo.<sup>155</sup>

Currently, there is no way to remove an embryonic stem cell from the inner core mass of a blastocyst without killing the embryo.<sup>156</sup> Once human embryonic stem cells are collected, they are grown in a culture and stimulated in several ways to determine the kinds of cells into which they

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144. CHRISTIANO, *supra* note 131, at 10.

145. PANNO, *supra* note 125, at 3.

146. *Id.* at 26.

147. PEREIRA, *supra* note 124, at 3.

148. SLACK, *supra* note 128, at 5.

149. CHRISTIANO, *supra* note 131, at 8.

150. PANNO, *supra* note 125, at 1.

151. PEREIRA, *supra* note 124, at 2.

152. *Id.* at 46.

153. PEREIRA, *supra* note 124, at 43.

154. *Id.* at 43.

155. PANNO, *supra* note 125, at 5.

156. *Id.* at 23.

may differentiate.<sup>157</sup> Stem cells can also be harvested from umbilical cords after birth and stored later for therapeutic treatment.<sup>158</sup> These “cord cells” can also produce blood cells and are commonly used to treat cancer patients.<sup>159</sup>

### *C. Limitations.*

There are academics that argue that the promise of stem cell research therapy has been overstated and that there exist significant obstacles and limitations associated with stem cell research.<sup>160</sup> First, they argue, regardless of the method of stem cell therapy, donor compatibility is still an issue; because the issue of compatibility exists, the industry associated with the banking of umbilical cords after a person’s birth is growing.<sup>161</sup> A recent example of the problems associated with donor compatibility is the success researchers have found treating beta-thalassemia, an inherited blood disorder, that affects only 228,000 people worldwide. Despite the success from to a new treatment, that success is dependent upon finding a donor match as to avoid other health risks.<sup>162</sup>

Second, academics argue that most of what we know about stem cells comes from studying mice and rats.<sup>163</sup> Clinical trials involving stem cells and humans did not occur until 2010 largely due to safety concerns associated with injecting stem cells into the human body.<sup>164</sup> Research suggests that stem cells from other mammals can’t be used to cure diseases in humans.<sup>165</sup> Consequently, critics argue that it is too early to say that stem cell therapies are safe for human use.<sup>166</sup>

Third, critics argue that biomedical research is quite expensive. A research team focusing on the standard practice of testing on animals followed by four stages of human application can range between \$500,000 and \$3 billion.<sup>167</sup> Due to the cost associated with biomedical research, most activity in this area is conducted by pharmaceutical firms.<sup>168</sup>

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157. *Id.* at 24.

158. CHRISTIANO, *supra* note 131, at 9.

159. *Id.*

160. PANNO, *supra* note 125, at 61.

161. PEREIRA, *supra* note 124, at 27.

162. Sarah Troy, *Gene Therapy Shows Promise in Patients with a Blood Disorder*, WALL ST. J. (April 19, 2018: 4:21AM), <https://www.wsj.com/articles/gene-therapy-shows-promise-in-patients-with-a-blood-disorder-1524085227?mod=searchresults&page=1&pos=3>.

163. PANNO, *supra* note 125, at 18.

164. PEREIRA, *supra* note 124, at 58-59.

165. PANNO, *supra* note 125, at 18.

166. SLACK, *supra* note 128, at 39.

167. *Id.* at 51.

168. *Id.*

Fourth, and more directly related to science, critics argue that embryonic stem cells do not compare well to adult tissue as the former are programmed to become fetuses and therefore can grow too rapidly in a context other than pregnancy when the two types of cells are forced to interact.<sup>169</sup>

Lastly, critics fear on grounds that the science behind it is unsafe, that stem cell research will lead to the cloning of humans despite the fact that human cloning has never occurred and virtually all scientists oppose it for safety reasons.<sup>170</sup>

### III. HIGHLIGHTS OF STATUTORY LAW REGULATING THE STEM CELL INDUSTRY IN EUROPE.

#### *A. The European Patent Convention.*

Article 52(1) of the EPC states that inventions can be protected by a patent in all fields of technology so long as the invention is new, involves an inventive step, and is susceptible of industrial application.<sup>171</sup> However, Article 52(2) enumerates what is not an invention and thus not patentable and includes scientific theories, mathematical methods, aesthetic creations, business methods, rules for playing games, computer programs, and presentations of information.<sup>172</sup> Article 53 specifies exceptions to patentability, separate from what is not considered an invention pursuant to Article 52(2), and includes inventions for which the commercial exploitation would be contrary to a member-state's public order or morality, plant varieties, animal varieties, biological processes for the production of plants or animals, and methods for the treatment of the human or animal body by surgery, therapy, or diagnostic methods practiced on the human or animal body.<sup>173</sup>

Rule 28 (ex 23d) of the EPC further expands upon the exceptions to patentability found in Article 53.<sup>174</sup> Specifically, Rule 28 prohibits processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and 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

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169. BERMAN & LANDER, *supra* note 135, at 1.

170. SLACK, *supra* note 128, at 37.

171. EPC, Article 52.

172. *Id.*

173. *Id.*

174. EPC, Rule 28.

animals resulting from such processes.<sup>175</sup> Rule 29 (ex 23e) of the EPC prohibits the human body from patentability including any stage of human development, the simple discovery of one of the human body's elements, and the sequence or partial sequence of a gene from patentability.<sup>176</sup> However, Rule 29 does allow for the patentability of an element isolated from the human body or produced by a technical process which could include the sequencing of a gene or partial sequencing of a gene even if what is produced (i.e., the element) is identical to the natural element.<sup>177</sup> However, any attempt to patent a process including the sequencing or partial sequencing of a gene must be fully disclosed in the patent application.<sup>178</sup>

### *B. The TRIPs Agreement.*

Article 27 of the Trade Related Aspects of Intellectual Property Rights Agreement ("TRIPs Agreement") has nearly identical language to Article 52 of the EPC. This language provides that an invention is patentable if it is (1) new, (2) involves an inventive step, and (3) is capable of industrial application.<sup>179</sup> Article 27 also states that member-states *may* prohibit inventions for which a member-state believes it needs to prohibit patentability to protect public order and morality, to protect human, animal, or plant life or health, and/to protect the environment.<sup>180</sup> Additionally, Article 27 allows member-states to prohibit the patenting of inventions for (1) diagnosis, therapy, and surgical methods for humans or animals; and (2) biological processes for the production of plants or animals.<sup>181</sup> However, the TRIPs Agreement, unlike the EPC, is not mandatory.

### *C. Directive 98/44/EC.*

Directive 98/44/EC is the chief statutory source of law promulgated by the EU governing stem cell research despite its broader scope to define the legal protection for all biological inventions.<sup>182</sup> In the fairly lengthy preamble to Directive 98/44/EC, that the European Parliament and the European Council recognized that there existed deep divisions and many

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175. EPC, Rule 28.

176. EPC, Rule 29.

177. *Id.*

178. *Id.*

179. TRIPs Agreement, Art. 27.

180. *Id.*

181. *Id.*

182. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions 1998 O.J. (L 213).

approaches as to how the various member-states protected biological inventions.<sup>183</sup> If these diverging approaches were to continue, the EU's common market could be threatened.<sup>184</sup> The preamble also, however, specifically acknowledges the need to safeguard and respect the dignity and integrity of persons and the human body at virtually all stages of development.<sup>185</sup>

Article 3 of Directive 98/44/EC defines the general framework for the patentability of a biological invention including that the invention is new, involves an inventive step which is susceptible to industrial application. Specific to biological inventions, Article 3 states that biological material that is isolated from its natural environment by way of a technical process can also be patented even if that same biological material previously occurred in nature.<sup>186</sup> Article 1 immediately strikes a balance between national and international law stating that, although inventions are to be protected pursuant to a member-state's national law, member-states must adhere to the principles of EU law and other international agreements such as the TRIPs Agreement and the Convention on Biological Diversity.<sup>187</sup> Article 2 broadly defines biological material as any genetic material capable of reproducing itself or being reproduced in a biological system.<sup>188</sup> Article 6 serves as a significant limitation on the patentability of biological inventions, in the form of an exception even if the requirements of Article 3 are met by an inventor, in that biological inventions that through commercial exploitation would be contrary to public order and morality cannot be patented with exact prohibitions identified by category including the cloning of human beings, a process for modifying the genetic identity of a human being, the use of human embryos for industrial or commercial purposes, and the a process for modifying the genetic identify of animals.<sup>189</sup>

Articles 15 and 16 are administrative in context yet are quite important. Article 15 orders member-states to align their law with the requirements of Directive 98/44/EC by July 30, 2000 and by doing so must provide in law a reference to this Directive but allows each member-state to unilaterally determine how this reference shall be found within its law.<sup>190</sup> Article 16 requires the EU to develop a report that identifies any issues associated with the harmonization of law governed by Directive 98/44/EC

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183. *Id.*

184. *Id.*

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*

189. *Id.*

190. *Id.*

and conflicts with international agreements germane to Directive 98/44/EC.<sup>191</sup>

*D. Directive 2004/23/EC.*

The focus of Directive 2004/23/EC aims to promote the biological innovation industry by ensuring the safety of the industry and the quality of the industry's products.<sup>192</sup> The range of regulation for this Directive includes the procurement, testing, processing, storage, and distribution of human tissues and cells across the EU.<sup>193</sup> Under Directive 2004/23/EC, regulation extends specifically to blood, umbilical cord and bone marrow stem cells, reproductive cells including eggs and sperm, fetal tissues, adult stem cells, and embryonic stem cells.<sup>194</sup> Although stem cells are not specifically identified, the term "cells" is defined in Article 3 as "individual human cells or a collection of human cells when not bound by any form of connective tissue." Article 5 articulates that professionals working within this industry and their employers must be well certified, have training and expertise, and must be employed by an entity operating with approval from a member-state's proper authority.<sup>195</sup> Article 7 requires that member-states put into place an inspection regime whereby inspections are performed when serious incidents occur.<sup>196</sup> Relatedly, Article 8 requires the member-state's regulatory regime to develop a process whereby donated human tissue and cells can be traced to the donor while Article 14 requires that all information including information concerning the donor's genetics remains confidential.<sup>197</sup>

*E. Directive 2015/566/EU.*

Much like Directive 2004/23/EC (discussed *supra* ), Directive 2016/566 sets standards for industry safety regarding the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells.<sup>198</sup> This Directive places significant emphasis on consumer protection and the inspection of imported human tissues and

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191. *Id.*

192. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells 2004 O.J. (L 103).

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells Text with EEA relevance 2015 O.J. (L 93).

cells.<sup>199</sup> This ensures that professionals and certified professional establishments are the routine providers of these services.<sup>200</sup> Those involved in these activities should be authorized and licensed by a member-state's regulatory regime.<sup>201</sup> Article 1 makes clear that the Directive applies to any human tissues and cells that will be the subject of human application yet were imported into the EU but are not subject to Directive 2004/23/EC.<sup>202</sup> Article 3 states that any entity having the desire to import human cells and tissues must do so by using the services of establishments that are accredited, designated, authorized, or licensed by the proper legal authority of the member-state and any importation must have prior approval from a member-state's legal authority.<sup>203</sup>

#### IV. THE PURPOSE OF THIS WORK.

There are five aspirations for this work. First, this work seeks to inform the practitioner of the scope, limitations, and environment of stem cell and biotechnological research and patentability in the EU which will include the basic law of patentability but also a dive into related issues of law in this area. Second, this work should make the practitioner aware of the issues of morality that affect the legal environment encompassing stem cell and biotechnological research and patentability in European countries. Third, this work will describe the interplay between the ECJ and the European Patent Office including the latter's judicial bodies. Fourth, a set of threats to the harmonization of law on the subject of stem cell and biotechnological research will be identified. Lastly, a body of recommendations will be identified that could assist EU and EPC member-states in their attempts to harmonize law across the European continent.

#### V. CASE LAW FROM THE ECJ REGARDING STEM CELL RESEARCH AND RELATED RESEARCH.

##### A. *Patentability.*

The ECJ's decision in *The Netherlands v. Parliament* is critical to understanding the scope and limitations of patentability. In that case, three member-state governments challenged Directive 98/44/EC almost as

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199. *Id.*

200. *Id.*

201. *Id.*

202. *Id.*

203. *Id.*

soon as the Directive became law.<sup>204</sup> The challenging countries first complained that the Directive was not within the scope of authority granted to the EU governmental bodies designed to protect the functioning of the internal market.<sup>205</sup> The ECJ disagreed stating that the Directive clearly was designed to make sure that all member-states were acting uniformly on issues associated with biotechnological inventions that would otherwise interfere with trade across the member-states.<sup>206</sup>

Additionally, the ECJ remarked that Directive 98/44/EC was crafted to address divergent points of view across the member-states on the patentability of inventions relating to the human body and plant varieties and that such divergent mentalities could damage trade, where, in regard to a particular subject matter, some member-states might grant patent protection and others may not.<sup>207</sup> According to the ECJ, differences in patentability of the same subject matter could not only cause problems associated with trade across member-state borders, but could also create conflicts with various international trade agreements to which the EU's member-states are a party.<sup>208</sup> However, the ECJ was careful to point out that Directive 98/44/EC does not create an EU-wide patent and that any patent granted is a patent granted only by a member-state government.<sup>209</sup> The ECJ also noted that the Directive was needed to establish harmonization regarding biotechnological inventions because such uniformity could not be established by the member-states acting on their own.<sup>210</sup>

Most interestingly the challenging member-states expressed concerns that Directive 98/44/EC did not harmonize the law on patentability. Instead, they argued, the directive created the possibility of divergent laws among the member-states due to the ability of member-states to prohibit the patenting of inventions that violate public order and morality.<sup>211</sup> The ECJ admitted that although allowing member-states to prohibit the patenting of inventions that violate morality and public order gave member-state governments and their courts "a wide scope," this result was desirable because each member-state is best-suited to determine what

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204. Case C-377/98, Kingdom of The Netherlands, supported by the Italian Republic and the Kingdom of Norway v. the European Parliament and the Council of the European Union, [2001] ECR I-7079, at ¶ 1. Norway was a party to the action due to its concern that Directive 98/44/EC would interfere with the Agreement on the European Economic Area. *Id.* at ¶ 6.

205. *Id.* at ¶ 13.

206. *Id.* at ¶ 7.

207. *Id.* at ¶¶ 17-18.

208. *Id.* at ¶¶ 19-22.

209. *Id.* at ¶¶ 25.

210. *Id.* at ¶ 32.

211. *Id.* at ¶ 35.

its culture and social context will tolerate.<sup>212</sup> Many international agreements give parties to those agreements similar latitude in determining patentable subject matter.<sup>213</sup> Further, the ECJ made clear that Directive 98/44/EC provides guidelines to member-states as to how to apply a sense of public order and morality; mere commercial exploitation of the subject matter is not contrary to public order and morality simply because it is contrary to national law.<sup>214</sup> More subtly, the ECJ provided that the slight difference in language between the Directive and the EPC did not put the Directive in jeopardy.<sup>215</sup>

More specific to human biotechnology, the ECJ stated that the absence of a requirement in Directive 98/44/EC that a human donor of biological material provide consent did not violate the EU right of self-determination that would nullify the Directive.<sup>216</sup> The ECJ contended that it is the ECJ's responsibility to safeguard the fundamental right to human dignity and integrity.<sup>217</sup> The Directive itself provides language prohibiting the patentability of the human body at various stages of formation and development.<sup>218</sup> Directive 98/44/EC's prohibitions on human patentability are sufficient to protect against violations of human dignity and integrity along with the more specific prohibitions against patentability including processes for cloning of human beings, uses of human embryos, and the processes for modifying germ line genetic identity.<sup>219</sup> Importantly, to any researcher in this field, the ECJ also pointed out that Directive 98/44/EC does not address whether certain forms of research are permitted, to which member-states may address on their own, and only addresses the patentability of subject matter.<sup>220</sup>

In *Brustle v. Greenpeace*, the ECJ faced several technical questions regarding stem cell science including the definitions of "human embryo," "industrial or commercial use," and "technical teaching."<sup>221</sup> In *Brustle*, Greenpeace urged the German courts to nullify a patent for, among other things, the isolation and purification of neural precursor cells, and the

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212. *Id.* at ¶¶ 37-38.

213. *Id.* at ¶ 38.

214. *Id.* at ¶ 39.

215. *Id.* at ¶ 61. The prohibitive phrase used in Directive 98/44/EC is "whose commercial exploitation would be contrary to order public or morality." The prohibitive phrase used in the European Patent Convention is "inventions the publication or exploitation of which would be contrary to order public or morality." *Id.* The ECJ stated that a breach of public order or morality could equally be established by the subject matter of the invention either by publication, exploitation, or commercialization. *Id.* at ¶ 62.

216. *Id.* at ¶ 69.

217. *Id.* at ¶¶ 70-71

218. *Id.*

219. *Id.* at ¶¶ 72, 74, 76.

220. *Id.* at ¶¶ 79, 80.

221. Case C-34/10, *Brustle v. Greenpeace e.V.*, 2011 E.C.R. I-9821, at ¶ 23.

process for the production of embryonic stem cells, and the use of neural precursor cells for the treatment of neural defects.<sup>222</sup> Mr. Brustle contended in his patent application that transplantation of such cells could treat neurological diseases and that some attempts had been made prior to treat patients with Parkinson's disease.<sup>223</sup> Controversially, Mr. Brustle's process required the transplant of immature precursor cells from the cerebral tissue of human embryos still in their development phase.<sup>224</sup> In his patent application, Mr. Brustle was hopeful for the possibility of embryonic stem cell transplants because such technology could lead to an unlimited amount of isolated and purified cells with both neural and glial (suited for brain and spinal cord areas) properties.<sup>225</sup> Greenpeace's chief concern was that the precursor cells were obtained from human embryonic stem cells.<sup>226</sup>

The Convention on the Grant of European Patents ("CGEP"), which binds the individual member-states of the EU but not the EU itself, allows for the patenting of biological inventions generally so long as the patented product or process meets the traditional conditions of newness, inventive step, and the potential for industrial application.<sup>227</sup> Directive 98/44/EC goes even further and allows patent protection for biological material, processes developed through the use of biological material, and biological material that is produced, processed, or used.<sup>228</sup> The third prohibition, that patents cannot be awarded for products and processes that violate public order and morality and as identified by an individual member-state is much more general and certainly more open to interpretation.<sup>229</sup> Even within Directive 98/44/EC's prohibitions on morally questionable patents, a member-state can grant a patent the use of human embryos for therapeutic or diagnostic purposes which are applied and useful to a human embryo.<sup>230</sup> Further, an element of the human body (e.g., organs, cells) that is isolated due to the identification, purification, and classification for reproduction outside the body can be patented by a member-state.<sup>231</sup>

German law on the patentability of biological inventions mirrors Directive 98/44/EC but goes further in creating criminal offenses whereby ova is fertilized for any other purpose than to impregnate a

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222. *Id.* at ¶ 15.

223. *Id.* at ¶ 16.

224. *Id.* at ¶ 17.

225. *Id.* at ¶ 18.

226. *Id.* at ¶ 19.

227. *Id.* at ¶ 4.

228. *Id.* at ¶ 7.

229. *Id.*

230. *Id.*

231. *Id.*

woman from which the ova originated, when a human embryo is sold after conception either by in vitro or removed from a woman before the nidation process has been completed in the uterus, when ova is transferred or acquired for the use other than preservation, and when in vitro fertilization occurs for the development of human embryos for any other purpose than inducing pregnancy.<sup>232</sup> German law also provides two crucial definitions including the definition of an embryo which is defined as a fertilized human ovum capable of develop and/or any cell removed from a cell that is totipotent.<sup>233</sup> In contrast, a stem cell is defined as a cell capable of developing into any kind of cell yet cannot be developed into a complete human being.<sup>234</sup> but pursuant to German law can be the subject of scientific research if several conditions are met by the researcher.<sup>235</sup> For a stem cell to be used in scientific research, German law requires that the stem cells (1) were obtained in compliance with the member-state's law, (2) were originally produced with the goal of in vitro fertilization but became superfluous, (3) were not exchanged for remuneration, (4) were not imported in violation of any other law, (5) were not obtained in a way that offends the German legal order, and (6) are to be used pursuant to "high-level" research aims.<sup>236</sup>

According to the ECJ, the EU intended to prohibit the patentability of something whereby human dignity would be infringed upon and to make sure that "human embryo" was well defined across the member-states.<sup>237</sup> The ECJ stated that the definition of a human embryo, which should be shared across the member-states, is any human ovum as soon as it is fertilized if the fertilization is such as to commence the process of developing a human being.<sup>238</sup> Additionally, the ECJ contended that the definition of human embryo must include non-fertilized ovum that has received, by transplant into its cell nucleus, a mature human cell and non-fertilized human ovum whose division and development have been stimulated by parthenogenesis.<sup>239</sup> Despite these definitions, the ECJ stated that stem cells obtained from human embryos at the blastocyst stage are not necessarily included within the human embryo definition.<sup>240</sup> The ECJ allowed that member-states' courts are free to determine whether these stem cells should be included within the definition of human embryo and excluded from patentability. Despite these clear-cut definitions, the

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232. *Id.* at ¶¶ 8-11.

233. *Id.* at ¶ 12.

234. *Id.* at ¶ 12.

235. *Id.* at ¶¶ 13.

236. *Id.* at ¶¶ 13-14.

237. *Id.* at ¶ 34.

238. *Id.* at ¶ 35.

239. *Id.* at ¶ 36.

240. *Id.* at ¶ 37.

ECJ stated that stem cells obtained from human embryos at the blastocyst stage are not necessarily included within the human embryo definition and that national courts are free to determine, based on their interpretation of scientific knowledge as to whether these stem cells can become human beings, should be included within the definition of human embryo for the purposes of the exclusion on patentability.<sup>241</sup>

The ECJ also stated that the prohibition on the use of human embryos for industrial and commercial purposes also included a prohibition on the use of human embryos for scientific research.<sup>242</sup> Therefore, the ECJ held that what is produced through human embryos for industrial and commercial purposes, and scientific research, is not patentable.<sup>243</sup> The ECJ did recognize that the aims of industrial/ commercial research are different and Directive 98/44/EC did not separate patent eligibility based on those aims.<sup>244</sup> Lastly, and most harmfully to Mr. Brustle, the ECJ held that patentability was prohibited under Directive 98/44/EC—even for technical teaching claims.<sup>245</sup> Mr. Brustle’s patent required stem cells obtained from embryos at the blastocyst stage.<sup>246</sup> This required the destruction of human embryos.<sup>247</sup> The ECJ contended that the embryos’ stage of development was irrelevant when the end result destroyed human embryos at any stage.<sup>248</sup>

Although the ECJ left the final determination to member-states’ courts, the ECJ urged uniformity in this area of law.<sup>249</sup> First, the ECJ felt it was important to provide a uniform definition of human embryo since Directive 98/44/EC failed to do so.<sup>250</sup> Second, the ECJ remarked that the harmonization of law governing the patentability of biological inventions across the member-states would improve the free flow of trade and strengthen the EU’s common market while also increasing the amount of research in the area of genetic engineering.<sup>251</sup> Third (and most importantly to firms trying to nullify patents on biological inventions), the ECJ stated that different definitions of “human embryo” could incentivize firms to patent their inventions in more flexible jurisdictions.<sup>252</sup> Despite the

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241. *Id.*

242. *Id.* at ¶ 44.

243. *Id.* at ¶¶ 44, 46.

244. *Id.* at ¶ 43.

245. *Id.* at ¶ 52. when the inventor makes the argument that the harvesting of the base materials requires the prior destruction of the human embryos and even if the technical teaching does not claim or refer to the use of human embryos. *Id.*

246. *Id.* at ¶ 49.

247. *Id.*

248. *Id.* at ¶ 49.

249. *Id.* at ¶¶ 26-29, 53.

250. *Id.* at ¶ 26.

251. *Id.* at ¶ 27.

252. *Id.* at ¶ 28.

aforementioned statements on the need for unity of law, the ECJ found that Directive 98/44/EC did allow for wide discretion in regard to the exclusions to patentability based on a member-state's need for public order and morale.<sup>253</sup>

In *ISCC*, the ECJ held that the intent of its decision in *Brustle* was to state that a non-fertilized human ovum should be considered a human embryo within the scope of Directive 98/44/EC in that such an organism has the capability of beginning the process of development of a human being.<sup>254</sup> In contrast, according to the ECJ, Directive 98/44/EC must be interpreted to mean that a non-fertilized human ovum incapable of development of a human being cannot be a human embryo.<sup>255</sup> Tying these two points together, the ECJ proclaimed that any ovum possessing the capability of development into a human being, fertilized or not, must be defined for the purposes of Directive 98/44/EC as a human embryo.<sup>256</sup>

In *ISCC*, the ECJ relied on several provisions of Directive 98/44/EC's preamble to guide its reasoning. Collectively, the cited preamble provisions make clear that although the EU recognizes the importance of research and development in biotechnology, such research must be regulated to safeguard human dignity and integrity.<sup>257</sup> Specific to this concern for the protection of the fundamental principles and human dignity and integrity is research of germ cells and the sequencing of human genes either fully or partially.<sup>258</sup> The EU is trying to strike a balance between specifically enumerating prohibited patents and allowing member-states to determine which inventions violate the states' own sense of morality and public order.<sup>259</sup> Regardless, the preamble makes it clear that processes developed for therapeutic and/or diagnostic purposes can be patented.<sup>260</sup>

The ECJ further asserted that although the Directive allowed for biotechnical inventions, it did not allow the human body—or any part of the human body or its formation—to be patented.<sup>261</sup> Additionally, any biotechnological invention that violates the public order or morality of a member-state may be prohibited from patentability.<sup>262</sup>

In this case, *ISCC* filed two patent applications with the United

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253. *Id.* at ¶ 29.

254. Case C-364/13, *Int'l Stem Cell Corp. v. Comptroller Gen. of Patents, Designs and Trade Marks*, ECLI:EU:C:2014:2451, at ¶ 27.

255. *Id.* at ¶ 29.

256. *Id.* at ¶ 30.

257. *Id.* at ¶ 3.

258. *Id.*

259. *Id.*

260. *Id.*

261. *Id.* at ¶ 6.

262. *Id.* at ¶ 7.

Kingdom Intellectual Property Office (“UKIPO”), one for the parthenogenetic activation of oocytes for the production of human embryonic stem cells, and another for a synthetic cornea made from retinal stem cells.<sup>263</sup> The UKIPO denied both applications on grounds that this technology involved unfertilized human ova that could, when stimulated by parthenogenesis, develop into a human being.<sup>264</sup> ISCC appealed to the ECJ, arguing that Brustle merely prohibited patenting human embryos capable of developing into a human being while ISCC contended that its biological material could not do this.<sup>265</sup>

The ECJ had to determine whether unfertilized human ova, stimulated by parthenogenesis and incapable of becoming human beings, are the same as human embryos for purposes of patentability.<sup>266</sup> The ECJ noted the limits on patenting biological subject matter, which did not extend to the scientific development of biotechnology as a whole. The ECJ furthered its holding from Brustle that a non-fertilized ovum is not a human embryo for purposes of patentability, as long as any development process involved is not sufficient to form a human being.<sup>267</sup> However, the ECJ also stated that if parthenogenesis can lead a human ovum (a parthenote) to develop into a human being, that human ovum would have to be treated like fertilized ovum and thus considered a human embryo for the purposes of patentability under Directive 98/44/EC.<sup>268</sup> On the subject of the balance between these two positions, specifically whether or not parthenogenesis can transform human ovum to a human being, the ECJ found the more relevant question to be whether the ISCC’s method of parthenogenesis had the capacity to develop unfertilized ova into human beings based on current scientific knowledge.<sup>269</sup> The ECJ left this question open to its member-states.<sup>270</sup>

In *Commission v. Italy*, the ECJ addressed the question of whether Italy had met its obligation to fully implement Directive 98/44/EC in regard to its domestic patent law.<sup>271</sup> Italian law recognizes patent rights for industrial inventions that are new, involve inventive steps, and are susceptible to industrial application.<sup>272</sup> Regarding specific prohibitions, Italian patent law provided that an invention is prohibited when it causes a permanent diminution of physical integrity or is in violation of law,

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263. *Id.* at ¶ 10.

264. *Id.* at ¶¶ 10-12.

265. *Id.* at ¶¶ 15-18.

266. *Id.* at ¶ 20.

267. *Id.* at ¶¶ 29-30.

268. *Id.* at ¶ 31.

269. *Id.* at ¶¶ 32-33.

270. *Id.* at ¶ 36.

271. Case C-456/03, *Comm’n v. Italy*, 2005 E.C.R. I-5335, at ¶ 1.

272. *Id.* at ¶ 11.

public policy, or if the invention allowed for a biological process to obtain an animal breed.<sup>273</sup> Italy's patent law had additional prohibitive language stating that inventions are not patentable subject matter if the exploitation of the subject matter would be contrary to public policy and morality, yet stated that a public policy or morality violation would be found merely because the invention is prohibited by domestic law.<sup>274</sup> Italian law also provided the patentee with exclusive rights to the invention, whether a product or process, and thus to prohibit third parties from producing, using, marketing, or selling, or importing the product or process.<sup>275</sup>

Italian law was in contradiction to Directive 98/44/EC and Italy conceded that it did not implement the Directive within the required time period. The EU complained that Italian patent law did not allow for biotechnological patents.<sup>276</sup> The ECJ's standard for determining compliance with a Directive is if the member-state's law is sufficiently clear and precise to enable an individual to know of their rights and responsibilities.<sup>277</sup> There is no specific manner by which a member-state must implement domestic legislation pursuant to a Directive.<sup>278</sup> The Italian government argued that the term "industrial invention" within its domestic patent law was broad enough to include biotechnological inventions.<sup>279</sup> The ECJ disagreed, arguing that the definitional distinction between Italian law and that of other member-states could create contradictions in patent law across the EU.<sup>280</sup> The ECJ believed that Italian law must specifically mention the patentability of biological material.<sup>281</sup>

The EU Commission complained that Italian law did not provide for the patentability of an element isolated from the human body or otherwise produced by a technical process.<sup>282</sup> Italy responded that its definition of the word "invention" was sufficiently inclusive.<sup>283</sup> The ECJ disagreed, holding that the elements of the human body are not patentable unless the invention combines natural elements with technical processes.<sup>284</sup> The ECJ stated that Italian patent law was not specific enough to satisfy the

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273. *Id.* at ¶¶ 9, 12.

274. *Id.* at ¶ 12.

275. *Id.* at ¶ 10. The patent law of Italy as well prohibited the patentability of surgical or therapeutic processes and diagnostic procedures for the treatment of humans or animals. *Id.* at ¶ 11.

276. *Id.* at ¶ 45.

277. *Id.* at ¶ 51.

278. *Id.* at ¶ 51.

279. *Id.* at ¶ 55.

280. *Id.* at ¶ 58.

281. *Id.* at ¶¶ 59-61.

282. *Id.* at ¶ 63.

283. *Id.* at ¶ 65.

284. *Id.* at ¶¶ 66-67.

requirement of clarity as to what is and what is not patentable subject matter.<sup>285</sup>

Lastly, this lack of harmony between Directive 98/44/EC and Italy's patent law forced the EU Commission to contend that Italy had not met its obligation to fully synthesize the Directive with its domestic law.<sup>286</sup> According to the European Commission, Italy did not provide for the prohibition against the patentability of inventions leading to the cloning of human beings and the use of human embryos for industrial and commercial purposes.<sup>287</sup> Italy suggested that provisions of Italian law, outside of its patent law, that dictate human cloning and modification of the genetic identity of humans as practices contrary to public policy and morality meet the requirements of Directive 98/44/EC.<sup>288</sup> Moreover, Italy contended that its prohibition against activities involving the disposition of the human body is sufficient notice that the modification of the genetic identity of a human being could not be patentable pursuant to Italian law.<sup>289</sup> After listing the various specific prohibitions to patentability pursuant to Directive 98/44/EC and reminding the reader that member-states are given wide discretion in determining which inventions would be contrary to public order and morality, the ECJ still commanded that specific prohibitions are not subject to the level of wide discretion as those inventions that might generally violate public order or morality.<sup>290</sup> According to the ECJ, the specific prohibitions found in Directive 98/44/EC are to be excluded "unequivocally" from patentability and that a member-state's law must provide clarity on these specific prohibitions.<sup>291</sup>

### B. Taxation.

EU member-states maintain much discretion over the marketplace for stem cells. In *CopyGene v. Skatteministeriet*, the ECJ held that national courts of the member-states can determine whether the activities of stem cell banks are exempt from the value-added tax ("VAT").<sup>292</sup> At issue in *CopyGene* was whether the Danish government could make the activities of a private sector stem cell bank, which engaged in various activities including the collection, transportation, analysis, and storage of blood

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285. *Id.* at ¶ 73.

286. *Id.* at ¶ 75.

287. *Id.*

288. *Id.* at ¶ 76.

289. *Id.*

290. *Id.* at ¶ 78.

291. *Id.* at ¶¶ 78, 81, 83.

292. Case C-262/08, *CopyGene A/S v. Skatteministeriet*, 2010 E.C.R. I-5053, at ¶ 81.

from umbilical cords for the purpose of securing stem cells from the umbilical cords for future medical treatment, subject to the EU-wide VAT.<sup>293</sup> The Danish courts referred the case to the ECJ after a firm, CopyGene A/S, challenged the Danish government's refusal to exempt its activities from the VAT on the basis that the potential for the medicinal use of stem cells and stem cell research is so distant into the future that the activities of firms like CopyGene could not qualify as current medical treatment, which by definition would exclude such activities from the VAT.<sup>294</sup>

The Sixth Council Directive 77/388/EEC ("the Sixth Directive") establishes the VAT framework in the EU and exempts activities within hospitals, medical care, and related activities.<sup>295</sup> The Sixth Directive also states that the provider of these services must be conducted by an entity governed by public law, an entity acting under similar social conditions to that of an entity governed by public law, hospitals, medical centers, or other duly recognized establishments.<sup>296</sup> Directive 2004/23/EC establishes safety standards for donation, procurement, testing, processing, preservation, storage, and distribution of human tissue and cells.<sup>297</sup> Directive 2004/23/EC also states that member-states have the responsibility of accrediting, designating, authorizing, and licensing the providers of stem cell-related services.<sup>298</sup> Danish law met Directive 2004/23/EC's mandates.<sup>299</sup> However, when CopyGene applied for VAT exemption, the Danish government rejected the application.<sup>300</sup> CopyGene appealed to the Danish courts, arguing that its activities qualified as "closely related" to the services of a hospital and/or would meet the definition of "medical care."<sup>301</sup> Complicating this case, the Danish government previously approved CopyGene to engage in stem cell-related activities.<sup>302</sup> CopyGene specifically would enter into a contract with clients (parents expecting children) for the collection, transportation, analysis, and storage of cord blood of the clients' newborn children for the only purpose of medical treatment if the child suffered from a serious illness.<sup>303</sup> CopyGene would not own the stem cells, they would be owned by the newborn child by representation of the newborn's mother, nor have

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293. *Id.* at ¶ 2.

294. *Id.* at ¶ 43.

295. *Id.* at ¶¶ 2, 3.

296. *Id.* at ¶ 4.

297. *Id.* at ¶¶ 7-9.

298. *Id.* at ¶ 10.

299. *Id.* at ¶¶ 12-13.

300. *Id.*

301. *Id.* at ¶¶ 20-21.

302. *Id.* at ¶ 19.

303. *Id.* at ¶ 16.

the authority to engage in research endeavors.<sup>304</sup> However, these services were not covered nor reimbursed by the Danish government's public health care system.<sup>305</sup>

The ECJ's decision largely rested on the language of the Sixth Directive. The ECJ found the VAT's scope to be broad, encompassing virtually all traded goods and services.<sup>306</sup> Any exemptions found in the Sixth Directive are designed to ensure that member-states treat all commercial transactions alike.<sup>307</sup> Accordingly, the ECJ held that the Sixth Directive covers virtually all medical services that can lead to diagnosis and cure of health problems.<sup>308</sup> For example, the ECJ noted that the definition of medical care within the Sixth Directive has been interpreted to include medical care that is prophylactic in nature and care that is designed to reduce the cost of medical care, restore health, and/or protect health.<sup>309</sup>

The ECJ held that the stem cell-related services provided by CopyGene were within the scope of the terms "closely related" to "hospital and medical" care within the meaning of the Sixth Directive.<sup>310</sup> The ECJ contended that, because of the nature of stem cells and stem cell research, including the collection, storage, transportation, and analysis activities, even if the medical care has not yet been performed, commenced, and/or envisaged, the Sixth Directive allows for a VAT exemption.<sup>311</sup> The ECJ further stated that "medical care" was not limited to current scientific knowledge.<sup>312</sup> As such, VAT exemptions should rest on current medical practices as opposed to courts' predictions for the future of medical care.<sup>313</sup>

The ECJ next had to resolve the issue of whether the activities specific to the firm itself, CopyGene, were within the definition of an entity that could be described as acting similar in nature to hospitals and medical centers.<sup>314</sup> In a somewhat confusing manner, the ECJ held that the language of the Sixth Directive, as it applied to an entity like CopyGene, does not require a member-state to exempt it from VAT nor does it require a member-state to not exempt it from VAT regardless of whether,

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304. *Id.* at ¶ 18.

305. *Id.* at ¶ 16.

306. *Id.* at ¶¶ 23-24

307. *Id.*

308. *Id.* at ¶¶ 28-29.

309. *Id.* at ¶ 30.

310. *Id.* at ¶ 52.

311. *Id.*

312. *Id.* at ¶¶ 43-45.

313. *Id.* Although almost ancillary to the decision, but significant to the science, the ECJ made clear that the only way in which to harvest stem cells was at birth and at such a time in a person's life, the future benefits are unknown. *Id.* at ¶ 45.

314. *Id.* at ¶ 53.

objectively, the activities are covered by the VAT exemption and that neither an entity like CopyGene nor its clients receive support from the public health care system.<sup>315</sup> While agreeing with the Danish government, the ECJ stated that the mere authorization by a member-state to allow a private entity to engage in the various stem cell-related activities does not mean the entity is operating in similar fashion to a hospital or medical care facility for the purposes of the Sixth Directive's exemption.<sup>316</sup> Although the ECJ returned the decision of whether a firm, such as CopyGene, and its activities should meet the requirements of the VAT exemption to the member-state, the ECJ did state that there are factors, although not decisive, that a member-state should consider such as: (1) whether the entity receives support from the public health service and (2) whether the entity is governed by public or private law.<sup>317</sup>

In similar fashion, the ECJ in *Future Health v. United Kingdom* found several stem cell-related activities to be outside the exemption for VAT.<sup>318</sup> *Future Health* followed the *CopyGene* case and the ECJ relied on the latter case to find that the mere storage of stem cells for possible, future therapeutic use was not within the confines of "hospital and medical care" for the purposes of the VAT exemption.<sup>319</sup> A key difference between the two decisions is that Directive 2006/112 repealed and replaced the Sixth Council Directive 77/388/EEC, thus revamping the VAT system across the EU in order to make the law on VAT clearer and more rational but without a substantial change of the scope of the VAT.<sup>320</sup> However, the ECJ stated that the terms of Directive 2006/112 and the Sixth Directive were identical and that the two laws should be interpreted in the same manner.<sup>321</sup>

Specific to the facts in *Future Health*, the ECJ was asked to determine whether five activities were within the scope of the VAT tax exemption for "hospital and medical care" including: (1) providing parents of an unborn child with a kit used to collect blood from an umbilical cord at the time of the newborn's birth, which would be used by a trained professional at the time of birth; (2) the testing of the harvested blood so that stem cells could be extracted without contamination; (3) the processing of the blood in order to extract stem cells for later therapeutic use; (4) the storage and preservation of the blood and stem cells; and (5)

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315. *Id.* at ¶¶ 77-79.

316. *Id.* at ¶ 75.

317. *Id.* at ¶¶ 69, 71-72.

318. Case C-86/09, *Future Health Tech. Ltd v. The Comm'rs For Her Majesty's Revenue and Customs*, 2010 E.C.R. I-5215, at ¶ 52.

319. *Id.* at ¶ 49.

320. *Id.* at ¶ 3.

321. *Id.* at ¶¶ 25-27.

the release of blood upon the request of the parents of the child.<sup>322</sup> The firm seeking the exemption from VAT, Future Health Technologies Ltd (“FHT”), was a private stem cell services provider that would provide parents of a soon-to-be-born child with a kit to be used by a qualified health professional (who would be compensated by the parents for his or her services, separately) to collect blood from the umbilical cord at birth.<sup>323</sup> Then, FHT would provide crytopreservation, storage, testing, and analysis services that would allow the parents to tap into the blood and stem cells at the later request of the parents if therapeutic treatment was needed.<sup>324</sup> The ECJ found from the existing court records that the British government at one time believed that the collection and testing of the blood and stem cells would be exempt from VAT, but the storage services were not exempt.<sup>325</sup> The British government later changed its position and contended that none of the services provided by FHT could fall within the VAT exemption because the services could not be separated into individual transactions.<sup>326</sup>

While deciding that none of the services offered by FHT were within the scope of the VAT exemption, the ECJ stated that the various exemptions within the VAT—both in Directive 2006/112 and the former Sixth Directive—were not designed to exempt all activities that would be considered within the public interest.<sup>327</sup> Instead, the exemptions were more so present to prevent the member-states from diverging on what transactions should and should not be exempted from the VAT.<sup>328</sup> Next, the ECJ stated that while services within the scope of the hospital and medical care VAT exemption are for therapeutic aims and the protecting, maintaining, and restoring of human health, the mere collecting, testing, and storing of umbilical cord blood and stem cells are not services directed at the actual diagnosis, treatment, or cure of human health problems nor for the maintenance, restoration, or protection of human health.<sup>329</sup> In contrast, the ECJ believed that the services provided by FHT would ensure that the resource for the later, potential therapeutic treatment, maintenance, restoration, and/or protection of human health and that what FHT was providing in terms of services had no bearing on diagnosis, treatment, and/or cure of human disease.<sup>330</sup> The ECJ also declared that it made no difference whether the services offered by FHT

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322. *Id.* at ¶ 24.

323. *Id.* at ¶¶ 16, 17.

324. *Id.* at ¶ 16.

325. *Id.* at ¶ 21.

326. *Id.* at ¶ 22.

327. *Id.* at ¶ 29.

328. *Id.* at ¶¶ 26, 28.

329. *Id.* at ¶ 43.

330. *Id.* at ¶¶ 44-47.

were offered individually or collectively in terms of whether they resembled “hospital and medical care” for the purposes of the VAT exemption.<sup>331</sup>

In another case, the ECJ held that for purposes of the VAT exemption, the removal of joint cartilage cells from a human patient’s cartilage material and the later multiplication of those cells for reimplantation for therapeutic purposes falls within the definition of “provision of medical care” as defined by the Sixth Directive 77/388/EEC.<sup>332</sup> In *Germany v. VTSI*, the results and material involving human tissue cells were treated as a service yet the locale of the service and whether the transaction involved was subject to a VAT exemption were in dispute.<sup>333</sup> VTSI was a German-based biotechnology services firm engaged generally in the fields of research, development, production, and marketing of technologies to diagnose and treat human tissue diseases with the focus on diseases affecting human cartilage.<sup>334</sup> Specific to this case, VTSI would engage in the multiplication of chondrocytes for reimplantation into a patient whereby the doctors and/or clinics referring the work to VTSI would be located in other EU member-states.<sup>335</sup> In a typical business transaction, VTSI would be sent cartilage taken from a human patient for a biopsy and VTSI would treat the tissue to make it possible to remove the chondrocytes.<sup>336</sup> After preparing the chondrocyte cells in their own blood serum, the resulting cells may or may not be introduced into a collagen membrane leading to the production of a cartilage plaster that would be sent back to the referring doctor or clinic residing in another member-state and then reimplanted in the patient.<sup>337</sup> VTSI believed that its services were not subject to the VAT because its referring doctors and clinics were located in other member-states.<sup>338</sup> The German government disagreed, arguing that cell movement from doctor/clinic/patient to VTSI in what the German government called a “short-term separation from the body” and cell multiplications did not constitute “work” pursuant to German law.<sup>339</sup> Interestingly enough, the referring German court held that VTSI’s customers (doctors and clients) had used the VAT identification numbers issued to them by the member-state in which those customers

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331. *Id.* at ¶¶ 46-47.

332. Case C-159/09, *Germany v. Verigen Transplantation Serv. Int’l (VTSI)*, 2010 E.C.R. I-11746, at ¶ 32.

333. *Id.* at ¶¶ 10, 18.

334. *Id.* at ¶ 9.

335. *Id.* at ¶ 10.

336. *Id.* at ¶¶ 10-11.

337. *Id.* at ¶¶ 11.

338. *Id.* at ¶ 12.

339. *Id.* at ¶¶ 12, 17.

resided and thus the transactions were not taxable in Germany.<sup>340</sup> additionally, the referring German court believed that the transfer of the multiplied cartilage cells by VTSI to the doctor/clinic/patient did not make those cells a supply of goods since VTSI did not have the authority to dispose of the cells freely.<sup>341</sup>

The Sixth Directive 77/388/EEC states that the supply of goods or services occurs where the supplier has established a business and/or has a fixed establishment from which the service is supplied or, in cases whereby those two possibilities do not exist, a place where there exists a permanent address or a usual residence.<sup>342</sup> However, in cases where the subject matter of the service involves work on tangible, movable property, the service locale is the place where the services are physically conducted.<sup>343</sup> Also specific to tangible movable property, the services locale in cases where a customer has been issued a VAT tax identification number should be the member-state where the same member-state has issued that VAT tax identification number.<sup>344</sup> The ECJ also reminded the reader that the Sixth Directive 77/388/EEC exempts transactions that provide medical care by medical or paramedical professions from the VAT.<sup>345</sup> German law also dictates that the service locale should be the member-state that issued the VAT tax identification number and also provides exemptions from VAT for activities involving doctors, dentists, lay medical practitioners, physiotherapists, midwives, and/or similar professional activities.<sup>346</sup>

The ECJ stated that the Sixth Directive 77/388/EEC should be considered to encompass a wide range of transactions for the purposes of taxability, but that exemptions from VAT should be interpreted narrowly since the general principle of the Sixth Directive 77/388/EEC is to levy the VAT on all goods and services provided by a taxable person.<sup>347</sup> The ECJ also articulated that the exemptions should be interpreted in a manner consistent with the objectives supporting the exemptions and thus the strictness of interpretation should not interfere with the intended effects of the exemptions.<sup>348</sup> According to the ECJ, in regard to the exemption provided by the Sixth Directive 77/388/EEC for the provision of medical care for therapeutic purposes, while citing *CopyGene*, the therapeutic

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340. *Id.* at ¶ 16.

341. *Id.* at ¶ 18.

342. *Id.* at ¶ 4.

343. *Id.*

344. *Id.* at ¶ 6.

345. *Id.* at ¶ 5.

346. *Id.* at ¶ 7.

347. *Id.* at ¶¶ 21-23.

348. *Id.* at ¶ 23.

purpose itself should not be defined narrowly and that the removal of cartilage materials to extract cells for multiplication and later reimplantation in a human patient is clearly therapeutic.<sup>349</sup> The ECJ declared that the activities engaged in by VTSI were within the definition of “provision of medical care” pursuant to the Sixth Directive 77/388/EEC and such a determination supports the goal of that particular VAT exemption which is to reduce the cost of medical care.<sup>350</sup> Additionally, the ECJ stated that VTSI’s activities should not be found to be outside the definition of “provision of medical care” given that the cells were extracted from a human patient and later reimplanted into the same or another patient.<sup>351</sup>

### C. Access to records.

Although perhaps a minor case in regard to the full scope of law that governs stem cell use and research in the EU, the ECJ’s decision in *Sweden v. Commission* does help paint the four corners of this area of law in that it addresses the issue of patient and parental rights.<sup>352</sup> It also provides the practitioner with an idea as to how transparent the EU governmental institutions are in regard to its records and correspondence with member-states.<sup>353</sup> In *Sweden*, two parents lost their son due to a therapeutic treatment procedure involving the use of autologous stem cells which took place in a private clinic in Germany.<sup>354</sup> The parents stated that the private clinic was not able to engage in the treatment due to inaction by the German government in breach of EU law governing the use of advanced therapy medicinal products.<sup>355</sup> The EU Commission launched an investigation into the death through use of an EU Pilot procedure by contacting the German government authorities directly to gain information pursuant to the parents’ complaint.<sup>356</sup> The German government complied with the EU Commission’s two requests for information.<sup>357</sup> However, after being petitioned by the parents for the documents comprising the German government’s response to the EU Commission, the European Commission rejected access to the specific documents and replied to the parents that they were not able to find fault

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349. *Id.* at ¶¶ 24, 25.

350. *Id.* at ¶ 27.

351. *Id.* at ¶ 29.

352. Case C-562/14, *Sweden v. Comm’n*, 2017 E.C.R. ECLI:EU:C:2017:356.

353. *Id.*

354. *Id.* at ¶ 8.

355. *Id.* at ¶ 9.

356. *Id.* at ¶ 10.

357. *Id.* at ¶ 15.

on the part of the German government.<sup>358</sup>

The foundation of the EU's Pilot procedure is found in Regulation 1049/2001 which provides for access to public records to the greatest extent possible but also allows certain public and private interests to be protected through a set of exceptions that are collectively designed to allow EU governmental institutions to fulfill their internal functions, especially when personal data is involved.<sup>359</sup> Specifically, the EU governmental bodies can deny records to citizens when the disclosure of such records could undermine the purpose of inspections, investigations, and audits, unless there is an overriding public interest in making those records open to request.<sup>360</sup> More narrowly, Regulation 1049/2001 states that the above-mentioned limitations on the disclosure of records applies to documents that EU governmental institutions have crafted or have received.<sup>361</sup>

While upholding the decision of the EU Commission to refuse to provide the parents of the deceased with the documents delivered to it by the German government, the ECJ stated that there does not exist a general overriding interest.<sup>362</sup> Instead, evaluation of an overriding interest must be found on the specific facts of the case at the time the facts arise.<sup>363</sup> Narrow to the facts of the case at bar, the ECJ found that the parents' general assertion that they needed access to the documents in order to protect human health without providing specific allegations as to how and why the documents would have protected human health was not sufficient to establish an overriding interest.<sup>364</sup> In order to establish an overriding interest promoting the disclosure of the requested documents, there must be a specific need that is met by such disclosure.<sup>365</sup>

#### *D. Legal notice.*

While the ECJ's decision in *Commission v. Poland* clearly touches on the issue of human biological tissues and cells, it is also illustrative of the responsibility of a member-state to meet its obligations under EU law.<sup>366</sup> Directive 2004/23/EC, implemented through a procedures dictated in Directive 2006/86/EC, requires that member-states adopt certain administrative procedures in handling human tissues and cells which

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358. *Id.* at ¶¶ 12-15.

359. *Id.* at ¶¶ 2-5.

360. *Id.* at ¶ 7.

361. *Id.* at ¶ 6.

362. *Id.* at ¶¶ 56-58.

363. *Id.* at ¶¶ 56, 57, 63.

364. *Id.* at ¶ 55.

365. *Id.*

366. Case C-29/14, *Comm'n v. Poland*, 2015 E.C.R. ECLI:EU:C:2015:379.

cover activities such donation, procurement, storage, testing, processing, preservation, and distribution.<sup>367</sup> A member-state is deemed to have fulfilled its obligations when it officially publishes the requirement set forth by an EU directive in its specific law.<sup>368</sup> Directive 2006/23/EC requires that each collection of donated biological material be assigned a single European code at the time and place of donation and that the main characteristics and properties of those tissues and cells be identified at the same time.<sup>369</sup> Associated with Directives 2004/23/EC and 2006/86/EC is Directive 2006/17/EC, which requires member-state governments to ensure that the donors of reproductive cells undergo biological tests and also states requirements for those tests.<sup>370</sup>

The Polish law in question did identify procedures for the removal, storage, and transplantation of several forms of biological material including cells, tissues, and organs; but, its law stated that these procedures did not apply to the removal and transplant activities involving reproductive cells, gonads, fetal tissues, embryonic tissues, reproductive organs, or any associated elements thereof.<sup>371</sup> Because the Polish law excluded from its procedures requirements—identified in EU Directives 2004/23/EC, 2006/17/EC, and 2006/86/EC—on the handling of reproductive cells, fetal tissue, and embryonic tissue, the EU Commission charged the member-state with failing to meeting its obligations under EU law.<sup>372</sup> The Polish government disputed the alleged failure to meet its obligations under EU law, stating that although it had not exactly word for word transposed the requirements of the various Directives into Polish law, it could cite several other sources of domestic law in the form of acts, including laws governing the medical and dental professions, health care law generally, laboratory medicine, patient rights, and personal data collection, that maintained the same requirements as the Directives with the same intended force of law.<sup>373</sup>

The EU Commission countered the Polish government's argument by contending, first, that the member-state could not explain as to why the procedural requirements required by the EU Directives applied to some forms of human biological matter but not for reproductive cells, gonads, fetal tissue, and embryonic tissue.<sup>374</sup> Second, the EU Commission believed that the Polish government's attempt at adopting the

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367. *Id.* at ¶¶ 1, 4.

368. *Id.* at ¶ 4.

369. *Id.* at ¶ 9.

370. *Id.* at ¶¶ 6, 8.

371. *Id.* at ¶¶ 11-12.

372. *Id.* at ¶ 14.

373. *Id.* at ¶ 24.

374. *Id.* at ¶ 26.

requirements of the EU Directives was not clear and precise and therefore constituted measures that would not be mandatory as required by the Directives.<sup>375</sup> More narrowly, the EU Commission's concern was that the domestic law cited by Poland consisted largely of administrative rules governing medical practice that could be freely amended, are not always properly disseminated, and, thus, lack binding authority.<sup>376</sup>

The ECJ held that, by excluding reproductive cells, fetal tissue, and embryonic tissue, Poland failed to meet its obligations by transposing the EU Directives into its domestic law.<sup>377</sup> According to the ECJ, Poland's attempt at codifying the requirements of the EU Directives, as Poland contends that it did in its domestic law, was insufficient because the sources of law cited by Poland varied in their legal nature and included non-binding acts and general applications of Polish civil and criminal law.<sup>378</sup> The ECJ was clear in stating that a member-state does not meet its obligations pursuant to the requirements of EU law by identifying various sources of law of questionable applicability, while also identifying specific exclusions in coverage.<sup>379</sup> The ECJ also stated that any transposition of EU law into domestic law must be clear and precise so that individuals understand their rights and obligations so that these rights and obligations can be invoked in front of national courts.<sup>380</sup> Perhaps most damaging to Poland's argument that its collection of domestic law provided the necessary procedural requirements associated with the handling and processing of human biological material was the fact that the domestic law did not mention the EU Directives as the EU Directives required when the domestic law was published.<sup>381</sup>

#### *E. Funding for stem cell research.*

Any reader of *One of Us v. Commission* will learn extensively about the EU's democratic, legislative, and judicial processes, and how under three provisions of the TFEU, Articles 225 (ex 192, 138b), 227 (ex 194, 138d), and 241 (ex 208, 152), along with Regulation 211/2011, provide individuals and interest groups with unique access to the EU

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375. *Id.* at ¶¶ 28, 30.

376. *Id.* at ¶ 30.

377. *Id.* at ¶ 51.

378. *Id.* at ¶ 47.

379. *Id.*

380. *Id.* at ¶ 38.

381. *Id.* at ¶ 49.

government.<sup>382</sup> In *One of Us*, an interest group calling itself “One of Us” proposed a set of changes to EU legislation through the European Citizens’ Initiative (“ECI”) with the general purpose of “the juridical protection of the dignity, the right to life and of the integrity of every human being from conception in the areas of EU competence in which such protection is of particular importance.”<sup>383</sup> More narrowly, the ECI defined the human embryo as the beginning of development of the human body, ensured consistency within EU law whereby the life of the human embryo is at stake, and created a general ban on, and an end to, EU financial support for activities leading to the destruction of human embryos.<sup>384</sup> Narrower still, One of Us called for specific language that excluded EU funding for research activities that destroyed human embryos for the purposes of obtaining human stem cells and research that involves steps leading to the garnering of human embryonic stem cells.<sup>385</sup> More broadly, however, the ECI also proposed language that would prohibit the EU from funding abortion activities directly or from funding other organizations that either encourage or promote abortion.<sup>386</sup> The position taken by One of Us was clearly provoked by the ECJ’s decision in *Brustle*.<sup>387</sup>

After entertaining the ECI, the EU Commission refused to take action on the recommendations included within it on several grounds. First, all EU legislation on the subject matter at issue must comply with both the TFEU and the European Charter of Rights and Freedoms regarding human dignity, right to life, and the right to the integrity of the person which, according to the EU Commission, includes activities involving stem cell research.<sup>388</sup> Second, the EU Commission stated that the thrust of the ECJ’s decision in *Brustle* was not to address the research activities

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382. Case T-561/14, *One of Us v. EU Comm’n*, 2018 E.C.R. ECLI:EU:T:2018:210; Article 225 (ex 192, 138b) of the TFEU states: “The European Parliament may, acting by a majority of its component Members, request the Commission to submit any appropriate proposal on matters on which it considers that a Union act is required for the purpose of implementing the Treaties. If the Commission does not submit a proposal, it shall inform the European Parliament of the reasons.” TFEU at art. 225. Article 227 of the TFEU states: “Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have the right to address, individually or in association with other citizens or persons, a petition to the European Parliament on a matter which comes within the Union’s fields of activity and which affects him, her or it directly.” TFEU at art. 227. Article 241 of the TFEU states: “The Council, acting by a simple majority, may request the Commission to undertake any studies the Council considers desirable for the attainment of the common objectives, and to submit to it any appropriate proposals. If the Commission does not submit a proposal, it shall inform the Council of the reasons.” TFEU at art. 241.

383. *Id.* at ¶¶ 1, 2. The ECI for the purposes of later reference is ECI (2012) 000005. *Id.* at ¶ 1.

384. *Id.* at ¶ 3.

385. *Id.* at ¶ 7.

386. *Id.* at ¶ 8.

387. *Id.* at ¶ 3.

388. *Id.* at ¶ 16.

of individuals and firms within the EU in regard to stem cells, but to only address the issue of patentability of such related inventions.<sup>389</sup> Third, the EU Commission commented on the EU's Horizon 2020 research and innovation program and defended the program as one that operated within a strict ethical framework consisting of a "triple lock" system providing three safeguards that included: (1) the respect for national legislation in this area of research; (2) that all research projects were subject to peer review pursuant to a rigorous ethical review; and (3) that EU funds could not be used for derivation of new stem cell lines or for research that destroyed embryos or for the procurement of stem cells.<sup>390</sup> The EU Commission argued that the triple lock system removed many of the concerns put forth in the ECI by *One of Us*, as both the EU Parliament and the EU Council had considered ethical issues when crafting Horizon 2020.<sup>391</sup> Fourth, the EU Commission contended that all of its funded activities which require coordination among the member-states meet the standards set by the Millennium Development Goals and the International Conference on Population and Development Program of Action, the latter of which has identified unsafe abortion practices as an area of major concern for public health.<sup>392</sup> Fifth, and more generally on the subject of EU budget, the EU Commission argued that all expenditures made by the EU in the areas of research and developmental cooperation respect the priorities of human dignity, the right to life, and the right to the integrity of the person.<sup>393</sup> Lastly, and most politically, the EU Commission noted that the real mission behind the ECI articulated by *One of Us* was to reduce the number of abortions in developing countries where the EU provides assistance; and that the existing EU programs indeed accomplish this mission by way of activities designed to provide access to various health services including family planning, contraception, newborn and child health services, and sex education.<sup>394</sup>

Although the procedural matters associated with *One of Us* are beyond the scope of this work, it should be noted that the EU Commission, EU Parliament, EU Council, and the International Planned Parenthood Federation first argued that the interest group and namesake of the case did not have the authority to submit the ECI nor have it addressed by the ECJ pursuant to Regulation 211/2011.<sup>395</sup> The ECJ, however, believed that it should entertain the petition brought by *One of Us* pursuant to

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389. *Id.*

390. *Id.* at ¶ 18.

391. *Id.* at ¶ 24.

392. *Id.* at ¶ 20.

393. *Id.* at ¶ 23.

394. *Id.* at ¶ 25.

395. *Id.* at ¶¶ 31-36.

Regulation 211/2011.<sup>396</sup> Thus, the ECJ has authority to determine whether the content of the ECI as submitted to the EU Commission should be forwarded on to the EU Parliament and EU Council for its consideration when drafting new legislation on the subject matter.<sup>397</sup>

Specific to the subject of ethical considerations in the area of research on human embryos and stem cells, One of Us contended that the triple lock system was an inadequate system to safeguard the interests of human dignity because the mere observance of a member-state's national law does not set ethical standards and, therefore, the protections for human dignity rest with the lone philosophy of the member-state.<sup>398</sup> Additionally, One of Us articulated that a peer review system only ensures that research is conducted pursuant to current scientific standards.<sup>399</sup> One of Us also believed that the prohibition of the use of EU funds for derivation of new stem cell lines, for research involving the destruction of human embryos and/or research for the procurement of stem cells, does not go far enough to protect human dignity since a ban does not exist for the financing of projects that *presuppose* the destruction of human embryos.<sup>400</sup> Lastly, One of Us remarked that adherence to the standards set by the Millennium Development Goals and the International Conference on Population and Development Program of Action were mere policy objectives and do not bind member-states in the traditional manner of law.<sup>401</sup> Thus, One of Us was concerned that member-states can freely allow abortions as a recourse and that the EU's funding priorities do not demonstrate how the financial support for access to abortion reduces maternal mortality.<sup>402</sup>

Despite these policy concerns, the ECJ made clear that the EU Commission should be granted considerable lee-way when drawing legislation because the EU Commission must (1) promote the general interest of the EU and (2) reconcile divergent interests across the EU member-states.<sup>403</sup> Likewise, the ECJ agreed with the EU Commission's point of view that the *Brustle* decision, although it did identify a human embryo as the point at which a human ovum is fertilized, only addressed scientific research on human embryos and stem cells to the point by which the outcome might be patented, and did not address how such research should be conducted and funded.<sup>404</sup> The ECJ viewed the ECI's approach to human dignity as equating a human embryo as a human being and then

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396. *Id.* at ¶¶ 1, 63.

397. *Id.* at ¶¶ 97-98, 101.

398. *Id.* at ¶ 163.

399. *Id.*

400. *Id.*

401. *Id.* at ¶ 164.

402. *Id.*

403. *Id.* at ¶ 169.

404. *Id.* at ¶ 173.

assessing the right to human dignity and the right to life to that human embryo.<sup>405</sup> The ECJ found the EU Commission's ethical approach to, although take into account the rights to life and human dignity for human embryos, take into consideration the potential for the discovery of treatments for diseases that are currently incurable and/or life threatening, such as Parkinson's, stroke, diabetes, heart disease, and blindness.<sup>406</sup> In an attempt to harmonize the two positions, the ECJ found that the EU Commission's ethical approach was not one of error, but merely one of difference in contrast to the approach preferred by One of Us.<sup>407</sup> The ECJ also, while citing a World Health Organization publication, stated that the practice of unsafe abortions was indeed a threat to maternal health and a source of mortality; thus, the funding of certain related services does reduce the likelihood of death for pregnant women.<sup>408</sup>

#### *F. Common customs tariff.*

In a case that sheds light on the vast issues an inventor, firm, or practitioner may face in the EU regarding stem cell research, the ECJ took a deep dive into the chemistry of a product containing stem cells to determine its appropriate nomenclature for the purposes of Regulation 2658/87, which constitutes the Common Customs Tariff for the EU.<sup>409</sup> In *Abbott GmbH v. Germany*, the parties disagreed on the proper classification of a product that was essentially a medical testing kit used to determine the presence of certain substances in human serum and plasma.<sup>410</sup> The test kits were designed for retail sale and contained various laboratory reagents, where the essential character of the product was a monoclonal diagnostic reagent that takes a B-lymphocyte-type stem cell from spleen plasma in a donor animal.<sup>411</sup> The lymphocyte, which is responsible for producing the desired monoclonal antibody, is then fused with a cancer cell and the new cell produced following the fusion, called a hybridoma, is later cultivated in a suitable medium for multiplication.<sup>412</sup> According to the ECJ, the B-lymphocytes are blood fractions, as are the monoclonal antibodies hidden in the blood by the B-lymphocytes, and thus should be categorized pursuant to the Common Customs Tariff as "antisera and other blood fractions" and anything possessing a

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405. *Id.* at ¶ 176.

406. *Id.*

407. *Id.*

408. *Id.* at ¶ 180.

409. Case C-191/91, *Abbott GmbH v. Germany*, 1993 E.C.R. I-867, at ¶¶ 10-13, 16.

410. *Id.* at ¶¶ 1-3.

411. *Id.* at ¶¶ 3, 10.

412. *Id.* at ¶ 11.

monoclonal diagnostic reagent should be labeled as such.<sup>413</sup>

*G. Free movement of goods.*

In a case that could impact both stem cell-containing and non-stem cell-containing elements of blood donations, the ECJ held that Articles 34 (ex 28, 30) and 36 (ex 30, 36) of the TFEU do not allow a member-states to prohibit the inter-member-state shipments of blood products when the donors of those blood products have been compensated for their donations.<sup>414</sup> Generally, Article 34 of the TFEU prohibits restrictions on imports moving from one member-state to the next while Article 36 provides exceptions to the free movement of goods when justified in order to protect the health and life of humans.<sup>415</sup> The free movement of goods is one of the fundamental freedoms of the TFEU and, according to the ECJ, the exception permitted in Article 36 can only be justified in the face of Article 34 if the restriction imposed by a member-state is appropriate to the attainment of the member-state's goal and does not go beyond what is necessary to attain that goal.<sup>416</sup>

In *Humanplasma*, the ECJ was called on by the Austrian courts to determine whether Article 34 should prevent the application of Austrian law, which prohibited the importation of erythrocyte concentrates from Germany when the blood materials were donated by donors which had received some form of compensation.<sup>417</sup> The Austrian law in question governing "medicinal imports" stated that such materials could only be imported if the governmental body with the appropriate authority deemed the materials as safe for the market.<sup>418</sup> The Austrian law also had strict requirements regarding: (1) the donor's identity, (2) proof that the donor had been chosen, (3) donation compliance with relevant international laws on the subject, and (4) proof the donor was not suffering from identified viral infections.<sup>419</sup> The Austrian law was later amended to strictly prohibit blood materials from being placed on the market in

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413. *Id.* at ¶¶ 12, 13, 16.

414. Case C-421/09, *Humanplasma GmbH v. Republik Österreich*, 2010, E.C.R. I-12871, at ¶ 46.

415. *Id.* at ¶¶ 31-32. Article 30 (ex 28, 30) of the TFEU reads: "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States." TFEU art. 30; Article 36 (ex 30, 36) of the TFEU reads: "The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States." TFEU art. 36.

416. *Id.* at ¶ 34.

417. *Id.* at ¶ 23.

418. *Id.* at ¶ 8.

419. *Id.* at ¶ 9.

Austria if the donor had been compensated in any way, except for cases where the blood harvesting establishment was in immediate need for a donation based on an emergency (in such case, only expenses of the donor would be reimbursed).<sup>420</sup> However, the definition of an emergency under Austrian law did not include the need for blood materials for rare blood types.<sup>421</sup> Additionally, Austrian law required that all importers of blood materials covered by the law certify that blood materials were donated without any form of compensation whatsoever unless the emergency clause applied.<sup>422</sup>

Directive 2002/98/EC, another form of statutory law, covers the quality and safety of human blood and blood components when they are collected, tested, processed, stored, and distributed.<sup>423</sup> Specifically, Directive 2002/98/EC, while incorporating reference to Article 168 (ex 152, 129) of the TFEU, provides that member-states of the EU are allowed to impose stricter guidelines for quality and safety standards for blood and blood components than what is provided for in the Directive itself.<sup>424</sup> Directive 2002/98/EC states that the idea of voluntary and unpaid donations of blood materials are a factor which contribute to the safety of such materials, thus contributing to human health. Additionally, Directive 2002/98/EC provides that a lack of compensation for blood donations should be promoted and donors should receive greater public recognition.<sup>425</sup> The Directive also allows member-states to impose the method by which voluntary and unpaid donations are regulated, including a prohibition and/or restriction of imported blood materials if those methods imposed by the member-state are not met by the importer.<sup>426</sup> Lastly, Directive 2002/98/EC identifies the required testing protocols for blood and blood materials.<sup>427</sup> Directive 2002/98/EC also references Article 2 of Recommendation No R (95) 14 of the Council of Europe, which covers the protection of donors and their health in regard to harvesting blood materials and also endorses: (1) the lack of payment to donors and (2) that such donations should be voluntary, and not compensated by cash or anything that might be a substitute for cash, including time off for work, unless the time off for work would include merely the time it takes to donate and travel to the donation site.<sup>428</sup> The

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420. *Id.* at ¶¶ 10, 12.

421. *Id.*

422. *Id.* at ¶ 11.

423. *Id.* at ¶ 3.

424. *Id.*

425. *Id.*

426. *Id.* at ¶ 4.

427. *Id.* at ¶ 6.

428. *Id.* at ¶¶ 3, 7.

Council of Europe Recommendation does state that refreshments and reimbursement for direct travel costs are compatible with voluntary and unpaid donations.<sup>429</sup>

The ECJ found the Austrian law incompatible with Articles 34 and 36 because, although Directive 2002/98/EC does give member-states the leeway to impose stricter standards for the safeguard of human health in regard to blood and blood donations, the Austrian law goes beyond what is necessary to meet the goal of protecting human life.<sup>430</sup> This is because the Directive identifies the testing protocol for such substances which ensures the safety of humans, which is more protective than a requirement that a blood materials importer guarantee that all donors were voluntary and were also not compensated for their donations.<sup>431</sup> The ECJ mentioned that Directive 2002/98/EC and Council of Europe Recommendation No R (95) 14 do not require donors to act voluntarily and donate without compensation; rather, these two forms of statutory law strongly encourage such practices.<sup>432</sup> In fact, the Council of Europe Recommendation acknowledged that donors could receive small tokens, refreshments, time off from work for direct travel and donation time, and reimbursement for travel costs.<sup>433</sup>

#### VI. DECISIONS FROM THE EUROPEAN PATENT OFFICE.

The Board of Appeals of the European Patent Office's ("BOAEPO") decision in *Howard Florey* provided several important declarative statements on not only the patentability of a particular subject matter, but also on the relationship between the EPC and Directive 98/44/EC.<sup>434</sup> Before settling on whether the elucidation of the genetic sequence of the H2-relaxin gene was patentable under the EPC, the BOAEPO stated that Article 53 of the EPC was applicable to cases filed with the BOAEPO before Directive 98/44/EC was enacted as well as afterward, and that Rules 23(b) and 23(e) were only designed to give Article 53 a more detailed interpretation.<sup>435</sup> Additionally, the BOAEPO stated that it would interpret Directive 98/44/EC in the same way that it interprets Article 53 of the EPC.<sup>436</sup>

In *Howard Florey*, two oppositions were filed against the EPO's initial

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429. *Id.* at ¶ 7.

430. *Id.* at ¶¶ 44, 45.

431. *Id.* at ¶¶ 39, 42-43.

432. *Id.* at ¶ 44.

433. *Id.* at ¶ 44.

434. Case T-0272/95, *Howard Florey Institute v. Aglietta*, (1999) E.C.R. ECLI:EP:BA:1999:T027295.19990415.

435. *Id.* at 4, 9.

436. *Id.* at 9.

decision to grant a patent with the title “Molecular cloning and characterization of a further gene sequence coding for human relaxin.”<sup>437</sup> According to the opinion, the oppositions were filed by a “green faction” of the European Parliament based on three grounds including: lack of novelty under Article 54 of the EPC, lack of inventive step under Article 56 of the EPC, lack of invention under Article 52, and subject matter in violation of the prohibition against patentability for inventions that violate the public order and morality clause within Article 53.<sup>438</sup> Interestingly enough, the Opposition Division of the EPO found that an invention associated with a human gene would not present a bar to patentability because it would not be considered “outrageous,” to which the Opposition Division defined as something akin to patenting life since DNA was not life itself but rather a chemical entity involved in a biological process.<sup>439</sup> Thus, since the invention was not outrageous, there existed no offense to human dignity because the woman who donated the tissue provided consent and her self-determination was not affected by the exploitation of the claimed molecules.<sup>440</sup>

On the issue of patentability in relation to a potential bar based on a violation of morality or public order, the appellants (i.e., the opposition) in *Howard Florey* contended that the subject matter that supported the grant of a patent was an exception to patentability under Article 53 of the EPC because the invention was based on a derivation of a person’s body and thus a violation of a person’s fundamental rights.<sup>441</sup> Furthermore, according to the appellants, the genetic material that supported the patent was really just genetic material whereby the inventor merely “cracked the code” by discovering the number and sequence of human relaxin genes.<sup>442</sup> Therefore, a discovery did not really exist since the substance supporting the patent had been around for thousands of years. Lastly, the appellants argued that an inventive step did not exist as the isolation of the genetic material involved well-known techniques and was performed with no difficulties, and that prior art made the invention nonobvious.<sup>443</sup> In contrast, the respondents (those defending the grant of patent protection) stated that Rule 23 of the EPC provides four categories of biotechnological inventions that are not patentable and the subject matter in question did not fall into any of those categories.<sup>444</sup> The respondents

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437. *Id.* at 1. European patent No. 0 112 149.

438. *Id.* at 2.

439. *Id.*

440. *Id.*

441. *Id.* at 4.

442. *Id.* at 4-5.

443. *Id.*

444. *Id.* at 6.

also articulated that Rule 23 makes clear the eligibility of patent for inventions consisting of the isolation of elements of the body and the technical processes that support that isolation and the H2-relaxin DNA fell into that description.<sup>445</sup> In regard to novelty and inventive step, the respondents declared that no prior art existed involving H2-relaxin and there existed no suspicion that H2-relaxin existed.<sup>446</sup>

The BOAEPO agreed with the respondents that Rule 23 provided a list of what is barred by the EPC in regard to biotechnological patents. The BOAEPO also stated that Rule 23 provided a non-exhaustive list of prohibitions and that Article 53 of the EPC could go further in prohibiting the patentability of subject matter involving material originating from the human body.<sup>447</sup> However, the BOAEPO found that the process for the elucidation of the H2-relaxin gene was a patentable subject matter as it did not fall into the specific prohibitions found in Rule 23 nor did it fall within the confines of the more general prohibitions potentially associated with EPC Article 53.<sup>448</sup> Additionally, the BOAEPO found the invention to be novel as it did not find prior art associated with the H2-relaxin gene nor anything relative to the sequences of the gene or the corresponding H2-relaxin protein.<sup>449</sup> Lastly, the BOAEPO found the invention to properly involve an inventive step. It found that a skilled person engaged in the science would not have known that a similar cloning technique used in the invention at issue would work despite some similar techniques existing, specifically involving the use of rats and hogs given that the sequence of human relaxin was not known.<sup>450</sup>

The Enlarged Board of Appeal of the European Patent Office's ("EBAEPO") decision in *Wisconsin Alumni Research Foundation* ("WARF") is perhaps the best case outlining both the relationship between the EPO's judicial tribunals and the ECJ.<sup>451</sup> Although the case originated with the question of whether the inventor's patent application could withstand the prohibitions on patentability set forth in Article 53 and Rule 28 of the EPC, the jurisdictional question answered by the EBAEPO settled that the condition of the relationship between the EPO and the ECJ in that the former does not have the authority to ask the latter for a preliminary ruling.<sup>452</sup> In *WARF*, the patent applicant submitted that since Rule 28(c) (ex 23d) mirrored the language in Article 6(2)(C) of Directive

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445. *Id.*

446. *Id.*

447. *Id.* at 10.

448. *Id.* at 10-11.

449. *Id.* at 11.

450. *Id.* at 12.

451. Case T-0002/06, *Wisconsin Alumni Research Foundation* ("WARF"), (2008), Enlarged Board of Appeal of the European Patent Office.

452. *Id.* at 17.

98/44/EC, there existed a question of EU law to which the question of patentability should be resolved by the ECJ.<sup>453</sup> The applicant further contended that the EBAEPO should be treated similarly to a EU member-state's national court since the vast number of member-states of the EPC are also member-states of the ECJ.<sup>454</sup> Lastly, the applicant argued that by not asking the ECJ for a ruling now risked the reality that EU member-state national courts will interpret Article 6 of Directive 98/44/EC in a dissimilar manner than required by the EPO.<sup>455</sup>

The EBAEPO discounted this argument on several grounds. First, the EBAEPO made note of the fact that the EPC itself nor the implementing regulations identify any situation whereby the EPO should refer questions of law to the ECJ and the EPO is a creation of the EPC in which the latter is the provider of the former's scope of authority.<sup>456</sup> Second, the EPO's judicial organs, although they may be treated as traditional courts, are not constructs of the EU but instead part of the EPC which is an international organization that maintains its own set of member-states, not all of which are part of the EU.<sup>457</sup> Third, the fact that EPC was amended to include language that mirrors Directive 98/44/EC on the patentability of biotechnological inventions does not allow the EPO to refer cases to the ECJ as some of the contracting states to the EPC are not part of the EU.<sup>458</sup> Additionally, and relatedly, according to the EBAEPO, the EPC only states that Directive 98/44/EC should be used as a supplementary source of interpretation for EPC Rules 26 through 29.<sup>459</sup> Fourth, the EBAEPO stated that it made no difference that the EPO's judicial bodies were located in Germany, an EU member-state.<sup>460</sup> Lastly, the EBAEPO stated that it was not aware of any precedent allowing for the EPO to refer a case to the ECJ.<sup>461</sup>

On the issue of patentability of the subject matter at issue in the patent application, the EBAEPO in *WARF* held that the patent application could not be sustained in the face of Article 53's prohibition against inventions

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453. *Id.* at 13.

454. *Id.* at 5. The patent applicant also argued that the EBAEPO was akin to a national court in that it was located in an EU member-state. *Id.*

455. *Id.*

456. *Id.* at 13-14.

457. *Id.* at 14.

458. *Id.*

459. *Id.* at 15.

460. *Id.* at 17.

461. *Id.* at 15-16. The EBAEPO did mention that the patent applicant contended that the ECJ's decision in *Dior v. Evora*, Case C-337/95, (2008) ECR I-2173, which allows the Benelux Court of Justice to refer cases to the ECJ. According to the EBAEPO, the Benelux Court of Justice is merely the highest national court of the three countries (Belgium, The Netherlands, and Luxembourg) whereby it has jurisdiction. *Id.* at 16-17.

that could only be obtained by the destruction of human embryos.<sup>462</sup> After making clear that Rules 26 through 29 were added to the EPC to harmonize the EPC with Directive 98/44/EC, the EBAEPO stated that it would focus its decision on an interpretation of the Directive and look at the ordinary meaning of the substance of the Directive pursuant to the Vienna Convention on the Law of Treaties.<sup>463</sup> According to the EBAEPO, Directive 98/44/EC's Article 6(2)(c) prohibits the patenting of an invention if a human embryo is used for industrial or commercial purposes. This language was the result of EU legislative intent to prevent the commodification of human embryos whereby one of the essential functions of the Directive's language was to protect human dignity.<sup>464</sup> The EBAEPO disagreed with the patent applicant's position that since the EU actually funds some forms of research on human embryos, the EU must have not wanted to prohibit inventions such as the one at issue.<sup>465</sup> In contrast, the EBAEPO stated that the EU's selective funding of such research does not allow for such an interpretation nor does the fact that the term embryo was not defined by the Directive nor EPC Rule 28, while the term is defined in the law of some member-states.<sup>466</sup>

The more technical part of the EBAEPO's decision in *WARF* focused on the actual invention as the patent applicant contended was that in order for the patent application to be denied, human embryos must actually be claimed in the application.<sup>467</sup> According to the EBAEPO, not only must the explicit wording of the application have to be examined, but also the technical teaching of the application, as well as the method by which the invention is performed.<sup>468</sup> On this point, the EBAEPO firmly stated that since the human embryos had to be destroyed in order to produce the stem cell cultures claimed in the patent application, the patent could not be granted.<sup>469</sup> The EBAEPO argued that to do otherwise would allow an inventor who develops a process or product that destroys human embryos to gain a patent through the artful crafting of a patent application by avoiding language depicting the entire process.<sup>470</sup> Lastly, while addressing the application of the phrase found in Directive 98/44/EC, "for industrial and commercial purposes," the EBAEPO found that the patent applicant could not argue that the invention did not meet this standard

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462. *Id.* at 29.

463. *Id.* at 20.

464. *Id.* at 21-22.

465. *Id.* at 22.

466. *Id.* at 22-23.

467. *Id.* at 23.

468. *Id.*

469. *Id.* at 23-24.

470. *Id.* at 24.

since the invention itself was for human embryonic stem cell cultures and not the use of actual human embryos.<sup>471</sup> Instead, the EBAEPO held that when an inventor, such as in the case of this patent application, must go through a process (the destruction of human embryos) to get the product (human embryonic stem cell cultures) that fits the definition of “for industrial and commercial purposes.”<sup>472</sup>

In a case that was temporarily stalled by the EPO in anticipation of the outcome of *WARF* to allow case law on this issue to develop, the BOAEPO stated that auxiliary statements added to a previous application could not save the patent application from failing on grounds of lack of patentability under EPC Article 53 and Rule 28 (ex 23).<sup>473</sup> In *California Institute of Technology* (“*CalTech*”), the namesake patent applicant sought a patent for an in vitro method of proliferating a clonal population of stem cells whereby the stem cells were capable of self-renewal but the culture where the stem cells would rest would not contain fetal calf serum to produce a population of neural crest-stem cells.<sup>474</sup> However, in an auxiliary request, the patent applicant added the phrase “wherein the cells are not derived from an embryo” just after the phrase “mammalian neural crest stem cells” and also added the phrase “capable of being derived from adult tissue” after the phrase “mammalian neural crest stem cells,” seemingly in an attempt to save the application’s patentability.<sup>475</sup> Immediately following the EPO’s release of the *WARF* decision, the EPO stated that applicant’s application would fail on lack of patentability grounds based on Article 53 and Rule 28.<sup>476</sup> Interestingly enough, the applicant withdrew its request for oral proceedings and did not object against the EPO’s initial rejection, following the notification by the EPO the EPO held the oral proceedings in abstentia.<sup>477</sup> According to the BOAEPO, the central issue in the matter was whether the patent

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471. *Id.*

472. *Id.* at 24-25.

473. Case T-0522/04, *California Institute of Technology* (“*CalTech*”), (2009), Board of Appeal of the European Patent Office, at 2, 5. The full text of Claim 1 under discussion in the original application read: “1. A method of proliferating in vitro a clonal population of mammalian neural crest stem cells, wherein the cells are cultured in vitro in a feeder cell-independent culture medium on a substrate, wherein the culture medium does not contain fetal calf serum to produce a population of neural crest-stem cells and differentiated progeny thereof, wherein the neural crest-stem cells are characterized by being capable of self-renewal in the culture medium and capable of differentiation to progeny cells that are peripheral nervous system neuronal or glial cells, wherein said neural crest-stem cells express low-affinity nerve growth receptor (LNGFR) and nestin, but do not express glial fibrillary acidic protein (GFAP), and wherein progeny cells that are peripheral nervous system neuronal cells do not express LNGFR or nestin but do express neurofilament and progeny cells that are peripheral nervous system glial cells express LNGFR, nestin and GFAP.” *Id.* at 2.

474. *Id.*

475. *Id.* at 2-3.

476. *Id.* at 3.

477. *Id.* at 4, 6.

application possessed subject matter that was in violation of the prohibition found in Article 53 and Rule 28 on the patenting of material or processes involving the use of human embryos for industrial or commercial purposes.<sup>478</sup> After making clear that Article 53 and Rule 28 prohibit both products and methods that lead to the destruction of a human embryo, the BOAEPO found that the application later after Claim 1 explained that the process stated that “the caudal-most 10 somites are dissected from early embryos” with the isolation process further described.<sup>479</sup> The BOAEPO found in the end that the two added phrases were not satisfactory disclaimers that could save the application’s patentability, given that a complete reading of the application, according to the BOAEPO, did not completely leave out the possibility of the use of human embryos.<sup>480</sup>

In *Sangamo BioSciences*, the BOAEPO found that although a patent applicant had used human embryonic stem cells in the research and process leading up to the invention, the applicant sufficiently disclaimed that portion of the invention.<sup>481</sup> In contrast to Claim 1 of the originally filed patent application, Claim 1 had been altered in a way that restricted the claim to a method of altering the state of differentiation in an embryonic stem cell or population of stem cells, comprising the step of administering a ZFP characterized by specific DNA-binding domains but with a disclaimer which specifically excluded human embryonic stem cells.<sup>482</sup> More narrowly, the claim had been changed to seek patent protection where the invention included only the embryonic stem cells of mice.<sup>483</sup> According to the BOAEPO, even though patents will not be granted for violations of EPC Article 53, a disclaimer can be used to disclaim subject matter which would otherwise be found offensive to the EPC but also allows the remainder of the patent application to result in a granted patent.<sup>484</sup> Once the patentee reduced the claim to allowable subject matter, hereby only claiming the method of altering the state of differentiation in a non-human stem cell (stem cells from mice), the BOAEPO recommended that the patent be granted.<sup>485</sup> However, in this particular case, the BOAEPO made it clear that the *exclusion* of the human embryonic stem cells did not introduce a new technical teaching or disclose any subject matter beyond the application as it was currently

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478. *Id.* at 5.

479. *Id.* at 7.

480. *Id.* at 8-9.

481. Case T-1176/09, *Sangamo BioSciences, Inc.*, (2008), Enlarged Board of Appeal of the European Patent Office, at 5.

482. *Id.* at 4.

483. *Id.*

484. *Id.* at 4-5.

485. *Id.* at 5, 8.

filed.<sup>486</sup>

Although not specific to stem cell research and patentability, the EBAEPO's decision in *Medi-Physics* helps shed light on EPC's lack of patentability provisions and the protection of the human body for which it presupposes.<sup>487</sup> The namesake applicant sought a patent for a surgical procedure that essentially involved the delivery of polarized 129-Xe, in gaseous, dissolved, or liquid phase, directly to a patient either by inhalation or injection directly into the heart.<sup>488</sup> The process described in the patent application stated that the process could be conducted before surgery or during surgery in an attempt to garner additional information (in real time) about the patient that could allow a surgeon to determine a course of action after receiving the garnered information.<sup>489</sup> Essentially, the debate at the EPO was whether the process described in the patent application was an invasive, risk-bearing surgical procedure or merely a non-invasive diagnostic tool; the former would not be considered patentable pursuant to EPC Article 53 (ex 52(d)).<sup>490</sup> According to the EBAEPO, the procedure at issue should be excluded under patentability pursuant to Article 53 even if it comprises or encompasses at least one feature describing a method that constitutes treatment of a human or an animal by surgery or therapy.<sup>491</sup> The EBAEPO viewed the description of the procedures in the application as an invasive step involving a substantial physical intervention of the human body requiring a medical professional's expertise.<sup>492</sup>

Although the substantive position of the EBAEPO is important for any practitioner seeking patent protection in Europe for a surgical procedure, what is more important for the purposes of this work is the discussion by the EBAEPO on the balance between patentability and professional activity. The EBAEPO, in an obvious fashion, stated that the basic purpose of the patent system was to provide and incentivize the development of inventions that can benefit the human condition, specifically in the field of human medicine.<sup>493</sup> The EBAEPO commented further that the patent system can be used to protect the investments made by inventors as they seek progress in the medical field and more specifically, in the area of medical diagnosis.<sup>494</sup> However, the EBAEPO

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486. *Id.* at 5.

487. Case G-0001/07, *Medi-Physics*, [2010] Enlarged Board of Appeal of the European Patent Office.

488. *Id.* at 4.

489. *Id.*

490. *Id.* at 4-5.

491. *Id.* at 40.

492. *Id.* at 65, 74.

493. *Id.* at 15.

494. *Id.*

in a sympathetic manner also made clear that although Article 53 excludes medically-related methods from patentability, the freedom of a practitioner to use the discovered methods is still available.<sup>495</sup> Further, the EBAEPO provided a comparison to the policy in the U.S. whereby methods of medical procedure have long been patented, including methods for diagnosis. It also stated that practitioners that mimic those patented methods cannot be sued for patent infringement.<sup>496</sup>

#### VII. THREATS TO THE HARMONIZATION OF THE LAW GOVERNING STEM CELL RESEARCH AND PATENTABILITY.

When the European Commission first reported on the ability of Directive 98/44/EC to harmonize the law on biotechnology throughout the EU, the report was negative regarding both the action of member-states to fully implement the Directive and the ability to achieve legal clarity.<sup>497</sup> The case law from both the ECJ and the EPO (the BOAEPO and EBAEPO inclusive) identified three significant threats to the harmonization of the law governing stem cell research and patentability. First, and perhaps the most obvious, is that there are 28 member-states the EU and 38 contracting members of the EPO, constituting a wide variety of social and political cultures. These social and political cultures have been enabled by the two primary sources of law, the EPC and Directive 98/44/EC, and the two primary judicial bodies, the EPO (again, inclusive of both the its judicial organs) and the ECJ, to allow member-states to determine for themselves what is considered to be against the public order and morality. Directive 98/44/EC recognizes the divisions among the member-states in regard to their domestic laws on this point and also recognizes the threat such divisions pose to harmonization on this topic. However, Directive 98/44/EC does not harmonize the law across the EU, as this source of law makes clear that patent protection is the domain of a member-state's national law. Further serving as a threat to harmonization, Directive 98/44/EC allows member-states to decide best how to conform to the EPC corpus of law on biotechnological inventions regarding the specific language a member-state can use to meet the conformity mandate.

The second threat to harmonization, and certainly related to the first, is that the case law of the ECJ seems to provide member-states with greater flexibility instead of a push toward harmonization, despite the ECJ's constant recognition of the need for harmonization. The ECJ's decision

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495. *Id.* at 15-16.

496. *Id.* at 16.

497. Graeme Laurie, *Patenting Stem Cells of Human Origin*, (2004) EUR. INTELLECT. PROPERTY REV. 59.

in *The Netherlands v. Parliament* best illustrates this problem. Although the ECJ went to great lengths to state that Directive 98/44/EC is designed to keep the internal market harmonized in regard to biotechnology, the Directive itself does not create an EU-wide patent and member-states can still create their own rules on public order and morality.<sup>498</sup> The ECJ in this same case stated that Directive 98/44/EC was a legitimate use of the EU's legislative authority to protect the internal market so that member-states would apply the law on biotechnology evenly.<sup>499</sup> Therefore, what the ECJ may have only accomplished is an EU-wide rule endorsing the flexibility of member-states to determine their own framework for patent protection that could be malleable to meet each member-state's political and social needs but may actually interfere with the internal market.

The problems associated with flexibility were further endorsed by the ECJ in *Brustle* whereby the ECJ commented that the public order and morality prohibition is open to interpretation by member-states and that national courts have the ability to rely on their own sense of scientific knowledge to define a human embryo.<sup>500</sup> The reader of this work should be reminded that the ECJ did attempt to define a human embryo, at least in part, by declaring that non-fertilized ovum received by transplant and non-fertilized ovum whose division has been stimulated by parthenogenesis.<sup>501</sup> Although the ECJ did state that greater uniformity was needed by the EU as to what the complete definition of a human embryo should dictate, the ECJ contradicted itself by stating that there existed some form of uniform definition and that there should be a greater effort toward a uniform definition because member-states are free to use their own discretion when determining the scope of a legal definition of a human embryo.<sup>502</sup> The ECJ did attempt to fill the void left open in *Brustle* by providing a broader definition of a human embryo in *International Stem Cell*, where it declared that a human embryo should include whatever could develop into a human being after showing great concern for the need for a more complete, EU-wide definition.<sup>503</sup>

Although not directly on the point of patentability, the ECJ was similarly guilty of providing flexibility to member-states in regard to whether biotechnology-related services are *exempt* from the VAT tax in

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498. Case C-377/98, Kingdom of The Netherlands, supported by the Italian Republic and the Kingdom of Norway v. the European Parliament and the Council of the European Union, (2001) ECR I-7079, at ¶¶ 7, 17-22, 25, 35.

499. *Id.* at ¶ 7.

500. Case C-34-10, Oliver Brustle v. Greenpeace eV, (2011) ECR I-9821, at ¶¶ 6-7, 37.

501. *Id.* at ¶ 36.

502. *Id.* at ¶¶ 26-29, 53.

503. Case C-364/13, International Stem Cell Corporation v. Comptroller General of Patents, (2013) (United Kingdom),

*CopyGene*.<sup>504</sup> Regardless of whether the reader of the ECJ's decision in *CopyGene* was the culprit in allowing the flexibility or whether the Sixth Directive truly requires the flexibility, the discretion afforded to the national courts and governments of the member-states inhibits the ability to achieve harmonization in regard to research in biotechnology. However, the ECJ assisted with harmonization efforts in stating that the stem cell-related activities in question in *CopyGene* were subject to an exemption from VAT. In doing so, the ECH seemingly took away some member-state discretion by holding that member-states cannot bar exemption for such services even if the true benefits of such services and related research may not be determined for years to come.<sup>505</sup>

In addition to this last part of the holding in *CopyGene*, the ECJ did recognize the void between an EU Directive and efforts toward harmonization in *Humanplasma*. The ECJ stated that although Directive 2002/98/EC provides for only a lower barrier for what member-states can require for the safety and quality of blood-related materials and that member-states can impose stricter guidelines, any set of stricter guidelines cannot go beyond what is necessary to ensure safety and quality or will otherwise violate the fundamental freedom of free movement of goods pursuant to TFEU Articles 30 and 36.<sup>506</sup> The *Humanplasma* decision is perhaps the best example in the ECJ's jurisprudence described in this line of work, whereby the ECJ checked the discretion held by the member-states in an effort to promote harmonization. However, and critically important for the practitioner in this area, the *Humanplasma* decision only served as a harness on an importing member-state's discretion and thus stricter guidelines can be imposed by a member-state if the blood-related products are not crossing from one EU member-state to another. Therefore, a member-state is within its discretion to impose stricter guidelines for the quality and safety of blood related products if the products remain wholly within that regulating member-state's political boundaries.

Although the ECJ could have accomplished more to harmonize the law governing stem cell and biotechnological research across the member-states, the EPO did no better. The BOAEPO's decision in *Howard Florey* at least curbed a member-state's discretion in regard to what would otherwise be a denial of patentability, by stating that merely because an invention is "outrageous" does not mean it does not meet the requirements for patentability.<sup>507</sup> However, despite this limitation on a member-state's

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504. Case C-262/08, *CopyGene A/S v. Skatteministeriet*, (2010) ECR I-5053, at ¶ 81.

505. *Id.* at ¶¶ 43-45.

506. Case C-421/09, *Humanplasma GmbH v. Austria*, (2010), ECR I-12869, at ¶¶ 31-32, 46.

507. Case T-0272/95, *Howard Florey Institute v. Aglietta*, (2002). Boards of Appeal of the European Patent Office, at 2.

discretion, the BOAEPO also contended that EPC Rule 23 did not provide an exhaustive list of what is prohibited from patentability and in regard to the human body, the EPO can adopt additional prohibitions subject to EPC Article 53.<sup>508</sup> Although it would seem that any additions to the category of prohibited inventions would apply equally to all EPC member-states, the lack of clarity on this point, especially in an area of patentability that is so controversial, will not promote harmonization.

Any practitioner curious or confused about the relationship between the ECJ and the EPO should read the EBAEPO's decision in *WARF*. The EBAEPO made it clear that the EPO does not have the legal ability to ask the ECJ for a preliminary ruling.<sup>509</sup> Problematically, although EPC Article 53 and Rules 26-29 are supposed to mirror EU Directive 98/44/EC, there exists two independent generators of jurisprudence on the patentability of stem cell inventions on the European continent. Further complicating matters, the membership of the EU does not mirror the membership of the EPO. Therefore, the gulf in the jurisprudence between these two institutions, notably a difference in the interpretation of these mirroring, yet jurisdictionally separate sources of law, could result in a gross lack of harmonization on the topic of stem cell patentability. This schism in jurisprudence represents the third threat to harmonization. Although this work is narrowly focused on stem cell patentability and research, one can imagine other problems associated with a divergence between the EPO and EU on other areas of scientific research.

#### VIII. RECOMMENDATIONS FOR GREATER HARMONIZATION AND PROMOTION OF STEM CELL AND BIOTECHNOLOGICAL RESEARCH.

Given what has been presented in this work up to this point, there are five recommendations that could be made to provide a framework for greater harmonization in the area of stem cell research, narrowly, and biotechnological research, generally, in the EU. First, the EPC could be amended so that the ECJ has jurisdiction over the decisions of the EPO and its judicial organs in a manner similar to when an EU member-state's national court refers a question of EU law to the ECJ. The amendment would require that the ECJ serve as the final arbiter of patent law in all EPC member-states and would therefore also become the court of last resort after either the BOAEPO and the EPAEPO have made a decision. This would, of course, require the member-states of the EPC, that are not member-states of the EU, to agree to the ECJ's jurisdiction in matters of patent law. Although these non-EU member-states may view this step as

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508. *Id.* at 10-11.

509. *Id.* at 17.

a significant limitation on their sovereignty, the trade-off and benefit to these member-states is that patent law would become more harmonious to the point whereby firms abroad may be more comfortable investing in those non-EU member-states and, relatedly, these investors will know that patent rights are identical across the EU. Already found within the body of case law from the ECJ that supports this point is a requirement by the ECJ in *Commission v. Italy* that patent law be clear and concise allowing inventors to have knowledge of their rights and obligations.<sup>510</sup> Such a reality could spur foreign direct investment across several neighboring countries by firms that find such countries an attractive marketplace for their biotechnological goods.

Second, and controversially, both the EPC and the TFEU could be amended to remove the public order and morality clauses from each agreement. This clause, found in EPC Article 53 and in Directive 98/44/EC Article 3, could be removed from the text of each document as this clause seems to create the most leeway for a member-state to engage in actions that would disrupt harmony in the field of stem cell and biotechnological patentability. Without question, this clause was placed in each document, as is the case also with the TRIPS Agreement, to satiate the concerns of member-states that wish to protect their own cultures within the scope of patent law as it applies to biotechnology. However, the removal of this clause would focus patent law as it applies to biotechnological patents, to issues such as cloning and genetic sequences—both of which are issues that are much more standardized in contrast to the much more flexible concepts of public order and morality. In other words, these more concrete concepts would be much easier to harmonize across a block of countries in contrast to concepts such as public order and morality which are not only flexible in the instant, but could also change based on social and political considerations over time.

Third, even if the public order and morality clauses were not removed from the corpus of patent law that governs biotechnological inventions across EU member-states, the ECJ should rethink its decision in *Brustle*, where the ECJ stated that despite the need for a uniform definition of a human embryo, national courts are free to use their own recognition of scientific knowledge to make such determinations.<sup>511</sup> Judicial bodies are almost never immune from political pressure—regardless of member-states' efforts to insulate their judiciaries from politics. If the national courts of EU member-states are free to use their own sense of scientific knowledge, then political pressures could certainly sway a national court to find a body of scientific knowledge to support the end result. Rather,

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510. Case C-456/03, *Commission v. Italy*, (2005) ECR I-5335, at ¶¶ 51, 78, 81, 83.

511. Case C-34/10, *Oliver Brustle v. Greenpeace eV*, (2011) ECR I-9821, at ¶ 37.

the ECJ should move to an international sense of scientific knowledge that would both harmonize law and science across the member-states, but also further immunize national courts from political pressure.

A fourth recommendation, and also one of judicial reconsideration, is for the ECJ to reevaluate its decision in *CopyGene*. The ECJ held in *CopyGene* that member-states are free to determine whether specific research activities fall within the scope of the VAT tax exception.<sup>512</sup> Much like a member-state's ability to determine its own sense of science to define a human embryo, the ability of a member-state to freely decide what is and what is not exempt from VAT equally allows member-states to judge whether certain activities, in this case biological research activities, are within the scope of their social and political cultures. A lack of VAT exemption might create a financial chilling effect on some biological research activities to the point where such activities are no longer viable in that member-state, and perhaps worse, pushes those research endeavors either to another member-state or to another country that is not a member-state of the EU. Admittedly, if the ECJ removed this level of home rule for member-states and replaced it with a harmonized rule as to whether certain biological research activities are within the scope of a VAT exemption, some of this research activity could leave the EU. However, if the mission is to increase harmonization, at least member-states would not work as rivals to either attract, or push out, the investment that supports biotechnological research. It should also be mentioned that the European Parliament and European Council could also do away with this level of discretion for member-states by amending the VAT tax directive.

The fifth and final recommendation is to shift the ethical debate in the area of stem cell research and patentability from the issue of patentability to funding. As stated above, the approach to patentability in the U.S. is one of agnostic nature whereby assuming the invention, biotechnological or otherwise, meets the basic criteria for patentability, there is no judgment associated with public order or morality. Although one could take the position that the award of a patent represents society's approval of the invention, perhaps the ethical debate should shift to whether member-state governments should provide funding for such biotechnological inventions either directly or indirectly through a tax subsidy. If this were the case, member-states would be using the power of the purse to determine society's approval instead of the potential award of patentability. If this framework were adopted by a member-states of the EU and the EPC, then a denial of public funding would serve as a determinant of economic development rather than EPC Article 53 and/or

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512. Case C-262/08, *CopyGene A/S v. Skatteministeriet*, (2010) ECR I-5053, at ¶ 81.

Directive 98/44/EC.

## IX. CONCLUSION.

Despite the attempts various institutions, including member-state governments of the EU and the EPC, and the EU itself, the ethical debate concerning the use of stem cells, human embryos and the patenting, funding, and research associated with stem cells and human embryos is unlikely to fade as any new stem cell-related invention on the European continent may be challenged on morality grounds.<sup>513</sup> Just recently, scientists have crafted hybrid embryos possessing both human and animal cells, called chimeras, in an attempt to grow human organs in such animals with the potential for later transplant into human patients.<sup>514</sup> A new law in the United States, dubbed “The Right to Try Law,” is designed to both increase the speed by which patients at grave risk of loss of life including those that can benefit from stem cell-based pharmaceuticals can access new therapies and legally protect the makers of those pharmaceuticals.<sup>515</sup> One can also imagine an ethics debate on the liability of firms crafting such pharmaceuticals and related therapies. A further ethical dilemma concerns the price at which these newly-found and successful stem cell therapies, which help researchers and medical professionals attack the most challenging illnesses, are distributed to patients.<sup>516</sup>

Intellectual property rights can assist countries with economic development, if their intellectual property regimes are trustworthy.<sup>517</sup> The lack of harmonization in the law governing stem cell research is problematic if the industry is to continue to grow in Europe. . A high level of intellectual property protection makes firms more comfortable when deciding to invest in another country.<sup>518</sup> Reliable intellectual property protection will allow a country to enjoy greater technology transfer, lower wage inequality, and greater economic development.<sup>519</sup> To be fair, there is also an argument that developing countries actually experience

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513. James Field, *The Patentability of Human Embryonic Stem Cell-Based Inventions in the European Union*, 6 ABERDEEN STUDENT L. REV. 1 (2015).

514. Clive Cookson, *Breakthrough Over Growing Human Organs in Animals*, FINANCIAL TIMES, (February 18, 2018), <https://www.ft.com/content/1eff740c-148b-11e8-9e9c-25c814761640>.

515. Sumathi Reddy, *The “Right to Try” Law Says Yes, the Drug Company Says No*, WALL ST. J. (June 6, 2018, 5:56PM), <https://www.wsj.com/articles/family-battling-a-rare-disease-sees-roadblocks-despite-right-to-try-law-1528293923?mod=searchresults&page=1&pos=1>.

516. Jonathan D. Rockoff, *The Million-Dollar Cancer Treatment: Who Will Pay?*, WALL ST. J. (April 26, 2018, 7:00AM),

517. PATRICK J. W. EGAN, GLOBALIZING INNOVATION: STATE INSTITUTIONS AND FOREIGN DIRECT INVESTMENT IN EMERGING ECONOMIES 48 (2017).

518. *Id.* at 168.

519. *Id.* at 242.

situations whereby intellectual property rights found inside international agreements can serve as a constraint on economic growth.<sup>520</sup> Assuming that the overwhelming majority of member-states, that maintain membership in the EU or the EPO, desire economic development, the case law presented in this work depicts both challenges and opportunities. The ECJ in *International Stem Cell* recognized the balance between the interests that a member-state may have in growing the economy, to which maintaining a patentability regime more open to stem cell research may produce. It also recognized the need for protecting human dignity, which may reduce the scope of what type of biotechnological inventions are patent eligible.<sup>521</sup> Problematically, the balance between economic development and the advancement of science in the area of stem cell and biotechnological research, and the potential harm these scientific advancements could bring, is not a balance where all member-states within the EU and EPC recognize a middle ground.

International treaties providing for intellectual property protection are increasing in number.<sup>522</sup> The EU and the EPO have clearly made great strides over the last four decades in an attempt to create a reliable, consistent body of law on the subject of biotechnology, generally, and to stem cell research, specifically. Without question, EPC Article 53 and Directive 98/44/EC were compromises designed to harmonize the law on stem cell and biotechnological inventions and to find as much agreement as possible among many member-states. However, as the case law and morality issues showcased in this work reflect, the compromise may be too large a gulf to harmonize the law on stem cell and related biotechnological research, without the ECJ directing its jurisprudence toward legal flexibility for the member-states.

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520. THEODORE H. MORAN, FOREIGN DIRECT INVESTMENT AND DEVELOPMENT: LAUNCHING A SECOND GENERATION OF POLICY RESEARCH 71 (2011).

521. Case C-364/13, *International Stem Cell Corporation v. Comptroller General of Patents (United Kingdom)*, (2014) ECR, ¶ 3. ECLI:EU:C:2014:2451,

522. EGAN, *supra* note 498, at 241.