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### Patentability of Stem Cell Research under TRIPS: Can Morality-Based Exclusions Be Better Defined by Emerging Customary International Law

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# Patentability of Stem Cell Research Under TRIPS: Can Morality-Based Exclusions Be Better Defined by Emerging Customary International Law?

## I. INTRODUCTION

Stem cell research is becoming a household term, yet it is very likely that neither the average citizen nor government legislature fully comprehends the ethical and legal conundrums which are now just beginning to plague researchers and global judicial systems. Because of ethical issues surrounding the use of embryonic stem cells and cloning, governments have either enacted strict regulations, neglected to fund research, or have shunned it entirely. Meanwhile, many companies are striving to become world leaders in this important field of medicine, as certain areas of stem cell research show promising results in the treatment of major illnesses, including heart failure.

In the United States, the perception is that funding regulations are both tough and limited to very particular methods and practices. Many believe that due to the dearth of funding for stem cell research, its potential growth, and development for critical care treatment seems stunted. As a result of funding limitations, some private companies have moved to countries whose government policies on stem cell advancement range from mere support to active encouragement. For example, a small company in Bangkok, Thailand, is currently using adult stem cells to treat patients with heart conditions.<sup>1</sup> At almost forty thousand dollars per procedure, and because Thailand is one of the few countries in the world allowing commercial stem cell treatment, patients are more than willing to travel from all over the world for

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1. Katie LaGrone, *Stem Cell Therapy Shows Promise in Heart Patients*, ABC7 NEWS ONLINE, Jan. 12, 2007, <http://www.abc-7.com/Articles/readnews.asp?articleid=10583>.

a second chance at life. Consequently, the company is enjoying both medical and financial success.

Licensing a new technology or practice is understandably crucial to an inventor's success and motivation. If a private company is endowed with the ability to develop promising treatments in critical care medicine by using stem cells, but is prevented from pursuing these goals due to financial constraints, the company should be allowed to seek out global investment opportunities without fear of retribution or restrictions, as long as it operates in accordance with international law. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and related international agreements are promising solutions in providing inventors adequate patent protection in the worldwide marketplace.<sup>2</sup> However, there is an element of uncertainty in the equation as the application of TRIPS to the area of stem cell litigation enters uncharted waters. For instance, the broad discretion given to Member States to exclude patents based on "*ordre public* or morality" under Article 27.2 may conflict with TRIPS's overall purpose of providing minimal protection of patent rights, especially where a patent may be within the bounds of customary international law adhered to by participating parties.

This Comment initially analyzes the current state of law regarding stem cell research in the international community. It seeks to discern some of the common roadblocks to the patentability and funding of emerging stem cell technologies, as well as the impact of existing legislation on its future proliferation throughout the global marketplace. Secondly, this Comment examines the role morality plays in the patentability of stem cell research, and whether customary international law may help to supplement interpretation of TRIPS and related agreements. Finally, this Comment offers suggestions on whether TRIPS is the best vehicle – as enacted or in a modified form – to serve society's interest in new and emerging critical care medicine.

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2. See generally Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS]. TRIPS was originally a part of the General Agreements on Tariffs and Trade (GATT), and was negotiated towards the end of the Uruguay Round in 1994.

## II. THE ETHICAL CONFUSION AND ITS ENSUING CONTROVERSY

A. *What are Stem Cells?*

A stem cell is a type of cell that can reproduce itself for long periods of time and develop into potentially any cell type present in the body.<sup>3</sup> When stem cells are injected into the body, evidence suggests that these cells engage in a “homing” process whereby they are attracted by and subsequently travel to an injured site.<sup>4</sup> The cells then change, or “differentiate,” into the mature type of cell or tissue structure which they can repair.<sup>5</sup> Because of this unique regenerative ability, stem cells offer the prospect of developing therapeutic cell-based treatments to repair or replace damaged tissues within the body, thereby offering a hope for curing some of the most debilitating diseases.<sup>6</sup>

Stem cells are found in the early embryo, fetus, umbilical cord, and in many tissues of the mature body.<sup>7</sup> Generally, there are two primary types of stem cells: (1) adult stem cells, also known as somatic stem cells; and (2) embryonic stem cells, also known as pluripotent stem cells.<sup>8</sup> Until recently, it was thought that only embryonic stem cells could be truly pluripotent<sup>9</sup> – having the ability to differentiate into any type of cell of in the body – and divide and multiply for extended periods of time.<sup>10</sup> This is important because it is easier to harvest the amount of cells

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3. See *Stem Cell Basics: Introduction*, in STEM CELL INFORMATION (Nat'l Inst. of Health, U.S. Dep't of Health & Hum. Services 2006), <http://stemcells.nih.gov/info/basics/basics1.asp>.

4. NAT'L INST. OF HEALTH, DEP'T OF HEALTH & HUM. SERVICES, STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS 1 (2001), available at <http://stemcells.nih.gov/staticresources/info/scireport/PDFs/fullrptstem.pdf>.

5. SELECT COMMITTEE ON STEM CELL RESEARCH, REPORT, 2001-2, H.L. 83-I, ¶ 2.2, box 1.

6. *Id.* ¶ 2.6.

7. NAT'L INST. OF HEALTH, DEP'T OF HEALTH & HUM. SERVICES, STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS 1 (2001), available at <http://stemcells.nih.gov/staticresources/info/scireport/PDFs/fullrptstem.pdf> [hereinafter STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS]; SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 2.2.

8. *Stem Cell Basics: Introduction*, *supra* note 3.

9. *What are the Similarities and Differences Between Embryonic and Adult Stem Cells?*, in STEM CELL INFORMATION (Nat'l Inst. of Health, U.S. Dep't of Health & Hum. Services 2006), <http://stemcells.nih.gov/info/basics/basics5.htm>.

10. *What are the Unique Properties of All Stem Cells?*, in STEM CELL INFORMATION (Nat'l Inst. of Health, U.S. Dep't of Health & Hum. Services 2006), <http://stemcells.nih.gov/info/basics/basics2.htm>.

needed for any viable treatment from pluripotent cells.<sup>11</sup> However, some recent breakthroughs in the area of private adult stem cell research may make adult stem cell treatments more feasible.<sup>12</sup> Nonetheless, even though there have been no proven therapeutic treatments on human subjects to date,<sup>13</sup> scientists believe that the unique abilities of embryonic stem cells must be studied in order to develop viable treatments to cure diseases.<sup>14</sup>

### *B. What are the Ethical Problems Surrounding Embryo Research?*

Much of the global controversy regarding stem cell research centers on the use of embryonic stem cells. Typically, harvesting embryonic stem cells specifically requires the destruction of a human embryo,<sup>15</sup> implicating the hotly debated and controversial issue over at which stage of embryonic development life actually "begins." One side argues that the embryo is a mere cluster of cells that enjoys no more moral status than any other cluster of human cells.<sup>16</sup> On the opposite side is the view that the embryo enjoys the same right to life, and therefore is placed in the same *moral* category, as children or adults.<sup>17</sup>

Even among different religious groups, contrasting views exist. For instance, the Roman Catholic Church, the Islamic

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11. SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 3.4.

12. Yael Porat et al., *Isolation of an Adult Blood-derived Progenitor Cell Population Capable of Differentiation into Angiogenic, Myocardial and Neural Lineages*, 135 BRIT. J. HAEMATOLOGY 703, 703 (2006). Because adult stem cell research does not involve the destruction of embryos, the ethical concerns surrounding embryonic research could be avoided. Gina Kolata, *Stem Cell Science Gets Limelight; Now It Needs a Cure*, N.Y. TIMES, Aug. 24, 2004, at F1. Many argue that adult stem cell research and its potential for treatment are often overlooked because of confusion with the more popular debate over embryonic stem cell research. See, e.g., Nancy Gibbs & Alice Park, *What a Bush Veto Would Mean for Stem Cells*, TIME, July 25, 2005; Irving Weissman, *Understanding the Institute for Cancer/Stem Cell Biology and Medicine*, STANFORD REPORT, Jan. 22, 2003, <http://news-service.stanford.edu/news/2003/january22/weissman.html>.

13. 152 CONG. REC. 93 (daily ed. July 17, 2006) (statement of Sen. Grassley).

14. See, e.g., SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 3.15.

15. Stem cells form as part of earliest stages of development of the embryo, called the blastocyst. The blastocyst is formed six to seven days after in vitro fertilization or somatic-cell transfer procedure. The stem cells are then "derived from the inner cell mass of the blastocyst at a stage before it would [normally] implant in the uterine wall." STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS, *supra* note 7, at 1; see also Rick Weiss, *Universal Stem Cell Principles Proposed: Rules Would Guide Research Efforts*, WASH. POST, Mar. 2, 2006, at A12.

16. NAT'L BIOETHICS ADVISORY COMM'N, REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 49 (1999).

17. *Id.*

Medical Association, and some Christians believe either that life begins at conception or that, as long as there is not total certainty as to when it begins, it must be given the benefit of the doubt and treated as such.<sup>18</sup> Traditional Hindu views are similar in this regard.<sup>19</sup> Other religious faiths disagree, and thus do not assign full moral status to an early embryo.<sup>20</sup>

Most governments have carefully weighed the ethical arguments, domestic abortion laws, international religious views, and the science behind the ongoing development of an embryo to determine when the benefit of research can no longer outweigh the view that the embryo is at a stage deserving of moral regard.<sup>21</sup> Nearly all nations, as well as the U.S. National Bioethics Advisory Commission, take the position that embryonic research should not be performed on an embryo once initial organized development begins.<sup>22</sup>

### III. THE RESEARCH DILEMMA

One of the most significant hurdles for embryonic stem cell research is the existence of a limited number of stem cell lines from which viable stem cells can be obtained, either for research or treatment.<sup>23</sup> Opponents generally object out of concern that the large amount of eggs necessary to make mass treatment viable will result in the use of unethical methods to obtain embryos. For instance, opponents of California's Proposition 71 argued that "women may be subjected to the substantial risks of high dose hormones and egg extraction procedures just for the purpose of research."<sup>24</sup> Another problem is that stem cells harvested from

18. SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 4.18.

19. *Id.*

20. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 50. Jewish law has been seen to take a gradualist position in believing that "[p]ersonhood, with its attendant rights and responsibilities begins at birth." SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 4.19.

21. See SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶¶ 4.1-22; see also NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 99-104.

22. SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 4.22; Pil Ryul Lee, *Pre-Embryo Not Equivalent to Human Being?*, in ASIAN BIOETHICS IN THE 21ST CENTURY § 4.1 (Sang-Yong Song et al. eds., 2003); Research Involving Human Embryos and Prohibition of Human Cloning Act, 2003, § 13 (Austl.).

23. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 8-9.

24. *Proposition 71: Argument in Favor, Rebuttal to Argument in Favor*, OFFICIAL VOTER INFO. GUIDE: NOV. 2, 2004 GEN. ELECTION (Cal. Sec'y of State, Sacramento,

embryos and used for cell-therapy would normally be subject to immunological rejection,<sup>25</sup> which occurs when the patient's immune system does not recognize the introduced cells and rejects them.<sup>26</sup> This is a weighty concern; in many instances, such rejection could prove fatal without a lifetime commitment to immunosuppressant drugs.

The most practicable suggestion to date, and perhaps also the most controversial, is to develop stem cell lines using a method called somatic cell nuclear transfer (SCNT). SCNT is the process by which the nucleus of an immature egg is removed and substituted with that of the patient.<sup>27</sup> The cell is then electrically stimulated to begin dividing,<sup>28</sup> and within the span of a few days forms a blastocyst, or early embryo.<sup>29</sup> The blastocyst is then destroyed to harvest new stem cells, just as with a normal embryo.<sup>30</sup> Because the stem cells were *born from the nucleus of the individual to be treated*, the resulting embryonic stem cells are expected to be completely compatible with the individual's tissue type,<sup>31</sup> and thus would not be rejected by the host immune system.<sup>32</sup> This process is often referred to as "therapeutic cloning."<sup>33</sup> Taken one step further, a successful pregnancy could result if the SCNT-derived embryo is transferred to a surrogate mother.<sup>34</sup> This is the exact method by which Dolly the sheep was created.<sup>35</sup>

Another controversial proposition is to use non-human donor eggs to create SCNT-derived embryos using human nuclei.<sup>36</sup> This process is called *chimeric* therapeutic cloning, and would supposedly foster a virtually unlimited amount of donor eggs to

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Cal.), Aug. 9, 2004, at 72, available at [http://www.sos.ca.gov/elections/bp\\_nov04/prop\\_71\\_argument\\_in\\_favor\\_rebuttal\\_to\\_argument\\_in\\_favor.pdf](http://www.sos.ca.gov/elections/bp_nov04/prop_71_argument_in_favor_rebuttal_to_argument_in_favor.pdf).

25. See, e.g., SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 2.15;

26. *Id.*

27. See NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 10.

28. See *id.* at 19; see also *Scientific Aspects of Human Animal Cloning* (President's Council on Bioethics, Staff Working Paper No. 2, 2002), available at <http://www.bioethics.gov/background/workpaper2.html>.

29. See NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 11 fig. 2-3.

30. See *id.* at 10-11.

31. *Id.* at 11.

32. *Id.*; see also SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 5.7

33. This is in contrast with "reproductive cloning," in which the resulting embryo would then be implanted into a woman's uterus to produce a baby. See SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 5.8.

34. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 10.

35. *Id.*

36. *Id.* at 2, 19.

produce the quantity needed for extensive research and mass treatment.<sup>37</sup> This process simultaneously preserves “the potential for generating tissues and organs for use in cross-species transplantation (xenotransplantation) in order to treat human diseases.”<sup>38</sup> The National Bioethics Advisory Commission noted that, while it is uncertain “whether the fusing of a human cell with the egg of a non-human animal would result in a human embryo[,] ‘any attempt to create a child through this process would raise profound ethical concerns and should not be permitted.’”<sup>39</sup>

#### IV. THE CURRENT STATE OF INTERNATIONAL LAW

Almost every nation has addressed the profound ethical concerns around stem cell research through either legislation, international treaty, or by general policy statement. Most nations have narrowly tailored their laws to impose criminal penalties on anyone seeking to produce a clone from an SCNT-derived embryo.<sup>40</sup> In 1997, the Council of Europe (EC) established the Convention on Human Rights and Biomedicine, further restricting research in the area by implicitly banning the creation of cloned SCNT-derived embryos with the broad and explicit proclamation that “[t]he creation of human embryos for research purposes is prohibited.”<sup>41</sup> Currently, the Convention has been signed by thirty-four European States, of which twenty have already ratified it. Several signatories, such as Sweden, have yet to complete the process and ratify the Convention, conceivably due to their current policies endorsing SCNT research methods.<sup>42</sup> Other countries, such as the United Kingdom (UK) and Germany, have made deliberate decisions to refrain from signing the Convention, leaving their own domestic laws to address the issue until more is known about the technology.<sup>43</sup>

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37. See generally Emily Singer, *Lack of Human Eggs Could Hamper US Cloning Efforts*, TECH. REV., June 15, 2006, <http://www.technologyreview.com/Biotech/16990>.

38. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 16.

39. See *id.* at 2 (citation omitted).

40. See, e.g., Human Reproductive Cloning Act, 2001, c. 23, § 1 (U.K.); Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (2003).

41. Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine art. 18, *opened for signature* Apr. 4, 1997, Europ. T.S. 164.

42. See SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 7.8.

43. See Kara L. Belew, *Stem Cell Division: Abortion Law and its Influence on the Adoption of Radically Different Embryonic Stem Cell Legislation in the United States, the United Kingdom, and Germany*, 39 TEX. INT'L L.J. 479, 515 (2004).



Although there seems to be a clear international consensus on banning reproductive cloning, the consensus regarding whether there should be an outright ban on SCNT and therapeutic cloning for stem cell research remains murky.<sup>44</sup> In March 2005, the United Nations General Assembly adopted the United Nations (UN) Declaration on Human Cloning. This Declaration called upon Member States “to prohibit all forms of human cloning inasmuch as they are incompatible with the protection of human life.”<sup>45</sup> Although the Declaration did not directly confront the issue, interpretation of the General Assembly’s mandate as to how it would apply to therapeutic cloning was central in the discussions. This was the primary reason for numerous abstentions from, or votes against, the Declaration.<sup>46</sup> Although there was general unanimity that reproductive cloning should be banned, most states wanted an exception set aside for therapeutic cloning in certain circumstances.<sup>47</sup> Indeed, several Member States voting in favor of the Declaration did so with the reservation that their interpretation of the agreement was that it did not apply to therapeutic cloning.<sup>48</sup>

#### *A. The Moral Balancing Act*

Virtually all nations under the UN umbrella have addressed the issues surrounding embryonic stem cell research, either by their ratification of the UN Declaration on Human Cloning or through their own domestic laws or policy statements. Whether Member States are acting in “respect of human life” or “human dignity,” all nations seem to share the underlying belief that they are obligated to balance the ethical concerns of embryonic research, in any form, with fundamental moral issues.<sup>49</sup> Additionally, several common themes in the regulation of stem cell research are pervasive throughout the world. These include

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44. See Aurora Plomer, *Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the UK*, 10 *MED. L. REV.* 132, 164 n.2 (2002).

45. Declaration on Human Cloning, G.A. Res. 59/280, U.N. Doc. A/RES/59/280 (Mar. 23, 2005).

46. See Press Release, General Assembly, General Assembly Adopts United Nations Declaration on Human Cloning by Vote of 84-34-37, U.N. Doc GA/10333 (Aug. 3, 2005).

47. *Id.*

48. *Id.*

49. See Rosario M. Isasi et al., *Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa*, 32 *J.L. MED. & ETHICS* 626, 636-37 (2004).

the universal prohibition against reproductive cloning, the prohibition against research on any embryo more than fourteen days old, the prohibition against embryonic research without informed donor consent, and the ban on the commercialization of both embryonic and fetal tissue.

### B. Restrictive Nations

Several nations, such as Germany and Canada, simply refuse to risk making any moral inquiry into whether an embryo is deserving of the rights of a human being, employing restrictive regulations over embryonic research. Canada not only refuses financial funding for stem cell research, but it strictly prohibits the “creat[ion] [of] an *in vitro* embryo for any purpose other than creating a human being,”<sup>50</sup> thereby broadly excluding any research other than for infertility treatment. Additionally, Canada forbids cloning, chimeric research, and any research which “maintains an embryo outside the body of a female person after the fourteenth day of its development . . . ,” a crime punishable with up to ten years imprisonment and a fine of five hundred thousand Canadian dollars.<sup>51</sup> Germany “ban[s], as a matter of principle, the importation and utilization of embryonic stem cells,”<sup>52</sup> fearing that even their mere importation would promote human embryo destruction. The German regulations extend to *all* German scientists, whether or not they practice within German territorial boundaries.<sup>53</sup> For example, scientists who e-mail or telephone cloning instructions to colleagues in other countries can be imprisoned for three years and fined more than sixty thousand U.S. dollars.<sup>54</sup> Due to the Nazi legacy of eugenics, any debate over the potential benefits of stem cell research is almost non-existent.<sup>55</sup>

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50. Assisted Human Reproduction Act, R.S.C., ch. 2, § 5(1)(b) (2004) (Can.).

51. *Id.*

52. Stammzellgesetz [Stem Cell Act], June 28, 2002, § 1 (F.R.G.).

53. See Weiss, *supra* note 15, at A12.

54. See Michael Woods, *U.S. Relatively Hospitable to Stem-cell Research*, PITTSBURGH POST-GAZETTE, June 5, 2005, Nation & World, at A1, available at <http://www.post-gazette.com/pg/05156/516098.stm>.

55. See Mark Henderson, *We Need Ethical Guidelines; Junk Medicine; Stem Cell Research*; TIMES (London), Mar. 4, 2006, Features, available at 2006 WLNR 3665223.

*C. Generally Permissive Nations*

Asia, for the most part, is at the other end of the spectrum. China, India, Japan, South Korea, Singapore, Taiwan, and Thailand have very limited or no regulation at the national level and grant a great deal of autonomy to medical professionals.<sup>56</sup> Singapore has no current legislation addressing either reproductive or research cloning, although it has drafted a bill that would require informed donor consent in any embryonic research and strictly prohibit any type of reproductive cloning.<sup>57</sup> The Bioethics Advisory Committee of Singapore has adopted the position that a human embryo has the status of a “potential human being, but not the same status as a living child or adult.”<sup>58</sup> In weighing the value of embryonic protection with the potential benefits of proposed research, the Committee issued Recommendations that would require researchers to (1) secure informed consent from donors and (2) only conduct experiments on embryos less than fourteen days old.<sup>59</sup> In addition, the Recommendations would prohibit the commercialization of embryos and reproductive cloning of any kind.<sup>60</sup> Alternatively, Thailand has no official position on stem cell research, and thus most research there is conducted in a regulatory vacuum, with scientific guidelines left to the discretion of the research institutions themselves.<sup>61</sup> However, Thailand generally follows the same guidelines as other Asian states, such as imposing a fourteen day rule.<sup>62</sup>

Although debate over embryo cloning (including SCNT) has been spurred by recent legislation in Hong Kong,<sup>63</sup> mainland China has yet to address the ethical and legal implications of embryonic stem cell research. China seems to be following the Western model of legislation by “firmly oppos[ing] reproductive cloning” while

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56. See Isasi et al., *supra* note 49, at 627.

57. *Id.* at 635.

58. BIOETHICS ADVISORY COMM., ETHICAL, LEGAL AND SOCIAL ISSUES IN HUMAN STEM CELL RESEARCH, REPRODUCTIVE AND THERAPEUTIC CLONING, at iv (2002), available at <http://www.bioethics-singapore.org/resources/reports1.html>.

59. *Id.* at vii.

60. *See id.* at viii.

61. See Isasi et al., *supra* note 49, at 635.

62. *Id.*

63. See *Human Embryo Cloning Prohibited in Hong Kong*, STEM CELL WK., Feb. 13, 2006, available at 2006 WLNR 2295482 (discussing Human Reproductive Technology Ordinance, (2000) Cap. 561, § 15 (H.K.) (not yet operative)). Although the statute is not yet fully operative, its prohibitions may still adversely impact research in Hong Kong. *Id.*

promoting embryonic research through strict control of therapeutic cloning.<sup>64</sup> The Chinese South Center Human Genome Project has passed guidelines supporting research carried out under the principles of informed consent, and recommends a “[s]trict prohibition against . . . maintaining researched embryos more than 14 days.”<sup>65</sup> The guidelines also recommend forbidding the buying and selling of embryos and fetal tissue, as well as any economic rewards to donors.<sup>66</sup>

In India, “respect for the embryo’s moral status can be shown by careful regulation of conditions of research, safeguards against commercial exploitation of embryo research, and limiting the time within which research can be done to 14 days.”<sup>67</sup> Indeed, India has drafted guidelines which allow chimeric cloning and other embryonic research and clinical trials, provided there is informed donor consent and research is not conducted beyond fourteen days.<sup>68</sup> These same guidelines restrict and reserve regulation over SCNT processes.<sup>69</sup> These guiding principles further recognize the commercial value of embryonic stem cell lines, and that patent protection should be recognized on a case-by-case basis.<sup>70</sup>

#### D. Moderate Nations

The UK, in passing the Human Fertilisation and Embryology Act,<sup>71</sup> was surely a pioneer in embryo research regulation. In its original form the Act allowed the creation of embryos *in vitro*, subject to conditions requiring written consent from the donor and a prohibition on the use or storage of the embryo after fourteen days.<sup>72</sup> The Act further imposed a criminal punishment of up to ten

64. See Isasi et al., *supra* note 49, at 634-35 (citation omitted); see also *China Needs Law to Prevent Cloning Misuse*, PEOPLE’S DAILY ONLINE (P.R.C.), Mar. 12, 2005, [http://english.peopledaily.com.cn/200503/12/eng20050312\\_176531.html](http://english.peopledaily.com.cn/200503/12/eng20050312_176531.html).

65. Yanguang Wang, *Chinese Ethical Views on Embryo (ES) Stem Cell Research*, in *ASIAN BIOETHICS IN THE 21ST CENTURY* § 3.1 (Sang-Yong Song et al. eds., 2003).

66. *Id.*

67. CENT. ETHICS COMM. ON HUM. RES., INDIAN COUNCIL OF MED. RES., *ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN SUBJECTS* 47 (2000), available at <http://www.icmr.nic.in/ethical.pdf>.

68. See INDIAN COUNCIL OF MED. RES., *NATIONAL GUIDELINES FOR STEM CELL RESEARCH AND THERAPY* 5-6 (2006) (draft), available at [http://www.icmr.nic.in/stem\\_cell/stem\\_cell\\_guidelines.pdf](http://www.icmr.nic.in/stem_cell/stem_cell_guidelines.pdf).

69. *Id.* at 6.

70. *Id.* at 12.

71. Human Fertilisation and Embryology Act, 1990, c. 37 (U.K.).

72. *Id.* §§ 3, 16.

years of imprisonment for violations.<sup>73</sup> In 2001, the UK introduced regulations expanding the licensing of research into embryo development, including embryos created by SCNT.<sup>74</sup> Prior to these regulations, licensing was only available to promote various developments or treatments in the areas of infertility, congenital disease and contraception.<sup>75</sup> The position of the UK on SCNT and its cautiously worded legislation was reached only after lengthy debate both inside and outside of Parliament on the “special status” of the embryo.<sup>76</sup>

The shift away from broader proscriptions on SCNT may be gaining some momentum. Many other nations have imposed regulations following or nearly following the format of the fourteen day rule, informed donor consent, and banning commercialization of embryonic tissue and reproductive cloning.<sup>77</sup> Australia, for instance, has recently modified its previously restrictive legislation to allow the use of SCNT in therapeutic cloning.<sup>78</sup> The Australian parliament narrowly passed the broader legislation with strong debate over the moral issues.<sup>79</sup> Nevertheless, research is restricted to embryos that are less than fifteen days old and that are obtained with proper consent.<sup>80</sup> Any violation of specifically prohibited research practices could result in punishment of up to fifteen years imprisonment.<sup>81</sup>

### *E. The U.S. Approach*

The most permissive actor in stem cell research is by far the United States. Unlike the UK, which tends to steer a middle

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73. *Id.* § 41.

74. See Human Fertilisation and Embryology (Research Purposes) Regulations, 2001, S.I. 2001/188, art. 2, ¶¶ 1-2 (U.K.); see also *R (Quintavalle) v. Secretary of State for Health*, [2002] Q.B. 628, 628.

75. Human Fertilisation and Embryology Act § 11, sched. 2.

76. See SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶¶ 1.2, 4.5, 7.10.

77. See *id.* ¶ 7.9 (noting that the Netherlands limits research on an embryo to fifteen days); see generally Isasi et al., *supra* note 49 (comparing research policies in Latin America, Asia, and Africa); see also NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 40.

78. See *CBS News: Aussie Lawmakers End Ban on Human Cloning* (CBS broadcast Dec. 6, 2006) (Austl.).

79. See *id.*

80. Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act, 2006, sched. 2 (2006) (Austl.) (amending Research Involving Human Embryos Act 2002).

81. *Id.* sched. 1 (amending Prohibition of Human Cloning Act 2002).

ground, the United States imposes no criminal liability for embryonic stem cell research or cloning in any form, and only seeks to enforce its policy against embryonic stem cell research by limiting otherwise available federal funding.<sup>82</sup> Numerous bills have circulated Congress seeking to either prohibit cloning or support embryonic stem cell research. With respect to federal legislation, the battle-lines have been drawn at SCNT and therapeutic cloning, and each piece of legislation has failed for either its inclusion or exclusion.<sup>83</sup>

To date, the only bill to pass both the House and Senate was vetoed twice by President George W. Bush.<sup>84</sup> That bill, originally enacted by Congress as H.R. 810, would have provided federal support for embryonic stem cell research providing the “stem cells were derived from human embryos donated from in vitro fertilization clinics, were created for the purposes of fertility treatment . . . were in excess of the clinical need . . . [, would have] never be[en] implanted in a woman, [and] donated . . . with written informed consent . . . .”<sup>85</sup> It is noteworthy that this legislation did not address SCNT research methods. Further, what makes this piece of legislation distinct is its diversion from the international norms seen in most other countries – specifically, informed donor consent to *use the embryos for research purposes* and a prohibition against maintaining an embryo for more than fourteen days.

President Bush officially supported research on only those stem cell lines created before August 9, 2001, but took the position that H.R. 810 “would support the taking of innocent human life” and that “America must never abandon [its] fundamental

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82. See Michael Woods, *U.S. Relatively Hospitable to Stem-cell Research*, PITTSBURGH POST-GAZETTE, June 5, 2005, <http://www.post-gazette.com/pg/05156/516098.stm>.

83. See Letter from Indep. Citizens Oversight Comm., Cal. Inst. for Regenerative Medicine, to Sen. Dianne Feinstein and Sen. Barbara Boxer (Aug. 5, 2005), available at [http://www.cirm.ca.gov/meetings/pdf/2005/08/080505\\_item\\_7b.pdf](http://www.cirm.ca.gov/meetings/pdf/2005/08/080505_item_7b.pdf); see also Human Cloning Prohibition Act of 2005, S. 658, 109th Cong. (2005); Human Cloning Prohibition Act of 2005, H.R. 1347, 109th Cong. (2005); 152 CONG. REC. 93 (daily ed. July 17, 2006) (statement of Sen. Grassley).

84. See David Jackson, *Bush cites ‘moral line’ in second veto of stem cell bill*, USA Today, June 21, 2007, [http://www.usatoday.com/news/washington/2007-06-20-bush-stem-cells\\_N.htm](http://www.usatoday.com/news/washington/2007-06-20-bush-stem-cells_N.htm).

85. Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. § 489D (2006).

morals.”<sup>86</sup> Still, most Americans support embryonic stem cell research, even if the ethical implications of such research and an understanding of other nations’ laws remain unclear.<sup>87</sup> The Democratic leadership came into control of Congress following the 2006 elections, and as a part of their new mandate, reintroduced the bill.<sup>88</sup> This time Congress coupled the original language with an endorsement of non-embryonic stem cell research,<sup>89</sup> and again, the President vetoed the bill citing the same reasons.<sup>90</sup> The President pointed to recent advances in alternative stem cell research and went on to issue an executive order supporting research that does not require the destruction of human embryos.<sup>91</sup>

In the absence of federal legislation, the Food and Drug Administration (FDA) has asserted jurisdiction over all stem cell related matters *intended for use* in therapeutic treatment.<sup>92</sup> However, FDA regulations do not apply to early embryonic research *not intended for use in the development of a FDA-related product*, and therefore the creation of embryonic stem cell lines by any means mostly remains unencumbered in the United States.<sup>93</sup> Whether therapeutic cloning should be specifically proscribed has generally been left for the individual states to decide.<sup>94</sup> California has recently adopted a state constitutional amendment which specifically establishes a fundamental “right to conduct stem cell research . . . which includes research involving . . . [p]luripotent

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86. Mary Dalrymple, *Bush Vetoes Stem Cell Bill as Promised*, BREITBART, July 19, 2006, [http://www.breitbart.com/article.php?id=D8IV7E080&show\\_article=1](http://www.breitbart.com/article.php?id=D8IV7E080&show_article=1).

87. *See id.*

88. Stem Cell Research Enhancement Act of 2007, S.5, 110th Cong. (2007).

89. *See id.*

90. *See Jackson, supra* note 84.

91. *See id.*; Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007).

92. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 93-95. As early as 1996, the FDA published guidance stating that “structural cells (autologous cells manipulated and then returned to the body for structural repair or reconstruction) would be subject to licensure” as biological products under section 351 of the Public Health Service Act, 42 U.S.C. 262. *Id.*; CTR. FOR BIOLOGICS EVALUATION & RES., U.S. FED. DRUG ADMIN., DOCKET NO. 95N-0200, GUIDANCE ON APPLICATIONS FOR PRODUCTS COMPRISED OF LIVING AUTOLOGOUS CELLS MANIPULATED EX VIVO AND INTENDED FOR STRUCTURAL REPAIR OR RECONSTRUCTION (1996).

93. *See* NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 16, at 67, 93.

94. *See* SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 7.11. New Jersey was the first state to appropriate funds for embryonic stem cell research. Nat'l Conference of State Legislatures, State Embryonic and Fetal Research Laws, <http://www.ncsl.org/programs/health/Genetics/embfet.htm> (last visited Dec. 6, 2006).

stem cells . . . derived from somatic cell nuclear transfer or from surplus products of in vitro fertilization treatments . . . donated under *appropriate* informed consent procedures.”<sup>95</sup> Again there is no reference to a fourteen day restriction. Opponents of the measure warned of the possibility of human cloning and danger to women from extraction procedures that might be undertaken solely for the purpose of research,<sup>96</sup> echoing common themes heard in the global arena.

At the time of this Comment, California, Connecticut, Massachusetts, New Jersey, and Rhode Island allow therapeutic cloning in research; Arkansas, Indiana, Iowa, Michigan, North Dakota, and South Dakota prohibit therapeutic cloning.<sup>97</sup> Massachusetts and New Hampshire incorporate a fourteen day rule into their research laws.<sup>98</sup> Apart from current and potential state and federal legislation, the U.S. National Bioethics Advisory Commission, established by President Clinton, made strong recommendations that embryonic research should be limited to fourteen days, subject to a donor’s informed consent as to whether her embryo would be used *for clinical research*, embryonic tissue should not be bought or sold, and that “federal funding should not be provided to derive ES cells from [SCNT procedures].”<sup>99</sup>

#### V. EMERGING CUSTOMARY INTERNATIONAL LAW

As previously discussed, practically every developed nation in the world has confronted the morality of embryonic stem cell research by enacting public ordinances, promulgating guidelines, or making clear policy statements.<sup>100</sup> The global consensus seems to be that embryonic research should not be done without *informed* donor consent, and should not be conducted on any embryo over fourteen days old. There is also a general disdain for the potential commercialization of embryos and other fetal tissue.

These widespread practices suggest the emergence of customary international law. Customary international law results from a general and consistent practice, widespread among nations,

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95. CAL. CONST. art. XXXV, § 5.

96. *Proposition 71: Argument in Favor, Rebuttal to Argument in Favor*, *supra* note 24, at 72.

97. *Id.*

98. *Id.*

99. NAT’L BIOETHICS ADVISORY COMM’N, *supra* note 16, at v - vi.

100. *See supra* Part IV.



that is followed due to a sense of legal obligation (*opinio juris sive necessitatis*).<sup>101</sup> There is no universal consensus as to what will create customary international law in any particular situation; but it is generally accepted that customary international law is rooted in government acts, public measures, international agreements between nations, as well as soft law such as official statements of policy and guidelines.<sup>102</sup>

Certainly, there is enormous international concern over balancing the ethical dilemma of embryo destruction with the potential benefit of stem cell research, and it is well understood that this balance is hard to maintain once the first sign of organized development begins in an embryo. Based on these moral principles, nations have explicitly chosen not to allow embryonic stem cell research past this critical stage. Unquestionably, the widespread enactment of strict criminal legislation surrounding embryonic research is based upon both a moral and legal obligation to basic human rights and human dignity. This is strong evidence that *opinio juris* is present. The same case can be made against the commercialization of embryonic materials. The buying and selling of embryos is tantamount to buying and selling body parts, a practice prohibited by nearly all developed nations;<sup>103</sup> and the potential for elevating the restriction to the status of a peremptory norm binding on all nations should not entirely be ruled out. Alternatively, while there is a strong prohibition against chimeric implantation in human subjects, the use of chimeric research on non-human subjects is still the subject of considerable debate.

Informed consent before medical treatment has already been deemed a matter of customary international law;<sup>104</sup> in reviewing the positions taken by the international community, the principles of informed consent undoubtedly extend to the context of donors of embryos *which may be used for research purposes*. Whether the use of a donor's egg in a SCNT procedure is subject to informed consent may be unsettled, but it is certainly the obvious logical extension of such measures. Despite its absence in select

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101. RESTATEMENT (THIRD) OF FOREIGN RELATIONS § 102 (2007).

102. *Id.*

103. Steve P. Calandrillo, *Cash for Kidneys? Utilizing Incentives to End America's Organ Shortage*, 13 GEO. MASON L. REV. 69, 86 (2004).

104. See Michele Forzley et al., *International Legal Developments in Review: 1999*, 34 INT'L LAW 749, 750 (2000).

legislation (such as that passed in California and New Jersey),<sup>105</sup> the fourteen day rule remains consistent practice within the international arena.

Inaction may constitute state practice for the purpose of forming customary international law. The failure of some states in adopting a practice, however, will not prevent the creation of a norm of customary international law for all other participating regions.<sup>106</sup> No states overtly dissent to the principles described above.

Moreover, a federal policy in the United States that is consistent with the policies of other nations could supplement or alter the “practice” in its own states such as California and New Jersey. Therefore, the emergence of a norm of customary international law that generally prohibits research on an embryo beyond fourteen days should not be precluded in the United States. It is interesting to see the divergence between bills passed in the U.S. Congress (and some state legislatures) with regulations passed by the international community. Arguably, some legislators are either uninformed as to these international norms or have made a conscious decision to disregard them altogether, and have thus missed an enormous opportunity to contribute to customary international law.

## VI. THE IMPORTANCE OF FUNDING AND PATENTS

### A. *Funding Limitations*

On August 9, 2001, U.S. President George W. Bush approved federal funding for research on stem cell lines which were cultivated from previously destroyed embryos.<sup>107</sup> By allowing the research to continue without promoting the further destruction of human embryos, the federal government drew a careful line between the potential of stem cell research and its moral implications. Under these restrictions, the United States provides approximately 40 million dollars annually in federal funding for

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105. See S. 1909, 210th Leg., Reg. Sess. (N.J. 2002) (enacting legislation which allows embryonic stem cell research, including that by SCNT, provided a policy of periodic review in accordance with applicable federal regulations).

106. See RESTATEMENT (THIRD) OF FOREIGN RELATIONS § 102, cmt. b.

107. See President George W. Bush, President Bush Announces Funding for Limited Embryonic Stem Cell Research (August 9, 2001), <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>.

public research activities involving human embryos.<sup>108</sup> But with California earmarking 3 billion dollars over the next ten years for stem cell research, and with New Jersey's investment in a 380 million dollar stem cell institute, the United States still takes the lead worldwide in funding.<sup>109</sup>

The European Union has embraced U.S. federal funding restrictions, yet it still provides little funding to projects which use unused embryos created by *in vitro* fertilization with donor permission consistent with European law.<sup>110</sup> Within Europe, the British government allocated just over 72 million dollars between 2004 and 2006.<sup>111</sup> While the Chinese government provided roughly 12 million dollars between 2000 and 2005, it further plans to devote up to 132 million dollars during the next five years.<sup>112</sup> With millions in capital, it seems as though research would be booming, but this is not entirely the case. No right to federal funding exists in this area, and there is no federal control of privately funded research.<sup>113</sup>

Thus, private institutions may be driven to take the lead.<sup>114</sup> As of June 2005, American firms engaged in stem cell research have raised 441 billion dollars from venture capitalists alone.<sup>115</sup> The global pharmaceutical market grew to 602 billion dollars in 2005 and is expected to grow to over 840 billion dollars by 2010.<sup>116</sup> These sales could possibly serve to further embryonic stem cell research and development.<sup>117</sup>

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108. Nat'l Inst. of Health, U.S. Dep't of Health & Hum. Services, Estimates of Funding for Various Diseases, Conditions, Research Areas, <http://www.nih.gov/news/fundingresearchareas.htm> (last visited Dec. 6, 2006).

109. See Fiona Murray & Debora Spar, *Bit Player or Powerhouse? China and Stem Cell Research*, 355 NEW ENG. J. MED. 1191, 1192 (2006), available at <http://content.nejm.org/cgi/reprint/355/12/1191.pdf>.

110. See Woods, *supra* note 82.

111. Murray & Spar, *supra* note 109, at 1192.

112. *Id.*

113. SELECT COMMITTEE ON STEM CELL RESEARCH, *supra* note 5, ¶ 7.11.

114. Dan Vergano, *States Dive Into Stem Cell Debates*, USA TODAY, Apr. 20, 2004, [http://www.usatoday.com/news/health/2004-04-20-stem-cell-cover\\_x.htm](http://www.usatoday.com/news/health/2004-04-20-stem-cell-cover_x.htm).

115. Murray & Spar, *supra* note 109, at 1192.

116. Edwin Bailey, *BioMarket Trends, Overview of the Global Pharmaceutical Market*, GENETIC ENGINEERING NEWS, Aug. 1, 2006, <http://www.genengnews.com/articles/chitem.aspx?aid=1820&chid=0>.

117. See *id.*

### B. Importance of Patents in the Biotechnology Industry

Funding of research is often secured through licensing. Indeed, licensing is vital to the biotechnology industry,<sup>118</sup> and the area most affected by future legislation will likely be in patent licensing. Patents grant an inventor an exclusionary right to prevent others from making, using, selling, offering to sell or importing the claimed invention for a fixed period of time in exchange for public disclosure of the invention.<sup>119</sup> Biotechnology patents therefore ensure market exclusivity, and theoretically they encourage further investment in the technology while stimulating further research through the free flow of scientific and technical knowledge. This exchange is further exemplified in the United States where the government is willing to bestow federal grantees (such as universities, small businesses, and non-profit organizations) the right to retain title to inventions in exchange for an agreement to attempt to commercialize them.<sup>120</sup>

At the domestic level, subject matter is usually not excluded from patentability for any reason other than the plain meaning of their patent statutes.<sup>121</sup> This scheme makes sense since patent examiners are not trained in making ethical decisions regarding patentability.<sup>122</sup> Moreover, exclusion of subject matter which is useful in some ways would go against the general intent of patent laws which is to “promote the Progress of Science and useful Arts.”<sup>123</sup> It should be the legislature who, working on behalf of the public, defines what is patentable and what is not based upon the common values of society at large.<sup>124</sup> For instance, in the pharmaceutical industry, courts generally have recognized that

118. Paul Elias, *Court Shakes up Biotech Patent World*, FORBES, Jan. 9, 2007, <http://www.forbes.com/feeds/ap/2007/01/09/ap3314966.html>.

119. DONALD S. CHISUM, CHISUM ON PATENTS § 1 (Matthew Bender & Co., 2007), available at LEXIS.

120. See Cal. Inst. for Regenerative Med., Intellectual Property Policy for Non-profit Organizations 34 (approved Feb. 10, 2006); Act to Amend the Patent and Trademark Laws, Pub. L. No. 96-517, 94 Stat. 3015 (1980).

121. See *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (“Congress is free to amend [the patent laws] as to exclude from patent protection organisms produced by genetic engineering.”); see also *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45, 47.

122. UNITED NATIONS CONFERENCE ON TRADE AND DEV. & INT’L CTR. FOR TRADE AND SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 380 (2005) [hereinafter UNCTAD & ICTSD].

123. U.S. CONST., art. I, § 8, cl. 8.

124. See UNCTAD & ICTSD, *supra* note 122, at 380.

balancing the risks of new, unproven medicines with the possibility of saving lives is not the job of the patent office, and the requirements for use and distribution of drugs are quite different from the requirements for patentability.<sup>125</sup> It should be noted that while the possibility of critical care therapy derived from embryonic stem cells is still unproven, no one is willing to say that the “substantial” utility requirement for patentability has not been met or that stem cells cannot “provide some immediate benefit to the public.”<sup>126</sup>

A patent does not exempt the owner from regulation or prohibition,<sup>127</sup> and thusly patented stem cell lines or processes from which they derive will certainly depend upon the nation’s laws. It would seem that the business-savvy inventor (or investor) would pursue these opportunities only if avenues of marketability existed. A local regulation which strictly excludes therapeutic cloning, prohibits funding, or imposes criminal liability for its practice can stifle research altogether in that nation. Even more so, the extraterritorial reach of a nation whose laws criminalize certain practices certainly can chill scientific research. A private corporation or any other entity seeking to gain global market-share, attract venture capital, or expand research opportunity may want to move its operations to a more permissive nation where a patent can both be secured and acted upon. Because intellectual property has global mobility, once the patent is secured, the owner can operate, perform research, and perhaps conduct clinical trials in an amicable environment while freely seeking licensing agreements throughout the global market and lobbying its own or other governments for relaxed legislation once the technology and practice is proven. If licensing can remain relatively unencumbered while preserving its commercial value, greater global access to research is more likely to be ensured.<sup>128</sup> Ultimately, if funding cannot be secured, research will be limited.

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125. See, e.g., *In re Watson*, 517 F.2d 465, 476 (Ct. Cust. App. 1975).

126. Cf. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (“[A]n asserted use must show that that claimed invention has a significant and presently available benefit to the public.”).

127. *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45, 86.

128. Maria Freire, Dir., Office of Tech. Transfer, Statement of National Institutes of Health Before Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies (Aug. 1, 2001), available at <http://stemcells.nih.gov/policy/statements/080101freire.asp>.

## VII. TRIPS AND OTHER INTERNATIONAL AGREEMENTS AS A VEHICLE FOR STEM CELL PATENTS

TRIPS attempts to set minimum standards for protection and enforcement of intellectual property rights, including patents, around the world.<sup>129</sup> TRIPS recognizes the long-term societal benefits for innovative medical breakthroughs and encourages innovation, thereby minimizing the short-term cost to society. The agreement incorporates the WTO's dispute settlement system and sets up various exceptions, such as compulsory licensing, which would prevent abuse of rights or withholding those breakthroughs which would greatly benefit society.<sup>130</sup> TRIPS further requires WTO Member States to make patents "available for any inventions, whether products or processes, in *all fields of technology . . .*" subject to the normal tests of novelty, non-obviousness and utility.<sup>131</sup> Article 27 further mandates that "patents . . . be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology[,] and whether products are imported or locally produced." These provisions make clear that countries are to extend patent protections regardless of any prior contrary practice.<sup>132</sup>

### A. Patent Exclusion Under TRIPS

Certain aspects of TRIPS would seem to preclude the free flow of emerging science, including the patentability of the therapeutic process, a subject crucial to promoting stem cell treatment. TRIPS allows nations to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."<sup>133</sup> Many nations and the European Union (EU) take advantage of TRIPS's discretionary exclusions from therapeutic methods.<sup>134</sup> Under this scheme, not only does

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129. See WTO SECRETARIAT, GUIDE TO THE URUGUAY ROUND AGREEMENTS 208 (1999).

130. See *id.* at 215, 219-20.

131. TRIPS, *supra* note 2, art. 27.1.

132. See PETER-TOBIAS STOLL & FRANK SCHORKOPF, WTO: WORLD ECONOMIC ORDER, WORLD TRADE LAW 216-17 (2006).

133. TRIPS, *supra* note 2, art. 27(3)(a).

134. See *e.g.* The Convention on the Grant of European Patents art. 52(4), Oct. 5, 1973, 1065 U.N.T.S. 255 [hereinafter European Patent Convention].

international licensing become problematic for licensors in permissive nations seeking worldwide patent protection of stem cell treatments, but it could seriously limit marketability by allowing exclusionary nations to “borrow” a patented method without risking litigation. Furthermore, process-permissive nations could adopt exclusionary laws once such treatments are proven effective in foreign countries, thereby creating an end-run around the sole purpose of patent protection: to “promote the Progress of Science and useful Arts”<sup>135</sup> by rewarding innovation with a temporary monopoly.

More important to this discussion, Article 27.2 of TRIPS allows for the

exclu[sion] from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public or morality*, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.<sup>136</sup>

This exclusion is significant because it presupposes a general rule of patentability,<sup>137</sup> and by its language can exclude any type of patent. This type of exclusionary principle is not entirely a new idea. Indeed, the provision was likely inspired by Article 53(a) of the European Patent Convention (EPC) which excludes European patents on “inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality . . . .”<sup>138</sup> The original text of the EPC was much broader than TRIPS. First, where TRIPS focuses on “commercial exploitation,” the EPC allowed exclusions where the mere “publication or exploitation” of the invention “would be contrary to ‘ordre public’ or morality.” Second, TRIPS prohibits a country from excluding a patent where exploitation was based on its own prohibitions. Under Article 53, it was not necessary for the exclusion to be grounded in the excluding country’s own laws; rather, a prohibition in “some or all the Contracting States” could exclude the patent.

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135. U.S. CONST., art. I, § 8, cl. 8.

136. TRIPS, *supra* note 2, art. 27(2).

137. *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45, 96.

138. UNCTAD & ICTSD, *supra* note 122, at 376; European Patent Convention, *supra* note 134, art. 53(a).

### B. *The European Patent Convention's Directive 98/44/EC*

The EPC was later enhanced by Council Directive 98/44/EC to clarify the legal protection of biotechnological inventions across the EU Member States.<sup>139</sup> This Directive seeks to bring biotechnology patents and their protection under TRIPS and to prevent barriers to trade by defining clear principles to govern the patentability of biotechnological inventions.<sup>140</sup> Notwithstanding each nation's own patent laws, the Directive excludes therapeutic and diagnostic processes yet automatically extends patentability to biological material directly obtained through a process which enables it to be produced.<sup>141</sup> Moreover, the Directive seeks to clarify the exceptions to patentability under the EPC "where . . . commercial exploitation would be contrary to *ordre public or morality*" and proscribes any potential patent for the "process for cloning human beings . . . modifying the . . . genetic identity of human beings [and] uses of human embryos for industrial or commercial purposes."<sup>142</sup> Rule 23(d) was subsequently amended to the EPC using this language to work in conjunction with Article 53.<sup>143</sup>

### C. *The History of Morality-Based Exclusions*

TRIPS is not self-executing, and unfortunately, a provision allowing a general exclusion based on *ordre public or morality* leaves a gap that is open to interpretation.<sup>144</sup> Without a doubt, these exceptions must be implemented under a nation's own domestic laws to be effective.<sup>145</sup> A problem arises in situations where, as under the EPC, this general language is retained and no clear definition follows. In particular, a dispute may ensue during patent prosecution or licensing where definitions from two different nations conflict. There is no specific WTO decision as to the precise definition of these terms.<sup>146</sup> In the United States, an

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139. See Council Directive 98/44/EC, On the Legal Protection of Biotechnological Invention, pmbl. ¶¶ 4-5, 1998 O.J. (L 213) 13 (EC).

140. See *id.* pmbl. ¶¶ 4-36, art. 1.

141. *Id.* pmbl. ¶ 26, arts. 3, 5. Article 5 permits a patent for "[a]n element isolated from the human body or otherwise produced by means of a technical process," but it precludes "the simple discovery of one of its elements." *Id.* art. 5.

142. *Id.* art. 6.

143. WARF/Stem Cells, [2006] E.P.O.R. 31, 336-38.

144. See *In re Rath*, 402 F.3d 1207, 1209-10. (Fed. Cir. 2005).

145. UNCTAD & ICTSD, *supra* note 122, at 375.

146. See *id.* at 381.



invention contrary to *ordre public* has been referred to as “frivolous or injurious to the well-being, good policy, or sound morals of society,”<sup>147</sup> whereas under European law, the definition is linked to public security and the physical integrity of individuals as a part of society.<sup>148</sup>

The European Patent Office (EPO) distinguishes *morality* from *ordre public*. The EPO’s Guidelines for the Examination show that whether a patent will be excluded for moral reasons will generally depend on whether “it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable,”<sup>149</sup> implying that the definition imparts regional and cultural distinctions. Although the United States and Canada have adopted TRIPS,<sup>150</sup> they and other similarly situated nations have not chosen to use *ordre public* or *morality* as a basis for exclusion.<sup>151</sup> In the United States, a patent will only be rejected for public policy reasons due to a lack of “any honest and moral purpose.”<sup>152</sup> Nonetheless, the EPC, many civil law systems, and international agreements continue to rely on this exclusionary provision.<sup>153</sup>

#### VIII. THE WARF PATENT

The Wisconsin Alumni Research Foundation (WARF) currently owns U.S. Patent No. 5,843,780, which claims to isolate a primate embryonic stem cell line. WARF submitted an application for a patent to the EPO claiming the actual cell cultures and the method to produce them.<sup>154</sup> The Examining Division refused the application because it did not comply with Article 53(a) in conjunction with Rule 23d(c) of the EPC.<sup>155</sup> Specifically, because the application described the use of human embryos as essential to the invention as a starting material, the invention fell within the exception Rule 23d(c) for “uses of human embryos for industrial

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147. *Id.* at 376 (citation omitted).

148. *Id.* at 379.

149. *Id.* at 379-80.

150. *See, e.g.*, Uruguay Round Agreement Act, 19 U.S.C. § 3511 (2000).

151. *See, e.g.*, Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 96.

152. CHISUM, *supra* note 119, § 4.03.

153. *See* Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 64.

154. WARF/Stem Cells, [2006] E.P.O.R. 31, 333.

155. *Id.* at 334.

or commercial purposes.”<sup>156</sup> On appeal, the Technical Board of Appeal recognized that “there was no consensus amongst Contracting States as to the ethical acceptability of using human embryonic stem cells.”<sup>157</sup> Before referring the matter to the Enlarged Board of Appeal as an “important point of law, the Technical Board of Appeal began an elaborate discussion of several important issues.

First, the Board seemed to agree with the appellant that Article 53(a) was unclear as to the patentability of resulting stem cells which used to require the destruction of an embryo but does not after the enactment of Rule 23d.<sup>158</sup> Second, the Board asked whether the adopted language of Rule 23d would exclude patents concerning “uses of human embryos for industrial or commercial purposes.”<sup>159</sup> It was clear that a narrow interpretation of *ordre public and morality* had been adopted,<sup>160</sup> however, “use” under Rule 23d was itself subject to interpretation. Two alternatives were proposed: (1) a broad interpretation of the statute to include the *unavoidable use* of human embryos, and consequently a refusal of the application on ethical grounds; (2) a narrow interpretation which would permit the grant.<sup>161</sup> The Board noted that the legislative history of Directive 98/44/EC showed that the legislature chose the text “uses of human embryos” as a replacement for “methods in which human embryos are used” to ensure that patents on inventions which were applied to an embryo and *useful to it* were not excluded.<sup>162</sup>

The Board finally concluded that, based on prior decisions, a narrow interpretation of the EPC provision should prevail after an intense analysis “by all the usual methods of legal interpretation.”<sup>163</sup> Such methods would include considering the words, object and purpose, consequences of a narrow or broad interpretation, the aspect of legal certainty, and historical background.<sup>164</sup> Further guidance could also be obtained from the

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156. *Id.*

157. *Id.* at 338.

158. *Id.* at 349.

159. *Id.* at 344.

160. *Id.* at 337-38.

161. *Id.* at 337.

162. *Id.* at 336.

163. *Id.* at 345.

164. *Id.*

principles of interpretation established by the Vienna Convention on the Law of Treaties.<sup>165</sup>

Normally, a patent is either granted or rejected based upon its claims and the category in which it falls: method, utility, or design.<sup>166</sup> The Board found that where “ethical objections against the exploitation of the technology involved . . . the claimed subject-matter” – in this case, a stem cell line derived from a previously destroyed embryo – the category of the claim was not relevant.<sup>167</sup> Compliance can be based on concerns centered on the invention. This reasoning is consistent with English courts on similar issues. For example, in *Regina (Quintavalle) v. Secretary of State for Health*,<sup>168</sup> the Court of Appeal held that the definition of “embryo” should be given a *purposive* construction so that an organism created by SNCT came within the definition under the Human Fertilisation and Embryology Act 1990.<sup>169</sup> The court in *Quintavalle* found it was the capacity to develop into a human being that mattered, and the legislative policy was that it was essential to bring the creation and use of embryos under strict regulatory control for ethical reasons.<sup>170</sup> If the Enlarged Board of Appeals follows this logic, then it is likely the WARF application will be excluded under the EPC.

Lastly, the Board elevated the issue of whether Article 53 could forbid patents, on moral ground, which were filed prior to the enactment of Directive 98/44/EC or to which Rule 23d doesn't apply.<sup>171</sup> The Board noted that the Guidelines for the Examination of the EPO promoted a narrow version of *ordre public and morality*, and that moral attitudes were constantly changing, evidenced by the European Parliament's recent vote to permit public funding for human embryonic stem cell research.<sup>172</sup> Despite the fact that the appellant's invention used spare embryos produced by *in vitro* fertilization donated for research with

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165. *Id.*; see also Convention on the Law of Treaties arts. 31-32, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331 [hereinafter Vienna Convention] (entry into force Jan. 27, 1980).

166. See generally CHISUM, *supra* note 119, § 1.01 (discussing patentable subject matter).

167. WARF/Stem Cells, [2006] E.P.O.R. 31, 346.

168. *R (Quintavalle) v. Secretary of State for Health*, [2002] Q.B. 628.

169. *Id.* at 628.

170. *Id.* at 640-41.

171. WARF/Stem Cells, [2006] E.P.O.R. 31, 348.

172. *Id.* at 338.

informed consent, further stem cell lines would require destruction of embryos.<sup>173</sup> Here, the Board had its doubts that it could ever be “ethically acceptable to make a decision by weighing the interests of human beings who could potentially benefit from the exploitation of . . . technology against a right, if any, of human embryos . . . to get to life . . . .”<sup>174</sup> Nonetheless, the Board’s opinion emphasized that the EPO’s “expertise should remain in the field of patents, not in resolving controversial moral or ethics issues,” and where a provision of the EPC could be subject to multiple interpretations a “narrow interpretation avoided the EPO acting as a moral censor.”<sup>175</sup>

#### IX. MORALITY-BASED EXCLUSIONS CAN BE BETTER DEFINED BY CUSTOMARY INTERNATIONAL LAW

There is no doubt that this will not be the first case concerning the patenting of embryonic stem cells and related technologies to come before the EPO.<sup>176</sup> The WARF patent prosecuted in the EU applied only to human embryos that were already fertilized *in vitro*.<sup>177</sup> The case did not discuss the moral implications of patents derived by SCNT or other processes, and whether the Enlarged Board of Appeal will broaden its ultimate decision is unknown. For example, if a *purposive* construction of “embryo,” as was given by English courts, is undertaken in a narrow reading of the statute, a patent based on SCNT technology would most likely be rejected because the embryo created by SCNT would be *capable* of human life;<sup>178</sup> the statute would be read as strictly prohibiting patent based upon the “use” of a human embryo. On the contrary, a plain-meaning construction would not define an embryo created by SCNT as a “human embryo” and would likely permit the patent. Alternatively, a *purposive* construction of “embryo” undertaken in a broad reading of the

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173. *Id.* at 341.

174. *Id.* at 348.

175. *Id.* at 337.

176. *See id.* at 339.

177. The United States Patent and Trademark Office granted requests from Foundation Taxpayer and Consumer Rights (FTCR) and the Public Patent Foundation (PUBPAT) to reexamine its patent. *See Warf Stem Cell Patents to be Re-examined at Request of FTCR, PUBPAT: Patent Office Finds "Substantial Question" Regarding Validity of WARF's Claims*, PUBPAT, Oct. 3, 2006, <http://www.pubpat.org/warfstemcellgranted.htm>.

178. WARF/Stem Cells, [2006] E.P.O.R. 31, 337-38.

statute would require an extensive understanding, and perhaps speculation, of legislative intent before a decision could be made.

*A. Morality-Based Exclusions Will Depend on Local or Regional Custom*

Other nations are certain to enact legislation regarding morality in the execution of their duties under TRIPS. In addition, adherence to international agreements and resulting change are both unavoidable. Whether it is a stem cell line, altered gene, chimeric research, or SCNT process, each new promise of medical breakthroughs brings with it new ethical dilemmas. With the Council of Europe Convention on Human Rights and Biomedicine forbidding SCNT on the one hand, and California declaring it a fundamental right on the other, the status of therapeutic cloning is uncertain. It is quite possible that the EPC may soon come under scrutiny in light of the condemnation of SCNT or therapeutic cloning practices by many Member States.

The fact that each nation or region has a different set of cultural beliefs, practices, religion, and laws only exacerbates the problem. The purpose of TRIPS is to unify legislation globally to provide a high standard of intellectual property protection.<sup>179</sup> What is moral to one, however, may most likely not be moral to others. Many nations abhor cultural relativism – the principle that a human's beliefs and activities should be interpreted in terms of his or her own culture. It is not hard to see why many countries would have serious reservations against a mandate to accept norms contrary to their own, especially those dealing with "morality."<sup>180</sup> Morality can be classified as either *private* or *public* morality; where *public* morality is characterized by the "ideals or general moral beliefs of a society."<sup>181</sup> By its own definition, morality includes the "totality of accepted norms" deeply rooted in a particular region or culture.<sup>182</sup> Therefore, signatories must not only enact clear patent laws that precisely state the limits of protection, but must also have a solid justification based upon their regional

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179. STOLL & SCHORKOPF, *supra* note 132, at 216.

180. Relevant definitions of morality include "a doctrine or system of ideas concerned with conduct" and "conduct conforming to the customs or accepted standards of a particular culture or group." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED 1469 (2002).

181. BLACK'S LAW DICTIONARY 812 (7th ed. 2000).

182. UNCTAD & ICTSD, *supra* note 122, at 380.

and cultural definition of morality. Where domestic legislation falls short, regional norms must play their part in interpretation.

### *B. Customary International Law Aiding Interpretation*

Article 31 of the Vienna Convention states that “[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”<sup>183</sup> Subsection (c) further mandates that interpretation “shall . . . take [] into account, together with the context . . . any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.”<sup>184</sup> Additionally, the WTO Dispute Settlement Understanding (DSU), Article 3(2) clearly indicates that existing provisions under WTO agreements are to be clarified “in accordance with customary rules of interpretation of public international law.”<sup>185</sup> There has been significant commentary seeking to establish that these provisions “should not be considered in isolation of general international law.”<sup>186</sup> In particular, there is “a presumption that the WTO system is to be interpreted consistently with general international law, and that the customary rule is to apply unless it can be shown that such an application would undermine the object and purpose of the WTO system.”<sup>187</sup> Of course, this proposition presupposes that any relevant customary norm has legal status on the parties to begin with,<sup>188</sup> and that the parties have not “contracted out” of the customary rule.<sup>189</sup> Where TRIPS is vague, either in its

183. Vienna Convention, *supra* note 165, art. 31

184. *Id.* art. 31 ¶ 3(c).

185. Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 3.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1226 (1994).

186. See Philippe Sands, *Treaty, Custom and the Cross-Fertilization of International Law*, 1 YALE HUM. RTS. & DEV. L.J. 85, 95 (1998). The WTO/GATT is not grounded in custom, and thus references to international norms have in the past only been on rare occasion. See *id.* at 93.; see also David Palmeter & Petros Mavroidis, *The WTO Legal System: Sources of Law*, 92 AM. J. INT’L L. 398, 406 (1998). In spite of this, the WTO Panel and Appellate Body have expressed an increased willingness to apply and interpret WTO/GATT rules in a broader international context. Sands, *supra* note 186, at 97.

187. Sands, *supra* note 186, at 104; see also JOOST PAUWELYN, CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW 253-54 (2003) (contending that the principle of conflict avoidance poses an inherent limit on treaty interpretation).

188. See Sands, *supra* note 186, at 102.

189. PAUWELYN, *supra* note 187, at 252.

implementation under domestic law or by judicial interpretation, customary international law should be allowed to supplement its provisions where appropriate and in such a way that it does not conflict with any other TRIPS provisions or international agreements between contracting parties.

*C. Patent Exclusions Should Be Necessary to Preserve the Customary Norm*

TRIPS itself prescribes that the *use* of an invention may be prohibited by law cannot, by itself, affect its patentability.<sup>190</sup> But before a patent can be declared ineligible, Article 27.2 imparts a “necessity test” which requires a specific link between *morality* and the commercial exploitation of a patent.<sup>191</sup> Therefore, it would seem that the provision would not be applicable to actual stem cell *research* as long as the research is not conducted with commercial intent. Patent law itself does not require commercialization, except in the unusual situation where the patent right is given in exchange for government funding and a promise to commercialize it. In the real world, however, patents and commercialization are often intertwined. The potential of commercialization enables channels of funding which in turn fuels research – it is very much a dependent cycle. If a form of stem cell research is deemed immoral under TRIPS, then it may not be patentable. Nonetheless, any company not intending to capitalize on it would still be free to undertake the research. Yet, without the ability to capitalize on the end product, research is likely to be frustrated.

It is hard to reason that banning a practice may be “necessary to protect . . . morality” when a nation and its courts have already deemed the practice permissible in the private sector under government supervision. For instance, just because the *Quintavalle* court determined that SCNT was subject to regulation under the Human Fertilisation and Embryology Act 1990 did not mean that SCNT was not permissible within the country itself.<sup>192</sup> The court recognized that the research would only be subject to state regulation.<sup>193</sup> TRIPS mandates that an exclusion cannot be justified merely because commercialization of the invention is prohibited

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190. TRIPS, *supra* note 2, art. 27(2).

191. UNCTAD & ICTSD, *supra* note 122, at 378, 381.

192. *R (Quintavalle) v. Secretary of State for Health*, [2002] Q.B. 628, 628.

193. *See id.*

by law, much less its potential commercialization. Accordingly, allowing a nation to exclude an invention from patentability merely because it has regulated, but has not banned, the area of its practice would create an end-run around Article 27 – a result which the drafters surely did not intend. The only convincing reason for exclusion, therefore, can be found only where the exclusion is *necessary* to prevent a contradiction of the accepted norms deeply rooted in a nation's culture and values.

#### *D. A Collaborative Solution*

Unless TRIPS is modified to impose a clear definition of its moral restrictions, a solid framework built upon an understanding of emerging customary international law should be drawn upon to guide global legislators and patent prosecutors in dealing with the potential conflicts between morality and emerging technologies such as SCNT-like processes and their derivatives. Thus, in the area of stem cell research, a collaborative solution will require the acceptance of four key principles:

##### 1. Principles of Embryonic Research

In embryonic research, the principles of informed donor consent, proscription against the commercialization of embryonic materials, and prohibition of research on an embryo beyond fourteen days are customary norms and emerging rules of customary international law.

##### 2. Customary Norms

Morality, as defined in TRIPS, is seen as a regional ideology or as adhering to a custom. Therefore, the rules above should supplant, or elaborate on, what the customary norm of the region is, and help to define what is permissible to society in the area of embryonic stem cell research.

##### 3. Interpretation of a Nation's Domestic Laws

Patent law itself should not be primarily concerned with morality, and the patentability of any invention dealing with embryonic research should be based entirely upon the interpretation of a nation's domestic laws as part of, but not exclusive of, its international obligation under TRIPS.



#### 4. Customary International Law

Where domestic laws are unclear or reference to TRIPS is necessary, interpretation of provisions such as or in accordance with Article 27.2 should be consistent with customary international law. In the case of embryonic research, the relevant customary international law would include informed donor consent, a proscription against the commercialization of embryonic materials, and a prohibition of research on an embryo beyond fourteen days; so long as the implemented rule is not contrary to any specific agreement between contracting parties.

The judicial interpretation of domestic legislation consistent with international obligations under customary international law is certainly not a new idea.<sup>194</sup> Such a scheme over embryonic stem cell research would help guide interpretation of the vaguer laws currently in existence and help legislatures to draft new laws which adhere to the norms of their society. In fact, it is by this ongoing process of adjudication that the normative content of international norms can continue to be further developed and solidified.<sup>195</sup>

#### X. CONCLUSION

Morality is an amorphous concept, taking on different forms in different areas of the world. Whether intentional or not, morality-based limitations imposed by TRIPS and other international agreements may inhibit the patent process. Patentability of inventions in one nation or another plays an important role in the global marketplace and upon the future availability of funding. Funding fuels innovation. Therefore, inventors need to understand both domestic and international laws in order to realize their dreams and capitalize upon them. If the concept of informed donor consent, prohibition against the commercialization of embryonic materials, and the fourteen day rule are recognized as customary international law, then these basic principles can be used as bases for drafting legislation that must ultimately confront emerging stem cell technology and the unavoidable litigation that will ensue from it. These principles may even help a nation to set policy or decide whether to exclude or criminalize a particular technology or practice altogether.

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194. See Sands, *supra* note 186, at 104-05.

195. See PAUWELYN, *supra* note 187, at 93.

Moreover, patents can be drafted with these considerations in mind to not only ensure compliance with international law, but also quite possibly with morality itself.

Each new technological development in the global arena brings the possibility for positive change. As with other patents, there should be a symbiotic relationship between new innovations in stem cell research and the international normalization of patent law. A harmony between customary international law, TRIPS, and the domestic legislation which follows can do no less than stimulate the marketability of new products on a global scale. With marketability comes innovation, and with each new innovation there is the tremendous potential for another addition to the feedback loop fueling global acceptance.

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