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**MARY DOE’S DESTINY: HOW THE UNITED STATES HAS  
BANNED HUMAN EMBRYONIC STEM CELL RESEARCH IN THE  
ABSENCE OF A DIRECT PROHIBITION**

By: Yi-Chen Su,\* Albert Wai-Kit Chan\*\*

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I. INTRODUCTION

[1] Mary Doe is a human embryo preserved in liquid nitrogen, in an unnamed in vitro fertilization clinic.<sup>1</sup> Mary Doe’s name was given by an organization dedicated to advocating for equal humanity and personhood of pre-born children, including “children in vitro.”<sup>2</sup> In response to President Clinton’s policy favoring embryonic stem cell [hereinafter ES-cell] research, the organization filed suit on behalf of Mary Doe, and all other frozen human embryos similarly situated, seeking a permanent

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<sup>1</sup> Doe v. Shalala, 122 Fed. App’x 600, 601 (4th Cir. 2004).

<sup>2</sup> Petition for a Writ of Certiorari, Doe v. Thompson, No. 04-1642, 2005 WL 1361857 (2005).

injunction against any and all plans to undertake human ES-cell experimentation.<sup>3</sup>

[2] In August 2001, while the lawsuit was pending, President Bush announced a new policy concerning human ES-cell research.<sup>4</sup> The new policy limited federal funding for human ES-cell research only to projects involving already-existing stem cell lines.<sup>5</sup> No federal funds would be used to further research involving the derivation of new stem cell lines from intact embryos like Mary Doe.<sup>6</sup> As a result, the district court granted the government's motion to dismiss the case as moot, because Mary Doe would no longer be threatened.<sup>7</sup> The Fourth Circuit Court of Appeals affirmed the decision.<sup>8</sup>

[3] Even in the absence of a direct ban, the government has numerous means that it can use to suffocate a disfavored subject matter. The U.S. policy on human ES-cell research is an example. Human ES-cell research has been primarily reliant upon private funding since its inception in the late 1990s.<sup>9</sup> Though federal money is prohibited from funding research that uses newly developed human ES-cell lines,<sup>10</sup> and few states have supported such research,<sup>11</sup> the lack of public funding does not fatally impact human ES-cell research in this country.

[4] However, the straw that will break the camel's back may have been placed by the U.S. Supreme Court's decision in *KSR International Co. v.*

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<sup>3</sup> *Doe*, 122 Fed. App'x at 601. In addition, the organization also sought a declaration that Mary Doe is entitled to due process of law and the equal protection of the laws under the Fourteenth Amendment. *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* at 603.

<sup>7</sup> *Id.* at 601.

<sup>8</sup> *Id.*

<sup>9</sup> Leroy Walters, *Human Embryo Research: Lessons from History*, 293 SCI. 1401, 1401 (2001), available at <http://www.sciencemag.org/cgi/content/summary/293/5534/1401>.

<sup>10</sup> R. John Davenport, *Drumming Up Dollars for Stem Cell Research*, 123 CELL 1169, 1169 (2005), available at <http://www.sciencedirect.com/science/journal/00928674> (follow "Volume 123" hyperlink; then follow hyperlink under "Drumming Up Dollars for Stem Cell Research.").

<sup>11</sup> *Id.* at 1171.

*Teleflex, Inc.*<sup>12</sup> The Court's decision—which is expected to have grave adverse effects on the issuance of biotechnology patents—along with the Patent and Trademark Office's decision to revoke landmark human ES-cell patents,<sup>13</sup> has sent a strong message to private investors that their investment in human ES-cell research is unlikely to receive patent protection, and therefore, they are not likely to gain monetary reward from such investment.<sup>14</sup> The withdrawal of private funding from human ES-cell research is foreseeable.

[5] Although human ES-cell research is not expressly banned, due to the lack of public funding and the lack of incentives for private investment, the joint efforts of the Executive Branch and the Supreme Court have inadvertently stifled such research. Without prompt action taken by Congress, human ES-cell research in this country may cease.

[6] As suggested by John A. Robertson, if direct bans are imposed on privately-funded human ES-cell therapies or the research necessary to produce them, a greater role for the judiciary is favored.<sup>15</sup> Though in the absence of a direct ban, the stacking adverse effects of U.S. policy on human ES-cell research have amounted to an effect equivalent to a direct ban and has reached the point that a greater role for the judiciary is favored. Unfortunately, a legislative effort attempting to support human ES-cell research may have a hard time surviving the Supreme Court's muster in light of *Gonzales v. Carhart*,<sup>16</sup> a decision which has extensively expanded the state's interest in promoting and preserving unborn life.<sup>17</sup>

[7] In this article, Part II seeks to clarify the basic information regarding human ES-cell research, the international scientific community's efforts in self-regulating such research, and alternative technologies which, although premature, have inspired politicians and vice versa. Part III examines the congressional and state efforts and obstacles in seeking to fund human ES-

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<sup>12</sup> *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734-35 (2007).

<sup>13</sup> Dillon Beardsley, *A Two-Front Assault on the Stem Cell Patents*, 6 J. MARSHALL REV. INTELL. PROP. L. 501, 513 (2007).

<sup>14</sup> *Id.* at 519.

<sup>15</sup> See John A. Robertson, *Embryo Culture and the "Culture of Life": Constitutional Issues in the Embryonic Stem Cell Debate*, 2006 U. CHI. LEGAL F. 1, 7 (2006).

<sup>16</sup> *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007).

<sup>17</sup> See generally *id.*

cell research with public money. Part IV examines the revocation and restriction of human ES-cell patents, and the impact on the supply of private funding. Finally, Part V explores the Supreme Court's latest teachings of abortion jurisprudence, which may shed some light on the Court's views regarding human ES-cell research.

## II. SCIENTIFIC BACKGROUND AND PROSPECT

[8] Human ES-cell research has been dubbed a promising technology that will eventually lead to the treatment of currently untreatable diseases.<sup>18</sup> Its promising future however, has been accompanied by moral and ethical concerns arising out of the destruction of human embryos.<sup>19</sup> Members of the international scientific community, such as the International Society for Stem Cell Research ("ISSCR"), have sought to self-regulate such research among researchers worldwide by formulating general guidelines.<sup>20</sup> Other scientists also seek to explore alternative technologies, such as the reprogramming phenomenon or the use of "dead" embryos, to alleviate the ethical concerns.<sup>21</sup> Though these alternative technologies are not mature at this stage, they have inspired politicians in formulating stem cell policy and relevant legislation.<sup>22</sup>

### A. WHAT IS AN EMBRYONIC STEM CELL?

[9] Embryonic stem cells are cells which can become all cell types of the body.<sup>23</sup> The proliferative nature and the developmental potential of human ES-cells have indicated a promising future of an essentially

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<sup>18</sup> See National Institutes of Health, *Stem Cells and Diseases*, <http://stemcells.nih.gov/info/health.asp> (last visited Mar. 23, 2008).

<sup>19</sup> See Louis Guenin, International Society for Stem Cell Research, *The Ethics of Human Embryonic Stem Cell Research*, <http://www.isscr.org/public/ethics.htm> (last visited Mar. 23, 2008).

<sup>20</sup> See *infra* note 35 and accompanying text.

<sup>21</sup> Alan Boyle, *Reprogramming Complicates Stem Cell Debate*, (Aug. 10, 2005), <http://www.msnbc.msn.com/id/> ("cell reprogramming avoids the political debate . . .").

<sup>22</sup> See *id.*

<sup>23</sup> National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/info/basics/basics5.asp> (last visited June 13, 2007).

unlimited supply of specific cell types for both basic research and transplantation therapies.<sup>24</sup>

[10] It is worth noting that the embryos from which human ES-cells are derived are not obtained from eggs fertilized in a woman's body.<sup>25</sup> Instead, embryonic stem cells for research purposes are obtained from embryos that develop from eggs which have been fertilized in vitro in a fertilization clinic.<sup>26</sup> The embryos remain at a stage before the time that implantation would normally occur in the uterus.<sup>27</sup> The embryos from which human ES-cells are derived are donated for research purposes with the informed consent of the donors,<sup>28</sup> and do not in any way look like a fetus or a newborn infant.<sup>29</sup> Typically, these embryos are four or five days old after fertilization and are a hollow microscopic ball of cells called the blastocyst.<sup>30</sup> The first differentiation event in human embryos usually occurs at approximately five days of development.<sup>31</sup> However, embryonic stem cells can remain undifferentiated if they are grown under certain conditions.<sup>32</sup>

[11] Scientists are trying to control the differentiation of embryonic stem cells in order to generate cultures of specific types of differentiated cells such as heart muscle cells, blood cells, or nerve cells.<sup>33</sup> If scientists can develop a reliable "directed differentiation" technique, they may be able to use the resulting differentiated cells to treat currently untreatable diseases

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<sup>24</sup>Junying Yu & James A. Thomson, *Embryonic Stem Cells*, Regenerative Medicine 1 (2006), [http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative\\_Medicine\\_2006.pdf](http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative_Medicine_2006.pdf).

<sup>25</sup>National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/info/basics/basics3.asp> (last visited June 13, 2007).

<sup>26</sup>*Id.*

<sup>27</sup>Yu & Thomson, *supra* note 24.

<sup>28</sup>*Stem Cell Basics*, *supra* note 25.

<sup>29</sup>Gina Kolata, *Embryonic Cells, No Embryo Needed: Hunting for Ways Out of an Impasse*, N.Y. TIMES, Oct. 11, 2005 at F1, available at <http://www.nytimes.com/2005/10/11/health/11stem.html>.

<sup>30</sup>*Id.*

<sup>31</sup>Yu & Thomson, *supra* note 24.

<sup>32</sup>*Stem Cell Basics*, *supra* note 25.

<sup>33</sup>*Id.*

such as Parkinson's disease, diabetes, traumatic spinal cord injury, and heart disease.<sup>34</sup>

[12] Regardless of the seemingly promising future of human ES-cell research, the ethical concerns arising from the destruction of human embryos have never eased. Responding to the concerns, the scientific community has basically adopted two approaches, namely formulating guidelines for self-regulation, and exploring alternative technologies seeking to replace the use and destruction of viable human embryos.

### B. THE ISSCR GUIDELINES

[13] The scientific communities did not ignore the ethical concerns surrounding human ES-cell research. The ISSCR has formulated a set of guidelines for researchers worldwide to follow.<sup>35</sup> Nevertheless, the ISSCR acknowledged that the guidelines should be "subservient to all applicable laws and regulations of the country or region where the actual research takes place."<sup>36</sup>

[14] Among other things, the ISSCR guidelines have expressly prohibited scientists from using human embryos to conduct certain experiments. For example, human reproductive cloning, and the interbreeding of animals likely to harbor human gametes are expressly prohibited.<sup>37</sup> The guidelines also ban the in vitro culture of human embryos which are beyond fourteen days or the formation of the primitive embryonic streak.<sup>38</sup>

[15] In addition, the ISSCR cautioned that financial considerations of any kind should not amount to an undue inducement involving egg

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<sup>34</sup> *Id.*

<sup>35</sup> George Q. Daley et al., *The ISSCR Guidelines for Human Embryonic Stem Cell Research*, 315 *SCI.* 603, 603 (2007), available at <http://www.sciencemag.org/cgi/content/full/315/5812/603?rss=1>. The guidelines were written by scientists, ethicists, and legal experts from fourteen countries. *Id.* The ISSCR guidelines are available at <http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf>.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* The rationale for the "14-day limit" is that embryos before fourteen days since fertilization have not begun to initiate organogenesis because they have not established even the most rudimentary rostral and caudal orientation. *Id.* at 604.

procurement.<sup>39</sup> For the research use of embryos generated with donated gametes,<sup>40</sup> explicit consent from both gamete donors is required.<sup>41</sup> The U.S. National Academy of Sciences (“NAS”) has formulated similar guidelines, but called for a precise form of stem cell research oversight.<sup>42</sup>

[16] Both the ISSCR and NAS guidelines have evidenced that the scientific communities have reached a general consensus with regard to the regulation of human ES-cell research. The guidelines have provided a sound foundation that a government may efficiently adopt a regulatory system overseeing such research if the government believes that regulation is better than prohibition in the context of human ES-cell research.

[17] Nevertheless, ethical concerns over human ES-cell research not only urged scientific communities to formulate guidelines for self-regulation, they also motivated scientists to seek alternative technologies to replace the use of viable human embryos. The most notable examples are the reprogramming phenomenon, and the proposal of deriving stem cells from embryos which are considered “dead.”

### C. ALTERNATIVE APPROACHES: REPROGRAMMING PHENOMENON

[18] Reprogramming is a technique by which scientists seek to revert adult stem cells so that the adult stem cells are indistinguishable from

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<sup>39</sup> *Id.*

<sup>40</sup> Mary Lyndon Shaley, *Collaboration and Commodification in Assisted Procreation: Reflection on an Open Market and Anonymous Donation in Human Sperm and Eggs*, 36 LAW & SOC’Y REV. 257, 258 (2002) (“A gamete can be either an egg or a sperm; a gamete is a cell that contains half the genetic material needed for human procreation.”).

<sup>41</sup> Daley et al., *supra* note 35. The ISSCR also proposed that, in the future, “informed consent for all gamete donors should include the possible use of donated materials and their derivatives in human stem cell research.” *Id.*

<sup>42</sup> *Id.* at 603; *see also* National Research Council & Institute of Medicine, *Guidelines for Human Embryonic Stem Cell Research*, available at [http://books.nap.edu/openbook.php?record\\_id=11278&page=R2](http://books.nap.edu/openbook.php?record_id=11278&page=R2); Frederick Grinnell, *Defining Embryo Death Would Permit Important Research*, 49 THE CHRON. REV. B13 (2003), available at <http://www4.utsouthwestern.edu/FrederickGrinnell/GrinnellWebMisc/embryodeath.pdf>. Alternatively, Frederick Grinnell suggested that the United States may establish a process analogous to that used in England, which requires the licensing of all in vitro production and use of human embryos in the public and private sectors. *Id.*



embryonic stem cells.<sup>43</sup> The ISSCR Guidelines do not include adult stem cell research.<sup>44</sup> Several groups of scientists have claimed success in reprogramming fetal mouse cells<sup>45</sup> and have expressed a belief that the same technique can also work on adult cells.<sup>46</sup>

[19] Adult stem cells and embryonic stem cells differ not only in the number of cells present, but also in the type of differentiated cells they can become.<sup>47</sup> Differentiation of adult stem cells is generally limited only to the cell types of their tissue of origin,<sup>48</sup> while embryonic stem cells can become all cell types of the body.<sup>49</sup> In addition, adult stem cells are rare in mature tissues and the method to proliferate them in large numbers is currently unavailable, while embryonic stem cells can be relatively easily grown in large numbers.<sup>50</sup>

[20] Optimists may assert that the success of reprogramming in fetal mouse cells essentially means that the limitation of adult stem cells, both in the number of cells and in the type of differentiated cells they can become, will soon be lifted. However, that is not so. In reality, “[i]t’s still a long road to potential therapies with reprogrammed adult cells.”<sup>51</sup> Though scientists can now reprogram fetal mouse cells, it does not necessarily guarantee that they can reprogram human adult cells in the foreseeable future. Furthermore, one group of scientists has observed that the offspring of the chimeras developed from reprogrammed fetal mouse cells have a high incidence rate of tumor, because the technology requires the use of viruses as vectors.<sup>52</sup> It is one of the major problems that needs to be solved before such a technique can be applied to humans. Therefore,

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<sup>43</sup> Constance Holden, *Stem Cells: Teams Reprogram Differentiated Cells—Without Eggs*, 316 SCI. 1404, 1404 (2007), available at <http://www.sciencemag.org/cgi/content/full/316/5830/1404a>.

<sup>44</sup> Daley, *supra* note 35, at 603.

<sup>45</sup> Holden, *supra* note 43.

<sup>46</sup> *Id.*

<sup>47</sup> *Stem Cell Basics*, *supra* note 25.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> Holden, *supra* note 43, at 1405.

<sup>52</sup> *Id.* at 1404. The scientists used retroviral vectors to induce the reprogramming phenomenon in fetal mouse cells, and found that the retroviral vectors can also turn on cancer-causing genes. *Id.*

based on the unsolved problems of the reprogramming phenomenon, using adult stem cells is not yet available and is not currently foreseeable as an effective alternative to embryonic stem cells.

D. ALTERNATIVE APPROACHES: DERIVING STEM CELLS FROM “DEAD”  
EMBRYOS

[21] In addition to the reprogramming phenomenon, scientists have also proposed that stem cells may be derived from embryos which are literally “dead.” It is suggested that “dead” embryos may contain some healthy stem cells.<sup>53</sup> A group of scientists proposed a new concept of “death,” which is only applicable to embryos.<sup>54</sup> Unlike traditional concepts such as heart and lung failure, or brain death, scientists proposed that “an embryo is dead when most of its cells have naturally and irreversibly stopped dividing.”<sup>55</sup>

[22] Many of the frozen embryos stored by in vitro fertilization clinics are not viable for implantation.<sup>56</sup> Scientists hypothesized that stem cell lines can be derived from “embryos that were created during in-vitro fertilization procedures but whose cells had stopped dividing naturally.”<sup>57</sup> Scientists reasoned that such embryos were “dead,” because they could not continue growing even if they were implanted in a womb.<sup>58</sup> These

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<sup>53</sup> Gautam Naik, *The Devout Doctor’s Prescription for Stem-Cell Research*, WALL ST. J., June 16, 2007, at A10.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* Alternatively, Frederick Grinnell suggested that embryonic death may be defined as “the failure of an embryo to implant itself successfully in a uterus” or “the loss of integration or the inability to develop.” Grinnell, *supra* note 42.

<sup>56</sup> Naik, *supra* note 53.

<sup>57</sup> *Id.* As Frederick Grinnell has argued, if the ethical considerations and regulatory strategies now have made it possible to use cells and tissues derived from aborted fetuses to study human development and seek new medical therapies, the same should be applicable to dead embryos and their cells. Grinnell, *supra* note 42.

<sup>58</sup> Naik, *supra* note 53; see also Helen Pearson & Alison Abbott, *Stem Cells Derived from “Dead” Human Embryos*, 443 NATURE 376 (2006). Scientists in Spain derived a stem cell line from “arrested” embryos. “Arrested” embryos were those that had stopped dividing for twenty-four or forty-eight hours after reaching various stages of development. *Id.*

embryos stop growing because of genetic abnormalities.<sup>59</sup> Many of them have a mixture of normal and abnormal cells.<sup>60</sup>

[23] Other scientists questioned the viability of this proposal. If the embryos stopped dividing because of their genetic errors, the genetic defects may be transmitted to patients who receive tissue transplants derived from these embryos.<sup>61</sup> Another concern is whether the embryos are really “dead.” It is cautioned that “[i]n our haste to obtain what we want, we may be killing an embryo . . . .”<sup>62</sup>

[24] A proposal cannot be an effective alternative if it raises new concerns while it does not solve the problems that it seeks to resolve. As previously mentioned, one major concern of ES-cell research is that it “kills” embryos.<sup>63</sup> Modifying the definition of “death,” as some scientists have suggested, does not change the underlying fact of whether an embryo is dead or not. Proposing a new definition of “death” different from that which has traditionally applied to humans is arguably acknowledging that embryos are not human beings.

[25] The alternative technologies, such as the reprogramming phenomenon and deriving stem cells from “dead” embryos, are not reliable at this stage. Nonetheless, they have served as the basis for the governmental policy and the congressional legislation on the issue of human ES-cell research.

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<sup>59</sup> Naik, *supra* note 53.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* Other scientists also questioned that there is no way to prove that an arrested embryo would have stopped growing if it had been put into a woman’s womb rather than a lab dish. It leaves open the possibility that it was the lab conditions that halted the embryos’ growth. See Naik, *supra* note 53.

<sup>63</sup> See *supra* §II.

## III. GOVERNMENTAL POLICY AND CONGRESSIONAL LEGISLATION

[26] The battle between President Bush and Congress on the stem cell issue began with an announcement made by the president on August 9, 2001.<sup>64</sup> The president announced a policy that would allow federal funds to be used for research only on stem cell lines already in existence at the time of the announcement, “where the life and death decision has already been made.”<sup>65</sup> According to the National Institute of Health (“NIH”), at the time of the announcement there were sixty-four stem cell lines available worldwide.<sup>66</sup> However, only twenty of these were derived in the United States.<sup>67</sup> The majority of cell lines were derived in Sweden, Australia, India, and Israel.<sup>68</sup> Later, the Secretary of Health and Human Services, Tommy Thomson, acknowledged before a Senate Committee that only twenty-four to twenty-five of the sixty-four cell lines were in fact established.<sup>69</sup>

[27] Regardless of the small number of stem cell lines available, the president also sought to justify his policy by partly relying on the preliminary research that stem cells may be derived from adult cells.<sup>70</sup> Therefore, in his view, destruction of more embryos was not necessary. The president’s belief led to his two vetoes on congressional efforts in funding research utilizing stem cell lines which were derived after the presidential announcement.<sup>71</sup>

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<sup>64</sup> *President Discusses Stem Cell Research*, <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html> (last visited Mar. 24, 2008); *see also* Robertson, *supra* note 15, at 2.

<sup>65</sup> *President Discusses Stem Cell Research*, *supra* note 64.

<sup>66</sup> AAAS Ctr. for Sci., Tech., and Cong., *AAAS Policy Brief: Stem Cell Research*, <http://www.aaas.org/spp/cstc/briefs/stemcells/index.shtml> (last visited Mar. 6, 2008).

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* Scientists were also concerned about the safety of the cell lines which were derived before a new technique was available, because most of the cell lines were developed in a culture with the help of mouse stem cells which could potentially introduce animal viruses dangerous to humans.

<sup>70</sup> *President Discusses Stem Cell Research*, *supra* note 64.

<sup>71</sup> Deb Riechmann, *Bush to Veto Stem Cell Bill*, S.F. CHRON., June 20, 2007, available at <http://www.sfgate.com/cgi-bin/article.cgi?f=/n/a/2007/06/19/national/wl173912D22.DTL&type=politics>.

## A. CONGRESSIONAL EFFORTS IN FUNDING HUMAN ES-CELL RESEARCH

[28] Congressional debate concerning human ES-cell research has centered on whether federal funding should cover such research. In 2006 and 2007, President Bush chose to use his veto pen twice on the stem cell issue.<sup>72</sup> The Congressional efforts to expand federal funding to newly derived stem cell lines has been impeded by the vetoes, regardless of a Gallup poll showing that fifty-six percent of Americans said they favor using taxpayer money for the research.<sup>73</sup>

[29] Federal grants have played a critical role in the biotechnology industry by providing early-stage or seed funding to companies engaged in pioneer research.<sup>74</sup> It is true for the industry as a whole, and it is true for human ES-cell research, which is a subset of the biotechnology industry. Particularly, the NIH is one of the major contributors to the federal grants used to fund biotechnology research.<sup>75</sup> However, because congressional efforts in funding human ES-cell research were aborted following President Bush's vetoes, the NIH has withheld federal grants to fund such research.<sup>76</sup>

[30] The impact of the policy on human ES-cell research is not limited only to the lack of funding. It has far-reaching effects, which could impede and burden scientists conducting the research. For instance, scientists working at a university have to raise private money to build new laboratories that duplicate facilities the university already has.<sup>77</sup> This is

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<sup>72</sup> *Id.*

<sup>73</sup> Margaret Talev, *Republicans Walk a Fine Line for Bipartisan Stem Cell Push*, SACRAMENTO BEE, Apr. 3, 2006, available at <http://dwb.sacbee.com/content/politics/story/14238209p-15058709c.html>. According to the Gallop poll, between 2002 and 2005, the percentage of adults who found embryonic stem cell research to be morally acceptable rose from fifty-two to sixty. *Id.*

<sup>74</sup> Lauren E. Komsa, *Save America's Biotechnology Industry Research Act: Support for Biotechnology or Corporate Welfare?*, 25 BIOTECH. L. REP. 534, 537 (2006).

<sup>75</sup> *Id.* For instance, in 2003, the NIH was the second largest contributor to the federal funding program under the Small Business Innovation Research Act. The Department of Defense was the largest contributor in the same year. *Id.*

<sup>76</sup> See Lee Silver, *George Orwell Bush: The Latest Stem Cell Veto*, AM. COUNCIL ON SCI. AND HEALTH, (June 21, 2007), [http://acsh.org/factsfears/newsid.979/news\\_detail.asp](http://acsh.org/factsfears/newsid.979/news_detail.asp).

<sup>77</sup> *Scientist Hopes for Stem Cell Success*, CBS NEWS, Feb. 26, 2006, available at <http://www.cbsnews.com>.

because scientists are not permitted to work with new stem cell lines in a university's laboratory (which often operates on federal funds), even though the scientists' other research projects receive federal funds.<sup>78</sup> The restriction on federal funding makes stem cell research very costly and time-consuming.<sup>79</sup>

[31] Nevertheless, the White House has signaled its "support for legislation that provides federal funding for stem-cell research using embryonic cells that have no chance of surviving."<sup>80</sup> The Hope Offered through Principled and Ethical Stem Cell Research Act ("HOPE Act")<sup>81</sup> sought to allow scientists to conduct research on embryos that "they determine are incapable of surviving in the womb but whose stem cells are still viable for research."<sup>82</sup> The bill would allow federal funding for "research on stem cells from embryos that have died during fertility treatment."<sup>83</sup> The White House acclaimed the bill, stating that, "[b]y intensifying support for nondestructive alternatives, we can advance medical research in valuable ways while respecting ethical boundaries."<sup>84</sup>

[32] As explained in Part II, modifying the definition of death for embryos may not be convincing even for opponents of human ES-cell research. The question remains whether the embryos can, in fact, be deemed dead. More importantly, according to some scientists, the genetic

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com/stories/2006/02/23/60minutes/printable1341635.shtml.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> Gregory Lopes, *White House Backs Stem-Cell Bill*, WASH. TIMES, Apr. 6, 2007, available at 2007 WLNR 6756279. The bill was authored by Sen. Johnny Isakson, Georgia Republican. *Id.*

<sup>81</sup> See Library of Congress, <http://thomas.loc.gov/cgi-bin/query/D?c110:1:/temp/~c1108n9QRg::> (last visited Mar. 23, 2008).

<sup>82</sup> Lopes, *supra* note 80.

<sup>83</sup> *Id.* The bill defined "naturally dead" as "having naturally and irreversibly lost the capacity for integrated cellular division, growth, and differentiation that is characteristic of an organism, even if some cells of the former organism may be alive in a disorganized state." Hope Offered through Principled and Ethical Stem Cell Research Act, S. 30, 110th Cong. § 498D (f) (1) (as passed by Senate, Apr. 11, 2007).

<sup>84</sup> *White House Supports Stem Cell Bill that Would Allow Research On Embryonic Stem Cells With No Chance of Survival*, MED. NEWS TODAY, Apr. 11, 2007, available at <http://www.medicalnewstoday.com/printerfriendlynews.php?newsid=67364>.

defects of the “dead” embryos may be transmitted to patients receiving stem cells derived from the embryos.<sup>85</sup>

[33] Although the federal government has restricted its funding only to research utilizing a couple dozen existing stem cell lines, California has enacted laws authorizing the funding of stem cell research with state money. However, the State was prevented from releasing the money because of lawsuits.

#### B. STATE EFFORTS IN FUNDING HUMAN ES-CELL RESEARCH

[34] Few states have passed laws providing state funding for stem cell research, with California being one of the few.<sup>86</sup> In 2004, over 59.1% of voters in California approved Proposition 71: The California Stem Cell Research and Cures Act.<sup>87</sup> The new law would provide funding of nearly \$3 billion for human ES-cell research over a ten-year period.<sup>88</sup> However, California’s support of human ES-cell research is conditional. Proposition 71 forbids funding for human reproductive cloning.<sup>89</sup> In fact, the ban on human reproductive cloning was added to the California Constitution.<sup>90</sup>

[35] Though the new law attracted some of the best researchers in the field to California, lawsuits challenging Proposition 71 under the state constitution have prevented the state from releasing the money.<sup>91</sup> In 2007,

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<sup>85</sup> See *Human Embryonic Stem Cells Extracted from Dead Embryos*, Sept. 24, 2006, <http://www.futurepundit.com/archives/003747.html> (last visited Apr. 2, 2008).

<sup>86</sup> Jodi Rudoren, *Stem Cell Work Gets States’ Aid after Bush Veto*, N. Y. TIMES, July 25, 2006, at A1, A16. In addition to California, Illinois offered \$5 million in grants for stem cell research. Connecticut, Maryland, and New Jersey also allocated state resources for research. *Id.* However, in November 2007, New Jersey voters rejected a ballot measure by a 53-47% margin that would have permitted the state to borrow \$450 million for stem cell research. David W. Chen, *New Jersey Voters Defeat Stem Cell Measure*, N.Y. TIMES, Nov. 7, 2007, at B1.

<sup>87</sup> *Stem Cell Research: Summary from the 2004 Ballot Pamphlet*, CA. HEALTH FOUND., available at [http://www.healthvote.org/index.php/site/prop\\_home/C28/](http://www.healthvote.org/index.php/site/prop_home/C28/).

<sup>88</sup> *Id.*

<sup>89</sup> Proposition 71 § 4, available at [http://www.sos.ca.gov/elections/bp\\_nov04/prop\\_71\\_text\\_of\\_proposed\\_law.pdf](http://www.sos.ca.gov/elections/bp_nov04/prop_71_text_of_proposed_law.pdf).

<sup>90</sup> *Id.*

<sup>91</sup> *Scientist Hopes for Stem Cell Success*, *supra* note 77.

the court in *California Family Bioethics Council v. California Institute for Regenerative Medicine*<sup>92</sup> held that “Proposition 71 suffers from no [state] constitutional or other legal infirmity.”<sup>93</sup> The court further expressed its regret concerning the delay, stating:

[T]he objective of the proposition is to find, “as speedily as possible,” therapies for the treatment and cure of major diseases and injuries, an aim the legitimacy of which no one disputes. The very pendency of this litigation, however, has interfered with implementation [of Proposition 71] for more than two years.<sup>94</sup>

[36] The California state court’s holding did not clear all of the clouds. Stem cell research has been primarily relying on private money since its inception.<sup>95</sup> Even in the absence of a direct ban, the government has numerous means to discourage private investment, which in turn have the same effect as a direct prohibition. One of the most effective ways to achieve that goal is by restricting issuance of patents to inventions flowing from human ES-cell research.

#### IV. PATENTABILITY AS A MEANS TO AFFECT PRIVATE FUNDING

[37] The first human ES-cell isolation reported in 1998 was not eligible for funding from the NIH, because the congressional ban on appropriating public funds for such research had been in effect since 1995.<sup>96</sup> Before 2001, no public funding was ever provided for human ES-cell research in this country.<sup>97</sup> Rather, human ES-cell research in the United States had been primarily relying on the support of private investment.<sup>98</sup>

[38] Even though stem cell research may lack public funding, if the patent system can provide incentives and predictable business opportunities to

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<sup>92</sup> Cal. Family Bioethics Council v. Cal. Inst. for Regenerative Med., 147 Cal. App. 4th 1319 (Cal. Ct. App. 2007).

<sup>93</sup> *Id.* at 1373.

<sup>94</sup> *Id.*

<sup>95</sup> AAAS Ctr. for Sci., Tech., and Cong., *supra* note 66.

<sup>96</sup> *See id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*



attract private investment, private money will continue to support such research (even in the absence of the endorsement by governmental funding). Unfortunately, the Supreme Court's recent decision in *KSR International Co. v. Teleflex, Inc.*,<sup>99</sup> has sent a strong message to the biotechnology industry, which includes human ES-cell research.<sup>100</sup> *KSR International* stands for the idea that it may be unrealistic to expect the patent system to continue to play a role in attracting private investment.

[39] Private investment, specifically venture capital funding, is essential to the biotechnology industry.<sup>101</sup> It provides financing to most of the industry's pioneers.<sup>102</sup> However, venture capitalists usually rely on certain kinds of "government endorsement" to determine whether to finance a particular technology.<sup>103</sup> For instance, receipt of a federal grant will make the recipient company which owns the new technology more attractive to a venture capitalist.<sup>104</sup> In turn, the venture capitalist will provide the majority of the funding.<sup>105</sup>

[40] Because human ES-cell research has generally been excluded from receiving federal funding, the remaining alternative that a venture capitalist may deem as a governmental endorsement concerning human ES-cell research is a predictable system that would grant patents to inventions flowing from such research. On the other hand, the lack of federal funding, in addition to an unpredictable patent system, would have a stacking effect on suffocating human ES-cell research, even if the government does not expressly prohibit the research.

#### A. PATENTABILITY

[41] The isolation of a human ES-cell in the United States was first reported in November 1998 by Dr. James A. Thomson, biologist at the

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<sup>99</sup> *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct.1727 (2007).

<sup>100</sup> *See generally id.*

<sup>101</sup> Komsa, *supra* note 74, at 535.

<sup>102</sup> *Id.* Approximately ninety-eight percent of research and development investment in the biotechnology industry comes from the private sector. *See infra* note 144, at 9.

<sup>103</sup> *Id.*

<sup>104</sup> Komsa, *supra* note 74, at 537.

<sup>105</sup> *Id.*

University of Wisconsin, Madison.<sup>106</sup> Dr. Thomson's research was not eligible for federal funding.<sup>107</sup> Instead, the research was supported by Geron Corporation of Menlo Park, California, and the Wisconsin Alumni Research Foundation ("WARF").<sup>108</sup>

[42] Dr. Thomson and his colleagues were issued a patent in March 2001.<sup>109</sup> Prior to October 2004, approximately thirty-eight patents claiming human ES-cell or process had been issued by the U.S. Patent and Trademark Office ("PTO").<sup>110</sup> Nevertheless, the "Thomson patents" on human ES-cells were overturned by the PTO in March 2007<sup>111</sup> after both the Foundation for Taxpayer and Consumer Rights ("FTCR") and the Public Patent Foundation ("PUBPAT") requested reexamination of them.<sup>112</sup> Though the patents were revoked by the PTO, WARF has the option to take the case to federal court if the PTO affirms the revocation.<sup>113</sup> However, it is unlikely that a federal court will rule in favor of the patent holders following the Supreme Court's recent decision in *KSR International*.<sup>114</sup>

#### B. INVALIDATION OF THE THOMSON PATENTS

[43] The Thomson patents include three patents covering the human ES-cell line and methods of obtaining and culturing the cells, which were derived by Dr. James A. Thomson.<sup>115</sup> They were the first human ES-cell

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<sup>106</sup> AAAS Ctr. for Sci., Tech., and Cong., *supra* note 66.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> Mark L. Rohrbaugh, *Intellectual Property Issues Surrounding Embryonic Stem Cell Research*, REGENERATIVE MED. 53 (2006), available at [http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative\\_Medicine\\_2006.pdf](http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative_Medicine_2006.pdf).

<sup>110</sup> *Id.*

<sup>111</sup> Alex Lash, *A Victory for "Obviousness" in Biotechnology*, 5 IP L. & BUS. 18 (June 2007).

<sup>112</sup> *Two Groups Try for Revocation of Human Embryonic Stem Cell Patents*, 25 BIOTECH. L. REP. 555 (Oct. 2006). The two groups were the Foundation for Taxpayer and Consumer Rights ("FTCR") and the Public Patent Foundation ("PUBPAT"). *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

<sup>115</sup> *WARF Offers Free Licenses if Companies Agree to Work in State*, 25 BIOTECH. L. REP. 683 (Dec. 2006).

patents issued in the United States,<sup>116</sup> and were revoked by the PTO in March 2007 on the ground of “obviousness.”<sup>117</sup>

[44] Under the U.S. patent system inventions must be “new and useful” to be considered patentable. This is according to 35 U.S.C. § 101, which provides that, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent...”<sup>118</sup> In addition, the invention needs to be “non-obvious” at the time it is made, to be considered new. Section § 103 provides that

[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.<sup>119</sup>

[45] In July 2006, two groups filed requests for reexamination and revocation of the “Thomson patents.”<sup>120</sup> The groups alleged that the “Thomson patents” “were obvious over prior art, and were blocking scientific progress . . . .”<sup>121</sup> They also argued that the patents were forcing researchers to leave the United States for other countries, where the “Thomson patents” are not recognized.<sup>122</sup> In response to the requests for reexamination, the PTO explained that the standard of reexamination is whether there is “a substantial likelihood that a reasonable examiner would consider the teachings [of the cited publications] important in deciding the patentability of the claims.”<sup>123</sup> The harm claimed by the two groups was irrelevant.<sup>124</sup>

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<sup>116</sup> Rohrbaugh, *supra* note 109.

<sup>117</sup> Lash, *supra* note 111.

<sup>118</sup> 35 U.S.C. § 101 (2000).

<sup>119</sup> 35 U.S.C. § 103 (2000).

<sup>120</sup> *Two Groups Try for Revocation of Human Embryonic Stem Cell Patents*, 25 BIOTECH. L. REP. 555 (Oct. 2006).

<sup>121</sup> *Warf Offers Free Licenses if Companies Agree to Work in State*, *supra* note 115.

<sup>122</sup> *Id.*

<sup>123</sup> *Id.* (alteration in original).

<sup>124</sup> *Id.*

[46] The PTO invalidated the three “Thomson patents” on the grounds of obviousness in March 2007 by a non-final decision.<sup>125</sup> It appears that the PTO has followed in the footsteps of its European counterpart in rejecting unmodified human ES-cell patents.<sup>126</sup> In Europe, the European Patent Convention has even adopted a strict rule excluding the patentability of any invention involving the use of human embryos for industrial or commercial purposes.<sup>127</sup>

[47] On the other hand, as John A. Robertson has observed, it may be naïve to expect that a government agency traditionally relying on scientific data, not politics, will be untainted by pro-life influence.<sup>128</sup> Robertson cited the FDA’s refusal to approve non-prescription sales of Plan B, an emergency contraceptive, as an example.<sup>129</sup> Robertson stated that “[d]espite near unanimous advisory committee approval of the benefits from over-the-counter sales of Plan B, the Commissioner of the FDA refused to approve it, disingenuously issuing a notice for further comment and rulemaking instead.”<sup>130</sup>

[48] Similarly, there is no guarantee that the PTO will be shielded from the influence of leading politicians’ moral and ethical views regarding human ES-cell issues. Nevertheless, even if WARF appeals to a federal

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<sup>125</sup> Lash, *supra* note 111.

<sup>126</sup> See Rohrbaugh, *supra* note 109.

<sup>127</sup> See European Patent Convention (“EPC”), part II, ch. VI, rule 23d, *available at* [http://legis.obl.gr/espacedvd/legal\\_texts/epc/r23d.html#R23d](http://legis.obl.gr/espacedvd/legal_texts/epc/r23d.html#R23d) (last visited Mar. 21, 2008).  
Exceptions to patentability:

European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

<sup>128</sup> See Robertson, *supra* note 15, at 18-19.

<sup>129</sup> *Id.* at 19.

<sup>130</sup> *Id.*

court challenging the PTO's decision to revoke the "Thomson patents," it is unlikely the patents will be reinstated in the wake of *KSR International*.

C. *KSR INTERNATIONAL CO. v. TELEFLEX, INC.*

[49] The Supreme Court issued a decision restricting the issuance of patents approximately one month after the PTO's non-final decision revoking the first patents in this country issued to human ES-cell lines and methods of obtaining the cell lines. In *KSR International Co. v. Teleflex, Inc.*,<sup>131</sup> the Supreme Court rejected the Federal Circuit Court of Appeals "teaching, suggestion, or motivation" test ("TSM test"),<sup>132</sup> and replaced it with an "expansive and flexible approach" to be used when determining the question of obviousness.<sup>133</sup> Before *KSR International*, the Federal Circuit Court of Appeals had developed and adopted the more rigid TSM test. These tests are necessary because a patent cannot be granted if the subject matter was obvious to a person having ordinary skill in the art, at the time the subject matter was invented.<sup>134</sup>

[50] The Federal Circuit's TSM test was a way of "[s]eeking to resolve the question of obviousness with more uniformity and consistency . . . ."<sup>135</sup> Under the test, a court is obliged first to presume that the issued patent was valid and then to render its own independent judgment of obviousness based on a review of the prior art.<sup>136</sup> A patent claim is only proved obvious if "some motivation or suggestion to combine the prior art teachings' can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art."<sup>137</sup> In other words, "unless the 'prior art references address[ed] the precise problem that the patentee was trying to solve,' the problem would not motivate an inventor to look at those references."<sup>138</sup> In addition, the fact that the PTO had

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<sup>131</sup> *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007).

<sup>132</sup> *Id.* at 1730.

<sup>133</sup> *Id.* at 1739.

<sup>134</sup> 35 U.S.C. § 103 (2000).

<sup>135</sup> *KSR Int'l Co.*, 127 S. Ct. at 1734.

<sup>136</sup> *Id.* at 1739.

<sup>137</sup> *Id.* at 1734.

<sup>138</sup> *Id.* at 1738 (alteration in original).

rejected a broader version of the claim has no place in the analysis under the TSM test.<sup>139</sup>

[51] In rejecting the TSM test, the Supreme Court replaced it with an expansive and flexible approach by stating that, “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”<sup>140</sup> The Court further noted that “[o]ne of the ways in which a patent’s subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent’s claims.”<sup>141</sup> Moreover, courts are invited to look at any secondary considerations that would prove instructive, wherever appropriate.<sup>142</sup> Under the test, a court can take account of any inferences and creative steps that a person of ordinary skill in the art would employ.<sup>143</sup>

[52] The Supreme Court’s flexible approach has raised concerns that the issuance of patents, especially in the field of biotechnology, will become unpredictable and deter private investment as a result. As the Biotechnology Industry Organization has argued in its amicus brief, if the standards of obviousness under 35 U.S.C. § 103(a) become less objective, the increased uncertainty about the availability of patent rights will have a direct impact on investment incentives in biotechnology, and will deter investment within the industry.<sup>144</sup> In addition, “[i]nventors would have no predictable defenses against [challengers] seeking to invalidate biotechnology inventions many years, or even decades, after the ideas were first conceived.”<sup>145</sup>

[53] Human ES-cell research, as a subset of the biotechnology industry, would be particularly adversely affected by the flexible obviousness approach. Many patentable inventions in biotechnology, including human

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<sup>139</sup> *Id.* at 1739.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 1742.

<sup>142</sup> *Id.* at 1739.

<sup>143</sup> *Id.* at 1741.

<sup>144</sup> Brief for Biotechnology Industry Organization as Amicus Curiae Supporting Respondents, *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (No. 04-1350), at 2.

<sup>145</sup> *Id.* at 4.

ES-cell research, spring from known components and methodologies found in prior art. Such combinations of prior art may be logical to try, because the advances “are only won through trial and error, at great effort and expense, and with only a low probability of success in achieving the claimed invention . . . .”<sup>146</sup> Furthermore, “[r]esearch and development in the biotechnology industry is particularly expensive, time-consuming, and presents an unusually high-risk investment that relies on an objective and predictable application of obviousness law.”<sup>147</sup>

[54] In the wake of *KSR International*, not only are the “Thomson patents” unlikely to be reinstated in a federal court, but more human ES-cell patents which have been issued by the PTO may be vulnerable to the challenge of invalidation. The withdrawal of private funding from such research is at stake.

[55] In addition to the restriction on the issuance of patents and federal funding, the aborted congressional legislation supporting human ES-cell research, and the struggle of California’s funding for such research, the Supreme Court has extensively expanded its abortion jurisprudence. The recently extended abortion jurisprudence established in *Gonzales v. Carhart*<sup>148</sup> may have paved the way for the Court to invalidate legislation approving public funding for human ES-cell research, which is deemed by

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<sup>146</sup> *Id.* at 6. Following the Supreme Court’s *KSR International* decision, the Patent and Trademark Office published Examination Guidelines to help USPTO examiners make decisions regarding the obviousness of claimed inventions. In the Guidelines, the PTO laid out five rationales to support rejections under 35 U.S.C. § 103 (2008). One of the rationales was “obvious to try.” The Guidelines further defined “obvious to try” as “choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.” Biotechnological inventions are especially vulnerable to the challenge of “obvious to try.” Unlike the other four rationales, it was not coincident that all the examples employed in the Guidelines to illustrate the rule of “obvious to try” were found in the field of biotechnology. The Guidelines have substantiated the Biotechnology Industry Organization’s concern that the *KSR International* decision has a grave adverse impact especially on the issuance of biotechnology patents. *See Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex, Inc.*, 72 Fed. Reg. 57,526 (Oct. 10, 2007).

<sup>147</sup> Brief for Biotechnology Industry Organization as Amicus Curiae Supporting Respondents, *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct.1727 (2007) (No. 04-1350), at 8.

<sup>148</sup> *See Gonzales v. Carhart*, 127 S. Ct.1610 (2007).

some as a means of destroying prospective human lives in conflict with the states' interest in promoting and preserving life.

#### V. THE TEACHINGS OF THE SUPREME COURT'S ABORTION JURISPRUDENCE

[56] Human ES-cell research and abortion are both arguably affecting the "prospective humans' right to live," from the opponents' point of view. Nevertheless, within the anti-abortion movement itself, the opponents of abortion do not share the same view concerning human ES-cell research.<sup>149</sup> Some consider themselves purists, who oppose both abortion and stem cell research, and the others see stem cell research as a matter of pragmatism.<sup>150</sup> Though the Supreme Court has yet to decide the issue concerning human ES-cell research or an embryo's right to live under the U.S. Constitution, the Court's recent opinion regarding the propriety of abortion procedures may have shed some light on the Court's view concerning the propriety of human ES-cell research.

#### A. THE APPLICABILITY OF THE ABORTION JURISPRUDENCE

[57] Before examining the Supreme Court's abortion jurisprudence, it is important to note the similarities and differences between embryos and fetuses. Embryos and fetuses are similar in that they both have the potential of becoming human beings if an adequate supporting system has been given, though the complexity and the extent of support varies.<sup>151</sup>

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<sup>149</sup> Talev, *supra* note 73; *see also* Grinnell, *supra* note 42. As Frederick Grinnell has stated:

The discovery that human eggs could be fertilized outside the body coincided more or less with the 1973 Supreme Court decision in *Roe v. Wade* that made abortion legal. Abortion and in vitro fertilization have been linked indirectly ever since, with those who oppose abortion arguing that research that leads to the destruction of embryos is equivalent to abortion.

*Id.*

<sup>150</sup> Talev, *supra* note 73; *see also* Robertson, *supra* note 15, at 26 (stating "[i]f there is a right to create and discard embryos to achieve pregnancy, then a fortiori the right to create and destroy embryos to stay alive and reduce pain and disability should also be recognized . . .").

<sup>151</sup> *See generally* Robert P. George, *Embryo Ethics*, 137 DAEDALUS 23, 25 (2008).



[58] The differences between embryos and fetuses include not only that the fetuses are at a developmental stage much closer to a human form,<sup>152</sup> but also that the fetuses are a life form with much complex biological entanglement with its bearing mother, while embryos in the fertilization clinics are a life form already separated from the persons originally bearing the germ cells by a medical procedure. Arguably, an embryo frozen in the fertilization clinic is akin to the fetal tissue which has been taken out of the mothers' womb by an abortion procedure, rather than viable fetuses. Whether an embryo has a chance to become a human being depends on another intrusive medical procedure to place the embryo in a woman's womb, and the possibility of carrying the embryo to term is relatively low.<sup>153</sup>

[59] The chance of an embryo becoming a human being is much lower than a fetus in the first trimester, even if there is a woman willing to accept the intrusive medical procedure to place the embryo in her womb.<sup>154</sup> The first obstacle is the low implantation rate. It has been shown that only one in every four embryos can be successfully implanted in a woman's womb after the medical procedure.<sup>155</sup> If the recipient is older, a technique called "multiple embryo transfers," which allows multiple embryos to compete for implantation, is usually needed to secure a better result.<sup>156</sup> In other words, a large proportion of embryos will be screened out by the recipient's body even though they are deemed normal and healthy.

[60] In addition, the chance of carrying a human embryo to term is even lower if the embryo has been frozen and thawed. The miscarriage rates are higher among pregnancies conceived with frozen and thawed embryos,

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<sup>152</sup> *Id.* at 26.

<sup>153</sup> See American Pregnancy Association, *In Vitro Fertilization: IVF*, <http://www.americanpregnancy.org/Infertility/ivf.html> (last visited Mar. 23, 2008).

<sup>154</sup> See *id.*

<sup>155</sup> Steven D. Spandorfer, *The Impact of Maternal Age and Ovarian Age on Fertility*, <http://www.inciid.org/article.php?cat=&id=489> (last visited July 30, 2007). The Center for Reproductive Medicine and Infertility of the New York Hospital-Cornell Medical Center analyzed 1621 consecutive cycles of IVF for implantation efficiency as a function of age. The study found that the overall implantation rate was 23.3%. *Id.*

<sup>156</sup> *Id.* The study also showed that implantation rates remained almost constant until the age of thirty-five, and then decreased in a significant linear fashion by approximately 2.77% per year. *Id.*

which are the subjects of human ES-cell research, compared to those using freshly fertilized embryos.<sup>157</sup>

[61] As a result, though the fetuses and embryos are both arguably prospective humans, the chance of an embryo becoming a human being is much lower than a fetus. Judging from the already-high natural miscarriage risk of a fetus in the first trimester,<sup>158</sup> it may be a step too far to recognize embryos as prospective humans.

[62] On the other hand, it is not clear whether the assertion that embryos are prospective humans will be accepted by the Court. Nevertheless, in the wake of *Gonzales v. Carhart*,<sup>159</sup> Mary Doe's destiny in a courtroom is probably more like a fetus, rather than a frozen embryo (as it should be), which statistically has a much lower chance to develop into a human being.

#### B. *GONZALES V. CARHART*

[63] Similar to human ES-cell research, the issue regarding whether to ban partial-birth abortions—which allegedly involves piercing the fetal skull with scissors or crushing it with forceps<sup>160</sup>—was a tug of war between Congress and President Clinton. In 1996 and 1997, President Clinton twice vetoed congressional legislation on this issue.<sup>161</sup> In 2003, Congress passed the Partial-Birth Abortion Ban Act,<sup>162</sup> and President Bush

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<sup>157</sup> See generally Jeanie Lerche Davis, *Infertility Treatments and Miscarriage? Assisted Reproductive Treatments not Shown to Increase Miscarriages*, <http://www.webmd.com/infertility-and-reproduction/news/20030502/infertility-treatments-miscarriage> (last visited July 31, 2007); Grinnell, *supra* note 42 (stating “[i]n 2000 . . . statistics from the Centers for Disease Control and prevention showed that the success rate for assisted reproduction using fresh eggs or embryos was only about 30 percent, and with embryos that had been frozen the rate was even lower.”).

<sup>158</sup> Gina Kolata, *Study Finds 31% Rate of Miscarriage*, N. Y. TIMES, July 27, 1988 (stating “[t]hirty-one percent of all conception ends in miscarriage, usually in the early months of pregnancy and often before women even know they are pregnant . . .”); Grinnell, *supra* note 42 (stating “once a pregnancy begins, as many as 30 to 40 percent fail during the first few weeks.”).

<sup>159</sup> See *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007).

<sup>160</sup> *Id.* at 1623.

<sup>161</sup> *Id.*

<sup>162</sup> 18 U.S.C. § 1531 (2008)

signed the Act into law.<sup>163</sup> The validity of the Partial-Birth Abortion Ban Act later became the issue in *Gonzales v. Carhart*.<sup>164</sup>

[64] *Gonzales* is the latest teaching of the Supreme Court's "abortion jurisprudence." Doctors performing second-trimester abortions challenged the constitutionality of the Partial-Birth Abortion Ban Act and sought a permanent injunction against its enforcement.<sup>165</sup> The Court held that, among other things, the ban on the abortion procedure did not impose an undue burden on a woman's right to abortion either based on the Act's over-breadth or lack of a health exception.<sup>166</sup>

[65] For the purpose of this article, it is important to note that the Supreme Court in *Gonzales* expressly abandoned the distinction of fetal "viability" in weighing the propriety of an abortion procedure. In *Gonzales*, the Court found that the Partial-Birth Abortion Ban Act applied both previability and postviability.<sup>167</sup> By rejecting the distinction of fetal viability, the Court further stated that "a fetus is a living organism while within the womb, whether or not it is viable outside the womb."<sup>168</sup>

[66] The dissent commented that the majority's decision in *Gonzales* was alarming.<sup>169</sup> As Justice Ginsburg stated in the dissenting opinion, the *Gonzales* decision has blurred the line between previability and postviability abortions as firmly drawn in *Planned Parenthood v. Casey*.<sup>170</sup>

[67] Consequently, a state's interest in preserving and promoting life may extend to "embryos" without the need for weighing other competing interests since the outset of the pregnancy. Although the Court acknowledged in *Gonzales* that "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life

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<sup>163</sup> *Gonzales*, 127 S. Ct. at 1623-24.

<sup>164</sup> *See id.* at 1619.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.* at 1639. In addition, the Court held that, as a facial matter, "[r]espondents [had] not demonstrated that the Act . . . [was] void for vagueness." *Id.*

<sup>167</sup> *Id.* at 1627.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.* at 1641.

<sup>170</sup> *Id.*; *see Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

of the fetus that may become a child,”<sup>171</sup> and that it was the principle that “require[d] the most extended discussion,”<sup>172</sup> the Court nevertheless upheld the state’s interest in preserving fetal life by stating that, “[w]hatever one’s views concerning the *Casey* joint opinion, it is evident a premise central to its conclusion--that the government has a legitimate and substantial interest in preserving and promoting fetal life . . . .”<sup>173</sup> As Justice Ginsberg stated in the dissent, “for the first time since *Roe*, the Court blesses a prohibition with no exception safeguarding a woman’s health.”<sup>174</sup>

[68] Furthermore, the *Gonzales* Court reaffirmed the government’s interest in “protecting the integrity and ethics of the medical profession.”<sup>175</sup> The Court deferred to the congressional finding that the partial-birth abortion is a “brutal and inhumane procedure . . . .”<sup>176</sup> and recognized that Congress “was concerned with ‘draw[ing] a bright line that clearly distinguishes abortion and infanticide.’”<sup>177</sup> The *Gonzales* Court reaffirmed the government’s regulatory power to bar certain medical procedures by stating that

[w]here it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn.<sup>178</sup>

[69] However, the *Gonzales* Court’s conclusion that the Partial-Birth Abortion Ban Act does not impose an undue burden was rooted in the considerations that alternatives to the prohibited procedure were available.<sup>179</sup> The medical profession is obligated to adopt “less shocking

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<sup>171</sup> *Gonzales*, 127 S. Ct. at 1626 (quoting *Roe v. Wade*, 410 U.S. 113 (1973)).

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at 1641.

<sup>175</sup> *Id.* at 1633 (quoting *Washington v. Glucksberg*, 521 U.S. 702 (1997)).

<sup>176</sup> *Id.*

<sup>177</sup> *Id.* at 1633-34 (alteration in original).

<sup>178</sup> *Id.* at 1633.

<sup>179</sup> *Id.* at 1637.

methods” to accommodate legislative demand, if they are available.<sup>180</sup> In addition, the *Gonzales* Court acknowledged that where there is medical and scientific uncertainty, the courts should give state and federal legislatures wide discretion to pass legislation in such areas.<sup>181</sup>

[70] To a certain extent, *Gonzales* may be viewed as a double-edged sword if the issue regarding the validity of legislation sought to fund human ES-cell research is brought to court. On one hand, the opponents of human ES-cell research can argue that in the wake of *Gonzales*, the government has legitimate interests in preserving and promoting life regardless of the viability of the living organism outside the womb, including an embryo frozen in liquid nitrogen. In furtherance of that interest, the government is not obligated to weigh other competing interests—such as the imminent medical needs of patients suffering from incurable diseases—since the abortion statute in *Gonzales* was upheld by the Court even though it did not provide an exception to protect a woman’s health.

[71] On the other hand, the proponents of human ES-cell research may argue that contrary to the congressional finding in *Gonzales*, human ES-cell research is not a “brutal and inhumane” procedure. Even if human ES-cell research is considered inherently or impliedly “brutal and inhumane,” there is no alternative available because as discussed earlier, neither the reprogramming phenomenon nor the use of “dead” embryos is a reliable technique at this stage. Moreover, as the *Gonzales* Court has stated, where there is medical and scientific uncertainty, the courts should give legislatures wide discretion to pass legislation in such areas.<sup>182</sup>

[72] Nevertheless, to some commentators’ dismay, it may not be realistic to expect the Supreme Court to play a significant role in upholding rights to research or rights to treatment after *Gonzales*, if lawsuits regarding the restrictions on human ES-cell research arise. As John A. Robertson has suggested, there are situations when the judiciary should become more involved in the stem cell issues:<sup>183</sup> When restrictions on research become

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<sup>180</sup> *Id.* at 1634.

<sup>181</sup> *Id.* at 1636.

<sup>182</sup> *Id.*

<sup>183</sup> Robertson, *supra* note 15, at 40.

intolerable and lawsuits about rights to research arise,<sup>184</sup> and when safe and effective treatments are available but cannot be used, and constitutional rights to treatment are asserted.<sup>185</sup> In light of *Gonzales*, the best a proponent of stem cell research may be able to expect from the Supreme Court would be that the Court would defer to the legislature rather than imposing its own view on the legislature following *Gonzales*. This is in light of the fact that the *Gonzales* decision has expanded the justification of the state's interest in preserving and promoting unborn life before viability, even if at the expense of the health of a woman, who is a born person.

[73] In addition, deriving stem cells from an embryo may be viewed as “infanticide” if the distinction of viability no longer exists. The *Gonzales* Court sought to distinguish abortion from infanticide.<sup>186</sup> It was the latter that justified the ban on the partial-birth abortion procedure.<sup>187</sup> The physicians' overt act causing the fetus' death, rather than delivery, incurs liability.<sup>188</sup> It does not bode well if the Court imposes a similar view on the issue of human ES-cell research.

[74] After *Gonzales*, it is not likely that a legislative effort authorizing public funding for human ES-cell research, which is in conflict with the state's interest in promoting and preserving life, can survive in the Supreme Court. Contrary to John A. Robertson's view before the *Gonzales* decision that “a greater role for the judiciary [is favored if] direct bans on privately funded [human] ESC therapies or on the research necessary to produce them,”<sup>189</sup> the best a proponent of human ES-cell research can expect from the Court after *Gonzales* may be deference by the Court to the legislature.

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<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Gonzales*, 127 S. Ct. at 1634.

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> Robertson, *supra* note 15, at 7.

## VI. CONCLUSION

[75] The United States has effectively banned human ES-cell research in the absence of a direct prohibition declared by the government. The joint efforts of the Executive Branch and the Supreme Court have essentially made the revival of human ES-cell research in this country unlikely. Even if there is a legislative effort attempting to support such research, again, the legislation is less likely to survive the Supreme Court's muster after *Gonzales*.

[76] Nevertheless, the legislative branch is better situated in conducting the balancing test to weigh the public interest that will flow from human ES-cell research against the ethical and moral concerns arising from the use of human ES-cells in research or treatment.<sup>190</sup> Nonetheless, the Supreme Court's *Gonzales* decision may have paved the way for a challenger's success in claiming the frozen embryo's right to live. The issue in the abortion case revolved around medical procedures which were inherently cruel and inhumane in terminating fetuses' lives when alternative medical procedures were available. However, there exists no such cruel and inhumane procedure<sup>191</sup> in human ES-cell research, and reliable alternative techniques are not available.

[77] Traditionally, human ES-cell research has relied on private money, and the patent system has played an important role in attracting private investment. However, in the wake of the Supreme Court's *KSR International* decision, the issuance of patents in the field of biotechnology has become unpredictable. It does not seem likely that private investments will continue to play a significant role in ES-cell research, since the issuance of patents has been restricted and the strictures further increase the risk of investment in an industry where the risk is already high.

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<sup>190</sup> *Id.* at 22. "A Supreme Court leery of substantive due process lawmaking might also be reluctant to interfere in legislative judgment about tradeoffs between health, safety, protection of unborn human life, and patient needs for therapy." *Id.* at 14.

<sup>191</sup> The medical procedure in the abortion case comprises of pulling out the fetus' neck, and inserting a needle in the fetus' skull to drain the content. See *Gonzales*, 127 S. Ct. at 1622.

[78] In sum, the government has numerous methods that it can use to suffocate a disfavored subject matter. Though the Executive Branch and the Supreme Court may not have intended to ban the research, they have adopted an approach essentially suffocating such research.