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## Speaking Words of Wisdom: Let it Be: The Reexamination of the Human Embryonic Stem Cell Patents

Julia vom Wege Dovi

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## COMMENTS

### **Speaking Words of Wisdom: Let it be The Reexamination of the Human Embryonic Stem Cell Patents**

“Science is a first-rate piece of furniture for a man’s upper chamber, if he has common sense on the ground-floor.”<sup>1</sup>

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1. OLIVER WENDELL HOLMES, SR., THE POET AT THE BREAKFAST TABLE 140 (1891).

## INTRODUCTION

On July 17, 2006, the Foundation for Taxpayer and Consumer Rights (FTCR) filed a request for reexamination of the three stem cell patents owned by the Wisconsin Alumni Research Foundation (WARF) through the Public Patent Foundation. The consumer groups argue that the patents hinder the progression of research.<sup>2</sup> The United States Patent and Trademark Office (USPTO) granted the request in September 2006. Such reexamination could result in narrowing or canceling of some or all of the claims. This Comment will outline why the USPTO should not invalidate or significantly narrow the patents. Specifically, this Comment will explain that the patents should remain valid. First, this Comment will outline what stem cells are and what the patents at issue cover. This Comment will then briefly explain the applicable law and policy considerations. Finally, this Comment discusses why the patents should withstand their current challenge.

### I. WHAT ARE STEM CELLS?

There is no single definition of what a stem cell is or what its characteristics are.<sup>3</sup> However, there are a number of properties the scientific community agrees upon being innate to stem cells. Stem cells are undifferentiated precursor cells to other cells of the body.<sup>4</sup> They have the ability to propagate themselves, through proliferation, essentially indefinitely without losing their undifferentiated character.<sup>5</sup> This key characteristic significantly distinguishes stem cells from somatic cells.<sup>6</sup> Somatic cells undergo only a finite number of replications in culture because of a sequential shortening of the chromosome ends (telomeres) during each cell division.<sup>7</sup> Stem cells, in contrast to human somatic cells, express a protein (telomerase) that permits for the

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2. Andrew Pollack, *Agency Agrees to Review Human Stem Cell Patents*, N.Y. TIMES, Oct. 4, 2006, at C3.

3. See The National Institute of Health Resource for Stem Cell Research, *Stem Cell Basics* (2006), available at <http://stemcells.nih.gov/info/basics/defaultpage.asp>.

4. *Id.*

5. Kevin A. D'Amour & Fred H Gage, *Genetic and Functional Differences Between Multipotent Neural and Pluripotent Embryonic Stem Cells*, 100 PROC. NAT'L. ACAD. SCI. U.S. 11866 (2003).

6. Somatic cells are all body cells that are not stem cells or reproductive cells. Wikipedia, *Somatic Cell* (May 28, 2007), [http://en.wikipedia.org/wiki/Somatic\\_cells](http://en.wikipedia.org/wiki/Somatic_cells).

7. Richard J. Hodes, *Telomere Length, Aging, and Somatic Cell Turnover*, 190 J. EXP. MED. 153, 153 (1999).

maintenance of chromosome ends and thereby allows for indefinite replication.<sup>8</sup>

Embryonic stem cells (ES cells) retain the ability to form “all three embryonic germ layers even after prolonged culture.”<sup>9</sup> Adult stem cells, those that are found in an individual’s tissues, are typically limited in their ability to differentiate into only those cells inherent to the tissue in which they reside.<sup>10</sup> For example, adult stem cells in the brain (neural stem cells) can differentiate into nerve cells, astrocytes, and oligodendrocytes, all of which reside in brain tissue.<sup>11</sup> However, adult stem cells that can differentiate into cells of tissues other than the one in which they reside have been isolated and are currently under investigation.<sup>12</sup>

The great hope for ES cells rests in their use as replacements for human tissues and organs that failed as a result of accidents, disease, or age.<sup>13</sup> For example, scientists speculate that ES cells could alleviate or cure the insulin insufficiency in individuals suffering from diabetes.<sup>14</sup> If the ES cells could integrate into the pancreatic islets and become insulin-producing cells, they would effectively ameliorate or even completely cure the diseased phenotype.<sup>15</sup> Similar hope exists in the field of degenerative disorders, such as Alzheimer’s and Parkinson’s diseases.<sup>16</sup> In addition, stem cells are important study objects to discern the human developmental process as well as biological processes.<sup>17</sup>

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8. James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 *SCIENCE* 1145, 1145 (1998).

9. *Id.* at 1146.

10. The National Institute of Health Resource for Stem Cell Research, *What are Adult Stem Cells?* (2006), <http://stemcells.nih.gov/info/basics/basics4.asp>.

11. *Id.*

12. See, e.g., R. W. Mays et al., *Development of Adult Pluripotent Stem Cell Therapies for Ischemic Injury and Disease*, *EXPERT OPIN. BIOL. THER.* 7(2):173 (2007). See also The National Institute of Health Resource for Stem Cell Research, *What are Adult Stem Cells?*, *supra* note 10. Yu et al., *Induced Pluripotent Stem Cell Lines Derived From Human Somatic Cells*, *SCIENCE*, November 20, 2007, <http://www.sciencemag.org/cgi/content/abstract/1151526>.

13. Junying Yu & James A Thomson, *Chapter 1: Embryonic Stem Cells*, in *REGENERATIVE MEDICINE*, 4, (D.H.H. Sede), 2006, available at <http://stemcells.nih.gov/info/scireport/2006report.htm> (Sept. 2, 2007) (follow “Chapter 1: Embryonic Stem Cells” hyperlink).

14. Gretchen Vogel, *Stem Cells: New Excitement, Persistent Questions*, 290 *SCIENCE* 1672, 1673 (2000).

15. National Cancer Institute, *What would you hope to achieve from human pluripotent stem cell research?* (2000), <http://stemcells.nih.gov/news/newsArchives/achieve.asp>.

16. *Id.*

17. See White House Press Release, *Fact Sheet: Embryonic Stem Cell Research* (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>.

However, it is important to note that this technology is still in its infancy and its true value is unclear.<sup>18</sup>

Currently, federal funds are available only for work with defined, already-existing human embryonic stem cell lines, i.e. federal funding may not be used to generate or work with new human embryonic stem cell lines.<sup>19</sup>

## II. THE STEM CELL PATENTS

A patent grants the “right to exclude others from making, using, offering for sale, or selling the invention.”<sup>20</sup> The three stem cell patents that are being reexamined are U.S. Patent numbers 5,843,780 (“Primate embryonic stem cells,” “the ‘780 Patent”),<sup>21</sup> 6,200,806 (“Primate embryonic stem cells,” “the ‘806 Patent”),<sup>22</sup> and 7,029,913 (“Primate Embryonic Stem Cells,” “the ‘913 Patent”).<sup>23</sup> The ‘780 Patent issued in 1998 and claims “purified preparation of primate embryonic stem cells.”<sup>24</sup> The ‘806 Patent issued in 2001 and claims “purified preparation of pluripotent human embryonic stem cells.”<sup>25</sup> The ‘913 Patent issued in 2006 and claims “methods of obtaining human hematopoietic cells from human pluripotent embryonic stem cells using mammalian stromal cells.”<sup>26</sup> All three patents list Dr. James Thomson as the inventor, are

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18. James A. Thomson, *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145, 1145-47 (1998).

19. Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles (Mar. 19, 2002), [hereinafter *Guidance*]. See also, Diane T. Duffy, *Background and Legal Issues Related to Stem Cell Research*, Congressional Research Service (2002); National Institute of Health Resource for Stem Cell Research, What are Adult Stem Cells?, *supra* note 10. “Research on existing human embryonic stem cell lines may be conducted with Federal support [only] if the cell lines meet the U.S. President’s criteria which he announced on August 9, 2001.” OFFICE OF THE DIRECTOR, NIH, NOTICE OF CRITERIA FOR FEDERAL FUNDING OF RESEARCH ON EXISTING HUMAN EMBRYONIC STEM CELLS AND ESTABLISHMENT OF NIH HUMAN EMBRYONIC STEM CELL REGISTRY (2001), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html> [hereinafter NIH NOTICE].

20. 35 U.S.C. § 154 (2006 & Supp. 2004).

21. Primate Embryonic Stem Cells, U.S. Patent No. 5,843,780 (filed Jan. 18, 1996) (issued Dec. 1, 1998) [hereinafter “‘780 Patent”].

22. Primate Embryonic Stem Cells, U.S. Patent No. 6,200,806 (filed Jun. 26, 1998) (issued Mar. 13, 2001) [hereinafter “‘806 Patent”].

23. Primate Embryonic Stem Cells, U.S. Patent No. 7,029,913 (filed Oct. 18, 2001) (issued Apr. 18, 2006) [hereinafter “‘913 Patent”].

24. See ‘780 Patent, *supra* note 21.

25. See ‘806 Patent, *supra* note 22.

26. See ‘913 Patent, *supra* note 23.

assigned to WARF, and are licensed to Geron Corporation.<sup>27</sup> This California biotechnology company “has an exclusive license to the WARF patents for heart, pancreas and neural cells.”<sup>28</sup> Geron had provided significant financial support for Dr. Thomson’s research.<sup>29</sup>

### III. REEXAMINATION

“A patent shall be presumed valid.”<sup>30</sup> To challenge the validity of a patent, any person can apply for reexamination with the USPTO.<sup>31</sup> The grounds for which such reexamination may be requested are limited to new questions of patentability raised by prior art, i.e. a printed publication or patent.<sup>32</sup> The requestor must make his request in writing and explain the relevance of the cited prior art with regard to every claim to be reexamined. For such a reexamination request to be granted, the examiner has to find that the cited prior art raises “a substantial new question of patentability.”<sup>33</sup> Prior art raises a substantial new question of patentability if “there is a substantial likelihood that a reasonable examiner would consider the prior art . . . important in deciding whether or not the claim is patentable.”<sup>34</sup>

While a patent owner could potentially lose his patent, a requestor has nothing to lose because the USPTO refunds a large portion of the reexamination application fee should the request for reexamination not be granted.<sup>35</sup> Requestors cannot appeal the USPTO’s decision not to grant the request for reexamination.<sup>36</sup>

The Public Patent Foundation, on behalf of the FTCR, filed a

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27. ‘780 Patent, *supra* note 21; ‘806 Patent, *supra* note 22; ‘913 Patent, *supra* note 23.

28. Alex Lash, *Government Nixes Stem-Cell Patents*, THE FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS (Apr. 4, 2007), available at <http://www.consumerwatchdog.org/healthcare/nw/?postId=7671>.

29. *See id.*

30. 35 U.S.C. § 282 (2000 & Supp. 2004).

31. 4 DONALD S. CHISUM, CHISUM ON PATENTS § 11.07 (2004).

32. U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2216 (8th ed. 2006) [hereinafter MPEP]. Under 35 U.S.C. 304, the Office must determine whether “a substantial new question of patentability” affecting any claim of the patent has been raised. 37 C.F.R. 1.510(b)(1) requires that a request for *ex parte* reexamination include “a statement pointing out each substantial new question of patentability based on prior patents and printed publications.” *Id.*

33. 35 U.S.C. § 303(a) (2006).

34. MPEP § 2242 (2006).

35. *Id.* at § 1.26(c) (2006).

36. 35 U.S.C. § 303(c) (2006 & Supp. 2004).

request for reexamination of the three stem cell patents in July, 2006.<sup>37</sup> The FTCT cited five sources, only four of which were deemed by the USPTO to raise “a substantial new question of patentability.”<sup>38</sup> The fact that the FTCT’s request for reexamination was granted is not unusual. The USPTO grants between 90% (*ex parte*) and 98% (*inter partes*) of reexamination requests.<sup>39</sup> The claims at issue were changed in some way in nearly two-thirds of the *ex parte* proceedings, but all claims were cancelled in only 10% of the proceedings.<sup>40</sup> The challenged claims remained unaltered in more than one-fourth of the proceedings. Since 90% of all reexamination proceedings resulted in either modified or unaltered claims and only 10% in cancellation, the USPTO history makes it unlikely that the FCTR will prevail in its desired cancellation of the ‘780 Patent and the ‘806 Patent. In contrast, for the ‘913 Patent, an *inter partes* proceeding was granted. In *inter partes* proceedings, less than one-third of the claims remained unaltered or were modified, while over 70% were cancelled.<sup>41</sup>

On April 3, 2007, the USPTO issued a preliminary rejection of the stem cell patents due to obviousness.<sup>42</sup> This is not unusual, however, and signifies only the first of many steps.<sup>43</sup> In its response filed on May 31, 2007, WARF refutes the USPTO’s preliminary rejection.<sup>44</sup> Further proceedings are likely to take months, if not years.

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37. WARF Stem Cell Patents, Public Patent Foundation (2007), <http://www.pubpat.org/warfstemcell.htm>.

38. 35 U.S.C. § 303(a) (2006).

39. Joseph D. Cohen, *What’s Really Happening in Inter Partes Reexamination*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 207, available at <http://www.stoel.com/Files/InterPartes.pdf> (last visited Sept. 20, 2007). An *ex parte* reexamination “allows a challenger to initiate a review by producing prior art . . . but . . . excludes the challenger from further participation in the examination process.” BLACK’S LAW DICTIONARY 1306 (8th ed. 2004). An *inter partes* reexamination “allows a challenger to initiate a review by producing prior art, to respond to a patentee’s statements regarding the new prior art, to address the patentee’s responses to any office actions, and to request a hearing.” *Id.*

40. *See id.*

41. *See id.*

42. Andrew Pollack, *3 Patents on Stem Cells are Revoked in Initial Review*, N.Y. TIMES, Apr. 3, 2007, at C2.

43. *See* 37 C.F.R. §§ 1.510-1.570 (2006); MPEP § 2201 (8th ed. 2006) (displaying flowcharts on reexamination).

44. WARF, Wisconsin Alumni Research Foundation Defends Patents in Response to Initial U.S. Patent and Trademark Office Action, (May 31, 2007), [http://www.warf.org/news/news.jsp?news\\_id=212](http://www.warf.org/news/news.jsp?news_id=212). The response is available at [http://www.warf.org/uploads/media/WARF\\_Response\\_to\\_PTO\\_Action\\_without\\_exhibits.pdf](http://www.warf.org/uploads/media/WARF_Response_to_PTO_Action_without_exhibits.pdf).

## IV. SHOULD THE PATENTS REMAIN VALID?

The WARF patents should remain valid because the prior art cited by the requestors does not render the inventions obvious. Also, the patents should remain valid because they do not stifle but rather promote the progress of science by allowing access to those who want it for a reasonable fee (or no fee at all). Finally, the patents should remain valid to foster investors' confidence in investing in embryonic stem cell research so that such research can continue despite current restrictions on available federal funding.

A. *Obviousness*

To be patentable, an invention must be novel and useful<sup>45</sup> as well as nonobvious.<sup>46</sup> “Nonobviousness . . . means that an invention must not have been obvious to one with ordinary skill in the art to which the subject matter of the invention pertains at the time of the invention and in the light of . . . the prior art.”<sup>47</sup> In contrast to novelty, an invention can be obvious even in the absence of a single prior reference as long as all components are described in prior references and “some motivation or suggestion to combine the references is provided by the prior art taken as a whole.”<sup>48</sup> It should be noted that this general standard of nonobviousness was recently rejected by the Supreme Court.<sup>49</sup> It is not entirely clear yet how this decision will impact biotechnological inventions. However, it is speculated that “the impact of the Supreme Court’s ruling may not be as profound on life-science patents.”<sup>50</sup> This notion is supported by the fact that “[w]ith life science inventions, ‘we can extrapolate and guess, but until we conduct an experiment, we don’t know if it’s going to work.’”<sup>51</sup>

When dealing with biotechnological inventions, the standard for obviousness has been more difficult to define. In 1995, Congress amended 35 U.S.C. § 103 with subsection (b) to include a provision specific to biotechnology.<sup>52</sup> This subsection “has been interpreted as

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45. 35 U.S.C. §§ 101 and 102 (2006 & Supp. 2004).

46. *Id.* § at 103(a).

47. 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.01 (2004).

48. *Id.* at § 5.04[1][e][ii] (citing *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992)).

49. *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007).

50. Joe Vanden Plas, *Supreme Court Ruling Seen as Blow to WARF Stem Cell Patents*, WISCONSIN TECHNOLOGY NETWORK (May 2, 2007), <http://wistechnology.com/article.php?id=3889>.

51. *Id.*

52. 35 U.S.C. § 103(b) (2006 & Supp. 2004).



requiring that the prior art lead to the production of the invention and that there be a reasonable expectation that the invention can be carried out successfully for the invention to fail the non-obvious requirement.”<sup>53</sup>

Robertson,<sup>54</sup> Piedrahita,<sup>55</sup> and Robertson,<sup>56</sup> three of the cited prior art references in the application for reexamination, exclusively use and discuss animal models, mostly murine.<sup>57</sup> There is no doubt that murine

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(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if--

(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)--

(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means--

(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to--

(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

*Id.*

53. Damon J. Whitaker, *The Patentability of Embryonic Stem Cell Research Results*, 13 U. FLA. J.L. & PUB. POL'Y 361, 370 (2002).

54. ELIZABETH J. ROBERTSON, *Isolation, Properties, and Karyotype Analysis of Pluripotential (EK) Cell Lines from Normal and Parthenogenetic Embryos, in TERATOCARCINOMAS AND EMBRYONIC STEM CELLS: A PRACTICAL APPROACH*, 71-112 (Elizabeth J. Robertson ed., IRL Press, Oxford 1987).

55. J.A. Piedrahita et al., *On the Isolation of embryonic Stem Cells: Comparative Behavior of Murine, Porcine and Ovine Embryos*, 34 THERIOGENOLOGY 879 (1990).

56. ELIZABETH J. ROBERTSON, *Embryo-derived stem cell lines, in TERATOCARCINOMAS AND EMBRYONIC STEM CELLS: A PRACTICAL APPROACH*, 71-112 (Elizabeth J. Robertson ed., IRL Press, Oxford 1987).

57. The term "murine" is used by scientists to refer to a mouse, but includes all things "of or relating to a murid genus (*Mus*) or its subfamily (*Murinae*) which includes the common household rats and mice." MERRIAM-WEBSTER ONLINE DICTIONARY, <http://www.m->

embryonic stem cells have been isolated and cultured, at least to a certain extent, prior to the successful culture of human embryonic stem cells. However, these previous experiments do not render the patented technology obvious.

First, the vast majority of technologies designed for human applications have some form of animal test precursor.<sup>58</sup> It is neither practical nor economical, let alone ethical, to conduct initial experimentations on humans.<sup>59</sup> Therefore, virtually every experiment, trial, or treatment with human tissue had to begin with animal experimentation. It would defeat the purpose of the patent system to allow for individuals that conduct the preliminary animal experiments to claim exclusive rights to any possible human applications without having had successfully translated the technology at issue to human tissue. Patents grant the right to exclude others from making and using an invention.<sup>60</sup> Researchers should not be allowed to “call dibs” on a technology that was never successfully reduced to practice in humans merely because successful animal experimentation has been conducted. Neither should such animal experimentation render the human application obvious so as to make it unpatentable for any researcher who adapts the technology for human application. This would discourage researchers from communicating possible alternative species applications of the technology to others. Rather, it would encourage researchers to keep their animal data under a veil of secrecy to preclude the possibility of barring themselves from possible application to other species. Secrecy is the very thing the patent system intends to discourage.<sup>61</sup>

Second, an obviousness rejection requires that the “prior art suggests to a person of ordinary skill in the art to make the claimed invention.”<sup>62</sup> In other words, the prior art made it “obvious to try.”<sup>63</sup>

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w.com/dictionary/murine (last visited Sept. 30, 2007).

58. See, e.g., 45 C.F.R. § 46 (2006).

59. See, e.g., David J. Rothman, *Ethics and Human Experimentation: Henry Beecher Revisited*, 317 NEW ENG. J. MED. 1195 (1987); Joseph V. Brady & Albert R. Jonsen, *The Evolution of Regulatory Influences on Research with Human Subjects*, in HUMAN SUBJECTS RESEARCH – A HANDBOOK FOR INSTITUTIONAL REVIEW BOARDS (Robert A. Greenwald et al. eds., Plenum Press 1982).

60. See 35 U.S.C. § 154(a)(1) (2006 & Supp. 2004); 35 U.S.C. § 271 (2006 & Supp. 2004).

61. See Gideon Parchomovsky, *Publish or Perish*, 98 MICH. L. REV. 926 (2000).

62. DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 617 (Foundation Press 3rd ed. 2004).

63. *In re O’Farrell*, 853 F.2d 894, 902 (Fed. Cir. 1988).

However, an invention that is obvious to try is not necessarily obvious under Section 103.<sup>64</sup> A second requirement for an obviousness rejection under Section 103 is that there must be a “reasonable expectation of success.”<sup>65</sup> This second requirement is important because otherwise everything that is obvious to try would be unpatentable. In other words, while people may have thought of trying to make a given invention, nobody has the incentive to invest in actually going forward with the research because their investment cannot be returned in the absence of patent protection. Such a view would clearly defeat the purpose of the patent system.

Even if the FTCE could establish that there was a suggestion in the prior art to establish human stem cells, it lacks the second required showing, the expectation of success. In fact, as discussed in the next paragraph, the prior art, if anything, teaches away from establishing human stem cells.

Third, several promising technologies have not yet been tried on human subjects because the interspecies differences make initial success unlikely.<sup>66</sup> This is especially true for experiments that have been conducted with the experimental animal most scientists work with, the mouse. In the case of stem cells, “[h]uman and murine ESCs differ from each other in a wide spectrum of genes.”<sup>67</sup> These differences affect growth rates, culture requirements, and marker expression.<sup>68</sup> Most importantly, these differences affect pathways required to maintain the stem cell phenotype.<sup>69</sup> Although the details and underlying mechanisms of those differences are only recently being elucidated, the fact that human cells are not identical to murine cells is evident because it took scientists almost a decade to replicate the murine experiments in human cells.<sup>70</sup> The “derivation and manipulation of murine stem cells was an elite skill.”<sup>71</sup> “[T]he manipulation of [human embryonic stem cells is] an even more highly skilled art and one that few scientists have yet

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64. *See id.* at 902-04.

65. *Id.* at 904.

66. *See* Gretchen Vogel, *Four Genes Confer Embryonic Potential*, 313 *SCIENCE* 27 (2006).

67. Chia Lin Wei et al., *Transcriptome Profiling of Human and Murine ESCs Identifies Divergent Paths Required to Maintain the Stem Cell State*, 23 *STEM CELLS* 166, 173 (2005).

68. *Id.* at 167.

69. *Id.*

70. *See, e.g.*, Wikipedia, Key E Stem Cell Research Events (Aug. 31, 2007), [http://en.wikipedia.org/wiki/Stem\\_cell](http://en.wikipedia.org/wiki/Stem_cell).

71. Melissa Little, Wayne Hall, & Amy Orlandi, *Delivering on the Promise of Human Stem-Cell Research*, 7 *EMBO REPORTS* 1188, 1191 (2006).

mastered.”<sup>72</sup>

It is important to remember that this is not an area of science that was inactive and has only now become popular. Quite the opposite is true; stem cell research is one of the “hottest” areas of scientific research because of its enormous potential to revolutionize the way medicine is practiced.<sup>73</sup> In fact, scientists have desired success in this area so much that it has led some to falsify research results and pretend to have been successful.<sup>74</sup>

Even if a *prima facie* case of obviousness can be established, it can be rebutted by secondary considerations.<sup>75</sup> In *Graham v. John Deere Co.*, the Supreme Court enumerated such secondary considerations that can rebut a *prima facie* case of obviousness, which are (1) commercial success; (2) long-felt but unsolved need; and (3) failure of others.<sup>76</sup>

With regard to the WARF patent, all three considerations clearly weigh against obviousness. The patented technology is commercially successful because the patents have resulted in a large number of licensing agreements as well as the formation of start-up companies.<sup>77</sup> There was a long-felt but unsolved need in the scientific arena to establish human embryonic stem (“hES”) cell cultures. As mentioned above, even after successfully practiced with murine cells, it took several more years before human embryonic cell lines were established.<sup>78</sup> Finally, it is difficult to estimate how many other scientists have tried but failed to grow stable hES cells *in vitro*. However, given the

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72. *Id.*

73. The National Institute of Health Resource for Stem Cell Research, Frequently Asked Questions, <http://stemcells.nih.gov/info/faqs.asp> (last visited Sept. 2, 2007); Fiona M. Watt & Kevin Eggan, *Molecular Mechanisms of Stem-Cell Identity and Fate*, NATURE REVIEWS, available at <http://www.nature.com/nrc/posters/stemcell/index.html> (last visited Sept. 30, 2007).

74. S Korea Scientist on Fraud Charge, BBC NEWS (May 12, 2006), <http://news.bbc.co.uk/2/hi/asia-pacific/4763973.stm>; Nathan Seppa, *Stem Cell Controversy: Scientist is Retracting Landmark Finding*, SCIENCE NEWS ONLINE (Dec. 24, 2005), <http://www.sciencenews.org/articles/20051224/fob7.asp>.

75. *Graham v. John Deere Co.*, 383 U.S. 1, 18-19 (1966).

76. *Id.* at 17.

77. “WiCell has distributed cells to more than 360 research groups in 40 states and 24 countries. . . . [O]f all of the academic papers published in scientific journals between 2002 and 2004, a full 67 percent used [the WARF] cells. . . . Over the past year, the number of WARF commercial licenses has doubled, reflecting an increase in industry-supported research and development.” *Wisconsin Alumni Research Foundation Changes Stem Cell Policies to Encourage Greater Academic, Industry Collaboration*, WARF NEWS, Jan. 23, 2007, [http://www.warf.org/news/news.jsp?news\\_id=209](http://www.warf.org/news/news.jsp?news_id=209).

78. Wei et al., *supra* note 67, at 167.

enormous excitement and anticipation for hES cell research in the academic as well as industry settings, it can be presumed that numerous other scientific groups have unsuccessfully tried to achieve this goal. For example, Time Magazine described Dr. Thomson as “one of the people ‘who are changing the world’ and . . . *Science* . . . called his invention ‘one of the most significant milestones in the history of science.’”<sup>79</sup> Further, Dr. Thomson has obtained countless awards and recognitions for his achievements in stem cell research.<sup>80</sup> This portrayal of Dr. Thomson’s work by lay as well as scientific journals and institutions demonstrates that ““at the time of the discoveries, leading scientist and scholars from around the world saw Thomson as the first scientist to isolate and proliferate human embryonic stem cells.””<sup>81</sup> Therefore, even if a *prima facie* case of obviousness could be established, it could easily be rebutted with these secondary considerations.<sup>82</sup>

*B. The Validity of the Stem Cell Patents Is Consistent with the Purpose of Patent Law*

The constitutional objective of patents is to “promote the Progress of Science.”<sup>83</sup>

In other words, the purpose of the patent system is to provide incentives for invention and creation.<sup>84</sup> However, science for science’s sake is rare these days. Although most scientists do not conduct their research with a patent in mind, the organization for which the scientists

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79. Joe Vanden Plas, *WARF Questions Relevancy of Documents Used to Uphold Patent Challenge*, WISCONSIN TECHNOLOGY NETWORK (May 31, 2007), <http://wisconsintechology.com/printarticle.php?id=3965>.

80. See, e.g., University of Wisconsin-Madison Endocrinology-Reproductive Physiology Program Faculty Webpage for Dr. James Thomson, <http://www.erp.wisc.edu/faculty/thomson.html> (last visited Sept. 9, 2007) (listing such awards as: American Academy of Achievement Golden Plate Award (1999); World Technology Award Finalist, Health and Medicine, The Economist-London (1999); Man of the Year, Madison Magazine (2001); Hall of Fame Award for Scientific Achievement, 15th Annual Conference of Biotechnology CEOs (2001); Featured as "One of the most intriguing people of 2001," People Magazine (2001); Featured as one of eighteen scientists representing "America's Best in Science and Medicine," Time magazine (2001); Wilson S. Stone Memorial Award for Biomedical Research (2001); Lois Pope Award Annual LIFE International Research Award (2002)).

81. Vanden Plas, *supra* note 79 (quoting WARF managing director).

82. MPEP § 1504.03(III) (8th ed. 2006).

83. U.S. CONST. art. I, § 8, cl. 8.

84. See, e.g., *Sinclair & Carroll Co., Inc. v. Interchemical Corp.*, 325 U.S. 327, 330-31 (1945).

work probably does.<sup>85</sup> Both universities and private companies have a vested interest in developing and protecting intellectual property;<sup>86</sup> many funding sources look to the patent portfolio, or patenting potential, of such organizations before even considering making an investment. Thus, from the organization's point of view, the objective is not only for the scientist to conduct his or her research, but is also for investors to fund such research. "Investors in any new technology are concerned to protect their investment."<sup>87</sup> Without the possibility of patent protection of a research product, investors would be far less likely to invest because the opportunities for financial return would be minimal. In other words, the investors would carry the risk and would have marginal expectations of return.

This is especially true for stem cell research.<sup>88</sup> "Investors have . . . been reluctant to make . . . investments into [related research] for a number of good reasons."<sup>89</sup> Among those reasons is the concern whether future intellectual property protection is possible should useful results be obtained.<sup>90</sup> "[R]isk aversion among potential investors is a real barrier to . . . this research."<sup>91</sup> Thus, solid patent protection of current and future technology is critical to the progress of science because it vitally depends on private investments, especially in the absence of federal funding.

Society is gaining many things from the patent protection of an invention. One of the most important is disclosure. The tradeoff for obtaining this temporary monopoly is that the patent holder has to disclose the invention and enable someone with ordinary skill in that art to reproduce or use the invention.<sup>92</sup>

It is true that "unwarranted monopoly power must be vigilantly guarded against."<sup>93</sup>

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85. See, e.g., Stacey Higginbotham, *How Open? That's the Big Patent Question*, CNET News.com, Sept. 25, 2005, [http://news.com.com/How+open+Thats+the+big+patent+question/2100-1014\\_3-5877028.html](http://news.com.com/How+open+Thats+the+big+patent+question/2100-1014_3-5877028.html).

86. See, e.g., Nathaniel Lipkus, *How to Understand Product Development: Public-Private Partnerships as Vehicles for Innovation in Combating Neglected Disease*, 10 MICH. ST. J. MED. & LAW 385 (2006).

87. Gareth Williams, *Patenting of Stem Cells*, 1 REGEN MED. 697 (2006).

88. See Little, *supra* note 71, at 1191.

89. *Id.* at 1190.

90. *Id.* at 1191.

91. *Id.*

92. 35 U.S.C. § 112 (2006).

93. Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157,

However, WARF is not in possession of such an unwarranted monopoly. WARF permits scientists to use the invention during the patent's lifetime with only a few restrictions. One can hardly characterize WARF's use of its patent as rendering the monopoly "unwarranted." It merely protects the investors' capital that enabled the research culminating in these stem cells.

Investment enables research. This is especially true since no federal funding is currently available for the generation of new hES cell lines.<sup>94</sup> Any research in this area has to be funded through private investments. Private investment was what made Thomson's research possible as well. The stem cell project would never have been able to go forward without Geron's funding for the University of Wisconsin. Geron would not have funded research that is purely academic with no prospect of financial return for the company. In fact, such a decision would have been against the business purpose to maximize shareholder wealth.<sup>95</sup> Financial return can be secured only through the protection of a patent.

It can hardly be true that the WARF patents stifle research. Quite the opposite is true. Scientific progress is accelerated because researchers can use the WARF ES cells, rather than having to establish their own ES cell lines. Furthermore, the patents act as incentives for scientists to explore other avenues to design around the patents. It is important to remember that WARF "did not contract for limitations on [California's] ability to compete."<sup>96</sup> WARF "may compel rivals . . . to do more work to develop [alternatives] independently, but this promotes rather than restricts competition."<sup>97</sup> For example, promising research has come from the generation of pluri-potent cells from somatic (adult body) cells.<sup>98</sup> In addition, StemCells, Inc. obtained a patent on generating human neural stem cell cultures from "embryonic .

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172 (2002).

94. "Research on existing human embryonic stem cell lines may be conducted with Federal support [only] if the cell lines meet the U.S. President's criteria which he announced on August 9, 2001." NIH NOTICE, *supra* note 19. See also Duffy, *supra* note 19.

95. *Dodge v. Ford Motor Co.*, 170 N.W. 668, (684 Mich. 1919) ("A business corporation is organized and carried on primarily for the profit of the stockholder.").

96. *Idx Sys. Corp. v. Epic Sys. Corp.*, 285 F.3d 581, 585 (7th Cir. 2002) (stating that non-disclosure agreements are not subject to the same restrictions as non-compete agreements).

97. *Id.*

98. Gretchen Vogel, *Researchers Turn Skin Cells into Stem Cells*, SCIENCE NOW DAILYNEWS, November 20, 2007, <http://sciencenow.sciencemag.org/cgi/content/full/2007/1120/1>.

.. fetal, neonatal, and adult tissue.”<sup>99</sup>

Other human embryonic stem cell lines might be created via a different, perhaps better, method in the future. Without the patent, there would be no need to invest research dollars into designing such new techniques. Therefore, the patent acts as an incentive for future scientific research in the field of stem cell research. “No one doubts this with physical property: General Motors is entitled to control 100% of its own output of mufflers, without handing any of them over to Ford or Toyota or Volkswagen.”<sup>100</sup>

### C. Disclosure

One of the goals of the patent system is “to motivate disclosure of inventions and reduce the use of trade secrets as a method of protecting intellectual property.”<sup>101</sup> This is especially important for the biological sciences. First, due to the high cost of conducting biomedical research, it is important not to use tax dollars to fund research that merely duplicates scientific research already conducted. Only when findings are disclosed, not concealed, can such duplicative research be avoided.

Second, the ability to disclose scientific findings is the life-blood of scientists. Publications in peer-reviewed journals and presentations at national or international meetings allow the scientist to share his or her result with the scientific community. Thereby, the scientist does not only disseminate his knowledge to others but may get valuable feedback from other scientists, establish collaboration among institutions, and gain valuable recognition in his field of study. Without publishing the results of his or her research, the scientist cannot establish a track record in the scientific community. Without a track record, it will be challenging for the scientist to obtain funding for future research undertakings. Thus, disclosing his research results serves many important functions that propel scientific research at large. However, scientists that make disclosures without the protection of a patent may find themselves barred from continuing with their research because someone else “scooped” them.<sup>102</sup> Publications are typically reviewed for

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99. Posting of Douglas Sorocco to Phosita | An Intellectual Property Law Blog!, *US Stem Cell Patent Issued*, [http://www.okpatents.com/phosita/archives/2004/08/us\\_stem\\_cell\\_pa.html](http://www.okpatents.com/phosita/archives/2004/08/us_stem_cell_pa.html) (Aug. 23, 2004, 12:44 CST).

100. *Idx Sys. Corp.*, 285 F.3d at 585.

101. David J. Weitz, *The Biological Deposit Requirement: A Means of Assuring Adequate Disclosure*, 8 HIGH TECH L.J. 275, 298 (1993).

102. A patent provides the “right to exclude others from making, using, offering for sale, or selling the invention.” 35 U.S.C. § 154(a)(1) (2006). Should an inventor disclose his



novelty. Thus, if someone else has published the same results elsewhere, the editors of another journal are unlikely to accept an article with the same results.

Grants of patents are useful not only to the owner but also to the public, especially with regard to break-through scientific findings in the biosciences. This is due to the fact that, in the special case of biological material, a patentee may be required to make a deposit with the PTO.<sup>103</sup> Such a deposit is available for public inspection.<sup>104</sup> Because it is often impossible for other researchers to reproduce a biotechnological invention, the interest of the pertinent scientific community is safeguarded through a patent on the invention.<sup>105</sup> The patentee “has a strong economic incentive” to keep his biological material inaccessible to the public.<sup>106</sup> A patent, however, allows for the researcher to share his findings safely with the public.

*D. Not Research but Profit-Making Is Limited by the Patents*

The Patents, especially ‘806, are quite broad and may therefore be vulnerable. Nevertheless, the USPTO should not invalidate the patents. It is clear what the patents would not cover, i.e., the generation of stem cells from somatic tissue or by nuclear transfer. Experiments attempting this task are currently underway.<sup>107</sup> The patents do not describe the one and only method to generate stem cells and maintain the desired embryonic phenotype and genotype *in vitro*.

Experimentation for new methodology is currently only possible through private funding frustrating academic scientists. However, academic scientists do not need to generate other cell lines because they can use the patented cell lines for a minimal fee.<sup>108</sup> It should be noted that “WARF imposes no restrictions on patenting or publishing the results of basic academic research.”<sup>109</sup> Research itself is thus not stifled.

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invention without this protection, other companies or individuals are free to duplicate and practice the invention.

103. See 37 C.F.R. §§ 1.801-1.809 (2006); 37 C.F.R. § 1.93 (2006); MPEP Appendix R, Patent Rules § 1.93 (8th ed. 2006).

104. 37 C.F.R. § 1.808(c) (2006).

105. See Weitz, *supra* note 101.

106. *Id.* at 299-300.

107. See, e.g., Jeffrey M. Perkel, *Life Science Technologies Stem Cells: Beyond Somatic Cell Nuclear Transfer*, SCI. MAG., Apr. 4, 2007, available at [http://www.sciencemag.org/prod/contents/lst\\_20070420.dtl](http://www.sciencemag.org/prod/contents/lst_20070420.dtl).

108. See *infra* Part V.G.

109. Posting of Kevin E. Noonan to Patent Docs, *It's Time to Stop the Hypocrisy over*

Rather, the licensing conditions limit the amount of commercial profit companies can make using the patented invention. Limits imposed onto the ability of individuals or companies to profit from an invention that was patented by another can hardly be a reason for finding a patent invalid.

#### *E. The Upstream Technology Argument*

Opponents of the WARF patents argue that the patents cover “upstream” technology.<sup>110</sup> In other words, stem cells can be useful for making future biotechnological discoveries and inventions. However, an “upstream-downstream” distinction can hardly be made in biotechnology because there is no workable line-drawing mechanism. Even if there was a method to distinguish what is and what is not upstream technology, it would hardly be reasonable to propose that upstream technology is generally unpatentable. Upstream technology should especially be patentable because it includes all pioneer work.<sup>111</sup>

For most inventions, especially in biological sciences, the true significance is rarely clear. For example, in the 1940s, two scientists studied a virus that infects bacteria.<sup>112</sup> Perhaps some were wondering why it would be of any significance to study these bacteriophages. Most certainly, the discovered methods and observations would not have been characterized as upstream technology. Later, it became clear that the two scientists, Max Delbrück and Salvador Luria, had developed a simple model system for DNA transfer, the first cloning of genetic information.<sup>113</sup> This simple example illustrates that characterizations of technological advancements as “upstream” or “not upstream” are hardly possible. The potential for future scientific use rests in every scientific discovery. Thus, essentially all technologies are “upstream” in some way. One cannot punish an inventor by making his discovery unpatentable simply because his or her invention is highly useful.

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*Stem Cell Patent – Part II*, available at [http://patentdocs.typepad.com/patent\\_docs/2007/04/its\\_time\\_to\\_sto\\_1.html](http://patentdocs.typepad.com/patent_docs/2007/04/its_time_to_sto_1.html) (Apr. 26, 2007).

110. See, e.g., Amy Rachel Davis, *Patented Embryonic Stem Cells: The Quintessential “Essential Facility”?*, 94 GEO. L. J. 205 (2005).

111. A pioneer work or invention refers to something entirely new rather than an improvement within an existing branch of science. See James E. Rogan, Prepared Remarks at the Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy (Feb. 6, 2002), available at <http://www.uspto.gov/web/offices/com/comm06feb2002.html>.

112. S. E. Luria & M. Delbrück, *Mutations of Bacteria from Virus Sensitivity to Virus Resistance*, 28 GENETICS 491 (1943).

113. *Id.*

Formerly, the government provided funding for “premarket or ‘upstream’ research and encouraged broad dissemination of results in the public domain.”<sup>114</sup> However, because the technology was freely available, commercial development was unattractive to investors. To remedy this situation, Congress encouraged patenting of federally funded research results.<sup>115</sup> Patent protection provided the needed economic incentive to encourage investors to support research as well as commercial development.<sup>116</sup> Critics argue, however, that “[a] proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development.”<sup>117</sup> The obvious counterargument to this criticism is that upstream innovations would never be made without the expectation of financial returns. “Scientific research is an expensive endeavor.”<sup>118</sup> Funding for such research would be unavailable and “[c]ommercialization would be impossible if not for the temporary monopoly rights.”<sup>119</sup>

*F. WARF Is Not “Keeping It All to Itself”*

The FTCR argues that the patents should be invalid because of the danger that WARF will keep stem cell research to itself and thereby stifle the scientific progress.<sup>120</sup> Nothing could be further from the truth. Science is rarely conducted in a vacuum. In fact, the scientific community operates to support and inspire its constituents. Therefore, it is not in WARF’s interest to keep the benefits of embryonic research to itself.

WARF has not only shared the patent with over 400 scientists worldwide,<sup>121</sup> but has also included training for a reasonable royalty or free of charge.<sup>122</sup> Further, scientists at the NIH and FDA, as well as

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114. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

115. *See id.*

116. *See id.*

117. *Id.*

118. Diana A. Villamil, *Redefining Utility in Determining the Patentability of DNA Sequences*, 5 J. MARSHALL REV. INTELL. PROP. L. 238, 252 (2006).

119. *Id.*

120. John M. Simpson, *Wisconsin Group Eases Stem Cell Patent Restrictions After FTCR – PubPat Challenge*, January 23, 2007, <http://www.pubpat.org/warfstemcelleased.htm>.

121. Elizabeth L.R. Donley, *How Wisconsin Moved to the Front Line of Stem Cell Research*, MILWAUKEE J. SENTINEL, Sept. 2, 2006, available at <http://www.jsonline.com/story/index.aspx?id=489946>.

122. *See* WiCell Research Institute – Technical Classes,

scientists within the State of Wisconsin, are free to use the technology without paying any royalty.<sup>123</sup> There are not many examples where the owner of a patent shares its protected invention as extensively as WARF does right now.

It is also worth noting that the patented technology is not simply blocking others from practicing the technique. Scientists at the University of Madison and at the WiCell Research Institute<sup>124</sup> have been enormously prolific. This productivity is reflected in successful competition for research grants, thirty-eight peer-reviewed publications, and over thirty patent applications.<sup>125</sup> Using the patented stem cells, scientists have produced blood and plasma supplies, generated “insulin-producing cells to develop new treatments for diabetes,” and were successful in restoring motor movement in several animal models by regenerating spinal cord tissue.<sup>126</sup>

Finally, WiCell is giving back to the public, which initially funded some of the research that resulted in the patented invention. It is doing so not only through the furthering of research, as discussed above, but also through raising public awareness of stem cell technology. Specifically, “the institute already offers one- and three-day courses for journalists and teachers.”<sup>127</sup> In a few months, WiCell will launch a “major public education initiative” to educate anyone interested in this important technology and its potential in improving the way medicine is practiced today.<sup>128</sup> Thus, the WARF patents are most certainly not “stopping . . . domestic human ES cell research at its infancy.”<sup>129</sup>

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[http://www.wicell.org/index.php?option=com\\_content&task=blogsection&id=16&Itemid=149](http://www.wicell.org/index.php?option=com_content&task=blogsection&id=16&Itemid=149)  
(last visited Jan. 11, 2008).

123. The NIH signed a memorandum of understanding with WARF and its subsidiary WiCell. See Press Release, National Institute of Health, National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement (Sept. 5, 2001), available at <http://www.nih.gov/news/pr/sep2001/od-05.htm>.

124. WiCell is a non-profit supporting organization of the University of Madison to advance the science of stem cells. See WiCell and The National Stem Cell Bank Home Page, <http://www.wicell.org> (last visited Sept. 2, 2007).

125. Carl Gulbrandsen, *Stem-Cell Patent Holder's View of the California Challenge*, WIS. TECH. NETWORK (Nov. 16, 2004), <http://wistechology.com/printarticle.php?id=1352>.

126. Donley, *supra* note 121.

127. *Id.*

128. *Id.*

129. See Letter from Foundation for Taxpayer and Consumer Rights to USPTO (Mar. 13, 2001), available at <http://www.pubpat.org/assets/files/warfstemcell/806Request.pdf> (Sept. 21, 2006) (requesting reexamination of U.S. Patent No. 6,200,806).

*G. The Cost Is More Than Reasonable*

The embryonic stem cells are available for a reasonable fee. Scientists at academic institutions can obtain free licenses and a vial of embryonic stem cells for \$500.<sup>130</sup> This fee includes scientific training to enable interested researchers to work with the cells effectively.<sup>131</sup> This fee is not only reasonable but in fact quite affordable. For example, a single vial of murine embryonic stem cells costs \$250 at the American Type Culture Collection (ATCC).<sup>132</sup> This ATCC fee does not include any training.<sup>133</sup> Also, the same hES cells cost \$6,000 when provided by ES Cell International, a company located in Singapore.<sup>134</sup>

Importantly, the fee is reasonable when considering that it would take tens of thousands of dollars to create an equivalent cell line independently. The cost of salaries, tissue culture media, sterile culture dishes, disposable pipette tips, etc., would exceed \$500 in just a day. Generating a comparable cell line could take years. Thus, the cost for the cell line is reasonable and affordable for any academic scientists that desire to work with these cells. Licensing costs for commercial entities are considerably higher.<sup>135</sup> But these fees are not burdensome to companies, and “it would be unrealistic (and inequitable) for a company to obtain the cells for a simple licensing fee.”<sup>136</sup> However, the fact that commercial entities have to invest several thousand dollars before they can utilize the patented technology should not render the patent invalid.

*H. California v. Wisconsin?*

California proclaims that “[b]y nearly any measure, California is the national leader in innovation.”<sup>137</sup> Further, “California is responsible for one in four patents, attracts half of all venture capital and provides 20 percent of [all] technology jobs in the United States. From [its] world-

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130. Pollack, *supra* note 42, at C2.

131. See WiCell Research Institute – Unlocking the Potential of Human Embryonic Stem Cells, [http://www.wicell.org/index.php?option=com\\_frontpage&Itemid=102](http://www.wicell.org/index.php?option=com_frontpage&Itemid=102) (last visited Jan. 11, 2008).

132. ATCC: Cell Biology Collection, <http://www.atcc.org/common/catalog/numSearch/numResults.cfm?atccNum=SCRC-1029> (last visited Aug. 31, 2007).

133. See Pollack, *supra* note 42.

134. ESI – Stem Cell Products – Order hES, <http://www.escellinternational.com/stemcellprod/ordercells.htm> (last visited Aug. 31, 2007).

135. \$75,000 to \$400,000. Pollack, *supra* note 38.

136. Noonan, *supra* note 109.

137. Governor Arnold Schwarzenegger, State of the State Address (Jan. 9, 2007), available at [http://gov.ca.gov/sots/research\\_innovation.html](http://gov.ca.gov/sots/research_innovation.html) (last visited Jan. 9, 2007).

leading stem cell research initiative to renewable energy and alternative fuels, California is the birthplace of innovation.”<sup>138</sup> It has “the world’s largest concentration of biotechnology companies” and because of its commitment to stem cell research, it “has other countries treating the state like it is its own nation.”<sup>139</sup>

There can be no doubt that the numerous outstanding scientists at California’s universities as well as in industry form a highly productive network. To support research development and maintain California’s “world-leading” position in the scientific arena, California voters approved a funding initiative for stem cell research.<sup>140</sup> The state is proposing a budget of \$300 million per year over the next ten years in California, which exceeds the NIH’s annual spending for the entire nation tenfold.<sup>141</sup>

The geographical location of the adverse institutions may not be coincidental to the pending reexamination. It has been speculated that the challenge is “politically and financially motivated”<sup>142</sup> and would not have been brought forward had the patent been owned by a California institution. It is conceivable that, had a California institution owned the stem cell patents, the validity of the patents would not have been questioned.

In 2004, after the Bush administration had announced its restrictions on stem cell research,<sup>143</sup> California amended its constitution with the California Stem Cell Research and Cures Initiative.<sup>144</sup> This amendment renders stem cell research a constitutional right in the state of California.<sup>145</sup> Further, three billion dollars over a period of ten years will be made available to fund and provide infrastructure for stem cell

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138. *Id.*

139. Terri Somers, *Stem Cell Research no Dream for California*, SignOnSanDiego (2006), <http://www.signonsandiego.com/news/business/biotech/20061219-9999-1z1n19stem.html>.

140. *American Association for the Advancement of Science Policy Brief: Stem Cell Research*, Stem Cells in the States, available at <http://www.aaas.org/spp/cstc/briefs/stemcells> (last visited Aug. 31, 2007).

141. The NIH spent \$29 million in 2003 for stem cell research in the entire nation. Gulbrandsen, *supra* note 125.

142. Pollack, *supra* note 2.

143. President Discusses Stem Cell Research, The White House, Aug. 9, 2001, available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html> (last visited Aug. 31, 2007).

144. Proposition 71 was codified as CAL. CONST. art. XXXV. California Stem Cell Research and Cures Initiative, Prop. 71, 2004 Cal. Text of Proposed Laws, available at <http://www.cirm.ca.gov/pdf/prop71.pdf>.

145. *Id.*

research.<sup>146</sup> This outstanding commitment to the advancement of science is unique in terms of magnitude and structure. California is the “first state to publicly fund embryonic stem cell research.”<sup>147</sup>

It is thus not surprising that California has a strong interest in the availability of stem cell technology. However, while this strong interest is understandable and even honorable, the validity of a patent is not dependent on state interests. The FTCR alleges that the “patents could impede th[e] state’s \$3 billion stem cell research program.”<sup>148</sup> The opposite is true, however, because the patents make many aspects of this program possible. Without the patents, the technology would not be in the hands of scientists outside of Geron and the Thomson laboratory. Instead, the technology would be a strictly guarded trade secret in the hands of Geron who paid for research, and neither academia nor industry would have access to it. Surely, scientists would be free to try to generate their own stem cells in the absence of a patent. However, before Dr. Thomson’s success, scientists have failed for decades to do so.<sup>149</sup> Thus, the patents under reexamination make many aspects of human stem cell research possible, rather than hindering it.

#### *I. Scientists Are Not Moving Abroad to Conduct Their Research*

Opponents to the stem cell patents have argued that scientists interested in working in the stem cell field will flee to other countries.<sup>150</sup> While this argument sounds plausible, it has not been corroborated by any sound statistical analysis.

Quite the opposite is true. There are over 5,000 federally funded current or past stem cell-related research projects in the United States.<sup>151</sup> Furthermore, there are numerous private and public companies, not included in this number, that have “taken a good look at stem-cell research.”<sup>152</sup> In fact, the stem cell research “field is cluttered

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146. *Id.*

147. Richard Guerra, *States Take the Initiative to Regulate And Resolve the Stem Cell Debate*, 7 FL. COASTAL L. REV. 35, 46 (2005).

148. Pollack, *supra* note 42.

149. *See* Wei et al., *supra* note 67, at 167.

150. Press Release, Foundation for Taxpayer and Consumer Rights, Groups Challenge Stem Cell Patents That Loot Taxpayer Funds and Force Research Overseas (July 18, 2006), available at <http://www.consumerwatchdog.org/pr/?postId=6572> (last visited Sept. 23, 2007).

151. [http://crisp.cit.nih.gov/crisp/crisp\\_query.generate\\_screen](http://crisp.cit.nih.gov/crisp/crisp_query.generate_screen) (last visited Aug. 31, 2007).

152. Matthew Herper, *Stock Focus: Stem-Cell Companies*, FORBES, Aug. 3, 2001, available at <http://www.forbes.com/2001/08/03/0803sf.html>.

with companies.”<sup>153</sup> Thus, it can hardly be said that the stem cell patents force U.S. research endeavors and stem cell scientists abroad.

There may be several reasons why U.S. stem cell scientists are unlikely to go abroad to conduct their research. The most obvious one is that individuals are more likely to switch their research focus than leave their country. It is a great personal commitment and requires great courage to leave behind your home and endeavor into the unknown. Many are not willing to adapt into foreign cultures, learn new languages, and leave their roots, just to work in a particular area of science. Second, foreign countries have granted several stem cell patents.<sup>154</sup> Further, some countries do not permit any stem cell research.<sup>155</sup> Thus, U.S. scientists are unlikely to move their operations abroad because the technology is either patented or prohibited. Third, it is not clear if U.S. scientists' work abroad will be favorably reviewed in the United States. In other words, scientists that are hoping to establish themselves in the scientific community and move up within a U.S. institution may not be able to accomplish this goal with research conducted abroad. Finally, not all countries that would provide for equivalent research facilities permit unbridled embryonic stem cell research.<sup>156</sup> Thus, the argument that the WARF patents drive U.S. scientists to move abroad is unlikely to be meaningful. While there might be individual examples, there is no empirical evidence to support this argument and there is not likely to be any in the future. It might be added that even if there was “stem cell off shoring,” it is due to “the 2001 order by President Bush that restricts federal funding here to research on a small number of embryonic stem cell lines.”<sup>157</sup>

#### CONCLUSION

The stem cell patents currently under reexamination by the USPTO should be upheld. WARF's patents are not obvious in light of the newly

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153. *Id.*

154. *See, e.g.*, Matt Wilkinson, *ReNeuron Awarded EU Stem Cell Patents*, Drug Researcher, Apr. 4, 2007, <http://www.drugresearcher.com/news/printNewsBis.asp?id=75830>.

155. Human embryonic stem cell research is permitted in Belgium, Britain, Denmark, Finland, Greece, the Netherlands, and Sweden, but not permitted in Austria, Germany, Ireland, Italy and Portugal. *See, e.g.*, Wikipedia, Stem Cell Research Policy, [http://en.wikipedia.org/wiki/Stem\\_cell\\_research\\_policy](http://en.wikipedia.org/wiki/Stem_cell_research_policy) (last visited Aug. 31, 2007).

156. *E.g.*, Germany enacted the Embryoneschutzgesetz in 1990, EschG, BG1. L 2001, S. 2702.

157. Tom Still, *Here's why Wisconsin's Stem Cell Patents are Being Challenged*, WIS. TECH. NETWORK (Apr. 18, 2007), <http://wistechnology.com/printarticle.php?id=3857>.



cited prior art. In addition, in times where embryonic research is largely dependent on private investors, it is especially important to provide for reliable protection of intellectual property. WARF has shared the patented technology extensively with the scientific community and will continue to do so. The fact that commercial entities cannot use the patented technologies to maximize their company's wealth is not sufficient to hold the patents invalid.

Importantly, the patent system ought to provide a sense of stability that withstands any political winds. It is currently challenging for competitors to design around the stem cell patents due to the restrictions on the generation of new lines. However, patents should be inert against any changes in the political climate. Otherwise, a patent's term would be effectively reduced to the term of government.

Patents ensure that the protected technology is used to its fullest. Scientific research is moved by "trends" that temporarily make a technology "de jour" popular for use by researchers in different fields.<sup>158</sup> Once the next trend comes along, all interest is focused on this new technology. The investment in a patent assures that a technique, if it is promising, will be developed and exploited to its fullest. Stem cell research bears enormous promise. This technology must be protected to ensure investment of time, money, and effort to ensure its development to the fullest possible benefit to mankind.

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158. The use of dendritic cells, for example, once was such a technology "de jour."

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