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# MORAL DISHARMONY: HUMAN EMBRYONIC STEM CELL PATENT LAWS, WARF, AND PUBLIC POLICY

JENNY SHUM\*

**Abstract:** Human embryonic stem cells have unique regenerative properties and the ability to develop into a variety of different cell types. Based on these properties, stem cell research is considered a promising biomedical field for the development of cell-based therapies to treat diseases. It is also a highly contentious field because these cells are derived from human embryos. The United States, unlike the European Union, does not have a moral component to the patent grant process and has granted several stem cell patents. This Note examines the intersection of these broad patents and U.S. policies limiting stem cell research funding and highlights their deleterious effects on the progress of human embryonic stem cell research. This Note also evaluates the feasibility of incorporating ethical criteria, as used in the European Union, for U.S. patent grants and concludes that uniform moral standards would be impossible to determine and effectuate for this process.

## INTRODUCTION

The cornerstones of patent protection for an invention are that it grants the inventor the rights to his or her invention and gives the inventor the right to exclude others from practicing the invention.<sup>1</sup> Notwithstanding these basic protections, patents do not confer the patentee the right to practice the invention itself.<sup>2</sup> That specific right may be governed by domestic laws within a particular State.<sup>3</sup> Patents may be granted based on several principles, including: (1) as an incentive to

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<sup>1</sup> See 35 U.S.C. § 154 (2006); JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 4 (2008); ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 126–27 (4th ed. 2006).

<sup>2</sup> RUSSELL KOROBKIN, STEM CELL CENTURY: LAW AND POLICY FOR A BREAKTHROUGH TECHNOLOGY 96 (2007); Berthold Rutz & Siobhan Yeats, *Patenting of Stem Cell Related Inventions in Europe*, 1 BIOTECHNOLOGY J. 384, 384 (2006).

<sup>3</sup> KOROBKIN, *supra* note 2, at 96; Rutz & Yeats, *supra* note 2, at 384.

invent and (2) as a reward to the inventor for disclosing his or her invention.<sup>4</sup> Indeed, the United States Constitution affords exclusive rights for an inventor's discoveries to "promote the Progress of Science and useful Arts."<sup>5</sup> Conflicts may arise between protecting an inventor's patent rights and issuing overly broad patents that discourage further innovation.<sup>6</sup>

Biotechnology has produced numerous advances across various fields, including agriculture and medicine.<sup>7</sup> As a result, there has been a steady surge of biotechnology patents sought and granted since the early-1990s.<sup>8</sup> One major biomedical breakthrough has been the isolation of adult and embryonic stem cells, first in mice and later in humans.<sup>9</sup> Stem cells are immature cells that have not differentiated into a specialized cell type and are capable of self-renewal.<sup>10</sup> Due to their undifferentiated state and ability to self-perpetuate, stem cells are thought to hold special promise for a number of therapeutic uses, including as cellular replacements in damaged and degenerative cell or tissue disorders.<sup>11</sup> Extensive research has gone into determining how to direct the differentiation of stem cells such that they form cells of a specific type.<sup>12</sup> For example, stem cells could be induced to differentiate into insulin-producing pancreatic  $\beta$  cells to treat Type I diabetics who lack them, or into osteoblasts, cells necessary for bone formation, to repair

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<sup>4</sup> Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–31 (1989).

<sup>5</sup> U.S. CONST. art I, § 8, cl. 8.

<sup>6</sup> See BESSEN & MEURER, *supra* note 1, at 4.

<sup>7</sup> See BARRY R. SCHALLER, UNDERSTANDING BIOETHICS AND THE LAW: THE PROMISES AND PERILS OF THE BRAVE NEW WORLD OF BIOTECHNOLOGY 2–3 (2008). See generally BIOTECH. INDUS. ORG., GUIDE TO BIOTECHNOLOGY (2008), <http://bio.org/speeches/pubs/er/BiotechGuide2008.pdf> (highlighting biotechnological innovations).

<sup>8</sup> Karl Bergman & Gregory D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development*, 25 NATURE BIOTECHNOLOGY 419, 420 (2007); Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 165 (2000).

<sup>9</sup> Martin Evans & Matthew H. Kaufman, *Establishment in Culture of Pluripotential Cells from Mouse Embryos*, 292 NATURE 154–56 (1981); James Thompson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145–47 (1998).

<sup>10</sup> L. Buttery, F. Rose & K. Shakesheff, *Stem Cells and Tissue Engineering*, in MEDICAL BIOTECHNOLOGY 149, 154–55 (Judith Pongracz & Mary Keen eds., 2009). Differentiation is the process by which cells acquire particular characteristics that give the cell its functionality. *Id.* at 155.

<sup>11</sup> KOROBKIN, *supra* note 2, at 18–21.

<sup>12</sup> *Id.*

bone defects in people suffering from osteoporosis or other related ailments.<sup>13</sup>

Embryonic stem cells (ESCs) are pluripotent, meaning that they can differentiate into almost all of the various cell types in the body.<sup>14</sup> An additional characteristic of ESCs is that they are capable of indefinite self-renewal.<sup>15</sup> In contrast, adult stem cells (ASCs) are multipotent and are therefore limited to differentiating only into a particular cell type(s), usually from the tissue of origin.<sup>16</sup> Furthermore, ASCs differ in that they tend to have a finite period of proliferation and cannot replicate indefinitely.<sup>17</sup> There are also totipotent stem cells, which can develop into any cell in the human body, thus having the potential to develop into a complete living organism.<sup>18</sup> The use of human ESCs (hESCs) is controversial and fraught with ethical concerns due to the isolation process, which results in the destruction of the embryo.<sup>19</sup> Unlike hESCs, ASCs are extracted via invasive procedures from tissues in the body and are typically present in exceptionally low numbers. Additionally, ASCs present challenges for culturing them *in vitro*, a process which restricts their potential clinical applications.<sup>20</sup>

In the United States and several other countries, including Sweden and the United Kingdom, stem cell patents are permitted.<sup>21</sup> In 1998,

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<sup>13</sup> Buttery et al., *supra* note 10, at 155; Jojanneke M. Jukes et al., *Endochondral Bone Tissue Engineering Using Embryonic Stem Cells*, 105 PROC. NAT'L. ACAD. SCI. U.S. AM. 6840, 6840 (2008).

<sup>14</sup> Buttery et al., *supra* note 10, at 155–56.

<sup>15</sup> *Id.* at 156.

<sup>16</sup> *Id.* at 155–56. Pluripotent stem cells are extracted after the cells have developed beyond the totipotent stage. Pluripotent stem cells cannot give rise to extraembryonic cells, such as placental cells, and cannot form a living organism. Pluripotent stem cells that have undergone partial differentiation, in turn, develop into multipotent progenitor cells. Examples of multipotent stem cells would be those obtained from the bone marrow or hematopoietic stem cells, which could only differentiate into various types of blood cells and not others, such as neural cells. *See id.* Recent studies suggest that adult tissues may contain small numbers of ASCs that may be pluripotent. *See generally* Mariusz Z. Ratajczak, *A Hypothesis for an Embryonic Origin of Pluripotent Oct-4<sup>+</sup> Stem Cells in Adult Bone Marrow and Other Tissues*, 21 LEUKEMIA 860 (2007) (noting that evidence is accumulating that adult tissues contain stem cells that express certain markers characteristic of pluripotent embryonic stem cells).

<sup>17</sup> Buttery et al., *supra* note 10, at 156.

<sup>18</sup> *Id.* at 155.

<sup>19</sup> KOROBKIN, *supra* note 2, at 21; *see* Buttery et al., *supra* note 10, at 160.

<sup>20</sup> Buttery et al., *supra* note 10, at 156, 160.

<sup>21</sup> Primate Embryonic Stem Cells, U.S. Patent No. 5,843,780 (filed Jan. 18, 1996) (issued Dec. 1, 1998) [hereinafter '780 Patent]; Aurora Plomer, *Constitutional Limits on Moral Exemptions to European Biotech Patents*, in FESTSKRIFT TILL MARIANNE LEVIN 487, 489, 493 (Antonina Bakardjieva Engelbrekt et al. eds., 2008).

the United States issued the first patent on stem cells to James Thomson and assigned it to the Wisconsin Alumni Research Foundation (WARF).<sup>22</sup> WARF later obtained two additional stem cell patents in 2001 and 2006.<sup>23</sup> Taken together, the patents broadly claimed both the process of developing hESC lines and all hESCs themselves as a composition of matter claim, regardless of how they are generated.<sup>24</sup> The validity of these patents was subsequently upheld by the U.S. Patent and Trademark Office (PTO).<sup>25</sup>

The Enlarged Board of Appeal (EBoA) of the European Patent Office (EPO) issued a landmark ruling in 2008 in which it refused to allow a WARF hESC patent on the grounds that it was contrary to “public order or morality” because it requires the use and destruction of human embryos.<sup>26</sup> In distinct contrast to the United States, the European Union (EU), operating through the European Patent Convention (EPC) and the Directive by the European Parliament and the Council of the EU (Biotech Directive), incorporates ethical considerations into its patentability analysis.<sup>27</sup> Article 53(a) of the EPC, also mirrored in Article 6 of the Biotech Directive, states that European patents will not be granted for “inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality.”<sup>28</sup> Moreover, the Biotech Directive specifically notes, in particular, that “uses of human embryos for industrial or commercial purposes” are to be excluded from patent protection.<sup>29</sup> In 1999, the rules of the EPO were amended to

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<sup>22</sup> '780 Patent, *supra* note 21.

<sup>23</sup> Primate Embryonic Stem Cells, U.S. Patent No. 7,029,913 (filed Oct. 18, 2001) (issued Apr. 18, 2006) [hereinafter '913 Patent]; Primate Embryonic Stem Cells, U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001) [hereinafter '806 Patent].

<sup>24</sup> '913 Patent, *supra* note 23; '806 Patent, *supra* note 23; '780 Patent, *supra* note 21.

<sup>25</sup> Press Release, Wis. Alumni Research Found., United States Patent and Trademark Office Upholds Key WARF Stem Cell Patent (Feb. 28, 2008), [http://www.warf.org/uploads/media/Key\\_hES\\_Cell\\_Patent-Upheld\\_Release\\_v6-3.pdf](http://www.warf.org/uploads/media/Key_hES_Cell_Patent-Upheld_Release_v6-3.pdf) [hereinafter WARF-PTO PR1]; Press Release, WARF, Patent Office Upholds Remaining WARF Stem Cell Patents (Mar. 11, 2008), [http://www.warf.org/news/news.jsp?news\\_id=226](http://www.warf.org/news/news.jsp?news_id=226) [hereinafter WARF-PTO PR2]; Press Release, WARF, U.S. Patent Office Issues Certificates to Uphold WARF Stem Cell Patents (June 26, 2008), [http://www.warf.org/news/news.jsp?news\\_id=234](http://www.warf.org/news/news.jsp?news_id=234).

<sup>26</sup> Wisconsin Alumni Research Foundation, Case G 0002/06, Eur. Patent Off., 23–26 (Nov. 25, 2008) [hereinafter EBoA Decision].

<sup>27</sup> Convention on the Grant of European Patents, art. 53, Oct. 5, 1973 [hereinafter EPC]; Eur. Parliament & Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 (EC) [hereinafter Biotech Directive].

<sup>28</sup> EPC, *supra* note 27, art. 53(a); Biotech Directive, *supra* note 27, at 18–19.

<sup>29</sup> Biotech Directive, *supra* note 27, at 18.

include a new section on biotechnological inventions that incorporated the exclusions delineated within the Biotech Directive.<sup>30</sup>

This Note first examines the differing approaches toward the patentability of human embryonic stem cells in the United States and the EU, with particular attention to the WARF patents. It next analyzes whether moral criteria should play a role in the determination of patentability. It also assesses whether the United States should harmonize its stem cell patent policy with that of the EU. Finally, this Note considers the impact of U.S. policies regulating human embryonic stem cell research, both domestically and internationally.

## I. BACKGROUND

### A. Patentability of Stem Cells in the United States

Patents in the United States are granted for inventions that are useful, novel, and nonobvious.<sup>31</sup> Section 101 of Title 35 of the United States Code states that patentable inventions consist of “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . .”<sup>32</sup> In 1889, the Commissioner of the U.S. Patent Office first addressed the issue of patenting living subject matter in *Ex parte Latimer*, by ruling that allowing patents to products of nature would be “unreasonable and impossible.”<sup>33</sup> This stance changed in the seminal case of *Diamond v. Chakrabarty*, where the U.S. Supreme Court held that genetically modified bacteria, living organisms, could be patented.<sup>34</sup> In making its decision, the Court noted that it was irrelevant to patentability whether the invention was living or inanimate.<sup>35</sup> Subsequently, in *Ex parte Allen*, the U.S. PTO’s Board of Patent Appeals and Interferences (BPAI) ruled that a chromosomally altered oyster, modified to be sterile, was patentable.<sup>36</sup>

*Allen*, taken together with *Chakrabarty*, indicated that the complexity of the organism was also irrelevant to patentability.<sup>37</sup> Shortly after

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<sup>30</sup> Implementing Regulations to the Convention on the Grant of European Patents, R. 28, Nov. 29, 2000.

<sup>31</sup> 35 U.S.C. §§ 101–103(a).

<sup>32</sup> *Id.* § 101.

<sup>33</sup> Dec. Com. Pat. 123, 126 (1889).

<sup>34</sup> See 447 U.S. 303 (1980).

<sup>35</sup> *Id.* at 313.

<sup>36</sup> 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Int. 1987).

<sup>37</sup> ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 127 (4th ed. 2007).

the BPAI's ruling in *Allen*, the Commissioner of the U.S. PTO issued a notice stating that nonnaturally occurring, nonhuman multicellular living organisms, including animals, were patentable subject matter.<sup>38</sup> The BPAI explicitly clarified the issue of whether patenting of human beings was permissible, stating “[a] claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. [§] 101.”<sup>39</sup> The basis for the BPAI's analysis was that the patenting of human beings was akin to slavery and, since one person cannot be the property of another, it was therefore a contravention of the Thirteenth Amendment.<sup>40</sup> The U.S. PTO patent examiner guidelines also require that “[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. § 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.”<sup>41</sup>

The moral and ethical controversy surrounding the patentability of human embryonic stem cells arises from their isolation process, which renders the embryo non-viable.<sup>42</sup> Under the judicial doctrine of beneficial utility, emanating from an 1817 case, *Lowell v. Lewis*, an otherwise patentable invention is not patentable if it is “injurious to the well-being, good policy, or sound morals of society.”<sup>43</sup> Furthermore, after a patent application was filed for animal-human hybrids—chimeras—the U.S. PTO issued a position statement indicating that “inventions directed towards human/non-human chimeras could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.”<sup>44</sup> Subsequently in 1999, although *Lowell* was not specifically overruled, the U.S. Court of Appeals for the Federal Circuit indicated that the PTO and patent laws were not intended to serve as arbiters of what constitutes immoral or illegal activities.<sup>45</sup> The court suggested that the determination of whether particular inventions

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<sup>38</sup> U.S. Pat. & Trademark Off. Notice: Animals—Patentability, *reprinted in* 1077 OFFICIAL GAZETTE PAT. & TRADEMARK OFF. 24 (Apr. 7, 1987).

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

<sup>40</sup> *See id.*

<sup>41</sup> U.S. Pat. & Trademark Off., Manual of Patent Examination Procedure § 2105 (8th ed. rev. 2008) [hereinafter MPEP].

<sup>42</sup> KOROBKIN, *supra* note 2, at 21; Buttery et al., *supra* note 10, at 160.

<sup>43</sup> 15 Fed. Cas. 1018, 1019 (C.C.D. Mass. 1817).

<sup>44</sup> Media Advisory, U.S. Patent and Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998), <http://www.uspto.gov/news/pr/1998/98-06.jsp>.

<sup>45</sup> *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999).

should be unpatentable was best left to Congress.<sup>46</sup> In light of these prior rulings and the position of the U.S. PTO, hESCs are indeed considered patentable subject matter, as evidenced by the issuance of the WARF patents.<sup>47</sup>

### B. Stem Cell Patentability in the European Union

In the EU, patents are granted through the EPO, which was established by the EPC in 1973.<sup>48</sup> Patents are granted for inventions that are novel, susceptible to industrial application, and involve an inventive step.<sup>49</sup> Article 53 of the EPC also lays out the exclusions for patentability.<sup>50</sup> Inventions whose exploitation would be contrary to public order and morality are precluded from being patented.<sup>51</sup> In the Guidelines for Examination to the EPO, the criteria for its application are quite narrow, stating: “This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.”<sup>52</sup>

In 1998, the European Parliament and the Council of the EU issued Directive 98/44/EC concerning the patenting of biotechnological innovations.<sup>53</sup> This biotechnology directive was subsequently incorporated into the EPC.<sup>54</sup> Within it, Article 5(1) states that “[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.”<sup>55</sup> In addition, Article 6(1) reiterates the moral component to patentability assessments. It also specifically notes in Article 6(2)(c) that patents are excluded for inventions involving “uses of human embryos for industrial or commercial purposes.”<sup>56</sup>

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

<sup>47</sup> See '913 Patent, *supra* note 23; '806 Patent, *supra* note 23.

<sup>48</sup> EPC, *supra* note 27, art. 4.

<sup>49</sup> *Id.* art. 52(1).

<sup>50</sup> *Id.* art. 53(a)–(c).

<sup>51</sup> *Id.* art. 53(a).

<sup>52</sup> EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, pt. C, ch. IV-4.1 (2005) [hereinafter EPO GUIDELINES].

<sup>53</sup> Biotech Directive, *supra* note 27.

<sup>54</sup> *See id.*

<sup>55</sup> *Id.* art. 5(1).

<sup>56</sup> *Id.* art. 6(2)(c).



While both the United States and the EU permit the patenting of human cell lines,<sup>57</sup> the EBoA of the EPO issued their decision in November 2008 on the appeal of a WARF patent that had been previously rejected on moral grounds.<sup>58</sup> The EBoA affirmed the earlier ruling based on moral objections, under Article 53(a) of the EPC, and added that that it was “not possible to grant a patent for an invention that necessarily involves the use and destruction of human embryos,” which is a violation of Rule 28(c) of the Convention.<sup>59</sup>

## II. DISCUSSION

While the recent ruling on the WARF patent by the EBoA of the EPO and the traditional stance in the United States towards permitting such patents may have clarified respective national standards on the patenting of stem cells, the differing criteria utilized renders it difficult for a prospective patentee to ensure comprehensive intellectual property protection on an international scale.<sup>60</sup> Moreover, individual national policy towards stem cell research and funding must also be considered in terms of its effects on innovation and intellectual property rights.<sup>61</sup>

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<sup>57</sup> See generally *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985); European Patent No. 0428656 (filed May 14, 1990) (issued May 29, 1991).

<sup>58</sup> EBoA Decision, *supra* note 26, at 23–26. The EPC was revised in 2000. The current Rule 28(c) was Rule 23(d)(c) in the original EPC of 1973. EPC, *supra* note 27 (entered into force December 13, 2007).

<sup>59</sup> European Patent Office, No European Patent for WARF/Thomson Stem Cell Application, Nov. 27, 2008, <http://www.epo.org/topics/news/2008/20081127.html>.

<sup>60</sup> See generally '913 Patent, *supra* note 23; '806 Patent, *supra* note 23; '780 Patent, *supra* note 21; EBoA Decision, *supra* note 26.

<sup>61</sup> See Address to the Nation on Stem Cell Research, in 2 PUB. PAPERS 953 (Aug. 9, 2001) [hereinafter *GWB Address*]; European Commission Directorate General: Research, Summary of the 25 EU Member States Regulations on Human Embryonic Stem Cells Research (Feb. 2006), [http://ec.europa.eu/research/fp6/p1/stemcells/pdf/stemcell\\_hesc\\_regulations\\_2006feb.pdf](http://ec.europa.eu/research/fp6/p1/stemcells/pdf/stemcell_hesc_regulations_2006feb.pdf); EUR. COMM'N DIRECTORATE GENERAL: RESEARCH, DIRECTORATE E - BIOTECHNOLOGY, AGRICULTURE & FOOD, SURVEY ON OPINIONS FROM NATIONAL ETHICS COMMITTEES OR SIMILAR BODIES, PUBLIC DEBATE AND NATIONAL LEGISLATION IN RELATION TO HUMAN EMBRYONIC STEM CELL RESEARCH AND USE: IN EU MEMBER STATES I (July 2004) (Line Matthiessen-Guyader ed.), available at [http://ec.europa.eu/research/fp6/p1/stemcells/pdf/stemcell\\_survey\\_2004\\_i.pdf](http://ec.europa.eu/research/fp6/p1/stemcells/pdf/stemcell_survey_2004_i.pdf); EUR. COMM'N DIRECTORATE GENERAL: RESEARCH, DIRECTORATE E - BIOTECHNOLOGY, AGRICULTURE & FOOD, SURVEY ON OPINIONS FROM NATIONAL ETHICS COMMITTEES OR SIMILAR BODIES, PUBLIC DEBATE AND NATIONAL LEGISLATION IN RELATION TO HUMAN EMBRYONIC STEM CELL RESEARCH AND USE: COUNTRIES ASSOCIATED TO FP6 AND THIRD COUNTRIES 2 (July 2004) (Line Matthiessen-Guyader ed.), available at [http://ec.europa.eu/research/fp6/p1/stemcells/pdf/stemcell\\_survey\\_2004\\_ii.pdf](http://ec.europa.eu/research/fp6/p1/stemcells/pdf/stemcell_survey_2004_ii.pdf).

### A. Patents, Policy, and Scientific Research in the United States

The historical importance of patents in the United States is reflected in the constitutional grant of authority, which formed the foundation for a national patent system, by the Framers of the U.S. Constitution.<sup>62</sup> Furthermore, one of the earliest acts passed by the first Congress was the first U.S. patent statute in 1790.<sup>63</sup> Despite the significance given to the “promot[ion] of the Progress of Science,” tensions may arise when political policy agendas conflict with scientific research and hinder innovation, thereby impacting intellectual property.<sup>64</sup>

#### 1. WARF Patents

Patents for living biological matter, such as cell lines or organisms, have been allowed since *Chakrabarty*.<sup>65</sup> In 1998, James Thomson published his work, which was funded by the University of Wisconsin and Geron Corporation, on the first isolation of human ESC lines.<sup>66</sup> For this work, three patents, known respectively as the '780, the '806, and the '913 patent, were issued between 1998 and 2006, and the rights were assigned to WARF.<sup>67</sup> All three patent terms will expire by 2015.<sup>68</sup> The '780 patent claims both pluripotent primate ESCs and a method of isolating a primate ESC line.<sup>69</sup> Additionally, the '806 patent claims both pluripotent human ESCs and a method of isolating an hESC line.<sup>70</sup> The '913 patent also claims pluripotent hESCs.<sup>71</sup> Taken together, the breadth of the WARF patents could potentially cover any and all hESCs regardless of the process by which the cells are derived.<sup>72</sup> Subsequently, WARF has come under intense criticism by U.S.-based researchers for the cost and restrictiveness of its licensing practices.<sup>73</sup>

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<sup>62</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>63</sup> Patent Act of 1790, ch. 7, 1 Stat. 109, 109–12 (Apr. 10, 1790).

<sup>64</sup> See U.S. CONST. art. I, § 8, cl. 8; KOROBKIN, *supra* note 2, at 26–60.

<sup>65</sup> See MPEP, *supra* note 41, § 2105. See generally *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>66</sup> Carl Gulbransen, *WARF's Licensing Policy for ES Cell Lines*, 25 NATURE BIOTECHNOLOGY 387 (2007); Thompson, *supra* note 9.

<sup>67</sup> '913 Patent, *supra* note 23; '806 Patent, *supra* note 23; '780 Patent, *supra* note 21.

<sup>68</sup> See '913 Patent, *supra* note 23; '806 Patent, *supra* note 23; '780 Patent, *supra* note 21.

<sup>69</sup> '780 Patent, *supra* note 21.

<sup>70</sup> '806 Patent, *supra* note 23.

<sup>71</sup> '913 Patent, *supra* note 23.

<sup>72</sup> See '913 Patent, *supra* note 23; '806 Patent, *supra* note 23; '780 Patent, *supra* note 21; KOROBKIN, *supra* note 2, at 93, 96.

<sup>73</sup> KOROBKIN, *supra* note 2, at 96–99; Editorial, *Burning Bridges*, 25 NATURE 2 (2007).

In 2006, the Public Patent Foundation and the Foundation for Taxpayer and Consumer Rights filed requests with the U.S. PTO for the reexamination of all three WARF patents.<sup>74</sup> The two groups sought to invalidate the patents citing that they were obvious and not novel.<sup>75</sup> Upon reexamination, the U.S. PTO in 2007 issued a preliminary, non-final, rejection of the three WARF patents on the basis that they had not met the nonobviousness requirement.<sup>76</sup> The U.S. PTO upheld the '913 patent in February 2008.<sup>77</sup> They then issued final decisions upholding the '780 and '806 patents in March 2008.<sup>78</sup>

## 2. Stem Cell Policies and Restrictions

While there has been considerable debate over the moral and ethical use of human embryos in scientific research and for medical conditions, it was not until 1996 that Congress passed an appropriations bill that included a rider directed toward the issue of hESC research.<sup>79</sup> Congressman Jay Dickey introduced an amendment to the bill (The Dickey Amendment) that prohibited the Department of Health and Human Services (HHS) from using its funds for “the creation of a human embryo or embryos for research purposes” or for “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero.”<sup>80</sup> HHS also provides the funding for the National Institutes of Health (NIH), a major source of scientific research grants in the United States.<sup>81</sup> President William Clinton signed

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<sup>74</sup> *Two Groups Try for Revocation of Human Embryonic Stem Cell Patents*, 25 BIOTECHNOLOGY L. REP. 555 (Oct. 2006).

<sup>75</sup> KOROBKIN, *supra* note 2, at 118.

<sup>76</sup> *Id.* at 119.

<sup>77</sup> Press Release, Geron Corp., U.S. Patent Office Upholds Key Human Embryonic Stem Cell Patent (Feb. 28, 2008), <http://www.geron.com/media/pressview.aspx?id=833>; WARF-PTO PR1, *supra* note 25.

<sup>78</sup> Press Release, Geron Corp., U.S. Patent Office Upholds Two Additional Human Embryonic Stem Cell Patents in Reexamination Decisions (Mar. 11, 2008), <http://www.geron.com/media/pressview.aspx?id=834>; WARF-PTO PR2, *supra* note 25. It is not unusual for the U.S. PTO to issue preliminary rejections and then later affirm the patents. U.S. PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2008 127–28 (2008), available at <http://www.uspto.gov/web/offices/com/annual/2008/2008annualreport.pdf>.

<sup>79</sup> Balanced Budget Downpayment Act, I, Pub. L. No. 104–99, § 128, 110 Stat. 26, 34 (1996).

<sup>80</sup> *Id.* § 128, 110 Stat. at 34.

<sup>81</sup> See DEP'T OF HEALTH AND HUMAN SERVS. FISCAL YEAR 2008 CITIZENS' REPORT: SUMMARY OF PERFORMANCE AND FINANCIAL RESULTS, <http://www.hhs.gov/budget/Citizens->

the Dickey Amendment into law, which has been renewed annually ever since.<sup>82</sup> Essentially, the amendment rendered any scientific research on hESCs ineligible for federal funding.<sup>83</sup> Indeed, the breakthrough hESC research by Thomson, which led to the WARF patents, was, as a matter of course, funded through private sources.<sup>84</sup>

Soon after Thomson revealed his successful creation of hESC lines, the General Counsel of HHS, Harriet S. Rabb, issued a legal opinion, at the request of the Director of NIH, on whether federal funding was necessarily prohibited for research on hESC lines that were already established.<sup>85</sup> Rabb stated that the “statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply” to research on hESCs because the cells did not meet the statutory definition of a human embryo.<sup>86</sup> Furthermore, the memorandum noted that hESCs “cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term.”<sup>87</sup> Subsequently, in 2000, NIH published guidelines for research on hESCs.<sup>88</sup> The NIH guidelines permitted federal funding for hESC research where the cells were not derived from human embryos created for research purposes.<sup>89</sup> Upon taking office in 2001, President Bush ordered the Secretary of HHS, Tommy Thompson, to evaluate the new NIH guidelines and to postpone the review of pending hESC research grant applications.<sup>90</sup>

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port.pdf; National Institutes of Health, NIH Budget, <http://www.nih.gov/about/budget.htm> (last visited Mar. 23, 2010).

<sup>82</sup> See KOROBKIN, *supra* note 2, at 27; *see, e.g.*, Omnibus Appropriations Act, 2009, Pub. L. No. 111–8, § 509, 123 Stat. 524, 803 (2009); Consolidated Appropriations Act, 2008, Pub. L. No. 110–161, § 509, 121 Stat. 1844 (2007); Dep’t of Labor, Health and Human Servs., and Educ., and Related Agencies Appropriations Act, 2006, Pub. L. No. 109–149, § 509, 119 Stat. 2833, 2880 (2005); Consolidated Appropriations Act, 2005, Pub. L. No. 108–447, § 509, 118 Stat. 2809, 3163–64 (2004).

<sup>83</sup> See KOROBKIN, *supra* note 2, at 27.

<sup>84</sup> Gulbransen, *supra* note 66, at 387; Thompson, *supra* note 9.

<sup>85</sup> Memorandum from Harriet S. Rabb, General Counsel of the Dep’t of Health and Human Servs., to Harold Varmus, M.D., Director, NIH, on Federal Funding of Research Involving Human Pluripotent Stem Cells (Jan. 15, 1999), <http://kie.georgetown.edu/nrdbl/documents/rabbmemo.pdf>.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> Nat’l Insts. of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,978–79 (Aug. 25, 2000).

<sup>89</sup> *Id.*

<sup>90</sup> Gretchen Vogel, *Embryonic Stem Cells: Court Asked to Declare NIH Guidelines Legal*, 292 SCI. 1463 (2001).

On August 9, 2001, President Bush delivered a presidential address to the nation and announced that his administration would only permit federal funding for stem cell research on cell lines already in existence at the time.<sup>91</sup> Within hours of the President's address, the Secretary of HHS and the Acting Director of NIH issued statements in support of the policy.<sup>92</sup> NIH later withdrew the earlier guidelines for hESC research.<sup>93</sup>

Despite his announced policy, President Bush never formally issued an executive order that called for the prohibition of funding for hESC lines created after August 9, 2001 or that banned research that involved the destruction of embryos.<sup>94</sup> In response to Congress's attempt in 2006 to relax the policy restraints on hESC research by passing the Stem Cell Research Enhancement Act, President Bush issued the first veto of his presidency, then in its fifth year.<sup>95</sup> In 2007, Congress tried again to enact the Stem Cell Research Enhancement Act, and, once more, it was vetoed by President Bush.<sup>96</sup> On the same day, President Bush signed an executive order requiring the Secretary of Health and Human Services to conduct and direct research towards the isolation of hESCs that could be obtained through alternative methods of derivation.<sup>97</sup> This executive order gave priority to and federal funds for

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<sup>91</sup> See GWB Address, *supra* note 61. The NIH then created the Human Embryonic Stem Cell Registry to comply with this policy. This registry originally only listed the hESC lines that were eligible for federal funding. Nat'l Insts. of Health, Notice on NIH Funding of Research Using Specified Existing Human Embryonic Stem Cells, NOT-OD-01-058 (Aug. 27, 2001), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-059.html>. The NIH later expanded the list, changing the name to the NIH Human Pluripotent Stem Cell Registry pursuant to an Executive Order, to include human pluripotent stem cells that are derived from non-embryonic sources. Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 22, 2007) [hereinafter EO 13435]; National Institutes of Health, Human Pluripotent Stem Cell Registry FAQs [Stem Cell Information], [http://stemcells.nih.gov/research/registry/pluripotent\\_faq.asp](http://stemcells.nih.gov/research/registry/pluripotent_faq.asp) (last visited Mar. 23, 2010).

<sup>92</sup> Press Release, Ruth Kirschstein, Acting Dir. of the Nat'l Insts. of Health, NIH Statement on the President's Stem Cell Address (Aug. 9, 2001), <http://www.nih.gov/news/pr/aug2001/od-09.htm>; Press Release, Tommy G. Thompson, Sec'y, Dep't of Health and Human Servs., Regarding the President's Decision on Human Embryonic Stem Cell Research (Aug. 9, 2001), <http://www.hhs.gov/news/press/2001pres/20010809.html>.

<sup>93</sup> Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells, 66 Fed. Reg. 57,107 (Nov. 14, 2001).

<sup>94</sup> KOROBKIN, *supra* note 2, at 39.

<sup>95</sup> President's Message to the House of Representatives Returning Without Approval the "Stem Cell Research Enhancement Act of 2005," 42 WEEKLY COMP. PRES. DOC. 1365 (July 19, 2006).

<sup>96</sup> President's Message to the Senate Returning Without Approval the "Stem Cell Research Enhancement Act of 2007," 43 WEEKLY COMP. PRES. DOC. 833 (June 20, 2007).

<sup>97</sup> EO 13435, *supra* note 91.

identifying new methods of isolating, deriving, producing, and testing hESCs and still maintained the funding ban on any research on established hESC lines derived from embryos.<sup>98</sup>

There were indications early on that these restrictions on federal funding for hESC research would be lifted by the incoming presidential administration.<sup>99</sup> As part of his election platform, and also soon after taking office, candidate and later President Barack Obama stated his intent to revisit the issue of federal funding of hESC research beyond the prescribed cell lines.<sup>100</sup> On March 9, 2009, President Obama signed an executive order that revoked President Bush's 2007 executive order and restored federal funding for research on all hESC lines, regardless of derivation methods.<sup>101</sup>

### 3. Hindering the "Progress of Science"?

The confluence of a restrictive government policy on hESC research and the broad scope of the WARF patents have constrained the ability of many scientists to conduct hESC research.<sup>102</sup> While President Bush, in articulating his policy towards limiting federal funding to only then-established hESC lines, stated that "more than 60 genetically diverse stem cells lines already exist,"<sup>103</sup> hESC researchers were quick to question not only the accuracy of the number but also the adequacy of the cell lines.<sup>104</sup> Indeed, some have stated that the actual

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<sup>98</sup> *See id.*

<sup>99</sup> Rob Stein, *Scientists Await Action on Stem Cells*, WASH. POST, Feb. 19, 2009, at A02.

<sup>100</sup> *See* The White House, *The Agenda: Technology*, <http://www.whitehouse.gov/agenda/technology> (last visited Mar. 23, 2010) (advocating greater federal government funding on a wider array of stem cell lines); Barack Obama & Joe Biden: *The Change We Need, Technology*, <http://www.barackobama.com/issues/technology> (last visited Mar. 23, 2009) (stating campaign platform on advancing stem cell research through increased funding).

<sup>101</sup> Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009) [hereinafter EO 13505].

<sup>102</sup> *See generally* Constance Holden & Gretchen Vogel, "Show Us the Cells," *U.S. Researchers Say*, 297 SCI. 923 (2002); *New Limits on Funding of Stem Cell Research Questioned*, 18 ISSUES SCI. & TECH. 29 (2001).

<sup>103</sup> GWB Address, *supra* note 61.

<sup>104</sup> *See* COMM. ON GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH, NAT'L RESEARCH COUNCIL, GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 18 (2005) [hereinafter NRC GUIDELINES]; *see also* Press Release, Am. Ass'n for the Advancement of Sci., President Bush's Stem Cell Policy (Aug. 17, 2001), [http://rp.www.aaas.org/spp/cstc/docs/01-08-17\\_stemstmt.htm](http://rp.www.aaas.org/spp/cstc/docs/01-08-17_stemstmt.htm). The National Research Council outlined the potential difficulties associated with the hESC lines cited to by President Bush:

Not all the original hES cell lines thought to be available for federally funded research have been viable, nor do they exhibit sufficient genetic diversity for all research endeavors and possible future clinical use. Furthermore, the roughly 22 lines now available were grown on mouse-feeder cell layers. . . .

number of viable stem cell lines at the time may have been less than five.<sup>105</sup>

Moreover, the utilization of a combination of Material Transfer Agreements (MTA) and licensing fees for the WARF patents has proved onerous on not only commercial hESC endeavors but also on academic research.<sup>106</sup> The MTAs require an initial cash payment and include commercial reach-through rights, which prohibit commercial research without another licensing agreement.<sup>107</sup> Departing from the convention of a single payment per academic institution, WARF also sought to charge per cell line and for each individual investigator within an institution.<sup>108</sup> Commercial licensing fees ranged from \$75,000 to \$400,000, plus royalties on any sales.<sup>109</sup> In response to the objections raised by the scientific community, WARF modified its policy and no longer requires a license for industry-sponsored research performed at academic or non-profit institutions.<sup>110</sup>

### B. *Biotechnology and EU Standards*

The EPO, which is an organ of the European Patent Organization, governs the granting of patents in Europe.<sup>111</sup> The Organization is an intergovernmental organization that was established by the EPC.<sup>112</sup> There are currently 35 member states within the Organization.<sup>113</sup> While the EPO may grant patents, the enforcement of these patents is left to the individual member states and their respective national laws.<sup>114</sup> Several European Patent Organization member states also have their own

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The presence of animal feeder cells increases the risk of transfer of animal viruses and other infectious agents to humans that receive the hES cells and in turn to many others.

NRC GUIDELINES, *supra*.

<sup>105</sup> Gerald D. Fischbach & Ruth L. Fischbach, *Stem Cells: Science, Policy, and Ethics*, 114 J. CLINICAL INVESTIGATION 1364, 1368 (2004); *see* Holden & Vogel, *supra* note 102, at 923.

<sup>106</sup> Kenneth S. Taymor, Christopher T. Scott & Henry T. Greely, *The Paths Around Stem Cell Intellectual Property*, 24 NATURE BIOTECHNOLOGY 411, 411 (2006).

<sup>107</sup> *Id.*; *Burning Bridges*, *supra* note 73, at 2.

<sup>108</sup> *Burning Bridges*, *supra* note 73, at 2.

<sup>109</sup> *Id.*

<sup>110</sup> Press Release, WARF, Wisconsin Alumni Research Foundation Changes Stem Cell Policies to Encourage Greater Academic, Industry Collaboration (Jan 23, 2007), [http://www.warf.org/news/news.jsp?news\\_id=209](http://www.warf.org/news/news.jsp?news_id=209).

<sup>111</sup> EPC, *supra* note 27, art. 4(2).

<sup>112</sup> *Id.*

<sup>113</sup> European Patent Office, Member States of the European Patent Organisation, <http://www.epo.org/about-us/epo/member-states.html> (last visited Mar. 23, 2010).

<sup>114</sup> EPC, *supra* note 27, art. 74.

independent patent offices, which grant national patents.<sup>115</sup> Furthermore, inventors must still file individual national patent applications in those states that are not signatories to the EPC.<sup>116</sup> The European Parliament and EU Council issued a Biotech Directive, which prohibited patents for inventions that used human embryos for commercial purposes, to harmonize divergent patent laws between the EU and EPO member states.<sup>117</sup> This Biotech Directive was then incorporated into the EPC.<sup>118</sup> All twenty-seven EU member states have implemented its provisions into their domestic laws.<sup>119</sup>

## 1. WARF European Patent Application

While fetal and adult stem cells are patentable in Europe,<sup>120</sup> the issue of whether hESCs are patentable had not been settled when WARF sought just such a patent.<sup>121</sup> The patent application was initially refused by the EPO on the grounds that it was prohibited under Article 53(a) and Rule 28(c) of the EPC.<sup>122</sup> Article 53(a) excludes inventions that would be contrary to “ordre public” or morality.<sup>123</sup> Rule 28(c) further specifies that patents cannot be granted for inventions concerning the “use of human embryos for industrial or commercial purposes.”<sup>124</sup> Upon appeal, the EPO Technical Board of Appeal (TBA) referred four questions to the EPO EBoA, as permitted under Article 112(a) of the EPC.<sup>125</sup> Decisions by the EBoA are binding on the EPO.<sup>126</sup>

The TBA asked the EBoA to clarify several issues: (1) whether Rule 28(c) was applicable to the WARF patent application, given that the application had been filed prior to the entry into force of the rule; (2) if Rule 28(c) was in force, then is the rule applicable to the WARF application even if the method is not part of the claims?; (3) if the answers to questions 1 and 2 were no, did Article 53(a) forbid the patent-

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<sup>115</sup> Marco T. Connor & Lin Yasong, *How to Get Patent Protection in Europe?*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 169, 170–79 (2008).

<sup>116</sup> *Id.*

<sup>117</sup> See Biotech Directive, *supra* note 27.

<sup>118</sup> See *id.*; EPC, *supra* note 27, R. 28.

<sup>119</sup> European Union, State of Play of the Implementation of Directive 98/44/EC (Jan. 15, 2007), [http://ec.europa.eu/internal\\_market/indprop/docs/invent/state-of-play\\_en.pdf](http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf) [hereinafter State of Play].

<sup>120</sup> See EPC, *supra* note 27, R. 29(2).

<sup>121</sup> See generally EBoA Decision, *supra* note 26.

<sup>122</sup> *Id.* at 3.

<sup>123</sup> EPC, *supra* note 27, art. 53(a).

<sup>124</sup> *Id.* R. 28(c).

<sup>125</sup> *Id.* art. 112(a); EBoA Decision, *supra* note 26, at 3.

<sup>126</sup> EPC, *supra* note 27, art. 112(3).



ing of such claims?; and (4) is it relevant that after the filing date, the same products could be obtained without using a method that necessarily involved the destruction of human embryos?<sup>127</sup>

On November 25, 2008, the EPO EBoA issued its decision. In addressing the first question, the EBoA ruled that Rule 28(c) was applicable to pending patent applications because it did not require transitional provisions for pending cases.<sup>128</sup> As such, the rule must encompass the pending patent applications.<sup>129</sup> With respect to question 2, the EBoA noted that the text of Rule 28(c) is not directed toward the claims but refers to “inventions” as a whole.<sup>130</sup> Since questions 1 and 2 were answered in the affirmative, the EBoA did not reply to the third question.<sup>131</sup> The EBoA answered the final question by ruling that technical developments that became public after the filing date were irrelevant to determining whether a claim violates Rule 28(c).<sup>132</sup> The EBoA concluded that its decision was “not concerned with the patentability in general of inventions relating to human stem cells or human stem cell cultures” but that it prohibited patents for “inventions concerning [human stem cell cultures] which can only be obtained by the use involving their destruction of human embryos.”<sup>133</sup>

## 2. United Kingdom—A Nuanced Perspective

The United Kingdom Intellectual Property Office (U.K.-IPO) has issued its own guidance on the patentability of biotechnological inventions.<sup>134</sup> Similar to the EPO, they note that certain processes and things are not patentable for commercial purposes because they would be contrary to public morality, where the excluded inventions encompass “the commercial or industrial use of human embryos.”<sup>135</sup>

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<sup>127</sup> EBoA Decision, *supra* note 26, at 1–2.

<sup>128</sup> *Id.* at 17–19, 30.

<sup>129</sup> *See id.*

<sup>130</sup> *Id.* at 19–28, 30; EPC, *supra* note 27, R. 28(c).

<sup>131</sup> *See* EBoA Decision, *supra* note 26, at 28, 30.

<sup>132</sup> *Id.* at 28–30.

<sup>133</sup> *Id.* at 29–30.

<sup>134</sup> U.K. Intellectual Property Office, Intellectual Property Office—Biotechnological Inventions – Excluded Inventions, <http://www.ipo.gov.uk/pro-types/pro-patent/p-policy/p-policy-biotech/p-policy-biotech-excluded.htm> (last visited Mar. 23, 2010).

<sup>135</sup> *Id.*

Notwithstanding the public morality criteria, the U.K.-IPO currently permits patent applications for pluripotent hESCs.<sup>136</sup> The U.K.-IPO draws a distinction between totipotent and pluripotent hESCs, stating that human totipotent cells, unlike pluripotent hESCs, can potentially develop into an entire human body.<sup>137</sup> The U.K.-IPO thus holds them unpatentable because “the human body at various stages of its formation and development is excluded from patentability.”<sup>138</sup>

### III. ANALYSIS

There are several rationales for the pursuit of global harmonization of patent laws and the creation of a unified patent system.<sup>139</sup> Harmonization would bring increased efficiency to patent offices and certainty to patentees.<sup>140</sup> In addition, harmonization could reduce disparate patent status across states, where an invention would be granted a patent in one state, but a parallel patent application in another state would be denied.<sup>141</sup> By setting a common standard, patent offices would be able to coordinate their prior art searches and patent application examinations.<sup>142</sup> This effect would not only reduce the overall cost to the patent offices, but it would also reduce the expenses of the patent applicant, as the applicant need not be concerned with addressing varying national patent standards.<sup>143</sup>

Moreover, uniformity may enhance the effectiveness in enforcing intellectual property rights.<sup>144</sup> This increased certainty in the value and security of global intellectual property rights may also lead to greater disclosures by inventors, which ultimately benefits the public.<sup>145</sup> Indeed, it has been proposed that harmonization would balance the incentive

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<sup>136</sup> U.K. Intellectual Property Office, Intellectual Property Office—Inventions Involving Human Embryonic Stem Cells (Feb. 3, 2009), <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm> (last visited Mar. 23, 2010).

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

<sup>138</sup> *Id.*; see Patents Act, 1977, Schedule A2(3)(a) (Eng.).

<sup>139</sup> See generally Donald S. Chisum, *The Harmonization of International Patent Law*, 26 J. MARSHALL L. REV. 437 (1993); Annelise M. Seifert, *Will the United States Take the Plunge into Global Patent Law Harmonization? A Discussion of the United States' Past, Present, and Future Harmonization Efforts*, 6 MARQ. INTELL. PROP. L. REV. 173 (2002).

<sup>140</sup> See Chisum, *supra* note 139, at 449–52; Seifert, *supra* note 139, at 200.

<sup>141</sup> Chisum, *supra* note 139, at 449–50.

<sup>142</sup> *Id.* at 451.

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

<sup>144</sup> *Id.*

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

system and “no country will take a ‘free ride’ on the investment in research and development that other countries’ patent systems induce.”<sup>146</sup>

While harmonization of patent laws would provide much needed clarity to patent holders seeking to protect their intellectual property rights globally, there are also disincentives to states seeking to adopt uniform patent laws.<sup>147</sup> These disincentives may include initial difficulties in achieving agreement between states on precisely what these patent laws should be and later problems with altering undesirable or obsolete provisions.<sup>148</sup>

#### A. Moral Relevance in Stem Cell Patentability

Unlike the EU, the United States presently divorces the issue of morals from that of whether stem cells are patentable subject matter.<sup>149</sup> Despite this formal separation, the United States can interject morality and limit what inventions may be patentable through the enactment of legislation.<sup>150</sup> The mere granting of a patent does not necessarily result in the practice of the patented invention.<sup>151</sup> States may choose to enact legislation that prevents the application or dissemination of the invention.<sup>152</sup>

A major impediment to injecting morals into determining patentability is that any such criteria are necessarily subjective and may not be universal in scope.<sup>153</sup> Morality may differ from state to state depending on a number of factors, including ethics and cultural influences.<sup>154</sup> Even within the EU itself, questions have been raised about how to

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<sup>146</sup> *Id.* at 450–51; *see also* James A. Sfekas, *Controlling Business Method Patents: How the Japanese Standard for Patenting Software Could Bring Reasonable Limitations to Business Method Patents in the United States*, 16 PAC. RIM L. & POL’Y J. 197, 223–24 (2007).

<sup>147</sup> Chisum, *supra* note 139, at 452–54; Paul H. Jensen, Alfons Palangkaraya & Elizabeth Webster, *Disharmony in International Patent Office Decisions*, 15 FED. CIR. B.J. 679, 683 (2006).

<sup>148</sup> Chisum, *supra* note 139, at 452–53; Jensen et al., *supra* note 147, at 683–84.

<sup>149</sup> *See generally* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999); EPC, *supra* note 27, art. 53(a); ‘913 Patent, *supra* note 23; ‘806 Patent, *supra* note 23; Media Advisory, *supra* note 44.

<sup>150</sup> *See Juicy Whip*, 185 F.3d at 1368; *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

<sup>151</sup> UNCTAD-ICTSD, *RESOURCE BOOK ON TRIPS AND DEVELOPMENT* 382–83 (2005).

<sup>152</sup> KOROBKIN, *supra* note 2, at 96; Rutz & Yeats, *supra* note 2, at 384.

<sup>153</sup> UNCTAD-ICTSD, *supra* note 151, at 375 (noting that “[t]he concept of morality is relative to the values prevailing in a society. Such values are not the same in different cultures and countries, and change over time”); *see also* Chisum, *supra* note 139, at 438 (“[N]o harmonization model will conform exactly to the laws of any country. . . . It is possible that consensus cannot be reached . . .”).

<sup>154</sup> *See* UNCTAD-ICTSD, *supra* note 151, at 375; Chisum, *supra* note 139, at 453.

identify the European morality standard.<sup>155</sup> Further inconsistency has been noted with respect to the two distinct tests that have been used for assessing patent challenges based on morality under the EPC.<sup>156</sup> One test relies on whether there would be “public abhorrence” over the granting of a patent.<sup>157</sup> The second test examines whether the patent grant would be “unacceptable” under “conventionally accepted standards of conduct of European culture.”<sup>158</sup> It is not difficult to see where an invention might not reach the standard of “public abhorrence” but could still be found “unacceptable” and be denied a patent.<sup>159</sup>

An additional consideration is whether patent offices themselves would be reluctant or have sufficient guidance to make determinations on whether an invention overcomes the morals hurdle to obtaining a patent.<sup>160</sup> Under EPO patent examination rules, the examiner would look first to see if an invention is within the list of specifically exempted inventions and then consider the morality issue.<sup>161</sup> Commentators have noted that a temporal ambiguity exists for the morality assessment.<sup>162</sup> It is unclear as to whether this determination should be performed at the time of the patent application or after the granting of the patent.<sup>163</sup> This ambiguity raises additional issues concerning if, by whom, and when opponents of the patents should be notified.<sup>164</sup>

Should the United States choose to harmonize its patent laws with those of the EU and introduce moral hurdles to patentability, there may well be confusion over precisely which standards should prevail.<sup>165</sup>

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<sup>155</sup> See AURORA PLOMER, UNIVERSITY OF NOTTINGHAM: SCHOOL OF LAW, STEM CELL PATENTS: EUROPEAN PATENT LAW AND ETHICS REPORT 1, 111–12 (2006), <http://www.nottingham.ac.uk/law/StemCellProject/project.report.pdf> [hereinafter NOTTINGHAM REPORT] (summarizing several different perspectives of what constitutes European morality, including “common European concepts,” “fairly widely shared perceptions,” or as laid out in the European Convention on Human Rights and Fundamental Freedoms).

<sup>156</sup> Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT’L L. 1, 21–36 (2001).

<sup>157</sup> *Id.* at 21–27.

<sup>158</sup> *Id.* at 21.

<sup>159</sup> *See id.*

<sup>160</sup> Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 709–13 (2004); *see* Gitter, *supra* note 156, at 36–43.

<sup>161</sup> EPO GUIDELINES, *supra* note 52, pt. C, ch. II-7.1 to 7.2, ch. IV-4.1; NOTTINGHAM REPORT, *supra* note 155, at 107–08.

<sup>162</sup> Enerson, *supra* note 160, at 712; Gitter, *supra* note 156, at 39.

<sup>163</sup> Enerson, *supra* note 160, at 712; Gitter, *supra* note 156, at 39.

<sup>164</sup> *See* ENERSON, *supra* note 160, at 712; Gitter, *supra* note 156, at 39.

<sup>165</sup> *See* NOTTINGHAM REPORT, *supra* note 155, at 51–52, 111–12, 133; Heike Vogelsang-Wenke, *Patenting of Stem Cells and Processes Involving Stem Cells According to the Rules of the European Patent Convention*, 23 BIOTECHNOLOGY L. REP. 155, 158 (2004).

In instances where a definitive European wide moral standard has yet to be established, it has been suggested that patents be granted and individual states can then invalidate the patents, if necessary, according to their national norms.<sup>166</sup> Moreover, cultural shifts may also affect morality standards over time.<sup>167</sup> Allowing current measures of morality to influence the patenting of innovations would introduce more unpredictability into the patent system.<sup>168</sup> Patents, once granted, may run the risk of revocation.<sup>169</sup> Indeed, in 2006, the Bundespatentgericht/BPatG (German Federal Patent Court) partially revoked a 1999 patent directed to a method for producing ESCs.<sup>170</sup> Despite the fact that the patent did not claim industrial or commercial use of human embryos, the BPatG nullified the patent claims directed toward ESC lines derived from human embryos while upholding the claims for ESCs derived from other sources.<sup>171</sup> Given that Germany incorporated the Biotech Directive into the German Patent Act in 2004,<sup>172</sup> and that the patent itself was granted in 1999, this decision was a retroactive application of the moral patentability exclusion for inventions.<sup>173</sup>

Amid these concerns, the application of moral criteria to U.S. patentability determinations will likely only add uncertainty into the patent application process.<sup>174</sup> Furthermore, morality standards are not static, and meaningful consensus on such moral patentability criteria may be

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<sup>166</sup> NOTTINGHAM REPORT, *supra* note 155, at 112–13.

<sup>167</sup> UNCTAD-ICTSD, *supra* note 151, at 375.

<sup>168</sup> See ENERSON, *supra* note 160, at 714–15.

<sup>169</sup> See NOTTINGHAM REPORT, *supra* note 155, at 112–13.

<sup>170</sup> Bundespatentgericht [BPatG] [Federal Patent Court] Dec. 5, 2006, ref. no. 3 Ni 42/04 (F.R.G.) [hereinafter BPatG Decision]; Stefan Danner, *Stem Cell Patent Partially Revoked*, MANAGING INTELL. PROP., May 1, 2007, <http://www.managingip.com/Article/1377031/Stem-cell-patent-partially-revoked.html>; see *Neurale Vorläuferzellen, Verfahren zu ihrer Herstellung und ihre Verwendung zur Therapie von neuronalen Defekten* [Neural Precursor Cells, Method for the Production and Use Thereof in Neural Defect Therapy], F.R.G. Patent No. DE 19756864 (issued Apr. 29, 1999).

<sup>171</sup> BPatG Decision, ref. no. 3 Ni 42/04; Thomas Friede, *German Federal Patent Court Decided on the Morality of Deriving Cells (3 Ni 42/04—Greenpeace v. Oliver Brüstle) from Human Embryonic Stem (ES) Cells*, VI BARDEHLE PAGENBERG IP REP. 3 (2006), [http://www.bardehle.com/uploads/media/IP\\_Report\\_2006\\_VI.pdf](http://www.bardehle.com/uploads/media/IP_Report_2006_VI.pdf).

<sup>172</sup> State of Play, *supra* note 119, at 1–2; Franz-Josef Zimmer & Svenja Sethmann, *Act Implementing the Directive on the Legal Protection of Biotechnological Inventions in Germany (BioPatG)*, 24 BIOTECHNOLOGY L. REP. 561, 561 (2005).

<sup>173</sup> Friede, *supra* note 171, at 3. The German Patents Act, in language that mirrors that of the Biotech Directive, prohibits the granting of patents for inventions involving the use of human embryos for industrial or commercial purposes. Das deutsche Patentgesetz [German Patents Act], Dec. 18, 1980, BGBl. I, § 2, available at <http://www.gesetze-im-internet.de/bundesrecht/patg/gesamt.pdf>.

<sup>174</sup> See ENERSON, *supra* note 160, at 714–15.

difficult to reach.<sup>175</sup> The potential for retroactive revocation of patents, based solely on newly established standards, may also serve to discourage patentees.<sup>176</sup> Higher litigation costs may result from increased patent revocation attempts, which may be encouraged by the enactment of moral hurdles to patentability.<sup>177</sup>

### B. Confluence of Policy and Patents: Impact on Stem Cell Research

Patents are granted to encourage innovation and as a reward for disclosing the invention.<sup>178</sup> This quid pro quo of sufficient disclosure for the monopoly granted to the patentee has been a fundamental principle of the patent system.<sup>179</sup> The intersection of patent law, legislative policy, and science has retarded the progress of stem cell research, where privatization of resources, concomitant with a withdrawal of federal funding, has impeded research and development.<sup>180</sup>

#### 1. Policy and WARF Factors Have Hindered U.S. Stem Cell Research

Given the broad scope of the patent claims over the development of hESCs and over hESCs themselves, WARF is able to prohibit any derivation, use, importation, or research into hESC lines in the United States unless interested parties first enter into licensing agreements.<sup>181</sup>

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<sup>175</sup> Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 539–45 (2003); see also Enerson, *supra* note 160, at 714–15.

<sup>176</sup> See Bagley, *supra* note 175, at 539–45; Adam Inch, *The European Patent Convention: A Moral Roadblock to Biotechnological Innovation in Europe*, 20 HOUS. J. INT'L L. 203, 215–16 (2007); Robin Beck Skarstad, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. PA. J. INT'L ECON. L. 353, 371–72 (1999). In *Patlex Corp. v. Mossinghoff*, the Federal Circuit held that retroactive application of the reexamination statute was constitutional and did not violate the due process clause because it was in the class of curative statutes “designed to cure defects in an administrative system.” 758 F.2d 594, 603 (Fed. Cir.), *modified*, 771 F.2d 480 (Fed. Cir. 1985).

<sup>177</sup> See Skarstad, *supra* note 176, at 371–72.

<sup>178</sup> Eisenberg, *supra* note 4, at 1017.

<sup>179</sup> *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002); *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944).

<sup>180</sup> See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998); Aurora Plomer et al., *Challenges to Human Embryonic Stem Cell Patents*, 2 CELL STEM CELL 13, 13–15 (2008); Patrick L. Taylor, *The Gap Between Law and Ethics in Human Embryonic Stem Cell Research: Overcoming the Effect of U.S. Federal Policy on Research Advances and Public Benefit*, 11 SCI. ENG'G ETHICS 589, 600–05 (2005).

<sup>181</sup> Plomer et al., *supra* note 180, at 13; Jeanne F. Loring & Cathryn Campbell, *Intellectual Property and Human Embryonic Stem Cell Research*, 311 SCI. 1716, 1717 (2006); *Burning Bridges*, *supra* note 73, at 2.

Additionally, due to the essential nature of having access to and the ability to generate new hESCs for research purposes, WARF's patents are substantial impediments to the ideal of granting patents to "promot[e] the Progress of Science."<sup>182</sup> Granting a monopoly on a basic scientific research tool can severely limit subsequent research.<sup>183</sup> Commentators have warned of the danger in granting overly broad patents in biotechnology because it enables "the individual or firm who first came up with a particular practical application to control a broad array of improvements and applications."<sup>184</sup> Innovation and discoveries in biotechnology are dependent on building upon fundamental techniques.<sup>185</sup> The granting of a patent that covers all hESC lines without regard to the method of derivation does little to encourage subsequent innovation and improvements.<sup>186</sup> In this instance, the public benefit is not at all commensurate with the monopoly rights.<sup>187</sup>

While financial interests may provide incentive for patent holders to license their innovations for commercial purposes, academic researchers have often been spared the full brunt of transaction costs associated with utilizing patented innovations.<sup>188</sup> With the increased interest by academic institutions in patenting and protecting their intellectual property, there is less of a distinction between academic and purely commercial entities.<sup>189</sup> Although the WARF patents were a significant hindrance to academic stem cell researchers, the limiting of federal funding by President Bush was equally, if not more, onerous.<sup>190</sup> The combination of these

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<sup>182</sup> U.S. CONST. art I, § 8, cl. 8.

<sup>183</sup> Heller & Eisenberg, *supra* note 180, at 698. "A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development." *Id.*

<sup>184</sup> Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 884 (1990).

<sup>185</sup> See Heller & Eisenberg, *supra* note 180, at 698.

<sup>186</sup> See Merges & Nelson, *supra* note 184, at 904. "If the initial patent is granted on the product, rather than the process for making it, subsequent process research by others will be discouraged. This is a good example of a prospect that will likely reduce competition for improvements." *Id.*

<sup>187</sup> See *id.* at 843-44.

<sup>188</sup> See Heller & Eisenberg, *supra* note 180, at 698 (noting that intellectual property claims now exist on research that would have previously been in the public domain); Loring & Campbell, *supra* note 181, at 1717 (stating that the NIH signed agreements with WARF for hESC research rights and WARF agreed to not impose more restrictive terms on non-profit institutions); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 294 (2003).

<sup>189</sup> See Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in the Proper Place*, 47 B.C. L. REV. 217, 218-19 (2006); Heller & Eisenberg, *supra* note 180, at 698; Rai & Eisenberg, *supra* note 188, at 294.

<sup>190</sup> See GWB Address, *supra* note 61.

two factors had effects on not only issues pertaining to seeking new sources of research funds but also where and how stem cell research would be pursued.<sup>191</sup>

Federal funds have consistently accounted for the majority of academic funding for scientific research and development.<sup>192</sup> In 2006, federal support accounted for approximately 63% of the funding spent by academic institutions on research and development.<sup>193</sup> The funding limitations created by President Bush's stem cell policy forced academic institutions and researchers to carefully segregate any research conducted on non-sanctioned hESCs from all other federally funded research occurring in their facilities.<sup>194</sup> Essentially, no federally funded equipment, space, materials, supplies, or staff could be used for any such research.<sup>195</sup> In practice, the inability to utilize existing laboratory equipment and the difficulties associated with ensuring strict separation of consumables and staff required institutions to seek and use private funds to establish duplicate research facilities for the sole purpose of conducting stem cell research.<sup>196</sup> In response to the federal policy, additional funding for hESC research was authorized by eight states, including California and New York.<sup>197</sup>

While early fears of vast numbers of stem cell researchers leaving the United States for foreign institutions have been unfounded, several prominent stem cell researchers have left to pursue their research in Asia.<sup>198</sup> Singapore, with more liberal research laws, has devoted government resources to establishing itself as a leader in stem cell research and enticing notable scientists there.<sup>199</sup> By contrast, the diverse stem cell research regulations among the EU member states, ranging from permissive to prohibitive towards embryo research and hESC deriva-

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<sup>191</sup> See Taylor, *supra* note 180, at 596–98.

<sup>192</sup> RONDA BRITT ET AL., NAT'L SCI. BD., SCIENCE AND ENGINEERING INDICATORS 5–11 (2008), available at <http://www.nsf.gov/statistics/seind08/toc.htm>.

<sup>193</sup> *Id.*

<sup>194</sup> KOROBKIN, *supra* note 2, at 55; Taylor, *supra* note 180, at 597–98.

<sup>195</sup> See KOROBKIN, *supra* note 2, at 55; Taylor, *supra* note 180, at 597–98.

<sup>196</sup> See KOROBKIN, *supra* note 2, at 55; Taylor, *supra* note 180, at 597–98; see also Harvard Stem Cell Institute, Frequently Asked Questions, <http://www.hsci.harvard.edu/frequently-asked-questions> (last visited Mar. 23, 2010) (stating that the Institute is supported by private funding, which allows it to support research activities that could not be supported by NIH funding).

<sup>197</sup> KOROBKIN, *supra* note 2, at 54; John Wagner & Rosalind S. Helderman, *U.S. Stem Cell Funds Freed; Md. Debates Its Own*, WASH. POST, Mar. 10, 2009, at B01.

<sup>198</sup> KOROBKIN, *supra* note 2, at 49–50.

<sup>199</sup> Wayne Arnold, *Science Haven in Singapore; Luring Top Stem Cell Researchers with Financing and Freedom*, N.Y. TIMES, Aug. 17, 2006, at C1.



tion, may have been deterrents to researchers dismayed by U.S. funding limitations.<sup>200</sup>

## 2. Current U.S. Stem Cell Policy

On March 8, 2009, within seven weeks of taking office, President Obama revoked the eight-year old policy enacted by President Bush that limited federal funding of stem cell research and the 2007 executive order directed toward developing alternative methods of deriving hESCs.<sup>201</sup> President Obama ordered the NIH to “support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research” and to establish guidelines to that effect in 120 days.<sup>202</sup> This policy change will now permit federal grants to be used for research on hESC lines created after the August 9, 2001, cutoff date set by President Bush.<sup>203</sup> In his accompanying remarks, President Obama stated, “In recent years, when it comes to stem cell research, rather than furthering discovery, our Government has forced what I believe is a false choice between sound science and moral values. In this case, I believe the two are not inconsistent.”<sup>204</sup> Reactions from the scientific community were overwhelmingly positive.<sup>205</sup> Inter-

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<sup>200</sup> See Lori P. Knowles, *A Regulatory Patchwork—Human ES Cell Research Oversight*, 22 NATURE BIOTECHNOLOGY 157, 157–61 (2004); Rutz & Yeats, *supra* note 2, at 386–87.

<sup>201</sup> EO 13505, *supra* note 101.

<sup>202</sup> *Id.*

<sup>203</sup> See *id.* Nine months after President Obama issued the Executive Order that revoked President Bush’s stem cell funding limitations, on Dec. 2, 2009, the NIH approved the first hESC lines for use in NIH-funded research. Thirteen new hESC lines were approved while another ninety-six lines have been submitted for review to determine eligibility for inclusion in the NIH Human Embryonic Stem Cell Registry. Press Release, NIH Office of the Director, First Human Embryonic Stem Cell Lines Approved for Use Under New NIH Guidelines (Dec. 2, 2009), <http://www.nih.gov/news/health/dec2009/od-02.htm> [hereinafter NIH Dec. PR].

<sup>204</sup> Remarks on Signing an Executive Order Removing Barriers to Responsible Scientific Research Involving Human Stem Cells and a Memorandum on Scientific Integrity, DAILY COMP. PRES. DOC. DCPD200900135 (Mar. 9, 2009), available at <http://www.gpoaccess.gov/presdocs/2009/DCPD200900135.pdf>.

<sup>205</sup> Erika Check Hayden, *Obama Overturns Stem Cell Ban*, NATURE NEWS, Mar. 9, 2009, <http://www.nature.com/news/2009/090309/full/458130a.html>; Lisa Kamen & Meagan Comerford, International Society for Stem Cell Research, ISSCR Scientists Elated for Future of Human Embryonic Stem Cell Research After Obama Lifts Funding Ban, (Mar. 9, 2009), [http://www.isscr.org/press\\_releases/obama\\_repeals.html](http://www.isscr.org/press_releases/obama_repeals.html); Letter from Alan I. Leshner, Chief Executive Officer, Am. Ass’n for the Advancement of Sci. to Barack Obama, U.S. President (Mar. 9, 2009), [http://www.aaas.org/news/releases/2009/media/0309stem\\_cell\\_letter.pdf](http://www.aaas.org/news/releases/2009/media/0309stem_cell_letter.pdf).

estingly, scientists in the U.K. have expressed some reservations that the new policy will lead more stem cell researchers to the United States.<sup>206</sup>

Although the federal limitations have now been lifted, it will likely take approximately a year for the first stem cell research grants to be approved under this new policy and for such funds to reach researchers.<sup>207</sup> Scientists utilizing federal funds will no longer have to carefully demarcate expenditures for hESC research.<sup>208</sup> Nonetheless, federal funding is still prohibited for the purposes of deriving new hESC lines from embryos, since the Dickey Amendment is still in effect.<sup>209</sup> Until Congress acts to eliminate this bar on creating hESC lines, researchers will still be dependent upon private funding or must license established hESC lines.<sup>210</sup>

#### CONCLUSION

While harmonization of patent laws will bring uniformity to global intellectual property protection, the application of moral criteria to patentability standards would only serve to increase uncertainty due to the great variability in cultural and social mores. As seen in the EU, and despite the implementation of the Biotech Directive, there are still interpretative differences over stem cell patentability standards. Moreover, in light of the monopoly that patents provide and the importance of basic research in biotechnology, a balance must be struck between incentives to patentees and drawbacks to society as a whole.

Although the employment of moral criteria in U.S. policy is not novel, its application to the allocation of federal funding has been to the detriment of basic scientific endeavors. In combination with the overly expansive scope of the WARF patents, the funding limitations unduly constrained hESC research within the United States. As the WARF pat-

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<sup>206</sup> Michelle Roberts, *What Next for Stem Cell Research?*, BBC NEWS, Mar. 9, 2009, <http://news.bbc.co.uk/1/hi/health/7932611.stm>.

<sup>207</sup> See Karen Kaplan, *What Obama's Executive Order on Stem Cells Means*, L.A. TIMES, Mar. 10, 2009, at A16. As of Dec. 2, 2009, more than thirty NIH grants funded in 2009 had been restricted due to the lack of approved hESC lines in the NIH hESC registry. With the approval of the NIH and if the newly available hESC lines are appropriate for the research projects, these researchers can then proceed with their research. NIH Dec. PR, *supra* note 203.

<sup>208</sup> See Kaplan, *supra* note 207, at A16; KOROBKIN, *supra* note 2, at 55.

<sup>209</sup> Kaplan, *supra* note 207; Sheryl Gay Stolberg, *Obama Is Leaving Some Stem Cell Issues to Congress*, N.Y. TIMES, Mar. 9, 2009, at A1.

<sup>210</sup> See KOROBKIN, *supra* note 2, at 55; Taylor, *supra* note 180, at 597–98. Upon the expiration of the WARF patents in 2015, the broad intellectual property constraints on hESC line derivation will also be lifted. See '913 Patent, *supra* note 23; '806 Patent, *supra* note 23; '780 Patent, *supra* note 21.

ents will not expire for many years to come, it remains to be seen what effects the new U.S. funding policy will have on hESC research.