# LEGAL UPDATE

# EMBRYONIC STEM CELL RESEARCH: SHIFTING AVAILABILITY OF FEDERAL FUNDS

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#### I. INTRODUCTION

On August 10, 2001, President George W. Bush announced his support for limited federal financing of human embryonic stem ("hES") cell research.<sup>1</sup> President Bush's decision represents a change in the requirements with which researchers must comply in order to obtain federal funding for hES cell research.<sup>2</sup> The President's announcement lessened the controversy surrounding a wide range of political and policy issues involving hES cell research, but raised questions of intellectual property law and research policy which must be resolved by Congress and the research community. This legal update addresses the state of federally funded hES cell research and the potential implications of President Bush's recent announcement.

#### II. HUMAN EMBRYONIC STEM CELL RESEARCH

In 1998, Dr. James A. Thompson, a developmental biologist at the University of Wisconsin, first isolated and cultured hES cells derived from the inner cell mass of human embryos at the blastocyst stage.<sup>3</sup> Dr. Thompson assigned the patents, which covered the method for isolating hES cells as well as the hES cells themselves, to the Wisconsin Alumni Research Foundation

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<sup>&</sup>lt;sup>1</sup> See George W. Bush, *Remarks by the President on Stem Cell Research*, http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html (last visited Jan. 12, 2002). [hereinafter BUSH REMARKS].

<sup>&</sup>lt;sup>2</sup> See Fact Sheet: Embryonic Stem Cell Research, at http://www.whitehouse.gov/ news/releases/2001/08/print/20010809-1.html (Aug. 9, 2001); see also Robin Toner, The President's Decision: The Reaction; Each Side Finds Something to Like, and Not, N.Y. TIMES, Aug. 10, 2001, at A17.

<sup>&</sup>lt;sup>3</sup> See James A. Thompson et al., *Embryonic Stem Cell Lines Derived From Human Blastocysts*, SCIENCE, Nov. 6, 1998, at 1145; NATIONAL INSTITUTES OF HEALTH, STEM CELLS: A PRIMER, May 2000, *at* http:// www.nih.gov/news/stemcell/primer.htm 2000 (last visited Jan. 12, 2002) [hereinafter NIH PRIMER].

("WARF") at the University of Wisconsin.<sup>4</sup> WARF then granted Geron Corporation, a biotechnology company that helped fund Dr. Thompson's research, exclusive rights to develop hES cells into six of the most promising tissue types for therapeutic use.<sup>5</sup>

Scientists believe hES cells can develop into any cell in the body, and thereby possess unique potential that would enable significant advances in disease treatment.<sup>6</sup> The most debated and discussed application of hES cells involves the use of hES cells for the development of cell therapies.<sup>7</sup> Presently, those treating diseases and disorders caused by the disruption of cellular function or the destruction of bodily tissues rely on a limited supply of donated organs and tissues for treatment.<sup>8</sup> Through research, many believe that hES can develop into specialized cells and have a broad impact upon disease treatment, providing treatments for diseases and disorders ranging from "juvenile diabetes to Alzheimer's, from Parkinson's to spinal cord injuries."<sup>9</sup> In short, "[t]here is almost no realm of medicine that might not be touched by this innovation."<sup>10</sup>

### III. FEDERAL FUNDING OF HUMAN EMBRYONIC STEM CELL RESEARCH

Congressional involvement in the issues relating to hES cell research predates Dr. Thompson's breakthrough.<sup>11</sup> In 1995, Congress banned the use of federal funds for use in research in which human embryos were destroyed. The Appropriations Act for the Departments of Labor, Health and Human Services, and Education and Related Agencies provides:

None of the funds made available through this Act may be used for (1) the creation of human embryo or embryos for research purposes; or (2) 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 under 45 CFR 46.208(a)(2) and 42 U.S.C.

<sup>&</sup>lt;sup>4</sup> See Sheryl Gay Stolberg, *Patent on Human Stem Cell Puts U.S. Officials in Bind*, N.Y. TIMES, Aug. 17, 2001, at A1 [hereinafter Stolberg, *Patent on Human Stem Cell*]. Scientists have also derived hES cells "from fetal tissue obtained from terminated pregnancies. Informed consent was obtained from the donors after the had independently made the decision to terminate their pregnancy." NIH PRIMER, *supra* note 3.

<sup>&</sup>lt;sup>5</sup> See Stolberg, Patent on Human Stem Cell, supra note 4, at A1.

<sup>&</sup>lt;sup>6</sup> See Bush Squeezes Between the Lines on Stem Cells, SCIENCE, Aug. 17, 2001, at 1242-43.

<sup>&</sup>lt;sup>7</sup> See NIH PRIMER, supra note 3.

<sup>&</sup>lt;sup>8</sup> See NIH PRIMER, supra note 3.

<sup>&</sup>lt;sup>9</sup> BUSH REMARKS, *supra* note 1, ¶ 6; *see also Bush Squeezes Between the Lines on Stem Cells*, SCIENCE, Aug. 17, 2001, at 1242 ("Embryonic stem cells can in theory develop into any cell type in the body, and many scientists think they could eventually be used to treat chronic diseases such as diabetes and Parkinson's.").

<sup>&</sup>lt;sup>10</sup> NIH PRIMER, *supra* note 3.

<sup>&</sup>lt;sup>11</sup> See H.R. 2127, 104th Cong. § 511 (1995).

#### 289g(b).<sup>12</sup>

Congress has included this language in each appropriations bill enacted since, leaving research projects on human embryos ineligible for federal funding.<sup>13</sup>

Several years later, shortly after Dr. Thompson first isolated and cultured hES cells, the Clinton Administration created an exception to this prohibition, enabling scientists to apply for and spend federal funds on human embryonic stem cell research.<sup>14</sup> The National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells<sup>15</sup> ("Guidelines"), published on August 25, 2000 by the NIH, allowed researchers to acquire federal funds after providing the NIH a number of assurances and documentary support in their proposal.<sup>16</sup> Although researchers were permitted to use federal funds to underwrite their research of hES cells, the Guidelines placed limitations on how the scientists could obtain human embryos. The Guidelines provided, in part:

Studies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.<sup>17</sup>

Thus, researchers wishing to use federal funds could only use embryos acquired from the excess of the clinical need for infertility treatment at in vitro fertilization clinics.<sup>18</sup>

President Bush's announcement restricting the availability of federal funds for research of human embryonic stem cells came less than one year after the effective date of the Guidelines. In his speech, President Bush recognized that:

Scientists... believe that rapid progress in [research on human embryonic stem cells] will come only with federal funds. Federal dollars help attract the best and brightest scientists. They ensure new discoveries are widely shared at the largest number of research facilities and that the

<sup>17</sup> Id.

<sup>&</sup>lt;sup>12</sup> *Id*.

<sup>&</sup>lt;sup>13</sup> See H.R. 3755, 104th Cong. § 512 (1996); H.R. 2264, 105th Cong. § 512 (1997); H.R. 4274, 105th Cong. § 511 (1998); H.R. 3424, 106th Cong. § 510 (1999); H.R. 4577, 106th Cong. § 510 (2000).

<sup>&</sup>lt;sup>14</sup> See National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (August 25, 2000).

<sup>&</sup>lt;sup>15</sup> "Human pluripotent stem cells" are synonymous with hES. *See id.* 51,979. The Guidelines describe them as "cells that are self-replicating, are derived from human embryos or human fetal tissue, and are known to develop into cells and tissues of the three primary germ layers. Although human pluripotent stem cells may be derived from embryos or fetal tissue, such stem cells are not themselves embryos." *Id.* 

<sup>&</sup>lt;sup>16</sup> See id.

<sup>&</sup>lt;sup>18</sup> See id. at 51,979-80.

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research is directed toward the greatest public good.19

Despite this recognition, President Bush, expressed concern that "extracting the stem cell destroys the embryo and thus destroys its potential for life." The President characterized the issue as "a difficult moral intersection, juxtaposing the need to protect life in all its phases with the prospect of saving and improving life in all its stages."<sup>20</sup>

With these issues in mind, President Bush determined that federal funds may only be used for research on hES cells which meet the following requirements: The cell lines must be "derived with (1) informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors."<sup>21</sup> The President estimates that approximately 60 existing genetically diverse hES cell lines meet these criteria.<sup>22</sup> Private researchers developed all of these cell lines.<sup>23</sup>

In addition to setting forth the eligibility requirements for use of federal funds for research on existing cell lines, President Bush highlighted three categories for which no federal funds may be used. Federal funds may not be used for: "(1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose."<sup>24</sup> Finally, the President established a President's Council on Bioethics "to study the human and moral ramifications of developments in biomedical and behavioral science and technology."<sup>25</sup> These requirements have no effect on privately funded research.

The announcement has not been warmly embraced by any of the interested parties.<sup>26</sup> Instead, the opponents of hES cell research are relieved that the federal government will not be more broadly involved in the research, while proponents of federally funded research were only relieved that President Bush

<sup>26</sup> See Mike Pezzella, Few Satisfied with Bush Stem Cell Compromise, BIOTECHNOLOGY NEWSWATCH, Aug. 20, 2001, at , available at LEXIS, News, By Individual Publication; Stolberg, The President's Decision: A Question of Research; Disappointed by Limits, Scientists Doubt Estimate of Available Cell Lines, N.Y. TIMES, Aug. 10, 2001, at A17 [hereinafter Stolberg, Disappointed by Limits]; Toner, supra note 2, at A17.

<sup>&</sup>lt;sup>19</sup> BUSH REMARKS, *supra* note 1,  $\P$  9.

<sup>&</sup>lt;sup>20</sup> See id. ¶ 10, 16.

<sup>&</sup>lt;sup>21</sup> Fact Sheet: Embryonic Stem Cell Research, supra note 2.

<sup>&</sup>lt;sup>22</sup> See id. The scientific community was surprised by the President's estimate that approximately 60 genetically diverse hES cells lines which met these requirements existed. See Bush Squeezes Between the Lines on Stem Cells, SCIENCE, Aug. 17, 2001, at 1242. Many scientists believe the number of hES cell lines in existence which meet the new requirements falls well below 60. See id.; see also Research Community: Greets Decision Cautiously, AMERICAN HEALTH LINE, Aug. 10, 2001, available at LEXIS, News, By Individual Publication.

<sup>&</sup>lt;sup>23</sup> See BUSH REMARKS, supra note 1, ¶ 24.

<sup>&</sup>lt;sup>24</sup> Fact Sheet: Embryonic Stem Cell Research, supra note 2.

<sup>&</sup>lt;sup>25</sup> Id.

did not completely ban the use of federal funds.<sup>27</sup> Consequently, it is likely that opponents and proponents of human embryonic stem cell research will continue to lobby Congress and the President to modify the extent of federal involvement.<sup>28</sup>

# IV. THE IMPLICATIONS OF THE NEW GUIDELINES ON BIOTECHNOLOGY AND INTELLECTUAL PROPERTY

Although the new policy managed to keep opponents and proponents content by limiting but not totally banning the use of federal funds or expanding the use of federal funds, it primarily addressed political concerns surrounding the issue.<sup>29</sup> Evan P. Schultz captured the essence of the primary difficulty President Bush's recent decision failed to resolve: President Bush "forgot about patent law."<sup>30</sup> The Wisconsin Alumni Research Foundation at the University of Wisconsin, in conjunction with Geron Corporation, owns patents relating to human embryonic stem cells.<sup>31</sup> The patents cover the method of isolating the cells as well as the cells themselves.<sup>32</sup> As the patent owner, WARF may exclude others from making, using, selling or importing "inventions" within the scope of its patents.<sup>33</sup> Essentially, President Bush's decision created an atmosphere in which a limited number of private suppliers

<sup>&</sup>lt;sup>27</sup> See Stolberg, Disappointed by Limits, supra note 26, at A17 ("Leading [scientists] were sorely disappointed by his decision, describing it as a baby step, rather than a giant leap, for medical research... [and patients' advocates] warned that they would press Congress to enact legislation that would expand scientists' ability to do stem cell work."); Toner, *supra* note 2, at A17 ("President Bush's proposal for carefully limited federal research on embryonic stem cells was greeted with relief tonight by many abortion opponents and other conservatives, who had feared a much broader federal effort. On the other side, patients' advocates and other supporters of the research said they had many questions about the Bush decision but were pleased that the president had embraced the basic concept and importance of embryonic stem cells as a potential boon in the treatment of many diseases.").

<sup>&</sup>lt;sup>28</sup> See Stolberg, Disappointed by Limits, supra note 26, at A17.

<sup>&</sup>lt;sup>29</sup> See id.; Toner, supra note 2, at A17.

<sup>&</sup>lt;sup>30</sup> Evan P. Schultz, *Oped, Promoting the Progress of Science?*, N.J. LAW J., Sept. 10, 2001. Paul Berg, a professor emeritus as the Stanford University School of Medicine, also raised similar concerns, nothing that "the president may have been unaware of the legal and intellectual property constraints that complicate the availability of the various lines." Paul Berg, Editorial, *Progress with Stem Cells: Stuck or Unstuck?*, SCIENCE, Sept. 14, 2001, at 1953.

<sup>&</sup>lt;sup>31</sup> See Robert C. Scheinfeld & Parker H. Bagley, *The Current State of Embryonic Stem Cell Patents*, N.Y. LAW J., Sept. 26, 2001, at 3, 8 (providing an overview of the small number of entities that currently hold patents on hES cell lines and the methods related to isolating and culturing hES cells); Stolberg, *Patent on Human Stem Cell, supra* note 4, at A1.

<sup>&</sup>lt;sup>32</sup> See Stolberg, Patent on Human Stem Cell, supra note 4, at A1.

<sup>&</sup>lt;sup>33</sup> See Stolberg, Patent on Human Stem Cell, supra note 4, at A1; see also 35 U.S.C. § 271 (2000) (setting forth grounds for patent infringement).

exert monopoly power over scientists because of the limited availability of human embryonic stem cell lines available to those researchers who desire to use funds drawn from the federal government.<sup>34</sup>

Litigation concerning the research and development of human embryonic stem cells commenced just days after President Bush announced his guidelines.<sup>35</sup> WARF sued Geron, their partners in the isolation and growth of human embryonic stem cells.<sup>36</sup> The parties are embroiled in a dispute concerning Geron's attempt, made pursuant to their agreement, to extend its commercial rights to one dozen derivative cell types.<sup>37</sup> Due to the potential scope and applicability of WARF's patents, it is likely that litigation between patent holders and would-be researchers will increase.

The Public Health Service ("PHS") will enable "government researchers to obtain cell lines, do basic research, and publish unfettered by intellectual property restrictions."<sup>38</sup> Although researchers may obtain hES cells for \$5,000, they are subject to a number of conditions which scientists may be unwilling to accept.<sup>39</sup> One scientist expressed dissatisfaction with the terms stating, "Those conditions would mean that I am the ideal employee of Geron. They don't pay my salary, they don't pay my benefits, but anything I discover they own."<sup>40</sup>

It is still likely that courts may be asked to determine the proper scope of the patents and whether human embryonic stem cells are patentable subject matter.<sup>41</sup> The resolution of the issues related to these patents will likely determine the role of the United States in human embryonic stem cell research. Although it is too early to estimate the full impact of the WARF patents, it seems likely that much of the research involving human embryonic stem cells may occur overseas unless the federal government and other researchers are successful at the negotiating table or researchers are successful in restricting the scope of the WARF patents.<sup>42</sup>

<sup>&</sup>lt;sup>34</sup> See Stolberg, Patent on Human Stem Cell, supra note 4, at A1.

<sup>&</sup>lt;sup>35</sup> See Geron Files Motion in Lawsuit, BUS. WIRE, Oct. 3, 2001, available at LEXIS, News, By Individual Publication. On August 13, 2001, WARF filed a complaint "ask[ing] the court to declare Geron's exercise of their option [for additional cell types] invalid." *Id.* 

<sup>&</sup>lt;sup>36</sup> See id.

<sup>&</sup>lt;sup>37</sup> See id.

<sup>&</sup>lt;sup>38</sup> HHS Inks Cell Deal; NAS Calls for More Lines, SCIENCE, Sept. 14, 2001, at 1966.

<sup>&</sup>lt;sup>39</sup> See Stolberg, Patent on Human Stem Cell, supra note 4, at A1.

<sup>&</sup>lt;sup>40</sup> See Stolberg, supra note 4, at A1 (quoting Dr. Douglas Melton of Harvard University).

<sup>&</sup>lt;sup>41</sup> See Scheinfeld & Parker, supra note 31.

<sup>&</sup>lt;sup>42</sup> See Pezzella, supra note 26, , available at LEXIS, News, By Individual Publication.