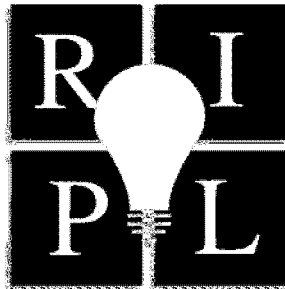


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



A TWO-FRONT ASSAULT ON THE STEM CELL PATENTS

DILLON BEARDSLEY

ABSTRACT

The recent establishment of human embryonic stem cell lines has inspired a new revolution in therapeutic treatments and cures for injuries or disease. Individual states have begun to circumvent the lack of federal funding by independently raising monetary support for the research. The patentee, The Wisconsin Alumni Research Foundation, has reminded those hoping to benefit from the state funding that the Foundation will require royalties for the commercial use of its patented technology. The loss of state taxpayer money to the patent holder ignited a challenge on the patents themselves. Interest groups requested a reexamination of the stem cell patents and succeeded as the United States Patent & Trademark Office has rejected all of the claims in each patent. This comment analyzes specific issues raised in the reexamination and evaluates the righteousness of the royalties. The comment proposes retention of patent law policy by continuing to reward innovation in order to promote future invention and permitting a patentee to assess royalties for his efforts. The comment also recommends an improved patent review process to lessen harassment of patentees and strengthen the quality of patents issued.

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A TWO-FRONT ASSAULT ON THE STEM CELL PATENTS

DILLON BEARDSLEY*

Patents are extremely important And so hopefully the field as a whole can reach some sensible accommodation to WARF for the pioneering work that they did do, but at the same time not stop the entire field from going forward. It's a hard problem actually.¹

INTRODUCTION

Recently, a research group at Johns Hopkins University utilized transplanted embryonic stem cell-derived nerve axons to partially restore neuromuscular activity in paralyzed rats.² A Spanish research team has made advances in generating insulin-producing pancreatic cells from embryonic stem cells, which may ultimately aid diabetes sufferers.³ Current advancements, such as these, have only begun to tap into the benefits of human embryonic stem cell (“HESC”) research.⁴ However, problems that may obstruct, and delay, the future of stem cell research have surfaced. In particular, the scope of the stem cell patents and the licensing fees levied by the patent holders are at issue.

This comment begins by introducing various issues resulting from stem cell research along with the trials and tribulations scientists have faced in its infancy. This comment then analyzes the issue of the stem cell patents' validity in light of the recent claim rejections imposed by the United States Patent and Trademark Office and whether the licensing agreements attached to the stem cell technology are burdensome to research and therapeutic progress. Finally, this comment proposes

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¹ *Hearing Before the IP Task Force of the Independent Citizens' Oversight Comm. to the California Institute for Regenerative Medicine*, 114–15 (2006), available at <http://www.cirm.ca.gov/transcripts/pdf/2006/04-27-06.pdf> (statement of chairman, Dr. Edward Penhoet)

² See generally Deepa Deshpande et al., *Recovery from Paralysis in Adult Rats Using Embryonic Stem Cells*, 60 ANNALS OF NEUROLOGY 32 (2006) (describing the first report of the anatomical and functional replacement of a motor neuron circuit within the adult mammalian host partially rescuing the adult rat from paralysis).

³ See generally Pilar Vaca et al., *Induction of Differentiation of Embryonic Stem Cells Into Insulin-Secreting Cells by Fetal Soluble Factors*, 24 STEM CELLS 258 (2006) (elucidating techniques that may be instrumental in engineering pancreatic beta cells from stem cells and demonstrating normalization of blood glucose levels after transplantation of differentiated stem cells into diabetic mice and hyperglycemia after graft removal).

⁴ Susanne Rust & Kathleen Gallagher, *Stem Cell Work Crosses Boundaries: UW Scientists Aim to Make Wisconsin the Epicenter of a Medical Revolution*, MILWAUKEE J. SENTINEL, April 23, 2006, at B1. “There isn’t much known about these cells. So, we try things and see what happens. And every time we do, we find something. We’re seeing things people haven’t seen before.” *Id.* (quoting Sean Palecek, associate professor of chemical and biological engineering, and stem cell scientist).

legislative reform and maintenance of patentee rights to satisfy both the incentive to invent revolutionary science, such as stem cell technology, and the incentive to bring helpful therapeutics to the masses.

I. BACKGROUND

This section elucidates the present struggle in stem cell science as ethical, research, and patent interests try to find some accord. First, this section introduces an overview of stem cell science. Second, this section explains the current policy in the United States towards stem cell production and research. Finally, the section discusses the State of California's response to the Federal government's policy on stem cell funding and the State's current conflict with the stem cell patent holders.

A. Human Embryonic Stem Cell Science

Human embryonic stem cells possess unique capabilities and characteristics that have excited many in research and therapeutic treatment.⁵ HESCs are derived from human embryos at the most initial stages of development (approximately 5 days after fertilization).⁶ The cells at this point exist undifferentiated, meaning they have yet to commit to becoming a specific adult specialized cell line, i.e., muscle or nervous cell lines.⁷ Most importantly for scientists, HESCs can grow endlessly and differentiate into any cell type of the human body.⁸ These characteristics provide thrilling potential for the study of life-threatening diseases such as cancer, diabetes, Alzheimer's, Parkinson's, and HIV/AIDS via stem cell technology and/or creating stem cell therapies.⁹

B. The Current Policy in Human Stem Cell Research

⁵ Junying Yu & James A. Thomson, *Embryonic Stem Cells*, in NATIONAL INSTITUTES OF HEALTH, REGENERATIVE MEDICINE 2006 1 (2006), available at http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative_Medicine_2006.pdf (explaining that the developmental potential of human ES cells in combination with the immortalization characteristics of these cells will offer unending resources for beneficial research and therapy).

⁶ See generally James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145 (1998) (detailing the process used by stem cell pioneer, Dr. James Thomson, to derive stem cells from five-day-old human embryos produced via *in vitro* fertilization ("IVF")).

⁷ Yu & Thomson, *supra* note 5, at 1, 3 (noting that each of the cells of the inner cell mass ("ICM") are undifferentiated, i.e., they do not look or act like the specialized cells of the adult and may later progress into nearly every type of cell line present in the adult human).

⁸ *Id.* at 2 fig.1.2 (illustrating that stem cells are pluripotent and give rise to cells from all three embryonic germ layers, [1] the ectodermal line including: brain, spinal cord, nerve cells, hair, skin, ears nose, and mouth; [2] the mesodermal line including: muscles, blood, blood vessels, and the heart; and [3] the endodermal line including: the pancreas, liver, stomach, lungs, eggs, and sperm).

⁹ *Id.* at 7; CAL. CONST. art. XXXV, § 2 ("Recently medical science has discovered a new way to attack chronic diseases and injuries. . . . [T]hrough the use of new regenerative medical therapies including a special type of human embryonic cells, called stem cells.").

HESCs in use today are most commonly derived from human embryos produced by *in vitro* fertilization.¹⁰ These embryos are usually created for infertile couples hoping to have children of their own.¹¹ However, thousands of the embryos are not used and are necessarily discarded.¹² These previously discarded embryos became the source of many HESCs used today.¹³ Soon after taking office, President George W. Bush tackled this ethically charged issue.¹⁴ As a result, President Bush established a ban on federal funding for any research utilizing HESCs created after August 9, 2001.¹⁵ However, experimentation on the existing HESCs is now greatly inhibited as the number of satisfactory HESC cell lines has dwindled.¹⁶ Many dispute Bush's policy and its great limitation to the future of stem cell research.¹⁷

In response to the Bush policy, opposition has formed to persuade the government to disencumber stem cell research. A group of past Nobel Prize winners

¹⁰ Yu & Thomson, *supra* note 5, at 3 (explaining creation of HESCs through the process of oocytes and sperm combination and fertilization in a culture dish); JUDITH A. JOHNSON & ERIN D. WILLIAMS, *STEM CELL RESEARCH 1-2* (2005), available at http://www.camradvocacy.org/resources/CRS_Report_Stem_Cell_Research_Aug05.pdf.

¹¹ David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063, 1066 (2003) (noting there are nearly 400,000 IVF-produced embryos in frozen storage in the United States alone, most of which will be used to treat infertility).

¹² *Id.* (observing that of the 400,000 IVF-produced embryos in storage, approximately 2.8% are destined to be discarded).

¹³ *Id.* at 1063.

¹⁴ Petition for Writ of Certiorari at *4, *Doe v. Thompson*, 126 S. Ct. 116 (2005) (No. 04-1642) (noting the Bush administration already announced its intention to review the Government's stem cell research policy early after taking over the office).

¹⁵ Press Release, The White House, Remarks by the President on Stem Cell Research, Aug. 9, 2001, <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html> (last visited Apr. 19, 2007) (announcing George W. Bush's policy that federal funds may be awarded for research using human embryonic stem cells if the research meets certain criteria). The derivative [i.e., the extraction] process (which begins with the destruction of the embryo) had to be initiated prior to 9:00 p.m. EDT on August 9, 2001. *Id.* The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed. *Id.* Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements. *Id.*

As a result of private research, more than 60 genetically diverse stem cell lines already exist. . . . I have concluded that we should allow federal funds to be used for research on these existing stem cell lines where the life and death decision has already been made. . . . This allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life.

Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953, 955 (Aug. 9, 2001) (quoting President George W. Bush).

¹⁶ National Institutes of Health, Stem Cell Information: FAQs, <http://stemcells.nih.gov/info/faqs.asp#classes> (last visited Apr. 19, 2007) (stating that the available number HESC cell lines listed in the NIH Human Embryonic Stem Cell Registry is twenty-two); see also Claudia Kalb & Debra Rosenberg, *Stem Cell Division*, NEWSWEEK, Oct. 25, 2004, at 42 (noting that of the original HESC lines, only a small amount were viable for research while others perished when thawed).

¹⁷ *E.g.*, Peter Wallsten & Maura Reynolds, *Frist Throws Support Behind Stem Cell Research*, L.A. TIMES, July 30, 2005 (noting that researchers should be given federal funding for research on newer, more promising HESC lines).

wrote a letter to the President urging a change in the funding policy.¹⁸ Popular figures such as Michael J. Fox for Parkinson's Disease¹⁹ and Ronald Reagan, Jr. for Alzheimer's Disease²⁰ have become active in the funding issue. Senator John Kerry, during his 2004 bid for the presidency, vowed to ease the strict regulations against the federal funding of HESC research.²¹ On May 24, 2005, the House of Representatives responded to the funding concerns by passing House Resolution 810, "The Stem Cell Research Enhancement Act of 2005."²² This bill would have reversed President Bush's ban by permitting the use of federal funds in stem cell research under certain conditions.²³ However, President Bush remained steadfast and exercised the first veto of his administration to negate the bill.²⁴ Subsequently, the House tried but failed to overcome the veto.²⁵ Undeterred by this legislative loss, some states have continued their circumvention of the Bush policy by promoting stem cell research through state-led funding initiatives.²⁶

¹⁸ See Gretchen Vogel, *Nobel Laureates Lobby for Stem Cells*, 291 SCIENCE 1683, 1683 (2001) (stating on Feb. 22, 2001, eighty Nobel Prize winners signed a letter urging President Bush to allow government-funded researchers to work on human pluripotent stem cells even though the Bush Administration is under ethical pressure from anti-abortion groups to block federal funding for research on human embryonic stem cells).

¹⁹ Letter from Michael J. Fox to President George W. Bush (July 18, 2006) (on file with author) (asking him to pass House Bill 810 and reverse the federal policy restricting funding of stem cell research).

²⁰ Robin Toner & Todd S. Purdum, *On 2nd Night, Unity Is Theme For Democrats*, N.Y. TIMES, July 28, 2004, at A1. "[W]hatever else you do, come Nov. 2, I urge you, please, cast a vote for embryonic stem cell research." *Id.* (quoting Ronald Reagan, Jr.).

²¹ Petition for Writ of Certiorari, *supra* note 14, at 10.

²² Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2005).

²³ *Id.* § 498D(b) (denoting the ethical requirements of human embryonic stem cells that shall be eligible for use in any research conducted or supported by the Secretary).

(1) The stem cells were derived from human embryos that have been donated from *in vitro* fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment.

(2) Prior to the consideration of embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded.

(3) The individuals seeking fertility treatment donated the embryos with written informed consent and without receiving any financial or other inducements to make the donation.

Id.

²⁴ 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). "If we are to find the right ways to advance ethical medical research, we must also be willing when necessary to reject the wrong ways. For that reason, I must veto this bill." *Id.* (quoting President George W. Bush).

²⁵ 152 CONG. REC. H5435 (daily ed. July 19, 2006) (noting that on July 19, 2006, H.R. 810 failed passage in the House over veto of President Bush by not garnering two-thirds of the vote (235 Yea-193 Nay)).

²⁶ Tina Kelley, *In Race Toward First Stem Cell Research Institute, New Jersey Stalls*, N.Y. TIMES, July 31, 2005, at 1; see also Betsy Morris, *Fighting for Their Lives*, FORTUNE, Aug. 22, 2005, at 48 (noting the other states in various stages of the legislative and initiative process); Associated Press, *Wisconsin Announces Stem-Cell Funding*, MSNBC, Nov. 18, 2004, <http://www.msnbc.msn.com/id/6515491/> (last visited Feb. 11, 2007) (announcing Wisconsin Governor

C. California's Response Via Proposition 71

California has responded against the current federal policy with the passage of Proposition 71 that has earmarked an astounding \$3 billion of publicly raised money for stem cell research for the simultaneously created California Institute for Regenerative Medicine ("CIRM").²⁷ The passage of Proposition 71 in California signaled further evidence of disagreement with the Bush Administration's stance and further evidence that stem cell research requires public funding outside of the federal government's control.²⁸ Surprisingly, neither Proposition 71's supporters nor its detractors made this issue into a pro-life vs. pro-choice battle.²⁹ Moreover, neither side was opposed to stem cell research itself.³⁰

In spite of the progressive support for stem cell research, opponents have argued against CIRM for the potential negative effects it may have on California.³¹ The opponents feel it will increase the state of California's debt, shift money away from other needy causes, and fill the pockets of the few corporations for which most of the funds are destined.³² One prominent Californian regards Proposition 71 to be "the wrong way to do the right thing."³³ Specifically, the very companies standing to benefit from the funding will undertake the institutional control of CIRM and CIRM

Jim Doyle's stem cell research funding initiative that will invest \$750 million of public and private money to build two research centers and support stem cell research).

²⁷ CAL. CONST. art. XXXV, § 3 (clarifying the intent of the people of California in enacting this measure). The policy authorizes an average of \$295 million per year in bonds over a ten-year period to fund stem cell research at newly established facilities at California's universities and medical research facilities within the state. *Id.* The policy will maximize research funds by giving priority to stem cell research with the greatest potential therapeutic benefit. *Id.* The policy will focus on pluripotent stem cell and progenitor cell research that will overcome this area's deficiencies in federal funding and will be unencumbered by limitations that would impede the research. *Id.*

²⁸ CENTER FOR GENETICS AND SOCIETY, ASSESSMENT OF THE CALIFORNIA STEM CELL RESEARCH AND CURES ACT (2004) <http://www.genetics-and-society.org/policies/california/assessment.html> (last visited Apr. 19, 2007) (contrasting the \$300 million stem cell research award with the California Breast Cancer Research Program, the largest state-sponsored research effort in the nation, that has granted scientists an average of \$15 million a year since 1994 or twenty times less than the level that Proposition 71 would provide for stem cell research); see Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665, 676 (2005).

²⁹ O'Connor, *supra* note 28, at 676 ("[N]either the official Rebuttal to Argument in Favor of Proposition 71 nor the Argument Against Proposition 71 presented in the election materials was there an opposition to stem cell research, embryonic or otherwise").

³⁰ See Official Voter Information Guide, State of California Proposition 71, *available at* <http://vote2004.ss.ca.gov/voterguide/propositions/prop71-arguments.htm> (last visited Apr. 19, 2007).

³¹ *Id.* (arguing other research and medical needs, already proven cost effective, should be funded instead). The program is too costly and without adequate accountability or oversight. *Id.* The proposition is a "blatant taxpayer rip-off" that will line the pockets of a few large corporations. *Id.* Proposition 71 will give the proponents power over California "open meeting" laws and prohibit the Governor and Legislature from exercising any oversight. *Id.*

³² Dan Gillmor, *Some Thoughts on California's Propositions*, SAN JOSE MERCURY NEWS, Oct. 24, 2004, at 1F ("The scope of this project is too massive for comfort given the state's shaky fiscal position. And the benefits to taxpayers — who are likely to foot a large bill — are too abstract. The whiff of corporate welfare is unmistakable.")

³³ Posting of Mitch Kapur to Of By and For, <http://www.ofbyandfor.org/node/view/830> (Oct. 25, 2004, 21:25 PST).

funds.³⁴ CIRM is also exempt from public oversight and is allowed to implement its own rules and policies, i.e., informed consent and protection for research subjects.³⁵ Furthermore, CIRM has set itself apart from the normal ground rules under which research is conducted and commercialized, greatly increasing risk of ensuing lawsuits and other unforeseen problems.³⁶

The opponents feel this lack of CIRM accountability leaves the researchers, taxpayers, and businesses involved more vulnerable.³⁷ It is also not currently clear how the state or its citizens would benefit from any subsequent profitable technologies.³⁸ Further, unresolved intellectual property issues, such as ownership of future state-sponsored discoveries, often results in detrimental legal fights.³⁹ Additional concerns have also surfaced as a conflict between CIRM and the owners of the stem cell patents.⁴⁰ In this matter, the patent holder's monopoly is balanced opposite the desire of the powerful Californian corporations to enter unencumbered into stem cell research. The taxpayers of California, who do not want state money leaving the state, are also included in this conflict as patent royalty demands threaten to reach into their own pockets.⁴¹

³⁴ *Id.* (noting this as a conflict of interest and asking for a diversified oversight board, found in similar research interests, to balance any conflicts); see Steve Johnson, *Lawsuits Will Delay Stem-Cell Research*, SAN JOSE MERCURY NEWS, Aug. 2, 2005, at A1 (stating that a current lawsuit claims individuals in charge of CIRM have conflicts of interest that will impede the institution's ability to fairly allocate taxpayer money).

³⁵ Posting of Kapur, *supra* note 33.

Because there are significant health risks to women who agree to undergo the egg retrieval necessary to conduct the embryo cloning, a much clearer and stricter regulatory framework needs to be created before proceeding. The FDA has received over 4000 reports of adverse drug events among women given the drug Lupron to prepare them for the hyperstimulation that enables egg extraction. This includes 325 hospitalizations and 25 deaths. Proposition 71 would create a huge need and therefore huge pressure for women to donate eggs and raises the possibility of exploitation as has happened in similar situations such as blood donors.

Id.

³⁶ *Id.* (noting that separating itself from normal operating rules for research institutions, it may set itself up for unforeseen legal problems and result in hesitancy for those who may want to enter the field); see also Carl T. Hall, *Stem Cell Group Ready to Disburse Funds; Institute, Critics Near Agreement on Conflicts, Meetings*, SAN FRAN. CHRON., July 2, 2005, at B1 (noting concerns involving intellectual property and patent rights are yet to be resolved in addition to the other finance and oversight issues of CIRM).

³⁷ Posting of Kapur, *supra* note 33.

³⁸ *Id.* (suggesting it would be far better to promote stem cell research either through Federal activity (when favorable) or through the California legislature rather than through CIRM).

³⁹ *Id.*

⁴⁰ California Stem Cell Report, <http://californiastemcellreport.blogspot.com/2006/05/warf-to-cirm-dont-mess-with-us.html> (last visited Apr. 19, 2007) (referring to comments in California concerning WARF's position on the Wisconsin patents). Andrew Cohn, government and public relations manager for the organization, said, "These folks are absolutely going off the deep end. If it wasn't for WiCell and for the University of Wisconsin, they wouldn't have anything to spend the \$3 billion on in the first place." *Id.* The patent dispute between California and Wisconsin "promises to be an intense fight" and "WARF has proven over and over again that it will enforce its patents and its contracts." *Id.*

⁴¹ Kathleen Gallagher, *Stem Cell Patents Make Group a Target Challenge Points up State's Role in Bringing Technology to Market*, MILWAUKEE J. SENTINEL, July 23, 2006 at D1 (noting that opponents hold the WARF patents harm both science and the California taxpayers).

D. Stem Cell Patents and the Conflict with California

The United States Patent and Trademark Office (“PTO”) issued United States Patent Nos. 5,843,780 (“the ’708 patent”); 6,200,806 (“the ’806 patent”); and 7,029,913 (“the ’913 patent”) — all relating to embryonic stem (“ES”) cells — to researcher Dr. James A. Thomson who in turn assigned the patents to the Wisconsin Alumni Research Foundation (“WARF”).⁴² The ’780 patent, issued on December 1, 1998, contains claims directed to the broad category of all primate ES cells and a method for isolating primate ES cells.⁴³ The ’806 patent, issued on March 13, 2001, is virtually identical to the ’780 patent, except that the claims are directed specifically to HESCs.⁴⁴ The claims of the ’913 patent, issued April 18, 2006, are directed to HESCs maintainable without the application of anti-differentiation factor.⁴⁵

WARF has openly shipped the stem cell lines it possesses to more than 300 research groups in twenty-one countries.⁴⁶ The cost for the cell lines for each group was \$5,000 until last fall when a National Institutes of Health subsidy helped lower the price to \$500 for academic researchers.⁴⁷ Additional costs totaling \$125,000 or more, plus annual fees, were assessed for private, non-academic labs.⁴⁸ Recently, WARF has done away with these increased fees for private institutions in order to encourage more research in this area deficient in federal funding.⁴⁹ However, licensing fees are still mandatory when any product related to the stem cells becomes commercialized.⁵⁰ These potential licensing costs have raised concern among consumer advocates in matters of health and taxpayer money.⁵¹ CIRM stipulated in

⁴² Primate Embryonic Stem Cells, U.S. Patent No. 5,843,780 (filed Jan. 18, 1996); Primate Embryonic Stem Cells, U.S. Patent No. 6,200,806 (filed June 26, 1998); Primate Embryonic Stem Cells, U.S. Patent No. 7,029,913 (filed Oct. 18, 2001).

⁴³ ’780 Patent col.21–22 (claiming a purified preparation of primate embryonic stem cells with the ability to differentiate into all tissues derived from all three embryonic germ layers and a method for isolating a primate embryonic stem cell line).

⁴⁴ ’806 Patent col.21–22 (claiming identical preparations and methods to Patent No. 5,843,780 only for human embryonic stem cells).

⁴⁵ ’913 Patent col.21–22 (claiming HESCs which are capable of proliferation in *in vitro* culture for over one year without the application of exogenous leukemia inhibitory factor).

⁴⁶ David Wahlberg, *Wisconsin, California in a Stem-Cell Skirmish*, WIS. ST. J., June 18, 2006, at A1.

⁴⁷ *Id.*; see also WiCell, FAQs for Requesting Stem Cell Lines, http://www.wicell.org/index.php?option=com_content&task=blogcategory&id=124&Itemid=19 (last visited Apr. 19, 2007) (noting WiCell entered into a contract with NIH and was named the National Stem Cell Bank effective September 30, 2005). An agreement with the National Institutes of Health has allowed WiCell Research Institute to offer HESCs to U.S. academic researchers at \$500/line in an effort to encourage more scientists to explore this new field of research. *Id.*

⁴⁸ Wahlberg, *supra* note 46.

⁴⁹ WiCell, *Wisconsin Alumni Research Foundation Changes Stem Cell Policies to Encourage Greater Collaboration*, Jan. 22, 2007, available at http://www.wicell.org/index.php?option=com_content&task=view&id=166&Itemid=170 (last visited Apr. 19, 2007) (explaining that private stem cell research industry may now sponsor research performed at public or non-profit institutions).

⁵⁰ WARF – Licensing Process, available at <http://www.warf.org/industry/index.jsp?cid=1> (last visited Apr. 19, 2007).

⁵¹ Foundation for Taxpayer and Consumer Rights, *Groups Challenge Stem Cell Patents That Loot Taxpayer Funds and Force Research Overseas*, <http://www.consumerwatchdog.org/pr/?postId=6572> (last visited Apr. 19, 2007) (describing the concern over health, hindrance of research, exodus

its funding proposal that twenty-five percent of any royalties gained as a result of research accomplished with its funding would return to the state of California.⁵² However, WARF deems this research is commercialization of their product and necessarily interjected its right to any royalties.⁵³ This could result in millions of dollars of California taxpayer money leaving the state.⁵⁴

The transfer of California taxpayer money to Wisconsin is unacceptable to many Californians; thus, the first salvo, Requests for Reexamination on each stem cell patent, was submitted to the United States Patent Office.⁵⁵ Consumer advocates at the Foundation for Taxpayer and Consumer Rights (“FTCR”) and attorneys at the Public Patent Foundation (“PUBPAT”) asked the PTO to revoke the stem cell patents on grounds they overreach and disclose claims covered by prior art.⁵⁶ Additionally, the concern of “suffocation of product” due to excessive layers of royalties is an issue that must be scrutinized.⁵⁷

Proponents of CIRM have argued that the patents on stem cell science have been a more serious hindrance to research on stem cells than President Bush’s limitation in federal funding in 2001.⁵⁸ Thus, the patent-holder, WARF, faces a potentially long assault attacking the validity of the stem cell patents. Further, arguments over the “excessive” royalties are likely to persist. Perhaps a more sympathetic presidential administration, growing public sentiment for disease cures, or the influx of money and celebrity may find a way to circumvent WARF’s control over stem cells.

of research, and wasted taxpayer money due to WARF requiring researchers, even taxpayer funded, to pay royalties and seek approval before engaging in stem cell research).

⁵² CIRM Intellectual Property Policy at 19, *available at* <http://www.cirm.ca.gov/policies/pdf/IPNPO.pdf> (last visited Apr. 19, 2007) (noting that the 25% royalty is only enacted when commercial proceeds exceed the threshold amount of \$500,000).

⁵³ CALIFORNIA STEM CELL REPORT, THE STEM CELL MEETING (2006) *available at* http://californiastemcellreport.blogspot.com/2006_03_01_californiastemcellreport_archive.html (last visited Apr. 19, 2007) (quoting Beth Donley, general counsel Wisconsin Alumni Research Foundation “[I]f CIRM stipulates twenty-five percent royalties for California that requirement amounts to commercialization. And that means WARF wants a payment from California.”).

⁵⁴ *Id.* (noting Beth Donley’s remarks that licenses will start at around a bottom figure of \$75,000). Peter Balbus, managing director at Pragmaxis LLC, of Glen Ellyn, Ill., estimated Wisconsin could receive \$200 million for \$4 billion in stem cell product revenues. *Id.*

⁵⁵ Foundation for Taxpayer and Consumer Rights, *supra* note 51 (explaining that the three overreaching stem cell patents “should have never been issued in the first place”).

⁵⁶ Public Patent Foundation, <http://www.pubpat.org/warfstemcellsfiled.htm> (last visited Apr. 19, 2007) (listing the Requests for Reexamination of the stem cell patents, Nos. 5,843,780; 6,200,806; and 7,029,913 and filing a letter of support by Dr. Jeanne F. Loring); *see also* Foundation for Taxpayer and Consumer Rights, *supra* note 51 (arguing the patents on human embryonic stem cells should not have been granted because the previous work of other scientists made the derivation of human embryonic stem cells obvious and therefore unpatentable).

⁵⁷ California Stem Cell Report, *supra* note 53 (citing Todd Lorenz’s, chair, Life Sciences and Health Care, Dorsey & Whitney L.L.P., concerns with Donley’s account towards the issue of “suffocation of product” defined as excessive layers of royalties of as much of twenty-five to thirty percent that stifle commercialization of therapies).

⁵⁸ Jennifer Washburn, Op-Ed., *The Legal Lock on Stem Cells*, L.A. TIMES, April 12, 2006, at 13 (explaining that the stem cell patents cover all human embryonic stem cells and the method by which they’re made, thus exerting a dangerous monopoly that may counter the policy behind patents, namely stimulation of innovation). The licensing fees charged by WARF are limiting the researchers and companies able to participate in stem cell research. *Id.* (questioning the Patent Office’s grant of “building blocks” in science and explaining that the Thompson stem cell patents are unreasonably broad since they cover all human embryonic stem cell lines).

II. ANALYSIS

This section evaluates the issues raised by FTTCR and PUBPAT in their fight to invalidate the scope and royalties of the WARF patents. First, this section explains the necessary hurdle FTTCR and PUBPAT overcame to initiate its challenge on patentability. Second, this section evaluates the patentability of the WARF patents by scrutinizing the recent PTO rejection of the WARF patent claims. Finally, this section introduces a secondary challenge introduced by FTTCR and PUBPAT, namely the imposition of excessive royalties, and investigates the merit of these accusations.

A. The PTO Finds a Substantial New Question of Patentability Raised by the Reexamination

A third party may ask for reexamination and submit to the PTO “prior art consisting of patents or printed publications that may bear on the patentability of any claim of a patent.”⁵⁹ FTTCR and PUBPAT initiated a request for reexamination⁶⁰ of WARF’s stem cell patents by submitting references that include: (1) U.S. Patent No. 5,166,065 (“the ’065 patent”);⁶¹ (2) a Robertson et al., publication (“Robertson ’83”);⁶² (3) a second Robertson et al. publication (“Robertson ’87”);⁶³ (4) a Piedrahita et al. publication (“Piedrahita ’90”);⁶⁴ and (5) a declaration of Dr. Jeanne F. Loring.⁶⁵ The PTO previously considered the Piedrahita ’90 reference during the rejection of the abandoned parent application of the ’780 patent and, thus, there are limitations on using this reference during the reexamination.⁶⁶ However, so long as the substantial new question of patentability does not rely solely on this previously considered Piedrahita reference, it may be used in conjunction with the newly submitted prior art.⁶⁷ The declaration of Dr. Loring was not considered a prior art

⁵⁹ 35 U.S.C. § 301 (2006) (“Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent.”); *see also* 35 U.S.C. § 302 (2006) (“The request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested.”).

⁶⁰ PUBPAT, *Groups Challenge Stem Cell Patents That Loot Taxpayer Funds and Force Research Overseas: University of Wisconsin Affiliate Claims Rights to All Embryonic Stem Cells Used for Research*, <http://www.pubpat.org/warfstemcellsfiled.htm> (last visited Apr. 19, 2007).

⁶¹ *In Vitro Propagation of Embryonic Stem Cells*, U.S. Patent No. 5,166,065 (filed May 31, 1990).

⁶² ROBERTSON ET AL. I, TERATOCARCINOMAS AND EMBRYONIC STEM CELLS 647-83 (1983) (Cold Spring Harbor Laboratory).

⁶³ ROBERTSON ET AL. II, TERATOCARCINOMAS AND EMBRYONIC STEM CELLS, A PRACTICAL APPROACH 71-112 (1987).

⁶⁴ Piedrahita et al., *On the Isolation of Embryonic Stem Cells: Comparative Behavior of Murine, Porcine and Ovine Embryos*, 34 THERIOGENOLOGY, 879 (1990).

⁶⁵ Declaration of Dr. Jeanne F. Loring, <http://www.pubpat.org/assets/files/warfstemcell/LoringDeclarations.pdf> (submitted to PTO July 17, 2006).

⁶⁶ PADMASHRI PONNALURI, UNITED STATES PATENT & TRADEMARK OFFICE, CONTROL NO. 90/008,102 *EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM, Sept. 29, 2006, <http://www.pubpat.org/assets/files/warfstemcell/90008102-1granted.pdf>.

⁶⁷ *In re Portola Packaging*, 110 F.3d 786, 790 (Fed. Cir. 1997) (noting that Congress intentionally limited the scope of reexamination to prior art not previously considered in order to

patent or publication within the statutory requirement and was not used in the examination.⁶⁸

The PTO held each request for *ex parte* reexamination, filed by FTTCR and PUBPAT, to raise a substantial new question of patentability.⁶⁹ The PTO concluded each piece of prior art and the “old” Piedrahita reference describe technology so near to the invention claimed by WARF that the art must be examined anew to determine the validity, or obviousness, of the WARF patents.⁷⁰ The references describe isolation of ES cells, maintenance of these cells, and general aspirations of future research in humans.⁷¹ This PTO determination may not bode well for WARF as approximately 70% of reexaminations result in altered or cancelled claims.⁷² However, closer comparative analysis is necessary to determine if the PTO determination will subsist and render the WARF patents obvious.

B. Are the Stem Cell Patents Obvious in Light of the Prior Art?

Upon further review by the PTO, the substantial new question of patentability raised by FTTCR and PUBPAT blossomed into a complete rejection of all WARF claims as obvious or anticipated by the prior art.⁷³ Now, WARF has sixty days to respond to the remarks made by the PTO in the rejections.⁷⁴ WARF’s burden entails a rebuttal of the points raised by the PTO with the intention of declaring that the stem cell patents WARF possesses were nonobvious and not anticipated at the time of their issue.

A patent claim is obvious, and thus invalid, when the differences between the claimed invention and the prior art “are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.”⁷⁵ This judgment proceeds on a claim-by-claim basis.⁷⁶

prohibit patentees from harassing reexamination requests); see 35 U.S.C. § 303(a) (2006); see also *Markman v. Lehman*, 987 F. Supp. 25, 28 (D.C. Cir. 1997) (requiring new prior art or a combination of new prior art with additional previously considered art as a standard for patent reexamination).

⁶⁸ *Ex Parte* Reexamination Communication Transmittal Form, *supra* note 66.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Kathleen Gallagher, *Wisconsin Stem Cell Patents to Get Review*, MILWAUKEE J. SENTINEL, Oct. 4, 2006, at D1. “One or more of a patent’s claims are changed 59% of the time when a third party has requested a re-exam. All of the claims are confirmed 29% of the time and the patent is cancelled 12% of the time.” *Id.* (quoting U.S. Patent & Trademark spokesperson Brigid Quinn).

⁷³ PONNALURI, *supra* note 66; BENNETT CELSA, UNITED STATES PATENT & TRADEMARK OFFICE, CONTROL NO. 90/008,139 OFFICE ACTION IN *EX PARTE* REEXAMINATION, Mar. 30, 2007, <http://www.pubpat.org/warfstemcell.htm> (rejecting Patent No. 6,200,806); GARY L. KUNZ, UNITED STATES PATENT & TRADEMARK OFFICE, CONTROL NO. 95/000,154 OFFICE ACTION IN *INTER PARTES* REEXAMINATION, Mar. 30, 2007, <http://www.pubpat.org/warfstemcell.htm> (rejecting Patent No. 7,029,913).

⁷⁴ 37 C.F.R. 1.550(b) (2000) (the PTO must give at least thirty days for a response).

⁷⁵ 35 U.S.C. § 103(a) (2006); *Graham v. John Deere Co.*, 383 U.S. 1, 13 (1966).

⁷⁶ 35 U.S.C. § 282 (2006) (“Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim”).

Obviousness determinations rely on a factual examination of: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims of the patent in question; (3) the level of skill in the art at the time of the invention; and (4) the objective secondary factors of nonobviousness.⁷⁷ Until recently, the standard articulated by the Court of Appeals for the Federal Circuit held that obviousness based on the teachings of multiple prior art references must provide for some explicit "suggestion, teaching, or motivation" that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed.⁷⁸ This standard guarded against the often-misapplied hindsight-based obviousness analysis.⁷⁹ The Supreme Court modified this obviousness analysis applied to combinations of prior art references by disavowing the rigid Federal Circuit standard.⁸⁰ Nonetheless, the WARF patents should prevail under the current obviousness inquiry.

1. *The Prior Art*

The '065 Patent teaches a method of isolating and maintaining mammalian ES cells.⁸¹ The '065 Patent provides a list of mammalian representatives, including humans, for which this invention would extend.⁸² Importantly, the '065 patent specification does not denote any actual practice of the claimed method in an application for isolating HESCs.⁸³ This invention also denotes the use of specialized media for the purpose of modulating the survival and growth of the ES cells for up to twenty weeks.⁸⁴ The Robertson '83 and Robertson '87 references cover like ground (also in mouse ES cells) in the obviousness analysis, disclosing a "recipe" for embryonic stem cell isolation and maintenance similar to the '065 Patent.⁸⁵ The previously considered Piedrahita '90 reference proclaims a method for isolating

⁷⁷ *Graham*, 383 U.S. at 17–18 (solidifying the requirements of patentability with regards to obviousness following difficulties in application after the enactment of the 1952 Patent Act).

⁷⁸ *See* *Teleflex, Inc. v. KSR Int'l Co.*, 119 F. App'x 282, 285 (Fed. Cir. 2005); *see also In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) ("[P]articulate findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."); *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) ("In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.")

⁷⁹ *In re Demiczak*, 175 F.3d 994, 998–99 (Fed. Cir. 1999) ("[C]ritical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field."); *see also Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 664–65 (Fed. Cir. 2000) (explaining that the temptation to engage in impermissible hindsight is especially strong with seemingly simple mechanical inventions).

⁸⁰ *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __ (2007).

⁸¹ *See In Vitro Propagation of Embryonic Stem Cells*, U.S. Patent 5,166,065 (filed May 31, 1990).

⁸² *Id.* at col.2 l.37–40 (listing humans, chickens, mice, fish, sheep, pigs, cattle, and goats).

⁸³ *Id.*

⁸⁴ *Id.* at col.10 (claiming a process for maintaining animal embryonic stem cells in vitro while retaining their pluripotential phenotype that comprises culturing cells in a culture medium containing leukaemia inhibitory factor ("LIF")).

⁸⁵ *See* ROBERTSON ET AL. I, *supra* note 62; *see* ROBERTSON ET AL., *supra* note 63.

embryonic stem cells attempted in mice, pigs, and sheep.⁸⁶ Of note in the Piedrahita reference were the conflicting results found using the same isolation and maintenance methods on each animal species.⁸⁷

The PTO supplemented the prior art submitted by FTICR and PUBPAT with: (1) U.S. Patent No. 5,453,357 (“the ’357 patent”)⁸⁸; (2) U.S. Patent No. 5,690,926 (“the ’926 patent”)⁸⁹; and (3) the Bongso et al., publication (“Bongso”).⁹⁰ The ’357 patent discloses yet another isolation and maintenance of embryonic stem cells.⁹¹ The ’357 patent includes broad claims that encompass human cells even though HESC isolation and maintenance was not specifically taught in the specification.⁹² The ’926 patent is a continuation-in-part of the ’357 patent and claims similar coverage under “non-mouse” terminology.⁹³ The Bongso reference was considered during the prosecution of the WARF patents but is now presented in a “new light” for the obviousness analysis.⁹⁴ Bongso discloses an isolation technique for HESCs, but the maintenance of these cells only lasted two passages.⁹⁵

2. *The WARF Patents*

By comparison, the ’780 patent describes an advantageous embodiment wherein primate ES cells are isolated and continue to proliferate in an undifferentiated state for at least eleven months.⁹⁶ Further, the ES cell lines also have the ability to differentiate into all tissues even after maintained in an undifferentiated state for long periods of time.⁹⁷ Claim 11 of the ’780 Patent also specifically claims a “cell line.”⁹⁸ The ’780 patent also notes “dramatic differences in primate and mouse development limits the usefulness of mouse ES cells as a model of human development.”⁹⁹ Thus, the ’780 patent utilized rhesus monkeys to isolate ES cells for a more accurate model for human studies.¹⁰⁰ Last, the patent specifically notes that no other primate (human or non-human) ES cell line exists, and others have failed to

⁸⁶ Piedrahita et al., *supra* note 64 (comparing the efficiency of isolation and the characteristics of embryo-derived cell lines from murine, porcine, and ovine embryos).

⁸⁷ *Id.*

⁸⁸ Pluripotential Embryonic Cells and Methods of Making the Same, U.S. Patent No. 5,453,357 (filed Oct. 8, 1992).

⁸⁹ Pluripotential Embryonic Cells and Methods of Making the Same, U.S. Patent No. 5,690,926 (filed Mar. 25, 1994).

⁹⁰ Ariff Bongso et al., *Isolation and Culture of Inner Cell Mass Cells from Human Blastocysts*, 9 HUMAN REPRODUCTION 2110 (1994).

⁹¹ ’357 Patent.

⁹² *Id.*

⁹³ ’926 Patent col.15.

⁹⁴ PONNALURI, *supra* note 66; CELSA, *supra* note 73.

⁹⁵ Bongso et al., *supra* note 90, at 2110.

⁹⁶ Primate Embryonic Stem Cells, U.S. Patent No. 5,843,780 (filed Jan. 18, 1996).

⁹⁷ *Id.* at col.4 (holding a qualification for the patent as continuous growth in cell culture for at least one year).

⁹⁸ *Id.* at col.22.

⁹⁹ *Id.* at col.2 (explaining that because humans are primates, and development is remarkably similar among primates, primate ES cells lines will provide a better model for understanding cellular differentiation in humans).

¹⁰⁰ *Id.* at col.6.

create permanent primate ES cell lines and demonstrate full differentiation capabilities in isolated primate ES cells.¹⁰¹

The '806 patent of WARF is a divisional of the '780 patent.¹⁰² The patent's innovative extension is to human embryonic stem cell lines.¹⁰³ The '806 patent discloses aims for future treatment of diseases via transplantation of HESC-derived cells.¹⁰⁴

Finally, the '913 patent is a continuation of the '806 patent and claims the advantageous maintenance of HESCs without the addition of anti-differentiation media.¹⁰⁵ Simply put, this invention illustrates a novel characteristic of these primate ES cells and provides a new method of HESC maintenance.¹⁰⁶

3. Analysis of the WARF Against the Prior Art Patents Belies Obviousness

A first patent examiner rejected each of the pioneering WARF '780 patent claims. The second and third patent examiners rejected the claims of the '806 patent and the '913 patent, respectively. The approach in these two subsequent rejections parallel the grounds for rejecting the '780 patent. One common theme presented and relied on by the examiners was the ease with which the prior art would extend to other species, especially humans. The claims of the '780 patent may fall under the literal interpretation of the prior art patents. However, the literal extension does a distinct injustice to the innovative elements of the WARF patents. For example, the examiner states that the '065 patent "teaches" the isolation and maintenance of "animal" embryonic cells and correlates this to primates/humans.¹⁰⁷ The examiner also unfairly extends the maintenance of embryonic stem cells of the '065 from the specified "about 20 weeks" to cells "capable" of proliferation of over one year.¹⁰⁸ Similarly, the examiner rejects the claims of the '780 patent in light of the '926 patent by extending "at least 20 passages" to "capable of indefinite maintenance."¹⁰⁹ Further, the examiner focuses on the unpatentable inherent properties of embryonic stem cells; however, the claims of the patent are for "a purified preparation of primate embryonic stem cells" and this "preparation" differs greatly from naturally

¹⁰¹ *Id.* at col.4; see also Bongso et al., *supra* note 90, at 2110 (reporting that in the only published report on attempts to isolate HESCs, conditions were used (LIF in the absence of fibroblast feeder layers) that did not result in HESCs which can remain in an undifferentiated state and failed to continue to proliferate after 1 or 2 subcultures).

¹⁰² Primate Embryonic Stem Cells, U.S. Patent No. 6,200,806 (filed June 26, 1998).

¹⁰³ *Id.* at col.21.

¹⁰⁴ *Id.* at col.16–17 (explaining human diseases potentially treatable with HESCs include neurological disorders such as Parkinson's disease, juvenile onset diabetes or AIDS, and because undifferentiated ES cells can proliferate indefinitely in vitro they can be genetically manipulated either to prevent immune rejection after transplantation, or to give them new genetic properties to combat specific diseases).

¹⁰⁵ Primate Embryonic Stem Cells, U.S. Patent No. 7,029,913 (filed Oct. 18, 2001).

¹⁰⁶ *Id.* at col.21–22 (declaring cell culture of the HESCs no longer requires exogenous addition of leukemia inhibitory factor to maintain the cells in an undifferentiated state).

¹⁰⁷ PONNALURI, *supra* note 66, at 10.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 13, 15.

occurring embryonic stem cells.¹¹⁰ HESCs do not inherently grow *in vitro*; nor do HESCs inherently proliferate in an undifferentiated state.

The examiner rejected the method claims of the '780 patent that detailed the isolation of the primate embryonic stem cells.¹¹¹ The examiner used each prior art reference available to show the methods were similar or "the exact same method."¹¹² These arguments may have merit and WARF may have to consider an amendment concerning these claims. Importantly, the method claims of the '780 patent would not dampen the true innovative establishment of immortal HESCs, namely the inventive creation of cell culture conditions sufficiently mimicking the growth conditions of the primate body.¹¹³

Embryonic stem cell science at the time of the invention was shackled with considerable unpredictability, particularly in regards to any methods in human research. The prior art references disclose research methodologies in embryonic stem cell science and mention the desire to extend the science to humans. However, in view of the state of the art at the time, the extensions towards HESC creation were more likely classified as "merely invitations to those skilled in the art to try to make the claimed invention" or "obvious to try."¹¹⁴ This "obvious to try" notion is not a permissible grounds for rejection of a patent as obvious.¹¹⁵ Additionally, when an invention was "obvious to try" following the disclosure of a new technology or methodology related to a new area of research, the invention may be considered nonobvious if the prior art only revealed generalities towards the result.¹¹⁶

Those skilled in the art of embryonic stem cell science, at the time of the invention, possessed extraordinary scientific abilities necessary for the cutting edge area of technology. However, obviousness is not determined from the views of these specialists or the patentee.¹¹⁷ Obviousness analysis is viewed in terms of one having *ordinary* skill in the art.¹¹⁸ Also, only a reasonable expectation of success from the combination of prior art is required to find an invention obvious.¹¹⁹ When viewing the prior art, there is considerable evidence that one of ordinary skill in the art would not be able to easily, or reasonably, generate HESCs from the combined teachings of the prior art. The previously considered Piedrahita reference exemplifies this by disclosing a complete failure in establishing embryonic stem cells from sheep using

¹¹⁰ *Id.* at 3–6.

¹¹¹ *Id.* at 17–19.

¹¹² *Id.*

¹¹³ CHRISTOPHER THOMAS SCOTT, *STEM CELL NOW: FROM THE EXPERIMENT THAT SHOOK THE WORLD TO THE NEW POLITICS OF LIFE 2* (2006) (describing the replication of the *in vivo* growth environment as the first major groundbreaking hurdle).

¹¹⁴ *In re* Patrick H. O'Farrell, 853 F.2d 894, 902 (Fed. Cir. 1988).

¹¹⁵ *Id.* ("Any invention that would in fact have been obvious under § 103 would have also have been, in a sense, obvious to try.")

¹¹⁶ *Id.* at 903; *see also In re* Dow Chemical Co., 837 F.2d 469, 473 (Fed. Cir. 1988).

¹¹⁷ *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448 (Fed. Cir. 1985) ("[O]ne should not go about determining obviousness under § 103 by inquiring into what *patentees* (i.e., inventors) would have known or would likely have done, faced with the revelations of references.")

¹¹⁸ 35 U.S.C. § 103(a) (2006).

¹¹⁹ *In re* O'Farrell, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (noting that inventions might seem obvious on the surface, but the actual reduction to practice is more telling because there are always unexpected results or delays).

the same methods successful in mice.¹²⁰ Moreover, the Bongso reference isolated HESCs but could not maintain these cells for over two passages.¹²¹ In fact, the maintenance of HESCs requires a complex solution of nutrients and growth media.¹²² More telling, present research still holds that “[h]uman embryonic stem cells are notoriously difficult to handle.”¹²³

When compared, the WARF patents do not describe inventions obvious or anticipated in light of the prior art submitted by FTTCR and PUBPAT. The prior art lacks any teaching for the creation HESCs; only teaches isolation of mouse or pig ES cells; and with a few keystrokes, suggests application of this groundbreaking, complex methodology in humans.¹²⁴ It is often found in research that what works in animals may not always translate to humans.¹²⁵ The prior art recites species-specific isolation procedures, but does not follow up with future implications for human cells.¹²⁶ Importantly, none of the references taught a protocol for maintenance of HESCs. Even though human welfare is usually an implicit motivation in scientific studies, the simple broadening of a particular invention in the claim language to encompass a complex human-based undertaking should not be enough to satisfy the requirements for finding an invention obvious in light of a combination of prior art references.

4. *The Secondary Factors also Favor Nonobviousness*

The secondary factors of nonobviousness, although not determinative, support the alternative considerations for the ultimate ascertainment of nonobviousness of an invention.¹²⁷ These secondary factors may comprise: (1) evidence of copying; (2) a long-felt, but unmet need; (3) the failure of others; (4) commercial success; (5) unexpected results from the claimed invention; (6) unexpected properties of the claimed invention; (7) licenses of the invention; and (8) skepticism of those skilled in the art before the invention.¹²⁸

¹²⁰ Piedrahita *supra* note 64.

¹²¹ Bongso et al., *supra* note 94, at 2110.

¹²² MELISSA K. CARPENTER et al., *Protocols for the Isolation and Maintenance of Human Embryonic Stem Cells*, in HUMAN EMBRYONIC STEM CELLS 116–120 (Totowa NJ: Humana Press, A. Y. Chiu and M. S. Rao, eds., 2003).

¹²³ Gareth Cook, *U.S. Stem Cell Research Lagging Without Aid, Work Moving Overseas*, BOSTON GLOBE, May 23, 2004, A1. “A lot of stem cell biology is like gardening, [s]ome people can grow orchids, and some can't grow tomatoes.” *Id.* (quoting Stephen Minger, who isolated the cystic fibrosis cell line and is an American scientist who now works at King's College London).

¹²⁴ See *In Vitro* Propagation of Embryonic Stem Cells, U.S. Patent No. 5,166,065; see ROBERTSON ET AL. II, *supra* note 63; see ROBERTSON ET AL. I, *supra* note 62; see Piedrahita, *supra* note 64.

¹²⁵ Stephen S. Hall, *Adult Stem Cells: With Research on Embryonic Stem Cells Mired in Controversy, Adult Stem Cells are Quietly Providing the Basis for Striking Advances Toward New Therapies*, TECHN. REV., Nov. 2001, at 2 (detailing intriguing findings of neural cell growth from stem cells in mice, but noting the experiments are far from definitive).

¹²⁶ See '065 Patent; see ROBERTSON ET AL. I, *supra* note 62; see ROBERTSON ET AL. II, *supra* note 63; see Piedrahita, *supra* note 64.

¹²⁷ Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1483 (Fed. Cir. 1997).

¹²⁸ Amgen, Inc. v. Hoescht Marion Roussel, Inc., 126 F. Supp. 2d 69, 113 (D. Mass. 2001).

The inclusion of the evidence supporting the secondary factors also precludes a finding of obviousness for the WARF patents. It was well recognized that the invention was the first evidence disclosing the creation of viable embryonic stem cell lines.¹²⁹ Specifically, the patent declares that the creation of immortal primate embryonic stem cell lines had never been accomplished before.¹³⁰ Similarly, the development of ES cells and HESCs that remain undifferentiated and continue to replicate forever were unexpected inventions definitely not anticipated by the others skilled in the art at the time of the WARF patents.¹³¹ The span of fifteen years from Robertson '83 to the first WARF patent only highlights the innovation, or long-felt need, behind the patents. Stated another way, as no one was able to extend any previously available isolation procedures into isolation of HESCs for such a period of time, an argument stating that HESC science was obvious contradicts the actual progression of embryonic stem cell science. Additionally, the great number of licensees of the HESC technology in this highly technical area of research also indicates commercial success and a validation of the innovative characteristics of the HESCs.¹³² The inclusion of the secondary factors involved with the WARF patents only strengthens the preceding arguments of nonobviousness.

Overall, WARF should prevail when the PTO considers its response. The PTO concedes that it “does not have the facilities or resources to provide factual evidence needed” for a proper comparison.¹³³ The PTO simply shifts the burden to WARF after the preliminary finding of obviousness.¹³⁴ For WARF, these issues were fought over during the initial patent prosecution, so “[t]here’s really nothing new here.”¹³⁵

5. *WARF is not Without Alternative Options*

WARF will rebut the results of this reexamination by clearly pointing out why the subject matter as claimed is not anticipated or rendered obvious by the prior art.¹³⁶ Additionally, if necessary, the reexamination procedure allows the patent owner an opportunity to propose any amendment or narrow the scope of the patent

¹²⁹ *E.g.*, Thomas H. Maugh II, Scientists Move Closer to Ability to Grow Tissue Research: Cell Reproduction Technique Holds Potential for Producing Organs for Transplant, L.A. TIMES, Nov. 6, 1998, at 1.

¹³⁰ '780 Patent.

¹³¹ Cathy Tran, *WARF Stem Cell Patents Challenged*, SCIENTIST, available at <http://www.the-scientist.com/news/home/25037/> (last visited Apr. 19, 2007). “From firsthand painful experience, [the techniques were] not obvious in the scientific community . . . is easy in retrospect, but you really have to base it on real firsthand experiences of the people in those days.” *Id.* (quoting one of the groups that tried and failed to isolate HESCs, researcher Michael West, CEO of Advanced Cell Technology and founder of Geron Corporation).

¹³² Wahlberg, *supra* note 46.

¹³³ PONNALURI, *supra* note 66, at 15.

¹³⁴ *Id.*

¹³⁵ John Schmid, *Stem-Cell Patents Tossed: Preliminary Decision Against UW May Set Up Years-Long Battle*, MILWAUKEE J. SENTINEL, Apr. 2, 2007.

¹³⁶ 37 C.F.R. § 1.530(c) (2000).

claims to avoid the newly proffered prior art.¹³⁷ Finally, a patent owner is also entitled to seek court review with respect to a decision of unpatentability.¹³⁸

One of the chief avenues WARF may tackle is the enablement issue in the prior art. Patents issued are presumed to have satisfied the statutory requirement of enablement.¹³⁹ Normally, a prior art reference must be enabling to satisfy a full disclosure of the invention to the public.¹⁴⁰ However, during this reexamination, the enablement considerations of the prior art were held to a lower requirement than the enablement necessary under statutory analysis of a patent.¹⁴¹ Neither the '065 or '926 patents teach a specific method for isolation and maintenance of HESCs even though these cells do fall under their respective claims.¹⁴² Therefore, WARF is challenged with the burden of showing that the mere suggestion of extending the claimed methods of embryonic stem cell isolation and maintenance in the '065 and '926 patents to humans was not sufficiently taught, or enabled, by the specifications.¹⁴³ Some of the previously stated points will bolster this enablement argument in favor of WARF; notably, the span of time between the '065 patent and the first WARF patent, and the difficulty in isolating and maintaining an immortal HESC line will diminish the legitimacy of the suggestions in the prior art.

C. Are the Royalties for WARF's Patents Excessive?

The attacks on the validity of the WARF patents have also included deliberations on the patent royalties levied by WARF on any entity that uses its inventions in a commercial setting.¹⁴⁴ The opponents argue that the royalties are excessive and are driving both money and research out of the United States.¹⁴⁵

¹³⁷ 35 U.S.C. § 305 (2006) (“[T]he patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art . . . or in response to a decision adverse to patentability.”); *see, e.g.*, *Total Containment, Inc. v. Environ Products, Inc.*, 921 F. Supp. 1355, 1378–79 (E.D. Pa. 1995), *affirmed in part, vacated in part*, 106 F.3d 427 (Fed. Cir. 1997) (explaining that the statute does not allow the patent owner to expand the scope of the claims as this can only be done by patent reissue).

¹³⁸ 35 U.S.C. § 306 (2006) (“[P]atent owner involved in a reexamination . . . may appeal under the provisions of section 134 of this title, and may seek court review . . . with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.”).

¹³⁹ *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003).

¹⁴⁰ *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 114 (D. Mass. 2001).

¹⁴¹ CELSA, *supra* note 66, at 9.

¹⁴² *See In Vitro Propagation of Embryonic Stem Cells*, U.S. Patent 5,166,065; *Pluripotential Embryonic Cells and Methods of Making the Same*, U.S. Patent No. 5,690,926.

¹⁴³ *Amgen*, 314 F.3d at 1354–55.

¹⁴⁴ *See* Steven Ertelt, *Patent Debate Stalling Stem Cell Research More Than President Bush Veto*, <http://www.lifenews.com/bio1657.html> (last visited Apr. 19, 2007). “The patents are impeding our research . . . it is making scientists go overseas to do this sort of research. It isn’t the funding that’s sending us overseas. It’s the patent issues.” *Id.*

¹⁴⁵ *Id.* (explaining that the licenses for the embryonic stem cells are not difficult to obtain, but the costs may be \$75,000–\$250,000 for the biotech firms hoping to initiate stem cell research).

WARF counters that it is a necessary right of the patentee to assess royalties that may be used to fund its future research and promote scientific progress.¹⁴⁶

“The applicant, patentee, or his assigns or legal representatives may . . . grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.”¹⁴⁷ Furthermore, a patentee may also refuse to grant anyone a patent license altogether.¹⁴⁸ Any motive for refusing to offer licenses, valid or otherwise, is of no consequence.¹⁴⁹ Thus, the long-standing law grants the inventor absolute property rights in his invention.¹⁵⁰ Unsurprisingly, the courts have thus held that a patentee is free to set any royalty for their patented product.¹⁵¹ In contrast to these foundational rules of the patent monopoly, there has been the rare occasion for the court to hold, where a patent owner controls a major portion of an industry, the imposition of exorbitant and oppressive royalties may detrimentally affect public interests.¹⁵² The actions of WARF in the HESC research community do not rise to these exceptional levels.

Recent trends have alluded to an initial exodus of money and research in stem cell science.¹⁵³ This is likely a response to the aforementioned lack of federal funding in stem cell research. Others distinctly blame the loss on the excessive royalties and the uncertainty any entity would face if it brought a stem cell-related product to the commercial market.¹⁵⁴ Yet, WARF cheaply distributes HESCs to hundreds of researchers around the world.¹⁵⁵ If these recipients strive to make money off the innovation of WARF, it is only just that WARF also benefit in order to bolster its own

¹⁴⁶ California Stem Cell Report, *supra* note 53 (noting that WARF would not allow CIRM to “trade on Wisconsin technology to build a commercial program” and that Wisconsin was entitled to receive payments for use of its products and that the funds would go for research and education).

¹⁴⁷ 35 U.S.C. § 261 (2006).

¹⁴⁸ 35 U.S.C. § 271(d)(4) (2006) (explaining that the patent statute provides that no patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having refused to license or to use any rights to the patent); *see* SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1206 (2d Cir. 1981) (explaining that the threat of treble damages liability for refusing to license might inhibit potential patent holders from disclosing patents for commercial exploitation, and the efficacy of the economic incentives afforded by our patent system might be severely diminished).

¹⁴⁹ Radio Corp. of Am. v. Hygrade Sylvania Corp., 10 F. Supp. 879, 883 (D.N.J. 1934).

¹⁵⁰ *Id.* (explaining that if the court held the power to compel the patentee to license its invention the rights of the patent owner and the patent itself would be worthless).

¹⁵¹ W.L. Gore & Assocs. v. Carlisle Corp., 529 F.2d 614, 623 (3d Cir. 1976) (stating that a price “so high as to preclude acceptance of a license offer is, after all, not appreciably different from a refusal to license upon any terms.”); *see* Brulotte v. Thys Co., 379 U.S. 29, 33 (1964) (“A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly.”).

¹⁵² Am. Photocopy Equip. Co. v. Rovico, Inc., 359 F.2d 745, 748 (7th Cir. 1966) (finding the oppressive royalties, control of an industry, and price fixing of a plaintiff warrants relief to a defendant in a preliminary injunction motion). *But cf.* Standard Oil Co., Inc. v. United States, 283 U.S. 163, 170 (1931) (holding that a patent pool had no obligation to charge a reasonable royalty).

¹⁵³ Cook, *supra* note 122, at A1 (noting that stem cell companies are moving overseas due to better funding policies). The United States is losing its competitive edge as other countries are producing their own HESCs. *Id.*

¹⁵⁴ Posting of Kapor, *supra* note 33 (explaining terms under which the state would benefit and the taxpayers repaid in the event of successful commercialization are murky and lack sufficient protection for the public).

¹⁵⁵ WiCell, *supra* note 49.

scientific output. WARF has disclosed its invention to all and has earned its patent monopoly. Perhaps due to the outside influences described herein, the boundaries of this monopoly, specifically the scope of the claims or extent of the royalties, may be altered in a more stem cell-friendly governmental environment. Until then, the stem cell patent royalties levied by WARF should not be judged excessive.

III. PROPOSAL

Pioneering work may become a target in any industry following an award of a patent monopoly. Therefore, this section recommends guidelines and legislation to protect the valid interests of the stem cell pioneers. First, adherence to the policy of patent protection for revolutionary inventions must occur to “promote the useful arts.” Second, patent reform proposing post-grant opposition procedures will reduce later conflict against pioneering patents. Last, a perceived trend of the courts towards compulsory licensing must be resisted.

A. The Incentive to Innovate Should Be Protected

“[T]he idea that exclusive rights in new knowledge will promote scientific progress is counterintuitive to many observers of research science, who believe that science advances most rapidly when the community enjoys free access to new discoveries.”¹⁵⁶ However, courts have upheld the Constitutional purpose of promoting the sciences by enforcing patent monopolies, thereby inducing the incentive to research new inventions, in exchange for disclosure of the invention to the public.¹⁵⁷ The disclosure enables those “skilled in the art” to make and use the invention to further science and the useful arts.¹⁵⁸

Without incentive provided by patent protection, fewer inventions will be made and disclosed if others can simply use novel discoveries without sharing in the costs.¹⁵⁹ This is especially pertinent in biotechnology where commercial interests in academic biomedical research have gathered momentum.¹⁶⁰ Academic institutions are generally not equipped to manufacture and distribute products, and they typically license the patented innovations to the commercial interests.¹⁶¹ Proper patent protection allows for correlative royalties awarding the institution for its

¹⁵⁶ See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1017 (1989).

¹⁵⁷ *Kewanee Oil Co. v Bicron*, 416 U.S. 470, 480–81 (1974) (noting that the stated objective of the Constitution in granting power to Congress to legislate in the area of intellectual property is to promote the progress of science and useful Arts by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs of time, research, and development).

¹⁵⁸ 35 U.S.C. § 112 ¶ 1 (2006).

¹⁵⁹ See Eisenberg, *supra* note 156, at 1025–26 (explaining that if others freely exploited patents, prices would fall and the patent owners would get diminishing returns on their hard earned inventions).

¹⁶⁰ See *id.* at 1018.

¹⁶¹ Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1698 (1996).

discoveries and providing funding for future research.¹⁶² WARF is entitled to its royalties benefit and should not be penalized because of the pioneering nature of its invention.

However, a stronger patent protection policy may have a detrimental effect on the benefit to competitors.¹⁶³ Competitors may face increased costs, difficulties in trying to circumvent patented technologies, and the risk of infringement lawsuits.¹⁶⁴ Therefore, an important factor in the counterbalance of the patent protection and rights is the limited term of the patent.¹⁶⁵ The WARF patents will persist until at least 2015.¹⁶⁶ This period may seem extensive. Yet, in the adolescent field of stem cell science, the patent term is constructively reduced in duration as commercial discoveries often endure a prolonged path to the market.¹⁶⁷ As such, WARF is only more justified in benefiting monetarily from its labor to augment its own incentive to continue to innovate.

B. Support for The Patent Reform Act Will Aid Patent Validity

Legislators have already begun to attempt to reform the patent opposition process. For instance, the House of Representatives has proposed “The Patent Reform Act” (“the Act”) that contains a section detailing post-grant opposition proceedings.¹⁶⁸ Under the Act, a non-owner of a patent may file a petition to institute a proceeding to cancel patent claims the petitioner believes to be invalid.¹⁶⁹ The Act limits the opposition request to twelve months after the grant of a patent.¹⁷⁰ During the twelve-month period, the opposition must provide the issues against the patent claims with particularity, allowing the patentee to respond to, amend, or add claims during the proceedings.¹⁷¹ The determination of the post-grant opposition concludes with certification that denies an opposer the opportunity to raise the issue again before the PTO or the courts.¹⁷²

¹⁶² See WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 300 (2003).

¹⁶³ See *id.* at 297–300 (analyzing the marginal costs of competitors versus residual demand that results in a higher share of the market for a patentee).

¹⁶⁴ See *id.* at 299.

¹⁶⁵ See 35 U.S.C. § 154 (2006).

¹⁶⁶ See *Primate Embryonic Stem Cells*, U.S. Patent No. 5,843,780 (filed Jan. 18, 1996 but claiming, as a continuation-in-part application, the priority date of Jan. 20, 1995 from a previous abandoned application); see *Primate Embryonic Stem Cells*, U.S. Patent No. 6,200,806 (filed June 26, 1998, and also claiming the Jan. 20, 1995, priority date); see *Primate Embryonic Stem Cells*, U.S. Patent No. 7,029,913 (filed Oct. 18, 2001, and also claiming the Jan. 20, 1995, priority date).

¹⁶⁷ Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266–68 (1977) (explaining the “prospect theory” in which early grants for patents not yet commercially viable actually benefits society by reducing wasteful duplicative efforts by competitors).

¹⁶⁸ Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007) (introduced to amend title 35, United States Code, relating to the procurement, enforcement, and validity of patents).

¹⁶⁹ *Id.* § 321.

¹⁷⁰ *Id.* § 322.

¹⁷¹ *Id.* §§ 324, 325 (“The party advancing a proposition under this chapter shall have the burden of proving that proposition by a preponderance of the evidence.”).

¹⁷² *Id.* §§ 333, 334.

The Senate proposal offered is substantively similar to the House's proposed Act.¹⁷³ The filing period is also twelve months after the grant of the patent¹⁷⁴ and a second window is available if the petitioner "establishes a substantial reason to believe that the continued existence of the challenged claim in the petition causes or is likely to cause significant economic harm," the petitioner has been notified of alleged infringement, or if the patentee consents to the proceeding.¹⁷⁵

This legislative reform effort aims to improve public confidence in the validity and quality of issued patents. The legislation will allow the PTO to bolster its own asset of trained professionals in the sciences and patentability requirements with knowledgeable persons timely filing challenges to a patent's validity.¹⁷⁶ Further, the legislative efforts hope to diminish the amount of subsequent litigation that diverts money and resources from more productive purposes, purposes such as promoting innovation and commercializing inventions.¹⁷⁷ Litigation costs have skyrocketed, averaging \$1.5 million to \$4 million per party, depending on the scope of the technology.¹⁷⁸ A comprehensive post-grant review process for patents may alleviate this drain and protect society and patentees alike.¹⁷⁹ Specifically, the legislation would validate issued patents and prevent harassment of patent owners after patent issuance.¹⁸⁰

The stem cell patents could have benefited from this proposed legislation. Foremost, the time limits for post-grant review would have brought challenges to validity immediately. Thus, WARF could have profited from the patent's innovation at the time of issuance without the problematic hindsight of later patent reexaminations. Future disputes similar to the present stem cell patent challenge may be averted if this legislation is enacted. Moreover, societal trust in the patent system will strengthen and costs associated to questionable patents will be reduced.

¹⁷³ Patent Reform Act of 2007, S. 1145, 110th Cong. (2007) (describing a robust post-grant opposition system for challenging the validity of problematic or suspect patents in an administrative proceeding instead of waiting to assert invalidity as a defense in an infringement action).

¹⁷⁴ *Id.* § 322.

¹⁷⁵ *Id.*

¹⁷⁶ *Patent Quality Improvement: Post-Grant Opposition Hearing Before Subcomm. on Courts, the Internet, and Intellectual Property, Comm. on the Judiciary*, 108th Cong 18 (2004) (noting that the PTO can decrease the rate of litigation by using its own professionals with scientific or technical expertise in the field of the invention in addition to agents intimately familiar with the application of certain of the patentability requirements: novelty, nonobviousness, written description, enablement and utility for these post-grant reviews).

¹⁷⁷ *Id.* at 7 (2004) (statement of Lamar Smith, Chairman, Subcomm. On Courts, the Internet, and Intellectual Property).

¹⁷⁸ *Id.* at 32.

¹⁷⁹ *See id.* at 15 (stating that the review procedure is "designed to be more efficient than litigation while preserving enough of the full participation according to parties in litigation that challengers will be able to risk being able to be bound by the result").

¹⁸⁰ *Id.* at 18 (declaring that frivolous challenges would tie up a patent in a long and endless administrative proceeding and be just as detrimental to the patent users, the community, and the needs of the public).

C. Compulsory Licensing Should Be Avoided

The opposition to the stem cell patents believes the monopolistic power of patent holders is waning.¹⁸¹ The landmark *eBay, Inc. v. MercExchange, L.L.C.*¹⁸² decision is thought to weaken the rights of the patent holder by refusing to automatically grant a permanent injunction against an infringer.¹⁸³ The Supreme Court opted against the Federal Circuit's general rule for permanent injunctions barring exceptional circumstances and utilized the traditional factors for an equitable decision on the need for an injunction.¹⁸⁴ Importantly, the Court noted that the patentee might not be allowed its right to exclude despite willful infringement by eBay.¹⁸⁵ Those favorable to the inventors or patentees believe the holding of this case amounts to a compulsory license in favor of potential infringers.¹⁸⁶ The patent holder has lost its bargaining power of injunction, and any judicial outcome between the parties will only result in royalties under the discretion of the courts.¹⁸⁷ Accordingly, the stem cell patent opposition believes this result will open the gateway to sanctioned use, at a judicially created price, of the stem cell patents for the betterment of society and the benefit of those in need of the therapeutic technology.¹⁸⁸

Compulsory licensing is not commonplace and is heavily disfavored in the patent system.¹⁸⁹ In fact, it has only been granted in narrow cases presenting a strong countervailing public interest,¹⁹⁰ or in cases brought by the government as a remedy

¹⁸¹ Foundation for Taxpayer and Consumer Rights, *Supreme Court's eBay Ruling Weakens Position of Stem Cell Patent Holder, But Vital California Research Still Impeded, Consumer Advocates Say*, May 18, 2006, available at <http://www.consumerwatchdog.org/healthcare/pr/?postId=6256> (last visited Apr. 19, 2007).

¹⁸² 126 S. Ct. 1837 (2006).

¹⁸³ Foundation, *supra* note 180.

¹⁸⁴ *eBay*, 126 S. Ct. at 1839 (providing the factors that a plaintiff must demonstrate for an injunction as: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction).

¹⁸⁵ *Id.* at 1841 (noting the difficulty of equating the right to exclude with monetary damages).

¹⁸⁶ Anne Broache, *Supreme Court Rules in Favor of eBay*, NEWS.COM, May 15, 2006, http://news.com.com/Supreme+Court+rules+in+favor+of+eBay/2100-1030_3-6072150.html (last visited Apr. 19, 2007).

Without injunctions as leverage, inventors may only be entitled to receive monetary damages from any infringement proceeding—this “amounts to a compulsory license at the whim of a judge.” *Id.* (quoting Ronald Riley, president of the Professional Inventors Alliance, which advocates for independent inventors and small- and medium-size businesses).

¹⁸⁷ *See id.*

¹⁸⁸ *See* Foundation, *supra* note 180 (explaining that patent holders, like WARF, may find it more difficult to prove that an injunction is necessary under the new guidelines established by *eBay*).

¹⁸⁹ *See, e.g., Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 186 (1980) (“Compulsory licensing is a rarity in our patent system, and we decline to manufacture such a requirement out of [the patent statute].”).

¹⁹⁰ *See* 28 U.S.C. § 1498 (2006) (allowing a patent owner to sue for reasonable and entire compensation in the Court of Federal Claims when the federal government manufactures or uses a patented invention without a license); 42 U.S.C. § 2183(a) (2006) (subjecting certain kinds of patents relating to nuclear energy to licensing by the Nuclear Regulatory Commission following notice to the patent holder and a hearing); 7 U.S.C. § 2404 (2006) (subjecting certain plant varieties to a two-year compulsory license when the Secretary of Agriculture finds it “necessary in order to insure an

for monopolistic restrictions or pricing.¹⁹¹ It is alleged that the implementation of compulsory licensing would lead to a “regime of routine infringement—and therefore routine litigation” between parties at odds over a patent technology.¹⁹² The influx of infringement would in turn diminish the value of patents and negatively effect innovation normally protected by infringement lawsuits and injunctions.¹⁹³

The policy against compulsory licenses also survives challenges to excessive royalties.¹⁹⁴ The “imposition on a patent owner who would not have licensed his invention for a given royalty is a form of compulsory license, against the will and interest of the person wronged, in favor of the wrongdoer.”¹⁹⁵ Furthermore, the courts do not require a licensee to even make a profit in the license negotiation.¹⁹⁶ These principles, as they pertain to infringers, do not favor those praying for compulsory license on the grounds of excessive royalties.

This precedent suggests the courts are reticent to apply compulsory licenses at all and the royalties imposed by WARF on private research entities are not likely to be deemed overly excessive. The government should thus uphold these well-reasoned policies against compulsory licensing and protect patentee’s rights barring an exceptional circumstance.¹⁹⁷

IV. CONCLUSION

Human embryonic stem cells are a true innovation full of promise for the scientific and therapeutic community. The myriad of possibilities inherent in these cells is yet to be determined. WARF has enabled the scientific community in this regard by providing HESCs at a minimal cost to basic science researchers. However, WARF levies a royalty on any entity utilizing WARF’s patents in a commercial fashion in order to fund WARF’s own future research. Now, with the benefit of hindsight, interest groups are challenging the validity of the WARF’s patents. Furthermore, an outcry from these same interest groups has arisen over “stifling” royalties. These charges oppose the practice of the PTO and the rights of patent ownership. In the end, the innovation behind the WARF stem cell patents must be

adequate supply of fiber, food, or feed in this country,” with the remuneration a reasonable royalty, or greater if litigation is necessary to collect).

¹⁹¹ *E.g.*, *Hartford-Empire Co. v. United States*, 323 U.S. 386, 419 (1945) (enforcing compulsory licensing when defendants cooperated in obtaining and licensing patents, limited and restricted the use of the patented machinery by a network of agreements, and illegally set prices).

¹⁹² Brief of Rembrandt IP Management, L.L.C. as Amicus Curiae in Support of Respondent at 15, *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006) (No. 05-130) (arguing that companies may forego a license because infringement, litigation, and payment of damages may be a better business decision under the new injunction guidelines for patents).

¹⁹³ See F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 733–35 (2001).

¹⁹⁴ See, e.g., *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1384 (Fed. Cir. 2004).

¹⁹⁵ *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1328 (Fed. Cir. 1987).

¹⁹⁶ *Monsanto*, 382 F.3d at 1384.

¹⁹⁷ Public Health Emergency Medicines Act, H.R. 4131, 109th Cong. (2006) (stating that “In the case of any invention relating to health care the Secretary of Health and Human Services shall have the right to authorize use of the subject matter of the patent without authorization of the patent holder . . .”).

recognized, as it was at the time of discovery. The royalties charged by WARF are equally just and illustrate the use of the patent right to further stimulate innovative discovery. To find any different would weaken the patent system and restrain the progress of the sciences.