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Patenting Human Embryonic Stem Cells: What Is So Immoral?

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PATENTING HUMAN EMBRYONIC STEM CELLS: WHAT IS SO IMMORAL?

INTRODUCTION

Stem cell research is at the center of an international ethical and political debate. Stem cells are unspecialized cells, meaning they have the potential to develop into multiple types of cells in the body.[1] Because of this unspecialized quality and stem cells' ability to divide for indefinite periods in lab culture,[2] a significant portion of the scientific community believes that stem cell research is the key to finding new treatments for a variety of human diseases, conditions, and injuries.[3] But stem cells come in different degrees of unspecialization and from a variety of sources, some of which are objectionable to segments of the population. At the forefront of the stem cell debate are human embryonic stem cells ("hESCs"),[4] whose cultivation typically requires an initial destruction of a human embryo.[5] Yet hESCs are the least differentiated type of stem cell, capable of giving rise to any cell type in the human body. Therefore, hESC research, according to many, is far more likely to lead to life-saving treatments than the research of any other stem cell type.[6]

The hESC controversy draws lines through the population similar, but not identical, to those in the abortion rights battle. Opponents of abortion rights commonly assert that a human fetus[7] has the right to life. Although hESC research, in its current state, also involves the destruction of potential human life, it does so at a far earlier stage in human development: to

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1. *See* NAT'L INST. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., STEM CELL BASICS (2009), *available at* http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf [hereinafter STEM CELL BASICS].

2. *See id.* at 1, 22.

3. *See id*. at 13.

4. Researchers Matthew Kaufman and Martin Evans are credited with deriving the first stem cells, from mice, in 1981; it was more than a decade later when the first hESCs were derived. *See* NAT'L INST. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS, at ES-3, 11–12, 30 (2001), *available at* http://stemcells.nih.gov/staticresources/info/scireport/PDFs/fullrptstem.pdf.

5. *See* H.W. Denker, *Potentiality of Embryonic Stem Cells: An Ethical Problem Even with Alternative Stem Cell Sources*, 32 J. MED. ETHICS 665 (2006).

6. *See* Gautam Naik, *Stem-Cell Advance May Skirt Ethical Debate: Scientists Return Adult Cells Back to Embryonic State: 'We'll All Get More Money*,*'* WALL ST. J., June 7, 2007, at B1.

7. The embryo typically develops into the fetus at about eight weeks after fertilization. *See* STEM CELL BASICS, *supra* note 1, at 19.

develop hESC lines,[8] researchers typically harvest the human blastocyst, a preimplantation[9] embryo consisting of about 150 cells and comprised of an outer layer of cells, a fluid-filled cavity, and an inner cell mass.[10] The human blastocyst is essentially a hollow ball, smaller than a pinhead, completely lacking in any features recognizable as human.[11] Because occasionally a blastocyst may be fatally flawed, the probability of a blastocyst developing to the stage of viability is significantly lower than that of a fetus developing to a viable baby.[12] While the line between "fetus" and "child" is hazy, the line between "blastocyst" and "child" is even less clear. Supporters of embryonic stem cell ("ESC") research have a mission quite different from that of abortion rights activists. Human ESC research is performed for the purpose of improving or saving the lives of the now-living and yet-to-be-born. This goal is entirely unrelated to whether a woman has a constitutional right to choose whether to carry out her pregnancy.[13]

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8. An embryonic stem cell line is defined as "embryonic stem cells, which have been cultured under *in vitro* conditions that allow proliferation without differentiation for months to years." *Id*.

9. Preimplantion means before the embryo has attached itself to the uterine wall. *Id*. at 22.

10. The blastocyst is one of the earliest stages of human development, forming around a week after fertilization. The outer layer of cells is known as the trophoblast, which gives rise to the placenta and other supporting tissues. The fluid-filled cavity is known as the blastocoel. The inner cell mass eventually develops into the fetus. *See* NIH, MedlinePlus Medical Encyclopedia: Fetal Development, http://www.nlm.nih.gov/medlineplus/ency/article/002398.htm (last visited Mar. 4, 2009); STEM CELL BASICS, *supra* note 1, at 18–23. For more information and high quality photos of early stages of human development, see Advanced Fertility Center of Chicago, IVF Blastocyst Pictures & Blastocyst Stage Embryo Grading Photos & Images, http://www.advancedfertility.com/blastocystimages.htm (last visited Mar. 4, 2009).

11. *See* Australian Stem Cell Centre, Fact Sheet 6: Ethics of Stem Cell Research, http://stemcellcentre.edu.au/media-centre_resource-library.aspx (last visited Mar. 4, 2009).

12. Theoretically, any healthy human embryo has the potential to develop into a human child if implanted properly. Still, a significant percentage of human sex cells contain genetic or chromosomal abnormalities that may prevent an embryo from developing properly. *See* David K. Gardner & William B. Schoolcraft, *Controversies in Assisted Reproductions and Genetics*, 15 J. ASSISTED REPRODUCTION & GENETICS 455, 455 (1998); Naik, *supra* note 6. About fifteen to twenty percent of pregnancies end in miscarriage; more than eighty percent of miscarriages occur during the first trimester. *See* BabyCenter, Understanding Miscarriage, http://www.babycenter.com/0_understanding-miscarriage_252.bc (last visited Mar. 4, 2009).

13. Because of these disparities, some pro-lifers support hESC research, despite the prerequisite destruction of a human embryo. *See, e.g.*, Michael D. Shear, *Conservatives Ready to Battle McCain on Convention Platform*, WASH. POST, July 7, 2008, at A1; Jeff Zeleny, *House Votes to Expand Stem Cell Research*, N.Y. TIMES, June 8, 2007, at A24.

Because of the clinical promise of hESCs, hESC-based inventions constitute valuable intellectual property.[14] While the humanistic benefits are what make embryonic stem cells research so appealing to scientists, it is the patent system that provides the true incentives for the pharmaceuticals industry and universities to invest in research that guarantees a reasonable opportunity for economic gain.[15]

The Wisconsin Alumni Research Foundation ("WARF") owns three U.S. patents relating to the first ESC lines derived from human blastocysts.[16] The first of these patents issued on December 1, 1998, as U.S. Patent No. 5,843,780 ("'780 patent"). WARF has licensed its patent rights to Geron Corporation,[17] which holds the exclusive rights to develop any of the five hESC lines claimed in WARF's patents.[18]

WARF also filed a European patent application[19] that was nearly identical in content to the '780 patent. Despite this near identity, the European application faced quite different obstacles before the European Patent Office ("EPO"), which is bound by the laws of the European Patent

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14. As of 2002, there were over 2,000 patent applications involving stem cells of any origin, a quarter of which were directed to ESCs. Over a third of the general stem cell applications and a quarter of all embryonic stem cell applications were granted. EUROPEAN GROUP ON ETHICS IN SCI. & NEW TECH. TO THE EUROPEAN COMM'N, ETHICAL ASPECTS OF PATENTING INVENTIONS INVOLVING HUMAN STEM CELLS 10 (May 7, 2002), *available at* http://ec.europa.eu/european_group_ethics/docs/avis16_en.pdf [hereinafter EGE OPINION].

15. *See* James C. De Vellis, *Patenting Industry Standards: Balancing the Rights of Patent Holders with the Need for Industry-wide Standards*, 31 AIPLA Q. J. 301, 310 (2003).

16. Dr. James A. Thomson invented the first embryonic stem cell lines derived from human blasocysts. *See* James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145 (1998). The U.S. Patent and Trademark Office granted three patents for Dr. Thomson's inventions. Dr. Thomson in turn assigned these three U.S. patents to WARF. The three Thomson U.S. patents are as follows: U.S. Patent No. 5,843,780 (issued Dec. 1, 1998); U.S. Patent No. 6,200,806 (issued Mar. 13, 2001); and U.S. Patent No. 7,029,913 (issued Apr. 18, 2006).

17. *See* News Release, Geron Corp., Geron Supports WARF's Claims to Human Embryonic Stem Cell Patents, Apr. 2, 2007, http://www.geron.com/media/pressview.aspx?id=795.

18. *See* Andrew Pollack, *'Politically Correct' Stem Cell Is Licensed to Biotech Concern*, N.Y. TIMES, Dec. 11, 2002, at C8; Sheryl Gay Stolberg, *U.S. Concedes Some Cell Lines Are Not Ready*, N.Y. TIMES, Sep. 6, 2001, at A1.

19. WARF's European patent application, European Patent Application No. 96903521.1, was a regional stage entry of PCT International Application No. PCT/US96/00596 (filed Jan. 19, 1996), which claimed priority and was a continuation-in-part of U.S. Patent Application Serial No. 08/376,327 (filed Jan. 20, 1995).

Convention ("EPC").[20] While the U.S. Patent and Trademark Office ("USPTO") granted the '780 patent relatively quickly,[21] the EPO outright refused to examine the European application on the ground that the invention was "contrary to morality."[22] After years of appeals, the Enlarged Board of Appeal ("Enlarged Board")—the highest level of legal authority in the EPO, responsible for resolving the most important issues of European patent law—ruled on November 25, 2008, that European patent law banned the patenting of ESC inventions whose preparation necessarily involved the destruction of human embryos.[23]

This disparity in treatment underscores a significant divergence between the U.S. and European patent systems.[24] Unlike the USPTO,[25] the

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20. In this Note, "EPO" refers to the European Patent Office, not the European Patent Organization. The EPO is an organ of the legal entity, the European Patent Organization. The EPO was established under Chapter III of the EPC. Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, 1065 U.N.T.S. 254 [hereinafter EPC 1973]. A revised version of the EPC 1973 went into force on December 13, 2007. Convention on the Grant of European Patents (European Patent Convention) as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, *available at* http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/$File/EPC_13th_edition.pdf [hereinafter EPC 2000]. *See also* Stacey J. Farmer & Martin Grund, *Revision of the European Patent Convention and Potential Impact on European Patent Practice*, 36 AIPLA Q.J. 419 (2008).

21. The '780 patent was issued on December 1, 1998; its application was filed on January 18, 1996. Unhappy with Geron's licensing fees, two consumer groups fought back by filing petitions for reexamination of WARF's patents, asserting that WARF's claims were obvious in light of previous stem cell research. The USPTO granted the petition and preliminarily invalidated the claims of the three WARF patents. WARF appealed and won with respect to all three patents. *See* Andrew Pollack, *3 Patents on Stem Cells Are Revoked in Initial Review*, N.Y. TIMES, Apr. 3, 2007, at C2; Grady Frenchick, *WARF Is Likely to Hold on to Stem Cell Patent Right*, WIS. TECH. NETWORK, Apr. 12, 2007, http://wistechnology.com/article.php?id=3844; Press Release, WARF, Patent Office Upholds Remaining WARF Stem Cell Patents, Mar. 11, 2008, http://www.warf.org/uploads/media/Patent_Office_Upholds_Remaining_WARF_SC_Patents_03-11-08.pdf.

22. *See* Case T-1374/04, [2007] E.P.O. O.J. 313 (Technical Bd. App. 2006).

23. Case G-2/06, unpublished op. at 27–28 (Enlarged Bd. App. Nov. 25, 2008), *available at* http://legal.european-patent-office.org/dg3/pdf/g060002ex1.pdf. *See also* Press Release, EPO, No European Patent for WARF/Thomson Stem Cell Application, Nov. 27, 2008, http://www.epo.org/about-us/press/releases/archive/2008/20081127.html.

24. For an overview of the main differences between U.S. and European patentability requirements, see Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AIPLA Q.J. 193 (2007).

25. *See* Ex parte Murphy, 200 U.S.P.Q. 801 (Pat. & Trademark Off. Bd. App. 1977) ("Just as the court in *In re Watson* and in *In re Anthony* made clear that the Patent and Trademark Office is not the governmental agency charged with the responsibility for

EPO is bound by morality provisions. Specifically, Article 53(a) of the EPC prohibits granting a patent for an invention "the commercial exploitation of which would be contrary to 'ordre public' or morality."[26] In addition, Rule 28(c) of the EPC[27] explicitly prohibits patenting inventions concerning "uses of human embryos for industrial or commercial purposes."[28]

While the Enlarged Board's decision is legally sound, it is disturbing that a question of morality—a factor generally unrelated to the classic patentability requirements[29]—has prevented an invention of proven scientific importance and economic value from receiving patent protection in any European state. While Europe appears more close-knit than ever,[30] it is still a pluralistic society. Each of the Member States of the European Patent Organization[31] is its own sovereign State, with its own national patent laws and its own understanding of what "morality" means.[32] While an individual European State may choose to craft its do-

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determining drug safety, we think this Office should not be the agency which seeks to enforce a standard of morality with respect to gambling, by refusing, on the ground of lack of patentable utility, to grant a patent on a game of chance if the requirements of the Patent Act otherwise have been met.") (citations omitted).

26. EPC 2000, *supra* note 20, art. 53(a). On December 13, 2007, a revised version of the EPC entered into force. The previous 1973 version of the EPC worded Article 53(a) slightly differently, prohibiting inventions "*the publication or exploitation* of which would be contrary to 'ordre public' or morality." EPC 1973, *supra* note 20, art. 53(a). (emphasis added). According to the Enlarged Board, "The changes are not relevant to the issues considered in this decision." Case G-2/06, at 2, 27. This Note similarly ignores the discrepancy.

27. Implementing Regulations to the Convention on the Grant of European Patents, Dec. 7, 2006, R. 28, *available at* http://documents.epo.org/projects/babylon/eponet.nsf/0/E4F8409B2A99862FC125736B00374CEC/$File/EPC_13th_edition.pdf [hereinafter EPC Regs.]. The provisions of Rule 28 used to be contained in Rule 23d. Implementing Regulations to the Convention on the Grant of European Patents, Dec. 13, 2001, R. 23d. In the revised version of the EPC, Rule 23d was renumbered as Rule 28. Because this change went into effect between the Technical Board of Appeal's decision in 2006 and the Enlarged Board of Appeal's decision in 2008, the decisions cited in this Note refer to these provisions differently. Case G-2/06, at 2. For the ease of the reader, this Note refers to these provisions hereinafter only as Rule 28.

28. EPC Regs., *supra* note 27, R. 28(c).

29. In other words, some combination of novelty, inventive step, nonobviousness, utility, and industrial applicability.

30. *See* Tony Judt, *The Nation: Fortunes of War: Europe Finds No Counterweight to U.S. Power*, N.Y. TIMES, Apr. 20, 2003, at 41.

31. EPO, Member States of the European Patent Organisation, http://www.epo.org/about-us/epo/member-states.html (last visited Mar. 4, 2009).

32. *See, e.g.*, Case C-377/98, Kingdom of the Netherlands v. Eur. Parliament & Council of the Eur. Union, 2001 E.C.R. I-7079. *See generally* COMM'N OF THE EUROPEAN COMMUNITIES, COMMISSION STAFF WORKING PAPER: REPORT ON HUMAN EMBRYONIC

mestic law to limit the patentability of "immoral" inventions, an outright ban by the EPO robs a State of that choice, regardless of whether the invention would be contrary to the morality of that particular State. Moreover, refusing patents in hESC inventions slows the pace of research at a time when stem cell technology is still in its infancy and large pharmaceutical companies are already somewhat hesitant to invest heavily.[33]

Part I of this Note begins with a general overview of stem cells, including stem cell science, the current state of stem cell research, and ethical concerns facing ESC research. Part II continues with an explanation of the morality exception to patentability present in European patent law. Part III discusses WARF's European patent application, including why the EPO suspended the examination of the application; the procedural history of the case before the Enlarged Board; and the decision of the Enlarged Board. Part IV compares the European and U.S. patent systems and the ramifications of codifying moral issues into patent law. This Note argues that patent offices should not have the authority to make morality determinations because a patent office's expertise is in technology and classic issues of patentability, and mixing patent, a classically objective area of law, with the predominantly subjective arena of moral values undermines the legal certainty of the patent system and its effectiveness in promoting research and investment. This Note concludes by offering a few alternatives to the EPO's current practice of automatically refusing morally dubious patent applications that may serve the purposes of patent law more effectively.

I. OVERVIEW OF STEM CELL SCIENCE AND ETHICAL CONCERNS

Stem cells are unspecialized cells that can differentiate into specialized cells upon receiving specific chemical signals.[34] Unspecialized cells exist at several stages: totipotent stem cells are capable of developing into a complete organism; pluripotent stem cells are capable of differentiating into any specialized cell type in the body, but are incapable of forming the complete organism; and multipotent stem cells are capable of differentiating into more than one, but not every, type of specialized cell.[35]

STEM CELL RESEARCH 43 (2003), *available at* http://europa.eu.int/comm/research/conferences/2003/bioethics/index_en.html [hereinafter CEC REPORT] (comparing the hESC research regulations of EU Member States).

33. *See, e.g.*, Eric Noe, *Stem-Cell Industry, Research Evolving: With Limits on Federal Funding for Stem Cells, Researchers Look for Private and Business Backing*, ABC NEWS, Nov. 23, 2004.

34. The more unspecialized a stem cell, the greater the number of cell types into which it can differentiate. STEM CELL BASICS, *supra* note 1, at 3–4.

35. *Id*. at 21, 23.

Specialized cells, on the other hand, are incapable of differentiating into other types of cells and often replicate slowly, if at all.[36] Accordingly, scientists are trying to manipulate stem cells to regenerate or repair tissues whose specialized cells were damaged, destroyed, or never formed in the first place.[37]

Stem cells can be found in the body at both adult and embryonic stages of life, but in different quantities and qualities.[38] The inner cell mass of the blastocyst—the early, hollow, spherical stage of the embryo—consists of ESCs, which ultimately differentiate into the various 200 or so specialized cell types in the body as the embryo matures into the fetus.[39] Scientists have learned to isolate these pluripotent ESCs and grow them *in vitro* while seemingly retaining the cells' pluripotency indefinitely.[40]

There is a strong movement pushing for continued and increased ESC research, with the hope that scientists will develop methods of treating or curing a wide variety of genetic disorders, diseases, medical conditions, and physical injuries.[41] The major aim of ESC research is to perfect a method of controlling and precisely directing the differentiation of ESCs in order to transplant the healthy differentiated cells into a suffering patient.[42]

But stem cells also exist in adult (i.e., postembryonic) animals; these stems cells are referred to as adult stem cells.[43] There is plenty of re-

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36. *Id*. at 3–4.

37. *Id*. at 13.

38. *Id*. at 12.

39. European Commission, About Stem Cells, http://ec.europa.eu/research/quality-of-life/stemcells/about.html (last visited Mar. 4, 2009); STEM CELL BASICS, *supra* note 1, at 4–5.

40. STEM CELL BASICS, *supra* note 1, at 5–7.

41. *See* Zeleny, *supra* note 13. *But see* Sheryl Gay Stolberg, *Bush Vetoes Bill Removing Stem Cell Limits, Saying "All Human Life Is Sacred*," N.Y. TIMES, June 21, 2007, at A21.

42. NIH, Stem Cells and Diseases, http://stemcells.nih.gov/info/health.asp (last visited Mar. 4, 2009).

43. For example, hematopoietic stem cells (adult stem cells) from the bone marrow give rise to red blood cells, white blood cells, and platelets. STEM CELL BASICS, *supra* note 1, at 4. Stem cells have also been found in extra-embryonic tissues, such as umbilical cord blood stem cells and amniotic stem cells. *See* Paolo De Coppi et al., *Isolation of Amniotic Stem Cell Lines with Potential for Therapy*, 25 NATURE BIOTECH. 100 (2007); Erica Lloyd, *Umbilical Cord Blood: The Future of Stem Cell Research?*, NAT'L GEOGRAPHIC NEWS, Apr. 6, 2006, *available at* http://news.nationalgeographic.com/news/2006/04/0406_060406_cord_blood.html. In addition, in a well publicized case of fabricated research, Korean scientist Hwang Woo Suk claimed in 2004 to have derived embryonic stem cells from the adult cells of a patient, which could have skirted the ethical

search going into adult stem cells, and there are those who believe that adult stem cells will provide benefits similar to, or even greater than, those of embryonic stem cells.[44] However, because adult stem cells are generally multipotent, they are incapable of differentiating into as many cell types as pluripotent ESCs. Therefore, much of the scientific community sees less clinical potential for adult stem cells.[45]

In addition, there is ongoing research into other sources of stem cells,[46] especially those sources that do not require the destruction of human "life."[47] For example, scientists are attempting to "reprogram" adult stem cells back to a less developed, embryonic-like state.[48] This would bypass the ethical concerns posed by ESCs. Additionally, adult stem cells would provide a potential advantage over ESCs in that they would already

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issues attached to deriving embryonic stem cells from living embryos. Although Dr. Hwang's research was later discredited, recently Boston scientist concluded that Dr. Hwang, without even realizing it, had in fact derived his embryonic stem cells from an unfertilized egg through parthenogenesis, a scientific first. *See* Nicholas Wade, *Within Discredited Stem Cell Research, A True Scientific First*, N.Y. TIMES, Aug. 3, 2007, at A16.

44. *See* Matthew Weed, *Discourse on Embryo Science and Human Cloning in the United States and Great Britain: 1984–2002*, 33 J.L. MED. ETHICS 802, 808 (2005). Still, there is some evidence that certain adult stem cell types are pluripotent. Stem cell plasticity is "[t]he ability of stem cells from one adult tissue to generate the differentiated cell types of another tissue." STEM CELL BASICS, *supra* note 1, at 21.

45. *See* Naik, *supra* note 6. *But see* Weed, *supra* note 44, at 804, 808 (reviewing various claims that breakthroughs in adult stem cell technology will eventually make unnecessary the ethically undesireable use of hESCs).

46. *See* PRESIDENT'S COUNCIL ON BIOETHICS, A WHITE PAPER: ALTERNATIVE SOURCES OF HUMAN PLURIPOTENT STEM CELLS (2005), *available at* http://bioethics.gov/reports/white_paper/alternative_sources_white_paper.pdf [hereinafter WHITE PAPER] (discussing the ethical and scientific soundness of alternative sources of human pluripotent stem cells, including pluripotent stem cells derived from "dead" embryos; pluripotent stem cells via blastomere extraction from living human embryos, i.e., extracting a few stem cells from the preblastocyst embryo while retaining its viability; pluripotent stem cells derived from biological artifacts, i.e., artificial, "less than human" embryos similar enough to "true" human embryos to derive pluripotent stem cells from them; and pluripotent stem cells derived from somatic cell dedifferentiation, i.e., reprogramming differentiated adult stem cells to restore an undifferentiated pluripotency typical of embryonic stem cells).

47. *See* DOMESTIC POL'Y COUNCIL, ADVANCING STEM CELL SCIENCE WITHOUT DESTROYING HUMAN LIFE (2007), *available at* http://georgewbush-whitehouse.archives.gov/dpc/stemcell/2007/stemcell_040207.pdf.

48. *See generally* WHITE PAPER, *supra* note 46.

match the patient's genetic makeup and would therefore be less prone to rejection by the patient's immune system.[49]

In the early part of this decade, a group of scientists reported the discovery of a type of adult stem cell derived from bone marrow that could be reprogrammed to differentiate into any tissue type.[50] However, the study was eventually discredited when it was discovered that some of the group's findings were falsified.[51] Notably, in November 2007, scientists reported the discovery of a technique using viruses that converts adult skin cells into cells that behave like ESCs, able to replicate indefinitely and differentiate into any cell type.[52] While the technique potentially represents a major breakthrough for nonembryonic stem cells, it also has a major deficiency: it can potentially lead to mutations and cancers.[53] Although scientists are searching for techniques that do not use cancer-causing viruses, an efficient method has not yet been perfected.[54]

While ESC research may be more promising than adult stem cell research, ESCs have generated a considerable amount of public dissent due

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49. *See, e.g.*, UCSF Children's Hospital, Bone Marrow Transplant, http://www.ucsfhealth.org/childrens/medical_services/cancer/bmt/treatments/leukemia.html (last visited Mar. 4, 2009).

50. Yuehua Jiang et al., Abstract, *Pluripotency of Mesenchymal Stem Cells Derived from Adult Marrow*, 418 NATURE 41 (2002), *available at* http://www.nature.com/nature/journal/v418/n6893/full/nature00870.html.

51. Yuehua Jiang et al., *Corrigendum: Pluripotency of Mesenchymal Stem Cells Derived from Adult Marrow*, 447 NATURE 880 (2007). *See* Peter Aldhous & Eugenie Samuel Reich, *Stem-Cell Researcher Guilty of Falsifying Data*, NEW SCIENTIST, Oct. 7, 2008, http://www.newscientist.com/article/dn14886-stemcell-researcher-guilty-of-falsifying-data.html.

52. *See* Andrew Pollack, *After Stem-Cell Breakthrough, the Real Work Begins*, N.Y. TIMES, Nov. 27, 2007, at F1.

53. The new technique involves inserting into a patient's isolated skin cells viruses carrying genes that cause the cells to revert to an embryonic-like stage. The modified cells would then be administered back to the patient. However, these same viruses can incorporate themselves randomly into the patient's genes, potentially causing mutations and cancers. *See id*. *See also* Peter Aldhous, *Stem Cell Breakthrough May Reduce Cancer Risk*, NEW SCIENTIST, Feb. 27, 2008, *available at* http://www.newscientist.com/article/dn13384-stem-cell-breakthrough-may-reduce-cancer-risk.html; Alan I. Leshner & James A. Thomson, *Standing in the Way of Stem Cell Research*, WASH. POST, Dec. 3, 2007, at A17.

54. *See* Peter Aldhous, *Ethical Stem Cells Stripped of 'Cancer' Genes*, NEW SCIENTIST, Mar. 1, 2009, http://www.newscientist.com/article/dn16684-ethical-stem-cells-stripped-of-cancer-genes.html; Peter Aldhous, *Stem Cells Created Without Cancer-Causing Viruses*, NEW SCIENTIST, Sep. 25 2008, *available at* http://www.newscientist.com/article/dn14816-stem-cells-created-without-cancercausing-viruses.html; Rob Stein, *Scientists Report Advance in Stem Cell Alternative*, WASH. POST, Sep. 26, 2008, at A17.

to ethical concerns.[55] One of the shortcomings of ESC research is the difficulty in retaining the viability of the embryo undergoing stem cell extraction.[56] The process of deriving stem cells from the blastocyst typically spells death for the embryo. Because any developing human embryo could ultimately result in the birth of a child, hESC research has drawn its major opponents from religious groups, whose ethical convictions against hESC research mirror those held by groups against abortion.[57] A similar but separate argument against hESC research is that hESC researchers fail to respect human dignity by treating potential human life like that of a lab rat.[58] Still, others fault ESC researchers for touting ESCs as an imminent cure for all diseases. Proponents of ESC research are accused of setting unrealistic goals and underhandedly raising the hopes of those in need of life-saving treatment, when potential treatments are arguably years, or even decades, away from fruition.[59]

There is a precautionary concern with the long-term consequences of granting patents directed to hESCs: granting property rights in human derivatives would be a slippery slope toward commercialization and

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55. *See* NIH, Research Ethics and Stem Cells, http://stemcells.nih.gov/info/ethics.asp (last visited Mar. 4, 2009).

56. While the current general practice for deriving embryonic stem cells entails destroying the embryo, with no attempt to retain viability, recent research suggests that embryonic stem cells may be prepared one day without destroying the embryo. *See* Young Chung et al., *Human Embryonic Stem Cell Lines Generated Without Embryo Destruction*, 2 CELL STEM CELL 113 (2008); Andy Coghlan, *Stem Cell Breakthrough Leaves Embryos Unharmed*, NEW SCIENTIST, Jan. 10, 2008, *available at* http://www.newscientist.com/article/dn13170-stem-cell-breakthrough-leaves-embryos-unharmed.html. *But see* Andy Coghlan, *'Hype' Accusation Blights Stem Cell Breakthrough*, NEW SCIENTIST, Aug. 29, 2006, *available at* http://www.newscientist.com/article/dn9873-hype-accusation-blights-stem-cell-breakthrough.html.

57. *See, e.g.*, Robert P. George, *Our Struggle for the Soul of Our Nation*, http://www.thepublicdiscourse.com/viewarticle.php?selectedarticle=2009.01.22.001.pdart (last visited Mar. 4, 2009); Rebecca Taylor, *Abortion, Stem Cells, and Cloning*, MARY MEETS DOLLY, Oct. 25, 2007, *available at* http://www.lifeissues.net/writers/tayl/tayl_01abrstemcells cloning.html.

58. *See, e.g.*, Press Release, Ctr. for Bioethics & Human Dignity, New Embryonic Stem Cell Study Smoke and Mirrors Says Bioethicist (Aug. 24, 2006), http://www.cbhd.org/media/pr/2006-08-24.htm. *See generally* Moore v. Regents of Univ. of Cal., 793 P.2d 479, 491 (Cal. 1990) ("Nor is it necessary to force the round pegs of 'privacy' and 'dignity' into the square hole of 'property' in order to protect the patient, since the fiduciary-duty and informed-consent theories protect these interests directly by requiring full disclosure.").

59. *See* Nicholas Wade, *Concerns of Dashed Hopes from Promised Miracles*, N.Y. TIMES, Jan. 12, 2007, at A19. *See also* Letters to the Editor, *No Taxation If There Is Fertilization*, WALL ST. J., Aug. 4, 2006, at A17.

moral devaluation of the human body.[60] Many believe financial profit from the human body or its element is impermissible.[61] Some opponents of hESC research worry that increased research will lead to a black market for human embryos.[62] Another fear is the creation of human embryos purely for research purposes, which is widely viewed as unethical and is outlawed in most countries.[63] Still, pursuant to the Human Fertilisation and Embryology Act ("HFEA"), the United Kingdom permits the creation of human embryos for research purposes as long as the researcher first obtains a license from the relevant government authority.[64]

II. EUROPEAN PATENT LAW: THE MORALITY EXCEPTION TO PATENTABILITY

A. Article 27 of TRIPs

The Agreement on Trade-Related Aspects of Intellectual Property Rights[65] ("TRIPs") set forth powerful international standards for intellectual property. Article 27(1) of TRIPs provides that "patents shall be

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60. *See* CEC REPORT, *supra* note 32, at 9. *Cf.* U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS, 33–35, 46 (1987), *available at* http://www.fas.org/ota/reports/8719.pdf ("The ease of application of biotechnology processes has allowed researchers to turn undeveloped human tissues and cells into human biological products with significant therapeutic promise and commercial potential. Yet the ultimate value of these technologies may not be simply their end products; their greater value may be the insights they provide about disease processes.").

61. EGE OPINION, *supra* note 14, at 2. *See also* CEC REPORT, *supra* note 32, at 66–69 (providing examples of national regulatory regimes with varying levels of prohibition on embryonic research and commercialization of embryos). *See generally* Gloria G. Banks, *Legal and Ethical Safeguards: Protection of Society's Most Vulnerable Participants in a Commercialized Organ Transplantation System*, 21 AM. J.L. & MED. 45 (2005); Jonathan G. Stein, *A Call to End Baby Selling: Why the Hague Convention on Intercountry Adoption Should Be Modified to Include the Consent Provisions of the Uniform Adoption Act*, 24 T. JEFFERSON L. REV. 39 (2001).

62. *See, e.g.*, Daniel McConchie, *Using Stem Cells from Embryos Will Make Human Flesh Profitable*, CTR. FOR BIOETHICS & HUMAN DIGNITY, June 29, 2001, http://www.cbhd.org/resources/stemcells/mcconchie_2001-06-29.htm.

63. *See* CEC REPORT, *supra* note 32, at 9, 66–69; *Survey of European Scientists on Ethics of Scientific Advancements*, GENETIC ENGINEERING & BIOTECH. NEWS, Jun. 15, 2005, http://www.genengnews.com/articles/chitem.aspx?aid=502&chid=0.

64. Human Fertilisation and Embryology Act (HFEA), 1990, c. 37, §§ 3, 9–15, *available at* http://www.opsi.gov.uk/Acts/acts1990/pdf/ukpga_19900037_en.pdf.

65. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPs].

available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step[,] and are capable of industrial application."[66] But under Article 27(2), Member States may enact laws to exclude inventions from patentability where necessary to protect ordre public or morality.[67] The morality exclusion from patentability is optional. For example, the United States has not enacted a statute prohibiting patents directed for "immoral" subject matter. Europe, on the other hand, has implemented a morality exclusion to patentability in its laws.[68]

B. Directive 98/44/EC on the Legal Protection of Biotechnological Inventions

In July 1998, the European Union adopted Directive 98/44/EC ("Directive") on the legal protection of biotechnological inventions.[69] The purpose of passing the Directive was to harmonize the patent laws of EU Member States[70] in order to give Europe "a competitive advantage in biotechnology innovation."[71] Article 1 of the Directive provides that each Member State must protect biotechnogical inventions under its national patent laws and in accordance with the Directive, and, if necessary, adjust its laws to conform to the Directive.[72] The Directive goes on to define biotechnological terms, patentable biotech inventions, and patentability requirements.[73] Article 6(1), however, specifically excludes from patentability inventions whose "commercial exploitation would be contrary to ordre public or morality."[74] Subsection (2)(c) further states that "uses of

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66. *Id*. art. 27(1).

67. *Id*. art. 27(2) ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.").

68. Council Directive 98/44/EC, 1998 O.J. (L 213) 13 [hereinafter Directive].

69. *Id*.

70. The current EU Member States are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. European Union, Offices, http://www.eurunion.org/states/offices.htm (last visited Mar. 4, 2009).

71. Jasemine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy Is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 237 (2002).

72. Directive, *supra* note 68, art. 1.

73. *Id*. art. 2, 3.

74. *Id*. art. 6 (italics omitted).

human embryos for industrial or commercial purposes" are explicitly unpatentable inventions.[75]

Article 7 of the Directive provides that the Commission's European Group on Ethics in Science and New Technologies ("EGE") shall evaluate all ethical aspects of biotechnology.[76] In a May 2002 opinion on the ethics of patenting human stem cell inventions, the EGE stated that it believed that it was ethically acceptable to permit patenting inventions involving the transformation of unmodified hESCs into genetically modified stem cell lines or specific differentiated stem cell lines for specific therapeutic or other uses, provided that the inventions meet the standard patentability requirements and would not lead to uses of human embryos for industrial or commercial purposes.[77]

Although most EU Member States have transposed the Directive into their national laws, not all the Member States have done so completely voluntarily.[78] Notably, the Swedish National Council on Medical Ethics ("SMER")[79] strongly opposed the Swedish government making such

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75. Article 6(2) specifically excludes from patentability

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

Id.

76. *Id*. art. 7.

77. EGE OPINION, *supra* note 14, at 16.

78. Article 15 of the Directive requires that each of the Member States comply with, or adjust its law to comply with, the Directive by July 30, 2000. Directive, *supra* note 68, art. 15. As of June 29, 2005, twenty Member States (Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom) had complied with Article 15, while the remaining Member States were at various stages in the process of transposing the Directive. *See Report from the Commission to the European Parliament, the Council, the Committee of the Regions and the European Economic and Social Committee—Life Sciences and Biotechnology—A Strategy for Europe—Third Progress Report and Future Orientations*, COM(2005) 286 final (June 29, 2005). Over the last several years, the European Commission has instituted various infringement actions to encourage the noncomplying States to transpose the Directive into their national laws. *Id*.

79. "The Swedish National Council on Medical Ethics is an advisory board to the Swedish government on ethical issues raised by scientific and technological advances in biomedicine." Swedish National Council on Medical Ethics (SMER), http://www.smer.se/Bazment/2.aspx (last visited Mar. 4, 2009).

changes to its patent laws.[80] The SMER objected to, *inter alia*, the Directive's branding of certain aspects of ESC research as contrary to ordre public and morality, even though ESCs constitute a highly progressive and promising field of research; the SMER argued that this fact was completely unknown at the time the Directive was formulated, but that —had it been known—ESC research would not be considered contrary to ordre public and morality.[81] Yet Sweden yielded to European pressure and implemented the Directive into its national laws.[82]

In a case decided in 2001 by the Court of Justice of the European Communities, the Netherlands, supported by Italy and Norway, sought to enjoin implementation of the Directive on six separate grounds.[83] One such ground was that Article 6 would allow Member States to refuse to provide patent protection for a controversial biotechnological invention simply by asserting that it was contrary to ordre public or morality.[84] Although the court rejected all of the Netherlands' arguments, the fact that the case even exists supports the proposition that the morality provision was not universally popular among European States.[85]

C. Article 53(a) and Rule 28 of the European Patent Convention

The European Patent Convention has contained a morality provision in Article 53(a) since its inception in 1973.[86] Article 53(a)—its language mirroring that of Article 6(1) of the Directive—prohibits the granting of patents for inventions "the commercial exploitation of which would be contrary to 'ordre public' or morality."[87] In September 1999, the Euro-

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80. SMER, Opinion on Directive 98/44/EC on the Legal Protection of Biotechnical Inventions, and Its Implementation in Sweden (Feb. 25, 2002), *available at* http://www.smer.gov.se/english/opinion/patent.eng.htm.

81. *Id.*

82. *See* THE SWEDISH GROUP OF AIPPI, REPORT Q166: INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE (July 2006), *available at* http://www.aippi.org/reports/q166/quest06/q166_sweden06.pdf.

83. Case C-377/98, Kingdom of the Netherlands v. Eur. Parliament & Council of the Eur. Union, 2001 E.C.R. I-7079

84. *Id.*

85. *Id.* For a thorough overview of this case, see Juliane Kokott & Thomas Diehn, Kingdom of the Netherlands v. European Parliament & Council of the European Union*, Case C-377/98. 2001 ECR I-7079*, 96 AM. J. INT'L L. 950 (2002).

86. EPC 1973, *supra* note 20, art. 53(a).

87. Article 53 provides in full:

> European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; (b) plant or

pean Patent Organization followed in the EU's footsteps and adopted the language of Article 6(2) of the Directive.[88] Consequently, Rule 28 of the EPC, in providing specific examples of inventions that fit the patentability exclusion of Article 53(a), states that "European patents shall not be granted in respect of biotechnological inventions which, in particular, concern . . . uses of human embryos for industrial or commercial purposes."[89]

III. PATENTING EMBRYONIC STEM CELL LINES IN EUROPE

A. The WARF Stem Cell Case: EPO's Refusal of WARF's European Patent Application

WARF's European patent application contained ten claims.[90] Claim 1 was directed to primate embryonic stem cell cultures.[91] Specifically, claim 1 provided:

> A cell culture comprising primate embryonic stem cells which (i) are capable of proliferation in vitro culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered through culture for over one year, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on a fibroblast feeded layer.[92]

> animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof; (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

EPC 2000, *supra* note 20, art. 53(a).

88. Press Release, EPO, The EPO Follows the EU's Directive on Biotechnology Patents, Oct. 27, 2005, *available at* http://www.epo.org/about-us/press/releases/archive/2005/27102005.html.

89. EPC Regs., *supra* note 27, R. 28.

90. As amended by WARF on June 18, 2003. Reply to Examination Report, T.J. Duckworth on behalf of WARF (June 18, 2003) (on file with the EPO). *See also* Case T-1374/04, [2007] E.P.O. O.J. at 314.

91. Reply to Examination Report, *supra* note 90. *See also* Case T-1374/04, [2007] E.P.O. O.J. at 314.

92. Reply to Examination Report, *supra* note 90, at claim 1 (emphasis omitted). *See* Case T-1374/04, [2007] E.P.O. O.J. at 314.

WARF acknowledged that "primate embryonic stem cells," as recited in claim 1, included *human* embryonic stem cells.[93] Claims 2–8 were directed to further embodiments of the cell culture of claim 1.[94] Claim 9 was directed to a method of maintaining such a cell culture, and claim 10 to a method of obtaining differentiated primate cells from such a cell culture.[95]

The EPO Examining Division refused WARF's European application for the failure of claims 1–7, 9, and 10 to comply with Article 53(a) in conjunction with Rule 28(c).[96] WARF appealed to the EPO Technical Board of Appeal, challenging the Examining Division's interpretation of Article 53(a) and Rule 28(c).[97] Because of the potential impact of the EPO's interpretation of the EPC provisions on future patentees and stem cell research in general, the Technical Board of Appeal referred the case to the Enlarged Board of Appeal posing the following questions:

> 1. Does Rule [28](c) EPC apply to an application filed before the entry into force of the rule?
>
> 2. If the answer to question 1 is yes, does Rule [28](c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which—as described in the application—at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?
>
> 3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?
>
> 4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)? [98]

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93. Case T-1374/04, [2007] E.P.O. O.J. at 328.

94. Reply to Examination Report, *supra* note 90, at claims 2–8. *See also* Case T-1374/04, [2007] E.P.O. O.J. at 314.

95. Reply to Examination Report, *supra* note 90, at claims 9–10. *See also* Case T-1374/04, [2007] E.P.O. O.J. at 314–15.

96. Case T-1374/04, [2007] E.P.O. O.J. at 315. Claim 8 was directed to a cell culture of any of claims 1–7 wherein the cells were *non-human* primate cells; accordingly, claim 8 was not refused as contrary to morality. Reply to Examination Report, *supra* note 90, at claim 8. However, because claim 8 depended on claims 1–7, it was unpatentable on its own. *Id*.

97. Case T-1374/04, [2007] E.P.O. O.J. at 340.

98. *Id*. The purpose of the Enlarged Board of Appeal is to ensure uniform application and to resolve important questions of European patent law. EPC 2000, *supra* note 20, art 112.

Question 1, pertaining to the retroactivity of Rule 28, would not have any bearing on future ESC patent applications because these applications would presumably be filed after Rule 28 was already in force.[99] In addition, Question 4 was quite specific to the WARF patent application, so the Question's solution is unlikely to significantly affect future ESC cases.[100] Accordingly, this Note largely ignores Questions 1 and 4.[101]

The crux of the case rested in the answers to Questions 2 and 3. The Technical Board noted that the main issue was whether Rule 28(c) should be construed narrowly or broadly.[102] If construed narrowly, according to WARF, Rule 28(c) would exclude from patentability "only applications whose claims were directed to the use of human embryos"; a broad interpretation would likely exclude patents claiming products "whose isolation necessitated the direct and unavoidable use of human embryos."[103] As a general principle, exceptions to patentability, such as

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99. In referring Question 1 to the Enlarged Board, the Technical Board cited two Technical Board decisions that ostensibly answer the question. In Case T-272/95, unpublished op. at 9 (Technical Bd. App. Oct. 23, 2002), *available at* http://legal.european-patent-office.org/dg3/pdf/t950272eu2.pdf, the Technical Board concluded that Rules 23b–e (now Rules 26–29) were merely interpretive of Article 53(a) and therefore went into force on September 1, 1999. Case T-1374/04, [2007] E.P.O. O.J. at 329. Similarly, in Case T-315/03, [2006] E.P.O. O.J. 15 (Technical Bd. App. 2004), the Technical Board held that Rule 23d (now Rule 28) applied to cases pending on September 1, 1999, because this Rule was merely interpretive of Article 53(a) and did not previously cause an unpredictable change in its interpretation. Case T-1374/04, [2007] E.P.O. O.J. at 330. Accordingly, the EPO may not grant a patent for any application that was pending on September 1, 1999, if the application claims an invention that concerns uses of human embryos for industrial or commercial purposes. *Id*. at 331.

100. First, the Enlarged Board would only need to address Question 4 if it concluded in response to Questions 2 or 3 that Rule 28(c) and/or Article 53(a) rendered WARF's invention unpatentable. Furthermore, future ESC inventions are unlikely to necessitate the destruction of human embryos, but will instead rely upon available hESC lines.

101. Nevertheless, in discussing Question 4, the Technical Board did raise an interesting issue of whether a law enforcing moral attitudes should be based on the state of public opinion at a patent application's priority date or based on the *current* state of public opinion. Case T-1374/04, [2007] E.P.O. O.J. at 339. On the one hand, the attitude toward ESC research has become more favorable since the inception of the Directive. On the other hand, the Technical Board decided in Case T-315/03, [2006] E.P.O. O.J. 15, that a "Rule 23d type" or Article 53(a) assessment should be made based on the state of affairs at the filing or priority date. *Id*. at 51–56.

102. Case T-1374/04, [2007] E.P.O. O.J. at 317.

103. *Id*. at 317. The Technical Board cited several of WARF's arguments in favor of a narrow construction: First, Rule 28 refers to the unpatentability of certain "inventions," which is arguably a reference only to the claimed subject matter, not the indirect and unclaimed use of human embryos. Second, Rule 28(d) explicitly specifies that the product of "processes for modifying the genetic identity of animals" (i.e., genetically modified animals) is unpatentable, whereas Rule 28(c) clearly omits any reference to the

those provided in Rule 28(c) and Article 53(a), should be interpreted narrowly.[104] While the Enlarged Board once stated that this narrow construction rule "did not apply without exception," the Enlarged Board never clarified exactly what would constitute an exception to the general rule.[105]

In the opinion, the Technical Board also reasserted the Examining Division's position that Rule 28(c) excludes the WARF application for patentability, even under a narrow construction.[106] According to the EPO, Directive 98/44/EC, from which Rule 28(c) was derived, was drafted with an aim of emphasizing that technologies using human embryos for an "ethically unacceptable" purpose should be barred from patenting.[107] Although Article 6(2) was amended just prior to the Directive's adoption to replace the phrase "methods in which human embryos are used" with "uses of human embryos,"[108] the Examining Division concluded that the incorporation of the new language was not made with the intent to allow patenting of products derived from such uses of human embryos.[109] The Examining Division reasoned that the European Commission was not necessarily aware of the establishment of the hESC lines at the time of the Directive's adoption, and therefore could not have deliberately allowed patenting of inventions involving hESCs.[110]

With regard to Question 3, WARF argued that the Board should apply a balancing test in deciding whether patent application claims violate

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product of using human embryos; therefore Rule 28(c) should not exclude the WARF application from patentability. Another argument supporting a narrow construction is that prior to its enactment, the Directive was amended to replace the phrase "methods in which human embryos are used" with "uses of human embryos." As amended, the Directive's prohibition seems to be limited to direct uses of human embryos, rather than any invention in which human embryos are used even indirectly. *Id*. at 318–19.

104. *Id*. at 332–33.

105. *Id*. (citing Case G-1/04, [2006] E.P.O. O.J. 334, 350 (Enlarged Bd. App. 2005)) ("It is also true that the frequently cited principle, according to which exclusion clauses from patentability laid down in the EPC are to be construed in a restrictive manner, does not apply without exception. However, the Enlarged Board of Appeal considers that the principle of a narrow interpretation of such exclusion clauses is to apply in respect of the scope of the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods.").

106. Case T-1374/04, [2007] E.P.O. O.J. at 335–36.

107. *Id*.

108. *Id*. at 319–20.

109. *Id*. at 335–38.

110. Although the WARF application was published in 1996, the first scientific journal article reporting on WARF's discovery was not published until November 1998, after the Directive had already been adopted. *Id*. at 337. *See* Thomson et al., *supra* note 16.

Article 53(a).[111] However, the Technical Board expressed doubts over the ethics of balancing the interests of patients who could potentially benefit from the exploitation of ESCs against the rights of human embryos.[112]

The Enlarged Board, recognizing the prevalent public and governmental interest in the case, invited third parties to file amici curiae with the court.[113] The Enlarged Board received over 160 submissions from a wide variety of individuals, organizations, and special interest groups.[114] Notably, the United Kindom Intellectual Property Office ("UKIPO") filed an amicus brief in strong support of WARF's interpretation of the EPC provisions.[115] The United Kingdom heavily promotes hESC research and has arguably the most relaxed embryonic research regulations of any Western nation.[116] The United Kingdom adopted the language of the Directive into its national laws because it considered the Directive to restrict only the granting of patents for processing stem cells from human embryos or totipotent stem cells, but not from pluripotent hESCs.[117] Applying a balancing test, the UKIPO reasoned that the danger of commercial exploitation of pluripotent hESCs was outweighed by the "enormous potential of stem cell research, including embryonic stem cell research, to deliver new treatments for a wide range of serious diseases."[118] Consequently,

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111. Case T-1374/04, [2007] E.P.O. O.J. at 338.

112. *Id*. ("The Board has doubts whether, when it comes to human life, it would be ethically acceptable to make a decision by weighing the interests of human beings who could potentially benefit from the exploitation of the technology against a right, if any, of human embryos (whether or not they can already be qualified as human beings), to get to life and of not being destroyed for the benefit of others. The Board will not add more on this matter than just voicing its doubts on the position advocated by the appellant.").

113. Communication from the Enlarged Board of Appeal Concerning Case G 2/06, [2006] E.P.O. O.J. 393.

114. *See* Amici Curiae in EP0770125, http://www.epoline.org/portal/public/registerplus (search "Publication No." for "EP0770125"; then follow "All Documents" hyperlink) (last visited Mar. 4, 2009).

115. UKIPO, Patentability of Human Embryonic Stem Cells: WARF's European Patent Application, http://www.ipo.gov.uk/p-policy-biotech-stemcell.htm (last visisted Mar. 4, 2009).

116. *See* CEC REPORT, *supra* note 32, at 11.

117. UKIPO, PRACTICE NOTICE ON INVENTIONS INVOLVING HUMAN EMBRYONIC STEM CELLS (Apr. 2003), *available at* http://www.ipo.gov.uk/p-pn-stemcells.htm [hereinafter 2003 PRACTICE NOTICE] ("[T]he Office is ready to grant patents for inventions involving such [human embryonic pluripotent stem] cells provided they satisfy the normal requirements for patentability."). However, the 2003 Practice Notice was superseded in 2009 after the Enlarged Board's decision on the patentability of hESC lines. UKIPO, PRACTICE NOTICE ON INVENTIONS INVOLVING HUMAN EMBRYONIC STEM CELLS (Feb. 3, 2009), *available at* http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm.

118. 2003 PRACTICE NOTICE, *supra* note 117.

the UKIPO's amicus brief stressed that the Examining Division's restrictive interpretations of Rule 28(c) and Article 53(a) were contrary to the United Kingdom's goals of encouraging investment in stem cell research.[119]

As a matter of universal patent law, an invention is only as broad as its patented claims.[120] According to the UKIPO, Article 53(a) is only concerned with whether exploitation of the claimed invention would be contrary to morality, "not with whether other acts, preparatory, ancillary or subsequent thereto may be morally objectionable."[121] The main invention claimed in WARF's European patent application was stem cell lines originally derived from primate (including human) ESCs.[122] Therefore, the United Kingdom concluded, WARF's invention involved only a product of a primate embryo, not the primate blastocystic inner cell mass itself.[123]

The UKIPO further contended that, "in order for exploitation of an invention to be contrary to morality within the meaning of Art. 53(a), it must offend against common European standards of morality."[124] The specific exceptions to patentability set forth in Rule 28(c) were derived from the Directive, and there was a "limited consensus" among European States that exploitation by destruction of human embryos for industrial or commercial purposes was contrary to morality.[125] Exceptions to patenta-

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119. Amicus Curiae Submission of the United Kingdom (Oct. 26, 2006), at 8–9 (on file with the EPO), *available at* http://www.ipo.gov.uk/warf.pdf. *See also* James Randerson, *Warning for UK Stem Cell Research If US Relaxes Rules*, GUARDIAN, Sep. 28, 2007, at 6.

120. *See, e.g.*, EPC 2000, *supra* note 20, art. 84 ("The claims shall define the matter for which protection is sought."); Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996) ("The claim defines the scope of a patent grant.") (internal quotations omitted).

121. Amicus Curiae Submission of the United Kingdom, *supra* note 119, at 2.

122. *Id*. at 12.

123. *Id*. at 3 ("There are certain matters which are regarded across the EPC area as being immoral, for example the use of anti-personnel mines. Patents for anti-personnel mines would rightly be rejected under Art. 53(a). But there are other matters on which differing strands of respectable opinion exist within the EPC area. In some cases the divergence of opinion will exist within each Contracting State. In other cases the opinions will differ between Contracting States, so that in one Contracting State something is generally regarded as immoral, whereas in other Contracting States it is generally regarded as being acceptable. . . . It is submitted that if exploitation of an invention would be regarded as moral in (at least) a major Contracting State, then a patent should not be refused under Art. 53(a).").

124. *Id*. at 10–11.

125. *Id*. at 6, 14 ("It cannot be said that it would generally be regarded as immoral to use the claimed stem cells. The only circumstance in which an issue arises is if the applicant (or his licensee) wishes to prepare further stem cell cultures with additional proper-

bility must be construed narrowly; the consensus cannot be extended beyond what was actually agreed upon by the European Community.[126]

Still further, the UKIPO argued that the purpose of WARF's use of human embryos was neither industrial nor commercial, but solely to "carry[] out precursor research activities."[127] Therefore, the UKIPO concluded, the WARF patent application did not meet the specific, narrow exception to patentability of Rule 28(c), nor would use of WARF's claimed invention be contrary to the general consensus of morality.[128]

B. The Enlarged Board's Decision

WARF's arguments on appeal were similar to those in the UKIPO's amicus brief.[129] At the June 24, 2008, oral proceedings before the Enlarged Board, WARF prefaced its arguments with the following comments:

> In 1998[,] the named inventor using the methods suggested in the application was the first to successfully isolate and culture human embryonic stem cells that can grow *in vitro*. The provision of these is a major scientific breakthrough and pioneering invention opening up a new and very exciting field of research having great potential for promising medical therapies and other applications, and worthy of patent protection.[130]

The basis of WARF's main argument was that under Article 27(2) of TRIPs and Article 53(a) of the EPC, the EPO can only exclude an invention from patentability if the "claimed monopoly . . . embraces the use of an embryo for an industrial or commercial purpose."[131] The claimed mo-

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ties to those of the one already prepared. This would require research using another spare embryo—an activity which also cannot be said to be generally regarded as immoral.").

126. Thus, the UKIPO concluded:

> (1) Article 53(a) does not prevent the patenting of claims to human embryonic stem cells where the claimed stem cells can be made by the skilled person without the use or destruction of human embryos. (2) Article 53(a) does not prevent the patenting of claims to human embryonic stem cells where the applicant or his licensee can make the claimed stem cells without the use of human embryos for industrial or commercial purposes.

Id. at 14.

127. *Id*.

128. *Id.*

129. Reply to May 11, 2006 Communication from the Enlarged Board, T.J. Duckworth on behalf of WARF (Oct. 31, 2006) (on file with the EPO).

130. Case G-2/06, unpublished op. at 4 (Enlarged Bd. App. Nov. 25, 2008), *available at* http://legal.european-patent-office.org/dg3/pdf/g060002ex1.pdf.

131. *Id*. at 6.

nopoly of WARF's application, WARF asserted, was not to the "use of an embryo" and not "for an industrial or commercial purpose"; rather, the monopoly was to the use of an ESC, which "at most . . . is a product [that] ultimately was derived from an embryo."[132] WARF noted that there was neither treaty nor common tradition among the European Member States banning human embryos under fourteen-days-old[133] from being used in hESC research.[134] WARF reasoned that the Directive's specific prohibition on the patenting of uses of embryos should not be interpreted broadly to prohibit uses of anything outside of the definitional embryo, because otherwise the Directive would have explicitly provided as such.[135] Furthermore, the purpose of the morality exception to patentability was to prevent industrial or commercial exploitation of human embryos. The preparatory extraction of cells from the blastocyst for the purpose of starting an hESC line in no way constituted an industrial or commercial act.[136]

The Enlarged Board disagreed, however.[137] The Enlarged Board stated that the purpose of enacting Rule 28 was to align the EPC with Article 6(2) of the Directive.[138] Therefore, the Directive constituted a "supplementary means of interpretation" of Rule 28.[139] Looking at the history of Article 6(2) of the Directive, the Enlarged Board noted that the European Council's first drafts of the Directive in 1996 did not contain specific prohibitions on patenting uses of human embryos.[140] In 1997, it was first proposed that Article 6(2) should place limits on the patentability of human embryos by specifically excluding "methods in which human embryos are used."[141] The European Council amended Article 6(2) in February 1998, to exclude "uses of human embryos for industrial or commercial purposes"; this was the text officially adopted by the EU in the final version of the Directive in July 1998.[142]

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132. *Id*.

133. According to WARF, in the medical field, an embryo is by definition an "embryo" only once it is fourteen-days-old. *Id*. at 22.

134. *Id*. at 6.

135. *Id*. at 6–7.

136. *Id*.

137. The Enlarged Board answered "yes" to Question 1, meaning Rule 28 applied retroactively. *Id*. at 17.

138. *Id*. at 20.

139. *Id*.

140. *Id*. at 21.

141. *Id*.

142. The Enlarged Board also rejected WARF's argument that the European Community funds hESC research because the European Community actually used a selective funding regime under which (i) the European Community chose not to seek funding for

The Enlarged Board then moved on to address WARF's specific argument. First, the Enlarged Board rejected WARF's definition of "embryo" as an embryo at least fourteen-days-old.[143] The Enlarged Board noted that German law defined "embryo" as including a fertilized egg;[144] and the U.K. HFEA defined "embryo" to encompass "an egg in the process of fertilisation," after "the appearance of a two cell zygote."[145] In light of the purpose of Article 6(2) of the Directive and Rule 28 of the EPC "to protect human dignity and prevent the commercialization of embryos," the Enlarged Board inferred that the legislatures left the term "embryo" undefined in the Directive and EPC in order to adopt the nonrestrictive meanings used in national laws.[146]

The Enlarged Board further rejected WARF's argument that Rule 28(c) was only triggered if the application specifically claimed "the use of human embryos."[147] The Enlarged Board reasoned that Rule 28's exclusion of an "invention," rather than a "claim," required it to look at "the technical teaching of the application as a whole" to determine if human embryos were used.[148] Because at the time of the filing, the only known method of acquiring hESCs required the destruction of a human embryo, WARF's invention fell within Rule 28(c)'s meaning of "use of human embryos."[149]

Furthermore, the Enlarged Board found that WARF's use of human embryos was for "industrial or commercial purposes."[150] The Enlarged Board reasoned that the steps involved in making an industrial or commercial product (such as WARF's ESC lines) are themselves industrial or commercial exploitations of the product.[151] Thus, the required preliminary destruction of the human embryo was "an integral and essential

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"research activities [that] destroy human embryos, including for the procurement of stem cells"; and (ii) "the exclusion of funding for this step of research will not prevent the Community funding of subsequent steps involving human embryonic stem cells." *Id*. at 22.

143. *Id*. at 22–23.

144. Gesetz zum Schutz von Embryonen [Embryo Protection Act], Dec. 13, 1990, BGBl. I at 2746, § 8, *available at* http://www.bmj.bund.de/files/-/1147/ESchG%20englisch.pdf.

145. HFEA, 1990, c. 37, § 1(1).

146. Case G-2/06, unpublished op. at 23 (Enlarged Bd. App. Nov. 25, 2008), *available at* http://legal.european-patent-office.org/dg3/pdf/g060002ex1.pdf.

147. *Id*.

148. *Id*. at 23–24.

149. *Id*. at 24 ("To restrict the application of Rule 28(c) . . . to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.").

150. *Id*. at 24–26.

151. *Id*.

part of the industrial or commercial exploitation of the claimed invention."[152] The Enlarged Board further rejected WARF's assertion that the Directive's legislative history (i.e., the change of "methods in which human embryos are used" to "uses of human embryos for industrial or commercial purposes") indicated a narrowing of the scope of Rule 28(c).[153] Instead, the Enlarged Board inferred a legislative intent to differentiate between commercially exploitative uses of human embryos (excluded from patentability) and "therapeutic or diagnostic purposes applied to the human embryo and useful to it" (patentable).[154]

Finally, the Enlarged Board rejected any notion that its interpretation of Rule 28(c) rendered Rule 28(c) *ultra vires* to Article 53(a) of the EPC and Article 27(2) of TRIPs.[155] WARF argued that the Enlarged Board's broad construction went beyond the scope of these two Articles, which only permit excluding from patentability inventions that themselves are "against ordre public or morality."[156] However, the Enlarged Board emphasized,

> [i]n this context, . . . it is not the fact of the patenting itself that is considered to be against ordre public or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts.[157]

The European patent community understood the Enlarged Board's decision to mean that claims directed to processes of obtaining stem cells from human embryos could not receive patent protection through the EPO, but supposedly could still receive protection directly through the national patent offices of the Member States whose laws did not exclude such inventions from patentability.[158] On a grander scale, some experts believe that the Enlarged Board's decision will bolster the stem cell re-

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152. *Id*. at 25.

153. *Id*. at 25–26.

154. *Id*.

155. *Id*. at 26–28.

156. *Id*. at 26 (emphasis omitted).

157. *Id*. (italics omitted). Having already answered Question 2 in the affirmative, the Enlarged Board declined to address Question 3 because Rule 28 (the specific exclusion) fell within the scope of Article 53(a) (the general exclusion). *Id*. at 28. *See also id*. at 29 ("Thus question 4 must be answered to the effect that it is not of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos.").

158. James Randerson, *Europe Rejects Patent Governing Use of Embryonic Stem Cells*, GUARDIAN, Nov. 27, 2008, *available at* http://www.guardian.co.uk/science/2008/nov/27/embryonic-stem-cells-patent.

search market in Europe, because European biotech companies will be able to conduct hESC research without having to pay costly patent licensing fees.[159]

IV. COMPARING THE U.S. AND EUROPEAN PATENT SYSTEMS: RAMIFICATIONS

The moral boundaries of hESC research are difficult to draw. Still, most countries allow hESC research within their borders in at least some limited capacity.[160] However, the morality of patenting inventions based on derivatives of human embryos is a separate issue. The difference in treatment of Dr. Thomson's invention by the USPTO and the EPO underscores a divergence in policies between two of the world's principal patent systems.

In the WARF stem cell case, the Enlarged Board adopted the legislature's determination under Rule 28(c) that industrial or commercial exploitation of WARF's invention would be "contrary to morality."[161] By specifically addressing only Question 2, and not Question 3, the Enlarged Board did not take the opportunity to perform a cost-benefit analysis to ascertain the net morality of WARF's invention.[162] After all, hESCs were not specifically contemplated when the European Council drafted Article 6(2) of the Directive.[163] Had the EPO never adopted Rule 28(c) (i.e., never specifically excluded "uses of human embryos for industrial or commercial purposes"), it is not clear that WARF's invention would have been excluded from patentability as "contrary to morality" under Article 53(a) alone. The EPO's Technical Board of Appeal has performed such a case-by-case morality analysis and allowed the application to undergo patent examination after finding that the harm the invention caused to animals was outweighed by the potential benefits to human health (as discussed below in the Oncomouse case[164]). A factual "morality" analysis in the WARF stem cell case would have been far more difficult than a straightforward legal determination of the scope of Rule 28(c), especially because the morality and efficacy of hESC research is still hotly debated across Europe.[165]

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159. *Id*.

160. *See* William Hoffman, Stem Cell Policy: World Stem Cell Map, http://www.mbb net.umn.edu/scmap.html (last visited Mar. 4, 2009).

161. Case G-2/06, at 27–28.

162. *Id*. at 28.

163. Case T-1374/04, [2007] E.P.O. O.J. 313, 337 (Technical Bd. App. 2006).

164. Case T-19/90, [1990] E.P.O. O.J. 476 (Technical Bd. App. 1990).

165. For examples of conflicting European views on the morality, therapeutic potential, and legal position of hESCs, see Amici Curiae in EP0770125, *supra* note 114.

Similarly, the United States has not reached a consensus on the morality of hESC research. Yet the USPTO would not even consider addressing this morality issue.[166] To better understand this discrepancy, an overview of U.S. stem cell law and policy is necessary.

In 1996, the U.S. Congress passed legislation (known as the "Dickey Amendment"), which prohibited the National Institutes of Health ("NIH") from funding research (1) involving the creation of human embryos for research purposes; or (2) in which human embryos are destroyed.[167] Congress has renewed the provisions of the Dickey Amendment every year since.[168]

On August 9, 2001, then-President George W. Bush announced that federal funds would be available only for ESC research utilizing one of the seventy-eight ESC lines then in existence.[169] The Bush administration had concluded that the value of human life—even embryonic human life—outweighed the benefits of speeding up hESC research by deriving new stem cell lines from new embryos.[170]

The U.S. Congress reached a different conclusion than the executive branch, twice passing legislation (entitled Stem Cell Research Enhancement Act of 2005 and 2007, respectively) that would have eased ESC research funding restrictions by permitting federal funds to be allocated for the creation of new ESC lines derived from excess embryos that were created for the purpose of fertility treatments and that would otherwise be discarded.[171] However, President Bush vetoed both bills, and issued a June 20, 2007 Executive Order that further enforced his August 9, 2007 Presidential Statement.[172]

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166. *See generally* Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003).

167. Balanced Budget Downpayment Act, Pub. L. No. 104-99, 110 Stat. 34 (1996). *See* WHITE PAPER, *supra* note 46, at 1.

168. *E.g.*, Consolidated Appropriations Act, Pub. L. No. 110-161, 121 Stat. 2209 (2008); Consolidated Appropriations Act, Pub. L. No. 106-554, 114 Stat. 2763A-71 (2001); Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 106-554, 112 Stat. 2681-386 (1999). *See* Sheryl Gay Stolberg, *New Stem Cell Policy to Leave Thorniest Issue to Congress*, N.Y. TIMES, Mar. 9, 2009, at A1.

169. As it turned out, only about twenty of these stem cell lines were viable for research purposes. *See* Leshner & Thomson, *supra* note 53. For a concise, yet broad, overview of patenting and regulatory issues facing stem cell research in the United States, see Raymond R. Mandra & Alicia A. Russo, *Stem Cells and Patenting and Related Regulatory Issues: A United States Perspective*, 7 BIO-SCI. L. REV. 143, 146 (2005).

170. *See* Editorial Desk, *Downside of the Stem Cell Policy*, N.Y. TIMES, Aug. 31, 2001, at A18.

171. *See* Zeleny, *supra* note 13.

172. Exec. Order No. 13,435, 72 Fed. Reg. 34,589 (June 22, 2007), *available at* http://edocket.access.gpo.gov/2007/pdf/07-3112.pdf. *See* Sheryl Gay Stolberg, *First Bush*

While ESC research struggled politically to gain federal support during the Bush-era, some states passed laws promoting ESC research.[173] Additionally, President Bush's limits on federal funding did not prevent the biotech sector from using private, nonfederal funds to conduct hESC research.[174] Still, the 2001 federal funding ban slowed the pace of hESC research.

But the future for federally funded hESC research suddenly looked brighter during the 2008 presidential campaign. Both then-Senator Barack Obama and Senator John McCain had voted in favor of the Stem Cell Research Enhancement Act of 2007.[175] Senator McCain's stance with respect to hESC research was quite liberal compared to that of the Republican Party which, in August 2008, adopted a party platform of a "ban on the creation of or experimentation on human embryos for research purposes" and "ban on all embryonic stem-cell research, public or private."[176] Then-Senator Obama had vowed, once elected, to reverse about 200 of President Bush's executive orders and policies, including the limits on federally funded hESC research.[177]

On March 9, 2009, newly elected President Obama followed through on his promise and set aside the Bush-era funding restrictions. President Obama's Executive Order explicitly revoked President Bush's August 9, 2001 Presidential Statement and June 20, 2007 Executive Order.[178] The

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Veto Maintains Limits on Stem Cell Use, N.Y. TIMES, July 20, 2006, at A1; Stolberg, *supra* note 41.

173. *See* Mandra & Russo, *supra* note 169, at 149. *See also* Andrew Pollack, *California Stem Cell Research Is Upheld by Appeals Court*, N.Y. TIMES, Feb. 27, 2007, at A11. *But see* Monica Davey, *For Missouri, Stem Cell Act Changes Little*, N.Y. TIMES, Aug. 10, 2007, at A12.

174. *See* Mandra & Russo, *supra* note 169, at 147.

175. U.S. Senate Roll Call Votes, 110th Congress, 1st Session, http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=110&session=1&vote=00127 (last visited May 16, 2009).

176. Larry Rohter, *Back and Forth on Stem-Cell Research Energizes Race*, N.Y. TIMES, Sep. 10, 2008, at A22; Republican National Committee, 2008 Republican Platform, http://www.gop.com/2008Platform/HealthCare.htm (last visited Mar. 4, 2009).

177. Ceci Connolly & R. Jeffrey Smith, *Obama Positioned to Quickly Reverse Bush Actions: Stem Cell, Climate Rules Among Targets of President-Elect's Team*, WASH. POST, Nov. 9, 2008, at A16.

178. Exec. Order No. 13,505, 74 Fed. Reg. 10,665 (Mar. 11, 2009), *available at* http://edocket.access.gpo.gov/2009/pdf/E9-5441.pdf. Many believed President Obama would lift the federal funding ban in his first week in office, stem cell scientists were left waiting for several weeks for President Obama to follow through on his promise. *See* Gardiner Harris & William J. Broad, *Scientists Welcome Administration's Words but Must Wait for Action*, N.Y. TIMES, Jan. 22, 2009, at A23; Carle Hulse, *Democrats Weigh Methods For Ending Stem Cell Ban*, N.Y. TIMES, Jan. 3, 2009, at A11; Jacqueline L. Salmon & Michelle Boorstein, *Progressive Faith Groups Now Trying to Shift Debate: Activists Opti-*

Executive Order specifically permitted the NIH to fund "responsible, scientifically worthy human stem cell research, including human embryonic stem cell research"; and it directed the Secretary of Health and Human Services to draft within 120 days new NIH guidelines and safeguards consistent with the decree.[179] Still, the President did not seek to annul the Dickey Amendment; the Executive Order left up to the U.S. Congress the question of whether the federal government should fund experiments on embryos themselves.[180]

Despite Europe's adoption of Rule 28, the moral debate surrounding hESC research is far from settled.[181] The eastern, more conservative European States generally oppose hESC research funding, while the western half of Europe largely favors it.[182] At one extreme, Germany prohibits the procurement of hESCs, but allows importation of hESC lines for research purposes.[183] At the opposite end of the regulatory spectrum, the United Kingdom permits the procurement of hESCs even from human embryos created solely for research purposes.[184] Nearly half of the EU Member States have passed legislation allowing the procurement of hESCs from supernumerary embryos, "leftover" embryos that would otherwise be discarded after fertilization treatments.[185] Still other Euro-

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mistic That Obama Will Back Causes, WASH. POST, Jan. 31, 2009, at A4; Rob Stein, *Scientists Await Action on Stem Cells: Some Proponents Had Expected Obama to Immediately Reverse Bush Policies*, WASH. POST, Feb. 19, 2009, at A2.

179. Exec. Order No. 13,505, 74 Fed. Reg. 10,665.

180. *Id*. *See* Stolberg, *supra* note 167.

181. *See* Samantha Halliday, *A Comparative Approach to the Regulation of Human Embryonic Stem Cell Research in Europe*, 12 MED. L. REV. 40 (2004) (comparing the various hESC research regulatory schemes of Europe).

182. *See* Nicholas Watt, *US Faces Science Brain Drain After Europe Backs Stem Cell Funding*, GUARDIAN, July 25, 2006, at 17 ("But deep European divisions were exposed at yesterday's ministerial meeting in Brussels. Poland, Austria, Malta, Slovakia and Lithuania voted against stem cell research. They were opposed yesterday by France, Britain, the Netherlands, Spain and Portugal, showing that the divisions were not simply between Catholic and non-Catholic countries.").

183. *See* Halliday, *supra* note 181, at 43.

184. *Id*.

185. European Consortium for Stem Cell Research, Regulations in EU Member States Regarding hES Cell Research (Feb. 2007), http://archive.eurostemcell.org/Documents/Outreach/stemcell_hesc_regulations_2007FEB.pdf [hereinafter EuroStemCell]. *See also* Int'l Consortium of Stem Cell Networks, Global Regulation of Human Embryonic Stem Cell Research and Oocyte Donation, http://icscn.files.wordpress.com/2008/09/global-regulation-hesc-research-oocyte-donation-sep-08.pdf [hereinafter ICSCN]. In order to compete effectively with States like the United Kingdom, in 2004 Swiss voters overwhelming approved a law allowing experimentation on stem cells derived from human embryos. *See* Luke Harding, *Swiss Voters Back Stem Cell Research*, GUARDIAN, Nov. 29, 2004, at 3.

pean States have not regulated ESCs at all.[186] The European scientific community is similarly divided.[187]

Yet even with the back-and-forth political debate in the United States, the USPTO has never rejected an ESC patent on the ground of it being immoral. An invention is patentable in the United States if it meets the requirements of utility, novelty, and nonobviousness, and is adequately described in the patent specification.[188] While permitted by TRIPs to impose a morality exception to patentability, the United States does not have a statute on the books that excludes "immoral" inventions from patentability. In fact, the USPTO may not make moral judgments about an invention disclosed in a patent application.[189] As the U.S. Supreme Court has stated, "Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted."[190]

In truth, the early view in the United States was that patent law's utility requirement[191] contained a morality element.[192] In the 1817 circuit court case of *Lowell v. Lewis*, Justice Story established what came to be known as the "moral utility" doctrine,[193] under which inventions "frivolous or injurious to the well-being, good policy, or sound morals of society" were unpatentable.[194] Courts applied the moral utility doctrine for over a

186. EuroStemCell, *supra* note 185.

187. *Survey of European Scientists on Ethics of Scientific Advancements*, *supra* note 63.

188. 35 U.S.C. §§ 101–03, 112 (2007).

189. *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999).

190. Webber v. Virginia, 103 U.S. 344, 347–48 (1880).

191. The utility requirement is found in 35 U.S.C. § 101 (2009) ("Whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and *useful* improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.") (emphasis added). *See also* Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) ("The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].'").

192. *See* 1 DONALD S. CHISUM, CHISUM ON PATENTS § 4.03 (2007).

193. *See* Bagley, *supra* note 166, at 476.

194. Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D. Mass 1817) ("The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention. But if the invention steers wide of these objections, whether it be more or less useful is a circumstance very material to the interests of the patentee, but of no importance to the public.").

hundred years, particularly to invalidate patents on gambling devices.[195] The moral utility doctrine prevented inventions that facilitated consumer fraud or deception from receiving patent protection.[196]

In 1980, the U.S. Supreme Court held in *Diamond v. Chakrabarty* that a genetically modified bacterium constituted patentable subject matter under Section 101, based on the legislative intent that patentable subject matter include "anything under the sun that is made by man."[197] While *Chakrabarty* is famous for paving the path for future biotech patents, by declaring the breadth of patentable subject matter, it essentially marked the death knell for the moral utility doctrine.[198] In April 1987, the USPTO, relying on the Supreme Court's holding in *Chakrabarty*, announced that it considered "nonnaturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter."[199] About a year later, the USPTO issued to Harvard the first U.S. patent for a genetically modified animal: a transgenic mouse genetically engineered to carry an activated gene (specifically, an oncogene) that greatly increased the mouse's susceptibility to cancer, making the mouse a prime specimen for cancer research and the development of cancer treatments ("Oncomouse").[200]

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195. *E.g.,* Brewer v. Lichtenstein, 278 F. 512 (7th Cir. 1922); Meyer v. Buckley Mfg. Co., 15 F. Supp. 640 (N.D. Ill. 1936); Nat'l Automatic Device Co. v. Lloyd, 40 F. 89 (N.D. Ill. 1889); Schultze v. Holtz, 82 F. 448 (N.D. Cal 1897). *But see* Chicago Patent Corp. v. Genco, Inc., 124 F.2d 725, 727–28 (7th Cir. 1941) (finding that a pinball machine is not inherently a gambling device).

196. Rickard v. Du Bon, 103 F. 868, 873 (2d Cir. 1900) (When determining that the claimed process for producing counterfeit tobacco leaves lacked utility, the court found that "[i]n authorizing patents to the authors of new and useful discoveries and inventions, congress did not intend to extend protection to those which confer no other benefit upon the public than the opportunity of profiting by deception and fraud. To warrant a patent, the invention must be useful; that is, capable of some beneficial use as distinguished from a pernicious use."). *See also* Scott & Williams, Inc. v. Aristo Hosiery Co., 7 F.2d 1003 (2d Cir. 1925) (concluding that a patent in seamless stocking designed to trick consumers into thinking it was of higher quality was invalid for lack of utility).

197. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

198. *See* Bagley, *supra* note 166, at 476–77, 495 ("For many years a judicially created 'moral utility' doctrine served as a type of gatekeeper of patent-eligible subject matter. . . The gate, however, is currently untended, as a result of judicial decisions . . . [b]eginning in 1980 with [*Diamond v. Chakrabarty*], ... [which] flung open the doors of the USPTO to biotech subject matter.").

199. Commissioner of Patents and Trademarks, *Animals—Patentability*, 1077 OFFICIAL GAZ. PAT. OFF. 24 (Apr. 21, 1987).

200. U.S. Patent No. 4,736,866 (issued Apr. 12, 1988). Claim 1 provides: "A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage." *Id*.

In 1999, the Federal Circuit declared in *Juicy Whip, Inc. v. Orange Bang, Inc.*, that although "years ago courts invalidated patents on gambling devices on the ground that they were immoral[;] . . . that is no longer the law."[201] The court continued:

> Of course, Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness. Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.[202]

The *Juicy Whip* court also noted that the utility requirement was not a directive to the USPTO or the courts "to serve as arbiters of deceptive trade practices" and that there are other federal agencies, such as the Food and Drug Administration and Federal Trade Commission, that are responsible for protecting consumers from fraud and deception.[203]

Over the last few decades, the U.S. legal system has limited the USPTO's power of discretion to its area of expertise: patentability requirements. This policy shift has taken the morality "ax" out of the hands of the USPTO and the courts, a shift that is in line with the fundamental purposes of U.S. patent law "to encourage inventions, their disclosure, and their commercialization."[204] Innovation in technology should be driven by investment in scientists and engineers instead of an arbitrary or unpredictable moral compass. "A patent is a creature of statute,"[205] so only Congress should have the power to declare certain inventions unpatentable.

Patent law is supposed to strike a balanced bargain between the inventor and the public. The public encourages industry to invest in technological research and development with the promise of a set number of years of exclusive rights over commercial exploitation of the claimed invention. In return, the public benefits from the use of the new technology. The new knowledge the patent brings about enables further investment in technology, which is again fueled by the incentives of the patent system.

The purpose of European patent law is the same as that of U.S. patent law: "to promote technical innovation and the dissemination of its

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201. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (Fed. Cir. 1999).

202. *Id*. at 1368 (citation omitted).

203. *Id*. *See also* Whistler Corp. v. Autotronics, Inc., 14 U.S.P.Q.2D 1885 (N.D. Tex. 1988) (upholding radar detector patent); Murphy, 200 U.S.P.Q. 801 (Pat. & Trademark Off. Bd. App. 1977) (upholding slot machine patent).

204. In re Sarkar, 588 F.2d 1330, 1332 (C.C.P.A. 1978).

205. Arachnid, Inc. v. Merit Indus., Inc., 939 F.2d 1574, 1578 (Fed. Cir. 1991).

fruits."[206] Theoretically, inventions whose monopolized exploitation would promote that purpose should qualify for patent protection in both the United States and Europe. Yet the hESC controversy is not the first time that the EPO has deviated from the USPTO on the basis on morality. The USPTO granted Harvard a U.S. patent in 1988 for its Oncomouse invention.[207] But the Oncomouse European application, filed in June 1985, faced troubles similar to those of WARF's European patent application.[208] On July 14, 1989, the Examining Division initially refused the application on the ground that the invention violated Article 53(b) of the EPC,[209] which excludes from patentability "plant or animal varieties or essentially biological processes for the production of plants or animals."[210] While the United States had already affirmed the patentability of transgenic species in *Chakrabarty*,[211] the EPO had never addressed the issue of whether Article 53(b) prohibits patents in transgenic animals.[212] On appeal, the Technical Board concluded that Article 53(b) excluded animal varieties, but not animals in general.[213] On remand, the Examining Division granted the patent after concluding that Oncomouse did not constitute an animal variety,[214] nor did Oncomouse violate the morality provision of Article 53(a).[215] In reaching its conclusion on the morality issue, the Examining Division found that the potential benefit to humanity (i.e., cancer prevention) outweighed the detriment to animals.[216] Al-

206. *See* EGE OPINION, *supra* note 14, at 6 ("The inventor gets exclusive rights to control commercial exploitation of his invention for some years and in return, he discloses detailed description of his invention, making the new knowledge available to all. This disclosure enables others[, e.g.,] researchers[,] . . . to build on the achieved knowledge.") (internal punctuation omitted).

207. U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

208. Press Release, EPO, "Oncomouse" Opposition Proceedings Resume at EPO (Nov. 5, 2001), http://www.epo.org/about-us/press/releases/archive/2001/05112001.html [hereinafter 2001 EPO Press Release].

209. EPC 1973, *supra* note 20, art. 53(b).

210. *See* 2001 EPO Press Release, *supra* note 208.

211. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

212. *See* 2001 EPO Press Release, *supra* note 208.

213. Case T-19/90, [1990] E.P.O. O.J. 476 (Technical Bd. App. 1990).

214. Grant of European Patent No. 0 169 672 (Onco-mouse/Harvard), [1992] E.P.O. O.J. 588, 590 (Examining Div. 1992).

215. *Id*. at 593.

216. *Id.* ("In the overall balance the Examining Division concludes that the present invention cannot be considered immoral or contrary to public order. The provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals together with a low risk connected with the handling of the animals by qualified staff can generally be regarded as beneficial to mankind. A patent should therefore not be denied for the present invention on the grounds of Article 53(a) EPC.").

though the EPO eventually granted the Oncomouse patent,[217] the case exemplifies the uncertain status of a patent system with an ambiguous morality exception to patentability.

The problem with excluding hESC inventions is that the benefits of stem cell research are hugely in the public interest.[218] Innovation in hESC, as evidenced by the global research effort, is a reward for which the public should be willing to pay handsomely. Rejecting an invention for being "against morality" unjustifiably shifts the balance of the patent system by eliminating the inventor's most valuable incentive, exclusive rights, while simultaneously expropriating for public use the new knowledge disclosed in the patent. This shift in balance upsets the equilibrium of the patent system and is an impediment to innovation.

Morality itself is a public interest factor. If a patent office is required to factor morality into the patentability equation, it should consider morality in light of all other public interest factors, especially human health benefits. Whereas morality is largely a subjective category, subject to substantial public deviation and change over time, human health benefits are objectively and universally in the public interest. While some may oppose the use of such a cost-benefit analysis because it involves putting a price on human life, these kinds of valuations are done all the time. Courts award damages in wrongful death suits. People purchase health and life insurance policies. Actuaries assess the costs and risks of death.

The scientific community has demonstrated a significant reason to pursue hESC technology. Despite the moral haziness presented by hESCs, most countries allow hESC research to some extent.[219] The scientific promise and potential health benefits of hESC research cannot be ignored. The world is craving a breakthrough in hESC technology. The patent system should not stand in the way.

CONCLUSION: SUGGESTED ALTERNATIVE PRACTICES

The Directive was originally adopted in order to establish "legal certainty" among the Member States in the area of biotechnological innovation.[220] Theoretically, this legal certainty was supposed to make Europe a better landscape for attracting investment in biotechnology.[221] But not all the Member States can agree on what constitutes an "immoral" invention.[222]

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217. European Patent No. EP 0169672 (published May 13, 1992).
218. *See* NIH, *supra* note 42.
219. ICSCN, *supra* note 185. *See generally* Hoffman, *supra* note 139.
220. *See* EGE OPINION, *supra* note 14, at 6.
221. *Id*.
222. *See, e.g.*, Amicus Curiae Submission of the United Kingdom, *supra* note 119.

The EPO has a few alternatives to its current practice of blackballing "immoral" inventions. As a first alternative, the EPO could still resolve whether an invention is contrary to morality, but—instead of refusing to examine the application—the EPO could "yellow-flag" it for having a "contrary-to-morality" status and continue with standard examination procedures. The EPO could then notify the national ethics committee of each Member State so that each could make a determination of patentability based solely on domestic norms. After each national ethics committee notified the EPO of its conclusion, the EPO could advise the applicant which States refused to grant patent protection. The applicant could then make an informed decision whether to proceed further with examination, while simultaneously avoiding the lengthy delays and heavy costs associated with appealing a decision of the Examining Division.

The EPO could supplement the yellow-flag system by requiring applicants of yellow-flagged applications to post a significant bond in order to keep the application in examination. If the applicant posted the bond and the application was green-lighted by a certain proportion of Member States, the EPO would return the bond to the applicant. If too many Member States found the invention to be "contrary to morality," the applicant would forfeit the bond. The bond system would avoid an influx of applications that disclose clearly "immoral" subject matter, or at least compensate the EPO for wasting its time on meritless cases.

Europe also has the option of granting a reduced patent term to inventions deemed to be morally reprehensible, instead of refusing to examine the application.[223] Although this alternative would not satisfy people who believe that granting property rights in "immoral" inventions is never permissible,[224] it would constitute a fair compromise on the difficult issue and still promote the purposes of patent law. The EPC could also establish statutory licensing fees for patents for immoral inventions; this would minimize the ethical costs of the commercial exploitation of the "immoral" invention by limiting the economic power of the patentee's exclusive rights.

Another alternative is to repeal Article 53(a), but preserve Rule 28. The adoption of Rule 28 has arguably rendered Article 53(a) obsolete. Rule 28 is a declaration of a consensus among the Member States of what specifically constitutes an invention unpatentable for being contrary

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223. EPC 2000, *supra* note 20, art. 63(1) provides: "The term of the European patent shall be [twenty] years as from the date of filing of the application." *Id*.

224. *See, e.g.*, Ronald L. Conte Jr., *Against Embryonic Stem*, CATHOLIC PLANET, Dec. 2, 2004, http://www.catholicplanet.com/articles/article95.htm.

to ordre public or morality. The Enlarged Board in the WARF stem cell case found it unnecessary to address Article 53(a) after concluding WARF's invention was unpatentable under the specific exclusion of Rule 28(c).[225] The Enlarged Board found that the legislature had predetermined that the invention was contrary to morality.[226] This is essentially how the U.S. system works; any invention meeting all the Title 35 patentability requirements is patentable in the United States[227] unless it is specifically excluded by statute. For example, Congress explicitly used its powers to promote public health and welfare to exclude the patenting of nuclear weapons.[228]

A judicial finding of "contrary to morality" under Article 53(a) would require the EPO to make a much broader determination than under any of the specific, legislatively mandated exceptions to patentability under Rules 28 and 29(1).[229] If an invention does not explicitly fall within one of the unpatentable categories elucidated in Rules 28 or 29(1), an established European social norm that the invention's exploitation is immoral likely does not exist. Otherwise, the legislature would have explicitly guarded against such a patent. Instead of relying on Article 53(a) as a backstop to Rule 28, the legislature could build upon Rule 28 to include any other categories of invention whose exploitation is commonly deemed immoral across Europe. In order to prevent the patenting of breakthrough technology that falls outside of the explicitly prohibited categories but whose exploitation would be contrary to morality, the legislature would have to keep up with the latest advances in science and technology, especially those relating to human health.

It is surprising that Europe has decided to burden its patent office with understanding categories and degrees of morality, rather than leaving the EPO to exercise its expertise in determining novelty, industrial applicability, and inventive step.[230] Morality has no place as a tool in the hands of a patent office,[231] especially a regional patent office such as the EPO, which controls whether the various national patent offices of Europe even lay eyes on an application. While it might feel good to prohibit pa-

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225. Case G-2/06, unpublished op. at 28 (Enlarged Bd. App. Nov. 25, 2008), *available at* http://legal.european-patent-office.org/dg3/pdf/g060002ex1.pdf.

226. *Id*.

227. 35 U.S.C. § 101–03, 112 (2009).

228. 42 U.S.C. § 2181 (2009).

229. EPC Regs., *supra* note 27, R. 29(1) provides: "The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions." *Id*.

230. EPC 2000, *supra* note 20, art. 52(1).

231. *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999).

tents for inventions in morally dubious areas of science, in the end, morality restrictions on patentability only slow the pace of technology and frustrate the purposes and effectiveness of patent law.

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