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Oh, The Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research

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Oh, The Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research

Oh, the Places You'll Go!

Congratulations!

Today is your day.

You're off to Great Places!

You're off and away!

You have brains in your head.

You have feet in your shoes

You can steer yourself

any direction you choose.

You're on your own. And you know what you know.

And YOU are the guy who'll decide where to go.

...

OH!

THE PLACES YOU'LL GO!

...

You'll get mixed up, of course,

as you already know.

You'll get mixed up

with many strange birds as you go.

So be sure when you step.

Step with care and great tact

and remember that Life's

a Great Balancing Act . . .

And will you succeed?

Yes! You will, indeed!

(98 and 3 / 4 percent guaranteed.)

...

—Dr. Seuss*

* DR. SEUSS, OH, THE PLACES YOU'LL GO 1-48 (1990).

TABLE OF CONTENTS

- I. INTRODUCTION
- II. GENERAL PATENT LAW
 - A. The Basic Premises for Granting a Patent
 - B. Patent Law Requirements
 - 1. Patentability and Utility – § 101
 - 2. Novelty - § 102
 - 3. Non-Obviousness – § 103
 - 4. Disclosure – § 112
 - C. Patents and Biotechnology
 - D. Relevant Cases and Guidelines
 - 1. Patentable Subject Matter and Utility
 - E. Obviousness
 - F. Enablement
- III. STEM CELL RESEARCH
 - A. Historical Basis
 - B. Stem Cell Potential
- IV. UNITED STATES GOVERNMENTAL REGULATIONS OF STEM CELL RESEARCH
 - A. 1999 Regulations
 - B. 2001 Regulations of Stem Cell Research
 - C. International Impact and Presence
- V. PATENT LAW IMPLICATIONS
 - A. Intellectual Property Protection of Embryonic Stem Cells
 - B. Pressure on WARF and Geron
 - C. General Industry Pressure
 - D. General Responses
- VI. FUTURE OF STEM CELL RESEARCH
 - A. General Advancement Potential
 - B. Drug Development
 - C. Therapeutic Potential
 - D. Economic Impact
 - E. International Developments
- VII. GENERAL CONSIDERATIONS AND RECOMMENDATIONS
 - A. Considerations
 - B. Recommendations
- VIII. CONCLUSION

I. INTRODUCTION

The United States Constitution provides that patents are to be granted to “[p]romote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹ This constitutional basis for the protection of intellectual property rights provides a strong reason why the unwavering need for intellectual property security is of such significance in the United States today.

In the United States, a patent may be granted for those things that are the result of “human ingenuity.”² Nevertheless, recent developments in the field of biotechnology have highlighted the significance and ramifications of patent protection and thereby have created great controversy as to what exactly is “human ingenuity.” Indeed, biotechnology carries with itself enormous social, academic, and commercial consequences.³ Therefore, granting a monopoly right, such as that which takes place when a patent is awarded, places an extremely significant power in the hands of one or a few people. A predominate example of this overwhelming power is currently being experienced in the field of embryonic stem cell research, where a single patent that protects a method of isolating embryonic stem cells, as well as the cells themselves, has created great controversy.⁴

This Comment will outline the various aspects of current United States patent law that inevitably impact the scope of the research performed on and pertaining to embryonic stem cells. Many of these implications are currently being felt in the biotechnology industry. However, the majority of these ramifications and the extent of the impact are yet to be experienced. Part II of this Comment will focus on the general requirements set forth by United States patent law. Parts III and IV respectively, will address the scope of embryonic stem cell research and the United States governmental impact. Part V explains the implication of current patent laws on embryonic stem cell research. Finally, Parts VI and VII focus on the potential future of embryonic stem cell research and various considerations and recommendations that should be noted as scientific advances in the field continue to be made. Thus, this Comment will describe and analyze the

1. U.S. CONST. art. I, §8, cl. 8.

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

3. Byron V. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments, and Licensing the “Useful Arts,”* 7 ALB. L.J. SCI. & TECH. 295, 298 (1997) (noting that granting patents on gene fragments may actually hinder advancements in biotechnology).

4. Sheryl Cay Stolberg, *Patent on Human Stem Cell Puts U.S. Officials in Bind*, N.Y. TIMES, Aug. 17, 2001, at A1.

state of the law and its many possible implications on embryonic stem cell research while elucidating areas of discrepancies and inconsistencies in the legal structure that impact an area of technology that will inevitably affect everyone on a global and personal level.

II. GENERAL PATENT LAW

A. *The Basic Premises for Granting a Patent*

A United States patent is a grant from the government to an inventor of the right to exclude others from making, using, or selling the inventor's invention.⁵ As a result, a patent permits controlled access to, and income from, an invention's commercial, therapeutic, and/or scientific value. Generally, there are three types of patents: design patents, plant patents, and utility patents.⁶

A plant patent provides property protection to "any person who has invented or discovered and asexually reproduced [a] new variety of plant" that is not a tuber-propagated plant⁷ or one that is found in an uncultivated state.⁸ Notably, just as it is possible to obtain patent protection for the modification of bacteria, a plant patent may be granted for the modification of plant cells.⁹ However, when dealing with the current controversies surrounding the area of biotechnology, plant patents are usually of little significance.

A design patent is directed at protecting the overall appearance of an invention, such as how the invention looks.¹⁰ An inventor may be granted a design patent for a new, original, and ornamental design for an article of manufacture.¹¹ Because a design patent is limited to protecting the unique design of various objects, it is seldom used in the field of biotechnology.¹²

A utility patent is the type that is granted most frequently in the field of biotechnology. Generally, utility patents protect the structure and/or

5. BLACK'S LAW DICTIONARY 1125 (7th ed. 1999).

6. Thomas G. Field, Jr., *Brief Survey of Intellectual Property*, 31 IDEA 85, 91-92 (1990).

7. Tubers are the underground stems on certain plants that are complete with nodes and axillary buds, otherwise known as eyes. The propagation of tubers may occur by either planting the entire tuber or cutting the tuber into pieces. Dewayne Ingram, *Landscape Plant Propagation Workbook: Unit IV. Propagation by Division*, University of Florida, Institute of Food & Agricultural Sciences, at http://www.edis.ifas.ufl.edu/BODY_MG361 (last visited May 7, 2002).

8. *Introduction to Understanding Patents*, at <http://www.lib.umich.edu/ummu/pattm/whatis.html#plant> (2001).

9. *Ex parte* Hibberd, 227 U.S.P.Q. 443, 444 (PTO Bd. of Patent Appeals and Interferences 1985).

10. 35 U.S.C. § 171 (2002).

11. *Id.*

12. Olsen, *supra* note 3, at 311.

function of the invention, such as how it works or how it is used, and is normally sought when an inventor seeks protection over how the invention operates.¹³ A utility patent can be issued to any person for a process, machine, manufactured article, composition of matter, or any new and useful improvement to the aforementioned types of inventions.¹⁴ Thus, both a product itself and the process by which the product is made may be patentable with a utility patent.¹⁵

In most cases, inventors pursue the protection offered by a utility patent because protecting the structure and/or function of the invention is preferable to protecting the ornamental design of the invention.¹⁶ However, where a meaningful utility patent may not be available, or if the appearance of an invention is more important than its structure and/or function, design patent protection may be the best option. There are also those situations where an inventor feels that both the structure and/or function and the appearance are important, and in such instances, both utility and design patents may be sought for the same invention. Notably, when considering patent protection for biotechnology, most applications are for utility patents.¹⁷

B. Patent Law Requirements

A patent serves to protect that which is novel, unique, and useful. There are four statutory requirements that must be satisfied before a patent can be issued. That which is sought to be patented must fall within the class of those things that are patentable, demonstrate some utility, be non-obvious to a practitioner in the relevant field, and provide adequate disclosure.¹⁸

1. Patentability and Utility – § 101

Section 101 of the Patent Act¹⁹ provides that patent protection may be obtained for “any new and useful process, machine, manufacture, or

13. 35 U.S.C. § 101 (2002); *see also* 35 U.S.C. § 151 (2001) (explaining general issues in determining patentability).

14. Field, *supra* note 6, at 91.

15. *Id.*

16. *See, e.g.*, Olsen, *supra* note 3, at 311.

17. *See id.*; *see also* John K. Flanagan, *Gene Therapy and Patents*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 739, 746 (1998) (noting that most of the patents granted in the field of gene therapy have been utility patents in the form of process claims).

18. 35 U.S.C. §§ 101-104 (2002).

19. The Patent Act refers generally to Sections 1-376 of Title 35 of the United States Code. Unless otherwise noted, all sections referred to pertain to the Patent Act.

composition of matter, or any new and useful improvement thereof.”²⁰ This basic utility requirement demands a showing that the invention has some practical application or use, but does not require that the invention be more useful than an existing product or process.²¹ In practice, a lack of utility rarely serves as a bar to the grant of a patent.²²

2. Novelty - § 102

To be patentable, an invention must also be novel. As such, Section 102 of the Patent Act generally provides that the invention cannot have been in the hands of others and cannot have been disclosed, whether through presentation or publication, to the public prior to the patent application.²³ A publication by the inventor will not prevent the satisfaction of the novelty requirement as long as the patent application is filed within one year from the time of the publication.²⁴

3. Non-Obviousness – § 103

Section 103 provides that differences between the invention and the prior art must not be such that the prior art and “the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.”²⁵ In determining whether an invention is non-obvious, courts will look to secondary considerations as indicia of non-obviousness.²⁶ Such secondary considerations include evidence of commercial success, a basic need for the invention, and the failure of others to develop the invention previously.²⁷

4. Disclosure – § 112

In exchange for the grant of the monopoly right associated with a patent, an inventor must provide sufficient disclosure of the invention to the public.²⁸ Section 112 provides that a sufficient disclosure is that disclosure of the invention, which would allow one skilled in the art to practice the

20. 35 U.S.C. § 101 (2002).

21. *Id.*

22. Flanagan, *supra* note 17, at 749-50 (explaining that “[t]he utility requirement generally does not pose much difficulty for applicants in any field of invention.”).

23. 35 U.S.C. § 102 (2002).

24. *Id.*

25. 35 U.S.C. § 103 (2002).

26. *See, e.g.*, *Electro Scientific Indus., Inc. v. Gen. Scanning, Inc.*, 247 F.3d 1341 (Fed. Cir. 2001).

27. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

28. 35 U.S.C. § 112 (2002).

invention.²⁹ Generally, this disclosure requirement has two primary objectives: 1) it ensures that the public will receive the complete benefit of the invention when the patent term expires and, 2) it allows the Patent and Trademark Office ("PTO") to determine that the patent applicant has truly "developed an operative and useful embodiment of the invention."³⁰ Indeed, the two functions served by the disclosure requirement "parallel[] scientific norms by calling upon patent applicants, like publishing scientists, to dedicate their inventions to the public . . . [and] to supply sufficient information and materials to demonstrate to a knowledgeable audience that they have in fact achieved what they claim."³¹

C. *Patents and Biotechnology*

As modern biotechnology progresses, it is becoming more and more evident that the same human creativity and ingenuity that gave rise to inorganic discoveries has made significant advances in the biological sciences possible.³² Therefore, "it is as logical to issue patents for work on the truly novel and beneficial creations derived from the life sciences, as it is to issue patents for inventions in the areas of computer science or metallurgy."³³

Additionally, it is important to note that all patents, and in particular, patents based on biotechnology, are to be evaluated within the appropriate time frame. That is, although an invention to be patented may have obvious potential to support an even greater invention or scientific advancement, its novel, unique, and useful characteristics should be assessed based on the state of the art at the time of the invention.³⁴ In fact, the purpose of granting "[p]atents [is to] encourage the dissemination of information about new inventions, thus permitting competitors to build upon or develop improved versions of patented inventions."³⁵ Therefore, in a most basic sense, the patenting of discoveries in biotechnology is essentially aimed at promoting

29. *Id.*

30. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 207 (1987).

31. *Id.* at 207-08.

32. Olsen, *supra* note 3, at 317.

33. *Id.*

34. Lawrence M. Sung, *Stranger in a Strange Land: Biotechnology and the Federal Circuit*, 2 WASH. U. J.L. & POL'Y 167, 197 (2000).

35. Jay P. Kesan & Marc Banick, *Administrative Law Issues: Patents as Incomplete Contracts: Aligning Incentives for R&D Investments With Incentives to Disclose Prior Art*, 2 WASH. U. J.L. & POL'Y 23, 23 (2000).

the spread of these technologies to enhance further scientific advancements. There is, nevertheless, a strong belief that patent laws should follow historical guidelines to the extent that “[c]ertain things and objects considered important or central to life or to the fundamental tenets of society,” should not be subject to the same rights as private property.³⁶ A primary reason for this position is based on the historical goal of making “such things available to all citizens and in some cases to humanity at large.”³⁷

D. Relevant Cases and Guidelines

In a decision that significantly impacted the property protection available to stem cell innovations, the Court in *Diamond v. Chakrabarty*³⁸ upheld a theory that human-manipulated life is patentable.³⁹ With the passing of over two decades since this decision, the rationale set forth by the Court has been applied in the granting of patents on gene sequences,⁴⁰ viruses, embryos, fetuses,⁴¹ embryonic stem cells, and even on a human-engineered mouse.⁴² In addition to this decision, however, the patenting of stem cell discoveries also follows the basic patentability guidelines.

1. Patentable Subject Matter and Utility

While the laws of nature, physical phenomena, and abstract ideas have been held to be unpatentable, when patenting a biological discovery, the PTO continues to follow the guidelines set forth in *Graham v. John Deere*⁴³ which noted that “ingenuity should receive a liberal encouragement.”⁴⁴ As such, applicants have been able to satisfy the patentable subject matter and utility requirements under the theory that the patentee “has produced a new [object] with markedly different characteristics from any found in nature and one having the potential for significant utility... [h]is discovery is not

36. Kojo YelPaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 32 MCGEORGE L. REV. 111, 136 (2000).

37. *Id.*

38. 447 U.S. 303 (1980).

39. *Id.* at 310 (reasoning that “the patentee produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”).

40. Olsen, *supra* note 3, at 319.

41. Adam L. Penenberg, *U.S. Patent Law Can’t Cope With Human Clones*, at <http://www.wired.com/news/politics/0,1283,2292,00.html> (1997).

42. L.J. Deftos, *Patenting Life: The Harvard Mouse That Has Not Roared*, THE SCIENTIST, Nov. 27, 2000, at 6.

43. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

44. *Id.* at 7-10 (internal citations omitted).

nature's handiwork, but his own; accordingly it is patentable subject matter under Section 101."⁴⁵

Early interpretations of the utility standard only mandated that "the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society."⁴⁶ This standard, however, was narrowed when the United States Supreme Court in *Brenner v. Manson*⁴⁷ held that "until a process is refined and developed [so that] specific benefit exists in currently available form there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."⁴⁸ Nevertheless, the PTO has recognized that it does not want to restrict the biotechnology field by making the utility threshold too high, because in the eyes of the PTO, this would unnecessarily burden this leading-edge industry.⁴⁹

Therefore, to address the ever-changing world of biotechnology, the PTO did revisit the Utility Examination Guidelines on January 5, 2001.⁵⁰ The new guidelines prescribe that a claimed invention either have a well-established utility or assert "a specific, substantial, and credible utility."⁵¹ This language is essentially adopted from the 1999 Revised Interim Utility Examination Guidelines, which were a change to those prescribed in 1995, in that they required a specific, not a substantial utility.⁵²

The "heightened standard was based on the PTO's adoption of the United States Supreme Court's position in *Brenner v. Manson* that a patent is not given as a reward for the search of an invention's utility but, rather, a reward for actually discovering that utility."⁵³ Some believe that the new

45. Chakrabarty, 447 U.S. at 309-10 (citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

46. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

47. *Brenner v. Manson*, 383 U.S. 519 (1966).

48. *Id.* at 534-35 (holding that a compound with only hypothetical utilities does not satisfy the utility requirement of § 101).

49. Michael Lane, *Invention or Contrivance? Biotechnology, Intellectual Property Rights and Regulation*, Convention on Biological Diversity, at <http://www.acephale.org/bio-safety/loC-indx.htm> (Nov. 1995).

50. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

51. *Id.* at 1093 (reasoning that a patent application for a steroid compound was rejected for failure to state a substantial utility).

52. See Revised Interim Utility Examination Guidelines, 64 Fed. Reg. 7144 (Dec. 21, 1999).

53. Comment, *The Fate of Gene Patents Under the New Utility Guidelines*, 2001 DUKE L. & TECH. REV. 0008, available at <http://www.law.duke.edu/journals/dltr/articles/2001dltr0008.html> (citing *Brenner v. Manson*, 383 U.S. 519, 536 (1966) (stating that "a patent is not a hunting license. It is not a reward for the search but compensation for its successful conclusion."); see also Mark Jagels, *Dr. Moreau Has Left the Island: Dealing With Human-Animal Patents in the 21st Century*, 23 T. JEFFERSON L. REV. 115, 137 (2000) (explaining that the holding in *Brenner* essentially required "that the invention must be shown to have a definite, immediate and demonstrable utility.")).

guidelines reflect the PTO's perception of "the genetically altered state of Utility."⁵⁴ These new guidelines prescribe the following:

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. However, when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement.⁵⁵

It is this relatively broad concept of utility that has permitted the patenting of embryonic stem cells.⁵⁶ However, while some perceive these revised utility guidelines of the PTO to be broad and standardized,⁵⁷ many in the biotech community contend that the utility guidelines actually are too narrow and thereby may in fact operate as a deterrent to research.⁵⁸

E. Obviousness

That which constitutes obviousness in biotech inventions has been outlined in several court cases. The Federal Circuit Court in *In re Deuel*⁵⁹ reversed a decision of the PTO Board of Patent Appeals ("the Board") and held that the patent claims to a process of isolating and making deoxyribonucleic acid ("DNA") molecules were not obvious.⁶⁰ However, in *In re Mayne*,⁶¹ claims to proteins comprising methionine connected to the enterokinase cleavage site and coupled to human Growth Hormone ("hGH") or bovine Growth Hormone ("bGH") were rendered obvious because the prior art taught the use of fusion proteins and identified cleavage sites for enterokinase.⁶² Recent decisions by the Board have applied this logic in noting that "[w]hen obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the

54. Albert L. Jacobs & Jeffrey A. Glazer, *The PTO Redefines Genomic Ingenuity*, New York Law Journal, available at <http://www.gtlaw.com/pub/articles/2001/jacobsa01a.htm> (March 12, 2001).

55. *Id.*

56. *See infra*, notes 92-121 and accompanying text.

57. *See Lane, supra* note 49.

58. Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 135 (2001) (noting that the 2001 Utility Guidelines could potentially restrict advances in DNA research).

59. 51 F.3d 1552 (Fed. Cir. 1995).

60. *Id.* The court determined that DNA and complimentary deoxyribonucleic acid ("cDNA") molecules encoding proteins that stimulated cell division were not obvious in light of a prior art reference teaching a method of gene cloning together with a reference disclosing a partial amino acid sequence for a protein that stimulated cell division. *Id.*

61. 104 F.3d 1339 (Fed. Cir. 1997).

62. *Id.* at 1343-44.

teachings of that reference.”⁶³ Additionally, a “reasonable expectation of success” is not the sole consideration in an obviousness determination; it is also necessary to consider whether the prior art would have suggested the proposed modification.⁶⁴

F. Enablement

The court in *Enzo Biochem, Inc. v. Calgene, Inc.*⁶⁵ held that claims of antisense nucleic acids to regulate gene expression in eukaryotic and prokaryotic cells, when the application only provided examples for prokaryotic cells, failed to meet the enablement requirement.⁶⁶ Additionally, in *Genentech, Inc. v. Novo Nordisk*,⁶⁷ claims to cleavable fusion expression failed to meet the enablement requirement because the patent failed to provide any specific cleavable conjugate proteins or any reaction conditions under which cleavable fusion expression would work.⁶⁸ Thus, in the biotech community, it is generally believed that “courts have applied a fairly stringent enablement standard to . . . claims because of the perceived unpredictability of biotechnology.”⁶⁹

III. STEM CELL RESEARCH

A. Historical Basis

The term “stem cell” is typically used to refer to cells within an adult organism that renew tissue.⁷⁰ More specifically, a stem cell is a type of cell that has special abilities to renew itself and form different specialized cell types.⁷¹ Stem cells are of various types,⁷² including the most recent to be

63. *Ex Parte* Stephan J.W. Platzer, No. 1997-3334, 2001 WL 1057504, at *2A (Bd. Pat. App. & Interf. 2001) (citing *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir.1996)).

64. *Id.*

65. 188 F.3d 1362 (Fed. Cir. 1999).

66. *Id.* at 1362-63.

67. 108 F.3d 1361 (Fed. Cir. 1997).

68. *Id.* at 1367.

69. Eric Guttag, *Unpredictability – The Two-Edged Sword in Patenting Biotechnology*, at <http://tenonline.org/art/ip1/0003.html> (2001).

70. National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research: Executive Summary*, at <http://www.bioethics.georgetown.edu/ubac/execsumm.pdf> (Sept. 1999).

71. Nat'l Inst. of Health, *Stem Cells: Scientific Progress and Future Research Directions*, U.S. Dep't of Health and Human Services, ES-1 (2001), available at <http://www.nih.gov/news/stemcell/scireport.htm>.

discovered, embryonic stem cells, which were first isolated at Johns Hopkins University School of Medicine in 1997.⁷³ Embryonic stem cells differ from adult stem cells in that they are found naturally in the early stage of embryonic development.⁷⁴ Generally, embryonic stem cells can be located “after the egg is fertilized and has begun dividing, but before the mass of cells attaches itself to the wall of the uterus.”⁷⁵

One of the most valuable features of embryonic stem cells is that they are pluripotent or, put another way, have the ability to divide and thereby give rise to differentiated cell types from all three germ layers of the embryo, the endoderm,⁷⁶ the mesoderm,⁷⁷ and the ectoderm.⁷⁸ More simply stated, unlike other human cells, such as heart cells or skin cells [which] are committed to conduct a specific function, a stem cell is uncommitted and remains uncommitted, until it receives a signal to develop into a specialized cell, and maintains the ability to form any kind of adult cell or adult cell precursor.⁷⁹ As a result, embryonic stem cells present great potential for

72. Nelle S. Paegel, *Use of Stem Cells in Biotechnological Research*, 22 WHITTIER L. REV. 1183, 1185 (2001) (noting that “[w]hile human bone marrow stem cells have been used for research for many years, embryo stem cells have not.”).

73. Ricki Lewis, *Embryonic Stem Cells Debut Amid Little Media Attention*, THE SCIENTIST, Sept. 29, 1997, at 1.

74. *See id.*

75. David Tenenbaum, *Finally, Generic Human Cells Discovered*, at http://whyfiles.org/shorties/stem_cell.html (Nov. 20, 1998); *see also* University of Wisconsin, *Embryonic Stem Cell Fact Sheet*, Office of News and Public Affairs (Nov. 5, 1998), available at <http://www.news.wisc.edu/thisweek/Research/Bio/Y98/facts.html> (noting that human embryonic stem cells can be derived from in vitro fertilized embryos that are less than one week old).

76. *Meta Library*, at <http://www.meta-library.net/biogloss/endrm-body.html> (last visited Oct. 29, 2002) (stating that “The endoderm is the innermost of the germ layers of an embryo and is the source of the epithelium of the digestive tract and its derivatives.”).

77. *Meta Library*, at <http://www.meta-library.net/gengloss/index-frame.html> (last visited Oct. 28, 2002) (stating that the mesoderm is the middle of the three primary germ layers of an embryo, which forms many of the bodily tissues and structures including bone, muscle, connective tissue, and skin).

78. *Id.* The ectoderm is the outermost of the three primary layers of an embryo and is responsible for producing “the nervous system, the epidermis and epidermal derivatives, as well as the lining of various body cavities such as the mouth.” *Id.*; *see also* Jason H. Casell, *Lengthening the Stem: Allowing Federally Funded Researchers to Derive Human Pluripotent Stem Cells From Embryos*, 34 U. MICH. J.L. REFORM 547, 551 (2001) (explaining that stem cells, which potentially can give rise to all cells in the body, hold promise for treating almost all, if not all, diseases); *see also* Nat’l Inst. of Health, *Stem Cells: Scientific Progress and Future Research Directions*, Dep’t of Health and Human Services, ES-1 (2001), available at <http://www.nih.gov/news/stemcell/scireport.htm>.

79. *Meta Library*, at <http://www.meta-library.net/gengloss/index-frame.html> (last visited Oct. 28, 2002); *see also* J.W. McDonald, et al., *Transplanted Embryonic Stem Cells Survive, Differentiate and Promote Recovery in Injured Rat Spinal Cord*, NATURE MEDICINE, Dec. 1999, at 1410-12; *see also* Sharon M. Parker, *Bringing the “Gospel of Life” to American Jurisprudence: A Religious, Ethical, and Philosophical Critique of Federal Funding for Embryonic Stem Cell Research*, 17 J. CONTEMP. HEALTH L. & POL’Y 771, 777 (2001).

therapeutic treatments and possible cures for many life-threatening diseases.⁸⁰

Embryonic stem cells can be formed by different methods. Most of these methods have been subject to great debate as the process involves the manipulation of human embryos "to provide a source of embryonic stem cells which can be isolated and extracted from the inside layer or the inner cell mass of a pre-embryo (known as a blastocyst)."⁸¹ One method involves the extraction of the stem cells from human embryos.⁸² The human embryos used to harvest the stem cells may be those that were created by in vitro fertilization for couples who are attempting to overcome infertility.⁸³ The primary manner by which these embryos become available to scientists for manipulation is when they are donated for research purposes by couples that no longer have plans to use the embryos as a means to deal with their personal infertility issues.⁸⁴ Human fetal tissue following an elective abortion may also provide access to the embryonic germ cells that can be manipulated to produce embryonic stem cells.⁸⁵ Researchers may also obtain access to human embryos by acquiring these embryos created by in vitro fertilization using gametes donated for the sole purpose of facilitating research or by human or hybrid embryos generated asexually.⁸⁶ This is a process similar to the one used to clone the well-known sheep "Dolly" in Edinburgh Scotland in 1997.⁸⁷

80. Nat'l Inst. of Health, *Stem Cells: Scientific Progress and Future Research Directions*, Dep't of Health and Human Services, ES-1 (2001), available at <http://www.nih.gov/news/stemcell/scireport.htm>.

81. Lori P. Knowles, *Science Policy and the Law: Reproductive and Therapeutic Cloning*, 4 N.Y.U. J. LEGIS. & PUB. POL'Y 13, 14 (2000); see also Paegel, *supra* note 72, at 1187-88 (noting that the role of scientists is to find a way to stimulate stem cells into differentiating into specific cells in hopes that it is possible to treat stem cells in "a way as to effectuate this 'trigger' mechanism, perhaps for example, through the growing medium. Assuredly, if there is a way in which to accomplish this feat of engineering, these highly talented scientists will figure it out, given sufficient time and resources.").

82. The method of acquiring embryonic stem cells is of great ethical debate. That is, the legal status of a human embryo is often highlighted, particularly when determining whether or not federal funds should be allocated to stem cell research, which requires the destruction of human embryos. Parker, *supra* note 79, at 787-89; see also National Legal Center for the Mentally Dependent & Disabled, Inc., *On Human Embryos and Medical Research: An Appeal for Ethically Responsible Science and Public Policy*, 16 ISSUES IN LAW & MEDICINE 261, 265 (2001).

83. Parker, *supra* note 79, at 783.

84. *Id.*

85. *Id.*

86. National Bioethics Advisory Commission, *Ethical Issues in Stem Cell Research: Executive Summary*, at <http://bioethics.georgetown.edu/hbac/exec.summ.pdf> (Sept. 1999)

87. Knowles, *supra* note 81, at 14-15. The process used to clone "Dolly" is referred to as Somatic Cell Nuclear Transfer. The technique, which has been subject to intense international

B. Stem Cell Potential

There is a general belief in the scientific community that various embryonic stem cell stocks of different immunotypes could be used for the replacement of distinct dysfunctional cell types in the body.⁸⁸ It is further believed that this could be accomplished without the need for cross matching a donor or suppressing the immune system.⁸⁹ As a result, one of the greatest outcomes of embryonic stem cell research could be the treatment of diseases that affect various isolated cell types such as juvenile onset diabetes, Alzheimer's disease, which affects brain cells, and Parkinson's disease, which degrades nerve cells.⁹⁰ Furthermore, "failing hearts and other organs, in theory, could be shored up by injecting healthy cells to replace damaged or diseased cells."⁹¹ Thus, embryonic stem cells are invaluable for their potential use as an "unlimited quantit[y] of normal human cells of virtually any tissue type" for use in drug screening.⁹²

debate, involves the creation of embryos to provide a source of stem cells. Scientists believe that these stem cells can then be cultured to produce cells or tissue that can be used as replacements for tissue that has been destroyed or damaged by disease. Thus, the Somatic Cell Nuclear Transfer process, which is often called therapeutic cloning, allows for the creation of stem cells and resultant tissue cultures that are genetically identical to that of the donor/recipient from which the stem cells were harvested, thereby reducing or eliminating the incidence of rejection. See also Alexandra Hawkins, *Protecting Human Dignity and Individuality: The Need for Uniformity in International Cloning Legislation*, 14 TRANSNAT'L LAW 243, 268 (2001) (reasoning that despite a general belief that United States laws could push stem cell research abroad, following the creation of "Dolly," "[n]umerous international organizations and many countries immediately sought to place restrictions on the use of nuclear transfer and to ban any use of the procedure for human cloning."); see also Paegel, *supra* note 72, at 1183-84.

88. Daniel McConchie & Linda Bevington, *Stem Cell Research: A Constructive Way Forward*, The Center for Bioethics and Human Dignity (1999), available at <http://www.bioethix.org/newsletter/992/992mcc-bev.htm>.

89. David Tenenbaum, *Finally, Generic Human Cells Discovered*, at http://whyfiles.org/shorties/stem_cell.html (Nov. 20, 1998).

90. University of Wisconsin, *Embryonic Stem Cell Fact Sheet*, Office of News and Public Affairs (Nov. 5, 1998), available at <http://www.news.wisc.edu/thisweek/Research/Bio/Y98/facts.html>; see also Parker, *supra* note 79, at 773; see also Stolberg, *supra* note 4, at A1 (noting that "[t]heoretically the cells can be coaxed in the laboratory to grow into any cell or tissue – insulin-producing cells to use against diabetes, for example, or nerve cells that might treat Parkinson's disease."); see also Knowles, *supra* note 81, at 15 (indicating that the use of therapeutic cloning techniques could be used to create autologous embryonic stem cells that could be stimulated to develop into skin for use in treating burn patients).

91. University of Wisconsin, *Embryonic Stem Cell Fact Sheet*, Office of News and Public Affairs (Nov. 5, 1998), available at <http://www.news.wisc.edu/thisweek/Research/Bio/Y98/facts.html>.

92. Eliot Marshal, *A Versatile Cell Line Raises Scientific Hopes, Legal Questions*, SCIENCE, Nov. 6, 1998, at 1145-47 (internal quotations omitted); see also Paegel, *supra* note 9, at 1185 (indicating that stem cells have the potential to be grown artificially and thereby may be used to replace tissues that are dead or damaged by diseases such as Parkinson's disease, Alzheimer's disease, heart maladies, and stroke); see also Nat'l Inst. of Health, *Stem Cells: Scientific Progress and Future Research Directions*, Dep't of Health and Human Services (2001) (noting that the full extent to which embryonic stem cells will be instrumental in developing cell-based therapies to treat disease remains unknown at the present time), available at <http://www.nih.gov/news/stemcell/>

IV. UNITED STATES GOVERNMENTAL REGULATIONS OF STEM CELL RESEARCH

A. 1999 Regulations

In 1999, a bill prohibiting the extraction of embryonic stem cells using federal funds was passed and placed in the bylaws of the National Institutes of Health (“NIH”).⁹³ The 1999 regulations further noted that embryonic stem cells that were able to be isolated could only be multiplied ten to one hundred times.⁹⁴ A direct ramification of this multiplication restriction was that many embryos would need to be destroyed for routine clinical testing and experimentation.⁹⁵ Furthermore, in light of these regulations, it appeared that federal funds to support embryonic stem cell research were, by all essential means, out of the question.⁹⁶

B. 2001 Regulations of Stem Cell Research

In April 2001, Senator Arlen Specter (R-Pa.) introduced the Stem Cell Research Act of 2001.⁹⁷ The proposed act is aimed at giving federally funded researchers more freedom to work with embryonic stem cells and is based on the premise that:

[W]e have a duty to accelerate medical research by allowing researchers to utilize Federal funds to derive their own stem cells. Human embryonic stem cell research holds such potential for millions of Americans who are sick and in pain that we believe it is wrong for us to prevent or delay our world-class scientists from building on the progress that has been made. Our legislation creates one narrow and specific source for Federal researchers to obtain embryos for use in stem cell research: embryos which would otherwise be discarded from in-vitro fertilization clinics, with the

scireport.html.

93. Nat'l Inst. of Health, *Stem Cells: Scientific Progress and Future Research Directions*, Dep't of Health and Human Services (June 2001), available at <http://www.nih.gov/news/stemcell/scireport.html>.

94. *Id.*

95. *Id.*

96. Natalie Larsen, *Cultured Neural Stem Cells Reduce Symptoms in Model of Parkinson's Disease*, Nat'l Inst. of Health News Release (July 20, 1998), available at http://www.ninds.nih.gov/news_and_events/pressrelease_stemcells_072098.htm?type=archived.

97. Casell, *supra* note 78, at 567.

expressed consent of the donating families. In addition, a provision is included which requires that all Federally-funded research must adhere to strict procedural and ethical guidelines to ensure that such research is conducted in an ethical, sound manner. It is important to note that as it stands today, embryonic stem cell research in the private sector is not subject to Federal monitoring or ethical requirements.⁹⁸

This bill, which Senator Specter admitted would be controversial, laid the foreground for what would be the first of many steps taken by the United States federal government in response to embryonic stem cell innovations.⁹⁹

Thus, in August 2001, United States President George W. Bush, responding to the heightened public awareness of the ramifications of stem cell research, approved the use of over \$250 million in federal funding to support existing stem cell lines.¹⁰⁰ The decision, which was made after the completion of an investigation by the National Bioethics Advisory Commission on behalf of the NIH, further outlined that taxpayer money may not be used to finance the creation of new stem cell lines in the United States.¹⁰¹ In light of these guidelines, President Bush's decision has been criticized for its inconsistencies with the Federal Consolidated Appropriations Act of 2000.¹⁰² The Consolidated Appropriations Act of 2000 provides in part:

None of the funds made available in this Act may be used for - - (1) the creation of a human embryo or embryos for research purposes; or (2) research in which human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed on fetuses in utero. . . .¹⁰³

The NIH, the governmental agency in charge of implementing President Bush's new plan,¹⁰⁴ contends that the use of embryonic stem cells is not in violation of the language in the budgets.¹⁰⁵ The use of federal funds for embryonic research is available for limited circumstances, such as stem cell research, through "a loophole in the law" which notes that embryos can be used provided:

98. 147 CONG. REC. S3553 (daily ed. Apr. 5, 2001) (statement of Sen. Specter).

99. Casell, *supra* note 78, at 568.

100. Paegel, *supra* note 72, at 1183.

101. *Id.*

102. *Id.*

103. *Id.*

104. Stolberg, *supra* note 4, at A1.

105. Paegel, *supra* note 72, at 1184.

(1) the cells used in NIH-funded research come from excess embryos derived through in vitro fertilization at fertility clinics¹⁰⁶, (2) the donors give informed consent to using their embryos for research, (3) the donors donate the embryos, (4) no embryos are created specifically for research purposes, (5) only private firms harvest the cells, (6) the stem cells are not to be used to clone a human being, and lastly, they cannot be combined with animal cells to create a hybrid.¹⁰⁷

The NIH, based on the investigations of the Department of Health and Human Services, further justified the exemption of embryonic stem cell research from the congressional ban on human embryo research in that “the cells are not an embryo as defined by statute . . . since human embryonic stem cells ‘do not have the capacity to develop into a human being’”¹⁰⁸ Nevertheless, in questioning Bush’s stem cell policy, a spokesman for the American Association for the Advancement of Science has stated:

We need to know how many of the existing cell lines have been derived in a manner that would meet or exceed the ethical standards that the American public expects will be associated with such research. Too often we have learned that procedures used in other parts of the world in research with human subjects do not measure up to the ethical standards that we embrace in this country.¹⁰⁹

These and other ramifications of the new embryonic stem cell policy remain of optimal concern to the NIH.¹¹⁰ For instance, President Bush indicated that there are allegedly over sixty stem cell lines currently existing in the world and researchers are free to work with any of these lines.¹¹¹

106. Teresa Wood, *University of Florida: New Cell Research Guidelines Help University of Florida Scientists Find Cures*, U-WIRE, Aug. 30, 2000 (reasoning that the supply of embryos federally supported to be used by embryonic stem cell researchers are those that are left over from fertility treatment facilities, however, federal funds are specifically not permitted for these facilities), available at 2000 WL 24490957.

107. Paegel, *supra* note 72, at 1184.

108. *Id.* at 1198 (noting that even if implanted into the womb of a human female, embryonic stem cells are not to be considered embryos).

109. Ted Agres, *Stem Cells: Steady Momentum Toward Funding*, THE SCIENTIST, Sept. 17, 2001, at 8.

110. Paegel, *supra* note 72, at 1220 (noting that the “[e]ase of embryo acquisition is integral to researchers who need them.”).

111. Agres, *supra* note 109, at 8 (explaining that ten organizations have said they have stem cell lines that meet all of the criteria to qualify for federal funding under President Bush’s new guidelines).

However, it is important to note that while the government may dictate which cell lines may receive the benefit of federal funding, the government does not have control over whether researchers get access to these lines.¹¹² And, while no real federal restraints exist on the scope of embryonic stem cell research in the private sector, “private research is hindered by economic constraints.”¹¹³ Thus, all of those involved in the development of stem cell technologies are affected by the current state of property rights and general legislation.

C. *International Impact and Presence*

Unlike the United States, other countries, such as the United Kingdom, do not have as many restrictions on the use of human embryos in research.¹¹⁴ In fact, in January of 2001, the United Kingdom passed a law making it legal to create human embryos for the sole purpose of research.¹¹⁵ Thus, scientists in the United Kingdom currently may derive their own cell lines and continue to do so until they get what they need.¹¹⁶

Indeed, other nations, such as the United Kingdom, do not appear to fear regulation, as does the United States.¹¹⁷ That is, in the United States, “there is a widespread belief that mere political discourse about the collective good inevitably threatens individual conceptions of what is good. Americans tend to believe that collective good is somehow oppressive.”¹¹⁸ Thus, the general thought among the biological community is that the regulations that exist in the United Kingdom are clear and predictable in comparison to those in the United States.¹¹⁹

112. *Id.*

113. Paegel, *supra* note 72, at 1189.

114. Stolberg, *supra* note 4, at A1; *see also* Paegel, *supra* note 72, at 1188-89 (reasoning that while the government in the United States is lagging behind other countries in the race for stem cell development, private companies are extremely diligent in working on the technology but are constrained by a lack of funding and access to quality scientists such as those employed at the National Institute of Health).

115. *U.K. Embryonic Stem Cell Research Expansion Approved By The House of Lords*, BLUE SHEET, Jan 24, 2001 (documenting votes by both the House of Lords and the House of Commons to allow the expansion), *available at* 2001 WL 7810876; *see also* Knowles, *supra* note 81, at 20-21 (noting that the United Kingdom, after first considering the consequences of assisted reproductive technologies in the Warnock Report of 1984, adopted a broad regulatory framework that allows for flexibility and adaptability when faced with new human embryological and fertilization technologies).

116. *U.K. Embryonic Stem Cell Research Expansion Approved By The House of Lords*, BLUE SHEET, Jan 24, 2001, *available at* 2001 WL 7810876.

117. Knowles, *supra* note 81, at 21.

118. *Id.* at 21-22 (noting that “the United States fails to discuss the larger scientific and societal context relevant to cloning technologies.”).

119. Arlene Judith Klotzko, *Embryonic Victory: Americans Are Looking to Britain to get Them Out of Bush's Stem Cell Morass*, THE GUARDIAN, Aug. 20, 2001, at 19; *see also* Rebecca Hover, *Stem Cell Debate Worth Study, Even Adjustment* (Aug. 22, 2001) (reasoning that there is

One potentially adverse ramification of this industry sentiment is that in the United Kingdom, and incidentally throughout the global scientific community, there is a sense of satisfaction that the United States is creating such complicated legal and regulatory burdens in the area of embryonic stem cell research, that researchers in the United Kingdom and other countries will obtain a sustainable competitive advantage over the United States in this area.¹²⁰ Notably, this perspective could have an adverse impact not only on the United States but the world's economy and society as a whole.

It is important to note that international applications of biotechnological innovations augment the need for greater integration of scientific experimentation, ethical discourse, and legislative responses. It can only be beneficial to take note of the wisdom and experience of international thinkers and policymakers on a bioethical issue of domestic import. "A comparative international analysis can be useful in confirming society's beliefs or in highlighting societal differences and responses."¹²¹ Thus, many in the biotech field believe that the United States should be very attentive of international developments in embryonic stem cell research because it not only holds significant scientific potential, but political, social, and economic possibility as well.

V. PATENT LAW IMPLICATIONS

A. Intellectual Property Protection of Embryonic Stem Cells

In 1998, Patent 6,200,806 ("806") was granted to the University of Wisconsin's Wisconsin Alumni Research Foundation ("WARF"). The '806 patent was the result of extensive experimentation by "Dr. James A. Thomson, a developmental biologist at the University of Wisconsin, [who] shook up the stem cell world by reporting that he had isolated human embryonic stem cells."¹²² Dr. Thomson and his team of researchers established five independent cell lines using fourteen blastocysts¹²³ that the

international belief that President Bush's stem cell "policy is so political that it must hinder the practicalities of research."), at <http://www.heraldnet.com/Stories/01/8/22/14252291.cfm>.

120. Rebecca Hover, *Stem Cell Debate Worth Study, Even Adjustment* (Aug. 22, 2001), at <http://www.heraldnet.com/Stories/01/8/22/14252291.cfm>.

121. Knowles, *supra* note 81, at 18.

122. Stolberg, *supra* note 4, at A1.

123. David Gardner, et al., *A Prospective Randomized Trial of Blastocyst Culture and Transfer in In-Vitro Fertilization*, HUMAN REPRODUCTION, Dec. 1998, at 3434. A blastocyst, which is generally formed in humans on the fifth day after fertilization, is an embryo that has developed to the stage where it has two different cell types and a central fluid-filled cavity: the surface cells of the

University had obtained from surplus donated embryos.¹²⁴ The resulting patent on the discovery was then assigned by Dr. Thomson to WARF, as is customary practice at the University of Wisconsin.¹²⁵

The '806 patent covers a method of isolating stem cells as well as the stem cells themselves.¹²⁶ That which is of particular intrigue to the biotechnology community is that, as far as experts know, the '806 is the only patent of its type in the entire world.¹²⁷ Notably, however, "[t]he patent is valid only in this country," but WARF "has also applied for patents in Europe."¹²⁸

Through a private contract, WARF has granted rights to Geron Corporation, a biotechnology company located in Menlo Park, California.¹²⁹ Geron, incidentally, contributed over \$1 million in 1995 to the research that resulted in the stem cell line patented by WARF.¹³⁰ While this agreement between WARF and Geron did not give Geron the complete rights to the stem cell line,¹³¹ it did provide Geron with the rights to develop stem cells into six different types, each of which are of great medical significance.¹³² These six cell types include blood, liver, muscle, nerve, bone and pancreas cells.¹³³

In its most basic sense, this agreement provides Geron with an almost exclusive say over who eventually profits from the stem cell therapies.¹³⁴

blastocyst become the placenta, and the inner cells become the fetus. *Id.*

124. See University of Wisconsin, *Embryonic Stem Cell Fact Sheet*, Office of News and Public Affairs (Nov. 5, 1998), available at <http://www.news.wisc.edu/thisweek/Research/Bio/Y98/facts.html>.

125. *Id.* (noting that WARF had already obtained a patent on the primate embryonic stem cell, after Dr. Thomson derived those cells from rhesus monkeys).

126. *Id.*

127. *Id.*

128. *Id.* (noting that "at least two biotechnology companies say their cell lines may fall outside Wisconsin's claim and have applied for patents of their own in the United States and elsewhere).

129. ABC NEWS, *A Powerful Patent* (Aug. 18, 2001), available at http://www.abcnews.go.com/sections/wnt/DailyNews/wnt_stemcells010818.html.

130. *Id.*; see also Jason Gertzen, *Stem Cell Patents Put UW Agency in Spotlight*, MILWAUKEE JOURNAL SENTINEL, Aug. 26, 2001 (noting that when Dr. Thomson began attempting to isolate human embryonic stem cells, he used private financial backing since federal regulations prohibited the funding of research for human embryos).

131. See Stolberg, *supra* note 4, at A1 (noting that according to WARF's managing director, Mr. Carl Gulbrandsen, "[Geron] wanted all rights . . . [w]e felt it was too much to expect a small company to develop this technology fully, and giving them all rights would not be fair to them or the public.>").

132. *Id.*; see also Rebecca Hover, *Stem Cell Debate Worth Study, Even Adjustment* (Aug. 22, 2001) (explaining that "patent law is becoming a key concern for many scientists. Some fear that prospects for practical new cures will be blocked by a combination of broad patents held [by WARF] and a licensing agreement the foundation has with [Geron]."), at <http://www.heraldnet.com/Stories/01/8/22/14252291.cfm>.

133. Stolberg, *supra* note 4, at A1.

134. *Id.* (reasoning that Geron's rights, "coupled with the Wisconsin patent, might mean that anyone seeking to develop commercial applications of stem cells in these six areas must negotiate

Thus, agreements such as that between WARF and Geron, present researchers with an overwhelming concern that they will not be able to gain access to stem cell lines that are patented by private companies.¹³⁵ As a result, there is a strong belief among researchers and businesses that President Bush's recent financing guidelines, which disallow federal funding to be used for the development of new lines, seriously hinders the chance of a threat to the '806 patent monopoly.¹³⁶ In fact, many in the biotechnology community contend that:

[t]he Bush compromise actually locks in the commercial advantage of WARF and Geron by perpetuating the status quo. The inability of federally-funded researchers to derive their own stem cell lines will make it harder for them to figure out a derivation method that would get around WARF's patent. Even more ominously, publicly funded scientists will find it much harder to be doing the first class science they should be doing. And making the discoveries they could be making.¹³⁷

In addition to the controversy created by the very existence of the Geron-WARF agreement, in August of 2001, WARF filed a lawsuit against Geron.¹³⁸ The complaint by WARF alleged that Geron sought to extend its commercial rights to another twelve derivative cell types.¹³⁹ It is generally perceived that WARF took this action in an alleged attempt to limit Geron's ability to work with other researchers.¹⁴⁰

Nevertheless, in order to promote the issues of access to the embryonic stem cell lines, the University of Wisconsin has set up a non-profit subsidiary, the WiCell Research Institute, to distribute the five embryonic stem cell lines currently developed.¹⁴¹ Academic researchers who wish to access the stem cell lines through WiCell Research are subject to a "materials transfer and license agreement" and must pay the institute \$5000.¹⁴² In addition, the researchers must agree to certain restrictions such

with Geron first.").

135. Andrea Tortora, *Research Rush: Cincinnati May be in the Perfect Position to Capitalize on Bush's Embryonic Stem Cell Ruling*, BUSINESS COURIER, Aug. 20, 2001.

136. See Stolberg, *supra* note 4, at A1.

137. Klotzko, *supra* note 119, at 19.

138. *Id.*

139. *Id.*

140. *Id.*

141. See Gertzen, *supra* note 130.

142. *Id.*

as not using the lines commercially.¹⁴³ The ultimate effects of the actions taken by the University of Wisconsin are that the university, and by extension, Geron, have the ultimate control over the derivative cells. This fact alone has led to the frustration of many scientists.¹⁴⁴ For instance, one prominent stem cell scientist has noted that he is indeed the ideal employee of Geron: “[t]hey don’t pay my salary, they don’t pay my benefits, but anything I discover they own.”¹⁴⁵ As a result, this scientist will not agree to the terms of the agreement between WARF, WiCell, and Geron.¹⁴⁶

B. Pressure on WARF and Geron

Despite the legal battle between the two, both WARF and Geron are being pressed to provide access to the patented stem cell line because it is a fundamental tool for stem cell research.¹⁴⁷ However, WARF and Geron are very hesitant to provide this demanded access because each, individually and collectively, wants to protect their legal rights to a discovery that could potentially be worth millions of dollars, particularly to WARF researchers.¹⁴⁸ In fact,

President Bush’s decision may have strengthened the hands of the Wisconsin group and Geron. By refusing to allow taxpayer money to finance [the] creation of new cell lines in this country, Mr. Bush reduced the chances that scientists would derive and patent cells that might challenge Wisconsin’s dominance in the field.¹⁴⁹

Rebecca S. Eisenberg, an expert in biotechnology and patent law at the University of Michigan, notes that “[w]hat constrains the monopoly power of a patent holder is the prospect of new technology being developed that will make it unnecessary to deal with them, . . . [t]he president’s decision limits that threat.”¹⁵⁰ Interestingly, the NIH, which is assigned to carry out President Bush’s plan, admits that:

143. *Id.* (noting that researchers who make a discovery using the patented stem cell lines may publish the results or even obtain patents of their own without WARF’s permission, but if seeking to commercialize on the discovery, the researcher must first negotiate licensing terms with WARF and possibly Geron).

144. See Stolberg, *supra* note 4, at A1.

145. *Id.* (internal quotations omitted).

146. *Id.*

147. *Id.*

148. Gertzen, *supra* note 130 (noting that WARF insists that it must strictly enforce its patents because failure to do so could invalidate them).

149. Stolberg, *supra* note 4, at A1.

150. *Id.* (internal quotations omitted).

Scientists upon making new discoveries often verify reported results in different laboratories and under different conditions. Similarly, they will often conduct experiments with different animal models or, in the case, different cell lines. However, there have been very few studies that compare various cell lines with each other. It may be that one source proves better for certain applications, and a different cell source proves better for others.¹⁵¹

Indeed, this suggestion by the NIH promotes the antithesis of the effects that current stem cell regulations, which are to be carried out by the NIH, will most likely impose.

C. General Industry Pressure

In efforts to create various types of blood cells that are needed to treat a multitude of blood diseases, researchers at Johns Hopkins University in Maryland have patented processes for the separation of adult bone marrow stem cells.¹⁵² Incidentally, these patents have already been subject to a myriad of litigation, including that in *Johns Hopkins University v. CellPro, Inc.*¹⁵³ Five years of litigation resulted in CellPro being required to pay nearly \$7 million in damages.¹⁵⁴ However, CellPro contended that they should not have to pay and that the infringement of the patents should not be punished because of the high level of societal import associated with the patents.¹⁵⁵ The court, nonetheless, did not follow CellPro's logic, but the case did leave a rather perplexing legal idea that patent infringement could be left unpunished if the value of the product being infringed upon was thought to be significant enough.¹⁵⁶ Indeed, "[l]itigation resulting from such a decision would certainly result in simultaneously clogging court dockets and stifling research."¹⁵⁷ Thus, it is almost certain that "[e]mbryo stem cell

151. Nat'l Inst. of Health, *Stem Cells: Scientific Progress and Future Research Directions*, Dept. of Health and Human Services, ES-1 (2001), available at <http://www.nih.gov/news/stemcell/scireport.htm>.

152. Paegel, *supra* note 72, at 1191.

153. 152 F.3d 1342 (Fed. Cir. 1998).

154. Paegel, *supra* note 72, at 1197.

155. *Id.*

156. *Id.*

157. *Id.*; see also Peter Mikhail, *Hopkins v. CellPro: An Illustration that Patenting and Exclusive Licensing of Fundamental Science is Not Always in the Public Interest*, 13 HARV. J.L. & TECH. 375, 381 (2000) (noting that governmental policies designed to promote technology transfer may indeed be backfiring, causing licensees who have the potential to make life-sustaining discoveries millions of dollars).

research promises to be fraught with litigation for many decades, as companies and other countries such as Great Britain, Scotland, Holland, France, and Japan vie for first rights, or, like CellPro, merely factor infringement into part of the cost of doing business.”¹⁵⁸

D. General Responses

The ownership and control of biotech discoveries that is afforded with the grant of a patent, is subject to great controversies ranging from:

disapproval of genetic modification technologies, . . . questioning of the intent behind the legal strategies of biotech companies, debate and political maneuvering over the social, ethical, legal and policy implications of the use of some human biological materials, and protests over the clinical protocols used for testing new biotech products on human subjects.¹⁵⁹

While some biotechnology companies fully support the intellectual property protection of their inventions, mainly due to the economic potential, “[a]ssorted groups have expressed concerns . . . including groups and individuals ranging from the National Conference of Catholic Bishops and other clergy to anti-abortionist groups, bio-ethicists, scientists, government officials, members of Congress, and patient advocate groups.”¹⁶⁰ Generally, “[e]thical concerns over stem cell research derive from what bioethicists often speak of as the moral or special nature of the embryo.”¹⁶¹ One of the primary concerns is over what should and should not be

158. Paegel, *supra* note 72, at 1197.

159. S. Van McCrary & Cheryl J.C. Erwin, *Thinking Globally About Biotech Ethics: Is the Law Enough?*, 666 PRAG. L. INST. 983, 993-94 (2001) (noting the “ethical implications for the practicing attorney who has a duty to make the client aware of all significant factors that may impact a decision about legal strategy.”).

160. Paegel, *supra* note 72, at 1186.

161. Casell, *supra* note 78, at 556 (explaining that “[t]he embryo has qualities of a living being and a human being, but it is not a human life because it lacks neurological attributes that we ascribe to humans in the special sense. . . [it is] alive in a general sense, but it does not have cerebral functions that give rise to consciousness.”); *see also* *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992) (holding that embryos “are not, strictly speaking, either ‘persons’ or ‘property,’ but occupy an interim category that entitles them to special respect because of their potential for human life.”); *see also* *Kass v. Kass*, 696 N.E.2d 174, 181 (N.Y. 1998) (holding that a divorced couple was obligated to abide by a signed agreement which provided that if the Kasses no longer wished to initiate a pregnancy, they would donate the frozen embryos for biological studies and research approved by the clinic’s in vitro fertilization program and thereby preventing Ms. Kass from being implanted with an embryo when Mr. Kass did not want a child.); *see also* Casell, *supra* note 78, at 560 (reasoning that the courts in both *Davis* and *Kass* acknowledged the special nature of the embryo in its usefulness for medical research as a preferred alternative to destruction as well as a dignity inherent in the embryo that prefers the use of the embryos for implantation, or, if not, at least for a noble purpose such as medical research).

permitted a patent.¹⁶² This position does not really address whether patents based on biotechnology are good or bad; rather, it simply notes, "that we must balance the incentive patents give to firms . . . versus the cost."¹⁶³ Another school of thought regarding the patenting of biotechnology is based in more fundamentalist ideals and strongly discourages "patents on life."¹⁶⁴ This position is very political in nature while the concern over the balancing of incentives is more policy-oriented.¹⁶⁵

While it remains unanswered how these issues will be resolved, they will inevitably impact the direction that the patenting of biotechnological intellectual property will take.¹⁶⁶ Indeed, it is important to note:

Biotechnology has fostered political debate since its inception. Extremists on both sides fail to balance the values inherent in biotechnology. In the European community, a spokesman for the Social Democrat party contends that 'where human dignity is affected, economic arguments do not count.' While such statements represent an underlying truth about the moral dimensions of biotechnology, they do not fully define the dimensions in this arena any more than purely legal analysis exhausts the complexity of

162. Henry T. Greely, *The Revolution in Human Genetics: Implications for Human Societies*, 52 S.C. L. REV. 377, 388 (2001) (addressing the social consequences of the major developments in human genetics).

163. *Id.*; see also Casell, *supra* note 78, at 563-64 (noting that: [a]dherents of the middle position, that the embryo is something other than living or dead, do not object to the destruction of unwanted embryos or to their use for scientific and medical research. Indeed, the American Medical Association has stated that frozen embryos may be donated, but not sold, to infertile couples or researchers, or may be allowed to thaw and deteriorate. Acknowledging that the embryo is alive, but that its special nature comes from the recombinant DNA within it, may be one step toward appeasing stem cell research opponents. This argument rests on the fact that DNA is the personifying feature of a 100-cell blastocyst, rather than the egg wall, cytoplasm, and mitochondria, which are destroyed in stem cell derivation. [Human pluripotent stem cells] derived from harvested embryos are directed to form cell lines, each of which contains, in dormant form, the full component of embryonic DNA. The DNA has a higher probability of existing for many years than the DNA of a frozen embryo, which will most likely be discarded by an [in vitro fertilization] clinic. In this sense, the life within the embryonic DNA lives on in the [human pluripotent stem cells] derived from the embryo. (citations omitted).

164. Greely, *supra* note 162, at 388; see also David Tenenbaum, *Finally. Generic Human Cells Discovered*, at http://whyfiles.news.wisc.edu/shorties/stem_cell.html (Nov. 20, 1998) (noting that even greater controversy may result from stem cell research than from the well-known cloned sheep "Dolly" in that "[w]ith Dolly, the clone of an adult sheep, at least researchers could reasonably know what to expect when she grew up. In stem-cell work, no adult has been seen.").

165. Greely, *supra* note 162, at 388.

166. *Id.* (noting the importance of following these issues when it comes to the ramifications associated with gene patents).

issues. Enlightened biotechnology firms understand the potential implications of ignoring public perception in the marketplace of ideas. These implications include the negative economic consequences to a company of a frightened public, or a public convinced that the company has acted unethically or in a socially irresponsible manner.¹⁶⁷

It must therefore be recognized that “although ethical deliberations initially coincide with legislative responses, ethical deliberations require much more time to develop carefully and completely, and therefore continue well beyond the advent of legislation.”¹⁶⁸

VI. FUTURE OF STEM CELL RESEARCH

A. General Advancement Potential

Generally, the ultimate hope among researchers and those in the biotechnology community is to use embryonic stem cells as a “universal donor cell” or an “in-stock item that could serve as raw material for new liver cells . . . or new spinal cord cells.”¹⁶⁹ Thus, the cells could potentially be useful in the development of life-saving pharmaceuticals and inevitably could have an extreme economic, sociological, and international impact.

B. Drug Development

One of the greatest potential benefits of embryonic stem cell research is the possible benefit in drug development. Stem cell discoveries could provide sources for testing new drugs and toxicological agents.¹⁷⁰ That is, specific cell types could be treated

with chemicals and measuring their response offers a short-cut to sort out chemicals that can be used to treat the diseases that involve those specific cell types. Ramped up stem cell technology would permit the rapid screening of hundreds of thousands of chemicals

167. McCrary & Erwin, *supra* note 159, at 1013-14 (further noting that “[a]s recent psychological and economic research makes clear, persons do not always evaluate risk in a purely rational manner. Thus, the choice of a decision frame is an ethically significant act. This ethical dimension is especially true in cases involving biotechnology.”).

168. Knowles, *supra* note 81, at 16-17.

169. David Tenenbaum, *Finally. Generic Human Cells Discovered*, at http://whyfiles.news.wisc.edu/shorties/stem_cell.html (Nov. 20, 1998).

170. Paegel, *supra* note 72, at 1192.

that must now be tested through much more time-consuming processes.¹⁷¹

Thus, “[t]ests could be conducted on stem cells instead of animals or humans.”¹⁷² This would essentially eliminate the need for human guinea pigs as well as increase the speed at which results are obtained because stem cells have the ability to divide much faster than normal cells in human and animal test subjects.¹⁷³ Furthermore, drugs could be screened by testing them on cultured human embryonic stem cells so as to lower the incidence of drug-related birth defects.¹⁷⁴ Notably, it is believed that the results obtained using stem cells could be more reliable than the conventional testing that is currently available because it allows for increased benefits while minimizing side effects.¹⁷⁵

C. Therapeutic Potential

It is believed that embryonic stem cells could offer great benefits to the general public by providing a means to gain a greater understanding of genetically transmitted disease by tracking the cells differentiation process.¹⁷⁶ Until now,

[t]he earliest stages of human development have been difficult or impossible to study. Human embryonic stem cells will offer insights into developmental events that cannot be studied directly in humans in utero or fully understood through the use of animal models. Understanding the events that occur at the first stages of development has potential clinical significance for preventing or treating birth defects, infertility and pregnancy loss. A thorough

171. University of Wisconsin, *Embryonic Stem Cell Fact Sheet*, Office of News and Public Affairs (Nov. 5, 1998), available at <http://www.news.wisc.edu/thisweek/Research/Bio/Y98/facts.html>.

172. Paegel, *supra* note 72, at 1193.

173. Shirley J. Wright, *Human Embryonic Stem-Cell Research: Science and Ethics*, 87 AMERICAN SCIENTIST 352, July 1, 1999, available at 1999 WL 3555448.

174. University of Wisconsin, *Embryonic Stem Cell Fact Sheet*, Office of News and Public Affairs (Nov. 5, 1998), available at <http://www.news.wisc.edu/thisweek/Research/Bio/Y98/facts.html>.

175. Paegel, *supra* note 72, at 1193.

176. Wright, *supra* note 173.

knowledge of normal development could ultimately allow the prevention or treatment of abnormal human development.¹⁷⁷

Additionally, embryonic stem cells may also be used to harvest tissue that is genetically identical to a recipient patient, thereby reducing or eliminating the potential for “rejection,” the immunological response that often serves as a severe complication following organ or tissue transplants.¹⁷⁸ Thus, the overall possible uses of embryonic stem cells are vast and the potential benefits to the general public appear to be unparalleled. Legal experts generally contend that United States patent law has usually “worked well in providing incentives for scientific advances to reach the public.”¹⁷⁹ Many in both the legal and scientific professions feel that it will take time to resolve whether an adequate number and range of cell lines are available to researchers. Regardless, all groups in the industry seem to agree, that the primary concern should remain science benefiting the public.

D. Economic Impact

Many people who are aware of the legal developments in the field of biotechnology believe that “[t]he current judicial environment favors protection of biotechnology research institutions and investors who look to financial rewards for the enormous expense and risk involved in the making of biotech products.”¹⁸⁰ Commercial success of biotechnology depends on several factors. These factors include continued research, the ability to attract necessary capital, and the time lapse between initiation of research and approval of an applied product or process. As for the latter, one of the greatest concerns in the industry is the growing backlog of patent applications, particularly because the PTO is generally known for its inconsistencies in patent approval.¹⁸¹

Stem cell research also holds great economic potential because biotechnology and start-up companies want access to the lines. In fact, some in the industry feel that President Bush’s stem cell policy could actually generate millions of dollars in new research and business.¹⁸² Thus, many of

177. University of Wisconsin, *Embryonic Stem Cell Fact Sheet*, Office of News and Public Affairs (Nov. 5, 1998), available at <http://www.news.wisc.edu/thisweek/Research/Bio/Y98/facts.html>.

178. Knowles, *supra* note 81, at 14-15.

179. Rebecca Hoover, *Stem Cell Debate Worth Study, Even Adjustment* (Nov. 21, 2001), at 179. Rebecca Hoover, *Stem Cell Debate Worth Study, Even Adjustment* (Nov. 21, 2001), at <http://www.heraldnet.com/Stories/01/8/22/14252291.cfm>

180. McCrary & Erwin, *supra* note 159, at 1005.

181. Olsen, *supra* note 3, at 310.

182. Tortora, *supra* note 135 (noting the economic potential for Cincinnati, Ohio because it is

those in a post-dot-com troubled economy are hopeful that biotechnology provides the spark that the United States economy currently needs.

Indeed, there is an enormous amount of money to be generated by advances in stem cell technology not only in the medical industry, but in agriculture as well.¹⁸³ However, there is a significant justifiable fear in the struggling United States economy that if research is pushed overseas, the United States will lose a valuable economic opportunity at a time when it is needed the most.¹⁸⁴ Therefore, stem cell research, while it has the enormous capability of increasing prosperity in the United States economy, could also be very detrimental to the economy if pushed in the wrong direction.

E. International Developments

Despite the fact that the '806 patent may be challenged in court, its mere existence could push stem cell research overseas.¹⁸⁵ One reason for this arises from the idea that, if the over sixty cell lines allegedly supported by President Bush's new regulations "match the description in the broadly worded Wisconsin patent . . . their owners must obtain approval from the foundation before distributing them."¹⁸⁶ Additionally, scientists in other countries may derive embryonic stem cell lines without the fear of infringement that researchers in the United States face.¹⁸⁷ Along the same lines, "companies in other countries are concerned that, if they distribute their stem cells in the United States, the foundation might charge them with patent infringement."¹⁸⁸ Thus, many international companies are manifesting the idea that, not only should they conduct their research abroad, but they should keep it there and away from introduction in the United States as well.

Such ramifications are already being felt. For example, ES Cell International, a biotechnology company in Singapore, asserts that it has six stem cell lines, but is not releasing any information until it further evaluates

home to several universities and hospitals that are currently researching adult stem cell technologies).

183. See, e.g., Philip Cohen, *Why would anyone in their right mind want to clone a baby when animal cloning can go disastrously wrong?* NEW SCIENTIST, May 19, 2001, at 14.

184. Tortora, *supra* note 135.

185. Stolberg, *supra* note 4, at A1.

186. *Id.*

187. *Id.*

188. *Id.* (reporting that "experts suggest that the Wisconsin patent is one reason researchers have said little about many of the 60 stem cell lines that President Bush said exist around the world; the owners of those cell lines are probably afraid to come forward.").

the lines to see if they fall within the scope of the '806 patent.¹⁸⁹ On the other hand, BresaGen, Inc. in Athens, Georgia contends that the company has developed four stem cell lines at a slightly later stage in embryo development than those in the '806 patent held by the University of Wisconsin.¹⁹⁰ BresaGen further notes that it is being cautious so as to avoid infringement claims of the '806 patent, but hopes to obtain its own separate patent in the near future and will "make its four stem cell lines available to researchers with no upfront cost provided the company receives the right of first refusal for any resulting discovery having commercial potential."¹⁹¹

Other international developments in the field of stem cell research include the goal of Dr. Ian Wilmut, the biotechnologist who cloned Dolly the sheep at Scotland's Roslin Institute, to clone embryos to serve as the source of stem cells.¹⁹² In Great Britain, a prominent biotech company has patented techniques for developing neural stem cells that may be used for brain transplantation.¹⁹³ Additionally, the French equivalent of the NIH has been partially successful in treating patients inflicted with Huntington's chorea by implanting fetal stem cells in their brains, while Japan is near the final stages of approving guidelines for embryonic stem cell research.¹⁹⁴

A likely effect of withholding federal funding from private researchers and companies is that "the private sector will continue using embryo stem cells for research on [their] own, but the effect is likely to discourage and slow progress."¹⁹⁵ If the United States is absent from the race for embryonic stem cell technology because of legal and political constraints, other countries may immediately take a "position to reap the potentially enormous economic benefits should they become successful with their research."¹⁹⁶ An extreme perspective on the possible consequences of this is that the United States could become dependent on countries with stem cell technologies to the degree that it relies on the Organization of Petroleum Exporting Countries ("OPEC") for its oil.¹⁹⁷

189. *Id.*

190. Agres, *supra* note 109, at 8.

191. *Id.* (explaining that this is a fairly common relationship between researchers and developers).

192. Robert Frank & Ralph T. King, Jr., *Creator of Dolly Seeks Partners to Clone Embryos*, WALL ST. J., Jan. 21, 1999, at B6 (further indicating that the Roslin Institute has talked with Geron Corporation as a potential commercial partner to help aid in the institute's research efforts).

193. *Emerging Applications in Human Stem Cell Therapy*, CHEM. BUS. NEWSBASE (Apr. 5, 2000), available at 193.*Emerging Applications in Human Stem Cell Therapy*, CHEM. BUS. NEWSBASE (Apr. 5, 2000), available at 2000 WL 17082990.

194. Paegel, *supra* note 72, at 1194-95.

195. *Id.* at 1201.

196. *Id.* at 1201-02.

197. *Id.* at 1202.

VII. GENERAL CONSIDERATIONS AND RECOMMENDATIONS

A. Considerations

Generally, “scientific experimentation most often precedes the announcement of the discovery or innovation by many years.”¹⁹⁸ Although it has traditionally been that “the announcement of a scientific development takes place in a scientific publication, recent increases in industrial funding for scientific innovation has resulted in these announcements increasingly being made in newspapers.”¹⁹⁹ Since new scientific techniques or applications that take years to develop, especially in the field of biotechnology “often spark public reaction and prompt legal and ethical analysis and discussion,” upon public announcement, spontaneous public policy and ethical discourse often “begin[s] much too late,” and “develops more slowly.”²⁰⁰ Thus, “[c]areful science develops over a long period of time, but once a development is announced, public reaction follows swiftly, and in many cases, pressure mounts to quickly introduce a legislative response.”²⁰¹ Isolated analysis and decision-making of an issue, particularly a biotechnological issue, often results in “laws [that] may be drafted too vaguely, broadly, or narrowly so as to inhibit the development of scientific innovation.”²⁰²

Illustrative of the seemingly ad hoc legislation adopted in response to untimely public reaction is the initial legislation that occurred during former President Clinton’s administration in response to public concerns over the use of federal funding to support embryonic stem cell research.²⁰³ When the general public first became informed that embryonic stem cells were being cultured, public and political reaction on one side soon demanded that laws

198. Knowles, *supra* note 81, at 15.

199. *Id.*

200. *Id.* at 15-16 (noting that “while science progresses behind metaphorically closed doors, little or no discussion of policy or regulation intersects with this process. Hence, those engaged in public policy and ethical discourse must struggle to understand the new science or technology, as well as the implications of these scientific developments for society.”).

201. *Id.* at 16.

202. *Id.* at 20 (remarking that President Clinton’s announcement that federal funds were not to be used for human cloning was only meant to cover reproductive cloning, but on its surface appeared to pertain to therapeutic cloning as well, all at a time when embryonic stem cell research would soon turn out enormous technological advances).

203. *Id.* at 17. When the public became aware of the issue of reproductive human cloning, even before the National Bioethics Advisory Commission could complete its advisory report, several bills had already been presented to Congress in support of a ban on human cloning, and President Clinton declared that federal funding would not be permitted to support human cloning. *Id.*

restrict federal funding of the research, while the other side called for funding expansion.²⁰⁴ The National Bioethics Advisory Commission, after being commissioned by President Clinton, eventually completed a report on the ethical implications raised by embryonic stem cell research, indicating that the then existing ban on the use of federal funds for embryonic research should be eliminated so as to allow the use of embryonic stem cells in research.²⁰⁵ However, by the time this report was released, President Clinton had already announced that federal funding would not be available to support embryo research to isolate stem cells.²⁰⁶ Thus, before the ramifications of the research could be fully assessed, legislation, in direct response to public outcries, was already underway.²⁰⁷

Additionally, when determining whether an incidence of infringement exists, it is important that a patent is evaluated in the proper time frame.²⁰⁸ There should be an evaluation of the patent within the proper time frame because “standards for patentability and disclosure center[s] on the level of skill in the art at the time of patent application filing.”²⁰⁹ Therefore, “[a]s biotechnology matures, an otherwise unpredictable art,” such as embryonic stem cell technology, “can become more predictable and thus might permit increasingly broader claims based on limited examples.”²¹⁰ Such consideration is of great importance when making an effective assessment of the social, political, and economic impact that changes to current patent laws may bring. This is especially true given that universities and/or companies that object to the manner by which WARF is handling its patent rights could look to the courts for remedies.²¹¹ While experts are generally divided on whether or not WARF’s patents would hold up if challenged in court, some experts admit that the patents in question, which “cover stem cells in any primate, from monkey to man,” are very broad, and “[g]enerally speaking, broad patents in the biotechnology area tend to be vulnerable.”²¹²

204. *Id.* at 17-20. Unlike the United States, in 1984 the United Kingdom issued the Warnock Report on the ramifications of assisted reproductive technologies which included a broad mandate promoting the continued pursuit of knowledge and identifying potential areas of ethical and public concern so as to create a broad regulatory framework that would allow for flexibility around issues that were to be specifically addressed when they arose. *Id.*

205. *Id.* at 17-18.

206. *Id.* at 17.

207. *Id.* at 18.

208. Sung, *supra* note 34, at 197.

209. *Id.* at 197-98 (noting that “appreciation of this temporal distortion is particularly important where the issue involves whether the patent disclosure of a specific species supports the scope of broad genus claims.”).

210. *Id.*

211. Gertzen, *supra* note 130.

212. *Id.* (discussing Arti K. Rai, a University of Pennsylvania law professor who has been following stem cell research very closely).

In April 1998, Stuart Newman and Jeremy Rifkin, president of the Foundation of Economic Trends and a biotechnology activist, filed a United States patent application for a chimera, or a bio-engineered human-animal hybrid.²¹³ The applicants admitted that the application was filed

not to obtain exclusive rights for further development and commercialization of the technology. On the contrary, the application was filed with the parallel intentions of forcing a policy stand on the part of Congress and the PTO regarding the patentability of human material, and to hinder further development of the technology.²¹⁴

Rather unsurprisingly, the PTO issued a statement noting that it was prepared to reject the application, or those of its kind, based on "public policy and morality."²¹⁵ While this announcement was in accord with the position taken by the PTO in 1987 when it declared that "a claim directed to or including within its scope a human being will not be considered to be patentable subject matter,"²¹⁶ the PTO failed to define where the line was to be drawn.²¹⁷ That is, despite the 1987 statement, "[t]he PTO has not adopted a policy of excluding all patents involving human materials."²¹⁸ In fact, patents have been granted to cover transgenic animals, or those animals that have had one or more human genes incorporated into their genetic sequence for the purpose of encoding human proteins.²¹⁹ It is this type of inconsistency and lack of clarity in existing patent laws that creates

213. Jagels, *supra* note 53, at 116; see also Carole B. Fehilly, *Interspecific Chimaerism Between Sheep and Goat*, 307 NATURE 634 (1984) (stating generally that a chimera is an organism composed of heterogeneous cells that are created by combining embryonic cells from two or more species).

214. Jagels, *supra* note 53, at 116 (citing Jenna Green, *He's Not Just Monkeying Around*, 22 LEGAL TIMES, S17 (1999)). The beauty of the strategy was, that if the PTO rejected the application, the policy underlying the rejection would discourage further development. *Id.* On the other hand, if the patent was issued, Newman and Rifkin would retain the rights to develop the invention, removing commercial incentives for other parties to pursue the technology. *Id.*

215. U.S. Patent and Trademark Office Media Advisory, No. 98-6, *Facts on Patenting Life Forms Having a Relationship to Humans*, (April 1, 1998), at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>; see also Jagels, *supra* note 53, at 138 (reasoning that because the Patent Act "does not specifically require moral balancing, and because social concepts of morality are in a continuous flux, courts have rightfully been reluctant to use the morality doctrine as the sole basis for rejecting patent applications.").

216. Commissioner of Patents and Trademarks, *Policy Statement on Patentability of Animals*, 1077 OFF. GAZ. PAT. OFFICE 24 (1987), reprinted in DONALD S. CHISUM, CHISUM ON PATENTS, app. 24-2 (1999).

217. Jagels, *supra* note 53, at 117.

218. *Id.*

219. *Id.*

confusion and promotes legitimate scientific, economic, political and ethical concerns, such as those currently being expressed in the area of embryonic stem cell research.²²⁰

B. Recommendations

The primary “goal of United States patent law is to ‘[p]romote the progress of [s]cience and [u]seful [a]rts,’ not to set social policy.”²²¹ It is almost undeniable that something, at some level in the scientific, political, ethical, and legislative processes needs to change or be altered.²²² One such change is “the need for increased transparency and dialogue between scientists, ethicists, and policy makers,” throughout.²²³ The United States should attain,

a more comprehensive understanding of new developments and draft laws that reflect that understanding. It is possible to develop a broadly framed legislative mandate and to structure regulatory bodies that are responsive to change. In so doing, we could use the law to promote flexibility and continued conversation regarding the issues involved, and to make transparent the ethical commitments implicit in our governing policies.²²⁴

As a result, “[w]e must, for example, ask where [embryonic stem cell] technology fits in embryo research; how it may pose problems for our human subjects research guidelines; and even how we can design a comprehensive regulatory system,” based on these projections.²²⁵

There also needs to be an increase in the amount of integration that exists between international and domestic scientists, ethicists, and legislators.²²⁶ Since embryonic stem cell research is an issue that affects

220. See, e.g., Knowles, *supra* note 81, at 17-18.

221. Jagels, *supra* note 53, at 146-47 (citing U.S. CONST. art I, § 8, cl. 8.).

222. See, e.g., Rebecca Hover, *Stem Cell Debate Worth Study, Even Adjustment* (Aug. 22, 2001), at <http://www.heraldnet.com/Stories/01/8/22/14252291.cfm> (indicating that in light of President Bush’s new policy on stem cell research, both Republican and Democratic lawmakers are already looking at the possibility that patent laws will have to be revised to ensure the ability of scientists to develop and distribute possible medical advances); see also United Press International, *Stem Cell Research Called Revolutionary* (1999), at <http://cigna.syndication.thehealthnetwork.com/InHealth/newsbasicdisplay.asp?docid=417&a> (noting that Todd Dickinson, Patents and Trademarks Commissioner, suggests that since stem cell research is extremely expensive and requires a large amount of time for commercial development, “federal patent laws need to be changed to give the biotechnology industry greater patent protection so its researchers can attract more investment.”).

223. Knowles, *supra* note 81, at 18.

224. *Id.* at 20.

225. *Id.* at 21.

226. *Id.* at 21; see also Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men*, 2 WASH. U. J.L. & POL’Y 247, 285 (2000) (reasoning that “[e]ven if ethics were to be incorporated in the United States’ patent laws, further study of the purpose of such an

everyone both globally and personally, isolated examination of the research and its ramifications may “result in recommendations for oversight.”²²⁷ Therefore, increased integration and cooperation between scientists of all nations will allow them to uncover strengths and weaknesses at a more rapid pace, which inevitably results in a beneficial situation for everyone on a global scale.

Additionally, under recent embryonic stem cell research regulations, various regulatory agencies oversee scientific applications. Gene transfer issues are the responsibility of the recombinant DNA advisory committee, while the Food and Drug Administration avers that it has the capability to regulate human cloning mechanisms under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.²²⁸ These are essentially isolated regulatory systems that operate independently of one another, resulting in a central weakness that inhibits the formation of “a comprehensive picture of the state of the science at any given time.”²²⁹

One way to change the impact that intellectual property protection has on embryonic stem cell research is to actually change that which the PTO presently determines to be patentable.²³⁰ Ironically, the 2001 Utility Guidelines suggest that the PTO has changed its position on patentability, particularly in the field of biotechnology.²³¹ By requiring that a claimed invention have a “substantial, specific, and credible utility,” these new utility guidelines, if appropriately applied, may restrict inventors from seeking patent protection for findings based upon speculation so that subsequent research and development may be controlled.²³² That is, “requiring an inventor to assert a specific, substantial, and credible utility may prevent ‘shotgun’ [inventors] who assert only speculative utility . . . from obtaining patent protection.”²³³ Thus, one way to limit the amount of control that

exclusion, as well as how that impacts the patent system, would have to be considered.”)

227. Knowles, *supra* note 81, at 20.

228. *Id.* at 19; *see also* Establishment and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,744 (May 14, 1998) (to be codified at 21 CFR pts. 207, 807, and 1271) (setting forth the proposition that the Public Health Service Act, 42 U.S.C. § 262 (1994), enables the Food and Drug Administration to regulate human cellular and tissue products).

229. Knowles, *supra* note 81, at 19.

230. *See, e.g.*, Olsen, *supra* note 3, at 298.

231. Worrall, *supra* note 58, at 131-32.

232. *Id.* at 135.

233. *Id.* at 134-5 (explaining that the 2001 Utility Guidelines could prevent inventors from claiming uncharacterized DNA sequences that discourage subsequent research and development, hindering the inventors' ability to obtain broad patent rights over DNA compositions that will give the patent holder excessive control over therapeutic developments related to the gene product which, at the time of patenting, may only be a speculative utility for a putative protein); *see* Jagels, *supra* note 53, at 145 (noting that “[a] stronger utility requirement would not only limit patents based on

organizations like WARF and Geron hold over the embryonic stem cell field is to promote this suggested requirement that a higher level of utility be established before patent protection can be granted on embryonic stem cell lines and their derivatives.

Additionally, when propositioned for patent protection by inventors of other embryonic stem cell lines, the PTO, rather than asserting that stem cell lines with homology to known stem cell lines have well-established utility, should consider whether the utility of the new stem cell line meets the specific and substantial utility requirement.²³⁴ Since slight differences in stem cell lines can cause extremely significant differences in biological activity and great variations in functionality, homology should be thought of as a very limited predictor of actual function by those skilled in the art.²³⁵ Thus, the PTO should recognize the extreme “limitations of [the] homology arguments,” because failing to do so “risks granting patents that the courts may subsequently invalidate for lack of utility.”²³⁶

An immediate measure that may be taken to ensure that scientists have adequate access to the embryonic stem cell line covered by the WARF ‘806 patent would be the forced licensing of the patent.²³⁷ Notably, “[w]ithin a system where universities have title to patents sponsored by government-funded research, we must ask whether the way universities license these patents comports with the public interest.”²³⁸ For instance, the federal government could require that WARF and Geron exploit the patent to its fullest by allowing scientists to fully access the technology at minimal or no

questionable motives (such as the Newman application), but would also keep in check the patenting of newly discovered genes and processes until a clearly defined function or use can be established.”).

234. Jagels, *supra* note 53, at 142 (noting that “[i]nstead of asserting that sequences with homology to known sequences have well-established utility, the PTO should consider whether the utility of the claimed sequence establishes the threshold specific and substantial practical utility required by the courts.”).

235. *Id.* at 142-43 (reasoning that although proteins of similar sequences often have similar functions, small differences in the sequences of other proteins may result in an extremely different functionality, thereby diminishing the reliance that should be placed on a homology argument when assessing the utility of a sequence); *see also* Steven E. Brenner et al., *Assessing Sequence Comparison Methods with Reliable Structurally Identified Distant Evolutionary Relationships*, 95 PROCEEDINGS OF THE NAT’L ACAD. OF SCI. 6073 (1997).

236. Worrall, *supra* note 58, at 143.

237. *See* Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1357-62 (Fed. Cir. 1998) (holding that CellPro, a biotechnology company that had received federal approval for the process of isolating and separating stem cells, had infringed patents claiming purified suspensions of stem cells and monoclonal antibodies used to produce such suspensions); *see also* Mikhail, *supra* note 157, at 381 (explaining that “[w]hile encouraging the private sector to develop federally funded basic research is an important goal, *Hopkins v. CellPro* illustrates that allowing a university to patent, hold title, and maintain unlimited control of the results is not without its shortcomings.”).

238. Mikhail, *supra* note 157, at 381 (noting that the passage of the Bayh-Dole Act in 1980 was aimed at allowing universities to patent and hold title to inventions developed with government funding with the goal that the patent system would promote the utilization of inventions that resulted from federally funded research and development).

cost.²³⁹ Such measures would indeed remedy at least part of the concern by scientists and biotechnology companies that they are not able to use the stem cell lines and corresponding technology for which they may receive the much needed federal funding.

Additionally, revisions to President Bush's 2001 stem cell policy may be necessary. For example, there is concern that the policy is too limited on the number of lines that may receive funding for research and the mere existence of these lines.²⁴⁰ While "it will take time for the NIH to resolve scientific questions about whether an adequate number and range of stem cell lines exist . . . the president ought to consider more flexibility in his policy."²⁴¹

VIII. CONCLUSION

It is nearly undeniable that advances in stem cell research have the potential to change the nature of human society forever. However, while these developments could serve to "cure or prevent human suffering," it should be noted that "they also give us a greater ability to inflict such suffering."²⁴² Thus, it is extremely evident that at some point in the process that allows for the patent protection of technologies or key components of technologies that could shape the future of human existence, a change inevitably needs to be made. When addressing this, however, both lawmakers and ethicists alike need to take note of the depth of the issue at hand and to recognize the long-term ramifications of their decisions. Therefore, any decisions concerning the future of embryonic stem cell research and its associated technologies should be made considering a broad

239. See, e.g., North American Free Trade Agreement, *entered into force* Jan. 1, 1994, U.S.-Can.-Mex., 32 I.L.M. at 605 art. 1709(8) (explaining that the North American Free Trade Agreement establishes the minimum requirements the three countries must offer within their respective territories to the nationals of each of the other two countries in order to mandate that there is adequate and effective protection and enforcement of intellectual property rights, while further ensuring that the measures to enforce such rights do not become barriers to trade); see also Ryan H. Flax, 5 NAFTA L. & BUS. REV. AM. 461, 474 (1999) (prior to the North American Free Trade Agreement, the United States had no laws mandating that patent holders "exploit their patents in a particular country, with failure to do so resulting in forced licensing," while Mexico did "permit the granting of compulsory licenses for failure to exploit unless the patent holder" was importing a patented product or products made by a patented process).

240. See, e.g., Agres *supra* note 109, at 8 (noting that there are allegedly sixty stem cell lines that are currently approved for federally funded research under President Bush's policy).

241. Rebecca Hoover, *Stem Cell Debate Worth Study, Even Adjustment* (Aug. 22, 2001), at <http://www.heraldnet.com/Stories/01/8/22/14252291.cfm>.

242. Greely, *supra* note 162, at 390.

time frame, with extreme scrutiny, and of utmost importance, with a great amount of care, because, indeed, there is no telling the places we'll go.

Stacy Kincaid