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The Patentability of Embryonic Stem Cell Research Results

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NOTE

THE PATENTABILITY OF EMBRYONIC STEM CELL RESEARCH RESULTS

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I. INTRODUCTION

On August 9th, 2001, President George W. Bush announced his decision to allow federal government funding for human embryonic stem cell research.[1] The President's decision limited funding to research on existing embryonic stem cell lines only, due to the moral and ethical issues surrounding this type of research.[2] In addition, President Bush approved

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* This Note is dedicated to my family. You have always been my source of encouragement and inspiration, for which I am eternally grateful. Thank you for always being there. This Note received the Barbara W. Makar Writing Award for the outstanding note for Fall 2001.

1. Remarks by President George W. Bush on Stem Cell Research, *at* http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html (Aug. 9, 2001).

2. *See id.* at 3.

aggressive funding for research on human adult stem cells, along with research on stem cells derived from umbilical cord, placenta, and animals.[3] This decision was based upon the belief that such research would lead to breakthrough scientific discoveries that would result in treatments and cures for a myriad of diseases and ailments that affect people worldwide.[4] Describing stem cell research as a "new frontier,"[5] the President's decision to allow stem cell research funding is the first step toward turning science fiction into fact.

Even without federal funding, researchers have undertaken the tasks of stem cell discovery.[6] While federal funds greatly aid the research process, private companies have incentives of their own. The possibility of financial gains from new technologies and inventions borne from research influences companies to invest in the research and development of such technologies. These financial rewards are embodied in intellectual property rights and may be manifested in the area of biotechnology in the form of licensing agreements involving patented inventions and processes. These patent rights are provided by the federal government, through 35 U.S.C. §§ 100-57 (Patent Act),[7] as a means to promote technological advancement.[8] However, for public policy purposes, the availability of this protection is limited.

This Article explores the patentability of the theoretical results of human embryonic stem cell research. Section II provides background information regarding embryonic stem cells. Section III provides an overview of general patent law and the requirements for patentability. Section IV deals with patent protection of biological organisms, including the availability of patent protection for human DNA and gene sequences. Section V concludes with a discussion and application of the current patent laws to possible future inventions and discoveries due to stem cell research.

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3. President Bush stated that the federal government would spend $250 million on this form of research. *Id.*

4. *Id.*

5. *Id.*

6. Private researchers have created more than sixty distinct stem cell lines. Remarks by President George W. Bush, *supra* note 1, at 3.

7. 35 U.S.C. §§ 100-157 (2001).

8. *See* Kevin Cuenot, *Perilous Potholes in the Path Toward Patent Law Harmonization*, 11 U. FLA. J.L. & PUB. POL'Y 101, 101 (1999).

II. HUMAN EMBRYONIC STEM CELL RESEARCH

The use of human embryonic stem cells for research purposes has received national and international attention.[9] In fact, President Bush's decision to allow federal funding for stem cell research was not the first time this issue was reviewed by the Office of the President. In November 1998, President Bill Clinton ordered the National Bioethics Advisory Commission to review and balance all of the ethical and medical considerations involved with this form of research.[10] But what is a human embryonic stem cell?

A. *Human Embryonic Stem Cells*

At the cellular level, the human body is composed of millions of cells.[11] These cells are different, based upon the tissues or organs that they comprise.[12] However, all of these cells have the same origin, thus, the cells that make up the brain were at one point identical to the cells that make up the heart. This origin is the embryonic stem cell. Stem cells are undifferentiated cells that are able to undergo indefinite cell division and that have the ability to become any type of specialized cells.[13] In humans, these cells are created following fertilization of an egg cell by a sperm cell.

During normal human development, gametes[14] fuse at fertilization, creating a single cell zygote.[15] This cell has the potential, under the proper

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9. *See* National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research, Executive Summary* at 2, *at* http://bioethics.georgetown.edu/nbac/pubs.html (Sept. 1999).

10. *Id.* at 1.

11. GERALD J. TORTORA & SANDRA REYNOLDS GRABOWSKI, PRINCIPLES OF ANATOMY AND PHYSIOLOGY 7 (8th ed. 1996). The human body is composed of eleven different "systems" each made up of organs which consist of millions of cells. *Id.*

12. *See id.* at 94-119 (discussing the major classifications of body tissues, including cell differences between them). *See also* DOUGLAS E. KELLY ET AL., BAILEY'S TEXTBOOK OF MICROSCOPIC ANATOMY 17 (Toni M. Tracy ed., 18th ed. 1984) (stating that the various shapes, sizes, and composition of cells is due to their functions in different tissues and organs of the body).

13. *See* National Institutes of Health, *Stem Cells: A Primer 1*, *at* http://www.nih.gov/news/stemcell/primer.htm (May 2000). Stem cells undergo differentiation, the changes that cause a cell to develop from an unspecialized cell to a specialized, or specific cell type. *See also* TORTORA & GRABOWSKI, *supra* note 11, at 83.

14. Gametes or sperm and egg cells are the human reproductive cells. *See* TORTORA & GRABOWSKI, *supra* note 11, at 83.

15. *Id.* A zygote is the single cell produced from gamete fusion (fertilization). This cell contains a DNA set from each parent, and has the potential to develop into another human being. *Id.*

conditions, to divide and grow, eventually forming a viable human being.[16] Following fertilization, the zygote undergoes several rounds of cell division,[17] creating identical cells.[18] These duplicate cells all have the possibility to differentiate into any of the various cell types in the human body. These cells eventually begin to specialize to form a blastocyst, an early structure in the embryonic process.[19] This structure is made up of two distinct cell types, the outer cells which will ultimately form the tissues and structures required to support fetal development in the uterus, and the inner cell mass, a group of cells which will ultimately differentiate to form all of the various cells of the human body.[20] The cells in this inner mass are embryonic stem cells.[21]

The differentiation of these stem cells occurs in part from the activation of certain genes within the cells' nuclei.[22] These genes are comprised of deoxyribonucleic acid (DNA), and once activated, will produce specific proteins and other biochemical materials that will determine the future identity of each cell.[23] Thus, prior to this gene expression, stem cells have the potential to become any type of cell in the human body.[24]

B. The Potential of Stem Cell Research

Stem cell research may lead to discoveries that can be used to treat a multitude of human diseases.[25] These discoveries may provide cures for diseases which have yet to be uncovered by current medical research.[26] Stem cell research may also provide scientists with a better understanding

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16. *See* National Institutes of Health, *supra* note 13.

17. The zygote undergoes cell division, during which DNA, the genetic material enclosed in the dividing cell's nucleus, is duplicated. TORTORA & GRABOWSKI, *supra* note 11, at 80-83. The cell divides, forming two identical cells. *Id.* at 80. During this process, the number of identical cells increases exponentially. *Id.* at 80-83. This process continues until a signal is given to the cell division machinery to cease dividing. *Id.*

18. *See* National Institutes of Health, *supra* note 13.

19. *Id.*

20. *Id.* at 1-2.

21. *Id.* at 2.

22. SCOTT F. GILBERT, DEVELOPMENTAL BIOLOGY 97 (6th ed. 2000).

23. *Id.* at 54. Cell differentiation involves biochemical changes. *Id.*

24. *See* National Cancer Institute, *Institutes and Centers Answers to the Question: "What Would You Hope to Achieve From Human Pluripotent Stem Cell Research?," at* http://www.nih.gov/news/stemcell/achieve.htm (Apr. 26, 2000).

25. *See* White House Press Release, *Fact Sheet, Embryonic Stem Cell Research 2, at* http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html (Aug. 9, 2001).

26. *See id.*

of human biological functions.[27] Furthermore, new means of evaluating the safety and effectiveness of existing and newly developed drugs may result from stem cell research.[28]

Researchers believe that stem cells will play an important role in cancer research, treatment, and cures.[29] Diseases of the nervous system, such as Parkinson's and Alzheimer's disease may eventually be treated and even cured through stem cell developed technology.[30] Even more incredible, damage to the nervous system due to stroke and spinal cord injuries may be reversed;[31] thus, stem cell research may one day lead to a cure for paralysis by regenerating severed spinal cord tissue. In addition, researchers believe that diseases such as acquired immunodeficiency syndrome (AIDS) may be treated effectively in the future as a result of stem cell research.[32]

In addition to advances in the treatment of diseases, stem cell research could lead to the capability of regenerating damaged organs or the creation of new organs for transplantation purposes.[33] This could be possible once researchers uncover the specific processes of cell specialization and gene

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27. *See id.*

28. *Id.*

29. National Cancer Institute, *supra* note 24, at 1. Researchers at the National Cancer Institute (NCI) believe that stem cells may be the key to unlocking the mystery of cancer cell proliferation and resistance to current methods of treatment. The NCI also feels that stem cells may one day be utilized to replenish tissues and organs damaged by current chemotherapy treatments. *Id.* Currently, adult bone marrow and blood stem cells are used for such purposes. These cells are further differentiated than embryonic stem cells, however, and lack the potential of such cells. *Id.*

30. *See id.* at 7. Both the National Institute of Neurological Disorders and Stroke and the National Institute on Aging support the "enormous potential" stem cell research may have on developing cell and tissue replacement therapies on these degenerative neurological diseases. *Id.* These diseases occur as a result of lost nerve cells, which cannot be replaced by mature nerve cells due to their inability to undergo cell division. *Id.* However, experiments involving stem cell replacement therapies on animals have shown promising results that these nerve cells may one day be replaced using stem cells. *Id.* at 8. *See also* Remarks by President George W. Bush, *supra* note 1; White House Press Release, *supra* note 25.

31. *See* National Cancer Institute, *supra* note 24, at 3.

32. The National Institute of Allergy and Infectious Diseases asserts that stem cell research may yield results that help restore immune functions damaged or destroyed by HIV infection. *Id.* at 5.

33. *See* Remarks by President George W. Bush, *supra* note 1. This could alleviate the current discrepancy between those individuals requiring organ transplants and the number of organs available for transplantation. *See also* National Institutes of Health, *supra* note 13, at 3.

activation.[34] Using stem cells, researchers may be able to gain valuable insight into the operations of the human genome and into human biology, ultimately using this knowledge to create in vitro tissues and organs for transplantation.[35]

Not only may stem cells be valuable for direct use in the treatment and cure of diseases, stem cell research may provide new means of developing and testing the effectiveness and safety of medicines.[36] Stem cell lines could allow drug developers to test new drugs on a variety of human cell types prior to animal and human testing.[37] Thus, only those drugs that show a potential for safety and efficacy during cell line testing would move on for further clinical tests required by the FDA.[38] This could "streamline" the drug development process and reduce research and development costs for investing corporations.[39]

These possible breakthrough developments are still only potential possibilities.[40] Scientists asserting the possible applications and benefits of stem cell research note that such developments may be years away,[41] because significant technological roadblocks must still be negotiated before the possibilities become realities.[42] Recognizing the possibilities of such research and the need for further development, President Bush announced that federal funding would be provided for stem cell research.[43] In addition, the President created a Council on Bioethics to monitor this research and to make recommendations for guidelines and regulations.[44]

While the President's decision ensures that federally funded research will be conducted, private companies will continue to fund such research

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34. *See* National Cancer Institute, *supra* note 24. The National Human Genome Research Institute is currently using stem cells to study gene expression profiles during cell differentiation. *Id.* at 10.

35. *See id.*

36. *Id. See also* White House Press Release, *supra* note 25.

37. National Institutes of Health, *supra* note 13, at 3.

38. *Id.*

39. *Id.* By reducing costs and decreasing the time it takes to receive FDA approval for a newly developed drug, corporations may be more apt to invest capital in research and development of drugs.

40. For a more in depth treatment of the possibilities stem cell research offers, see National Cancer Institute, *supra* note 24.

41. *Id.* at 10.

42. *See* National Institutes of Health, *supra* note 13, at 4.

43. Remarks by President George W. Bush, *supra* note 1.

44. *See* White House Press Release, *supra* note 25. *See also* Remarks by President George W. Bush, *supra* note 1.

as well. These investments are made with the ultimate goal of reaping a profit from the discoveries made. This profit can be made based on patents granted on the specific procedures used and even on the end results, the compounds, themselves. Therefore, patent law also plays an important role in promoting stem cell research.[45]

III. UNITED STATES PATENT LAW

A. *General History and Purpose*

Congressional authority to grant patents to individuals is derived from the U.S. Constitution.[46] The grant of a patent is a decision of public policy, whereby the U.S. Government rewards the inventor of a useful invention that benefits the general public, thus advancing the particular technology via a limited monopoly on the use of the invention.[47] This reward is a means of inducing creativity and inventions in the sciences.[48]

The first Patent Act was passed by Congress in 1790.[49] Since that time, several changes have been made,[50] resulting in the current Patent Act embodied in Title 35 of the United States Code.[51] This version of the Act has been modified to comply with international agreements concerning

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45. James J. Muchmore, *Proprietary Rights and the Human Genome Project: A Legal and Economic Perspective*, 8 DIGEST 45, 48 (2000) (stating that the "possibility of patent protection and property rights in biotechnology provides the potential for great financial return to investors"). *See also* Cuenot, *supra* note 8, at 109 (asserting that patents allow investors to recover their investment in research and development of an invention, and may also allow them to make a profit on the patented invention); Alexander K. Haas, *The Wellcome Trust's Disclosures of Gene Sequence Data into the Public Domain & the Potential for Proprietary Rights in the Human Genome*, 16 BERKELEY TECH. L.J. 145, 154 (2001) (finding that patent protection provides the biotechnology industry an incentive to conduct research).

46. In relevant part, Art. I, § 8, clause 8 of the U.S. Constitution provides that "Congress shall have power to . . . promote the progress of science . . . by securing for limited times to . . . inventors the exclusive right to their respective . . . discoveries." U.S. CONST. art. I, § 8, cl. 8.

47. *See* Cuenot, *supra* note 8, at 109.

48. *See* Muchmore, *supra* note 45, at 48.

49. Patent Act of 1790, ch. 7, §§ 109-112, 1790 Stat. 1.

50. *See generally* DONALD S. CHISUM, CHISUM ON PATENTS apps. 9-1 to 25-1 (2001) (treatise appendix containing the various Patent Acts and amendments from 1790 through 1988).

51. 35 U.S.C. §§ 100-157 (2001).

intellectual property, including the Paris Convention[52] and the Agreement on Trade-Related Aspects of Intellectual Property Rights.[53]

B. *Requirements for Patentability*

The current version of the Patent Act[54] sets forth the requirements that must be met for an invention to receive a patent.[55] To receive patent protection, an invention must first involve appropriate subject matter.[56] The invention must also be useful,[57] novel,[58] and non-obvious.[59] In addition, the invention must be adequately disclosed to enable others to reproduce the invention and use it successfully.[60] If these requirements are met, a patent may be issued.

Patentable subject matter comprises "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[61] Any possible invention or process, including compositions of matter such as tissues and organs, that will result from human stem cell research will pertain to biological organisms. The issue of whether living, biological organisms, specifically human cells, tissues, and organs, are patentable subject matter will be addressed in Section IV.

Currently, an invention may meet the requirement of usefulness of 35 U.S.C. § 101, often termed the utility requirement, in one of two ways.[62] The inventor need only have a credible assertion of the invention's specific

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52. International Convention for the Protection of Industrial Property, Mar. 20, 1883, 1883 U.S.T. *LEXIS* 23.

53. General Agreement on Tariffs & Trade-Multilateral Trade Negotiations (the Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, including trade in counterfeit goods, Apr. 15, 1994, art. 39, 33 I.L.M. 81, 98 (1994).

54. 35 U.S.C. §§ 100-157 (2001).

55. For purposes of the Act, an invention is any "invention or discovery." *Id.* § 100(a). The Act also protects a process, which includes a "process, art or method, . . . a new use of a known process, machine, manufacture, composition of matter, or material." *Id.* § 100(b). *See also* CHISUM, *supra* note 50, at OV-12 (The PTO reviews patent applications and will not issue a patent until finding that an invention meets the Title 35 requirements); Mark Jagels, *Notes and Comments: Dr. Moreau Has Left the Island: Dealing with Human-Animal Patents in the 21st Century*, 23 T. JEFFERSON L. REV. 115, 127 (2000).

56. 35 U.S.C. § 101 (2001). *See also* CHISUM, *supra* note 50, § 1.01.

57. 35 U.S.C. § 101 (2001).

58. *Id.* § 102.

59. *Id.* § 103.

60. *Id.* § 112.

61. *Id.* § 101.

62. *See* PTO Examination Guidelines on Utility Requirement, 50 PAT. TRADEMARK & COPYRIGHT J. (BNA) 295 (1995).

utility or have an apparent belief of its usefulness.[63] This standard is based on utility guidelines issued by the Patent and Trademark Office (PTO) in 1995[64] and is easier to meet than the "exacting standard"[65] set forth by the U.S. Supreme Court in *Brenner v. Manson*.[66] This new standard is extremely important since the majority of discoveries and inventions that may result from stem cell research will probably not have a specific benefit in their initial forms.

The novelty requirement for a patent is embodied in 35 U.S.C. § 102.[67] This statutory provision requires an invention to be "new at the time of discovery . . . to be patentable."[68] The invention is not novel if it was known, used, patented, or described in a publication prior to its invention by the patent applicant.[69] Public use or sale of the invention prior to the patent application will also destroy its novelty.[70] However, similar inventions may already exist without destroying the new invention's novelty. These prior inventions comprise what is known as the "prior art."[71] Novelty will remain intact so long as no single invention in the prior art contains the exact identical elements of the new invention.[72] Even if these requirements are met, a biotechnological invention that involves a living organism is not novel if it is a naturally occurring phenomenon.[73] Thus, a living organism must be the non-natural result of human engineering and ingenuity.[74]

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63. *See id.*

64. *See id. See also* Jagels, *supra* note 55, at 137.

65. *See* Jagels, *supra* note 55, at 137.

66. 383 U.S. 519 (1966) (holding that a specific benefit must exist in an available form before the statutory requirement of utility is met). *See also* Mattias Luukkonen, Note, *Gene Patents: How Useful are the New Utility Requirements*, 23 T. JEFFERSON L. REV. 337, 351-52 (2001). *Brenner v. Manson* still requires an invention's purpose and use to have an immediate value to the public and must be capable of performing its intended purpose. *Id.* at 351. However, the PTO revised the utility guidelines in 2001. *Id.* at 352. The new requirements are met when a person ". . . skilled in the art [can] appreciate why the invention is useful based on its characteristics." *Id.*

67. 35 U.S.C. § 102 (2001).

68. *See* CHISUM, *supra* note 50, at 3-3.

69. 35 U.S.C. § 102(a) (2001).

70. *See id.* § 102(b). If the invention was used or sold, the patent application must be filed within one year from such sale or use in order to retain the invention's novelty. *See id.* Furthermore, if the invention has already been described in a pending patent application it cannot be considered novel. *Id.* § 102(e)(1).

71. *See* Jagels, *supra* note 55, at 140.

72. *See* CHISUM, *supra* note 50, at 3-6.

73. *See* Jagels, *supra* note 55, at 140.

74. *Id.*

An invention must also be non-obvious in order to obtain patent protection.[75] This requirement is not met if, based on the information found in the prior art at the time of the invention, the invention itself would be obvious to someone who possessed the ordinary skills in the relevant art.[76] In addition to this general non-obvious requirement, the Patent Act sets forth a specific standard for biotechnological inventions.[77] This provision addresses biotechnological processes[78] and has been interpreted as requiring that the prior art lead to the production of the invention and that there be a reasonable expectation that the invention can be carried out successfully for the invention to fail the non-obvious requirement.[79]

Even if an invention pertains to appropriate subject matter and is useful, novel, and non-obvious, it must still meet the enablement and disclosure requirement of 35 U.S.C. § 112 to obtain a patent.[80] This section of the Patent Act requires that a written disclosure adequately describing the invention be provided to the PTO.[81] This writing must be in "full, clear, concise, and exact terms," and must disclose "the manner and process of making and using [the invention]."[82] This ensures that anyone skilled in the relevant art will be able to reproduce the invention and employ it for its specific purpose, thus enabling them to make and use the invention.[83] The writing should also describe the inventor's "best mode" for using the

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75. *See* 35 U.S.C. § 103 (2001).
76. *See* CHISUM, *supra* note 50, at 5-10, 5-11.
77. 35 U.S.C. § 103(b) (2001).
78. The Patent Act defines biotechnological processes as:

> (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to — (i) express an exogenous nucleotide sequence, (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or (iii) express a specific physiological characteristic not naturally associated with said organism; (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

Id. § 103(b)(3).

79. *See* Luukkonen, *supra* note 66, at 349. For an in-depth treatment of the non-obvious requirement for biotechnological inventions, see CHISUM, *supra* note 50, at 5-475 to 5-499.
80. 35 U.S.C. § 112 (2001).
81. *See id.*
82. *Id.*
83. *See id.*

invention.[84] If the written description of the invention provides this information, then the innovation provided by the invention will be available to the public and will increase the scope of the prior art. In the area of biotechnology, the enablement requirement is met if one skilled in the relevant art can produce and utilize the invention without "undue experimentation."[85]

IV. PATENT PROTECTION FOR BIOLOGICAL ORGANISMS

A. *The Problems of Appropriate Subject Matter*

To receive a patent, an invention must pertain to patentable subject matter.[86] Prior to 1980, living biological organisms were not considered patentable subject matter.[87] Inventions involving naturally occurring biological organisms are considered discoveries of a product of nature.[88] Like natural laws such as the laws of physics, etc., these natural discoveries were automatically presumed to be unpatentable because they were not considered inventions.[89] However, this belief was significantly altered when the U.S. Supreme Court decided *Diamond v. Chakrabarty*.[90]

In this landmark case, the U.S. Supreme Court decided whether a bacterium, a living biological organism, was patentable subject matter under 35 U.S.C. § 101.[91] Microbiologists genetically modified the bacterium in question to digest crude oil components.[92] The PTO had granted a patent for the process used to create these modified bacteria.[93]

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84. *See id.*

85. *See* Luukkonen, *supra* note 66, at 350 (discussing the success rate and nature of the invention, the state of the art, and whether the experimentation conducted was routine, as factors for determining if experimentation required to successfully produce and use a disclosed invention is considered undue).

86. *See supra* text accompanying notes 56-61.

87. *See* Jagels, *supra* note 55, at 127 (The U.S. Supreme Court decided in 1980 that a living biological organism could be considered patentable material).

88. *Id.*

89. *See id.*

90. 447 U.S. 303 (1980).

91. *See id. See also* Marsha L. Montgomery, Note, *Building a Better Mouse—and Patenting It: Altering the Patent Law To Accommodate Multicellular Organisms*, 41 CASE W. RES. L. REV. 231, 238-39 (1990).

92. *See Chakrabarty*, 447 U.S. at 305.

93. *See id.*

However, the bacterium itself was not given patent protection as a composition of matter.[94] In reversing the PTO's decision, the U.S. Supreme Court found that the bacterium was not naturally occurring, but a product of human creation.[95] As a biological organism that had been genetically altered by humans, the bacterium was not a product of nature but a "composition of matter" or a "manufacture" per 35 U.S.C. § 101.[96] Therefore, the Court held that the organism encompassed patentable subject matter.[97] In further support of its holding, the Court cited the Congressional Committee Reports that accompanied the Patent Act, stating that the intent of Congress was for the Act to apply to "anything under the sun that is made by man."[98] However, the Court limited this holding by requiring that the organism be man-made and not simply discovered.[99] Thus, after *Chakrabarty*, certain biological organisms could be patented.

Seven years after *Chakrabarty*, a patent application claiming a genetically engineered multi-cellular organism was filed.[100] The organism was not found in nature in this manipulated state, and was therefore patentable subject matter as a man-made invention.[101] As a result of this patent application, the PTO issued a policy statement regarding the patentability of multi-cellular biological organisms.[102] The statement affirmed that non-naturally occurring multi-cellular organisms, including animals, were patentable subject matter, but emphasized that "[a] claim directed to or including within its scope a human being [would] not be considered. . .patentable subject matter."[103] This ban on patenting human beings is due to the constitutional prohibition of property rights in

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94. *See id.*

95. *See id.* at 309.

96. *See id.* at 307, 310 (quoting 35 U.S.C. § 101 (2001)).

97. *See Chakrabarty*, 447 U.S. at 307, 310.

98. *See id.* at 309.

99. *See id. See also* Jagels, *supra* note 55, at 128 (stating that *Chakrabarty* allows organisms to be patented if they are created via artificial means).

100. *See Ex Parte* Allen, 2 U.S.P.Q. 2d 1425 (BPAI 1987). (The organism was an oyster).

101. *See id.* The multi-cellular organism qualified as patentable subject matter under 35 U.S.C. § 101, however, a patent was denied due to failure to meet the non-obvious requirement. *Id.* at 1427.

102. Commissioner of Patents and Trademarks, Policy Statement on Patentability of Animals, 1077 OFF. GAZ. PAT. OFF. 24 (1987), *reprinted in* CHISUM, *supra* note 50, at app. 24.

103. *See id.* at app. 24-1.

humans.[104] However, organisms that include human genes may still be patentable, as long as they are identified as non-human.[105]

Within a year of the PTO's statement, the first patent was issued for a genetically modified animal.[106] The animal, a mouse, had been genetically infused with a human cancer gene and would be used for experimentation purposes.[107] After the granting of this patent, the floodgates were opened for other patents involving animals infused with human genes.[108] This practice went unchallenged by the PTO until 1998 when a patent application was filed claiming techniques for combining embryonic cells of humans and animals.[109] In response to this application, the PTO issued a media advisory to clarify its position on patenting human-related organisms, stating that such an invention could fail to meet the utility requirement.[110] However, without referring to the advisory, the patent was denied for several reasons, including the failure to meet the subject matter requirement.[111] Despite this particular rejection, it is clear that biological organisms can meet the statutory subject matter requirement of the Patent Act.[112]

B. *The Patentability of Human DNA Sequences and Human Genes*

The ability to patent genetically manipulated biological organisms opened the door for researchers to patent specific human DNA[113] sequences, including whole genes. This practice of granting patents to

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104. *See* Montgomery, *supra* note 91, at 242 (citing the Fourteenth Amendment's ban on slavery).

105. *See id.*

106. *See* U.S. Patent No. 4,736,866 (issued Apr. 12, 1988). *See also* Jagels, *supra* note 55, at 132.

107. *See* Jagels, *supra* note 55, at 132.

108. *See id.* (stating hundreds of similar patents have been granted since this particular patent).

109. *See id.*

110. U.S. Patent and Trademark Office Media Advisory, No. 98-6, *Facts on Patenting Life Forms Having a Relationship to Humans*, (Apr. 1, 1998). This was based on the seldom used "morality doctrine," stating that an invention cannot be useful if it is designed for an immoral use. *See* Jagels, *supra* note 55, at 137-38 (discussing the origin and erratic application of this judicial doctrine).

111. *See* Jagels, *supra* note 55, at 133. The patent application also failed to meet the non-obvious and enablement requirements. *Id.*

112. *See* CHISUM, *supra* note 50, at 1-48.

113. DNA molecules contain the genetic material, the hereditary code of an organism. KELLY ET AL., *supra* note 12, at 25. Individual genes form the many segments of each DNA molecule. TORTORA & GRABOWSKI, *supra* note 11, at 47.

researchers for sequences of human DNA that comprise all or part of a human gene is known as gene-patenting.[114] DNA, found in the nucleus of every cell,[115] contains thousands of genes (specific sequences that control heredity), as well as the requisite information for protein synthesis, and directs the overall function, proliferation, and differentiation of cells.[116] Since the discovery of the structure of DNA in 1953, researchers have been able to separate and identify particular gene sequences from the entire DNA molecule.[117] During this time, several countries and organizations have attempted to determine the entire human genome — the sequences and locations of all the genes found in human DNA molecules.[118] As a result, an international cooperative, the Human Genome Project, has undertaken this task.[119]

In 1991, the first U.S. patent application was filed claiming partial DNA sequences.[120] In response to this action, private companies and governmental agencies filed patent applications claiming thousands of partial DNA sequences.[121] This action led to international criticism.[122] Those opposed to the patenting of human DNA sequences insist that it is unethical to grant someone property rights in something that is part of the "universal heritage" of all humans, since these gene sequences are shared in common by all of humanity.[123] Furthermore, the purpose of the Human Genome Project is to cooperatively share information in order to expedite the mapping of the entire human genome.[124] The drive to obtain a profit through patent rights will diminish the open dissemination of information during this vital research endeavor.[125]

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114. *See* Patricia A. Lacy, Comment, *Gene Patenting: Universal Heritage vs. Reward for Human Effort*, 77 OR. L. REV. 783, 784 (1998).

115. *See* KELLY ET AL., *supra* note 12, at 25.

116. *See* Muchmore, *supra* note 45, at 46-47.

117. *See id.* at 47.

118. *See id.*

119. *See id.*

120. This patent application was filed by the National Institutes of Health. It claimed that the invention met the statutory requirements, contending that full-length DNA sequences were not required since they could be gained without undue experimentation. *See id.* at 49. *See* G. Kenneth Smith & Denise M. Kettelberger, *Patents and the Human Genome Project*, 22 AIPLA Q.J. 27, 46 (1994).

121. *See* Muchmore, *supra* note 45, at 49. *See also* Haas, *supra* note 45, at 150 (stating that companies have sought patents for gene sequence data).

122. *See* Lacy, *supra* note 114, at 783.

123. *See id.* at 798.

124. *See id.*

125. *See id.* at 792.

Proponents of patenting human DNA sequences acknowledge the problems associated with allowing such a policy.[126] However, they insist that the pursuit and subsequent grant of patents increases the general knowledge on the subject and leads to the creation of products that are beneficial to the public.[127] Thus, by allowing patents on DNA sequences, the PTO will not only encourage, but ensure the continued research and development of the entire human genome. While both sides have legitimate arguments, their differing views exemplify the ethical dichotomy presented by this issue.[128]

Facing this ethical issue, the PTO rejected the initial applications claiming partial DNA sequences, but in 1995, issued a patent to the National Institute of Health for a genetically developed human cell line.[129] Since those initial filings, the PTO has granted patents on DNA gene sequences, both partial and complete.[130] By doing so, the PTO has provided a means of securing proprietary rights in the human genome through patents.[131] But how can patents be issued on gene sequences since they are naturally occurring products found in all humans? This problem has been circumvented by the current human-manipulated organism subject matter classification.[132] Genes do not naturally exist as individual compositions of matter.[133] However, once researchers identify particular gene sequences, these genes can be isolated and considered patentable subject matter.[134]

Although patents have been successfully received for genes and gene sequences, another problem exists for the issuing of such patents. The Human Genome Project has already completed a "working draft" of the human genome's approximately 30,000 genes and should have a final

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126. *See id.* at 797.

127. *See* Lacy, *supra* note 114, at 797.

128. *See id.* at 785. The first question is, "is it ethically permissible to patent segments of the human genome when these segments represent part of our individual and collective 'natural' heritage?" while the second question is, "is it ethical to deny patenting parts of the human genome given the vast economic resources and human effort expended in identifying it?" *Id.*

129. *See id.* at 793. *See also* Muchmore, *supra* note 45, at 49.

130. *See* Melissa L. Sturges, Comment, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT'L L. REV. 219, 234 n.91 (1997) (patents granted to Maryland company for individual genes).

131. *See* Muchmore, *supra* note 45, at 49.

132. *See supra* text accompanying notes 92-99.

133. *See* Mark Christopher Farrell, Comment, *Designer DNA for Humans: Biotech Patent Law Made Interesting for the Average Lawyer*, 35 GONZ. L. REV. 515, 522 (2000).

134. *See id.*

version of the genome map completed within the next two years.[135] In response to this accomplishment, a medical research charity involved with the Human Genome Project announced that it would place the raw sequence of the entire genome into a database readily accessible by the public.[136] When this sequence data is made available to the public, researchers will no longer be able to receive patent protection for any portion of the "raw" genomic sequence, in accordance with sections 102 and 103 of the Patent Act.[137] However, this does not mean that the end products and other "useful benefits derived from [the] genetic information" would no longer be patentable.[138] Therefore, while the future of gene sequence patenting is uncertain, the ultimate innovations from such research should still retain their patentability.

V. THE PATENTABILITY OF HUMAN CELLS AND ORGANS

Human embryonic stem cell research may lead to technological processes that could produce, among other things, in vitro human tissues and organs.[139] This technology would most likely utilize previously discovered DNA gene sequences as well as those yet to be determined.[140] In addition, these processes and their ultimate end products may also contain or utilize embryonic stem cells themselves.[141] More importantly, they would involve a subject matter that is clearly human. Thus, these possible innovations may not be patentable due to their subject matter.[142]

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135. *See* Haas, *supra* note 45, at 146.

136. *See id.* at 145. The medical research charity, known as the Wellcome Trust, is the largest in the world and contributed approximately one-third of the research into the human genome. *Id.* at 151.

137. *Id.* (Once disclosed to the public, these genomic sequences lose their novelty and non-obvious status). *See also infra* § III.B and accompanying notes for a discussion of the statutory requirements of the Patent Act.

138. *See* Haas, *supra* note 45, at 152 (quoting the Human Genome Organization, HUGO Statement on Patenting of DNA Sequences, *at* http://www.gene.ucl.ac.uk/hugo/patent2000.html (Apr. 2000)). *See id.* at 158 (products "more removed . . . from the raw sequence, would still be patentable").

139. *See infra* § II.B.

140. *See* National Institutes of Health, *supra* note 13.

141. *See id.*

142. Since these theoretical products, which could be considered as compositions of matter under 35 U.S.C. § 101, must be viewed as human-related, they could be deemed non-patentable subject matter. *See supra* text accompanying notes 102-05.

However, the specific processes used to produce them may still remain eligible to receive patent protection.

Patents have already been issued for inventions involving specific procedures for isolating and purifying human embryonic stem cells. Dr. James Thompson was one of the first researchers to develop a patentable technique for isolating these cells from the human body, purifying them, and creating a cell line.[143] One such patent, U.S. Patent number 6,200,806, granted on March 13, 2001, covers claims of specific human embryonic stem cell lines, including the method used to obtain them.[144] Dr. Thompson assigned these and other patent rights to the University of Wisconsin Alumni Research Foundation, which subsequently licensed these rights to a commercial corporation.[145] This agreement is the subject of a current lawsuit between the parties regarding the scope of the agreement.[146] However, the validity of the patents have not been challenged.[147] Therefore, it appears that the PTO does not consider a claim of human stem cell lines to be directed to, or include within its scope, a human being.

Finding human stem cell lines to be patentable subject matter, the PTO has issued patents claiming human stem cells as compositions of matter.[148] Such patents have also been held valid in United States courts. For instance, in *Johns Hopkins University v. CellPro, Inc.*,[149] the U.S. Court of Appeals for the Federal Circuit found valid a patent claiming a suspension of human stem cells.[150] The issuing of such patents and the failure of

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143. *See* U.S. Patent No. 6,200,806 (issued Mar. 13, 2001). *See also* U.S. Patent No. 6,280,718 (issued Aug. 28, 2001) (claiming the method for isolating human embryonic stem cells).

144. *See* U.S. Patent No. 6,200,806 (issued Mar. 13, 2001), claims 1, 9, 11.

145. *University Foundation Sues Over Stem-Cell Patent*, INTELL. PROP. LITIG. REP., Sept. 18, 2001, at 8.

146. The University of Wisconsin Alumni Research Foundation (WARF) is suing the Geron Corporation regarding the extent of the licensing agreement. *Id.* As of October 30, 2001, the case was still in the pleadings stage with Geron filing an answer to the complaint and a motion for summary judgment on October 3, 2001 and WARF filing a response to the motion on October 30, 2001. *See Geron Continues Aggressive Development of Embryonic Stem Cell Technology*, BUS. WIRE, Nov. 1, 2001 [hereinafter *Geron Continues*].

147. *See Geron Continues*, *supra* note 146.

148. *See, e.g.*, U.S. Patent No. 4,965,204 (issued Oct. 23, 1990) (monoclonal antibodies and cells); U.S. Patent No. 6,090,622 (issued Jul. 18, 2000) (human embryonic germ cell line); U.S. Patent No. 6,117,675 (issued Sept. 12, 2000) (human retinal stem cells).

149. 152 F. 3d 1342, 1368 (Fed. Cir. 1998).

150. *See id.* at 1356. The type of stem cells involved were not embryonic stem cells, but a form of adult hematopoietic stem cells, which can form the different types of blood cells found in the body. *Id.* at 1346-47.

subsequent challenges to their validity proves that the patentability of human cells and biological materials is not within the scope of the PTO based on its policy statements.[151] However, once stem cell technology advances to include compositions of matter such as human organs, it is likely that the PTO will find that any claims to such inventions do violate the "human scope" policy statement. Thus, it is doubtful that patent protection will be available for these compositions of matter.

While the extent of patentability of human cells and biological materials appears unsettled, the patentability of other types of possible end products of stem cell research, such as new drugs and treatment techniques, appears to be more firmly established. If these inventions do not claim human "compositions" as an end product, then they should be patentable, even if the research methods involved employment of human stem cells. If the inventions fall under the "human scope" prohibition, the methods of obtaining these products could still be patentable. To date, several patents have been issued for the methods utilized in the isolation and purification of stem cells and in corresponding research.[152] These methods, along with those developed in the future, must only meet the patentability requirements set forth in the Patent Act. If they do, they should qualify for patent protection.

VI. CONCLUSION

The U.S. Government grants patents for useful inventions that benefit the general public. To receive patent protection, these inventions must be useful, novel, non-obvious, and adequately disclosed.[153] In addition, they must involve appropriate subject matter.[154] The PTO has indicated that it will not view a claim that includes within its scope, or is directed to, a

151. *See* U.S. Patent and Trademark Office Media Advisory, *supra* note 110.

152. *See, e.g.*, U.S. Patent No. 5,639,618 (issued Jun. 17, 1997) (method for isolating specific embryonic cells); U.S. Patent No. 5,843,780 (issued Dec. 1, 1998) (claiming a method for isolating primate embryonic stem cells); U.S. Patent No. 6,030,836 (issued Feb. 29, 2000) (method of maintaining human stem cells in vitro); U.S. Patent No. 6,090,622 (issued Jul. 18, 2000) (human embryonic germ cell line); U.S. Patent No. 6,093,531 (issued Jul. 25, 2000) (method of transforming neural stem cells into hematopoietic cells); U.S. Patent No. 6,117,675 (issued Sept. 12, 2000) (human retinal stem cells and a method for obtaining them); U.S. Patent No. 6,280,718 (issued Aug. 28, 2001) (method for isolating and purifying human embryonic stem cells).

153. *See* 35 U.S.C. §§ 101–103, 112 (2001).

154. *See id.* § 101.

human being, as encompassing patentable subject matter.[155] Therefore, patent laws may not protect inventions involving human biological materials.

The PTO's policy of denying patents for human-related subject matter is based on the constitutional prohibition of slavery. Thus, one cannot have property rights in humans. Although patents have been allowed for inventions that are human related, including inventions comprised of human genetic sequences and isolated and purified human stem cells, this practice cannot be extended to include the human end products of stem cell research. If researchers are able to grow human organs, such as kidneys and livers, in laboratory petri dishes, these inventions should not be patentable. While these products would definitely be the result of human genetic manipulation, they should still be considered part of the common heritage of humankind. In addition, they could not meet the subject matter requirement used by the PTO at this time. However, the specific processes and methods for creating such innovations should still remain eligible for patent protection. This will ensure that the ethical dichotomy is adequately addressed. Researchers, and their backing investors, will still be rewarded for their efforts and expenditures in creating technologies that can benefit the public. At the same time, the ethical and constitutional concerns will be met.

155. *See* Commissioner of Patents and Trademarks, *supra* note 102.