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AN OVERVIEW OF THE REGULATION AND PATENTABILITY OF HUMAN CLONING AND EMBRYONIC STEM CELL RESEARCH IN THE UNITED STATES AND ANTI-CLONING LEGISLATION IN SOUTH KOREA

Mikyung Kim†

I. INTRODUCTION

Scientists in South Korea have succeeded in obtaining embryonic stem (“ES”) cells from cloned human embryos.¹ A report published by the journal *Science* describes the work, in which thirty embryos, of about one hundred cells each, were created and used to harvest ES cells that later differentiated into a variety of tissue types.² While the findings offer hope for treating disease through so-called therapeutic cloning, they have revived legal and ethical debates in the United States.³

In this work, a team of researchers led by Woo Suk Hwang of Seoul National University collected two hundred forty oocytes⁴ from sixteen unpaid volunteers, who knew their oocytes would be used for scientific experiments.⁵ The researchers transferred the nucleus of a

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1. See Sarah Graham, *Cloned Human Embryos Yield Stem Cells*, SCIENTIFIC AMERICAN.COM, Feb. 13, 2004, at <http://www.sciam.com/article.cfm?articleID=000E0F1C-EF9D-102B-AF9D83414B7F0000>.

2. *Id.*; see also Woo Suk Hwang, et al., *Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst*, 303 SCIENCE 1669, 1669-74 (2004).

3. See Graham, *supra* note 1.

4. An oocyte is a developing egg cell. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1083 (24th ed. 1974).

5. See Hwang et al., *supra* note 2, at 1670. The researchers obtained approval for this study from the Institutional Review Board on Human Subjects Research and Ethics Committee (Hanyang University Hospital, Seoul, Korea).

somatic cell⁶ into an oocyte, which had had its nucleus removed, from the same donor.⁷ They used a slightly different technique to extract the contents of the egg—a gentle extrusion technique⁸ instead of the more commonly used suction technique⁹—which, together with the optimization of several critical steps, including careful timing and the freshness of the donated eggs, may have aided their success.¹⁰

Even with these improvements, the researchers could culture only thirty hollow balls of cells called blastocysts, which yielded just one ES cell line.¹¹ The resulting ES cells differentiated into three tissue types.¹² Furthermore, when transplanted into mice, the cells became more specialized, turning into cartilage, muscle, and bone.¹³

Recent developments in biotechnology confirm the rapid advances in cloning research, exacerbating fears that the specter of human clones looms in the near future.¹⁴ If scientists continue to overcome the technological difficulties, a legal regime that can address human cloning issues may be the only means of controlling the use of this revolutionary technology.

6. A somatic cell is a non-reproductive cell such as a cumulus cell (a follicular cell surrounding the ovum in the side of a developing vesicular ovarian follicle). DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1438 (24th ed. 1974).

7. See Hwang et al., *supra* note 2, at 1670. This is so-called somatic cell nuclear transfer ("SCNT"). In SCNT, the nucleus of an oocyte is removed and replaced by the nucleus from a mature body cell, such as a skin cell or cumulus cell. See *id.*

8. See Michael D. Lemonick, *Cloning Gets Closer*, TIME, Feb. 23, 2004, at 48, 50 (explaining that while most cloning researchers extract an egg's nucleus with a tiny pipette, Moon and Hwang made a pinhole in the cell wall and used a tiny glass needle to apply pressure and squeeze the nucleus out).

9. See Ian Wilmut, *Cloning for Medicine*, ISLAM SET, at <http://www.islamset.com/healnews/cloning/wilmut.html> (last visited May 5, 2005).

10. See Graham, *supra* note 1. The list of successfully cloned animals includes sheep, mice, horses and cats, among others, but primates have proved difficult. *Id.*; see also Hwang et al., *supra* note 2, at 1670 (stating that they optimized several critical steps, including reprogramming time, activation method, and in vitro culture conditions).

11. See Hwang et al., *supra* note 2, at 1670 (stating that a total of 30 SCNT-derived blastocysts were cultured, 20 inner cell masses were isolated by immunosurgical removal of the trophectoderm, and one ES cell line (SCNT-hES-1) was derived).

12. See *id.* Clumps of ES cells were cultured *in vitro* in suspension to form embryoid bodies. The resulting embryoid bodies were found to differentiate into a variety of cell types, including derivatives of endoderm, mesoderm, and ectoderm.

13. See *id.* When undifferentiated SCNT-hES-1 cells were injected into the testes of severe combined immunodeficient mice, teratomas were obtained six to seven weeks after injection. The resulting teratomas contained tissue representative of all three germ layers. Differentiated tissues include neuroepithelial rosettes, pigmented retinal epithelium, smooth muscle, bone, cartilage, connective tissues, and glandular epithelium. *Id.*

14. See Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?* 15 HARV. J.L. & TECH. 85, 96 (2001).

The scientific “society opposes reproductive cloning but strongly supports studies related to stem cells.”¹⁵ The National Academy of Sciences declared that therapeutic cloning has scientific potential and should be allowed to continue under appropriate guidelines.¹⁶ The National Institutes of Health and forty Nobel Laureates also attest to the value of this important research.¹⁷ Professor Hwang, who led the research, said, “Our inspiration is to treat incurable disease,” and “[a]s scientists, we think that this is our moral obligation [to treat incurable disease].”¹⁸ However, Professor Hwang’s work has global political implications, and legislators in many countries remain sharply divided on how to regulate cloning advances or whether to permit them at all.¹⁹ Cloning is not safe. For example, Dolly the sheep was the result of two hundred and seventy-seven attempts to create a living clone.²⁰ Some believe that cloning treats human life like a commodity.²¹ Although it is broadly agreed upon that cloning should not be used to reproduce humans, the technology’s use in the laboratory for making ES cells continues to provoke strong feelings on both sides of the debate.²²

Human cloning is explicitly banned in many countries, including South Korea.²³ Many regulatory positions distinguish between creating a cloned embryo for reproductive purposes (reproductive cloning) and for other purposes such as therapeutic or research

15. Antonio Regalado, *Koreans Clone Human Embryo, Reap Stem Cells*, WALL ST. J., Feb. 12, 2004, at B1 (quoting Donald Kennedy, Editor-in-chief of *Science*). Experts say this is the first bona fide publication disclosing how to clone human embryos. The technology, sometimes called “therapeutic cloning,” could open the door to custom-tailored transplant treatments for such conditions as diabetes and spinal-cord injury. *Id.*

16. See 149 CONG. REC. H1397, H1398 (daily ed. Feb. 27, 2003) (statement of Rep. McGovern).

17. See *id.*

18. See Regalado, *supra* note 15.

19. See *id.*

20. See 149 CONG. REC. H1397, H1399 (daily ed. Feb. 27, 2003) (statement of Rep. Pitts).

21. *Id.*

22. See Regalado, *supra* note 15. Because of hopes it will lead to cures, patient groups have rallied strongly behind the technique. Paralyzed actor Christopher Reeve called therapeutic cloning his best chance for a cure, and had joined advocates in California who planned to introduce a ballot measure to raise \$3 billion from the state for such research. Critics oppose therapeutic cloning both on religious grounds and out of concern that human embryos are becoming an industrial commodity, created specifically for use in medical experimentation. *Id.*

23. See Shaun D. Pattinson & Timothy Caulfield, *Variations and Voids: The Regulation of Human Cloning around the World*, BMC Medical Ethics, at <http://www.biomedcentral.com/1472-6939/5/9> (last visited Apr. 17, 2004); see also Lemonick, *supra* note 8, at 49.

cloning.²⁴ No jurisdiction has adopted legislation or guidelines permitting reproductive cloning.²⁵ However, with regard to the banning of non-reproductive cloning, countries have taken different positions.²⁶ According to a report, out of thirty countries studied, seventeen prohibit non-reproductive cloning and thirteen permit it.²⁷ The regulatory approaches of countries that have adopted regulatory measures on cloning vary greatly and the legal position in some countries remains uncertain.²⁸

The patentability of inventions created via human cloning and stem cell research raises another issue, specifically the United States Patent and Trademark Office's ("USPTO") human being exception. Professor Hwang filed applications for patents based on the results of his research.²⁹ In Professor Hwang's patents, he might have claimed a pluripotent ES cell line ("SCNT-hES-1") from a cloned human blastocyst; a method for establishing SCNT-hES-1; and/or specialized cells subsequently developed from SCNT-hES-1 such as neuronal cells. In the light of the human being exception under the current USPTO policy, the availability of patent protection for such inventions in the United States would eventually call for an answer to the question of what is the definition of a human being.³⁰

This article will review human cloning and ES cell research, the federal regulation of human cloning and ES cell research in the United States in comparison to the anti-cloning legislation in South Korea, and the availability of patent protection of the results derived from human cloning and ES cell research in the United States will be reviewed.

24. See Pattinson & Caulfield, *supra* note 23.

25. See *id.* There are essentially only two regulatory approaches to reproductive cloning: prohibition or regulatory silence. *Id.*

26. See *id.*

27. *Id.*

28. *Id.*

29. See Claudia Dreifus, *2 Friends, 242 Eggs and a Breakthrough: A Conversation with Woo Suk Hwang and Shin Yong Moon*, N.Y. TIMES, Feb. 17, 2004, at F1 (quoting Hwang, "We have applied for a worldwide P.C.T. [Patent Cooperation Treaty] patent for the technique we developed and also the cloned human embryo stem cells.").

30. See *infra* Part IV.A.1.b.

II. HUMAN EMBRYONIC STEM CELL RESEARCH

A. Characteristics and Types of Stem Cells

Stem cells have three important characteristics that distinguish them from other types of cells.³¹ All stem cells, regardless of their source, are capable of dividing and renewing themselves for long periods; are undifferentiated³²; and can give rise to specialized cell types such as nerve, blood, or liver cells.³³ Stem cells come in different varieties, relating to when and where they are produced during development, and how versatile they are in terms of developmental capabilities.³⁴ In the three- to five-day-old cloned embryo, called a blastocyst, a small group of about thirty cells, called the inner cell mass, gives rise to the hundreds of ES cells, very special cells which can transform into any type of tissue.³⁵ In the developing fetus, stem cells in developing tissues differentiate into multiple specialized cell types that form the heart, lung, skin, and other tissues to make up an adult organism.³⁶ An adult stem cell that is an undifferentiated cell of unknown origin is found among differentiated cells in a tissue or organ.³⁷ An adult stem cell can renew itself, and can differentiate to yield the major specialized cell types of the particular tissue or organ.³⁸ The primary physiological roles of adult stem cells in a living organism are to maintain and repair the tissue in which they are found.³⁹ Scientists primarily work with ES cells and

31. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: STEM CELL BASICS: II. WHAT ARE THE UNIQUE PROPERTIES OF ALL STEM CELLS?, at <http://stemcells.nih.gov/info/basics/basics2.asp> (last visited Apr. 6, 2005) [hereinafter NATIONAL INSTITUTES OF HEALTH II].

32. See *id.* (stating that undifferentiated means not having changed to become a specialized cell type); see also DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1672 (24th ed. 1974) (stating that undifferentiated means absent of normal differentiation).

33. See NATIONAL INSTITUTES OF HEALTH II, *supra* note 31.

34. See *id.*

35. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: STEM CELL BASICS: III. WHAT ARE EMBRYONIC STEM CELLS?, at <http://stemcells.nih.gov/info/basics/basics3.asp> (last visited Feb. 26, 2005) [hereinafter NATIONAL INSTITUTES OF HEALTH III].

36. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: REPORT ON STEM CELLS, APPENDIX A: EARLY DEVELOPMENT, at <http://stemcells.nih.gov/info/scireport/PDFs/appendixa.pdf> (last modified Aug. 20, 2004).

37. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: STEM CELL BASICS: IV. WHAT ARE ADULT STEM CELLS?, at <http://stemcells.nih.gov/info/basics/basics4.asp> (last visited Feb. 26, 2005) [hereinafter NATIONAL INSTITUTES OF HEALTH IV].

38. See *id.*

39. *Id.*

adult stem cells obtained from animals and humans.⁴⁰ The relative merits of using ES cells and adult stem cells for research are still a subject of debate.⁴¹

B. Cloning Employing Human Somatic Cell Nuclear Transfer (SCNT)

Human ES cell research can further be divided based on whether human ES cells come from cloning employing human somatic cell nuclear transfer (“SCNT”) or from conventional *in vitro* fertilization. SCNT is generally defined as transferring the nucleus of a human somatic cell⁴² into an oocyte from which the nucleus has been removed or rendered inert.⁴³ As mentioned earlier, the focus of the debate over governmental regulation on human ES cell research in the United States is whether ES cells come from cloning employing SCNT or from conventional *in vitro* fertilization.

Human ES cell research using cells created by SCNT, can be classified as reproductive cloning or therapeutic cloning.⁴⁴ Reproductive cloning is generally defined as the use of cloning technology, for initiating a pregnancy, while therapeutic cloning is defined as conducting research on pluripotent stem cells that are derived from a cloned embryo.⁴⁵ Therefore, both reproductive cloning and therapeutic cloning involve creating human embryos, only for different purposes—initiating a pregnancy by implanting a cloned embryo rather than conducting research on cloned embryos to develop cell-based therapies.

Any discussion about the propriety of cloning should identify both the type of technique being contemplated and the ends to which

40. *Id.*; see NATIONAL INSTITUTES OF HEALTH II, *supra* note 31.

41. See Stuart H. Orkin & Sean J. Morrison, *Biomedicine: Stem-Cell Competition*, 418 NATURE 25, 25–27 (2002) (referencing two papers that look at the abilities of embryonic and adult stem cells; one by Kim Jong-Hoon et al., *infra* note 63 and the other by Jiang Yuehua et al., *infra* note 69).

42. A somatic cell is a body cell, as opposed to a germ cell, which is an egg [oocyte] or sperm cell. See DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1083, 1438 (24th ed. 1974).

43. See Jose B. Cibelli, et al., *The First Human Cloned Embryo*, SCIENTIFIC AMERICAN.COM, Nov. 24, 2001, at http://www.sciam.com/print_version.cfm?articleID=0008B8F9-AC62-1C75-9B81809EC588EF21; see also Jana Brenning, *Therapeutic Cloning: How It’s Done*, SCIENTIFIC AMERICAN.COM, Nov. 24, 2001, at http://www.sciam.com/print_version.cfm?articleID=00016CF7-CE54-1CF4-93F6809EC5880000.

44. See Cibelli et al., *supra* note 43.

45. See *id.*

that technique is directed.⁴⁶ The term cloning encompasses a variety of research techniques and cloning technologies can be used for other purposes besides producing the genetic twin of a non-human organism.⁴⁷ Many cloning techniques are already widely accepted for both scientific and industrial purposes.⁴⁸ Current debate over governmental regulation is focused on the use of human therapeutic cloning to create genetically identical ES cell lines using a patient's own genetic material obtained using nuclear transfer for the purpose of cell-based therapies.

C. *The Scientific Importance of Stem Cell Research*

Human cloning employing SCNT is scientifically important because of the utility of human embryonic stem cells in research, and perhaps, in patient treatment. Studies of human embryonic stem cells are advancing knowledge about how an organism develops from a single cell and how healthy cells replace damaged cells in adult organisms.⁴⁹ These studies are also leading scientists to investigate the possibility of cell-based therapies to treat disease, often referred to as regenerative or reparative medicine.⁵⁰ Many biologists are interested in using cloning techniques to genetically match cells to patients for rejection-free transplants and research.⁵¹

Human ES cells and adult stem cells each have advantages and disadvantages regarding their potential use for cell-based regenerative therapies.⁵² ES cells derived from very early human embryos can proliferate indefinitely in culture while retaining the potential to differentiate into virtually any cell type when coaxed.⁵³ Stem cells collected from tissues of adults or older embryos are typically more

46. See Merrill & Rose, *supra* note 14, at 92.

47. See *id.* at 90–97. Cloning, which literally means to make a copy, is the asexual reproduction of a precise genetic copy of a molecule, cell, tissue, plant, or animal. The word “cloning” can be used as a generic term to describe several different techniques of cloning. Molecular cloning refers to the copying of DNA fragments. For example, the human gene for insulin has been cloned into bacteria to produce insulin for the treatment of diabetes. In addition, human cells are routinely cloned to study cancer or genetic diseases. *Id.*

48. See *id.*

49. See NATIONAL INSTITUTES OF HEALTH II, *supra* note 31.

50. See *id.*

51. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: STEM CELL BASICS: V. WHAT ARE THE SIMILARITIES AND DIFFERENCES BETWEEN EMBRYONIC AND ADULT STEM CELLS?, at <http://stemcells.nih.gov/info/basics/basics5.asp> (last visited Apr. 9, 2005) [hereinafter NATIONAL INSTITUTES OF HEALTH V].

52. See *id.*

53. See Orkin & Morrison, *supra* note 41, at 25.

restricted in their developmental potential and ability to proliferate.⁵⁴ These distinctive properties are important, as stem cell replacement therapies need a large number of cells as well as different kinds of cells in order to effectively treat different diseases.⁵⁵

However, there are technical obstacles to the use of ES cells.⁵⁶ First, ES cells can only be obtained from very early embryos and, although several cell lines have been made from the ES cells obtained; they will not be immunologically compatible with most people who require cell transplants.⁵⁷ Thus, researchers need to derive more ES cell lines unless they customize ES cells on an individual patient basis using therapeutic cloning.⁵⁸ Second, after being transplanted undifferentiated ES cells form teratomas, which contain various tissue types.⁵⁹ In order to be used for a specific cell-based therapy, ES cells must be reliably differentiated into the appropriate cell type in culture before transplantation.⁶⁰ Finally, it has not yet been proved that specialized cells derived from cultured ES cells actually function within tissues after transplantation.⁶¹ It is possible that cells generated *in vitro* are not equivalent to those arising *in vivo*.⁶² Cells generated *in vitro* lack the benefit of the extensive cellular interactions and education that take place during *in vivo* development.⁶³

One potential advantage of using adult stem cells is that a patient's own cells could be multiplied in culture and reintroduced into the patient without being rejected by the immune system.⁶⁴ This represents a significant advantage, as immune rejection is a major problem that can only be circumvented with immunosuppressive

54. *See id.* For example, hematopoietic stem cells make all types of blood cells *in vivo*, but proliferate little in culture and have been though not to make cells of other tissues. *Id.*; *see also* NATIONAL INSTITUTES OF HEALTH II, *supra* note 31. Adult stem cells are rare in mature tissues and methods for expanding their numbers in cell culture have not yet been worked out. *Id.*

55. *See* NATIONAL INSTITUTES OF HEALTH III, *supra* note 35.

56. *See* Orkin & Morrison, *supra* note 41, at 25.

57. *See id.*

58. *Id.*

59. *Id.*; *see* Hwang et al., *supra* note 2, at 1671-72.

60. *See generally* Orkin & Morrison, *supra* note 41.

61. *See id.*

62. Orkin & Morrison, *supra* note 41, at 25.

63. *Id.*; *see also* Jong-Hoon Kim et al., *Dopamine Neurons Derived from Embryonic Stem Cells Function in an Animal Model of Parkinson's Disease*, 418 NATURE 50, 50-56 (2002) (reporting that the research team has overcome this problem in its work on rats with symptoms of human Parkinson's disease).

64. *See* NATIONAL INSTITUTES OF HEALTH V, *supra* note 51.

drugs.⁶⁵ Another advantage of using adult stem cells is that certain kinds of adult stem cells seem to have the ability to differentiate into a number of different cell types, given the right conditions.⁶⁶ For example, neural stem cells seem to have a previously unsuspected developmental flexibility.⁶⁷ Adult stem cells in which differentiation can be controlled in the laboratory, may become the basis of therapies for many serious common diseases.⁶⁸ Therefore, exploring the possibility of using adult stem cells for cell-based therapies has become a very active area of investigation by researchers.⁶⁹

Human therapeutic cloning employing SCNT has raised the possibility of generating potentially unlimited sources of undifferentiated cells for use in research, with potential applications in tissue repair and transplantation medicine.⁷⁰ Particularly, after directed cell differentiation, SCNT-derived ES cells carrying the nuclear genome of the patient⁷¹ could be transplanted without invoking immune reaction.⁷² Further, the pluripotency of ES cells has the potential to accommodate the various needs of patients affected by many devastating conditions including diabetes, osteoarthritis, and Parkinson's disease.⁷³

65. *Id.*; see NATIONAL INSTITUTES OF HEALTH IV, *supra* note 37 (noting that adult blood forming stem cells from bone marrow have been used in transplants for thirty years).

66. See NATIONAL INSTITUTE OF HEALTH IV, *supra* note 37. Developments in research on adult stem cells have led scientists to ask whether adult stem cells could be used for transplants. In the 1960s, researchers discovered that the bone marrow contains at least two kinds of stem cells: hematopoietic stem cells, which forms all the types of blood cells in the body, and bone marrow stromal cells, which have potential to generate bone, cartilage, fat, and fibrous connective tissue. *Id.*

67. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: REPORT ON STEM CELLS, THE ADULT STEM CELL, at <http://stemcells.nih.gov/info/scireport/chapter4.asp> (last modified Aug. 20, 2004). Scientists now agree that the adult brain does contain stem cells that are able to generate the brain's three major cell types—astrocytes and oligodendrocytes, which are non-neuronal cells, and neurons or nerve cells. *Id.*

68. See NATIONAL INSTITUTES OF HEALTH IV, *supra* note 37.

69. See, e.g., Yuehua Jiang et al., *Pluripotency of Mesenchymal Stem Cells Derived from Adult Marrow*, 418 NATURE 41, 41–49 (2002).

70. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: STEM CELL BASICS: VI. WHAT ARE THE POTENTIAL USES OF HUMAN STEM CELLS AND THE OBSTACLES THAT MUST BE OVERCOME BEFORE THESE POTENTIAL USES WILL BE REALIZED?, at <http://stemcells.nih.gov/info/basics/basics6.asp> (last visited Feb. 26, 2005) [hereinafter NATIONAL INSTITUTES OF HEALTH VI].

71. See Cibelli et al., *supra* note 43; see also Brenning, *supra* note 43.

72. See Cibelli et al., *supra* note 43.

73. See NATIONAL INSTITUTES OF HEALTH VI, *supra* note 70.

III. REGULATION OF HUMAN CLONING AND EMBRYONIC STEM CELL RESEARCH

A. *Federal Regulation of Human Cloning and ES Cell Research in the United States*

Currently, no United States laws or regulations prohibit all cloning research.⁷⁴ Cloning techniques remain legal in the United States.⁷⁵ Congress has failed to enact anti-cloning legislation. However, human cloning and ES cell research in the United States have been severely limited. The federal government allows the use of federal funds for work on embryonic stem cells, but only on cell lines from sanctioned samples.⁷⁶ Those cells lines, far fewer than were promised, have many limitations and may be unsuitable for future therapeutic applications.⁷⁷

1. Constitutional Basis for a Federal Government Ban on Human Cloning

The federal government may justify regulation of human cloning by linking such regulation to its spending power or its power to regulate interstate commerce.⁷⁸ First, a federal ban on human cloning research using federal funds is a permissible exercise of federal spending power.⁷⁹ The federal government regulates a variety of medical and scientific activities that are linked to government funding.⁸⁰ For example, as a condition of receiving Medicare funds, the federal government has imposed regulations on health care providers which prohibit certain forms of fraud and abuse.⁸¹ In

74. See JUDITH A. JOHNSON & ERIN WILLIAMS, CRS REPORTS FOR CONGRESS: HUMAN CLONING, at CRS-3 (Aug. 17, 2004), available at <http://hutchison.senate.gov/RL31358.pdf>.

75. See Pattinson & Caulfield, *supra* note 23.

76. See Press Release, Office of the Press Secretary, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>.

77. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: INFORMATION ON ELIGIBILITY CRITERIA FOR FEDERAL FUNDING OF RESEARCH ON HUMAN EMBRYONIC STEM CELLS, at <http://stemcells.nih.gov/registry/eligibilityCriteria.asp> (last modified Aug. 11, 2004); Alvin Powell, *From the Laboratory to the Patient: Stem Cell Institute Will Call on Expertise from around the University to Turn Research into Therapy*, HARV. UNIV. GAZETTE, Apr. 22, 2004, at <http://www.news.harvard.edu/gazette/2004/04.22.99-StemOver.html>.

78. See Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 670 (1998).

79. See *id.*

80. *Id.*

81. *Id.*

conjunction with providing federal funds for scientific research, scientists must abide by federal regulations governing research.⁸² Therefore, the federal government may prohibit human cloning by banning the use of government funds for any research related to human cloning or by requiring researchers to avoid such activities as a condition of receiving federal funds.

Additionally, under the Commerce Clause the federal government may regulate private research, which is conducted with non-governmental funds or at institutions that do not receive federal funding.⁸³ Pursuant to the commerce power, Congress may regulate interstate commerce, i.e., the channels and instrumentalities of interstate commerce.⁸⁴ Congress is also empowered to regulate things or persons in or using those channels or instrumentalities if the regulated activities are economic activities that substantially affect interstate commerce as defined under governing United States Supreme Court cases.⁸⁵

In *United States v. Darby*, the Supreme Court stated that the power of Congress over interstate commerce “extends to those activities intrastate which so affect interstate commerce or the exercise of the power of Congress over it as to make regulation of them appropriate means to the attainment of a legitimate end, the exercise of the granted power of Congress to regulate interstate commerce.”⁸⁶ In *Wickard v. Filburn*, the Court ruled that Congress may regulate wheat production even if homegrown wheat only indirectly caused a substantial economic effect on interstate commerce.⁸⁷ The Court sustained the Agricultural Adjustment Act when private consumption of homegrown wheat could collectively have a substantial effect on interstate commerce.⁸⁸

In *Katzenbach v. McClung*, the Court held that Congress may regulate racial discrimination by a private restaurant that received food from out-of-state suppliers.⁸⁹ The Court reasoned that while such activity by one local restaurant might have very little impact on interstate commerce, the aggregation of that restaurant and others

82. *Id.*

83. *Id.*

84. See Allan Ides, *The Partial-Birth Abortion Ban Act of 2003 and the Commerce Clause*, 20 CONST. COMMENT. 441, 443–44 (2003–04).

85. See *id.* at 444–45.

86. See *United States v. Darby*, 312 U.S. 100, 118 (1941).

87. See *Wickard v. Filburn*, 317 U.S. 111, 125 (1942).

88. See *id.* at 127–29.

89. See *Katzenbach v. McClung*, 379 U.S. 294 (1964).

similarly situated could have a substantial effect on interstate commerce.⁹⁰ In *Perez v. United States*, the Court upheld the federal regulation of “loan sharking,” largely controlled by organized crime, by deferring to Congress’ determination that purely intrastate extortionate credit transactions affect interstate commerce.⁹¹

While the Court had maintained an expansive reading of the Commerce Clause in deference to Congress in *Darby*, *Wickard*, *McClung*, and *Perez*, the Court restricted the breadth of the Clause in the more recent cases, holding that Congress exceeded its commerce power by attempting to regulate matters that were non-economic and that had at best an attenuated connection with interstate commerce.⁹² In *United States v. Lopez*⁹³ and *United States v. Morrison*,⁹⁴ the Court held that the Gun-Free School Zones Act of 1990 and 42 U.S.C. § 13981, which provided a federal civil remedy for the victims of gender-motivated violence, respectively, exceeded the authority of Congress to regulate commerce among the several states under the Commerce Clause. The Court held that both possession of a gun in a local school zone and gender-motivated crimes of violence are not an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce.⁹⁵ Both the Act and § 13981 contained no jurisdictional element insuring that the firearm possession in question affected interstate commerce⁹⁶ or establishing a federal cause of action that was in pursuance of Congress’ power to regulate interstate commerce.⁹⁷ In both cases, the Court stated that the Constitution required a distinction between what was truly national and what was truly local in recognition of general state police power.⁹⁸

With respect to whether the Tenth Amendment limits the commerce power, in *National League of Cities v. Usery*, the Court concluded that the Tenth Amendment placed a substantive restriction on the commerce power.⁹⁹ Under the notion of state sovereignty, the Court found the federal regulations that impaired the states’ authority

90. *See id.* at 300–01.

91. *See Perez v. United States*, 402 U.S. 146 (1971).

92. *See Ides, supra* note 84, at 445.

93. *See United States v. Lopez*, 514 U.S. 549 (1995).

94. *See United States v. Morrison*, 529 U.S. 598 (2000).

95. *See Lopez*, 514 U.S. at 561; *Morrison*, 529 U.S. at 613.

96. *See Lopez*, 514 U.S. at 561; *Morrison*, 529 U.S. at 613.

97. *See Morrison*, 529 U.S. at 611–12.

98. *See Lopez*, 514 U.S. at 557; *Morrison*, 529 U.S. at 617–18.

99. *See Nat’l League of Cities v. Usery*, 426 U.S. 833, 842 (1976).

to govern in matters of traditional state concern were outside the scope of the commerce power.¹⁰⁰ However, in *Garcia v. San Antonio Metropolitan Transit Authority*, the Court found that the states' involvement in federal decision-making gave them a remedy through the political process, implying that if a statute contains the requisite connection to interstate commerce, it is constitutional despite any encroachment on areas of traditional state authority.¹⁰¹ Still more recently, in *New York v. United States*, the Court spoke of the Tenth Amendment as a restriction on the federal government's enumerated powers.¹⁰²

From the analysis of the prior United States Supreme Court cases regarding federal powers, whether any anti-human cloning bill would be sustained under the Commerce Clause would depend upon whether 1) human cloning would involve the use of channels or instrumentalities of interstate commerce, or 2) the cloning activities would have a substantial relationship to interstate commerce. The second category would depend upon whether a) the cloning activity would be an economic activity that substantially affects interstate commerce; and b) the regulation including a jurisdictional element would require that the cloning activity be connected to interstate commerce. The court would also consider whether the regulation of the cloning would encroach on matters of traditional state concern.

According to Professor Lori B. Andrews, a close analysis of United States Supreme Court cases regarding federal powers provides justification for federal action in the area of human cloning.¹⁰³ Cloning can be considered a commercial activity or product like medicine.¹⁰⁴ Cloning could have a substantial impact on interstate commerce similar to the activities of health care providers such as dentists.¹⁰⁵ When analogized to the cases challenging the constitutionality of the Freedom of Access to Clinic Entrances Act,¹⁰⁶ cloning clinics as well as cloning facilities would encompass activities that would substantially affect interstate commerce.¹⁰⁷ Any business involved with cloning that hires employees and purchases equipment from out of state and then brings them into the state where

100. *See id.* at 855.

101. *See Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 554 (1985).

102. *See New York v. United States*, 505 U.S. 144, 155-57 (1992).

103. *See Andrews, supra* note 78, at 669-75.

104. *See id.* at 671-72.

105. *Id.* at 672-73.

106. 18 U.S.C. § 248 (1994).

107. *Andrews, supra* note 78, at 673-74.

they are located is engaged in interstate commerce.¹⁰⁸ Additionally, by sharing information and research findings in a national arena, and traveling and attending national classes and conferences, cloning activity may satisfy the “substantially affects” requirement.¹⁰⁹

Professor Andrews differentiated the activity of cloning from the activities at issue in *Lopez*.¹¹⁰ Unlike primary and secondary education, cloning activity does not affect an area of historically extensive state regulation; and cloning would be provided at a national level rather than a local level by a limited number of facilities around the country that draw personnel and patients from a national market.¹¹¹ It was also noted that human research has primarily been funded and regulated by the federal government; a few states have regulated the conduct of human research.¹¹² At least ten states have introduced bills to deal with the issue of cloning.¹¹³ The importance of providing a sufficient legislative history was also noted. A sufficient legislative history is necessary to indicate how cloning would affect interstate commerce, establish why cloning is of national importance, and document state legislative actions specifically asking for the federal government to intervene in this area.¹¹⁴

2. Federal Ban on Human Cloning Research

a. *Rider to the Consolidated Appropriations Act*

A rider has affected funding for the National Institutes of Health (“NIH”).¹¹⁵ The rider prohibits the Department of Health and Human Services (“HHS”) from using appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed.¹¹⁶ This rider has been attached to the Labor, HHS and Education Appropriations Acts for the 1997 fiscal year

108. *Id.* at 674.

109. *See id.* at 674.

110. *See id.*, *supra* note 78, at 674–75.

111. *See id.* at 675.

112. *See id.*; *see also* National Conference of State Legislature, *State Human Cloning Laws*, available at <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm> (last updated Mar. 12, 2004).

113. *See Andrews, supra* note 78, at 75; *see also* National Conference of State Legislature, *supra* note 112. As of March 12, 2004, at least ten states have enacted anti-cloning statutes. *Id.*

114. *See Andrews, supra* note 78, at 675.

115. *See JOHNSON & WILLIAMS, supra* note 74, at CRS-5.

116. *See id.*

through the 2004 fiscal year.¹¹⁷ Current statutory language prohibits HHS from using 2004 fiscal year appropriated funds for:

(1) the creation of a human embryo or embryos for research purposes; or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 . . . that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.¹¹⁸

b. Moratorium by President Clinton

In response to the creation of Dolly the sheep¹¹⁹ and concerns about the potential application of cloning humans, politicians around the world proposed or implemented bans on human cloning.¹²⁰ In the United States, President Bill Clinton instituted a moratorium on federal funding for human cloning experiments.¹²¹ Clinton also urged the private sector to adopt a voluntary ban on the cloning of human

117. *Id.* at CRS-5 n.15; *see, e.g.*, Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 510(a), 118 Stat 3, 277 (2004).

118. *See* Consolidated Appropriations Act of 2004 § 510.

119. *See* Tim Beardsley, *A Clone in Sheep's Clothing*, SCIENTIFIC AMERICAN.COM, Mar. 3, 1997, at http://www.sciam.com/print_version.cfm?articleID=0009B07D-BD40-1C59-B882809EC588ED9F (discussing results of experiments reported in I. Wilmut, et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810, 810-13 (1997)). Scientists in Scotland had used SCNT in 1996 to produce the first cloned adult mammal, Dolly, the sheep. Scientists at the Roslin Institute in Edinburgh removed the nucleus from a sheep egg and replaced it with the nucleus of a mammary gland cell from an adult sheep. The resulting embryo was then transferred to the uterus of a surrogate sheep. A total of 277 such embryos were transferred, but only one lamb was born. Analyses of Dolly's genetic material confirmed that she was derived from the adult lamb's mammary cell. They reported their results in *Nature*. *Id.*

120. *See* Pattinson & Caulfield, *supra* note 23.

121. *See* *Clinton Bars Federal Funds for Human Cloning Research*, CNN.COM, Mar. 4, 1997, at <http://www.cnn.com/TECH/9703/04/clinton.cloning/>; *see also* JOHNSON & WILLIAMS, *supra* note 74, at CRS-5. One month after the Dolly announcement, on March 4, 1997, President Clinton sent a memorandum to the heads of all executive departments and agencies making it "absolutely clear that no federal funds will be used for human cloning." *Id.* This action extended the congressional ban beyond HHS to all federally supported research. *Id.*

beings.¹²² The *NIH Guidelines on Stem Cell Research*, published by the Clinton Administration in August 2000, would not fund research in which: (1) human stem cells were used for reproductive cloning of a human; (2) human stem cells were derived using SCNT; or, (3) human stem cells that were derived using SCNT were utilized in a research project.¹²³

c. Decision by President Bush

The August 9, 2001 Bush Administration policy decision on stem cell research stated that federal funds would not be used for the cloning of human embryos for any purpose.¹²⁴ The President announced that federal funds may be awarded for research on existing stem cell lines that were derived: (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors.¹²⁵ In contrast, no federal funds would be used for: (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose.¹²⁶

According to a NIH report, investigators from ten laboratories in the United States, Australia, India, Israel, and Sweden had already derived stem cells from seventy-one individual, genetically diverse blastocysts before President Bush's announcement.¹²⁷ The NIH reports approximates that sixteen existing stem cell lines from genetically diverse populations around the world would satisfy the Bush Administration's criteria and be available for federally-funded research.¹²⁸ It is debatable whether the existing cell lines can satisfy all needs of scientists in terms of their availability and quality.¹²⁹ President Bush's decision in 2001 does not prohibit a private

122. See JOHNSON & WILLIAMS, *supra* note 74, at CRS-5.

123. See *id.*

124. *Id.* at CRS-5 to CRS-6.

125. See Press Release, Office of the Press Secretary, *supra* note 76.

126. See *id.*

127. See NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: NIH'S ROLE IN FEDERAL POLICY, at <http://stemcells.nih.gov/policy/NIHFedPolicy.asp> (last modified Jun. 10, 2004).

128. See NATIONAL INSTITUTES OF HEALTH, *supra* note 77.

129. See Carol Ezzell, *Cloning and the Law*, SCIENTIFIC AMERICAN.COM, Nov. 24, 2001, at http://www.sciam.com/print_version.cfm?articleID=000D0F6B-D3A0-1CF4-93F6809EC5880000.

company from conducting stem cell research if it uses its own funds.¹³⁰

d. Legislative Activities

Eight federal cloning bills that would prohibit SCNT to create human beings and which could be interpreted as banning any cloning technique in which an embryo is used, were proposed between March 1997 and February 1998.¹³¹ Five of the proposed bills would ban both private and federal funding for conducting or supporting human cloning or human cloning research, while three of the proposed bills would only ban the use of federal funding.¹³²

Interest in the issue began almost immediately at the beginning of the 107th Congress, with independent announcements by two scientists and a religious cult leader that they were working on the technology to clone humans.¹³³ In addition, the announcement by Advanced Cell Technology, a biotechnology company, that it had cloned the first human embryos, galvanized opposition to cloning

130. See Powell, *supra* note 77 (noting that Douglas Melton of Harvard University announced he had created seventeen new ES cell lines with private funds in February 2004).

131. See Andrews, *supra* note 78, at 677–79 tbl. 1. The eight bills consisted of three House bills, four Senate bills and one by President Clinton. Of the eight proposals, six could be read to ban transferring DNA into nonhuman cells; one was to ban embryo splitting. *Id.*

132. See *id.* Five proposals would impose civil penalties while one would impose criminal penalties. Two proposals would have a sunset clause. Four proposals would establish a review body that reports to legislature. *Id.*

133. See Office of Legislative Policy and Analysis, 107th Congress, *Legislative Updates: Cloning*, at <http://olpa.od.nih.gov/legislation/107/pendinglegislation/7cloning.asp> (last visited Apr. 19, 2005); see also Rick Weiss, *A Crucial Human Cell Isolated, Multiplied*, WASH. POST, Nov. 6, 1998, at A1, available at <http://www.washingtonpost.com/wp-srv/national/cell110698.htm>.

James A. Thomson, an embryologist at the University of Wisconsin, and his colleagues describe their success in today's issue of the journal *Science*. John D. Gearhart of the Johns Hopkins University School of Medicine in Baltimore led the other effort, results of which will appear in the Nov. 10 issue of the *Proceedings of the National Academy of Sciences*.

Id.; see also *Reproductive Cloning: They Want to Make a Baby*, SCIENTIFIC AMERICAN.COM, Nov. 24, 2001, at http://www.sciam.com/print_version.cfm?articleID=000CCD17-DB53-1CF4-93F6809EC5880000. The Raelians, a religious group, formed a company called Clonaid. A chemist of Clonaid told the National Academy meeting in August 2001 that Clonaid had hundreds of women willing to contribute eggs for use in cloning. The chemist argued that people should have the liberty to reproduce how they want, whether by combining their genetic material with another person's through sex or *in vitro* fertilization or by using only their own genetic material to create a clone. *Id.*

technology and led to the House passage of a measure that would criminalize both reproductive and therapeutic cloning.¹³⁴

During the 107th Congress, the debate centered on whether to legislatively ban reproductive cloning alone, or both reproductive cloning and therapeutic cloning.¹³⁵ The House of Representatives held four hearings on this issue.¹³⁶ The House passed a broad ban on all forms of human cloning,¹³⁷ but the Senate failed to act, leaving the matter to the 108th Congress to resolve.¹³⁸

During the 108th Congress, Congress continued to study various proposals for enacting a total ban of human cloning by exercising federal spending power and the power to regulate interstate commerce. The announcement by Clonaid led several members of Congress to introduce cloning bills soon after the 108th Congress convened.¹³⁹ Again, there was considerable disagreement regarding therapeutic cloning.¹⁴⁰ The Weldon-Stupak bill (House Bill 534), prohibiting both human reproductive and therapeutic cloning, passed the House of Representatives.¹⁴¹ The House rejected a competing proposal that would allow and encourage the creation of human embryos by cloning and would ban the use of any such cloned embryo to initiate a pregnancy.¹⁴²

134. See Office of Legislative Policy and Analysis, 107th Congress, *Legislative Updates: Cloning*, at <http://olpa.od.nih.gov/legislation/107/pendinglegislation/7cloning.asp> (last visited Apr. 19, 2005); see also Cibelli et al., *supra* note 43; Gary Stix, *What Clones?: Were Claims of the First Human Embryo Premature?*, SCIENTIFIC AMERICAN.COM, Dec. 24, 2001, at <http://www.sciam.com/article.cfm?articleID=000C5BD8-EE3D-1CF4-93F6809EC5880000&pageNumber=3&catID=4>.

135. See Office of Legislative Policy and Analysis, 107th Congress, *Legislative Updates: Cloning*, at <http://olpa.od.nih.gov/legislation/107/pendinglegislation/7cloning.asp> (last visited Apr. 19, 2005).

136. See *id.*

137. *Id.*

138. *Id.*

139. See Office of Legislative Policy and Analysis, 108th Congress, *Legislative Updates: Cloning*, at <http://olpa.od.nih.gov/legislation/108/pendinglegislation/cloning1.asp> (last visited Apr. 19, 2005). "On December 27, 2002, Clonaid, a company affiliated with the pro-cloning Raelian movement, announced that they had succeeded in cloning the first human baby." *Id.*

140. *Id.*

141. *Id.* On February 27, 2003, the House of Representatives passed, by a 241 to 155 vote, the Human Cloning Prohibition Act of 2003 (House Bill 534) sponsored by Congressmen Dave Weldon (R-Fl.). *Id.* This bill, backed by President Bush, would ban the creation of human embryos by cloning. See Executive Office of the President, Office of Management and Budget, *Statement of Administration Policy: H.R. 534—Human Cloning Prohibition Act of 2003*, Feb. 26, 2003, at <http://www.whitehouse.gov/omb/legislative/sap/108-1/hr534sap-hr.pdf>.

142. The House rejected (231 votes to 174) a competing bill proposed by Congressmen Jim Greenwood (R-Pa.) and Peter Deutsch (D-Fl.) that would have allowed and encouraged the creation of human embryos by cloning, while attempting to ban the use of any such cloned

In the Senate, the policy supported by President Bush was embodied in the Brownback-Landrieu bill (Senate Bill 245).¹⁴³ The language of Senate Bill 245 was nearly the same as House Bill 534 in that both banned the creation of and trafficking in cloned human embryos.¹⁴⁴ Both bills forbid the use of SCNT to clone human embryos, and banned private as well as public research on cloned human embryos.¹⁴⁵ The House bill, however, also banned importation of “any product derived from” cloned human embryos, while the Senate bill did not.¹⁴⁶ Both the House and Senate bills provided for up to ten years in prison or fines of up to \$1 million for violations.¹⁴⁷ Senate Bill 245, which had twenty-eight sponsors and cosponsors as of January 29, 2003, had been referred to the Senate Committee on Health, Education, Labor, and Pensions, which was chaired by Senator Judd Gregg (R-NH), who was a cosponsor of the bill in the 107th Congress.¹⁴⁸

The competing Hatch-Feinstein bill (Senate Bill 303) is different from Senate Bill 245 with respect to the definition of human cloning, the scope of prohibition, and penalties for violations.¹⁴⁹ Senate Bill 303 would have allowed the use of SCNT to clone human embryos while it would have banned implantation of a cloned human embryo into a uterus or the functional equivalent of a uterus.¹⁵⁰ It imposed a

embryo to “initiate a pregnancy.” See Office of Legislative Policy and Analysis, 108th Congress, *Legislative Updates: Cloning*, at <http://olpa.od.nih.gov/legislation/108/pendinglegislation/cloning1.asp> (last visited Apr. 19, 2005); Office of Legislative Policy and Analysis, *Bill Tracking: House Bills—108th Congress, H.R. 534—Human Cloning Prohibition Act of 2003*, at http://olpa.od.nih.gov/tracking/house_bills/session1/hr-534.asp (last visited Apr. 19, 2005). Following the House’s rejection of the Greenwood bill and its approval of the Weldon-Stupak bill, the President said in a written statement:

Like most Americans, I believe human cloning is deeply troubling, and I strongly support efforts by Congress to ban all human cloning. We must advance the promise and cause of medical science, including through ethical stem cell research, yet we must do so in ways that respect human dignity and help build a culture of life. I urge the Senate to act quickly on legislation banning all human cloning.

See Press Release, Office of the Press Secretary, Statement by the President (Feb. 27, 2003), at <http://www.whitehouse.gov/news/releases/2003/02/20030227-20.html>.

143. See S. 245, 108th Cong. (2003).

144. See *id.*; see also H.R. 534, 108th Cong. (2003).

145. See S. 245, 108th Cong. § 2 (2003); see also H.R. 534, 108th Cong. § 2 (2003).

146. See S. 245, 108th Cong. § 2 (2003); see also H.R. 534, 108th Cong. § 2 (2003).

147. See S. 245, 108th Cong. § 2 (2003); see also H.R. 534, 108th Cong. § 2 (2003).

148. See 2003 Bill Tracking S. 245, 108th Cong. (2003).

149. See S. 303, 108th Cong. § 101 (2003).

150. See *id.*

rule which prohibited the creation of a cloned human embryo, an “unfertilized blastocyst,” which had developed past fourteen days of age.¹⁵¹ Additionally, the rule prohibited any research on this cell mass because, at fourteen days, cell differentiation had begun.¹⁵² As of February 5, 2003, the bill had ten co-sponsors.¹⁵³

Since the ban on human cloning has not been enacted, scientists may continue their attempts to overcome technical obstacles and create cloned human embryos for research purposes. However, the bar on the use of federal funds for research involving ES cells permits federally funded scientists to experiment only with stem cell lines created before the August 2001 announcement, regardless of the quality and availability of these stem cell lines.¹⁵⁴

The debates are still ongoing. On July 10, 2002, the President’s Council on Bioethics issued recommendations with respect to cloning.¹⁵⁵ The President’s Council was split in its recommendations regarding therapeutic cloning while it was unanimous in recommending a permanent ban on reproductive cloning.¹⁵⁶ Ten members of the Council recommended a four-year moratorium on therapeutic cloning, in order to allow time for further review and “democratic deliberation” of the issue.¹⁵⁷ Seven members of the Council were in favor of therapeutic cloning, as long as standards are developed for the regulation of such research.¹⁵⁸

In the meantime, Harvard University has launched a multimillion-dollar center to grow and study human embryonic stem cells.¹⁵⁹ The center is expected to be the largest privately funded American stem-cell research project to date.¹⁶⁰ In addition, top scientists from the United States, South Korea, Australia, and Britain

151. *See id.* § 201.

152. *See id.*

153. 2003 Bill Tracking S. 245, 108th Cong. (2003).

154. *See* Press Release, Office of the Press Secretary, *supra* note 76.

155. *See* THE PRESIDENT’S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 2002), *available at* <http://www.bioethics.gov/reports/cloningreport/index.html>.

156. *See id.* at 199–227, *available at* <http://www.bioethics.gov/reports/cloningreport/recommend.html> (July 2002).

157. *See id.*

158. *Id.*

159. *See* Powell, *supra* note 77.

160. *See* Harvard to Create Stem-Cell Institute, THE WASH. TIMES, Mar. 1, 2004, *available at* <http://washingtontimes.com/national/20040301-124438-3363r.htm>.

pressed the United Nations on June 1, 2004 not to ban stem cell research as part of a global treaty banning human cloning.¹⁶¹

e. Weldon Amendment Banning Patents on Human Organisms

Congress has enacted a prohibition on the patenting of human embryos.¹⁶² The new law, known as the Weldon Amendment (House Bill 534), went into effect on January 23, 2004.¹⁶³ The ban was sponsored by Congressman Dave Weldon (R-Fl.), who, along with Senator Sam Brownback (R-Ks.), has led efforts to ban human cloning in the United States.¹⁶⁴ It received strong support from the House and Senate Republican leadership, and from the Bush administration.¹⁶⁵

The amendment provides congressional support for the current federal policy against patenting humans.¹⁶⁶ The House-approved amendment reads, "None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism."¹⁶⁷ Based on the statement that the amendment that mirrored "the current policy concerning patenting humans" had "exactly the same scope as the current USPTO policy," the amendment attempts to provide congressional support so that federal courts will not invalidate the USPTO policy as going beyond the policy of Congress.¹⁶⁸ While the

161. See Irwin Arief, *Scientists Press UN to Allow Stem Cell Research*, Religionhumanrights.com, June 1, 2004, available at <http://religionhumanrights.com/Ethics/Health/stem.un.treaty.jn1.4.htm>.

162. See Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat 3, 101 (2004); see also *Congress Bans Patents on Human Embryos; NRLC-backed Weldon Amendment Survives BIO Attacks*, National Right to Life, Feb. 4, 2004, at http://www.nrlc.org/Killing_Embryos/Human_Patenting/Weldonamendmentssurvives.html [hereinafter National Right to Life].

163. See National Right to Life, *supra* note 162.

164. See *id.*

165. *Id.*

166. *Id.*

167. See Consolidated Appropriations Act of 2004, § 634.

168. See 149 CONG. REC. H7274 (daily ed. July 22, 2003) (statement of Rep. Weldon); see also 149 CONG. REC. E2234-35 (daily ed. Nov. 5, 2003) (statement of Rep. Weldon).

Current USPTO [sic] policy, then, is that any claim that can reasonably be interpreted as "directed to" or "encompassing" a human being, and any claim reaching beyond "nonhuman" organisms to cover human organisms (including human embryos), must be rejected. My amendment simply restates this policy, providing congressional support so that federal courts will not invalidate the USPTO policy as going beyond the policy of Congress (as they invalidated the earlier USPTO policy against patenting living organisms in general).

amendment, which does not provide the definition of a human organism, may raise the concern of any expansive reading of the amendment, Congressman Weldon further clarified that the amendment would affect patenting human organisms, human embryos, human fetuses or human beings with no bearing on stem cell research or patenting genes.¹⁶⁹

House Bill 534 would have an impact on private funding of human cloning.¹⁷⁰ When considering an investment in a technologically-based company, venture capitalists typically will conduct an evaluation of a company's patent portfolio, the extent of which will depend, in part, on the importance of the patent portfolio to the company's business model.¹⁷¹ If the amendment will make it more difficult for biotech firms to receive patents over the results of human cloning and ES cell research, biotech companies may experience more difficulties convincing venture capitalists to invest. Due to the importance of private funding in many biotechnological inventions,¹⁷² House Bill 534 may have a significant impact on biotech companies' ongoing attempts to create human embryos through cloning.¹⁷³

Still, it is uncertain whether the amendment will change how the courts will rule. Currently, courts would refuse to construe the

Id.

169. See Biotechnology Industry Organization, *Cloning Patent Fact Sheet: New Patent Legislation Sets Dangerous Precedent and Stifles Research*, Sept. 2, 2003, at <http://www.bio.org/ip/action/cloningfactsheet.asp>; see also 149 CONG. REC. E2417 (daily ed. Nov. 22, 2003) (statement of Rep. Weldon).

What I want to point out is that the U.S. Patent Office has already issued patents on genes, stem cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.

Id.

170. See JOHNSON & WILLIAMS, *supra* note 74, at CRS-8. "This restriction could potentially deter human embryo research and stem cell research because researchers might not be able to claim ownership of their work." *Id.*

171. See William J. Fisher & Christopher J. Verni, *United States: What Venture Capitalists Expect from Your Company's Intellectual Property*, at http://www.buildingipvalue.com/n_us/97_101.htm (last visited Feb. 7, 2005).

172. See Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 737-38 (1990). The amount of federal funding (in the range of \$200 million per year) for the Human Genome Project is trivial compared to the amount of private funding for biotechnology research and development (\$1.5 to \$2 billion in 1987). *Id.*

173. See *id.* Assuming that continued private funding is contingent on the availability of patent protection, it is doubtful that federal funding for the Human Genome Project could compensate for the reduction in private incentives for research and development if patent protection were denied. *Id.*

language of the amendment as a total ban on broadly defined human cloning. For example, the courts may strike down the claim that dopamine neuron cells purified from stem cell lines derived from a cloned human embryo that did not develop a primitive streak are directed to or encompassing a human being. Further, the legislative history seems to support the position that the ban is meant to codify the USPTO's existing ban on the claims directed to humans even though courts do not necessarily look to the legislative history in interpreting statutes, and do not always consider it dispositive.¹⁷⁴

3. FDA Regulation of Human Cloning and Stem Cell Research

a. *FDA Assertion of Its Jurisdiction over Human Cloning*

The Food and Drug Administration (“FDA”) began to assert its jurisdiction over human cloning in 1998.¹⁷⁵ Initially, the FDA’s Acting Commissioner declared that, through the Federal Food, Drug, and Cosmetic Act (“FDCA”), the FDA has the authority to regulate human cloning and is prepared to assert that authority.¹⁷⁶ The Acting Commissioner explained that human cloning presents, “‘serious health and safety issues’ for [both] the fetus and mother.”¹⁷⁷ He also stated that human cloning may be considered a form of cellular or genetic therapy, which requires prior approval by FDA reviewers, because it involves “more than minimal manipulation” of human cells, and thus presents health and safety issues for the fetus and the mother.¹⁷⁸

i. Imposing a Warning and a Moratorium to Human-Cloning Researchers

The FDA’s assertion of jurisdiction over human cloning occurred in January 1998 in the context of a warning to a Chicago physicist who wanted to clone a human. FDA investigators made

174. See 149 CONG. REC. E2417 (daily ed. Nov. 22, 2003), *supra* note 169; see also Special Committee on the Weldon Amendment to H.R. 2799, the Appropriation Bill for the Departments of Commerce, Justice, State and the Judiciary, at 3 (2003–2004), available at http://www.abanet.org/intelprop/summer2004/spec_comm.pdf (last visited May 5, 2005).

175. See Rick Weiss, *Human Clone Research Will Be Regulated*, WASH. POST, Jan. 20, 1998, at A1.

176. See *id.*

177. *Id.*

178. *Id.*

clear to Dr. Seed that Federal regulations require him to file for FDA approval before making any efforts to clone and that receiving permission to proceed is highly unlikely.¹⁷⁹ In October 1998, the FDA's Associate Commissioner for Medical Affairs sent a letter to several hundred institutional review boards ("IRBs") throughout the nation.¹⁸⁰ The letter confirmed the FDA's jurisdiction over "clinical research using cloning technology to create a human being" and explained the FDA's regulatory process and the requirements that must be met before any investigator may proceed with such a clinical investigation.¹⁸¹ The letter clarified the formal means by which the FDA would exert authority, i.e., the investigational new drug ("IND") process and suggested that the FDA was already equipped to assess the research protocols that required agency approval.¹⁸²

The FDA's invocation of its IND regime had the effect of imposing a moratorium on most domestic human cloning research because investigators and their sponsors that would conduct the type of experiments subject to the FDA's jurisdiction were placed at legal risk if they failed to seek and secure agency approval.¹⁸³ Moreover, the Associate Commissioner's letter made it clear that the FDA may still reject any research proposal on the basis of "major unresolved safety questions pertaining to the use of cloning technology," regardless of a local IRB's approval.¹⁸⁴

ii. Scientific Concerns about Public Health and Safety

While there had been no evidence that any researcher sought FDA or IRB approval for any cloning experiment following the letter,

179. See 144 CONG. REC. S531, S562 (daily ed. Feb. 10, 1998). A letter from Sharon Smith Holston, Deputy Commissioner for External Affairs, FDA, to Senator Edward M. Kennedy stated:

[The] FDA already has jurisdiction over such experiments and is prepared to exercise that jurisdiction. While FDA's authority does not address the larger question of whether or not creating a human being using cloning technology should be altogether prohibited, this authority will ensure that such experimentation does not proceed until basic questions about safety are answered.

Id.

180. See Merrill & Rose, *supra* note 14, at 87.

181. See Letter from Dr. Stuart Nightingale, Associate Commissioner for Medical Affairs, FDA, to institutional review boards (Oct. 26, 1998), at <http://www.fda.gov/oc/ohrt/irbs/irbletr.html>.

182. See Merrill & Rose, *supra* note 14, at 102.

183. See *id.*; see also Weiss, *supra* note 175, at A1.

184. See Letter from Dr. Stuart Nightingale, *supra* note 181.

and there were no reports of any INDs submitted for such experiments, the FDA reiterated its claim to regulatory jurisdiction.¹⁸⁵ More importantly, the Director of the FDA's Center for Biologics Evaluation and Research clarified that the FDA's role and responsibilities in regulating the use of cloning technology to clone a human being will be based on the FDA's scientific concerns about public health and safety.¹⁸⁶ Therefore, the agency drew a distinction between the moral or ethical concerns underpinning the Bush administration's opposition to human cloning and the FDA's own scientific concerns about safety.¹⁸⁷

iii. Regulation under the FDCA and PHSA

The use of cloning technology, to clone a human being, and create somatic cell therapy products would be subject to the biologics provisions of the Public Health Service Act ("PHSA"),¹⁸⁸ as well as the drug and device provisions of the Food, Drug, and Cosmetic Act ("FDCA").¹⁸⁹ In addition, any somatic cell therapy product and clinical research using cloning technology to clone a human being would also be subject to IND application requirements.¹⁹⁰ Specifically, since 1997 the FDA has proposed a more comprehensive regulatory approach for cellular and tissue-based products that include somatic cell therapy products.¹⁹¹ In 2001, the FDA issued a final rule that establishes the regulatory approach for human cells, tissues, and

185. See Merrill & Rose, *supra* note 14, at 102–03. At a hearing convened by the Oversight and Investigations Subcommittee of the House Committee on Energy and Commerce, on March 28, 2001, the Director of the FDA's Center for Biologics Evaluation and Research reiterated the FDA's claim to regulatory jurisdiction, and in the process to elaborate its legal reasoning, in response to reports that a U.S. researcher and a compatriot in Italy were planning to produce the first human clone. *Id.*

186. See *Issues Raised by Human Cloning Research: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. On Energy and Commerce*, 107th Cong. 78-81 (2001) [hereinafter Zoon] (statement of Dr. Kathryn C. Zoon, Director, Center for Biologic Evaluation and Research, FDA), at www.fda.gov/ola/2001/humancloning.html (Mar. 28, 2001); see also

Merrill & Rose, *supra* note 14, at 103.

187. See Merrill & Rose, *supra* note 14, at 103–04.

188. Public Health Service Act, 42 U.S.C. §§ 201–300 (2004).

189. Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–397 (2004); see Merrill & Rose, *supra* note 14, at 104 (quoting the Director's statement).

190. Merrill & Rose, *supra* note 14, at 104.

191. See Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting, 62 Fed. Reg. 9721, 9722 (Mar. 4, 1997) (to be codified at 21 C.F.R. ch. I).

cellular and tissue-based products; the rule requires registration and listing.¹⁹²

iv. IND Process Requirements

Invoking the FDCA and PHSa, if human cloning falls within any of the biologics or drug, and device requirements, the FDA may address basic questions of safety and ensure that any human cloning experiment does not proceed until such questions are answered.¹⁹³ First, the FDA has the authority to require pre-market approval and/or licensing based upon reasonable, clinical assurance of safety, and efficacy.¹⁹⁴ Specifically, the FDA may obligate human cloning experiments to comply with the rigorous IND requirements of detailed clinical protocols, patient informed consent, safety reports, extensive record keeping, and continuing supervision by an IRB.¹⁹⁵

Second, the FDA may put a "clinical hold" on any product that is subject to the IND process.¹⁹⁶ The FDA may indefinitely delay or suspend a proposed clinical investigation if the FDA finds that "human subjects are or would be exposed to an unreasonable and significant risk of illness or injury."¹⁹⁷ Even after the FDA initially approves an IND for human cloning, it could later terminate the IND based upon safety concerns.¹⁹⁸

If the FDA has authority, any scientist who conducts human cloning research in the United States without obtaining or retaining the FDA's approval risks civil monetary penalties and/or criminal sanctions such as misdemeanor and felony charges for the violation of various provisions of the PHSa and FDCA.¹⁹⁹

192. See Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001) (to be codified at 21 C.F.R. pts. 207, 807, and 1271).

193. See Zoon, *supra* note 186.

194. See 21 U.S.C. § 355 (2004); see also 21 U.S.C. § 360c(a)(1)(C) (2004); 21 U.S.C. § 360(e) (2004); 42 U.S.C. § 262a (2004); FDA Biologics, 21 C.F.R. § 600.3(p)–(s) (2004).

195. See FDA Drugs for Human Use, 21 C.F.R. § 312.2(a) (2004); see also Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?* 11 HARV. J.L. & TECH. 619, 620–21 (1998).

196. See Price, *supra* note 195, at 621.

197. 21 C.F.R. § 312.42(b)(i) (2004).

198. See FDA Drugs for Human Use, 21 C.F.R. § 312.44(b)(i) (2004).

199. See Price, *supra* note 195, at 621 n.16 (referring to 42 U.S.C. § 262(f) and (d)(2)(B), and 21 U.S.C. § 303(a) and § 333(f)).

*b. Legal Basis for Regulation of Human Cloning by
FDA*

The FDA possesses a Constitutional power to regulate the marketing and distribution in interstate commerce of drugs, medical devices and biological products.²⁰⁰ As the Director of the FDA's Center for Biologics Evaluation and Research asserted,²⁰¹ the FDA's authority to regulate the use of human cloning technology is legitimate only if the use of the cloning technology and somatic cell therapy products derived from the use are considered drugs²⁰² or medical devices under the FDCA,²⁰³ or biological products under the PHSa.²⁰⁴ Additionally, the FDA would have the authority to regulate clinical research using human cloning technology itself, only if the

200. See Merrill & Rose, *supra* note 14, at 106–08.

201. See Zoon, *supra* note 186.

202. See 21 U.S.C. § 321(g)(1)(B)–(D) (2004). Under the FDCA the definition of the term “drug” includes:

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article . . .

Id.

203. See 21 U.S.C. § 321(h)(2)–(3) (2004) Under the FDCA, a “medical device” is defined as:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory [that is:]

. . .

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Id.

204. See 42 U.S.C. § 262(i) (2004). Under the PHSa a biological product is defined as: “[Any] virus, therapeutic serum, toxin, antitoxin, . . . or analogous product, or arsenamine or [its] derivative[s] . . . (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of disease or condition of human beings.” *Id.* Thus, the definition of a biological product has two components: (1) it must be a “virus, therapeutic serum . . . or analogous product”; and (2) it must be “applicable to the prevention, treatment, or cure of disease or condition of human beings.” The relevant questions are much the same as in the drug and medical device context: (1) is there an identifiable “product” involved in human cloning; and (2) if so, is that product “applicable to the prevention, treatment or cure of a disease or condition of human beings”? *Id.*

research involves an article within the meaning of the FDCA, whose commercial distribution the FDA can regulate.²⁰⁵

i. FDA's Authority to Regulate the Use of Human Cloning Technologies to Create Cloned Embryos or Somatic Cell Therapy Products

Whether a court would find a cloned embryo or any somatic cell therapy product derived therefrom as a drug or medical device under the FDCA, or a biological product under the PHSA depends upon whether the court would find that a cloned embryo or somatic cell therapy product from the embryo could properly be considered an "article"²⁰⁶ or "implant"²⁰⁷ within the meaning of the FDCA, or a "product"²⁰⁸ within the meaning of the PHSA.²⁰⁹ Because the court would not absurdly give the FDA authority to regulate the formation of human life by concluding that such product is an "an "article" or "implant" within the meaning of the FDCA, or "product" within the meaning of the PHSA, the court's reasoning would eventually depend upon whether a cloned embryo or somatic cell therapy product could be considered a human being.²¹⁰ In determining whether the embryo or any derivative product could be considered a human being, the court might consider particular properties of a cloned embryo or any derivative product from a cloned embryo. These properties may include the developmental stage or degree of differentiation of the embryo or its product, implantability of the embryo or its product, and any non-natural properties of the embryo or the product that cannot be found in human embryos created physiologically or, perhaps, in human embryos created by *in vitro* fertilization.

If a court were to conclude that a cloned embryo or any product therefrom is a human being, the court would not find the embryo or

205. See 21 U.S.C. § 321(g)(1) (2004).

206. See *id.* § 321(g)(1)(B)-(D).

207. See *id.* § 321(h)(2)-(3); Price, *supra* note 195, at 634. The medical device definitions depend upon the preliminary identification of a relevant "article," just as the drug definitions do. However, the term "article" in the medical device definition is illustrated with examples such as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article." 21 U.S.C. § 321(h) (2004). Assuming a court would be willing to entertain the notion that an embryo is an "article," a cloned embryo and any somatic cell therapy product could fall within the term "implant" among the examples of "articles" covered by the medical device definition. *Id.*

208. See 42 U.S.C. § 262(i) (2004).

209. See generally Price, *supra* note 195.

210. *Id.*

the product as an article or implant within the meaning of the FDCA, or a product within the meaning of the PHSA. Such construction would not be consistent with common sense, legislative intent,²¹¹ and the FDA's historical failure to assert jurisdiction over embryos created through *in vitro* fertilization.²¹² Therefore, products derived from reproductive cloning activity aimed at producing children would not be classified as drugs or medical devices, and would not be subject to any of the FDA's regulation.²¹³

In contrast, if a court were to conclude that a cloned embryo or any product therefrom is not a human being, then to be considered a drug or a medical device under the FDCA, or a biological product under the PHSA, the embryo or product must be intended to prevent, diagnose, or treat human or animal diseases or injuries; or intended to affect a human or animal body structurally or functionally.²¹⁴ Therefore, products derived from therapeutic cloning activity would properly be classified as drugs or medical devices and would be subject to the FDA's pre-market approval.²¹⁵

ii. Regulation of Clinical Research Employing Human Cloning Technology

The sources of the FDA's possible authority to regulate clinical research include (a) the power to regulate marketing new drugs and the shipping of experimental drugs under the FDCA²¹⁶; (b) its limited power to regulate transplantable human tissues based on the risk of transmission of communicable diseases under the PHSA²¹⁷; (c) the federal requirements for the recovery, processing, and distribution of transplantable human tissues under the FDA "plan for cellular and

211. See Price, *supra* note 195, at 630.

212. See *id.* at 630–31.

213. See *id.* at 641.

214. See 21 U.S.C. § 321(g)(1)(B) (2004) ("intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"); see also *id.* § 321(g)(1)(C) (2004) ("intended to affect the structure or any function of the body of man or other animals"); 42 U.S.C. § 262(i) (2004) ("applicable to the prevention, treatment or cure of a disease of condition"). A cloned embryo or any product could be manipulated to develop into a specific cell, organ, or tissue that may then be injected, infused, or implanted into an individual who needs it to compensate for any functional or structural insufficiency or deficiency. For example, dopamine neurons derived from ES cells can be grafted into the midbrain of the patient diagnosed with Parkinson's disease. Alternatively, an embryo or somatic cell therapy product could be programmed to develop into a specific organ or tissue for implantation or transplantation.

215. See Price, *supra* note 195, at 641.

216. See The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–397 (2004); see *id.* §§ 321, 331, and 355.

217. See 42 U.S.C. § 264(a) (2004).

tissue-based products”²¹⁸; (d) its power to regulate gene therapy experiments that involve the administration of unapproved biological drugs subject to the FDA’s IND regulations²¹⁹; and (e) the authority to require advance approval of human cloning experiments which rely upon the conclusion that such experiments involve the administration of unapproved drugs.²²⁰

The FDA oversight is an important feature of the medical research environment in the United States. The FDCA requires affirmative FDA approval for the marketing of any new drug.²²¹ The statute also specifies that, before granting approval, the FDA should obtain sufficient evidence of safety and efficacy based on the clinical trials in human subjects.²²² Experiments that require FDA approval to market new medical products encompass a major part of the clinical research conducted at medical centers and other health care institutions in the United States.²²³ Moreover, the FDCA imposes conditions, primarily designed to protect the trial subjects’ safety and autonomy, on a manufacturer who wants exemptions under the statute to ship experimental drugs for the purpose of conducting investigational studies that will become part of an application for marketing approval.²²⁴ Thus, federal oversight of medical research involving human subjects is widespread in the two circumstances that involve new drugs and experimental drugs, which comprise the bulk of, if not all, clinical research using reproductive cloning technology in the United States. The FDA’s jurisdiction depends on the purpose of the research and on the substances or products to which research subjects are exposed.²²⁵ Furthermore, the FDA only has the authority to regulate human research involving articles whose commercial distribution the FDA can regulate, based upon the FDA’s power under the Constitution’s Commerce Clause.²²⁶

The FDA establishes minimum requirements for the recovery, processing, and distribution of transplantable cellular and tissue-based

218. See THE FOOD AND DRUG ADMINISTRATION, PROPOSED APPROACH TO REGULATION OF CELLULAR AND TISSUE-BASED PRODUCTS (Feb. 28, 1997), available at <http://www.fda.gov/cber/gdlns/CELLTISSUE.txt>.

219. See Zoon, *supra* note 186.

220. See Merrill & Rose, *supra* note 14, at 119–24.

221. See *id.* at 108.

222. *Id.* at 109.

223. *Id.* at 106–07.

224. *Id.* at 109.

225. *Id.* at 107.

226. See Merrill & Rose, *supra* note 14, at 107; see also 21 U.S.C. § 321(g)(1) (2004).

products.²²⁷ However, the plan does not impose any restrictions on the clinical use of appropriately screened and tested tissue, nor does it require tissue banks to demonstrate that their products are safe or effective.²²⁸ Thus, without amending the regulations the FDA could not have required advance approval of clinical human cloning experiments using cellular and tissue-based products even if such material is defined as human tissue.²²⁹

The FDA's regulations governing transplantable human tissues under the PHSA would authorize the FDA to pursue a relatively narrow goal, i.e., the prevention of transmission of infectious diseases from the donor(s) of cellular material to a cloned embryo or its mother.²³⁰ The regulations do not require researchers to notify the FDA of, or to acquire its approval for, any clinical use of tissue.²³¹

The FDA announced that it considers somatic cell therapy products as both biological products and drugs.²³² The FDA also claimed that the statutory authority on which the FDA relies to regulate gene therapy also supports its jurisdiction over clinical cloning experiments.²³³ However, the FDA's regulation of gene therapy experiments is not based on an explicit legislative grant of jurisdiction.²³⁴ Rather, jurisdiction rests on the premise that the clinical administration of genetic material to humans requires approval of an IND because it constitutes the administration of an experimental drug.²³⁵ In reality, the FDA's regime over recombinant DNA gene therapy experiments gave primary responsibility to the Recombinant DNA Advisory Committee ("RAC"), an entity established by the NIH.²³⁶ Therefore, the FDA's regulation of gene therapy experiments may offer a precedent for its assertion of jurisdiction over cloning research, but it does not provide an

227. See THE FOOD AND DRUG ADMINISTRATION, *supra* note 218. In response to the emergence of AIDS and the technological advances within the biotechnology industry, the FDA promulgated these new regulations. *Id.*

228. See Merrill & Rose, *supra* note 14, at 113.

229. See *id.* at 113.

230. *Id.* at 110.

231. *Id.* at 111.

232. *Id.* at 117.

233. *Id.*

234. See Merrill & Rose, *supra* note 14, at 118.

235. *Id.*

236. *Id.* at 117-18. The RAC's expertise led to it taking responsibility for reviewing both medical and non-medical issues raised by proposed experiments, with FDA concurrence. *Id.*

independent legal basis for the positions announced by FDA officials.²³⁷

The FDA's authority to require advance approval of human cloning experiments depends upon the conclusion that such experiments involve the administration of unapproved drugs.²³⁸ For any clinical experiment to be subject to FDA authority under the FDCA, the procedure must involve the introduction of an article into a human subject, which must fit the definition of a drug or device under the FDCA.²³⁹

As the previous analysis demonstrates, use of reproductive cloning technology and the FDCA's drug definition does not comfortably encompass all of the applications now awaiting investigation.²⁴⁰ The statute would give the FDA authority to regulate human cloning experiments when it is used for disease prevention or treatment purposes, but not when used for human reproduction.²⁴¹

c. Pros and Cons of the FDA Regulation of Cloning Research

i. Plausible Arguments for Giving the FDA a Role in Overseeing Human Cloning Research

(1) De Facto Regulatory Regime

The FDA's assertion of jurisdiction over human cloning creates at least a *de facto* regulatory regime.²⁴² In the absence of targeted legislation, the FDA's program for regulating clinical studies of new medicines may be an instrument that enables the federal government to oversee research into human cloning and cloning-related technologies.²⁴³ The implementation of the FDA's regulatory regime may discourage human cloning experiments without the need for new legislation until the safety concerns surrounding human cloning can be addressed.²⁴⁴ The FDA's assertion of jurisdiction ostensibly might

237. *See id.* at 118.

238. *Id.* at 119.

239. *Id.*

240. *See Price, supra* note 195, at 641.

241. *See id.*

242. *See Merrill & Rose, supra* note 14, at 88.

243. *See id.* at 88-89.

244. *Id.* at 133.

provide control of this provocative technology until more finely calibrated requirements can be developed.²⁴⁵

(2) *Familiarity and Flexibility*

The basic outlines of the FDA regulatory regime are familiar to medical researchers, and the FDA requirements are already operational.²⁴⁶ The FDA regime also allows for flexibility by considering research proposals on an individual basis even though researchers must follow the basic requirements prescribed by agency regulations and supporting guidelines.²⁴⁷

(3) *Preferable Alternative to a Broad Legislative Ban*

The FDA regulation could avoid the chilling effect on ES cell research that would result from a congressional ban on all kinds of human cloning employing SCNT.²⁴⁸ Many professional and industry groups expressed concern that a broad ban would disrupt or end valuable ongoing genetic research.²⁴⁹ For them, latent FDA jurisdiction offers an alternative to possible efforts to craft finely-tuned controls through the legislative process.²⁵⁰

Legislation to regulate human cloning is particularly challenging to legislators. It has been difficult for advocates of legislation to agree on what they want to restrict.²⁵¹ In addition, fashioning a finely-tuned law in this complex area is not an easy task because technological advances may circumvent carefully drawn laws.²⁵² Any attempt to address the problem legislatively must not only consider the effect a ban would have on beneficial technologies, but must also take into account future technological breakthroughs and new applications of existing techniques.²⁵³ Finally, the nature of the cloning debate, which heightens emotions and inhibits reflective deliberation, has resulted in legislators hastily drafting bills that represent political statements of moral outrage rather than vehicles for exploration and dialogue.²⁵⁴

245. *Id.* at 131.

246. *Id.*

247. *Id.*

248. See Merrill & Rose, *supra* note 14, at 131-33.

249. See *id.* at 132.

250. *Id.*

251. *Id.*

252. *Id.*

253. *Id.* at 132-33.

254. See Merrill & Rose, *supra* note 14, at 133.

ii. Questionable Institutional Capacity

(1) Scientific Issues

The argument for FDA jurisdiction is strongest when one considers medical concerns raised by human cloning.²⁵⁵ Cloning technology has been unreliable with high error rates.²⁵⁶ Risks of fetal and neonatal death, severe birth or developmental defects, and the dangers to surrogates pregnant with clones that include miscarriage have been identified.²⁵⁷ For example, of the twenty-nine early embryos created by SCNT and implanted into various ewes by Roslin researchers, only one, Dolly, survived.²⁵⁸ Furthermore, there is little information regarding the complete genetic makeup, possible latent defects, or the survival and long-term health of clones like Dolly.²⁵⁹ Such potential physical risks make some administrative oversight reassuring.²⁶⁰

Other issues are important as well. For example, FDA officials have the experience to make judgments on primarily scientific tasks.²⁶¹ Also, the FDA's regulatory regime is structured to ensure the safety of new medicines before they are administered to human beings.²⁶² Finally, the FDA and the IRBs are generally capable of addressing the safety of dramatic scientific advances and novel medical applications.²⁶³

(2) Moral and Ethical Issues

It has been argued that an effective regime for regulating cloning must be capable of assessing not only scientific issues, but also moral and ethical issues.²⁶⁴ Cloning elicits unique moral and ethical issues that any governmental authority must surely confront in regulating

255. *See id.* at 134.

256. *Id.*; see 149 CONG. REC. H1397, H1399 (daily ed. Feb. 27, 2003) (statement of Rep. Pitts).

257. *See Merrill & Rose, supra* note 14, at 134.

258. *See* Ronald M. Green, *I, Clone*, SCIENTIFIC AMERICAN.COM, Sept. 3, 1999, at http://www.sciam.com/print_version.cfm?articleID=000329A6-CE72-1CFB-93F6809EC5880000.

259. *See Merrill & Rose, supra* note 14, at 134.

260. *See id.* at 135.

261. *Id.*

262. *Id.* at 134.

263. *Id.*

264. *Id.* at 133.

cloning research.²⁶⁵ The ethical issues raised by the use of SCNT to create children relate to serious safety concerns, individuality, family integrity, and treatment of children as objects.²⁶⁶ There are concerns about possible harms to children who may be born as a result of SCNT.²⁶⁷ Possible harms include physical harms from the manipulation of ova, nuclei, and embryos, which are integral to the technology, and psychological harms, such as a diminished sense of individuality and personal autonomy.²⁶⁸ Additionally, there are fears that widespread practice of such cloning would undermine important social values, such as opening the door to a form of eugenics, tempting some people to manipulate others as if they were objects instead of persons, and exceeding the moral boundaries inherent to the human condition.²⁶⁹ Whether administrative regulation is a normatively attractive means to address the complex scientific, moral, and ethical issues surrounding cloning, and whether the FDA has the qualifications and resources necessary for the task are big questions.²⁷⁰

(3) *Limitations of the FDA's IND Regime*

It is uncertain whether the FDA is fully prepared to address the risks presented by human cloning experiments.²⁷¹ The FDA's IND regime, which was designed long before cloning technologies were realistic possibilities, will be applied to regulate human cloning activities.²⁷² The IND regime was initially designed for the purpose of overseeing the clinical testing of new drugs.²⁷³ The primary goals of section 505(i) of the FDCA are to protect the safety and autonomy of human subjects and to assure that the FDA has access to all evidence relevant to assessing a drug's safety and efficacy.²⁷⁴ An IRB's

265. See Merrill & Rose, *supra* note 14, at 135–37. Concerns and issues that face governments include the status of cloned humans as autonomous individuals, the psychological burdens and identity distortions that cloning might entail, the concern for the protection of individuality from a fundamental threat to the concept and the reality of the human being as a unique and intrinsically valuable entity, and the debates over the moral status of clones. *Id.*

266. See NATIONAL BIOETHICS ADVISORY COMMISSION, CLONING HUMAN BEINGS: CH. 4 ETHICAL CONSIDERATIONS (June 1997), at http://earthops.org/cloning_report.html.

267. See *id.*

268. *Id.*

269. *Id.*

270. See Merrill & Rose, *supra* note 14, at 135–37.

271. *Id.* at 137.

272. *Id.* at 88.

273. *Id.* at 137–39.

274. *Id.* at 137–38.

primary responsibility is to protect the safety and assure the informed consent of study participants.²⁷⁵ Neither the FDA nor IRBs are directed to assess whether a study is morally acceptable or socially beneficial.²⁷⁶ The FDA has confined its own review to the immediate safety of study participants.²⁷⁷ Thus, rather than relying on established procedures, the FDA needs to specifically fashion new rules to encompass human cloning experiments.²⁷⁸

In summary, the FDA regulation over human cloning has limitations.²⁷⁹ Regardless of these limitations, the FDA may still be able to address foreseeable medical concerns related to therapeutic cloning.²⁸⁰ Additionally, it may be able to regulate procedures and experiments, including clinical trials, related to therapeutic cloning and any products resulting from therapeutic cloning. However, the current FDA regulation cannot assess moral or ethical issues regarding human cloning.²⁸¹ Furthermore, it cannot regulate any product, procedure or experiment related to reproductive cloning.²⁸²

B. Regulation of Human Cloning and Embryonic Stem Cell Research in South Korea

The Bioethics and Biosafety Act was passed by the National Assembly of South Korea on December 29, 2003.²⁸³ The process of reaching a national consensus in order to pass the act took approximately seven years and more than a dozen draft bills.²⁸⁴ Under this act, human reproductive cloning and experiments, such as interspecies nuclear fusion, are strictly banned in South Korea.²⁸⁵

275. *Id.* at 138.

276. *See* Merrill & Rose, *supra* note 14, at 138.

277. *Id.*

278. *Id.* at 133.

279. *Id.* at 135–39.

280. *Id.* at 134–35.

281. *Id.* at 135–37.

282. *See* Price, *supra* note 195, at 641.

283. *See* Soh Ji-young, *Bill Passed Banning Human Cloning*, THE KOREA TIMES, Dec. 30, 2003, available at

http://search.hankooki.com/times/times_view.php?terms=%22human+cloning%22+code%3A+kt&path=hankooki3%2Ftimes%2Fpage%2F200312%2Fkt2003123016143210160.htm.

284. *See* Han Sung-Goo, et al., *New Cloning Technologies and Bioethics Issues: The Legislative Process in Korea*, 13 EUBIOS J. ASIAN & INT'L BIOETHICS 216–19 (2003), at <http://www.biol.tsukuba.ac.jp/~macer/EJ136/ej136h.htm> (last visited Mar. 21, 2005).

285. *See* Joseph Wong, et al., *South Korean Biotechnology—A Rising Industrial and Scientific Powerhouse*, 22 NATURE BIOTECHNOLOGY SUPPLEMENT DC42, DC46 (2004), available at <http://www.utoronto.ca/jcb/home/documents/SouthKorea.pdf>.

However, therapeutic cloning is permitted in limited cases for the cure of otherwise untreatable diseases.²⁸⁶

1. Legislative Progress

a. *The Biotechnology Support Act of 1983 and Its Amended Bills*

The Biotechnology Support Act of 1983 ("1983 Act") was enacted to promote the development of biotechnology.²⁸⁷ Article 15 of the 1983 Act mandates that the Minister of Health and Welfare prepare and implement guidelines on experiments.²⁸⁸ It lists actions that should be taken in order to prevent ethical problems from arising, such as the prohibition of human gene recombination and any other experiments that may cause detrimental impacts to human dignity.²⁸⁹

In preparation for joining the Organization of Economic Cooperation and Development and the International Convention on Biological Diversity in 1997, the Korean government formulated guidelines reiterating Article 15 of the 1983 Act.²⁹⁰ Until now, there have been no regulatory provisions at the level of statutes, regulations, or guidelines notified by the governmental agencies, which address substantially bioethical concerns stemming from the application of advanced biotechnology, such as artificial

286. *See id.*

287. *See* The Biotechnology Support Act, Art. 1 (1983) ("build up the foundation for biotechnological research, and thereby to effectively foster and develop biotechnology and promote the industrialization of such developed technology"); *see also* Han et al., *supra* note 284.

288. *See* The Enforcement Decree of the Biotechnology Support Act, Art. 15(1) (issued in 1984) ("[N]ecessary measures to prevent foreseeable biological hazards, negative effects on the environment and ethical problems that may arise in the process of biotechnological research and industrialization, and shall include safety standards for the transfer, handling, and use of genetically converted biological organisms.").

289. *See id.* Art. 15(2).

290. *See* Un Jong Pak, *Legislative Progress on Bioethics and Safety in Korea and Suggestions for the Future* (Jan. 5-7, 2004) (article for the Beijing International Conference on Bioethics) (on file with the Santa Clara Computer & High Technology Law Journal). Accordingly, "The Guidelines for Gene Recombination Experiment" were created in 1997. *Id.* The Guidelines require "developing measures necessary for the prevention of ethical problems, such as prohibition of gene recombination experiment or any other experiments that may cause detrimental impact to human dignity." The Biotechnology Support Act, Art. 23 (1983). However, the Guidelines are just reiterating the provision in the Enforcement Decree of the Biotechnology Support Act, and thus, in effect cannot be deemed to contain a specific guidance on ethics.

insemination, human embryo research and handling, genetic testing, gene therapy, protection of genetic information, and the gene bank.²⁹¹

Two amendment bills (Young-dal Chang on July 2, 1997; Sang-hee Lee on November 19, 1998) were proposed at the 15th National Assembly, as amendments to the Biotechnology Support Act in 1997 and in 1998, respectively, in order to cope with the ethical and safety issues arising from the rapid development of biotechnology.²⁹² These draft bills drew public attention and provoked discussions, including several public hearings. Subsequently, another bill to prohibit human cloning was submitted in 1999, creating a deadlock situation of the standing committees with no progress.²⁹³ The third amendment bill (Sung-jae Lee on November 5, 1999) purported to deter the negative effects that may arise from the development of biotechnology.²⁹⁴

b. The Bill on Prohibition of Human Cloning and Stem Cell Research and the Bill on Bioethics and Safety

Beginning in early 2000, the developments in biotechnology to produce internal organs, cells for transplantation, and treatment of incurable diseases through human ES cell research began to be competitively implemented.²⁹⁵ The domestic research team reportedly created and cloned a human embryo using an egg and somatic cell donated by a thirty-year-old woman, and cultivated it until the point of implantation into the uterus.²⁹⁶ This success triggered public debates on the permissible scope of stem cell research and cloning.²⁹⁷ They also increased concerns about the possibility of human

291. See Pak, *supra* note 290. There exist guidelines on research ethics and standards on ethical reviews that are prepared by the relevant research institutes or the research evaluation institutes themselves. For example, there are "The Guidelines for Research and Handling of Human Stem Cells" prepared in September 2001 by the Research, Planning and Evaluation Board on Health and Medical Technology established in the Ministry of Health and Welfare, and "The Guidelines for Ethical Reviews on Stem Cell Research" prepared by the Ethics Committee of the Stem Cell Research Center in October 2002. *Id.*

292. See Pak, *supra* note 290.

293. See *id.*

294. *Id.*

295. *Id.*

296. See Hong Sun-hee, *Ethical Debate Expected After 1st Human Cloning Experiment Here*, THE KOREA TIMES, Dec. 15, 1998, available at

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki1%2F14_1%2F9812%2Ft4151520.htm.

297. See Pak, *supra* note 290.

cloning.²⁹⁸ Public opinion surged toward demanding prompt legislation to regulate human stem cell research.²⁹⁹

In response, bioethical and safety-related legislative proposals were prepared by two ministries. The Ministry of Health and Welfare (“MHW”) proposed the Life Science, Health and Safety, Ethics Act in December 2000³⁰⁰ and the Ministry of Science and Technology (“MST”) proposed the Bill on the Prohibition of Human Cloning and Stem Cell Research in July 2002.³⁰¹ Both proposed bills would ban human cloning and impose criminal penalties including up to ten years imprisonment.³⁰² However, both would have permitted stem cell research using frozen embryos, categorized as disposable subjects, and research using stem cells extracted from human body tissues.³⁰³ Moreover, both bills would mandate the creation of the National Bioethics Commission (“NBC”) under control of the President to review bioethics-related matters.³⁰⁴ Additionally, the bills would ban research employing SCNT or interspecies nuclear transfer, if otherwise permitted.³⁰⁵

Three important differences between the two bills were noted: who or what should be granted the authority 1) to determine the scope of permissible research employing SCNT; 2) to administer the research and development in biotechnology; and 3) and what legislative actions should be taken regarding other bioethical issues.³⁰⁶

The bill proposed by MHW would bestow the authority to administer the research and development-related issues on MHW while the bill proposed by MST would bestow the authority on

298. *See id.*

299. *See id.*; *Today's Editorial: Controversial Bill on Cloning*, THE KOREA TIMES, Dec. 11, 2000, available at

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki%2Fkt_op%2F200012%2F20001211171435481126.htm.

300. *See* Park Yoon-bae, *Gov't Seeks Ban On Human Cloning*, THE KOREA TIMES, Dec. 5, 2000, available at

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki%2Fkt_nation%2F200012%2F20001205175931411150.htm.

301. *See* Lee Chi-dong, *Maximum 10-Yr. Jail Term Suggested for Human Cloning Experimentation*, THE KOREA TIMES, July 18, 2002, available at

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki%2Fkt_nation%2F200207%2F2002071817204341110.htm.

302. *See* Pak, *supra* note 290.

303. *See id.*

304. *Id.*

305. *Id.*

306. *Id.*

MST.³⁰⁷ According to the bill proposed by MHW, after the appropriateness of the research had been considered by the Bioethics Advisory Committee, the President would make the final determination as to whether such research is permissible.³⁰⁸ In contrast, the bill proposed by MST would enable NBC to review and determine the issues on therapeutic embryonic cloning employing SCNT or interspecies nuclear transfer with some flexibility.³⁰⁹ Decisions would be made in response to international and national trends and needs.³¹⁰

The bill proposed by MHW contained provisions regarding embryo management, gene therapy, the protection of genetic information, a gene bank, and genetic testing, while the bill proposed by MST did not.³¹¹ The bill proposed by MST would place minimum restrictions on relevant researchers and industries in order to foster the further development of scientific technologies.³¹² The bill proposed by MHW focused on the issues of the safety and dignity of human beings in response to public concerns.³¹³ The different positions taken by the two ministries caused the passage of each bill to be delayed.³¹⁴

In the wake of the July 2002 announcement by the Korean branch of Clonaid and a domestic biotech company cooperating with Clonaid that human cloning tests were being conducted within the country,³¹⁵ the Office for Government Policy Coordination mediated the stalemate between the two governmental ministries in order to reach a resolution to formulate a single bill.³¹⁶ Accordingly, based on the public opinions previously collected by the Korea Health Society

307. *See id.*

308. Pak, *supra* note 290.

309. *Id.*

310. *Id.*

311. *Id.*

312. *Id.*; *see also* Lee Chi-dong, *Minister Kim Aims High for Science Development*, THE KOREA TIMES, Nov. 21, 2002, *available at*

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki3%2Ftimes%2Fpage%2Fnation%2F200211%2Fkt2002112117061910580.htm.

313. *See* Pak, *supra* note 290.

314. *See id.*

315. *See Gov't Probes Human Cloning Experiments*, THE KOREA TIMES, July 24, 2002, *available at*

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki1%2Ftimes%2F200207%2Ft2002072419034840110.htm; *see also* Na Jeong-ju, 'Korean Woman May Deliver Cloned Baby', THE KOREA TIMES, Dec. 30, 2002, *available at* http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki3%2Ftimes%2Fpage%2F200212%2Fkt2002123017030610160.htm.

316. *See* Pak, *supra* note 290.

Research Institute, MHW prepared the Act on Bioethics and Safety (“MHW bill”) in July 2002.³¹⁷ Notice of the proposed legislation was published from September 24, 2002 to October 14, 2002 and a public hearing regarding the MHW bill was held on October 9, 2002.³¹⁸

In addition to its main provisions, the MHW bill included an addendum. This addendum clarified a provisional measure for embryo research which stated that existing research on SCNT as of the effective date of the MHW bill, may be continued only upon approval by the Minister of Health and Welfare.³¹⁹ This bill also included a sunset provision, which mandated that the government take appropriate actions, including amending the relevant regulations, within three years from the date of the enactment of the MHW bill.³²⁰ This provision required the government to review all of the provisions of the MHW bill with respect to social and ethical changes in the society and the development of biotechnology.³²¹

The draft of the Act on Bioethics and Safety was completed after several rounds of expert forums and advice session, where opinions from medical groups, legal groups, ethical community and citizen groups were heard and considered.³²² However, MST, joined by the Ministry of Industry and Energy and the Ministry of Agriculture, objected to this bill.³²³ This MHW bill received a wide range of reactions and criticisms from different groups.³²⁴

In particular, the Joint Campaign Group for a Rapid Enactment of Bioethics Framework Act, an associated gathering of citizen groups, urged the legislature to include provisions which would prohibit embryonic cloning and interspecies hybridization without exception.³²⁵ The group called for provisions that would enhance the status and function of the National Bioethics Committee.³²⁶ The Joint Campaign Group filed a petition with the legislature containing its own draft bill, “Bioethics and Biosafety Act,” which amended the

317. See Soh Ji-young, *Gov't Finalizes Bill to Ban Human Cloning*, THE KOREA TIMES, Sept. 23, 2002, available at

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki1%2Fkt_nation%2F200209%2F2002092318192241110.htm.

318. See Pak, *supra* note 290.

319. See *id.*

320. *Id.*

321. *Id.*

322. *Id.*

323. *Id.*

324. Pak, *supra* note 290.

325. See *id.*

326. See *id.*

MHW bill.³²⁷ The amendments included upgrading the National Bioethics Committee from an advisory body to a review and decision-making body and banning human cloning and human embryonic cloning through SCNT (including interspecies nuclear transfer).³²⁸

Biotechnologists opposed the MHW bill because it prohibited embryonic cloning and interspecies hybridization.³²⁹ They wanted legislation that would ensure the freedom of research, while prohibiting human reproductive cloning.³³⁰ Additionally, they feared that passage of the bill would result in inefficient and rigid bureaucratic practices that would impede the procedures for seeking the Committee's review and permission.³³¹

The MHW bill was originally scheduled to be submitted to a regular fall session of the National Assembly in 2002.³³² However, it was withheld so that the governmental ministries could review the bill in light of their policies and public opinion.³³³ After reconvening for review, the government produced a final combined bill, which allows for the use of SCNT research (including interspecies transfer) for the treatment of rare and incurable diseases that are prescribed by the Presidential Decree.³³⁴

2. The Bioethics and Biosafety Act of 2003

On October 14, 2003, after a year-long discussion within the government and several rounds of public hearings, the government bill, Bioethics and Biosafety Act ("2003 Act"), was referred to the Health and Welfare Committee of the National Assembly.³³⁵ The bill passed the National Assembly on December 29, 2003.³³⁶ The 2003 Act was based on the MHW bill and revised that bill to set up the National Bioethics Review Committee ("NBRC") as a review body,

327. *Id.*

328. *Id.*

329. *Id.*

330. Pak, *supra* note 290.

331. *See id.*

332. *Id.*

333. *Id.*

334. *See id.*

335. *Id.*

336. *See* Pak, *supra* note 290; Soh, *supra* note 283 ("Reproductive cloning will be banned in the country . . .").

rather than an advisory body.³³⁷ The 2003 Act also extended the number of related ministers in the NBRC.³³⁸

The important provisions of the 2003 Act are: 1) the establishment of the NBRC comprised of government Ministers and scientific and non-scientific experts; 2) the creation of institutional bioethics review boards; 3) a total ban on human cloning; 4) a ban on embryonic cloning using SCNT with the exception of cases in which the NBRC permits the use of the technology; 5) conditions and criteria for utilizing excess embryos in research; 6) the prohibition of inter-species hybridization; 7) the restrictions on genetic testing and gene therapy; 8) the prohibition of creation of human embryos for any purposes other than conception; and 9) the prohibition of the offering of human eggs and sperms for trading or commercial purposes.³³⁹

a. Establishment of the National Bioethics Review Committee

The 2003 Act provides that the NBRC shall be established under the control of the President to respond to the President's inquiries regarding the discipline and safety of bioscience and biotechnology.³⁴⁰ The NBRC consists of sixteen to twenty-one members.³⁴¹ The members shall include seven Ministers, less than seven President-appointed members who are biotechnology or medical science experts, and less than seven President-appointed members from religious, philosophical, ethicists, legal, citizen, and feminist groups.³⁴²

The NBRC has the authority to review: 1) the national policy regarding bioethics and safety; 2) the type, subject, and scope of research utilizing excess embryos; 3) the type, subject, and scope of research employing SCNT technology; 4) the categories of prohibited genetic testing; 5) the diseases permitted for research and treatment utilizing gene therapy; and 6) other matters related to biotechnological research, development, and utilization that may have serious ethical or social implications.³⁴³

337. See Pak, *supra* note 290.

338. See *id.*

339. *Id.*

340. See The Bioethics and Biosafety Act of 2003 (South Korea), Art. 6 (2003).

341. See *id.* Art. 7(1).

342. *Id.* Art. 7(3).

343. *Id.* Art. 6.

b. Establishment of the Institutional Bioethics Review Board

The 2003 Act mandates that an institutional bioethics review board (“IRB”) should be established for each embryo research institute, gene bank, institute for gene therapy, and any other institute for biotechnological research, development, and utilization that may have serious ethical or social implications.³⁴⁴ An IRB will review the ethical and scientific validity of biotechnology research proposals, the proper acquisition of consent from a patient or a donor of sperm, ovum, or other specimen, and the measures to protect personally identifiable information in any form of a patient, or a donor of sperm, ovum, or other specimen.³⁴⁵

c. Total Ban on Human Cloning and on Interspecies Implantation

An act of implanting a cloned embryo through SCNT technology into a woman’s uterus, an act of maintaining the implantation of a cloned embryo, or an act of leading to the birth of a cloned baby is prohibited.³⁴⁶ A violator or a would-be violator shall be imprisoned up to ten years.³⁴⁷ Participating in, inducing one into, or brokering any act conducted for the purpose of human cloning is also prohibited and penalized.³⁴⁸

Article 12 provides a ban on interspecies implantation.³⁴⁹ Additionally, the following acts are prohibited: 1) fertilizing human eggs with animal sperms or vice versa; 2) transplanting a nucleus taken from an animal somatic cell into a human anucleated egg; 3) fusing a human embryo with an animal embryo; 4) fusing a human embryo with different genetic information; or 5) implanting an embryo created from the above acts into a human or animal uterus.³⁵⁰

344. *Id.* Art. 9.

345. *Id.*

346. *See* The Bioethics and Biosafety Act of 2003 (South Korea), Art. 11(1) (2003) (“an act of creating an embryo by using an embryo, fetus, a living person, brain dead, or dead people for the purpose of cloning a human” was prohibited).

347. *See id.* Art. 49.

348. *Id.* Art. 11(2), 50.

349. *Id.* Art. 12(1).

350. *Id.* Art. 12(2).

d. The Creation and Use of Human Embryos

Human embryos may not be created for any purpose other than pregnancy.³⁵¹ Moreover, human embryos shall not be produced by any of the following acts of fertilization: 1) selecting a sperm to select the sex of a baby; 2) using an egg or a sperm from a dead person; and 3) using a sperm or an egg from a minor.³⁵² Any person would be prohibited from acquiring or transferring human sperm or eggs for valuable consideration, such as monetary or property gains.³⁵³

Any medical institute that collects, conserves, or fertilizes human sperm or eggs to produce embryos should be designated as an Embryo-Producing Medical Institute by the Minister of Health and Welfare.³⁵⁴

Excess embryos, which were created more than five years earlier and that do not show the primary streak, may be used only for the purpose of: 1) research on the treatment of infertility and development of contraceptive techniques; 2) research on the treatment of rare or incurable diseases, such as muscular dystrophy; and 3) research prescribed by Presidential Decree after consideration by the NBRC.³⁵⁵ In order to study excess embryos pursuant to Article 17, a medical institute should register as an Embryo Research Institute with the Minister of Health and Welfare.³⁵⁶

e. Somatic Cell Nuclear Transfer

Somatic cell nuclear transfer is prohibited for any purpose other than therapeutic research as stipulated in Article 17(2), i.e., research on the treatment of rare or incurable diseases, such as muscular dystrophy.³⁵⁷ The permissible scope of such therapeutic research may be determined by Presidential Decree after consideration by the NBRC.³⁵⁸

f. Genetic Testing

Any institute for genetic testing may not perform a genetic test that is likely to mislead the tested person due to its uncertain value as

351. *Id.* Article 13(1).

352. *See* The Bioethics and Biosafety Act of 2003 (South Korea), Art. 13(2) (2003).

353. *See id.* Art. 13(3).

354. *Id.* Art. 14(1).

355. *Id.* Art. 17.

356. *Id.* Art. 18.

357. *Id.* Art. 22(1).

358. *See* The Bioethics and Biosafety Act of 2003 (South Korea), Art. 22(2) (2003).

scientific proof, i.e., a genetic test for any physical appearance or personality.³⁵⁹ Any genetic test on embryos and fetuses may not be conducted for any purpose other than diagnosing muscular dystrophy and other genetic diseases prescribed by Presidential Decree.³⁶⁰ Any non-medical institute for genetic testing may not conduct genetic tests related to the diagnosis of diseases other than those tests requested by a medical institute.³⁶¹

g. Protection and Use of Human Genetic Information

Genetic information may not be used to discriminate against any person with respect to his or her social activities, such as obtaining education, employment, promotion, and insurance.³⁶² People may not be forced to be subject to genetic tests or to be required to submit the results of genetic test without an order pursuant to other laws and regulations.³⁶³

h. Aftermath of the Enactment of the Bioethics and Biosafety Act

In March 2004, the Ministry of Health and Welfare launched the Bioethics and Safety Task Force Team.³⁶⁴ Its purpose is to create a national framework regarding cloning research in order to ensure the MHW's transparency and ethical integrity in relation to the Bioethics and Biosafety Act that will take effect in 2005.³⁶⁵ While making it clear that the recent cloning of human embryos by Professor Hwang's team should not be used by religious cults to justify their case for human cloning, the MHW supports research that is carried out within the current legal boundaries and is designed to develop therapeutic cloning to treat rare and intractable diseases.³⁶⁶

The Task Force Team has been responsible for establishing and running the NBRC.³⁶⁷ This responsibility has included putting together a group of advisers, composed of professors and experts,

359. *See id.* Art. 25(1).

360. *Id.* Art. 25(2).

361. *Id.* Art. 25(3).

362. *Id.* Art. 31(1).

363. *Id.* Art. 31(2).

364. *See* Press Release, Ministry of Health and Welfare, Bioethics and Safety Task Force Team Has Been Launched (Mar. 4, 2004), available at http://english.mohw.go.kr/board/press/press_view.jsp?CN=182&CUR_PAGE=7

365. *See id.*

366. *See id.*

367. *Id.*

considering feedback from the group of advisors, creating a pool of specialists who will work as members of the Committee, and conducting a survey on sterility clinics, human embryo labs, and DNA testing institutes around the country in order to frame a detailed standard of personnel and facilities in these institutions, which will be incorporated into the sub-regulations of the biological ethics law by June 2005.³⁶⁸

On January 12, 2005, the MHW established the Bioethics Policy Division to handle specific implementation of the 2003 Act.³⁶⁹ On the same date, the government approved embryonic stem cell research led by Seoul National University Professor Hwang Woo Suk.³⁷⁰ The Ministry of Health and Welfare authorized an application, filed by the research team led by Professor Hwang, for the registration of a research institute on embryos and a research institute on the cloning of stem cells from human embryos, as well as an application for authorization for stem cell research.³⁷¹ This authorization follows an inspection of the status of laboratories as well as a review of relevant documents. This was the first approval issued after the nation's new bioethics law went into effect.³⁷² This approval by the MHW is expected to boost Professor Hwang's stem cell research under the government management system.³⁷³

Arguably, the Korean government's hands-off attitude is the Korean researchers' strongest advantage.³⁷⁴ Moreover, most Koreans reacted to the news of Hwang's cloning achievement with patriotic fervor despite their awareness of the ethical issues.³⁷⁵ President Roh

368. *Id.*

369. See Press Release, Ministry of Health and Welfare, The Ministry of Health and Welfare Authorizes Stem Cell Research by Professor Hwang Woo-seok and His Team (Jan. 14, 2005), available at

http://english.mohw.go.kr/board/press/press_view.jsp?CN=282&CUR_PAGE=1.

370. *See id.*

371. *Id.* However, this authorization shall remain valid only until a separate Presidential decree on research on human stem cell cloning is announced following deliberation by the National Bioethics Review Committee, which is planned to be organized around the end of January. The Ministry of Health and Welfare has announced that the team needs to once again undergo official procedures for the authorization of research in accordance with the provisions in the 2003 Act following the promulgation of a new Presidential decree. *Id.*

372. See *Gov't Approves Cloning Research by Geneticist Hwang*, Korea Update, Jan. 21, 2005, at http://www.koreaemb.org/archive/2005/1_1/econ/econ5.asp.

373. *See id.*

374. See B. J. Lee, *Cloning College: South Korea's Biomedical Researchers, Unhindered by Politics, Do World-class Research on the Cheap*, NEWSWEEK INT'L, Mar. 1, 2005, available at <http://msnbc.msn.com/id/4339445/>.

375. *See id.*

has promised to “place top priority on the support of the bioengineering industry.”³⁷⁶ According to the MHW, South Korea will continue its stem cell research despite the anti-cloning resolution of a United Nations committee.³⁷⁷ The Korean government will increase support for Seoul National University Professor Hwang Woo Suk by nominating him as the nation’s first “Supreme Scientist.”³⁷⁸

IV. PATENT PROTECTION OVER THE RESULTS OF HUMAN CLONING AND EMBRYONIC STEM CELL RESEARCH

A. Requirements for Patentability under United States Patent Law

Congressional authority to grant patents to individuals is derived from the United States Constitution.³⁷⁹ The current version of the Patent Act was enacted in 1952 and sets forth the requirements for an invention to receive a patent.³⁸⁰ To be valid, the claimed invention must comprise patentable subject matter,³⁸¹ have utility,³⁸² be novel,³⁸³ be non-obvious,³⁸⁴ and enable others skilled in the art to practice the

376. *Id.*

377. See Kim Tae-gyu, *Korea to Continue Cloning Research*, THE KOREA TIMES, Feb. 21, 2005, available at

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki3%2Ftimes%2Fipage%2Ftech%2F200502%2Fkt2005022118122111780.htm.

378. See Kim Tae-gyu, *Cloning Scientist Hwang to Get More Funding*, THE KOREA TIMES, Mar. 2, 2005, available at

http://search.hankooki.com/times/times_view.php?terms=cloning+code%3A+kt&path=hankooki3%2Ftimes%2Fipage%2F200503%2Fkt2005030217325710160.htm.

379. See U.S. CONST. art. I, § 8, cl. 8.

380. See 35 U.S.C. §§ 100–103, 112 (2004).

381. See *id.* § 101 (2004). Patentable subject matter includes a “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” *Id.*; see also *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter . . . Such discoveries are “manifestations of . . . nature, free to all men are reserved exclusively to none.”

Id. (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

382. See 35 U.S.C. § 101 (2004). Claimed inventions must have a designated use to establish utility. *Id.*; see also *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (“The threshold of utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing some identifiable benefit.”).

383. See 35 U.S.C. § 102(a) (2004) Claimed inventions must be novel, i.e., distinct from prior art. Inventions may not be “known or used by others in this country . . . before the invention thereof by the applicant for patent.” *Id.*

384. See *id.* § 103 (2004) (stating that a claimed invention must embody a significant, non-obvious advance over prior art to be valid).

invention.³⁸⁵ Additionally, any inventions that result from human embryonic stem cell research and pertain to human biological materials are subject to the human scope prohibition.³⁸⁶

1. Patentable Subject Matter

To be valid, a patent must describe an invention that comprises patentable subject matter.³⁸⁷ Patentable subject matter is construed broadly as “anything under the sun that is made by man.”³⁸⁸

a. Results of Human Intervention

Products occurring in nature are not considered patentable subject matter since they are subject to discovery rather than invention.³⁸⁹ Human input, however, may transform a product of nature into a human-made product.³⁹⁰ A biological product cannot be patented unless it has been sufficiently manipulated to cease being “nature’s handiwork.”³⁹¹ By isolating pure cultures and microorganisms, the inventors may create a valid claim in a manufacture or process that does not occur separately and distinctly in nature.³⁹² Therefore, isolated DNA sequences that code for proteins that function in detecting or treating diseases may be patentable subject matter rather than a product of nature.³⁹³ The patentability of inventions pertaining to biological organisms, including human

385. *See id.* § 112 (2004) (stating that the patent specification must include a written description that enables others skilled in the relevant art to practice the invention).

386. *See* Damon J. Whitaker, *The Patentability of Embryonic Stem Cell Research Results*, 13 U. FLA. J.L. & PUB. POL’Y 361, 376–77 (2002).

387. *See* 35 U.S.C. §§ 101–103 (2004).

388. *See* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

389. *See id.*

390. *Id.*

391. *Id.* at 310 (holding that genetically engineered bacteria were patentable subject matter). *But cf.* *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (holding that naturally occurring bacteria were not transformed into patentable subject matter when they were merely isolated from nature).

392. *See In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *vacated*, 444 U.S. 1028 (1980); *In re Bergstrom*, 427 F.2d 1394 (C.C.P.A. 1970) (upholding patents for isolated human and animal prostaglandins); *see also* *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 104 (S.D.N.Y. 1911) (upholding patents for purified adrenaline isolated from surrounding tissues).

393. *See generally* U.S. Patent No. 5,977,333 (issued Nov. 2, 1999) (DNA Sequence Encoding the Myotonic Dystrophy Gene and Uses Thereof); U.S. Patent No. 5,840,491 (issued Nov. 24, 1998) (DNA Sequence Encoding the Machado-Joseph Disease Gene and Uses Thereof); U.S. Patent No. 4,703,008 (issued Oct. 27, 1987) (DNA Sequences Encoding Erythropoietin).

matter, depends upon whether they result from sufficient human intervention or manipulation.

b. The USPTO Policy of 'Human Scope' Prohibition

The current USPTO policy is set forth in two internal documents. One is a 1987 statement by the USPTO that states,³⁹⁴

The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101

A claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection.³⁹⁵

And the second is the USPTO's, Manual of Patent Examining Procedure ("MPEP") (Revised February 2003), section 2105: "Patentable Subject Matter—Living Subject Matter" which states that: "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter."³⁹⁶

Recently, a USPTO official testified to the President's Council on Bioethics:

When a patent claim includes or covers a human being, the USPTO rejects the claim on the grounds that it is directed to non-statutory subject matter. When examining a patent application, a

394. See Commissioner of Patents and Trademarks, *Policy Statement on Patentability of Animals*, 1077 OFF. GAZ. PAT. OFFICE 24 (1987), reprinted in 9 DONALD S. CHISUM, CHISUM ON PATENTS, app. 24 at 24-2 (1999).

395. *Id.* This notice responded to the Supreme Court's 1980 decision in *Chakrabarty*, concluding that a modified microorganism, a non-natural bacterium, could be patented, and a subsequent decision by the USPTO Board of Patent Appeals and Interferences in *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. and Interferences 1987) that a multicellular organism such as a modified oyster is therefore patentable as well. The USPTO sought to ensure that these policy conclusions would not be misconstrued to allow a patent on a human organism.

396. See UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (8th ed., Aug. 2001), available at http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r2_2100_508.pdf (latest revision May 2004).

patent examiner must construe the claim presented as broadly as is reasonable in light of the application's specification. If the examiner determines that a claim is directed to a human being at any stage of development as a product, the examiner rejects the claims on the grounds that it includes non-statutory subject matter and provides the applicant with an explanation. The examiner will typically advise the applicant that a claim amendment adding the qualifier, non-human, is needed, pursuant to the instructions of MPEP 2105. The MPEP does not expressly address claims directed to a human embryo. In practice, examiners treat such claims as directed to a human being and reject the claims as directed to non-statutory subject matter.³⁹⁷

According to the USPTO's policy statement, "non-naturally occurring nonhuman multicellular organisms," including animals, are patentable subject matter while a "claim directed to or including within its scope a human being will not be considered patentable subject matter."³⁹⁸ This ban on patenting human beings stems from the constitutional prohibition of slavery, in other words, the constitutional prohibition of property rights in humans.³⁹⁹

c. Inventions Involving Human Matter

The USPTO has not adopted a policy to exclude all patents which involve human material.⁴⁰⁰ The USPTO has issued patents claiming human transfected cells and cell lines as compositions of matter, finding human stem cell lines to be patentable subject matter.⁴⁰¹ However, it is doubtful that patent protection will be available for further advanced composition of matter, such as human organs, because the USPTO will likely find that any claims of such inventions violate the USPTO's human scope policy statement.⁴⁰² Any inventions that pertain to human matter may still be patentable if they are not identified as human beings.⁴⁰³ There is a controversy

397. See Testimony of Karen Hauda, United States Patent and Trademark Office, to the President's Council on Bioethics (June 12, 2002), at <http://bioethicsprint.bioethics.gov/transcripts/jun02/june21session5.html>.

398. See Mark Jagels, *Dr. Moreau Has Left the Island: Dealing with Human-Animal Patents in the 21st Century*, 23 T. JEFFERSON L. REV. 115, 131-32 (2000) (emphasis omitted).

399. See U.S. CONST. amend. XIII, § 1.

400. See Jagels, *supra* note 398, at 117.

401. See *id.* at 125.

402. See Whitaker, *supra* note 386, at 378.

403. See Jagels *supra* note 398, at 122-26.

about whether chimeras and transgenic animal inventions would be patentable.⁴⁰⁴

i. Cell Lines and Transfected Cells

Patents for human cell lines and transfected cells are now widely accepted.⁴⁰⁵ *Chakrabarty v. Diamond* was the landmark case which decided with whether or not a bacterium, which neither was derived from a human being nor contained a human gene, was patentable.⁴⁰⁶ The court ruled that a live, human-made microorganism is patentable subject matter under 35 U.S.C. § 101.⁴⁰⁷ The bacterium constituted a “manufacture” or “composition of matter” within that statute, and was not a hitherto unknown natural phenomenon.⁴⁰⁸ Subsequently, a patent claiming a bacterium expressing the human genes for proinsulin⁴⁰⁹ and another patent claiming both bacteria and human cell lines expressing the gene for human erythropoietin were issued.⁴¹⁰ Patents for cell lines either derived from human or animal tumors or that were artificially immortalized by manipulation were routinely granted patents.⁴¹¹

In the case of *Moore v. The Regents of the University of California*, the issue was whether or not the subject matter of the Regents’ patent—the patented cell line and the products derived from it—was Moore’s property.⁴¹² The *Moore* court concluded that a cell line was patentable because it was the result of an inventive effort.⁴¹³ Developing primary cells (the cells taken directly from the body) into a cell line is difficult, and is often an art with a low probability of success.⁴¹⁴ Arguably, the reasoning in *Moore* legitimizes the issuance of process patents, but does not address the legitimacy of issuing

404. See *id.* at 125; see also Valerie J. Phillips, *Half-Human Creatures, Plants & Indigenous Peoples: Musings on Ramifications of Western Notions of Intellectual Property and the Newman-Rifkin Attempt to Patent a Theoretical Half-Human Creature*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 383, 385–87 (2005) (explaining chimeras and hybridization of breeds).

405. *Id.* at 125–26.

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

407. See *id.* at 308–18.

408. *Id.* at 308–10.

409. See U.S. Patent No. 4,431,740 (issued Feb. 14, 1984).

410. See U.S. Patent No. 4,703,008 (issued Oct. 27, 1987).

411. See *Moore v. Univ. of Cal.*, 793 P.2d 479 (Cal. 1990); U.S. Patent No. 4,438,032 (issued Mar. 20, 1984).

412. See *Moore*, 793 P.2d at 488–89.

413. *Id.* at 492–93.

414. *Id.* at 481–82 n.2.

product patents for a cell line.⁴¹⁵ However, cell lines have generally been exempt from the policy prohibiting patents over living matter.⁴¹⁶ It has been estimated that more than one thousand patents involving human genes expressed by bacteria, yeast, or human cell lines have been issued.⁴¹⁷

The amount of human genetic material is not determinative of human essence for purposes of deciding the patentability of subject matter.⁴¹⁸ The USPTO has allowed patents on human cell lines that contain purely human DNA.⁴¹⁹ The USPTO may exclude any intact organism, presumably a mammal that expresses human genetic material, as inappropriate subject matter.⁴²⁰ As long as a cell line is incapable of differentiating into a human, it would not be considered a human being under the USPTO guideline.⁴²¹

ii. Multicellular Organisms Containing Human Material

Multicellular organisms have been manipulated to contain human genes. A number of patents have been issued for transgenic animals, which are produced by the introduction of a human gene into a fertilized animal ovum or early embryo.⁴²² For example, a mouse which had been genetically infused with a human cancer gene, for the purpose of experimentation, was deemed patentable.⁴²³ The mouse was novel under *Chakrabarty* because of its acquired cancer susceptibility and inserted human gene.⁴²⁴ The mouse had a utility as an animal model for research on carcinogenesis.⁴²⁵ It was non-obvious because of the novel technology employed and because of the newly identified human oncogenes that were introduced into the mouse.⁴²⁶ Hundreds of patents involving animals into which human genes have

415. See Jagels, *supra* note 398, at 129.

416. See *id.* at 130.

417. See Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 444 (1999).

418. See Jagels, *supra* note 398, at 129.

419. See *id.* at 125.

420. *Id.* at 129.

421. *Id.*

422. See *id.* at 124.

423. See U.S. Patent No. 4,736,866 (issued Apr. 12, 1988). The patent is known as the "Harvard transgenic mouse." The claims included animals into which human oncogenes were introduced.

424. See Jagels, *supra* note 398, at 132.

425. See *id.*

426. See *id.*

been introduced have been granted.⁴²⁷ The utility of the animals tends to be determined based on their commercial value.⁴²⁸

Multicellular organisms have also been manipulated to contain human cells by engrafting human ES cells or adult stem cells into a host organism⁴²⁹ or by combining human and non-human ES cells.⁴³⁰ For example, an animal model where mice with severe combined immune deficiency were given human bone marrow transplants was deemed patentable.⁴³¹ In contrast, in 1998, techniques for combining ES cells of humans and animals to produce a chimera were not patentable.⁴³² The USPTO did not reject the patent based upon public policy and moral reasons.⁴³³ However, the USPTO issued a media advisory stating that a "human/non-human chimera could . . . fail to meet the public policy and morality aspects of the utility requirement."⁴³⁴ The examiner stated, "[t]he [US]PTO believes that Congress did not intend 35 U.S.C. to include the patenting of human beings. Since applicant's claimed invention embraces a human being, it is not considered to be patentable subject matter."⁴³⁵ In fact, the claims were broadly written, including a variety of different combinations of human and animal cells as well as both embryos and fully developed organisms that would result from the combinations.⁴³⁶ Apparently, the claimed invention could be considered human even when an immeasurably minute amount of non-human material is present.⁴³⁷ Therefore, the extent of patentability of the results of manipulation of multicellular organisms containing human cells appears unsettled.⁴³⁸ A claim will very likely be rejected if it

427. *Id.*

428. *See id.* at 133.

429. *See id.* at 123.

430. Jagels, *supra* note 398, at 133.

431. *See* U.S. Patent No. 5,652,373 (issued July 29, 1997) (Engraftment and Development of Xenogenic Cells in Normal Mammals Having Reconstituted Hematopoietic Immune Systems).

432. *See Patent Application is Disallowed as 'Embracing' Human Being*, 58 PAT. TRADEMARK & COPYRIGHT J. (BNA) 203, 203 (June 17, 1999).

433. *See* Jagels, *supra* note 398, at 133; *see also* Media Advisory No. 98-6, United States Patent and Trademark Office, *Facts on Patenting Life Forms Having a Relationship to Humans* (Apr. 1, 1998), at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>.

434. *See* Jagels, *supra* note 398, at 133 (quoting Media Advisory No. 98-6, *supra* note 433).

435. *See id.* at 134.

436. *See id.* at 133.

437. *See id.* at 133-34.

438. *Id.* at 125.

potentially covers a composition made predominantly of human matter.⁴³⁹

iii. Patentability of Human Cloning and Embryonic Stem Cell Research

The extent of patentability of potential claims from human cloning and ES cell research has not yet been fully explored in the United States because of the continued governmental ban on human cloning and ES cell research. Possible claims include product claims on various human material created from the research, and process claims that include methods on how to obtain and how to use the product. Product claims and process claims will not necessarily have the same outcome with respect to whether they are patentable subject matter.⁴⁴⁰

As discussed above, currently no statutory foundation exists for excluding any invention that results from human cloning and embryonic stem cell research because of a subject matter rejection.⁴⁴¹ Title 35 of the United States Code does not provide the USPTO with a basis for making this determination, and does not expressly address human subject matter.⁴⁴² The USPTO has issued patents claiming human stem cell lines as a composition of matter.⁴⁴³ However, it is uncertain that the USPTO will grant patents claiming various human organs as composition of matter due to its human scope policy statement.⁴⁴⁴ Ultimately, whether any product or composition of matter is considered patentable subject matter depends upon how the scope of a human being is defined.⁴⁴⁵

Debates on whether human material created by the cloning process will be considered a human being have frequently focused on whether a two-week-old embryo, asexually produced by SCNT, is a human being.⁴⁴⁶ The biotechnology industry does not consider human

439. *Id.* at 133–34.

440. Jagels, *supra* note 398, at 136; *see also* Whitaker, *supra* note 386, at 378.

441. *See* Jagels, *supra* note 398, at 136.

442. *See id.*

443. *See, e.g.*, U.S. Patent No. 6,090,622 (issued July 18, 2000) (Human Embryonic Stem Cell Lines).

444. *See* Whitaker, *supra* note 386, at 378.

445. *See* Jagels, *supra* note 398, at 136.

446. *See* Dianne N. Irving, *Analysis: Stearns' Congressional Human Cloning Fairy Tale "Ban"; New Age and Transhumanist Legislation for "Converging Technologies"?*, Lifeissues.net, at http://www.lifeissues.net/writers/irv/irv_77_stearncloningtale1.html (last visited Mar. 20, 2005); *see also* Testimony of Michael D. West, President and CEO of

material created by SCNT a human being.⁴⁴⁷ Senator Feinstein (D-CA) referred to two-week-old cloned embryos as unfertilized eggs, and asserted that such an unfertilized egg is not capable of becoming a human being.⁴⁴⁸ It has not been debated that cloned mammals are created via asexual reproduction through the laboratory manipulation of a nucleus taken from a single parent and are unfertilized, in the sense that they are not created by the union of sperm and egg.⁴⁴⁹

In contrast, the National Right to Life Committee includes any human embryo, fetus, child, or adult as members of the species *Homo sapiens* in any discussion regarding human cloning issues.⁴⁵⁰ The Committee asserts that one of these cloned embryos can be born as a human baby if implanted into a uterus, just like Dolly the Sheep and other cloned mammals.⁴⁵¹ Furthermore, it argues that it cannot be said that an unfertilized human embryo is not a human being if such embryo is implanted, develops through the pre-natal period, is born, and lives.⁴⁵² The Committee finds some support for their argument from the 1997 report of President Clinton's National Bioethics Advisory Commission on *Cloning Human Beings* that states "[t]he Commission began its discussions fully recognizing that any effort in

Advanced Cell Technology, Inc., to the Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies (July 18, 2001), at

<http://www.advancedcell.com/testimony-2001-07-18.htm> ("[A]n individual human life, as opposed to merely cellular life, begins with the primitive streak (i.e., after 14 days of development).") (last visited Mar. 20, 2005). The appearance of the primitive streak at around fourteen days of the embryonal age is considered important biologically and developmentally because it signals the formation of three germ layers in an embryo that differentiate into all types of human cells. *Id.*

447. See Biotechnology Industry Organization, *The Value of Therapeutic Cloning for Patients*, at <http://www.bio.org/bioethics/background/tcloning.asp> (last visited Mar. 20, 2005) ("[SCNT] involves removing the nucleus of an egg cell, replacing it with the material from the nucleus of a 'somatic cell' . . . This egg cell is never fertilized by sperm . . . stem cells can be extracted from it 5–6 days later . . ."); see also Irving Weissman, *A Message from the Director of the Institute of Cancer/Stem Cell Biology and Medicine at Stanford*, THE STANFORD REPORT, Jan. 22, 2003, at

<http://news-service.stanford.edu/news/2003/january22/message.html> ("Technically, one should not use the term embryo to describe a blastocyst produced by nuclear transfer as an embryo, because it was not the product of sperm and egg . . .").

448. 148 CONG. REC. S5563, S5580 (daily ed. June 14, 2002) (statement of Sen. Feinstein).

449. See Beardsley, *supra* note 119; see also THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY 57–73 (July 2002), available at <http://www.bioethics.gov/reports/cloningreport/background.html>.

450. See 149 CONG. REC. H1397, H1401–02 (daily ed. Feb. 27, 2003) (statement of Rep. Musgrove).

451. See *id.*

452. *Id.*

humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term.”⁴⁵³

(1) Product Claims

Unmodified human cells and tissues, as they exist *in vivo*, cannot be patented under current United States law.⁴⁵⁴ For example, mature egg cells, mature sperm cells, zygotes, blastocysts, totipotent or pluripotent stem cells, embryos, fetuses, and humans are not patentable.⁴⁵⁵ In contrast, modified cells such as enucleated or genetically modified egg cells, sperm cells, somatic cells and tissues, cultured tissue or synthetic organs are patentable.⁴⁵⁶

Human embryonic stem cell lines derived from SCNT would fall under the same conditions of patentability as cell lines, genes, and other products of natural derivation.⁴⁵⁷ Patenting special types of stem cells that have been identified for the first time as useful for treatment and that can be isolated by a specific process, e.g., based on antigenic markers, is no different than the commercialization of the human body by patenting of novel genes.⁴⁵⁸ Moreover, the process of isolating, expanding, and characterizing human ES cell lines makes the cell lines eligible to receive patent protection under governing case law.⁴⁵⁹ Furthermore, it does not appear that the USPTO considers a claim encompassing a human stem cell line to be directed to, or included within its scope, a human being.⁴⁶⁰ Human adult stem cells, identified in adult bone marrow, were patentable as compositions of matter.⁴⁶¹ The issuance of such patents, and the lack of challenges to their validity, proves that the patentability of such human cells and biological materials is not within the human scope of the USPTO’s

453. See National Right to Life, *Are Human Clones Really “Human”?* at http://www.nrlc.org/Killing_Embryos/arecloneshuman.html (last visited Feb. 7, 2005).

454. See Biotechnology Industry Organization, *supra* note 169.

455. See *id.*

456. *Id.*

457. See R. Stephen Crespi, *Patenting and Ethics—A Dubious Connection*, 85 J. PAT. & TRADEMARK OFF. SOC’Y 31, 46 (Jan. 2003).

458. See *id.*

459. See Whitaker, *supra* note 386, at 376–77.

460. See *id.* at 377.

461. See Warren D. Woessner, *The Evolution of Patents on Life—Transgenic Animals, Clones and Stem Cells*, 83 J. PAT. & TRADEMARK OFF. SOC’Y 830, 841 (Nov. 2001) (referring to U.S. Patent No. 4,714,680 (issued Dec. 22, 1987) that claims a preparation containing hematopoietic stem cells: “4. A suspension of human cells from blood comprising pluripotent lympho-hematopoietic stem cells substantially free of mature lymphoid and myeloid cells.”).

regulations.⁴⁶² Indeed, a purified preparation of human embryonic stem cells, *per se*, was deemed patentable on March 14, 2001.⁴⁶³

The first issue regarding the patentability of cloned embryos, human tissues, and organs developed from cloned embryos, is whether or not those *in vitro* products are manmade, rather than a product of nature.⁴⁶⁴ To be patentable in accordance with existing law, the embryos “must be ‘given a new form, quality, properties or combination not present in the original article existing in nature.’”⁴⁶⁵ Presumably, only embryos and stem cells that have been modified by *in vitro* treatment or genetic modification are considered fit patentable subject matter.⁴⁶⁶ Growing oocytes in culture and performing SCNT on the oocytes would meet those requirements.⁴⁶⁷

It may be argued that the difference between SCNT and *in vitro* fertilization is not material; therefore, if *in vitro* fertilization does not transform a human embryo into a human invention, then SCNT does not transform a cloned embryo into an invention, either. Moreover, cloned embryos seem to retain the potential to develop to term if implanted *in utero* just like any fertilized ovum. However, it may still be argued that the difference between SCNT and *in vitro* fertilization is significant. It may also be argued that SCNT involves more extensive and drastic genetic manipulation than *in vitro* fertilization.

Whether cloned embryos, and human tissues and organs derived from them are patentable human subject matter is controversial and uncertain.⁴⁶⁸ The debates focus on the USPTO’s human scope

462. See Whitaker, *supra* note 386, at 378.

463. See Woessner, *supra* note 461, at 840 (referring U.S. Patent No. 6,200,806 (issued Mar. 13, 2001) that claims

1. A purified preparation of pluripotent human embryonic stem cells which (i) will proliferate in an *in vitro* culture for over one year, (ii) maintains a karyotype in which the chromosomes are euploid and not altered through prolonged culture, (iii) maintains the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) is inhibited from differentiation when cultured on a fibroblast feeder layer).

464. See *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. and Interferences 1987), *aff’d*, 846 F.2d 77 (Fed. Cir. 1988); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (holding that genetically engineered bacteria were patentable subject matter); *cf. Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (holding that naturally occurring bacteria were not transformed into patentable subject matter when they were merely isolated from nature).

465. See Woessner, *supra* note 461, at 830 (quoting a statement by the USPTO days after *Ex parte Allen* was decided).

466. See Biotechnology Industry Organization, *supra* note 454.

467. See *id.*

468. See Whitaker, *supra* note 386, at 376.

prohibition⁴⁶⁹ which was confirmed by recent amendment.⁴⁷⁰ The developmental stages of an embryo involved, as discussed earlier, the mode of sexual reproduction, and the potential to develop to term would be relevant to debates on whether the claimed product violates the human scope policy statement.

(2) Process Claims

The products and methods for cloning, in general, are usually patentable.⁴⁷¹ Methods of nuclear transfer, methods of making a transgenic mammal, methods of culturing gametes, zygotes, or embryonic tissues, methods of genetically modifying cells or tissues, etc. have been patented.⁴⁷² The USPTO has awarded patents for the creation of genetically modified non-human mammals via cloning.⁴⁷³ Moreover, the USPTO has issued a patent on a method for turning unfertilized eggs of mammals into embryos, which would extend to human embryos cloned by this method.⁴⁷⁴ The extension occurs because a nonhuman disclaimer is not included in the claims of the patent and it specifically mentions the use of human eggs.⁴⁷⁵ Patents have also been issued for the methods utilized in the isolation and purification of stem cells and in corresponding research.⁴⁷⁶

The patentability of other types of possible end-products of human ES cell research that do not directly relate to human material appears to be more firmly established.⁴⁷⁷ Applications in the areas of cell culture, tissue transplantation, drug discovery, and gene therapy have been patented.⁴⁷⁸ As long as inventions do not claim human

469. *See id.* at 378.

470. *See* Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat 3, 101 (2004).

471. *See* Biotechnology Industry Organization, *supra* note 454.

472. *See id.*

473. *See* U.S. Patent No. 5,945,577 (issued Aug. 31, 1999).

474. *See* U.S. Patent No. 6,211,429 (issued Apr. 3, 2001).

475. *See id.* at claim 12.

476. *See* U.S. Patent No. 6,602,711 (issued Aug. 5, 2003) (“10. The method of claim 1, wherein the primate embryonic stem cells are human embryonic stem cells and the primate embryoid bodies are human embryoid bodies”).

477. *See* Whitaker, *supra* note 386, at 378.

478. *See* U.S. Patent No. 6,534,052 (issued Mar. 18, 2003) (claiming a method for improving cardiac function in a living mammalian subject after the occurrence of a myocardial infarction within the heart tissue by implanting embryonic stem cells); *see also* U.S. Patent No. 6,562,619 (issued May 13, 2003) (claiming a method of isolating primordial germ cells from human embryonic tissue, such as from the gonadal ridges of human embryo; a method of producing human pluripotent embryonic germ cells); U.S. Patent No. 6,569,421 (issued May 27, 2003) (claiming a treatment of brain damage by cellular transplantation; a method for treating a

compositions as an end product and the claims meet all of the patentability requirements set forth in the Patent Act, the inventions are patentable, even if the research methods involve the employment of human ES cells and result in products that fall under the human scope prohibition.⁴⁷⁹ Thus, there seems to be an apparent acceptability of process patents.

2. Utility

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” may apply to obtain a patent on that invention.⁴⁸⁰ In *Brenner v. Manson*, the Supreme Court held, that in light of the policy considerations underlying the statutory requirement for utility, a patentable process must be useful and that a new chemical process was not inherently useful by virtue of its being a contribution to scientific researchers.⁴⁸¹ Proof of the practical utility of the compound produced by the process is an essential element in establishing a prima facie case for its patentability.⁴⁸² The court required that “until a process is refined and developed [such 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.”⁴⁸³ However, the fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding lack of utility, and some degree of utility is sufficient for patentability under patent law.⁴⁸⁴ Potential utility⁴⁸⁵ or

motor, sensory and/or cognitive deficit by administering a composition comprising pluripotent cells into the damaged brain in a region contralateral to that containing the site of damage); U.S. Patent No. 6,607,720 (issued Aug. 19, 2003) (claiming a therapeutic application of genetically altered mammalian embryonic stem cells and their living progeny for improving cardiac function after myocardial infarction); U.S. Patent No. 6,630,349 (issued Oct. 7, 2003) (claiming an isolated preparation of stable pluripotent trophoblast stem cell lines and uses of the cell lines).

479. See Whitaker, *supra* note 386, at 378.

480. See 35 U.S.C. § 101 (2004).

481. *Brenner v. Manson*, 383 U.S. 519, 534–36 (1996).

482. See *Brenner*, 383 U.S. at 534–35.

483. See *id.*

484. See *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 (Fed. Cir. 1984).

485. See *Brenner*, 383 U.S. at 534–35 (invalidating patent for a steroid because its asserted utility was speculative, based only on similarity to a compound that showed activity in inhibiting tumors).

usefulness for research purposes alone, do not satisfy the utility requirement.⁴⁸⁶

Courts have debated the appropriate application of *Brenner* to define standards for assessing utility in the areas of biotechnology. For example, in *Nelson v. Bowler*, the court held it was unnecessary for appellant to establish a specific therapeutic use, but that evidence of any utility, such as adequate proof of any pharmacological activity, was sufficient to show practical utility.⁴⁸⁷ In contrast, in *Cross v. Iizuka*, the court held that a consideration in the determination of whether a patent should be granted is the benefit derived by the public from an invention with substantial utility.⁴⁸⁸ In *Ex parte Balzarini*, the applicants claimed compounds with activity against the AIDS virus, by showing *in vitro* activity.⁴⁸⁹ However, the USPTO denied issuing a patent due to the absence of demonstrating *in vivo* efficacy.⁴⁹⁰ In response to the results of *Balzarini* and similar decisions that excessively restricted the patentability of potentially valuable compounds at early stages of development, the USPTO issued new utility guidelines in 1995. The new utility guidelines provided that an application is rejected on the basis of utility defects if no credible assertion of specific utility for the claimed invention is made by the applicant, and the claimed invention does not have a well-established utility.⁴⁹¹ Under the 1995 utility guidelines, the USPTO has the burden of a *prima facie* showing that the claimed invention has no utility.⁴⁹² This showing must be based on specific evidence that supports any fact-based assertions.⁴⁹³ Once the USPTO has met its burden, the applicant bears the burden of rebutting it.⁴⁹⁴

In deference to the USPTO's expertise and in the absence of binding authority to the contrary, courts applied the 1995 utility guidelines to assess utility of the claimed invention.⁴⁹⁵ The USPTO's

486. See *id.* at 536 (stating that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

487. See *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).

488. See *Cross v. Iizuka*, 753 F.2d 1040 (Fed. Cir. 1985).

489. See *Ex parte Balzarini*, 21 U.S.P.Q.2d (BNA) 1892, 1894 (Bd. Pat. App. and Interferences 1991).

490. See *id.* at 1895-96.

491. See Utility Examination Guidelines, 60 Fed. Reg. 36,263, 36,264 (July 14, 1995).

492. See *id.* at 36,265.

493. See *id.*

494. See *id.*

495. See *Cross v. Iizuka*, 753 F.2d 1040, 1044 n.8 (Fed. Cir. 1985) ("[Q]uestions regarding utility are factual in nature . . . and are to be determined in the first instance by the [US]PTO, the agency with the expertise in this regard."); *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995)

2001 Utility Examination Guidelines require a patent applicant to demonstrate either a “well-established” utility or a “specific, substantial, and credible” utility.⁴⁹⁶ To satisfy this standard, the applicant is required to affirmatively assert the utility of the claimed invention in the claims and the supporting written description.⁴⁹⁷ Thus, courts will assess the contested claims to determine whether they demonstrate “well-established” or “specific, substantial, and credible” utility.⁴⁹⁸

Well-established utility requires that a person of ordinary skill in the art will immediately appreciate the invention’s asserted utility, and that the utility is specific, substantial, and credible.⁴⁹⁹ Courts have found well-established utility in devices that were clearly effective in carrying out identifiable functions, including window fasteners and oil-drilling equipment.⁵⁰⁰

Substantial and specific utility standards require that the invention be useful for a particular purpose, and that the asserted utility for a particular practical purpose be considered credible by a person of ordinary skill in the art.⁵⁰¹ “Throw-away,” “insubstantial,” and “nonspecific” utilities fail these standards.⁵⁰² A claim has credible utility if one of ordinary skill in the art would consider the asserted utility to be reasonable in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents, or printed publications) that is probative of the applicant’s assertions.⁵⁰³ Additionally, if a compound demonstrates credible activity in the treatment of a specific disorder, this effect suffices to establish substantial and specific utility.⁵⁰⁴

(“[W]ith regard to questions of fact, we defer to the Agency unless its findings are ‘clearly erroneous.’”).

496. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001).

497. See *id.*

498. *Id.*

499. See *id.*; see also Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CAL. L. REV. 421, 428 n.37 (1999).

500. See *Elliott Core Drilling Co. v. Smith*, 50 F.2d 813, 816 (9th Cir. 1931) (finding well-established utility in a commercially successful rotary core drill that did not show sufficient novelty for patent protection); see also *Edwards v. Dayton Mfg. Co.*, 257 F. 980, 984 (6th Cir. 1918) (finding well-established utility for highly successful window holding and fastening devices that lacked new elements).

501. See Utility Examination Guidelines, 66 Fed. Reg. at 1098.

502. See *id.*

503. *Id.*

504. See *In re Brana*, 51 F.3d 1560, 1565 (Fed. Cir. 1995).

It would not be difficult for biotechnological inventions to meet the utility requirement under the USPTO guidelines.⁵⁰⁵ Most biotechnological inventions that are designed to produce commercially marketable products would disclose any readily apparent utility or at least one particular practical utility.⁵⁰⁶ With respect to results of human ES cell research scientists already see their potential uses in reparative/regenerative medicine, not only as a research tool, but also as a therapeutic tool.⁵⁰⁷ It is not necessary to establish immediate clear-cut applications of an invention derived from human ES cell research because the well-established utility of the invention need not to be shown.⁵⁰⁸ The claims only need to show any specific practical utility of an invention such as, the utility of the invention as an accepted, well-established research tool or therapeutic procedure.⁵⁰⁹

Nevertheless, the USPTO appears to be willing to invoke an alternative aspect of the utility requirement – the morality doctrine.⁵¹⁰ It has been suggested that there is some uncertainty as to the scope of this doctrine regarding stem cells.⁵¹¹ Admittedly, this doctrine refers only to the cloned embryo itself and not to entities derived from the embryo.⁵¹² However, harvesting stem cells from a human embryo with the intention to use them as the source of an intermediate or final product in a commercial-type context may not escape the scope of this doctrine simply because it is technology downstream from the embryonic source.⁵¹³ Furthermore, if the origin of the cells is to be disclosed in the patent application the relevance of this requirement will be clear.⁵¹⁴

505. See Jagels, *supra* note 398, at 137.

506. See *id.*

507. See Hwang et al., *supra* note 2; see also THE NATIONAL INSTITUTES OF HEALTH, STEM CELL INFORMATION: STEM CELLS AND DISEASES, at <http://stemcells.nih.gov/info/health.asp> (last modified on June 10, 2004) [hereinafter STEM CELLS AND DISEASES].

508. See Utility Examination Guidelines, 66 Fed. Reg. at 1098.

509. See *id.*; see also STEM CELLS AND DISEASES, *supra* note 507 (stating potential utility in human development research with respect to both physiological differentiation and abnormal cell division and differentiation such as cancer and birth defects; and in developing a new drug test model, and cell-based therapies for various diseases such as Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, rheumatoid arthritis, etc.).

510. See Media Advisory No. 98-6, *supra* note 433.

511. See Crespi, *supra* note 457, at 45–46.

512. See *id.*

513. *Id.*

514. *Id.*

a. *Morality Doctrine*

According to a USPTO media advisory, an invention of human-related organisms could specifically fail to meet the utility requirement under the morality doctrine.⁵¹⁵ This assertion was based on the seldom used “morality doctrine,” which states that an invention cannot be useful if it is designed for an immoral use. The morality doctrine, which originated as a part of the utility requirement,⁵¹⁶ has been applied and interpreted erratically partially due to the changes in social concepts of morality.⁵¹⁷ Some courts have applied a balancing test between the potential beneficial uses and immoral uses to determine any apparent utility⁵¹⁸ while some courts appear to have abandoned the morality doctrine entirely.⁵¹⁹ Therefore, the status of the morality doctrine is currently in dispute.⁵²⁰ Moreover, because Title 35 of the United States Code “does not specifically require moral balancing” and “social concepts of morality are in a continuous flux,” courts have been “reluctant to use the morality doctrine as the sole basis for rejecting patent applications.”⁵²¹ However, in light of their media statement, the USPTO appears to be willing to invoke the morality doctrine in determining utility of any invention pertaining to human material.⁵²²

3. Novelty

A patented invention will not issue unless the invention is novel.⁵²³ The novelty requirement both protects and rewards original inventors of an innovative device and prevents the grant of a patent to a device that is not innovative.⁵²⁴

In most cases involving human materials, this requirement would not seriously restrict patentability.⁵²⁵ Section 102 requires that no

515. See Media Advisory No. 98-6, *supra* note 433.

516. See Jagels, *supra* note 398, at 138 (citing *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568)).

517. See *id.*

518. *Id.* (citing *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903)).

519. See Jagels, *supra* note 398, at 138 (citing *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Tex. 1988)).

520. See Jagels, *supra* note 398, at 138.

521. See *id.*

522. See Media Advisory No. 98-6, *supra* note 433.

523. See 35 U.S.C. § 102(a), (e), and (g) (2004).

524. See 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.01 (2004) (“An invention must be new at the time of discovery by an original inventor to be patentable.”).

525. See Jagels, *supra* note 398, at 139.

single prior invention contains all of the elements of the claimed invention.⁵²⁶ In *Chakrabarty*, a cell line derived from a tumor could not be said to be novel because it would have been derived from a naturally occurring source.⁵²⁷ Rather, it could be said to be rendered an invention over the original cell because it has itself been changed through the art of growing the cell in culture.⁵²⁸ In cases involving newly identified, but naturally occurring genes, the genes have been considered novel if they were purified and isolated in an expressible form because they were no longer in their original context.⁵²⁹ Moreover, even a non-novel gene may create a novel invention when introduced into another species because it creates a non-natural life form.⁵³⁰ “Accordingly, the novelty requirement may only prevent approval of a patent if the disputed human composition has already been produced.”⁵³¹ If a similar, but non-human invention has been produced, it may trigger the non-obviousness requirement, but not the novelty requirement.⁵³²

It should be considered whether a cloned embryo or ES cell line is novel over the human oocyte donor and cumulus cells⁵³³ that certainly existed prior to the invention of the cloned embryo. The cloned embryo or ES cell line is not identical to either an oocyte or a cumulus cell because the embryo and the ES cells were produced when the oocyte was enucleated with the nucleus from the cumulus cell. Moreover, the existence of the embryo itself or human ES cells *in vitro* would establish novelty over any naturally occurring derivatives of a human oocyte and/or cumulus cell *in vivo*. Therefore, any human material resulting from SCNT, which is altered from its original form and isolated from its original context, should be deemed novel and thus, patentable.

4. Non-Obviousness

The claimed invention should represent an advance over the prior art to deserve patent protection.⁵³⁴ Where “the differences between the subject matter sought to be patented and the prior art are

526. *See id.* at 139–40.

527. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

528. *See id.*

529. *See Jagels, supra* note 398, at 140.

530. *See id.*

531. *Id.*

532. *Id.*

533. *See Hwang et al., supra* note 2, at 1670.

534. *See Eisenberg, supra* note 172, at 730.

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art," the invention is obvious and not patentable.⁵³⁵ This requirement is increasingly difficult to satisfy as scientific knowledge advances in a field.⁵³⁶ It is likely that scientific advances in biotechnology and related fields will make future developments obvious as of the time they are identified.⁵³⁷

"[A]n invention might be non-obvious . . . : (1) if there is no reasonable expectation of success; (2) if arriving at the invention requires undue experimentation . . . ; or (3) if the prior art merely suggests exploration of a promising field of experimentation and gives only general guidance as to the particular form of the claimed invention or how to achieve it."⁵³⁸

The critical inquiries are whether success was reasonably predictable based on the prior art, and whether the inventor has to develop a new technique to create the invention.⁵³⁹ If the prior art led to the production of the claimed biological invention, and there is a reasonable expectation that the invention can be carried out successfully, the invention would fail to satisfy the non-obvious requirement.⁵⁴⁰ Separate analysis may be done on the non-obviousness of the compound itself and on the non-obviousness of the process of obtaining the compound.⁵⁴¹

It would be difficult to predict all of the variations in ES cell lines or cloned embryos correctly. It is questionable whether a person having ordinary skill in the art could anticipate all the unique aspects of ES cell lines or cloned embryos and all aspects of their usefulness, as therapeutic or research tools, based on prior art (e.g., other stem cell lines or cloned non-human animals.) Although it may have been obvious for an inventor to experiment with disclosed stem cell lines or cloned embryos to locate unique differentiation and activities, the invention is not rendered invalid because research findings are unpredictable.⁵⁴²

535. See 35 U.S.C. § 103(a) (2004).

536. See Eisenberg, *supra* note 172, at 730.

537. See *id.*

538. See *id.* at 732–33.

539. *Id.* at 734.

540. *Id.*

541. *Id.* at 734–35.

542. See *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (although a DNA sequence of gene coding for a monkey protein was disclosed, the sequence of the human gene and protein chain was neither obvious nor predictable, even if the area was an obvious target for research).

Additionally, the claimed invention is not obvious under the “similar compound” test.⁵⁴³ Cloned embryos or ES cell lines differ in their functions based on minor differences in genetic and epigenetic material and based on environmental factors.⁵⁴⁴ Despite substantial similarity, the claimed invention may demonstrate unexpected new properties.⁵⁴⁵ Accordingly, obviousness would not invalidate any claimed invention derived from a human ES cell, at least until human cloning and ES cell research employing SCNT become commonplace and obvious to those skilled in the art.

543. See *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990) (holding that claimed new chemical compositions are not obvious when they exhibit unexpected new properties despite structural similarities).

544. See Rudolf Jaenisch & Adrian Bird, *Epigenetic Regulation of Gene Expression: How the Genome Integrates Intrinsic and Environmental Signals*, 33 NATURE GENETICS SUPPLEMENT 245, 245–54 (2003)

Cells of a multicellular organism are genetically homogeneous but structurally and functionally heterogeneous owing to the differential expression of genes. Many of these differences in gene expression arise during development and are subsequently retained through mitosis. Stable alterations of this kind are said to be ‘epigenetic’, because they are heritable in the short term but do not involve mutations of the DNA itself. Research over the past few years has focused on two molecular mechanisms that mediate epigenetic phenomena: DNA methylation and histone modifications. Here, we review advances in the understanding of the mechanism and role of DNA methylation in biological processes. Epigenetic effects by means of DNA methylation have an important role in development but can also arise stochastically as animals age. Identification of proteins that mediate these effects has provided insight into this complex process and diseases that occur when it is perturbed. External influences on epigenetic processes are seen in the effects of diet on long-term diseases such as cancer. Thus, epigenetic mechanisms seem to allow an organism to respond to the environment through changes in gene expression. The extent to which environmental effects can provoke epigenetic responses represents an exciting area of future research.

Id.; see also Shiv I.S. Grewal & Danesh Moazed, *Heterochromatin and Epigenetic Control of Gene Expression*, 301 SCIENCE 798, 798–802 (2003).

Eukaryotic DNA is organized into structurally distinct domains that regulate gene expression and chromosome behavior. Epigenetically heritable domains of heterochromatin control the structure and expression of large chromosome domains and are required for proper chromosome segregation. Recent studies have identified many of the enzymes and structural proteins that work together to assemble heterochromatin. The assembly process appears to occur in a stepwise manner involving sequential rounds of histone modification by silencing complexes that spread along the chromatin fiber by self-oligomerization, as well as by association with specifically modified histone amino-terminal tails. Finally, an unexpected role for noncoding RNAs and RNA interference in the formation of epigenetic chromatin domains has been uncovered.

Id.

545. See *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990).

5. Enablement and Disclosure Requirement

Sections 112 of Title 35 of the United States Code requires that, to be patentable, specifications of patents must enable any person skilled in the art to which the patent pertains, to make and use the claimed invention without undue experimentation.⁵⁴⁶ In the area of biotechnology, the enablement and disclosure requirement is met if one skilled in the relevant art can produce and utilize the invention without undue experimentation.⁵⁴⁷ One way to satisfy the enabling requirement is to deposit a sample of the subject matter of the patent application with the USPTO, thereby guaranteeing accessibility to the public.⁵⁴⁸

It has been known that the basic scientific concepts that apply to creating a transgenic animal and a cloned animal are virtually identical.⁵⁴⁹ Recently many patents were issued for transgenic animals.⁵⁵⁰ Based on the technical similarities between transgenic animals and cloned animals, cloned organisms appear to be as patentable as genetically engineered mice or pigs.⁵⁵¹ Additionally, if human cloning is approved, the disclosure requirement would not seriously restrict patentability in a majority of the cases involving human cloning results.⁵⁵²

There may be challenges in determining the novelty and nonobviousness of claims concerning cell lines isolated and characterized by different methods and described using different terminologies. Additionally, the scope and enforceability of these claims comparing relatively impure cellular populations versus later, purer populations will present a challenge.⁵⁵³ Issues of patentable subject matter enter the field when claims are drawn to manipulating

546. See 35 U.S.C. § 112 (2004). Section 112 requires:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Id.

547. See Jagels, *supra* note 398, at 134.

548. See Timothy G. Hofmeyer, Comment, *Everybody's Got Something to Hide Except Me and My Patented Monkey: Patentability of Cloned Organisms*, 16 J. MARSHALL J. COMPUTER & INFO. L. 971, 992 (1998).

549. See *id.* at 984.

550. *Id.*

551. *Id.* at 993.

552. See Jagels, *supra* note 398, at 140–41.

553. See Woessner, *supra* note 461, at 843–44.

embryonic material and ultimately regenerating embryos and even transgenic humans.⁵⁵⁴

V. CONCLUSION

Human stem cell research is scientifically important because of the utility of human stem cells for research, and perhaps, for patient treatment. Currently no United States laws or regulations would prohibit all cloning research.⁵⁵⁵ However, human cloning and ES cell research in the United States have been severely restricted because federal funds may be awarded only for research on existing stem cell lines that were derived in specified circumstances when the President announced the policy.⁵⁵⁶

The effective regulation of human cloning and ES cell research requires a regulatory regime that is fully prepared to address all scientific issues, including health risks presented by human cloning and ES cell research. It also requires the regulatory regime to be able to confront moral and ethical issues. The FDA regulation on human cloning has the advantage of having a *de facto* regulatory regime, making use of preexisting familiar and flexible guidelines, and providing a preferable alternative to a broad legislative ban as discussed earlier. However, the FDA regulation that is allegedly limited to scientific issues would need to confront moral and ethical issues. It is debatable whether or not the FDA's existing procedures, that were designed long before human cloning technology was realistically possible,⁵⁵⁷ could accommodate this new technology. Particularly, the IND's regime does not encompass reproductive cloning at all.⁵⁵⁸ It also does not extend to any research sponsored by private sectors.⁵⁵⁹

South Korea is now equipped with a framework of regulatory measures dealing with bioethical and safety issues regarding the application of biotechnology with its enactment of the Bioethics and Biosafety Act in December 2003. Under the Bioethics and Biosafety Act, a ban on human cloning is predicated on an act of implanting a cloned embryo through SCNT technology into a woman's uterus, an act of maintaining the implantation of a cloned embryo, or an act of

554. See *id.* at 844.

555. See JOHNSON & WILLIAMS, *supra* note 74, at CRS-3.

556. See Press Release, Office of the Press Secretary, *supra* note 76.

557. See Price, *supra* note 195, at 641.

558. *Id.*

559. See *id.*

facilitating the birth of a cloned baby.⁵⁶⁰ The 2003 Act prescribes the establishment of the NBRC, which will be responsible for reviewing national policy regarding bioethics and safety, and the types, subjects, and scope of the research utilizing excess embryos or employing SCNT technology.⁵⁶¹ IRBs will be responsible for reviewing the ethical and scientific validity of biotechnology research proposals, the proper acquisition of consent from a patient or donor, and the measures to protect personally identifiable information.⁵⁶² The Bioethics and Biosafety Act is a relatively new area of law that must continue to evolve with new developments in biotechnology. The key to success of the legislation will depend upon the performance of NBRC and IRBs in effectuating innovation, health, and humanity in relation to human cloning and ES cell research in Korea.

The patentability of product claims derived from human cloning and ES cell research in the United States depends upon whether the invention is patentable subject matter and whether it does not violate the morality doctrine. Currently, there is no statutory foundation for excluding any invention which results from stem cell research and human cloning based on the subject matter, with the exception of the USPTO policy against patenting a human being based on the Thirteenth Amendment. Ultimately, the outcome will depend upon the definition and the scope of a human being that could be refined only by courts or legislation.

Human cloning exposes the tension between science and morality that challenges existing legal structures.⁵⁶³ Although the accelerating pace of scientific discovery and advances may present an unprecedented challenge to legislators and regulators, any attempt to address the problem must address all the risks presented by human cloning and ES cell research, and must consider the effect a ban would have on beneficial technologies.

560. See The Bioethics and Biosafety Act of 2003 (South Korea), Art. 11 (2003).

561. See *id.*

562. *Id.* Art. 9.

563. See Merrill & Rose, *supra* note 14, at 148.