Cloning Human Organs: Potential Sonrces and Property Implications

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I. INTRODUCTION

On June 26, 2000, scientists involved in the Human Genome Project[1] announced

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1. The Human Genome Project ("HGP") is a "collection of... coordinated projects," with the ultimate goal of mapping the entire human genome. JOEL DAVIS, MAPPING THE CODE: THE HUMAN GENOME PROJECT AND THE CHOICES OF MODERN SCIENCE 3-4 (1990). The National Institutes of Health ("NIH") and the Department of Energy ("DOE") lead U.S. efforts, with private sector corporations (for example, Celera Genomics Corp.) making additional contributions. HGP is an international effort, with contributions from partners in England, Germany, and Japan, among others. Andre C. Frieden, *Regulating Gene Data*, NAT'L L.J., Mar. 27, 2000, at C1.

their success in mapping the human genome.[2] This is the latest step in an ongoing debate: should people be granted a property interest in living material? More specifically, may human genes and tissues be patented? The National Institutes of Health ("NIH") created a stir in 1991 when it filed numerous patent applications for gene sequences identified through its work on the Human Genome Project.[3] Although the NIH later withdrew the patents,[4] the controversy over property rights in human tissues remains.[5] With advances in biotechnology and the advent of cloning, it seems likely these issues will continue to cause controversy for many years to come.

The resolution of these issues will impact developing organ replacement technologies. As the shortage of organs available for transplantation continues to grow,[6] new methods of obtaining organs and tissues are being developed. These technologies raise several issues, including the extent of the property interest people have in their own tissues and the implications of the potential patenting of cloned organs and transgenic animals. This Note examines various organ procurement methods, discusses conflicting property interests these methods raise, and proposes a solution to the competing interests of potentially interested parties. Part II looks at potential sources for organs and tissues needed for transplantation, including the feasibility of cloning organs, cloning humans to be organ donors, and the use of animal organs and xenotransplantation issues. Part III addresses various property rights associated with the organ and tissue sources discussed in Part II, including both traditional property law and possible patent protection. Part IV concludes that a person should have a property interest in cloned organs. Such an interest should extend to organs cloned in a laboratory, but not to the organs of a human clone or to research innovations obtained through the use of donor DNA.

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2. Richard J. Berman, *Gene Sequences*, NAT'L L.J., Sept. 4, 2000, at B7. A genome is "all the genetic material in the chromosomes of a particular organism or species." DAVIS, *supra* note 1, at 284. Chromosomes are made of DNA, and contain genes separated by long segments of "junk DNA." *See* PHILIP KITCHER, THE LIVES TO COME 29-49 (1996).

3. *See* LORI B. ANDREWS, THE CLONE AGE 184-91 (1999).

4. The NIH failed "to demonstrate novelty, nonobviousness, and usefulness." *Animal and Gene Patent Moratorium Bill Is Reintroduced*, BUREAU OF NAT'L AFF. PAT., TRADE MARK & COPYRIGHT L. DAILY, Mar. 9, 1993, *available at* LEXIS, News Library, BNA Pat. File. Although the NIH withdrew its patent applications, other organizations have been granted such patents. PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTALS OF GLOBAL LAW, PRACTICE AND STRATEGY 248-49 (Clarendon Press 3d ed. 1999).

5. *See, e.g.*, Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721 (1990). For a discussion of some of the concerns arising from the HGP, see Mary Z. Pelias & Nathan J. Markward, *The Human Genome Project and Public Perception: Truth and Consequences*, 49 EMORY L.J. 837 (2000).

6. Danielle M. Wagner, Comment, *Property Rights in the Human Body: The Commercialization of Organ Transplantation and Biotechnology*, 33 DUQ. L. REV. 931, 943 (1995); *see also* Tim Bonfield, *Despite New Effort, Organ Giving Down Again*, CIN. ENQUIRER, Feb. 9, 2000, at B1. For a history of organ donation in the United States, see RENÉE C. FOX & JUDITH P. SWAZEY, SPARE PARTS: ORGAN REPLACEMENT IN AMERICAN SOCIETY 3-30 (1992).

II. POTENTIAL SOURCES FOR ORGANS AND TISSUES

This Part addresses the feasibility of using cloning technology as a potential source of transplantable organs. The need for a readily available source of transplantable organs and tissues becomes greater each year. Even though the number of organ transplants increases every year, so does the number of people waiting for a compatible organ.[7] Because of consent requirements[8] and compatibility problems,[9] traditional sources of transplantable organs such as cadaveric organ donation are inadequate to meet the growing demand.[10] Consequently, scientists have begun to look to alternative sources for transplantable organs, one of the most promising sources being cloned organs.

A. Cloned Organs: A Feasible Option?

One of the most beneficial potential uses of the new cloning technology is the possibility of cloning to obtain tissues for transplants.[11] Before the arrival of Dolly,[12] the prospect of successfully cloning humans seemed closer to science fiction than reality. However, when Dr. Ian Wilmut and his colleagues at the Roslin Institute in Scotland presented Dolly to the world, a whole new realm of possible medical uses for cloning technology emerged. This development sparked a debate among scientists, politicians, and scholars about the moral and ethical implications of exploiting the new technology to create human clones.[13] Despite the potential benefits of cloning

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7. U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2000, 130 tbl. 201 (120th ed. 2000), *available at* http://www.census.gov/prod/2001pubs/statab/sec03.pdf.

8. *See infra* notes 43-47 and accompanying text.

9. *See infra* notes 31-32 and accompanying text.

10. Peter A. Ubel et al., *Pennsylvania's Voluntary Benefits Program: Evaluating an Innovative Proposal for Increasing Organ Donation*, *in* 19 HEALTH AFF. 206, 206 (2000). Rates of cadaveric organ donation in the United States remain low, with only half of all eligible donors actually donating organs. *Id.*

11. In addition to the various ways cloning can be used to obtain tissues for transplants, see *infra*, cloning also has important implications for infertility, medical research, livestock production, and production of pharmaceuticals. *See Ethics of Human Cloning: Testimony on Ethics and Theology: A Continuation of the National Discussion on Human Cloning Before the Subcommittee on Public Health and Safety Committee on Labor and Human Resources* (June 17, 1997) (statement of John A. Robertson, J.D., Vinson & Elkins Chair in Law, University of Texas School of Law), *available at* 1997 WL 329510 (F.D.C.H.) (infertility); *see also* 143 CONG. REC. E607 (Apr. 9, 1997) (statement of Rep. Lee H. Hamilton) (medical research, agriculture, pharmaceuticals).

12. Dolly was the first animal cloned using DNA from a fully differentiated adult cell. Scientists used DNA from an udder cell from a female ewe to create her. As a joke, she was named after Dolly Parton. GINA KOLATA, CLONE: THE ROAD TO DOLLY, AND THE PATH AHEAD 3 (1998).

13. *See, e.g.*, Daniel R. Heimbach, *Cloning Humans: Dangerous, Unjustifiable, and Genuinely Immoral*, 32 VAL. U. L. REV. 633 (1998); Erin M. Stepno, *Successful Animal Cloning Raises Questions About Human Cloning Possibilities: Science Fiction No Longer*, 29

organs and the controversy surrounding this issue, there is still much work to be done before cloned organs are a reality.

1. Methods of Cloning

Cloning in its simplest sense "refers to a precise genetic copy of a molecule, cell, plant, animal, or human being."[14] There are, however, four separate ways to clone.[15] The first two methods, molecular and cellular cloning, cannot be used to produce a cloned human.[16] The simplest of the four processes, molecular cloning involves copying and amplifying DNA gene fragments in a host cell to produce large quantities of the DNA for use in experiments.[17] As its name indicates, cellular cloning occurs at the cellular level, by growing cells in culture in a laboratory to produce a cell line.[18]

The two remaining methods of cloning, blastomere separation and somatic nuclear transplantation cloning ("SNTC"), are capable of producing a cloned human.[19] Blastomere separation involves splitting an embryo soon after fertilization (while it is in the two-to-eight cell stage).[20] Each resulting cell is capable of producing an entire organism, genetically identical to the others.[21]

Like blastomere separation, SNTC is capable of producing a cloned human.[22] SNTC, the technique that produced Dolly, was an important breakthrough for cloning

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MCGEORGE L. REV. 666, 669-72 (1998); Sharon Begley, *Little Lamb, Who Made Thee?*, NEWSWEEK, Mar. 10, 1997, at 52; Ruth Macklin, *Human Cloning? Don't Just Say No*, U.S. NEWS & WORLD REP., Mar. 10, 1997, at 64. President Clinton commissioned the National Bioethics Advisory Commission ("NBAC") to examine ethical and legal issues raised by the prospect of human cloning. Exec. Order No. 12975, 3 C.F.R. 409 (1995). The NBAC concluded that at the time it was morally unacceptable for anyone to attempt to create a child using the techniques used to create Dolly. The NBAC based its finding partly on safety reasons (Dolly was the only success out of 277 attempts), among others, concluding that the techniques "are likely to involve unacceptable risks to the fetus and/or potential child." NAT'L BIOETHICS ADVISORY COMM'N, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 65, 108 (1997) [hereinafter NBAC REPORT]; *see also* Craig M. Klugman & Thomas H. Murray, *Cloning, Historical Ethics, and NBAC*, *in* HUMAN CLONING 37-42 (James M. Humber & Robert F. Almeder eds., 1998) [hereinafter HUMAN CLONING] (discussing ethical considerations of the NBAC report); *Cloning Human Beings: Responding to the National Bioethics Advisory Commission's Report*, 27(5) HASTINGS CENTER REP. 6-22 (1997) (critiquing the conclusions of the NBAC).

14. NBAC REPORT, *supra* note 13, at 13; *see also* HUMAN CLONING, *supra* note 13, at 6-8.

15. NBAC REPORT, *supra* note 13, at 14-15.

16. *Id.* at 14.

17. This technique is important for recombinant DNA technology. *Id.*

18. This technique is also useful in the production of new medicines. *Id.*

19. *Id.* at 15-16.

20. *Id.* at 15.

21. This is similar to the process that results in identical twins.

22. NBAC REPORT, *supra* note 13, at 15-16.

technology. In SNTC, the nucleus is removed from an egg cell and replaced with the nucleus from a somatic cell.[23] Prior to Dolly, scientists did not believe it was possible to clone using DNA from adult animals; these scientists believed that cell differentiation was irreversible.[24] However, Dr. Wilmut and his colleagues overcame this problem using a starvation technique.[25] By starving adult cells of nutrients, the cells become inactive.[26] Once the cells are inactivated, scientists can introduce the DNA from a differentiated cell, and essentially reprogram the DNA to express all its genes.[27] The resulting cell is capable of producing an animal genetically identical to the DNA donor.[28]

2. Human Clones as Organ Donors

Despite proposed legislation aimed at banning the cloning of human beings,[29] the prospect of cloning raises interesting possibilities for the field of organ transplantation. The current shortage of organs available for transplantation[30] is due in large part to the problems involved in finding a suitable donor. The biggest reason transplants fail is rejection of the transplanted organ.[31] The closer the match between

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23. *Id.* at 15. This differs from blastomere separation in that it can produce a clone from an adult animal—a twin separated in time. Blastomere separation, because it involves the splitting of embryos rather than the incorporation of DNA from a single individual, cannot produce a clone of a preexisting person. *Id.*

24. *Id.* at 16. Differentiation is the process through which certain portions of DNA are "turned off." KITCHER, *supra* note 2, at 328. When this occurs, it allows the cell to become part of different tissues in the body. *Id.*

25. NBAC REPORT, *supra* note 13, at 22.

26. *Id.*

27. This technique coordinated the cell cycles of the egg and donor cells. *Id.*

28. Although the nuclear DNA of clones produced using this technique is identical to that of the donor, there are some cellular differences. Cells contain organelles called mitochondria, which are found in the cytoplasm of cells, and contain some of their own genes. *Id.* at 18. Since only the nuclear DNA is transferred using this technique, the clone will retain the mitochondria present in the recipient egg cell. *Id.* Consequently, while genetically identical to the DNA donor, the clone is not an exact duplicate. *Id.* For a brief history of cloning, see KITCHER, *supra* note 2, at 328-30; Anne Lawton, *The Frankenstein Controversy: The Constitutionality of a Federal Ban on Cloning*, 87 KY. L.J. 277, 289-301 (1998-1999).

29. *See, e.g.*, CLONING PROHIBITION ACT OF 2001, H.R. 2172, 107th Cong. (2001); HUMAN CLONING RESEARCH PROHIBITION ACT, H.R. 1372, 107th Cong. (2001) (restricting federal funding for research utilizing SNTC technology); CLONING PROHIBITION ACT OF 1997, H.R. DOC. NO. 105-97 (1997); Lawton, *supra* note 28, at 301-12. While these bills generally ban the use of somatic cell nuclear transfer technology to initiate a pregnancy, use of SNTC to clone molecules or DNA, or to use in gene therapy, *in vitro* fertilization, or animal cloning is generally not prohibited. The bills also provide penalties of up to ten years imprisonment or fines of up to one to ten million dollars for violations.

30. U.S. CENSUS BUREAU, *supra* note 7.

31. GEORGE W. MILLER, MORAL AND ETHICAL IMPLICATIONS OF HUMAN ORGAN TRANSPLANTS 71 (1971). Rejection occurs when the recipient's immune system recognizes the

the tissue of the donor and the tissue of the recipient, the better the chances are for success.[32] Consequently, identical twins are ideal donors. There is no risk of rejection because the donor and recipient tissues are an exact match.[33]

One proposed source of compatible organs is cloned human beings. A clone of a candidate for an organ transplant would, like an identical twin, be a perfect tissue match. There would be no risk of rejection because the clone would contain the same genetic material as the organ recipient; the clone would essentially be a younger version of the recipient. Cloning for this reason would obviously be extremely beneficial. As former ethicist for the NIH, John Fletcher, commented, "'[t]he reasons for opposing this are not easy to argue.'"[34]

Even so, several commentators have raised objections to cloning for this purpose, most having to deal with the well-being of the cloned individual.[35] Concerns are largely based on the theory of personhood. Cloning a person for spare parts would "violate the clone's individual autonomy and liberty."[36] Creation for this purpose would be both psychologically and physically an abuse of power.[37] Cloning a human for use as a source of organs may also implicate the Thirteenth Amendment's prohibition on property interests in human beings.[38]

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transplanted organ as a foreign entity and attacks it. This can be regulated somewhat with immunosuppressive drugs, but they are not always effective. *Id.* See *id.* at 71-74 for a more thorough discussion.

32. *Id.* at 71.

33. *Id.*

34. Jeffrey Kluger, *Will We Follow the Sheep? It Will Be Up to Science to Determine if Human Cloning Can Be Done. It Is Up to the Rest of Us to Determine if It Should Be*, TIME, Mar. 10, 1997, at 66 (quoting John Fletcher). Indeed, cloning for this purpose would be comparable to parents of an ill child who have another child in the hopes the new child will be a compatible organ donor. *See id.* In both cases a new person is created with the hope he or she will be a compatible organ donor.

35. *See* Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 668 (1998); *see also* Kimberly M. Jackson, *Well, Hello Dolly! The Advent of Cloning Legislation and Its Constitutional Implications*, 52 SMU L. REV. 283, 298 (1999); Shannon H. Smith, *Ignorance Is Not Bliss: Why a Ban on Human Cloning Is Unacceptable*, 9 HEALTH MATRIX 311, 326-28 (1999).

36. Jackson, *supra* note 35, at 298.

37. Andrews, *supra* note 35, at 669 (quoting Francis C. Pizzulli, *Asexual Reproduction and Genetic Engineering: A Constitutional Assessment of the Technology of Cloning*, 47 S. CAL. L. REV. 476, 492 (1974)).

38. "Neither slavery nor involuntary servitude . . . shall exist within the United States . . ." U.S. CONST. amend. XIII, § 1. A fully functioning clone would be a person, and therefore presumably subject to the same rights and privileges afforded other citizens by the Constitution. In addition, protection against state mandated cloning may arise under the Fourteenth Amendment's incorporation doctrine. U.S. CONST. amend. XIV, §1.

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor

In addition to the lack of consensus on the morality of cloning in general, there is still much disagreement over the legitimacy of cloning to save lives.[39] However, even if there was greater support for human cloning in general, the existence of a clone would not necessarily guarantee the availability of organs and tissues for transplantation. A clone would presumably be a person in his or her own right, not an object from which to pick and choose organs. Consequently, the laws that currently govern organ donation would apply to clone donation as well.[40] It would be up to the clone to decide whether or not to donate organs, not the DNA donor.

Another suggested use of human clones as organ donors arose in 1997. Not long after the birth of Dolly, a group of British scientists announced that they had created a headless frog embryo named Freddy.[41] This announcement brought with it speculation that scientists may be able to apply the same technology used to create headless frogs to human embryos,[42] in effect creating headless human clones for the purpose of increasing the supply of organs and tissues available for transplantation.

Although it may sound ghoulish, the creation of brain-dead human clones as a source of organs may have certain advantages over fully functioning clones. For example, creation of brain dead human clones may bypass some of the donation consent problems present with cloning functional humans for organs. Under the Uniform Anatomical Gift Act ("UAGA"),[43] a donor must be dead before a physician may harvest his or her organs.[44] Death is traditionally defined as "the irreversible

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> shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Id.

39. NBAC REPORT, *supra* note 13, at 30. For a discussion of the pros and cons of cloning, see Michael Tooley, *The Moral Status of the Cloning of Humans*, *in* HUMAN CLONING, *supra* note 13, at 85-98.

40. *See* Smith, *supra* note 35, at 325 n.63.

41. Roger Hannah, *How a Headless Frog Could Help Us Grow Human Hearts*, SCOT. DAILY REC. & SUN. MAIL LTD., Oct. 20, 1997, at 8, LEXIS, News Library, Record File. Scientists created the headless frogs by using gene-modification techniques to damage the gene that codes for the development of a head, and then inserting this modified DNA into the nucleus of a frog egg. *Human Cloning and the Headless Frog Experiment*, HOUS. CHRON., Nov. 13, 1997, at 6, LEXIS, News Library, Hchrn File. [hereinafter *Headless Frog Experiment*].

42. *British Tinkering with Tadpoles Opens Way to Headless Humans*, AGENCE FRANCE PRESSE, Oct. 19, 1997, LEXIS, News Library, AFP File. In addition to using this technique to create headless human clones, it is speculated that the same method may eventually allow scientists to grow a human organ in a womb-like sac. *Headless Frog Experiment*, *supra* note 41.

43. For a discussion of organ donation under the 1987 UAGA, see Robert E. Sullivan, *The Uniform Anatomical Gift Act*, *in* ORGAN AND TISSUE DONATION: ETHICAL, LEGAL, AND POLICY ISSUES 24-33 (Bethany Spielman ed., S. Ill. Univ. Press 1996) [hereinafter ORGAN AND TISSUE DONATION].

44. UNIF. ANATOMICAL GIFT ACT § 4 (1987), 8A U.L.A. 19 (Supp. 2001).

cessation of all vital functions, including respiration, circulation, and heartbeat."[45] However, some courts define "death" for the purposes of the UAGA as including neurological or brain death.[46] Since the clone may meet this definition of death, the right to consent to donation would pass to the next of kin. In this way, transplant patients avoid consent problems.[47] This is to say nothing, however, of the moral and ethical problems associated with creating clones of this type. Many people find repugnant the very idea of creating a headless or brain dead clone for the purpose of harvesting organs.[48] At present, this moral barrier makes this option unrealistic. However, the morals of society change,[49] and it is possible to envision a time when the idea of creating such body clones would be less repugnant to society as a whole, making this a more attractive and feasible option.

3. Cloning Individual Organs

The same technology used to create headless frog embryos may also one day lead to the growth of individual human organs and tissues in the laboratory. Some scientists believe that "the technique could be adapted to grow human organs such as hearts, kidneys, livers and pancreases in an embryonic sac living in an artificial womb."[50] The progression of technology to this level could be the most beneficial and least objectionable of the three forms of human cloning previously discussed. Cloning individual organs would overcome the organ shortage and rejection problems,[51] as well as avoid some of the moral and ethical concerns surrounding human reproductive cloning.

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45. Thomas R. Trenker, *Tests of Death for Organ Transplant Purposes*, 76 A.L.R.3d 913, 914 (1977).

46. *See* New York City Health & Hosp. Corp. v. Sulsona, 367 N.Y.S.2d 686, 687-88 (N.Y. Sup. Ct. 1975). The hypothesized brain-dead clone scenario is comparable to the plight of anencephalic infants (children born typically with only a brain stem, but lacking a brain and skull). Smith, *supra* note 35, at 329 n.75. For a discussion on the pros and cons of organ donation by anencephalic infants, see Joseph N. Harden, *The "Gift" of Life: Should Anencephalic Infants Die to Serve Noble Goals?*, 27 CUMB. L. REV. 1279 (1996-1997).

47. *See infra* notes 114-17.

48. *See* Stephen Breen, *Human Clones 'Will Be Used as Organ Factories,'* SCOTSMAN, Oct. 20, 1997, at 5.

49. One of the most notable examples of this is the morality requirement for patents. In the past, courts rejected patents on things deemed immoral, such as gambling machines, on the grounds that they lacked moral utility. In recent years, society has shown a greater acceptance of gambling, and courts no longer reject such patents on morality grounds. For a general debate on patents and the morality issue, see Cynthia M. Ho, *Patent Law and Policy Symposium: Re-Engineering Patent Law: The Challenge of New Technologies*, 2 WASH. U. J.L. & POL'Y 247 (2000).

50. Breen, *supra* note 48, at 5.

51. Since scientists would clone the organs using the transplant recipient's cells, the cloned organs would be a perfect match, thus negating the need for immunosuppressive drugs. Steve Connor & Deborah Cadbury, *Headless Frog Opens Way for Human Organ Factory*, SUNDAY TIMES (LONDON), Oct. 19, 1997, News at 1.

Although the ability to clone human organs in a laboratory is still a long way off, research in the field looks promising. The most likely candidate for organ cloning thus far is bone marrow. The process would proceed in the same manner as embryo cloning: fusing cells from the patient with a denucleated egg cell.[52] The egg cell would reset the genetic clock of the DNA to resemble that of an embryo. Scientists could then add chemicals to direct the cells to differentiate into the desired tissue, in this case bone marrow.[53] The resulting tissues would be genetically identical to the patient's own, and thus carry no risk of rejection. In addition to bone marrow, scientists may use these techniques to develop other organs, including skin grafts for burn victims.[54]

New discoveries about the capabilities of stem cells[55] lend further encouragement to this type of research.[56] Experiments show that injecting bone marrow stem cells into rats results in the formation of new liver tissue.[57] If this technique could be extrapolated to humans, scientists may one day be able to use the technology to renew organs instead of replacing them.

This work with stem cells also has implications for tissue engineering.[58] In tissue engineering, "human cells are grown in the laboratory and then draped onto a fibrous, biodegradable scaffolding made in the shape of the desired tissue or organ."[59] The body's tissues then incorporate the new cells.[60] Consequently, the ability to clone stem cells could greatly benefit these developing organ technologies,[61] as well as the

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52. KOLATA, *supra* note 12, at 234.

53. *Id.*

54. J. Madeleine Nash, *The Case for Cloning: The Benefits of This Bold Technique Outweigh the Risks, and the Danger Is Not What You Think*, TIME, Feb. 9, 1998, at 81.

55. Stem cells are "primitive, undifferentiated cells from the embryo that are still totipotent," and are the precursors of all cell lines. NBAC REPORT, *supra* note 13, at 30.

56. Stem cell research also has implications for the treatment of several chronic human diseases, such as diabetes and Parkinson's disease.

57. *Scientists Discover Cell that Can Grow New Liver Tissue*, CHARLESTON GAZETTE, May 14, 1999, at 11A, *available at* LEXIS, News Library, Charleston Gazette File. Stem cell technology may also be useful in treating neurodegenerative diseases. *Cloning—Challenges for Public Policy: Testimony Before the Subcommittee on Public Health and Safety Committee on Labor and Human Resources* (Mar. 12, 1997), *available at* 1997 WL 136117 (F.D.C.H.) (testimony of Harold Varmus, M.D., Director, Nat'l Insts. of Health, Dep't of Health and Human Servs.).

58. Tissue engineering is the "rebuilding or repairing [of] parts of the body using a combination of artificial materials and living cells." Richard Saltus, *Engineered Body Parts to Renew Injured Organs*, THE SUNDAY GAZETTE-MAIL, Nov. 21, 1999, at 12D, *available at* LEXIS, News Library, Chrgaz File.

59. *Id.*

60. *Id.*

61. President George W. Bush's stated opposition to the use of stem cells from aborted fetuses for research purposes may somewhat hamper stem cell research. *See* Maggie Fox, *Bush Signals Opposition to Some Stem Cell Research, at* http://www.netlink.de/gen/Zeitung/2001/010127.html (last visited Jan. 28, 2002).

field of cell therapy.[62]

Cloning plays an important role in the development of stem cell research. For example, some scientists clone human embryos with the intent of harvesting the embryonic stem cells for transplantation into patients.[63] Stem cells obtained from this method would clearly be beneficial for treatment purposes. Because the stem cells would be a genetic match for the donor patient, there would be no risk of rejection which otherwise may occur if stem cells harvested from another embryo were used.[64]

Stem cell research is not without controversy, however. Many people fear that cloning embryos to harvest stem cells is the first step towards reproductive cloning.[65] Critics fear this research may lead to a greater success rate in creating healthy clones, undermining one of the strongest anticloning arguments.[66] Consequently, the controversy surrounding stem cell research has led to several proposals to limit federal funding of stem cell research.[67] In response, some scientists urge Congress to distinguish between human reproductive cloning and therapeutic cloning, which is essential for much stem cell research.[68]

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62. In cell therapy, scientists use fetal cells to revitalize older cells. Cloning would make numerous cells available for this type of therapy. Khristan A. Heagle, *Should There Be Another Ewe? A Critical Analysis of the European Union Cloning Legislation*, 17 DICK. J. INT'L L. 135, 151-52 (1998).

63. Rick Weiss, *Embryo Work Raises Specter of Human Harvesting: Medical Research Teams Draw Closer to Cloning*, WASH. POST, June 14, 1999, at A1. Cloning embryos to obtain their stem cells for use in treating human diseases is an example of therapeutic cloning. *Id.*

64. *See id.*

65. *See id.*

66. There are clear analogies between stem cell research and the abortion issue. For those who believe life begins at conception, creating embryos for the sole purpose of destroying them for their stem cells is unnecessary and immoral. *Prepared Testimony of Richard M. Doerringer on Behalf of the Committee for Pro-Life Activities United States Conference of Catholic Bishops Before the Senate Appropriations Committee Subcommittee on Labor, Health and Human Services, and Education*, FED. NEWS SERVICE, July 18, 2001, LEXIS, News Library, Fednew File. There are others who argue that the embryos used in such research are not technically human life. As the argument goes, human life, as opposed to cellular life, does not begin until after fourteen days of development (in other words, after the primitive streak has formed). In preimplantation embryos at the blastocyst stage "no body cells of any type have formed, and even more significantly, there is strong evidence that not even the earliest of events in the chain of events in somatic differentiation have been initiated." *Prepared Testimony of Michael D. West, Ph.D., President & CEO, Advanced Cell Technology, Inc., Before the Senate Appropriations Committee Subcommittee on Labor*, FED. NEWS SERV. July 18, 2001, LEXIS, News Library, Fednew File [hereinafter *West*]. Therefore, "no individual exists (in other words, the blastocyst may still form identical twins)." *Id.*

67. *See, e.g.*, Stem Cell Research Act of 2001, S. 723, 107th Cong. (2001); H.R. 2059, 107th Cong. (2001). Under the Stem Cell Research Act of 2001, research on embryos for the purpose of generating embryonic stem cells may be federally funded only if the embryos used would otherwise be discarded and were donated with the written informed consent of the donor. The Act further prohibits the use of such embryos in human reproductive cloning. *Id.*

68. *West*, *supra* note 66; *see also Human Cloning Prohibition Act of 2001 and Cloning*

B. Xenotransplantation[69] and Transgenic Animals

In addition to cloning organs using human cells, cloning technology can be utilized to increase the success of xenotransplantation. The major advantage of xenotransplantation,[70] in addition to providing a plentiful supply of transplantable organs, is that while animals can provide a pleutiful supply of transplantable organs, raising animals for the purpose of harvesting organs raises fewer moral objections than doing the same in humans. There are disadvantages to xenotransplantation, however. Aside from physiological differences in the shape and size of animal organs and the potential for infection with animal diseases, there is "a much more pronounced rejection response to nonhuman donor tissues"[71] than is normal for human-to-human transplants.[72]

Currently, two methods are available to prevent rejection. First, doctors attempt to match donor and recipient tissues as closely as possible.[73] This match is difficult enough to achieve with human-to-human donation,[74] but the differences between species make it an unfeasible option for xenotransplantation. The second method involves the use of immunosuppressive drugs.[75] Over the years, such drugs have

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Prohibition Act of 2001: Hearing on H.R. 1644 and H.R. 2172 Before the House Subcomm. On Health of the House Comm. on Energy and Commerce, 107th Cong. 47-50 (2001) (prepared testimony of Thomas Okarma, President, Genron Corp.), *available at* 2001 WL 695384 [hereinafter *Okarma*]. As its name indicates, in reproductive cloning, scientists clone embryos with the intention of creating a human or other organism, for example Dolly. Rick Weiss, *U.S. Ruling Aids Opponents of Patents for Life Forms*, WASH. POST, June 17, 1999, at A2. Therapeutic cloning, in contrast, involves cloning for the purposes of dedifferentiating a person's cells and obtaining, for example, embryonic stem cells for use in treating human diseases. *West*, *supra* note 66. Therapeutic cloning has many potential beneficial uses for regenerative medicines and treating various human diseases.

69. Xenotransplantation is "the transplantation of viable cells, tissues and organs from one species to another." ORG. FOR ECON. CO-OPERATION AND DEV., XENOTRANSPLANTATION: INTERNATIONAL POLICY ISSUES 9 (1999) [hereinafter XENOTRANSPLANTATION].

70. For a brief history of xenotransplantation, see Jodi K. Frederickson, *He's All Heart ... and a Little Pig Too: A Look at the FDA Draft Xenotransplant Guideline*, 52 FOOD DRUG COSM L.J. 429, 430-32.

71. Denise Faustman, *Xenogenic Transplantation: The Use of Animals for Organ Donors*, *in* FETAL RESEARCH AND APPLICATIONS: A CONFERENCE SUMMARY 58, 58 (Inst. of Med. ed., 1994).

72. There are three types of rejection involved in xenografts. With hyperacute rejection there is an immediate immunological response to the transplanted organ. The recipient's immune system recognizes proteins on the surface of the organ as foreign, causing the immune system to attack the organ. XENOTRANSPLANTATION, *supra* note 69, at 20-21. The two other types of rejection, delayed xenograft rejection and chronic rejection, occur over longer periods of time. The cause of these types of rejection is not fully understood, but the production of antibodies is a likely factor. *Id.* at 21-22.

73. *Id.* at 23.

74. *See supra* notes 25-27 and accompanying text.

75. XENOTRANSPLANTATION, *supra* note 69, at 23.

worked with varying degrees of success.[76]

Thus far, out of all animals, pigs show the greatest promise for successful xenotransplantation.[77] Although baboons are more immunologically compatible with humans, that very compatibility also results in a greater risk of cross-species disease infection.[78] Pigs, on the other hand, make good candidates because many of their organs are sufficiently similar in size and structure to those of humans, and there is less risk of cross-species disease infection.[79]

Cloning and transgenic technology may help increase the chances of successful xenotransplantation using pigs. Using transgenic technology, pig cells could be genetically modified in the laboratory by adding human genes to them.[80] The resulting cells would express human rather than pig proteins and would appear to the recipient's immune system to be a human organ.[81] Cloning these genetically modified pig cells would result in a ready supply of transplantable organs.[82] Advances in this technology may eventually enable transplant recipients to receive organs from pigs that were cloned using the transplant recipient's own cells, further eliminating the risk of rejection.

III. PROPERTY RIGHTS IN ORGANS AND TISSUES

The advent of cloning and related technologies also raises questions about who should have a property interest in the resulting products. In other words, who should control the use of the cloned organ? Courts already recognize a property interest in living material.[83] Several different parties may potentially claim cloned organs or tissues: the DNA/tissue donor, the clone, and the scientist who developed the cloned tissue/organ or transgenic animal. This section addresses issues surrounding the ownership and control of cloned organs by examining both traditional property law and patent law.

A. A Brief Overview of Law Governing Property Rights in Human Tissues

The competing property interests of the DNA donor and clone are best understood in light of the property law governing renewable and nonrenewable body parts. Recognition of some type of property right in human organs is important for advancing the clone's interest in his or her own organs. Likewise, in order for the DNA donor to have any claim over the organs of the clone, the DNA donor must first have a property interest in his or her own DNA. Absent such a property interest, there

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76. *See id.* at 23-25.

77. *Id.* at 32.

78. *Id.* at 37-39.

79. NBAC REPORT, *supra* note 13, at 26; *see also* XENOTRANSPLANTATION, *supra* note 69, at 33-34 (discussing things to look for in determining physiological compatibility).

80. NBAC REPORT, *supra* note 13, at 26.

81. KOLATA, *supra* note 12, at 9.

82. *Id.*

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

would be no justification for any type of claim over the clone's organs.

This section discusses the general law governing property interests in nonrenewable and renewable body parts. Subpart 1.a. examines some leading cases dealing with nonrenewable body parts. In addition, Subpart 1.b. addresses the implication of a property interest in human organs as derived from the Uniform Anatomical Gift Act[84] ("UAGA") and the National Organ Transplantation Act[85] ("NOTA"). Subpart 2 then turns to property interests in renewable body parts, including analogies to pre-zygotes and sperm.[86]

1. Property Interests in Genetic Material and Nonrenewable Body Parts

a. *Moore v. Regents of the University of California*[87]

In order for a tissue donor to be able to claim a property right in a cloned organ created from his or her DNA, he or she must first have a property interest in the DNA or tissues used. In *Moore*, the California Supreme Court addressed this issue. The plaintiff, John Moore, brought a cause of action for conversion when his physician (and others) used cells taken from his spleen for medical research without his permission.[88] While he was being treated for hairy-cell leukemia, doctors discovered that some of Moore's blood products were very valuable, both scientifically and commercially.[89] Relying on his physician's recommendations, Moore agreed to have his spleen removed.[90] His doctors took additional blood and tissue samples on subsequent visits and used these samples to establish a cell line that they subsequently patented.[91] The estimated worth of the patent was over three billion dollars.[92]

Although the court determined Moore had a cause of action for breach of fiduciary duty,[93] the court declined to find a cause of action for conversion.[94] To bring an action for conversion, Moore had to "establish an actual interference with his *ownership* or *right of possession*";[95] he had to have retained ownership of his cells after they had

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84. UNIF. ANATOMICAL GIFT ACT (1987), 8A U.L.A. 19 (1993 & Supp. 2001) [hereinafter 1987 UAGA]; UNIF. ANATOMICAL GIFT ACT (1968), 8A U.L.A. 94 (1993 & Supp. 2001) [hereinafter 1968 UAGA].

85. 42 U.S.C. §§ 273-74(l) (1994) [hereinafter NOTA].

86. *See infra* Part III.A.2.

87. 793 P.2d 479 (Cal. 1990).

88. *Id.* at 480.

89. *Id.* at 481.

90. *Id.*

91. *Id.* at 481-82.

92. *Id.* at 482.

93. The court determined that a physician must "disclose personal interests unrelated to the patient's health" and obtain the patient's informed consent before proceeding with a medical procedure from which the physician himself may benefit. *Id.* at 485.

94. *Id.* at 493.

95. *Id.* at 488 (quoting Del E. Webb Corp. v. Structural Materials Co., 176 Cal. Rptr. 824, 833 (Ct. App. 1981)) (emphasis in original).

been removed. Since he had no reasonable expectation of maintaining possession or ownership after their removal, he could not show a cause of action for conversion.[96] Part of the court's rationale for this decision rested on the conclusion that the cell line the doctors patented and derived from Moore's tissues was "factually and legally distinct" from the cells they took from Moore,[97] and was more the product of the work done by the researchers than the raw materials (cells) taken from Moore. In addition, the court stressed the important policy consideration of protecting scientific inquiry. If researchers had to worry about the source of their raw biological materials, they would be less likely to invest in beneficial research.[98]

Although the court did not find a property interest in the cells after their removal from the body, the court's language, stating that "Moore clearly did not expect to retain possession of his cells following their removal, [and] to sue for their conversion he must have retained an ownership interest in them,"[99] does not foreclose the possibility that if a patient reasonably expected to maintain control over his cells or tissues upon removal, a property interest may still be recognized. The opinions of Justices Broussard and Mosk pointed out this possibility. In the dissenting portion of his opinion, Justice Broussard pointed out that the Uniform Anatomical Gift Act "recognizes that it is the donor of the body part, rather than the hospital or physician who receives the part, who has the authority to designate, within the parameters of the statutorily authorized uses, the particular use to which the part may be put."[100] Justice Broussard went on to note that this concept of "donor control" is not limited to the context of deceased donors, but also is common in the transplantation context.[101] Likewise, in his dissent, Justice Mosk indicated that a person may retain a property interest in the use of his tissues following their removal.[102] Thus, if a tissue donor specifies the use of the tissue before it is removed, he or she may retain some sort of property interest in the resulting product, even if there is no property interest where the person has no expectation of maintaining any sort of control over the excised tissue.[103]

The court in *Cornelio v. Stamford Hospital*[104] followed a similar line of reasoning. In *Cornelio*, the plaintiff sued on a theory of replevin to recover pap smear specimen slides that contained her genetic material,[105] claiming in part that she never indicated an intent to relinquish possession.[106] The defendant claimed that patients had no

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96. *Id.* at 489. The court also concluded that there was no case law supporting Moore's claim of ownership, and that California law on the disposal of body tissues limited any interest Moore might have had in his cells. *Id.*

97. *Id.* at 492.

98. *Id.* at 494-95.

99. *Id.* at 488-89.

100. *Id.* at 501-02 (Broussard, J., concurring and dissenting); *see also* 1987 UAGA, *supra* note 84; 1968 UAGA, *supra* note 84.

101. *Moore*, 793 P.2d at 502 (Broussard, J., concurring and dissenting).

102. *Id.* at 510 (Mosk, J., dissenting).

103. For a more thorough discussion of *Moore*, see Wagner, *supra* note 6, at 935-43.

104. 1997 WL 430619 (Conn. Super. July 21, 1997), *aff'd*, 717 A.2d 140 (1998).

105. *Id.* at *1.

106. *Id.* at *4.

property interest in such slides, and therefore had no right to possession.[107] The court, following the reasoning of the *Moore* court, declined to find a property interest in the plaintiff's removed genetic material.[108] The court noted that the plaintiff could not show "an actual interference with ownership or right of possession."[109] In addition, the plaintiff signed a release form that the court interpreted as an indication that she did not expect to maintain control of her cells upon removal.[110]

At first glance, these two cases seem to indicate that a person does not have a property interest in his or her excised cells or tissues. However, based on the rationale behind the holdings, this interpretation is not necessarily the case if the patient can show an expectation of maintaining ownership upon removal. This scenario could have implications for those who have tissue removed for the purpose of cloning an organ.[111]

b. The Uniform Anatomical Gift Act and the National Organ Transplantation Act

In addition to case law, the UAGA[112] and the NOTA[113] also shed some light on the status of property interests in nonrenewable body parts. The 1968 UAGA authorizes a person (or his or her close relatives) to give away any body part[114] for transplantation or research purposes.[115] The UAGA sets out procedures for donating,[116] and allows the donor to gift an organ to a specific individual recipient.[117] The 1987 version of the UAGA prohibits the sale of body parts for transplant and therapy, but does not prohibit their sale for other purposes, such as research.[118] Consequently, the UAGA does seem to recognize at least a partial property interest in body parts. If there were not some form of property interest in the body, a person would not be able to give body parts away or sell them for research.

NOTA, likewise, prohibits the sale of organs for transplantation.[119] However, NOTA only addresses the disposition of organs. Consequently, it is silent on whether or not a property interest should continue for nonorgan body tissues. So, although

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107. *Id.*

108. *Id.* at *7.

109. *Id.*

110. *Id.* The form stated: "This request form is intended to include the right to administer drugs, anesthesia or blood transfusions and do all things necessary preliminary to, during or after such procedure, including the right to dispose of all tissue." *Id.*

111. *See infra* Part III.D.

112. 1968 UAGA, *supra* note 84.

113. NOTA, *supra* note 85.

114. 1968 UAGA, *supra* note 84, § 2.

115. *Id.* § 3.

116. *Id.* § 4.

117. *Id.* § 5.

118. *See* 1987 UAGA, *supra* note 84, § 10.

119. NOTA, *supra* note 85, § 274e(a). The Act states "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce." *Id.*

there does seem to be at least a limited property interest in body parts, that interest is not absolute.

2. Property Interests in Renewable Body Parts

Although cases such as *Moore* and *Cornelio* indicate there may not be a property interest in body tissues in certain circumstances, the same does not apply to renewable body tissues and fluids, such as hair, blood, and sperm. Several cases address this issue. In *York v. Jones*,[120] the court recognized a property interest for the plaintiffs in a cryopreserved pre-zygote.[121] The plaintiffs, who had gone to the defendant doctor for *in vitro* fertilization procedures, had signed an agreement detailing their property interest in the pre-zygote.[122]

A similar case, *Hecht v. Superior Court*,[123] involved property rights in sperm. In the decedent's will, he devised to his girlfriend, the plaintiff, fifteen vials of sperm he had deposited in a sperm bank for her use should she decide to have children.[124] In his will, he clearly indicated his desire that the plaintiff use the sperm to have a child.[125] The court distinguished the case from *Moore* on the grounds that there was clear evidence of the decedent's intent to retain control over the sperm upon its deposit in the sperm bank.[126] "[A] contract with the sperm bank purports to evidence decedent's intent and expectation that he would in fact retain control over the sperm following its deposit."[127] In addition, the very fact that the court recognized the sperm as a part of the decedent's estate for probate purposes is further evidence that the expectation a person has for the use of his or her tissues or fluids upon removal from the body may be an important factor in determining whether he or she retains a property interest in them.[128] So, taken together, these laws and cases seem to recognize a limited property interest in body parts, or at a minimum, leave open that possibility.

B. A Brief Overview of the Patent System

In addition to the potential protection of property interests in human body parts that property law may afford, patent law also plays a role. Much research still needs to be done before it is possible to clone individual organs in the laboratory.[129] The same is

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120. 717 F. Supp. 421 (E.D. Va. 1989).

121. *Id.*

122. *Id.* at 424.

123. 20 Cal. Rptr. 2d 275 (Ct. App. 1993).

124. *Id.* at 276.

125. *Id.* at 277.

126. *Id.* at 280 n.4.

127. *Id.*

128. For a discussion on the history of property interests in the human body, see William Boulier, Note, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693, 704-15 (1995).

129. *See supra* Part II.A.3.

true for the development of human organs in animals.[130] Research of this type is often very expensive and time consuming. Consequently, there is a need for an incentive system to encourage innovation that benefits society,[131] while allowing researchers and inventors to get a return on their investment.[132] The patent system, authorized under Article I, Section 8 of the U.S. Constitution,[133] sets up such an incentive system. When determining who should have a property interest in cloned organs, it is important to consider how a potential applicant's property interests interact with the property interest of the person whose DNA the applicant used to create the cloned organ. The conflict is even more apparent in cases like *Moore*, where the DNA used to create the cloned organ or tissue may be important for research purposes.

1. General Requirements for Patent Protection

Patents are only available for certain kinds of inventions. The Patent Act describes patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and nseful improvement thereof . . . ."[134] In addition to this utility requirement, to be patented, an invention must be novel,[135] nonobvious,[136] and capable of specification.[137] The present discussion will focus on the patentability of living material.[138]

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130. *See supra* Part II.B.

131. *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 50-52 (1998).

132. Patents grant, for a limited time, exclusive rights over eligible inventions for a period of twenty years from the date of application. 35 U.S.C. § 154(a)(2) (1994).

133. "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. 1, § 8, cl. 8. "The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts." Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980).

134. 35 U.S.C. § 101 (1994).

135. *Id.* § 102. In order to be novel, an invention cannot have been part of the prior art (in the United States or a foreign country) "more than one year prior to the date of application for patent." *Id.* § 102(b). In essence, if the invention was patented, described in a printed publication, or otherwise available for public use within this time, the invention is not patentable for lack of novelty. *Id.* §§ 102(a)-(b).

136. *Id.* § 103. Section 103(a) states that no patent is available if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *Id.* § 103(a).

137. *Id.* § 112. The specification should include:

> [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.

138. Although there are still unresolved issues surrounding the other patentability

2. Patentability of Living Things

The primary case dealing with the patentability of living things is *Diamond v. Chakrabarty*.[139] In *Chakrabarty*, the respondent filed a patent application for a genetically engineered bacterium capable of degrading oil, something which no naturally occurring bacteria is known to do.[140] The patent examiner rejected the claim on the grounds that "micro-organisms are 'products of nature,' and . . . as living things they are not patentable subject matter."[141] In affirming the reversal of this decision by the Court of Customs and Patent Appeals,[142] the Supreme Court found the bacterium to be patentable subject matter under § 101 of the Patent Act.[143]

In its analysis, the Court construed § 101 of the Patent Act broadly.[144] Although the Court recognized some limitations on the scope of patentable subject matter,[145] the respondent's bacterium nonetheless qualified as proper subject matter because the claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [, and] use.'"[146] The Court contrasted the present case to that of *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[147] The patentee in *Funk Bros.* tried to patent a combination of naturally occurring bacteria.[148] The Court in that case found no patentable subject matter because the bacteria did not act

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requirements of cloned organisms, this Note will assume that those requirements can be met. Other commentators have, however, addressed the issue of the patentability of cloned organisms. For a discussion of some of the problems involved in patenting cloned organisms, 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 (1998). Hofmeyer analyzes the patentability of cloned organisms by analogizing cloned organisms to patents that have been granted on transgenic animals. *Id.* at 980-93. For a discussion on the new Patent and Trademark Office ("PTO") utility guidelines and the problems associated with granting broad patents over the human genome, see Kenneth Skilling, *Controversy Over Gene Patenting Persists, Despite Clarifying Guidelines*, BNA PAT., TRADEMARK & COPYRIGHT LAW DAILY, June 13, 2000.

139. 447 U.S. 303 (1980).

140. *Id.* at 305.

141. *Id.* at 306.

142. *Id.*

143. *Id.* at 318.

144. The Court cites legislative history stating a patent "may include anything under the sun that is made by man." *Id.* at 309 n.6 (quoting *Patent Law Codification and Revision: Hearing on H.R. 3760 Before Subcomm. No. 3 of the House Comm. on the Judiciary*, 82d Cong., 37 (1951) (statement of P.J. Federico, Chief Examiner of Patent Office)).

145. "The laws of nature, physical phenomena, and abstract ideas have been held not patentable." *Id.* at 309.

146. *Id.* at 309-10 (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)) (alteration in original).

147. 333 U.S. 127 (1948).

148. *Id.*

differently than it did in nature.[149] In contrast, the *Chakrabarty* Court found the oil degrading bacteria to have "markedly different characteristics from any found in nature and . . . the potential for significant utility."[150]

Subsequent case law, as well as policy statements by the Patent and Trademark Office ("PTO"), reinforces the decision in *Chakrabarty*. In *Ex parte Allen*,[151] although a patent claiming polyploid oysters was denied on other grounds, the Court found the oysters to be nonnaturally occurring, indicating that multicellular organisms may be proper subjects of patent protection.[152] In addition, in 1987 the PTO issued a statement declaring nonnaturally occurring multicellular living organisms to be patentable subject matter.[153] Although the statement included animals as the proper subject of patents, it explicitly excluded human beings.[154] The decision in *Allen* and the PTO statement reinforce the proposition that living organisms may be protected, whether they are singular- or multicellular.

These developments set the stage for the later issuance of a number of patents on living material. One of the most famous of these patents was for the Harvard mouse.[155] The Harvard mouse is a transgenic mouse genetically engineered to exhibit an increased susceptibility to cancer.[156] In addition to patents issued on animals, the PTO has also issued patents on individual genes.[157]

The issuance of these patents raise the question that if living things and human genes can be patented, how close to a "human being" must something be before patent protection is denied? The PTO has denied patents for part animal, part human creatures that could have been used in medical experiments.[158] The PTO has, however, granted patents on transgenic animals that contain human genes and organs.[159] It would therefore seem logical that if scientists created an animal for use in growing a cloned human organ, it might constitute patentable subject matter as well.

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149. *Id.* at 130.

150. *Chakrabarty*, 447 U.S. at 310.

151. 2 U.S.P.Q.2d (BNA) 1425 (U.S. Patent & Trademark Office 1987).

152. *Id.* at 1427.

153. Donald J. Quigg, *Animals-Patentability*, 1077 OFFICIAL GAZETTE OF THE U.S. PAT. & TRADEMARK OFF. 24 (Apr. 21, 1987). Patents have also been issued for transgenic animals. *See also* Hofmeyer, *supra* note 138, at 985 n.95.

154. Quigg, *supra* note 153.

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

156. *Id.*

157. *See* GRUBB, *supra* note 4, at 248.

158. Weiss, *supra* note 68, at A1. The Patent and Trademark Office issued a statement saying that "inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement." *Facts on Patenting Life Forms Having a Relationship to Humans*, U.S. Patent and Trademark Office, *at* http://www.uspto.gov/web/offices/com/speeches/98-06.htm (last visited Apr. 1, 1998).

159. Weiss, *supra* note 158, at A2; *see also infra* notes 160-61.

C. Property Interests in Organs Derived from Human Clones

As discussed in Part II.A.2, as the prospect of human cloning becomes more feasible, people may turn to clones as a source of transplantable organs and tissues. If this phenomenon occurs, a conflict may arise over who may claim a property interest in the organs of the clone. While the prohibition on patents covering human beings indicates that the scientist who created the clone could not obtain patent protection over the organs,[160] the issue still remains whether the DNA donor should have a property interest in the organs of the clone.

1. Interest of the DNA/Tissue Donor

The first question that must be asked is does the person whose DNA was used to create the clone have a property interest in the clone's organs. Although the donor has a definite interest in the clone by virtue of sharing the same DNA, it does not necessarily follow that the donor should be allowed to control the clone's organs. Although cases such as *Moore* and *Cornelio* did not find a continuing property interest in cells excised from patients, they leave open the possibility that a person may maintain some control over his or her own tissues if he or she has a reasonable expectation of determining its use.[161] In the case of cells removed for the purposes of creating a clone from which to obtain an organ for transplant, it would seem a fairly simple matter to establish an expectation of continued possession. Even assuming that current property law does not foreclose the ownership of the excised cells and genetic material, the question still remains whether courts should grant the DNA donor a property interest in what eventually will be another person's organs.

Courts recognize property interests in renewable body parts where the person has specified their use upon removal.[162] In a sense, the DNA used to create a clone is like renewable body parts; since every cell in the body contains DNA, there is always a ready supply. Since it is the DNA that would be used to create a clone, a person must have some kind of property interest in his or her own DNA before he or she could claim an interest in the organs of a clone.

Some commentators assume people possess the DNA in their bodies because they are the exclusive users of the information stored in the DNA.[163] However, if DNA is removed to create a cloned individual, the DNA donor is no longer in exclusive possession of his or her genetic material—the clone now shares it as well.[164] Although typically a person could control the use of his or her DNA, "if the genetic information encoded in one's cells is no longer in the sole possession of that person but can be used by others, it cannot strictly be said that a right to exclude others from access to genetic information accompanies possession of a DNA code."[165] In other words, by

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160. *See supra* note 154 and accompanying text.

161. *See supra* Part III.A.1.a.

162. *See supra* Part III.A.2.

163. Mona S. Amer, *Breaking the Mold: Human Embryo Cloning and Its Implications for a Right to Individuality*, 43 UCLA L. REV. 1659, 1667-68 (1996).

164. *Id.* at 1668.

165. *Id.* at 1668-69.

virtue of creating the clone the DNA donor has relinquished some of the rights to control the use of the DNA that normally would be available.

2. Property Interest of the Clone

Much of the same interests the DNA donor has in his or her genetic material would also apply to the clone. In fact, a clone should have a greater property interest in his or her organs, since technically the clone would have "possession." There are several additional reasons why the clone's interest in his or her body parts is superior to the interest of the DNA donor. First, the Thirteenth Amendment, which would seem to prohibit the DNA donor from claiming the clone's organs as his or her own, prohibits a property interest in another person.[166] Given the current debate over stem cells and abortion, and the controversy over what constitutes life, it is unlikely that today's public would consider a clone anything less than a person with the same rights as everyone else. Consequently, to grant a property interest in the clone's organs to a DNA donor would seem to violate the Thirteenth Amendment.

In addition, many of the same reasons put forth by those opposed to cloning weigh in favor of the superiority of the clone's claim to his or her organs. One argument offered in opposition to cloning in general is that it would invite discrimination.[167] As the argument goes, people would make value judgments about the worth of the clone, thereby lessening the clone's dignity.[168] Applying this argument to the clone's organs, granting the DNA donor a property interest in the clone's organs would be comparable to saying the clone had less worth or value as a human being than the DNA donor does.

Others have advanced similar arguments with regard to the commercialization of the human body. On one side of the argument, granting a property interest in body parts would result in commodification of the human body, causing people to lose their sense of identity.[169] This commodification would degrade the person and decrease human dignity.[170] Applying this argument, not only the clone, but the DNA donor would lose dignity if the donor were granted a property interest in the clone's organs. The counterargument notes that since there is already a commercial interest in body parts, recognition of a property right in the body would actually protect dignity by helping a person control what happens to his or her own body parts.[171] This counterargument provides strong support in favor of the clone's interest. If courts

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166. U.S. CONST. amend. XIII, § 1. This amendment is the basis for why human beings are not patentable subject matter. *See* Quigg, *supra* note 153. There may also be Fourteenth Amendment implications in such situations. *See* U.S. CONST. amend. XIV, § 1.

167. Heimbach, *supra* note 13, at 638-39.

168. *Id.* It is also feared that the value and worth of the clone would be judged in relation to the achievements of the DNA donor, and not on an independent basis. *Okarma*, *supra* note 68.

169. Brian G. Hannemann, *Body Parts and Property Rights: A New Commodity for the 1990s*, 22 SW. U. L. REV. 399, 423 (1993).

170. Carson Holloway, *Monetary Incentives for Organ Donation: Practical and Ethical Concerns*, *in* ORGAN AND TISSUE DONATION 143, at 152-54 (Bethany Spielman ed., 1996).

171. Boulier, *supra* note 128, at 719.

recognize a property interest in the body, it follows that the clone would have a superior interest to his or her organs than would the DNA donor.[172] Consequently, advocates of cloning who list cloning as a potential source of organs for transplant are not entirely accurate in their portrayal of the situation. The clone would have a superior claim to his or her organs, even though the clone would have been created using the genetic material of the DNA donor.[173]

The situation of a body clone is slightly different. Although theoretically the creation of a body clone may avoid some donor consent problems, there are practical obstacles as well as moral and ethical problems with this approach. Setting aside the moral and ethical implications of the creation of a body clone, a body clone may meet the UAGA requirement of death, thus giving the next of kin the right to consent to organ donation.[174] In this situation, genetically speaking, the DNA donor would be the clone's closest relative. In this respect, he or she could consent to the transplant, and the issue of property interests in the clone's organs would be moot.

Although theoretically this approach may avoid some donor consent issues, there are many practical problems with the use of body clones as a source of transplantable organs—one such problem revolves around the legal definition of death. The creation of body clones has been analogized to the case of anencephalic infants.[175] Anencephaly is a birth defect in which an infant is born with a brain stem, but lacks a brain, skull, or scalp.[176] Anencephalic children typically do not live past a few years after birth.[177] Since they lack a cerebral cortex, they are incapable of conscious thought, and are in a persistent vegetative state.[178] Since the brain stem of some anencephalics may function, spontaneous breathing, movements, and heartbeat may occur, although some doctors believe that anencephalics do not have the capacity to suffer.[179] Since anencephalics lack a brain, but in many cases do have a functioning brain stem, courts have debated whether or not they should be considered legally dead for purposes of organ donation.

In *In re T.A.C.P.*, the Florida Supreme Court addressed the issue of whether an

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172. For a discussion of the argument advocating the recognition of property interests in the human body and biological material, see generally Boulier, *supra* note 128; Amy S. Pignatella Cain, Note, *Property Rights in Human Biological Materials: Studies in Species Reproduction and Biomedical Technology*, 17 ARIZ. J. INT'L & COMP. L. 449 (2000); Hannemann, *supra* note 169, at 419-21; Wagner, *supra* note 6, at 933-35.

173. This can be compared to the situation of identical twins. Even though they share identical DNA, no one has suggested that one twin may have a property interest in the body of the other twin. *See* Amer, *supra* note 163, at 1682-84.

174. *See supra* notes 43-47 and accompanying text.

175. *See supra* note 46.

176. *In re* T.A.C.P., 609 So. 2d 588, 589 (Fla. 1992). To be diagnosed as anencephalic, an infant must meet four criteria: 1. Missing a large portion of the skull; 2. Scalp is absent over the skull defect; 3. Skull and scalp defects result in hemorrhagic, fibrotic tissue being exposed; 4. Recognizable cerebral hemispheres are absent. *Id.* at 590.

177. *Id.* at 590.

178. *Id.*

179. *Id.* at 591.

anencephalic infant was legally dead for purposes of organ donation.[180] Upon learning that their child would be born with anencephaly, the parents of the child T.A.C.P. agreed to carry the pregnancy to term, with the intention of donating T.A.C.P.'s organs for use in transplant.[181] However, T.A.C.P.'s health care providers refused to declare her legally dead, thereby preventing her organs from being harvested.[182] The Florida Supreme Court upheld the lower court's refusal to declare the child legally dead, applying a cardiopulmonary definition of death.[183] In doing so, the court declined to create a new standard of death applicable to anencephalic children. The court expressed concern about the suitability for transplant of organs harvested from anencephalic children, stating "[w]e acknowledge the possibility that some infants' lives might be saved by using organs from anencephalics who do not meet the traditional definition of 'death' we reaffirm today. But weighted against this is the utter lack of consensus, and the questions about the overall utility of such organ donations."[184]

This case illustrates a potential problem with the use of body clones as a source of organs. What would happen with respect to organ donation consent if scientists created a body clone that had a brain stem, or even a portion of a brain? Such a clone may not meet the definition of death required for organ donation, especially in those states that recognize a cardiopulmonary definition of death.[185] Another issue, also raised by the court in *In re T.A.C.P.*, relates to ethical concerns about personhood. Treating a headless or brain dead clone as dead for purposes of organ donation is in essence treating them as nonpersons.[186] This is harmful not only for the clone, but may also be a slippery slope problem for other persons who lack cognition.[187]

D. Property Interests in Organs Cloned in a Laboratory or Harvested from Animals

When organs are cloned in a laboratory, the interests of the DNA donor are much the same as they were with regard to property interests in a human clone. With organs cloned in a laboratory, there is no competing interest from a human clone. There are also fewer moral and ethical problems involved in cloning in a laboratory.[188] Indeed, the argument supporting recognition of a property interest in the human body to protect dignity is even stronger in this situation.[189] The granting of a property interest in body parts would help ensure the DNA donor had some control over how his or

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180. *Id.* at 590-91.

181. *Id.* at 589.

182. *Id.*

183. *Id.* at 595. The court determined that because the child still exhibited cardiopulmonary function, she was not legally dead under Florida law. *Id.*

184. *Id.*

185. *See supra* notes 43-47 and accompanying text.

186. *In re T.A.C.P.*, 609 So. 2d at 595.

187. *Id.*

188. Even with respect to cloning embryos for their stem cells, it is thought this controversial procedure would only be necessary for a short time. *See West, supra* note 66.

189. *See supra* text accompanying notes 167-69.

her genetic material was used, and ensure him or her access to the resulting organ.

The scientist who created the cloned organ may also have a competing property interest in the form of a patent.[190] This scenario is very similar to that in the *Moore* case, in which no property interest was recognized in Moore's excised cells because he could not reasonably expect to control their disposition.[191] In the present situation, if the DNA donor were to specify the use of the DNA upon its removal from the body, he or she should not be precluded from claiming a property interest in any resulting organ or tissue. The contractual property rights afforded in cases involving rights in renewable body parts would more closely govern this situation.[192]

On the other side of the equation is the interest of the scientist or researcher who creates the cloned organ or transgenic animal. At present, there is a strong presumption favoring patentability of innovations,[193] including the patenting of transgenic animals used for research, to improve food, etc.[194] The PTO has issued patents on transgenic pigs created as a source of more compatible organs for transplant.[195] In addition to the current favorable climate for patents, the traditional economic incentive arguments for granting patents apply as well. The limited monopoly rights conferred by a patent encourage innovation by allowing the researcher to recoup some of the investment spent in the development of the product.[196]

Although patents are more likely to be granted for innovative techniques used to create cloned organs or more compatible transgenic animal organs,[197] a case can still be made for granting the researcher a property interest in cloned organs. However, granting such a property interest is more appropriately applied to scenarios like that in *Moore*, where the DNA used has valuable research aspects. In situations where an organ is cloned in the laboratory from a person's DNA for the specific purpose of transplanting that organ into the DNA donor, the donor's interest in the organ should predominate.

IV. CONCLUSION

As the previous discussion indicates, advances in cloning and the biotechnology field raise many interesting possibilities for organ procurement. Conflicting property interests arise, however, as these possibilities come closer to reality. To resolve these

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190. The same should be true when a person's DNA is cloned to create transgenic animals for the purpose of harvesting more compatible organs. *See infra* note 195 and accompanying text.

191. *See supra* Part III.A.1.a.

192. *See, e.g.*, Hecht v. Superior Court, 16 Cal. App. 4th 836 (Cal. Ct. App. 1993).

193. Robert D. Kalinoski, *The Role of Law in Our Technological World*, 33 MD. B.J. 2 (2000), WL 33-AUG MD. B.J. *2, *6.

194. Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals*, 5 HEALTH L.J. 147 (1997), *available at* LEXIS, 5 HEALTH L.J. 147, *176-78.

195. *Id.* at *178-79 n.205.

196. *See supra* notes 131-33 and accompanying text.

197. Robin Beck Skarstad, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. PA. J. INT'L ECON. L. 353, 382 (1999).

conflicts, a person should have a property interest in body parts and DNA relinquished for the purpose of cloning organs in a laboratory. The interest should not, however, extend to an interest in the organs of a human clone, or to innovations of researchers obtained through use of the DNA, if the donor agreed to have his DNA used for such purposes. Limiting the property interest in this way offers some form of protection to all the potentially interested parties.