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PATENTING TRANSGENIC HUMAN EMBRYOS: A NONUSE COST PERSPECTIVE

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Table of Contents

I. INTRODUCTION ........................................... 1598

II. GENES AND GENE THERAPY .............................. 1601
   A. DNA Structure and Function ..................... 1602
      1. Genetic Structure ............................ 1603
      2. Genetic Function ............................ 1604
   B. Manipulating Genes ............................... 1606
      1. Incorporating New Characteristics:
         Recombinant DNA Techniques .............. 1606
      2. Turning Off or Suppressing
         Deleterious Genes: Antisense
         and “Knockout” Techniques .............. 1607
      3. Amplifying Desired Characteristics:
         DNA Amplification ........................ 1609
   C. Gene Therapy ...................................... 1610
      1. Somatic Cell Therapy ....................... 1611
      2. Germ-line Therapy ........................ 1613

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1597
III. THE PATENT SYSTEM .............................................. 1615
   A. Patent Theory ............................................ 1616
   B. Patent Practice .......................................... 1620
      1. Patent Examination .................................. 1621
      2. Scope and Duration ................................... 1622
   C. Patent Limitations ........................................ 1625
      1. Statutory Subject Matter .............................. 1625
      2. Congressionally Excluded Inventions ............. 1627
      3. Fraudulent or Immoral Devices ..................... 1628
      4. Medical Processes .................................... 1630

IV. PATENTING HIGHER ORGANISMS ................................. 1633
   A. Transgenic Animals ....................................... 1634
      1. Patenting Opponents ................................ 1635
      2. Patent Proponents .................................... 1639
   B. Transgenic Humans .......................................
      1. Positive and Negative Eugenics .................... 1644
      2. The PTO Position .................................... 1647

V. PATENTING TRANSGENIC HUMAN EMBRYOS ....................... 1650
   A. Embryo Status ............................................ 1651
      1. Embryos and Abortion ................................ 1651
      2. Embryo Status and Biology ........................... 1653
      3. Embryos and the PTO ................................ 1656
   B. Balancing Costs .......................................... 1658
      1. "Thick" and "Thin" Harms ............................. 1660
      2. Nonuse Values ....................................... 1662
      3. Incentives to Invent ................................ 1665

VI. CONCLUSION ....................................................... 1668

I. INTRODUCTION

On April 7, 1987, the United States Patent and Trademark Office (PTO) announced that it would consider nonnatural, nonhuman multicellular organisms to be patentable subject matter.1 By 1988, the PTO had issued the first patent for such an organism.2 The policy of permitting transgenic animal

2. U.S. Patent No. 4,736,866 (1988). This patent is for a transgenic mouse containing an oncogene sequence to promote the development of malignant tumors. Id.
patenting has been more than controversial. Opponents have challenged the policy through lawsuits, and have introduced restrictive legislation in Congress. These opponents assert that animal patenting will lead to calamitous ethical and economic consequences such as the collapse of small farming, the mistreatment of animals, and widespread disregard for the sanctity of life. In addition, opponents of animal patenting have questioned whether such patents may lead to the patenting of human organisms, particularly human embryos.

Recent commentary on the patenting of higher life forms has focused almost exclusively on the patenting of transgenic animals, and has effectively answered ethical and economic concerns arising from animal patenting. In general, this

3. See, e.g., Diamond v. Chakrabarty, 447 U.S. 303, 306, 314-18 (1980) (rejecting petitioner’s claims that a genetically engineered bacterium can not be patented because it is a living product of nature, and holding that the microorganism is a patentable invention); Animal Legal Defense Fund v. Quigg, 710 F. Supp. 728, 729 (N.D. Cal. 1989) (dismissing plaintiff’s claim that the PTO does not have the authority to issue patents for non-naturally occurring multicellular organisms).


6. See 136 CONG. REC. S1611 (daily ed. Feb. 26, 1990) (statement of Sen. Hatfield) (“[T]here is growing concern about the possibility of patenting human forms, especially pre-embryos, since these forms are without constitutional protection.”); see also PATENTING LIFE, supra note 1, at 132 (stating that “rapid advances in genetics have fostered debate regarding a most sensitive issue—could human beings be patented?”); George J. Annas, Of Monkeys, Men, and Oysters, HASTINGS CENTER REP., Aug.-Sept. 1987, at 20, 22 (questioning whether a particularly “novel” and “useful” human embryo could be patented, cloned, and sold); Dresser, supra note 5, at 416 (asking if allowing manipulations on ‘partial humans’ will “ease the way to eugenic interventions on full humans, or commercialization of human embryos and fetuses?”); Barry Hoffmaster, The Ethics of Patenting Higher Life Forms, 4 INTELL. PROP. J. 1, 11 (1989) (posing that “[t]he crucial question, therefore, is whether the PTO’s decision to allow the patenting of animals would lead to the patenting, and thus the commercialization, of human traits”).

7. See Brody, supra note 5, at 147-49 (rebutting economic and moral criticisms); Dresser, supra note 5, at 416-24 (discussing the arguments animal patent advocates have used to rebut economic and ethical concerns); Merges, supra note 5, at 1058 (rebutting ethical concerns).
commentary has concluded that these concerns may be legitimate, but are better addressed through regulatory mechanisms other than the patent system.\textsuperscript{8}  Patenting of transgenic humans or of transgenic embryos has received less attention, despite obvious concern in Congress and the PTO.\textsuperscript{9}  The few commentators to address the patenting of transgenic humans have failed to draw appropriate distinctions between the issues raised by animal patenting and those raised by patentable human gene therapy.\textsuperscript{10}

This Article attempts to distinguish the issues surrounding human gene therapy from those surrounding the creation of transgenic animals. It argues that although the patent system has a role to play in regulating the creation of transgenic animals, it should not yet be used to provide an economic incentive for human gene therapy. The economic incentive to innovate which the patent system provides is often of uncertain benefit to society; this will be particularly true when the patent creates an incentive to alterations in the human germ line.\textsuperscript{11}  In particular, social costs resembling the "nonuse" costs recently identified for environmental damage make the patent bargain an undesirable incentive for human gene therapy.\textsuperscript{12}  Part II lays the foundation for this argument with a discussion of the technological potential for somatic and germ-line therapies. Part III reviews the purposes and procedures of the patent system to give a foundation to the discussion of patent-

\textsuperscript{8}  See Dresser, supra note 5, at 434-35; Merges, supra note 5, at 1067-68 (stating that regulations are the proper merchants to address policy concerns); see also PATENTING LIFE, supra note 1, at 18 ("Most arguments that have been raised both for and against the patenting of animals concern issues that would be materially unchanged whether patents are permitted or not.").

\textsuperscript{9}  See, e.g., 136 CONG. REC. S1611 (daily ed. Feb. 26, 1990) (statement of Sen. Hatfield) (discussing concerns about animal patents, and recognizing concerns that they could lead to human patents); PATENTING LIFE, supra note 1, at 93 (reprinting PTO Policy on Patenting of Animals) (restricting patents to nonhuman multicellular organisms on Constitutional grounds).


\textsuperscript{11}  Refer to part V infra.

\textsuperscript{12}  Refer to part V.B. infra.
ing higher organisms. Part IV reviews both the controversy surrounding the patenting of transgenic animals and more recent commentary regarding the patentability of humans or sub-human creatures. The discussion focuses on the high likelihood that these issues will arise regarding the patenting of processes or products related to human germ-line gene therapy. The potential product of such therapy would be a genetically altered human embryo. Part V reviews this embryo's uncertain legal and moral status, and advances an argument that a patent incentive is unnecessary and potentially counterproductive in fostering beneficial germ-line therapies.

II. GENES AND GENE THERAPY

The question of human embryo patentability is characteristic of the issues that emerge at the interface of law and empirical science. Science, which seeks to develop a coherent view of the universe through the tools of empirical research, offers humankind the intellectual tools for improved understanding of the physical world. This knowledge may then be transformed into advanced techniques for manipulating portions of the physical world to either the benefit or detriment of society. The calculus of benefit and harm that arises from such new capabilities necessarily involves the legal and political institutions that order costs and benefits in society; thus science and technology may give rise to novel legal and political issues.

Before analyzing such novel issues, it is imperative to

13. See generally Steven Goldberg, The Reluctant Embrace: Law and Science in America, 75 Geo. L.J. 1341 (1987) (stating that science's emphasis on progress is fundamentally different than law's emphasis on process and resolving disputes); Harold P. Green, The Law-Science Interface In Public Policy Decisionmaking, 51 Ohio St. L.J. 375 (1990) (discussing how judicial and legislative processes change with new advances in science, and examining how this interface effects litigation, regulation, and public funding of scientific endeavors).


15. See Milton R. Wessel, What is "Law, Science, and Technology" Anyway?, 29 Jurimetrics J. 259, 260-61 (1989) (stating that society has not learned how to control science and technology in a manner that maximizes benefit and minimizes harm); see also Vincent M. Brannigan, Biotechnology: A First Order Technico-Legal Revolution, 16 Hofstra L. Rev. 545, 549 (1988) (noting that discontinuities in the law arise when the legal system is unable to "easily classify a new technology in accordance with existing legal structures").

16. Brannigan, supra note 15, at 549 (stating that science and technology require legal institutions to analyze their processes to help social institutions respond satisfactorily).
define their proper dimensions. This definition must begin with
technology assessment—an accurate appraisal of the capabilities
and likely impact of the new technology. Improper technology
assessment leads almost inevitably to improper issue
resolution. In the case of transgenic human embryos, novel
legal issues arise from an increased understanding of the mo-
lecular basis of life. The parameters of this knowledge and
of its attendant technology, as reviewed below, define both the
problem of embryo patentability and potential resolutions of
the problem.

A. DNA Structure and Function

Living organisms are composed of microscopic units called
cells. Some organisms, such as bacteria, are composed of
only a single cell. Complex, multicellular organisms such as
human beings develop from a single cell, a fertilized ovum
called the zygote. The development and functioning of all
cells—whether bacteria, zygotes, or developed human cells—is
directed by chemical “blueprints” encoded in molecules of de-
oxyribonucleic acid, or DNA.

In the case of the zygote, half of its DNA is obtained from
each of its parents. The DNA directs the division of the zyg-
gote into an embryo, and the differentiation and growth of
embryonic cells into a mature individual. Because the DNA
in the developed person’s cells is derived from that originally
in the zygote, each cell contains a copy of the same DNA that
was in the zygote—a complete blueprint of the individual.

17. See Wessel, supra note 15, at 261-64 (discussing how to approach a technol-
ogy assessment of computer law).
18. See Dan L. Burk, DNA Identification Testing: Assessing the Threat to Privi-
cy, 24 U. TOL. L. REV. 87, 101-02 (1992) (stating that “when one begins with an
incorrect set of premises, one almost inevitably arrives at an incorrect set of conclu-
sions”).
19. See George J. Annas, Doctors and Lawyers and Wolves, 29 JURIMETRICS J.
437, 446-47 (1989) (stating that scientific breakthroughs, such as organ donation and
surrogacy, often prompt the legal community to create new law). As Annas points
out, although many of the questions raised by new technology are merely old legal
issues in new guises, genetic technologies are generating truly novel legal problems.
Id.
20. See JAMES D. WATSON ET AL., RECOMBINANT DNA: A SHORT COURSE 1-2
(1983) [hereinafter RECOMBINANT DNA]; MAXINE SINGER & PAUL BERG, GENES AND
21. Id.
22. SINGER & BERG, supra note 20, at 10.
23. See id.
24. Id. at 2, 11.
25. See id. at 893-96.
26. Id. at 2.
Because different body cells perform different bodily functions, not all of the blueprint is used in every cell; a particular cell uses only that portion of the blueprint that it needs to perform its particular bodily functions.27

1. Genetic Structure. DNA is found in structures within cells called chromosomes, which consist of enormously long strands of DNA coiled upon a type of cellular scaffolding.28 DNA is a linear molecule composed of a chain of nucleotide subunits.29 Normally in cells, DNA is double-stranded and resembles a twisted ladder or zipper of two backbone strands having “teeth” or “rungs” in the middle.30 The teeth of each DNA strand correspond to one of four bases designated A, T, G, or C.31 In forming the rungs that bridge the two strands, A pairs only with T, and G pairs only with C.32

The sequence of bases in particular portions of DNA, called genes, contain the code for cellular proteins.33 Proteins consist of long chains of subunits called amino acids whose linear sequence in the protein chain causes the chain to assume a distinctive three dimensional conformation.34 The amino acid chain of a protein is built up, link by link, by cellular machinery under the direction of DNA, the “master molecule” of the cell.35

DNA controls protein synthesis indirectly through an intermediate molecule known as messenger RNA (mRNA).36 Like DNA, mRNA is composed of a nucleotide chain.37 However, mRNA differs from DNA in that mRNA is single stranded,38 it contains uracil (U) instead of thymidine (T),

27. Id. at 893.
28. Id. at 2.
31. These letters stand for adenine, thymine, guanine, and cytosine. SINGER & BERG, supra note 20, at 36-37.
32. See id. at 42 (noting the A with T and G with C base pairs are complementary base pairs, which predominate in most DNAs while noncomplementary base pairs, A with C or G with T, are unfavored because they can not form appropriate hydrogen bonds, therefore, their formation is sterically hindered or disrupts the helix geometry).
33. RECOMBINANT DNA, supra note 20, at 32-33.
35. See RECOMBINANT DNA, supra note 20, at 9.
36. STRYER, supra note 29, at 95.
38. WATSON ET AL., supra note 30, at 80.
and it is less stable than DNA.\textsuperscript{39} In a process called transcription, mRNA is formed by RNA polymerase, an enzyme that unwinds a bit of DNA and "transcribes" or copies the DNA into mRNA as it passes over it.\textsuperscript{40} The mRNA strand thus formed is complementary to one of the DNA strands.\textsuperscript{41} The sections of DNA that direct the synthesis of mRNA also have associated control sequences, such as promoters or enhancers, which regulate where and how often a gene is transcribed to produce mRNA.\textsuperscript{42}

Once formed, the linear sequence of mRNA is read by cellular machines known as ribosomes which direct the synthesis of protein chains.\textsuperscript{43} Each sequential group of three bases in the mRNA chain, a codon, codes for a particular amino acid.\textsuperscript{44} The protein chain is assembled in the order of codons found in the mRNA, which in turn was derived from the order of bases in DNA.\textsuperscript{45} Thus, genes give rise to proteins, which give cells their microscopic characteristics; groups of specialized cells give organisms their macroscopic characteristics.\textsuperscript{46}

2. Genetic Function. Proteins give cells their characteristics because much of cellular structure and function is mediated by proteins.\textsuperscript{47} Proteins called enzymes direct the many chemical reactions that take place within the cell.\textsuperscript{48} Other types of proteins form the molecular scaffolding that gives shape to the cell and its components.\textsuperscript{49} These different functions are possible as a result of each protein's shape, which in turn is largely a result of the protein's composition.\textsuperscript{50} As a consequence, DNA is ultimately responsible for the physical characteristics of humans and other living creatures.\textsuperscript{51}

However, this also means that DNA can be ultimately responsible for physical or mental disabilities.\textsuperscript{52} Because the

\textsuperscript{39} SINGER & BERG, supra note 20, at 55-56.
\textsuperscript{40} MARIEB, supra note 37, at 91; WATSON ET AL., supra note 30, at 362.
\textsuperscript{41} WATSON ET AL., supra note 30, at 362.
\textsuperscript{42} Id. at 86, 368.
\textsuperscript{43} Id. at 84.
\textsuperscript{44} Id.
\textsuperscript{45} Id.
\textsuperscript{46} DAVID T. SUZUKI ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 206 (3d ed. 1986).
\textsuperscript{47} BENJAMIN LEWIN, GENES 4 (3d ed. 1987).
\textsuperscript{48} Id.
\textsuperscript{49} See id.
\textsuperscript{50} Id. at 7-8; STRYER, supra note 29, at 39.
\textsuperscript{51} SUZUKI ET AL., supra note 46, at 206.
\textsuperscript{52} SINGER & BERG, supra note 20, at 20; see also U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, HUMAN GENE THERAPY—A BACKGROUND PAPER 13-15.
architecture of proteins allows them to perform their characteristic functions, any perturbation in that architecture may inactivate the protein and change or halt a particular cellular function. Changes in either genes or their associated control sequences may give rise to defects in the resulting protein.

If this protein's function is important, the organism with the defect may be impaired or may die. An example of such a disease is sickle-cell anemia, in which a change in the nucleotide sequence of the gene for the protein hemoglobin gives rise to defective hemoglobin molecules, and ultimately to defective red blood cells. Because DNA is the basis of heredity, defects in the DNA may be passed from parent to offspring, continuing the particular disorder in successive generations.

Other genetic diseases include Huntington's disease, Tay-Sachs disease, familial type cholesterolemia, polycystic kidney disease, neurofibromatosis, Duchenne muscular dystrophy, and cystic fibrosis. These are known as single-gene diseases because they arise from a defect in a single gene. However, most traits are the consequence of complex interactions between many gene products. Thus, a genetic basis for an illness such as schizophrenia probably exists, but it appears to have a complex, multi-gene etiology that science does not yet completely understand. Similarly, defects in the sequences that control DNA expression may cause uncontrolled or inappropriate cellular function, such as the abnormal growth seen in tumors, although cancer appears to be the result of many different mutations.

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54. Id.
55. Id. at 70-71; see also HUMAN GENE THERAPY, supra note 52, at 57-59 (describing inherited hemoglobin disorders and treatment).
57. HUMAN GENE THERAPY, supra note 52, at 13, 15.
58. Id. at 15. See generally Jean Marx, Dissecting the Complex Diseases, 247 Science 1540, 1540 (1990) [hereinafter Complex Diseases] (recognizing the challenges geneticists face in determining the genetic components of multi-cause diseases).
59. Id. at 15. See generally Jean Marx, Many Gene Changes Found in Cancer, 246 Science 1386 (1989) [hereinafter Gene Changes] (noting that a number of diseases, including cancer, develop by a "stepwise accumulation of mutations"); Arthur B. Pardee, G1 Events and Regulation of Cell Proliferation, 246 Science 603, 603 (1989) (stating that cancerous cells exhibit deranged control of their proliferation).
B. Manipulating Genes

The science of molecular biology has created an explosive growth of understanding about the molecular processes that permit living creatures to function. From this intimate acquaintance with the basis of life, researchers have cultivated a series of techniques that allow them to employ these naturally occurring molecular processes in new and useful ways. Several of these new techniques have an important impact on the treatment of genetic disease in humans.

1. Incorporating New Characteristics: Recombinant DNA Techniques. The best known set of biotechnology techniques is probably that associated with recombinant DNA technology, which the media and general public have dubbed "genetic engineering." Recombinant DNA technology allows guided transfer of gene sequences between organisms. If the transfer is successful, the recipient, or host cell, will construct a new type of protein, causing the cell to express a new physical trait. Transfer of genetic material is fairly common in nature. For example, bacteria acquire resistance to antibiotics by gene transfer from other bacteria or fungi. However, recombinant DNA techniques allow precise control of which genes are transferred.

Recombinant DNA technology is partially based upon the discovery that special bacterial enzymes, called restriction enzymes, will cut a DNA chain where they find a specific base sequence. Another set of enzymes, called ligases, reconnect severed DNA strands. Using these enzymes, researchers are able to "cut and paste" DNA into new sequences, including splicing DNA from one organism into an organism of a different species.

63. Howard E. Simmons, Biotechnology: A New Marriage of Chemistry and Biology, in BIOTECHNOLOGY AND MATERIALS SCIENCE: CHEMISTRY FOR THE FUTURE 7-8 (Mary L. Good et al. eds., 1988) (noting the application of molecular biology to improve human life).
64. Id. (asserting that biotechnology provides a set of tools that has altered in a very basic way the capabilities of researchers trying to understand life).
65. SINGER & BERG, supra note 20, at 887.
66. Id. at 233.
67. Id.
68. Id. at 234-36.
69. STRYER, supra note 29, at 130.
70. SINGER & BERG, supra note 20, at 238.
71. Id. at 85.
72. Id. at 889-93 (discussing research aimed at incorporating foreign genetic
In order to successfully recombine DNA, however, more is needed than cutting and pasting enzymes. These powerful tools do not address the problem of transferring foreign, or heterologous, DNA into a host cell that will ultimately express the new characteristic. Although cells may be induced to take up free DNA, new DNA is best introduced into a new host through the use of a specialized vector: a DNA molecule that can carry foreign DNA and will reproduce or replicate in the host cell.\(^7\) One type of vector that is especially useful for introducing DNA into bacterial cells is a plasmid, a circular piece of DNA that is often transferred between bacteria.\(^7\)\(^4\) If a foreign gene is inserted into a plasmid by cutting and pasting with restriction enzymes and DNA ligase, that gene will be carried along when the plasmid transfers into the host bacterial cell.\(^7\)\(^5\)

In higher organisms, the vector of choice is usually a virus.\(^7\)\(^6\) Viruses are intracellular parasites composed of a nucleic acid and a protein coat.\(^7\)\(^7\) Viruses invade cells and hijack the cell's machinery to produce new viruses.\(^7\)\(^8\) If some viral DNA is replaced with a foreign gene of interest, that gene may be carried into the host cell when it is invaded by the virus, just as the viral DNA would have been.\(^7\)\(^9\) The cell may then express the gene of interest, conferring on the cell some new property or characteristic.\(^8\)\(^0\) Such cells are termed transformed,\(^8\)\(^1\) the animals they form are transgenic animals.\(^8\)\(^2\)

2. Turning Off or Suppressing Deleterious Genes: Antisense and "Knockout" Techniques. An important variation of recombinant DNA technology is antisense technology, which
in some aspects is the converse of the recombinant DNA techniques discussed above. Rather than allowing a recombinant cell to express a new gene, antisense causes the suppression of a gene that the cell normally expresses. Antisense technology takes advantage of DNA’s ability to form double-stranded, complementary nucleotide chains. The strands of DNA are directional and antiparallel, that is, the chemical bonds in each nucleotide chain are oriented in the opposite direction from those in the other strand. For a given gene, only one of the chains, the “antisense” or template strand, is oriented in such a way that the cellular machinery can transcribe its information. The complementary chain, or “sense” strand, is not read or transcribed, but reads the same as that gene’s resulting mRNA.

With recombinant DNA technology, it is possible to introduce a gene in an orientation such that the sense strand is transcribed by the cell, producing mRNA transcripts that are complementary to the gene’s normal mRNA. The complementary transcripts anneal to the normal mRNA, preventing the ribosomes from translating the sense transcripts into proteins. This provides a method for “switching off” unwanted or deleterious gene expression.

Foreign DNA that is introduced into a new host cell may have no effect unless it is situated to be transcribed into mRNA. Because the newly integrated DNA will interpose itself into the sequence of the host DNA, it is usually preferable for the integration to take place in some non-functional or non-

83. Refer to notes 65-82 supra and accompanying text.
84. See ALBERTS ET AL., supra note 57, at 195 (explaining that antisense mRNA hybridizes to the sense mRNA and thereby inhibits protein synthesis).
85. Id. at 195.
86. SINGER & BERG, supra note 20, at 40-42.
88. STRYER, supra note 29, at 705.
89. ALBERTS ET AL., supra note 57, at 195.
90. Id.
92. For microorganisms, it is often sufficient for the heterologous DNA to remain on the plasmid vector, which functions as an autonomous genetic unit within the cell. SINGER & BERG, supra note 20, at 235, 271. In other cases, particularly with higher organisms, the researcher must integrate the DNA into a chromosome to function. Id. The cellular machinery can attach the foreign gene to DNA sequences that will direct its integration into the host’s genetic material, or genome, although the researcher can not always predict the precise site of integration. Id.
essential portion of the genome.\textsuperscript{93} Integration into the coding sequence or control sequences of an important functional gene would disrupt that gene and actually introduce, rather than repair, a genetic defect.\textsuperscript{94} However, this scenario raises the possibility of purposefully integrating heterologous DNA into host genes whose expression is undesirable, thus disrupting their sequence and halting their function.\textsuperscript{95} Scientists have successfully demonstrated such gene disruption, known as insertional mutagenesis or gene "knockout," in animal models, providing a technique for permanently halting expression of an unwanted or deleterious gene.\textsuperscript{96}

3. \textit{Amplifying Desired Characteristics: DNA Amplification.} The latest and most revolutionary technology in the biotechnology tool kit is the Polymerase Chain Reaction (PCR) which has proven extremely important in detecting and identifying genetic defects.\textsuperscript{97} PCR allows small, virtually unusable samples of DNA to be quickly amplified to usable amounts.\textsuperscript{98} PCR amplifies DNA in the laboratory by using each strand of the DNA molecule as a template to assemble a complementary strand.\textsuperscript{99} By heating a sample of DNA, researchers may break the weak bonds between the strands, yielding two free molecules of single-stranded DNA.\textsuperscript{100} Researchers may then add short, single-stranded lengths of DNA primer molecules that will attach to the specific regions of the DNA to be replicated.\textsuperscript{101} The primers define the area for the cellular machinery to replicate, giving a starting place to the polymerase enzyme that does the replication itself.\textsuperscript{102} Beginning at the primer, the polymerase rapidly assembles nucleotide building blocks into chains that are complementary to the single stranded

\begin{itemize}
\item \textsuperscript{93} \textit{Id.} at 896-97.
\item \textsuperscript{94} \textit{Id.}
\item \textsuperscript{95} \textit{Id.}; John Travis, \textit{Scoring a Technical Knockout in Mice}, 256 SCIENCE 1392, 1392 (1992).
\item \textsuperscript{96} See \textit{SINGER \& BERG}, \textit{supra} note 20, at 897 (discussing recent trends in targeted modification of the mammalian genome with specially designed vectors to create or eliminate specific mutations); Travis, \textit{supra} note 95, at 1392.
\item \textsuperscript{97} Ruth L. Guyer \& Daniel E. Kosland, Jr., \textit{The Molecule of the Year}, 246 SCIENCE 1543, 1543 (1989) (designating PCR as the most important technology of the year).
\item \textsuperscript{98} \textit{SINGER \& BERG}, \textit{supra} note 20, at 420.
\item \textsuperscript{99} \textit{Id.} at 421; Norman Arnheim \& Corey H. Levenson, \textit{Polymerase Chain Reaction}, CHEMICAL \& ENGINEERING NEWS, Oct. 1, 1990, at 36, 36-37.
\item \textsuperscript{100} Arnheim \& Levenson, \textit{supra} note 99, at 36-37; Henry A. Erlich et al., \textit{Recent Advances in the Polymerase Chain Reaction}, 252 SCIENCE 1643, 1643 (1991).
\item \textsuperscript{101} \textit{SINGER \& BERG}, \textit{supra} note 20, at 421.
\item \textsuperscript{102} \textit{Id.}
DNA. The result is two molecules of double-stranded DNA that can be heated to yield four templates for another round of the PCR process. Because the copies of amplified DNA double in each round of PCR, researchers can amplify a small sample of DNA into a larger sample.

An additional amplification technique known as the ligase chain reaction (LCR) has recently come to prominence. Like PCR, the LCR technique heats double-stranded DNA to separate the strands through multiple rounds of amplification. However, rather than adding primers that bracket the region to be amplified, LCR employs two short lengths of DNA that together "cover" the region. The ligase enzyme then joins the two lengths of DNA, producing a complementary strand that can serve as a template on the next round of amplification.

C. Gene Therapy

Biotechnology holds great promise for assisting individuals whose bodies fail to produce important proteins. The techniques described above are key tools in detecting, identifying, and even treating genetic disorders. Treatment may develop using recombinant DNA techniques to replace missing or defective proteins. For example, researchers have placed both human insulin and human blood clotting Factor VIII:C genes in microorganisms. As the organisms grow and multiply, they produce large quantities of insulin or Factor VIII:C. This provides a plentiful supply of either insulin for diabetics,
whose body cells fail to produce functional insulin, or clotting
Factor VIII:C for hemophiliacs, whose body cells fail to produce
that protein.

The techniques for DNA manipulation hold additional
promise beyond supplying an outside source of injectable
bioproducts to treat genetic disorders. Recombinant DNA tech-
nology may also repair or replace defective genes in the body
cells of those suffering from genetic disease.\textsuperscript{111} Additionally,
antisense and “knockout” techniques provide methods of nega-
tive gene control, that is, shutting off undesirable genetic ex-
pression.\textsuperscript{112} Researchers could direct such gene therapy at
healing individuals afflicted with genetic diseases, or eradicat-
ing genetic defects completely from the DNA that is passed
from generation to generation.\textsuperscript{113}

1. Somatic Cell Therapy. Somatic cell therapy involves
the use of the techniques discussed above to accomplish a ge-
ettice transformation of cells that comprise the patient’s bodily
structure, except for the reproductive cells.\textsuperscript{114} Somatic cell
therapy may be effective when the victim of a genetic disorder
fails to produce some needed protein or biological sub-
stance.\textsuperscript{115} To be effective, the therapy need not introduce a
functional copy of the missing or inactive gene into every body
cell; rather, it need only introduce the gene into a population
of cells competent to supply the missing substance.\textsuperscript{116} Ideally,
the population of cells is a group that divides continuously to
replace individual cells that become senescent and die.\textsuperscript{117} In
addition, the cells transformed with the new DNA should ei-
ther be those affected by the genetic disease,\textsuperscript{118} or cells

\textsuperscript{111} See generally W. French Anderson, Human Gene Therapy, 256 SCIENCE 808
(1992) (noting the use of gene therapy in cancer patients); Richard C. Mulligan, The
Basic Science of Gene Therapy, 260 SCIENCE 926 (1993) (recognizing the possibility of
treating human disease by gene therapy).
\textsuperscript{112} Refer to part II.B.2. supra.
\textsuperscript{113} See HUMAN GENE THERAPY, supra note 52, at 7.
\textsuperscript{114} Id.
\textsuperscript{115} See SINGER & BERG, supra note 20, at 889 (providing an example in which
somatic cell modification might ameliorate severe immune system deficiencies suf-
fered by humans who are homozygous for nonfunctional mutations in the adeno
sine deaminase gene by introducing functional genes into blood cells).
\textsuperscript{116} See, e.g., Barbara J. Culliton, Designing Cells to Deliver Drugs, 246 SCIENCE
746, 746 (1989) (discussing efforts to place recombinant genes to correct immune
system deficiencies in bone marrow stem cells that produce immunologically active
blood cells); Michelle Hoffman, Putting New Muscle Into Gene Therapy, 254 SCIENCE
1455, 1455 (1991) (discussing research that uses genetically engineered immature
muscle cells to secrete growth factor into the body).
\textsuperscript{117} See Larry Thompson, Stem-Cell Gene Therapy Moves Toward Approval, 255
\textsuperscript{118} See Culliton, supra note 116, at 746 (describing genetically engineered bone
situated so as to secrete newly expressed products into body systems that will carry the product to affected tissues.119

The researcher must introduce the heterologous DNA for somatic cell therapy into the chosen body cells in a manner that will, depending on the treatment strategy, either allow the cell to express the new genetic material, or curtail unwanted genetic expression.120 To date, the vectors employed in somatic cell gene therapy are viruses such as retroviruses or adenoviruses.121 Researchers have also developed other methods of delivering heterologous genes into cells, such as a microscopic “shotgun” that blasts tiny DNA-coated gold beads into cells.122 Cells may also be chemically treated so that they take up free DNA, or their cell membranes may be fused with man-made membranes that encapsulate DNA.123

The researcher may direct delivery of heterologous DNA into cells toward either ex vivo or in vivo therapy.124 In the former, she introduces heterologous DNA into patient cells that have been removed from the body.125 She then reintroduces the transgenic cells into the patient, where they will hopefully produce the missing gene product.126 Available ex vivo techniques include removal, transformation, and replacement of the blood cell precursor cells from patient bone marrow,127 or incorporation of transformed cells into gortex “organoids” that are then implanted into the patient to secrete the needed biological material.128

In vivo gene therapy involves the introduction of genetic material directed at transforming cells still situated in the body.129 This requires fairly precise targeting of the heterologous DNA; unlike ex vivo transformation, cells are not reintroduced into a chosen area of the patient’s body.130

119. Hoffman, supra note 116, at 1445 (describing genetically engineered muscle cells that excrete growth hormones for the entire body).
120. Such as through antisense or “knockout” techniques. Refer to part II.B.2. supra.
121. Mulligan, supra note 111, at 926-27.
123. HUMAN GENE THERAPY, supra note 52, at 11-12.
124. Mulligan, supra note 111, at 926.
125. Id.
126. Id.
129. Mulligan, supra note 111, at 926.
130. HUMAN GENE THERAPY, supra note 52, at 10 (citing nerve and liver cells as examples).
Consequently, the vector and delivery system must initially be directed toward the appropriately situated tissues. For example, researchers could design inhalers to generate a mist of T lymphocytes, liposomes, or viruses that carry heterologous DNA to cells in the respiratory tract to combat the effects of cystic fibrosis or emphysema.

2. Germ-line Therapy. Germ-line therapy allows more comprehensive and far-reaching genetic alterations than are possible under somatic cell therapies. Unlike somatic cell manipulation, which is directed toward altering subsets of functional body cells, germ-line manipulation generally alters DNA in the embryo, which will later develop into a mature organism. All the cells derived from that first altered cell—all the individual's body cells—will carry the new genetic alteration. This includes the gametes, sperm, and ova that will engender the individual's offspring. Thus, germ-line techniques eradicate or introduce a genetic trait not only into the treated individual, but also into the individual's progeny.

Germ-line therapy requires not only sophisticated techniques for DNA manipulation, but also sophisticated techniques for gamete and embryo manipulation. Technology presently allows artificial fertilization in vitro or recovery of embryos after fertilization in vivo. Embryos may also be cryopreserved in liquid nitrogen. After proper thawing, the embryos remain viable for implantation and gestation. This means that, at least theoretically, embryos harvested at one time may be saved for future therapy or implantation. Similar benefits could attend cryopreservation techniques for

131. See generally Mulligan, supra note 111 (proposing viral and non-viral vectors researchers could use in in vivo human gene therapy).
133. HUMAN GENE THERAPY, supra note 52, at 8; see Anderson, supra note 111, at 812 (discussing ethical and medical dangers of germ-line therapy).
134. HUMAN GENE THERAPY, supra note 52, at 9. An alternative method of germ-line therapy would target the sperm or ova in a mature individual. Id. at 9. However, this is technically more difficult than manipulating the embryo. Id.
135. Id. at 7.
136. Id. at 8.
137. Id.
139. Id. at 933.
140. Id. However, researchers still consider the technique experimental due to uncertainty about the long term genetic effects of the freeze thaw cycle. Id.
gametes.\textsuperscript{141}

Advanced DNA manipulation techniques also allow genetic examination of embryos prior to implantation.\textsuperscript{142} Researchers can aspirate a single cell from an eight- or twelve-cell embryo without impairing subsequent development.\textsuperscript{143} Fluorescent DNA probes that will bind to specific chromosomal sequences can be used to detect abnormalities in chromosomal structure.\textsuperscript{144} PCR can also be used to amplify and detect single-gene abnormalities from the minute amount of DNA in the aspirated cell.\textsuperscript{145} The researcher may then discard or, as gene therapies advance, treat embryos showing genetic defects.

Researchers have already been successful at the rudiments of such treatments in animal models. They have introduced foreign or heterologous DNA into the genome of mice, primarily through microinjection of genetic material into zygotes.\textsuperscript{146} Although microinjection is the most common method for creating transgenic strains of mice, it is subject to drawbacks.\textsuperscript{147} The procedure is painstaking and time-consuming, and only a small number of zygotes\textsuperscript{148} incorporate the heterologous DNA as a functional gene.

Thus, other less tedious methods are becoming more common.\textsuperscript{149} For example, success has been achieved in gene transfer by introducing into mice embryos undifferentiated embryonal carcinoma or embryonal stem cells carrying foreign genes.\textsuperscript{150} The resulting animal is a mosaic of tissues, some of

\textsuperscript{141} Frozen storage of spermatozoa is fairly routine, but cryopreservation of ova, although possible, is still plagued by technical problems that may impair fertilization or subsequent development. \textit{Id.} at 934.

\textsuperscript{142} \textit{Id.} at 935.

\textsuperscript{143} \textit{Id.} at 935-36.

\textsuperscript{144} \textit{Id.} at 935. See generally Leslie Roberts, \textit{FISHing Cuts the Angst in Amnio-centesis}, 254 SCIENCE 378 (1991) (describing fluorescent detection technique in layperson terms).

\textsuperscript{145} Winston & Handyside, \textit{supra} note 138, at 935.

\textsuperscript{146} SINGER & BERG, \textit{supra} note 20, at 891. Because the zygote is microscopic, the procedure is carried out with tiny, delicate instruments. \textit{Id.} Suction from a tiny pipette holds the zygote in place; a microscopic needle then penetrates the zygote and injects the foreign gene into the cell pronucleus, where the chromosomes reside. \textit{Id.} In some of these zygotes, the DNA will integrate into the native genome and become functional. \textit{See id.} (noting that DNA integrates early enough into the recipients genome to transform both germ-line and somatic cell lineages).

\textsuperscript{147} \textit{HUMAN GENE THERAPY, supra} note 52, at 12.

\textsuperscript{148} \textit{Id.}

\textsuperscript{149} \textit{PATENTING LIFE, supra} note 1, at 95.

\textsuperscript{150} Florence M. Botteri et al., \textit{Recombinant Retroviruses in Transgenic Mice, 478 ANNALS N.Y. ACAD. SCI. 255, 255 (1986). The blastocysts are then reimplanted into female mice to develop, the undifferentiated foreign cells developing along with the native cells, differentiating into tissues comprising a fully-developed mouse. \textit{See id.; Travis, supra} note 95, at 1392. Techniques also exist to directly infect mouse
which arise from its original embryonic cells, and some of which arise from the transplanted, transgenic cells.\textsuperscript{161} Depending upon which tissues are derived from the transgenic cells, the foreign gene may or may not be expressed in the mosaic animal. However, if germ-line tissues—ova or sperm—arise from the transgenic cells, then cellular reproduction may pass the foreign gene to the next generation.\textsuperscript{162} Second-generation animals receiving the foreign gene from their parents will not be mosaic animals, but will carry the gene in all their nucleated body cells.\textsuperscript{153}

III. THE PATENT SYSTEM

The technology described above constitutes a profound series of advances in basic and applied science. The United States Constitution provides a legal mechanism for rewarding and encouraging such scientific advances.\textsuperscript{154} Article I, Section 8, Clause 8 grants Congress authority to “promote the Progress of Science and [the] useful Arts” by securing to inventors the rights to their work for a limited time.\textsuperscript{155} Congress has chosen to exercise this power by implementing a system of patents that grant a seventeen-year right to exclude others from making, using, or selling a new process, machine, article of manufacture, or composition of matter.\textsuperscript{156} In order to qualify for the patent, the inventor must disclose in detail how to make and use the invention.\textsuperscript{157} At the end of the seventeen-year period of exclusivity, this information passes into the public domain for all to use.\textsuperscript{158}

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\textsuperscript{151} Travis, supra note 95, at 1392. See generally Beatrice Mintz, Formation of Genotypically Mosaic Mouse Embryos, 2 AM. ZOOLOGIST 432 (1962); Andrzej K. Tarkowski, Patterns of Pigmentation in Experimentally Produced Mouse Chimaerae, 12 J. EMBRYOLOGY & EXPERIMENTAL MORPHOLOGY 575 (1964) (describing creation of mosaic animals).

\textsuperscript{152} See Travis, supra note 95, at 1392.

\textsuperscript{153} Id.

\textsuperscript{154} Refer to notes 155-56 infra and accompanying text.

\textsuperscript{155} U.S. CONST. art. I, § 8, cl. 8.


\textsuperscript{157} Id. § 112 (detailing the contents of the “specification”).

\textsuperscript{158} See id. §§ 154, 271(a).
A. Patent Theory

The federal patent system is intended to offer an economic incentive for the development and disclosure of new technology. Knowledge or ideas associated with technological advances may be created as pure intellectual goods or embodied to some degree in a physical form, such as an invention. Like physical goods, intellectual goods may have great industrial value. Further, generating such knowledge may entail significant production costs of time and effort.

However, unlike physical goods, intellectual goods often do not encompass natural physical barriers that will exclude potential consumers. Ideas, after all, may be held by more than one person at a time. In addition, the distribution costs for disseminating an intellectual good such as an idea are minimal or nonexistent. Once such intellectual goods are disclosed there are no real barriers to free appropriation of the good. In this way, intellectual goods appear to resemble public goods, such as national defense, which also may be held by more than one person at a time. Because it is difficult to exclude persons from deriving the benefit of the good,

159. See ROBERT P. BENKO, PROTECTING INTELLECTUAL PROPERTY RIGHTS: ISSUES AND CONTROVERSIES 16-21 (1987) (discussing various economic theories behind the patent system).
161. See Adelstein & Peretz, supra note 160, at 218-19 (analyzing the marginal cost and benefit of intellectual goods).
162. BENKO, supra note 159, at 17 (explaining the costs and benefits of the patent system and how the system should function).
163. See generally Paul A. Samuelson, The Pure Theory of Public Expenditure, 36 REV. ECON. & STAT. 387 (1954) (discussing collective consumption goods, goods that all individuals can enjoy in common such that any one individual's consumption of the good does not lessen any other individual's consumption of the same good).
164. See id. at 387; see also MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS 14-15 (1971) (recognizing that individuals who do not purchase a good still manage to participate in sharing in the consumption of that good).
165. See BENKO, supra note 159, at 17 (stating that the distribution cost of an intellectual good is zero or near zero).
166. See id. (explaining the difficulties posed by "free-riders" of intellectual goods).
167. See id.; see also OLSON, supra note 164, at 14-15; Palmer, supra note 160, at 275 (analogizing a public good to a beam of light sent out by a lighthouse that cannot be selectively withheld from non-paying passers-by).
a significant number of persons may consume the good without recompenning the originator of the good. This lack of rec-
ompense may create a disincentive to create the good, causing an undersupply of the good in the market.

The potential for an undersupply of intellectual goods is not precisely the same problem as the potential undersupply of public goods; the potential for “free riding” is likely much greater for intellectual goods. In the case of intellectual goods, unlike public goods, a consumer benefits only from the first unit consumed, and not from any additional units. In addition, although public goods can usually be obtained only from the initial source, each consumer of intellectual goods becomes a potential secondary source of supply. These additional complications in intellectual good supply amplify the difficulty of identifying potential consumers and estimating the value of the good. Consequently, the law has developed barriers such as the patent grant to accomplish what physical barriers do for physical goods: allow the intellectual good supplier to recapture his investment by excluding “free riders.”

Because patents grant the patent holder an exclusory right to the patented invention, some commentators have loosely labeled them “monopolies.” Patent lawyers have long pro-

168. See BENKO, supra note 159, at 17 (noting that although distribution costs may be minimal, the initial production costs may be significant).
169. See id. (explaining that with a distribution cost and selling price of near zero, there is no incentive to produce intellectual goods).
170. See Adelstein & Peretz, supra note 160, at 219. The ability to recover the cost of the intellectual good’s production is hopeless because it is impossible to limit its distribution and thus consumers can obtain the good at their demand. Id.
171. Id. at 218. The value of a pure intellectual good lies in its novelty or originality. Id. Initially, when a consumer “receives” an intellectual good, something new has been learned and gained; but when the consumer “receives” the same intellectual good the second time it has zero value. Id.
172. Id. at 218-19. Once the intellectual good is produced, a third party can receive benefits of the good from the original consumer without the third party having to go to the initial source. Id.
173. See id. (discussing the problems that arise in the consumption and the value of an intellectual good due to secondary sources of supply and the marginal benefit of a good); see also Palmer, supra note 160, at 275 (stating that consumers will under reveal their preferences because of “free riders” and thus cause inadequate supply).
174. See 35 U.S.C. §§ 101, 154, 271(a) (1988) (establishing regulations on the right to use another’s idea); see also Adelstein & Peretz, supra note 160, at 218-19 (arguing that without legal barriers, intellectual goods have no way of excluding non-buyers).
175. See Edmund W. Kitch, Patents: Monopolies or Property Rights?, in 8 RESEARCH IN LAW AND ECONOMICS 31, 32 (John Palmer & Richard O. Zerbe, Jr., eds., 1986) (recognizing that many consider a patent to be a monopoly).
tested this label, noting that patents do not meet the criteria of a "legal" monopoly.\textsuperscript{176} The patent only allows the holder to exclude others from making, using, or selling the invention, and does not confer on the holder an affirmative right to make, use, or sell.\textsuperscript{177} In addition, some evidence indicates that patents do not entirely meet the definition of an "economic" monopoly.\textsuperscript{178} Unlike the true monopolist, patent holders may well face a marketplace containing a variety of substitutes for their product, and be forced to price their products competitively.\textsuperscript{179} Additionally, failure to price a patent-derived product competitively may deprive the patent holder of information necessary to identify the boundaries of the market.\textsuperscript{180} Although this information may be irrelevant to the true monopolist, its lack may prevent the patent holder from dominating the market when the patent expires, allowing other firms to quickly enter and erode the patent holder's preeminence.\textsuperscript{181} "Patent" therefore would not seem to be synonymous with either definition of monopoly.

Nonetheless, some patents probably do confer a virtual monopoly on their holders,\textsuperscript{182} and all patents represent some restraint on trade.\textsuperscript{183} Consequently, patents are likely to generate the type of inefficiencies generally associated with monopolies such as higher prices, restricted supplies, and inefficient allocation of resources.\textsuperscript{184} Patents are, in fact, specifically designed to create such inefficiencies; otherwise, individuals may not produce the good at all.\textsuperscript{185} However, the societal

\begin{itemize}
\item \textsuperscript{176} See id. at 32-33 (explaining why a patent should never be referred to as a legal monopoly).
\item \textsuperscript{177} See 1 ERNEST B. LIPSOM III, LIPSOM'S WALKER ON PATENTS § 1:6, at 45 (3d ed. 1984).
\item \textsuperscript{178} See Kitch, supra note 175, at 33 (noting that many patent issues have close substitutes in the marketplace, thereby preventing an economic monopoly).
\item \textsuperscript{179} Id. at 33.
\item \textsuperscript{180} See id. at 38-39 (stating that it takes competitive pricing to remain a player in the field).
\item \textsuperscript{181} Id. If the patent holder can sell the patented product at a cost equal to any potential entrant, then he may be able to dominate the market for many years. Id. Otherwise, other firms may take over some of the market share. Id.
\item \textsuperscript{182} Id. at 39 (arguing that drug patents that achieve dramatic reductions in the cost and effectiveness of health care probably do confer a monopoly upon their owner).
\item \textsuperscript{183} See id. at 33.
\item \textsuperscript{184} BENKO, supra note 159, at 19 (stating that patents cause the same static inefficiencies associated with monopolies).
\item \textsuperscript{185} See Palmer, supra note 160, at 279 (stating that the patent statutes create a scarcity of the product); see also BENKO, supra note 159, at 17-19 (explaining that patents provide incentives for inventors because they guarantee profits through higher prices).
\end{itemize}
costs the patent system generates must not be allowed to exceed the benefits of the intellectual goods it fosters. This balance of costs and benefits is struck in large measure by severely restricting the availability of patents; patents are only available to inventions that meet narrowly defined standards of novelty, usefulness, and non-obviousness.

In addition to protecting the actual invention, the patent creates a zone of de facto protection against close substitutes. First, slight variations on the patented product will be unpatentable because they will fail to meet the novelty and non-obviousness requirements. Second, inventions using close substitutes for elements of a patent invention will infringe the patented claim if the substitute performs substantially the same function in substantially the same way. These characteristics of the patent, when coupled with the attribute of exclusivity, give patent protection an extremely broad scope. Such broad protection may be appropriate where the inventor requires total control of an intellectual good as an incentive to invent. Thus, patent protection is arguably the appropriate vehicle for encouraging new technology because generating such inventions requires a substantial investment by the inventor that may only be recovered by total control of the invention he produces.

Although this overview of patent economics suggests the manner in which patenting is supposed to function, little hard evidence exists as to whether patenting in fact works this way, or whether it works at all. Commentators suggest several competing theories to account for the beneficial effects of patenting. The first of these theories suggests that patents

186. See William F. Baxter, Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis, 76 Yale L.J. 267, 268-70 (1966) (explaining that consumers will pay the patent holder no more than the invention is worth to them).
188. See id. § 103 (stipulating that any subject matter that would have been obvious at the time the invention was made cannot be patented).
189. See id. §§ 102-03 (requiring a person to create something not at all similar in subject matter or idea as something previously patented in order to be entitled to a patent).
191. See 35 U.S.C. § 154 (1988) (granting patent holders the right to exclude others from making, using, or selling their invention for seventeen years).
192. See BENKO, supra note 159, at 22 (arguing that total control is necessary to give incentives to inventors).
193. Id.
194. See generally JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES § 2.18 (1992) (reviewing the major theories behind patent rights); Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental
encourage inventors to engage in inventive activity because of the potential rewards reaped from exclusive control of the result.⁹⁵ An alternative theory that "has been more popular with the courts than with [economist] commentators,"⁹⁶ holds that patents are socially useful because they encourage disclosure of inventions that might otherwise be kept secret.⁹⁷ Yet another set of theories suggests that patents, rather than facilitating invention or the disclosure of inventions, offer an incentive for firms to make the investment in innovation, that is, to develop an existing invention for practical purposes.⁹⁸ All of these explanations are open to question, and at least some economists have asserted that none of them are correct; rather, they say, the exclusionary aspect of the patent incentive actually generates greater societal cost than any benefit it provides.⁹⁹

B. Patent Practice

Even assuming that the patent incentive does provide a

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⁹⁵ Use, 56 U. CHI. L. REV. 1017, 1024-44 (1989) (reviewing the major theories behind patent rights and whether the theories actually work as designed).
⁹⁶ See Baxter, supra note 186, at 270 (stating that the monopoly over the invention increases incentive for the patentee because any other discovery in that field will now be subservient to the initial patent). See generally John S. McGee, Patent Exploitation: Some Economic and Legal Problems, 9 J.L. & ECON. 135 (1966) (explaining that people use patents to maximize their net income and profits).
⁹⁷ Eisenberg, supra note 194, at 1028.
⁹⁸ See, e.g., Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 331 (1945) (suggesting that the primary purpose of the patent system is to induce disclosure of inventions for the benefit of society); Universal Oil Prods. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944) (stating that a seventeen-year monopoly on the invention is a reward or incentive to encourage disclosure of the idea).
⁹⁹ See, e.g., BENKO, supra note 159, at 19-20 (stating that the inefficiencies created by patents generate high social costs).
benefit greater than its costs, it is clearly strong economic medicine to be offered only under the circumstances specified by statute.\textsuperscript{200} To ensure that patent protection is granted only in this tightly circumscribed set of cases, no patent issues without passing through an extensive administrative review.\textsuperscript{201} This administrative review, or examination, also ensures that the patent holder fully discloses her invention in return for the patent grant.

1. \textit{Patent Examination.} Patent examination is initiated by the inventor when she applies to the United States Patent and Trademark Office (PTO) for a patent.\textsuperscript{202} A patent examiner, an employee of the PTO who has some expertise in the field of the invention, reviews the application.\textsuperscript{203} As a general rule, the examiner will initially reject the application, stating the statutory reasons for doing so.\textsuperscript{204} The applicant may either amend the claims to conform with the examiner's comments, or attempt to persuade the examiner that the rejection is unjustified.\textsuperscript{205} The applicant's amendments and comments are resubmitted to the examiner, who may allow the claims or may maintain the rejection.\textsuperscript{206} Several iterations of this process may take place before the PTO grants the patent.\textsuperscript{207}

\textsuperscript{200} Refer to notes 186-87 \textit{supra} and accompanying text (discussing the boundaries set for patents to prevent too high of a societal cost).
\textsuperscript{202} ROMAN SALIWANCHIK, LEGAL PROTECTION FOR MICROBIOLOGICAL AND GENETIC ENGINEERING INVENTIONS 80 (1982) (explaining that this process is called the "prosecution" of the patent). Patent applications are usually drafted and prosecuted on behalf of the inventor by patent agents or patent attorneys who specialize in this particular type of administrative law. \textit{Id}.

The application must contain a specification that describes the invention in sufficient detail for one skilled in the relevant art to create and use the invention. 35 U.S.C. §§ 111, 112 (1988). Typically, a specification will include a background review of the technological field, a summary of the invention, and a detailed description of the preferred embodiment of the invention, often giving specific examples of the invention's use. See id. § 112; SALIWANCHIK, supra, at 62. The patent application may include drawings, 35 U.S.C. § 113 (1988), and must include one or more claims setting forth the specific "metes and bounds" of the invention that will be protected under the patent. \textit{Id} § 112.

\textsuperscript{203} See 3 CHISUM, supra note 190, § 11.03[1]; SALIWANCHIK, supra note 202, at 31-32 (stating that patent examiners are typically biologists, microbiologists, chemists, engineers, geologists, physicists).
\textsuperscript{204} 3 CHISUM, supra note 190, § 11.03[1], at 11-51 to 11-53; SALIWANCHIK, supra note 202, at 81.

\textsuperscript{205} See 35 U.S.C. § 132 (1988); SALIWANCHIK, supra note 202, at 81. Of course, the applicant may also abandon the application, and choose not to pursue it further. See 35 U.S.C. § 133 (1988). The applicant may abandon the application either explicitly or by failing to take further action. 37 C.F.R. §§ 1.135-138 (1993).

\textsuperscript{206} See SALIWANCHIK, supra note 202, at 81-82.

\textsuperscript{207} See 35 U.S.C. § 132 (1988). If the examiner continues to refuse allowance of
In this manner, the process of patent examination serves to limit both the general availability of patents and the scope of individual patents. First, the PTO excludes applications that altogether lack the statutory requirements of novelty, utility, and nonobviousness. Second, the examination process forces the applicant to draw his claims as narrowly as possible to encompass only what he is entitled to claim, and exclude technology that is either already familiar and available to society or is speculative and unavailable even to the inventor. Finally, the examination process creates a record of what the applicant believes the invention to be, and what the applicant intends to claim under the patent. This record of communications, known as the “file wrapper,” may be referred to by courts in future litigations where the scope or validity of the patent is at issue.

2. Scope and Duration. The process of patent examination is necessary to limit the scope and availability of patents because inventors will often take the greatest possible advantage of the exclusory right offered in a patent. However, even within the confines of patent examination, the protection available for a new discovery may be far broader than the uninitiated might expect. For example, an inventor who has isolated and characterized a new gene is likely to file not only a patent claims that the applicant believes are patentable, the applicant may appeal the examiner’s decision to the Board of Patent Appeals and Interferences, an administrative board within the PTO. Id. § 134 (stating that once the patent application has been rejected twice, the applicant may appeal that decision to the Board of Patent Appeals and Interferences); see also id. § 7 (explaining the membership and duties of the Board of Patent Appeals and Interferences); SALIWINCHIK, supra note 202, at 82 (discussing the process of administrative appeals); 3 CHISUM, supra note 190, § 11.06(1), at 11-153 (explaining that the Board of Patent Appeals and Interferences generally only has jurisdiction over rejections of claims on the merits, while other rejections are reviewed by a petition to the Commissioner). Once these administrative avenues are exhausted, the applicant may appeal to the United States Court of Appeals for the Federal Circuit. 35 U.S.C. § 141-44 (1988). A dissatisfied applicant may also have an adverse Board of Appeals decision reviewed in the United States District Court for the District of Columbia. 35 U.S.C. § 145 (1988). See generally 3 CHISUM, supra note 190, § 11.06[3], at 11-175 to 11-176 (describing judicial review options for Board of Appeals decisions). Only after all objections to the application’s suitability have been addressed will a patent issue for the claimed invention. See generally id. § 11.06, at 11-153 to 11-282 (discussing the appeals process for PTO decisions).

208. See generally 1 CHISUM, supra note 190, at OV-1 to OV-15 (providing an overview of the historical development of the patent law).

209. See generally 2 id. § 7 (discussing disclosure requirements).

210. See generally id. (discussing description requirements and claims).

211. See 4 id. § 18.02[3], at 18-15 to 18-20 (discussing the doctrine of file wrapper estoppel).
PATENTING HUMAN EMBRYOS

claim to his new DNA sequence, but also to a variety of other products and processes involving the new sequence. These might include claims to RNA or protein sequences derived from the DNA sequence; claims to vectors, probes, and primers comprising all or part of the DNA sequence; claims to antisense or triple-helix forming polynucleotides against the DNA sequence; claims to recombinant procaryotic or eukaryotic cells carrying the DNA sequence; as well as claims to methods of use, such as gene therapies, employing the sequence. Indeed, the patent applicant need not restrict her claims to aspects of an invention that she already has in hand; if she can describe aspects of the invention in sufficient detail that another could so construct and use the invention, then she need not herself actually construct, or "reduce to practice," the invention.

In some instances, the process of examination itself may actually add to the scope of patent protection by extending its temporal range. The seventeen-year period of exclusivity to the claimed aspects of an invention begins when the patent containing the particular claim issues. Patent applications for biotechnology inventions may take several years to wend their way through the patent office; such applications are effectively exclusive for the duration of the application process plus the seventeen years of exclusivity. Additionally, if claims protecting an invention are found in different patents, which are likely to issue at different times, the overall period of patent coverage for different aspects of the invention may be


214. SALIWANCHIK, supra note 202, at 79-80 (noting that the patent statute merely requires a full and enabling disclosure of the invention in the application).


217. Unauthorized manufacture, use, or sale of an invention begins to constitute infringement after a patent has issued. Gustafson, Inc. v. Intersystems Indus. Prods. Inc., 897 F.2d 508, 510-11 (Fed. Cir. 1990). However, such activity prior to the issue of the patent may constitute evidence of willful infringement if the infringer has notice of the pending patent. Id. A warning by the patentee that the patent is pending may be sufficient notice. See Pacific Furniture Mfg. Co. v. Preview Furniture Corp., 800 F.2d 1111, 1114 (Fed. Cir. 1986); Avia Group Int'l, Inc. v. L.A. Gear California, Inc., 853 F.2d 1557, 1566-67 (Fed. Cir. 1988).
considerably longer than seventeen years.

Indeed, it is common practice to claim many aspects of an invention in a single patent application, which often prompts a restriction requirement by the patent examiner. Such a restriction effectively dictates that unrelated aspects of the invention be broken out into separate applications. These derivative applications may be prosecuted sequentially, and the resulting patents will usually issue sequentially over an extended period of time. The inventor may claim newly discovered aspects of the invention in later continuations of the original application, leading to the issuance of new patents on those aspects of the invention, and effectively extending the period of statutory protection afforded the invention.

Thus, in practice, the patent exclusivity period for an important invention has the potential of running well beyond the life of the basic patent. Whether through the fortunes of administrative review or through calculated manipulation by a skilled patent attorney, the patent application rules and the PTO's inefficiencies may effectively extend patent coverage of an invention over a span of some decades. Although abuse of the examination process to extend the effective life of a patent endangers the validity of that patent, courts have generally given patent applicants the benefit of every doubt, and only in cases of explicit bad faith have they penalized inventors for abuse of the PTO procedure.

218. See 35 U.S.C. § 121 (1988) (stating that if an application claims two or more distinct inventions, the Commissioner may restrict the application to one of the inventions).


220. See generally 3 CHISUM, supra note 190, § 12.04, at 12-71 to 12-72 (outlining restriction procedures). In response to an examiner's restriction requirement, experienced patent attorneys will often pursue the least commercially important of these inventions first. See Gilbert H. Hennessey, Restriction Requirement and Election of Species, in 4 PATENT PRACTICE 14-5 (Irving Kayton & Karyl S. Kayton eds., 4th ed. 1989). The patent for the most commercially important invention will be sought last. Id. This ensures that the attorney's client will effectively receive patent protection during the extended pendency of that invention's application, while the other restriction applications are pursued, plus protection for the period of the actual issued patent. Id. As might be expected, patent attorneys are often pleased when the examiner issues a restriction requirement, and may even draft the application in such a way as to provoke a restriction. See id. at 14-4. But see American Type Culture Collection Hosts Biotech Patent Conference, 40 Pat. Trademark & Copyright J. (BNA) 164 (June 14, 1990) (statement of attorney Dale H. Hoscheit at American Type Culture Collection Biotechnology Patent Conference, April 30-May 1, 1990) (arguing that the expense of unnecessary restriction requirements is "the bane of biotechnology patent prosecution").

221. Hennessey, supra note 220, at 14-4 (noting the illegality of filing a single claim solely to prolong prosecution).

C. Patent Limitations

Although the availability of patent protection is limited by the explicit statutory criteria of novelty, utility, and non-obviousness, Congress and the courts have from time to time carved out other "public policy" exceptions to the patent grant. Some of these exceptions, like the statutory criteria, are themselves explicitly spelled out in statutes. Other exceptions have been formed by judicial interpretation of the patent law. All of these "public policy" exceptions, whether judicially or legislatively created, offer a foothold for critics of biotechnology patenting to create a new patent exclusion for controversial genetic discoveries.

1. Statutory Subject Matter. One of the most significant limitations on patenting new technology is the doctrine that laws and products of nature are not patentable.\(^{223}\) Courts have held that natural phenomena such as mathematical equations or naturally occurring chemicals do not fall within one of the categories of statutory subject matter found in 35 U.S.C. § 101.\(^{224}\) Some opinions have also suggested that one cannot patent a "manifestation of the laws of nature" because it is not "new," as required by § 101.\(^{225}\)

This doctrine has proved to be the subject of considerable controversy when applied to biotechnology. For example, in \textit{In re Chakrabarty},\(^{226}\) the inventor submitted patent claims drawn to a genetically engineered microorganism designed to be useful in biological control of oil spills by decomposing the

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1977) (rejecting an argument that the applicant abused the PTO examination process to deliberately extend the pendency of his application); Studiengesellschaft Köhle mbH v. Northern Petrochemical Co., 225 U.S.P.Q. (BNA) 194, 199 (N.D. Ill. 1984) (concluding that the plaintiff did not violate nor exceed any time limits provided by law in prosecuting its applications and that the defendant did not demonstrate any evidence of laches or intentional delay under the patent law), rev'd and remanded on other grounds, 784 F.2d 351 (Fed. Cir.), cert. denied, 478 U.S. 1028 (1986).


224. See Funk Bros., 333 U.S. at 130-31 (stating that a product must satisfy the statutory requirements of “invention or discovery” to be patentable in that it must “come from the application of the law of nature to a new and useful end”).

225. See id. at 132 (noting that one who merely discovers a previously unknown phenomenon of nature does not disclose a patentable invention or discovery); see also \textit{In re Bergstrom}, 427 F.2d 1394, 1401 (C.C.P.A. 1970) (discussing the meaning of “new” under 35 U.S.C. § 101).

The examiner rejected the claims to the microorganism, stating that living organisms were not within the stated classes of statutory subject matter because the microorganisms were "products of nature," and the claims were drawn to "live organisms." The Patent Board upheld the examiner on the grounds that the claims were drawn to live organisms, but reversed the examiner's rejection based on the "product of nature" grounds. The Board's decision was reversed by the United States Court of Customs and Patent Appeals, and eventually considered by the United States Supreme Court.

In a landmark decision that opened the doors of the PTO to commercial biotechnology, the Supreme Court ruled that Chakrabarty's recombinant organisms were not "products of nature," and were within the statutory definition of patentable subject matter. The Court first noted that the claim to a recombinant microorganism was not a claim to a newly discovered natural phenomenon, but rather to something not found in nature. The Court went on to reject arguments that living organisms were unpatentable because they were not within the subject matter contemplated by Congress under the patent statutes. The Court held that the terms "manufacture" and "composition of matter" as used in the patent statute contemplate "anything under the sun made by man," including living organisms altered by recombinant DNA manipulation. The opinion stated that Congress must determine any limitation on the scope of statutory subject matter.

2. Congressionally Excluded Inventions. In addition to the

227. Id. at 41.
228. Id. at 42.
229. Id. (agreeing with the applicant that the genetically engineered microorganisms were not naturally occurring).
230. Id. at 43 (holding that the claims were not outside the scope of patentable subject matter merely because they were drawn to live organisms).
232. Id. at 318. The Court cited several cases, including Funk Bros., for the proposition that natural phenomena are not patentable. Id. at 309.
233. Id. at 308-10 (noting that respondent's claim "is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter").
234. Id. at 311-14 (stating that the passage of certain plant patent statutes which excluded bacteria from their protection did not evidence congressional intent that living things are not patentable subject matter).
235. Id. at 308-10.
236. Id. at 315. This pronouncement, however, ignores the many judicially created limitations on patentability, including the Funk Bros. doctrine regarding patenting of natural laws and processes. Refer to notes 223-24 supra and accompanying text.
implied statutory exclusions under 35 U.S.C. § 101, Congress has expressly excluded some inventions from patentable subject matter, regardless of how novel, useful, and nonobvious the invention. Under the Atomic Energy Act, for example, inventions relating to military uses of fissile material are removed from patentable subject matter.\textsuperscript{237} In return, Congress has authorized a system of prizes and awards for meritorious research in this area.\textsuperscript{238} In addition, although the PTO may issue patents for inventions relating to civilian uses of fissile material, such patents are subject to a compulsory license administered by the Nuclear Regulatory Commission.\textsuperscript{239}

Commentators generally concede that Congress removed nuclear armaments from patentable subject matter because it judged that neither national security nor public health and safety would be well served by encouraging private innovation in that area.\textsuperscript{240} Curiously, the legislative history of the Atomic Energy Act indicates that the compulsory licensing scheme for domestic patents was instituted for a different purpose: To allow widespread access to the peacetime benefits of nuclear technology, and thus rapidly foster the growth of domestic atomic energy capability.\textsuperscript{241} Apparently, Congress believed that in the case of this technology, a seventeen-year period of exclusivity would unduly hamper access to the technology, which would be better disseminated by a governmental agency.\textsuperscript{242}

\begin{footnotes}

\footnote{238. 42 U.S.C. § 2187(b)(3) (1988) (stating that an award may be granted for the making of an invention or discovery useful in the production of special nuclear material or atomic energy).}

\footnote{239. \textit{Id.} § 2183.}

\footnote{240. Robert W. Valimont, \textit{Atomic Energy Patent Provisions and the American Economy}, 31 J. PAT. OFF. SOC’Y 743, 745-51 (1949) (explaining the reasoning behind the removal of fissile material from patentable subject matter); \textit{see also}, Dresser, \textit{supra} note 5, at 404 (discussing the Congressional purpose for enacting the Atomic Energy Act patent provision).}


\footnote{242. S. REP. NO. 1211, 79th Cong., 2d Sess. (1946), \textit{reprinted} in 1946 U.S.C.C.A.N. 1327, 1335 (stating that to eliminate the risk of disclosure of restricted information and to make the benefits of atomic energy widely available, “private patents can play no role” in this activity).}
\end{footnotes}
Such "patents" awarded for civilian nuclear technology are in essence no patents at all. The patent holder has no ability to recapture her development costs by excluding competitors from using her invention or bargaining for a license; she must settle for whatever royalty is set by a government agency. Thus, in allocating research and development resources, an inventor would be likely to shift her effort to some other technology where she could be sure of recapturing her costs. In the case of military applications of nuclear technology, Congress has not even offered an illusory monopoly incentive, further discouraging private investment in such research. Consequently, it is apparent that Congress found that both military and civilian aspects of nuclear technology involve a unique balance of costs and benefits. This balance requires Congress to treat these technologies differently than other technologies.

3. Fraudulent or Immoral Devices. Only in very limited circumstances have the courts, rather than Congress, explicitly carved out special exceptions to patentability. Because courts purport to interpret statutes rather than invent new ones, such court-generated exceptions hinge upon interpretation of an extant patent statute. One such exception is for the statutory subject matter discussed above; another exception involves lack of patentable utility in a social context. Courts have disallowed patents based upon a lack of utility where the claimed invention has no honest or legitimate use. This rule stems initially from Justice Story's famous dictum in a

243. Id. (providing only for reasonable royalty fees as determined by the Patent Compensation Board).
244. See, e.g., Southeastern Community College v. Davis, 442 U.S. 397, 405 (1979) (stating that in cases of statutory construction, the Court begins with the language of the statute). The Supreme Court has cautioned that courts "should not read into the patent laws limitations and conditions which the Legislature has not expressed." United States v. Dubilier Condenser Corp., 289 U.S. 178, 199, modified, 289 U.S. 706 (1933).
245. Refer to notes 237-39 supra and accompanying text.
246. 1 CHISUM, supra note 190, § 4.03 (discussing illegal, and harmful inventions). Similarly, the PTO routinely rejects claims to design patents containing offensive or scandalous material as contrary to sound public policy. See PATENT & TRADEMARK OFF., U.S. DEPT OF COM., MANUAL OF PATENT EXAMINING PROCEDURE § 1504, at 1500-07 (5th ed. 1989) (instructing examiners to reject applications containing subject matter offensive to members of any race, religion, sex, ethnic group, or nationality). Federal registration of trademarks is also prohibited for marks containing immoral, deceptive, or scandalous material. 15 U.S.C. § 1052(a) (1988). Curiously, however, copyright protection has been extended to materials with illegal or obscene content. See Mitchell Bros. Film Group v. Cinema Adult Theater, 604 F.2d 852, 858 (5th Cir. 1979) (concluding that the 1909 copyright statute contained no explicit or implicit bar to the copyrighting of obscene works), cert. denied, 445 U.S. 917 (1980).
nineteenth-century case opining that an invention lacks patentable utility if "frivolous or injurious to the well-being, good policy, or sound morals of society."²⁴⁷

Courts have seldom invoked this rule except in a handful of older cases involving devices to be used in gambling or games of chance.²⁴⁸ These cases initially denied the patentable utility of inventions that could be used for gambling and other purposes,²⁴⁹ but use of the rule was quickly narrowed to inventions with no use other than gambling.²⁵⁰ At the time courts made these decisions, the public considered gambling immoral and law makers deemed it illegal in much of the United States.²⁵¹ As the public attitude toward gambling softened, however, application of the utility requirement to gambling devices faded.²⁵²

In some older cases, courts found that inventions with no other use than to promote fraud lacked utility.²⁵³ Courts

²⁴⁷ Lowell v. Lewis, 15 F. Cas. 1018, 1019 (No. 8568) (C.C.D. Mass. 1817) (citing inventions designed "to poison people, or to promote debauchery, or to facilitate assassination"); see also Bedford v. Hunt, 3 F. Cas. 37, 37 (No. 1217) (C.C.D. Mass 1817) (Story, J.) (defining a useful invention as "one as may be applied to some beneficial use in society, in contradistinction to an invention, which is injurious to the morals, the health, or the good order of society").

²⁴⁸ See 1 CHISUM, supra note 190, § 4.03[1].

²⁴⁹ See, e.g., Schultze v. Holtz, 82 F. 448, 449 (C.C.N.D. Cal. 1897) (denying a patent for a coin return device used on slot machines); National Automatic Device Co. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889) (denying a patent for a toy horse race course used only for betting purposes).

²⁵⁰ See Fuller v. Berger, 120 F. 274, 275 (7th Cir. 1903) (stating that an invention lacks patentable utility only if it is incapable of serving any beneficial end), cert. denied, 193 U.S. 668 (1904).

²⁵¹ See Ronald J. Rychlack, Lotteries, Revenues and Social Costs: A Historical Examination of State-Sponsored Gambling, 34 B.C. L. REV. 11, 12 (1992) (noting that from the late 1800s to the mid 1960s, gambling was illegal in most states, in part because of the perception that gambling led "to personal downfall and societal decay").

²⁵² See Ex parte Murphy, 200 U.S.P.Q. (BNA) 801, 802 (PTO Bd. App. Apr. 29, 1977) (upholding a patent claim to a slot machine reasoning that there is no basis in 35 U.S.C. § 101 that justifies the conclusion that inventions which are only useful for betting purposes are "ipso facto" void of patentable utility).

²⁵³ See, e.g., Klein v. Russell, 86 U.S. (19 Wall.) 433, 445 (1873) (upholding a jury instruction that disallowed recovery for patented processes that cannot be made useful for any honest purpose and which result in perpetrating a fraud upon the public). For example, a process that artificially produced spots on tobacco leaf, making it resemble a more expensive grade of tobacco without improving the leaf's quality, was found to have no use other than to deceive the public, and was thus held to lack patentable utility. Rickard v. Du Bon, 103 F. 868, 872-73 (2d Cir. 1900) (reasoning that "congress did not intend to extend protection to those which confer no other benefit upon the public than the opportunity of profiting by deception and fraud"). This rule, however, has not been extended to inventions substituting cheaper materials for more expensive materials. Processes such as the softening of lambskin and sheepskin as a substitute for more desirable "dogskin" in gloves, or the whitening of flour, have been held patentable unless shown to have no use other than to
have not invoked the formulation of the utility requirement for decades, and more recent commentators have denigrated the courts’ apparent denial of patents on the basis of contemporary moral objections. Commentators have advanced similar arguments against the suggestion that the rule could be resurrected to bar controversial biotechnology patents. They argue that biotechnology patents threaten no readily identifiable social norm, and are therefore not limited in their uses to solely fraudulent or illegal ends.

4. Medical Processes. As previously discussed, methods and processes are patentable. Medical procedures are not excluded from the definition of “process.” However, the patenting of medical processes has troubled some commentators, primarily on ethical grounds. Commentators suggest that granting patents in this area will both restrict the availability of certain treatments and introduce untoward

decide the public. See, e.g., Naylor v. Alsop Process Co., 168 F. 911, 915 (8th Cir. 1909) (upholding the patentability of a flour whitening process, noting that “whiteness in flour constitutes utility, within the patent law as much as whiteness in sugar or yellowness in butter”).

254. One often quoted commentator argues:

Anyone whose life has spanned a decade or two in the 20th Century has witnessed how moral standards can change in a period of a few years. Gambling devices, frowned upon early in the century, are legalized in several states; race tracks and lotteries are now used to generate substantial amounts of income in many states. Birth control devices, in a period of thirty to forty years, have come from a position of illegality to a position where they are welcomed by some as a means of curbing a population explosion. Thus, in determining “utility” based on public mores, the courts should apply a test which will not penalize an inventor who may be prescient enough to be anticipating basic needs of a society changed by forces yet unrecognized by the general public.


255. See Merges, supra note 5, at 1065-66.

256. Id.

257. Refer to notes 212-14 supra and accompanying text.


259. See, e.g., George J. Annas, Surrogate Embryo Transfer: The Perils of Patenting, HASTINGS CENTER REP., June 1984, at 25, 26 (concluding that inventors and examiners must address ethical issues in the patenting of certain medical processes); Burch, supra note 258, at 1152-71 (discussing the ethical objection to medical process patents and recognizing that serious ethical dilemmas may result from such patenting). But see Timothy J. McCoy, Biomedical Process Patents: Should They Be Restricted By Ethical Limitations?, 13 J. LEGAL MED. 501, 519 (1992) (concluding that no ethical objection advanced so far outweighs the economic incentive of patenting).
proprietary and pecuniary motives into medical decision making, thus disrupting the physician-patient relationship, biasing medical research, and intruding on reproductive privacy. They argue that the prospect of these consequences militates against granting such patents.

Although some precedent exists in the patent law for restricting patents for medical processes, the cases are of uncertain value. Like the cases dealing with fraudulent and immoral devices, the medical process cases are grounded in considerations of utility and based on antiquated reasoning that has since been largely superseded. In Morton v. New York Eye Infirmary, known as the "Ether Case," use of ether as a general anesthetic was held to lack patentable novelty. The inhalation of vapors was a known process, and its use on a human was deemed insufficiently inventive. The Commissioner of Patents later relied upon the Ether Case in Ex parte Brinkerhoff to deny a patent claim for the treatment of piles. The Brinkerhoff decision appeared to articulate a broad rule against the patentability of medical treatments. This holding, however, was based on the inherent unpredictability of results for processes involving the human body.

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260. See, e.g., Annas, supra note 259, at 26 (arguing that the PTO should not issue a process patent unless the patent holder can assure the medical profession and the general public that he will utilize effective quality control measures); Burch, supra note 258, at 1152-59, 1161 (suggesting that a statutory prohibition of medical process patents is one possible alternative to accommodate ethical objections to such patents).

261. E.g., Annas, supra note 259, at 26; Burch, supra note 258, at 1152-57.

262. Cf. notes 244-56 infra and accompanying text.

263. 17 F. Cas. 879 (No. 9865) (C.C.S.D.N.Y. 1862).

264. Id. at 882-83 (stating that, in the eye of the law, use of ether as a general anesthetic is nothing more than the application of a well known agent, by well known means, to a new or more perfect use).

265. Id. at 884. The legal grounds for the result in the Ether Case are unclear. 1 CHISUM, supra note 190, § 1.03[3]. The vague reasoning of the case may be read as based on lack of novelty, utility, obviousness, or some combination of the three. Id.

266. 24 Comm'n Manuscript Decision 349 (1883), reprinted in 27 J. PAT. OFF. Soc'y 797, 797-98 (1945).

267. Id. at 798.

268. Id. (stating that "[t]he methods or modes of treatment of physicians of certain diseases are not patentable").

269. Id. (reasoning that no mode of treatment used in curing diseases will produce the same result in all persons under all circumstances, and thus granting such a patent would tend to deceive the public into believing that the method claimed would produce the desired result in all cases). The inherently unpredictable results of processes involving the human body seems to no longer serve as a viable ground for rejecting patents in the chemical arts, particularly for therapeutic methods such as cancer treatments. See, e.g., Ex parte Rubin, 5 U.S.P.Q.2d (BNA) 1461, 1461 (PTO Bd. App. & Int. 1987) (reversing the examiners ruling that the asserted utility of an invention must be substantiated by factual evidence of improved activity in a com-
In 1954, the Board of Patent Appeals in *Ex parte Scherer* rejected the approach of presumptively excluding all medical processes from patentability, in part because they reasoned that the inherent uncertainty of results is insufficient, by itself, to automatically refuse the patentability of certain medical processes. Since that decision, patents on medical processes have been routinely, although not frequently, granted.

Commentators suggest that because the *Scherer* decision is only a decision within the Patent Office, and not the ruling of a court, it provides only tenuous authority for the proposition that medical and surgical treatments are generally patentable. Nonetheless, some recent commentary argues that the rule of *Scherer* is the correct approach, even for controversial medical process methods involving reproductive technologies. Other commentators argue that patenting is inappropriate for such medical processes, essentially because of the disutility that the patent incentive could engender.

Such criticism draws authority from cases such as *Martin v. Wyeth Inc.*, in which the court observed that "[t]he professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage." However, no recent court has adopted the *Wyeth*
IV. PATENTING HIGHER ORGANISMS

Although the *Chakrabarty* decision may have foreclosed certain opportunities for the judiciary, it generated many others for inventors and the PTO. Not long after genetically altered microorganisms became routinely patentable, inventors asked the PTO to issue patents to genetically altered multicellular organisms. In response, the Commissioner of Patents issued a statement declaring that “[t]he Patent and Trademark Office now considers nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.”

This section analyzes the current arguments for and against patenting both transgenic animals and transgenic humans. These arguments often form the foundations of ideas surrounding the patenting of transgenic human embryos, and are, therefore, instrumental in evaluating the benefits and

ed vitamin D producing technique was contrary to public interest because of the impact on public health), *cert. denied*, 325 U.S. 876 (1945).

278. Refer to note 236 supra and accompanying text.

279. See, e.g., *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1426 (PTO Bd. App. & Int. 1987) (analyzing claims drawn to a method of inducing polyploidy in oysters); *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 443 (PTO Bd. App. & Int. 1985) (describing a patent for maize plants which have increased levels of free tryptophan). Although the PTO denied the application in *Allen* for genetically altered oysters on grounds of obviousness, the PTO’s willingness to consider the claim laid the foundation for its later policy on patenting complex organisms. See *Allen*, 2 U.S.P.Q.2d (BNA) at 1426-27.

The *Hibberd* decision involved a slightly more difficult issue. The claims of the application were drawn to a conventional utility patent for a genetically altered plant, and Congress provided separate statutes for special plant patents. *Hibberd*, 227 U.S.P.Q. (BNA) at 444 (noting that Congress specifically set forth how plant life would be protected by the statutes); see also 35 U.S.C. §§ 161-64 (1988) (comprising the plant patent statutes). The PTO concluded, however, that in light of *Chakrabarty*, the availability of a plant patent did not supersede or inhibit the availability of a utility patent. *Hibberd*, 227 U.S.P.Q. (BNA) at 446.

costs of granting patents for transgenic embryos.

A. Transgenic Animals

The most famous—or infamous—recombinant multicellular organism is probably the "Harvard mouse": a mouse carrying a recombinant gene making it prone to cancer, and for which the PTO issued the first patent on an animal.\(^{281}\) Since the patenting of the Harvard mouse, such recombinant mice have become fairly common as models for a variety of diseases, including high cholesterol,\(^{282}\) Alzheimer's disease,\(^{283}\) and others.\(^{284}\) Numerous patent applications for such animals are pending in the PTO, and after a hiatus of several years in granting animal patents, the PTO has again begun to issue patents for such transgenic animals.\(^{285}\)

Researchers expect recombinant animals to be useful in curing disease, not only as laboratory models for certain ailments, but also as producers of valuable pharmaceuticals in "molecular pharming."\(^{286}\) For example, by properly splicing the gene for a desired pharmaceutical protein into a mammal,

\(^{281}\) See PATENTING LIFE, supra note 1, at 98-99.

\(^{282}\) See, e.g., Masayuki Yokode et al., Diet-Induced Hypercholesterolemia in Mice: Prevention by Overexpression of LDL Receptors, 250 SCIENCE 1273, 1273 (1990) (using transgenic mice that abnormally overexpress human low density lipoprotein (LDL) receptors to determine whether overexpression of LDL receptors would ameliorate or prevent diet-induced hypercholesterolemia).

\(^{283}\) D.O. Wirak et al., Deposits of Amyloid β Protein in the Central Nervous System of Transgenic Mice, 253 SCIENCE 323, 323 (1991) (using transgenic mice to analyze a protein typically present in the brains of individuals with Alzheimer's disease and Down's syndrome).

\(^{284}\) See, e.g., Katrin Bothe et al., Progressive Encephalopathy and Myopathy in Transgenic Mice Expressing Human Foamy Virus Genes, 253 SCIENCE 555, 555 (1991) (analyzing transgenic mice to determine the pathological potential of the regulatory genes of the human retroviruses HTLV-1 and HIV); Karen K. Hsiao et al., Spontaneous Neurodegeneration in Transgenic Mice with Mutant Prion Protein, 250 SCIENCE 1587, 1587 (1990) (demonstrating that a neurodegenerative process similar to a human disease can be genetically modeled in transgenic mice); Yasushi Ito et al., Hypertriglyceridemia as a Result of Human Apo CIII Gene Expression in Transgenic Mice, 249 SCIENCE 790, 790-92 (1990) (describing the creation of a transgenic mouse containing an intact human apo CIII gene). See generally Rebecca Kolberg, Animal Models Point the Way to Human Clinical Trials, 256 SCIENCE 772 (1992) (stating that "gene therapists are now coming to prize animal models as a way to test the safety and efficacy of their gene transfer protocols" before applying them to human patients).

\(^{285}\) After issuing the Harvard Mouse patent, the PTO delayed further applications for several years, presumably to see how Congress would respond. 139 CONG. REC. S1792 (daily ed. Feb. 18, 1993) (statement of Sen. Hatfield); Lane, supra note 280, at 89-90 (noting that approximately 120 applications for patents on animals were pending with the PTO in Fall 1991).

researchers can induce the animal to secrete the protein in its milk.\footnote{287}

Additionally, researchers expect to introduce desirable traits into livestock through recombinant DNA techniques.\footnote{288} Such traits might include larger or hardier animals, or animals with leaner meat.\footnote{289} Traditionally, such traits have been produced by the lengthy process of selective breeding.\footnote{290} However, with the advent of biotechnology, researchers hope to introduce desired traits into animals from the same or even other animal species within a single generation.\footnote{291}

1. Patenting Opponents. The extension of the Chakrabarty ruling to higher organisms has proved contentious.\footnote{292} Transgenic animal patenting has been opposed by a coalition of "strange bedfellows" holding widely divergent views as to why such patents should not be granted.\footnote{293} This assemblage of opponents argues that Congress should carve out an exception for animal patents as it has done for nuclear weapons technology.\footnote{294} They buttress their stance by reference to the

\footnote{287. See GLOBAL ECONOMY, supra note 216, at 183-84; Jeremy Cherfas, Molecular Biology Lies Down with the Lamb, 249 SCIENCE 124, 124 (1990) (reasoning that the attraction for using mammals, such as sheep, to produce human proteins is that mammals would probably process the proteins properly after making them); Richard Seltzer, Transgenic Animals Make Drugs in Their Milk, CHEMICAL & ENGINEERING NEWS, Sept. 2, 1991, at 7 (describing the development of transgenic animals capable of producing human pharmaceuticals in their milk). Recombinant human hemoglobin has also been produced in pigs. Anne S. Moffat, Three Li'l Pigs and the Hunt for Blood Substitutes, 253 SCIENCE 32, 32 (1991) (explaining that it is advantageous to produce hemoglobin this way, as opposed to using fresh human blood, because it would have a longer shelf-life, not require refrigeration, and would be unlikely to transmit viruses such as hepatitis or HIV).

\footnote{288. See Mark Fischetti, A Feast of Gene-Splicing Down on the Fish Farm, 253 SCIENCE 512, 512 (1991) (stating that fish researchers are using genetic engineering to produce fish that weigh more and are more resistant to disease). Although researchers are also experimenting with genetic techniques that would improve the quality of livestock, the only practical procedure in use necessitates the removal of a fertilized egg from the animal, alteration of that egg, and then reimplantation into the animal. Id.}

\footnote{289. Id.

\footnote{290. See PATENTING LIFE, supra note 1, at 96-97.

\footnote{291. Id. at 97.}

\footnote{292. See Dresser, supra note 5, at 410 (noting the arguments made by opponents to animal patenting). See generally Patents and the Constitution: Transgenic Animals, Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary, 100th Cong., 1st Sess. (1988) [hereinafter Transgenic Animal Hearings] (presenting views and testimony of proponents and opponents to patenting transgenic animals); refer to note 5 supra.

\footnote{293. Dresser, supra note 5, at 410. See generally Transgenic Animals Hearings, supra note 292 (opponents testimony included the president of the National Farmer's Union and the president of the World Council of Churches, among others).

\footnote{294. See Dresser, supra note 5, at 404 (arguing that animal patents should be
disutility cases discussed above. These cases, they argue, lend credence to the exclusion of living organisms from patentability because, like devices for fraud or gambling, these patents are contrary to good public morals.

The most vigorous protest to animal patenting has come from those who assert that it encourages a technology that somehow violates the natural order. The most vocal opponent of biotechnology, Jeremy Rifkin, has claimed that patenting of transgenic animals will promote violation of their "species integrity," which he has defined as "the right to exist as a separate, identifiable creature." Rifkin and other opponents also assert that because patents entail a property interest, patenting transgenic animals, or recombinant microorganisms generally, is ownership of life itself, and unconscionable hubris on the part of our species.

Closely related to this objection is the argument that biotechnology allows humans to "play God" in a manner that may be morally or even theologically detrimental. The strongest version of this argument asserts that human manipulation and patenting of living organisms appropriates to humanity powers that are properly reserved only to the Supreme Being. They argue that humans have neither the moral standing nor the wisdom to meddle in the makeup of living creatures, and that some disaster is bound to occur from such meddling. A weaker version of this argument asserts that manipulation of life reduces living organisms, including humans, to mere

295. See PATENTING LIFE, supra note 1, at 127 (stating that the only way to stop the issuance of a patent on public policy grounds is to demonstrate that the invention has no possible use); Merges, supra note 5, at 1062-64 (discussing how the denial of patentable subject matter on grounds that it is immoral originated in dictum of a case addressing the issue of utility).

296. Dresser, supra note 5, at 404; Merges, supra note 5, at 1066; refer to notes 244-55 supra and accompanying text.

297. See Dresser, supra note 5, at 410-14 (observing that opponents believe animal patenting is inherently wrong because it threatens respect for God, species integrity, and the value of human morality).

298. Id. at 411 (quoting Jeremy Rifkin, Letter to William Gartland, 49 Fed. Reg. 37016 (Sept. 20, 1984)); see also Merges, supra note 5, at 1060 (explaining that the driving force of Rifkin's concept is that each species should have its genetic composition unaltered and that species should not be crossed).

299. See Merges, supra note 5, at 1058-59.

300. See Dresser, supra note 5, at 411 (citing WORLD COUNCIL OF CHURCHES, MANIPULATING LIFE: ETHICAL ISSUES IN GENETIC ENGINEERING 19 (1982)).

301. See Hoffmaster, supra note 6, at 4.

302. See id.; Dresser, supra note 5, at 411-12.
collections of molecules. Thus, we lose the sense of sacredness and dignity that we should hold for life.

Other members of the anti-patenting coalition hold that transgenic patents either directly or indirectly threaten the environment. As in the assertion that animal patenting allows humans to "play God," this argument suggests that we do not have the foresight to predict the outcome of our genetic manipulations. However, this version of the argument rests on more pragmatic grounds; if either purposely or inadvertently released into the wild, superior breeds of transgenic animals could outbreed and overrun wild species. Further, these opponents suggest that transgenic animals might escape their captivity and pass their new genetic traits on to animals in the wild, leading to unforeseen hybrids. Finally, they suggest that animal patenting will lead to increased genetic manipulation, and thus genetic homogeneity of species. This loss of genetic variety could leave strains of domestic animals susceptible to being wiped out by new pathogens.

Yet another faction within the coalition opposes animal patenting because they fear that it will lead to increased exploitation of animals. Some members of this faction

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303. Transgenic Animal Hearings, supra note 292, at 405-07 (statement of Michael Berenbaum, Scholar-in-Residence, Religious Action Center of Reform Judaism) (favoring a moratorium on granting transgenic animal patents to allow for reflection on "what constitutes life and what is merely an inert manufactured commodity"); see Dresser, supra note 5, at 410-11 (stating that this diminishes the "significance and mystery" of life).

304. Dresser, supra note 5, at 410-11 (stating that to patent opponents, animal patenting objectifies living things, making them mere inventions of man).

305. Id. at 411-12; Merges, supra note 5, at 1056-57.

306. Transgenic Animal Hearings, supra note 292, at 312 (statement of Stewart Huber, President, Farmer's Union Milk Marketing Cooperative) (doubting whether science has fully considered the health risks to the public from the milk of genetically engineered dairy cows); id. at 339-40 (statement of Debra Schwarze, Wisconsin Family Farm Defense Fund, Inc.) (citing the past decade's false sense of comfort with pesticides as an example of the fact that the safety claims made by proponents of transgenic animal patenting rest on limited knowledge and experience, and are, therefore, suspect).


308. Merges, supra note 5, at 1056.

309. Dresser, supra note 5, at 412; Merges, supra note 5, at 1057.

310. Dresser, supra note 5, at 412; Merges, supra note 5, at 1057-58.

311. Transgenic Animal Hearings, supra note 292, at 434-88 (statement of Jeremy Rifkin, President, Foundation on Economic Trends) (complaining that patenting transgenic animals allows life forms to be turned into factories); see Dresser, supra note 5, at 422-23 (describing the arguments of animal rights and welfare groups); Merges, supra note 5, at 1060-61 (noting that some philosophers consider animal patenting to be the "newest invasion of animals' inherent rights").
deplore the cruelty to animals that they believe occurs, for example, in laboratory experimentation or animal husbandry.\textsuperscript{312} These opponents of animal patenting believe that patenting will encourage further objectionable use of animals.\textsuperscript{313} Other members of this group hold the more extreme view that any use of animals or animal products is an offensive exploitation of another species;\textsuperscript{314} indeed, some holding this more extreme view argue that because of their consciousness and capacity to feel pain, animals have autonomy and inherent rights comparable to the rights society grants to human beings.\textsuperscript{315} This view also holds that a property right, such as a patent, offends the autonomous rights of animals much as slavery offends the autonomy of human beings.\textsuperscript{316}

Finally, some small agricultural interests oppose animal patenting because they believe that it will hasten the demise of the family farm.\textsuperscript{317} They believe patents for the most desirable breeds of farm animal will afford large corporations a stranglehold on small farms.\textsuperscript{318} The licensing fees and royalties attending transgenic farm strains may in turn accelerate the decline of small family-owned farms in favor of large agribusiness concerns.\textsuperscript{319} In addition, questions surrounding the ownership of offspring from licensed transgenic animals remain problematic for small farmers.\textsuperscript{320} There has been a strong

\begin{footnotes}
\begin{footnote}{312} See Hoffmaster, supra note 6, at 7-9 (weighing the competing values between the use of animals in medical research and the prospect of beneficial outcomes for humans).\end{footnote}
\begin{footnote}{313} Dresser, supra note 5, at 422-23.\end{footnote}
\begin{footnote}{314} Letter from Virginia Handley, Coordinator, The Fund For Animals, Inc., to the Honorable Robert Kastenmeier, House Judiciary Committee (Aug. 3, 1987), in Transgenic Animal Hearings, supra note 292, at 581 (arguing that patenting animals overlooks the immense pain and suffering felt by the animals); Merges, supra note 5, at 1058-61.\end{footnote}
\begin{footnote}{315} Merges, supra note 5, at 1061.\end{footnote}
\begin{footnote}{316} Id. at 1058-59.\end{footnote}
\begin{footnote}{317} E.g., Transgenic Animal Hearings, supra note 292, at 114-16 (statement of Cy Carpenter, President, National Farmer's Union) (pointing out that the patenting of plant seeds has transformed the plant seed industry into a virtual monopoly controlled by five producers, and that this trend will likely occur in animal husbandry if the government allows patents for transgenic animals). See Dresser, supra note 5, at 417-19 (stating that higher costs and increased productivity of genetically engineered animals may force family farmers out of business).\end{footnote}
\begin{footnote}{318} E.g., Transgenic Animal Hearings, supra note 292, at 114-16 (statement of Cy Carpenter, President, National Farmer's Union).\end{footnote}
\begin{footnote}{319} Dresser, supra note 5, at 417. But see Transgenic Animal Hearings, supra note 292, at 121 (statement of Dr. A. Ann Sorensen, American Farm Bureau) (stating that companies holding patents on transgenic animals are unlikely to spend the time and resources to prosecute infringing family farms).\end{footnote}
\begin{footnote}{320} See Merges, supra note 5, at 1071-72. These questions range from the pragmatic to the theoretical. On a practical level, the recordkeeping necessary to keep track of transgenic offspring and any required royalties or licenses to them could be
push for a "farmer's exemption" to animal patents to address these concerns.\textsuperscript{321}

2. Patent Proponents. Proponents of animal patenting have shown that the arguments advanced by animal patenting opponents, although emotionally and politically potent, rest on a poor logical foundation.\textsuperscript{322} For example, the meaning of the concept "species integrity" is ambiguous from the scientific viewpoint, in part because the meaning of "species" is ambiguous.\textsuperscript{323} The designation of "species" is largely an arbitrary classification for scientific convenience; there is considerable dispute over what constitutes a species, or how species boundaries might be recognized.\textsuperscript{324} Mating between organisms that scientists consider different species certainly occurs in nature.\textsuperscript{325} Thus, even without human intervention, the genetic integrity of species seems insecure.\textsuperscript{326}

Setting aside the problems of artificial taxonomies, the numerous examples of natural genetic exchange between organisms underscores the fallacy in the argument that creation of transgenic animals violates the natural order. The simple fact is that biotechnology cannot engage in anything unnatural; it can only mimic nature, using tools that nature provides.\textsuperscript{327}

\textsuperscript{321} Dresser, supra note 5, at 433; Merges, supra note 5, at 1070-73; Rochelle K. Seide & Katherine J. Daniels, Patent Protection for Animal Inventions, 1 J. PROPRIETARY RTS. 7, 12 (1989).

\textsuperscript{322} See Hoffmaster, supra note 6, at 23 (describing the moral objections criticizing genetic engineering as "amorphous" and "speculative," and the current debate about genetic engineering as "rhetorical").

\textsuperscript{323} See John Rennie, Are Species Specious?, SCI. AM., Nov. 1991, at 26 ("For many biologists, a species is a bit like pornography: hard to define exactly, but they know it when they see it.").

\textsuperscript{324} See PATENTING LIFE, supra note 1, at 100-02 (noting that many domestic species are difficult to discern, and that some are already the product of centuries of human manipulation).

\textsuperscript{325} Id. at 101 (noting that some species are "almost promiscuous" in that they interbreed frequently with related species).

\textsuperscript{326} Id. (noting that "[t]he issue of species integrity is more complex and subtle than that of species barriers") (emphasis omitted); see also Peter R. Grant & B. Rosemary Grant, Hybridization of Bird Species, 256 SCIENCE 193, 193-94 (1992) (discussing the prevalence of interbreeding across taxonomic "species" designations).

\textsuperscript{327} Refer to notes 63-64 supra and accompanying text; cf. Willard Gaylin, What's
Exchange of genetic material between species via mating clearly occurs in nature and is not considered "unnatural." Neith-
er can other types of genetic material transfer be considered "unnatural"; this occurs in nature via viral or virus-like vectors with some frequency between organisms that do not breed together.

To be sure, this new technology allows humans to accelerate and direct natural genetic exchange; however, proponents of animal patenting correctly point out that humans have been doing this for a very long time. Humans have practiced animal breeding throughout recorded history; the development of transgenic animals merely continues this practice. Indeed, the argument that patenting animals is a form of animal exploitation ignores the fact that humans have overwhelmingly engaged in, and approved of, the use of animals for our benefit. Thus, the problem, if one in fact

So Special about Being Human?, in THE MANIPULATION OF LIFE 51, 63 (Robert Eebjornson ed., 1984) (noting that humans are by nature technological animals). This point has also been made by Raymond Smullyan, a philosopher and mathematician, in his Socratic dialogue between God and a perplexed mortal:

Mortal: What do you mean that I cannot conflict with nature? Suppose that I were to become very stubborn, and I determined not to obey the laws of nature. What could stop me? If I became sufficiently stubborn, even you could not stop me!

God: You are absolutely right! I certainly could not stop you. Nothing could stop you. But there is no need to stop you, because you could not even start! As Goethe very beautifully expressed it, "In trying to oppose Nature, we are, in the very process of doing so, acting according to the laws of nature!" Don't you see that the so-called "laws of nature" are nothing more than a description of how in fact you and other beings do act. They are merely a description of how you act, not a prescription of how you should act, not a power or force which compels or determines your acts. To be valid a law of nature must take into account how in fact you do act, or, if you like, how you choose to act.


328. See Grant & Grant, supra note 326, at 193-94 (reporting the prevalence of interbreeding between different species of birds).


330. See Hoffmaster, supra note 6, at 16 (noting the greater capabilities of genetic engineering compared to selective breeding).

331. Id. at 15-16 (commenting that selective breeding has been used to accomplish the same ends as genetic engineering); Merges, supra note 5, at 1060 (pointing out that man has systematically altered species "for millennia").

332. See PATENTING LIFE, supra note 1, at 102 (noting that most of the species researchers now use in transgenic research have already been altered by centuries of human manipulation); Merges, supra note 5, at 1060 (stating that the animals currently used as transgenic hosts are the product of human intervention).

333. See PATENTING LIFE, supra note 1, at 132 (noting that society allows hu-
exists, will not be solved or even squarely addressed by banning animal patents.

This is also the case regarding the argument that genetic engineering could potentially create environmental disaster. Using a relatively new technology may carry a small but nonzero risk of some unforeseen disaster. However, managing that risk has little to do with whether the risky technology is patented; regulations ensuring acceptably safe use of the technology are a preferred route to risk management. Such an approach has already been taken in areas such as the pharmaceutical industry, where a patent holder cannot make, use, or sell a patented drug without FDA approval, and may not even possess the patented drug if it is contraband or distributed only by prescription.

This last point is perhaps the most telling against the objections raised thus far to animal patenting—the objections have very little to do with patenting itself. Objections to animal patenting appear largely as a surrogate for objecting to some other social concern; the patent system seems an inappropriate battlefield on which to wage these political conflicts. Commentators, notably Rebecca Dresser and Robert Merges, have suggested that this may call for action addressing the underlying concern, rather than action addressing animal patenting. They suggest the patent system is not the

man's to use animals for food, as a source of byproducts, and as pets).

334. Merges, supra note 5, at 1056-57.
335. See PATENTING LIFE, supra note 1, at 136 (noting that opponents of animal patenting voice concerns that releasing transgenic animals into the wild may have some unforeseen environmental impact, and that biotechnology could lead to a decline in the genetic diversity of animal populations); Merges, supra note 5, at 1056-57 (stating that recombinant animals do not pose a direct threat to the ecological balance, but that the possibility exists that large-scale, accelerated breeding could lead to unforeseen disaster).
336. PATENTING LIFE, supra note 1, at 136; Merges, supra note 5, at 1068.
337. The Federal Food, Drug, and Cosmetic Act requires that new drug manufacturers demonstrate a drug's safety for human consumption before the Food and Drug Administration (FDA) grants approval for commercial sale. 21 U.S.C. § 1 (1988). The FDA approval process entails seven basic testing stages through which the FDA screens risks that are not justified by therapeutic benefits. See Ronald L. Derosiers, The Drug Patent Term: Longtime Battleground in the Control of Health Care Costs, 24 NEW ENG. L REV. 115, 118 (1989). Many FDA pre-market testing requirements are performed after patents are obtained and this results in an inability on the part of patent holder to sell the drug. Id.
338. PATENTING LIFE, supra note 1, at 18 (noting that most objections raised concerning the patenting of animals will be "materially unchanged" regardless of whether or not patents are allowed).
339. Id. (suggesting that the appropriate regulations or statute should address the consequences of patenting).
340. See Dresser, supra note 5, at 424; Merges, supra note 5, at 1067-68; see also
proper forum to address concerns such as potential ecological disasters or animal suffering.\textsuperscript{341} These may be legitimate concerns, but legislation or regulations directly addressing these concerns would be preferable.\textsuperscript{342}

It follows from this argument that Congress should not emulate the nuclear weapons precedent\textsuperscript{343} to carve out a patent exception for transgenic animals; neither should the courts follow their precedent regarding gambling and fraudulent devices\textsuperscript{344} to deny the utility of animal patents. The commentary distinguishes the nuclear weapons exception as a matter of national security, which is not implicated in the transgenic animal debate.\textsuperscript{345} The exception for illegal or fraudulent devices rests on moral objections which may change, as the gambling device cases demonstrate, and so are not properly part of the patent law.

Consequently, the PTO should grant animal patents, but constrain the use of the patented technology by proper regulation where appropriate.\textsuperscript{346} The merit to this approach is demonstrated in the pharmaceutical example above: societal benefits are maximized and societal costs are minimized by first offering the incentive and then prohibiting the invention’s use in selected instances.\textsuperscript{347} Thus, if the patent incentive remains in place, the development of new technology will be encouraged while detrimental uses of the new technology will prohibited.

B. Transgenic Humans

The responses Dresser, Merges, and others offer the

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\textsuperscript{341} Noonan, \textit{supra} note 258, at 318 (concluding that “[p]atent law is morally neutral, and protection of animals is best left to agencies and laws specifically designed to achieve that purpose”).

\textsuperscript{342} Dresser, \textit{supra} note 5, at 424; Merges, \textit{supra} note 5, at 1067-68.

\textsuperscript{343} Id.

\textsuperscript{344} Refer to notes 237-43 \textit{supra} and accompanying text.

\textsuperscript{345} Refer to notes 244-56 \textit{supra} and accompanying text. Each commentator argues that it is improper to deny biological patenting and that protection of the public is better achieved through regulation. Dresser, \textit{supra} note 5, at 424; Merges, \textit{supra} note 5, at 1067-68.

\textsuperscript{346} Merges, \textit{supra} note 5, at 1067 (contrasting the complete absence of benefits and known, severe dangers associated with nuclear weapons, with the many benefits associated with transgenic animal patenting).

\textsuperscript{347} Dresser, \textit{supra} note 5, at 424; Noonan, \textit{supra} note 258, at 318; see also \textit{PAT- ENTING LIFE}, \textit{supra} note 1, at 18 (suggesting that concerns about the consequences of patenting should be addressed by regulation, rather than by amendments to the patent law).

\textsuperscript{348} \textit{C.f} Dresser, \textit{supra} note 5, at 434 (arguing that prohibiting animal patenting discourages scientific progress, and that biotechnology companies will probably find other ways to protect their interests in commercializing genetically manipulated animals).
opponents of transgenic animal patenting are rational responses to those opponents' objections regarding transgenic animals, but it is not clear that the opponents' objections are entirely rational. Rather, they appear to reflect a more fundamental objection to the technology itself, an objection that implicates more than an exclusive right to recover invention development costs. In particular, the objection that biotechnology violates the natural order or allows humans to "play God" seems to encapsulate a strong emotional response to a technology that some feel assaults their view of self and society.

At its most extreme, this response comprises a fear some commentators call the "Frankenstein Factor." At its most reasonable, the response comprises an attitude that other commentators have dubbed "genicity." These feelings are especially strong when the debate concerns human genetic alterations. Commentators advance few reasoned arguments that human recombinant DNA manipulations might lead to ecological disaster or economic trauma; rather, they proffer moral and emotional assertions. Yet, emotional or reasoned, these assertions are not unfounded, and commentators cite historical precedent in support. Most commentators consider somatic cell therapy relatively noncontroversial because it raises no more difficult questions than any other treatment for disease. However, germ-line genetic therapies have become a focal point of dispute, resurrecting the shadow of transgressions past—the specter of eugenics.

348. Refer to notes 292-321 supra and accompanying text.
349. Karen Lebacqz, The Ghosts Are On the Wall: A Parable for Manipulating Life, in THE MANIPULATION OF LIFE, supra note 327, at 22, 26 (defining the "Frankenstein Factor" as society's fears that the changing nature of the human race will undermine the good of the race in the interests of private profit and prestige).
351. Refer to notes 356-75 infra and accompanying text.
352. Refer to notes 114-32 supra and accompanying text.
353. See Anderson, supra note 111, at 812 (noting a general consensus that somatic cell gene therapy is an ethical therapeutic option).
354. Refer to notes 133-53 supra and accompanying text.
1. Positive and Negative Eugenics. In its broadest aspect, eugenics is the implementation of policies intended to improve human genetic traits. These policies could adopt a negative mode intended to eliminate certain genetic traits, a positive mode intended to foster certain traits, or some combination of the two. The technologies considered here clearly lend themselves to the implementation of such policies. For example, germ-line genetic therapy is arguably a type of negative eugenics designed to remove an undesirable genetic trait from the human gene pool. Biotechnology also makes possible enhancement genetic engineering, a type of positive eugenics, to enhance or improve a specific characteristic such as height.

Some such use of these technologies already exists. DNA diagnostics have been coupled with in vitro fertilization to remove an inherited disease from a family line. Doctors may identify and discard zygotes carrying the gene for the disease so that only a zygote that is free of the gene is implanted in the mother to gestate. Researchers have not yet attempted to repair or replace a defective human gene, rather than discard the carrier zygote, but it is within the foreseeable capabilities of present technology.

The use of biotechnology in a negative eugenics program to eliminate a genetic defect is at best beneficial, at worst innocuous. Yet Western societies, including the United States, have had direct and unpleasant experience with state-sponsored

356. See Kevles, supra note 355, at 260 (defining eugenics as the ideas and activities aimed at improving mankind by manipulating biological heredity); Harding, supra note 355, at 477 (describing eugenics as a social movement to improve the human species through technology).
357. Harding, supra note 355, at 478 ("Eugenics may be classified as either negative or positive. Negative eugenics seeks to reduce or eliminate deleterious genes, while positive eugenics encourages desirable or superior traits.")
359. W. French Anderson, Genetics and Human Malleability, HASTINGS CENTER REP., Jan.-Feb. 1990, 21, 22 [hereinafter Malleability] (stating that an example of enhancement genetic engineering is the insertion of a growth hormone gene into a normal child in hopes that it would make him grow larger).
360. See Winston & Handyside, supra note 138, at 935-36 (describing how preimplantation diagnosis of embryos has allowed parents who both carry the cystic fibrosis trait to bear healthy children).
361. See id.
362. Malleability, supra note 359, at 22 (noting that gene transfer applications will probably be carried out over the next five to ten years).
eugenic policies. During the early part of the twentieth century, a eugenic movement swept Europe and North America advocating improvement of the human species through directed breeding. This movement reached its most influential and gruesome status in the political creed adopted by Nazi Germany, embodied in the doctrine of a superior Aryan master race. The Nazi policies embraced both a negative eugenic campaign to exterminate millions of purportedly genetically "inferior" people, and a positive eugenic campaign to encourage marriage and breeding of those with "desirable" Aryan traits.

In the United States, the eugenic movement led to laws permitting compulsory sterilization of mentally handicapped individuals who courts adjudged guilty of crimes tainted with moral turpitude. Although initially condoned by the Supreme Court, such laws were eventually overturned in cases relying on equal protection under the Fourteenth Amendment, and led to the declaration of a constitutionally protected right of reproductive privacy based on concepts of equal protection and substantive due process. However, eugenic policies have left a lingering legacy in ethnically based immigration policies and statutes regulating marriage.

This dramatic history of misguided genetic policies urges...
caution for future genetic policies. More recent genetically-based policy fiascoes also raise concern such as the stigmatizing correlation purportedly found between criminal conduct and possession of an extra "Y" chromosome. Science has since cast this correlation into doubt and the law has discredited the policies arising from it. Other incidents, such as a disastrous program to screen for sickle-cell anemia in African-Americans, stand accused of carrying with them a racist taint reminiscent of Nazi eugenic policies.

Against these concerns is set the potential for genetic manipulation to permanently alleviate suffering from many genetic defects. Arguably, lawmakers could skirt the boundaries of objectionable eugenics by limiting use of recombinant DNA technology to therapies intended to cure genetic disease and disability, and by prohibiting use of the technology for genetic enhancement. However, the distinction between eliminating a disability and enhancing a trait is very fine, particularly where insertion of new genetic material may be the route to either outcome. Fuzziness as to the meaning of "disability" and "normal" make difficult the judgements as to where genetic therapy ends and genetic enhancement begins. This implicates further difficult decisions regarding what traits medicine should consider undesirable, and so eliminated or...

372. Daniel J. Kevles, In the Name of Eugenics: Genetics and the Uses of Human Heredity 279 (1985) (questioning "[w]ho will make the decisions about the genetic worth of prospective human beings?").


374. Id. at 239-41 (concluding that there is no convincing evidence that an extra Y chromosome retards intellectual development).

375. See id. at 67-68, 77-78 (highlighting the danger of legislative misunderstanding of genetics); Leslie Roberts, One Worked; The Other Didn't, 247 Science 18, 18 (1990) (reporting that charges of racism were leveled at those who advocated that African-Americans with sickle-cell anemia avoid having children).

376. See Harris, supra note 358, at 183 (stating that gene therapy will enable the genetically weak to give birth to the genetically strong). See generally E. Joshua Rosenkranz, Custom Kids and the Moral Duty to Genetically Engineer Our Children, 2 High Tech. L.J. 1 (1987) (arguing that genetic intervention is required by the moral duty to rescue).

377. See Malleability, supra note 359, at 22-23 (suggesting a line be drawn between therapeutic gene therapy and enhancement genetic engineering); John C. Fletcher & W. French Anderson, Germ-line Gene Therapy: A New Stage of Debate, Law Med. & Health Care, Spr.-Sum. 1992, 26, 32 (noting that the public has not yet achieved consensus on where to draw the line between curing serious genetic disorders and enhancing physical traits).

378. See Anderson, supra note 111, at 812 (finding it difficult to define the difference between treatment and enhancement); Harris, supra note 358, at 185 (noting that the distinction between preservation of life and health and other uses is difficult to draw).

379. See Anderson, supra note 111, at 812; Harris, supra note 358, at 180 (noting the difficulty in defining disability).
curtailed, and what traits medicine may consider desirable enough to be enhanced or improved.\footnote{380} Most importantly, there remains the question of who should have the power to make such decisions that will impact the characteristics of unborn generations.\footnote{381}

2. The PTO Position. Against this backdrop of difficult policy questions, the prospect of patenting a transgenic human carries an unwelcome hint of commerciality into an already uncomfortable discussion. Control or ownership of this type of biological invention may be perceived as an endorsement of an undesirable trend toward viewing other individuals as objects and commodities.\footnote{382} The PTO position on patenting transgenic multicellular organisms limits such patents to “non-human” organisms, presumably to short-circuit such concerns.\footnote{383}

On its face, this pronouncement seems contradictory to the broad language of \textit{Chakrabarty}, which proclaimed as patentable “anything under the sun that is made by man.”\footnote{384} Humans made by man were not explicitly exempted from this language. However, the PTO found an exemption elsewhere, in the United States Constitution. According to the PTO statement, transgenic humans are excluded from patentability by the Thirteenth Amendment, which prohibits slavery or involuntary servitude of another human being.\footnote{385}

These grounds for excluding transgenic humans from patentability are at best shaky. As recent commentators have pointed out, the legal basis for the PTO position is flawed; there is no reason to suppose that the Thirteenth Amendment

\footnotesize{\textsuperscript{380}} See \textit{Malleability}, supra note 359, at 23-24 (raising questions about the differences between serious genetic disorders and simple genetic variation).

\footnotesize{\textsuperscript{381}} See Robertson, supra note 358, at 124-25 (questioning the power of the state to regulate embryonic gene alteration).

\footnotesize{\textsuperscript{382}} See Scott Altman, (Com)mmodifying Experience, 65 S. Cal. L. Rev. 293, 320-21 (1991) (expressing concern that genetic engineering could exacerbate instances of lack of responsibility toward others). Altman notes that the term commodification has been used in a variety of related ways to denote, among other meanings, treating persons as things that can be sold, and causing persons to regard one another as less-than-human objects for sale. Id. at 295-96; see also Margaret J. Radin, Market-Inalienability, 100 Harv. L. Rev. 1849, 1925-27 (1987) (discussing baby-selling as turning people into commodities and impairing their self-conception).

\footnotesize{\textsuperscript{383}} See \textit{PATENTING LIFE}, supra note 1, at 93 (reprinting PTO Policy on Patenting Animals) (noting that the PTO considers nonnaturally occurring nonhuman multicellular living organisms to be patentable).

\footnotesize{\textsuperscript{384}} Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

\footnotesize{\textsuperscript{385}} U.S. Const. amend. XIII; see also \textit{PATENTING LIFE}, supra note 1, at 93 (reprinting PTO Policy on Patenting Animals) (noting that a grant of a property right in a human being is prohibited by the Constitution).}
addresses the type of right conferred by a patent. 386 A patent merely confers the right to prevent others from making, using, or selling the patented invention. 387 The grant of a patent does not, however, give the patent holder an affirmative right to practice or use the invention, or even to possess a physical embodiment of the invention. 388 This is the case, for example, in the pharmaceutical area, as described above. 389 Similarly, the holder of a patent for a transgenic human being could presumably prevent others from making, using, or selling such a transgenic human being, but this does not mean that the patent holder could impress the patented person into servitude or bondage. 390

This underscores the fact that the patent right is quite separate from any given embodiment of the invention. The holder of a patent to a transgenic person could buy, sell, or trade away the patent rights without buying, selling, or trading the embodiment of the invention—the person. Such a market would have no impact on the freedom or autonomy of the person himself, only upon the right to bar others from practicing that invention.

Neither is the PTO position saved by arguments that genetic manipulation gives rise to a sort of character determinism that could be considered "involuntary servitude." 391 Stretching the meaning of this word is inconsistent with the Supreme Court's reading of the term. The Court has interpreted the Thirteenth Amendment in light of its historical setting as directed toward eliminating the condition and "badges" of slavery imposed upon African-Americans in the United States. 392 Genetic determinism has not been recognized as a

386. See DeBr6, supra note 10, at 232 (arguing that mere ownership of patent rights in a gene does not interfere with the freedom of those possessing the patented gene); Fishman, supra note 10, at 474-75 (arguing that a patent right in a human is not necessarily analogous to slavery under the Thirteenth Amendment).
388. DeBr6, supra note 10, at 232.
389. Refer to note 337 supra and accompanying text.
390. DeBr6, supra note 10, at 232; Fishman, supra note 10, 474-76.
392. See Memphis v. Greene, 451 U.S. 100, 124-29 (1981) (holding that "badge of slavery" under the Thirteenth Amendment does not encompass the closing of a street from a white neighborhood into a black neighborhood); Palmer v. Thompson, 403 U.S. 217, 226-27 (1971) (asserting a narrow interpretation of "slavery" in the Thirteenth Amendment as applied to closing of public pools after desegregation of facilities). One commentator asserts that this reasoning precludes Congress from regulating transgenic human patents under the Thirteenth Amendment. See Fishman, supra note 10, at 474 n.122. However, such reasoning is probably wrong; the Court's narrow reading applies only to the operation of the amendment itself, not to the enforcement power granted to Congress under the amendment. See generally Nicholas
component of that history of bondage.\footnote{393} The broad reading of this provision could also lead to absurd and socially undesirable results, such as the conclusion that schoolteachers, parents, and others with a formative influence on children are subjecting them to "involuntary servitude" under the Thirteenth Amendment.

Although the Thirteenth Amendment is not implicated in patenting humans, perhaps another constitutional right may be. Patenting humans may conflict with the right of reproductive freedom or autonomy found under the Fourteenth Amendment.\footnote{394} For a variety of practical and doctrinal reasons, this position is as untenable as a limitation based on the Thirteenth Amendment. First, because the patent grant extends for only seventeen years, it is unclear to what extent, if any, a conflict with reproductive autonomy might arise; a patented human being would barely have time to reach maturity and procreate before the offending patent expired.\footnote{395} Second, the

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\footnote{393}{P. Terry, "Alas! Poor Yorick," I Knew Him Ex Utero: The Regulation of Embryo and Fetal Experimentation and Disposal in England and the United States, 39 VAND. L. REV. 419, 464-66 (1986). To the contrary, the scope of Congress' enforcement power has not been limited by the amendment's history. See Memphis, 451 U.S. at 124-25 (stating that Congress is granted broad remedial powers under the Thirteenth Amendment); Jones v. Alfred H. Mayer Co., 392 U.S. 409, 343-40 (1968) (holding that Congress has the authority to identify badges of slavery and respond with effective legislation).}

\footnote{394}{However, it is interesting to contemplate what may become of Supreme Court jurisprudence grounded in the concept of "immutable characteristics" should biotechnology render such characteristics mutable. See, e.g., Fullilove v. Klutznick, 448 U.S. 448, 496, 516 (1980) (Powell, J., concurring) (arguing that although classifications based upon "immutable characteristics," such as race, ancestry, and origin, are "fundamentally at odds with the ideals of a democratic society" and thus "cannot be imposed simply to serve transient or political goals," Congress nevertheless has a legitimate interest and the constitutional power to make "persons whole for injuries suffered on account of unlawful... discrimination"); Frontiero v. Richardson, 411 U.S. 677, 686-88 (1973) (concluding that classifications based upon sex, race, alienage, or national origin, which are "immutable characteristics," are "inherently suspect" and subject to strict scrutiny); Weber v. Aetna Casualty & Sur. Co., 406 U.S. 164, 175 (1972) (barring discriminatory legislation based on illegitimacy, a characteristic over which a child has no control).}

\footnote{395}{The Supreme Court has generally acknowledged that the right of reproductive autonomy arises under the Due Process Clause of the Fourteenth Amendment, although it has at times spoken of reproductive freedom in terms of the Fourteenth Amendment's Equal Protection Clause, or in terms of a kind of gestalt reading of the constitution's personal rights guarantees. See Eisenstadt v. Baird, 405 U.S. 438, 453-55 (1978) (determining that privacy is a fundamental right for equal protection purposes); Roe v. Wade, 410 U.S. 113, 153 (1973) (stating that the right of privacy arises from substantive due process); Griswold v. Connecticut, 381 U.S. 479, 484-85 (1965) (noting that the constitutional right of privacy arises from the Bill of Rights as a whole).}

\footnote{DeBré, supra note 10, at 238 n.98. Of course, it is possible to extend patent protection beyond the seventeen-year period of the basic patent. Refer to notes 215-22 supra and accompanying text. Even so, the patent period has less significance to...}
extent to which patent rights may be exhausted in a second generation transgenic organism is unclear. Finally, even if the Federal Constitution negates a patent holder’s exclusory rights when a transgenic human is “made” by procreation, there is no reason that his remaining patent rights should not remain intact; the entire fabric of the patent grant need not be unraveled by clipping one thread.

V. PATENTING TRANSGENIC HUMAN EMBRYOS

The issues relating to patents for higher life forms involve difficult policy questions to which firm solutions have not yet emerged. Yet embedded in these questions lie a set of more difficult issues relating to the patentability of embryos altered through human germ-line therapy. The technology for such manipulations is becoming readily available, and issues of ownership and control are close behind. The debate regarding patents for animals and human beings will undoubtedly shape in some measure the debate over embryo patents. Yet the sketchy answers that are beginning to develop for questions relating to the patenting of higher organism may not satisfy questions relating to embryo patenting. Unlike animals and persons, whose social and legal status is fairly well established, our society has barely begun to define the social and legal status of human embryos.

This Part first lays out these formative definitions and their implications, and then balances the costs and benefits of patenting human embryos. While the benefits of creating transgenic human embryos are great, the costs associated with patenting them are at best equally as great and at worst

human reproduction than mice or bacteria because the human generation cycle extends beyond seventeen years.

396. This question has been much debated in the agricultural sector, where rights to the offspring of patented animals purchased by farmers may be at issue. Refer to note 320 supra and accompanying text. A patent holder’s control over a patented animal’s offspring may be limited by the doctrine of patent exhaustion, which provides that after the sale of a patented item, the patent owner relinquishes control of subsequent uses or resale of the item. See id. The doctrine could have unforeseen applications in circumstances where, because of the Thirteenth Amendment, the patent holder has no right to even an initial sale or transfer. Cf. Fishman, supra note 10, at 476.

397. Refer to notes 133-53 supra and accompanying text (discussing germ-line therapy techniques).

398. See Brannigan, supra note 15, at 550 (noting that proprietary right disputes characteristically attend revolutionary technologies).

unresolved. These costs argue against issuing patents for transgenic human embryos at this time. This abeyance will in all likelihood have little impact on the pace of transgenic human embryo research, but will allow society as a whole to resolve its feelings about commodifying human embryos.

A. Embryo Status

Because the pace of biomedical technology has so greatly exceeded the pace of the law attending its use, any legal question involving the disposition of human embryos is likely to be fraught with uncertainty for the foreseeable future.400 Little help is available from traditional or common law doctrines because no opportunity to consider such questions arose before the last quarter of the twentieth century.401 Moral, ethical, and philosophical thought on the subject is of similarly recent vintage because of the newness of the technology for embryo manipulation. However, as in vitro fertilization and other assisted reproduction techniques become more and more routine, pressing questions arise regarding the creation, implantation, or disposal of embryos.402

1. Embryos and Abortion. Although a few states have begun to address these questions through legislation, much of the federal and state regulation concerning embryos is directed toward scientific investigation and experimentation involving embryos, and is derivative of, or corollary to, legislation directed toward fetal tissue experimentation.403 Because aborted fetuses provide the most ready source of tissue for experimentation, such research is directly tied to the acrimonious national debate over abortion, and questions of embryo status appear

401. See Legal Status, supra note 399, at 366-409 (outlining the "confusing terrain" this has caused in the development of law affecting the embryo).
to have become similarly implicated by association.\textsuperscript{404}

As a consequence, the discussion of embryo status is often colored with rhetoric drawn from the abortion debate.\textsuperscript{405} Based in part upon the anti-abortion position that a human being comes into existence at the moment of conception, some parties have argued that embryos must be accorded the same rights and respect as a fully developed human being.\textsuperscript{406} Others have responded that an unborn embryo stands in the same legal position as an unborn fetus, and need not be accorded any more consideration than required under \textit{Roe v. Wade} and its progeny.\textsuperscript{407}

Yet the discussion of the embryo's status must necessarily stand on a different legal footing than that of the discussion of fetal abortion. Much of the commentary and jurisprudence of abortion revolves around concern for a woman's right of bodily privacy or autonomy;\textsuperscript{408} indeed, this concern lies at the core

\textsuperscript{404} See Terry, supra note 392, at 425 (stating that a link between fetal and embryo research has probably been promoted by the public's perception that liberal abortion laws will create a ready supply of fetuses for experimentation); see also John A. Robertson, \textit{Embryo Research}, 24 U.W. ONTARIO L. REV. 15, 15-16 (1986) [hereinafter \textit{Embryo Research}] (arguing that scientists are fearful of undertaking embryo research because of the surrounding controversy and public disapproval).


\textsuperscript{406} See Harding, supra note 355, at 509 (noting that genetic engineering proponents reason that because a child is genetically different from its mother, it should be afforded status as an independent person); see also John A. Robertson, \textit{Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction}, 59 S. CAL. L. REV. 939, 971-72 (1986) [hereinafter \textit{Procreative Liberty}] (reviewing the extreme positions in the spectrum of opinion on embryo status).

\textsuperscript{407} Harding, supra note 355, at 505. The \textit{Roe v. Wade} decision created a trimester framework for determining the rights of an unborn child. 410 U.S. at 165, overruled by Planned Parenthood v. Casey, 112 S. Ct. 2791, 2818 (1992) (rejecting the trimester system). The Supreme Court stated that "the word 'person' as used in the Fourteenth Amendment, does not include the unborn." 410 U.S. at 158. However, as the fetus approaches viability, the state may have a "compelling interest" in protecting the potential human life. \textit{Id}. The newest formulation of the abortion right prohibits a state from imposing an "undue burden" that creates a "substantial obstacle" in the path of a woman seeking an abortion. \textit{Casey}, 112 S. Ct. at 2821.

\textsuperscript{408} See Peggy C. Davis, \textit{Neglected Stories and the Lawfulness of Roe v. Wade}, 28 \textit{HARV. C.R.-C.L. L. REV.} 299, 369 (1993) (asserting that the doctrinal core addressed in the abortion cases involves the fundamental principals of liberty, autonomy, and privacy underlying the constitutional liberty to choose abortion); Bruce C. Hofen, \textit{The Constitutional Status of Marriage, Kinship, and Sexual Privacy; Balancing the Individual and Social Interest}, 81 \textit{MICH. L. REV.} 463, 532 (1983) (abortion cases involving married and unmarried women, as well as minors, have relied explicitly on the right of privacy).
of constitutional jurisprudence on the issue. However, unlike a fetus, the embryo can exist independently outside the womb; this characteristic is inherent in the nature of in vitro fertilization, and through cryopreservation can be prolonged indefinitely. Consequently, the autonomy of the mother need not enter into the discussion of embryo status at all, and we must independently assess the embryo's status.

2. Embryo Status and Biology. In considering the embryo's independent status, some commentators have tended to stress the physiological aspects of the embryo. These commentators point out that although embryos have unique genetic compositions, they are masses of undifferentiated cells that cannot perceive or react to their surroundings. In particular, Professor John Robertson relies on these biological facts to reach the legal conclusion that embryos should not be accorded the full range of personal rights under the law. Robertson argues that embryos should be treated with "special respect" because of their symbolic importance and potential to become human, but cannot be considered fully human because they lack sentience and awareness.

Ironically, reasoning similarly based on biology has been

410. Refer to notes 138-41 supra and accompanying text.
411. See Legal Status, supra note 399, at 392 (noting that reproductive technologies involve embryos long before they reach viability, thus the states may not adopt restrictive laws governing such technologies); John A. Robertson, In the Beginning: The Legal Status of Early Embryos, 76 Va. L. Rev. 437, 451 (1990) (noting that a fetus must be viable to fall within protection of the law); Tamara L. Davis, Comment, The Unique Status of and Special Protections Due the Cryopreserved Embryo, 57 Tenn. L. Rev. 507, 514 (1990) (arguing that a frozen embryo should be considered viable because it can be sustained outside the mother's body); Marcia Joy Wurmbrand, Note, Frozen Embryos: Moral, Social, & Legal Implications, 59 S. Cal. L. Rev. 1079, 1092-93 (1986) (recognizing that the pre-implantation embryo is not dependent on the mother and thus any question regarding the embryo must be answered independently); cf. Lawrence Tribe, The Abortion Funding Conundrum: Inalienable Rights, Affirm Duties, and the Dilemma of Dependence, 99 Harv. L. Rev. 330, 340-41 (1985) (stating that "but for its biological dependence on the woman, it is at least arguable that the fetus could be regarded as a holder of rights under the due process clauses of the fifth and fourteenth amendments, as well as the equal protection clause of the latter").
412. See, e.g., Clifford Grobstein, Biological Characteristics of the Preembryo, 541 Annals N.Y. Acad. Sci. 346, 347 (1988); Martin & Lagod, supra note 405, at 275; Mary J. Seller, The Human Embryo: A Scientist's Point of View, 7 Bioethics 135, 137 (1993) (reasoning that an embryo is not a human being because it does not have a developed body and is thus not a person).
413. See Procreative Liberty, supra note 406, at 974; Robertson, supra note 358, at 446; Embryo Research, supra note 404, at 22-23.
414. See Robertson, supra note 358, at 446; Embryo Research, supra note 404, at 22-23.
used to bolster the arguments of those who would accord embryos full rights as persons under the law. For example, in *Davis v. Davis*, a Tennessee divorce case involving a dispute over control of the estranged couple's cryopreserved embryos, the trial court chose to treat the embryos as persons, equivalent to children, for purposes of determining custody. This ruling was based upon testimony that the cryopreserved embryos each had a unique, individual genetic complement. Consequently, the trial judge concluded that they deserved to be treated as unique individuals—as persons—under the law.

Such a ruling fails to appreciate that, while scientific facts may inform societal policy and the legal rules that implement policy, they cannot dictate policy. A unique genetic signature, for example, cannot compel the conclusion that an embryo is a legal individual. Plants, animals, and even microorganisms display unique genetic signatures, but there appears to be no societal consensus that this accords them individual rights under the law. Conversely, society has chosen to imbue a range of individual rights on legal constructs, such as corporations, that have no genetic signature whatsoever.

Biology affords equally uncertain support for the conclusion espoused by Robertson and others who suggest that embryos lack the indicia of humanity and so cannot be treated as "persons." The corporation stands once again as a counterexample of a legal "person" with no indicia of humanity.
at all. Even more disturbing is the realization that individuals have offered similar arguments in the past as to why women and African-American slaves should not be accorded the full rights of persons under the law; in each instance those individuals advanced some purportedly scientific grounds to show that those classes were not biologically competent to manage the full range of legal and societal rights. Our present society would overwhelmingly reject both of these policies and the biological "truths" on which they were based. Future generations could well regard biologically-based restriction of embryo rights in a similar manner.

Perhaps the most sensible observation that has been made in this regard is that the dichotomy faced by the Davis trial court, that embryos are either property or persons, is a false choice. Embryos fit neither of these categories, but are something quite new, entitled to a category of their own. This may be the conclusion that Robertson intended to reach, and as he suggests, some parameters of this unique status will likely be impacted by the symbolic importance of the embryo. However, contrary to his analysis, neither our present evaluation of biology nor our present categories should determine the status the law assigns to embryos.

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422. See, e.g., Bradwell v. Illinois, 83 U.S. (16 Wall.) 130, 141-42 (1872) (articulating a purportedly biological basis for excluding women from the legal profession); Dred Scott v. Sandford, 60 U.S. (19 How.) 393, 404-05 (1856) (noting that African slaves were considered a "subordinate and inferior class of beings" at the time that the Constitution was framed); RICHARD KLUGER, SIMPLE JUSTICE 38 (1975) (stating that "[n]orth and south, [the black man] was classified as a lower form of human life and therefore fair game for continual debasement").


425. See Jones, supra note 424, at 607; see also Martin & Lagod, supra note 405, at 276 (arguing in favor of a sui generis approach to embryo status).

426. See Embryo Research, supra note 404, at 31 (stating, for example, that toxicology studies on embryos should be limited). But see Legal Status, supra note 399, at 362-63 (noting that the symbolic importance of the embryo is not unlimited and that society should not "protect a symbol of life at the cost of undermining the possibilities of actual life").
3. Embryos and the PTO. Placing embryos in a unique legal position leaves their status more uncertain than ever, at least until the relationship between embryo status and other legal constructs is resolved. Their place in the PTO statement on patenting is no exception to this problem. First, because of the PTO policy's constitutional basis, its applicability to embryos is unclear. Embryos may very well not fit the Thirteenth and Fourteenth Amendment concept of "persons." If embryos do not fit our present understanding of "person" under the Thirteenth and Fourteenth Amendments, then the application of these constitutional provisions to the patentability of zygotes and embryos is even murkier than is their application to fully gestated transgenic humans.

The analytical deficiencies arising from the PTO's reliance on the Thirteenth Amendment are exacerbated by the potentiality factor of embryos. As noted above, a trade in patent rights can exist entirely independently of trade in people, and need have no impact on the autonomy of a patented transgenic person. Where embryos are concerned, this may be true for the embryo itself: the embryo may not constitute a "person," making its sale constitutionally unobjectionable, and in addition, the sale does not mean that the purchaser will have any power over the person into whom the embryo may develop. Thus, the existence of a patent on a transgenic entity is doubly attenuated from the Thirteenth Amendment.

Secondly, the definitional parameters of the PTO ban are unclear when applied to transgenic embryos. The PTO statement apparently assumes humans to be excluded from the patentable subject matter category of "compositions of matter" that encompasses microorganisms, plants, and animals. However, the PTO grants patents for some human biologics, such as hybridomas or other immortalized cell lines. Thus, the PTO ban would not seem to extend to the cellular level, or even to the level of tissues.

This limitation in scope may generate some doubt as to the ban's applicability to embryos. It is at least arguable that

427. Refer to notes 405-07 supra and accompanying text.
428. Refer to notes 391-96 supra and accompanying text.
429. Id.
430. See Procreative Liberty, supra note 406, at 1020.
431. Refer to notes 232-36 supra and accompanying text.
patented cells from a cell culture resemble the cell mass of early embryonic development.\textsuperscript{433} Like embryonic cells, patentable human cell lines are often undifferentiated.\textsuperscript{434} Cell lines will generally carry the full set of genetic instructions necessary to build a human body; the full measure of these instructions are unexpressed in the cell line cells, but then they are also unexpressed in the embryo.\textsuperscript{435} Certainly, both types of cells lack the "human" features that Robertson and others would argue determine personhood: awareness, rationality, sensation, and human morphology.\textsuperscript{436}

As a consequence of such ambiguities, it may be possible under the PTO policy to draft permissible claims drawn to transgenic embryos. Claims that contain language excluding developed human organisms that might be considered "persons" may satisfy the plain language of the PTO policy. In addition, patentable subject matter also includes methods or processes, including medical processes.\textsuperscript{437} The PTO statement does not mention processes,\textsuperscript{438} yet an inventor could potentially control the market for transgenic humans or transgenic embryos by patenting the method of gene transfer, rather than by attempting to patent the product of the gene transfer. Indeed, prior to opening the doors to patent claims drawn to higher organisms, the PTO routinely followed a policy of allowing claims drawn to the method of creating such organisms, thus granting de facto monopolies to the organisms themselves.\textsuperscript{439} Finally, because genes are patentable,\textsuperscript{440} an individual could patent both a given gene and the method of using it in gene therapy, offering yet another way to control the creation of transgenic humans or transgenic embryos without patenting the endproduct itself.

However, despite its legal and logical deficiencies, the PTO policy may not be wholly without merit—the statement may capture something of the symbolic importance of embryos,

\textsuperscript{433} Cf. Walker, supra note 10, at 113-16 (arguing that "human being" has not been well defined in legislation on transgenic human patenting).
\textsuperscript{434} SINGER & BERG, supra no 20, at 893-94.
\textsuperscript{435} Refer to notes 20-27 supra and accompanying text.
\textsuperscript{436} Refer to notes 412-14 supra and accompanying text.
\textsuperscript{438} PATENTING LIFE, supra note 1, at 93 (reprinting the PTO Policy on Patenting Animals).
\textsuperscript{439} See Seide & Daniels, supra note 321, at 14 n.5.
\textsuperscript{440} Refer to note 212 supra and accompanying text.
particularly the distaste with which many view the sale or trade of embryos. Such patents may still evoke analogies to slavery in the minds of the public. Patents are by definition a utilitarian legal construct with an economic purpose, and their connection with humans or human conception may suggest that by granting them the PTO is commodifying important personal values in a manner that many find distasteful. And, at the risk of further and perhaps paradoxical commodification, it may be that the value society places on uncommodified embryos is a value that should be taken into account in determining the social utility of patenting for transgenic embryos.

B. Balancing Costs

The forgoing discussion implies that our society has yet to decide exactly how to value the important symbolic aspect of human embryo status, and it is this valuation problem that separates transgenic embryo patenting from transgenic animal patenting. The uncertain status of the human embryo in our society stands in marked contrast to that of animals. With the exception of a very few, although comparatively loud, dissenting voices, our society consistently embraces the use of animals and animal products for food, clothing, research, transportation, domestication, and other uses. Enhancement of desirable genetic traits in animals has long been seen as entailing significant societal benefits, and a patent incentive to encourage new methods of genetic manipulation promises continued benefits.

By contrast, the beneficial results of genetic manipulation in humans or human embryos enjoys no such broad consensus. Indeed, aside from slight agreement regarding the desirability of treating certain genetic diseases, considerable disagreement exists as to what constitutes a benefit in this area. The uncertain legal and moral status of the embryo, the potential for

441. See, e.g., George J. Annas, Redefining Parenthood and Protecting Embryos: Why We Need New Laws, HASTINGS CENTER REP., Oct. 1984, at 50, 51 (arguing that it is intuitive that embryos not be bought and sold); Davis, supra note 408, at 535 (arguing against commodification and commercialization of embryos).
442. See Robertson, supra note 358, at 512.
443. See id.
444. See PATENTING LIFE, supra note 1, at 132; Dresser, supra note 5, at 423.
445. See Dresser, supra note 5, at 414 (noting that these benefits can be produced at a small cost to society).
animal-human hybrids, and the specter of eugenic manipulation all raise difficult and divisive issues. The debate over animal patenting may in fact be a surrogate for the debate over these larger questions. To the extent that it represents a lack of societal consensus, the animal patenting debate in fact represents a lack of consensus regarding questions of the human condition. For example, what effect will ownership of transgenic animals have on human perspectives? Where is the line between humans and animals? Will animal eugenics lead to human eugenics?

This level of societal ambivalence places the utility of a patent incentive for human genetic manipulation on a precarious footing. The patent bargain is, as discussed above, already a bargain of uncertain or even dubious benefit to society; it is unclear whether the costs of patent exclusivity are ever overcome by the benefits of the incentive. Offering such a costly incentive in areas where it is unclear that society wishes to encourage activity is a strategy guaranteed to maximize the probability that the societal benefit from the patent will never exceed its costs.

Congress and the courts have, for precisely this reason, denied patent protection to inventions that, as a matter of policy, are considered better not encouraged through the patent incentive. This is in part accomplished through initially restricting the availability of patents to a relatively narrow range of inventions meeting statutory criteria of subject matter, novelty, utility and non-obviousness. Additionally, certain classes of inventions are excluded from patentability because although they meet the initial criteria, they still entail

446. Id. at 415-16.
447. Refer to notes 348-81 supra and accompanying text.
448. See Dresser, supra note 5, at 416.
449. See id.
450. See id. Indeed, it seems likely that the concept of humane behavior toward other species says far more about what it means to be human than what it means to be a dog, a monkey, or a pine tree. See Gaylin, supra note 327, at 67-69. As Thomas Nagel points out, just as we cannot isomorph human perceptions onto another species, it follows that we have no idea how animals perceive or regard our use of them. See Thomas Nagel, What Is It Like to Be a Bat?, PHIL. REV., Oct. 1974, reprinted in THE MIND'S I, supra note 327, at 391. However, we probably can say something about how our use of animals affects our own sensibilities, and tailor our conduct accordingly. See Gaylin, supra note 327, at 69.
451. Refer to part III supra.
452. Cf. IRA H. CARMEN, CLONING AND THE CONSTITUTION 178 (1985) (suggesting that the patent system may prove a poor encouragement to biomedical research because its "propriety and efficacy" have always been in some doubt).
453. Refer to notes 223-78 supra and accompanying text.
patenting costs that outweigh patenting benefits. For example, atomic weapons, gambling devices, and fraudulent apparati are inventions that, as discussed above, have been excluded under one or another of these categories.455

The core insight of these exclusions is relevant to the discussion of human embryo patents. For example, the exclusion of gambling devices from patentability has been criticized on the grounds that societal conventions have changed, and such devices might now be not only accepted, but laudable.456 This shift reflects a change in society's valuation of such devices, which implicates their social utility.467 However, the analytical flaw both in the gambling cases and in subsequent analysis of those cases has been the focus upon the presence of social utility.458 The proper focus should instead be the presence of patentable utility: The cost/benefit calculus for offering an incentive to innovation is not the same as the cost/benefit analysis for societal use of that innovation. The question is not whether the social cost of an invention's use warrants offering an incentive for its development, but rather whether the social cost of offering the incentive warrants offering the incentive.

When viewed at this level of analysis, the so-called "morality" cases, together with the statutory exclusions for nuclear innovation, may have more bearing on patentability of recombinant DNA inventions than previously thought. Offering incentives for genetic manipulation in humans may, unlike offering such incentives for genetic manipulations in animals, share with fraudulent apparati, gambling, or nuclear inventions the criterion of excessive social cost.

1. "Thick" and "Thin" Harms. Alternatively, the calculus of cost and benefits attending a patent incentive for human genetic inventions should contemplate not only direct, tangible costs, but also indirect and intangible costs. In the language of risk assessment, the assessment of harm accompanying germ-line patenting should be viewed as "thick" rather than "thin."459 For example, the discussion of risks attending genetic engineering, particularly as formulated by the scientific community, has focused on a "thin" conception of harm.460

455. Refer to notes 223-56 supra and accompanying text.
456. Refer to notes 253-56 supra and accompanying text.
457. Refer to note 254 supra and accompanying text.
458. Refer to notes 244-56 supra and accompanying text.
460. See id.
Such a "thin" risk assessment considers only physical harm, such as death or disease, that could stem from employment of recombinant DNA technology.\textsuperscript{461} There appears to be a general consensus among the scientific community that the risk of such mortality and morbidity from genetic experimentation is small, and so concern among the general public over recombinant DNA technology is considered to be unfounded or of little consequence.\textsuperscript{462}

However, a more comprehensive view of genetic engineering risks might contemplate the potential for disruption of societal norms, beliefs, and institutions stemming from use of the technology.\textsuperscript{463} Costs associated with genetic engineering may be more extensive when viewed under this "thick" conceptualization of harm.\textsuperscript{464} Recombinant DNA technology, especially as applied to higher organisms, offers new challenges to established norms of medical ethics, to social structures and concepts such as family or parenthood, and even to concepts such as individuality or identity.\textsuperscript{465} Reassessing and reformulating these social concepts is bound to absorb a significant measure of societal resources; addressing the dislocation caused by the reformulation process will absorb further resources.

Additionally, a "thin" concept of risk, focusing primarily on biohazards, may invite dismissal of public concern on technical or technological grounds. Public perception of genetic engineering biohazards may be founded in ignorance or misperception of the technology, but the concern itself is nonetheless real.\textsuperscript{466} Popular uneasiness over biotechnology, or the "Frankenstein factor," demands allocation of the resources necessary to mount a thoughtful and deliberate response.\textsuperscript{467} Failure to do so invites repetition of the course of events surrounding the demise of the nuclear power industry; the lessons learned there suggest that dismissing or belittling popular concerns

\textsuperscript{461} Id.
\textsuperscript{462} See Lebacqz, supra note 349, at 27.
\textsuperscript{463} See Wachbroit, supra note 459, at 369 (noting that these "social harms" may include economic losses, social disruption, abandonment of values and the undermining of political institutions).
\textsuperscript{464} Id. at 369-70; see also Paul Slovic, Commentary, in BIOMEDICAL POLITICS 302, 305 (Kathi E. Hanna ed., 1991) ("The adverse impacts of a risk event sometimes extend far beyond these direct harmful effects and may include indirect costs . . . that far exceed direct costs.").
\textsuperscript{465} See Lebacqz, supra note 349, at 24-26 (noting that the new technologies for manipulating life, including genetic engineering, generate unresolved legal, ethical, and technical questions).
\textsuperscript{466} Id. at 27.
\textsuperscript{467} Id. at 26-27.
over a given technology can quickly lead to popular resistance against further use or development of that technology.\textsuperscript{468}

2. Nonuse Values. The cost differential between a "thin" and a "thick" assessment of genetic experimentation costs appears to closely parallel the concept of nonuse value that has recently been the focus of assessments of environmental damage.\textsuperscript{469} Conventional economic evaluation relies on the actions of individuals or firms to reveal the preferences or value that they assign to a given resource.\textsuperscript{470} However, value may also accrue to resources that are never traded, such as a remote pristine wilderness or an endangered species.\textsuperscript{471} Individuals may never "use" or fix a market price to these resources, but may nonetheless place value on their continued unspoiled existence.\textsuperscript{472} Such value may include bequest value, which is the value placed on being able to pass the resource on to future generations; and existence value, which is the value that inheres in simply knowing that the resource exists.\textsuperscript{473}

The human genome fits the description of a unique resource that is not traded by individuals, but nonetheless has value to many individuals and thus would induce them to surrender the benefits of certain types of genetic manipulation.

\textsuperscript{468} Once seen as the power source of the future, nuclear energy is now something of a technological pariah in the United States. See generally IRVIN C. BUPP & JEANE CLAUDE DERIAN, LIGHT WATER: HOW THE NUCLEAR DREAM DISSOLVED (1978); U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, NUCLEAR POWER IN AN AGE OF UNCERTAINTY (1984). Many commentators see the unhappy fate of nuclear technology as a possible portent of biotechnology's fate. See, e.g., Wachbroit, supra note 459, at 370. Empirical evidence on the general public's risk perception suggests that the term "DNA" has not yet been lumped in the same category as the term "nuclear"; however, the potential for such a tainted perception is certainly clear. See Paul Slovic, Perception of Risk, 36 SCIENCE 280, 285 (1987) (noting that data indicates that the terms "DNA" and "nuclear" evoke similar perceptions).

\textsuperscript{469} See generally John V. Krutilla, Conservation Reconsidered, 57 AM. ECONOMIC REV. 777 (1967). Diamond and Hausman have observed that the original concept of nonuse value as formulated by Krutilla was applicable to long-term damages of unique importance, such as those to the Grand Canyon. Peter A. Diamond & Jerry A. Hausman, On Contingent Valuation Measurement of Nonuse Values, in CONTINGENT VALUATION: A CRITICAL ASSESSMENT 5 (Jerry A. Hausman ed., 1933). More recent commentators such as Randall and Stoll have applied the concept more widely to everything from historic buildings to soft drink cans. Alan Randall & John R. Stoll, Existence Value in a Total Valuation Framework, in MANAGING AIR QUALITY AND SCENIC RESOURCES AT NATIONAL PARKS AND WILDERNESS AREAS 265 (Robert D. Rowe & Lauraine G. Chestnut eds., 1983).

\textsuperscript{470} See Diamond & Hausman, supra note 469, at 3-4.

\textsuperscript{471} See id. at 3.

\textsuperscript{472} Id. at 3-4.

rather than have science manipulate the human genome in particular ways. However, as in the gambling device cases, it is important to separate two different sets of nonuse social costs that could attend genetic therapy patents. 474 The first, and likely the larger, of these would encompass those costs associated with actual manipulation of the human genome. The second set of costs would be those associated with offering a patent incentive to encourage human germ-line intervention. Just as ownership, trading, and licensing of patents to a human embryo could exist independently of an actual market in human embryos, 475 nonuse costs associated with germ-line patents may arise independently of actual genetic therapy patents.

Precise measurement of costs associated with those two categories of patents would be problematic. Nonuse values have been predominantly calculated through contingent valuation, that is, by surveys that query individuals’ hypothetical willingness to pay to preserve an environmental resource. 476 This method appears to be fraught with the kind of inaccuracies that might be expected of a survey asking individuals to evaluate the worth of items that they do not, and usually cannot, purchase. 477 Consequently, nonuse value estimates computed through contingent valuation studies may not be reliable bases for computing liability damages or for determining public spending decisions. 478

However, impediments to the application of nonuse value estimates in quantitative decisionmaking does not preclude their use in qualitative decisionmaking. 479 The nonuse

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474. Refer to notes 459-68 supra and accompanying text.
475. Refer to notes 391-96 supra and accompanying text.
477. Diamond & Hausman, supra note 469, at 18-27 (analyzing the inconsistencies associated with the contingent valuation method of ascertaining nonuse values); Shavell, supra note 476, at 373-77 (concluding that contingent valuation produces statistics that have no clear meaning and are subject to manipulation); of. Fischoff et al., supra note 476, at 273 (discussing the drawbacks of the “expressed preference” risk evaluation method).
479. This has been pragmatically recognized in risk assessment:

   No approach to [evaluating] acceptable risk is clearly superior to the
component of social costs will often be a positive, and even significant, value.\textsuperscript{480} It may be that the parameters of this value cannot be ascertained with enough precision to determine exact dollar amounts, but cognizance of the overall configuration of this cost component may be helpful in shaping social policy.\textsuperscript{481}

As yet, no one has performed a study to ascertain society's willingness to forgo payment as an incentive for the development of new genetic therapies. However, some survey data exists that suggests the type of results likely to be obtained through such a study. Surveys conducted by the Congressional Office of Technology Assessment (OTA) during the late 1980s evaluated the attitude of the American populace toward application of recombinant DNA technology.\textsuperscript{482} The data indicate that eighty percent of Americans have an overall positive view of scientific research, and tend to believe that progress in scientific knowledge will better their lives.\textsuperscript{483} This positive viewpoint extends to progress in biotechnology; although the surveys showed a public awareness of the potential direct risks of biotechnology, a sixty-six percent majority considered that biotechnology would better their lives.\textsuperscript{484}

When the OTA examined attitudes toward specific applications of biotechnology, sixty-eight percent of those surveyed indicated that genetic manipulation of plants and animals is morally acceptable.\textsuperscript{485} Only fifty-two percent indicated that

\begin{itemize}
\item Fischoff et al., supra note 476, at 279.
\item Shavell, supra note 476, at 380-81.
\item Cf. Diamond & Hausman, supra note 469, at 33 ("Legislation . . . need not rely only on conventional economic values, but can reflect public concerns . . . ."); Shavell, supra note 476, at 23 ("The recommendation not to employ contingent valuation estimates hardly means that nonuse values do not enter into social decisionmaking.").
\item 482. See U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY—BACKGROUND PAPER: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY (1987) [hereinafter OTA BACKGROUND PAPER].
\item 483. See id. at 3 (noting, however, that 71\% of Americans believe that scientific and technological developments will pose some risks to them and to their families). The study was a survey of 1273 Americans over the age of 18, conducted between October 30 and November 17, 1986. Id.
\item 484. Id. at 49. In a follow-up question, 18\% of those responding stated that they believed biotechnology would make their lives "a lot better," and 48\% stated that they believed biotechnology would make their lives "somewhat better." Id. at 50.
\item 485. Id. at 58.
\end{itemize}
genetic manipulation of human cells is morally acceptable.  

Approximately the same number indicated strong approval for germ-line therapy to correct a fatal genetic defect.  

However, comparative approval dropped to eighteen percent or lower for enhancement or eugenic therapies to improve intelligence or physical characteristics.  

Thus, the survey suggests that the public appears to draw a clear distinction in its attitude toward eugenic applications of biotechnology versus other applications, including germ-line therapies.

3. Incentives to Invent. In light of the OTA survey data reviewed above, the additional costs accompanying a “thick” assessment of germ-line genetic manipulation may not be necessary before use of all such technology. The OTA data suggests that the public favorably views at least some germ-line therapies, such as correction of single-gene genetic defects.  

To the extent that these therapies are objectionable, they, like animal patenting, appear to be so only because they may lead to more controversial genetic intervention. As the nonuse costs associated with these single-gene therapies may be minuscule or acceptably low, should not the patent incentive be made available to prevent an undersupply of intellectual goods in this area of human genetic research?

The most practical answer to this question may be to nonetheless draw the line between patentability of somatic and germ-line manipulations. As discussed above, the line between correcting a defect and enhancing a trait is shadowy and blurred.  

Drawing the distinction between germ-line manipulation aimed at therapy and such manipulation aimed at enhancement or eugenics will be difficult. Courts, administrative agencies, and legislatures are likely to flounder in attempting to fashion or enforce credible and comprehensible rules based on such a distinction. Significant costs could be incurred

486. Id. at 71.
487. Id. at 73. An additional 33% of those responding stated that they “somewhat approved” of germ-line gene therapy. Id. In a follow-up question, 62% of those responding indicated that they approved of using both somatic cell and germ-line therapy to treat an inherited genetic disease; an additional 14% approved of using only germ-line, and not somatic cell therapy for treatment. Id. at 73-74.
488. Id. at 73. Eighteen percent strongly approved of use of germ-line treatment to enhance intelligence and 26% somewhat approved of such treatment; 16% strongly approved of germ-line treatment to improve physical characteristics and 28% somewhat approved. Id.
489. See id. (noting that only approximately 15% of Americans disapprove of the use of gene therapy to prevent children from inheriting a fatal genetic disease).
490. Refer to notes 338-42 supra and accompanying text.
491. Refer to notes 378-80 supra and accompanying text.
simply trying to sort genetic corrections from genetic enhancements. A "bright line" rule is desirable to avoid such effort, and the most serviceable rule would simply exclude processes directed to human germ-line gene therapy, and the products of those processes from patentability.

In addition, the patent monopoly may not be necessary as an incentive to investment in those forms of germ-line therapy that might be desirable. As discussed above, the economic theory of patenting assumes that a monopoly incentive is required to prompt development and disclosure of new technologies. However, other incentives are available to prompt the basic research and clinical studies necessary to develop such therapies.

These incentives are inherent in the professional norms and self-image of the scientific community that investigates and develops the techniques of genetic intervention. Sociological studies of the scientific community indicate that scientists are constrained by strong unwritten rules of professional conduct. These professional norms anticipate that a scientist will be forthright in reporting experimental results, will freely share those results with other scientists, and will acknowledge valid experimental results without regard to the researcher's status. In this environment, the reward for successful research is the acknowledgement and acclaim of one's peers. Thus, scientists have generally been motivated to vigorous original research in order to obtain the indicia of community acclaim, such as first publication of a new discovery in a peer-reviewed journal, or nomination for an international award such as the Nobel prize. Such a prize is valued not for its monetary value, but for the peer recognition it entails. Research grants, academic tenure, or laboratory directorships

494. See Chaucer, supra note 437, at 440-41 (stating that some level of research will continue even in the absence of patents).
495. Refer to notes 159-87 supra and accompanying text.
497. Id. at 272-76.
498. Id. at 237 (equating the scientific social structure to "communism" in which all scientific discoveries are community property and the scientists' only claim is that of recognition and esteem).
499. See id.
500. Id.
may also be rewards arising from scientific success, but again are closely tied to peer review and community recognition.501

The view that scientists have of themselves appears to be somewhat different than the sociological view, and includes at least one other important motivation to scientific discovery. It is not the promise of pecuniary gain. Indeed, the promise of financial advancement from scientific discoveries has been to some extent scorned as de rigueur by the scientific community: "Neither Newton nor Faraday, nor yet Norbert Weiner, spent their time in a scramble for patents."502 On the contrary, although the scientific community demands enormous dedication and long hours from its constituents, these traits arise out of feelings of professional pride and a "sense of urgent personal exploration"503 that our society has traditionally reserved for the stereotype of an impassioned artist:

The need of the age gives its shape to scientific progress as a whole. But it is not the need of the age which gives the individual scientist his sense of pleasure and of adventure, and that excitement which keeps him working late into the night when all the useful typists have gone home at five o'clock. He is personally involved in his work, as the poet is in his, and as the artist is in the painting.504

Thus, in contrast to the fundamental premises of the patent system, neither the norms of science nor the scientific community's self-image contemplate pecuniary gain as a motivating factor in the pursuit of knowledge. Only recently has the lure of monetary rewards, including patent monopolies, figured significantly in the motivations of researchers. This shift in attitude has primarily been confined to the area of biotechnology, where the nature of the technology puts commercial application only a step away from basic research.505 Were the patent

501. Id.; see also Tabitha M. Powledge, Commerce and the Future of Gene Transfer, in GENETICS AND THE LAW III, supra note 350, at 75, 76 (arguing that scientists will be motivated by the technical challenge and moral satisfaction of finding genetic cures for disease and defects, as well as by fame, career advancement, grant money, and possibly a Nobel Prize).

502. JACOB BRONOWSKI, SCIENCE AND HUMAN VALUES 8 (1965). This professional attitude has also been to some extent recognized by the courts. See Katz v. Horni Signal Mfg. Corp., 145 F.2d 961 (2d Cir. 1944) (noting that great scientists, such as Faraday, are generally not motivated by intellectual property incentives), cert. denied, 324 U.S. 882 (1945); Martin v. Wyeth Inc., 96 F. Supp. 689, 695 (D. Md.) (arguing that physicians' ethics are inconsistent with restrictive patent monopolies), aff'd, 193 F.2d 58 (4th Cir. 1951).

503. See BRONOWSKI, supra note 502, at 8-9.

504. Id. at 8.

505. See Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 YALE L.J. 177, 195 (1987) (noting that the products of
incentive to be withdrawn in a given area, such as human gene therapy, the traditional incentives would still exist, and would still induce a significant level of research.

The power of these traditional incentives to drive gene therapy research is evidenced by the work that has already gone on in gene therapy without any apparent pursuit of patent protection for product or process. Of course, from a societal viewpoint, there is no reason to suppose that the results prompted by the traditional motivations to scientific research will parallel those that might be prompted by the patent system; the two may very well impel researchers to different goals. Yet this disparity in results may prove to be an advantage; as one commentator points out, “it is unlikely that the profit-motive alone will lead us to a future worth living in.”

Thus, in the absence of a pecuniary incentive, traditional scientific incentives would not only motivate some continued research on germ-line therapy, but apparently motivate such research within acceptable societal parameters. Development of treatments for debilitating genetic diseases is both technically and promotionally the type of research calculated to bring a scientist the acclaim of her peers and the public. Forays into genetic enhancement, by contrast, are likely to draw professional and public criticism, and so will proceed slowly if at all.

VI. CONCLUSION

As with the debate over animal patents, the debate regarding patents for germ-line gene therapies is likely to be a surrogate for less concrete and less articulable public fears. As with the debate over animal patents, the patent system is perhaps not the proper vehicle to ultimately resolve such fears. In each case, however, opposition to patenting cannot be viewed as irrational: offering a financial incentive such as a patent will

biotechnology research are readily commercialized; Dan L. Burk, Copyrightability of Recombinant DNA Sequences, 29 Jurimetrics J. 469, 519-20 (1989) (noting that "biotechnology is driven by the availability of scientific advances rather than by the availability of finance"); see also Dresser, supra note 5, at 419-22 (discussing commercialization of biotechnology research). Indeed, at least some evidence suggests that the availability of this newer incentive distorts the traditional incentives in undesirable ways. See id. at 420; Eisenberg, supra, at 198-206 (discussing a controversy over the Journal of Biological Chemistry's policy requiring authors to make available to other researchers any biological materials referred to in published materials and their application to commercial biologists).

506. See Annas, supra note 6, at 22.
507. Cf. Procreative Liberty, supra note 406, at 982 (stating that scientists are hesitant to undertake embryo research because of controversy and public disapproval).
directly or indirectly increase the activity that is of true concern to patenting opponents. In the case of embryo patents, unlike that of animal patents, the benefits that might counter such concerns appear dubious or wildly controversial.

The inchoate and nebulous form of such doubts and controversies are likely to make their resolution difficult. Considering these concerns as a type of “nonuse cost” of patenting human embryos gives them form, allowing all concerned to view them plainly and discuss them more openly. Although precise valuation would be fraught with difficulties, the costs designated here as “nonuse” costs must nonetheless be factored into any discussion of an economic incentive to encourage human germline manipulations. In such discussions of policy, the ultimate question is not the array of possible outcomes, or even the risk associated with a particular outcome, but how society as a whole values a given outcome.

508. See Hoffmaster, supra note 6, at 3.