

## PATENTING THE MINOTAUR

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### INTRODUCTION

[1] Half man, half bull, the Minotaur was the most fearsome monster in Greek mythology. Human torso and bull's head, its horns were sharp as knives, its great hooves could kick the life out the strongest of heroes, and its food was human flesh. Yet under the surface, the Minotaur's myth was sad; his insatiable existence originated in jealousy and lust.

[2] The myth of the Minotaur can be used as a mirror for the modern life, in which fiction and reality are rapidly converging, as humans develop the knowledge to create hybrid humanoid creatures. This article uses the possibility of the creation of a Minotaur as a backdrop to revisit and analyze the rationales for the current patent policy on biotechnological inventions that transcend the human-animal barrier.<sup>1</sup> The objectives of this article are to (i) discuss the possibility of creating a human-animal chimera,<sup>2</sup> (ii) shed light on the current law regulating patentability of chimeras, (iii) consider important issues external to law, and (iv) address the question of who should decide the patentability of the Minotaur.

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<sup>1</sup> See, e.g., Oliver Brustle et al., *Chimeric Brains Generated by Intraventricular Transplantation of Fetal Human Brain Cells into Embryonic Rats*, 16 NATURE BIOTECH. 1040 (1998) (engrafting of human embryonic stem cells onto rat brains).

<sup>2</sup> Chimera is "an organism composed of two or more genetically distinct tissues . . . or an artificially produced individual having tissues of several species." RANDOM HOUSE UNABRIDGED DICTIONARY 359 (2d ed. 1993).

[3] It is not surprising that biotechnology discoveries dominate much of the contemporary discussion about patent law. Biotechnology is central to the current debate because the biotech industry is extremely patent-dependent<sup>3</sup> and has exposed fundamental uncertainties that plague the theory and principles of patent protection. Biotech patenting is a forum in which deeper questions regarding patent policy are being played out.<sup>4</sup> That those questions are still far from being resolved underscores the implausibility of securing consensus on matters of substantive patent law in the near future.

[4] Recent advances in genetics and other areas of biology have increased the fear and controversy over the effects of research with genetically modified organisms.<sup>5</sup> Groups opposed to transgenic research have advanced various areas of concern. These groups have chiefly attacked the prospect of cloning humans; at times, they have also opposed the production and patenting of transgenic animals.<sup>6</sup>

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<sup>3</sup> Josh Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & ECON. 463, 472 (1995).

<sup>4</sup> See Verbatim Transcript of Comm. on Intellectual Prop. in Genomic and Protein Research Innovation, National Academy of Sciences (Feb. 27, 2004) (transcript on file with National Academies), [http://www7.nationalacademies.org/step/Genomics\\_Committee\\_Meeting\\_1\\_transcript.pdf](http://www7.nationalacademies.org/step/Genomics_Committee_Meeting_1_transcript.pdf) (discussing the tasks of this recently established committee which include the review of patenting and licensing of human genetic material and proteins).

<sup>5</sup> See generally PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY (2002), available at <http://www.bioethics.gov/reports/cloningreport/>; U.S. CONG., OFFICE OF TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE-SPECIAL REPORT (1989), available at [http://www.wws.princeton.edu/ota/ns20/year\\_f.html](http://www.wws.princeton.edu/ota/ns20/year_f.html); U.S. CONG., OFFICE OF TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUE AND CELLS-SPECIAL REPORT (1987), available at [http://www.wws.princeton.edu/ota/ns20/year\\_f.html](http://www.wws.princeton.edu/ota/ns20/year_f.html); Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (July 20, 2002), [http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication\\_310.html](http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication_310.html); Nuffield Council on Bioethics, *Animal-to-Human Transplants: The Ethics of Xenotransplantation* (Mar. 1, 1996), [http://www.nuffieldbioethics.org/go/ourwork/xenotransplantations/publication\\_299.html](http://www.nuffieldbioethics.org/go/ourwork/xenotransplantations/publication_299.html); Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (Apr. 1, 1995), [http://www.nuffieldbioethics.org/go/ourwork/humantissue/publication\\_298.html](http://www.nuffieldbioethics.org/go/ourwork/humantissue/publication_298.html).

<sup>6</sup> See *Transgenic Animal Patent Reform Act of 1989: Hearing on H.R. 1556 Before the Subcomm. on Courts, Intellectual Property and the Admin. of Justice of the H. Comm. on the Judiciary*, 101st Cong. 110-18 (1989) (statement of John A. Hoyt, President, Humane

[5] In the United States, human-animal chimeras are not statutorily excluded from patentability, but the Patent and Trademark Office (PTO) has announced that it will not issue patents for such creations.<sup>7</sup> Although the basis for this exclusion is unclear, it has been suggested that it derives from the Thirteenth Amendment of the United States Constitution.<sup>8</sup> In the European Union (E.U.), the exclusion of human-related materials from patentability has a statutory basis in the European Patent Commission (EPC) pursuant to the incorporation of Directive 98/44, which determines that the human body, in its various stages of development, is not patentable.<sup>9</sup> In the E.U., patents cannot issue for human cloning

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Society of the United States) (expressing concern that granting of animal patents will present society with new animal health and welfare problems, and declaring the Humane Society's support for the enactment of the moratorium); *id.* at 124-33 (statement of Dr. Michael W. Fox, Vice President/Bioethics and Farm Animals Division, Humane Society of the United States) (describing physiological abnormalities that transgenic animals have displayed); *id.* at 237 (statement of Dr. Margaret Mellon, Director, National Biotechnology Center, National Wildlife Federation) (declaring NWF support for the moratorium until federal regulatory system is implemented); *id.* at 266 (statement of Andrew Kimbrell, Policy Director, Foundation on Economic Trends, on behalf of the Coalition on Animal Patenting) (declaring that the organization, which includes seventeen animal protection groups and twenty six religious leaders, supports the legislative moratorium on animal patenting); Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 411 (1988) (outlining religious objections to transgenic animal patents, including (1) objectification and exploitation of animal life; and (2) destruction of species integrity); David Manspeizer, Note, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417, 437-40 (1991) (describing religious concerns about transgenic animal patents as “[m]an is playing God,” and expressing concern that animal patenting will lead to patenting of genetically altered human beings); *see also* Darrell G. Dotson, Comment, *The European Controversy Over Genetic-Engineering Patents*, 19 HOUS. J. INT’L L. 919, 943-44 (1997) (quoting *EP Greens Launch a Campaign Against the Draft EEC Directive on Patenting Biotechnological Inventions*, REUTERS, Jan. 25, 1992).

<sup>7</sup> See Donald J. Quigg, Statement by Assistant Secretary and Commissioner of Patents and Trademarks, *Patent and Trademark Office Notice: Animals-Patentability*, 1077 O.G. TM 24 (1987).

<sup>8</sup> U.S. CONST. amend. XIII, § 1; Rachel E. Fishman, *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J.L. & MED. 461, 472-80 (1989) (rejecting this ground for exclusion, as the thirteenth amendment prohibits human servitude, not a right to combine human and animal genes); *see* Quigg, *supra* note 8.

<sup>9</sup> Council Directive 98/44, ¶ 38, 1998 O.J. (L 213) 13,16 (EC), *available at* [http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l\\_213/l\\_21319980730en00130021.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf).

“[P]rocesses, the use of which offend against human dignity, such as processes to

processes, or processes for modifying the germ line identity of human beings. In addition, uses of embryos for industrial or commercial application are unpatentable.<sup>10</sup>

[6] The patent regimes of both the United States and the European Union contain uncertainties in their terminology. In the United States, neither the PTO nor the judicial system has determined what constitutes a “human” and what constitutes an “animal.” Although the unpatentable inventions that relate to human beings are somewhat specified in European patent law,<sup>11</sup> their definitions still remain unclear. The EPC does not give a definition for what constitutes a “human being” and what constitutes an “animal.” Some scholars have argued that the generation of clear definitions of these materials and processes is of paramount importance.<sup>12</sup> However, in view of the rapidly advancing biotechnological research and innovations, perhaps a more productive approach would be to generate rules or standards for determining which organisms should and should not be patentable. As biotechnology rapidly advances, it is plausible that the definitions could become outdated and inaccurate in the near future.

[7] Opponents of patenting human-animal chimeras have raised a litany of criticisms ranging from philosophical objections to property rights, to fictional organismal horrors. Many concerns elicit a worst-case scenario of the perceived risks of biotechnological advances. Such concerns are often based on premonitions. Because many of the original risks that opponents of biotechnology foresaw have not eventuated over the past 20 years, the opponents now bear the procedural burden of proving danger from experimentation, rather than requiring the proponents of biotechnology research to prove safety.<sup>13</sup> The most passionate arguments

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produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability.” *Id.*

<sup>10</sup> *Id.* at ¶ 42.

<sup>11</sup> *Id.* at art. 5-6.

<sup>12</sup> Fishman, *supra* note 8, at 477-80; see Philippe Ducor, *The Legal Status of Human Materials*, 44 *DRAKE L. REV.* 195, 259 (1996).

<sup>13</sup> President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Splicing Life: The Social and Ethical Issues of Genetic Engineering with Human Beings*, at 12-13 (1982), *available at* <http://www.georgetown.edu/research/nrcbl/documents/pcemr/splicinglife.pdf>; see Andy Coghlan, *Landmark Report Aims to Lay Frankenfood Scares to Rest*, 179 *NEW SCIENTIST* 6 (2003).

against genetic engineering have been based upon moral, ethical, and philosophical grounds. Being based on personal beliefs, they have proven difficult to resolve through legislative and judicial pronouncements.<sup>14</sup>

[8] Congress created the patent system to promote technological research and innovation for the benefit of society. The United States patent system hinges on a principle of neutrality, whereby the system neither supports nor discriminates against technologies.<sup>15</sup> Hence, patents for chimeras should not be prohibited simply because they may entail risk. Any perceived risks could adequately be addressed through regulatory vehicles, such as research regulation.

[9] Potential dangers found in the invention should not be an obstacle to granting patents on life forms. Patent law is predicated on the concept that technological advances are for public good.<sup>16</sup> On one occasion in the past, the legislature has excluded a form of otherwise patentable subject matter.<sup>17</sup> However, analogies between that legislation, motivated by national security, and the speculative risks of transgenic research remain dubious.<sup>18</sup>

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<sup>14</sup> See Michael E. Sellers, *Patenting Nonnaturally Occurring, Man-Made Life: A Practical Look at the Economic, Environmental, and Ethical Challenges Facing Animal Patents*, 47 ARK. L. REV. 269, 290-91 (1994).

<sup>15</sup> *Transgenic Animal Patent Reform Act of 1989: Hearing on H.R. 1556 Before the Subcomm. on Courts, Intellectual Property and the Admin. of Justice of the H. Comm. on the Judiciary*, 101st Cong. 96 (1989) (statement of Donald S. Chisum, Professor, University of Washington School of Law) (emphasizing that the patent system is objective, and that it does not promote any one technology or industry); see Reagen A. Kulseth, *Biotechnology and Animal Patents: When Someone Builds a Better Mouse*, 32 ARIZ. L. REV. 691, 710 (1990) (maintaining that the patent system should remain ethically neutral); see also *Patents and the Constitution: Transgenic Animals: Hearing Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 100th Cong. 182 (1987) (testimony of Robert P. Merges, Professor, Columbia School of Law) (arguing that patent system is not correct forum for weighing technologies).

<sup>16</sup> Dresser, *supra* note 6, at 404.

<sup>17</sup> In 1954, Congress enacted a prohibition on the patenting of nuclear weapons technology. 42 U.S.C. § 2181(a) (2003).

<sup>18</sup> See Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1067 (1988) (distinguishing Congress' reason for placing prohibition on nuclear weapons technology from the rationale to enact similar prohibition against biotechnological innovations).

[10] Biotechnology has changed our understanding of ourselves, nature, and of our place in nature. Biotechnology carries risks, while helping us harness life and offering hope for life's improvement. It promises to profoundly change lives, both human and non-human. As this Article will highlight, there is a need for a more thoughtful conceptualization of biotechnology, and for more careful control over its development, use, and legal protection.

#### FEASIBILITY STUDY

[11] Before embarking onto a purely academic discourse, it is prudent to examine the current state of science and evaluate the degree of concern regarding our capability for creation of human-animal chimeras. Simply stated, our current command of genetic engineering might be insufficient for creation of such organismal hybrids. If the prospects for creating human-animal chimeras are distant enough (whatever that might mean), then perhaps the most prudent decision will be to endow the future generations with the difficult decision-making on the regulation of patenting such creatures.

[12] Chimeras have been with us for some time, and not only in Greek mythology.<sup>19</sup> Prior to the times when the tools of molecular biology became available, humans began creating chimeras through xenotransplantation, transplanting organs from one species into another (including themselves).

[13] The first documented heterologous bone graft was performed in 1668, when the Dutch surgeon Dr. Job van Meekeren used a bone graft from a dog's skull to repair a defect in a human cranium.<sup>20</sup> In 1905, the

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<sup>19</sup> In Greek mythology, chimera (Greek Χίμαιρα) was one of the offspring of Typhon and Echidna. Although descriptions vary, most frequently the chimera was depicted with the body of a goat, the hindquarters of a snake or dragon and the head of a lion. Chimera's offspring by Orthros were the Sphinx and the Nemean Lion. Wikipedia, [http://en.wikipedia.org/wiki/Main\\_Page](http://en.wikipedia.org/wiki/Main_Page), (search for "Chimera (creature)"); see also EDITH HAMILTON, MYTHOLOGY 137 (1942) (providing a description of Chimera as well as the story of Chimera's death).

<sup>20</sup> Barend Haeseker, *Van Meekeren and His Account of the Transplant of Bone from a Dog into the Skull of a Soldier*, 88 PLASTIC & RECONSTRUCTIVE SURGERY 173, 173-74 (1991).

French surgeon Dr. M. Princeteau grafted pieces of a rabbit kidney into a 16-year-old patient with kidney failure.<sup>21</sup> In 1920, monkey testicles were transplanted into humans for the first time.<sup>22</sup> Notwithstanding the wisdom of such procedures, hundreds of men were reported to have received testicles transplanted from primates.<sup>23</sup>

[14] Other examples of xenotransplants include renal transplantation from baboon to man.<sup>24</sup> A highly debated transplant of baboon bone marrow into an AIDS patient took place in 1995.<sup>25</sup> Clinicians regard pigs, however, as a preferred donor for xenotransplants, largely because they tend to be healthier and reproduce faster than primates.<sup>26</sup> Pig fetal brain cells have been transplanted into patients with Parkinson's disease and with Huntington's disease.<sup>27</sup> In general, clinical xenotransplantation of organs may become a widely accepted procedure.<sup>28</sup>

[15] Recent advances in genetic engineering have enabled researchers to more skillfully and precisely perform interspecies transplantations of cells, tissues, and organs. Molecular biologists created animal-animal chimeras

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<sup>21</sup> David M. Hume, *Early Experiences in Organ Homotransplantation in Man and the Unexpected Sequelae Thereof*, 137 AM. J. SURGERY 152, 153 (1979).

<sup>22</sup> In 1920, Dr. Serge Voronoff began transplanting monkey testicles into aging men. John E. Morley & Horace M. Perry III, *Androgen Deficiency in Aging Men: Role of Testosterone Replacement Therapy*, 135 J. LAB. & CLINICAL MED. 370, 370-71 (2000).

<sup>23</sup> Thierry Gillyboeuf, *The Famous Doctor Who Inserts Monkeyglands in Millionaires*, 9 SPRING 44, 45 (2000).

<sup>24</sup> See generally T.E. Starzl et al., *Renal Heterotransplantation from Baboon to Man: Experience With 6 Cases*, 2 TRANSPLANTATION 752 (1964).

<sup>25</sup> Sally Lehrman, *AIDS Patient Given Baboon Bone Marrow*, 378 NATURE 756, 756 (1995).

<sup>26</sup> Traci J. Hoffman, *Organ Donor Laws in the U.S. and the U.K.: The Need for Reform and the Promise of Xenotransplantation*, 10 IND. INT'L & COMP. L. REV. 339, 370 (2000); see Anthony Dorling et al., *Clinical Xenotransplantation of Solid Organs*, 349 LANCET 867, 868 (1997).

<sup>27</sup> J.S. Fink et al., *Porcine Xenografts in Parkinson's Disease and Huntington's Disease Patients: Preliminary Results*, 9 CELL TRANSPLANT 273-278 (2000); see generally Oliver Brüstle & Ronald DG McKay, *Neuronal Progenitors as Tools for Cell Replacement in the Nervous System*, 6 CURRENT OPINION IN NEUROBIOLOGY 688 (1996).

<sup>28</sup> See Dorling, *supra* note 26, at 867; see generally Stanley W. Jacob et al., *Transplantation of Tissues*, 98 AM. J. SURGERY 55 (1959) (surgical review article).

in the mid-1980s.<sup>29</sup> In 1988, elements of the human immune system were imported into mice.<sup>30</sup> It is now possible to transplant embryonic stem cells from pigs into humans to grow new organs.<sup>31</sup> Embryonic stem cells have been created by nuclear transfer of human somatic nuclei into rabbit oocytes.<sup>32</sup> Researchers used a human-sheep xenograft model to determine “whether long-term engrafting haematopoietic stem cells (HSC) are susceptible to human cytomegalovirus (HCMV) infection.”<sup>33</sup> These examples illustrate the extent to which humans have been proactively involved in creating human-animal chimeras over centuries.

[16] There is no doubt that the techniques that enable genetic engineering of human-animal chimeras are already in place or are being developed. In 2004, for example, British scientists received permission to clone human embryos for medical research.<sup>34</sup> Notwithstanding the political controversies and regulations on cloning and stem cell research that vary around the world, chances are that in your lifetime, dear reader, humans

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<sup>29</sup> See Carole B. Fehilly et al., *Interspecific Chimaerism Between Sheep and Goat*, 307 NATURE 634 (1984) (describing how researchers in Cambridge created a “geep,” an animal that was part goat and part sheep, by allowing a pair of sheep and a pair of goats to mate naturally, and manipulating the embryos obtained); see also Sabine Meinecke-Tillmann, *Experimental Chimaeras - Removal of Reproductive Barrier Between Sheep and Goat*, 307 NATURE 637, 637 (1984).

<sup>30</sup> See Alberto Gobbi et al., *Human Herpesvirus 6 Causes Severe Thymocyte Depletion in SCID-hu Thy/Liv Mice*, 189 J. EXP. MED. 1953 (1999); D.E. Mossier et al., *Resistance to Human Immunodeficiency Virus 1 Infection of SCID Mice Reconstituted with Peripheral Blood Leukocytes from Donors Vaccinated with Caccinia gp160 and Recombinant gp160*, 90 PROC. NAT'L ACAD. SCI. 2443–47 (1993).

<sup>31</sup> Smadar Eventov-Friedman et al., *Embryonic Pig Liver, Pancreas, and Lung As a Source for Transplantation: Optimal Organogenesis Without Teratoma Depends on Distinct Time Windows*, 102 PROC. NAT'L ACAD. SCI. 2928, 2928 (2005), available at <http://www.pnas.org/cgi/content/abstract/102/8/2928>.

<sup>32</sup> Ying Chen et al., *Embryonic Stem Cells Generated by Nuclear Transfer of Human Somatic Nuclei into Rabbit Oocytes*, 13 CELL RESEARCH 251, 251 (2003), available at <http://www.cell-research.com/20034/251.htm>.

<sup>33</sup> Kirsten B. Crapnell et al., *Human Haematopoietic Stem Cells that Mediate Long-Term In Vivo Engraftment Are Not Susceptible to Infection by Human Cytomegalovirus*, 124 BRIT. J. HAEMATOLOGY 676, 676 (2004).

<sup>34</sup> Human Fertilisation & Embryology Authority, HFEA Grants the First Therapeutic Cloning Licence for Research (Aug. 11, 2004), <http://www.hfea.gov.uk/PressOffice/Archive/1092233888>. The Human Fertilization and Embryology Authority (HFEA) allowed researchers at the Newcastle Centre for Life to create embryos as a source of stem cells to cure diseases.



will possess the knowledge and the skill to create a Minotaur *in vitro*. That proposition also represents the salvation of this article.

A BRIEF INTRODUCTION TO PATENT LAW AND PATENTING OF LIFE FORMS

[17] Few restrictions on patenting living organisms exist in the United States. United States patents on eukaryotes have been issued since 1873.<sup>35</sup> In 1980, the Supreme Court reaffirmed that “anything under the sun that is made by man” is patentable subject matter, including living organisms.<sup>36</sup> The landmark *Diamond v. Chakrabarty* decision boosted the investment into, and the progress of, biotechnology research. Five years later, the *Chakrabarty* principle was extended to non-naturally occurring, man-made plants, which were deemed patentable under 35 USC § 101.<sup>37</sup> In 1987, in *Ex Parte Allen*, multicellular animals (oysters) were found to be patentable subject matter.<sup>38</sup> Upholding the *Chakrabarty* mantra, the Supreme Court recently reaffirmed that created organisms such as newly developed plant breeds are patentable subject matter.<sup>39</sup>

[18] Although human organisms have not been patented in the United States, human material, including cells, is routinely patented.<sup>40</sup> It is interesting to observe the evolution of achievements in genetic engineering and the concomitant grant of patents for cellular, tissue, and

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<sup>35</sup> Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 447 (1999). In 1873, Louis Pasteur was granted a patent to a purified form of yeast. Improvement in the Manufacture of Beer and Yeast, U.S. Patent No. 141,072 (filed May 9, 1873) (issued July 22, 1873); Magnani, *supra* note 36, at 447.

<sup>36</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 313 (1980). *Chakrabarty*'s application consisted of claims on the method of producing bacteria, on the bacteria themselves, and on the process of using the bacteria to digest oil spills. *Id.* at 305-06; *see* Magnani, *supra* note 36, at 447. In the end, all three types of claims were allowed. *Chakrabarty*, 447 U.S. at 305-06, 318; *see* Magnani, *supra* note 36, at 447. The Court reasoned that Congress, in passing 35 USC § 101, did not distinguish between inanimate objects and living things as to patentable subject matter. *Chakrabarty*, 447 U.S. at 313.

<sup>37</sup> *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 447 (B.P.A.I. 1985).

<sup>38</sup> *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1425-26 (B.P.A.I. 1987). Despite holding that multicellular animals were patentable, the Board rejected the *Allen* declaration on grounds of obviousness due to a previous publication. *See id.* at 1427.

<sup>39</sup> *J.E.M. Agric. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 127 (2001).

<sup>40</sup> *See, e.g., Moore v. Regents of the University of California*, 793 P.2d 479, 481-82 (Cal. 1990); George J. Annas, *Outrageous Fortune: Selling Other People's Cells*, 20 HASTINGS CENTER REP., Nov./Dec. 1990, at 36, 36-39.

organismal chimeras. Patents on molecular chimeras were acquired in the 1980's, as biotechnology continued to advance.<sup>41</sup> Two decades later, the level of sophistication in genetic engineering has increased, and consequently so has the scope of allowed patent claims.<sup>42</sup> A multitude of patents have now been granted for compositions and methods that encompass various types of eukaryotic molecules, cells, and tissues; some of these are of human origin.<sup>43</sup> The allowance of such patent claims reflects our acceptance of the presence of some human cells in an animal (and conversely, the presence of some non-human cells in a human).<sup>44</sup> What might give us pause would perhaps be visible phenotypical

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<sup>41</sup> Process for Producing Biologically Functional Molecular Chimeras, U.S. Patent No. 4,237,224 (filed Jan. 4, 1979) (issued Dec. 2, 1980) (covering a method and compositions for replication and expression of exogenous genes in microorganisms, including plasmid chimeras); *see, e.g.*, Processes for Inserting DNA Into Eucaryotic Cells and for Producing Proteinaceous Materials, U.S. Patent No. 4,399,216 (filed Feb. 25, 1980) (issued Aug. 16, 1983) (claiming a process for inserting foreign DNA into a eucaryotic cell, such that foreign DNA becomes incorporated into the chromosomal DNA of said eucaryotic cell).

<sup>42</sup> *See, e.g.*, Chimeric Viral Proteins, U.S. Patent No. 6,436,648 (filed Mar. 26, 2001) (issued Aug. 20, 2002) (claiming nucleic acid constructs coding for chimeric viral proteins); Human Protease Molecules, U.S. Patent No. 6,855,811 (filed Sept. 26, 2001) (issued Feb. 15, 2005) (claiming chimeric antibodies).

<sup>43</sup> *See, e.g.*, In Vivo Use of Human Bone Marrow for Investigation and Production, U.S. Patent No. 5,633,426 (filed Feb. 10, 1994) (issued May 27, 1997) (claiming that "chimeric immunocompromised hosts are provided, comprising human bone marrow of at least [four] weeks from the time of implantation"); *see also* Mice Models of Human Prostate Cancer Progression, U.S. Patent No. 6,107,540 (filed Oct. 15, 1997) (issued Aug. 22, 2000) (claiming to produce an immune deficient mouse containing a human prostate xenograft of locally advanced or metastatic prostate cancer); Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988) (claiming to produce the famous Harvard "oncomouse," containing an activated oncogene sequence); Calcification Mitigation of Bioprosthetic Implants, U.S. Patent No. 5,002,566 (filed Apr. 18, 1989) (issued Mar. 26, 1991) (claiming to produce bioprosthetic implants made from tanned biological materials, such as porcine heart valves and bovine pericardium); Transgenic Non-Human Mammals Expressing Human Coagulation Factor VIII and Von Willebrand Factor, U.S. Patent No. 6,518,482 (filed May 7, 2001) (issued Feb. 11, 2003); Transgenic Mouse Expressing a Polynucleotide Encoding a Human Ataxin-2 Polypeptide, U.S. Patent No. 6,515,197 (filed Aug. 24, 2000) (issued Feb. 4, 2003); Transgenic Mice Expressing Mutant Human APP and Forming Congo Red Staining Plaques, U.S. Patent No. 6,509,515 (filed Mar. 2, 1999) (issued Jan. 21, 2003) (claiming mice expressing Alzheimer amyloid precursor proteins (APP)).

<sup>44</sup> Pig heart valves are now routinely transplanted into people with heart disease; ask Jesse Helms.

characteristics that transcend the interspecies boundary. A bull's head on a human torso would certainly raise a few eyebrows.

[19] To erase any doubt on the controversial subject of patenting life, the PTO issued a statement after *Allen*, clarifying that it considered “nonnaturally occurring nonhuman multicellular organisms, including animals, to be patentable subject matter.”<sup>45</sup> At the same time, the PTO excluded humans from patentability on the grounds that “[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.”<sup>46</sup> Remarkably, the PTO Commissioner did not specify the precise language in the Constitution that prohibits patenting human beings, but some believe that he was referring to the Thirteenth Amendment<sup>47</sup> ban on human slavery.<sup>48</sup>

[20] At the time, the basis for precluding patents on humans was overshadowed by the immediate concerns of whether the scientifically possible transgenic animals should become patentable.<sup>49</sup> In 1988, the PTO issued the first patent for a transgenic mammal containing heterologous DNA.<sup>50</sup> The patent was for the famous Harvard oncomouse, which contains a human gene that makes it predisposed to breast cancer.<sup>51</sup>

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<sup>45</sup> Magnani, *supra* note 35, at 448.

<sup>46</sup> *Id.*

<sup>47</sup> U.S. CONST. amend. XIII, § 1.

<sup>48</sup> Magnani, *supra* note 36, at 448; *see, e.g.*, Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1647-49 (1993); Kevin D. DeBre', *Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?*, 16 HASTINGS CONST. L.Q. 221, 229-33 (1989); Fishman, *supra* note 8, at 462; Jasmine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 230-31 (2002).

<sup>49</sup> Indeed, the first transgenic animal patent issued explicitly excluded humans from its claims. *Transgenic Non-Human Mammals*, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued April 12, 1988).

<sup>50</sup> *See* Keith Schneider, *Harvard Gets Mouse Patent, a World First*, N. Y. TIMES, Apr. 12, 1988, at A1. For a discussion of the implications of this invention on biotechnology patents, *see generally* Carrie F. Walter, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025 (1998).

<sup>51</sup> Magnani, *supra* note 35, at 448; *see also* Mark Dowie, *Gods and Monsters*, MOTHER JONES, Jan./Feb. 2004, at 49, *available at*

The PTO continues to issue patents on animals and on human cells lines. In a publicized case, a patent on a human cell line was obtained by physicians of the University of California at Los Angeles for a cell line made from T-lymphocytes, which they isolated from their patient John Moore while treating him for leukemia.<sup>52</sup>

[21] In 1998, Stuart Newman and Jeremy Rifkin filed a provocative patent application with the United States Patent and Trademark Office.<sup>53</sup> The application disclosed constructive reduction to practice<sup>54</sup> of human-animal chimeras that could be up to fifty percent human.<sup>55</sup> Newman and Rifkin filed the chimera patent in an attempt to raise awareness of this looming question in patent law, to prevent other scientists from creating human-animal chimeras for two decades, and to pressure policymakers into at least developing a set of formal rules regarding the patenting of life forms.<sup>56</sup>

[22] Molecular biologists possess the ability to create animal-animal chimeras.<sup>57</sup> A famous such example is the “geep,” an animal that was part goat and part sheep, created by allowing a pair of sheep and a pair of goats to mate naturally, and manipulating the embryos obtained; the two fused embryos began to grow and divide as one embryo.<sup>58</sup> The Newman-Rifkin

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[http://www.motherjones.com/news/feature/2004/01/12\\_401.html](http://www.motherjones.com/news/feature/2004/01/12_401.html); Schneider, *supra* note 51, at A1.

<sup>52</sup> See *Moore v. Regents of the Univ. of Cal.*, 51 Cal.3d 120, 124-27 (Cal. 1990) (en banc); see also Sharon Schmickle, *Patents Stir Debate Over Rights to Life*, PITTSBURGH POST-GAZETTE, Aug. 3, 1998, at A7.

<sup>53</sup> Dowie, *supra* note 52.

<sup>54</sup> Under U.S. Patent Law, an invention does not have to be built, created (“actually reduced to practice”); it is enough if the enabling disclosure allows one skilled in the art to create the claimed invention (“constructive reduction to practice”). See USPTO, *Reduction to Practice*, [http://www.uspto.gov/web/offices/pac/mpep/documents/2100\\_2138\\_05.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2138_05.htm) (last visited Nov. 5, 2005).

<sup>55</sup> See Rick Weiss, *Patent Sought on Making of Part-Human Creatures*, WASH. POST, Apr. 2, 1998, at A12.

<sup>56</sup> *Id.*

<sup>57</sup> Magnani, *supra* note 35, at 445; see Dowie, *supra* note 52; Emma Young, *Rare Clone Dies*, NEW SCIENTIST, Jan. 12, 2001, at 4-5 (discussing the cloning of an ox using a cow egg).

<sup>58</sup> Magnani, *supra* note 35, at 445-46; see Fehilly et al., *supra* note 30; Meinecke-Tillmann, *supra* note 29.

patent application<sup>59</sup> contained three procedures for producing human-animal chimeras, one of which is similar to the procedure used to create the “geep.”<sup>60</sup> Arguably, a human-animal chimaeric creature could be created through combining a human embryo with that of an animal closely related to human beings, e.g., with a non-human primate.<sup>61</sup> The Newman-Rifkin patent application cited the possibility of chimeras made from mice, chimpanzees, baboons, and pigs.<sup>62</sup>

[23] The Newman-Rifkin application succeeded both in stirring up a lively public debate on patentability of life forms, and in prompting a policy response from the PTO.<sup>63</sup> Presented with a serious legal and political quandary, the PTO rejected the human-animal chimera patent application in June of 1999, in part because the invention “embraces” a human being and is, therefore, unpatentable on the longstanding policy of the PTO that human beings are not patentable.<sup>64</sup> However, the PTO did not specify in the holding why animals containing human genetic material do not embrace a human being.<sup>65</sup> The holding that a being that is fifty percent human is too human to be patentable appeared to be, in part, a rejection of a patent based on (moral) utility grounds.<sup>66</sup>

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<sup>59</sup> A significant amount of ink was spent discussing this patent application. See Weiss, *supra* note 56, at A12; David Dickson, *Legal Fight Looms Over Patent Bid on Human-animal Chimeras*, 392 NATURE 423, 423-24 (1998); “Morality” *Aspect of Utility Requirement Can Bar Patent for Part-Human Inventions*, 55 PAT. TRADEMARK & COPYRIGHT J. 555 (1998); *Patent Application is Disallowed as “Embracing” Human Being*, 58 PAT. TRADEMARK & COPYRIGHT J. 203 (1999).

<sup>60</sup> Magnani, *supra* note 35, at 446; see Dowie, *supra* note 51.

<sup>61</sup> Magnani, *supra* note 35, at 446.

<sup>62</sup> *Id.* at 446-47.

<sup>63</sup> This provocative subject has received renewed interest in the popular press. See *id.*

<sup>64</sup> Rick Weiss, *U.S. Ruling Aids Opponent of Patents for Life Forms*, WASH. POST, June 17, 1999, at A2 (quoting the PTO ruling).

<sup>65</sup> *Id.*

<sup>66</sup> For a discussion on the morality component of the utility requirement for patentability, see generally *Lowell v. Lewis*, 15 F. Cas. 1018 (D. Mass. 1817) (No. 8568). More recently, the PTO has contemplated using a morality interpretation of the utility requirement in order to justify its rejection of patent applications for human-animal chimeras. See “Morality” *Aspect of Utility Requirement Can Bar Patent for Part-Human Inventions*, 55 PAT. TRADEMARK & COPYRIGHT J. 555, 556 (1998); see also U.S. Patent and Trademark Office, *Facts on Patenting Life Forms Having a Relationship to Humans*, Apr. 1, 1998, <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>.

[24] While the *Chakrabarty* court determined the patentability of bacteria, nothing in its opinion indicated that human-based inventions are to be excluded from patent protection.<sup>67</sup> Thus, the PTO could use no precedent, and wrongly responded to the Newman-Rifkin application with dicta from an outdated common-law case.<sup>68</sup> The PTO's glib announcement that inventions involving humans do not meet the standards for patentability under 35 U.S.C. § 101 was not supported by the Patent Act; it was simply a unilateral reinterpretation of the law.

[25] The denial of the Newman-Rifkin patent application arrived with a final Office action in August of 2004, rejecting all the claims.<sup>69</sup> From the applicants' point of view, perhaps the most victorious aspect of the Office action was the rejection under 35 U.S.C. § 101 as non-statutory subject matter.<sup>70</sup> The PTO disagreed with the applicants' position that humans are patentable subject matter.<sup>71</sup> The PTO examiner pointed out that, although § 101 does not explicitly restrict the patentability of humans, the PTO believes that its policy of denying such patents is supported by the statute.<sup>72</sup> It should be noted that this PTO's decision does not create a legal precedent; courts have not yet decided the issue of patentability of human-animal chimeras.

[26] Because mammal-mammal chimeras have already been produced, it is questionable whether the creation of a human-animal chimera will be considered novel or nonobvious over the prior art.<sup>73</sup> If a Minotaur is successfully created, a legal void will be opened.<sup>74</sup> Patent claims could be

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<sup>67</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980).

<sup>68</sup> *Lowell v. Lewis*, 15 F. Cas. 1018 (D. Mass. 1817) (No. 8568).

<sup>69</sup> United States Patent and Trademark Office, Final Rejection (Aug. 2, 2004), [http://portal.uspto.gov/external/portal/!ut/p/\\_s.7\\_0\\_A/7\\_0\\_CH/.cmd/ad/.ar/sa.getBib/c/6\\_0\\_69/.ce/7\\_0\\_1ET/p/5\\_0\\_18L/d/1?selectedTab=ifwtab&isSubmitted=isSubmitted&do\\_snum=08993564#7\\_0\\_1ET](http://portal.uspto.gov/external/portal/!ut/p/_s.7_0_A/7_0_CH/.cmd/ad/.ar/sa.getBib/c/6_0_69/.ce/7_0_1ET/p/5_0_18L/d/1?selectedTab=ifwtab&isSubmitted=isSubmitted&do_snum=08993564#7_0_1ET) (enter application number 08/993,564 and click "submit," then click on "Final Rejection" in the resulting document list).

<sup>70</sup> *Id.* at 19-22.

<sup>71</sup> *Id.* at 20.

<sup>72</sup> *See id.* at 21.

<sup>73</sup> This article assumes that the patent application on the Minotaur is technically sound and will satisfy the novelty and nonobviousness requirements for patentability of sections 101, and 102, and 103 of the Patent Act. 35 U.S.C. §§ 101-103 (2000).

<sup>74</sup> The issue of human cloning in order to help infertile couples has already garnered much public reaction. The White House has suggested that an outright ban could be

filed both for the product (Minotaur), and for the process of producing a chimaeric creature. The Minotaur could be deemed a person with full legal rights akin to a naturally born individual. Alternatively, the Minotaur could be viewed as fully proprietary in that its existence would be subject to its creator's wishes along the same lines as transgenic animals. Finally, the creator could possess a proprietary interest in the process of creation itself, but would not possess a right in the Minotaur. These options are not mutually exclusive, and the result would be influenced by a statutory regime dealing with the Minotaur's offspring.<sup>75</sup>

[27] It is easier to envisage obtaining a patent on the method (rather than the product) of creating a Minotaur. Indeed, the PTO has already allowed patentability of a process claim that might arguably be interpreted as covering a method for the creation of human-animal chimeras. In 2001, the University of Missouri received a patent on a technique for cloning mammals and subsequently licensed the patent to the xenotransplantation company Biotransplant.<sup>76</sup> Even though the '429 patent specifically

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instituted. However, this is counterproductive to a proper regulatory regime because industry will simply move elsewhere, unless a global ban on human cloning is instituted. See Lisa Krieger, *Ethicists Disagree on Cloning Regulations*, PLAIN DEALER, Jan. 9, 1998, at 8A.

<sup>75</sup> Significant legal scholarship on this question exists. See, e.g., Rochelle Cooper Dreyfuss & Dorothy Nelkin, *The Jurisprudence of Genetics*, 45 VAND. L. REV. 313 (1992).

<sup>76</sup> Complete Oocyte Activation Using an Oocyte-Modifying Agent and a Reducing Agent, U.S. Patent No. 6,211,429 (filed June 18, 1998) (issued April 3, 2001).

A method for producing a cloned mammal, comprising: (a) isolating a membrane-bounded nucleus from a cell of said mammal; (b) removing the nuclear chromosomal material from an unfertilized recipient mammalian oocyte, thereby preparing an enucleated recipient mammalian oocyte; (c) introducing said membrane-bounded nucleus from said cell of said mammal into said enucleated recipient mammalian oocyte to form an oocyte containing said nucleus from said cell of said mammal; (d) reprogramming the developmental cascade of events of said nucleus from said cell of said mammal; (e) incubating said oocyte containing within its cytoplasm said nucleus of said cell from said mammal with an oocyte-modifying agent followed by a reducing agent, wherein said oocyte is incubating with said oocyte-modifying agent and said reducing agent, respectively, for a time and under conditions such that said oocyte is activated; (f) culturing said activated oocyte of step (e) in vitro or in vivo; and (g) transferring said cultured, activated oocyte of step (f) to the oviduct or uterus of a recipient maternal mammal to produce a cloned mammal.

mentions human eggs, the patent lacks the standard “nonhuman” disclaimer that had previously been required for approval under the Manual of Patent Examination Procedure.<sup>77</sup> True, the patent is for a process and not for a product. However, the disclosure also encompasses “the living, cloned products produced by each of the methods described,” which theoretically includes human and chimeric embryos and organisms.<sup>78</sup>

[28] A similar development has occurred in the European Union. In the 1990s, the European Patent Office granted a patent to the company Amrad for the “use of leukemia inhibitory factor (LIF) in the maintenance and derivation of embryonic stem (ES) cells in culture.”<sup>79</sup> The patent method “extends to the generation and maintenance of ES cells from humans, mice, birds (e.g. chickens), sheep, pigs, cattle, goats and fish and to the generation of transgenic chimaeric animals and their transgenic progeny.”<sup>80</sup> European Patent Convention (EPC) law stipulates that the process of creating a being also includes the being itself. That is indicated in EPC Article 64(2): “If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.”<sup>81</sup> Arguably, the patented method could provide patent protection over the creation of a Minotaur.

[29] To complete this Patent Law primer, it should be noted that a patent right is exclusionary. Obtaining a patent merely gives the patent owner the right to exclude others from practicing the patented invention; it does not give the patent owner any affirmative right to practice the patented invention. Thus, obtaining a patent on the process for patenting a Minotaur does not necessarily allow one to practice the method.

[30] The PTO’s stance that patent claims including a human being will not be considered has not definitively settled the question of patents on

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*Id.* at claim 20.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> See E.U. Patent No. HK1003208 (filed Aug. 3, 1989) (issued May 31, 1990), available at <http://v3.espacenet.com/textdoc?DB=EPODOC&IDX=HK1003208&F=0>.

<sup>80</sup> *Id.*

<sup>81</sup> Convention on the Grant of European Patents art. 64, Oct. 5, 1973, available at <http://www.european-patent-office.org/legal/epc/e/ar64.html>.



human organisms.<sup>82</sup> Because “cloned human embryos are not persons protected by the Constitution and theoretically at least could be as ‘immortal’ as cloned cell lines,” perhaps a particularly “novel” and “useful” human embryo could be patented.<sup>83</sup> Patents on animals containing spliced human genes are permitted. These creatures often express human characteristics, such as human hormones or other chemicals that the animal would not produce in nature. In some sense, a transgenic mammal containing and expressing human genes is a chimera.<sup>84</sup> Why then all the fuss about patentability of human-animal hybrids?

[31] Patenting of a Minotaur could be possible under the rubric of “biological material,” since a multitude of patents on biological material have been allowed. Alternatively, a Minotaur could be patented as a product-by-process. Section 103(b) of the Patent Act provides that the products of biotechnological processes fall within the scope of the patent on the process.<sup>85</sup> The Minotaur could fall within the scope of a patent on the process from which it is derived. In light of recent precedents, one is hard pressed to come up with a reason for the Court of Appeals for the Federal Circuit or for the Supreme Court to deny a patent to a human-animal chimera.

[32] Congress, PTO, and the federal courts probably did not anticipate the creation of human-animal chimeras. Nevertheless, now that the creation of chimeras has become a possibility, there is a need to determine whether there is any current justification for excluding human or part human inventions. If there is no justification, then chimeras should be patentable. If there is, then where is the line drawn to satisfy the patentability requirements, to avoid the patent application being stricken on the ground of the organism being too human? To maintain a legitimate and efficient system of patents on life forms, a new analytical paradigm must replace the current amorphous regime. This new system should be flexible and adaptable to technological innovations; it could utilize a set of quantifiable

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<sup>82</sup> See Fishman, *supra* note 8, at 473.

<sup>83</sup> George J. Annas, *Of Monkeys, Man, and Oysters*, 17 HASTINGS CENTER REP., Aug./Sept. 1987, at 20, 22.

<sup>84</sup> See Fishman, *supra* note 8, at 480-81.

<sup>85</sup> 35 U.S.C. § 103 (2000).

scientific standards to establish a limit on the extent to which researchers could harness the power of biotechnology, while still allowing for patentability of transgenic organisms that contain human DNA.

[33] The PTO's policy of granting patents on human tissues and on genetically-engineered animals, some of which contain human genes, while abstaining from granting patents on humans outright, has left the question of the patentability of human-animal chimeras unanswered. In absence of statutory authority on point, the answer to this question depends largely on standards that will be adopted by the court to determine humanity under the Thirteenth Amendment.<sup>86</sup> Such standards may have implications in other high-technology industries.<sup>87</sup>

[34] Currently, no case law discusses precisely how much human biological material a creature must possess before it qualifies as human.<sup>88</sup> Both qualitative and quantitative models for defining "humanness" have been suggested.<sup>89</sup> Complexity exists as to what type of biological material should be used as a criterion for determination of the human character of an organism – should it be quantities of DNA, proteins, metabolites, number of cells, tissues, organs, etc. Transplant patients who receive animal organs are still considered human.<sup>90</sup> On the other hand, transgenic animals that possess human genes have been patented.<sup>91</sup> Possessing one or even a few human genes does not make an animal human.<sup>92</sup> Chimpanzees share far more than 50% genetic homology with humans.<sup>93</sup>

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<sup>86</sup> Magnani, *supra* note 35, at 449.

<sup>87</sup> *Id.* at 449 n.52. Remarkably, under an overly broad interpretation of the Thirteenth Amendment, androids, cyborgs, and similar part-human, part-robotic entities might be considered human.

<sup>88</sup> *Id.*, at 449.

<sup>89</sup> Sina A. Muscati, "Some More Human Than Others:" *Assessing the Scope of Patentability Related to Human Embryonic Stem Cell Research*, 44 JURIMETRICS J. 201, 216 (2004) (suggesting establishment of a threshold of, e.g., 50% of human genes as a criterion for "humanness").

<sup>90</sup> Magnani, *supra* note 35, at 449.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 449.

<sup>93</sup> The similarity between human and chimpanzee DNA is estimated to be 95% or greater. Roy J. Britten, *Divergence Between Samples of Chimpanzee and Human DNA Sequences Is 5%, Counting Indels*, 99 PROC. NAT'L ACAD. SCI. 13633, 13633 (2002), available at <http://www.pnas.org/content/vol99/issue21>. This fact begs the interesting questions –

Consequently, one cannot simply use a rule that says that any organism composed of over 50% human genetic material would be considered human.<sup>94</sup> Chimeras consisting of less than fifty percent human genetic material may be considered human.<sup>95</sup> The appropriate standard applied might be whether the Minotaur would consider itself to be human.<sup>96</sup> If the Minotaur possessed self-awareness, the PTO could find it to be human (enough) under the Thirteenth Amendment.<sup>97</sup>

[35] At most, “the Thirteenth Amendment is an unwieldy tool for regulating biotechnology inventions like the human-animal chimera.”<sup>98</sup> Thirteenth Amendment concerns over slavery are not applicable to the discussion over patenting a Minotaur.<sup>99</sup> The concerns reflect opinions that were voiced in the early stage of patenting human DNA in the late 1980s. Since then, numerous patents on human genes have been awarded. While one might accept that the Thirteenth Amendment could apply to biotechnology products, it does not restrict process claims in a patent application embodying a human-animal chimera.<sup>100</sup> In its initial reaction, the PTO interpreted the Thirteenth Amendment as a subject matter limitation.<sup>101</sup> However, “the Thirteenth Amendment cannot effectively and consistently be applied even to biotechnology product claims until the courts adopt a workable definition of ‘human being.’”<sup>102</sup> It is unlikely that

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how will a chimpanzee-human hybrid be classified, and what would we call a transgenic chimpanzee that contains the 5% of complemented human genome?

<sup>94</sup> See Magnani, *supra* note 35, at 449-450. Use of this type of standard has been defended by its simplicity, with analogy to the burden of proof in civil cases. To deny a particular patent, the government’s burden would be to show that the invention in question is “more human than not.” *Id.*, at 450 n.54. Such a standard is perhaps artificial and over simplistic. *Id.* at 450.

<sup>95</sup> *Id.* at 450.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> See *id.* at 449-50.

<sup>100</sup> *Id.* at 450. A product patent claims a structural entity (e.g., a chimera), whereas a process patent claims an operation or series of steps leading to a useful result. 1-1 DONALD S. CHISUM, CHISUM ON PATENTS §1.03 (2004).

<sup>101</sup> Magnani, *supra* note 35, at 449. The PTO does not generally employ this kind of limitation to deny a patent on a process that produces an unpatentable product. See Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals*, 5 HEALTH L.J. 147, 154 (1997).

<sup>102</sup> Magnani, *supra* note 35, at 450.

it could be used to reject patent applications for human-animal chimeras or applications for other products of biotechnology that are not entirely human in nature.<sup>103</sup>

#### ETHICAL CONCERNS OVER PATENTING A MINOTAUR

[36] Advances in transgenic animal research have spurred increasing fear and controversy over the genetic engineering possibilities of such research. As a result, groups opposed to transgenic animal research seek to impede its progress by attacking the patentability of transgenic animals. Through these efforts, opponents seek to eliminate a perceived incentive for the production of chimeras - economic gain.<sup>104</sup> The concerns raised by these groups may be consolidated into three major areas: economic, environmental, and other ethical.<sup>105</sup>

[37] Various ethical concerns related to patenting of life forms have been expressed in literature. They touch on subjects as divergent as animal welfare, protection of the environment, and other moral concerns. Frequently, these issues are interrelated, which further complicates the analyses. Sometimes the criticism is generally directed toward granting patent rights in general, based on the argument that patents unjustifiably restrict the liberty of others.<sup>106</sup> In other instances, the grants of patents on life forms are more specifically attacked.

[38] Moral acceptability is an exceedingly complex standard to implement as a criterion of patentability. Moral norms (d)evolve and can change over the course of only a few years.<sup>107</sup> The PTO is not institutionally equipped to make moral judgments.<sup>108</sup> Admittedly, a moral

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<sup>103</sup> *Id.*

<sup>104</sup> *See generally* Sellers, *supra* note 14.

<sup>105</sup> *Id.*

<sup>106</sup> *See* Tom G. Palmer, *Are Patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects*, 13 HARV. J. L. & PUB. POL'Y 817, 821 (1990).

<sup>107</sup> Note that in the field of patent law, the technical expertise and skills of "one of ordinary skill in the art" can also change in the course of a brief amount of time. 35 U.S.C. § 103(a) (2000). Such a fluid definition, based on standard rather than rules, can accommodate the constant technological advances.

<sup>108</sup> Merges, *supra* note 18, at 1062; *see* 1 DONALD CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 4.03 (2003) (providing a

utility doctrine played a part in the early development of United States patent law. The history of the morality component of the utility requirement can be traced to the 1817 case of *Lowell v. Lewis*, and is attributed to Justice Joseph Story.<sup>109</sup> Following the *Lowell* decision, courts in the nineteenth and early twentieth centuries generally struck down patents on the basis of immorality for inventions used to defraud buyers.<sup>110</sup> Courts also denied patents for items used in gambling or similarly “immoral” activity.<sup>111</sup> Since the middle of the last century, that trend has been reversed, and federal courts have stopped applying the moral utility doctrine to reject patent applications.

[39] Compelled to comment on the human-based Newman-Rifkin patent application, in 1998 the PTO issued a media advisory, stating that “[i]t is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.”<sup>112</sup> With that statement, the PTO shifted the focus of its stance away from a constitutional basis and toward an expansion of its statutory reading, while citing dicta from the *Lowell* decision.<sup>113</sup>

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review of relevant case law); Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J. L. & POL’Y 247 (2000).

<sup>109</sup> *Lowell v. Lewis*, 15 F. Cas. 1018 (D. Mass. 1817) (No. 8568). In a frequently quoted passage, Justice Story concluded “all that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral.” *Id.* at 1019. As examples of immoral inventions, Story cited “a new invention to poison people, or to promote debauchery, or to facilitate private assassination.” *Id.*

<sup>110</sup> *Merges*, *supra* note 18, at 1062; *Rickard v. Du Bon*, 103 F. 868, 868, 873 (2d Cir. 1900). A process for artificially producing spots on tobacco leaves used to wrap cigars, such that leaves resembled those used to wrap high-quality cigars, was unpatentable for lack of utility. *Id.* at 869, 873.

<sup>111</sup> *Merges*, *supra* note 18, at 1062; Brett G. Alten, Note, *Left to One’s Devices: Congress Limits Patents on Medical Procedures*, 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 837, 845-46 (1998); Magnani, *supra* note 36, at 451.

<sup>112</sup> Richard J. Basile et al., *Patent and Trademark Office Issues Statement on Patenting of Partial Human Life Forms*, 10 J. PROPRIETARY RTS. 17, 17 (1998).

<sup>113</sup> *Lowell*, 15 F. Cas. at 1019.

[40] The PTO also cited the 1991 *Tol-O-Matic* decision, in which the Federal Circuit upheld a patent on a rodless piston-cylinder, noting that 35 U.S.C. § 101 “has [] been interpreted to exclude inventions deemed to be immoral.”<sup>114</sup> That the Federal Circuit invoked such a controversial doctrine in a setting where the morality argument was not even raised might have implied that the court was preparing to invoke the doctrine with greater frequency in the future.<sup>115</sup> Such concerns were dispelled in 1999, when the Federal Circuit held that the moral utility doctrine has not been broadly applied by courts in recent years and upheld a patent even though the invention was designed to deceive customers by imitating another product.<sup>116</sup>

[41] Elsewhere, the European Union has used a form of the moral utility doctrine as a means of rejecting immoral or destructive patents.<sup>117</sup> The European Patent Office (EPO) has applied two morality criteria. One test espouses a “public abhorrence” standard, which denies a patent to any invention where public consensus determines that such a grant would be abhorrent.<sup>118</sup> The other test utilizes an “unacceptability” criterion, which denies a patent where the disadvantages of the patent to society would outweigh the advantages.<sup>119</sup> The “unacceptability” test is more stringent, since an invention that is not “abhorrent” may still be deemed so “unacceptable” as to preclude patent protection. Thus, variation in which of the two tests is applied results in inconsistent standards of patentability.

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<sup>114</sup> *Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft*, 945 F.2d 1546, 1552 (Fed. Cir. 1991).

<sup>115</sup> Magnani, *supra* note 35, at 453.

<sup>116</sup> *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1365-68 (Fed. Cir. 1999).

<sup>117</sup> Council Directive 98/44, art. 6, 1998 O.J. (L 213) 13, 16 (EC), *available at* [http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l\\_213/l\\_21319980730en00130021.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf).

<sup>118</sup> It seems that the public consensus test is not the easiest one to apply, because it has a very high standard to meet, if the word “consensus” is taken seriously. *See* application of the “public abhorrence” and “unacceptability” tests in *Greenpeace Ltd. v. Plant Genetic Systems N.V.*, T 356/93 - 3.3.4, 1995 O.J. E.P.O. 545 (Technical Bd. of App.). *Greenpeace* contended that the patent violated the Article 53(a) morality provision of the EPC. *Id.*

<sup>119</sup> *But see* *Leland Stanford/Modified Animal*, Application No. 88,312,222.8, 2002 E.P.O.R. 2, (Opp. Div. 2001) (rejecting a *public ordre-morality* opposition to a patent for an immunocompromised mouse implanted with human hematopoietic tissue, .i.e., “animal-human chimera,” on the ground that it would be presumptuous for the EPO to interfere in an unresolved public debate on the patenting of xenotransplantation technology by acting as moral censor and invoking the provisions of EPC art. 53(a)).

[42] The Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) has placed emphasis on morality.<sup>120</sup> Under TRIPs article 27(2), states may exclude an invention from patentability on the basis of ordre public where granting a patent would result in commercial exploitation of the invention.<sup>121</sup> Proponents of adding a morality test for patentability could argue that it comports United States law with an international treaty.<sup>122</sup>

[43] Proponents of the morality test argue that treating genetically altered organisms and genes as patentable inventions institutionalizes disrespect for life. They claim that all organisms possess morally considerable interests and are not tools or instruments that people are entitled to own through patents.<sup>123</sup> In their view, a patent is a legal and moral category that was developed for newly created inanimate devices.<sup>124</sup>

[44] Society's moral norms, as well as the courts' perceptions of those norms, have evolved and relaxed over time. Patents have been issued for inventions that might be considered immoral by some subcultures. These include guns, slot machines, cattle prods, and abortion-related instruments.<sup>125</sup> I do not advocate here that it is acceptable to uphold patents on subjects considered immoral – I attempt to illustrate the changes in patentability as a function of societal moral norms. As the law has undergone modifications, so have the skills of ordinary practitioners of

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<sup>120</sup> See Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, 1994, 33 I.L.M. 81.

<sup>121</sup> *Id.* (stating that a patent may be withheld in order to protect ordre public (law and order)).

<sup>122</sup> *Id.* In other words, with a morality tests, the PTO and U.S. courts would not be violating art. 27(2) of the TRIPs Agreement.

<sup>123</sup> Ned Hettinger, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, 22 B.C. ENVTL. AFF. L. REV. 267, 284 (1995).

<sup>124</sup> *Id.* at 284. See 35 U.S.C. § 101 (1988) (stating that patentable subject matter is “any new and useful process, machine, manufacture, or composition of matter.”); see also LEON KASS, TOWARD A MORE NATURAL SCIENCE: BIOLOGY AND HUMAN AFFAIRS 143-44 (1985).

<sup>125</sup> See Merges, *supra* note 18, at 1062-67 (discussing the history of patenting of “immoral” inventions). Merges argues that in determining “utility” 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.” *Id.* at 1065.

the legal art changed over time. Created in relatively broad strokes, the patent law is designed to largely adapt to the inevitable technological changes. There is no compelling reason why the law cannot adapt to moral changes as well.

CONCERNS OVER “HUMANNESS” OF THE MINOTAUR

[45] The traits that define humanity have been debated by philosophers since the humans first differentiated themselves from other animals. Some use both psychological and social criteria of personhood to argue that self-awareness is what distinguishes humans from other animals.<sup>126</sup> However, a fundamental division of opinion exists between those who see human life in terms of its intrinsic value or in terms of its utilitarian value. The divergent perspectives combine both philosophical and economic considerations. The perspectives range from essentialist with a penchant for the welfare state to utilitarian with a neoliberal accent with a myriad of approaches in between these two.<sup>127</sup>

[46] The paramount significance is in the standard that will be employed for patentability of the Minotaur. If the Minotaur is considered human, an argument must be identified to justify a no-patenting rule; otherwise, a patent to the Minotaur would need to be granted. Issues related to patenting humans and human material already abound. For instance, having the capability of creating human embryos *in vitro*, we face a decision of whether to allow their patenting. To decide that, first we need to define the legal status of embryos. Courts have spoken on that question. In *Davis v. Davis*, the Tennessee Supreme Court concluded that “preembryos are not, strictly speaking, either ‘persons’ or ‘property,’ but occupy an interim category that entitles them to special respect because of their potential for human life.”<sup>128</sup> Similarly, embryos are “not entitled to the protections granted to persons,” nor should they be given special treatment based on their potential of human life.<sup>129</sup> One court recently

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<sup>126</sup> Michael D. Rivard, *Toward a General Theory of Constitutional Personhood: A Theory of Constitutional Personhood for Transgenic Humanoid Species*, 39 UCLA L. REV. 1425, 1487 (1992).

<sup>127</sup> David P. Fidler, *Introduction to Written Symposium on Public Health and International Law*, 3 CHI. J. INT’L L. 1, 6 (2002).

<sup>128</sup> *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992).

<sup>129</sup> *Doe v. Irvine Scientific Sales Co.*, 7 F. Supp. 2d 737, 742 (E.D. Va. 1998).



indicated that the common law should recognize that a stillborn fetus, “while not a person, [i]s not ‘property’ or ‘tissue’ . . . [but] an intermediate category in the law entitled to a special respect that would not be given ordinary tissue.”<sup>130</sup> Scholars argue that embryos cannot be considered humans because they lack sentience and awareness.<sup>131</sup> To regulate the controversy over patents on human embryos Congress should pass a law that would adopt standards to distinguish between what organisms are not patentable (e.g., humans, some human-animal chimeras) and what biological material is patentable.<sup>132</sup>

[47] A distinctive genetic signature does not necessarily “compel the conclusion that an embryo is a legal individual.”<sup>133</sup> Many organisms “display unique genetic signatures, but there . . . [is] no societal consensus that this accords them individual rights under the law.”<sup>134</sup> It is possible that allowing patents on humans may come in direct conflict with the right of reproductive freedom granted by the Fourteenth Amendment.<sup>135</sup> “However, because the offspring of a patented person would be different from the person, it is unlikely that [such a] patent [would interfere] with the right to reproduce,”<sup>136</sup> unless reproduction constitutes unlicensed use of the parent’s patented genome.<sup>137</sup>

[48] If the Minotaur is not human enough to be classified as human, is it animal enough to be considered an animal? If the answer is yes, then

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<sup>130</sup> Janicki v. Hosp. of St. Raphael, 744 A.2d 963, 971 (Conn. 1999).

<sup>131</sup> See John A. Robertson, *Genetic Alteration of Embryos: The Ethical Issues*, in GENETICS AND THE LAW III 115, 120-21 (Aubrey Milunsky & George J. Annas eds. 1984) (arguing that gene therapy on embryos is ethical).

<sup>132</sup> But see Sellers, *supra* note 14, at 290-91. Sellers argues that it is “unlikely that legislative or judicial line-drawing on (animal patenting) will substantially affect a particular person's beliefs.” *Id.*

<sup>133</sup> Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1654 (1993).

<sup>134</sup> *Id.*

<sup>135</sup> U.S. CONST. amend. XIV, § 1; Burk, *supra* note 133, at 1649.

<sup>136</sup> John Miller, *A Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market*, 13 ALB. L.J. SCI. & TECH. 555, 580 n.147 (2003); see U.S. CONST. amend. XIV, § 1 (protecting liberty interests by the Due Process Clause).

<sup>137</sup> Because the offspring would not contain the patented genome, it (s/he) would not fall under the patent law prohibition against making. However, the parent might be able to argue unlawful use of patented genome.

issues related to animal welfare need to be considered. Scholars have supported protection of animal rights by taking a position known as “sentientism,” the view that all sentient beings possess morally considerable interests.<sup>138</sup> Sentientism’s view is that all beings who can feel pleasure and pain possess individual welfares served by their physical features.<sup>139</sup> Thus, animals are not mere resources to which people may be naturally entitled.

[49] In defense of anthropocentrism is the reality that owning animals has been a legitimate human tradition for millennia. Animals are valued in the marketplace on the basis of their rarity and utility; they are eaten and used for biomedical research. Consequently, patenting animals “seems relatively benign.”<sup>140</sup>

[50] Some commentators have come up with a Solomonic solution in accepting the biocentric ethic. Rejecting biocentric egalitarianism, they accept that all organisms are morally considerable, albeit not to the same degree.<sup>141</sup> These authors allow that individual organisms have different degrees of moral significance, and believe animal patents to be more problematic than plant or microbe patents.<sup>142</sup>

[51] Critics of biocentric ethics hold that the fact that organisms possess goods of their own does not mandate that people cannot be morally indifferent to them, nor that we have prima facie duties to respect

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<sup>138</sup> Ned Hettinger, *supra* note 123, at 285.

<sup>139</sup> This argument is developed through a defense of the environmental ethic known as “biocentrism.” The doctrine holds that all living beings possess morally-considerable interests that should be respected. Ned Hettinger, *supra* note 123, at 284-85.

<sup>140</sup> Lisa J. Raines, *The Mouse That Roared*, ISSUES SCI. & TECH., Summer 1988, at 64, 68.

<sup>141</sup> See Ned Hettinger, *supra* note 123, at 285; Tom Regan, *The Case for Animal Rights*, in IN DEFENSE OF ANIMALS 13, 23 (Peter Singer ed., 1985) (defending the so-called “reverence for life”). For a general discussion of the biocentric ideal of respect for all life, see generally ALBERT SCHWEITZER, *THE PHILOSOPHY OF CIVILIZATION* 240-64 (Am. ed. 1950).

<sup>142</sup> Ned Hettinger, *supra* note 123, at 285. Biocentric egalitarianism argues that all living beings are equally morally important. See PAUL W. TAYLOR, *RESPECT FOR NATURE: A THEORY OF ENVIRONMENTAL ETHICS* 14-25 (1986); Kenneth E. Goodpaster, *On Being Morally Considerable*, 75 J. PHIL. 308, 308-25 (1978).

organisms' welfare.<sup>143</sup> Owning animals certainly does not negate the claim that animals may have a good of their own or that animal welfare may be a coherent concept. On the other hand, being owned and taken care of by humans may sometimes be consistent with animals' best interests.

[52] Environmental concerns have been raised in the context of patenting life forms. For example, Greenpeace challenged the 1990 grant of a patent to Plant Genetic Systems N.V. for a method of developing plants and seeds resistant to a particular class of herbicides (production of transgenic plants).<sup>144</sup>

[53] The subject of patenting life forms has become fertile ground for interest groups to start a debate on topics far beyond patenting of life forms. The variety of ethical points raised represent proxies for a universe of moral standings, fears, harms, benefits, and religious and economic interests. Unfortunately, these arguments put an unjustified burden on patent law, asking it to solve socio-economic and philosophical questions. Patent law is ill equipped for such a task.

#### PROPERTY PROBLEMS RELATED TO CREATION OF A MINOTAUR

[54] The labor theory of property acquisition is frequently used in favor of property rights in general.<sup>145</sup> According to this theory, laborers are naturally entitled to the fruits of their labor.<sup>146</sup> The Lockean argument can be intuitively summarized: I made it and hence it is mine; it would not

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<sup>143</sup> See John O'Neill, *The Varieties of Intrinsic Value*, 75 *MONIST* 119, 131-32 (1992).

<sup>144</sup> *Greenpeace Ltd. v. Plant Genetic Systems N.V.*, Case T-356/93 - 3.3.4, 1995 O.J. E.P.O. 545 (Technical Bd. of App.). Greenpeace maintained that patenting of plant material could have disastrous environmental effects. Greenpeace asserted that the invention posed several environmental risks: (1) the plants could themselves become weeds or pests and pass their genes on to other plants which, in turn, might become herbicide-resistant; (2) the release of the plants could disrupt the ecostructure and lead to a reduction in biodiversity; and (3) the patent could increase the use of herbicides, and lead to the creation of more genetically engineered plants. *Id.*

<sup>145</sup> See Richard T. Jackson, *A Lockean Approach to the Compulsory Patent Licensing Controversy*, 9 *J. TECH. L. & POL'Y* 117, 124 (2004).

<sup>146</sup> See *id.* at 124-25.

exist but for me.<sup>147</sup> This property argument has been utilized to defend patents on transgenic animals.<sup>148</sup>

[55] Another argument for property rights in patenting life forms comes from the consequentialist-incentive rationale. The argument asserts that grants of patents on life forms “are necessary incentives for the production of socially optimal levels of biological innovation,” resulting in improved food, drugs, etcetera. “Without the patent incentive, such innovation would drastically slow.”<sup>149</sup>

[56] A desert rationale for property rights should be considered as well. According to this theory, laborers deserve to benefit from their labors, at least when their efforts aim to produce something socially useful.<sup>150</sup> Researchers invest time, energy, and resources into their labor. They ought to have something in return for the biotechnological products they generate.<sup>151</sup> Accordingly, patenting a Minotaur may be justified as just deserts for the researchers’ labor.<sup>152</sup>

[57] Opponents of patenting life forms contend biotechnological advances should be shared for the benefit of all humankind. The common heritage argument is that “living matter...is part of the ‘heritage of Humanity and Nature in general’ and should not be classified as ‘private property’ through the granting of patents.”<sup>153</sup>

[58] Invoking Kantian moral philosophy, some have criticized the award of property rights in bodily parts. These arguments are based on human

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<sup>147</sup> See JOHN LOCKE, THE SECOND TREATISE OF GOVERNMENT 14-26 (J.W. Gough ed., 1946).

<sup>148</sup> See generally Paul B. Thompson, Concepts of Property and the Biotechnology Debate (Sept. 1992), [http://nabc.cals.cornell.edu/pubs/occ\\_paper\\_1/Thompson.html](http://nabc.cals.cornell.edu/pubs/occ_paper_1/Thompson.html).

<sup>149</sup> Ned Hettinger, *supra* note 123, at 291-92.

<sup>150</sup> See generally GEORGE SHER, DESERT (1987) (analyzing philosophically what people deserve).

<sup>151</sup> Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31, 40-43 (1989).

<sup>152</sup> See *id.*

<sup>153</sup> Darrell G. Dotson, *The European Controversy Over Genetic-Engineering Patents*, 19 HOUS. J. INT’L L. 919, 944 (1997) (quoting *EP Greens Launch a Campaign Against the Draft EEC Directive on Patenting Biotechnological Inventions*, REUTERS, Jan. 25, 1992).

freedom, dignity, and self-respect.<sup>154</sup> In this view human freedom is postulated on the premise that human beings have free will, and that human dignity is priceless. If humans had property rights in their own bodies and exercised those rights by sale or licensing, they would treat their genetic material in ways conflicting with humanity and dignity. Persons would decline to the level of things with a price.<sup>155</sup> An extension of this view is the creation of a distinction between personal rights and property rights in regard to human bodies.<sup>156</sup> However, twenty-first century reality defeats Kant's philosophical arguments. Kant could not have foreseen the existence of markets for human gametes and organs; otherwise, he might have revised his position on human freedom and human dignity.

[59] Supporters of animal patents point out that humans have treated animals as property for thousands of years by buying them, selling them, breeding them, and keeping them as pets. Academic researchers developed the Harvard oncomouse; eventually, it became the property of the Du Pont pharmaceutical company.<sup>157</sup> One can acquire property rights in wild animals by taking exclusive possession.<sup>158</sup> Some have argued issuing patents for life forms would not change the nature of this normal commerce; it would simply ensure that inventors receive the profits resulting from their efforts.<sup>159</sup> We do not make sociological distinctions between owning patented animals and unpatented animals.<sup>160</sup>

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<sup>154</sup> Stephen R. Munzer, *Kant and Property Rights in Body Parts*, 6 CAN. J.L. & JURISPRUDENCE 319, 326-330 (1993).

<sup>155</sup> See IMMANUEL KANT, LECTURES ON ETHICS 121-25 (Louis Infield trans., Harper and Row 1963) (1930) (emphasizing that persons are neither property nor things and may not sell parts of their bodies; also arguing that humanity is degraded when individuals sell themselves for the sexual pleasure of others).

<sup>156</sup> See Stephen R. Munzer, *The Special Case of Property Rights in Umbilical Cord Blood for Transplantation*, 51 RUTGERS L. REV. 493, 497-98 (1999). See generally STEPHEN R. MUNZER, A THEORY OF PROPERTY (1990) (offering a multi-principled theory for justifying property rights).

<sup>157</sup> Alun Anderson, *Oncomouse Released*, 336 NATURE 300 (1988).

<sup>158</sup> *Pierson v. Post*, 3 Cai. 175 (N.Y. Sup. Ct. 1805).

<sup>159</sup> Mark W. Lauroesch, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100, 114-15 (1988) (stressing that it would be inconsistent to deny intellectual property rights over transgenic animals when personal property rights have historically been recognized in naturally occurring animals); see Dresser, *supra* note 7, at 413 (declaring that humans have long "objectified" animals).

<sup>160</sup> Raines, *supra* note 140, at 68.

[60] Fascinating conflicts of rights would be created if the Minotaur was patentable. If a chimera was capable of reproduction (as the mythological chimera was), a conundrum would arise over the question whether of the patent would be infringed by the chimera's natural offspring, and whether the patent holder is entitled to injunctive remedy. In addition, we can only surmise the social and symbolic ramifications of being a patented sentient entity.

#### METAPHYSICAL CONCERNS

[61] The delicate balance between the advancement of science and the maintenance of fundamental religious beliefs is disturbed by achievements in the area of genetic engineering.<sup>161</sup> Biotechnology brings into focus the sensitive issues of creation and evolution. Science has placed us on the threshold of discovering procedures which will allow the manipulation of processes that until now have only been known to nature or God (depending on the side taken). The gap that exists between that which can be explained by analytical science and that which is answerable through religious doctrines is shrinking in the favor of science. Nevertheless, for science to achieve beneficial results for all of humanity, religion must have its place in the debate. "The moral and spiritual ideals represented by religion must not be discarded for the sake of scientific progress."<sup>162</sup> Indeed, the more sophisticated proponents of religion have attempted to blend science with religion.

[62] In the new world of genetic engineering, religion's role in society must be reevaluated in order to help define the most beneficial route to improving life through technology. Fundamental religious teachings on the God-like ability to create life are being tested by potential achievements in genetic engineering. Differing views among the many religions complicate the religiously permissive genetic research. God's position differs, depending on which God one invokes. For example, the Vatican, in condemning attempts to clone humans, warned that because only God can create the spiritual soul, resulting clones would be

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<sup>161</sup> See Dorothy Nelkin, *Genetics, God, and Sacred DNA*, 33 *SOC'Y* 22, 22-25 (1996).

<sup>162</sup> Jason T. Corsover, Article, *The Logical Next Step? An International Perspective on the Issues of Human Cloning and Genetic Technology*, 4 *ILSA J. INT'L & COMP. L.* 697, 750 (1998).

psychically damaged.<sup>163</sup> Such a proposition is very intriguing; by extension of the Vatican's logic, God probably has not created souls for all of the IVF (*In Vitro* Fertilized) children. On the other hand, the spiritual guide for the Moslem Hezbollah, Sheikh Mohammed Hussein, claimed that because God has allowed science to progress, research into cloning should continue.<sup>164</sup> "Jewish law (*halakhah*) places supreme importance on...the preservation of human life – which overrides all other commandments in the Torah except for murder, idolatry, or adultery."<sup>165</sup> Genetic engineering of animals and plants with the goal of saving or prolonging human life would be permitted, if not required, by *halakhah*.

[63] Various religious groups claim that genetic engineering amounts to a form of playing God.<sup>166</sup> They argue that "[r]everence for all life created by God [is] eroded by . . . economic pressures to view animal life as if it were an industrial product invented and manufactured by humans."<sup>167</sup> The concern is that patenting life forms renders animals marketable commodities and that using animals as a means to an end degrades the sanctity of life. Moreover, "the classification of an animal as a 'manufacture' or 'composition of matter' invented by humans demeans the reverence of God."<sup>168</sup> Commenting on the PTO policy after the PTO lifted an apparently self-imposed moratorium on animal patents in 1992,

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<sup>163</sup> See Pontificia Academia Pro Vita, Reflections on Cloning, [http://www.vatican.va/roman\\_curia/pontifical\\_academies/acdlife/documents/rc\\_pa\\_acdlife\\_doc\\_30091997\\_clon\\_en.html](http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_30091997_clon_en.html) (last visited Nov. 6, 2005).

<sup>164</sup> See *Hezbollah Mentor Says "God Allowed" Cloning*, DEUTSCHE PRESSE-AGENTUR, Mar. 13, 1997.

<sup>165</sup> Jewish Center for Public Affairs, Jewish Perspectives on Genetic Engineering (Oct. 2001), <http://www.jcpa.org/art/jep2.htm>.

<sup>166</sup> See, e.g., National Information Resource on Ethics and Human Genetics, *Splicing Life: A Report on the Social and Ethical Issues of Genetic Engineering with Human Beings* (Nov. 1982), [http://www.bioethics.gov/reports/past\\_commissions/splicinglife.pdf#search='Splicing%20Life'](http://www.bioethics.gov/reports/past_commissions/splicinglife.pdf#search='Splicing%20Life').

<sup>167</sup> *Patents and the Constitution: Transgenic Animals: Hearing Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 100th Cong. 399 (1987) (statement of Rev. Wesley Granberg-Michaelson, National Council of the Churches of Christ in the U.S.A.).

<sup>168</sup> Morin, *supra* note 101, at 169. The real crux of the objection is perhaps the oft-cited *Chakrabarty* phrase that allows patentability of "anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). That phrase may be interpreted as a direct challenge to God the Creator.

Dr. Richard D. Land, executive director of the Christian Life Commission of the Southern Baptist Convention, stated, “We belong to the creator God. The PTO’s decision to grant patents on animal or human genetic information represents a usurpation of the ownership rights of the Sovereign of the universe.”<sup>169</sup>

[64] Humans alter the course of nature in ways other than through biotechnology. We have changed nature through irrigation of arid farmland, drilling for oil, selective breeding of plants and animals, birth controls, the use of medicine and technology to extend life, and through conservation of endangered species. Interestingly enough, these human interventions are not the object of criticism; genetic engineering is singled out.<sup>170</sup> In fact, religious tenets could also be used to support the position that humans have a duty to employ their God-given powers to harness nature for human benefit. “While there may be [religious] arguments against genetic engineering when it has detrimental consequences, an objection based solely on the alteration of nature is unfounded.”<sup>171</sup> The moral dilemma arising from genetic engineering is not its actual existence, but whether the technology is applied responsibly.<sup>172</sup>

[65] Theologians have expressed their views on the potential to clone humans and manipulate their genetic constitution. As a fundamental belief, human life is sacred and liberty is a basic right granted to humans out of respect for their autonomous and free nature. From there, differing views are formed on how humans should handle the knowledge to manipulate the creation and genetic development of their own species.<sup>173</sup>

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<sup>169</sup> Bruce Rubenstein, *Genetic Patents Pits Clients, Religion, Government*, CORP. LEGAL TIMES, Sept. 1995, at 1.

<sup>170</sup> See Heureka, *Genetic Engineering: Paradise on Earth or Descent Into Hell?* (Sept. 1999), <http://www.heureka.clara.net/gaia/genetics.htm>.

<sup>171</sup> Morin, *supra* note 101, at 169-70.

<sup>172</sup> *Id.* at 170.

<sup>173</sup> See Ralph C. Conte, *Toward a Theological Construct for the New Biology: An Analysis of Rahner, Fletcher, and Ramsey*, 11 J. CONTEMP. HEALTH L. & POL’Y 429, 442 (1995).



[66] The most fundamental objection to biotechnology patents relates to patenting life, and therefore the patent holders “own life.”<sup>174</sup> A problem with that assertion is the difficulty in defining “life,” both in the biological sciences, and as a legal term of art.<sup>175</sup> The word “life” is ordinarily used as an abstraction from concrete living things. From the point of view of patent law, patenting life seems to be a meaningless notion because the law does not provide for patenting of abstractions. This unfortunately does not prevent the use of “patenting life” objection as an effective slogan to mislead people into thinking that a sinister move is made to monopolize the essence of life.<sup>176</sup>

#### BENEFITS FROM PATENTING THE MINOTAUR

[67] Transgenic animals and human-animal chimeras have the potential for generating a multitude of societal benefits. These range from medical uses, such as gene correction and organ transplants, to production of specially tailored hybrid mammals for industrial applications. As sources of donor organs, these creatures could potentially save many human lives.<sup>177</sup> Non-sentient hybrid animals could be developed to industrialize the drug testing process for pharmaceutical products.<sup>178</sup> One would anticipate rapid progress in the development of new drugs with availability of human-ape chimeras as the ultimate model for clinical studies. Such an application could replace the current controversial use of sentient

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<sup>174</sup> See JEREMY RIFKIN, *THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD* 37 (1998). Rifkin speculates that there is a real “possibility of patenting all of the separate parts, if not the whole, of a human being.” See *id.* at 45.

<sup>175</sup> Consider the impossibility of reaching consensus on the definition of “life” in the abortion debate.

<sup>176</sup> See VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* 3-5 (1997) (suggesting that the cultural knowledge and biological diversity of non-Western societies are being plundered by means of obtaining patents on “life-forms” and by patenting their indigenous knowledge).

<sup>177</sup> Magnani, *supra* note 36, at 456. Organs such as livers, kidneys, pancreas, and hearts, may some day be developed in animals for transplant into humans. See generally Rebecca D. Williams, Food and Drug Administration, *Organ Transplants from Animals: Examining the Possibilities* (June 1996), [http://www.fda.gov/fdac/features/596\\_xeno.html](http://www.fda.gov/fdac/features/596_xeno.html).

<sup>178</sup> See Magnani, *supra* note 35, at 456; Manspeizer, *supra* note 6, at 425 (suggesting that transgenic animals may be used as “miniature drug factories”). That has since become reality.

laboratory animals, and neutralize the concerns of the animal rights movement.

[68] Human-animal chimeras could be created as purely laboratory organisms, to study genetic diseases and conduct “gene therapy” studies. In conducting gene therapy medical studies, as in any area of groundbreaking research, the promise of curing genetic diseases will have high costs, sometimes lethal.<sup>179</sup> Arguably, it is more acceptable to create new organisms for the purposes of testing novel, potentially lethal medical approaches, rather than risk human lives. Chimeras for use in medical experiments could be closely related to humans, yet rendered “decerebrate” through genetic engineering. That way, the chimeras would be physically incapable of experiencing pain.<sup>180</sup>

[69] Another use of the Minotaur and like creatures could be as a replacement for humans under conditions that are risky and dangerous. Chimeras might be utilized for activities in unwelcoming environments such as dangerous mines, proximity to radioactive sources, etc., where humans would be exposed to grave risks.

[70] In addition to being useful in the study of diseases and potentially as organ donors, human-animal chimeras can be designed to produce cost-effective human proteins in large quantities, in a process known as “genepharming.”<sup>181</sup> The chimeras could replace the transgenic animals that are today designed to produce cost-effective pharmaceutical products in large quantities. Proteins such as human hemoglobin, growth hormone and insulin can be retrieved from secreted milk of transgenic animals.<sup>182</sup>

[71] The establishment of unquestionable patent protection should generate an incentive for invention of chimeras. The medical and other

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<sup>179</sup> A clinical gene therapy experiment at the University of Pennsylvania killed a teenage volunteer. Rick Weiss & Deborah Nelson, *Methods Faulted in Fatal Gene Therapy*, WASH. POST, Dec. 8, 1999, at A1.

<sup>180</sup> See generally BERNARD E. ROLLIN, *THE FRANKENSTEIN SYNDROME: ETHICAL AND SOCIAL ISSUES IN THE GENETIC ENGINEERING OF ANIMALS* (Cambridge University Press 1995).

<sup>181</sup> See Thomas T. Moga, *Transgenic Animals As Intellectual Property (or the Patented Mouse That Roared)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 511, 531-32 (1994).

<sup>182</sup> *Id.*

benefits could help counterbalance the moral core of the religious opponents and of the animal rights movement.

#### CONCLUSION

[72] *Panta rei*. This Article continues the debate on attempts to add legitimacy to the issuance of patents on life forms. The core of the controversy is conflicting social policies which utilize the patent system as its vehicle of expression. Patent law should not be used for prohibiting activity that may be regarded as objectionable on grounds unrelated to patent law.<sup>183</sup> Opponents of patenting have attacked the patent system as a means of voicing their concerns over biotechnology. Proponents of patenting life realize that under the current regime a great deal hangs on the maturity and wisdom of the PTO. That is not a comforting thought. For those who see biotechnology as a method of furnishing benefits to society, the patent system provides a much needed incentive for vigorous pursuit of those ends.

[73] The proper forum for resolution of this issue and balancing these competing interests is the Legislature. A chief task of Congress is to promulgate legislation that maximizes the development and use of biotechnology by means of the patent incentive, while minimizing the potential risks by means of regulatory oversight.<sup>184</sup> The current case-by-case patent application evaluation, employing vague standards of review, is ill suited to deal with biotechnological developments.<sup>185</sup>

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<sup>183</sup> Issues such as abortion keep influencing patent policy. For example, Rep. Dave Weldon (R-FL) sponsored an amendment to the Consolidated Appropriations Act of 2004, aimed to prevent the use of federal funds to issue patents on human organisms, including embryos and fetuses. The vague, overly broad language does not define "human organism" and it could preclude patenting of many human-derived biotechnology inventions. 149 CONG. REC. E2417 (daily ed. Nov. 22, 2003) (statement of Rep. Weldon).

<sup>184</sup> The federal government already has guidelines on human experimentation. 45 C.F.R. § 46 (2004). These regulations are limited; they only apply to federally funded research institutions, voluntarily complying institutions, or to pharmaceuticals or devices that need FDA approval. *See id.* § 46.103.

<sup>185</sup> Courts recently recognized that the invalidation of patents based on immorality grounds is no longer widely used. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366-67 (Fed. Cir. 1999).

[74] The scope of patentable subject matter is currently determined by application of principles spelled out in 35 U.S.C. § 103.<sup>186</sup> A possible solution to the problem of patenting human-animal chimeras is to create a standard-based statute that will regulate patenting of life forms. Such a statute could be modeled on 35 U.S.C. § 103.<sup>187</sup> A standard-based statutory provision is flexible and suitable for the rapidly-advancing field of biotechnological innovation; it might allow for better accommodation of the legal (patentability) treatment of future chimaeric creatures, such as biomechanic hybrids and other types of organisms that we cannot now envision.

[75] Patents do not confer property rights in genetic material as it exists in nature and they do not sanction illegal acts. Instead of becoming mired in moral and ethical controversies, critics of patenting the Minotaur should call for more comprehensive regulations on genetic engineering, not a ban on patenting of chimeras. Such a ban is unlikely to prevent further experimentation in genetic engineering because acquiring patents is not the only motivating factor in scientific research.<sup>188</sup> Significant driving forces include the quest for knowledge, recognition, status and prestige.<sup>189</sup>

[76] If necessary, evaluation of the public interest in issuing patents might involve the creation of some body outside the PTO, whether an ethics advisory council to the PTO or a body concerned both with patenting and other areas of bioethics that are within federal jurisdiction. Lessons can be learned from the ongoing policy debate on the incorporation of ethical considerations in the regulation of genetically modified foods.<sup>190</sup>

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<sup>186</sup> 35 U.S.C. § 103 (2004).

<sup>187</sup> *Id.* Analogous to the non-obviousness statute, the standard-based statute can regulate grants of patents on living organisms, and perhaps on living matter in general (cells, tissues, organs, etc.).

<sup>188</sup> As Article 7 of the TRIPS Agreement explains, patents merely contribute to the promotion of technology. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, 1994, 33 I.L.M. 81.

<sup>189</sup> Barry Hoffmaster, *The Ethics of Patenting Higher Life Forms*, 4 INTELL. PROP. J. 1, 10 (1988).

<sup>190</sup> See PAUL B. THOMPSON, CANADIAN BIOTECHNOLOGY ADVISORY COMM., FOOD AND AGRICULTURAL BIOTECHNOLOGY: INCORPORATING ETHICAL CONSIDERATIONS (2000), available at <http://www.agriculture.purdue.edu/agbiotech/Thompsonpaper/Canadathompson.html> (discussing the ethical issues of genetically modified foods).

[77] Under the current state of genetic engineering art, human-animal chimeras could be created either through upward engineering of mammal animals or through downward genetic manipulation of human embryos.<sup>191</sup> The implication is that created transgenic humanoids and chimeras “could end up constituting a human underclass.”<sup>192</sup> In the absence of an applicable statute, the attempt to patent such an invention has prompted the PTO to disallow the patenting of human-animal chimeras.<sup>193</sup> It is doubtful that the PTO is the appropriate agency for making policy decisions of such scope and significance.

[78] The determination of what constitutes an immoral invention suffers from ambiguity and subjectivity. As is the case with language, definitions, and laws, (im)morality is society-dependent, and changes from generation to generation. It should be no surprise that the use of the doctrine of social utility in denying patents has, over the years, fallen out of favor with the federal courts, if not with the PTO.<sup>194</sup> Despite its acceptance of patent protection for animals and the strong language of *Chakrabarty*, the PTO has declared that patent claims directed to or including in their scope a human being would be denied. To legitimize this view, the PTO claimed rationale in the Patent Act and on the Constitution.<sup>195</sup> The PTO’s reliance on the eighteenth century view of a morality aspect of the utility requirement is flawed, since it assumes that any utility inherent in such an invention would necessarily violate public policy.<sup>196</sup> One is tempted to guess that today’s conservative Supreme Court would be hesitant to invoke a subjective doctrine, which has not seen much use over the last

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<sup>191</sup> Upward engineering of mammals already occurs in xenotransplantation. See Stevan M. Pepa, *International Trade and Emerging Genetic Regulatory Regimes*, 29 L. & POL’Y INT’L BUS. 415, 445-6 (1998) (citing M. Schmoeckel et al., *Xenotransplantation of Pig Organs Transgenic for Human DAF: An Update*, 29 TRANSPLANT PROC. 3157 (1997)).

<sup>192</sup> *Id.* at 446. This proposition sounds morally repugnant; however, some have argued that it is morally acceptable. *Id.*; see also Fishman, *supra* note 8, at 477-8.

<sup>193</sup> James P. Daniel, *Of Mice and “Manimal”*: *The Patent & Trademark Office’s Latest Stance Against Patent Protection for Human-Based Inventions*, 7 J. INTELL. PROP. L. 99, 100 (1999).

<sup>194</sup> See *id.* at 124-25.

<sup>195</sup> *Id.* at 118.

<sup>196</sup> It seems as if the PTO relied on both eighteenth century jurisprudence and eighteenth century morality views.

century.<sup>197</sup> Furthermore, the PTO, as an administrative agency, is not in a position to make decisions regarding fundamental constitutional rights. While the PTO may have valid concerns about the consequences of granting patents for human-based inventions, no reasons for a wholesale denial are persuasive. The PTO has not offered a rational basis for its wholesale denial of human-based patents in the face of Supreme Court language arguably holding otherwise.<sup>198</sup> Although there may be arguments, both legal and ethical, against the patenting of a parallel humanoid species, the PTO is not the organization to make such determinations.<sup>199</sup>

[79] Biotechnology issues new challenges to the PTO, the courts and Congress to realize the constitutional mandate “to promote the Progress of Science and useful Arts.”<sup>200</sup> With technological progress in focus, the traditional patent doctrine should be updated to accommodate the contemporary biotechnological innovations. Patent scope definitions should be fashioned to encourage new inventions. Instead of relying on the PTO and the courts to make ad hoc decisions concerning the constitutionality of inventions based on life forms, Congress should either proscribe patent protection for these inventions, or statutorily limit patent protection in a certain field of technology. To eliminate ethical/moral debates, Congress might choose to prescribe a *sui generis* system for patenting biotech inventions. Until Congress takes an affirmative action or publicly refuses to do so, human-based inventions will remain subject to the PTO’s wholesale prohibition, no matter how misdirected it may be.<sup>201</sup>

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<sup>197</sup> A cynical view might be that the Rehnquist Supreme Court has more often than not upheld conservative views of the world.

<sup>198</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980).

<sup>199</sup> See Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 715-17 (2004); see also Daniel, *supra* note 193, at 116.

<sup>200</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>201</sup> It is worth mentioning that another federal agency, the Food and Drug Administration (FDA), has claimed jurisdiction over human cloning; this assertion has been criticized as “highly dubious, resting on the twisted supposition that anyone trying to clone a person needs what the FDA calls ‘Investigative New Drug’ authority, really a license to conduct clinical trials of new drugs. But if no new drugs are used, it is hard to see why.” Editorial, *Legislate Carefully*, BOSTON HERALD, Jan. 24, 1998, at 14.

[80] The real issue is not about the granting of patents to life forms. The critics of the very notion of patenting life must realize that prohibiting such patents will not stop researchers from advancing the frontiers of biotechnology. On the contrary, allowing a patent on the Minotaur might help achieve better regulation, because in absence of patent protection, the proliferation of biotechnology is not controlled. The vocal opponents of patents on life forms must ask themselves whether it is the mere thought of owning life that is abhorrent or if the problem lies in a more fundamental technological and metaphysical uneasiness. Attacking patent law addresses the former concern but has little effect on the latter. Opponents should focus their efforts not on altering the patent laws, but on convincing Congress to pass legislation that would regulate the kinds of genetic engineering experiments that scientists may perform.<sup>202</sup> That might keep the Minotaur in the labyrinth for the time being, sparing the lives of a few heroes until we reach the next level of cognitive development.

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<sup>202</sup> This will not be easy. The United Nations recently “ducked the issue of whether to attempt to regulate human cloning,” delaying drafting a treaty on the subject. Gretchen Vogel, *U.N. Procrastinates on Cloning Ban*, SCI. NOW, Nov. 6, 2003, at 1, available at <http://sciencenow.sciencemag.org/cgi/content/full/2003/1106/2>.