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A Global Controversy: The Role of Morality in Biotechnology Patent Law

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Genetically modified transgenic mice. Human clones. Part-human, part-animal creatures. These are just a few of the morally controversial biotech inventions that have garnered public attention in recent years. Increasingly, it seems, biotechnology is an area in which many morally questionable inventions are generated.[1] In addition to those mentioned above, controversial biotech inventions include isolated genes, sequenced DNA, medical procedures, embryonic stem cells, and methods of human/animal chromosome transfer. The moral controversies surrounding these and other biotech inventions stem from several concerns including those arising from the mixing of human and animal species, the perceived denigration of human dignity, the destruction of human life, the exploitation of women for their eggs, and the concept of ownership of humans.

Controversy surrounding morally questionable biotech research is fierce and the topic is widely discussed, but the issue of patents on such research receives far less public attention. And yet the topic of patents on morally controversial biotech subject matter is important, largely because of the relationship between patents and research. A primary reason for granting exclusive patent rights is to provide incentives for the production of inventive public goods that otherwise would be underproduced. But, for some morally controversial biotech inventions, countervailing policies militate against government encouragement and private ownership of such subject matter. Not surprisingly, which inventions should fall into this category is a difficult question to answer.

Patents give their owners the right to exclude others from making, using, selling, offering to sell, or importing the patented invention for a term of about twenty years. These rights can be extremely lucrative and provide significant

* This chapter is largely based on an earlier article, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 Wm. & Mary L. Rev. 469 (2003). The reader is directed to the full article for a more detailed discussion of the topic and research sources.

incentives both for inventors to create innovations that can be patented and for investors to fund research that may result in a patent. For example, it is estimated that the Wisconsin Alumni Research Foundation (WARF), which owns broad patents covering embryonic stem cells and methods for producing them, could reap royalties of $200 million/year just from research performed under California's Proposition 71 alone.[2]

Patent law historically has been territorial in nature, with sovereign states granting patents and providing means for patentees to enforce their rights only within their borders. But morality-based controversies over the patenting of biotech inventions are not limited to the United States; groups in several countries have commissioned studies and drafted reports on the ethical and moral issues associated with patenting certain biotech inventions.[3] The diversity of approaches used by countries and regions to address these issues derive from and are shaped by localized cultural norms and political structures. As large, patent-granting entities, the United States and Europe provide contrasting examples of approaches to the patenting of morally controversial biotech subject matter. This chapter will focus on the approaches and results in these two regions to illuminate benefits and disadvantages that can inform current dialogue and future action around the globe.

BIOTECHNOLOGY PATENTS AND MORALITY: THE UNITED STATES

U.S. patent law contains no statutory basis for the United States Patent and Trademark Office (USPTO) or a court to deny patent protection to morally controversial biotech subject matter. The Patent Act of 1952 provides that a person is *entitled* to a patent if his or her invention meets the statutory patentability requirements specified in the act.[4] The burden is thus on the USPTO to show that a person does not meet the statutory requirements. Because the act has no morality inquiry, the United States has a *de facto* system of patenting first, and asking questions later with regard to morally controversial biotech subject matter. In other words, a patent issues, and then, to the extent that a significant, or at least vocal, portion of society finds it controversial, questions arise regarding whether the patent should have issued.

To understand how this "patent first" system arose, it is helpful to go back to its origins—the U.S. Constitution. Article I, section 8, Clause 8 of the Constitution authorizes Congress "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[5] Congress chose to promote progress in the useful arts by establishing a patent system whereby in exchange for adequately disclosing a useful, novel, and nonobvious invention to the public in a patent document, an inventor would obtain a right to exclude others from making, using, selling, or offering to sell the invention for a period of years.[6]

Section 101 of the Patent Act contains the requirement that an invention be useful in order to be patented, which is why inventions qualifying under that

provision are called "utility" patents. In addition to being useful, however, section 101 also requires the invention to be of the right type. These two requirements, utility and type, or subject matter, comprise the battlefield on which most disputes regarding the patenting of morally controversial biotech inventions traditionally have been fought.

Under section 101, patents may only be granted for new and useful processes, machines, articles of manufacture, and compositions of matter. These four subject matter categories are not mutually exclusive; an invention can be classifiable in more than one category. Likewise, an inventor need not specify which category his or her invention is properly classified in as long as it can be encompassed within one of the four. However, abstract ideas, natural phenomena, and laws of nature are categories of subject matter outside the four corners of section 101.[7]

Despite these limitations, over the past twenty-five plus years there has been an unprecedented judicial expansion in the scope of patent eligible subject matter which has been deemed to include "anything under the sun that is made by man."[8] The U.S. Supreme Court lifted the phrase from the legislative history of the Patent Act of 1952 as evidence of the broad reach Congress intended for section 101. The phrase provided the basis for the Court's path-breaking conclusion in *Diamond v. Chakrabarty*, that living organisms comprise patent eligible subject matter.[9] The phrase was also repeated by the Court in *Diamond v. Diehr*, a case that laid the groundwork for utility patents on computer software.[10] Most recently, in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, which relied heavily on the *Chakrabarty* decision, the Court again trotted out the phrase in support of its holding that sexually and asexually reproducible plants can be the subject of utility patents, despite Congress' enactment of more specific statutory protection schemes for both types of plants.[11] Moreover, in *State Street Bank and Trust v. Signature Financial Group, Inc.*, the U.S. Court of Appeals for the Federal Circuit effectively expanded patent-eligible subject matter to include business methods, opening the doors of the USPTO to a flood of patent applications from traditionally nontechnical disciplines such as the accounting and financial services industries.[12]

In *Diamond v. Chakrabarty*, the Court gave a green light to biotech researchers and investors by confirming that "life" can comprise patent-eligible subject matter. As explained by the Court, "the relevant distinction [is] not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." Dr. Chakrabarty's oil-eating microorganism thus qualified as patent-eligible subject matter because it was "a nonnaturally occurring manufacture . . . a product of human ingenuity."

Acknowledging the possible repercussions of its decision, the Court noted the "gruesome parade of horribles" identified by the USPTO and *amici* as potentially resulting from biotechnology patents:

> We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity,

> and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."[13]

The Court, however, declared itself to be "without competence" even to entertain such morality-laden "high policy" arguments. In broadly construing section 101, the Court circumscribed its ability to impose any moral limits on subject-matter eligibility. Rather, it identified its role as "the narrow one of determining what Congress meant by the words it used in the statute; once that is done, our powers are exhausted. . . . [U]ntil Congress takes . . . action, this Court must construe the language of § 101 as it is."[14] Consequently, the section 101 subject matter prong of patent eligibility does not provide a bar to the patenting of morally controversial biotech subject matter.

Likewise, for the vast majority of inventions, the section 101 utility requirement is a low hurdle to overcome. According to USPTO Utility Examination Guidelines, it is sufficient to meet the requirement if a patent application recites at least one "specific, substantial, and credible" use for an invention.[15] Historically, however, establishing utility was not always an easy task. Fairly early in the development of patent law, the courts considered the morality of an invention in the context of the utility requirement. Justice Story is credited with providing the first articulation of the doctrine as he instructed the jury in the 1817 *Lowell v. Lewis* decision. As he explained, "[a]ll 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*."[16]

Justice Story's language provided the foundation for what came to be known as the "moral utility" doctrine; the idea that to be "useful" within the meaning of the patent statute, and thus eligible for patent protection, an invention had to meet certain judicially identified standards of morality. For over 150 years, courts cited this requirement as the basis for rejecting a variety of morally controversial inventions, including gambling machines and fraudulent articles.

Not surprisingly, over time, courts began to whittle away at the scope of the requirement as societal views on morality shifted and difficulties in defining morally acceptable inventions multiplied. Instead of an invention being ineligible for patent protection if it could be used unlawfully, the test developed that an invention could meet the moral utility requirement if it had at least one moral, legal purpose. As articulated by the USPTO Board of Patent Appeals and Interferences, the test for utility under section 101 was a simple one: "[E]verything [is] useful within the meaning of the law, if it is used (or designed and adapted to be used) to accomplish a good result, though in fact it is oftener used (or is as well or even better adapted to be used) to accomplish a bad one. . . ."[17]

Eventually, courts began refusing to impose the requirement at all. The courts acknowledged that it was an area in which Congress could legislate, but

that such determinations were not the proper purview of the judiciary or the USPTO. In 1998, however, the moral utility doctrine seemed on the verge of revival when the USPTO threatened to invoke the requirement in response to receiving a controversial patent application. The application, filed by activist Jeremy Rifkin and biologist Stuart Newman, claimed the invention of human-animal chimera, creatures made, in theory, by blending human cells with those of various animals such as mice, chimpanzees, pigs, or baboons.[18] The applicants actually have not made such creatures, nor do they want anyone else to make them.[19] Rather, their purpose in filing the application was to provoke a debate and force Congress, the courts, or the USPTO to draw the line on patent-eligible subject matter.[20]

Shortly after receiving the chimera application, the USPTO issued a media advisory entitled *Facts on Patenting Life Forms Having a Relationship to Humans*.[21] In the advisory, the Office cited Justice Story's quote in *Lowell v. Lewis* and posited 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."[22]

Not long after the USPTO's announcement, however, the Federal Circuit handed down the decision of *Juicy Whip v. Orange Bang*, which explicitly sounded the death-knell for the moral utility requirement.[23] In rejecting an argument that the moral utility requirement should be applied to invalidate a patent on a deceptive invention, the court announced:

> It has been stated that inventions that are injurious to the well-being, good policy, or sound morals of society are unpatentable. . . . [B]ut [this] principle . . . has not been applied broadly in recent years. . . . As the Supreme Court put the point more generally, Congress never intended that the patent laws should displace the police powers of the States, . . . those powers by which the health, good order, peace and general welfare of the community are promoted. . . . course, Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness. . . . Until such time as Congress does so, however, we find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.[24]

Indeed, by its own admission in a more recent statement, the USPTO has acknowledged that it is without authority to deny a patent based on morality or public policy concerns and has actually issued several patents that arguably "encompass" humans.[25] In addressing a comment that the USPTO should deny patents on DNA for the public good, the Office stated:

> The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer. . . . Congress creates the law and the Federal judiciary interprets

> the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications.[26]

Thus, the judicially created moral utility requirement is now defunct, and no longer provides a basis for the rejection of morally controversial biotech patents, leaving the United States with a "patent first, ask (moral) questions later" system. As a result, morally controversial biotech patents have issued from the USPTO in increasing numbers since *Diamond v. Chakrabarty* flung open the doors of the USPTO to biotech subject matter.

The moral objections to biotech patents can be divided into at least two groups: (1) objections to a patent based on concerns about the morality of practicing the patent's underlying subject matter (for example, multicellular animals, human-animal chimera, and human cloning), or (2) objections to a patent based on concerns regarding the morality of allowing anyone to limit the practice of the patent's underlying subject matter (for example, medical process methods). These are very different morality-based concerns yet both involve objections to the issuance of a patent on the relevant subject matter. The following notable examples illustrate, to some extent, the difficulties with having a "patent first, ask questions later" approach to determining the patent eligibility of morally controversial biotech subject matter.

On April 7, 1987, the USPTO made the announcement that it considered "non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter" based on *Diamond v. Chakrabarty*.[27] The USPTO issued the notice after its internal Board of Patent Appeals and Interferences had held multicellular polyploidy oysters to be patent-eligible subject matter under 35 U.S.C. § 101.[28] News of the Office's plans to patent animals created significant public controversy and calls for bans on both the underlying research and patents on genetically modified animals.[29]

Representatives of myriad constituencies testified regarding the potential impacts, positive and negative, of such patents.[30] Commentators in favor of animal patents pointed to the potential for curing human diseases, ending human hunger, and maintaining U.S. dominance in biotechnology as reasons to continue awarding such patents, as well as the fact that the USPTO's Notice explicitly limited such patents to nonhuman organisms. Arguments supporting a ban or moratorium on animal patents included the concern that such patents would encourage the development of transgenic animals, devalue life and the dignity of life, disrupt traditional family farms and the environment, and increase animal suffering.[31]

Animal patent opponents also sought relief in court. Nine plaintiffs, including the Animal Legal Defense Fund, the American Society for the Prevention of Cruelty to Animals, and the Humane Farming Association, filed suit alleging that the USPTO commissioner had violated the Administrative Procedures Act

in filing the Notice without complying with the required public notice and comment period.[32] In affirming dismissal of the suit for lack of standing, the Federal Circuit noted:

> Essentially, appellants assert a right, as members of the public particularly interested in animals, to sue for what they perceive to be an unwarranted interference with the discretionary judgment of an examiner. However, it must be noted that whether patents are allowable for animal life forms is not a matter of discretion but of law. . . . Thus, if we assume examiners must follow the Notice—which the Commissioner denies—such action has no effect on the ultimate validity of any patent. *Either the subject matter falls within section 101 or it does not, and that question does not turn on any discretion residing in examiners.*[33]

The court's words made clear the absence of any authority on the part of the USPTO to deny patents on otherwise patentable subject matter, despite the reference to "non-human" organisms in the Notice. USPTO pronouncements on the scope and limits of patent-eligible subject matter are not determinative. Congress, with the Supreme Court as ultimate interpreter, sets patent eligibility limits.[34] Section 101 of the Patent Act, as interpreted, encompasses "anything under the sun that is made by man," including, apparently, animals and even other men.

While Congress was in the process of hearing testimony on the matter, the USPTO actually issued its first animal patent. On April 12, 1988, almost a year to the day after its earlier dramatic announcement, the USPTO heralded the issuance of the world's first patent on a higher life form, in this case a mouse, as "a singularly historic event."[35] The mouse, developed by Harvard researchers Philip Leder and Timothy Stewart, was genetically modified to increase its chances of developing cancer, making it a more useful research subject.[36] The patent's issuance further fueled the controversy, but it also complicated the issue because a real invention, with real potential for saving or improving human lives, was at stake. It thus is not surprising that bills that would have created an animal patent moratorium failed to pass. Once the patent engine begins to pick up speed, it can be very difficult to put on the brakes.

Congress was able to put on the brakes, to an extent, several years later when faced with a controversy over medical procedure patents. In 1993, Dr. Samuel Pallin sued Dr. Jack Singer for infringement of Pallin's patent covering a cataract surgery technique.[37] Although Pallin's patent was not the first on a medical procedure, it apparently was one of the first to be asserted against a medical practitioner. The lawsuit touched off a firestorm of controversy concerning whether medical procedures should be patentable.[38] Arguments against patents on medical procedures focused on several moral and ethical concerns, including the impact on patient access to life-saving techniques because of cost or a physician's fear of suit, possible invasions of patient privacy in the gathering of patent-related information, interference with physician autonomy regarding patient treatment,

and disintegration of the traditional culture of disclosure and peer review that pervades the medical community and enhances the overall quality of patient care.

This controversy differed from the one over animal patents in a very significant respect, one which clearly affected the legislative outcome. Whereas with animal patents, the potential inventors in the biotech community were in favor of the patents, a large portion of the potential inventors in the medical community—namely, physicians—were *against* such patents. The House of Delegates of the American Medical Association (AMA) voted to condemn efforts to patent surgical and medical treatment methods in 1994.[39] The Council on Ethical and Judicial Affairs of the AMA also issued a report in 1995, condemning the patenting of medical procedures by physicians as unethical.[40]

Two bills were introduced in Congress to address the perceived patent problem. One, preferred by the medical community, prohibited the issuance of patents on medical and surgical procedures. The other, which addressed the concerns raised by the biotechnology industry, only prevented medical procedure patents from being asserted against medical professionals engaged in noncommercial endeavors involving nonbiotechnology processes.[41] Congress chose the latter approach, which dealt with many, but not all, of the concerns of the medical community. The statute that was eventually passed by Congress allows for the continued issuance of medical procedure patents, but prohibits their enforcement against doctors.[42]

The Newman-Rifkin chimera application mentioned earlier represents an instance where, arguably, the USPTO asked morality questions first, but lacked the authority to do so. In this instance, the USPTO rejected the claims in the application under section 101 as directed to nonstatutory subject matter.[43] The applicants did not appeal the rejection so the USPTO's unauthorized policy decision was not subjected to judicial scrutiny. As discussed earlier, the USPTO has no basis, under the current judicial interpretation of the scope of section 101, for denying a patent on human/animal chimera as not being directed to statutory subject matter, and has, in fact, issued other, less controversial chimeric patents.[44] The USPTO's inconsistent application of its self-proclaimed policy only muddies waters that were already far from clear.

Interestingly, in an early rejection of the Newman-Rifkin chimera application, the USPTO invoked not only the now-defunct moral utility requirement to reject the application claims, but also the Thirteenth Amendment to the Constitution.[45] The USPTO first alluded to a possible Thirteenth Amendment-based rejection in its 1987 notice declaring "nonnaturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101."[46] The notice stated that a claim to a human being would not be considered patentable, because "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution," apparently referring to the Thirteenth Amendment.

Does the Thirteenth Amendment ban patents on humans? The Amendment states that "[n]either slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction."[47] But what meaning does this language have in relation to patent law? A patent does not give its owner the affirmative right to practice the subject matter of the invention, but only the right to exclude others from making, using, selling, or offering to sell the invention.[48] Thus a hypothetical patent on a genetically modified "human" would not entitle the patent owner to force the patented human to "do" anything. However, a problem could arise with, for example, "using" human/animal chimera for research if the chimera was sufficiently human to qualify for constitutional protection.[49]

While the Thirteenth Amendment may have relevance for the production and patenting of human/animal chimera, it likely is not implicated in the patenting of a variety of other morally controversial biotech inventions involving humans.[50] *Roe v. Wade* holds that at their earliest stages of development, embryos are not constitutionally protected as "persons."[51] This holding suggests that, at a minimum, the Thirteenth Amendment would not bar patents on embryos and fetuses prior to viability.

Although the Newman-Rifkin application was filed to start a debate, the issuance of patents on more and more complex human-animal chimera is swiftly leaving the realm of the hypothetical and nearing reality as research advances in this area. For example, "[i]n Minnesota, pigs are being born with human blood in their veins. In Nevada, there are sheep whose livers and hearts are largely human. In California, mice peer from their cages with human brain cells firing inside their skulls."[52] Moreover, the risks of animals expressing genes that will incorporate essential elements of "humanness" have increased with recent developments in chromosome transfer techniques. As one commentator explains:

> Thousands of [human] genes may be introduced into [an animal] with a single chromosome. Chromosome transfer may be an attractive method of introducing genes . . . however, although the functions of certain genes may be known, the functions of other genes on a chromosome may be unknown. Until the functions of all of the genes on a given chromosome are identified, there is no way of knowing what attributes may be transferred along with the genes of known function.[53]

The Newman-Rifkin HuMouse patent application, originally filed in 1997, was denigrated by scoffers and skeptics as unnecessary and ill-conceived.[54] In less than a decade, however, the activists' fears have been confirmed as prescient: already, other similar human animal chimera applications are pending in the USPTO.[55] Moreover, on November 13, 2002, at a forum organized by the New York Academy of Sciences and Rockefeller University to discuss standards for human embryonic stem cell research, scientists proposed injecting human

embryonic stem cells into mouse embryos which would then be "reimplanted into a female mouse and allowed to develop."[56] The reason given for the creation of such embryos was to test the human stem cells for pluripotency, the ability to "integrate into the embryo and contribute to the formation of every tissue, including the germ line which produces sperm and eggs."

Although the forum did not agree to support a document proposing the creation of such embryos, researchers say experiments combining the cells of different species in an embryo will likely become more common over time. This despite the fact that, as identified by one participant at the New York forum, viable stem cell testing alternatives to making interspecies chimera exist and these alternatives would not pose the same moral and ethical concerns. Consequently, without legislative limits on the patent eligibility of morally controversial biotech subject matter, we can expect to see human-animal chimera patents on creatures exhibiting increasing degrees of "humanness" issuing from the USPTO and continuing to spur research of this sort.

Another morally controversial biotech research area is human cloning. A recent biotech controversy centered on a cloning patent owned by the University of Missouri and claiming inventions developed by two researchers from that school. U.S. Patent No. 6,211,429 (the '429 patent) issued from the USPTO on April 3, 2001, but did not receive widespread attention until mid-2002.[57] Although principally directed to techniques for producing human organs from transgenic pigs for transplantation purposes, the patent's scope is much broader. The patent claims, among other things, methods for "producing a cloned mammal," for "producing a cloned mammalian embryo," and methods for transplanting a nucleus from a cultured mammalian cell, mammalian embryo, mammalian fetus, or adult mammal to a recipient mammalian oocyte.

Most disturbing is the fact that the patent disclosure states (but not in the claims) "the present invention encompasses the living, cloned products produced by each of the methods described herein." Under U.S. law, that is actually a true statement. Although there are no claims in the patent to any products of the method, and the claims define the scope of the invention to which patent rights attach, the University still has a patent-based property interest in clones produced by the claimed method. The property right is delineated in 35 U.S.C. § 271(g), which allows the owner of a U.S. patent on a process of making a product to prevent products made by the patented process from entering the United States. In other words, the '429 patent gives the University of Missouri the right to exclude clones made by the '429 patent from being imported into this country for commercial purposes.[58]

As in other situations involving issuance of a patent on morally controversial subject matter, the cloning patent generated negative commentary and calls for legislative action from a variety of sources.[59] Senator Sam Brownback offered an amendment to section 101 of the Patent Act to add a new subsection, "Unpatentability of Human Organisms," that would exclude from patent eligibility an organism of the human species at any stage of development, produced by

any method, a living organism made by human cloning, or a process of human cloning.[60] In defending the amendment, which ultimately failed, Senator Brownback cited news reports on the '429 patent and referenced the fact that three similar patents were pending in the USPTO.

In response, several senators derided Brownback's bill as premature and unnecessary in view of the USPTO's 1987 policy statement regarding the unpatentability of claims directed to or including human beings.[61] Brownback countered that lawyers were challenging the USPTO policy and that legislative action was needed "to provide clarity."

Whether the Brownback amendment was the correct response was a matter of policy for Congress to decide. Nevertheless, in making their decision, the members of Congress who opposed Brownback's amendment were laboring under a serious misapprehension. They believed the USPTO has the authority to deny patents on morally controversial inventions, at least to the extent they comprise humans. This misunderstanding was confirmed with the inclusion of the Weldon Amendment in the 2004 Consolidated Appropriations legislation. The amendment provided that none of the funds appropriated to the USPTO for that year could be used to issue patents directed to or encompassing a human organism.[62] However, the provision was flawed from the outset as it failed to define "human," did not amend the patent statute so as to provide a basis for the rejection of a claim, and, as part of a spending bill, is a temporary measure that requires yearly reenactment. The provision was included in the 2005 and 2006 appropriations legislation.

In introducing the measure, Representative Dave Weldon called the provision "a clarification" of the USPTO policy against patenting humans. What members of Congress failed to realize is that the USPTO "position" is neither the law, nor is it even the consistent practice of the USPTO. Numerous patents on transgenic animals that contain human genetic material exist already.[63] Moreover, the provision has not been interpreted by the USPTO to include human cloning patents so such patents that "encompass humans" by virtue of 35 U.S.C. §271(g).[64] Thus, instead of providing clarification, the Weldon amendment has further muddied the already confusing USPTO approach to patents on morally controversial subject matter.

As discussed earlier, under the U.S. Patent Act, a person is entitled to a patent if he or she meets the statutory requirements. In the absence of clear congressional action, researchers are essentially making patent policy and determining the limits of patent eligibility by the subject matter described in their applications. To a more limited extent, the USPTO is also making such decisions by reserving the right, on an ad hoc basis, to reject claims to inventions deemed to encompass humans, however, an examiner defines the term "human" on any given day. But are these researchers and examiners the individuals that we, as a society, want to make these important policy decisions? Are they the best actors, and is the closed environment of the USPTO the best forum for these determinations? This is unlikely to be the case.

At least in terms of comparative competence, scientists are certainly far less equipped than Congress to determine what the limits of patent eligible subject matter should be. Unlike Congress, scientists hold no public hearings, they are not accountable to any public constituency, and they have a cloak of relative anonymity to shield them from public view. This is not to say scientists and researchers are bad people, or enemies of the public or any such thing. Rather, the interests and goals of individual researchers should not be substituted for, nor denominated as, the interests of society at large.

Patent applications covering morally controversial biotech subject matter are not filing themselves in the USPTO; they are prepared by scientists, with the help of patent attorneys. These scientists may indeed have as a goal curing some dreaded disease, and the lure of patent protection may provide necessary funds for that research. If one takes the view that as long as an invention is related to the goal of alleviating human suffering, the government should grant patent rights on it, moral concerns notwithstanding, the result may soon be, among other things, patents on human fetuses that are genetically modified in ways one can only imagine. Patent protection could convert such fetuses, to the extent they are denied constitutional protection, into justifiable commodities, supplying life-saving tissue and organs to sick children and adults.[65]

Is relieving human suffering the supreme imperative that trumps all other values? Right now, in the realm of patents, it appears to be, with little or no consideration of whether patents on morally controversial biotech subject matter are a "strategic necessity" or even a moral necessity. Many scientists do not know where to draw the line, or whether there should even be a line addressing what "means" are morally unacceptable, even for achieving a moral "end." According to Drs. Maureen and Samuel Condic, this should not be surprising because:

> When it comes to morals, the key insight to remember is that scientific research is about the possible, not about the ethical or the good. As such, scientific evidence can inform society whether something can, at this point in time, be done and . . . can predict whether it is probable something will be done in the future, but science is inherently silent on the topic of whether it should be done. In other words, a scientist, qua scientist is no better equipped to weigh-in on the moral implications of some new technology by virtue of his scientific training than is any other person. Indeed, scientists are, in many respects, uniquely un-suited to make moral [j]udgments—precisely due to their focus on the possible. Much that is "possible," and a legitimate topic of investigation, from the perspective of science, is nonetheless objectively evil.[66]

It thus is not even realistic to expect patent applicants to set limits on the moral aspects of patent subject-matter eligibility. And while the USPTO may try, in some cases, to set limits, it has neither statutory authority nor articulated standards for doing so. It is for Congress, as the representative of the people, to set clear limits on patent rights over morally controversial means to morally desirable ends.

A popular argument among commentators in this area is that patents are not the issue: the underlying research is the issue, and moral considerations have no place in patent law.[67] But as Professor Peter Drahos explains: "[l]ike it or not, the creation, operation and interpretation of the patent system is linked to moral standards. Patent law is located within and not outside a public ethic of community values and shared economic and social interests. There is nothing surprising about this."[68] Moreover, the argument is contradicted by, among others, some actual proponents of the research. In a 2002 letter urging then-Senate Majority Leader Tom Daschle to oppose an amendment that would ban patents on human cloning via somatic cell nuclear transfer (SCNT), Carl Feldbaum, then-president of the Biotechnology Industry Organization (BIO), stated: "The Brownback amendment is a "backdoor" way of stopping stem cell research and SCNT in the United States of America. By removing the economic incentive to do this research, the amendment would effectively stop investment and research activity in this nation."[69]

The *Chakrabarty* decision was critically important because of the signal it sent to researchers and investors that "there's gold in them thar hills!," the "hills" of biotechnological advancement protected by patent rights to monopoly profits.[70] As Professor Dan Burk succinctly notes: "[O]pposition to patenting cannot be viewed as irrational: offering a financial incentive such as a patent will directly or indirectly increase the activity that is of true concern to patenting opponents."[71] The fact is, altruistic scientists currently are not banned from conducting research on morally controversial biotech subject matter, but without the promise of lucrative licensing contracts and royalties from government granted patent protection, much of the research likely would not continue.[72] Because diseases still must be cured, some researchers would be more likely to focus their efforts on less morally controversial solutions, for example, working with adult stem cells as opposed to embryonic stems cells, because patents would be freely available for such inventions.[73] In addition, the availability of patents on morally controversial biotech subject matter provides a strong motivation for interested parties to lobby Congress and to inhibit or overturn funding or research bans.

Focusing on patents on morally controversial biotech subject matter as well as on research is important because while Congress has the authority to determine patent subject matter, its power to halt such research may be in question. An argument gaining traction in the scientific community is that there is a constitutional right to research. California recently created a state constitutional right to conduct embryonic stem cell and cloning research, and some scientists are asserting that this is a right under the U.S. Constitution as well. According to Nobel Laureate Paul Berg, an emeritus professor at Stanford University in the field of cancer research:

> It seems relevant to ask if the freedom to conduct scientific research ... is legitimately different from the rights afforded to the press for their freedom of inquiry and publication. ... I believe the case can be made that the freedom to

> conduct scientific inquiry is inherent in the right to free speech granted in the Constitution's Bill of Rights.[74]

Current biotechnology research is headed toward full commoditization of human beings, made possible and encouraged by patent protection. As one commentator noted:

> [I]n just the last year we have seen how quickly moral lines dissolve in the face of promised medical progress. We have seen how the need to use only embryos "left over" from in vitro fertilization (which are going to die anyway, advocates said) has become the need to create cloned embryos explicitly for research and destruction. And we can imagine how the need for cloned embryos will soon become the need for later-term cloned fetuses—something these patents anticipate and endorse.[75]

Such comments should not be lightly dismissed as overly dramatic hyperbole. At least one recent chimera application claimed a mammalian fetus created by a claimed cloning method.[76]

As patents are issued first, Congress and the public are continually in a reactive, rather than proactive, mode. The grant of a patent also covers the subject matter with a veneer of legitimacy and a presumption of validity that can be difficult to overcome. Patents on biotech inventions are generally hyped as necessary, both for realizing the great promise for alleviating human suffering the invention offers, and for keeping the United States at the forefront of cutting edge, lucrative research. Perhaps a different order of inquiry, for example, patent eligibility before patentability, would be preferable.[77]

BIOTECH PATENTS AND MORALITY: EUROPE

The territorial model of patent rights is still in effect, but it is slowly changing. Several regional treaties that allow an applicant to file one application with a central office and obtain patent protection in multiple countries already exist, although the patent must be enforced in cases of infringement in each individual country. The most significant regional treaty is the Convention on the Grant of European Patents (EPC), signed in 1973 by a group of countries seeking to create a uniform European patent system.[78] The EPC established the European Patent Office (EPO) and contains substantive and procedural requirements for obtaining a European patent, valid in all member countries with only a single application. An applicant may still apply for patent protection in each individual member country, but the laws of each country have been modified to comply with the EPC.

In contrast to the U.S. "patent first" approach, the EPC (covering almost all European Union states plus several others) contains an express morality-based

patent eligibility bar. As such, it can be considered an "ask questions first, then patent" system. Article 53 of the EPC states: "European patents shall not be granted in respect of: (a) Inventions the publication or exploitation of which would be contrary to 'ordre public' or morality." Over the past two decades, the EPO has been called on several times to determine if inventions should be denied patent protection based on morality concerns, and its decisions evidence both benefits and challenges in employing a statutory morality provision.

The first EPO decision to apply the morality limitation of article 53 of the EPC dealt with the famous Harvard oncomouse.[79] In addition to filing an application in the USPTO, which issued a patent on the mouse in 1988, the inventors also filed applications in the EPO and other countries.[80] In considering the application of article 53(a) to the invention, the EPO Examining Division chose a very narrow focus for its inquiry, ignoring any objections to patents on animals in principle.[81] Instead, the Examining Division employed a balancing test, noting that "[f]or each individual invention [involving higher life forms] the question of morality has to be examined and possible detrimental effects and risks have to be weighed and balanced against the merits and advantages aimed at."[82] It then set about balancing three interests: (1) the interest in remedying human diseases, (2) the interest in protecting the environment from the uncontrolled spread of unwanted genes, and (3) the interest in avoiding cruelty to animals.

On the first interest, remedying human diseases, the Examining Division came down on the side of patentability, noting that the invention could be of great benefit to mankind if it could help in the search for a cure for cancer, one of the most frequent causes of human death. For the second interest, protection of the environment, the Examining Division admitted that the introduction of such genetically modified animals into the environment, where malignant foreign genes could be spread through mating, could cause unforeseen environmental problems. The Examining Division, however, did not consider this concern to be a significant bar to a patent since the animals would be used solely in laboratory settings and would not be released into the general environment. Finally, the third interest, preventing cruelty to animals, also was not a bar to a patent. The Examining Division reasoned that although more of the animals with the foreign gene would develop painful cancers, the invention allowed for the use of fewer animals in total so the invention would in effect reduce the overall extent of animal suffering. The absence of suitable alternatives was also relevant to the Examining Division's decision, which noted that animal models currently are considered indispensable in testing. In allowing a patent on the invention to issue, the Examining Division concluded:

> In the overall balance . . . the present invention cannot be considered immoral or contrary to public order. The provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals . . . can generally be regarded as beneficial to mankind. A patent should therefore not be denied [based on] Article 53(a) EPC.[83]

Although the balancing test provides an example of "asking questions first, patenting later," it is a far from perfect approach. One problem with the test is that the Examining Division never defined morality nor stated a rational basis for choosing those particular factors to balance as opposed to other possible concerns. For example, one objection to the patent during opposition proceedings was that "the Examining Division failed to consider the morality of every possible application of the patent which was being claimed."[84] The objection cited an "oncogiraffe" as a creature that would come within the literal terms of the claims, but would be highly unlikely to be used as a test model in cancer research, thus shifting the balance against a patent.

Moreover, the decision of the EPO did not vanquish controversy regarding the oncomouse patent. Even though the patent was issued, it quickly became the target of more than a dozen petitions to the EPO opposing its issuance.[85] Nevertheless, the test does provide the EPO with a mechanism for evaluating the patent eligibility of morally controversial biotech inventions before granting a patent. For example, a different transgenic animal, one genetically modified to lose its hair so that it would be useful in human baldness studies, apparently failed the balancing test according to a notice from the EPO to the Upjohn Corporation, the owner of the application.[86] Although the degree of animal suffering would be similar, the interest in curing baldness is certainly not as compelling as the interest in curing cancer.

Balancing competing interests is not the only approach the EPO has taken when evaluating the applicability of the article 53(a) exception. In two later cases, different bodies within the EPO articulated two additional morality tests: (1) the unacceptability test and (2) the public abhorrence test.[87]

A few years after the Oncomouse case, the EPO was confronted with applying article 53(a) in *Greenpeace v. Plant Genetic Systems*.[88] Greenpeace asserted article 53(a) during an opposition as a basis for revoking a patent on transgenic plants developed to be resistant to a particular class of herbicides. Greenpeace lost the opposition and appealed to the EPO Technical Board of Appeal (the Board), which maintained the patent, albeit in an amended form, concluding that the invention did not contravene the *ordre public* or morality requirements of article 53(a). In framing the nature of the morality inquiry under article 53(a), the Board looked to the intent of the drafters of the EPC, as evidenced by historical documents, and explained:

> The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is . . . European society and civilisation. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.[89]

The Board concluded that none of the claims in the patent violated the morality provision of article 53(a) because they concerned "activities (production of plants and seeds, protection of plants from weeds or fungal diseases) and products (plant cells, plants, seeds) which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture." In other words, the Board ignored the more fundamental concerns regarding the patent's subject matter and focused narrowly on the general types of products and activities the patent concerned. This narrow focus allowed the Board to avoid broader concerns and tied patentability to the "public acceptability" of the general categories of patentable subject matter.

In reaching its decision, the Board expressly declined to employ the balancing test used in the Oncomouse decision, noting that it "[was] not the only way of assessing patentability" under article 53(a) but was "just one possible way, perhaps useful in situations in which an actual damage [*e.g.*, suffering of animals] . . . exists."[90] The Board held that the balancing test could not be used, because sufficient evidence of actual disadvantages was not adduced in the case. This "unacceptability" standard is certainly a lower hurdle for an invention to overcome than the balancing test, because balancing does not even come into play unless concrete societal disadvantages of the invention are presented.

The third test for patentability under article 53(a), public abhorrence, has been cited in several EPO decisions, sometimes in combination with the unacceptability test. In *Howard Florey/Relaxin v. Fraktion der Grünen im Europäischen Parlament*, several groups filed an opposition in the EPO to the issuance of a patent on the hormone Relaxin.[91] They argued that the patent would offend article 53(a) because, among other things, it covered the patenting of human genes and involved taking tissue from a pregnant woman, thus offending human dignity. The EPO Board disagreed and articulated the "public abhorrence" test for exclusion under article 53(a):

> A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Article 53(a); otherwise not.[92]

The "public abhorrence" test thus presents an even lower hurdle for a morally controversial invention to overcome since fewer inventions are likely to be deemed "abhorrent" to society than simply "unacceptable" to society. This confusing and largely unsatisfactory panoply of tests to interpret the meaning and applicability of the morality proviso of article 53(a) added a further impetus for European Union-wide legislation that would clarify and delineate the specific patentable limits of morally controversial biotech subject matter. The result was the European Union Biotechnology Directive of 1998.[93]

In drafting the directive, the European Parliament and Council had two primary goals. The first was to clarify and harmonize the legal protection of biotech

inventions in the region to increase investment in biotechnology research. For years the European Union (EU) had lagged behind the United States and Japan in biotechnology, a deficit attributed to deficient, confusing, and overlapping patent rights.[94] The second goal was to preserve the right of EU member states to consider moral implications in determining patent-eligible subject matter, as they were able to do under article 53(a) of the EPC.[95]

To accomplish these goals, the drafters of the directive traversed a political tightrope, specifying a variety of biotech inventions that were eligible for patent protection, and ones that were not, to serve as a guide in determining how the morality exception (similar to article 53(a) of the EPC) should be interpreted. Under the directive, biological material isolated from the human body or other natural environment is patentable, as are uses of human embryos for therapeutic purposes, and plants and animals not confined to particular varieties. Conversely, and confusingly, the directive excludes from patentability the following examples as morally or ethically unacceptable patent subject matter: processes to produce chimera from germ or totipotent human and animal cells, human cloning, commercial uses of human embryos, and processes for modifying the genetic identity of animals that may cause them suffering without substantial medical benefits.

The directive is a result of political compromise, agreed upon by member states after ten years of negotiation. Unfortunately, some member states left their public constituents out of the dialogue until after approval of the directive, resulting in extremely negative public reaction to the agreement.[96] As a result, several EU member states defied EU law by failing to create national laws to implement the directive by the July 30, 2000, deadline, exposing those states to legal action and sanctions by other members.[97] This group of member states filed a lawsuit in the European Court of Justice requesting the annulment of the directive based on issues associated with its adoption, its conflicting provisions on human patenting, and basic human rights concerns.[98] The ECJ upheld the legality of the directive, but opposition to the directive was so fierce that despite losing the legal challenge, eight of the fifteen EU member states had not incorporated the directive into their national laws by the end of 2003, and four were still out of compliance in early 2005.[99]

Moreover, even in countries that have implemented the directive, the form of the implementation has generated controversy in some instances. For example, implementing legislation in both France and Germany narrowly limit gene patent protection to the specific use detailed in the patent.[100] Consequently, broad gene claims in patents issued by the European Patent Office may not be valid in those countries.

The European Patent Organization, which is not a member of the EU, voluntarily complied with the directive by amending the EPC implementing regulations. In particular, Rule 23(d) entitled "Exceptions to Patentability" further delineates EPC Article 53(a)'s *ordre public* and morality provisions and provides:

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(1) processes for cloning human beings;
(2) processes for modifying the germ line genetic identity of human beings;
(3) uses of human embryos for industrial or commercial purposes;
(4) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The EPO has cited paragraph (c) of this provision in rejections of patent applications claiming products created through the destruction of human embryos to obtain embryonic stem cells. In April 2006, questions regarding the rejection of the Wisconsin Alumni Research Foundation's (WARF) patent application relating to such stem cell products were referred to the EPO Enlarged Board of Appeals to provide clarification on the parameters of the Rule 23(d) exceptions.[101] By specifying certain inventions as violative of the EPC morality and *ordre public* provisions, the directive negates the need for balancing, public acceptability of public abhorrence determinations for such claims. However, the patent-eligibility of controversial biotech subject matter falling outside of the specific exclusions must still be assessed.

Some commentators criticize the directive for its continued inclusion of moral and ethical considerations suggesting, among other things, that the morality provision will impede the directive's goals due to vagueness and conflicting interpretations by member states, and that patent examiners should not be forced to make moral and ethical judgments about inventions. The directive, however, is noteworthy for its earnest, albeit inconsistent, attempt to provide specific guidance to patent offices and courts on what, from the legislature's view, constitutes morally unacceptable patent subject matter.

Beyond the United States and member countries of the EPC are numerous other countries with statutory provisions allowing inventions to be excluded from patentability on the basis of morality. Thus, it is not surprising that in negotiations on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), this large group of countries was able to incorporate a morality provision into the agreement despite U.S. opposition.

This right is expressed in article 27(2) of TRIPs, which requires that members provide patents for inventions in all fields of technology with one significant caveat: "Members may exclude from patentability inventions . . . [where such exclusion] is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health. . . ."[102] In other words, member nations do not have to provide patent protection for at least some morally controversial inventions. By providing this morality-based safe harbor, TRIPs accommodates both the U.S. view that "anything under the sun made by man" is patent-eligible, and the views of many other countries that deny patents on certain morally controversial inventions.

The idea that morality concerns may be the basis for denying patent protection appears to be a common theme across world patent systems. Even the United

States once ascribed to that view as evidenced by the moral utility doctrine. Consequently, it may be prudent for the United States to rejoin other nations in placing moral limits on certain categories of patent subject matter, even if the United States differs with other countries on the nature or scope of those limits.

CONSIDERATIONS IN ADDRESSING MORALLY CONTROVERSIAL BIOTECH PATENTS

If the United States is to have morality-based limits on patent subject matter eligibility beyond the vague and transitory Weldon Amendment, then who will set them and how? Just as the USPTO has no statutory basis, even under the Weldon Amendment, on which to reject patents on controversial technologies that meet the specified patentability requirements, the courts have no basis for reading moral limitations into any of the current patent provisions. Consequently, the only actor with the institutional competence to dictate the limits of patentable subject matter is the one given that authority by the Constitution: Congress. What is required, then, is a legislative solution with substantive guidance for the USPTO and carefully drafted language for the judiciary to interpret.

Admittedly, public choice theory would militate against congressional action in this area, because legislators are perceived to be subject to interest group capture to facilitate rent seeking. The effect of special interest groups in patent law is evident in, for example, the nature of congressional action regarding the transgenic mouse patent and the ban on enforcement of medical methods against medical practitioners. Nevertheless, a decision, for example, to ban patents on humans, however defined, by statute would implicate ideological concerns that, if the public were sufficiently aroused, could overcome interest group capture to some extent, or at least focus it on the contours of the ban, versus on the ban itself. As noted by one commentator, "organized interests will have less influence on the general nature of the [ideological] legislation that is passed than they will on the detailed implementation and enforcement of that legislation."[103] Of the available options, Congress seems clearly to be the best suited to make determinations in the context of setting federal patent policy for all technologies. Moreover, as articulated by the courts, Congress is the only body with the authority to adjust the scope of patent subject matter under 35 U.S.C. §101.

Of course, legislation excluding morally controversial subject matter from patent protection would not stop research into such subject matter from taking place. Rather, it would reduce the incentives for conducting the research and keep certain fruits of such research in the public domain precisely because the underlying activity is either (1) so controversial that the government should not place its imprimatur on it via a patent grant or (2) so socially beneficial that government should not grant anyone exclusive rights in it.

Undoubtedly, such legislation could have the effect of reducing discoveries and innovations in certain biotech areas of inquiry, a consequence which cannot

be dismissed lightly. Because patents require disclosure, such legislation could also have the negative effect of keeping such research hidden from public view and potential regulations. However, there are already areas of scientific research society does not promote or condone for moral reasons, such as various types of experiments on human subjects, despite the fact that useful, even life-saving information might be generated thereby. The blurring of the line between human and nonhuman animals occasioned by biotechnological advances and the lack of consensus on when life begins for human embryos and fetuses used for research purposes, among other things, supports the desirability of having at least an initial decision regarding the patent eligibility of morally controversial biotech subject matter be made by an informed Congress.

The expectation of a monopoly-like patent grant provides a significant incentive to inventors not only to engage in the creative process but also to disclose their inventions through the medium of the patent system. Such an incentive was clearly contemplated by the Framers, as the Intellectual Property Clause of the Constitution authorizes Congress to secure exclusive rights to inventors over their inventions in order to promote the progress of the useful arts. However, the clause is a utilitarian grant of power, not a mandate, and Congress is free to deny patent protection as well as to extend it.

Congress designed the patent system to have a positive effect on society, so it is certainly appropriate for Congress to limit the availability of patent protection when government-granted private ownership of certain subject matter may have a negative effect on society. Patents on morally controversial biotech subject matter, although having the potential for positive effects, also have a great potential for negative effects that may be difficult or impossible to overcome after such patents are granted.[104] The incentives patents provide to researchers to engage in patent-eligible research make it incumbent upon Congress to determine *ex ante* what types of inventions to encourage with patent protection.

In making that determination, Congress should tread very carefully. Social mores change over time and technology clearly advances with time as well. It can be difficult to make subject-matter rules in the abstract, when the technology to which the rules will be applied has not been developed. There may not, and probably will not, be full public consensus on morality constraints on patent-eligible subject matter, but Congress is used to legislating in such areas and has a variety of options open to it. In the words of one legislator, "[a]lthough it is difficult to legislate in these complex areas, Congress—as the elected representatives of the people—must play a role in seeing that a forum for discussion is provided and that these important problems are addressed openly."[105]

In terms of options, Congress could, of course, choose to acquiesce intentionally in the current "patent first" system and do nothing beyond renewing the Weldon Amendment each year. This seemingly would result in some number of allowed patent applications that arguably encompass humans piling up at the USPTO because no funds have been allocated by Congress to issue them but no statutory basis exists for rejecting their claims. An informed Congress, aware of

the lack of morality-based limitations in the patent system, also could allow the Weldon Amendment to lapse and make the normative choice to have a patent statute that defaults in favor of patent eligibility yet allows for reactive legislation. Such a result could be quite appealing to members of Congress, as the political fallout from placing morality based limits on patent-eligible subject matter is an unquantifiable risk. Alternatively, though likely more hazardous from a political standpoint, Congress could enact specific, subject matter-based legislation, more general morality-based legislation, or legislation implementing one or more of a variety of intermediate institutional procedures. Each approach has benefits and drawbacks that Congress should consider in its efforts to define the moral limits of patent-eligible subject matter.

Specific legislation will give more guidance to the USPTO and courts in making patent eligibility determinations. Some specific prohibitions, however, could be rendered effectively obsolete, or simply incomplete, by unanticipated advances in technology. To minimize these potential problems, Congress could decide to ignore morality concerns for the vast majority of inventions and have a very simple specific provision dealing only with an extreme limit, such as expressly excluding humans, and/or human-animal chimera, from the scope of 35 U.S.C. §101 with the definition of "human" provided in the statute.

Alternatively, Congress could implement one or more intermediate approaches to corralling morally controversial biotech subject matter. For example, Congress could choose to reactivate the Office of Technology Assessment,[106] a critically acclaimed group that for twenty-three years provided meticulously researched, nonpartisan reports to Congress on technological topics of emerging importance.[107] To the extent Congress would like time to study and evaluate the potential impact of morally controversial patents before their issuance, the USPTO could be required to submit special reports to a designated evaluator after receiving patent applications claiming morally controversial subject matter. If the designated evaluator, such as an ethics advisory committee within or outside of the USPTO, did not notify the applicant of an objection within a set period of time, the subject matter would be deemed eligible for patent protection. Moreover, a process could be instituted in which issuance of morally controversial patents would be delayed for a set period, during which time Congress, or its designated evaluator, could assess the patent-eligible status of the invention. The designated evaluator could be a body within or outside of the USPTO, created for this specific purpose, or an existing administrative body such as the Board of Patent Appeals and Interferences.

Further, in addition to any of these options, Congress could allow public input into the patent-eligibility determination by adopting some form of postgrant patent opposition. Such a system would create an opportunity for public opinion regarding controversial patent subject matter to be registered in the USPTO.[108] These possibilities are illustrative of the myriad options open to Congress in addressing the "patent first" problem, any of which should be preferable to the current approach.

Ultimately, any new statute designed to place limits on patent eligibility will provide an incomplete solution to concerns in society about the morality of certain inventions and will fail to meet expectations for at least some segment of the public. For some people, the legislation will go too far, for others, not far enough. Morally controversial patents will still issue from the USPTO and unpatented but morally controversial research will still be conducted unless banned pursuant to statutes or regulations outside of the patent system. Agencies such as the FDA, USDA, and FTC will continue to be the regulators of the use of technology in society, and other solutions will need to be developed to address moral and ethical concerns as both technology and societal mores evolve. The patent system cannot regulate morality, in whole or in part, but it need not provide incentives for research that tends to marginalize or commoditize humanity.[109]

CONCLUSION

What role, if any, should morality have in the issuance of biotech patents? Why does the issuance of certain patents invoke moral controversy? Why should anyone care whether human embryos, or fetuses, or clones, or human-animal chimera are patentable? We should care because patents are government-based, monopoly-like grants, designed to encourage the investment in and exploitation of patent-eligible subject matter. As Professor Drahos notes:

> In some deep way, when we invent and define property rights we also create a social trajectory for ourselves. It is precisely because the patent system has this important causal role to play in the evolution of biotechnology that the moral debates about the creation and definition of efficient property rights in such technologies must be had within the patent system.[110]

Patent owners have the right not only to exclude others from their invention, but also to alienate their property right, by sale, license, bequest, or otherwise. Thus, we should care about patents on, for example, human "matter" for therapeutic cloning, reproductive cloning, organ donation, or other purposes, if we as a society are uncomfortable with the concept of humans as personal property, commodities that can be bought or sold for commercial or even humanitarian benefit.

Because the patenting of morally controversial biotech research involves such serious, deeply felt issues, the patenting decision must not be left, as it currently is, to scientists pushing the frontiers of technology, motivated by factors beyond public comment and scrutiny. Nor should it be left to individual examiners to determine what is comprised in the word "human." No one person is competent to decide and resolve these moral issues and determine what the limits should be. Difficult though the task may be, Congress, through legislation, is the only

actor competent to clarify the limits of patentable subject matter and the extent to which moral issues should be considered in patentability determinations, if at all.

NOTES

1. The term "biotechnology" refers to "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." Biotechnology, Wikipedia, http://en.wikipedia.org/wiki/Biotechnology (last visited May 24, 2006). As one commentator notes: "The debates about the legal, ethical, and social problems connected with modern biotechnology has been on-going since this branch of technology came into being." Sigrid Sterckx, *European Patent Law and Biotechnological Inventions*, *in* Biotechnology, Patents, and Morality 1, 2 (Sigrid Sterckx ed., 1997).

2. See Kathleen Gallagher, *Wisconsin May Reap Stem Cell Royalties*, Milwaukee J. Sentinel Online, http://www.jsonline.com/story/index.aspx?id=303097 (last modified Feb. 20, 2005).

3. See generally Nuffield Council on Bioethics, The Ethics of Patenting DNA (2002) (U.K.); The European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (2002) (Opinion No. 16) (EU).

4. Sections 101 and 102 express the entitlement concept. Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . *may* obtain a patent therefor," and § 102 confirms that "a person *shall be entitled to a patent unless*." 35 U.S.C. §§ 101–102 (2004) (emphasis added).

5. U.S. Const. art. I, § 8, cl. 8.

6. See 35 U.S.C. §§ 112, 101–103, 154, 271.

7. See *Diamond v. Chakrabarty*, 447 U.S. 303, 305–306 (1980).

8. *Id.* at 309 (citing S. Rep. No. 82–1979, at 5 (1952); H.R. Rep. No. 82–1923, at 6 (1952)).

9. *Id.* at 313.

10. 450 U.S. 175, 182 (1981).

11. 534 U.S. 124, 134 (2001).

12. *State St. Bank & Trust v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998). Although the Court's discussion of the business method exception was *dicta*, the decision cleared the way for such patents and business method patent applications flooded into the USPTO in the wake of the decision.

13. *Chakrabarty*, 447 U.S. at 316. Jeremy Rifkin coauthored an *amicus* brief in the *Chakrabarty* case that listed some of the items in that parade:

> Scenarios which once appeared far-fetched—the manufacturing of mammals, including human beings, to specification; the creation of super-intelligent beings; the asexual reproduction of organisms through cloning; the advent of genetic surgery designed to alter the heredity of complex organisms—will become science fact, if not tomorrow, then certainly within the lifetimes of the majority of Americans.

Dashka Slater, huMouse^{TM}, Legal Affairs, http://www.legalaffairs.org/issues/November-December-2002/feature_slater_novdec2002.msp (Nov.–Dec. 2002). More than twenty-five years later, Rifkin considers his early concerns justified, as patents have issued covering many of these items.

14. *Chakrabarty*, 447 U.S. at 318.

15. Examination Guidelines for the Utility Requirement, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001).

16. 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (emphasis added).

17. Ex parte Murphy, 200 U.S.P.Q. (BNA) 801, 802 (Bd. App. 1977).

18. See U.S. Patent Application No. 10,308,135 (filed Dec. 3, 2002).

19. An interesting feature of U.S. patent law is that a patent applicant need not actually have made an invention in order to be able to patent it. As long as they file a U.S. application that provides an adequate written description of the invention and would enable persons of ordinary skill in the art to make and use the invention, not having actually made it themselves will not impair their ability to patent the claimed invention.

20. See, e.g., Aaron Zitner, *Patently Provoking a Debate: Two Friends Seek Rights to a Theoretical Human-Mouse, Thought up to Force Limits on Patenting Human Life*, L. A. Times, May 12, 2002, at A1.

21. See USPTO, *Media Advisory: Facts on Patenting Life Forms Having a Relationship to Humans*, http://www.uspto.gov/web/offices/com/speeches/98-06.htm (last modified Apr. 1, 1998).

22. *Id.*

23. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367 (Fed. Cir. 1999).

24. *Id.* at 1366–1368 (internal citations omitted).

25. See, e.g., U.S. Patent Nos. 6,511,830 (issued Jan. 28, 2003), 6,485,910 (issued Nov. 26, 2002), 6,524,819 (issued Feb. 25, 2003), 6,284,456 (issued Sept. 4, 2001), and 6,420,149 (issued July 16, 2002).

26. Examination Guidelines for the Utility Requirement, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

27. 1077 O. G. 24 (Apr. 21, 1987).

28. See Ex parte Allen, 2 U.S.P.Q. 2d (BNA) 1425 (B.P.A.I. 1987).

29. Legislation to halt or otherwise regulate animal patenting was introduced in the 100th and 101st sessions of Congress. See, e.g., H.R. 3247, 101st Cong. § 1 (1989); S. 2111, 100th Cong. (1988); H.R. 3119, 100th Cong. § 2 (1987).

30. See generally *Regulating and Patenting Transgenic Animals: Hearing Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the House Comm. on the Judiciary*, 100th Cong. 396 (1987).

31. See Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 Jurimetrics J. 399, 410, 414–424 (1988).

32. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 923–924 (Fed. Cir. 1991).

33. *Id.* at 929–930 (emphasis added).

34. *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980).

35. Keith Schneider, *Harvard Gets Mouse Patent, A World First*, N.Y. Times, Apr. 13, 1988, at A1.

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

37. *Pallin v. Singer*, 36 U.S.P.Q. 2d (BNA) 1050, 1051 (D. Vt. 1995).

38. See, e.g., Editorial, *As Doctors Patent Medical Procedures, Patients Pay*, USA Today, June 19, 1995, at 10A; Lauran Neergaard, *Move to Patent Surgical Procedure*

Sparks Fight, L. A. Times, Apr. 2, 1995, at A14; *Patently Ridiculous*, Tulsa World, Apr. 4, 1996, at A12.

39. Joel J. Garris, Note, *The Case for Patenting Medical Procedures*, 22 Am. J.L. & Med. 85, 86 (1996) (citing *AMA Speaks Out on Managed Care*, UPI, June 14, 1994, LEXIS, Nexis Library, UPI File).

40. American Med. Ass'n, Council on Ethical and Judicial Affairs, *Ethical Issues in the Patenting of Medical Procedures*, 53 Food & Drug L. J. 341, 343–344 (1998).

41. Weldon E. Havins, *Immunizing the Medical Practitioner "Process" Infringer: Greasing the Squeaky Wheel, Good Public Policy, or What?*, 77 U. Det. Mercy L. Rev. 62, 63–64 (1999); Eric M. Lee, *35 U.S.C. § 287(c)—The Physician Immunity Statute*, 79 J. Pat. & Trademark Off. Soc'y 701, 705 (1997); see also H.R. 1127, 104th Cong. (1995); S. 2105, 104th Cong. (1996).

42. Under the statute, known as the Medical Activity Act, protection from suit does not extend to the activities of persons engaged in other medical related activities such as "the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services." 35 U.S.C. § 287(c)(3) (2004).

43. U.S. Patent Application No. 10,308,135 (filed Dec. 18, 1997).

44. See Bratislav Stankovic, *Patenting the Minotaur*, 12 Rich. J. L. & Tech. 5, ¶¶ 18, 24 (2005), http://law.richmond.edu/jolt/v12i2/article5.pdf:

> 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. 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) . . .
>
> . . . 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.

45. See Slater, *supra* note 13, at 7–8.

46. *Nonnaturally Occurring Non-Human Animals Are Patentable Under Section 101*, 33 Pat. Trademark & Copyright J. (BNA) 664 (1987).

47. U.S. Const. amend. XIII, § 1.

48. 35 U.S.C. § 271(a) (2004).

49. See D. Scott Bennett, Comment, *Chimera and the Continuum of Humanity: Erasing the Line of Constitutional Personhood*, 55 Emory L. J. 347, 386 (2006); see also Russell H. Walker, Note, *Patent Law—Should Genetically Modified Human Beings Be Patentable?*, 22 Mem. St. U. L. Rev. 101, 110 (1991) (surmising that "the Constitution would seem to prevent enforcement of the 'making' clause of the patent infringement statutes against a human parent").

50. See Bennett, *supra* note 49, at 386.

51. *Roe v. Wade*, 410 U.S. 113, 158, 163–165 (1973).

52. Rick Weiss, *Of Mice, Men and In-Between: Scientists Debate Blending of Human, Animal Forms*, Wash. Post, Nov. 20, 2004, at A1.

53. Sander Rabin, *The Human Use of Humanoid Beings: Chimeras and Patent Law*, Nat. Biotech., May 2006, at 519.

54. Joshua Ortega, *Of Mice and Men: The Ethics of Chimerism*, Seattle Times, Jan. 9, 2003, at B7.

55. See U.S. Patent Application No. 09,828,876 (filed Sept. 22, 1997).

56. Natalie Dewitt, *Biologists Divided Over Proposal to Create Human-Mouse Embryos*, 420 Nature 255 (2002).

57. Justin Gillis, *A New Call for Cloning Policy*, Wash. Post, May 17, 2002, at A12; Andrew Pollack, *Debate on Human Cloning Turns to Patents*, N.Y. Times, May 17, 2002, at A14.

58. Neither the mainstream media or members of Congress seem to be aware of the importance or ramification of 35 U.S.C. § 271(g) for the '429 patent and the issue of patents on humans. Interestingly, it previously was USPTO policy to reject claims to methods of cloning humans. As an examiner stated in a 1999 Office Action rejecting mammalian cloning claims: "methods of cloning humans are non-statutory as it is patent office policy not to issue claims that are to or encompass humans (see 1077 OG 24, April 21, 1987)." Office Action, U.S. Patent Application No. 08,935,052, Mar. 28, 1999 (issued as U.S. Patent No. 6,235,970). This "policy" is no longer being followed, as several patents have issued from the USPTO that "encompass" humans by claiming mammals/animals/organisms without a nonhuman limitation in the claim itself. See, e.g., U.S. Patent Nos. 6,511,830 (issued Jan. 28, 2003), 6,485,910 (issued Nov. 26, 2002), 6,524,819 (issued Feb. 25, 2003), 6,284,456 (issued Sept. 4, 2001), and 6,420,149 (issued July 16, 2002).

59. See, e.g., *Group Faults PTO for Issuing Patent on "Method of Producing Cloned Mammal,"* Pat. Trademark & Copyright J.(BNA) No. 1574, at 81–82 (May 24, 2002); Antonio Regalado, *Patent on Human-Cloning Method Is Granted, Despite Current Policy*, Wall St. J., May 16, 2002, at D3.

60. *Senate Refuses to Attach Ban on Clone Patents to Terrorism Bill*, Pat. Trademark & Copyright J. (BNA) No. 1578, at 174–175 (June 21, 2002).

61. See, e.g., 148 Cong. Rec. S5579 (daily ed. June 14, 2002) (statement of Sen. Edward Kennedy) ("Of course we should reject the offensive idea that human beings could be patented, as the Patent Office already rightly does. But the Brownback amendment goes far [beyond] this commonsense proposal."); 148 Cong. Rec. S5519 (daily ed. June 13, 2002) (statement of Sen. Arlen Specter) (noting that the USPTO's policy "renders totally unnecessary the amendment that is being offered").

62. Consolidated Appropriations Bill of 2004, H.R. 2673, Pub. L. No. 108–199.

63. See, e.g., U.S. Patent Nos. 6,518,482 (issued Feb. 11, 2003); 6,515,197 (issued Feb. 4, 2003); 6,509,515 (issued Jan. 21, 2003); 5,545,807 (issued Aug. 13, 1996); 4,736,866 (issued Apr. 12, 1988).

64. See U.S. Patent No. 6,781,030 (issued Aug. 24, 2004).

65. This is a classic slippery slope argument, but one that seems quite valid in light of the progression in biotech patenting towards more human-derived products and life forms and the almost visible public desensitization to patents on higher life forms that has occurred since the patenting of the Harvard oncomouse in 1987.

66. Maureen L. Condic & Samuel B. Condic, *The Appropriate Limits of Science in the Formation of Public Policy*, 17 Notre Dame J. L. Ethics & Pub. Pol'y 157, 161–162 (2003).

67. See, e.g., Sterckx, *supra* note 1, at 7–9 (discussing such arguments and providing a counter perspective).

68. Peter Drahos, *Biotechnology Patents, Markets and Morality*, 1999 Eur. Intell. Prop. Rev. 441.

69. Carl B. Feldbaum, *BIO Opposes Brownback Amendment*, Biotechnology Industry Organization, http://bio.org/ip/action/brwnamend.asp (last modified Jun. 14, 2002).

70. See, e.g., Martin J. Adelman, Randall R. Rader, John R. Thomas & Harold C. Wegner, Cases and Materials on Patent Law 156 (1998) ("*Chakrabarty* was a clear signal, however, [that patenting was broadly available in the biotechnology field, and it] opened the coffers of Wall Street to the biotechnology industry." (internal citations omitted)).

71. Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 Hous. L. Rev. 1597, 1668–1669 (1993).

72. *Id.* at 1667 (noting that the lure of pecuniary gain traditionally has not been the motivating factor for scientists, but a shift has occurred, confined largely to the biotech area).

73. See, e.g., Gary Elijah Dann, *New Use for Embryos Is Disturbing*, Record, Mar. 5, 2002, at A7:

> A recent study carried out by researchers at New York University . . . Yale University . . . and John Hopkins School of Medicine has shown reason to believe that an adult stem cell in the bone marrow can transform itself into almost any organ in the body. . . . Why, then, insist on engaging in morally thin research when more time and research may very well make the use of human embryos unnecessary?

74. Paul Berg, *Right to Inquire, Freedom of Expression Go Hand in Hand*, San Jose Mercury News, Jan. 2, 2005, *quoted in* Pamela Winnick, A Jealous God: Science's Crusade Against Religion 296 (2005).

75. William Krystol, *Brave New Patents*, Weekly Standard, http://www.weeklystandard.com/Content/Public/Articles/000/000/001/262ruhsv.asp (last modified May 27, 2002). The article also mentions a pending patent application filed by researchers that would allow them to "'use tissues derived from [cloned] embryos, fetuses or offspring, including human and ungulate tissues,' and to own the patent rights to the 'progeny of the [cloned] offspring.'"

76. See U.S. Patent Application No. 09,828,876 (filed Apr. 10, 2001) (abandoned Sept. 30, 2004).

77. But see Oliver Mills, Biotechnological Inventions: Moral Restraints and Patent Law 173 (2005) (suggesting the U.S. system deserves consideration in the EU).

78. Convention on the Grant of European Patents, Oct. 5, 1973, *as amended by* Decision of the Administration Council of the European Patent Organization of Dec. 21, 1978, 13 I.L.M. 268 (1974). The EPC went into effect in 1977.

79. T19/90, Harvard/Onco-mouse, [1990] E.P.O.R. 501 (Technical Board of Appeal 3.3.2 Oct. 3, 1990), *reprinted in* Edward Armitage, *Updating the European Patent Convention*, 22 Int'l Rev. Indus. Prop. & Copyright 73, 74–84 (1991) (citing In re President and Fellows of Harvard College, Examining Division of the European Patent Office, OJ EPO 1989, 451 [20 Int'l Rev. Indus. Prop. & Copyright 889 (1989)]).

80. See European Patent No. EP–B1696000072 (issued May 13, 1992).

81. The Technical Board of Appeal noted that article 52(1) of the EPC contains a "general rule . . . that European patents should be granted" subject only to express exclusionary provisions such as article 53(a) and that such exclusions were to be interpreted narrowly.

82. Harvard/Onco-mouse, 1990 E.P.O.R. 501, 527.

83. *Id.*

84. Alison Abbott, *Oncomouse Hearing Ends Up in Confusion*, 378 Nature 427, 427 (1995).

85. See Hans-Rainer Jaenichen & Andreas Schrell, *The "Harvard Onco-mouse" in the Opposition Proceedings Before the European Patent Office*, 15 Eur. Intell. Prop. Rev. 345 (1993).

86. See, e.g., Robin Nott, *The Biotech Directive: Does Europe Need a New Draft?*, 17 Eur. Intell. Prop. Rev. 563, 565–566 (1995); Steve Conner, *Patent Ban on Baldness "Cure" Mouse*, Independent (London), Feb. 2, 1992, at 5.

87. Howard Florey/Relaxin, Application No. 83307553.4, [1995] E.P.O.R. 541 (Opposition Div. 1994); T0320/87, Lubrizol Hybrid Plants, [1988] E.P.O.R. 173 (Tech. Bd. App. 1988).

88. [1995] E.P.O.R. 357, 373 (Tech Bd. App. 1995).

89. *Id*. at 366.

90. *Id*. at 373. The Board also discounted the relevance of submitted survey and poll evidence of opposition to plant patents and genetic engineering.

91. Howard Florey/Relaxin, App. No. 83307553.4, [1995] E.P.O.R. 541, 544 (Opposition Div. 1994).

92. *Id*.

93. See Council Directive 98/44/EC, ¶¶ 1–4, 1998 O.J. (L 213) 13.

94. See, e.g., David G. Scalise and Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 Fordham Int'l L.J. 990, 991 (1993) (characterizing Europe's competitive disadvantage in the biotech industry as "approaching perilous dimensions").

95. See Council Directive 98/44/EC, *supra* note 93, ¶¶ 36–40; see also Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 Berkeley J. Int'l L. 1, 2 (2001).

96. See Sabine Louet, *French Refuse to Implement Biotech Patent Directive*, 18 Nature Biotechnology 820 (2000), http://www.nature.com/nbt/journal/v18/n8/full/nbt0800_820.html (quoting French MP Jean-Francois Mattei as explaining that opposition was emerging at that time because there had been no public discussion about the directive in France previously).

97. See *Single Market: Ten Years On, Commission Has Something to Celebrate*, Eur. Report No. 2647, Jan. 8, 2003, at 1.

98. See Case C–377/98, Kingdom of the Netherlands v. Eur. Parliament & Council of the Eur. Union, 2001 E.C.R.I–7079. The action was filed by the Netherlands and joined by Italy and Norway. See *Council of Europe Calls for Revision of Biotechnology Directive*, Eur. Report No. 2514, Jul. 5, 2000, at 1.

99. See Case C–377/98, *supra* note 98, at 14. France's Justice Minister publicly denounced the Directive claiming that it was "incompatible with French law in general, with the 1994 law on bioethics, with the code on industrial property and with the French code of civil law which prohibits the commercialisation of the human body." *Community Law Takes Precedence over National Law*, Eur. Report No. 2510, Jun. 21, 2000, at 1. On November 30, 2000, and again on December 19, 2002, the EU Commission sent letters of formal notice and official requests, respectively, to the nine remaining countries, Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands, Portugal, and Sweden, requesting that they implement the Directive. See Press Release, Commission of the European Communities, Industrial Property: Commission Calls on Nine Member States to Implement the Directive on the Legal Protection of Biotechnological Inventions (Dec. 19, 2002). These actions were the first steps in the process of bringing infringement proceedings against noncompliant states under the article 226 of the EC Treaty. See also Nina White, *The EU Biotech Directive-Legislation for Disharmony?*

Boult Wade Tennant, http://www.boult.com/information/articlePrint.cfm?articleID=47 (last modified Oct., 2005).

100. *See* White, *supra* note 99.

101. See Case No. T 1374/04–3.3.08, Decision of 21 April 2006 Correcting an Error in the Interlocutory Decision of the Appeal Case T 1374/04 Dated 18 November 2005, available at http://legal.european-patent-office.org/dg3/biblio/t041374ex1.htm (last visited Oct. 8, 2006).

102. Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994). Diagnostic, therapeutic, and surgical methods may also be excluded.

103. Dwight R. Lee, *Politics, Ideology, and the Power of Public Choice*, 74 Va. L. Rev. 191, 196 (1988); see also Daniel A. Farber & Philip P. Frickey, *The Jurisprudence of Public Choice*, 65 Tex. L. Rev. 873, 926 (1987) ("The social science literature suggests that ideology plays an important role in the political process; thus neither voters nor legislators are wholly captives of self-interest.").

104. See generally Gary Elijah Dann, *New Use for Embryos Is Disturbing*, Record, Mar. 5, 2002, at A7 (discussing stem cell research and positing that "it may be worth considering that those who constantly warn of 'the slippery slope' may be right this time. Will our treatment of the human embryo and fetus lead to a desensitization of our conviction in the inherent worth of life, human or otherwise?").

105. Mark O. Hatfield, *From Microbe to Man*, 1 Animal L. 5, 9–10 (1995).

106. Or create a similarly functioning body.

107. *OTA Archive*, Office of Technology Assessment, http://www.access.gpo.gov/ota/ (last visited Oct. 25, 2003).

108. See, e.g., Patent Act of 2005, H.R. 2795, 109th Cong. (2005). See also Cynthia M. Ho, *Do Patents Promote the Progress of Justice? Reflections on Varied Visions of Justice*, 36 Loy. U. Chi. L.J. 469, 481 (2005).

109. See, e.g., Walker, *supra* note 49, at 110 (advocating patents on genetically modified encephalic fetuses for the generation of body parts).

110. Peter Drahos, *Biotechnology Patents, Markets and Morality*, 1999 Eur. Intell. Prop. Rev. 441, 447.