WORKING DRAFT

Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law

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This Article explores the de facto U.S. "patent first, ask questions later" approach to determining what subject matter should receive patent protection. Under this approach, the U.S. Patent and Trademark Office issues patents on "anything under the sun made by man," and to the extent a patent's subject matter is sufficiently controversial, Congress acts retrospectively in assessing whether patents should issue on such inventions. The practice has important ramifications for morally controversial biotechnology patents specifically, and for American society generally.

For many years a judicially created "moral utility" doctrine served as a type of gatekeeper of patent eligible subject matter. The doctrine allowed both the USPTO and courts to deny patents on morally controversial subject matter under the fiction that such inventions were not "useful."

The gate, however, is currently untended. A combination of the demise of that doctrine, along with expansive judicial interpretations of the scope of patent-eligible subject matter have resulted in virtually no basis on which the USPTO or courts can deny patent protection to otherwise patentable, morally controversial subject matter, despite position statements by the Agency to the contrary.

Biotechnology is an area in which many morally controversial inventions are generated. Congress has been in react-mode following the issuance of a stream of morally controversial biotech patents, including patents on transgenic animals, surgical methods, and methods of cloning humans. Consequently, with no statutory limits on patent eligibility, and with myriad concerns complicating Congressional action following a patent's issuance, it is not Congress, the representative of the people, determining patent eligibility. Instead, it is patent applicants -- scientists, who are deciding matters of high public policy through the contents of the applications they file with the USPTO.

This Article explores how the U.S. has come to be in this position, exposes latent problems with the "patent first" approach, and considers the benefits and disadvantages

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of "ask questions first, patent later" approaches employed by some other countries. The Article concludes that granting patents on morally controversial biotech subject matter and then asking whether such inventions should be patentable is bad policy for the U.S. and its patent system, and posits workable, proactive ways for Congress to guard the patent eligibility gate.

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Introduction

In "Cloning Trevor," journalist Kyla Dunn chronicles the unsuccessful efforts of a group of scientists at Advanced Cellular Technologies ("ACT") to create an embryonic clone of a two-year-old boy afflicted with a rare genetic disorder.[2] Theoretically, the

[22] Kyla Dunn, *Cloning Trevor*, The Atlantic Monthly, Vol. 286 (Jun. 2002) [hereinafter *Cloning Trevor*]. The efforts were unsuccessful because the researchers were unable to achieve fusion of the skin

development of such an embryo, made with one of the boy's skins cells and a donated human egg, could yield embryonic stem cells which, when injected back into the boy, might halt and reverse the disorder.[3] Such efforts are an example of therapeutic cloning, the creation of genetically modified embryos that will ultimately be destroyed in order to produce cures for various human ailments.[4] By contrast, reproductive cloning has as its aim the development, also from a genetically modified embryo, of a fully formed child. Therapeutic cloning is less abhorrent to many than reproductive cloning, but both are morally controversial,[5] and neither type of research is eligible for federal funding.[6] Thus private sector sources, like the ACT researchers that attempted to clone Trevor, are funding work in these areas.

But while federal funding may not be available for cloning research, federal patent protection, which provides incentives for private funding, is available. For example, a cloning patent issued to the University of Missouri in April 2001 claiming inventions directed to, among other things, methods for "producing a cloned mammal" and for "producing a cloned mammalian embryo."[7] Moreover, the patent disclosure

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cell and donor egg before Trevor (not his real name) began exhibiting symptoms of the disorder, necessitating a more conventional, but risky, bone marrow transplant treatment for the boy.

[3] *Id*. at 36.

[4] *Id*. at 31.

[5] *See* Meredith Wadman, *Politicians Accused of "Shooting from the Hip" on Human Cloning*, 386 NATURE 97, 97 (1997) (citing an ABC News Nightline poll result that 87% of respondents believed human cloning should be banned, and 82% believed cloning humans would be morally wrong). Therapeutic cloning tends to be controversial primarily because human embryos are destroyed during the process. Reproductive cloning is controversial because, among other things, there are high failure rates in obtaining cloned creatures, and most complex clones exhibit genetic abnormalities that may cause them suffering. As one commentator notes:

> SCNT [human cloning] is rarely successful when performed on complex life forms. As an example, only about 20% of cow clones survive to the blastocyst stage of embryonic development. . . . Today about 97% of the simplest cloned animals die prior to birth in cloning trials. . . . In general, born clones suffer from serious - some say gross – genetic abnormalities and, therefore, live short lives. This is likely due to dormant genetic abnormalities that blossom with age, bypassing the protective mechanisms present in germ cells that correct DNA errors, as well as the chronological age of the DNA inserted into the egg (which is that of an adult, not an infant).

Nathan A. Adams, IV, *Creating Clones, Kids & Chimera: Liberal Democratic Compromise at the Crossroads*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 71, 84-85 (2003) [hereinafter Adams, *Creating Clones*]. Dolly the cloned sheep, for example, had to be put down after reaching only half her life expectancy due to premature aging and disease caused by cloning. *See* Nicholas Christian, *Dolly's Death Fuels Cloning Debate*, Scotland on Sunday, *at* http://www.news.scotsman.com/topics.cfm?id=197102003 (last modified Feb. 16, 2003).

[6] *See* Dunn, *Cloning Trevor* at 32. *See* Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 33 WEEKLY COMP. PRES. DOC. 281 (Mar. 4, 1997). Federal funding of human embryo research has been banned since December, 1994. However, because the restrictions "[did] not explicitly cover human embryos created for implantation and do not cover all Federal agencies," President Clinton felt the need for an order specifically prohibiting federal funding of human cloning research. *Id.*

[7] *See* U.S. Patent No. 6,211,429.

states that "the present invention encompasses the living, cloned *products* produced by each of the methods described herein."[8] The patent, and news reports of other human cloning activity, drew critical reaction, commentary, and calls for legislative action from a variety of sources.[9] However, none of the proposed amendments, either to ban patents on cloning or to ban cloning research, have been enacted to date.[10]

Why is the federal government granting exclusive property rights, which in effect act as indirect research funding, in inventions for which it will not, for public policy reasons, provide direct research funding? Patents can be seen as a type of indirect funding because they provide incentives for parties to undertake expensive and risky research.[11] Patents induce upfront funding of projects with the expectation that monopoly profits can be generated over the longer-term.[12] This situation, which appears inconsistent, does not necessarily involve active authorization of patents on such morally controversial inventions by Congress. Rather, Congress simply may not appreciate the ramifications of its inaction in sustaining the current "patent first, ask questions later" U.S. patent regime.

Under a "patent first, ask questions later" approach, a patent issues, and to the extent its claimed subject matter conflicts with norms or values held by a meaningful portion of society, the patent generates, among other things, public expressions of outrage, questions of how it issued in the first place, and, often, calls for Congress to legislatively address the perceived problem. The U.S. "patent first" approach has the

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[8] *Id*. (Emphasis added). Because 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 has no patent-based property interest in any such clones. *See* 35 U.S.C. § 112, para. 1. *See also* Markman v. Westview Instruments, Inc., 52 F.3d 967, 975 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.")

[9] *See, e.g.*, BNA, *Group Faults PTO for Issuing Patent on 'Method of Producing a Cloned Mammal'*, 64, No. 1574, PAT. TRADEMARK & COPYRIGHT J. 81 (2002) (discussing the Center for Technology Assessment's criticism of the PTO for issuing the patent), Antonio Regalado, *The University of Missouri Receives Patent for Human-Cloning Method*, www.msnbc.com, *at* http://www.msnbc.com/news/753193.asp?0si=-&cp1=1 (last modified May 16, 2002), See also House Rep. 108-018 (on Human Cloning Prohibition Act of 2003).

[10] A bill to prohibit human cloning, reproductive and therapeutic alike, passed the House February 27, 2003. *See* Human Cloning Prohibition Act of 2003, H.R. 534.

[11] *See, e.g.*, Jasmine C. Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 225 (2002) ("Patents help attract the investments needed to continue research and facilitate the relationship between government, academia and the private sector. . . [T]he potential to protect the fruits of expensive research speeds up the research process as well."); Clarissa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 653 (2002) ("Among venture capitalists, both the quantity and quality of patents have long been factors that are taken into consideration when deciding whether to invest in a company, particularly in its early stages."); Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 144 (2000) (suggesting that "one of the reasons people are patenting at a very early stage in the process is precisely in order to attract or appease venture capital. That is, they get patents in order to define their market model for their financiers.").

[12] *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1037 (1989) [hereinafter *Patents and the Progress of Science*] (discussing theories that patents provide incentives to innovate and obtain future patents).

potential to create problems in a variety of technical disciplines and on topics only tangentially related to morality concerns.[13] However, the problems the approach creates with regard to morally controversial biotech subject matter make a compelling case for why Congressional action in this area is necessary and long overdue. For this reason, this Article focuses on whether morality has a role to play in patents on biotech inventions.[14]

Biotechnology is an area in which many morally questionable inventions are generated.[15] Controversial patented biotech inventions include**:** isolated genes, sequenced DNA, medical procedures, embryonic stem cells, genetically modified transgenic animals, and methods of cloning mammals.[16] The moral controversy surrounding these and other biotech inventions stems from several concerns, including those surrounding the mixing of human and animal species, denigration of human dignity, destruction of potential human life, and ownership of humans.[17] The availability

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[13] For example, the issuance of patents on business methods, while not overtly implicating moral concerns, have generated quite a bit of controversy and Congressional action that would have been better addressed pre-issuance. *See, e.g.*, Malla Pollack, *The Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History*, 28 RUTGERS COMPUTER & TECH. L.J. 61 (2002); Margo A. Bagley, *Internet Patents, Obvious By Analogy*, 7 Mich. Telecomm & Tech. L. Rev. 597 (2001); Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263 (2000); Kathleen Ellis, *Net Patent Bill Introduced*, Wired News, *at* http://www.wired.com/news/politics/0,1283,39238,00.html (last modified Oct. 03, 2000); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 580 (1999); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. Rev. 1139 (1999). A full discussion of problems with a patent first approach outside of the context of morally controversial biotech patents is beyond the scope of this Article.

[14] For purposes of this Article, the phrase "morally controversial biotech inventions (or subject matter)"is used to denote biotechnology-related inventions that provoke public controversy because of personal or societal beliefs that it is either right or wrong, "moral or "immoral," to engage in such research or own such inventions. *See*, WEBSTER'S NEW WORLD DICTIONARY AND THESAURUS 402 (MacMillan 1996) (defining morality as "rightness or wrongness, as of an action").

[15] The term "biotechnology" refers to "the use of biological organisms for commercial ends." Adams, *Creating Clones*, *supra* note --, at 79. "Biotechnology is leading to a more radical transformation of the political economy than any previous cluster of innovations, because it will impact not merely our tools, but our species." *Id*. at 72.

[16] *See, e.g.*, U.S. Patent No. 6,200,806 (stem cells); U.S. Patent No. 6,211,429 (mammalian cloning); U.s. Patent No. 4,736,866 (transgenic non-human mammal).

[17] *See, e.g.*, Carol Grunewald, *Monsters of the Brave New World*, New Internationalist, *at* http://www.newint.org/issue215/monsters.htm (last modified Jan. , 1991); *See, e.g.*, Dashka Slater, *huMouse*, Legal Affairs, *at* http://www.legalaffairs.org/issues/November-December-2002/feature_slater_novdec2002.htm# (visited Feb. 10, 2003); Francis Fukuyama, *Sorry, But Your Soul Just Died*, THE GUARDIAN, May 13, 2002, at 2; Gilbert Meilander, *The Point of a Ban: Or, How to Think About Stem Cell Research*, HASTINGS CTR. RPT. 9, 12 (2001); Natalie Dewitt, *Biologists Divided Over Proposal to Create Human-Mouse Embryos*, 420 NATURE 255 (2002); William Krystol, *Brave New Patents*, The Weekly Standard, *at* http://www.weeklystandard.com/Content/Public/Articles/000/000/001/262ruhsv.asp (last modified May 27, 2002). As Drs. Maureen and Samuel Condic note:

> The rapid pace of [biotech] advancement raises very real moral and prudential questions. . . . [M]odern biology has . . . brought to light the question of when (and where) we become "alive" and when we become "dead." Since much of what science

of a government imprimatur granting excusive rights over morally controversial inventions is especially problematic in the area of biotechnology because there may be some inventions that no one should "own" or be encouraged by the government to invent.[18]

The U.S. patent system has not always had this "patent first" approach to moral issues. For many years a judicially created "moral utility" doctrine served as a type of gatekeeper of patent eligible subject matter. The doctrine allowed both the USPTO and courts to deny patents on morally controversial subject matter under the fiction that such inventions were not "useful." The gate, however, is currently untended, as a result of judicial decisions interpreting the scope of the statutory utility and subject matter standards under the Patent Act of 1952 in a way that left no room for a moral utility doctrine.[19] And beginning in 1980 with *Diamond v. Chakrabarty*[20] and continuing to the present,[21] the United States Supreme Court has expansively and consistently held that Congress intended the definition of subject matter eligible for protection under the 1952 Patent Act to include any type of living or non-living matter, as long as it is "made by man." Combining these decisions with the Court's generous deference to Congress in

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> discovers is so completely removed from previous experiences, how are sound moral and prudential judgments to be made? Given that prudence demands that dangerous technologies be controlled and decency demands that evil technologies be prohibited, we are left with the question of exactly when a technology becomes dangerous or evil. . . . [N]o other field raises issues as profound or as critical to our self-conception, our values, and our very lives.

Maureen L. Condic and Samuel B. Condic, *The Appropriate Limits of Science in the Formation of Public Policy*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 157, 159-160 (2003) [hereinafter Condic, *The Limits of Science*].

[18] Patent protection has often been justified on the basis that intellectual property is a "public good." *See, e.g.*, Wendy J. Gordon, *Authors, Publishers, and Public Goods: Trading Gold for Dross*, 36 LOY. L.A. L. REV. 159, 164 (2002). As Professor Gordon explains:

> A "public good" is a good that can be shared non-rivalrously by many and from whose use non-payers are not easily physically excluded. Goods with these characteristics are susceptible to free riding, and thus difficult to produce in a normal competitive market. Inventions and works of authorship are "public goods" whose creation is stimulated by the limited private exclusion rights known as patent and copyright. Lighthouses and public defense are "public goods" for which governments usually provide direct support.

Id. The primary reason for granting exclusive patent rights is to provide incentives for the production of inventive public goods that would otherwise be under-produced. For some morally controversial biotech inventions, countervailing policies militate against government encouragement of and private ownership of, such subject matter.

[19] *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 533 (1966); Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (Fed. Cir. 1999).

[20] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[21] The Court's most recent pronouncement came in *J.E.M Ag Supply v. Pioneer Hi-Bred* , 122 S. Ct. 593, 599 (2001).

Intellectual Property Clause matters[22] means there is no explicit basis for denying patent protection to otherwise patentable, morally controversial subject matter.

Members of Congress may not fully appreciate this change of events because of statements by the USPTO declaring that it would deny patents on certain morally controversial inventions for public policy or, in the case of inventions comprising humans, Thirteenth Amendment reasons.[23] Members of Congress have cited such statements in arguments against specific legislation directed at banning human cloning patents.[24] But the USPTO is claiming power that it does not have. The U.S. Supreme Court has already interpreted the patent statute without reference to any limits based on moral considerations and the idea that the Thirteenth Amendment could support the denial of patents, on genetically modified pre-viable fetuses for example, is doctrinally unsound.[25] The USPTO thus lacks the authority to deny patents on morally controversial inventions, even ones that comprise human subject matter.

Further complicating Congressional action to address the patent eligibility of morally controversial biotech subject matter may be misunderstandings of the basic nature of the U.S. patent-grant system. The Patent Act of 1952 entitles a person to a patent on her invention if it meets the statutory requirements for patentability which include novelty, utility and non-obviousness.[26] As most of the morally controversial biotech inventions are new[27] and targeted, if only tangentially, at curing human disease, such express statutory requirements have not and likely will not prove too difficult to surmount. Therefore, in the absence of statutory limits *researchers* and their patent attorneys are making patent policy and determining the limits of patent eligibility by the subject matter described in their patent applications. Congress may not be aware that inaction on its part has placed patent applicants in the position of de facto arbiters of patent eligibility and that it is thus providing private entities with incentives, via granted patents, to develop and exploit morally controversial inventions, without engaging in any analysis of the policy implications of such decisions. As a result, Congress may be debating, in the not too distant future, whether patents on human-animal chimera, or genetically modified pre-viability fetuses, developed to be destroyed in the fight against some dread disease, should have been granted.[28]

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[22] As exhibited in the 2003 decision in Eldred v. Ashcroft, 123 S. Ct. 769 (2003).

[23] *See, e.g.*, *Media Advisory: Facts on Patenting Life Forms Having a Relationship to Humans* (last modified Apr. 1, 1998) <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>; *Media Advisory: Facts on Patenting Life Forms Having a Relationship to Humans* (last modified Apr. 1, 1998) http://www.uspto.gov/web/offices/com/speeches/98-06.htm; *Nonnaturally Occurring Non-Human Animals are Patentable Under Section 101*, 33 PAT. TRADEMARK & COPYRIGHT J. 664 (1987).

[24] See discussion *infra* at ___.

[25] *See* Roe v. Wade, 410 U.S. 113, 157 (1973) (concluding that "the word 'person' as used in the Fourteenth Amendment, does not include the unborn). Moreover, the Supreme Court has narrowly defined slavery under the Thirteenth Amendment in a series of cases. *See, e.g.*, Civil Rights Cases, 109 U.S. 3 (1883); Slaughterhouse Cases, 83 U.S. (16 Wall.) 36 (1873).

[26] *See* 35 U.S.C. §§ 101 et.seq.

[27] At least under current judicial interpretations of the novelty requirement.

[28] See discussion *infra* at ____.

Congress could certainly choose to create a "patent first" patent system in which advancing technology was the only concern. Alternatively, Congress could acquiesce in the operation of such a system, by declining to enact legislation to correct it. However, a variety of evidence suggests that Congress has not intentionally created such a system, nor even intentionally acquiesced in such a system.[29] Rather, as posited in this Article, Congress is "unaware" of the complete lack of morality-based limits in the U.S. patent system and has yet to speak definitively on this issue.[30]

Without statutory bars to the issuance of morally controversial patents, the public and Congress are continually in a reactive instead of proactive mode in assessing the potential impact of patenting such subject matter. Issues surrounding takings and government interference with property rights and contractual relations complicate and confound Congress' ability to adequately define patent eligible subject matter after the fact.[31] In addition, a lack of public understanding regarding how the patent system operates likely traps some people in the "is-ought fallacy," the erroneous assumption that because the law allows some governmental action, such as the issuance of a morally controversial patent, that action must be proper.[32] Finally, as with therapeutic cloning, the ends to be achieved by exploitation of these patents, e.g., curing serious human ailments, are seductively desirable, and politically explosive.[33] These factors combine to make the necessary but now ex post inquiry, into whether the morally controversial "means" to achieve these desirable ends are appropriate subjects for patent protection, exceedingly difficult to undertake.

A different order or type of inquiry, e.g., patent subject matter eligibility before a patent issues, and different institutions, could provide a way to improve the current state of affairs. It makes little sense to execute people and then try to ask them questions regarding their guilt or innocence (i.e. whether it was "right" to execute them). Similarly,[34] granting patents on morally controversial biotech subject matter and then

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[29] See discussion *infra* at ___.

[30] I say Congress has not *intentionally* acquiesced, because Congress, as a body, is "unaware" of this situation in the way the proverbial ostrich that sticks its head in the sand when trouble approaches is unaware of the problem it is facing. However, Congress has had plenty of warning, and explicit indications that the current "patent first" order is problematic. *See* discussion *infra* at __.

[31] *See, e.g.*, POLLY J. PRICE, PROPERTY RIGHTS (ABC-CLIO forthcoming June 2003) (discussing takings issues with government intervention in patent rights); Courtenay C. Brinkerhoff, *Medical Method Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking?*, 4 U. BALT. INTELL. PROP. L.J. 147, 177 (1996) (same); *See* LON L. FULLER, THE MORALITY OF LAW 53 (Yale University Press 1964) (discussing retroactive laws and morality).

[32] *See* Eugene Volokh, *The Mechanisms of the Slippery Slope,* 116 HARV. L. REV. 1026, 1079 (2003) citing *See* DAVID HUME, A TREATISE OF HUMAN NATURE 293-306 (David F. Norton & Mary J. Norton eds., 2000) (discussing the "is-ought" fallacy).

[33] *See, e.g.*, Francis Fukuyama, *Sorry, But Your Soul Just Died*, THE GUARDIAN, May 13, 2002, at 2 ("[B]iotechnology, in contrast to many other scientific advances, mixes obvious benefits with subtle harms in one seamless package."); Dunn, *Cloning Trevor, supra* note __ at 49 (quoting Trevor's mother as saying "it's like [a ban on human cloning], how dare they tell me that I cannot save my son's life?").

[34] Admittedly, the analogy is imperfect. When someone is executed, she is destroyed. When a patent is granted, a new right is created. Nevertheless, in both cases, an inquiry should have taken place before the decisive action (which cannot be undone in one case and not easily undone in the other) is taken.

asking whether such inventions should be patentable is a problematic policy for the United States and its patent system. Interestingly, other countries have taken "ask questions first, then patent" approaches to morally controversial subject matter that, while imperfect, provide illustrative alternatives to the haphazard course the U.S. is currently pursuing.[35] The most recent example is the December 2002 decision of the Canadian Supreme Court excluding higher life forms from patent protection without an express statutory authorization from Parliament.[36]

Admittedly, while a "patent first" approach is problematic, there are clearly good reasons for leaving questions of morality out of patent law. Some commentators point to the patent system being ill-equipped to engage in such inquiries, which are better left to other regulatory agencies.[37] Others correctly note that denying patents on morally controversial inventions will not stop the underlying research that is the source of public concern.[38] Still others posit that failing to grant patents on promising technology, perhaps because of public misunderstandings of science, may hinder important discoveries and deny life-saving cures to millions.[39] In essence they argue that the system is not broken, and to the extent it is, it would be better not to fix it since the solution, any type of morality-based limitation, could be far worse than the current problem, if there even is a problem.

This Article analyzes arguments against morality-based patent legislation in light of the larger themes of institutional competence and federal patent policy. By identifying which actor (Congress, the judiciary, the executive branch, or scientists) should make decisions of high public policy, as well as which actor is actually making such decisions,

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[35] See discussion *infra* at _____.

[36] *See* Harvard Coll. v. Canada (Commissioner of Patents), 2002 SCC 76.

[37] *See, e.g.*, James R. Chiapetta, Comment, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 WM. MITCHELL L. REV. 155, 178 (1994) ("The proper venue for consideration of moral issues of biotechnology is within the regulatory agency entrusted with the product's oversight, not the PTO."); Cynthia M. Ho, Note, *Building a Better Mousetrap: Patenting Biotechnology in the European Community*, 3 DUKE J. COMP. & INT'L L. 173, 195 (1992) [hereinafter Ho, *Building a Better Mousetrap*] ("The grant of a patent is not an ethical event. Instead it is the regulatory system of a given nation that monitors social concerns as it implements general legislation—concerns which frequently encompass ethics and morality.")

[38] *See, e.g.*, Carrie F. Walker, Note, *Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law*, 73 IND. L.J. 1025, 1026 (1998) ("Eventually it will become apparent that the root of the debate about patents for biotechnology has less to do with patent law, and more to do with fundamental concerns about the science itself."); Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 459 (1999) ("The ethical concerns . . . about biotechnology inventions do not actually relate to the patenting of such inventions, but to whether these inventions should be created at all.").

[39] *See, e.g.*, Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1075 (1988) ("Patents on new technology should be granted, reserving the right to regulate specific applications. This is the only sensible course"); Keith Schneider, *Harvard Gets Mouse Patent, A World First*, THE NEW YORK TIMES, Apr. 13, 1988, at A22 (quoting then-Commissioner of Patents Donald J. Quigg as citing the transgenic mouse's potential to hasten the development of cancer treatments as an important factor in granting the patent and saying "but how can anybody say this kind of development is unethical or wrong?").

the Article exposes a key flaw in the current system that requires a remedy.[40] Also, the Article posits that framing the issue of patent eligibility with reference to the policies Congress seeks to effectuate via the patent system further supports the conclusion that legislative action is indeed necessary, though not free from risk.

Part I of the Article provides an introduction to the subject matter and utility requirements of the U.S. patent statute which provide the basis for most arguments concerning the patentability of morally controversial biotech inventions. Part I focuses on the historical role of the judicially created "moral utility" requirement and describes the reasons for its demise, as well as the problems with relying on the Thirteenth Amendment to ban patents on humans.[41] Part II contrasts the U.S. approach in which the USPTO issues a patent on a morally controversial biotech invention and *then* Congress, the courts, and others debate whether such subject matter *should* be patentable, with that of other countries which have statutory barriers to the issuance of morally controversial biotech patents.[42] Such provisions, in theory and as exemplified in recent cases, allow for some type of discussion to take place regarding possible moral issues related to otherwise patentable subject matter before a patent finally issues. Informed by the analyses of Parts I & II, Part III identifies Congress as the actor most competent to define patent subject matter eligibility and explores legislative options for including moral issues in federal patent policy without hampering the development of U.S. patent law. The Article concludes that if Congress does not set limits on the patenting of morally controversial subject matter no one will, and asking patent questions "later" will one day be too late.

I. PATENT ELIGIBILITY[43]

Art. I, § 8, cl. 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." At the time the framers crafted this language, the word "science" did not have the specialized meaning that it has today. Instead, it referred to knowledge generally and has been understood to provide the basis for the U.S. copyright system.[44] Consequently, the promotion of progress in the

[40] The U.S. Constitution leaves the choice of actor and type of patent system effectively up to Congress. *See* U.S. CONST. art. 1,, § 8, cl. 8.

[41] All commentators do not agree that the moral utility requirement is defunct and some even argue for its application to biotech inventions. However, as will be explained in Part I, any notion that a moral utility requirement still exists in U.S. patent law is fallacy, not fact. See discussion *infra* at _____

[42] It should be noted that not all of the statutory barriers to be discussed explicitly address biotech inventions; some affect *any* morally controversial invention. *See, e.g.,* Article 53(a) EPC.

[43] The phrase "patent eligibility" usually refers solely to whether an invention comprises subject matter that falls within one of the four §101 categories. *See* MARTIN J. ADELMAN, RANDALL R. RADER, JOHN R. THOMAS, HAROLD C. WEGNER, CASES AND MATERIALS ON PATENT LAW 207, 314 (1998) [hereinafter ADELMAN ET. AL.,]. In this Article, however, the phrase will be used to refer to both §101 determinations: subject matter and utility, because questions of the morality of an invention implicate both concerns.

[44] *See also* H.R.Rep.No.1923, 82d Cong., 2d Sess. 4 (1952); S.Rep.No.1979, 82d Cong., 2d Sess. 3 (1952), U.S.Code Cong. & Admin.News 1952, pp. 2394, 2396, *cited in* In Re Bergy, 596 F.2d 952, 958 (C.C.P.A. 1979).

"useful arts" is the basis for Congress' authority to create a patent system.[45] Congress chose to promote progress in the useful arts by establishing a patent system whereby in exchange for adequately disclosing a useful, novel, and non-obvious invention[46] 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.[47]

The current patent statute, enacted in 1952, is codified at 35 U.S.C. §§ 1-300. Section 101 of that title 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.[48] In addition to being useful, however, §101 also requires the invention to be of the right type. The patent statute provides that: "whoever invents or discovers any new and useful *process*, *machine*, *manufacture*, or *composition of matter*, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and

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[45] In Re Bergy, 596 F.2d 952, 958 (C.C.P.A. 1979).

[46] The disclosure requirements (written description, enablement, best mode, and distinct claiming) are codified in 35 U.S.C. § 112, first paragraph, which provides, in pertinent part:

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

35 U.S.C. § 102 contains the novelty requirement and provides, in pertinent part, that:

A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented . . . by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country . . . filed more than twelve months before the filing of the application in the United States, or

(e) The invention was described in (1) an application for patent, published . . . by another filed in the United States before the invention by the applicant . . . or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, . . ; or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. . . .

The non-obviousness requirement is codified at 35 U.S.C. § 103 which provides, in pertinent part:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

[47] The original patent term was 14 years from issuance. "An Act to Promote the Progress of Useful Arts," ch. 7, §4, 1 Stat. 110 (1790). It is currently 20 years from the filing date, with the possibility of extensions for delays not attributable to acts or omissions of the inventor. 35 U.S.C. §§ 154 and 271.

[48] In addition to utility patents, the patent statute also provides for the issuance of design patents on ornamental designs for articles of manufacture and plant patents on asexually reproduced plants. *See* 35 U.S.C. §§ 159, 164 (?)

requirements of this title."[49] These two requirements, utility and "type" or subject matter, are the battlefield on which most disputes regarding morally controversial biotech inventions have traditionally been fought.

A. Subject Matter

Section 101 of the Patent Act provides for the grant of patents only on new and useful processes, machines, articles of manufacture, and compositions of matter. The four subject matter categories of §101 are not mutually exclusive; an invention can be classifiable in more than one category.[50] Likewise, an inventor need not specify which category her invention is properly classified in as long as it can be encompassed within one of the four. Abstract ideas that have not been reduced to a functional form, natural phenomena such as uncultivated plants found in the wild, and laws of nature such as $E = mc^2$ are categories of subject matter determined by the United States Supreme Court to be outside the four corners of §101.[51] The justifications for such exclusions are the wording of the statute identifying four specific subject matter categories and a policy determination that patents should not be granted on subject matter that is not new or that consists of fundamental principles regarding the way the world works, principles which should be free for all to use.[52] However, the apparent breadth of these exclusions is considerably narrower now than 25 years ago due to a series of judicial decisions that have, in the eyes of some, carved out portions of the public domain (certain types of abstract ideas and natural phenomena) and made them eligible for utility patent protection.[53]

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[49] 35 U.S.C. § 101 (emphasis added).

[50] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[51] *Id.* ("This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. . . . Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none. ")

[52] *Id*.

[53] *See* Charles R. McManis, *Re-Engineering Patent Law: The Challenge of New Technologies*, 2 WASH. U. J.L. & POL'Y 1, 3 (2000). In describing the expansion of patent-eligible subject matter, Professor McManis notes:

> [P]atent protection for inventions has been held to exclude any protection for abstract ideas, natural laws, or principles, and phenomena of nature. For a time courts also purported to exclude business methods from the subject matter of protection. Today, however, inventors of software-related inventions have come perilously close to obtaining patents on mathematical algorithms, . . . Likewise, biotechnology patents have come very close to claiming phenomena of nature, namely isolated genetic sequences. . . . The result has been . . . "[a] patent gold rush," in which "inventions long thought unpatentable-everything from gene sequences of unknown function to one-step purchasing over the Internet-are now being claimed as property.

Id., citing Arti K. Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL'Y 199 (2000).

"Anything under the sun that is made by man" has been the mantra for the unprecedented expansion in patent eligible subject matter articulated by the United States Supreme Court over the past 20+ years.[54] The Court lifted the phrase from the legislative history of the Patent Act of 1952 as evidence of the wide scope Congress intended for §101. The phrase provided the basis for the Court's path-breaking conclusion in *Diamond v. Chakrabarty*, that living organisms, namely, a man-made bacterium with properties unlike any known naturally occurring organism, comprised patent eligible subject matter.[55] The phrase was also repeated by the Court in *Diamond v. Diehr*, a case that involved the claimed use of a law of nature in a computerized manufacturing process and laid the groundwork for utility patents on computer software.[56] Most recently, in *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 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.[57] Moreover, in *State Street Bank v. Signature Financial*, the Court of Appeals for the Federal Circuit, following the Supreme Court's lead, effectively expanded patent eligible subject matter to include business methods, opening the doors of the USPTO to a flood of patent applications from traditionally non-technical disciplines such as the accounting and financial services industries. [58]

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 under § 101.[59] The *Chakrabarty* case presented the Court with a profoundly important choice.

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[54] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) ("Congress intended statutory subject matter to include 'anything under the sun that is made by man.'") citing S. REP. NO. 1979, 82d Cong., 2d Sess., at 5 (1952), H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) U.S. Cod Cong. & Admin. News 1952, pp. 2394, 2399.

[55] Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980). A much earlier decision, (Parke Davis) in combination with *Chakrabarty*, set the stage for the patenting of genes, DNA, and other naturally occurring biological material isolated from, and in a purified state relative to its natural condition. However, as with abstract ideas, how subject matter is defined impacts its patent eligibility. The allowance of patents in isolated genes and purified DNA narrows the scope of "natural phenomena" that is in the public domain and not eligible for patent protection.

[56] *See, e.g.*, Diamond v. Diehr, 450 U.S. 185 (1981); In re Alappat, 33 F2d 1526, 1557 (Fed. Cir. 1994)(en banc); AT&T v. Excel Communications, 172 F3d 1352, 1356 (Fed. Cir. 1999). In a previous decision, *Parker v. Flook*, the Court had invalidated a patent on a similar process because it was deemed to comprise an abstract idea. To the extent computer software and/or business methods do consist of abstract ideas, such subject matter is, by judicial decree, no longer part of the public domain but is now eligible for patent protection. *See, e.g.* State Street Bank & Trust v. Signature Fin. Group, Inc., 149 F.3d 1368 (Fed. Cir.), *cert. denied*, 119 S. Ct. 851 (1999); John R. Thomas, *The Patenting of the Liberal Professions*, 40 BOSTON C. L. REV. 1139 (1999).

[57] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 122 S. Ct. 593, 599 (2001).

[58] State Street Bank & Trust v. Signature Fin. Group, Inc., 149 F.3d 1368, 1375 (Fed. Cir.), *cert. denied*, 119 S. Ct. 851 (1999). 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. *See, e.g.*, Bagley, *Obvious by Analogy supra note* __ at __; Thomas, *Liberal Professions*, supra note ___ at .

[59] 447 U.S. at 313.

It could agree with the USPTO and its own advice and "proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress," by leaving the question of the patent eligibility of genetic inventions to "the legislative process" which was "best equipped to weigh the competing economic, social, and scientific considerations involved."[60] Alternatively, it could conclude that Congress had already spoken, and had intended § 101 to have a broadly inclusive scope.[61] It chose the latter approach, with fateful consequences. 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."[62] 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."[63]

Acknowledging the possible repercussions of its decision, the Court adverted to a "gruesome parade of horribles" cited by the USPTO and *amici* that could result from patents on genetic research:

> 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."[64]

However, the Court declared itself to be "without competence" even to entertain such morality-laden "high policy" arguments.[65] In broadly construing § 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."[66]

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[60] *Id*. at 315.

[61] *Id.* at 313.

[62] *Id*.

[63] *Id*. at 309.

[64] Jeremy Rifkin co-authored 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." Over 20 years later, Rifkin considers his early concerns justified, as patents have issued covering many of these items. Dashka Slater, *huMouse*^{TM}, Legal Affairs, *at* http://www.legalaffairs.org/issues/November-December-2002/feature_slater_novdec2002.htm# (visited Feb. 10, 2003).

[65] Id. at 317.

[66] Id. at 318. The Court recently reaffirmed its deferential role in reviewing Congressional enactments under the Constitution's Intellectual Property clause in *Eldred v. Ashcroft*, 123 S. Ct. 769, 790 (2003). While *Eldred* is not a patent case, the Court employed analogies to patent law in reaching its

Having thus emphatically interpreted the statute to encompass any invention "made by man" the Court is without competence to exclude such inventions from patent eligibility by its own admission. Like Dr. Chakrabarty's oil-eating bacterium, the morally controversial biotech inventions presented to the USPTO generally involve human manipulation of genetic material. Consequently, the § 101 subject matter prong of patent eligibility does not provide any bar to the patenting of morally controversial biotech subject matter.

B. Utility: "Useful" Does Not Mean "Moral"

Section 101 of the Patent Act authorizes the issuance of patents only for "useful" inventions.[67] For the vast majority of inventions, the 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, credible, and substantial" use for an invention.[68]

Historically, however, establishing utility was not always an easy task. Fairly early in the development of patent law, the morality of an invention was considered 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*."[69]

Justice Story's language provided the foundation for what came to be known as the "moral utility" requirement, 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[70] and fraudulent articles.[71]

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conclusion that it lacked authority to strike down the Copyright Term Extension Act of 1998. The Court concluded its decision by stating that "[t]he wisdom of Congress' action, however, is not within our province to second guess. Satisfied that the legislation before us remains inside the domain the Constitution assigns to the First Branch, we affirm the judgment of the Court of Appeals." *Id*. Of course, if the Court perceived a constitutional conflict, for example between the Thirteenth Amendment and patents on constitutionally protected humans (e.g. viable fetuses), it likely would act.

[67] 35 U.S.C. § 101.

[68] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (2001). The Utility Examination Guidelines are instructions to be used by USPTO examiners when assessing the patentability of a claimed invention.

[69] Lowell v. Lewis, 15 Fed. Cas. 1018, No. 8568 (C.C. Mass. 1817) (Story, J.).

[70] *See, e.g.*, Meyer v. Buckley, 15 F. Supp. 640 (N.D. Ill. 1936); Brewer v. Lichtenstein, 278 F. 512 (7th Cir. 1922); Schultze v. Holtz, 82 F. 448 (N.D. Cal. 1897); National Automatic Device Co. v. Lloyd, 40 F. 89 (N.D.Ill. 1889).

Not surprisingly, 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.[72] 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.[73]

Eventually, however, courts began refusing to impose the requirement at all, noting that it was an area in which Congress could legislate, but that such determinations were not the proper purview of the courts or the USPTO.[74]

In 1998, however, the moral utility doctrine seemed on the verge of revival when the USPTO invoked 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.[75] The applicants have not actually made such creatures, nor do they want anyone else to make them.[76] Rather, their purpose in filing the application was to

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[71] *See, e.g.*, Scott & Williams v. Aristo Hosiery Co., 7 F.2d 1003 (2d Cir. 1925) (seamless "seamed" stockings); Mahler v. Animarium Co., 111 F. 530 (8th Cir. 1901 (incredible medical device); Rickard v. DuBon, 103 F. 868 (2d Cir. 1900) (process for "spotting" tobacco leaves).

[72] Fuller v. Berger, 120 F. 274, 275 (7th Cir. 1903) (identifying test for no lack of utility as whether the invention "is incapable of serving any beneficial end").

[73] Ex parte Murphy, 200 U.S.P.Q. 801, 802 (B.P.A.I. 1977).

[74] *See, e.g.*, Whistler Corp. v. Autotronics, Inc., 1988 WL 212501 (N.D. Tex. Jul. 28, 1988)(refusing to invalidate radar detector patent for lack of utility since "[u]nless and until detectors are banned outright, or Congress acts to withdraw patent protection for them, radar detector patentees are entitled to the protection of the patent laws."); Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (Fed. Cir. 1999) (refusing to invalidate patent on deceptive device).

[75] *See* U.S. Patent Application No. 10/308,135. While news reports mention both Newman and Rifkin as applicants, Newman is listed as the sole inventor on the application. The applicants even created a trademark for one of the chimera -- the humouse™. *See* Dashka Slater, *huMouse*, Legal Affairs, *at* http://www.legalaffairs.org/issues/November-December-2002/feature_slater_novdec2002.htm# (visited Feb. 10, 2003).

[76] An interesting feature of U.S. patent law is that a patent applicant need not have actually 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. MARTIN J. ADELMAN, RANDALL R. RADER, JOHN R. THOMAS, HAROLD C. WEGNER, CASES AND MATERIALS ON PATENT LAW 207, 329 (1998) ("An inventor may reduce an invention to practice in two ways: constructively, by filing a patent application, and actually, by building and testing a physical embodiment of the invention.").

provoke a debate and force Congress, the courts, and the USPTO to draw the line on patent eligible subject matter.[77]

Shortly after receiving the chimera application, the USPTO issued a media advisory entitled "*Facts on Patenting Life Forms Having a Relationship to Humans.*"[78] 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 requirements of the utility requirement."[79] However, by its own admission in a more recent statement, the USPTO is without authority to deny a patent based on morality or public policy concerns. In addressing a comment that the USPTO should deny patents on DNA for the public good, the Agency 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 . . . . [80]

If the USPTO persists in maintaining a rejection of the chimera application claims under the moral utility doctrine, such a rejection is bound to be overturned in court. Not long after the USPTO's announcement, the Court of Appeals for the Federal Circuit handed down a decision in *Juicy Whip v. Orange Bang* which sounded the death-knell for the moral utility requirement.[81] In rejecting an argument that the moral utility requirement should be applied to invalidate a patent on a deceptive invention, the court stated:

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[77] *See, e.g.*, Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 248 (2000).

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

[79] *Id.* A few days later, then-Commissioner of Patents Bruce Lehman re-emphasized the position of the USPTO with the infamous statement "We will grant no patents on monsters." BNA, *"'Morality' Aspect of Utility Requirement Can Bar Patent for Part-Human Inventions,"* PAT. TRADEMARK & COPYRIGHT J. NEWS 555 (Apr. 9, 1998). Unfortunately for Mr. Lehman, his promise was broken the moment he made it: at the time of the statement, the USPTO had already issued several patents on "monsters," animal-animal chimera evocative of the mythical creature, part goat, part lion, and part serpent from which the name "chimera" originated. Apparently, the USPTO did not consider animal-animal chimera to be monsters. The USPTO has rejected the chimera application for several years but may ultimately have to let a court decide the issue. *See* Natalie Dewitt, *Biologists Divided Over Proposal to Create Human-Mouse Embryos*, 420 NATURE 255 (2002).

[80] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (2001).

[81] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (Fed. Cir. 1999).

> It has been said that inventions that are injurious to the well-being, good policy, or sound morals of society are unpatentable but 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, . . . [t]hose powers by which the *health, good order, peace and general welfare* of the community are promoted. . . . Of 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.[82]

The judicially created moral utility requirement thus suffered a judicial demise in complete accord with the U.S. Supreme Court's "anything under the sun made by man" subject matter interpretation.[83] Nevertheless, based on its statement regarding the chimera application, the USPTO may wish to revive the moral utility requirement to deal with morally controversial biotech subject matter.[84] However, it would be difficult in the extreme to resurrect a rule which, based on judicial interpretations of 35 U.S.C. § 101, does not exist under the current 1952 patent statute.[85] Moreover, the watered-down

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[82] *Id*.

[83] *See* 2 JOHN G. MILLS III, ROBERT C. HIGHLEY, AND DONALD C. REILEY III, PATENT LAW FUNDAMENTALS § 9:5 (2003) ("In light of the Federal Circuit's decision in *Juicy Whip v. Orange Bang*, it would seem that immorality or illegality is no longer a bar to an invention's eligibility for a U.S. patent."). *See also* Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law* (working paper 2003), where Professors Burk and Lemley outline how the Federal Circuit's resistance to patent policy has led the court to expressly eliminate several long-standing patent law policy doctrines on the basis that no specific statutory authorization supports their existence. While one may lament the lack of flexible policy standards for judicial decision-making, the fact remains that the Federal Circuit is unlikely to reverse its position on the moral utility doctrine, precisely because the requirement cannot be read into the statute, Congress must explicitly place it there.

The Supreme Court's own last word on utility is not to the contrary. In Brenner v. Manson, 383 U.S. 519, 533 (1966), the Court, in dicta, quoted Justice Story's well-known statement and essentially dismissed it, stating:

> Justice Story's language sheds little light on our subject. Narrowly read it does no more than compel us to decide whether the invention in question is 'frivolous and insignificant'—a query no easier of application than the one built into the statute. Read more broadly, so as to allow the patenting of any invention not positively harmful to society, it places such a special meaning on the word 'useful' that we cannot accept it in the absence of evidence that Congress so intended.

Id. Again, because the moral utility doctrine would place a special meaning on the word "useful" that Congress has nowhere indicated, the Court would be unlikely to read such a vague and nebulous requirement into the statute.

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

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

moral utility requirement invoked prior to *Juicy Whip* would be of little assistance in any event, since morally controversial biotech inventions generally can claim at least one legal and beneficial use, e.g., to help cure disease.[86] A better approach might be to consider ways that other countries have addressed the patenting of such subject matter in hopes of gleaning useful ideas to inject into the U.S. system.

II. COMPARATIVE APPROACHES TO MORALLY CONTROVERSIAL BIOTECH SUBJECT MATTER

Patent law has historically been territorial in nature, with sovereign states granting patents and providing means for patentees to enforce their rights only within their borders.[87] Consequently, if a person wants to obtain patent protection for an invention in multiple countries, she has to apply for a patent in each country of interest[88] because the exclusionary rights provided do not extend beyond the state's borders.[89]

A. U.S.: Patent First, Ask Questions Later

In contrast to the patent laws of many other countries, U.S. patent law contains no statutory basis for the 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 her invention meets the statutory patentability requirements specified in the Act.[90] The burden is thus on the USPTO to show that a person does not meet the statutory requirements, and, since there is no statutory morality inquiry, the U.S. has a defacto system of patenting first, and asking questions later. As noted earlier, Members of Congress seem to be unaware of the lack of subject matter limits in this system, but the lack of awareness is akin to that of the proverbial ostrich that sticks its head in the sand when trouble approaches and is thus unaware of the problem it is facing. As summed up by Senator Mark Hatfield, "Public officials have too often preferred to allow such issues to be decided by default in a vacuum of leadership."[91] Congress has had plenty of warning, as the examples below show, that the current "patent first" order is problematic, but has failed to extrapolate from those specific situations, e.g. proposals for

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[86] *See* Fuller v. Berger, 120 F. 274, 275 (7th Cir. 1903).

[87] *See, e.g.*, 35 U.S.C. 271(a), remedy for infringement that occurs within the U.S.; *See* Margo A. Bagley, *Patently Unconstitutional: Geographical Limitations on Priori Art in a Small World,* 87 MINN. L. REV. 679, 729 (2003); Curtis A. Bradley, *Territorial Intellectual Property Rights in an Age of Globalism*, 37 Va. J. Int'l L. 505, 520 (1997) (discussing territoriality of U.S. patent law).

[88] Except in places where a regional application system, such as the EPC, exists. *See* discussion *infra* at ___.

[89] GRAEME B. DINWOODIE, WILLIAM O. HENNESSEY, AND SHIRA PERLMUTTER, INTERNATIONAL AND COMPARATIVE PATENT LAW 3 (LexisNexis 2002).

[90] Both 35 U.S.C. §§ 101 and 102 express the entitlement concept: Section 101 provides that *"[w]h*oever 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* . . ." (emphasis added).

[91] Mark O. Hatfield, *From Microbe to Man*, 1 ANIMAL L. 5 (1995).

a moratorium on animal patents, to the general, e.g., the need to evaluate patent-eligibility before any patent issues, at least for morally controversial inventions.

1. Lessons from Mice, Methods, Monsters, and "Mini-Me"

Morally controversial biotech patents have issued from the USPTO in increasing numbers since *Diamond v. Chakrabarty* flung wide the doors of the Office to biotech subject matter.[92] Several notable examples illustrate the difficulties with having a "patent first, ask questions later" approach to determining patent eligibility of morally controversial biotech subject matter.

a. Multicellular Animals ("Mice")

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. Chakarabarty.*[93] 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.[94] News of the issuance of the oyster patent and the Agency's plans to patent animals created significant public controversy and calls for bans on both the underlying research and patents on genetically modified animals.[95]

Representatives of myriad constituencies testified regarding the potential impacts, positive and negative, of such patents.[96] 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 non-human organisms.[97]

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[92] See discussion *supra* at __.

[93] 1077 O.G. 24 (April 21, 1987). *See also* BNA, *Nonnaturally Occurring Non-Human Animals are Patentable Under Section 101*, 33 PAT. TRADEMARK & COPYRIGHT J. 664 (1987). *See also* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[94] Ex Parte Allen, 2 U.S.P.Q.2d 1425 (BPAI 1987).

[95] 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., 1st Sess. § 1 (1989); H.R. 3119, 100th Cong., 1st Sess. § 2 (1987); S. 2111, 100th Cong., 2d Sess. (1988).

[96] For arguments in favor of an animal patent moratorium, *see, e.g., Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and The Administration of Justice of the Committee on the Judiciary*, 100th Cong. 396 (1987) (statement of Rev. Wesley Granberg-Michaelson, National Council of Churches). *Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and The Administration of Justice of the Committee on the Judiciary*, 100th Cong. 423 (1987) (statement of Margaret Mellon, National Wildlife Federation). For arguments a moratorium, *see, e.g., Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and The Administration of Justice of the Committee on the Judiciary*, 100th Cong. 436 (1987) (statement of Geoffrey M. Karny, Dickstein, Shapiro & Morin).

[97] *Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and The Administration of Justice of the Committee on the Judiciary*, 100th Cong. 375 (1987) (statement of Leroy Walters, Ph.D,). Dr. Walters concluded his remarks with the caveat that:

> sustained research should be devoted to defining appropriate boundaries between human and nonhuman organisms . . . In the twenty-first century, molecular biologists may have the capability of transferring not only individual genes but also gene

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.[98] Theological arguments urging a moratorium included this statement by Rabbi Michael Berenbaum:

> To understand what must be done regarding the issue of animal patenting, we must ask what constitutes life and what is merely an inert manufactured commodity. So too we must ask what are the limits of scientific knowledge and what are its frontiers. Should there be constraints on scientific experimentation and/or industrial exploitation of these experiments. And perhaps even more importantly, who shall regulate, who shall decide?[99]

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.[100] In affirming dismissal of the suit for lack of standing, the Court of Appeals for 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.*[101]

If Congress had been paying attention, the court's words would have made clear the absence of any ability on the part of the USPTO to deny patents on otherwise patentable subject matter, despite the reference to "non-human" organisms in the Notice. PTO pronouncements on the scope and limits of patent-eligible subject matter are not

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> complexes . . . across species lines. One hopes that timely, calm, and systematic discussion of these technical possibilities will lead to a social consensus on reasonable ethical limits to human curiosity and ingenuity.

Id. at 390. Unfortunately, such a "timely, calm, and systematic discussion" has not occurred.

[98] *See* Rebecca Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 410 (1988).

[99] *Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and The Administration of Justice of the Committee on the Judiciary*, 100th Cong. 405 (1987) (statement of Rabbi Michael Berenbaum).

[100] Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 924 (Fed. Cir. 1991).

[101] *Id*. at 929-930 (emphasis added).

determinative. Rather, Congress, with the Supreme Court as ultimate interpreter, sets patent eligibility limits.[102] Section 101 of the Patent Act, as interpreted, includes anything under the sun 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."[103] 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.[104] 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.[105] Thus, it 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.

b. Medical Procedures ("Methods")

Interestingly enough, 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.[106] 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.[107] The lawsuit touched off a firestorm of controversy concerning whether medical procedures should be patentable.[108] Arguments against patents on medical procedures focused on

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[102] According to the Supreme Court, it is the province of the judiciary to "say what the law is." Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177 (1803).

[103] Keith Schneider, *Harvard Gets Mouse Patent, A World First*, THE NEW YORK TIMES, Apr. 13, 1988, at A1.

[104] *See* U.S. Patent No. 4,736,866. The patent claims are not limited to mice but include any non-human mammal. *Id*.

[105] *See Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and The Administration of Justice of the Committee on the Judiciary*, 100th Cong. 405 (1987) (statement of Margaret Mellon, National Wildlife Federation) (testifying that during the hearings, a *Washington Post* article reported on a new transgenic mouse developed to secrete a heart drug in its milk, in such high concentrations that it could provide a vastly improved drug production method).

[106] Pallin v. Singer, 36 U.S.P.Q.2d 1050 (D. Vt. 1995).

[107] *See* John R. Thomas, *The Patenting of the Liberal Professions*, 40 BOSTON C. L. REV. 1139, 1176 (1999). *See also* William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 653 (1995).

[108] *See, e.g*., *Patently Ridiculous*, TULSA WORLD, Apr. 4, 1996, at A12 ("This case [Pallin v. Singer] demands a decision in the public interest. Congress ought to act quickly to ban this type of patent."); *As Doctors Patent Medical Procedures, Patients Pay*, USA TODAY, Jun. 19, 1995, at 10A (citing costs and privacy concerns associated with medical method patents and advocating legislation to ban such patents); Lauran Neergaard, *Move to Patent Surgical Procedure Sparks Fight*, LOS ANGELES TIMES, Apr. 2, 1995, at A14 ("[Dr. Pallin] has sparked an uproar by U.S. doctors who say patenting the way they practice medicine is unethical and drives up health care costs. They've persuaded Congress to consider outlawing the practice.").

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.[109]

This controversy differed from that 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, i.e. physicians, were *against* such patents.[110] The House of Delegates of the American Medical Association ("AMA") voted to condemn efforts to patent surgical and medical treatment methods in 1994. 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.[111] The report concluded:

> A physician has the ethical responsibility not only to learn from but also to contribute to the total store of scientific knowledge when possible. Physicians should strive to advance medical science and make their advances known to patients, colleagues and the public. This obligation provides not merely incentive but imperative to innovate and share the ensuing advances. The patenting of medical procedures poses substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis. Accordingly, the Council believes that it is unethical for physicians to seek, secure, or enforce patents on medical procedures. [112]

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.[113] The other, preferred by the biotechnology industry, only prevented medical procedure patents from being asserted against medical professionals engaged in non-commercial endeavors practicing non-biotechnology processes.[114] Not surprisingly, Congress chose the latter approach, which dealt with many, but not all, of the concerns of both the medical and biotechnology communities. The statute, codified

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[109] *See, e.g.*, Beata Gocyk-Farber, Note, *Patenting Medical Procedure: A Search for a Compromise Between Ethics and Economics*, 18 CARDOZO L. REV. 1527, 1544 (1997) (briefly describing economic and ethical arguments for and against medical procedure patents); Robert M. Portman, *Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress*, 4 U. BALT. INTELL. PROP. L.J. 91, 111 (1996) (providing detailed arguments against medical procedure patents).

[110] *Id*. at 1534.

[111] *Reprinted in* "Ethical Issues in the Patenting of Medical Procedures, Food & Drug L.L., 53(2): 341-357 (1998).

[112] *Id.*

[113] H.R. 1127, 104th Cong. (1995).

[114] S. 2105, 104th Cong. (1996).

at 35 U.S.C. § 287(c), thus allows for the continued issuance of medical procedure patents, but prohibits their enforcement against doctors.[115]

While Congress was able to put on the brakes in relation to medical procedure patents, the compromise solution is problematic and incomplete. Medical procedure patents that issued before the effective date of the patent are still enforceable against medical practitioners.[116] Also, by not completely banning such patents, the statute still leaves medical practitioners and others open to the possibility of liability if faced with patent claims drafted to capitalize on the complex language of the statute. Moreover, it has been argued that the statute effects a government "taking" of property under the Fifth Amendment,[117] an issue that is much more likely to be implicated under a "patent first" system.

c. Human-Animal Chimera ("Monsters"):

The Newman-Rifkin chimera application mentioned in Part I and pending in the USPTO is a "patent first, ask questions later" problem in the making. Congress has expressed no view on the patentability (or lack thereof) of human-animal chimera, thus the USPTO has no basis (as long as the standard patentability criteria are met) for denying a patent on a seriously morally controversial biotech invention. In dealing with the chimera application discussed in Part I, the USPTO appears to have invoked not only the now defunct moral utility requirement to reject the application claims but also the Thirteenth Amendment to the Constitution.[118] 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 USC 101."[119] 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.[120]

Does the Thirteenth Amendment ban patents on humans? It is not at all clear that the provision has anything to say about this. The Thirteenth Amendment states that "[n]either slavery nor involuntary servitude, except as punishment for crime whereof the

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[115] 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).

[116] *Id.*

[117] *See* Courtenay C. Brinkerhoff, *Medical Method Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking?*, 4 U. BALT. INTELL. PROP. L.J. 147, 177 (1996) (concluding that the new statute effected a Fifth Amendment taking of property entitling patentees and patent applicants to government compensation.).

[118] *See* Dashka Slater, *huMouse*, Legal Affairs, *at* http://www.legalaffairs.org/issues/November-December-2002/feature_slater_novdec2002.htm# (visited Feb. 10, 2003).

[119] *Nonnaturally Occurring Non-Human Animals are Patentable Under §101*, 33 PAT. TRADEMARK & COPYRIGHT J. 664 (1987).

[120] *Id.*

party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction."[121] 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.[122] Thus a hypothetical patent on a genetically modified "human" would not entitle the patent owner to force the patented human to "do" anything.[123]

The Newman-Rifkin application discloses a creature with less than 50% human genetic material.[124] Would that creature be "human" enough to be entitled to constitutional protection? Neither Congress nor the courts have as yet made that determination. In the cloning context, researchers are currently interested in harvesting stem cells from four to fourteen day old embryos. But what if advances in science indicate better results from using four *week* or fourteen *week* old fetuses, for stem cells or some other medically beneficial purpose? *Roe v. Wade* holds that at their earliest stages of development, embryos are not constitutionally protected as "persons," which would suggest that the Thirteenth Amendment would not bar patents on embryos and fetuses prior to viability at a minimum.[125]

Of course, Congress has the power to enact legislation banning patents on human beings, however defined, simply pursuant to the Constitution's Intellectual Property Clause. But as several commentators have noted, the USPTO or even a court may not have the authority, absent congressional action, to invoke the Thirteenth Amendment as a basis for denying a patent on subject matter containing human genetic material.[126] Numerous patents have already issued on transgenic animals and animals being produced for xenotransplantation that contain human genetic material.[127]

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[121] U.S. Constitution, Amendment XIII.

[122] 35 U.S.C. §271(a)

[123] However, the patent could theoretically allow the patent owner to keep the patented human from doing something: procreating, in essence "making" the claimed invention. As procreation is a fundamental, constitutionally protected right, the patent would be unenforceable to the extent it conflicted with that right, but that would not, without more, remove a genetically modified human from patent subject matter eligibility. *See* 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.").

[124] U.S. Patent Application No. 10/308,135.

[125] Roe v. Wade, 410 U.S. 113 (1973).

[126] *See, e.g.*, Paul Lesko and Kevin Buckley, *Attack of the Clones . . . and the Issues of Clones*, 3 COLUM. SCI. & TECH. L. REV. 1, 59 (2002); Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 459 (1999); Russell H. Walker, Note, *Patent Law--Should Genetically Modified Human Beings Be Patentable?*, 22 MEM. ST. U. L. REV. 101, 110 (1991).

[127] Xenotransplantation involves the transfer of organs between different species. *See* Margaret A. Clark, *Ethical Issues*, Frontline, *at*wysiwyg://19/http://www.pbs.org/wgbh/pages/frontline/shows/organfarm/regulators/clark.html (visited Feb. 10, 2003).

This is not to say that the Thirteenth Amendment has no applicability to patent law. Congress is empowered under the Amendment to identify and remedy badges and incidents of slavery.[128] While patent rights are exclusionary, not affirmative, in nature, a document evidencing "ownership" of a human being which has the attributes of personal property seems sufficiently akin to a "badge or incident of slavery" to trigger the protections of the constitutional provision. Moreover, despite the Supreme Court's historically narrow[129] interpretations of the Thirteenth Amendment, and even without explicit legislation enforcing it in this context, the Court could determine, *sua sponte,* that a patent covering human subject matter beyond the fetal viability stage should be barred, or otherwise remediable, under the Thirteenth Amendment.[130] But the Amendment is unlikely to have much impact beyond situations where the patent subject matter is explicitly human and past the stage of fetal viability.

While the Newman-Rifkin application was filed to start a debate, the issuance of patents on human-animal chimera is swiftly leaving the realm of the hypothetical and nearing reality. The Newman-Rifkin Humouse™ patent application originally filed in 1997, was denigrated by scoffers and skeptics as unnecessary and ill-conceived. However, in just five short years the activists' fears have been confirmed as prescient. Already, at least one other human animal chimera application is pending in the USPTO, filed by researchers at the University of Massachusetts.[131] 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*.[132] The reason given for the creation of such embryos would be 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."[133] While the forum did not

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[128] The Thirteenth Amendment provides that "Congress shall have power to enforce this article by appropriate legislation." *See* Jones v. Alfred H. Mayer Co. 392 U.S. 409, 440 (1968) (noting that Congress has the power under the Thirteenth Amendment rationally to determine what are the badges and incidents of slavery, and the authority to translate that determination into effective legislation.)

[129] *See, e.g.*, Baher Azmy, *"Unshackling the Thirteenth Amendment: Modern Slavery and a Reconstructed Civil Rights Agenda,"* 71 Fordham L. Rev. 981, 1053-55 (2002).

[130] Even without legislation, Bivens v. Six Unknown Named Agents, 403 U.S. 380 (1971) could provide the basis for an action against the USPTO or, perhaps, even against a patent owner. *See* Baher Azmy, *"Unshackling the Thirteenth Amendment: Modern Slavery and a Reconstructed Civil Rights Agenda,"* 71 Fordham L. Rev. 981, 1053-55 (2002) ("*Bivens* thus supplies strong authority for the availability of a cause of action for damages directly under the Thirteenth Amendment even in the absence of congressional authorization. The Thirteenth Amendment, like the Fourth Amendment, creates a substantive federal right. . . . If someone currently held in a condition of slavery or involuntary servitude were to sue, that person would assuredly be able to obtain the equitable remedy of an injunction releasing her from servitude.").

[131] See U.S Patent Application No. 09/828,876 (claiming a method of producing a cloned chimeric mammalian embryo).

[132] Natalie Dewitt, *Biologists Divided Over Proposal to Create Human-Mouse Embryos,* 420 NATURE 255 (2002).

[133] *Id.*

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.[134] This despite the fact that, as identified by one participant at the New York forum, there are viable stem cell testing alternatives to making interspecies chimera that would not pose the same moral and ethical concerns.[135] Consequently, without legislative limits on the patent eligibility of morally controversial biotech subject matter, we can expect to see human-animal chimera patents of varying degrees of "humanness" issuing from the USPTO and continuing to spur research of this sort.

d. Human Cloning ("Mini Me"):

The diminutive clone "Mini Me" of Austin Powers fame (or infamy)[136] may be fictional, but human cloning is fast becoming a reality. A very recent controversy over a biotech patent 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. While principally directed to techniques for producing human organs from transgenic pigs for transplantation purposes, the patent's scope is much broader than that.[137] 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."[138] 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."[139] However, because 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 has no patent-based property interest in any such clones.[140]

As in other situations involving issuance of a patent on morally controversial subject matter, the patent drew critical reaction, commentary, and calls for legislative action from

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[134] *Id.*

[135] *Id.* (Citing alternatives such as "assessing how the embryonic stem cells behave in culture, or testing whether they can engraft and form different tissues after injection into adult mice or mouse fetuses.") Of course, the use of human embryonic stem cells is morally controversial in the first instance, and while the mentioned alternatives may be less disturbing than the idea of human-animal chimera, they are still morally controversial in and of themselves.

[136] *See Cloning Manual*, Austin Powers.com, *at* http://www.minime.com (visited Feb. 10, 2003) (spoofing the cloning process as "mixing pure evil + parts . . . cloned at 1/8th size . . . Dr. Evil's clone Mini Me").

[137] *See* U.S. Patent No. 6,211,429. BNA, *See also* BNA, *Group Faults PTO for Issuing Patent on 'Method of Producing Cloned Mammal'*, 64, No. 1574, PAT. TRADEMARK & COPYRIGHT J. 81 (2002).

[138] U.S. Patent No. 6,211,429. The patent document describes the claimed methods as being "generally applicable to a wide array of unfertilized mammalian oocytes" including mouse, sheep, cow, horse, cat, dog, and unfertilized human oocytes. *Id.*

[139] *Id.*

[140] *See* 35 U.S.C. § 112, para. 1. *See also* In Re Bergy, 596 F.2d 952, 958 (C.C.P.A. 1979).

a variety of sources.[141] Senator Sam Brownback (D-Kan.) offered an amendment to Section 101 of the Patent Act adding 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.[142]

The amendment failed, with lawmakers refusing to attach it to a bill that ultimately became the "Terrorism Risk Insurance Act of 2002."[143] In defending his action in offering the amendment, Sen. Brownback cited news reports on the '429 patent and the fact that three similar patents were pending in the USPTO.[144]

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.[145] Brownback countered that the USPTO policy was being challenged by lawyers and that legislative action was needed "to provide clarity." Sen. Orrin Hatch (R-UT) called the amendment a "red herring" since the real debate, to his mind "has little to do with patents. It has to do with whether or not we will allow important research to proceed."[146]

Whether the Brownback amendment is good or bad is a matter of policy for Congress to decide. Nevertheless, in making their decision, the members of Congress

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[141] *See, e.g.*, BNA, *Group Faults PTO for Issuing Patent on 'Method of Producing Cloned Mammal'*, 64, No. 1574, PAT. TRADEMARK & COPYRIGHT J. 81 (2002) (discussing the Center for Technology Assessment's criticism of the PTO for issuing the patent), Antonio Regalado, *The University of Missouri Receives Patent for Human-Cloning Method*, www.msnbc.com, *at* http://www.msnbc.com/news/753193.asp?0si=-&cp1=1 (last modified May 16, 2002).

[142] Amendment No. 3843, June 13, 2002. The amendment defined "human cloning" as "human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is virtually identical to an existing or previously existing human organism." *Id.* Senator Brownback had previously tried to introduce a bill (S. 1899) that would ban human embryo cloning for research and reproductive purposes. *See* BNA, *Senate Refuses to Attach Ban on Clone Patents to Terrorism Bill*, 64 PAT. TRADEMARK & COPYRIGHT J. 174 (2002).

[143] *See* BNA, *Senate Refuses to Attach Ban on Clone Patents to Terrorism Bill*, 64 PAT. TRADEMARK & COPYRIGHT J. 174 (2002).

[144] 61 PTCJ 81, 5/24/02.

[145] *See, e.g.*, Statement of Senator Arlen Spector (R-Pa) (noting that the PTO's policy "renders totally unnecessary the amendment that is being offered."); Statement of Senator Orrin Hatch (R-UT) (calling the amendment "grossly premature"); Statement of Senator Edward Kennedy (D-Mass) ("Of course we should reject the offensive idea that human beings could be patented, as the Patent Office already does, . . . but the Brownback amendment goes far beyond this common sense proposal."). Get statements in the June 13, 14, 17, and 18 2002 Congressional Record at pp. S5514-S5527, S5580-S5581, S5624-S5626 and S5643-S5649)

[146] Cite statement. Senator Hatch also voiced concerns over the breadth of the bill and exactly what it would cover, concluding that "it is very dangerous for us to adopt such a measure without appropriate hearings and a complete review of this matter." While Sen. Hatch is correct that a full review and hearings are appropriate for legislation of this nature, he unfortunately did not propose that the Senate actually *hold* any hearings or review of the matter.

who opposed Brownback's amendment are laboring under at least two serious misapprehensions. First, they believe the USPTO has the authority to deny patents on morally controversial inventions, at least to the extent they comprise humans.[147] But, as discussed above, the Thirteenth Amendment likely would not bar patents on many inventions, or creatures, which encompass some portion of human genetic material.[148] There are already numerous patents on transgenic animals that contain human genetic material.[149] The USPTO has no authority to deny patents on morally controversial subject matter that meets the statutory patentability requirements.[150] Hence any such appealed rejection would have to be overturned in court.

Second, these legislators underestimate the significance and impact of granting U.S. patents on such inventions, in the presence or absence of a research ban. While the determination of whether to allow the research to continue is a critically important issue, the availability of a government imprimatur granting excusive rights over morally controversial inventions is a separate but important issue as well.[151] As Sen. Brownback succinctly summarized "This is about whether or not we as a government will allow a person, a human in any stage of its development and growth to be patented."[152]

So if Congress has not yet spoken directly to the issue, and the USPTO and courts have no say, then who gets to decide what gets patented? The answer: biotech patent applicants, also known as scientists or researchers.

2. Scientists: The Real Decision-makers

As discussed earlier, under the U.S. Patent Act, a person is entitled to a patent if they meet the statutory requirements. In the absence of congressional action, researchers are making patent policy and determining the limits of patent eligibility by the subject matter described in their applications. But are these the individuals that we, as a society, want to make these important decisions? Are they the best actors, and is the closed environment of the USPTO the best forum for these determinations? Hardly. Dr. Robert Weinberg, winner of the 1997 National Medal of Science, member of the Whitehead Institute for Biomedical Research, and a biology professor at MIT crystallized the issue in a recent article on therapeutic cloning:

> None of us needs a degree in bioethics to find the bottom line in the arguments. They all ultimately converge on a single question: When

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[147] Lawmakers apparently are not the only ones with this misconception. *See* Dr. Jordan J. Cohen, *Letter Opposing Cloning Patents*, Association of American Medical Colleges, *at* http://www.aamc.org/advocacy/library/research/corres/2002/061802.htm (last modified Jun. 18, 2002) (citing the 1987 PTO policy and stating "[t]hus, the amendment offered by Senator Brownback is superfluous.").

[148] *See* discussion *supra* at__.

[149] *See, e.g.*, U.S. Patent Nos. 6,518,482; 6,515,197; 6,509,515; 6,505,080; 4, 736,866.

[150] Of course the relevant patent applications must also meet other requirements such as the written description, enablement, and best mode provisions of 35 U.S.C. § 112.

[151] *See* discussion *infra* at ____.

[152] *See* BNA, *Group Faults PTO for Issuing Patent on 'Method of Producing Cloned Mammal'*, 64, No. 1574, PAT. TRADEMARK & COPYRIGHT J. 81 (2002).

> does human life begin? Some say it is when sperm and egg meet, others when the embryo implants in the womb, others when the fetus quickens, and yet others when the fetus can survive outside the womb. *This is a question that we scientists are neither more nor less equipped to decide than the average man or woman in the street, than a senator from Kansas or a cardinal in Cologne.*[153]

While scientists may not be better equipped than anyone else to determine when life begins, they are certainly far less equipped than Congress to determine what the limits of patent eligible subject matter should be. Unlike Congress, they hold no public hearings, they are not accountable to any public constituency, and 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.[154] 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 created by scientists, with the help of patent attorneys. These scientists may indeed have as a goal curing some dread disease and the lure of patent protection may provide necessary funds for that research. But 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, genetically modified in ways one can only imagine. As Drs. Maureen and Samuel Condic explain:

> At their cores, scientists are motivated by curiosity. . . . There are no necessary limits to scientific curiosity-not even the limits of decency. . . . The infamous experiments of Milgrim or the Tuskegee Syphilis study, . . . are the kind of science some may elect to pursue if left with only "scientific curiosity" as a guide. Endorsing [via a patent] scientific research simply because it is interesting and might prove useful is a dangerous path . . . . Much useful information can be derived from experiments that are objectively evil. The ends, no matter how noble, cannot justify any and all possible means. The challenge to society is: How will the line be drawn, and by whom? By virtue of their disposition and their focus on "the possible," scientists are not particularly well-suited to make such prudential decisions.

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.[155]

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[153] Robert A. Weinberg, *Of Clones and Clowns*, THE ATLANTIC MONTHLY, June 2002, at 54, 59 (emphasis added).

[154] The author, herself a former scientific researcher and co-inventor on a patented invention, sincerely intends no disrespect or denigration to scientists and other patent applicants, but is simply highlighting the lunacy of allowing patent applicants to set patent policy.

[155] 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

But is relieving human suffering the supreme imperative that trumps all other values? Right now, in the realm of patents, it appears to be, with no consideration of whether patents on morally controversial biotech subject matter are a "strategic necessity" or even a moral necessity.[156] Many scientists clearly 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 since:

> 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 *unsuited* to make moral judgments-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.[157]

Thus, it is not even realistic to expect patent applicants to set limits on the moral aspects of patent subject matter eligibility. But even if scientists cannot set such limits Congress, as the representative of the people, must set limits on patent rights over morally controversial means to morally desirable ends.

A popular argument among commentators is that patents are not the issue, the underlying research is the issue and a focus on patents is simply a bothersome distraction.[158] This fallacy has helped propel the U.S. to the edge of, and over the side of, the precipice it is arguably now sliding down. 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.[159] As succinctly stated by Professor Burk, "opposition to patenting

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visible public desensitization to patents on higher life forms that has occurred since the patenting of the Harvard oncomouse in 1987. *See* Eugene Volokh, *The Mechanisms of the Slippery Slope*, 116 HARV. L. REV. 1026, 1079 (2003) (discussing a variety of slippery slope mechanisms and the real risks such slippage poses).

[156] *See* Gilbert Meilander, *The Point of a Ban: Or, How to Think About Stem Cell Research*, HASTINGS CTR. RPT. 9, 12 (2001).

[157] Condic, *The Limits of Science*, *supra* note --, at 161 (emphasis added).

[158] *See, e.g.*, BNA, *Group Faults PTO for Issuing Patent on 'Method of Producing Cloned Mammal'*, 64, No. 1574, PAT. TRADEMARK & COPYRIGHT J. 81 (2002); Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 248 (2000); Amanda Warren, *A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by 'Dolly'"*, 20 EUR. INTELL. PROP. REV. 445, 447 (1998) [hereinafter Warren, *A Mouse in Sheep's Clothing*].

[159] *See, e.g.*, MARTIN J. ADELMAN, RANDALL R. RADER, JOHN R. THOMAS, HAROLD C. WEGNER, CASES AND MATERIALS ON PATENT LAW 107 (2nd ed. 2003) [hereinafter ADELMAN ET. AL.,]("Charabarty was a clear signal that patenting was broadly available in the biotechnology field, and this ruling opened

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."[160] 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 made available as a result of government granted patent protection, much of the research likely would not go on.[161] Moreover, 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, since patents would be freely available for such inventions[162] Conversely, the availability of patents on morally controversial biotech subject matter provides a strong motivation for interested parties to lobby Congress and inhibit or overturn funding or research bans.

This dichotomy, placing a ban on research but allowing the issuance of patents on the fruits of the research, can be analogized to what Professor Volokh calls a "political power" slippery slope. If Congress allows the issuance of morally controversial biotech patents but bans certain types of morally controversial biotech research, owners of patents that could be practiced if the bans were lifted would have a strong incentive to lobby Congress.[163] Thus allowing the issuance of morally controversial patents could change the balance of political power "by empowering an interest group that might use this power to promote B [e.g., freedom to research/commercialize inventions]; getting to A [e.g., patents] first and then to B [freedom to research/commercialize] would thus be politically easier than getting to B [freedom to research/commercialize] directly."[164] Because patents already issue first in the U.S., such interest groups will generally be at an advantage in relation to Congress. The fact that patents issued on embryonic stem cells

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the coffers of Wall street to the biotechnology industry."); Carol Grunewald, *Monsters of the Brave New World*, New Internationalist, *at* http://www.newint.org/issue215/monsters.htm (last modified Jan. , 1991) ("[T]wo historic events spurred the growth in what is now referred to as the 'biotech industry.' In 1980, the US Supreme Court ruled . . . that 'man-made' micro-organisms can be patented. Then in April 1987, without any public debate, the U.S. Patent Office[] suddenly announced that all forms of life-including animals but excluding human beings-may be considered 'human inventions.'").

[160] *See, e.g.*, Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1668-69 (1993).

[161] *Id.* at 1668 (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).

[162] *See* Gilbert Meilander, *The Point of a Ban: Or, How to Think About Stem Cell Research*, HASTINGS CTR. RPT. 9, 12 (2001). *See also* Gary Elijah Dann, *New Use for Embryos is Disturbing*, THE RECORD, Mar. 5, 2002, at A7 ("A recent study carried out by researchers at New York University . . . Yale University . . . and Johns 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?").

[163] As of course, would people who otherwise might benefit from the products or therapies commercialization of the patented inventions would supposedly provide. Eugene Volokh, *The Mechanisms of the Slippery Slope*, 116 HARV. L. REV. 1026, 1115 (2003).

[164] *Id.*

and methods of mammalian cloning before Congress was in a position to study the issues has no doubt affected Congress' ability to pass legislation banning such research.

While senators and scientists refuse to credit the idea of patents on humans, the abovementioned cloning patent that has already issued, as well as the pending University of Massachusetts chimera patent application, provides clear proof of where researchers are headed. The University of Missouri patent sought ownership of the "living, cloned products produced by each of the methods described herein."[165] The owners of the patent claim to have no interest in cloning humans, let alone owning humans, but if that is the case, why claim ownership? Such research is headed toward full commoditization of human beings, made possible, and encouraged, by patent protection.[166] As one commentator notes:

> [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.[167]

Such comments should not be lightly dismissed as overdramatic hyperbole. The University of Massachusetts chimera application claims a mammalian fetus prepared by a claimed cloning method.[168]

According to the Supreme Court, the moral limits of patent subject matter eligibility "is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot."[169] Yet Congress, probably unintentionally, has placed patent applicants in the position of de facto arbiters of patent eligibility.[170] This is not a situation where we can say that inaction by Congress indicates Congress' approval of patent subject matter being unlimited by morality concerns.[171] The fact that U.S. Senators believe (1) that

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[165] U.S. Patent No. 6,212,429.

[166] *See* Carol Grunewald, *Monsters of the Brave New World*, New Internationalist, *at* http://www.newint.org/issue215/monsters.htm (last modified Jan. 1991)("[W]e must remember that the mind that views animals as pieces of coded genetic information to be manipulated and exploited at will is the mind that would view human beings in a similar way.").

[167] William Krystol, *Brave New Patents*, The Weekly Standard, *at* 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 from Massachusetts 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.'" *Id.*

[168] *See* U.S. Patent Application No. 09/828,876.

[169] Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980).

[170] BNA, *Senate Refuses to Attach Ban on Clone Patents to Terrorism Bill*, 64 PAT. TRADEMARK & COPYRIGHT J. 174 (2002).

"appropriate hearings and a complete review of this matter" is necessary, (2) that "we should reject the offensive idea that human beings could be patented," and (3) that the USPTO has the authority to deny patents on humans, all make clear that Congress has yet to speak definitively on this issue.

Moreover, as previously discussed, on at least three other occasions, the issuance of a patent on morally controversial biotech subject matter prompted the introduction of a bill in Congress to ban either patents on the subject matter, research into the subject matter, or both.[172] But because patents issue first, the public, and Congress, are continually in a reactive vs. proactive mode, and the grant of a patent covers the subject matter with a veneer of legitimacy and a presumption of validity that can be hard to overcome.[173] Patents on such inventions are generally hyped as necessary both for realizing the great promise for alleviating human suffering the invention offers, and for keeping the U.S. at the forefront of cutting edge lucrative research.[174]

Furthermore, even if Congress enacts legislation to disallow patents on certain subject matter after a controversial patent has issued, the legislation is unlikely to be retroactive to invalidate the issued patent(s).[175] As described by Professor Polly Price:

> [A]lthough Congress is not required to create intellectual property rights at all, once it has done so, there may be some constitutional constraint upon retroactive modification to those rights. . . . The U.S. Supreme Court has long recognized that the federal government, as well as the states, ought not to change expectations retroactively, particularly to impair previously conferred benefits supported by investment-backed expectations.[176]

Such concerns about legislation implicating takings further frustrates Congress' ability to make the necessary inquiry, into whether the morally controversial "means" to the desirable "ends" are appropriate subjects for patent protection, exceedingly difficult to undertake *ex post*. Might a different order of inquiry, e.g., patent eligibility before patentability, be preferable?

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[171] *See, e.g.*, Johnson v. Transportation Agency, Santa Clara County, 480 U.S. 616, 628 (1987) ("Congress has not amended the statute to reject our construction, nor have any such amendments even been proposed, and we therefore may assume that our interpretation was correct."); Bob Jones Univ. v. United States, 461 U.S. 574, 599 (1983) (In view of its prolonged and acute awareness of so important an issue, Congress' failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the IRS rulings of 1970 and 1971.").

[172] *See* discussion *supra* at ____ .

[173] *See* 35 U.S.C. § 282.

[174] *Regulating and Patenting Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and The Administration of Justice of the Committee on the Judiciary*, 100th Cong. 405 (1987) (statement of _____).

[175] An example of this is the Medical Activity Act which only applied to patents issuing after the effective date of the Act. *See* 35 U.S.C. § 287(c) (2002).

[176] POLLY J. PRICE, PROPERTY RIGHTS ch. 4, at 8 (ABC-CLIO, 2003).

B. Europe, Canada and Beyond: Ask Questions First, Then Patent

The territorial model of patent rights is still in effect, but it is slowly changing. A variety of treaties designed to streamline the process of multi-country patent application filings and reduce associated costs are in place and more are in development.[177] Several regional treaties already exist that allow an applicant to file one application with a central office and obtain patent protection in multiple countries, although the patent must be enforced (in cases of infringement) in each individual country.[178] 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.[179] The EPC, which currently has twenty contracting members, and six extension states,[180] 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.[181] 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.[182]

The EPC (covering all EU states plus others) contains an express bar to patentability based on morality concerns. EPC Article 53 states that "European patents shall not be granted in respect of: (a) Inventions the publication or exploitation of which

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[177] *See, e.g.*, WIPO, *Patent Law Treaty* [hereinafter PLT] (visited Feb. 27, 2001) http://www.wipo.org/treaties/ip/plt/plt.doc; Patent Cooperation Treaty [hereinafter PCT], June 19, 1970, 28 U.S.T. 7645; Paris Convention for the Protection of Industrial Property, *reprinted in* Selected Intellectual Property and Unfair Competition Statutes, Regulations and Treaties 950 (Roger E. Schecter ed., West 2001). *See also* Gerald J. Mossinghoff & Vivian S. Kuo, World Patent System Circa 20XX, A.D., 38 IDEA 529 (1998) (discussing treaties).

[178] European Patent Convention, 29 I.L.M. 1417; Eurasian Patent Convention, 36 Indus. Prop. & Copyright 30 (1997).

[179] *See, e.g.*, *What is the European Patent Office?*, European Patent Office website, *at* http://www.european-patent-office.org/epo/pubs/brochure/general/e/epo_general.htm (visited Mar. 12, 2002). The EPC went into effect in 1977.

[180] *Id*. Current contracting states are: Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden, Turkey. Current Extension states are: Albania, Lithuania, Latvia, Former Yugoslav Republic of Macedonia, Romania, Slovenia. Membership in the organization is not limited to European Union ("EU") countries although all EU countries are members. "Extension states" are expected to become members in due course and patent applicants can currently designate them on a European patent application.

[181] The European patent is treated as a national patent in each member country. Applicants can still seek patent protection in individual EPC member countries exclusively or concurrently, however, only one patent (national or European) will ultimately be maintained. The laws of all member states must be in harmony with the EPC so those laws do not geographically limit sources of prior art either. Unfortunately, there is no central means for enforcing a European patent. A patentee must still (in most circumstances) bring suit in each country where the patent is being infringed. Efforts are underway to create a Community patent that would be a "true" European patent, enforceable in a single court with community-wide effect. *See Proposal for a Council Regulation on the Community Patent (presented by the Commission)*, European Union website at http://europa.eu.int/eur-lex/en/com/pdf/2000/en_500PC0412.pdf.

[182] *See* GRAEME B. DINWOODIE, WILLIAM O. HENNESSEY, AND SHIRA PERLMUTTER, INTERNATIONAL AND COMPARATIVE PATENT LAW 3 (LexisNexis 2002).

would be contrary to *ordre public* or morality . . . ."[183] Article 53(a) not only provides a basis for EPO examiners to reject a patent application, but any member of the public can lodge an opposition to the grant of a patent on this or any other patentability basis, at any time within nine months of the EPO decision to issue the patent.[184] 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.

1. Balancing Interests, Unacceptability, and Public Abhorrence

The first EPO decision to apply the morality limitation of EPC Article 53 dealt with the famous Harvard oncomouse. In addition to filing an application in the USPTO which issued as a patent in 1988, the inventors also filed applications on the mouse in the EPO and in the patent offices of several other countries.[185] The Examining Division of the EPO originally rejected the application based on a conclusion that the application was directed to non-patentable subject matter and contained an insufficient disclosure.[186] The EPO Technical Board of Appeal reversed and remanded the application instructing the Examining Division to consider, among other things, whether the *ordre public* and morality provisions of Article 53(a) were a bar to patenting the invention.

In considering the application of Article 53(a) to the invention, the Examining Division chose a very narrow focus for its inquiry, ignoring any objections to patents on animals in principle.[187] 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."[188] The Examining Division then set about balancing three state interests: (1) the interest in remedying human diseases, (2) the interest in protecting the environment from the uncontrolled spread of unwanted genes, and 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

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[183] EPC Article 53(a).

[184] EPC Article 99. The U.S. has no comparable post-grant proceeding allowing for public intervention in the issuance of a patent. Moreover, as established by the Court of Appeals for the Federal Circuit in *Animal Legal Defense Fund v. Quigg*, members of the public also lack standing to challenge the validity of a patent in court. *See* 932 F.2d 920, 924 (Fed. Cir. 1991).

[185] Including Japan and Canada. See *infra* ___.

[186] In Re President and Fellows of Harvard College, Technical Board of Appeal 3.3.2 of the European Patent Office (Oct. 3, 1990), reported at 22IIC 74-84 (1991).

In Re President and Fellows of Harvard College, Examining Division of the European Patent Office, 1992 Official Journal EPO 588 at __.

[187] In Re President and Fellows of Harvard College, Examining Division of the European Patent Office, 1992 Official Journal EPO 588 at __. The Examining Division noted that Article 52(1) of the EPC contains a "general principle of patentability" subject only to express exclusionary provisions such as Article 53(a) and that such exclusions were to be interpreted narrowly.

[188] *Id*. at

if it could help in the search for a cure for cancer, one of most frequent causes of human death.[189] 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. However, the Examining Division 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.[190] Finally, the third interest, preventing cruelty to animals, was not determined to be a bar to a patent because, while more of the animals with the foreign gene would develop painful cancers, the invention allowed the use of fewer animals in total so, the Examining Division theorized, the invention would in effect reduce the overall extent of animal suffering.[191] The absence of suitable alternatives was also relevant to the Examining Division's decision, which noted that animal models are currently considered indispensable in testing.[192] 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.[193]

While 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 basis (other than instructions from the Technical Board) 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 claims.[194] The objection cited an "oncogiraffe" as a creature which would come within the literal terms of the claims, but which would be highly unlikely to be used as a test model in cancer research, thus shifting the balance (in view of animal welfare considerations) against a patent.[195]

Moreover, the decision of the EPO did not vanquish controversy regarding the mouse patent. Even though the patent issued, it quickly became the target of more than a

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[189] *Id*. at

[190] *Id*.

[191] *Id*.

[192] *Id*.

[193] *Id*.

[194] Amanda Warren, *A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by 'Dolly'"*, 20 EUR. INTELL. PROP. REV. 445, 447 (1998), citing Alison Abbott, *Oncomouse Hearing Ends Up in Confusion*, 378 NATURE 427 ((1995)).

[195] *Id*.

dozen petitions to the EPO opposing its issuance.[196] 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 mouse application.[197] Although the degree of animal suffering would ostensibly be identical, 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,[198] and (2) the public abhorrence test.[199]

A few years after the Oncomouse case, the EPO was again confronted with applying Article 53(a) in *Greenpeace v. Plant Genetic Systems*.[200] 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 Article 53(a)'s ordre public or morality requirements.[201] 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 behavior is right and *acceptable* whereas other behavior 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 civilization. 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.[202]

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,

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[196] *See* Hans-Ranier Jaenichen & Andreas Schrell, *The 'Harvard Oncomouse' in the Opposition Proceedings before the European Patent Office*, 9 Eur. Intell. Prop. Rev. 345 (1993).

[197] *See, e.g.*, Robin Nott, *The Biotech Directive: Does Europe Need a New Draft?*, 12 Eur. Intell. Prop. Rev. 563, 565-66 (1995); Steve Conner, *Patent Ban on Baldness 'Cure' Mouse*, Independent (London), Feb. 2, 1992, at 5.

[198] Greenpeace v. Plant Genetic Systems, 1995 WL 1081384, [1995] E.P.O.R. 357, 373.

[199] Lubrizol Genetics, Inc., T0320/87, 1990; Hormone Relaxin, 1995, O.J.E.P.O. 388.

[200] 1995 WL 1081384, [1995] E.P.O.R. 357, 373.

[201] *Id* at 374.

[202] *Id*. at 366. (emphasis added).

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.[203]

Greenpeace had submitted both surveys and opinion polls conducted among farmers and the general public showing opposition to patents on plants and animals and genetic engineering generally as a way of establishing that such patents were contrary to the norms of European society. The Board dismissed the surveys and polls noting that such results can fluctuate within a short time period, can be easily influenced and controlled based on the type of questions asked and do not necessarily reflect deeply rooted moral norms. Most importantly, since the applicability of Article 53(a) must be determined on a case by case basis, such polls would have to be made "ad hoc on the basis of specific questions in relation to the particular subject matter claimed."

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."[204] Because sufficient evidence of actual disadvantages was not adduced in the case, the Board held that the balancing test could not be used.[205] This "unacceptability" standard is certainly a lower hurdle for an invention to overcome than the balancing test, since 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.[206] In *Howard Florey Institute V. Fraktion der Gronen im europCischen Parlament*, several groups filed an opposition in the EPO to the issuance of a patent on the hormone relaxin.[207] 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.[208] The EPO Board disagreed and articulated the "public abhorrence" test for exclusion under Article 53(a):

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[203] The Board cited their narrow focus as in keeping with principles of construing exceptions to patentability narrowly. *Id*. at 366, 370.

[204] *Id*. at 373.

[205] *Id*.

[206] *See* Greenpeace v. Plant Genetic Systems, 1995 WL 1081384, [1995] E.P.O.R. 357, 373, (employing the unacceptability test as the basis for the Board's decision, but also citing the public abhorrence test.). *See also* Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY TECH. L.J. 1, 3 (2001) (discussing cases).

[207] Howard Florey Institute v. Fraktion der Gronen im europCischen Parlament, Paul Lannoye, 0008/94, [1994] E.P.O.R. 388.

[208] *Id*. at 395.

> 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.[209]

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 Article 53(a)'s morality proviso 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? The European Union Biotechnology Directive of 1988.

2. The Biotech Directive: Earnestly Inconsistent

In drafting the European Union Biotechnology Directive ("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 in order to increase investment in biotechnology research.[210] For years the European Union ("EU") has lagged behind the U.S. and Japan in biotechnology, a deficit attributed to deficient, confusing, and overlapping patent rights.[211] 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 EPC Article 53(a).[212]

The Directive accomplished these goals, at least in part, by 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 retained morality exception (similar to EPC Article 53(a)) should be interpreted.[213] 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.[214] Conversely, and confusingly, the Directive excludes from patentability 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

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[209] *Id*.

[210] *See* Council Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998, O.J. (L 213) 13, para. 1-4.

[211] *See, e.g*., Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY TECH. L.J. 1, 3 (2001) (; David G. Scalise & 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.") .

[212]*See* Council Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, 1998, O.J. (L 213) 13, para. 36-40. *See also* Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY TECH. L.J. 1, 3 (2001).

[213] Council Directive, 98/44/EC at para. 38, and Articles 5-7.

[214] *Id*. at Articles 1, 2, 5.

identity of animals which may cause them suffering without substantial medical benefits, as specific examples of morally or ethically unacceptable patent subject matter.[215]

The Directive, which was ten years in the making,[216] created such confusion and controversy that a group of member states filed a lawsuit in the European Court of Justice requesting the annulment of the directive based on issues with its adoption, its conflicting provisions on human patenting, and basic human rights concerns.[217] Several member states also defied EU law by failing to create national laws to implement the Directive by the July 30, 2000 deadline.[218] Failure to implement the Directive can subject a state to infringement proceedings and sanctions by other members.[219] Nevertheless, opposition to the Directive is so fierce, that as of early 2003, and in spite of losing the legal challenge to the Directive, nine of the fifteen EU member states had not transposed the Directive into their national laws.[220]

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[215] *Id*. at para. 38, and Articles 5-7. The Directive also contains a farmer's exemption and other exclusions from patentability. *Id*. at Articles 4, 11, and 12.

[216] *See* David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 991 (1993) (noting that the first proposal for the Directive was presented by the EC Commission to the EC Council on October 20, 1988.).

[217] *See* Kingdom of the Netherlands v. European Parliament and Council EU, Case-377/98, O.J. C 331 (ECJ 2001). The action was filed by the Netherlands and joined by Italy and Norway. *See Council of Europe Calls for Revision of Biotechnology Directive*, EUROPEAN REPORT, NO. 2514, Jul. 5, 2000, at 1. One report provides an example of the confusion:

> Problems notably arise regarding the precise scope of Article 5 of Directive 98/44/EC concerning the protection liable to be extended to inventions concerning elements drawn from the human body. The first paragraph of this article indicates that "the human body at the various stages of its constitution and development, as well as the mere discovery of one of its constituent elements, including a complete or partial gene sequence, cannot constitute patentable elements". However, the next paragraph of the same article stipulates that "an element isolated from the human body or otherwise produced though some technical process, including a complete or partial gene sequence, can be considered to constitute a patentable invention, even if its structure is identical to that of a natural element."

Luxembourg Parliament Calls for Renegotiation of Inventions Directive, EUROPEAN REPORT, NO. 2665, Mar. 6, 2002, at 1.

[218] *See Single Market: Ten Years On, Commission Has Something to Celebrate*, EUROPEAN REPORT, NO. 2647, Jan. 8, 2003, at 1.

[219] *See* Treaty of Rome, Article 226. *See also Single Market: Ten Years On, Commission Has Something to Celebrate*, EUROPEAN REPORT, NO. 2647, Jan. 8, 2003, at 1.

[220] *See* Kingdom of the Netherlands v. European Parliament and Council EU, Case-377/98, O.J. C 331 (ECJ 2001). *See also Single Market: Ten Years On, Commission Has Something to Celebrate*, EUROPEAN REPORT, Jan. 8, 2003, at 1. France's Justice Minister publicly denounced the Directive claim 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*, EUROPEAN REPORT, NO. 2510, Jun. 21, 2000, at 1.

On November 30, 2000, and December 19, 2002, the EU Commission sent formal letters 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*

Some commentators criticize the Directive for its continued inclusion of moral and ethical considerations.[221] However, the Directive is noteworthy and commendable 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.

3. Canada: Bucking the Trend

In December 2002, the Canadian Supreme Court stunned the world by denying patent protection to the Harvard oncomouse, the same mouse first patented in the U.S. in 1987 and a few years later in the EPO and Japan.[222] Unlike the EPC, Japanese Patent Act, or EU Biotech Directive, the Canadian Patent Act does not contain an express statutory provision allowing for a morality inquiry into patent subject matter.[223] Rather, it simply has a provision defining an invention that is nearly identical to 35 U.S.C. § 101.[224] Under Section 2 of the Canadian Patent Act, an invention is "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[225]

Industrial Property: Commission Calls on Nine Member States to Implement the Directive on the Legal Protection of Biotechnological Inventions, RAPID Press Release (Commission of the European Communities); IP: 02/1928 , Dec. 19, 2002, at 1. These actions are the first steps in the process of bringing infringement proceedings against non-compliant states under the Article 229 of the EC Treaty (The Treaty of Rome). Apparently, the resisting members hope to create sufficient momentum for a renegotiation of the Directive to clarify ambiguities and further address moral and ethical concerns. *See Luxembourg Parliament Calls for Renegotiation of Inventions Directive*, EUROPEAN REPORT, NO. 2665, Mar. 6, 2002, at 1.

[221] *See, e.g.*, Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY TECH. L.J. 1, 3 (2001) (suggesting that the morality provision will impede the Directive's dual goals due to vagueness and conflicting interpretations by member states); Lydia Nenow, Comment, *To Patent or not to Patent: The European Union's New Biotech Directive*, 23 HOUS. J. INT'L L. 569, 573 (2001) (arguing that patent examiners should not be forced to make moral and ethical judgments about inventions); Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 248 (2000); Jasmine C. Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 225 (2002).

[222] Harvard Coll. v. Canada (Commissioner of Patents), 2002 SCC 76. *See* discussions *supra* at ___ and ____. *See also* (cite Japanese patent No.) Harvard's Canadian patent application was initially filed in 1985.

[223] See EPC Article 53(a), Japan Patent Act , EU directive. However, as noted by the dissent, in 1993, the Canadian Parliament repealed a prohibition against patenting "an invention that has an illicit object in view" and did not include a blanket "ordre public or morality" provision even though the statutory revision was to bring Canadian law into compliance with international agreements. Harvard Coll. v. Canada, 2002 SCC 76 at 10 (Binnie J. dissenting).

[224] Patent Act, R.S.C. ch. P-4, § 2 (1985) (Can.). Section 101 of the U.S. Patent Act authorizes patents for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Apparently, the provisions are so close because the Canadian definition is taken from the U.S. Patent Act of 1793. Harvard Coll. v. Canada, 2002 SCC 76 at 8 (Binnie J. dissenting).

[225] Patent Act, R.S.C. ch. P-4, § 2 (1985) (Can.).

In interpreting this statutory provision, the Canadian court traveled the road not taken by the U.S. Supreme Court in *Diamond v. Chakrabarty.*[226] The court, in a 5-4 decision, concluded that the words "manufacture" and "composition of matter" in the statute did not encompass higher life forms, if read "in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act and the intention of Parliament."[227] The court noted that the commissioner of Patents lacked the discretion to deny a patent on the basis of public policy considerations, but was bound by the statutory provision.[228] The court also distinguished the statute from the U.S. Act by stressing that Parliament did not define invention as "anything under the sun made by man," that the patentability of higher life forms was not contemplated by Parliament, and that it was for Parliament to provide expressly for the patenting of such subject matter.[229]

The court's decision met with both praise and criticism[230] and elicited an eloquent and forceful dissent from Justice Binnie.[231] The court's decision is surprising, as it is so at odds with that of its neighbor the United States. However, by declining to expand patent eligible subject matter to include controversial higher life forms, the court placed the decision on the correct institutional actor: the legislature. As the court explained:

> The lack of direction currently in the Patent Act to deal with issues that might reasonably arise signals a legislative intention that higher life forms are currently not patentable. . . . [T]his Court does not possess the institutional competence to deal with issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing societal interests and intricate legislative drafting.[232]

Similarly, Congress, not the courts, not the USPTO, not patent applicants, is the proper institutional actor in the U.S. to set the limits of patent-eligible subject matter. Congress can certainly choose to impose no limits, but that also is a choice for Congress to make.

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[226] *See* discussion *supra* at ___.

[227] Harvard Coll. v. Canada (Commissioner of Patents), 2002 SCC 76 at 32.

[228] *Id.* at 30.

[229] *Id*. at 37.

[230] *See, e.g*., Stuart Laidlaw, *A Poem as Lovely as a Mouse*, THE TORONTO STAR, Dec. 7, 2002, at H06 (noting diverse reactions to the decision); Kirk Makin, *Harvard Mouse Patent Rejected: It's Up to Parliament to Determine Use of Altered Life Forms, Top Court Decides*, THE GLOBE AND MAIL, Dec. 6, 2002, at A4 (same); Rachel Ross, *Of Mice and Patents and Copyright Law*, THE TORONTO STAR, Dec. 9, 2002, at D02 (same).

[231] Harvard Coll. v. Canada, 2002 SCC 76 at 8-25 (Binnie J. dissenting) (citing, among other things, evidence from pending legislation that Parliament intended higher life forms to be patentable).

[232] Harvard Coll. v. Canada, 2002 SCC 76 at 37. The court may have been influenced by a Canadian Biotechnology Advisory Committee Report in June 2002 which concluded that members of Parliament must have the final say on the patentability of plant and animal life, because too many issues were not covered by the current patent regime. *See Developments in Biotechnology Require Decisions on Patenting Life*, THE CANADIAN PRESS, Jun. 7, 2002, 2002 WL 21938397.

4. TRIPS: Multinational Accommodation

The Agreement on Trade Related Aspects of Intellectual Property ("TRIPs") represents a world first: an agreement by more than 140 nations on substantive minimum protections for intellectual property.[233] The TRIPs Agreement succeeded where prior intellectual property agreements failed by tying requirements for substantive protections, such as a standard patent term, with trade.[234] This important connection means that a member state's failure to comply with TRIPs requirements can result in trade sanctions by other members following a binding dispute resolution proceeding.[235]

Beyond the member countries of the EPC are numerous other countries with statutory provisions allowing inventions to be excluded from patentability on the basis of morality.[236] Thus it is not surprising that in TRIPS negotiations, this large group of countries was able to maintain the right to make morality based patent eligibility decisions despite U.S. opposition to the practice.[237]

This right is expressed in TRIPS Article 27(2), which requires that members provide patents for inventions in all fields of technology with one huge 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 . . ."[238] In other words, member nations do not have to provide patent protection for at least some kinds of 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 morally controversial inventions.

The idea that morality concerns may be the basis for denying patent protection appears to be a common theme among world patent systems. Even the U.S. ascribed to

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[233] Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, I.L.M. 1 (1994) [hereinafter, TRIPs Agreement].

[234] *See, e.g.*, Margo A. Bagley, *Legal Movements in IP: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, __Emory Int'l L. Rev. __ (forthcoming summer 2003); Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPs and Dispute Settlement Together*, 37 Va. J. Int'l L. 275 (1997).

[235] *See Dispute Settlement*, World Trade Organization website, at http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm (visited Mar. 23, 2003).

[236] *See, e.g.*, Agreement Relating to the Creation of an African Intellectual Property Organization, Constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property ("OAPI"), J.W. Baxter, *Baxter World Patent Law*, §10.23 (Matthew Bender 2002) (specifying as unpatentable inventions that are "contrary to public order or morality"). Member states of the OAPI are Benin, Burkina-Faso, Cameroon, Central African Republic, Chad, Congo, Gabon Guinea, Guinea-Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal and Togo. Other countries with statutory morality exclusions to patentability include Japan, South Korea, Indonesia, European Union member countries, the Czech Republic, Iceland, Romania, and Angola. *See* Baxter World Patent Law, §§10.16, 16.01-25, (Matthew Bender 2002). In addition to the U.S., Canada and Mexico are among countries without statutory morality provisions.

[237] Cite Kirk congressional testimony.

[238] *Id*. at 83-111. Diagnostic, therapeutic, and surgical methods may also be excluded.

that view early on as evidenced by the moral utility doctrine, though the Supreme Court's broad interpretation of Section 101 of the Patent Act has effectively eliminated morality considerations from the patent eligibility inquiry in this country.[239] Nevertheless, it makes sense for the U.S. to rejoin other nations on the idea of some moral limits on the subject matter of patents, even if it differs with other countries on the nature or scope of those limits.

III. TO LIMIT OR NOT TO LIMIT: CONSIDERATIONS IN ADDRESSING MORALLY CONTROVERSIAL BIOTECH PATENTS

If the United States is to have morality-based limits on patent subject matter eligibility, who shall set the limits, and how? As previously discussed, patent applicants are currently setting such limits by the contents of the applications they file in the USPTO. And, just as the USPTO has no statutory basis on which to deny 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.[240] 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 real guidance for the USPTO and real language for the judiciary to interpret.

Admittedly, public choice theory would militate against Congressional action in this area since legislators are perceived to be subject to interest group capture to facilitate rent seeking.[241] The effect of special interest groups in this area is evident in the nature of the actions by Congress in relation to the transgenic mouse patent and the ban on enforcement of medical methods against medical practitioners.[242] Nevertheless, of the available options, Congress seems clearly to be the best suited to make these determinations in the context of setting federal patent policy for all technologies.

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[239] *See* discussion *supra* at ___.

[240] *See* discussion *supra* ___.

[241] *See, e.g.*, Mark D. Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001 ILL. L. REV. 387, 399 (2001) ("Public choice theory builds upon the premise that a rational politician will act to maximize his or her utility (defined in terms of retaining office). Interest groups can intervene to alter the politician's calculus of social cost and benefits. In particular, powerful interest groups might influence a legislator to act contrary to probable constituent wishes by offering political benefits that exceed the costs of diverging from the constituents' wishes."); (get other cites). *See also* Jonathan R. Macey, *Transaction Costs and the Normative Elements of the Public Choice Model: An Application to Constitutional Theory*, 74 VA. L. REV. 471 (1998) (discussing differing view on the impact of the separation of government powers on interest group activity and legislative capture).

[242] *See* discussions *supra* at ____.

A. Legislating Patent Rights, not Morality

Often when Congress is perceived to be legislating morality, red flags go up, sirens go off, and public protests ensue.[243] Many in society are concerned that legislation to effectuate morality based policies will unacceptably encroach upon the freedoms of choice and belief that are so fundamental to this democracy. But is legislation concerning moral issues truly anathema in our society? To a large extent, such legislation is critically necessary for our way of life and society to continue. Rules that allow society to operate in an orderly fashion and protect values we hold dear often have moral overtones.

The government legislates regarding pornography, criminal offenses such as stealing and murder (both of which are generally considered morally wrong), and more.[244] However, creating legislation to deny government-granted property rights over certain types of subject matter in order to further policies relating to the public welfare, the protection of human dignity, animal welfare, and environmental preservation would be legislating patent rights, not legislating morality. This is because an invention ineligible for patent protection can still be practiced, in fact, it can be practiced by more entities than if covered by a patent, there just may not be the same economic incentives, or "fuel" for doing so. As stated by the Supreme Court:

> The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. *Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all*.[245]

Consequently, 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 of the fruits of such research in the public domain.[246] However,

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[243] *See, e.g.*, Zach Calef, *Politicians Can't Raise your Kids for You*, IOWA STATE DAILY, Jun. 26, 2001 (criticizing Congressional efforts to prevent marketing of explicit material to children as legislating morality); Chandra Jacobs, *A Vote for Pot*, THE CHRONICLE, Nov. 6, 2002 (advocating the legalization of marijuana and less regulation of morality by government); Jon Swartz, *How Best to Protect kids Online*, THE SAN FRANCISCO CHRONICLE, Feb. 1, 1999, at B1 (discussing the Child Online Protection Act and concluding that "you can't legislate decency on a national scale.").

[244] See Katherine Shaw Spaht, Symeon C. Symeonides, SYMPOSIUM (PART II) COVENANT MARRIAGE AND THE LAW OF CONFLICTS OF LAWS, 32 Creighton L. Rev. 1085, 1089 (1999) ("Despite protestations synoptically described by the oft-repeated phrase "you can't legislate morals," everyone knows that Congress and legislatures do it every day")see what you can find on this

[245] Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980) (emphasis added).

[246] In all likelihood, any legislation in this area would prohibit patents only on some of the inventions derived from research in morally controversial areas. For example, 35 U.S.C. § 287(c) only bars patent enforcement actions against medical practitioners who perform claimed "medical activities, such as

enacting legislation to ban such research, in effect, prohibiting people from engaging in certain activities, could indeed be characterized as "legislating morality," but would have nothing to do with patent law.

B. Fueling Fires

According to Abraham Lincoln, patents "added the fuel of interest to the fire of genius in the production and discovery of new and useful things."[247] In other words, 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.[248] The framers did not adopt a natural rights view of intellectual property, under which an inventor would be entitled to exclusive rights to her invention by the simple expedient of having invented it.[249] Instead, the Clause is a utilitarian grant of power, not a mandate, and Congress is free to deny patent protection as well as extend it. As explained by Thomas Jefferson, the first administrator of the U.S. patent system:

> Inventions then, cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.[250]

Congress, as authorized by the Constitution, determines what federal patent policy levers will best promote "the progress of the useful arts." Congress is the arbiter of what inventions are eligible for patent protection, and Congress has made clear that, as a matter of policy, all inventions are not patentable; i.e., the patent incentive is not available for all inventions. For example, unpatentable inventions include those that fall within the categories of abstract ideas, laws of nature, or natural phenomena,[251] inventions that are

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medical or surgical procedures" (*process* claims) on a body. The provision does not apply to the activities of people engaged in the commercial development, manufacture, sale, importation, or distribution of a patented *machine, manufacture*, or *composition of matter*, or the provision of pharmacy or clinical lab services involving patented subject matter. *See* 35 U.S.C. § 287(c)(3) (2002). Likewise, at least some inventions (processes, machines, manufactures, or compositions of matter) developed during research on morally controversial biotech subject matter would likely be eligible for patent protection.

[247] Abraham Lincoln, a Lecture on Discoveries and Inventions (1859), *cited in* MICHAEL NOVAK, THE FIRE OF INVENTION, THE FUEL OF INTEREST: ON INTELLECTUAL PROPERTY 6 (AEI Press 1996).

[248] U.S. CONST. art. 1,, § 8, cl. 8. According to the Supreme Court: "The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts." Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980).

[249] *See* infra note__.

[250] VI Writings of Thomas Jefferson, at 180-181 (Washington ed. Year?) *cited in* Graham v. Deere, 383 U.S. 1, 6 (1966).

[251] Cite Diamond v Diehr about Congress policy decision re abstract ideas, etc.)

obvious, [252] inventions that may impact national security,[253] and inventions solely useful in connection with special nuclear material or atomic weapons.[254]

Furthermore, once a patent is granted, Congress may still limit the enforcement of that patent. Examples of government limitations on issued patents include the unenforceability of medical process patents against medical practitioners[255] and a variety of compulsory patent licensing provisions.

A compulsory license is a type of government-sanctioned patent infringement. The license allows third parties to perform otherwise infringing activities by paying a mandated royalty to the patent holder.[256] Several federal statutes provide for compulsory licensing of inventions. Examples include inventions related to air pollution control devices under the Clean Air Act,[257] atomic energy inventions under the Atomic Energy Act,[258] and a general provision for licensing inventions for federal government use in return for "reasonable and entire compensation."[259]

One unusual licensing statute was the 1917 Trading with the Enemy Act, which authorized the President to license enemy-owned patents to U.S. citizens when, in his opinion, the license would be for the public welfare and "tend to the successful prosecution of the war."[260] The grant was in the nature of a compulsory license in that the U.S. citizen was required to pay royalties for use of the patented invention to a government custodian with the proviso that the owner of the patent could file an action to obtain the royalties after the end of the war.[261] However, Congress later amended the Act and gave the government custodian the authority to actually seize the patents and sell them to third parties.[262] In adjudicating a dispute regarding royalties collected on several patents, the Court of Appeals for the Third Circuit described the basis for the Congressional action. Speaking of the German plaintiffs, the court opined:

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[252] 35 U.S.C. § 103.

[253] 35 U.S.C. § 181 (authorizing the PTO to order that an invention be kept secret and to withhold the publication of an application or grant of a patent on the invention)

[254] 35 U.S.C. §

[255] 35 U.S.C. § 287(c), discussed *supra* at __. Congress enacted 35 U.S.C. § 287(c) in response to public furor over the assertion of a medical process patent against a doctor using the claimed method to treat patients. Section 287(c) eliminates any remedy a patent owner might otherwise be entitled to for patent infringement, if the claimed method is used by a medical practitioner.

[256] MARTIN J. ADELMAN, RANDALL R. RADER, JOHN R. THOMAS, HAROLD C. WEGNER, CASES AND MATERIALS ON PATENT LAW 1235 (1998) [hereinafter ADELMAN ET. AL.].

[257] 42 U.S.C. § 1857.

[258] 42 U.S.C. § 2183.

[259] 28 U.S.C. § 1498.

[260] Farbwerke vormals Meister Lucius & Bruning v. Chemical Found., 39 F.2d 366, 367 (3d Cir. 1930). The Act also applied to trademarks and copyrights. 50 App. U.S.C.A. § 10 (1917). The Act was repealed August 8, 1946. Section 13, 60 Stat. 944.

[261] *Id*. at 368.

[262] *Id*. at 370.

> They were, however, at that time enemy owners and it was because of the exigencies of war as well, that the use and enjoyment of the patented inventions were taken from them and, in the interest of the *public welfare* and the *successful prosecution of the war*, turned over to the defendant through the medium of a license.[263]

Thus the license, as with all compulsory licenses, was designed to further some rational Congressional purpose. As explained by the Supreme Court,

> The authority of Congress is exercised in the hope that '[t]he productive effort thereby fostered will have a *positive effect on society* through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.'[264]

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 where government-granted private ownership of certain subject matter may have a *negative* effect on society.[265] Patents on morally controversial biotech subject matter, while having the potential for positive effects, also have a great potential for negative effects which may be difficult or impossible to overcome after such patents have issued.[266] Because of the incentives patents provide to researchers to engage in patent-eligible research, it is incumbent upon Congress to determine which "fires" to "fuel" with patent protection.

C. Specificity vs. Generality: the Dilemma

How should Congress go about making that determination? Very carefully. Societal mores change over time and technology clearly advances with time.[267] 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

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[263] *Id*. (Emphasis added).

[264] Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980).

[265] *Id*. at 318 ("Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. . . . Or it may choose to craft a statute specifically designed for such living things.")

[266] *See generally* Gary Elijah Dann, *New Use for Embryos is Disturbing*, THE 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?").

[267] *See generally* Mark L. Johnson, *How Moral Psychology Changes Moral Theory*, *in* MIND AND MORALS: ESSAYS ON COGNITIVE SCIENCE AND ETHICS 45, 65 (Larry May, Marilyn Friedman, and Andy Clark, MIT Press 1996) ("Because our moral understanding is necessarily partial, morality is not a set of absolute, universal rules but an on-going experimental process. We must continually be experimenting with new possibilities for action, new conceptions of human flourishing, and new forms of interaction that permit us to adjust to, and also to manage, the ever-changing conditions of human existence.").

Congress is used to legislating in such areas and has a variety of options open to it. Moreover, legislating prospectively, while difficult is generally preferable to legislating retrospectively, especially where property rights are involved. As explained by Professor Lon Fuller:

> Taken by itself, . . . a retroactive law is truly a monstrosity. Law has to do with the governance of human conduct by rules. To speak of governing or directing conduct today by rules that will be enacted tomorrow is to talk in blank prose.[268]

Since retroactive legislation is so undesirable, Congress is unlikely to enact such legislation in response to the issuance of a morally controversial biotech patent. Therefore, even if Congress passes a law to prevent the patenting of similar subject matter in the future, the patent(s) on which the controversy was based will still be viable and enforceable.

In terms of options, Congress could, of course, choose to intentionally acquiesce in the current "patent first" system and do nothing. Alternatively, and preferably, 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.[269] Each approach has benefits and drawbacks that should be considered by Congress in its efforts to define the moral limits of patent eligible subject matter.

Congress could enact a broad, general morality provision like Article 53(a) of the EPC or Article 27 of TRIPS.[270] Such a provision, allowing the USPTO to deny patents on the basis of morality, would provide the Agency with substantial discretion in making patent eligibility determinations, limited only by judicial constructions of the meaning of "morality" in the statute. While generality in a statute can provide important flexibility, it can also lead to arbitrary, overly broad, or overly narrow interpretations, arguably problems exemplified in the balancing, unacceptability, and public abhorrence tests under the EPC.[271] Such generality could in effect result in returning the U.S. to a "moral utility" type of regime, without any meaningful subject matter based patent eligibility limits.

Alternatively, Congress could enact specific legislation that would detail subject matter expressly ineligible for patent protection. The EU Biotechnology Directive is an example of a specific, subject matter-based statute, but the problems engendered by the drafting of that provision illustrate the limitations of such an approach.[272] Specific legislation will give more guidance to the USPTO and courts in making patent eligibility determinations. However, some specific prohibitions could be rendered effectively

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[268] LON L. FULLER, THE MORALITY OF LAW 53 (Yale University Press 1964).

[269] My goal in this Article is not to specify which particular approach Congress should take, but rather to expose and focus attention upon a very real problem and identify a variety of avenues open to Congress in addressing the problem.

[270] TRIPS Agreement, Article 27.

[271] *See* discussion *supra* at ___.

[272] *See* discussion *supra* at ___.

obsolete, or simply incomplete, by unanticipated advances in technology.[273] 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 prohibiting patents on humans, and/or human-animal chimera, with the definition of "human" provided in the statute.[274] Even that limited provision would be an improvement over the current U.S. "anything under the sun made by man" approach.

A third option open to Congress is the implementation of one or more intermediate approaches to corralling morally controversial biotech subject matter. 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 a patent advisory committee within 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. This would be similar to the current national security provisions of the Invention Secrecy Act,[275] whereby a patent applicant is entitled to a foreign filing license for her invention if she does not hear otherwise from the USPTO within six months of filing her application.[276] 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.[277]

Further in addition to any of these options, or in combination thereof, Congress could allow public input into the patent-eligibility determination by adopting a post-grant patent opposition system such as is present under the EPC. Such a system would likely apply to all issued patents but would create a USPTO proceeding in which public opposition to morally controversial patents could be registered.[278] 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.

Regardless as to whether legislation providing patent eligibility standards is specific, general, or intermediate in nature, the USPTO and the courts will encounter

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[273] *See* Ho, *Splicing Morality and Patent Law*, *supra* note ___at 284 ("[T]he type of in-depth consideration necessary prior to developing such a fundamental change to the patent system would inevitably lag behind the progression of technology and the issuance of controversial patents.")

[274] *See generally* Russell H. Walker, Note, *Patent Law--Should Genetically Modified Human Beings Be Patentable?*, 22 MEM. ST. U. L. REV. 101, 110 (1991) (favoring "near-human" patenting but providing an express definition for "human.").

[275] 35 U.S.C. § 181.

[276] 35 U.S.C. § 184.

[277] (Describe current responsibilities of Board)

[278] Cite articles proposing a US post-grant opposition system. See Levin & Levin article)

difficulties applying it in practice.[279] However, the expectation of such difficulties should in no way deter Congress from setting necessary standards. The USPTO and courts are required to apply difficult tests all the time; the non-obviousness test of 35 U.S.C. § 103 being a prime example.[280] As explained by the Supreme Court in *Graham v. Deere*:

> This is not to say, however, that there will not be difficulties in applying the non-obviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the court in such frames of reference as negligence and scienter, and should be amenable to case-by-case development.[281]

Of course, since patent legislation is not morality legislation, any new statute directed to 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.[282] 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.[283]

Conclusion

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,

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[279] *See* Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 248 (2000) (suggesting that "any temptation to incorporate morality into the U.S. patent laws should be tempered with the reality that a change to the patent laws may just create new issues to address, rather than addressing the issues that currently exist.").

[280] *See* Jerzy Koopman, *The Patentability of Transgenic Animals in the United States of America and the European Union: A Proposal for Harmonization*, 13 Fordham Intell. Prop. Media & Ent. L.J. 103, 195 (2002) ("Obviously a moral test is hard to apply, but so is the test of nonobviousness, or, in general contract law, the tests of equity or reasonableness and fairness.")

[281] Graham v. Deere, 383 U.S. 1, __ (1966).

[282] *See, e.g.,* Amanda Warren, *A Mouse in Sheep's Clothing: The Challenge to the Patent Morality Criterion Posed by 'Dolly,'"* 20 EUR. INTELL. PROP. REV. 445 (1998) (discussing difficulties associated with assessing morality in the patent context and public misconceptions of patent morality criteria under the EPC); Ho, Splicing Morality and Patent Law (describing patents as "at best a blunt tool to regulate controversial matter" and calling the focus on patents "an incomplete one.").

[283] *See* Russell H. Walker, Note, *Patent Law--Should Genetically Modified Human Beings Be Patentable?*, 22 MEM. ST. U. L. REV. 101, 110 (1991) (advocating patents on genetically modified encephalic fetuses for the generation of body parts).

designed to encourage the investment in and exploitation of patent-eligible subject matter.

The U.S. patent system is unashamedly utilitarian, with patents providing a specific bargain between the patent owner and the government for the ultimate promotion of the public good.[284] 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.

That tissue from embryos and fetuses may be useful in halting or curing horrific diseases does not negate the human potential of such entities, and, as noted earlier, the denial of patent protection for such subject matter will not prevent some scientists from continuing morally controversial biotech research. Importantly, however, ownership rights in the fruits of any such research, and the incentives generated by anticipation of those rights, would not have been provided by the U.S government via a patent grant.

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, up to scientists, pushing the frontiers of technology, motivated by factors beyond public comment and scrutiny. No one person is competent to decide and resolve these moral issues and determine what the limits should be. Difficult thought 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. Such legislation, as with all legislation, will require interpretation by the courts. However, judicial *interpretation* of a statute is far preferable to judicial *creation* of a statute.

Specific legislation, detailing exceptions to patent eligibility, or simply its outer limits, will give more guidance to the USPTO and courts in making determinations but may be rendered effectively obsolete over time by unanticipated advances in technology. More general legislation may retain temporal relevancy with changes in societal mores and advances in technology, but will grant courts considerable leeway in creating, or eliminating, limits driven by moral considerations. An intermediate regime whereby Congress, or its delegate, retains the ability to assess patent eligibility issues on an ad-hoc, pre-issuance basis may be the optimal approach. While no one solution is ideal, each is consistent with our stated system of government "of the people, by the people, for the people,"[285] as opposed to our current "real" patent system of government of the people, by the researchers, for their chosen beneficiaries, e.g., investors and/or suffering humanity. Until Congress comes to terms with the fact that patents as well as bans are important, it will continue to provide contradictory policy signals with detrimental results to society at large. Without Congressional action, the United States will continue to

[284] *See* Eldred v. Ashcroft, 123 S. Ct. 769, 791 (2003) (describing patent quid pro quo).

[285] Abraham Lincoln, Gettysburg Address (1863).

patent first, and ask questions later. However, “later” may, from a moral standpoint, one day turn out to be too late.