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Separation of Church and State While Promoting the Progress of Biotechnology and Modern Science: Does Morality Have Its Place in United States Patents?

Christopher J. Asakiewicz
cj.asakiewicz@gmail.com

Abstract: *This article rebuts a renewed interest by scholars in requiring the United States Patent and Trademark Office, an administrative arm of the government, to practice moral patenting through revisions in interpretations of either patentable subject matter or utility standards. If this administrative office adopts such a practice, however, it will disrupt the purpose of the Patents and Copyrights power "to promote the Progress of Science and useful Arts." Through an exploration of the decline of frivolous and injurious standard in patent law, all governmental arms in the United States are hesitant to bestow such broad discretion on the patent office. Declines in the application of similar standards in trademarks and copyrights, and with comparisons to the international approaches, the United States must not succumb to arbitrary judgments based on morality when making patent decisions. Market and social pressures alone will keep immoral inventions at bay. With a focus on stem cells, genes, cloning and other inventions that patent life, the patent's purpose is for the moral instruction of man, regardless of the moral debates that underlie those ideas. Let society then choose to reward those innovations that it feels is moral with profits, not have useful, patentable inventions faltered and sifted off by an arbitrary examiner at the patenting stage. Strict separation from moral decision-making is the only way to promote the progress of Modern Science.*

1. Introduction

Thomas Jefferson once wrote,

> "that ideas should freely spread from one to another over the globe, *for the moral and mutual instruction of man*, and the improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, … incapable of confinement or exclusive appropriation." [1]

The Patents and Copyrights clause of the Constitution sets forth that "Congress shall have the Power to promote the Progress of Science and useful Arts, by securing for limited Times to … Inventors the exclusive Right to their respective … Discoveries." [2] However, "Congress shall [also] make no law respecting an establishment of religion." [3] This paper rebuts a renewed interest by scholars in requiring the United States Patent and Trademark Office ("USPTO"), the administrative arm of the government, to practice "moral" patenting. If the USPTO adopts this practice, it will disrupt the purpose of the Patents and Copyrights power "to promote the Progress of Science and useful Arts." [4]

[1] Letter from Thomas Jefferson to Isaac McPherson (August 13, 1813), in Adrian Koch and William Peden, eds., *The Life and Selected Writings of Thomas Jefferson* 629-30 (1944) (emphasis added).
[2] U.S. CONST. art. I, § 8, cl. 8.
[3] U.S. CONST. amend. I (Religion).
[4] U.S. CONST. art. I, § 8, cl. 8.

Analogous to the principle of separation of religion ("Church") and governments or government actors ("State") under the Establishment clause, within United States ("US") patent law there should be remain a stark divide between moral and patent decision making. Edward Westermark, in THE ORIGIN AND DEVELOPMENT OF THE MORAL IDEAS, postulated, "[t]he moral rules which are prevalent in the society to which we belong are supported *by appeals not only to human, but to divine, authority*, and to call in question their validity is to *rebel against religion* as well as against public opinion." [5] Westermark conveys that morals, although a social construct, have roots in the Church, but as he explores the development of morality and moral ideas, he ultimately concludes: "Custom has proved stronger than law and religion combined." [6] Society or in Westermark's words, Custom, shapes moral decisions and therefore moral based limits should not be imposed on technologies at the patenting stage, but rather, society will apply moral limits through its markets and decide on its own to further and incentivize technology. The belief that ideas must therefore flow freely for the moral instruction of humanity through unencumbered patents, not hindered by subjective interpretations made by patent examiners through secular regulation is the premise of this paper. Patents free from entanglement with moral ideas rooted in an appeal to the divine will place the onus on the public to determine which technologies to innovate in, through markets and local custom and not the USPTO.

Under US Patent Act of 1952 (the "Patent Act"), "a person shall be entitled to a patent unless… " [7] Some scholars argue that this statement requires an express morality prohibition because of the lack of adequate control of immoral inventions through the current tests for patentable subject matter and utility. [8] Granting a patent to immoral subject matter is considered by some to be an official seal of approval, which some segment of the public relies. [9] Should the US continue to encourage and widen the search for such inventions, in particular the area of biotechnology, for the benefit of science? [10]

At least one scholar believes the answer to this question should be no, especially in regards to morally controversial biotechnology. This leading scholar, Professor Margo Bagley, has coined the phrase "patent first, ask questions later" to describe the hands off approach of the USPTO. [11] As the first line of defense, Bagley posits that the USPTO's role in policing immoral inventions is through narrow interpretations of patentable subject matter or moral utility. [12] She argues that deficiencies in congressional action in the realm of biotechnology coupled with the repeal of morality based limits on patentability, creates a need for the resurrection of the moral utility doctrine. [13] This view is shared by many moral scholars including the Nuffield Council of Bioethics ("Nuffield") during a recent round table discussion focusing on the ethical implications of patenting the building blocks of life, deoxyribonucleic acid, known commonly as DNA. Nuffield specifically opposes the patenting or granting of rights to DNA sequences as a research tools and recommends stringent utility standards to police this field of study. [14] However, these reformationists fail to realize that the USPTO is

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[5] EDWARD WESTERMARK, THE ORIGIN AND DEVELOPMENT OF THE MORAL IDEAS: VOLUME 1 10 (London, MacMillan 1906) (emphasis added).
[6] *Id.* at 164.
[7] 35 USC § 102 (emphasis added).
[8] *See* Joanne Yong, *Morality and Biotechnology Patent Laws*, 3 INT'L J. OF PRIVATE L. 148, 162 (2010) ("Patent law reform should be done through an ethical dimension. Biotechnology patent laws are in a state of crisis because they are lacking in an adequate moral underpinning.").
[9] *Cancer Research Technology v. Barr Laboratories, Inc.*, 2010 WL 286639, at 11 (D. Del. 2010) ("because a patent gives a kind of official imprimatur to the medicine in question on which as a moral matter some members of the public are likely to rely.").
[10] *See Brenner v. Manson*, 383 U.S. 519, 532-33 (1966).
[11] Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003).
[12] *Id.* at 474; Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1073 (2009) ("Intellectual property is a form of government subsidy.").
[13] Bagley, *supra* note 11, at 474.
[14] The Nullfield Council of Bioethics, The ethics of patenting DNA, xiii (July 2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf.

ill suited to institute such a policy, as the lack of uniformity and arbitrary decision-making taints any such interpretations by patent agents. Moreover, Congress, the President and administrative agencies already legislate and regulate such inventions. Thus, this article focuses not on rebutting the "patent first, ask questions later" approach, but the problems with the revival movement pushing for morality based limits to patentability.

Gene patenting is one example that raises moral and ethical concerns. Due primarily to the USPTO's ability to award patents on genetic material, currently, over twenty to twenty-five percent of our human genome is claimed. [15] A recent decision in the Southern District of New York concerning the patentability of BRCA1 and BRCA2, markers for high-risk breast cancer, may serve to reshape the current rubric of gene patenting. [16] The case brought by the American Civil Liberties Union Foundation ("ACLU") and other interested parties against the USPTO, Myriad Genetics ("Myriad") and the University of Utah, asserts that it is morally wrong to issue genome patents. [17] In the complaint, the ACLU asserts gene patenting is patenting life and then admonishes Myriad for using the patent to block access to researchers with high licensing fees, up to $3000. [18] However, these genes are isolated mutations of the genomic sequence that do not exist in nature. In the words of Myriad General Counsel Richard Marsh, "[w]ithout patents, who is going to do the work and spend the money to make this product accessible to people?" [19]

The intent of this paper is not to present any particular view of the morality of any given technology. It is meant only to address and argue for the continued need for separation of the USPTO from making moral determinations by analogizing the idea of separation of Church and State. The USPTO is an administrative agency, staffed with individuals, like you and I, charged with the task of promoting the useful Arts. Entangling subjective ideas regardless of those ideas basis in religion or religious principles with arbitrary government entities such as the USPTO will lead to catastrophic consequences for the US system of law and biotechnology. Issues of morality and moral concerns are your personal beliefs. Moreover, these views are not static, but fluid, as society's view of about moral and immoral choices change daily. [20] After Pandora succumbed to her curiosity and released the ills and toils on humanity, self-interest and the frailty of the human soul now plays a strong role in changing views of morality. [21] For example, when a technology is beneficial to one's personal health or loved ones', such as stem cell infusions as treatment for cancer, that impact shapes and changes many people's views of the need for that technology. [22] As beliefs exist on a spectrum, many others may share as well as dispute your beliefs. Thus, the answer does not lie in secular regulation and arbitrary application by an inherently fallible patent system, but rather for you, in the interest of autonomy, to decide for yourself.

2. Anything under the Sun Including Frivolous and Deceptive Soda Machines and an Administrative State: the Decline of Moral Utility

"Inventions then cannot, *in nature*, be a subject of property." [23] However, quite contradictory, some believe that the Supreme Court's decision in *Diamond v. Chakrabarty* extending patentable subject matter to anything under

[15] David Ewing Duncan, *What DNA, Patents and Lady Gaga have in common*, FORTUNE, March 17, 2010, at 1; *See also* National Human Genome Research Institute, Intellectual Property and Genomics, *available at* http://www.genome.gov/19016590 (last visited Mar. 19, 2010); Amy Dockser Marcus, *Licenses Drive Gene Debate Duke Study Claims Staked on Genome Could Derail Promise of New Technology*, WALL ST. J, April 15, 2010, at 1.
[16] *Association for Molecular Pathology v. United States Patent and Trademark Office*, No. 09 Civ. 4515 (S.D.N.Y. March 29, 2010).
[17] David Ewing Duncan, *supra* note 15, at 1.
[18] *Id.*
[19] *Id.*
[20] Margo A. Bagley, *Stem Cells, Cloning and Patents: What's Morality Got to Do With It?*, 39 NEW ENG. L. REV. 501, 502 (2005).
[21] *Id.*
[22] *Id.*
[23] Letter from Thomas Jefferson to Isaac McPherson, *supra* note 1 (emphasis added).

the sun that is made by man sanctions the USPTO to grant property rights in nature. [24] The USPTO is statutorily empowered to issue patents to a person who invents or discovers "any new and useful manufacture or composition of matter." [25] Chakrabarty had filed a patent relating to his invention of a genetically engineered bacterium capable of breaking down crude oil, a microbial property not possessed by naturally occurring bacteria. [26] In analyzing if the bacterium constitutes patentable subject matter, the Court focuses on both past legislative history and findings. [27] Congressional committee reports accompanying the Patent Act informed the Court that Congress intended subject matter to "include anything under the sun that is *made by man*." [28] The Court, thus, construed patentable subject matter broadly, allowing a man-made, genetically engineered bacterium to constitute a "manufacture" or "composition of matter" under § 101. [29]

After *Chakrabarty*, courts used the phrase "anything under the sun that is made by man" to expand the breath of patentable subject matter to limitless bounds. For example, in *Diamond v. Diehr*, a case involving the use of the Arrhenius equation, a common mathematical algorithm, in a manufacturing process, anything under the sun was used to expand patentability to software. [30] Moreover, in *State Street Bank and Trust v. Signature Financial Group, Inc.*, the Court of Appeals for the Federal Circuit, following the Supreme Court's lead, expanded patent-eligible subject matter to include business methods. [31] Last, in another biotechnological opinion of *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the Court again used the emblematic *Chakrabarty* interpretation to support a holding that sexually and asexually reproducible plants can be patentable matter. [32]

Returning to Bagley's hypothesis, with this background, some academics argue that by broadening the scope of subject matter, under § 101, life is now patentable. [33] However, these intellectuals fail to consider that although *Chakrabarty* considers the legislative intent of anything under the sun as patentable subject matter, the Court bounded its holding with the fact that the microorganism's ability to digest oil slicks was a biologic process genetically introduced by Chakrabarty and therefore a product of human ingenuity, or made by man. [34] The Southern District of New York in its decision of the Myriad case concerning the breast cancer genes reinterpreted this anything man-made under the sun imposed bound recently. District Judge Sweet concludes that *Chakrabarty* and the line of cases that followed its reasoning required a product of nature to be "transformed" and purification alone of the BRCA1 and BRCA2 genes was not "markedly different" to hurdle the patentable subject matter requirement under § 101. [35] Although conclusions cannot yet be drawn from this lower court case, the Myriad decision highlights a burgeoning area of the limits of patentable subject matter. These limits require there not only be just a law of nature, but also a transformation by human ingenuity. In the words of John Locke, "every individual had property in his own person and his own labor, and so could rightfully appropriate to himself from the common whatever he mixed his labor with." [36] What more stringent subject matter requirements then need to be imposed?

[24] Bagley, *supra* note 11, at 469-70.
[25] 35 U.S.C. § 101 (1952).
[26] *Diamond v. Chakrabarty*, 447 U.S. 303, 308-9 (1980).
[27] *Id.*
[28] S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952) (emphasis added).
[29] *Chakrabarty*, 447 U.S. at 303.
[30] 450 U.S. 175, 182 (1981).
[31] 149 F.3d at 1375.
[32] 543 U.S. 124, 134 (2001).
[33] Bagley, *supra* note 11, at 486 (2003).
[34] *Chakrabarty*, 447 U.S. at 309.
[35] *Association for Molecular Pathology*, No. 09 Civ. 4515, slip op. at 120, 135.
[36] CRAWFORD BROUGH MACPHERSON, EDITORS INTRODUCTION: JOHN LOCKE, SECOND TREATISE OF GOVERNMENT xvi (Hackett Publishing Company eds., 1980) (1690).

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3. The Man of Faith: Justice Story and The Story of a Moral Patent Society

Absent this disregard by moral enthusiasts and until the decision by Judge Sweet is reviewed by a higher court, it is well settled that if the USPTO is to be used as *dextera domini*, or the right hand of a higher being in a battle against evil, patentable subject matter cannot be used as the sword to exclude immoral inventions. [37] Excluding a law of nature under subject matter does not involve judgment into "human conduct, ethics [and] morals," [38] and therefore early immoral inventions were instead bounded by a "moral utility standard." [39] The origins of this standard lie in the persuasive opinion of Justice Story in *Lowell v. Lewis.* [40]

Justice Story scripts:

> "All that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people ... promote debauchery, or to facilitate private assassination, is not a patentable invention." [41]

Narrowly read, Justice Story's frivolity standard means nothing more than some use to an invention. [42] The broad interpretation, adopted by supporters of moral utility standards to exclude of immoral patents, places too much meaning on the words frivolous and injurious. [43] Justice Story himself did not mean to impose such meaning and therefore US patent law must not accept it. Initially, after Lowell countless immoral inventions were denied patentability based on the broad reading of this non-frivolous or injurious moral standard. [44] Nevertheless, by the early twentieth century, there was a stark decline in the application of the judicially imposed moral utility standard as courts applied the doctrine in such a way that an invention with at least one morally accepted purpose, regardless of other frivolous or injurious purposes, could meet the requirement. [45] For example, in *Fuller v. Berger*, the Court of Appeals rejected moral utility notions because patents being denied "by the mere fact that the thing in question is sometimes injurious to morals, or to the health, or to good order ... would be fatal to … steam engines, dynamos, electric railroads, and indeed many of the noblest inventions of the nineteenth century." [46] One can only imagine how far humanity would have progressed if this moral limit had been applied strictly by both the courts and the USPTO.

Ultimately, the Federal Circuit was forced to take up the question of a moral standard to patenting again, in Juicy Whip, Inc. v. Orange Bang, Inc. [47] This time, the court took judicial notice of the fact that although courts

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[37] *Application of Musgrave*, 431 F.2d 882, 890 (Ct. Cust. App. 1970).
[38] *In re Bilski*, 545 F.3d 943, 1003 n.6 (Fed. Cir. 2008).
[39] *Bedford v. Hunt*, 3 F.Cas. 37, 37 (C.C.Mass. 1817).
[40] *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).
[41] *Id.*; *See also Bedford v. Hunt*, 3 F.Cas. 37, 37 (C.C.Mass. 1817).
[42] *Brenner*, 383 U.S. at 532-3.
[43] *Id.*
[44] *See Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 945 F.2d 1546 (Fed.Cir.1991); *In re Nelson*, 280 F.2d 172, 178-79 (C.C.P.A. 1960), *Brewer v. Lichtenstein*, 278 F. 512 (7th Cir. 1922); *Meyer v. Buckley Mfg. Co.*, 15 F. Supp. 640 (N.D. Ill. 1936); *Schultze v. Holtz*, 82 F. 448 (N.D. Cal. 1897); *Nat'l Automatic Device Co. v. Lloyd*, 40 F. 89 (N.D. Ill. 1889); *Scott & Williams, Inc. v. Aristo Hosiery Co.*, 7 F.2d 1003 (2d Cir. 1925); *Mahler v. Animarium Co.*, 111 F. 530 (8th Cir. 1901); *Rickard v. Du Bon*, 103 F. 868 (2d Cir. 1900).
[45] *See Fuller v. Berger*, 120 F. 274 (7th Cir. 1903) ("while some may consider gambling to be injurious to the public morals and the good order of society, we cannot find any basis in 35 U.S.C.A. 101 or related Sections which justify a conclusion that inventions which are useful only for gambling ipso facto are void of patentable utility."); *Ex Parte Murphy*, 200 U.S.P.Q. (BNA) 801, 802 (Bd. App. 1977) ("We think this office should not be the agency which seeks to enforce a standard of morality with respect to gambling, by refusing, on the ground of lack of patentable utility, to grant a patent on a game of chance if the requirements of the Patent Act otherwise have been met.").
[46] *Fuller*, 120 F. at 274.
[47] 185 F.3d 1364, 1366 (Fed. Cir. 1999).

continued to recite in their respective opinions Justice Story's immoral, frivolous or injurious standard, there was a subsequent rejection of the standard in application. [48] Considering this, a quorum of the court decided to obsolete this moral standard from its interpretation of the Patent Act, by concluding, "[t]he threshold of utility is not high: An invention is 'useful' under § 101 if it is capable of providing some identifiable benefit." [49] After the decision in Juicy Whip, moral utility no longer has a place in US patent law, a concept both the federal courts and the USPTO have embraced. [50] This is exampled in the current Manual of Patent Examining Procedure ("MPEP") which instructs examiners that "[a] rejection under 35 U.S.C. § 101 for lack of utility should not be based on grounds that the invention is frivolous, fraudulent or against public policy." [51]

In the court's opinion, the Federal Circuit dispels moral utility by stating the words of the Supreme Court that "Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted." [52] Further the Court found that "[t]he requirement of 'utility' in patent law is not a directive to [USPTO] or the courts to serve as arbiters of deceptive trade practices; [but that] other agencies, such as the Federal Trade Commission ["FTC"] and the Food and Drug Administration ["FDA"], are assigned the task of protecting consumers from fraud and deception in the sale of food products." [53] The drug approval process and the patent system are distinct and separate bodies of law, a concept that requires a firm dividing line and strict allocation on the issue of policing morality concerns. [54] This is not the place of the USPTO, and at least in the area of new medicines created by biotechnology, only the role of the FDA. [55]

Moreover, the court in Juicy Whip reserved the right, a right that is bestowed by Art. I, § 8, cl. 8 of the Constitution, for Congress to declare particular types of inventions nonpatentable based upon immorality or deceptiveness. [56] For example, Congress has already declared those inventions with nuclear material or atomic bombs non-patentable inventions. [57] By deferring to other agencies and reserving the power with Congress to define the scope of the patent grant, Juicy Whip makes it clear that it is not the place of the USPTO to determine or decide which inventions are frivolous, injurious or in contravention to the morals of society.

Circuit Judge Rader of the Court of Appeals reinforced this sentiment recently within the Federal Circuit. Judge Rader begins an adamant dissent about statutory interpretation of the written description requirement of patents with: "The Constitution of the United States gives Congress, not the courts, the power to promote the progress of the useful arts by securing exclusive rights to inventors for limited times. Yet this court proclaims itself the body responsible for achieving the 'right balance' between upstream and downstream innovation." [58] No longer should patents be limited by subjective standards of morality imposed by the USPTO or courts, but this remains Congress' role to proclaim. Subjective and arbitrary interpretations without a system of checks and balances could cause problems for patents on material that have moral implications while providing benefit to society. For example, firearms and automobiles both cause deaths, but also have benefits such as sport, defense, and transportation. [59]

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[48] *Id.*
[49] *Id.*
[50] *See, e.g., Chiron Corp. v. Genentech, Inc.*, 268 F.Supp.2d 1148, 1168 (E.D.Cal. 2002); *Diamond Heads, LLC v. Everingham*, 2009 WL 1046067, 5 (M.D.Fla. 2009).
[51] MPEP § 706.03(a).
[52] *Juicy Whip, Inc.*, 185 F.3d at 1368 (quoting *Webber v. Virginia*, 103 U.S. 344, 347-48 (1880).
[53] *Juicy Whip, Inc.*, 185 F.3d at 1368.
[54] *In re Watson*, 517 F.2d 465, 474-76 (C.C.P.A. 1975).
[55] *See Kundu v. Ragunathan*. 2002 WL 32728579, 12 n.13 ("Just as the use of utility and enablement rejections to police drug efficacy improperly confuses the respective roles of USPTO and FDA … Each body of law must be approached on its own terms.").
[56] *Juicy Whip, Inc.*, 185 F.3d at 1368.
[57] *Cf.* 42 U.S.C. § 2181(a) (2000) ("No patent shall hereafter be granted for any invention…").
[58] *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co*., 2008-1248, 1 (Fed. Cir. 2010) (Rader, J., dissenting).
[59] *Ex Parte Murphy*, 200 U.S.P.Q. (BNA) 801 (B.P.A.I. 1977).

The Supreme Court, in *Chakrabarty*, even echoes this sentiment with, "[t]he choice we are urged to make 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." [60] Even in the genetic engineering context, Congress and other legislative bodies have not been sitting idly by. For example, the National Institutes of Health ("NIH") released guidelines for NIH-sponsored genetic research, which established conditions under which genetic research could be performed, an issue that have been further addressed by various congressional committees. [61] With these inventions already regulated after inventorship, is there even a place for the USPTO to act alongside Congress, the President and a wide array of administrative agencies already empowered to police this area?

After Juicy Whip, moral utility revivalists highlight the lack of enthusiasm by the USPTO in promoting the broad interpretation of moral utility doctrine. [62] Nevertheless, Congress is the appropriate forum to share or debate one's ethical concerns about inventions in biotechnology, not an administrative agency, like the USPTO. So reformationists must lobby Congress to amend the patent statute, not try to force the USPTO into acting arbitrarily and capriciously or without congressional mandate. [63] With anything under the sun that is made by man, the Supreme Court set out a clear command that if Congress intended the patent laws to be broad, the USPTO must abide by that mandate and should not impose its own limitations on patentability without congressional action. [64] Unlike Congress, the USPTO is not accountable to the people, through the electoral process, and therefore it must not create policy unless duly authorized. [65]

Additionally, in the field of biotechnology and the chemical arts, courts have required there to be claimed more than mere utility, a standard that has been adopted by the USPTO in its administrative guidelines to examiners, the MPEP. [66] For the chemical arts, this enhanced guideline is first set out in *Brenner v. Mason*, a Supreme Court case concerning the patent application of a steroid that attempted to derive a utility from a homologous class of steroids use. [67] For the majority, Justice Fortas writes,

> "we believe a more compelling consideration is that a … patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute... The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." [68]

A standard of specific and substantial utility that now extends to biotechnological inventions. In re Fisher, the Federal Circuit upheld the USPTO rejection of patentability for express sequence tags ("ESTs") on utility grounds. ESTs are purified nucleic acid sequences of complementary DNA ("cDNA") created by isolating the messenger sequences of ribonucleic acid ("mRNA"). As asserted by Fisher and stated by the Federal Circuit, the ESTs have a use as a research tool that can hybridize to DNA sequences and "help scientists to isolate the

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[60] *Chakrabarty*, 447 U.S. at 317.
[61] 41 Fed.Reg. 27902; *See e. g.*, Hearings on Genetic Engineering before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare, 94th Cong., 1st Sess. (1975); Hearings before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science, and Transportation, 95th Cong., 1st Sess. (1977); Hearings on H.R. 4759 et al. before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, 95th Cong., 1st Sess. (1977).
[62] Bagley, *supra* note 11, at 491.
[63] Thomas Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 459 (1999).
[64] *Id.*
[65] *Id.*
[66] *See* MPEP § 2107, art. II(A)(3)("An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.").
[67] *Brenner*, 383 U.S. at 522.
[68] *Brenner*, 383 U.S. at 534 (emphasis added).

particular underlying protein-encoding genes and conduct further experimentation on those genes." [69] However, the court notes this is not enough to meet the specific and substantial utility standard "upon which scientific research could be performed with no assurance that anything useful will be discovered in the end." [70] If therefore the moral enthusiasts main assertion is that their needs to be more stringent standard of utility to keep immoral biotechnology in check, that higher standard of specific and substantial utility is already ingrained, by both courts and the USPTO, into the US patent system. What more protection is needed?

4. Intellectual Property's Moral Remnants: Morality in Trademarks and Copyrights

Moral intellectual property rights are not a new concept. Intellectual property systems both in the US and abroad have morality ingrained within the law. In the US, trademarks can be refused registration on the principal register if the mark "[c]onsists of or comprises immoral, deceptive, or scandalous matter." [71] Moreover, works of visual art, under US copyright law, have inherent rights of attribution and integrity under the Visual Rights Act of 1990 ("VARA"). [72] These provisions of US trademark and copyright law may already seem to you as commingling of both morality and the administrative state, but both facially and as applied are constitutionally permissible. [73] The USPTO's Trademark Trial Appeal Board ("T.T.A.B.") went as far as to say that "[w]e do not see [§2(a)] as an attempt to legislate morality, but, rather, a judgment by the Congress that such marks [should] not occupy the time, services and use of funds of the federal government." [74] Notwithstanding this assertion, in practice, the doctrines have had the opposite effect, due primarily to arbitrary and subject applications of the principles and little to no uniformity in decisions by reviewing courts. Reintroduction of either moral utility or limits on subject matter into US patent law will have the same effects.

> Animals, Native Americans and the Finger, the Waxing and Waning of Control By the Dead Hand of Authors, and Moral Corporate Practices

Along the lines of this mentality, various examples of disparaging or immoral trademarks have been denied protection. [75] The T.T.A.B. has gone so far as to say that scandalous matter is that which offends the conscience or moral feelings, or shocks the sense of decency or propriety of a substantial composite of the general public. [76] To date, however, the T.T.A.B.'s representation of disparaging trademarks is unclear as the question remains whether a scandalous, immoral mark is one that shocks the sense of decency of one individual or the many, comprising the public. [77] Furthermore, in reality, this rule is scarcely used to invalidate a mark.

The only standard that appears to exist is the constant wavering of trademark examiners' and the T.T.A.B.'s devote sense of morality in a morass of opinions. For example, *In re Bad Frog Brewery* the administrative court is faced with a refusal by the trademark examiner to register a mark of a frog "flipping the bird" based on scandalous material under 2(a). [78] Two of the three administrative law judges do not consider "the bird" to be

[69] *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005).
[70] *Id*.
[71] 15 USC §1052(a) [hereinafter §2(a)].
[72] 104 Stat. 5089, 5128 (1990).
[73] *In re Mavety Media Group Ltd.*, 33 F.3d 1367 (Fed. Cir. 1994).
[74] *In re Old Glory Condom Corp.*, 26 U.S.P.Q.2d 1216, 1220 (T.T.A.B. 1993).
[75] *In re Tinseltown, Inc.*, 212 U.S.P.Q. 863 (T.T.A.B. 1981) (**Bullshit** for clothing and accessories is immoral or scandalous); *Greyhound Corp. v. Both Worlds Inc.*, 6 U.S.P.Q.2d 1635, 1638–9 (T.T.A.B. 1988) (**a dog defecating**, applied to shirts, was also held a scandalous mark).
[76] *In re Tinseltown, Inc.*, 212 U.S.P.Q. at 863.
[77] *See Harjo v. Pro-Football Inc.*, 50 U.S.P.Q.2d 1705, 1748–9 (T.T.A.B. 1999), *rev'd* 284 F. Supp. 2d 96 (D.D.C. 2003) ("**Redskins**" for a football team was held not scandalous in view of its "clear acceptance by a substantial composite of the general population").
[78] *In re Bad Frog Brewery, Inc.*, 1999 WL 149819, at *1 (T.T.A.B. Mar. 16, 1999).

immoral or scandalous, [79] whereas in a forceful dissent, Judge Simms, the remaining opinion, believes the gesture to be "inconsistent with… purity, or good morals." [80] With *In Re Bad Frog Brewery* being only one of many examples of the inconsistent stances of the T.T.A.B. on morality standards, would not the Lanham Act and the public be better off without such standards? [81]

Copyright, in the US, poses similar issues in its implementation of rights of integrity and attribution, known commonly as copyright's moral rights. Although rights of integrity and attribution differ from generally accepted definitions of morals, copyright law's implementation of these rights help to understand how US courts view authors controlling their works based on honor or reputation and extrapolates in application to patent law. Once a work is publicly available, courts ended up making subjective determinations to determine terms such as recognized stature, a practice that continues to be detrimental to the copyright's moral rights.

For an era, US copyright law had no moral rights bestowed to authors or artists. During the dawn of US copyright law, our law provided little remedy to the creators of works of art, in any media. This founding principal of law, however, changed as US saw necessity to enter the worldwide intellectual property community. The European Union ("EU") and its resident authors and artists had a long tradition of rights of integrity and attribution to their works, allowing the author to retain an interest in the integrity of the work or their name. Contrary to the EU's tradition, in the US, once a work is sold, its possessor can then dispose or utilize the work as he or she may see fit.

The US approach of treating copyrighted material as pure property appears to change in the 1976 case of *Gilliam v. American Broadcasting Companies, Inc.*, when the group Monty Python, arguing for a right of integrity as authors in their work, sought a preliminary injunction against American Broadcasting Companies from depicting "Monty Python's Flying Circus" in a time lapsed form. [82] Rather surprisingly, the Court of Appeals for the Second Circuit was the first to hold that Monty Python retained a right of integrity based solely on its copyright in the script and rights as an author. [83] Initially, *Gilliam* appeared to be a turning point for copyright in terms authors ability to control their works after the first sale or exhaustion, however, the case more than likely only a jurisprudential showing of good faith in order for the US to comply with the Berne Convention. It has yet to be followed by courts. [84]

The decision was subsequently followed up with the introduction of VARA, which added § 106A rights to a copyright owner's exclusive rights. [85] VARA introduced both rights of integrity and attribution to US law. [86] These are not rights that regulate the subject matter of copyright or those materials that shock the conscious, rather, rights of attribution and integrity. Now, an author may prevent the use of her name on a work she did not create or that is prejudicial to her reputation; prevent the intentional distortion, mutilation, or other modification that is prejudicial to her honor or reputation; or prevent destruction of a work of recognized stature. [87] Although this may sound as a huge step towards moral rights in copyrights, both the law itself and courts have construed it otherwise. VARA comes with substantial limitations, including a requirement that it only be applied to a "work

[79] *Id.*
[80] *In re Bad Frog Brewery, Inc.*, 1999 WL 149819, at *10 (Simms, J., dissenting).
[81] *See, e.g., McDermott v. San Francisco Womens Motorcycle Contingent*, 81 U.S.P.Q.2d 1212 (T.T.A.B. 2006) (DYKES ON BIKES); *Harjo v. Pro Football Inc.*, 30 U.S.P.Q.2d 1828 (T.T.A.B. 1994) (REDSKIN); *In re Squaw Valley Development Co.*, 80 U.S.P.Q.2d 1264 (T.T.A.B. 2006) (SQUAW and SQUAW ONE).
[82] *Gilliam v. American Broadcasting Companies, Inc.*, 538 F.2d 14 (2d Cir. 1976).
[83] *Gilliam*, 538 F.2d at 26.
[84] *See* Natalie C. Stahl, *Moral Rights Protection in the United States Under the Berne Convention: A Fictional Work?*, FORDAM INTELL. PROP., MEDIA & ENT. L. J.1204, 1224 (2002) ("While *Gilliam* is a landmark on the map of integrity protection in the U.S., it is an anomaly.").
[85] 104 Stat. 5089, 5128 (1990).
[86] Rep. Robert W. Kastenmeier, Chair of the House Judiciary Subcommittee on Courts, Intellectual Property, and the Administration of Justice, H.R. Rep. No. 101-514, at 5 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6915, 6917.
[87] 17 U.S.C. § 106 (2002).

of visual art" and in some cases works of visual art that are of "recognized stature." [88] In all, courts have interpreted VARA to be almost fruitless for moral rights. [89]

After the US signed on to the Berne Convention and implemented VARA, the Supreme Court quickly scaled back or at least limited the scope of moral rights in US copyright law. [90] VARA provides that the author of an artistic work "shall have the right ... to claim authorship of that work." [91] However, many scholars have characterized copyright authorship or inventorship, in the words of the Constitution as communal property because of the idea's roots in communal practice, rather than individual achievements. [92] Therefore, that express right of attribution has been carefully limited and focused by the Supreme Court because society and not individual authors should shape the principles that underlie copyright and any grants of moral rights that stems from it.

Finally, morality already governs trade secrets. [93] Maintaining morality in commerce is a cardinal concept of trade secret law. In *Pioneer Hi-Bred Intern. v. Holden Foundation Seeds, Inc.*, this circuit explains, "by labeling certain wrongful, if not actually otherwise illegal, acts 'improper,' trade secret law plays an important role in regulating commercial behavior. … Our analysis is consistent with the stated purposes of trade secret protection: (1) maintaining commercial morality, and (2) encouraging innovation." [94] If trade secret law effectively controls commercial morality while still encouraging innovation, why must the US patent law that serves a different function, need to concern itself with similar moral trivialities, and do the same?

5. Immoral Inventions or the Cusp of Innovation?

If US patent law were to reinstate the moral utility requirement, this practice would significantly affect a variety of innovative inventions. Primarily biotechnological inventions, such as patenting genes, stem cells and transgenic organisms would be the first affected by this commingling moral concern and their underpinnings with governmental arms like the USPTO. Drs. Maureen and Samuel Condic warn, "[w]hen it comes to morals, the key insight to remember is that scientific research is about the possible, not about the ethical or the good." [95] Notwithstanding this ethical criticism, no matter how one may view this research, everyone will agree that these possible inventions are on the cusp of innovation. Should the USPTO be standing guard at the pearly gates of patentability as Saint Peter and decide which of these inventions are worthy of a patent? Contrarily, would it be better alternative to allow all innovation a patent and leave it up to its effect on society during that patent's life to define its ability to enter Heaven?

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[88] 17 U.S.C. § 101 (2000).
[89] *See Phillips v. Pembroke Real Estate, Inc.*, 459 F.3d 128, 143 (1st Cir. 2006) ("VARA does not protect site-specific art and then permit its destruction by removal from its site pursuant to the statute's public presentation exception. VARA does not apply to site-specific art at all.").
[90] *See Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 34-35 (2003) ("When Congress has wished to create such an addition to the law of copyright, it has done so with much more specificity than the Lanham Act's ambiguous use of "origin."); Madhavi Sunder, *The Invention of Traditional Knowledge*, 70-SPG Law & Contemp. Probs. 97, 101 (2007) ("In Shamans, Software, and Spleens, Boyle was concerned about the morality of legally recognizing some members of society as authors and not others.").
[91] 17 U.S.C. § 106A(a)(1)(A) (1990).
[92] *See* David Opderbeck, *A Virtue-Centered Approach to the Biotechnology Commons (Or, the Virtuous Penguin)*, 59 ME. L. REV. 315, 325 (2007) ("Authorship or inventorship, in this reading, is properly considered a communal practice, rather than an individual achievement. It is improper, then, to grant any individual monopoly control over what should remain accessible to the entire community.").
[93] *See Pioneer Hi-Bred Intern. v. Holden Foundation Seeds, Inc.*, 35 F.3d 1226, 1239 (8th Cir 1994) ("Trade secret law and patent law-both aspects of the elusive concept of intellectual property-serve quite different functions.").
[94] *Id.*
[95] Bagley, *supra* note 11, at 512 (quoting Maureen L. Condic & Samuel B. Condic, *The Appropriate Limits of Science in the Formation of Public Policy*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 157, 159-60 (2003)).

6. Playing God with Genes, the Building Blocks of Life, Stem Cells, the Beginning of Life, and Transgenics, the Creation of Life

Genes, the building blocks of humanity and life, are considered by many to be patent ineligible subject matter. [96] However, as seen in *Diamond v. Chakrabarty*, the scope of eligible subject matter is broad, including almost anything under the sun created by man. Similar to Chakrabarty's creation of a microorganism that does not exist in nature, the USPTO considers "isolated and purified" genes to be patentable subject matter. [97] Thus, a wide array of patents on genes have been considered by the USPTO and granted patentability, under the guise of being isolated and purified. [98] In an effort to prevent intellectual property rights on such knowledge, some scientists have instituted a race against the private sector by placing this information in the public domain through the Human Genome Project. [99]

Regardless of this effort though, some genes are privately patented, an issue that has resulted in recent litigation concerning the genes associated with breast and ovarian cancer. [100] The suit asserts that the University of Utah, by granting an exclusive license to Myriad, has stifled research by limiting the medical options that are available for diagnosis. [101] Myriad, the exclusive license holder, is entitled to be the sole provider of tests for the genes. [102] It is asserted in the complaint that this exclusive relationship stalls innovation, resulting in complaints of mediocre tests with false positives and no availability of second opinions. [103] Anthony Romero, executive director of the ACLU has stated about the case that "[t]he government should not be granting private entities control over something as personal and basic to who we are as our genes." [104] A morality argument that has initially convinced the lower district court that precedent interprets § 101 as "[establishing] that purification of a product of nature, without more, cannot transform it into patentable subject matter." [105] However, instead of excluding genes from patentability, the district court should have narrowed the issue in terms of the legality of the grant of an exclusive license. By limiting the holding, the court would not be restricting the free market for this beneficial technology.

Currently genetic tests are specific to a set of genes (BRCA1 and BRCA2 for breast cancer), a single gene (CFTR for cystic fibrosis) or a single mutation (CAG repeat in the Huntington gene for Huntington's disease), but this is an area of science that is quickly mutating itself. [106] The European Society of Human Genetics postulates that genetic tests are trending to increase in complexity, as many tests will either be phenotype-based, requiring exploration of many genes or combine detection of several mutations with protein or metabolite measurements. [107] Imagine what will happen when patents do not incentivize this area of research through a

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[96] MPEP § 2106.
[97] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 ("A patent on a gene covers the isolated and purified gene"); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 13 U.S.P.Q.2d 1737, 1959 (D. Mass. 1990) ("The invention claimed … that is a nonpatentable natural phenomenon 'free to all men and reserved exclusively to none.' ... Rather, the invention as claimed in claim 2 of the patent is the "purified and isolated" DNA sequence encoding erythropoietin.").
[98] *See, e.g.*, U.S. Patent No. 4,370,417 (Jan. 25, 1983) (claiming DNA sequence for plasminogen activator protein); U.S. Patent No. 4,703,008 (Oct. 27, 1987) (claiming DNA sequence for erythropoietin); U.S. Patent No. 4,713,332 (Dec. 15, 1987) (claiming DNA sequence for human T cell antigen receptor); U.S. Patent No. 4,757,006 (July 12, 1988) (claiming recombinant vectors containing DNA sequence for human factor VIII:C).
[99] Committee on Mapping and Sequencing the Human Genome of the National Research Council, Mapping and Sequencing the Human Genome, 99-100 (1988).
[100] ACLU, *Others Attack Patents on Breast Cancer Genes*, 28 BIOTECHNOLOGY L. REP. 514, 514 (2009).
[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] *Association for Molecular Pathology*, 1:09-cv-04515-RWS, 09 Civ. 4515, at 121.
[106] S Aymé, G Matthijs and S Soini , *Recommendations of the European Society of Human Genetics, Patenting and licensing in genetic testing* , EUROPEAN JOURNAL OF HUMAN GENETICS 16, S3–9 (2008), *available at* http://www.nature.com/ejhg/journal/v16/n1s/full/5201929a.html.
[107] *Id.*

moral utility doctrine. Lack of incentives in this increasingly convoluted niche area of research will hamper the development of gene chips or beneficial detection systems. [108] US patent law and the USPTO must not therefore hinder these beneficial screening tools because of moral utility, but rather, public need through the market of disease prevalence is the appropriate area to select and sift out such technology or tools. No one wants to be the patent agent, legislator or even the constituent who held up early detection of cancer.

While considering cancer, another debated, but burgeoning area of research is in the area of embryonic stem cells. In the US, at least one patent has been granted to the University of Wisconsin on human embryonic stem cells and the method of isolation. [109] In Europe, however, the EPO concluded otherwise, by rendering an opinion that under the EPC, it is impossible to patent matter that results in the destruction of human embryos. [110] Ethical concerns aside on this subject matter's patentability, on March 9, 2009, after the issuance of President Obama's Executive Order No. 13505 addressing removing the barriers to responsible scientific research, there has been an explosion in the area of stem cell research. [111] The NIH, under new guidelines, has recently approved thirteen new cell lines. [112] This effort has allowed scientists to find potential uses for the cells, such as treatment for memory loss or Alzheimer's disease. In irradiated rat models, scientists at the University of California Irvine and San Francisco have been able to show increased cognitive functioning after injections with human embryonic stem cells. [113] Further, some scientists believe this method can be amended using reprogrammed pluripotent stem cells with similar effect as the embryonic cells. [114] The reprogrammed cells would remove the ethical concerns surrounding embryonic stem cells. Nevertheless, without innovation in this area, scientists would not be where they are today, in areas like cancer and other debilitating and deadly diseases.

Transgenic organisms also highlight some of the issues when entangling subjective morality standards and legality. On April 12, 1988, the USPTO issued a patent on transgenic non-human mammals. [115] The patent claims a transgenic non-human eukaryotic animal whose cells contain an activated oncogene sequence. [116] This gene sequence renders the mouse susceptible to malignancy and carcinogens. [117] Regardless of the morality implications of playing with nature and creating species, the genetically altered mouse is a valuable tool for studying human cancers, in particular human breast cancer. [118] This fact has led to an explosion of research in the biotechnology sector producing transgenic animal models. [119] These models give us the necessary tools to test potentially harmful or malignant compounds, prior to instituting human trials.

7. Morality's Sedimentation into the International Patent Community

Contrary to the US approach to separate the USPTO from moral decision-making, Europe and several Asian countries have taken the reverse approach by permitting the exclusion from patentability inventions against

[108] *Id.*
[109] Sheryl Gay Stolberg, *Patent on Human Stem Cell Puts U.S. Officials in Bind*, N.Y. TIMES, Aug. 17, 2001, at 1.
[110] Andrea Gawrylewski, *Europe rejects stem cell patent*, THE SCIENTIST, Dec. 1, 2008, at 1.
[111] National Institutes of Health, *First Human Embryonic Stem Cell Lines Approved for Use Under New NIH Guidelines*, NEWS RELEASE, December 2, 2009, at 1, *available at* http://www.nih.gov/news/health/dec2009/od-02.htm.
[112] *Id.*
[113] Karen Kaplan, *Embryonic stem cells may restore brains damaged by radiation*, L.A. TIMES, November 10, 2009, at 1.
[114] *Id.*; Gabsang Lee and Lorenz Studer, I*nduced pluripotent stem cell technology for the study of human disease*, NATURE METHODS, January 2010, at 1.
[115] *See* U.S. Patent No. 4,736,866 (April 12, 1988) (Transgenic non-human mammals).
[116] *Id.*
[117] FDC Reports, Inc., *Transgenic Animal Patents: Two Year Moratorium Request*, 50 THE PINK SHEET NO. 50, at T&G-9 (Apr. 18, 1988).
[118] Rachel E. Fishman, *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J.L. & MED. 461, 466 (1989).
[119] *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice.* 100th Cong. 372 (1987) (testimony of Dr. Leroy Walters that since October of 1984 "[t]here has been a veritable explosion of research in the area of germline interspecies transfers.").

either morality or the public order. [120] To disclaim upfront, unlike the US patent system with a sharp divide between patentable subject matter, covered by the *Chakrabarty* "anything under the sun that is made by man" line of cases, and utility doctrines, such as *Juicy Whip*, the international community has blurred the lines between these two theories. Exploring these commingling approaches first is article 53 of the European Patent Convention ("EPC"), governing the patentability in Europe by the European Patent Office ("EPO"). [121] Article 53, states "European patents shall not be granted in respect of: inventions the commercial exploitation of which would be contrary to *ordre public* or morality." [122] Even the TRIPS Agreement, which the EU and US are members, states: "Members *may* exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality." [123]

Nonetheless, as the EPO interprets the meaning of *ordre public* and morality as requiring a judicial notice of the majority of laws of the European member states, [124] the morality restrictions imposed by the EPC may actually be nothing but inconsequential rhetoric. In the context of environmental impacts of biotechnological inventions, Carolyn Abbot and David Booton persuasively argue that the EPO and USPTO interpret morality in the same manner. [125] This principle extends far beyond just its environmental roots. For example, in a symposium paper addressing the current patent regime in Europe, Monique Morneault shows that even the EPO examiners have had difficulties making those determinations, a difficulty evidenced by the plethora of tests to determine if an invention is immoral. [126] Precedent interpreting the EPC Article 53 seems to contest where the European Union truly stands on the question of morality. [127]

First, on remand from the EPO Technical Board of Appeal (the "Board"), the EPO's Examining Division (the "Division") was required to consider the *ordre public* and morality proviso in its review of the application for the Harvard oncomouse, [128] which was issued a patent in 1988 by the USPTO. [129] Ultimately, the Division employed a case-by-case balancing test, weighing the states interest in patentability. The Division notes in its opinion that the invention could be of great benefit in the search for a cure for cancer. [130] Allowing the patent on the oncomouse, in an effort to promote innovation in a promising area of science, the Examining Division concluded, "the present invention cannot be considered immoral or contrary to public order." [131]

During the opposition of *Plant Genetic Systems v. Greenpeace*, the EPO was confronted again with considering morality when patenting. [132] Greenpeace asserted the *ordre public* or morality clause in opposition of a patent on transgenic plants producing glutamine synthetase inhibitors. [133] On appeal from loosing that opposition, the Board affirmed, concluding that this invention again, did not exceed a threshold of becoming

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[120] Shubha Ghosh, *Patent Law and the Assurance Game: Refitting Intellectual Property in the Box of Regulation*, 18 CAN. J.L. & JURIS. 307, 327-8 (2005).
[121] Carolyn Abbot & David Booton, *Using Patent Law's Teaching Function to Introduce an Environmental Ethic Into the Process of Technical Innovation*, 21 GEO. INT'L ENVTL. L. REV. 219, 255 (2009).
[122] European Patent Convention art 53, Jul. 13, 2007, *available at* http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/acii_i.html [hereinafter EPC]
[123] Agreement on Trade Related Aspects of Intellectual Property art. 27, Jan. 1, 1995, 19 U.S.C. 3511, *available at* http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5 (emphasis added) [hereinafter TRIPS].
[124] *See* Harvard/Onco-Mouse: Decision of the Opposition Division dated 7th November 2001, [2003] O.J. E.P.O. 473, 501-4.
[125] *See* Carolyn Abbott, *supra* note 121, at 227 ("It is fair to say then that the U.S. Patent and Trademark Office's impotence under U.S. patent law is matched by an absence of enthusiasm on the part of the EPO to exercise its power under the EPC to refuse a patent on the ground of likely environmental harm.").
[126] Monique Morneault, *Cloning Issues and the Current Patent Systems in the United States and Europe*, 39 NEW ENG. L. REV. 523 (2005).
[127] *Id.*
[128] HECTOR L. MACQUEEN ET AL., CONTEMPORARY INTELLECTUAL PROPERTY: LAW AND POLICY 425-6 (2007).
[129] Bagley, *supra* note 11, at 519-24.
[130] *Harvard/Onco-mouse (T19/90)*, [1990] E.P.O.R. 501, 527 (Tech. Bd. App. Oct. 3, 1990).
[131] *Id.*
[132] [1995] E.P.O.R. 357, 373 (Tech. Bd. App. Feb. 21, 1995).
[133] *Id.*

immoral. [134] While focusing on the intent of the drafters of the EPC, none of the claims in the patent violated the morality provision of Article 53(a) because they "cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture." [135] In other words, the Board affirmed once again, that morality is a social standard, not to be handled by administrative bodies or administrative reviewers in the EPO.

Lastly, in an opposition to the patent on a hormone Relaxin, several contesters argue that the issuance of a patent violates Article 53(a) because it offended human dignity by extracting tissue from a pregnant woman and patenting the resulting human genes. [136] Nevertheless, reaffirming its position, the Board disagreed by articulating that under Article 53(a) one must "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." [137] This "public abhorrence" test promotes a low standard since very few inventions are considered abhorrent in today's society. [138] Interestingly, the test articulated by the court and preceding case law considers not the individual patent examiners subjective abhorrence, but society's objective level of abhorrence.

Further evidence of the EU's battle with morality is depicted in its implementation of the Biotechnology Directive 98/44/EC (the "Directive"). Drafters of this Directive depict its goal as preserving the right of EU member states to consider moral implications in determining patent-eligible subject matter, as an extension of EPC Article 53(a). [139] Unlike USPTO examiners, some commentators critique the Directive because it forces patent examiners to judge inventions by ethical standards. [140]Even with this main premise of excluding morally or ethically unacceptable patent subject matter, isolated DNA, human embryos as well as transgenic plants and animals are all patentable under the Directive. [141]

In implementing the Directive, the Netherlands, joined by Italy and Norway, filed a lawsuit in the European Court of Justice ("ECJ") requesting the annulment altogether. [142] In this lawsuit, the countries argued that the Directive, like Article 53(a) violated the fundamental rights of human dignity and integrity by granting patentability to genetic material. [143] The ECJ disagreed and held that the Directive "frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded." [144] Consequently, the ECJ upheld the validity of the Directive and instructed the member states to implement it. [145] Contrary to the ECJ's instructions and to the pillars of EU supranational law, several member states failed to adhere and implement national laws in accord with the Directive by the deadline and therefore the European Commission was forced to take action against these noncompliant states. [146] Thus, legislatures and proponents for reintroduction of moral utility standards should take notice of what happens when a governmental entity imposes moral standards on innovation, as not everyone has the same views or values, a harsh lesson that the EU has learned through implementation of the Directive.

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[134] *Id.* at 374.
[135] *Id.* at 370.
[136] *Howard Florey v. Fraktion der Grunen Im Europaischen Parlament*, [1995] E.P.O.R. 541, 544, 549 (Opp'n Div. Dec. 8, 1994).
[137] *Id.* at 550.
[138] Bagley, *supra* note 11, at 524.
[139] Bagley, *supra* note 11, at 526; Council Directive 98/44/EC, 1998 O.J. (L 213) 13, ¶¶ 1-4, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF.
[140] Jasemine C. Chambers, Note, *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).
[141] Council Directive 98/44/EC, *supra* note 139, ¶38, arts. 2, 5.
[142] Case C-377/98, *Kingdom of the Netherlands v. Eur. Parliament & Council of the Eur. Union*, 2001 E.C.R.I-7079, ¶¶ 52-4.
[143] *Id.* at ¶¶ 70-4.
[144] *Id.* at ¶ 77.
[145] *Id.* at ¶¶ 29, 34, 49, 68, 81, 88.
[146] *Single Market: Ten Years On, Commission Has Something to Celebrate*, Eur. Report No. 2647, Jan. 8 2003, at 1; State of Play of the Implementation of Directive 98/44/EC, *available at* http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf (Last revision Jan. 1 2007).

Similar to the EPC, Article 32 Japanese Patent Act ("JPA") disallows "inventions liable to contravene public order, morality or public health" from patentability. [147] However, even the Japanese Patent Office ("JPO") allows review of full-length DNA and cDNA fragments, provided the inventions meet the minimum requirements of enablement and inventive step under the JPA. [148] With this disparity, the question remains how effective the worldwide patent offices are in protecting against inventions that contravene the public order or, so called, morality standards.

Equally pertinent are two successful examples of international morality regulations in Canadian and Chinese legislations. On October 1, 2009, as protectionist policy of Chinese genetic resources, Article 5 of the Third Amendment to the Chinese Patent Law ("Article 5") became effective. [149] Under Article 5, "[n]o patent right shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to the public interest. No patent right shall be granted for any invention-creation which is completed on the basis of genetic resources of which the acquisition or use breaches the stipulations of related laws and regulations." [150] Commentators believe the new provisions purpose is to combat bio-piracy, or acquiring the genetic resources of diversity-rich countries, without compensation. [151] Since Article 5 only recently was enacted, it may be too soon to tell its direct impact. However, if the patent claims are invalid under the provision, it is expected that revenues and compensation from the patent will decline.[152] Because of this negative result, other diversity-rich countries, like China, have therefore decided not to stifle innovation by mandating the patent to be unenforceable within their borders, and instead, allow the governments to share in the financial benefits that stem from the grants. [153] Thus by analogy Article 5 in an effort to protect biodiversity will have little to no effect.

An international patent body that has been praised by individuals fighting against evil inventorship is a decision by the Canadian Supreme Court denying the oncomouse patent territorially Canada. [154] On the issue of patentable subject matter, Canada has a similar statute to the US, as § 2 of the Canadian Patent Act states 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." [155] However, even with the similarities between the two statutes, the Canadian court distinguishes its statute's birth from the US Patent Act, by stating that unlike Congress, the Canadian Parliament did not have a long legislative history and judicial precedent of defining invention as anything under the sun that is made by man. [156] Nevertheless, even without the rationale, the Canadian court agrees with the *Juicy Whip* analysis that Parliament, and in the US, Congress, not the courts or the USPTO, are the most competent to set the limits whether it be on patent-eligible subject matter or utility standards. [157]

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[147] *WIPO Database of Intellectual Property, Legislative Texts*, Art. 32, Japanese Patent Act, *available at* http://www.wipo.int/clea/docs_new/pdf/en/jp/jp006en.pdf.
[148] Japanese Patent Office, Part VII, Chapter 2: Examination Guidelines for Inventions in Specific Fields, Biological Inventions, at 41, http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm (last visited Mar. 3, 2010).
[149] Yan Wenfeng, *NPC OKs New Patent Law*, CHINA REP. INTELL. PROP., Dec. 31, 2008, *available at* http://www.sipo.gov.cn/sipo_English/news/ChinaIPNews/2008/200904/P020090408579902833623.pdf.
[150] Margo Bagley, *The New Invention Creation Activity Boundary in Patent Law*, 51 WM. & MARY L. REV. 577, 584 (2009) (quoting EU-China IPR2, European Patent Office, Third Revision of China's Patent Law: Legal Texts and Documents on the Drafting Process 2006-2008, at 11 (2009), *available at* http://www.ipr2.org/images/eu_patent_law-090805-7-final.pdf).
[151] Bagley, *supra* note 150, at 589.
[152] *Id.*
[153] *Id.*
[154] *Harvard Coll. v. Canada*, [2002] 4 S.C.R. 45, 2002 SCC 76 (Can.).
[155] Canada Patent Act, R.S.C., ch. P 4, §2 (1985).
[156] *Harvard Coll.*, 4 S.C.R. 45, at ¶ 158.
[157] Laruen Cirlin, *Human or Animal: A Resolution to the Biotechnological Blurring of the Lines*, 32 SW. U. L. REV. 501, 519 (2003).

In the US after Juicy Whip, has the law changed so drastically to exclude morality from patent decision-making especially when the USPTO still claims to consider morality in decisions? [158] In *Geneva Pharms. Inc v. GlaxoSmithKline, PLC*, at least one court disagree it has, as this court held that a patent will possess utility "if it will operate to perform the functions and secure the results intended, and its use is not contrary to law, moral principles, or public policy." [159] Thus, Juicy Whip has not fully dispelled morality considerations from the progress of science. Consider also that the standards worldwide may be markedly different from the US, but those characteristic differences may an inherent result of being a unique "use based, first to invent" as opposed to "first to file" system. [160]

8. Conclusion

Ethical dilemmas are "better dealt with by either trained professionals, or elected officials, not by underpaid and overworked examiners at the patent office." [161] Some scholars and the Supreme Court believe that the correct place to address these questions is not through the patent system, but in the regulatory agencies that have oversight of the patented products. [162] Regulation by the USPTO imposing ethical requirements at the initial stage of patent filing and review will more than likely inhibit innovation in the US. [163] When coupled together with the USPTO's lack of resources and competence to deal with these ethical dilemmas, [164] there is no other solution for the US patent system, but promote innovation in a disinterested manner and place aside considerations of morality.

Others see benefit to reinstitution of a broad reading of Justice Story's frivolity standard in order to check these immoral inventions at the patenting stage. This interpretation of the Patent Act must not be implemented absent congressional action. [165] The USPTO must continue to "encourage inventors of new processes … for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." [166] Reinstituting a moral utility standard, absent congressional action, provides unclear standards for patent examiners, a concept that both courts and the USPTO seem to embrace when interpreting other intellectual property's moral right provisions. [167] For instance, what would an examiner do if asked to review the application of the Colt revolver, an instrument used to commit both violence and even homicide, but also a means of livelihood, protection and defense for individuals or soldiers? [168] Although it may be true that patentable subject matter today constitutes almost anything under the sun that is made by man and the moral utility age has sunset, moral utility revivalists fail to consider that the current US patent system already has a more stringent utility standard of "specific and substantial utility" for biotechnological inventions.

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[158] *See* U.S. Patent and Trademark Office, *Facts on Patenting Life Forms Having a Relationship to Humans*, MEDIA ADVISORY (Apr. 1, 1998), *available at* http:// www.uspto.gov/web/offices/com/speeches/98-06.htm. ("Notwithstanding the CAFC's decision in Juicy Whip, the [USPTO] does still claim to consider the "moral utility" of inventions.").
[159] 213 F. Supp. 2d 597, 610 (E.D. Va. 2002).
[160] *See generally* Andrew Smith, Note, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159, 186 ("The most glaring difficulty recognized by the courts and the USPTO is that moral utility most readily applies to an invention's use--a property right not conferred by the patent grant.").
[161] Dov Greenbaum, *Research Fraud: Methods for Dealing with an Issue That Negatively Impacts Society's View of Science*, 10 COLUM. SCI. & TECH. L. REV. 61, 129 (2009).
[162] *See* 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.").
[163] *See, e.g.*, Yandell Henderson, *Patents Are Ethical*, 77 SCI. 324, 325 (1933) ("Any new practice rule or regulation that ... in any way impairs scholarly freedom, will tend rather to diminish than to insure the maintenance of scholarly ethics and faculty morale. Regulations impair ethics.").
[164] Dov Greenbaum, *supra* note 161, at 129.
[165] *Brenner*, 383 U.S. at 533.
[166] *Brenner*, 383 U.S. at 533.
[167] *See infra* pp. 14-8; *Application of Anthony*, 414 F.2d 1383, 1395 (Ct. Cust. App. 1969) ("if it could, it would make the validity of the patents to depend on a question of fact to which it would often be impossible to give a reliable answer.")
[168] *Id.*

Notable scholars also disagree with the contention that moral utility needs to be resurrected after *Juicy Whip*. Professor Donald Chisum, for instance, in his treatise CHISUM ON PATENTS, rather than making the principle obsolete, instead, guides patent scholars to consider moral utility doctrine, in a scaled back form, as an available patent test. Chisum discusses that an invention must "operate and perform the functions and secure the result intended … achieve some minimum human purpose [and] … achieve a human purpose that is not illegal, immoral or contrary to public policy." [169] Limiting his application of this principle with words that "the courts should not apply subjective ideas of honesty and morality" when considering utility, he subtlety hints at the problem of incongruence and inconsistency of applying moral standards. [170] Nevertheless, Chisum's treatise highlights that even after *Juicy Whip* moral utility may still be applied.

Moral enthusiasts believe "[i]t is the role of Congress to maximize the public welfare through legislation," [171] therefore, these devout followers propose three legislative remedies requiring the USPTO to deny patents on the basis of morality, either through subject matter or utility. [172] These methods excluding immoral inventions by subject matter or utility standards however have already failed in the global community. [173] Even Bagley agrees with refuting scholars that a general statute has a benefit in flexibility for the USPTO, but also conflicting problems in arbitrary application and overbroad pronouncements, a problem faced currently in the EU with their Directive. [174] Further, she attests to the fact that because morality is a fluid concept any statute limiting moral patent eligibility provides an incomplete solution to those concerns. [175] Since this morality is a personal and subjective choice, some segment of the public, because of differing beliefs or standards will always believe some patents issued and research conducted is morally reprehensible. [176]

Furthermore, some scholars argue that using the patent system to exclude such controversial technologies from society would not prevent their development, because although profitability diminishes, patentability is not the only mechanism of promoting innovation. [177] For instance, a fact that even moral utility sympathizers do not dispute is that the academic sector that operates without a profit motive will continue to conduct research on such technologies. [178] If a practical application for a morally reprehensible technology is found, someone will put it to use as a tool without a patent, particularly if the technology may lead to the development of later arising inventions, such as a cure for cancer. [179] Contrary to Bagley's view, these scholars posit that removal of patent protection for a class of inventions might actually produce the opposite result. Without the limited monopoly granted by the patent law, everyone will be free to make and use a new invention without first obtaining a license from the patent holder. [180] Given these considerations, opponents of biotechnology should focus their efforts, not on altering the patent laws to stifle innovation, but on convincing Congress to pass legislation that would regulate the kinds of experiments scientists may perform, such as the recently repealed presidential directives on experimentation on existing stem cell lines. [181] Predictable is that reintroduction of a moral utility standard and its arbitrary application by the patent office is not the correct method of curtailing immoral inventions. [182]

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[169] DONALD S. CHISUM, CHISUM ON PATENTS § 4.03 (2002).
[170] *Id.* § 4.03, at ¶¶ 4-17.
[171] *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 865 (Fed. Cir. 1984).
[172] Bagley, *supra* note 11, at 541.
[173] *See infra* pp. 23-9.
[174] *See generally* Andrew Smith, Note, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159, 201 (2003) ("The simple charge to 'promote the Progress of Science and useful Arts . . . ' should not be sacrificed for the imposition of subjective moral determinations or on the basis of laws originating in the criminal code."); Bagley, *supra* note 11, at 545.
[175] *Id.*
[176] *Id.*
[177] Thomas Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 459 (1999).
[178] Bagley, *supra* note 11, at 509-10 ("In the absence of congressional action, researchers are essentially making patent policy and determining the limits of patent eligibility by the subject matter described in their applications.").
[179] *Id.*
[180] *Id.* at 460.
[181] *Id.*

To conclude, the US government already regulates morality. The president has issued executive orders and the legislature has deliberated on some of today's biggest ethical dilemmas. [183] The administrative armies of this supranational federal entity such as the FDA, USDA and FTC will continue to police this area. [184] Why then should the patent arena regulate morality? In some manner, Bagley seems to agree, "[t]he patent system cannot regulate morality, in whole or in part …" [185]

Patent registration promotes the useful Arts by incentivizing disclosure through granting a monopoly for limited times. Accordingly, inventions should be created regardless of if those inventions are good or bad, right or wrong, leaving the decision up to the public and the associated markets to further the technology. [186] If a moral utility requirement is reinstated, the USPTO will be forced to make decisions on moral grounds, surely leading to the demise of at least some of the technologies addressed in this paper. Consider for a moment, yourself as a patent examiner, which technologies would you reject on moral grounds? What if this technology, although immoral, could clean up the environment, like *Chakrabarty*'s bacteria, aid in the development of a test for adolescent or prenatal disease, or be the cure for cancer? However, you have no way of knowing at the patenting stage the downstream effects or slippery slope caused by your decision. Is it not therefore better to grant patentability to the invention and allow the market to decide?

Professor Bagley concedes that after patents have issued, the State through its legislative, judicial, executive or administrative branches no longer have the power to pull the strings and remove such subject matter from patent eligibility. [187] Advancements in science will ultimately solve this debate. Many researchers today believe that the key to diagnosing genetic disorders is not single gene markers, like BRCA1 and BRCA2, but multiple risk factors and interactions between those sequences. [188] A system of law that attempts to entangle moral concerns with patenting, similar to an entanglement between Church and State, will not provide the necessary structure and support to promote innovation. Furthermore, the beliefs of some of our history's most notable scientists, including Darwin, Galileo and even the head of the Human Genome Project, Dr. Francis Collins, have not been hindered, but rather aided by their individual scientific pursuits. [189] Science paves the path to the answers of life's questions. Therefore, we come full circle and conclude with the words of Thomas Jefferson, the father of the US patent system,

> "that ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man … Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may pursue utility, but this may or may not be done, according to the will and convenience of society, without claim or complaint from anybody...." [190]

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[182] Thomas Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 459-60 (1999).
[183] *Accord* Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (March 11, 2009); Human Cloning Prohibition Act of 2003, H.R. 18, 108th Cong. (1st Sess. 2003), *reprinted in* 2003 WL 550319 (2003); Human Cloning Prohibition Act of 2001, H.R. 170, 107th Cong. (1st Sess. 2001), *reprinted in* 2001 WL 847030 (2001); Human Cloning Prohibition Act of 2009, H.R. 1050, 111th Congress (1st Sess. 2009).
[184] *Id.*
[185] *Id.*
[186] *See* Andrew Smith, Note, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159, 196 ("Basing an invention's legal protection on societal considerations of morality or legislative determinations of the legality of its use strips from the scientific community any incentive to find legal or beneficial uses while at the same time decreasing our possible understanding of an entire field of innovation.").
[187] Bagley, *supra* note 11, at 508-9.
[188] *See* David Ewing Duncan, *supra* note 15, at 1. ("Already the notion that one gene marker can best determine a person's risk for a common disease is becoming outmoded. The latest science suggests that risk factors for maladies such as diabetes are increased by the interaction of dozens -- or even hundreds -- of genes and other molecular structures in the body.").
[189] FRANCIS S. COLLINS, THE LANGUAGE OF GOD: A SCIENTIST PRESENTS EVIDENCE FOR BELIEF 145-59 (Simon and Schuster, Inc. ed., 2006).
[190] Letter from Jefferson to Isaac McPherson, *supra* note 1.

The US must continue to patent for the moral instruction of man by encouraging men and women to pursue ideas, regardless of the moral debates that underlie those ideas. Let society then choose to reward those innovations that it feels is moral with profits, not have useful, patentable inventions faltered and sifted off by an arbitrary examiner at the patent stage. Strict separation from moral decision-making is the only way for the USPTO to promote the progress of modern science.

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