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Politicizing Patents - Patenting Biotechnology in the Wake of Section 33, Prometheus, and CLS Bank

Jonathan R. K. Stroud
American University Washington College of Law

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IS CONGRESS POLITICIZING PATENTS? PATENTING BIOTECHNOLOGY IN THE WAKE OF SECTION 33, *PROMETHEUS*, AND *CLS BANK*

Jonathan Stroud
AMERICAN UNIVERVISTY WASHINGTON COLLEGE OF LAW

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Jonathan Stroud, American University Washington College of Law

It is characteristic of the military mentality that nonhuman factors . . . are held essential, while the human being, his desires, and thoughts. . . are considered as unimportant and secondary . . . . The individual is degraded . . . to 'human material.'

– Albert Einstein

I. INTRODUCTION

For the first time, there is a statutory limitation on patentable subject matter in the United States.[1] The limitation is a late addition to the America Invents Act (AIA) of 2011.[2] It reads in pertinent part: "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[3] Pro-life advocates added it to the end of the AIA bill at § 33(a).

Section 101 of the Patent Act,[4] the foremost statute governing patent law, defines patentable subject matter as:

> 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 requirements of this title.[5]

The only previous exceptions to this broad grant of patentability were the judicially recognized exceptions of law of nature, natural phenomena, and abstract ideas.[6] The new exception took effect immediately following the Act's signing.[7]

By recognizing a vague subject-matter exception for human organisms despite the fact that internal policies had long militated against such patent claims, Congress has politicized the patent law to an unheard-of degree. While textually consistent with internal United States Patent and Trademark (USPTO) policy, the passage of § 33 should not be seen as an invitation to litigators to expand § 101 unpatentable subject-matter challenges to cover validity by including arguments that medical methods, genetic tests, biological chimeras, or emerging cell and tissue therapies are now unpatentable in light of recent Court decisions.

The express Congressional legislative purpose,[8] the history surrounding the section,[9] and preexisting and subsequent case law (particularly the *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,*[10] and *CLS Bank International v. Alice Corp.*[11] cases) serve to narrowly tailor the exception to only very rare circumstances, such as attempts to patent human clones or human offspring for unethical, unsafe, or unconstitutional purposes.[12]

POLICY RECOMMENDATIONS

The United States Patent and Trademark Office should:

- Work quickly to reinforce their longstanding narrow view of the human-subject-matter exception by issuing further memoranda, amending the MPEP, and maintaining that view in court;
- Ensure examination standards do not change by instituting training for the patent examination corps;
- Combat any overreaching use of § 33 in conjunction with related § 101 doctrines, such as the obviousness-plus-natural-law analysis applied in *Prometheus*, by issuing guidance to all PTAB judges to narrowly construe § 33.

This Article shows that the statutory ban on the issuance of patents encompassing human organisms merely codified the longstanding policy of both the courts and the USPTO to deny patentability of claims that encompass an entire human being. It did not limit the preexisting scope of patentable subject matter, and therefore should not disturb longstanding precedent, procedure, or practice. The USPTO should act quickly to quash any suggestion otherwise, and issue guidance to its Patent Trial and Appeal Board (PTAB)[13] to maintain the longstanding limited application of the exception. Further, administrative law principles require courts to exercise *Auer* deference to the USPTO's informed reading. Consequently, litigators, legislators, and the courts should not attempt to expand the scope of § 33 as broader evidence of patent invalidity. Finally, the USPTO should train examiners to narrowly apply § 33 to avoid blocking innovation, to preserve patent rights, and to accurately reflect Congressional intent.

Part I gives a brief background on the case law surrounding the patentability of living things, and analyzes the political history of the Weldon Amendment, *Prometheus*, and *CLS Bank*. Part II analyzes § 33 and discusses different approaches to implementation. Part III makes recommendations based on administrative law principles, arguing that § 33 should be narrowly construed to avoid blocking necessary innovation and keeping patent examination nonpolitical and scientifically based.

A. A Brief History of Living Subject Matter

I. *Diamond v. Chakabarty* – Living Subject Matter is Patentable

The founding fathers recognized the value of a patent system and charged Congress, in the text of the Constitution, "[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[14] The First Congress responded almost immediately by passing the Patent Act, holding that "[w]hoever 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 requirements of this title."[15] Thus, the broad grant was limited prospectively only by a few judicially recognized exceptions, namely laws of nature, natural phenomena, and abstract ideas.[16]

Prior to the growth of the biotechnology industry in the 1970s,[17] the question of the patentability of living subject matter was little explored. In 1873, the USPTO issued the first widely recognized American patent for a living thing to Louis Pasteur for purified yeast, defining it as an article of manufacture under § 101.[18] Similarly, in the nineteenth century, the United States and manufacturers developed and used viral vaccines and antitoxins, on which patents issued. There was never any serious question concerning its patentability.[19] However, with the growth of the biotechnology industry in the 1970s following the development of recombinant DNA techniques,[20] as well as the rise in cultural relevance of both dystopian genetic engineering, science fiction,[21] and the abortion rights debate,[22] the Supreme Court was forced to confront whether man could generally patent living subject matter.

In 1980, the Court answered by ruling in *Diamond v. Chakrabarty* that bioengineered living organisms are patentable subject matter.[23] The Court held that bacteria engineered to be beneficial in cleaning up oil spills was altered enough that it deserved patent protection.[24]

II. The Quigg Memo and Longstanding USPTO Policy

Following the *Chakrabarty* decision, the United States Patent and Trademark Office (USPTO) wrestled with the question of the patentability of other emerging forms of biotechnology. In 1987, the USPTO circulated the "Quigg Memo," stating that: "The Patent and Trademark Office now considers nonnaturally occurring *non-human* multicellular living *organisms*, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101 . . . *A claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 USC 101*."[25] It based its reasoning, in part, on the 13th Amendment ban on slavery,[26] and may have been a reaction to the attempted patenting of human embryos.[27] Furthermore, the Quigg Memo states that any claim directed to "a non-plant multicellular organism which would include a human being within its scope include the limitation 'nonhuman' to avoid this ground of rejection."[28] Federal Courts upheld the Quigg Memo as a valid exercise of the USPTO's statutory authority under administrative law principles.[29]

The USPTO's longstanding policy has been to reject patents only for claims clearly involving "entire" or "complete" human beings; it has largely granted patents on living tissue, genetically modified cells, and other emerging forms of biotechnology. For instance, the USPTO has long held that isolated human genes — segments of human genes that have

been excised, with non-important parts spliced out, and then isolated in the laboratory—are patentable,[30] and thousands of gene isolation patents have issued over the years.[31] Likewise, the USPTO has issued patents on surgical techniques[32] and autologous heart valves,[33] and may soon receive patent applications on complete, genetically-modified human organs.[34]

The USPTO policy is also contained in an "official media advisory" issued on April 2, 1998 in response to negative news coverage concerning a patent application directed to a human/non-human chimera. There, the USPTO claimed that patent "*inventions directed to human/non-human chimera could*, under certain circumstances*, not be patentable* because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement."[35] This is fascinating, as it is the first time the USPTO relied on morality or public policy to dictate the boundaries of patentable subject matter.

The USPTO policy is now contained in the Manual of Patent Examining Procedure (MPEP) § 2105 under the heading "Patentable Subject Matter." The MPEP states that the USPTO:

> "would now consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. *If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter*."[36]

The USPTO, however, is supposed to be morally neutral on the merits of the patents it issues,[37] as it is merely implementing the technical requirements of the patent statutes.[38] Thus, the only limits on patentability are those that are Constitutional,[39] statutory,[40] or judicially imposed.[41]

III. The Weldon Amendment

Historically, Congress has considered legislation banning a variety of subject matter, from patentability of business method patents[42] to patentability of surgical and other medical procedure patents.[43] The American Bar Association's Intellectual Property Section, among others, has long-counseled against any form of limitation on patentability and argued against each one of these proposed exceptions.[44]

In the past, conservative activists have tried and failed to amend the patent law to expressly exclude the patentability of human life.[45] Perhaps as a compromise or an alternative way to get such an amendment passed, in 2004, then-Representative David Weldon proposed a different kind of amendment—to the appropriations bill—that would prevent funding the USPTO if it issued any patents directed to or "encompassing" a living human via the appropriations process.[46] In effect, the USPTO was allowed to issue such a patent, despite their policy against doing so; they simply could not use agency funds to issue said patent.

According to Representative Weldon's remarks, the language of his funding ban precludes only the patenting of full human organisms at a stage of development, and did not expand the scope or severity of the USPTO's longstanding practice denying such patents on moral grounds.[47] Further, the limitation was not intended to conflict whatsoever with a § 101 patentability analysis.[48] Thus, by this limited logic, practitioners could simply avoid it by including the word "nonhuman" in any questionable claim.

The American Bar Association's Intellectual Property Section convened a Special Committee to assess the funding ban,[49] and came out vigorously against it. In contrast, in a letter to the Congress from then-USPTO Director and Bush appointee James Rogan, the USPTO endorsed the amendment primarily because it indicated that it did not "alter the longstanding" USPTO policy on the unpatentability of full human life forms.

IV. Section 33 – Patenting Humans

Section 33 of the Leahy-Smith America Invents Act (AIA) reads in pertinent part: "Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[50]

It had immediate effect and applies to all applications still pending on the date of passage of the AIA,[51] but includes a saving provision indicating that it "shall not affect the validity of any patent issued on an application" not pending on, or filed after, the date in question.[52]

Thus, it will not take effect until the patents currently pending or yet to be applied-for are subject to examination, reexamination, post-grant review, *inter parties* review, eventual litigation, and/or appeals. It *does* immediately affect Patent Examiners' patentability analyses on Requests for Continued Examination, divisionals, and continuations, as the text indicates it applies to all applications "pending" on the date of passage.

The legislative history of § 33 narrowly cabins its application.[53] The Congressional Record includes Representative Weldon's many speeches from 2003 stating that his amendment "simply reaffirms current U.S. patent policy," that it "would not interfere in any way with any existing patents with respect to stem cells," that it would "not forbid funding research on embryonic stem cells, because a human embryo is an 'organism' but a stem cell clearly is not," and, most importantly, it quoted a letter stating that the USPTO "viewed the Weldon amendment as fully consistent with USPTO's policy on the non-patentabiliy of human life-forms."[54]

In nearly immediate response to the passage of the AIA and § 33, Acting Associate Commissioner for Patent Examination Policy Robert W. Bahr issued a memorandum to the USPTO Patent Examining Corps (Bahr memo).[55] In it, he indicated that § 33 "of the Leahy–Smith America Invents Act does not change existing law or long-standing PTO policy that a claim encompassing a human being is not patentable . . . Thus, § 33(a) of the Leahy-Smith America Invents Act codifies existing PTO policy,"[56] similar to the exact language of the original Quigg Memo, which was upheld by the Federal Circuit in 1991 as a valid exercise of the PTO's authority.[57]

That longstanding policy is found at MPEP § 2105, which states that: "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter."[58] Additionally, the Bahr memo and MPEP suggest a form paragraph that examiners use in rejecting such a claim, invoking § 33(a) as the basis for the rejection as "directed to or encompassing a human organism."[59]

Thus, the legislative history, the Bahr memo, and the MPEP purport to cabin the scope of § 33's codification of the Weldon Amendment's codification to just that: the longstanding USPTO position that entire human beings are unpatentable, but that § 33 would not affect any other related patents, such as heart valves, tissue engineering, bioengineered organisms, or somatic stem cell treatments.[60]

II. THE PROBLEM: REINVIGORATING SECTION 101 JURISPRUDENCE

Excluding only "complete human beings" would thus support the validity of all cellular-level biotechnology patents. Examples of long-patented tissue-engineered devices include heart valves, skin grafts, bioengineered artery or vein replacements,[61] hair follicles,[62] human blood protein therapies like synthetic erythropoietin, and perhaps, in the near future, entire tissue-engineered replacement organs.[63]

Problematically, the pace of biotechnology has outgrown our limited understanding of the difference between human and nonhuman cellular creations. For instance, patents have long issued on autologous heart valves that have been removed from patients, chemically preserved and strengthened through a process called crosslinking, and reimplanted in other patients (thus extending those patients' lives by years).[64] In another example, Amgen has long patented Epogen—synthetic human erythropoietin, a key blood component.[65]

Recently, with the discovery and creation of the first-ever artificial life form, a cell constructed entirely from tiny DNA building-blocks,[66] new questions of patentability are emerging faster than an already-gridlocked Congress and USPTO can deal with. Thus, it is in the best interest of Congress, the general public, and the patent-holders in this country to necessarily view § 101 as a "coarse filter" generally unaffected by § 33.

Some scholars have argued that the Weldon amendment, and thus § 33 as well, preclude the patentability of human/animal chimeras.[67] While this is technically correct—some legislative history evidences the Office's intent to prevent the patenting of fully realized human/animal hybrids—the argument misconstrues the scope of the term "chimera," which encompasses many valuable experimental cell and tissue technologies.

Additionally, the use of the term "chimera" risks a play to emotion, evokes science fiction horror stories, and obfuscates the real issue: preventing Constitutional abuse of the patent system while ensuring innovation and broad patent protection for important technological industries.[68]

The agency's decision to regulate menu labeling in such a broad manner was controversial. Following the publication of the rule, several members of Congress wrote letters to FDA urging it to adopt the alternative, which narrowed the range of establishments regulated.[69] The House Agricultural Appropriations Subcommittee also weighed in with report language expressing concerns over the rule.[70]

Several months before the rule was published, President Obama issued Executive Order 13563, which reiterated the principles of Executive Order 12866 stating that each agency must: (1) issue regulations only upon a reasoned determination that the benefits justify the costs; (2) tailor regulations to impose the least burden on society; and (3) select approaches that maximize net benefits. The Administration has been called upon to ensure these principles are applied to the menu labeling rule.[71]

The supermarket industry has estimated that food retailers face a greater than $1 billion regulatory burden in the first year of compliance with the proposed rule, and hundreds of millions of dollars annually thereafter.[72] The implications of whether the FDA has authority to regulate supermarkets as restaurants are immense. The manner in which the Administration enforces Executive Order 13563 has similarly high stakes.

III. THE SOLUTION: DEPOLITICIZING PATENTS

A. The Agency Continues to Have No Substantive Authority After AIA

As noted recently in the *Administrative Law Review* by Professor James Miller, the USPTO, as an Office tasked only with the procedural requirements of implementing examination procedures, lacks the substantive authority to issue binding substantive rules.[73] Courts agree: in the string of cases known popularly as the *Tafas*[74] decisions, the federal courts struck down a promulgated rule package as outside of the Office's substantive authority.[75] Normally, a federal agency would receive *Chevron* deference for its construction of a statute governing the substance of its mission, so-called because of the famous *Chevron v. NRDC*[76] decision. Yet, courts have held the USPTO has no substantive rulemaking authority and thus they deserve no *Chevron* deference whatsoever.[77]

B. *Auer* Deference Should Apply to Internally Consistent Interpretations

However, in another seminal administrative law case, *Auer v. Robbins*,[78] the Supreme Court established that when an agency is reviewing its own promulgated regulations, courts should grant it greater deference than even *Chevron*.[79] In evaluating an agency's interpretation, the courts will apply a deferential "plainly erroneous or inconsistent with the regulations" standard unless the regulation is plain on its face.[80] Scholars analyzed empirical evidence of reversal rates based on the type of administrative deference courts apply, and determined that only *Auer* deference is truly more deferential than other standards.[81]

Here, we have a reverse-parroting issue: the statute adopted the identical language that has been contained in informal USPTO practice manuals and procedures for years.[82] While the language of the statute on its face is ambiguous (what constitutes "comprising," for instance?) the regulatory history is abundantly clear. *Auer* made no mention of an agency's substantive rulemaking authority—and here, no greater substantive authority is needed to invoke *Auer*. Indeed, by adopting the USPTO's own interpretation into statute, Congress has given that interpretation regulatory authority and life of its own.

C. Any New Form of Technology Unanticipated by the Weldon Amendment Should Survive Its Application

Perhaps decisively, the Federal Circuit upheld *that very interpretation* in 1991 as within the USPTO's substantive authority, calling it "interpretive."[83] If that seems tautological, it is; the PTO should be free to interpret the statute as consistent with its prior interpretation. There is no reason to think that *Auer* deference would not apply to the USPTO's *interpretation* of *its own longstanding interpretation*, particularly one that has been so carefully limited in the legislative history, the original memo, the Weldon amendment, the MPEP, and in the text of § 33 itself. Thus, *Auer* deference should apply and the Court should defer to the agency's view that § 33 does not apply to technologies like cellular and tissue engineering, autologous implants, transplants, and other forms of modified human tissue.[84]

When the Quigg Memo issued in 1988, it purported to explain the USPTO's application of *Diamond v. Chakabarty*.[85] The Weldon amendment, in turn, only suggested it was codifying the Quigg Memo and longstanding USPTO policy. In turn, §

33 simply adopted into statute the USPTO's own longstanding policy. Thus, to construe it, as the agency has in their most recent memo,[86] they look *to their own preexisting regulations*. The memo reads: "This provision of the Leahy–Smith America Invents Act does not change existing law or long-standing PTO policy that a claim encompassing a human being is not patentable . . . Thus, section 33(a) of the Leahy-Smith America Invents Act codifies existing PTO policy."[87] That longstanding policy is found at MPEP § 2105, which states that: "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter." Thus, *Auer* deference is appropriate. It would likewise be appropriate to any training materials, memoranda, or guidance the USPTO would issue governing § 33's application and scope. Thus, it serves to reinforce the policy directive that the USPTO should issue guidance, memoranda, and training to the PTAB judges and the Examination Corps, and amend the MPEP to reflect this narrow view.

D. Prometheus Applies Very Limitedly to Manifestly Abstract Ideas, Not Statutory Exceptions

In *Prometheus,* the unanimous Court found that a diagnostic method patent dealing with the pharmacokinetic relationship between blood and drugs was invalid under § 101 because it "set forth mere laws of nature."[88] It held that even patents that *apply* so-called natural laws using known processes are invalid.[89] Thus, the Supreme Court endorsed a "law-of-nature-plus-obviousness" test for patentable subject matter, where any mathematical equation or natural relationship (regardless of novelty) that is applied using an obvious methodology is invalid under § 101.[90]

The Court agreed with the argument that if it allows patent protection over the body's natural response to drugs, then "the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care."[91] Thus, petitioners believed a "future preemption" argument had emerged, and have begun to argue this to the Federal Circuit.[92]

The Federal Circuit, however, responded with force in *CLS Bank*.[93] In the first § 101 case decided since *Prometheus*, a divided Federal Circuit panel rejected any limits to their prior precedent from the Supreme Court's § 101 approach.[94] Judge Linn, writing for the majority, applied a newfound standard, holding that "when . . . it is not *manifestly evident* that a claim is directed to a patent ineligible abstract idea" a § 101 challenge fails.[95] He went on to add that "[u]nless the *single most reasonable understanding* is that a claim is directed to *nothing more than* a fundamental truth or disembodied concept, with no limitations in the claim attaching that idea to a specific application," a claim will survive a § 101 challenge.[96]

Applying the "manifestly evident" standard reinforces limiting the expansion of § 33 beyond the limitations introduced in the legislative history, the USPTO's interpretations, and the USPTO's history of utilizing the Weldon amendment and the Quigg Memo.

A hybrid natural-law-plus-obviousness analysis post-*Prometheus*[97] should not be possible in conjunction with an express statutory exception. The Federal Circuit foreclosed such a reading in *CLS Bank.*[98] In the future, litigants and appellees may try to argue that when claims encompassing part of a human body are modified by obvious methodology, they are therefore unpatentable after *Prometheus*. This would conflate *Prometheus'* natural-law-plus-obvious analysis with an unduly broad reading of § 33 and should be avoided.

Patents to genetic isolation methods; patents directed to the pharmacokinetic relationship between the body; and drugs, surgical techniques, and autologous implants extracted from the human body, modified, and transplanted to another, should all be exempt from § 33's reach. Accordingly, the USPTO should institute Examiner training, amend MPEP guidance, and memoranda to the PTAB and the Examination Corps reinforcing this view. Only then can the true Congressional purpose be realized and can proper deference be granted to the longstanding USPTO policy, which has merely been codified into statute.

IV. CONCLUSION

The USPTO should provide clear, express guidance to both examiners and PTAB judges in an attempt to keep the first statutory exemption for patentable subject matter appropriately narrow. It should use guidance, internal memoranda, training sessions, policy meetings, and dialogue with the federal courts and outside stakeholders to combat any attempted overreach of § 33 in conjunction with other related § 101 doctrines, such as the obviousness-plus-natural-law analysis found in *Prometheus*. Lastly, it should amend the MPEP accordingly. This will ensure innovation, certainty, and profitability in the lucrative and promising area of biotechnology, guaranteeing that the United States remains competitive in the international market. It is not the province of the Patent and Trademark Office, or patent law, to become embroiled in a political conflict that is irrelevant to innovation.

ABOUT THE AUTHOR

Jonathan Stroud is a candidate for Juris Doctor at the American University Washington College of Law (expected 2013). He is currently a Summer Associate at the law firm Finnegan, Henderson, Farabow, Garrett & Dunner LLP. From 2007 to 2012, he acted as a Patent Examiner at the United States Patent and Trademark Office. He would like to thank Aaron Gleaton and Viki Economides for their helpful edits, brainstorming support, and excellent suggestions.

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[1] America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 288 (2011).
[2] *Id.*
[3] *Id.* at § 33, 125 Stat. at 331.
[4] 35 U. S. C. §101 (2012).
[5] *Id.*
[6] As many judicial opinions on 35 U.S.C. § 101 challenges lay out, the broad grant of patentability is subject to the "implicit exception[s]" of "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U. S. 175, 185 (1981); *Diamond v. Chakrabarty*, 447 U. S. 303, 309 (1980). In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Court recently referred to the oft-cited examples of "a new mineral discovered in the earth," a "new plant found in the wild," Einstein's celebrated $E=mc^2$ equation, and Newton's law of gravity. 132 S. Ct. 1289, 1291 (2012). The famous quote is that these are "manifestations of . . . nature, free to all men and reserved exclusively to none." *Chakrabarty*, 447 U.S. at 309 (quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U. S. 127, 130 (1948)).
[7] AIA § 33, 125 Stat. at 331.
[8] *See infra*, Part II.B.
[9] *See infra*, Part I.C.
[10] 132 S. Ct. 1289 (2012).
[11] No. 2011-1301 (Fed. Cir. July 9, 2012).
[12] *See* U.S. CONST., Am. XIII (banning human slavery—i.e., the ownership of property rights over a human organism).
[13] The Board of Patent Appeals and Inferences (BPAI) will be renamed the Patent Trial Appeals Board (PTAB) on September 16, 2012; and all appeals, post grant reviews, derivation proceedings, and other trial-like proceedings will go to the PTAB, thus expanding the adjudicative authority and reach of the USPTO. *See* AIA, 35 U.S.C. § 134 (2012).
[14] U.S. CONST. Art. I, § 8, cl. 8.
[15] 35 U.S.C. § 101 (2012).
[16] *See supra*, note 2 and accompanying text; *see also Diamond v. Diehr*, 450 U. S. 175, 185 (1981); *Parker v. Flook*, 437 U. S. 584, 590 (1978); *Gottschalk v. Benson*, 409 U. S. 63, 67 (1972) (widely considered the "patentability" trilogy, recognizing that an "application" of any of these exceptions would survive patentability).
[17] *See* Jonathan Stroud, Comment, *The Illusion of Interchangeability: The Benefits and Dangers of Guidance-Plus Rulemaking in the FDA's Biosimilar Approval Process*, 63 ADMIN. L. REV. 599, 612 (2011).
[18] *See Diamond v. Chakabarty***,** 447 U.S. 303, 305 n.9 (1980).
19 JONATHAN LIEBENAU, MEDICAL SCIENCE AND MEDICAL INDUSTRY: THE FORMATION OF THE AMERICAN PHARMACEUTICAL INDUSTRY 3–5, 11 (1987) (discussing antitoxins); *see Singla*, *infra* note 48, at 31 (discussing early smallpox vaccinations).
[20] *See supra*, note 15 and accompanying text.
[21] *See e.g.*, ORSON SCOTT CARD, ENDER'S GAME (1977); PHILLIP K. DICK, UBIK (1969); ALDOUS HUXLEY, BRAVE NEW WORLD (1931).
[22] *See e.g.*, *Roe v. Wade*, 410 U.S. 113 (1973).
[23] 447 U.S. 303, 310 (1980) (stating that the ability of man resulted in bacteria with "markedly different characteristics" and the "potential for significant utility").
[24] *Id.*
[25] *Animals – Patentability*, *1077 Off. Gaz. Pat. Office 24* (April 24, 1987) (emphasis added) (*Quigg Memo)*.
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *See Animal Legal Def. Fund v. Quigg*, 710 F. Supp. 728 (N.D.Cal. 1989), *affirmed* 932 F.2d 920, 927 (Fed. Cir. 1991).
[30] *See e.g.,* 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (stating the longstanding policy).
[31] *See Myriad I*, 653 F.3d at 1355 ("It is estimated that the PTO has issued 2,645 patents claiming 'isolated DNA' over the past twenty-nine years, and that by 2005, had granted 40,000 DNA-related patents covering, in non-native form, twenty percent of the genes in the human genome." [internal citations omitted]); *id.* at 1367 (Moore, J., concurring) ("[T]here are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof.").
[32] *See e.g.*, U.S. PATENT NO. 5,735,278 (Apr. 7, 1998) ("surgical technique with magnetic resonance imaging").
[33] U.S. PATENT NO. 6,830,585 (Dec. 14, 2004) ("percutaneously deliverable autologous tissue heart valve and methods of implantation")**.**
[34] Notably, during the oral arguments in the *Myriad* case remand, the judges question whether a transplanted kidney could be patentable under certain standards. *See* Stephen F. Badylak, Doris Taylor & Korkut Uygun, *Whole-Organ Tissue Engineering: Decellularization and Recellularization of Three-Dimensional Matrix Scaffolds*, 13 ANN. REV. BIOMEDICAL ENGINEERING 27 (2010).
[35] U.S. PATENT & TRADEMARK OFFICE, PTO OFFICIAL MEDIA ADVISORY (April 2, 1988).
[36] MANUAL OF PATENT EXAMINATION PROCEDURE (MPEP) (2012).
[37] *See e.g.*, Timothy R. Holbrook, *The Expressive Impact of Patents*, 84 WASH. U. L.R. 573, 606–08, 615–16 (2006) (finding that the USPTO is intended to be morally blind, and although it sometimes makes moral judgments, a truly neutral approach is probably the best policy).
[38] 35 U.S.C. § 1(a) (2012) ("The United States Patent and Trademark Office is established as an agency of the United States, within the Department of Commerce. *In carrying out its functions, the United States Patent and Trademark Office shall be subject to the policy direction of the Secretary of Commerce*, but otherwise shall retain responsibility for decisions

regarding the management and administration of its operations and shall exercise independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions . . . ." (emphasis added)).

[39] U.S. CONST. Art. I, § 8, cl. 8.

[40] 35 U.S.C. 101 (2012).

[41] *See supra*, note 3 and accompanying text.

[42] Business Method Patent Improvement Act of 2001, H.R. 1332, 107th Cong. (failed passage in the Senate). The Act updates the Business Method Patent Improvement Act of 2000, H.R. 5364, 107th Cong. (2001) (same). For an example of a business method patent, *see e.g.*, U.S. Patent No. 5,806,048 (issued Sept. 8, 1998) (claiming an "open end mutual fund securitization process").

[43] Biotech Process Patent Protection Act of 1995, Pub. L. No. 104-41 (codified at 35 U.S.C. §§ 103, 282 (2003)).

[44] *See* AM. BAR ASSOC. INTELL. PROP. SECTION, SPECIAL COMMITTEE ON THE WELDON AMENTMENT TO H.R. 2799, THE APPROPRIATION BILL FOR THE DEPARTMENTS OF COMMERCE, JUSTICE, STATE AND THE JUDICIARY (1993).

[45] *See e.g.,* the Transgenic Animal Patent Reform Act, H.R. 4970, 100th Cong. (1988). Under that amendment, § 101 would have read: "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 therefore, subject to the conditions and requirements of this title, *except that human beings are not patentable subject matter.*" *Id.* (emphasis added).

[46] Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101 (2004).

[47] 149 CONG. REC. H1397 at 1398 (daily ed. Feb. 27, 2003) (statement of Rep. Weldon).

[48] *Accord* Ryan Hagglund, *Patentability of Human-Animal Chimeras,* SANTA CLARA COMP. & HIGH TECH. L.J. 51, 52 (2009) ("Despite Congress's apparent attempt to foreclose the patentability of human inventions using its appropriations power, analysis of the patent law and the Weldon Amendment and its legislative history indicates that Congress did not intend to create a conflict with § 101's broad scope of patentable subject matter when it enacted the Weldon Amendment. Thus, a court would likely hold that the Amendment did not completely foreclose patentability of human inventions.").

[49] *See* AM. BAR ASSOC. INTELL. PROP. SECTION, SPECIAL COMMITTEE ON THE WELDON AMENTMENT TO H.R. 2799, THE APPROPRIATION BILL FOR THE DEPARTMENTS OF COMMERCE, JUSTICE, STATE AND THE JUDICIARY (1993), *available at* http://apps.americanbar.org/intelprop/summer2004/spec_comm.pdf..

[50] The Leahy-Smith America Invents Act § 33(a), H Pub. L. No. 112-29, 125 *Stat.* 288, 293 (2011).

[51] § 33(b)(1) ("IN GENERAL—Subsection (a) shall apply to any application for patent that is pending on, or field on or after, the date of the enactment of this Act.").

[52] § 33(b)(2).

[53] *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. Bar J. 435, 510–513 (2012).

[54] 157 Cong. Rec. E1177–80, 78 (daily ed. June 23, 2011).

[55] Memorandum from Robert W. Bahr, Senior Patent Counsel and Acting Associate Comm'r for Patent Examination Policy, U.S. Patent & Trademark Office, to Patent Examining Corps (Sept. 20, 2011) (on file with author).

[56] *Id.*

[57] *See infra*, footnote 29 and accompanying text.

[58] U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINATION PROCEDURE § 2105 (2012).

[59] Additionally, the form paragraph reads:

7.04.01 *Human Organism*

Claim [1] is rejected under 35 U.S.C. 101 and section 33(a) of the America Invents Act as being directed to or encompassing a human organism. *See also Animals –Patentability*, 1077 *Off. Gaz. Pat. Office* 24 (April 24, 1987) (indicating that human organisms are excluded from the scope of patentable subject matter under 35 U.S.C. 101).

Id.

[60] Representative Lamar Smith, in particular, provided very specific enumeration in the record of the types of subject matter the ban will *not* apply to:

1. any chemical compound or composition, whether obtained from animals or human beings or produced synthetically, and whether identical to or distinct from a chemical structure as found in an animal or human being, including but not limited to nucleic acids, polypeptides, proteins, antibodies and hormones;

2. cells, tissue, organs or other bodily components produced through human intervention, whether obtained from animals, human beings, or other sources; including but not limited to stem cells, stem cell derived tissues, stem cell lines, and viable synthetic organs;

3. methods for creating, modifying, or treating human organisms, including but not limited to methods for creating embryos through in vitro fertilization, methods of somatic cell nuclear transfer, medical or genetic therapies, methods for enhancing fertility, and methods for implanting embryos;

4. a nonhuman organism incorporating one or more genes taken from a human organism, including but not limited to a transgenic plant or animal, or animal models used for scientific research.

157 Cong. Rec. E1177–80 (daily ed. June 23, 2011).

[61] *See e.g.*, U.S. Patent No. 7,112,218 (Sept. 26, 2006) ("Tissue engineered blood vessels and apparatus for their manufacture").

[62] *See e.g.*, U.S. PATENT APP. NO. 2005/0214344 ("Tissue engineered biomimetic hair follicle graft").

[63] *See e.g.,* Stephen F. Badylak, Doris Taylor, & Korkut Uygun, *Whole-Organ Tissue Engineering: Decellularization and Recellularization of Three-Dimensional Matrix Scaffolds*, 13 ANN. REV. BIOMEDICAL ENGINEERING 27 (2010).

[64] *See e.g.*, U.S. PATENT NO. 6,830,585 (Dec. 14, 2004) (percutaneously deliverable autologous tissue heart valve and methods of implantation).

[65] *See* MERRILL GOOZNER, THE $800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS 16–29 (2004) (describing the growth of Amgen and the discovery and marketing of Epogen—artificial erythropoietin). It is unclear if a purely synthetic *substitute*—i.e., a protein therapy derived from nonhuman sources but identical to human material—would fall under the aegis of § 33).
[66] *See* Ian Sample, *Craig Venter Creates Synthetic Life Form*, THE GUARDIAN (May 20, 2010 12.42 EDT) http://www.guardian.co.uk/science/2010/may/20/craig-venter-synthetic-life-form (building the genome of a single-celled bacterium from scratch, and thus completely authoring a synthetic life form).
[67] *See* Hagglund, *supra*, note 67 at 52.
[68] *See id*. Mr. Hagglund argues that research on human embryos is morally wrong, chimera research may lead to needless human suffering, and it may result in "potential deformities" "with regard to chimeras that have enough human genetic material or characteristics to qualify as human." Mr. Hagglund's list continues, suggesting, without support, that "[t]hese chimeras would receive heightened legal rights and protections," and that scientists could "compel a chimera that was predominately human, such as a xenotransplant recipient, to involuntarily act as a research subject." He continues, citing religious objections "to synthesis of chimeras" as "new types of animals" that "should only be the province of God" and lastly, that chimeras "denigrate[] humanity by commingling human and animal organisms." *Id.* at 56. While these ethical-shock arguments have unfortunately driven the scientific debate and limited funding and profitability of certain forms of research, this is precisely not the province of the USPTO, as an agency without substantive rulemaking authority. The USPTO is blind to policy concerns, being without the authority to make substantive policy. Ironically, the grant of a patent actually serves to diminish the availability of a technology, allowing the patentee to exclude others from making or using it. *See* 66 Fed. Reg. 1092, 1093–94 (Jan. 5, 2001) ("Patents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor's legal right to exclude other people from making, using, offering for sale, selling, or importing."). Thus, Mr.Hagglund's argument misses the point.
[69] *See* Letter from Rep. Robert Latta, et al., to Commissioner Margaret Hamburg (July 26, 2011); *see also* Letter from Sen. Jerry Moran, et al., to Margaret Hamburg (July 25, 2011).
[70] H.R. Rep. No. 112-101 at 53 (2011).
[71] Letter from the Food Marketing Institute to Hon. Cass R. Sunstein (Nov. 21, 2011), http://www.fmi.org/docs/newsletters-comments/omb-menu-labeling---omb-review-pursuant-to-executive-order-12866-and-13563.pdf?sfvrsn=2 (last visited June 21, 2012).
[72] FMI Comments to FDA on Proposed Menu Labeling Rule (July 5, 2011). http://www.fmi.org/docs/newsletters-comments/fda-proposed-menu-labeling-rule-%28fda-2011-f-0172%29.pdf?sfvrsn=2 (last visited June 21, 2012).
[73] James Miller, *Substance, Procedure, and the Divided Patent Power,* 63 ADMIN. L. REV. 31 (2010).
[74] *Tafas v. Dudas* (*Tafas I*), 541 F. Supp. 2d 805 (E.D. Va. 2008); *Tafas v. Doll* (*Tafas II*), 559 F.3d 1345 (Fed. Cir. 2009).
[75] *Id.*
[76] *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984) (creating the infamous *Chevron* two-step test for deference to an agency's interpretation of its own governing statutes).
[77] *Id.*
[78] 519 U.S. 452 (1997),
[79] *Chevron*, 467 U.S. at 837.
[80] *Id.* at 461–63 (1997).
[81] *See* Richard J. Pierce, *What Do the Studies of Judicial Review of Agency Actions Mean?*, 63 ADMIN. L. REV. 77 (2011).
[82] 157 Cong. Rec. E 1183 (daily ed. June 23, 2011) (citing U.S. PATENT & TRADEMARK OFFICE MANUAL OF PATENT EXAMINING AND PROCEDURE (MPEP) § 2105 (ed. 8 rev. 8 2010)).
[83] *Animal Legal Def. Fund v. Quigg*, 710 F. Supp. 728 (N.D.Cal. 1989), *transferred by* 900 F.2d 195 (9th Cir. 1990), *affirmed* 932 F.2d 920, 927 (Fed. Cir. 1991) ("The genesis and effect of the Notice demonstrates that it represents no change in the law effected by the Commissioner and that, in reality, it is merely 'interpretative' of prior decisional precedent.").
[84] *See infra*, notes 33, 74 and accompanying text; MPEP § 2105 (encouraging decisions on a case-by-case basis). The USPTO, by allowing thousands of patents on isolated genes, heart valves, cellular engineering, and crosslinked tissue, signaled that these technologies are patentable.
[85] *Animals – Patentability*, 1077 OFF. GZ. PAT. OFFICE 24 (April 21, 1987) (emphasis added) (*Quigg Memo).*
[86] Memorandum from Robert W. Bahr, Senior Patent Counsel and Acting Associate Comm'r for Patent Examination Policy, U.S. Patent & Trademark Office, to Patent Examining Corps (Sept. 20, 2011) (on file with author).
[87] *Id.*
[88] *Id.*
[89] *Prometheus*, 132 S.Ct. at 1297.
[90] *Id.*; *accord* Dennis Crouch, *Mayo v. Prometheus: Natural Process + Known Elements = Normally No Patent*, PATENTLY-O.COM (May 20, 2012) http://www.patentlyo.com/patent/2012/ 03/mayo-v-prometheus-natural-process-known-elements-normally-no-patent.htm (suggesting broadly that the *Prometheus* test invalidates any naturally occurring processes coupled with known processes, and is a blow to the biotechnology industry).
[91] *Id.* (quotation and citation omitted).
[92] Supplemental Brief for Appellees at 3, *Assoc. for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. June 15, 2012) ("It is clear that patents on 'isolated' DNA that claim laws and products of nature impermissibly foreclose future scientific work and innovation.").
[93] No. 2011-1301 (Fed. Cir. July 9, 2012).
[94] *Id.*

[95] *Id.* slip op. at *20 (emphasis added).
[96] *Id.* slip op. at *21 (emphases added).
[97] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).
[98] No. 2011-1301, slip op. at *20–*21 (Fed. Cir. July 9, 2012).