ON PATENTING HUMAN ORGANISMS OR HOW THE ABORTION WARS FEED INTO THE OWNERSHIP FALLACY

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The idea of ominous technologies that put human individuals or parts of their bodies under someone else's control has been stirring emotions and terrifying people for centuries. It was a recent offshoot of this idea—the notion of "patenting humans"—that mobilized certain members of Congress to pass legislation prohibiting the issuance of patent claims "directed to or encompassing a human organism." The values underlying this legislation may well have been agreeable, even admirable. Yet, the actual motivation for it was misguided; its execution, deeply flawed; its potential outcomes, hazardous.

This Article reviews the history and background of this prohibition. It fleshes out the prohibition's numerous flaws, including, primarily, the lack of an agreed-upon definition of "human organism." It explains why the perception that humans could be patented is part of what the Article labels as the "Ownership Fallacy," which is founded on a misunderstanding of patent laws. The Article further discusses why the prohibition on the patenting of inventions "directed to or encompassing a human organism"—while unnecessary and unlikely to achieve its purpose—poses a danger to technological innovation, especially in the area of biomedical technology. The Article then discusses ways of minimizing the potential negative ramifications of the prohibition by construing it narrowly. Finally, the Article calls for the repeal and substitution of the prohibition on the patenting of inventions "directed to or encompassing a human organism" with a scientifically-informed legislative effort aimed at expanding the boundaries of the concepts of slavery and involuntary servitude.

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INTRODUCTION

What is "human?"

Who is "human?"

Lying at the heart of one of the most hotly debated public policy battles to have ever been fought in this country, these ageless questions are as perplexing today as they have ever been. It is therefore puzzling that some of the participants in this debate chose patent law—arguably, one of the least suitable areas for policy wars of this sort—as their battleground. The benefits of this decision are questionable or, at the very least, unclear; the potential harm, far-reaching.

After seven years of legislative efforts, on September 8, 2011, Congress passed the Leahy-Smith America Invents Act (AIA),[1] the most significant patent legislation since the Patent Act of 1952.[2] Yet, at the last minute,[3] the AIA bill was appended with a provision dictating that "[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[4] Enumerated as Section No. 33 of the AIA, the language of the new provision was taken from an earlier provision added to annual consolidated appropriations bills between 2004 and 2011, which was known as the Weldon Amendment.[5] The Weldon Amendment dictated that "[n]one of the funds appropriated or otherwise made available under this [appropriations] Act may be used to issue patents on claims directed to or encompassing a human organism."[6] Crucially, however, neither Section 33 nor the Weldon Amendment defines what may be regarded as "directed to or encompassing a human organism." To make things worse, not only do their respective legislative histories not fill this gap, but they also are riddled with internal contradictions, ad hoc exceptions

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1 Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 15 U.S.C., 28 U.S.C., 35 U.S.C.).

2 *See* JOHN R. THOMAS, CONG. RESEARCH SERV., R42014, THE LEAHY-SMITH AMERICA INVENTS ACT: INNOVATION ISSUES 1 (2014), *available at* http://fas.org/sgp/crs/misc/R42014.pdf ("[T]he [America Invents Act] arguably made the most significant changes to the U.S. patent statute since the 19th century . . . ."); Dan L. Burk, *Patent Reform in the United States: Lessons Learned*, REG., Winter 2012–2013, at 20 ("After seven years of controversy and debate, on September 16, 2011, President Obama signed into law the first major revision of American patent law in nearly 60 years.").

3 *See* 157 CONG. REC. E1177, E1177 (daily ed. June 23, 2011) (speech of Rep. Christopher H. Smith) (commending inclusion of the amendment as "a provision that will codify an existing pro-life policy rider").

4 Leahy-Smith America Invents Act § 33(a).

5 *See infra* Part I.B.

6 Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3 (2004); *see infra* notes 44–46 and accompanying text.

and, generally, a lack of any coherent guiding principle. With no meaningful, coherent guidance on the meaning of Section 33, resolving the mighty questions of what and who is a "human organism" is left, inevitably, to United States Patent and Trademark Office (USPTO) employees and, eventually, the courts. The consequences of this conundrum are yet to unfold, but as one delves into the language of Section 33, its many pitfalls become increasingly apparent while its benefits are cast in questionable light.

Like the Weldon Amendment, Section 33 is based on what I will refer to as the "Ownership Fallacy"—a misunderstanding of patent law that is based on the misperception that patents convey affirmative property rights in their underlying inventions[7]—that undercuts its justification. In adding Section 33 to the AIA bill, its sponsors sought to achieve pro-life objectives similar to those of the Weldon Amendment.[8] However, this Article argues that Section 33 misses the mark on these stated objectives and is likely to lead to unexpected consequences that might deviate from—and even run counter to—the intent of its sponsors and the goals of patent law. Exploring the background and history of Section 33, this Article further argues that Section 33 is redundant in light of existing laws and represents a missed opportunity to set meaningful policy on the moral standing[9] of beings possessing advanced mental faculties. Ultimately, this Article shows how the intended meaning of Section 33, its actual meaning, its purpose, and its potential consequences are four different things, divorced from each other.

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7 *See infra* notes 71, 75 and accompanying text.

8 *See* 157 CONG. REC. E1177, E1177 (daily ed. June 23, 2011) (speech of Rep. Christopher H. Smith) (describing the amendment to the AIA bill, "commonly known as the Weldon amendment" as designed to "codify an existing pro-life policy rider included in the CJS Appropriations bill since FY2004"). Notably, as part of the discussion of the proposal to include Section 33 in the America Invents Act bill, the sponsors of Section 33 also submitted into the Congressional Record a letter from the Family Research Council (FRC), a lobbying organization, which is set to advance and advocate for "pro-life" positions. *See* 157 CONG. REC. E1182, E1184–85 (daily ed. June 23, 2011) (letter from FRCAction, the Family Research Council, regarding the Weldon Amendment), *available at* http://www.gpo.gov/fdsys/pkg/CREC-2011-06-23/pdf/CREC-2011-06-23-pt1-PgE1182.pdf. For further discussion of the pro-life goal underlying the Weldon Amendment and Section 33, see *infra* notes 115–16 and accompanying text.

9 According to the STANFORD ENCYCLOPEDIA OF PHILOSOPHY:

> An entity has moral status [a.k.a. "moral standing"] if and only if it or its interests morally matter to some degree for the entity's own sake, such that it can be wronged. For instance, an animal may be said to have moral status if its suffering is at least somewhat morally bad, on account of this animal itself and regardless of the consequences for other beings, and acting unjustifiably against its interests is not only wrong, but wrongs the animal. Others owe it to the animal to avoid acting in this way.

Agnieszka Jaworska & Julie Tannenbaum, *The Grounds of Moral Status*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., 2013), *available at* http://plato.stanford.edu/archives/sum2013/entries/grounds-moral-status.

Part I of this Article reviews the historical background and scientific developments that led to the legislation of AIA Section 33. Part II discusses the plethora of problems with which Section 33 is riddled, including its being premised on the Ownership Fallacy; its inherent irreconcilable ambiguities; the numerous bioethical issues implicated by its language and legislative history; and its redundancy in light of other laws. It ends with a call to repeal Section 33 and suggests a more constructive (though, admittedly, unlikely) direction for future legislation seeking to advance Section 33's underlying values. Part III provides recommendations on how to construe Section 33 so as to minimize its potentially dire consequences. Building on the earlier discussion, Part IV illustrates how Congress could have benefitted from unbiased, reliable scientific advice prior to enacting Section 33.[10] Part V concludes this Article.

I. THE BACKGROUND AND LEGISLATIVE HISTORY OF SECTION 33

A. *From* Diamond v. Chakrabarty *to the Weldon Amendment*

To understand the origins of Section 33, it is necessary to venture back to the early 1970s, to the origins of the famous Supreme Court case, *Diamond v. Chakrabarty*.[11] In 1972, a microbiologist named Ananda Chakrabarty filed a patent application directed to a human-made, genetically-engineered, non-naturally occurring bacterium, which was capable of breaking down crude oil.[12] Despite the bacterium's clear benefits, the USPTO rejected Chakrabarty's claims on the bacterium under the "product of nature" doctrine[13] and held that, as living things, bacteria are not patentable.[14] On appeal, the Court of Customs and Patent Appeals overturned the USPTO's rejections and ruled that the fact that microorganisms are alive is without legal significance for purposes of patentability.[15] The Supreme Court granted certiorari to address the issue of patentability of living things and did so

10 It has been argued that Congress has been suffering from a lack of unbiased scientific advice ever since it defunded its own Office of Technology Assessment in 1995. *See* Chris Mooney, *Requiem for an Office*, 61 BULL. ATOMIC SCIENTISTS 40 (2005); M. Granger Morgan, Editorial, *Death by Congressional Ignorance*, PITTSBURGH POST-GAZETTE, Aug. 2, 1995, at A11; Letter from "Ninety Diverse Organizations" to House Representatives (May 7, 2010), *available at* http://www.ucsusa.org/assets/documents/scientific_integrity/OTA-sign-on-letter-1.pdf.

11 Diamond v. Chakrabarty, 447 U.S. 303 (1980).

12 *Id.* at 305.

13 Under the product of nature doctrine, "in order for a product of nature to [be patent-eligible] it must be qualitatively different from the product occurring in nature, with markedly different characteristics from any found in nature." *See infra* note 155 and accompanying text.

14 *Chakrabarty*, 447 U.S. at 306.

15 *Id.*

while applying a rather formalistic approach. It construed the language of 35 U.S.C. § 101 and reached the conclusion that Chakrabarty's microorganisms could fall under either or both "manufacture" and "composition of matter" categories of things that are patentable.[16] The Supreme Court explained:

> The Committee Reports accompanying the 1952 [Patent] Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." . . . [T]he patentee has produced a new bacterium with *markedly different characteristics from any found in nature* and one having *the potential for significant utility*. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.[17]

In the aftermath of *Chakrabarty*, the USPTO received numerous patent applications that required applying the *Chakrabarty* ruling to multi-cellular organisms, including animals.[18] Subsequently, in 1987, the USPTO issued the following policy statement:

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16 *Id.* at 309–10 ("[R]espondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" (alteration in original) (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887))); *cf.* 35 U.S.C. § 101 (2012) ("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.").

17 *Chakrabarty*, 447 U.S. at 309–10 (emphases added) (quoting S. REP. NO. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 82-1923, at 6 (1952)). 35 U.S.C. § 101 lists categories of inventions that, categorically, may be the subject of a patent and that are cumulatively known as "patentable subject matter." *See* 35 U.S.C. § 101 ("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."). The term "patentable subject matter" is also synonymous with "patent-eligible subject matter" and "subject matter eligible." Notably, over the years, the Supreme Court has carved out of "patentable subject matter" certain categories of things that, categorically, may not be patented: natural phenomena, laws of nature, and abstract ideas. *See* Diamond v. Diehr, 450 U.S. 175, 185 (1981) ("This Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas."). Things falling under these categories are thus synonymously referred to as "non-patentable subject matter," "non-patent eligible subject matter," "non-eligible patent subject matter," etc. In addition, the terminology of patent subject matter eligibility is to be further distinguished from the issue of patentability, which has to do with the compliance of inventions with the formal and substantive requirements of the Patent Act, such as novelty, non-obviousness, enablement, written description, and definiteness, etc. *See* 35 U.S.C. §§ 102, 103, 112. To clarify, to become the subject of a patent, an invention must be of patent-eligible subject matter as well as patentable; many inventions, however, while falling squarely within what is considered as patentable subject matter are nonetheless unpatentable for non-compliance with one or more of the Patent Act's formal and substantive requirements. *See id.*

18 *See In re* Allen, No. 87-1393, 1988 WL 23321 (Fed. Cir. Mar. 14, 1988) (holding that a polyploid oyster may be proper subject of a patent under 35 U.S.C. § 101 if all other criteria for patentability are satisfied).

> A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection.[19]

As indicated by the 1987 USPTO Policy, the exclusion of human beings from the scope of patentable subject matter—i.e., from what categorically may be the subject of a patent—in the 1987 USPTO Policy was not rooted in the Supreme Court's *Chakrabarty* decision. Rather, its reference to a prohibition under the Constitution was an allusion to the Thirteenth Amendment's prohibition on slavery and involuntary servitude.[20] Hence, the 1987 USPTO Policy immediately became the topic of much controversy, drawing support for what some saw as the USPTO's brave moral stance, while others criticized as lacking legal grounding.[21]

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19 Notice: Animals – Patentability, 1077 Off. Gaz. Pat. & Trademark Office 24 (Apr. 7, 1987) [hereinafter 1987 USPTO Policy], *available at* http://www.uspto.gov/web/offices/com/sol/og/2010/week52/TOCCN/item-120.htm.

The 1987 USPTO Policy has since become an integral part of the Manual of Patent Examining Procedure (MPEP), according to which:

> [Further to the 1987 Statement, 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.

U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (9th ed. Mar. 2014) [hereinafter MPEP]. In another place, the USPTO further explained that "[t]he current policy of the USPTO is to consider any claim encompassing a human being at any stage of development, not to be patent eligible subject matter under 35 U.S.C. 101." Karen Hauda, U.S. Patent & Trademark Office, Address to the President's Council on Bioethics (June 20, 2002) (transcript available at http://biotech.law.lsu.edu/research/pbc/transcripts/jun02/june21session5.html) (describing implementation of the 1987 USPTO Policy under MPEP § 2105 and explaining what the USPTO does *not* consider as falling under the label of "human being"); *see also* 157 CONG. REC. E1182, E1185 (daily ed. June 23, 2011) (discussing the codification of the Weldon Amendment into patent reform legislation).

20 *See* Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1647 (1993); Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y 247, 251–52 (2000) [hereinafter *Mice and Men*]. The reference to the Constitution in and of itself was also the subject of significant critique. *See Mice and Men*, *supra*.

21 *See Mice and Men*, *supra* note 20, at 251–52 (arguing that the 1987 USPTO Policy was at odds with the Patent Act as interpreted by the Supreme Court in *Chakrabarty* and that, although the USPTO may be of a different opinion with respect to the patentability of human beings, its opinion does not have the force of law); Andrew R. Smith, Comment, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159, 181 (2003); Jasemine Chambers, Note, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy Is Public Policy?*, 34

Following the publication of the 1987 USPTO Policy, in order to allow Congress to address the issue of patentability of living organisms, the USPTO declared an eight-month self-imposed moratorium on granting patents on animals.[22] Several bills were introduced that sought to address this issue, but none of them became law.[23] Some attempts were also made to prevent the USPTO from applying its 1987 Policy. In *Animal Legal Defense Fund v. Quigg*, for instance, the plaintiffs argued that in issuing the 1987 USPTO Policy the USPTO had not complied with the requirements of the Administrative Procedure Act (APA), and that in announcing the Policy the Commissioner of Patents exceeded his authority under the Patent Act.[24] The Federal Circuit, while rejecting the claim, did hold that the 1987 USPTO Policy was only *mostly* consistent with *Chakrabarty*, "with the only caveat being the statement that section 101 does not extend to humans."[25] This judicial characterization of the 1987 USPTO policy as inconsistent with *Chakrabarty* later played a role in the legislative effort that culminated in the enactment of Section 33.[26]

After the lapse of the eight-month moratorium on the patenting of multicellular organisms, in April 1988, the USPTO granted its first

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GEO. WASH. INT'L L. REV. 223, 231 (2002); *see also* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1357 (Fed. Cir. 2012) (Bryson, J., concurring in part and dissenting in part) ("[A]s we have recognized, the PTO lacks substantive rulemaking authority as to issues such as patentability. . . . In areas of patent scope, we owe deference only commensurate with 'the thoroughness of its consideration and the validity of its reasoning.'" (citation omitted) (quoting Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996))), *cert. granted in part*, 133 S. Ct. 694 (2012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); Kara W. Swanson, *Patents, Politics and Abortion*, *in* INTELLECTUAL PROPERTY LAW IN CONTEXT: LAW AND SOCIETY PERSPECTIVES ON IP (William T. Gallagher & Debora J. Halbert eds., forthcoming) (arguing that the perception of the USPTO as an apolitical actor in the abortion wars is incorrect and that "[t]he patent office has always been engaged in politics in its daily acts of granting and denying patent applications, creating power hierarchies by each action").

22 *Legislation: Bill on Animal Patenting Is Approved by House Panel*, 36 PAT. TRADEMARK & COPYRIGHT J. 271 (1988), *available at* 1988 WL 423661 ("At the request of Representative Kastenmeier, however, the USPTO agreed to a voluntary eight-month moratorium on animal patenting. Upon the expiration of that moratorium, on April 12 of this year . . .").

23 The most prominent of these bills, the Transgenic Animal Patent Reform Act, was passed on a vote by the House in September 1988, but never made it to the Senate. *See* 134 CONG. REC. H7436 (daily ed. Sept. 13, 1988); *see also* Hugo A. Delevie, *Animal Patenting: Probing the Limits of U.S. Patent Laws*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 492, 500–05 (1992) (describing legislative efforts to restrict patent rights in animals); Hauda, *supra* note 19 (describing legislative efforts aimed at curtailing the ability to patent human beings); *Legislation: House Passes Patent Legislation Bill*, 36 PAT. TRADEMARK & COPYRIGHT J. 485 (1988).

24 Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 922 (Fed. Cir. 1991).

25 *Id.* at 928 (footnote omitted).

26 According to former Rep. Dave Weldon, "My amendment simply restates [the USPTO 1987] policy, providing congressional support so that federal courts will not invalidate the USPTO policy as going beyond the policy of Congress (as they invalidated the earlier USPTO policy against patenting living organisms in general [in *Animal Legal Defense Fund v. Quigg*])." 157 CONG. REC. E1177, E1179 (daily ed. June 23, 2011) (Nov. 5, 2003 speech of Rep. Dave Weldon, submitted into record).

patent on a mammal for what came to be known as the "Harvard Oncogenic Mouse."[27] Since then, the USPTO has granted many other patents claiming living organisms, including mammals.[28] Since the announcement of the USPTO Policy in 1987, there has apparently been only one instance—involving two related patent applications—in which the USPTO expressly rejected an application for violating its 1987 Policy.[29]

In December 1997, in a naked attempt to elicit a legislative reaction that would prohibit the patenting of all living organisms, especially humans, self-described "anti-biotech activists" filed U.S. Patent Application No. 08/993,564 ('564 Application) entitled "Chimeric Embryos and Animals Containing Human Cells."[30] The '564 Application claimed human-animal chimeric embryos[31] made from human and animal embryos, including human-mouse (humouse), human-baboon, human-domestic pig, and human-chimpanzee (humanzee) embryos.[32] The USPTO, while refusing to publicly address the '564 Application as such (as it was not yet published at that time), responded with a media advisory entitled "Facts on Patenting Life

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27 U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988). The "Harvard Mouse" patent claimed mammals that incorporated a gene which made them extremely prone to developing cancer, so that exposure to any cancer-causing compound (carcinogen) would likely cause them to develop a tumor. *See id.* These animals have since been extensively used in research.

28 *See, e.g.*, U.S. Patent No. 8,076,531 (filed Nov. 25, 2009) (issued Dec. 13, 2011) (claiming transgenic nonhuman animals—including such mammals as primates, ungulates, canines and felines—genetically modified to include certain nucleic sequences); U.S. Patent No. 8,022,268 (filed June 11, 2008) (issued Sept. 20, 2011) (claiming transgenic mice whose genome was modified so that the mice would serve as an Alzheimer's disease model).

29 *See* U.S. Patent Application No. 08/993,564 (filed Dec. 18, 1997) and U.S. Patent Application No. 10/308,135 (filed Dec. 3, 2002), published as Publication No. 2003/0079240, at A-1 (published Apr. 24, 2003). *See, e.g.*, USPTO, Patent Application Information Retrieval, http://portal.uspto.gov/pair/PublicPair (select "Application Number" under "Search for Application: Choose type of number"; then search "08/993,564"; then click "Image File Wrapper" tab) (last visited Sept. 21, 2014).

30 *See* Specification at 1, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Dec. 18, 1997), Image File Wrapper No. 6; *see also* Burk, *supra* note 20, at 1633–42 (recounting the debate regarding the patentability of higher organisms); Aaron Zitner, *Patently Provoking a Debate*, L.A. TIMES, May 12, 2002, at A1; Dashka Slater, *huMouse™*, LEGAL AFF., Nov./Dec. 2002, http://www.legalaffairs.org/issues/November-December-2002/feature_slater_novdec2002.msp.

31 The specification of the '564 Application defined chimeric embryos as "embryos derived from cells whose origin is in two different species, or in two different strains or genotypes of a single species." Specification, *supra* note 30.

In Greek mythology, a chimera is a creature composed of parts of different animals. This term is usually used in biological sciences to describe an organism or a cell culture that is composed of cells originating from two or more different organisms, usually members of the same species. Unlike the transgenic technologies—which involve implantation of genes from one organism into another, not necessarily belonging to the same species—creation of chimeras involves the clumping together of whole cells from the organisms of origin. *See infra* note 93 and accompanying text.

32 Specification, *supra* note 30, at 18–21; *see also* Eliot Marshall, *Legal Fight over Patents on Life*, 284 SCIENCE 2067 (1999).

Forms Having a Relationship to Humans," in which it made the following statement:

> [T]he existence of a patent application directed to human/non-human chimera has recently been discussed in the news media. It is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, *they would fail to meet the public policy and morality aspects of the utility requirement*.[33]

Surprisingly, rather than reiterating its position from the 1987 USPTO Policy that human beings are not patentable subject matter—i.e., that they are categorically excluded from being the subject of a patent—the USPTO resorted to an old (and, by then, almost extinct) patent law doctrine known as the moral utility doctrine.[34] Eventually, during the examination of the '564 Application, this was only one of many grounds for which the USPTO rejected the '564 Application claims.[35] Among these grounds was also the USPTO's assertion of its 1987 Policy, according to which the claims of the '564 Application covered subject matter that was not patent eligible.[36] The USPTO reasoned:

> While the PTO recognizes that the scope of protection covered by 35 U.S.C. 101 is expansive and the fact that a claimed invention which embraces a human being is not within one of the exclusions enumerated by the Supreme Court in *Chakrabarty* . . . the PTO believes that Congress did not intend 35 U.S.C. 101 to include the patenting of human beings. . . . For more than 10 years the PTO has consistently taken the position that a claim directed to or including within its scope a human being is not considered to be patentable subject matter under 35 U.S.C. 101 . . . . Since applicant's claimed

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33 *See* Press Release, U.S. Patent & Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998) [hereinafter 1998 USPTO Media Advisory] (emphasis added), *available at* http://www.uspto.gov/web/offices/com/speeches/98-06.htm.

34 *See infra* Part II.E.4.

35 Notably, all or some of the claims of the '564 Application were also rejected for lack of enablement and for indefiniteness under 35 U.S.C. § 112, as well as for being anticipated by and obvious in view of numerous prior art references under 35 U.S.C. §§ 102(b) and 103(a). *See* Non-Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Patrick J. Coyne, Esq. at 3–14, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Mar. 18, 1999), Image File Wrapper. No. 25 [hereinafter Non-Final Rejection 3/18/99]; *see also* Non-Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Collier Shannon Scott, PLLC at 27–29, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Jan. 29, 2003), Image File Wrapper. No. 65 [hereinafter Non-Final Rejection 1/29/03] (citing the *Lowell v. Lewis* moral utility doctrine).

36 According to the USPTO, "the broadest reasonable interpretation of the claimed invention [of the '564 Application] as a whole embrace[d] a human being . . . [which] falls outside the scope of protection under 35 U.S.C. 101." Non-Final Rejection 3/18/99, *supra* note 35, at 2.

> invention embraces a human being, it is not considered to be patentable subject matter under 35 U.S.C. 101.[37]

The applicants responded by amending the '564 Application's claims and attempting to counter the USPTO's rejections, including by arguing that "the claimed subject matter is not a human being but rather, man-made chimeric cell lines, embryos and animals developing from them" and that they "claim[ed] a chimeric embryo, a cell line, or animal derived from a chimeric embryo [while a] human being is not claimed."[38] The USPTO, however, maintained its rejections throughout the examination of the '564 Application and a continuation of that application.[39] Eventually, the '564 Application and its continuation

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37 *Id.* at 2–3.

38 Supplemental Response at 4, U.S. Patent Application No. 08/993,564, No. 45010-00601 (June 19, 2002), Image File Wrapper No. 62; *see also* Applicant's Response to Office Action, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Feb. 9, 2004), Image File Wrapper No. 115; Applicant's Supplemental Amended Arguments and Remarks, U.S. Patent Application No. 08/993,564, No. 45010-00601 (June 5, 2003), Image File Wrapper No. 73; Applicant's Amended Arguments and Remarks, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Apr. 29, 2003), Image File Wrapper. No. 70; Applicant's Amended Arguments and Remarks, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Feb. 7, 2001), Image File Wrapper No. 56; Applicant's Amended Arguments and Remarks, U.S. Patent Application No. 08/993,564, No. 45010-00601 (May 1, 2000), Image File Wrapper No. 40; Declarations of Tim Karr and Scott Gilbert in Support, U.S. Patent Application No. 08/993,564, No. 45010-00601 (June 28, 1999), Image File Wrapper No. 35; Applicant's Preliminary Amended Arguments and Remarks, U.S. Patent Application No. 08/993,564, No. 45010-00601 (June 16, 1999), Image File Wrapper No. 31 [hereinafter Preliminary Amended Arguments and Remarks 6/16/99].

39 *See* Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Rothwell, Figg, Ernst, & Manbeck P.C., U.S. Patent Application No. 08/993,564, No. 45010-00601 (Aug. 2, 2004), Image File Wrapper No. 129; Non-Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Rothwell, Figg, Ernst, & Manbeck P.C., U.S. Patent Application No. 08/993,564, No. 45010-00601 (Oct. 7, 2003), Image File Wrapper No. 113; Non-Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Collier Shannon Scott, PLLC, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Jan. 29, 2003), Image File Wrapper No. 65; Non-Final Rejection Letter from Deborah J.R. Clark, Patent Exam'r, U.S. Patent & Trademark Office, to Patrick J. Coyne, Esq., U.S. Patent Application No. 08/993,564, No. 45010-00601 (Aug. 7, 2000), Image File Wrapper No. 50; Final Rejection Letter from Deborah J.R. Clark, Patent Exam'r, U.S. Patent & Trademark Office, to Patrick J. Coyne, Esq., U.S. Patent Application No. 08/993,564, No. 45010-00601 (Oct. 29, 1999), Image File Wrapper No. 36 [hereinafter Final Rejection 10/29/99].

On December 3, 2002, the applicants of the '564 Application filed U.S. Patent Application No. 10/308,135 ('135 Application) as a divisional application from the '564 Application. The '135 Application claimed similar subject matter, namely: chimeric human-nonhuman animal embryos, cell lines and fully developed animals thereof, and descendants of such fully developed animals. The USPTO rejected the '135 Application claims on essentially the same grounds as those raised during the examination of the '564 Application, including its being directed to non-patentable subject matter under 35 U.S.C. § 101 due to claiming a "human being." *See* Non-Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Collier Shannon Scott, PLLC, U.S. Patent Application No. 10/308,135 (filed Dec. 3, 2002), No. 45010-00601 (Mar. 5, 2003), Image File Wrapper No. 17. As with the '564 Application, the USPTO maintained its rejections, despite amendments and responses by the applicants. *See* Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Rothwell, Figg, Ernst, & Manbeck P.C., U.S. Patent Application No. 10/308,135, No. 45010-00601

application were both abandoned in early 2005, never to be pursued further.[40]

The '564 Application was media fodder for a while.[41] Ultimately, however, it seems to have failed to convince policymakers of the moral hazards supposedly posed by allowing the issuance of patent claims covering living organisms as argued by the '564 applicants.[42] It took a few more years for the issue of patenting of humans to be picked up from where it was left off by the anti-biotech movement.

B. *The Weldon Amendment*

The 1990s and early 2000s were marked by several attempts by the federal government to restrict the use of certain biomedical technologies that were ethically controversial.[43] As part of this trend, in 2004, for the

(Aug. 11, 2004), Image File Wrapper No. 34; Non-Final Rejection Letter from Deborah Crouch, Primary Exam'r, U.S. Patent & Trademark Office, to Rothwell, Figg, Ernst, & Manbeck P.C., U.S. Patent Application No. 10/308,135, No. 45010-00601 (Oct. 7, 2003), Image File Wrapper No. 30; *see also* Applicant's Amended Arguments and Remarks, U.S. Patent Application No. 10/308,135, No. 45010-00601 (Feb. 9, 2004), Image File Wrapper No. 32; Applicant's Amended Arguments and Remarks, U.S. Patent Application No. 10/308,135, No. 45010-00601 (June 5, 2003), Image File Wrapper No. 24; Applicant's Preliminary Amended Arguments and Remarks, U.S. Patent Application No. 10/308,135, No. 45010-00601 (Mar. 28, 2003), Image File Wrapper No. 22.

40 *See* Notice of Abandonment, U.S. Patent Application No. 08/993,564, No. 45010-00601 (Mar. 2, 2005), Image File Wrapper No. 134; Notice of Abandonment, U.S. Patent Application No. 10/308,135, No. 45010-00601 (Mar. 2, 2005), Image File Wrapper No. 38 (duplicate of Notice of Abandonment for '564 application).

41 *See, e.g.*, Slater, *supra* note 30; Zitner, *supra* note 30.

42 Evidently, the '564 Application failed to instigate any legislative or regulatory action by Congress and the USPTO.

43 *See, e.g.*, 148 CONG. REC. S5545, S5556 (daily ed. June 13, 2002), *available at* http://www.gpo.gov/fdsys/pkg/CREC-2002-06-13/pdf/CREC-2002-06-13-pt1-PgS5545-2.pdf (proposing prohibition of patenting "(A) an organism of the human species at any stage of development produced by any [asexual reproductive] method, whether in vitro or in vivo, including the zygote, embryo, fetus, child or adult; (B) a living organism made by human cloning; or (C) a process of human cloning"); Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings from William J. Clinton, President of the U.S., to Heads of Executive Department and Agencies (Mar. 4, 1997), *available at* http://www.presidency.ucsb.edu/ws/?pid=53818 (President Clinton's directive banning the use of federal funding for the purpose of cloning); Press Release, The White House, President Discusses Stem Cell Research (Aug. 9, 2001), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html (announcing the withholding of federal funding for research involving stem cell lines created subsequent to Aug. 9, 2001); Statement on Federal Funding of Research on Human Embryos from William J. Clinton, President of the U.S. (Dec. 2, 1994), *available at* http://www.presidency.ucsb.edu/ws/?pid=49545 (stating that federal funds should not "be used to support the creation of human embryos for research purposes" and directing that "NIH not allocate any resources for such research"); *see also* Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007) (a bill seeking to prohibit the patenting of human genetic sequences); Cynthia M. Ho, *Do Patents Promote the Progress of Justice? Reflections on Varied Visions of Justice*, 36 LOY. U. CHI. L.J. 469, 474 n.15 (2005) [hereinafter *Visions of Justice*] (describing the failed attempt to enact the Unpatentability of Human Organisms amendment introduced by former Sen. Sam Brownback).

first time ever, Congress restricted the USPTO's ability to grant patents on ethical grounds in what came to be known as the "Weldon Amendment." Named after its sponsor, former Rep. Dave Weldon (R-FL), the Weldon Amendment was first passed as part of the Consolidated Appropriations Act of 2004.[44] It read:

> None of the funds appropriated or otherwise made available under this [appropriations] Act may be used to issue patents on *claims directed to or encompassing a human organism*.[45]

From 2004 through the enactment of Section 33 in September 2011, the Weldon Amendment was kept in force either via express attachment to appropriations acts or through implicit adoptions by continuing appropriations acts.[46]

As is evident from its language and context, the Weldon Amendment did not directly ban the issuance of patents on "human organisms." Rather, it sought to back the 1987 USPTO Policy by "restricting funds for issuing patents on human embryos, human organisms."[47] The primary motivation for the enactment of the Weldon Amendment was its sponsors' view that an explicit Congressional show of support of the 1987 USPTO Policy was necessary to prevent its being overruled by a court.[48] The sponsors of the Weldon Amendment were wary of what they viewed as the possibility that without Congressional "backing" of the 1987 USPTO Policy, a court might overturn that Policy

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44 Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3 (2004).

45 *Id.* (emphasis added).

46 Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, § 518, 123 Stat. 3034 (2009); Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 518, 123 Stat. 524; Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, § 520, 121 Stat. 1844 (2007); Science, State, Justice, Commerce, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-108, § 623, 119 Stat. 2290 (2005); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, § 626, 118 Stat. 2809 (2004).

47 157 CONG. REC. E1177, E1178 (daily ed. June 23, 2011) (July 22, 2003 speech of Rep. Dave Weldon, submitted into record).

48 *See supra* note 26 and accompanying text. In enacting the Weldon Amendment, Congress specifically referred to the fact that a previous USPTO policy against patenting living organisms was "invalidated by the U.S. Supreme Court in 1980, on the grounds that the policy has no explicit support from Congress." 157 CONG. REC. E1177, E1180 (daily ed. June 23, 2011) (Dec. 8, 2003 speech of Rep. Dave Weldon, submitted into record). Notably, in another place, former Rep. Weldon described the Weldon Amendment as follows: "My amendment simply restates [the USPTO's] policy, providing congressional support so that federal courts will not invalidate the USPTO policy as going beyond the policy of Congress (as they invalidated the earlier USPTO policy against patenting living organisms in general)." *Id.* at E1179 (Nov. 5, 2003 speech of Rep. Dave Weldon, submitted into record). This statement appears to reflect a misunderstanding of both the concept of legislative intent and its role in statutory construction; not only are courts not bound by legislative intent, clear as it may be, but they are also not committed to take under advisement the positions of later Congresses on a particular issue that was the subject of legislation by earlier Congresses. *See infra* note 90. Hence, the positions of Congresses passing the Weldon Amendment on the issue of patentability of a human organism were, arguably, irrelevant to the issue of statutory patentable subject matter under Section 101 of the Patent Act.

in much the same way that the *Chakrabarty* court overruled the USPTO's policy of not allowing patent claims directed to living organisms.[49] Specifically, the sponsors of the Weldon Amendment were under the impression that industry advocates such as the Biotechnology Industry Organization (BIO) believed that humans should be patentable and would seek to challenge the USPTO 1987 Policy in court.[50]

A question remains, however, regarding the timing of the Weldon Amendment. Namely, even if one is to accept the validity of the factual and legal assertions of the sponsors of the Weldon Amendment, it is not clear what prompted their legislative action almost twelve years after the Federal Circuit's 1991 decision in *Animal Legal Defense Fund v. Quigg* and twenty-four years after *Chakrabarty*. An explanation is found in an address given by Rep. Weldon before the House of Representatives on July 22, 2003:

> Several weeks ago, at a meeting of the European Society of Human Reproduction and Embryology in Madrid, Spain, it was reported that scientists had created the first male-female hybrid human embryos.[51] The researchers transplanted cells from male embryos into female embryos and allowed them to grow for 6 days. . . . Furthermore, the scientists who created these she-male embryos reportedly want to patent this research.
>
> It is important that we, as a civilized society, draw the line where some rogue scientists fail to exercise restraint. Just because something can be done does not mean that it should be done. A patent on such human organisms would last for 20 years. We should not allow such researchers to gain financially by granting them an exclusive right to practice such ghoulish research.[52]

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49 157 CONG. REC. E1177, E1179 (daily ed. June 23, 2011) (Nov. 5, 2003 speech of Rep. Dave Weldon, submitted into record).

50 *Id.*

51 Embryo hybrids are embryos comprised of cells originating from more than one embryo, which were fused together earlier in the embryo formation process and were left to develop as a single embryo. *See* 157 CONG. REC. E1182, E1184 (daily ed. June 23, 2011) (explaining what is included in the "human organism" under the Weldon Amendment); *see also* 157 CONG. REC. E1177, E1178 (daily ed. June 23, 2011) (citing to Rep. Dave Weldon's July 22, 2003 speech regarding House Amendment 286 (H. Admt. 286) to clarify the intent of the provisions). Former Rep. Weldon apparently referred to research conducted by Dr. Norbert Gleicher and Dr. Ya Xu Tang as reported in their abstract published subsequent to the 19th Annual Meeting of the European Society of Human Reproduction and Embryology. *See* Norbert Gleicher & Ya Xu Tang, *Blastomere Transplantation as a Possible Treatment*, 18 HUM. REPROD. (SUPPL. 1) xviii57 (2003) [hereinafter Gleicher & Tang 2003]. This research was also the subject of a later article published by Dr. Gleicher and Dr. Tang. *See* Norbert Gleicher & Ya Xu Tang, *Blastomere Transplantation in Human Embryos May Be a Treatment for Single Gene Diseases*, 81 FERTILITY & STERILITY 977 (2004) [hereinafter Gleicher & Tang 2004].

52 157 CONG. REC. E1177, E1178 (citing to Rep. Dave Weldon's July 22, 2003 speech regarding H. Admt. 286 to clarify the intent of the provision).

Evidently, outrage at what former Rep. Weldon and others viewed as unethical scientific research played a crucial role in prompting the legislative efforts that eventually led to the enactment of the Weldon Amendment.[53]

Inflated (and inflammatory) media reports aside,[54] the research to which former Rep. Weldon apparently referred—which was conducted by Dr. Norbert Gleicher and Dr. Ya Xu Tang—was intended to serve as proof of concept of a potentially novel medical treatment technique for genetic diseases via implantation of healthy embryonic cells in another genetically-compromised embryo.[55] Also, by the time the Gleicher and Tang research was published in 2003, it was not even the first to attempt assembling human embryonic cells from different embryos into one embryo and allowing the "hybrid" embryo to develop into a blastocyst.[56] It thus seems that the only "fault" of the Gleicher and Tang research—and, in all likelihood, the reason that it received the kind of media attention that ultimately brought it to the attention of former Rep. Weldon—was the fact that it involved the mixing of embryonic cells of *different genders* rather than a more mundane genetic difference.[57] The use of the term "she-male," with all its numerous connotations and allusions,[58] in the public discourse also did not serve to promote an

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53 *See also* Rick Weiss, *Mixed-Sex Embryos Raise Ethical, Oversight Concerns*, CHI. TRIB., July 3, 2003, at 11.

54 *See, e.g.*, David Derbyshire, *Test-tube 'Monster' Condemned by Scientists*, TELEGRAPH, July 3, 2003, http://www.telegraph.co.uk/science/science-news/3310044/Test-tube-monster-condemned-by-scientists.html; Ian Sample, *Scientists Hit out at Creator of 'She-males'*, GUARDIAN, July 2, 2003, http://www.theguardian.com/science/2003/jul/03/genetics.sciencenews; *Creation of Human 'She-Males' Sparks Outrage*, REUTERS, July 2, 2003.

55 *See* Gleicher & Tang 2004, *supra* note 51, at 977–78 ("Blastomere transplantation in human embryos may be a treatment for single gene diseases."). At least by some accounts, the Gleicher and Tang research was not at all the product of provocateur "rogue scientists," but rather an acclaimed researcher that was nominated for two scientific awards. *Id.*

56 *See, e.g.*, Mina Alikani & Steen M. Willadsen, *Human Blastocysts from Aggregated Mononucleated Cells of Two or More Non-Viable Zygote-Derived Embryos*, 5 REPROD. BIOMED. ONLINE 56 (2002), http://www.rbmojournal.com/article/S1472-6483(10)61599-4/pdf (reporting the creation of "hybrid" embryos made from cells taken from different donor embryos and observing the development of such embryos to blastocyst stage).

57 The choice of gender rather than any other genetic trait apparently had to do with the ease of ascertaining this trait in the embryonic culture, namely the ability to confirm and measure the presence of male cells on the background of female cells in the embryo. *See* Gleicher & Tang 2004, *supra* note 51, at 979–80 ("the appearance of a green marker (y chromosome) against a red background (x chromosome) would thus represent one half of the donor genotype accepted and integrated by the recipient embryo").

58 The term "she-male" is often used pejoratively to describe a male-to-female transsexual or a transgender person, and is frequently used to describe transsexuals working in the sex industry. *See* Ray Blanchard et al., *Sexual Attraction to Others: A Comparison of Two Models of Alloerotic Responding in Men*, 41 ARCHIVES OF SEXUAL BEHAV. 13, 26 (2012) ("She-males are biological males who have partially feminized their bodies with estrogenic hormones or breast implants but have not undergone surgical modification of the genitals, thus creating the appearance of a woman with a penis . . . . She-males are commonly employed in sex work or the adult entertainment industry." (citations omitted)). Thus, the use of the term "she-male embryos" by

evenhanded, rational discussion of the Gleicher and Tang research. However, the mingling of sex, embryo research, and the context of the abortion debate generated sufficient outrage to persuade Congress to reenact the Weldon Amendment time and again until it finally found a permanent home in Section 33 of the America Invents Act.

C. *The Legislation of the Leahy-Smith America Invents Act*

Talks of patent reform long preceded the enactment of the Weldon Amendment,[59] and as legislative efforts ensued, the inclusion of the Weldon Amendment in such reform was never on the agenda.[60] The language of Section 33 was added to the bill of what would become the America Invents Act one day before the conclusion of the seven-year legislative effort,[61] as follows:

> LIMITATION ON ISSUANCE OF PATENTS.
>
> (a) LIMITATION.—Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.
>
> (b) EFFECTIVE DATE.— (1) IN GENERAL.—Subsection (a) shall apply to any application for patent that is pending on, or filed on or after, the date of the enactment of this Act.
>
> (2) PRIOR APPLICATIONS.—Subsection (a) shall not affect the validity of any patent issued on an application to which paragraph (1) does not apply.[62]

Its sponsors described Section 33 as "a provision that will codify [the Weldon Amendment,] an existing pro-life policy rider included in . . . Appropriations bill[s] since FY2004."[63] Further, according to its

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the sponsors of the Weldon Amendment to describe the embryos created by scientific research (rather than the more accurate term "male-female embryos") is instructive of their perception of such scientific research as well as of their attempt to portray it as morally compromised. *See supra* note 52 and accompanying text.

59 *See, e.g.*, American Inventors Protection Act of 1999, H.R. 1907, 106th Cong. (1999) (passed by the House, this bill proposed numerous revisions—some major—of the Patent Act).

60 *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 510 (explaining that the Section 33 language was added to the AIA bill as a floor manager's amendment in June 2011 and, as such, was "not addressed in the 2011 Committee Report for the bill").

61 The House of Representatives passed the Leahy-Smith America Invents Act on June 23, 2011. *Final Vote Results for Roll Call 491*, H.R. 1249, 112th Cong., *available at* http://clerk.house.gov/evs/2011/roll491.xml. The Senate passed the bill on September 8, 2011. *See Senate Vote 129 – Passes Patent Reform Bill*, N.Y. TIMES (Sept. 8, 2011, 5:30 PM), http://politics.nytimes.com/congress/votes/112/senate/1/129. On September 16, 2011, President Obama signed the Leahy-Smith America Invents Act into law.

62 157 CONG. REC. H4420, H4450 (daily ed. June 22, 2011).

63 157 CONG. REC. E1177, E1177 (daily ed. June 23, 2011) (speech of Rep. Christopher H.

sponsors, while the Weldon Amendment did not directly ban the issuance of patents on "human organisms" (but rather only the use of federal funds for this purpose), Section 33 was meant to ensure that the USPTO did not issue patents "directed to or encompassing a human organism."[64]

The reasoning behind the need for Section 33 (rather than continuing to rely on the annual passage of the Weldon Amendment) was that the AIA "may authorize the USPTO to pay for the issuance of patents with 'user fees' instead of with Congressionally appropriated funds."[65] Thus, the sponsors of Section 33 were concerned that the Weldon Amendment's funding restrictions might no longer effectively bar the patenting of "human organisms."[66] The sponsors of Section 33 also stressed that it was necessary to prevent a commodification of "human organisms," which they believed would occur if the patenting of "human organisms" were allowed.[67]

Shortly after the enactment of Section 33 as part of the AIA, the USPTO issued an internal memorandum to its Patent Examining Corps in which it characterized Section 33 as a reaffirmation and codification of its existing 1987 Policy.[68]

Smith). In so doing, the sponsors of Section 33 seem to have tried to portray Section 33 as carrying the same distinction as the Weldon Amendment purportedly did. However, it is important to note that the Weldon Amendment itself was the subject of vehement controversy and did not in fact enjoy the kind of longstanding legitimacy as implied by the sponsors of Section 33. *See, e.g.*, *Vision of Justice*, *supra* note 43, at 475 (characterizing the Weldon Amendment as lacking "broad consensus by or from either the public or the PTO"); Rick Weiss, *Funding Bill Gets Clause on Embryo Patents*, WASH. POST, Nov. 17, 2003, at A4 (criticizing the stealthy inclusion of the Weldon Amendment and noting that "[u]nexpectedly, and, some say, inappropriately, it now appears that those questions are to be dealt with by Congress for the first time in the relative obscurity of an appropriations bill for the Commerce, Justice and State departments"); Press Release, Coalition for the Advancement of Medical Research, Anti-Patent Legislation Could Cripple Medical Research (Nov. 19, 2003) (expressing opposition to the inclusion of the Weldon Amendment in appropriations legislation without any public debate).

64 According to Rep. Christopher Smith, the incorporation of the Weldon Amendment into the AIA was intended "to put the weight of law behind the USPTO [1987 P]olicy" by expressly prohibiting patenting of human organisms. 157 CONG. REC. E1177, E1177 (speech of Rep. Christopher H. Smith).

65 157 CONG. REC. E1182, E1184 (daily ed. June 23, 2011) (discussing the codification of the Weldon Amendment into patent reform legislation).

66 *Id.* ("If this funding mechanism [under AIA] becomes law, the Weldon Amendment restriction would not apply since it only covers funds appropriated under the CJS bill. The USPTO could, thereby, issue patents directed to human beings with non-appropriated funds.").

67 157 CONG. REC. E1177, E1177 ("Patents on human organisms commodify life and allow profiteers to financially gain from the biology and life of another human person.").

68 Memorandum on Claims Directed to or Encompassing a Human Organism to Patent Examining Corps from Robert W. Bahr, Senior Patent Counsel, Acting Assoc. Comm'r for Patent Examination Policy, U.S. Patent & Trademark Office (Sept. 20, 2011) (citing 1987 USPTO Policy, *supra* note 19) ("[Section 33] does not change existing law or long-standing USPTO policy that a claim encompassing a human being is not patentable. . . . This long-standing policy is reflected in MPEP § 2105 . . . .").

II. THE MANY PROBLEMS OF SECTION 33

Section 33's language, legislative history, context, and its place in the grand scheme of patent law raise a variety of issues, the most prominent of which are discussed below.

A. *Section 33 Is Based on the Ownership Fallacy*

Setting aside for the moment the debate regarding the patent subject matter eligibility of human genes, human body parts, etc.,[69] the notion of "patenting humans" tends to evoke images that offend our sensibilities. Indeed, one can hardly remain unmoved by the imagined plight of helpless fellow humans "tagged" with patent numbers (perhaps on their forearms[70]) who are the property of someone, perhaps an ominous, heartless regime or corporate entity. This perception, which is an example of what I will call the "Ownership Fallacy,"[71] seems to have been the image that stood before the eyes of the sponsors of the Weldon Amendment and, later, Section 33. Stated in their own words, the sponsors of the Weldon Amendment sought to "ensure there is not

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69 This debate, despite the recent Supreme Court decision in the matter of *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), seems to be far from conclusion, as is evident from the multitude of legal proceedings that have been initiated between Myriad Genetics and its affiliates and their competitors in different district courts subsequent to the Supreme Court's decision. *See* Univ. of Utah Research Found. v. Ambry Genetics Corp., MDL 2:14-MD-2510, 2014 WL 931057 (D. Utah Mar. 10, 2014) (order denying preliminary injunction); Defendant Myriad Genetics, Inc.'s Motion to Dismiss Under Fed. R. Civ. P. 12(b)(1), or in the Alternative, to Transfer Plaintiff Counsyl, Inc.'s Complaint for Declaratory Judgment; and Motion to Dismiss Under Fed. R. Civ. P. 12(b)(6), Counsyl, Inc. v. Myriad Genetics, Inc., No. 5:13-CV-04391, 2013 WL 7122122 (N.D. Cal. Sept. 20, 2013); Complaint, Univ. of Utah Research Found. v. Lab. Corp. of Am. Holdings, No. 2:13-cv-01069-BCW (D. Utah Dec. 3, 2013); Complaint, Univ. of Utah Research Found. v. Invitae Corp., No. 2:13-CV-01049-EJF (D. Utah Nov. 25, 2013); Complaint Demand for Jury Trial, Univ. of Utah Research Found. v. Quest Diagnostics, Inc., No. 2:13-cv-00967-BSJ, 2013 WL 6192921 (D. Utah Oct. 22, 2013); Complaint, Univ. of Utah Research Found. v. GeneDX, Inc., No. 2:13-CV-00954-TS, 2013 WL 6192930 (D. Utah Oct. 16, 2013); Complaint for Institute, Declaratory Judgment, Quest Diagnostics, Inc. v. Myriad Genetics, Inc., No. 13-cv-1587, 2013 WL 5651580 (C.D. Cal. Oct. 10, 2013); Complaint, Univ. of Utah Research Found. v. Gene by Gene, Ltd., No. 2:13cv-00643-EJF, 2013 WL 3810325 (D. Utah July 10, 2013).

70 I wish to take this opportunity to commemorate my late grandfather, Mordechai Noyovitch (1925–2012), who passed away while I was working on this Article, and who, for his entire adult life, carried on his forearm the number "A10408" tattooed onto it by the Nazis in the concentration camp Auschwitz in 1944.

71 The term "Ownership Fallacy" coined herein is defined as the misperception that patents convey affirmative property rights in the inventions that are the subject of their claims. *See infra* note 75. Specifically, in the context of Section 33, the Ownership Fallacy is the belief that patent claims "directed to or encompassing a human organism" convey affirmative property rights in such "human organisms" covered by such claims—e.g., the right to sell, offer for sale, make, use, and import such "human organisms."

financial gain or ownership of human beings"[72] and that "researchers [do not] gain financially . . . [from] an exclusive right to practice . . . ghoulish research."[73] However, Section 33's prohibition on the issuance of patent claims "directed to or encompassing a human organism" is unlikely to further these goals.[74]

When discussing patents in such ethically sensitive contexts, it is essential to keep in mind what patents are and what they are not. Despite popular misperception—which was, evidently, shared by the sponsors of the Weldon Amendment and Section 33—patents do not convey affirmative rights in tangible property.[75] Rather, patents convey limited rights to exclude others from selling, offering to sell, using, or making a patented invention or importing such a patented invention into the United States.[76] In other words, patents do *not* convey a right to use an invention, make it, sell it, etc. Thus, a prohibition on the issuance of patent claims "directed to or encompassing a human organism" does *not* mean that potential patentees to whom such claims would have otherwise been issued are denied the right to make, use, sell or offer to sell such a "human organism" or import such a "human organism" into the United States.[77] Rather, the prohibition only means that such potential patentees are *denied the right to exclude others* from doing those things. The denial of potential patentees' ability to exclude others from making, using, importing, selling, and offering to sell "human

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72 157 CONG. REC. E1177, E1178.

73 *Id.*

74 As will be explained later in this Article, human embryos, tissues, and the variety of biotechnological products originating from humans have been and will most likely continue to be "profitable commodities," irrespective of any patent rights associated with such technologies. This fact was vividly clear even to the sponsors of the Weldon Amendment when they sought to exclude such technologies from being subject to the prohibition on the patenting of inventions "directed to or encompassing a human organism." *See infra* note 88 and accompanying text.

75 That at least former Rep. Weldon shared the misperception that patents convey an affirmative right to practice the patented invention is evident in his argument that the amendment that he sponsored was necessary because "[w]e should not allow such researchers to gain financially [from patents on human organisms] by granting them an exclusive right to practice such ghoulish research." *See supra* note 52 and accompanying text.

Importantly, the Ownership Fallacy—at least as it pertains to living organisms—is apparently quite common and is held not only by non-jurists. *See, e.g.*, Kevin D. DeBré, Note, *Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?*, 16 HASTINGS CONST. L.Q. 221, 232 (1989) (wrongly arguing that "[a]n inventor holding a patent on a new form of human genotype would have an exclusive right only to practice the patent—that is, to make, use, or sell the patented genotype himself").

76 35 U.S.C. § 271(a) (2012).

77 *See* Burk, *supra* note 20, at 1618 ("The patent only allows the holder to exclude others from making, using or selling the invention and does not confer on the holder an affirmative right to make, use, or sell."); *id.* at 1648 ("[T]he holder of a patent for a transgenic human being could presumably prevent others from making, using, or selling such a transgenic human being, but this does not mean that the patent holder could impress the patented person into servitude or bondage. . . . [T]he patent right is quite separate from any given embodiment of the invention." (footnote omitted)).

organisms" does not really "ensure there is not . . . ownership of [a] human being[]"[78] or that "researchers [do not] gain financially [from] . . . practic[ing] . . . ghoulish research."[79] Hence the misperception that constitutes the Ownership Fallacy and which underlies Section 33.

B. *Lack of Accepted Definition of "Human Organism" and Its Implications*

Section 33 mandates that once the USPTO identifies a claim in a patent application as "directed to or encompassing" something that may be regarded as a "human organism" it must decline to issue that claim. Given patent law's primary purpose "[t]o promote the Progress of Science and useful Arts,"[80] it is essential that patent examiners at the USPTO know what is and what is not patentable.[81] The need for such clarity is especially acute in light of patent law's true purpose—indeed its *raison d'être*—to push the outer boundaries of technology and human knowledge into new and unknown terrain.

However, Section 33 does not provide a definition of "human organism." Nor do the six paragraphs of Section 33's own legislative history provide further clarity in this regard.[82] According to the

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78 *See* 157 CONG. REC. E1177, E1178.

79 *See id.* at E1180.

80 U.S. CONST. art. I, § 8, cl. 8.

81 Notably, the last few years have been marked by a loss of such clarity in the area of patent eligible subject matter under 35 U.S.C. § 101. *See, e.g.*, Dan L. Burk, Editorial, *Are Human Genes Patentable?*, 44 IIC: INT'L REV. INTELL. PROP. & COMPETITION L. 747, 749 (2013) ("While the [Supreme Court] *Myriad* decision confirms that there *is* a distinct product of nature doctrine, it leaves the substance of that doctrine, as well as its boundaries and application more uncertain than ever."); Arti K. Rai, Essay, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111 (2013) ("While the Supreme Court's opinions rightly focus on innovation, they fall short in their efforts to prescribe *how* patent eligibility can be used to promote innovation goals. Critics have bemoaned the uncertainty created by the Court's decisions [in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) and *Myriad*]."); Kevin E. Noonan, *The Broader Meaning of the* CLS Bank *Decision*, PATENT DOCS (May 27, 2013, 10:57 PM), http://www.patentdocs.org/2013/05/the-broader-meanings-of-the-cls-bank-decision.html ("Much has and will continue to be written about the Federal Circuit's *en banc* decision in *CLS Bank Int'l v. Alice Corp*. . . . The decision establishes without doubt that Section 101 jurisprudence has been broken by the Supreme Court's return to its subjective, non-statutory approach exemplified in *Benson v. Gottschalk* and *Parker v. Flook*, first in *Bilski v. Kappos* and then in full flower in *Mayo v. Prometheus*."). This reality is considered extremely harmful by patent practitioners and scholars, as all seem to agree that there is a crucial need for clarity in the categorization of what may and may not be patentable. *See* sources cited *supra* note 81. On the other hand, one can envision some who would argue that ambiguity in the definition of bioethically charged terms such as "human organism" may serve a constructive purpose in giving the USPTO sufficient discretion to deny patentability to novel technologies that raise ethical issues.

82 If anything, the brief six-paragraph discussion of Section 33 in the Congressional Record only makes it more difficult to understand the meaning of the term "human organism" as it

sponsors of the Weldon Amendment the term "human organism" has had "a long history of clear interpretation in federal law."[83] Yet, despite these contentions, neither the Federal Code nor the Code of Federal Regulations offers a definition of the term "human organism"[84] and very little, if anything, may be gleaned about the meaning of this term from the decisions of the federal courts.[85]

One thing that is clear, however, is that the sponsors of Section 33 intended to give the term "human organism" the same meaning that they believed that it had under the Weldon Amendment, based on which Section 33 was fashioned.[86] Although the Weldon Amendment itself also did not include a definition of "human organism," its legislative history, which is more robust than that of Section 33, may provide some insight into what the sponsors of Section 33 sought to characterize as "human organism." The following statements from the legislative history of the Weldon Amendment are particularly telling:

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includes at least four additional terms synonymous to "human organism" that the sponsors of Section 33 used to describe what they sought to have excluded under the Section: "member of the human species"; "human person"; "human"; and "human life." 157 CONG. REC. E1177, E1177.

83 *Id.* at 1179 (citing testimony before the Senate Appropriations Subcommittee on Labor/HHS/Education on December 2, 1998).

84 The only place in the Code of Federal Regulations in which the term "human organism" even appears is under the definitions of the Nuclear Regulatory Commission for the term "embryo/fetus." *See* 10 C.F.R. § 20.1003 (2014) ("Embryo/fetus means the developing human organism from conception until the time of birth.").

85 A WestlawNext advanced search of the exact phrase "human organism" in the Federal Cases database yields about fifty cases, none of which provides a clear interpretation of the term "human organism." It is quite possible, however, that in choosing the term "human organism," the sponsors of the Weldon Amendment and Section 33, who had a pro-life political agenda, sought to draw reference to cases discussing challenges to anti-abortion laws in which the term "human organism" was used to refer to human embryos and fetuses in utero. *See, e.g.*, Corkey v. Edwards, 322 F. Supp. 1248, 1251 (W.D.N.C. 1971), *vacated*, 410 U.S. 950 (1973) (holding that the State of North Carolina could "constitutionally assign to a human organism in its early prenatal development as embryo and fetus the right to be born"); Rosen v. La. State Bd. of Med. Exam'rs, 318 F. Supp. 1217, 1225 (E.D. La. 1970), *vacated sub nom.* I.I. Rosen, M.D. v. La. State Bd. of Med. Exam'rs, 412 U.S. 902, 1226 (1973) ("In our opinion, the State of Louisiana values embryonic or fetal human organisms to the extent that such organisms—forms of human life—are entitled to enjoy in at least some basic respects the right to survive on a basis of equality with human beings generally."); *see also* Margo A. Bagley, *Stem Cells, Cloning and Patents: What's Morality Got to Do with It?*, 39 NEW ENG. L. REV. 501, 508 (2005) (discussing the ambiguity of the term "human organism").

86 The sponsors of Section 33 viewed the Section as mere codification of the Weldon Amendment and, as such, as a direct extension of the Weldon Amendment's jurisprudence, including the meaning of the term "human organism." 157 CONG. REC. E1177, E1177–78 ("Chairman Lamar Smith [included] in the manager's amendment to . . . the America Invents Act, a provision that will codify an existing pro-life policy rider included in the CJS Appropriations bill since FY2004. This amendment, commonly known as the Weldon amendment, ensures the U.S. Patent and Trade Office, USPTO, does not issue patents that are directed to or encompassing a human organism. . . . I also submit into the Record items from previous debate on the Weldon amendment that will add further clarification to the intent of this important provision.").

> The [Weldon] amendment applies to patents on claims directed to or encompassing a human organism at any stage of development, including a human embryo, fetus, infant, child, adolescent, or adult, regardless of whether the organism was produced by technological methods (including, but not limited to, in vitro fertilization, somatic cell nuclear transfer, or parthenogenesis). This amendment applies to patents on human organisms regardless of where the organism is located, including, but not limited to, a laboratory or a human, animal, or artificial uterus. . . . The term "human organism" includes an organism of the human species that incorporates one or more genes taken from a nonhuman organism. It includes a human-animal hybrid organism (such as a human-animal hybrid organism formed by fertilizing a nonhuman egg with human sperm or a human egg with non-human sperm, or by combining a comparable number of cells taken respectively from human and nonhuman embryos). However, it does not include a non-human organism incorporating one or more genes taken from a human organism (such as a transgenic plant or animal).[87]

And elsewhere:

> [N]othing in this section should be construed to limit the ability of the PTO to issue a patent containing claims directed to or encompassing:
>
> 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

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87 *Id.* at E1180.

> transgenic plant or animal, or animal models used for scientific research.[88]

And in yet another place:

> The Weldon Amendment's use of the term "human organism" does include human embryos, human fetuses, human-animal chimeras, "she-male" human embryos, or human embryos created with genetic material from more than one embryo.
>
> The Weldon Amendment's use of "human organism" does not include the process of creating human embryos, such as human cloning, nor does it include non-human organisms, e.g., animals.[89]

However, even if one accepts the legislative history of the Weldon Amendment or any particular portion thereof as an authoritative source for understanding of the meaning of the term "human organism" under Section 33,[90] the guidance that it provides is limited at best. First, the legislative history of the Weldon Amendment skirts the meaning of the term "human organism" without actually saying what a "human organism" *is*; rather, it mainly focuses on what *is not* to be considered as a "human organism."

Second, the legislative history of the Weldon Amendment contains several internal conflicts and contradictions that render what little guidance it could have provided on the meaning of "human organism" even less useful and more difficult to apply to future technologies. For example, it fails to draw a distinction between a "nonhuman organism incorporating one or more genes taken from a human organism"—which the sponsors of the Weldon Amendment considered patentable—and "an organism of the human species that incorporates one or more

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88 157 CONG. REC. E1182, E1183 (daily ed. June 23, 2011). These exclusions were made, according to the sponsors of the Weldon Amendment, in recognition of the need for economic incentives for the biotechnology industry. *Id.*

89 *Id.* at E1184 (letter from FRCAction, Family Research Council, discussing the codification of the Weldon Amendment into patent reform legislation), *available at* http://www.gpo.gov/fdsys/pkg/CREC-2011-06-23/pdf/CREC-2011-06-23-pt1-PgE1182.pdf.

90 There have been prominent scholars and judges who did not and do not accept legislative intent as a useful or even legitimate source for understanding the meaning of statutory language. *See, e.g.*, Locke v. Davey, 540 U.S. 712, 732 (2004) (Scalia, J., dissenting) ("We do sometimes look to legislative intent to smoke out more subtle instances of discrimination, but we do so as a *supplement* to the core guarantee of facially equal treatment, not as a replacement for it."); Conroy v. Aniskoff, 507 U.S. 511, 528 (1993) (Scalia, J., concurring) ("The language of the statute is entirely clear, and if that is not what Congress meant then Congress has made a mistake and Congress will have to correct it. We should not pretend to care about legislative intent (as opposed to the meaning of the law), lest we impose upon the practicing bar and their clients obligations that we do not ourselves take seriously."); Anna Lumelsky, Diamond v. Chakrabarty*: Gauging Congress's Response to Dynamic Statutory Interpretation by the Supreme Court*, 39 U.S.F. L. REV. 641, 642 (2005) (describing different approaches to statutory interpretation, including textual interpretation and two modes of "dynamic statutory interpretation"); Max Radin, *Statutory Interpretation*, 43 HARV. L. REV. 863, 869–72 (1930) (offering a critique of the concept of legislative intent and its legitimacy).

genes taken from a nonhuman organism"—which they considered non-patentable.[91] Thus, the legislative history of the Weldon Amendment fails to provide a method or guiding principle by which one would be able to determine at what point the genetic makeup of the cells of a non-human organism having human genes becomes that of a "human organism." Ten human genes? One hundred? A thousand? A whole human chromosome? A full set of twenty-three human chromosomes? All forty-six human chromosomes (in addition to the animal's own chromosomes)? Are some genes more "humanizing" than others? And what about the epigenetics[92] of such genes? Can the human genes be "humanizing" even if they are silenced? And, if so, to what extent?

The same confusion exists with respect to "nonhuman organism incorporating one or more genes taken from a human organism"—which the sponsors of the Weldon Amendment considered patentable—and "human-animal chimeras"[93]—which they considered non-patentable.[94] The sponsors of the Weldon Amendment give no

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91 *See supra* note 88 and accompanying text.

92 Epigenesis is the "[r]egulation of the expression of gene activity without alteration of genetic structure." *See* Definition of Epigenesis, MEDILEXICON DICTIONARY, http://www.medilexicon.com/medicaldictionary.php (search for "epigenesis" in "Medical term" search box); *see also* PAUL SINGLETON, DICTIONARY OF DNA AND GENOME TECHNOLOGY (3d ed. 2012) ("The study of certain (heritable) factors—other than nucleotide sequence—which influence gene expression. One factor is the pattern of methylation of bases in DNA. Methylation can influence gene expression e.g. by affecting transcription; thus, for example, methylation of specific bases may block access to the transcription initiation factors in a simple, mechanical way, and/or may promote recruitment of specific repressor protein(s).").

93 The term "chimera" is typically used to describe a mixture of cells or tissues originating from different creatures, which is formed by fusion or grafting of such cells or tissues together. The fusion or grafting may take place as early as embryonic stages or as late as in a fully developed adult organism. A "human-animal chimera" is the term used to describe a mixture of cells or tissues originating from a human and a non-human animal source. Human-animal chimeras are instrumental in a variety of biomedical research efforts, including our understanding of certain diseases. *See* Jonathan D. Moreno, *Why We Need to Be More Accepting of 'Humanized' Lab Animals*, ATLANTIC (Oct. 4, 2011, 1:56 PM), http://www.theatlantic.com/health/archive/2011/10/why-we-need-to-be-more-accepting-of-humanized-lab-animals/246071. A famous example of one kind of human-animal chimera is the "earmouse" (the "Vacanti mouse"), which was an immunologically suppressed mouse grafted with human ear cartilage cells on an ear shaped mold. *See* U.S. Patent No. 6,171,610 (filed Nov. 25, 1998) (describing methods for generating tissue by grafting tissue precursor cells onto an animal); U.S. Patent No. 6,027,744 (filed Apr. 24, 1998) (describing methods for generating tissue by grafting tissue precursor cells onto an animal); Yilin Cao et al., *Transplantation of Chrondrocytes Utilizing a Polymer-Cell Construct to Produce Tissue-Engineered Cartilage in the Shape of a Human Ear*, 100 PLASTIC & RECONSTRUCTIVE SURGERY 297 (1997); *see also* Graca D. Almeida-Porada et al., *Detection of Human Cells in Human/Sheep Chimeric Lambs with In Vitro Human Stroma-Forming Potential*, 24 EXPERIMENTAL HEMATOLOGY 482 (1996) (reporting a stable long-term chimerism of hematopoietic stem cells in lambs transplanted in utero with human hematopoietic stem cells); Brenda M. Ogle et al., *Spontaneous Fusion of Cells Between Species Yields Transdifferentiation and Retroviral Transfer In Vivo*, 18 FASEB J. 548 (2004) (reporting the injection of pig embryos with human hematopoietic stem cells, which led to the creation of piglets with human cells in their circulation and tissues).

94 *See supra* notes 87, 89 and accompanying text. According to former Rep. Weldon, "a human/animal 'chimera' [is] []an embryo that is half human, half animal" and "can broadly but

indication as to the characteristics or admixture ratios that would turn a "nonhuman organism incorporating one or more genes taken from a human organism" into a "human-animal chimera" for purposes of deeming it patent ineligible. Indeed, being well aware of this very tension, the USPTO did not allow it to get in the way of issuing patent claims covering at least certain kinds of human-animal chimeras.[95] Hence, to hold outright that every kind of human-animal chimera is patent ineligible is not only against established USPTO precedent but also without justification.

Third, the legislative history of the Weldon Amendment reflects confusion and inconsistency with respect to the criteria based on which "humanity" is to be determined. In some places, the sponsors of the Weldon Amendment seem to have preferred a zoological-anthropological definition of "human organism" as a member of the "human species," *Homo sapiens*;[96] in other places they seem to have

reasonably be construed as a human organism." *See* 157 CONG. REC. E1177, E1179 (daily ed. June 23, 2011).

95 As recognized by the USPTO in the matter of the '564 Application, "a chimeric organism may be obviously non-human in an extreme case (e.g., 99% non-human cells, 1% human cells) and of ambiguous humanity in other cases (50% human cells, 50% non-human cells) . . . [and] even human beings whose bodies contain cells from different species are not considered non-human." Final Rejection 10/29/99, *supra* note 39, at 7. This viewpoint—that human-animal chimeras are not necessarily patent ineligible due to falling within the scope of the term "human being"—was apparently the basis for the USPTO's grant of patents directed to such subject matter even subsequent to the issuance of the 1987 Policy. *See, e.g.*, U.S. Patent No. 5,698,767 (filed Oct. 16, 1995) (issued Dec. 16, 1997) (claiming mice engrafted with human leukocytes exhibiting an immune response characteristic of a human, including the production of human antibodies); U.S. Patent No. 5,476,996 (filed May 4, 1993) (issued Dec. 19, 1995) (claiming immune-deficient mice engrafted with human cells). Interestingly, the "humanzee" patent applicants took the same position during the prosecution of the '564 Application, namely, that even the engraftment of human cells into animal fetuses "does not now qualify the [animal] as a human being, nor does it create a human being" and "a proportion of human cells in an organism does not make that organism a human being." *See* Preliminary Amended Arguments and Remarks 6/16/99, *supra* note 38, at 11–12.

As is evident in scientific literature, the technology of human-animal chimeras has a variety of biomedical and research uses. *See, e.g.*, Richard R. Behringer, *Human-Animal Chimeras in Biomedical Research*, 1 CELL STEM CELL 259 (2007); Akira Hara et al., *Folate Antagonist, Methotrexate Induces Neuronal Differentiation of Human Embryonic Stem Cells Transplanted into Nude Mouse Retina*, 477 NEUROSCI. LETTERS 138 (2010) (reporting the transplantation of human embryonic stem cells into the retinas of mice in order to determine their neuronal differentiation and teratogenic potential under certain regimes); Masakazu Kakuni et al., *Chimeric Mice with Humanized Livers: A Unique Tool for In Vivo and In Vitro Enzyme Induction Studies*, 15 INT'L J. MOLECULAR SCI. 58 (2014) (establishing the potential use of chimeric mice with humanized livers to serve as a model for human metabolic enzyme induction studies); Xinhua Zhang et al., *Therapeutic Effect of Human Umbilical Cord Mesenchymal Stem Cells on Neonatal Rat Hypoxic-Ischemic Encephalopathy*, 92 J. NEUROSCI. RES. 35 (2014) (demonstrating the therapeutic potential of human umbilical cord blood mesenchymal stem cells for the treatment of neonatal hypoxic-ischemic encephalopathy).

96 *See* 149 CONG. REC. E2234, E2235 (daily ed. Nov. 5, 2003) ("BIO's stated support for reducing members of the human species to patentable commodities makes the passage of my amendment more urgently necessary than ever."). Notably, as part of the discussion of the proposal to include Section 33 in the America Invents Act bill, the sponsors of Section 33 also

reverted to a genetic or morphologic standard of defining "human organism," as reflected in the "counting of genes" in the organism,[97] or the cellular makeup of the organism.[98]

Finally, the legislative history of the Weldon Amendment (as well as that of Section 33) is completely silent and provides no guidance on whether a variety of new and emerging technologies and beings would fall under the definition of "human organism." Examples of such technologies include, human-machine hybrids, de-extinct members of the genus Homo, human-chimpanzee hybrids (not chimeras), imprints of human consciousness preserved outside of a human body, and more.[99]

In view of their many deficiencies, ambiguities, and inconsistencies, the legislative histories of the Weldon Amendment and Section 33 are poor sources of guidance on the meaning of what may be regarded as "human organism." Other potential sources of understanding for the meaning of the term "human organism" may include the USPTO's own treatment of the similar term "human being" which is used in the 1987 USPTO Policy.

As mentioned earlier, the roots of the Weldon Amendment were planted in the 1987 USPTO Policy. However, the Amendment's language was markedly different from that of the 1987 USPTO Policy. Primarily, while the Weldon Amendment used the term "human organism," the 1987 USPTO Policy refers to "human beings."[100] According to the sponsors of the Weldon Amendment, the reason for this variance was that "[the term 'human organism'] is more politically neutral and more precise" than "human being."[101] Given the many ambiguities associated with the term "human organism," it is difficult to see how that term is markedly clearer than "human being." Quite to the contrary, as opposed to the term "human organism," the term "human

submitted into the Congressional Record a letter from the former Director of the PTO, James Rogan, stating that "[t]he USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species Homo sapiens at any stage of development . . . including a human embryo or human fetus[.]" *See* 157 CONG. REC. E1182, E1184 (daily ed. June 23, 2011) (letter from James E. Rogan, former Under Secretary of Commerce and Director of the USPTO, submitted into record).

97 *See* 157 CONG. REC. E1177, E1180 ("The term 'human organism' includes an organism of the human species that incorporates one or more genes taken from a nonhuman organism. . . . However, it does not include a non-human organism incorporating one or more genes taken from a human organism.").

98 *See supra* note 93 and accompanying text for a discussion of "human-animal chimeras."

99 *See infra* Appendix.

100 *See supra* note 19 and accompanying text.

101 157 CONG. REC. E1177, E1179 (citing testimony before the Senate Appropriations Subcommittee on Labor/HHS/Education, S. Hrg. 105-939, Dec. 2, 1998).

being" *does* have a definition in the Federal Code.[102] Under Section 8 of Title 1 of the Federal Code:

> (a) In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words "person", *"human being"*, "child", and "individual", *shall include every infant member of the species homo sapiens who is born alive at any stage of development.*
>
> (b) As used in this section, the term "born alive", with respect to a member of the species homo sapiens, means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.
>
> (c) *Nothing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being "born alive" as defined in this section.*[103]

The USPTO has taken the position that, from a practical standpoint, there is not much of a difference between the terms "human organism" and "human being."[104] If one accepts this viewpoint, then the definition of "human being" under 1 U.S.C. § 8 may provide a more

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102 Similarly, there seems to be no state legislation defining the term "human organism," yet there are a handful of state statutes defining "human being." *See, e.g.*, KAN. STAT. ANN. § 65-6709(m)(1) (West 2014) ("The term 'human being' means an individual living member of the species of homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation."); MONT. CODE ANN. § 45-2-101(29) (West 2014) ("'Human being' means a person who has been born and is alive."); N.D. CENT. CODE ANN. § 14-02.1-02 (West 2014) ("'Human being' means an individual living member of the species of homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation."); OR. REV. STAT. ANN. § 163.005(3) (West 2014) ("'Human being' means a person who has been born and was alive at the time of the criminal act.").

103 1 U.S.C. § 8 (2012) (emphases added).

104 In a 2003 letter submitted to Congress in connection with AIA Section 33, former Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office, James Rogan, took the position that the meaning and scope of the USPTO 1987 Policy and the Weldon Amendment are the same. *See* 157 CONG. REC. E1182, E1184 (daily ed. June 23, 2011) (letter from James E. Rogan, former Under Secretary of Commerce and Director of the USPTO, submitted into record) ("As indicated in Representative Weldon's remarks . . . the referenced language precludes the patenting of human organisms, including human embryos. He further indicated that the amendment has 'exactly the same scope as the current USPTO policy,' [sic] which assures that any claim that can be broadly construed as a human being, including a human embryo or fetus, is not patentable subject matter. . . . Given that the scope of Representative Weldon's amendment does not alter the USPTO policy on the non-patentability of human life-forms at any stage of development and is fully consistent with our policy, we support its enactment.").

authoritative insight into the meaning of "human organism" under Section 33. Nonetheless, if one is to afford any significance to legislative history, the two terms seem to be at odds on a crucial point. Under 1 U.S.C. § 8(c), the definition of "human being" clearly precludes any embryos and fetuses of the species homo sapiens,[105] whereas the legislative history of the Weldon Amendment indicates that its sponsors clearly intended to include human embryos and fetuses under the definition of "human organism."[106] Furthermore, arguably, the explicit reference to the species *Homo sapiens* in the 1 U.S.C. § 8 definition of "human being" precludes any beings that cannot be classified as belonging to that biological species, whereas the sponsors of the Weldon Amendment clearly intended to include beings that may not be classifiable as belonging to the species *Homo sapiens* under the definition of "human organism."[107]

Thus, to the extent that one gives legislative history any weight in the construction of legislation, it seems that 1 U.S.C. § 8 may not serve as an authoritative means to understanding the term "human organism." If one, however, chooses to accept the clearer definition of "human being" under 1 U.S.C. § 8 as an authoritative source of insight into the meaning of the term "human organism," then one would have to forego much—or perhaps even all—of the expressions of legislative intent found in the legislative history of the Weldon Amendment as to the proper way to construe that term. Regardless, it is important to note that *neither* of these mutually exclusive authorities on the construction of Section 33 provides a single, coherent definition of what "human organism" *is* (rather than what it *includes or excludes*).

This is hardly surprising. "Humanity" is one of the most vigorously debated and disputed concepts in law, biology, philosophy, medicine and the sciences in general. As recognized by the applicants during the prosecution of the "humanzee" '564 Application,[108] attempting to draw a clear line between that which is "human" and "nonhuman" is a hopeless endeavor—a perpetual "hot potato" that is bound to burn the hands of those who try to handle it. Even if one accepts the proposition that humanity should be defined as inclusive of all members of the species *Homo sapiens*, one would find herself in the midst of a fervent debate among anthropologists about the classification of the species

105 1 U.S.C. § 8(c) (2012).

106 *See supra* note 87 and accompanying text ("The [Weldon] amendment applies to patents on claims directed to or encompassing a human organism at any stage of development, including a human embryo, fetus . . . .").

107 *See supra* notes 87, 89 and accompanying text (the inclusion of human-animal chimeras under what the sponsors of the Weldon Amendment viewed as "human organism[s]").

108 *See* Preliminary Amended Arguments and Remarks 6/16/99, *supra* note 38, at 10 (arguing that the term "human being" is "vague and hopelessly subjective" and that it is unclear how something may "'embrace a human being' or what features of a human are critical in doing so").

Homo sapiens as separate and distinct from other hominids.[109] And even if one were to define "human organisms" by their high level of mental capacities as observed by psychologists and neurologists,[110] one would likely concede that comatose individuals or individuals suffering from a mental handicap are, nonetheless, "human organisms." Such disagreement and ambivalence also pervade current attempts at defining humanity using genomic tools;[111] so much so, that some have argued that the striking similarity of human and chimpanzee genomes begs the reclassification of humans and chimpanzees (as well as bonobos) as members of the same genus.[112]

No matter which standard one prefers for defining humanity, the answer always seems to lead back to the question from which it originated: who or what does one regard as human?[113] Thus, arguably, the mere question of who or what we should consider as a "human organism" or a member of the "human species" for purposes of Section 33 inevitably results in a tautology, which not only casts the validity of our chosen definition of "human organism" in dubious light but also raises the question of why we needed the definition in the first place.

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109 *See* Efthimios Parasidis, *Defining the Essence of Being Human*, 13 MINN. J. L. SCI. & TECH. 825, 834–41 (2012) (offering a population-based definition of "human" based on physical, cognitive, and cultural characteristics while conceding that "[a]lthough a number of disciplines provide relevant insights into factors that distinguish humans from other species, there remains significant disagreement on what characteristics are uniquely human" and "there are over twenty definitions for that which is encompassed by the species Homo sapiens, [thus,] use of this term provides little guidance in defining what it means to be human"); Ian Tattersall & Jeffrey H. Schwartz, *The Morphological Distinctiveness of* Homo Sapiens *and Its Recognition in the Fossil Record: Clarifying the Problem*, 17 EVOLUTIONARY ANTHROPOLOGY 49 (2008) (highlighting difficulties in classifying hominid skeletons as belonging to the species Homo sapiens based solely on their morphology).

110 *See, e.g.*, Ryan Hagglund, *Patentability of Human-Animal Chimeras*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 51, 52 (2008) ("[T]he preferred standard that best reflects moral, intuitional, and biological conceptions of humanity classifies an organism as human if it is characterized by the higher mental faculties and physical characteristics associated with human beings to a significant degree."); Rachel E. Fishman, Note, *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J.L. & MED. 461, 480 (1989) (proposing a statutory definition of "human being" based on the being's mental faculties).

111 While genomics may one day assist in elucidating the differences between different hominid species, the current state of knowledge in the field of human genomics does not provide an effective tool for doing so. *See* Parasidis, *supra* note 109, at 843 ("Although comparative genomics reveals that humans and chimpanzees share approximately 98.4% of their genes, and that Homo neanderthalensis and Homo sapiens are approximately 99.5% equivalent, these figures provide little guidance as to the functional significance of the genetic distinctions between the species." (footnote omitted)).

112 *See* Derek E. Wildman et al., *Implications of Natural Selection in Shaping 99.4% Nonsynonymous DNA Identity Between Humans and Chimpanzees: Enlarging Genus Homo*, 100 PNAS 7181 (2003). *But see* JONATHAN MARKS, WHAT IT MEANS TO BE 98% CHIMPANZEE: APES, PEOPLE, AND THEIR GENES 23–50 (Cal. Univ. Press 2002) (criticizing the view that the genetic closeness of humans and chimpanzees lends itself to near-identity between the two species).

113 *See* MARKS, *supra* note 112, at 48–50 (arguing that any classification, as such, is a cultural act and inevitably reflects and relies on subjective criteria).

It is difficult to believe that the sponsors of the Weldon Amendment and Section 33 were not aware of the impracticability of providing a clear and coherent definition of "human organism." To the contrary, it appears that the sponsors of the Weldon Amendment and Section 33 purposefully chose to use the term "organism" in "human organism" over the term "being." This was, in all likelihood, due to the explicit exclusion of human embryos and fetuses from "human being" under 1 U.S.C. § 8.[114] The sponsors of the Weldon Amendment and Section 33 sought to use a term that would be amenable to an interpretation that would include human embryos and fetuses, which, they believed, would support their long-term goal of equating the legal status of human embryos and fetuses to that of humans born alive.[115] Hence, the sponsors of the Weldon Amendment chose the more ambiguous and less-established term "human organism" exactly because it was able to accept the meaning that they preordained it to have.

Paradoxically, the choice of "organism" over "being" by the sponsors of the Weldon Amendment and Section 33 might achieve the opposite result to the one for which they aimed. This is due to the understanding of the term "organism" in the scientific literature, which may well be at odds with the meaning that the sponsors of the Weldon Amendment and Section 33 sought to give it, as inclusive of fetuses and embryos.[116] It is not necessary for this Article to directly take a position

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114 This substitution is evident in the fact that the term "human being" has been better defined than "human organism" as well as in its continuous use by the USPTO in the context of this same policy issue, at least since 1987. *See supra* notes 19, 102–06 and accompanying text. Hence, arguably, had they aimed to achieve clarity, it would have made more sense for the sponsors of the Weldon Amendment and Section 33 to use the term "human being" rather than "human organism" in drafting the respective provisions. The most likely explanation for the fact that the sponsors of the Weldon Amendment and Section 33 did not do so is that they sought to avoid the meaning of "human being" under 1 U.S.C. § 8, which they found undesirable. Thus, the sponsors' statement that they chose the term "human organism" (impliedly, over "human being") because it had an established history was factually baseless and only meant to excuse the deviation from the more established and better defined term "human being."

115 *See supra* notes 8, 86; *see also* 149 CONG. REC. H7248, H7274 (daily ed. July 22, 2003) (speech of Rep. Dave Weldon) ("I am trying to put us on record that we support the Patent Office in this position that human life in any form should not be patentable"); Letter from Cardinal William Keeler, Archbishop of Balt. & Chairman, Comm. For Pro-Life Activities, U.S. Conference of Catholic Bishops, to Bill Frist, Majority Leader, U.S. Senate (Nov. 18, 2003) ("This amendment to the Commerce/Justice/State appropriations bill . . . reaffirms an internal policy that has guided the U.S. Patent and Trademark Office (USPTO) since 1987, reflecting a common-sense understanding that no member of the human race at any stage of development is merely an invention or property to be licensed, bought and sold.").

116 The term "organism" appears to be widely understood in the scientific literature as pertaining to an individual living member of a biological species. *See, e.g.*, INTERNATIONAL DICTIONARY OF MEDICINE AND BIOLOGY 2019 (E. Lovell Becker et al. eds., 1986) (defining "organism" as "[a]ny living individual considered as a whole, whether plant or animal, viral or microbial"); LARRY L. MAI ET AL., THE CAMBRIDGE DICTIONARY OF HUMAN BIOLOGY AND EVOLUTION 354 (2005) (defining "organism" as "any individual living creature"); RAUNO TIRRI ET AL., ELSEVIER'S DICTIONARY OF BIOLOGY 490 (1st ed. 1998) (defining "organism" as "a living

on the proper definition of the term "organism." Yet, it is important to note that expressions of legislative intent may not carry weight with judges and USPTO personnel, who may prefer interpreting the term "human organism" in a manner consistent with its understanding in the scientific literature.[117]

Regardless, patent law is worse off due to the ambiguity of the term "human organism." This is because patent law is especially intolerant of unclarity in the area of patentable subject matter.[118] The very purpose of patent law dictates that it creates a legal environment sufficiently predictable to encourage technological innovation. The lack of a clear, agreed-upon definition for "human organism" under Section 33 detracts from this predictability in ways that may have dire consequences to innovation, especially in the important area of biomedical technology.[119] Such disincentivization of technological innovation due to the ambiguity of Section 33 may be attributed to several potential underlying causes, including uncertainty regarding: (1) the prospects of being able to obtain patents on technologies that might be characterized by the USPTO as "directed to or encompassing a human organism"; (2) the possibility of having to defend patent claims that may be characterized by third parties as "directed to or encompassing a human organism" in post-grant proceedings in the USPTO and/or in declaratory judgment actions; (3) the prospects of successfully doing so; and (4) the ability to enforce such patent claims in patent infringement actions.[120] As a result, the incorporation of Section 33 into our patent laws might, in the future, disincentivize technological innovation that is socially beneficial and not particularly ethically controversial.[121] For

individual, i.e. an animal, plant, fungus, or microorganism; an organic unit of continuous lineage with an individual evolutionary history").

117 *See supra* note 90 and accompanying text.

118 As discussed earlier, the shortcomings and dangers of ambiguities with relation to what may and may not be considered as patentable subject matter have been lamented by many, especially in light of a line of Supreme Court cases addressing this issue, over the past few years. *See supra* note 81 and accompanying text.

119 *See* BIOTECH. INDUSTRY ORG., NEW PATENT LEGISLATION SETS DANGEROUS PRECEDENT AND STIFLES RESEARCH (2003) [hereinafter BIO Cloning Fact Sheet], *available at* http://www.bio.org/sites/default/files/CFS_Sept.2003.pdf (arguing that the Weldon Amendment's language "is vague, overly broad and would jeopardize many human-derived biotechnology inventions" and providing a chart of inventions in the biomedical field whose patenting might be precluded by the Amendment).

120 This dangerous possible ramification of the ambiguity surrounding the language of Section 33 was recognized early in the legislative efforts to enact the Weldon Amendment, in 2004. *See* 149 CONG. REC. H12766, H12830 (daily ed. Dec. 8, 2003) (statement of Rep. John Conyers, Jr.) ("[The Weldon Amendment] also would stifle research on life-saving drugs and treatments. . . . While this provision has been marketed as targeted toward human cloning, it would have a much broader effect.").

121 Despite the difficulty in predicting future technologies, it is possible to envision how Section 33, if construed broadly, could potentially undermine incentives for the development of such new biotechnologies. Obviously, Section 33 could similarly undermine the incentives for the

example, one could envision how Section 33 could have prevented the patenting of inventions such as baby incubators and life-support machines, thereby undermining the incentives to develop such technologies.

Furthermore, because of the impracticability of agreeing on what is to be considered as "human organism," ultimately, every decision regarding what falls under that label requires making the kind of moral judgment that, arguably, should not be within the purview of USPTO employees. Not only are patent examiners lacking expertise in resolving this kind of ethical dilemma,[122] but they may well lack the democratic legitimacy necessary to create the distinctions between what is and what is not "human" that are necessary under Section 33.[123]

C. *Unclear Meaning of "Directed to or Encompassing" and Its Potential Ramifications*

The ambiguity of Section 33 is not limited to the term "human organism." Rather, even if one were able to resolve the conundrum surrounding the meaning of "human organism" there would still be the

development of ethically controversial technologies. However, the fact that a technology raises ethical controversy should not necessarily deem such a technology unworthy of development, as it is generally ill-advised to measure the potential social value of a technology against the level of controversy that it initially raises. Generally speaking, many technologies that are later considered commonplace and even indispensable, may initially be viewed as unethical, at least by some, due to their disruption of existing social constructs and norms. *See, e.g.*, EVERETT M. ROGERS, DIFFUSION OF INNOVATIONS 240 (5th ed. 2003) (introducing the concept of "compatibility" of a technology with societal values and the effect of such compatibility on the technology's rate of diffusion); Paul A. Geroski, *Models of Technology Diffusion*, 29 RES. POL'Y 603 (2000) (explaining that the diffusion/usage of new technologies over time typically follows an S-curve and that forces of legitimation and competition affect the rate of diffusion of such technologies into society); Bronwyn H. Hall & Beethika Khan, *Adoption of New Technology* (U.C. Berkeley Dep't of Econ., Working Paper No. E03-330, 2003), *available at* http://escholarship.org/uc/item/3wg4p528 (surveying different factors affecting the rate of diffusion of new technologies).

122 Regardless of the ongoing debate regarding whether one needs ethical expertise in order to make ethical decisions that implicate public policy issues, see, e.g., John-Stewart Gordon, *Moral Philosophers are Moral Experts! A Reply to David Archard*, 28 BIOETHICS 203 (2014), there is no dispute that USPTO employees are typically inexperienced in ways of approaching and resolving such disputes, *see Mice and Men*, *supra* note 20, at 283 ("[M]orality is not within the technical capacity of present patent examiners[.]").

123 Arguably, USPTO employees lack the level of democratic legitimacy necessary to settle matters that have been at the epicenter of national debates such as whether human embryos should be considered a "human organism." *See* Fabienne Peter, *Political Legitimacy*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., 2014), *available at* http://plato.stanford.edu/archives/spr2014/entries/legitimacy (discussing the concepts of political and democratic legitimacy); *see also* Jon Garthoff, *Legitimacy Is Not Authority*, 29 LAW & PHIL. 669, 669–70 (2010) ("A law or policy is legitimate . . . just in case its enactment meets the conditions necessary for it to serve as a normative authority for those whom it regulates, where its normative authority is understood as its capacity to render citizens morally obligated to do as it prescribes.").

issue of what is to be considered as "directed to or encompassing" such an organism under Section 33.

Let us assume for the purpose of this discussion that the term "human organism" is to be construed as narrowly as the term "human being" under 1 U.S.C. § 8.[124] What would be the meaning, then, of "directed to or encompassing a human organism?" At first blush, it appears that even under that relatively narrow meaning of "human organism," the term "directed to or encompassing a human organism" could have an extraordinarily broad scope. If we give the words "directed to" and "encompassing" their plain and ordinary meaning in the English language,[125] then, arguably, the term "directed to or encompassing a human organism" would include almost anything that is man-made and that is meant to be used by and/or for the benefit of human organisms. In contexts of patents and innovation, one may view almost any kind of invention and technology as "directed to" benefitting or, ultimately, somehow serving members of the species *Homo sapiens* who are born alive (as dictated by the 1 U.S.C. § 8 definition).

The ambiguity as to the scope of "directed to or encompassing" might compound the uncertainty regarding the meaning of "human organism," which would further increase the level of uncertainty in the sensitive area of patentable subject matter.[126] Such an increase in uncertainty as to patentability is likely to raise doubts among potential investors about their ability to gain financially from research that they fund, which would dissuade them from investing in such research and development efforts.[127] This is especially true to inventions in the areas of pharmaceuticals, medical devices, vaccines, and medical therapies, the vast majority of which may be described as "directed to or encompassing" members of the species *Homo sapiens* who are born alive.[128] Indeed, as early as 2004, opponents of the Weldon Amendment recognized and highlighted the potential hazards of the phrase "directed to or encompassing" a human organism for biomedical research as follows:

> Arguably, any medical treatment is "directed to or encompasses" human organisms. This is [sic] broad and vague prohibition could

124 *See supra* note 103 and accompanying text.

125 According to the MERRIAM-WEBSTER ONLINE DICTIONARY, "encompass" means "to include (something) as a part" or "to cover or surround (an area)." *See* Definition of Encompass, MERRIAM-WEBSTER ONLINE DICTIONARY, http://www.merriam-webster.com/dictionary (search for "encompass" in "Dictionary" search box). I was unable to find a dictionary definition of "directed to."

126 *See supra* notes 118–20 and accompanying text.

127 *See* BIO Cloning Fact Sheet, *supra* note 119, at 2 ("Investment and research into developing biotechnology products would halt if the [Weldon A]mendment were enacted into law.").

128 *See id.* (explaining how the vagueness of the term "encompassing a human organism" might create uncertainty about what is patentable subject matter in the area of biotechnology).

> prevent patents on, and thus discourage research into, drugs and treatments for Alzheimer's, in vitro fertilization, and virtually any other area of medicine that pertains to the human body. This poorly-drafted provision is an example of why Congress should not legislate on medical practices and should not make important policy decisions without the input of experts in the field.[129]

Clearly, construing the term "directed to or encompassing a human organism" in such a manner would wreak havoc on our patent system and economy. It would render most of what we perceive to be patentable technology as falling under Section 33 thereby making most patents issued from applications pending on or filed subsequent to September 16, 2011 potentially invalid and/or non-patentable. Such construction of "directed to or encompassing" would be contrary not only to the intent of the sponsors of Section 33[130] and to viable innovation policy, but also to common sense.

As discussed later in this Article, it would make more sense to interpret "directed to" in accord with the way that this term has been used and understood in the context of patent claim construction.[131] Nevertheless, until the issue of construction of "directed to or encompassing" is clarified, this phrase instills into our patent system a substantial amount of uncertainty that might, potentially, lead to abuse and disincentivizing of socially beneficial innovation.

D. *Section 33 as an Ineffective and Insufficient Barrier to Unethical Research*

Section 33 does not prohibit anything beyond and outside the issuance of patent claims "directed to or encompassing a human organisms." As such, it does not, for example, prohibit scientists who wish to experiment with "nascent individuals of the human species" or "turn [them] . . . into profitable commodities to be owned, licensed, marketed and sold"[132] from doing so. The Supreme Court explained the inadequacy of patent law as a means of curbing undesirable scientific research in *Chakrabarty*:

> The grant or denial of patents . . . is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or

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129 *See* 149 CONG. REC. H12766, H12830 (daily ed. Dec. 8, 2003) (statement of Rep. John Conyers, Jr.).

130 *See supra* Parts I.B, II.A.

131 *See infra* Part III.

132 157 CONG. REC. E1177, E1180 (daily ed. June 23, 2011).

> judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.[133]

The sponsors of the Weldon Amendment recognized that patent law is an ineffective tool for barring research, but believed that by denying scientists partaking in embryonic research the ability to patent "human organisms," they would be preventing them from gaining financially from the outcome of such research.[134] The history of stem cell and cloning research in this country teaches us, however, that this might not be so. Even when federal law makes it difficult for ethically controversial, but otherwise potentially profitable, research to obtain financial support, alternative sources of funding for such research typically present themselves.[135] It is, thus, doubtful that Section 33

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133 Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980); *see also* Chambers, *supra* note 21, at 243–44 (arguing that patent law is simply unsuitable for making moral decisions). Professor Robert Merges further raises the idea that part of the function of patents is to bring changes in moral conceptions through the introduction of new technologies into society. *See* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1064 (1988) ("[C]hanges in moral norms are at least in part a function of the very thing patents are supposed to bring about—new technologies.").

134 *See* 149 CONG. REC. H7248, H7274 (daily ed. July 22, 2003) (statement of Rep. Dave Weldon) ("Though this amendment would not actually ban [research activities involving human embryos], it is about time that Congress should . . . ensure there is not financial gain or ownership of human beings by those who engage in these activities.").

135 *See* Yaniv Heled, *On Presidents, Agencies, and the Stem Cells Between Them: A Legal Analysis of President Bush's and the Federal Government's Policy on the Funding of Research Involving Human Embryonic Stem Cells*, 60 ADMIN. L. REV. 65, 67 (2008) (describing the ban imposed by President George W. Bush on federal funding of research involving human embryonic stem cell lines created subsequent to Aug. 9, 2001); Editorial, *Human Embryonic Stem Cell Research in the US: Time for Change?*, 12 NATURE CELL BIOLOGY 627 (2010) (listing private and state sources of funding for stem cell research that have become available during the Bush era ban to meet the need for funds for research involving human embryonic stem cells).

The same is apparently true with respect to research of human cloning techniques. In 1997, President Clinton issued an executive order banning the use of federal funding for the purpose of cloning. Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 1997 PUB. PAPERS 233 (Mar. 4, 1997) (President Clinton's directive banning the use of federal funding for the purpose of cloning); Remarks Announcing the Prohibition on Federal Funding for Cloning of Human Beings and an Exchange with Reporters, 1997 PUB. PAPERS 230 (Mar. 4, 1997). For a discussion of further political responses to the idea of human cloning, see generally Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 644–46 (1998) (describing the responses to an announcement that human cloning was technologically feasible). Despite this ban, there have recently been reports in the scientific literature that indicate that not only has funding been available for such research efforts in the United States, but also that these efforts bore fruit by producing cloned human embryos. *See* Christine L. Mummery & Bernard A. J. Roelen, *Stem Cells: Cloning Human Embryos*, 498 NATURE 174 (2013) (reporting the successful cloning of human embryos using a somatic-cell nuclear transfer technique—the same technique used in the famous cloning of the sheep named Dolly—in 1996).

would effectively dampen such research.[136]

In addition, it is important to note that, in some cases, inventions resulting from biomedical research[137] are eligible to non-patent competitive benefits, regardless of whether such inventions are "directed to or encompassing a human organism." For example, under the Biologics Price Competition and Innovation Act (BPCIA), biological products, once approved by the Food and Drug Administration (FDA), are eligible for twelve years of market exclusivity.[138] Similarly, under the Orphan Drug Act, pharmaceutical products approved by the FDA for the treatment of an orphan condition[139] are eligible for seven years of market exclusivity.[140] The enforcement of such exclusivities, primarily by the FDA, would potentially enable developers of such biological products and orphan pharmaceutical products to profit from their inventions, notwithstanding the availability of patent protection for such inventions.

Ironically, it may be Section 33's prohibition on patenting of some biomedical technologies that may drive certain types of research (especially those involving human gametes and embryos) beyond the preliminary stages to more advanced stages. This is because while patents are typically available during early stages of research, the exclusivities and other benefits administered by the FDA are dependent on marketing approval, which necessitates more robust and advanced research to show that the technology meets the FDA's safety and efficacy requirements.[141] Hence, where patent protection is not available to a technology due to its being "directed to or encompassing a human organism," the availability of the competitive benefits under FDA law may create an incentive to further develop the technology beyond its early stages so as to secure the competitive benefits available under FDA law.

To summarize, not only does Section 33 not categorically prevent scientific research involving "human organisms," unethical as it might

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136 To clarify, from an innovation policy perspective, the problem with Section 33 is not in situations where an ethically controversial technology has a clear profitability potential. Rather, it is in those cases where the development of ethically *uncontroversial* technology would be stifled by a lack of resources due to unclear profitability of such technology, owing to legal uncertainty resulting from Section 33.

137 As mentioned earlier, biomedical research is one of the most likely (if not the most likely) types of research to result in what may be regarded as "directed to or encompassing a human organism."

138 *See* 42 U.S.C. § 262(k)(7)(A) (2012).

139 *See* 21 U.S.C. § 360bb(a)(2) (2012) (defining "rare disease or condition").

140 *See id.* § 360cc(a)(2) (creating the seven-year market exclusivity).

141 The Orphan Drug Act, for example, provides tax benefits to developers of approved drug applications designated for orphan populations for the treatment of rare diseases or conditions. *See* 26 U.S.C. § 45C (2012) (instituting a tax credit for expenses related to clinical testing for drugs for rare diseases or conditions).

be, but also its effectiveness in thwarting the patenting of inventions resulting from such research and the ability to financially gain from it in the absence of patents is, at best, questionable.[142] To prohibit unethical research effectively and make financial gain from such research more difficult, a far more comprehensive legislation is necessary; one that is not limited to the narrow context of patent claims.[143]

E. *Section 33's Redundancy in Light of Existing Patent Law, Federal Criminal Law, and the Thirteenth Amendment*

There are several existing constitutional and statutory constructs that render technology potentially "directed to or encompassing a human organism" patent ineligible and/or unpatentable,[144] and which have been in place long before the enactment of Section 33.[145]

1. Potential Lack of Novelty of Inventions "Directed to or Encompassing a Human Organism" Under 35 U.S.C. § 102

One of the pillars of patentability is novelty; namely, the requirement that in order for an invention to be patentable, it must be new.[146] This requirement has changed somewhat over the years, including under the AIA.[147] Yet, it has consistently required that (with

142 *See Mice and Men*, *supra* note 20, at 285 ("[T]he denial of a patent does not eliminate all incentives to utilize an invention. . . . Patents are at best a blunt tool to regulate controversial matter because patents are not necessary to utilize or commercialize innovations. Accordingly, the focus on patents is an incomplete one. The issue of whether researching or using biotechnology is ethical can and should be separated from the patenting question, which tends to conflate divergent issues.").

143 To effectively curb the research and development of a technology and/or its dissemination, it is necessary to regulate such a technology directly, for example, by legislation that bans experimentation involving that technology as well as its use. In this case, to make their legislative efforts effective, the sponsors of Section 33 should have advanced legislation in lieu of Section 33 that would, for example, ban altogether or foreclose federal funding for attempts to create human-chimpanzee hybrids. Generally speaking, however, such prohibitions must be drafted narrowly and carefully due to the risk of overreach, namely, that the prohibitions would hinder the development and dissemination of technologies that were never intended to be curbed.

144 For a discussion of the difference between these two terms, see *supra* note 17.

145 Importantly, none of the legal constructs discussed below imposes a complete bar on technologies that could be regarded as "directed to or encompassing human organism[s]." However, as explained later in this section, the aggregate of the bars these statutory provisions pose to the patentability of humans significantly narrows the scope of patentability of known or envisioned technologies that may potentially be regarded as "directed to or encompassing a human organism."

146 35 U.S.C. § 102 (2012).

147 *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284 (2011) (amending 35 U.S.C. § 102 from a first-to-invent to a first-inventor-to-file system); Press Release, 13-10, U.S. Patent & Trademark Office, USPTO Publishes Final Rules and Guidelines Governing

certain exceptions) an invention be unknown and not in public use prior to patenting.[148] While there may well be inventions "directed to or encompassing a human organism" that would be novel, "human organisms" as such greatly predate even the earliest of patent laws and, therefore, cannot be regarded as novel.[149] As a result, patent claims directed to already existing manifestations of "human organisms" would be unpatentable as directed to anticipated subject matter under 35 U.S.C. § 102, regardless of Section 33.[150] Examples of such manifestations may include, for example, cloned humans[151] and humans who have undergone certain kinds of gene therapy.[152]

First-Inventor-to-File (Feb. 13, 2013), *available at* http://www.uspto.gov/news/pr/2013/13-10.jsp (announcing final examination guidelines for "how the first-inventor-to-file provision alters novelty and obviousness determinations for an invention claimed in a patent application[, i]n particular . . . how the AIA [] changes . . . the scope of what is prior art to a claimed invention and how the new grace period operates").

148 35 U.S.C. § 102 (2012).

149 To clarify, the novelty requirement would not render any and all inventions "directed to or encompassing a human organism" unpatentable. For example, humans transfected or transduced with genetic material originating from a nonhuman source such that the resulting "human organism" would have a genetic makeup and, possibly, characteristics that did not exist in humans prior to the transfection or transduction would be "new" under patent law.

150 "Anticipated" subject matter means that the invention as claimed does not meet the novelty requirement under Section 102 of the Patent Act.

151 For purposes of the current discussion, "cloned humans" are humans produced via reproductive cloning. *See* Nat'l Human Genome Research Inst., *Cloning*, GENOME.GOV, http://www.genome.gov/25020028 (last visited Sept. 7, 2014) ("Reproductive cloning produces copies of whole animals."). While there has been no verifiable successful attempt to produce cloned humans to date, recent reports in scientific literature have indicated that such a procedure is now feasible. *See* Mummery & Roelen, *supra* note 135.

Human clones may be regarded as "anticipated" based on a comparison of their genetic sequences with that of the human from whom the genetic material was taken. Patent claims directed to human clones may, however, be unanticipated when the claim focuses not only on the clone's DNA, but also on the clone's epigenetics, which will almost certainly be different from the epigenetics of the original human from whom the genetic material was taken. *See* Kunio Shiota & Ryuzo Yanagimachi, *Epigenetics by DNA Methylation for Development of Normal and Cloned Animals*, 69 DIFFERENTIATION 162 (2002). A similar reasoning—although in the context of patent subject-matter eligibility under 35 U.S.C. § 101—lay in the heart of the Federal Circuit's recent ruling that a "[cloned animal]'s genetic identity to [its] donor parent renders [it] unpatentable" and that "clones are exact genetic copies of patent ineligible subject matter. Accordingly, they are not eligible for patent protection." *In re* Roslin Inst. (Edinburgh), 750 F.3d 1333, 1337 (Fed. Cir. 2014) (footnote omitted).

152 According to *Elsevier's Dictionary of Biology*, "gene therapy" is the cure of genetic diseases by substituting a defective gene with a normal gene transferred to the diseased tissue using gene manipulation. *See* TIRRI ET AL., *supra* note 116, at 269.

From a genetic perspective, humans who undergo gene therapy may be viewed as "anticipated" under patent law where the genetic makeup of such individuals would be made identical to that of "normal" healthy individuals. In other words, where a gene "fixed" or replaced by gene therapy is made identical to a "normal" version of the gene, the alteration would result in a human whose genetic makeup (at least when it comes to the particular gene that is the subject of the therapy) is made identical to that of other human individuals. There may be, however, several caveats to such a viewpoint. First, since no individual is truly genetically identical to any other individual (save identical twins before each starts acquiring individual mutations in her DNA), gene therapy would inevitably result in an individual whose genetic makeup would be unique and

2. Inventions "Directed to or Encompassing a Human Organism" as Potentially Falling Under the Product-of-Nature Doctrine

Despite being subject to ongoing critique,[153] the existence and validity of the product-of-nature doctrine has recently been reaffirmed by the Supreme Court in the *Myriad* case.[154] Under the doctrine, "in order for a product of nature to [be patent-eligible], it must be qualitatively different from the product occurring in nature, with markedly different characteristics from any found in nature."[155] Thus, the product-of-nature doctrine would render inventions "directed to or encompassing a human organism" that do not have "markedly different characteristics from any found in nature" as patent ineligible subject matter.[156] For example, if one accepts that a human embryo is a "human

therefore new. Notably, the Federal Circuit recently rejected this difference as sufficient for purposes of patent eligibility. *See In re Roslin*, 750 F.3d at 1337–39. Second, where the gene therapy may result in a human whose genetic makeup includes a copy of the dysfunctional gene as well as the "normal" gene, the genetic makeup of that human will be new as compared to individuals in the general population. Lastly, this argument does not apply to gene therapy whose purpose is to insert artificial genes that are, in and of themselves, new and would therefore render their recipients "new" from a genetic perspective. An interesting question, which exceeds the scope of this Article, is whether and to what extent do existing patents claiming methods of gene therapy also contain claims that may be construed as directed to or encompassing human organisms that are the result of such gene therapies.

153 *See, e.g.*, Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STAN. TECH. L. REV. 257 (2013); Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 985 (1996) ("[P]roducts of nature purportedly are not patentable. . . . Using this traditional approach, courts have unsatisfactorily distinguished products of nature from patentable subject matter, and, consequently, the 'natural phenomena' gloss has served as a source of confusion rather than as a pillar of instruction."); Richard Seth Gipstein, Note, *The Isolation and Purification Exception to the General Unpatentability of Products of Nature*, 4 COLUM. SCI. & TECH. L. REV. 1, 2 (2002) ("[T]here is nothing in any section of the Patent Act that expressly forbids the patenting of a product of nature. Therefore, the precise foundation for the general unpatentability of a product of nature remains somewhat ambiguous.").

154 *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013) ("[W]e hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.").

155 Intervet Inc. v. Merial Ltd., 617 F.3d 1282, 1294–95 (Fed. Cir. 2010) (Dyk, J., concurring in part and dissenting in part) (internal quotation marks omitted). The relevance of the distinction between human-made inventions and products of nature for the purpose of patent eligibility has long been recognized by the Supreme Court and served as a basis for findings of ineligibility for patent by the Federal Circuit and its predecessor, the Court of Customs and Patent Appeals. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) ("Congress . . . recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."); *In re* Marden, 47 F.2d 958, 959 (C.C.P.A. 1931) ("[P]ure vanadium is not new in the inventive sense, and, it being a product of nature, no one is entitled to a monopoly of the same.").

156 *See In re Roslin*, 750 F.3d at 1339 (holding that the claimed cloned animals are directed to patent ineligible subject matter as "the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies").

organism," then even human embryos created by using a new assisted reproductive technology (ART) would not be patent eligible subject matter under the product-of-nature doctrine if they do not have "markedly different characteristics from any found in nature."[157] Hence, when it comes to inventions that fall under the product-of-nature doctrine, Section 33 is redundant.

3. Lack of Definiteness Under 35 U.S.C. § 112(b) of Claims "Directed to or Encompassing a Human Organism"

The Patent Act requires that the patent document "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."[158] Such patent claims constitute the operative portion of the patent, in which the patentee notifies the public, through the claims' language, what, specifically, she regards as the subject of her right to exclude others. Generally speaking, patentees have significant latitude in shaping the terminology that defines their inventions as claimed in patent claims.[159] Still, some inventions lend themselves more easily than others to "particular pointing out" and "distinct claiming." In view of the difficulties inherent to defining the term "human organism,"[160] it is fair to expect that patentees seeking to use terms that mention or allude to humanity[161] would encounter substantial difficulties in "particularly pointing out and distinctly claiming" their inventions. It is to be further expected that inventions "directed to or encompassing a human organism" (as well as those seeking to explicitly exclude such subject matter[162]) may necessitate the use of such terms. Thus, arguably, claims "directed to or encompassing a human organism" making use of terms that mention or allude to humanity might be invalid for being insolubly ambiguous in violation of Section 112(b)'s definiteness requirement.[163] This is another reason for why

157 *See Intervet Inc.*, 617 F.3d at 1294–95 (internal quotation marks omitted).

158 35 U.S.C. § 112(b) (2012).

159 According to well-established case law, "[a]lthough words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning[.]" Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

160 *See* discussion *supra* Part II.A.

161 Examples of such terms may include "human," "nonhuman," "human organism," "human being," "human species," "*Homo sapiens*," etc.

162 According to the 1987 USPTO Policy, the USPTO currently requires that where "the broadest reasonable interpretation of the claimed invention as a whole encompasses a human [being]," the relevant claims should "include the limitation 'non-human' to avoid [a rejection under 35 U.S.C. 101]." *See* sources cited *supra* note 19 and accompanying text.

163 *See, e.g.*, Power-One, Inc. v. Artesyn Techs., Inc., 599 F.3d 1343, 1350 (Fed. Cir. 2010) ("When a claim is 'not amenable to construction or [is] insolubly ambiguous' it is indefinite."

patent claims "directed to or encompassing a human organism" may be invalid as such, regardless of Section 33.

4. Inherent Lack of Utility of Inventions "Directed to or Encompassing a Human Organism" Under 35 U.S.C. § 101

Known as the "utility requirement," under 35 U.S.C. § 101, to be patentable, an invention must be useful.[164] Courts have interpreted the utility requirement as consisting of two components: first, the invention must be operable; and, second, it must have a "specific beneficial result."[165] Thus, under current law, to fulfill the utility requirement, all that inventions "directed to or encompassing a human organism" must do is be operable and have a "specific beneficial result."

However, at least from an ethical-philosophical perspective, inventions "directed to or encompassing a human organism," arguably, cannot by definition comply with the utility requirement, because "human organisms" must not and cannot be regarded as having a "use." Stated differently, "human organisms" ought not to be subject to an evaluation of their "operability" and their ability to achieve a "specific beneficial result"—the two elements of the utility requirement—because doing so would depreciate them to the level of mere objects.

The basis of this argument is grounded in deontological ethics[166] and, more specifically, the famous second formulation of Kant's categorical imperative to "[a]ct in such a way as to treat humanity, whether in your own person or in that of anyone else, always as an end

(quoting Datamize LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005))); Star Sci., Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1371 (Fed. Cir. 2008) ("[I]f reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness."); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 453 (Fed. Cir. 1985) ("'[P]artially soluble' was too vague . . . to particularly point out and distinctly claim the invention, as required by the second paragraph of § 112.").

164 35 U.S.C. § 101 (2012).

165 *See* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (holding that until an invention is sufficiently developed so as to confer a specific benefit, it does not comply with the utility requirement); *In re* Swartz, 232 F.3d 862, 864 (Fed. Cir. 2000) (finding that an alleged invention of "cold fusion" was irreproducible and therefore inoperable); *see also* Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 488 (2003) ("For the vast majority of inventions, the utility requirement is a low hurdle to overcome.").

166 According to the STANFORD ENCYCLOPEDIA OF PHILOSOPHY, deontology is a normative theory that guides and assesses choices of what we ought to do in contrast to what kind of person (in terms of character traits) we should be. *See* Larry Alexander & Michael Moore, *Deontological Ethics*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., Winter 2012), *available at* http://plato.stanford.edu/archives/win2012/entries/ethics-deontological.

and never merely as a means."[167] Applying the second formulation of Kant's categorical imperative to the context of Section 33 dictates that "human organisms" must not be evaluated in terms of utility and therefore should be deemed as inapposite to fulfilling the utility requirement. Thus, following this line of argumentation, inventions "directed to or encompassing a human organism" are unpatentable because of their categorical non-compliance with the utility requirement. I will refer to this principle as the "non-utility argument."

The non-utility argument is, admittedly, reminiscent of the old "moral utility" doctrine,[168] which, in recent years, seems to have fallen out of favor with the United States Court of Appeals for the Federal Circuit[169]—the court having exclusive national subject matter jurisdiction over matters relating to patents.[170] According to the moral utility doctrine, in order to comply with the utility requirement, "the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society."[171] Notably, despite their resemblance, the moral utility doctrine and the non-utility argument are not the same. Whereas the moral utility doctrine has traditionally been invoked to deny patentability to inventions considered as having "bad" or "immoral" uses,[172] the non-utility argument is based on the premise that humans cannot, by definition, have utility at all. Thus even if the moral utility doctrine had not fallen out of judicial favor, the mere attempt to evaluate the utility of inventions "directed to or encompassing a human organism" would have been inappropriate in the first place because "human organisms" ought not to be measured against the sliding scale of "morality" that is inherent to the moral utility evaluation.

In sum, under the non-utility argument, inventions "directed to or encompassing a human organism" lack utility as such, which renders Section 33 unnecessary and redundant.

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167 IMMANUEL KANT, GROUNDWORK FOR THE METAPHYSIC OF MORALS 29 (Jonathan Bennett ed., 2008), *available* at http://www.earlymoderntexts.com/pdfs/kant1785.pdf.

168 *See* Bagley, *supra* note 165, at 489 (discussing the moral utility doctrine and its historical roots).

169 *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366–67 (Fed. Cir. 1999) ("[T]he principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years."). Some have even argued that the moral utility doctrine suffered judicial demise. *See* Bagley, *supra* note 165, at 470 ("[T]he demise of the moral utility doctrine, along with expansive judicial interpretations of the scope of patent-eligible subject matter, has resulted in virtually no basis on which the USPTO or courts can deny patent protection to morally controversial, but otherwise patentable, subject matter.").

170 28 U.S.C. § 1295(a) (2012).

171 Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568).

172 For example, inventions involving gambling machines used to be considered as unable to fulfill the utility requirement due to a lack of moral utility. *See, e.g.*, Fuller v. Berger, 120 F. 274 (7th Cir. 1903); Nat'l Automatic Device Co. v. Lloyd, 40 F. 89 (N.D. Ill. 1889).

5. The Triviality of Section 33 in Light of the Thirteenth Amendment and Federal Criminal Legislation

The Thirteenth Amendment commands that "[n]either slavery nor involuntary servitude . . . shall exist within the United States, or any place subject to their jurisdiction."[173] Although the Supreme Court has construed this prohibition against slavery and involuntary servitude relatively narrowly over the years,[174] ownership of humans—any humans—and such badges and incidents of slavery as the sale, offer for sale, use (as an object) and importation (as mere goods) of humans falls squarely within the four corners of the Thirteenth Amendment's prohibition.[175] Hence, if one views patent claims "directed to or encompassing a human organism" as creating affirmative rights such as those mentioned above in "human organisms"—i.e., accepts the Ownership Fallacy as it pertains to such claims[176]—then it must follow that Section 33 was unnecessary. This is because (1) under the Thirteenth Amendment it would be impossible for the USPTO to allow and issue such patent claims; and (2) the Thirteenth Amendment would make it impossible to secure the assistance of the courts in enforcing such claims.[177] Indeed, a comparison of patent subject-matter eligibility

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173 *See* U.S. CONST. amend. XIII, § 1.

174 *See* The Civil Rights Cases, 109 U.S. 3 (1883) (restricting the applicability of the Thirteenth Amendment strictly to matters under the purview of the federal government and holding that the Thirteenth Amendment did not give Congress the power to pass legislation pertaining to private conduct); The Slaughter-House Cases, 83 U.S. 36 (1872) (rejecting the argument that a state statute creating a monopoly is unconstitutional under the Thirteenth Amendment). *But see, e.g.*, Jones v. Alfred H. Mayer Co., 392 U.S. 409 (1968) (holding that a statute that barred racial discrimination in both private and public property was within Congress's power under the Thirteenth Amendment.).

175 *Slaughter-House Cases*, 83 U.S. at 72 ("Undoubtedly while negro slavery alone was in the mind of the Congress which proposed the thirteenth article, it forbids any other kind of slavery, now or hereafter. . . . [W]hat we wish to be understood is, that in any fair and just construction of any section or phrase of [the Thirteenth through Fifteenth] amendments, it is necessary to look to the purpose which we have said was the pervading spirit of them all, the evil which they were designed to remedy, and the process of continued addition to the Constitution, until that purpose was supposed to be accomplished, as far as constitutional law can accomplish it."); *id.* at 90 ("[T]he language of the amendment is not used in a restrictive sense. It is not confined to African slavery alone. It is general and universal in its application. Slavery of white men as well as of black men is prohibited, and not merely slavery in the strict sense of the term, but involuntary servitude in every form.").

176 As explained earlier, patents do not convey affirmative rights, but rather the right to exclude others from partaking in certain acts. *See supra* Part II.C. Nevertheless, it appears that the sponsors of the Weldon Amendment and Section 33 committed the Ownership Fallacy and, thus, mistakenly thought of patents as granting such affirmative property rights in the subject of the invention. *See supra* notes 71, 75 and accompanying text.

177 Interestingly, the USPTO has also taken the position that an attempt by an owner of a patent on a "human organism" to exclude others from "making" such an organism would "conflict with the constitutional right to privacy enunciated by the Supreme Court." *See* Final Rejection 10/29/99, *supra* note 39, at 4–5.

of existing and envisioned technologies under Section 33 and the Thirteenth Amendment (viewed through the lens of the Ownership Fallacy) reveals some interesting results.[178] Not only does the Thirteenth Amendment exclude every kind of invention excluded under Section 33,[179] but it also renders patent ineligible other technologies whose patenting would be possible under Section 33, despite the fact that such patenting may well raise ethical issues.[180] In other words, if we accept the rationale that led to the enactment of Section 33, then the Thirteenth Amendment would have done a much better job than Section 33 at preventing the patenting of technologies "directed to or encompassing a human organism" as well as other ethically controversial technologies.[181]

Furthermore, if we were to understand patent claims "directed to or encompassing a human organism" as creating affirmative rights in "human organisms"—i.e., by accepting the Ownership Fallacy as it pertains to such claims)—then the issuance of such claims and attempting to enforce them—not to mention the practicing of the underlying inventions—would be outright criminal. There is a multitude of state and federal criminal statutes prohibiting human trafficking, false imprisonment, peonage, and a variety of other badges and incidents of slavery and involuntary servitude.[182] Under these

178 *See infra* Appendix.

179 Notably, the Appendix of this Article reflects the applicability of Section 33 when it is construed narrowly. As explained earlier, if we were to construe Section 33 broadly, it would apply to all of the technologies listed in Table 1, including such technologies that the sponsors of Section 33 did not intend to include under the Section.

180 Examples of technologies whose patenting would likely be precluded under the Thirteenth Amendment (if we accept the Ownership Fallacy), but not under Section 33, include: (1) de-extinct *Homo neanderthalensis* and other members of "archaic" *Homo* species that are not classified as *Homo sapiens*; (2) synthetically-created sentient biological organisms that cannot be classified as members of the genus *Homo*; (3) sentient non-biological beings—e.g., artificial intelligence; and (4) imprints of human consciousness preserved outside of a human body—e.g., in a computer or as a "brain in a vat." *See infra* Appendix.

181 *Id.*

182 *See, e.g.*, 18 U.S.C. § 1201(a) (2012) ("Whoever unlawfully seizes, confines, inveigles, decoys, kidnaps, abducts, or carries away . . . any person, except in the case of a minor by the parent thereof, when—(1) . . . the offender travels in interstate or foreign commerce or uses the mail or any means, facility, or instrumentality of interstate or foreign commerce in committing or in furtherance of the commission of the offense . . . shall be punished by imprisonment for any term of years or for life"); 18 U.S.C. § 1581(a) (2012) ("Whoever holds or returns any person to a condition of peonage, or arrests any person with the intent of placing him in or returning him to a condition of peonage, shall be fined under this title or imprisoned not more than 20 years, or both"); 18 U.S.C. § 1584(a) (2012) ("Whoever knowingly and willfully holds to involuntary servitude or sells into any condition of involuntary servitude, any other person for any term, or brings within the United States any person so held, shall be fined under this title or imprisoned not more than 20 years, or both"); 18 U.S.C. § 1590(a) (2012) ("Whoever knowingly recruits, harbors, transports, provides, or obtains by any means, any person for labor or services in violation of this chapter shall be fined under this title or imprisoned not more than 20 years, or both"); Victims of Trafficking and Violence Protection Act of 2000, Pub. L. 106-386, 114 Stat. 1464 (2000) (fighting the phenomenon of human trafficking, or "modern slavery"); CAL. PENAL

statutes, if patent claims "directed to or encompassing a human organism" were indeed to create affirmative rights in "human organisms"—e.g., to sell, offer for sale, use, or import "human organisms"—Section 33 would have been the least of one's concerns when it came to the monetization of the underlying inventions in such "human organisms." These same laws also, arguably, impose on USPTO patent examiners a duty to refuse to allow and issue patents creating affirmative rights in "human organisms" and impose on judges a duty to deny enforcement attempts of such patents.

In light of the above, if, like the sponsors of Section 33, we adopt the Ownership Fallacy, then Section 33 must be held not only unnecessary but also trivial as compared to the more authoritative, comprehensive, and unequivocal dictates of the Thirteenth Amendment and federal criminal legislation. Furthermore, as explained earlier, long-standing patent law principles already make it impossible to secure patent rights in inventions and enforce patent claims "directed to or encompassing a human organism" in many—if not all—such cases. In short, Section 33 has been unnecessary and redundant in view of earlier constitutional and statutory provisions that were in place long before its enactment. The redundancy of Section 33 presents not only the question of why was Section 33 necessary in the first place, but also whether it would not be simply better to repeal it in its entirety, in light of the many problems that it creates.

F. *Section 33 as a Missed Opportunity to Make a Meaningful Statement Regarding the Moral Standing of Beings Possessing Certain Mental Faculties*

Perhaps the most unfortunate thing about Section 33 is that it represents a missed opportunity to start a discussion that could have led to the passage of legislation that would have lent protection to all beings who possess certain mental faculties.[183] Setting aside the context of the

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CODE §§ 236–237 (West 2014) (making the deprivation or violation of the personal liberty of another a crime).

183 Using the term "mental faculties" is not meant to categorically exclude any type of being. I chose this term for lack of a better one, and because it was the broadest and least specific term I could find to describe what is sometimes referred to as "sentience," "consciousness," "high intelligence," "awareness," "self awareness," etc. With the debate regarding the mind-body problem, see Howard Robinson, *Dualism*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY, *supra* note 166, *available at* http://plato.stanford.edu/archives/win2012/entries/dualism, still far from conclusion and the area of cognitive neuroscience still unable to answer the ultimate question of the source of cognition, there seems to be not just one term to describe the kind of characteristics to which I refer herein. Thus, the term "mental faculties," as used herein is meant to encompass all of these terms and others without necessarily taking a position on the "makeup" and nature of such faculties.

abortion debate from which Section 33 arose and the Ownership Fallacy on which it is premised, at its core the prohibition on the patenting of inventions "directed to or encompassing a human organism" stems from the belief that slavery and involuntary servitude are an evil that must not be allowed. In this current day and age, it would be difficult to find people (at least in this country) who would disagree with this maxim. Yet, the meaning of "slavery" and "involuntary servitude" as well as our understanding of who or what ought to be protected from slavery and involuntary servitude are still evolving.[184]

The sponsors of the Weldon Amendment and Section 33 sought to harness the consensus surrounding the abolition of slavery and involuntary servitude to promote their view that human embryos ought to be afforded human rights. In this Article, I have thus far shown that they did so unskillfully and that Section 33 is unlikely to advance their goals (and perhaps even achieve result opposite to those intended)[185]. One of the reasons for this is that the sponsors of the Weldon Amendment and Section 33 limited themselves to the context of patent law, where they met with little resistance from their ideological opponents in the abortion debate. I argue that the sponsors would have more fully advanced the core values that underlie their efforts if they had lifted themselves from the narrow context of this debate.

Judging by the current state of the political divide, it looks like we may never reach a broad agreement on the appropriate legal status of human embryos and fetuses. And yet, that does not mean that we cannot agree on other issues that implicate the same values and beliefs that underlie this debate. The rejection of slavery and involuntary servitude is one such value. Had the sponsors of Section 33 sought to advance this value *effectively*, they should have, for just a brief

184 *See, e.g.*, Geoff Brumfiel, *NIH Takes Another Step Toward Retirement of Research Chimps*, NPR SHOTS BLOG (June 26, 2013, 3:08 PM), http://www.npr.org/blogs/health/2013/06/26/195926114/nih-takes-another-step-toward-retirement-of-research-chimps (announcing a decision by the National Institute of Health's director, Francis Collins, to follow a plan issued by its internal working group to retire approximately 310 chimps into designated sanctuaries and who stated that "'[c]himpanzees are very special animals'" that "'deserve special consideration'"); Alex Dobuzinskis, *Judge Dismisses Suit Accusing SeaWorld of Enslaving Whales*, REUTERS, Feb. 8, 2012, *available at* http://www.reuters.com/article/2012/02/09/us-usa-seaworld-lawsuit-idUSTRE81809E20120209 (describing the ruling of U.S. District Judge, Jeffrey Miller that "orcas had no standing to seek constitutional rights as people" and that the "only reasonable interpretation of the 13th Amendment's plain language is that it applies to persons, and not to non-persons such as orcas" (internal quotation marks omitted)); Michael Mountain, *New York Cases – Judges' Decisions and Next Steps*, NONHUM. RTS. PROJECT (Dec. 10, 2013), http://www.nonhumanrightsproject.org/2013/12/10/new-york-cases-judges-decisions-and-next-steps (describing three lawsuits in New York state for the release of chimpanzees into sanctuaries under the legal theory that they are "legal persons with the fundamental right to bodily liberty, based on their level of complex cognition, self-awareness and autonomy, rather than simply pieces of property that can be owned, imprisoned and used for experiments").

185 *See supra* notes 116–17, 141 and accompanying text.

"legislative moment," set aside their agenda on the abortion debate and turned their attention to the examination of the kind of mental faculties necessary for entitlement to protection from slavery and involuntary servitude. I do not suggest that they should have abandoned their long-held beliefs that humans are entitled to such protections *regardless* of the state of their mental faculties—e.g., people who have suffered "brain death." Rather, they could have leveraged such momentary shift in focus to reach an agreement with their traditional adversaries on other possible subjects worthy of protection from slavery and involuntary servitude.

Developments in the fields of cognitive neuroscience and artificial intelligence in the last decade or so have yielded new understandings and realizations on the nature of cognition.[186] Further developments in the study of apes and marine mammals have also resulted in realizations regarding the existence of advanced mental faculties in such beings and, perhaps, others.[187] These discoveries are already challenging our perceptions of the dichotomy between the "human" and "nonhuman," as well as traditional legal notions on the concept of personhood.[188] Rather than focusing on genetic and morphologic characteristics of humanity, the sponsors of the Weldon Amendment and Section 33 would have done well to take a potentially more constructive route, had they also given attention to the neurologic and cognitive characteristics of humanity. In so doing, they could have brought Congress into one of the most interesting and relevant scientific and legal debates that are currently taking place. Rather than making another (and probably inconsequential) statement in the abortion debate, they could have initiated a legislative effort aimed at reexamining our preconceptions about the things that supposedly makes humans unique in their capacity to be the subjects of slavery and involuntary servitude.

Such a legislative effort could have resulted in valuable legislation that could have advanced the causes of freedom for those who can

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186 *See* Nick Bostrom & Eliezer Yudkowsky, *The Ethics of Artificial Intelligence*, *in* CAMBRIDGE HANDBOOK OF ARTIFICIAL INTELLIGENCE 3–6 (William Ramsey & Keith Frankish eds., 2014), *available at* http://www.nickbostrom.com/ethics/artificial-intelligence.pdf (highlighting realizations regarding the nature of intelligence reached via the development of artificial intelligence); Adenauer G. Casali et al., *A Theoretically Based Index of Consciousness Independent of Sensory Processing and Behavior*, 198 SCI. TRANSLATIONAL MED. 198ra105 (2013) (describing a method to evaluate consciousness based on a measurement of electrical activity of neurons).

187 *See, e.g.*, THE GREAT APE PROJECT (Paola Cavalieri & Peter Singer eds., 1993); Gregory Berns, Op-Ed., *Dogs Are People, Too*, N.Y. TIMES, Oct. 6, 2013, at SR5 (describing the results of screening dogs in an M.R.I. machine); PHILIP LOW, THE CAMBRIDGE DECLARATION ON CONSCIOUSNESS (Jaak Panksepp et al. eds., 2012), *available at* http://fcmconference.org/img/CambridgeDeclarationOnConsciousness.pdf ("[T]he weight of evidence indicates that humans are not unique in possessing the neurological substrates that generate consciousness. Nonhuman animals, including all mammals and birds, and many other creatures, including octopuses, also possess these neurological substrates." (internal quotation marks omitted)).

188 *See supra* note 184.

appreciate such freedom and the prevention of their exploitation for purposes to which they would not have given their consent, if given the choice. It could have set parameters by which we may determine who is entitled to such choice and who is able to appreciate freedom. Alas, in the current state of our politics, such a scenario is, admittedly, extremely unlikely and so the above discussion reflects more of a wish than a realistic suggestion or viable critique.

III. LEARNING TO LIVE WITH SECTION 33: CONSTRUING SECTION 33 IN THE CONTEXT OF EXISTING AND FUTURE TECHNOLOGIES

While patent law would be better served by repealing Section 33, such repeal (not to mention substitution with the kind of legislation described in the previous section) is unlikely to garner sufficient congressional support under the current political circumstances. Thus, it is necessary to consider how to rectify or at least minimize the potentially harmful effect of Section 33's many problems.

Some of the problems presented by Section 33 are difficult to redress using legal means. For instance, little can be done to retrieve legislative time and energy wasted on the enactment of futile articles of legislation. The definitional problems presented by Section 33, however, may be effectively addressed by using the kind of tools that are readily available to patent examiners and judges. To avoid the possible hazards to the patent system and technological innovation discussed earlier, it is advisable to construe Section 33 as narrowly as possible.

First, the language "directed to or encompassing" ought to be given its meaning in patent jargon. Those versed in patent law typically use the term "directed to" in the context of a patent or a specific patent claim to indicate that the patent or specific claim covers a certain technology. A few examples of such use of "directed to" in the context of patents may include: "[a] single patent may include claims directed to one or more of the classes of patentable subject matter";[189] "[a]lthough directed to a particular use, [the claim] nonetheless covers a broad idea";[190] and "Sunovian's patents covering its Lunesta® product, directed to eszopiclone and methods of using that compound, are not infringed, invalid, and/or unenforceable."[191] By interpreting the terms "directed to or encompassing" in view of how they are likely to be understood by patent scholars and practitioners, Section 33 may be read as prohibiting

189 Microprocessor Enhancement Corp. v. Texas Instruments Inc., 520 F.3d 1367, 1374 (Fed. Cir. 2008).

190 Dealertrack, Inc. v. Huber, 674 F.3d 1315, 1334 (Fed. Cir. 2012).

191 Sunovian Pharm. Inc. v. Teva Pharm. USA, Inc., No. 09-CV-1302, 2012 WL 1191142, at *1 (D.N.J. Apr. 10, 2012), *aff'd*, 731 F.3d 1271 (2013).

only the issuance of patent claims explicitly covering or including a "human organism." Such interpretation of "directed to or encompassing" would not only give Section 33 a logical and manageable scope—one that would not spell doom to our patent system[192]—but it would also comport with what the sponsors of the Weldon Amendment and Section 33 seem to have had in mind.

Second, Section 33 should not apply to categories of subject matter that the sponsors of the Weldon Amendment and Section 33 explicitly excluded from the prohibition of issuance of patent claims "directed to or encompassing a human organism," including, for example, human embryonic stem cell lines, human organs, non-human organisms whose genetic makeup includes portions of human genome, etc.[193]

Third, Section 33 should be construed as limited to cases in which patent claims might, in earnest, create slavery and/or involuntary servitude or impose such a condition on a "human organism" in contravention of the Thirteenth Amendment.[194] Fourth, consistent with its language as well as its legislative history, Section 33 ought to be construed as limited only to "composition of matter" and "manufacture" claims—namely, the "human organism" itself—rather than claims covering processes of making or treating "human organisms."[195] And fifth, in accordance with the intent of its sponsors, the ambiguous term "human organism" ought to be read as referring exclusively to "organisms," namely living individual members of a biological species, rather than to clumps of highly similar cells, such as cells in a culture (including cell lines) and early embryos.[196] Adopting these five strictures would minimize Section 33's potential innovation-dampening effects on existing, new, and emerging technologies.

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192 *See supra* Part II.C.

193 *See supra* notes 87–89 and accompanying text.

194 Admittedly, owing to the Ownership Fallacy, one would be hard pressed to envision such cases.

195 This construction is supported not only by the language of Section 33 itself, but also by its legislative history. *See* 157 CONG. REC. E1182, E1184 (daily ed. June 23, 2011) (letter from FRCAction, Family Research Council, stating that "The Weldon Amendment's use of 'human organism' does not include the process of creating human embryos, such as human cloning, nor does it include non-human organisms, e.g., animals."), *available at* http://www.gpo.gov/fdsys/pkg/CREC-2011-06-23/pdf/CREC-2011-06-23-pt1-PgE1182.pdf.

196 This was the reasoning given by the sponsors of the Weldon Amendment for the exclusion of human stem cells (including embryonic stem cells) and genes from the scope of the Amendment. *See* 157 CONG. REC. E1177, E1179 (daily ed. June 23, 2011) (Nov. 5, 2003 speech of Rep. Dave Weldon, submitted into record) ("[A] human embryo is an 'organism' but a stem cell clearly is not . . . That same conclusion was later reached by HHS general counsel Harriet Rabb, in arguing that the Clinton administration's guidelines on stem cell research were in accord with statutory law . . . . To argue now that a ban on patenting 'human organisms' somehow bans patenting of stem cells or stem cell lines would run counter to . . . years of legal history, and would undermine the legal validity of any federal funding for embryonic stem cell research.").

IV. SECTION 33 AS A SIGN OF CONGRESS'S NEED FOR RELIABLE AND IMPARTIAL ADVICE ON ISSUES OF SCIENCE AND TECHNOLOGY

The legislative histories of the Weldon Amendment and Section 33 contain strong admonitions regarding biotechnology and biomedical research. The sponsors of the Weldon Amendment and Section 33 warned that society must "draw the line where some rogue scientists fail to exercise restraint."[197] They emphatically stressed that "[i]n an age when the irresponsible use of biotechnology threatens to make humans themselves into items of property, of manufacture and commerce, Congress cannot let this happen again in the case of human organisms."[198] They also argued that "[w]e should not allow such researchers to gain financially by granting them an exclusive right to practice such ghoulish research."[199]

The Ownership Fallacy aside, the sponsors of the Weldon Amendment and Section 33 did not mince words in expressing their reservations about what they perceived as unworthy scientific research. Yet, speaking of "rogue scientists" who "fail to use restraint" and who must not be allowed "to gain financially" from their "ghoulish research," and of "irresponsible use of biotechnology" that "threatens to make humans themselves into items of property" was unjustified[200] and unnecessarily incendiary, setting a negative tone in what could have otherwise been a fruitful discussion.

The words of the Presidential Commission for the Study of Bioethical Issues are instructive:

> [I]ndividuals and deliberative forums should strive to employ clear and accurate language. The use of sensationalist buzzwords and phrases such as "creating life" or "playing God" may initially increase attention to the underlying science and its implications for society, but ultimately such words impede ongoing understanding of both the scientific and ethical issues at the core of public debates on these topics.[201]

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197 157 CONG. REC. E1177, E1178 (citing to H. Admt. 286).

198 *Id.*

199 *Id.* (citing to Rep. Dave Weldon's July 22, 2003 speech regarding H. Admt. 286 to clarify the intent of the provision).

200 As explained by Dr. Gleicher and Dr. Tang, their research was not meant to "make humans themselves into items of property, of manufacture and commerce" but rather to serve as a proof of concept for a novel kind of treatment for congenital genetic disorders. *See* Gleicher & Tang 2004, *supra* note 51, at 977 ("Objective: To determine whether human embryos accept blastomere transplants and integrate them normally into the architecture of the developing embryo.").

201 PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES 15 (2010) [hereinafter PRESIDENTIAL COMMISSION 2010 REPORT], *available at* http://bioethics.gov/sites/default/files/PCSBI-Synthetic-Biology-Report-12.16.10_0.pdf.

Indeed, if we are to have the kind of informed and open discussion that is necessary where potential bioethical issues present themselves, we would all do well to avoid inflammatory language.

This unjustifiable use of inflammatory language as well as many of the flaws underlying Section 33 may be attributed to the apparent absence of scientific input from the legislative discussions that preceded the enactment (and repeated re-enactment) of the Weldon Amendment and, ultimately, Section 33.[202] This fact seems to have been well recognized during the legislative discussions of the Weldon Amendment, as is evident from the words of Rep. John Conyers: "[t]his poorly-drafted provision is an example of why Congress should not legislate on medical practices and should not make important policy decisions without the input of experts in the field."[203]

The fact that the sponsors of the Weldon Amendment and Section 33 did not receive meaningful scientific advice is at least partially attributable to the lack of impartial scientific input available for Congress since its defunding of the Office of Technology Assessment (OTA) in 1995. The unfortunate consequences of the termination of OTA have been well recognized and documented.[204] Still, the legislative processes that led to the enactment of the Weldon Amendment and Section 33 are a reminder of how sorely Congress misses reliable and impartial advice on matters of science and technology.

CONCLUSION

The prohibition on the patenting of inventions "directed to or encompassing a human organism" enacted as Section 33 of the AIA is an exercise in legal futility. Unnecessary from the outset in light of

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202 This is evident, for example, in the apparent lack of perspective of the sponsors of the Weldon Amendment on the true purpose and meaning of the Gleicher and Tang research and their inappropriate use of the term "she-male" in relation to it. *See supra* notes 51, 58 and accompanying text. As noted by Dan Burk:

> Science and technology may give rise to novel legal and political issues. Before analyzing such novel issues, it is imperative to define their proper dimensions. This definition must begin with technology assessment—an accurate appraisal of the capabilities and likely impact of the new technology. Improper technology assessment leads almost inevitably to improper issue resolution . . . when one begins with an incorrect set of premises, one almost inevitably arrives at an incorrect set of conclusions.

See Burk, *supra* note 20, at 1601–02.

203 *See* 149 CONG. REC. H12766, H12830 (daily ed. Dec. 8, 2003) (statement of Rep. John Conyers, Jr.).

204 *See, e.g.*, *Hearing on 2011 Appropriations Before the H. Comm. on Appropriations*, 111th Cong. (2010), *available at* http://www.ucsusa.org/assets/documents/scientific_integrity/Grifo_OTA_Written_Testimony_24_Feb_2010.pdf (written testimony of Francesca T. Grifo, Senior Scientist, Union of Concerned Scientists Scientific Integrity Program).

existing laws, it is premised on the Ownership Fallacy, a misunderstanding of patent law that mistakes patent rights for ownership of the thing that is patented. Furthermore, the controversy surrounding the meaning of the term "human organism" and the legislative history of Section 33, which is fraught with inconsistencies, contradictions, and lack of a general guiding principle, render Section 33 extremely difficult, if not impossible, to construe coherently. As a result, Section 33, while meant to appease and appeal to a variety of interest groups,[205] is drafted in such a way that not only makes it unlikely to achieve its sponsors' goals but may well backfire, resulting in outcomes opposite to those originally intended by its sponsors.[206]

Worse yet, Section 33 might prove harmful to innovation, especially in the area of biomedical technology. By construing the term "directed to or encompassing a human organism" in any but the narrowest way, whole areas of technology (and sectors of the economy) might become devoid of the economic incentives necessary for the innovation upon which they are premised. This reason alone presents enough justification to repeal Section 33. Indeed, ironically, Section 33 and its predecessor, the Weldon Amendment, are the epitome of a warning made by former Rep. Weldon during the legislative discussions of "his" Amendment: "[j]ust because something can be done does not mean that it should be done."[207] Borrowing from former Rep. Weldon: not everything that could be enacted should actually be made into law.

The sponsors of the Weldon Amendment and Section 33 rationalized their legislative efforts by tying them to the abolition of slavery and involuntary servitude.[208] Yet, the profound question of who or what should be the subject of protection from slavery and involuntary servitude requires consideration that far exceeds the narrow scope of patent law.[209] Advances in the areas of cognitive neuroscience and artificial intelligence, as well as important discoveries regarding the mental faculties of some animals, are challenging our traditional

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205 Section 33 may well be what Mark Tushnet and Larry Yackle call a "symbolic statute;" namely a statute enacted "to make a point, or to be able to tell . . . constituents that [its sponsors] have done something about a problem." *See* Mark Tushnet & Larry Yackle, *Symbolic Statutes and Real Laws: The Pathologies of the Antiterrorism and Effective Death Penalty Act and the Prison Litigation Reform Act*, 47 DUKE L.J. 1, 2–3 (1997).

206 *See supra* Part II.D (explaining how the unavailability of patent protection for inventions "directed to or encompassing a human organism" might actually further push the research of biomedical technologies underlying such inventions rather than dampen it).

207 157 CONG. REC. E1177, E1178 (daily ed. June 23, 2011) (citing to Rep. Dave Weldon's July 22, 2003 speech regarding H. Admt. 286 to clarify the intent of the provision).

208 *See id.* (the sponsors of the Weldon Amendment sought to "ensure there is not financial gain or ownership of human beings").

209 *See also* Burk, *supra* note 20, at 1641 (making the observation that objections to patenting of certain inventions are sometimes a surrogate for objecting to other social concerns and that "the patent system seems an inappropriate battlefield on which to wage these political conflicts").

perceptions and understanding of the concepts of slavery and involuntary servitude. The debate regarding the rights of nonhuman beings is already taking place, and it is only a matter of time before Congress is forced to pass legislation addressing it. The sponsors of Section 33 would have done well to capitalize on their commitment to the prevention of slavery and involuntary servitude by advancing legislation—outside and beyond the limited context of patent law—that would protect *any being* that might suffer from slavery and involuntary servitude. In so doing, they could have lit the way to original and beneficent legislation that would have had the potential to transform current perceptions of what we wrongly (and wrongfully) call "human rights."

Like money in the national coffers, legislative time, efforts, and opportunities are limited national resources, with which legislators should not be wasteful. The legislative efforts to pass the Weldon Amendment and Section 33 represent a waste of these resources. Policymakers in general—and Congress in particular—have the responsibility to proceed with caution and back their efforts with sound information obtained from unbiased sources, rather than just media headlines. This is especially true for efforts that may affect the structure of incentives for research and development in a technology-driven economy such as ours. Hence, Congress would do well not only to repeal Section 33, but also to (re)institute mechanisms that would assist it to adequately inform itself on matters that require expertise.

APPENDIX

Technology	**Applicability of Section 33 when Construed Narrowly[210] (and Reason for that in Parentheses)**	**Unpatentable and/or Unenforceable in light of the Thirteenth Amendment?[211]**
Existing Technologies:		
A "human being"/"person" under 1 U.S.C. § 8	Yes (although might not be novel)	Yes
Human organs, including synthetic (as separate from and independent of a "human organism")	No (excluded in legislative history;[212] not an "organism")	No
Human stem cells (including embryonic stem cells)	No (excluded in legislative history;[213] not an "organism")	No
Human genes	No (excluded in legislative history; [214] not an "organism")	No
Transgenic non-human organisms having one or more human genes (e.g., "a non-human organism incorporating one or more genes taken from a human organism"[215])	No[216] (non-human by definition; excluded in legislative history)	Yes, if capable of slavery and involuntary servitude

210 The construction of Section 33 for purposes of the analysis brought in this Table is in accordance with the recommendations listed in Part III.

211 This comparison of the applicability of Section 33 to certain technologies to that of the Thirteenth Amendment (under the Ownership Fallacy) is illustrative of the discussion in Part II.E.5. *See supra* note 177 and accompanying text.

212 157 CONG. REC. E1182, E1183 (daily ed. June 23, 2011).

213 *See supra* note 177 and accompanying text.

214 *See supra* note 177 and accompanying text.

215 157 CONG. REC. E1178, E1178 (daily ed. June 23, 2011) ("[T]his has no bearing on stem cell research or patenting genes[.]"); *id.* at E1179 ("[T]he U.S. Patent Office has already issued patents on genes, stem cells, animals with human genes . . . . My amendment would not affect [this.]"). Interestingly, this was made abundantly clear for the Wisconsin representatives, as Former Rep. Weldon "recognize[d] that there are many institutions, particularly in Wisconsin, that have extensive patents on human genes, human stem cells." *Id.* at E1178.

216 Since the Supreme Court's decision in *Chakrabarty* and the Federal Circuit's decision in *In re Allen*, the USPTO has viewed living organisms (including animals) and transgenic organisms as patentable subject matter and has granted many patents directed to such subject matter before and after the passage of the Weldon Amendment. This is evident in the many hundreds of patents

Human embryo hybrids (e.g., male-female embryos)[217]	? (not an "organism"[218] but included in legislative history)	No
Genetically modified members of the species *Homo sapiens* (e.g., products of gene therapy used on *Homo sapiens*,[219] including with non-human genetic material)	Yes (although might not be novel)	Yes
Human-machine hybrids (e.g., humans wearing advanced prostheses)[220]	Yes	Yes

classified under art class 800: Multicellular Living Organisms within the USPTO patent database, *USPTO Patent Full-Text and Image Database*, U.S. PATENT & TRADEMARK OFFICE, http://patft.uspto.gov/netahtml/PTO/search-adv.htm (last visited Sept. 7, 2014); a similar search for patents classified under the Transgenic Nonhuman Animal subcategory (ccl/800/13) yielded over 260 results dating before and after the Weldon Amendment and the passage of Section 33. There are recent examples of issued patents having claims directed to nonhuman organisms incorporating one or more human genes. *See, e.g.*, U.S. Patent No. 8,193,408 (filed June 2008) (issued June 5, 2012) (claiming "[a] genetically modified nematode belonging to the genus Caenorhabditis said nematode expressing human alpha-synuclein under the control of a Caenorhabditis neuronal promoter"); U.S. Patent No. 7,816,578 (filed Sept. 30, 2005) (issued Oct. 19, 2010) (entitled "[t]ransgenic transchromosomal rodents for making human antibodies"); U.S. Patent No. 7,968,762 (filed July 12, 2005) (issued June 28, 2011) (entitled "[i]mmune-compromised transgenic mice expressing human hepatocyte growth factor (hHGF)"); s*ee also* MPEP, *supra* note 19, § 2105 (including guidelines on the patentability of "Living Subject Matter" following *Chakrabarty*).

Interestingly, the only direct reference in the MPEP to transgenic animals as such appears in a section unrelated to the issue of patentable subject matter. *See* MPEP, *supra* note 19, § 2121.01 (discussing the case of Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003), in the context of the inquiry of whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation). Still, the reference is instructive of the USPTO's general view of transgenic animals as patentable subject matter, as also recognized by the sponsors of the Weldon Amendment. *See* 157 CONG. REC. E1177, E1178 (daily ed. June 23, 2011) ("The Patent Office has, since 1980, issued hundreds of patents on living subject matter, from microorganisms to nonhuman animals"); *id.* at E1179 ("The USPTO has already granted [such] patents . . . (see U.S. patent nos. 5,625,126 and 5,602,306).").

217 *See supra* note 51.

218 *See supra* note 116 and accompanying text.

219 *See supra* note 152.

220 Human-machine hybrids are beings consisting of direct interfaces between the human body and a mechanical or technological component. Examples may include people with cochlear implants, people with a pacemaker, an artificial heart, advanced prosthetics, etc. In popular culture, technologically extensive versions of such hybrids are commonly referred to as "cyborgs." *See infra* note 225.

Human-animal chimeras[221]	No (when "non-human"[222]); Yes (when classifiable as "human")	Yes, if capable of slavery and involuntary servitude
Methods of cloning humans	No (excluded in legislative history[223])	No
Emerging Technologies:		
Human clones (*not* including methods of making them)[224]	Yes	Yes
Cyborgs[225]	Yes (so long as not solely a machine)	Yes, if capable of slavery and involuntary servitude

221 *See supra* note 93.

222 *See* Final Rejection 10/29/99, *supra* note 39, at 7 ("[A] chimeric organism may be obviously non-human in an extreme case (e.g., 99% non-human cells, 1% human cells) and of ambiguous humanity in other cases (50% human cells, 50% non-human cells)[.]"). Hence, as described above, the USPTO has been granting patents on such human-animal chimeras. *See supra* notes 93, 95 and accompanying text. Nevertheless, even under a narrow construction, it is likely that Section 33 would apply to human-animal chimeras under some circumstances in which the "human component" (in terms of proportion of cells, physical features, the presence of cognition, etc.) would be of notable quantity or quality.

223 *See supra* note 88 and accompanying text ("[N]othing in this section should be construed to limit the ability of the PTO to issue a patent containing claims directed to or encompassing . . . methods for creating embryos . . . [and] methods of somatic cell nuclear transfer[.]"). Notably, the USPTO has indeed allowed and issued at least one patent claiming methods of cloning mammals without restricting the claims to nonhuman organisms. *See* U.S. Patent No. 6,781,030 (filed Nov. 2, 1999) (issued Aug. 24, 2004). This grant is possibly in contravention of the 1987 USPTO Policy, according to which "any claim directed to a non-plant multicellular organism, which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection." *See supra* note 19 and accompanying text.

224 *See supra* note 151.

225 Cyborgs are persons "whose physical tolerances or capabilities are extended beyond normal human limitations by a machine or other external agency that modifies the body's functioning; an integrated man-machine system." 4 THE OXFORD ENGLISH DICTIONARY 188 (2d ed. 1989); *see also* JAMES HUGHES, CITIZEN CYBORG: WHY DEMOCRATIC SOCIETIES MUST RESPOND TO THE REDESIGNED HUMAN OF THE FUTURE 75–106, 221–32 (2004) (highlighting the problems created by the prevalent dichotomy between "human" and "nonhuman" and proposing to replace it with a more subtle distinction between persons and nonpersons, which would give more room for consideration of nonhuman modes of consciousness).

Section 33 does not provide a standard by which it may be determined when a cyborg ceases to be an "organism" and is classifiable solely as "machine," which may be patented as no longer "directed to or encompassing a human organism" under the Section.

Envisioned Technologies:[226]		
De-extinct *Homo neanderthalensis* and other "archaic" *Homo* species not classified as *Homo sapiens*[227]	No (not a member of the species *Homo sapiens*)	Yes[228]
A human-chimpanzee/orangutan hybrid[229]	Yes	Yes, if capable of slavery and involuntary servitude
Synthetically created sentient biological organisms that cannot be classified as members of the genus *Homo*[230]	No (not human)	Yes, if capable of slavery and involuntary servitude

226 The "technologies" listed herein are brought for illustrative purposes only.

227 *See* Carl Zimmer, *Bringing Them Back to Life*, NAT'L GEOGRAPHIC, Apr. 2013 (describing de-extinction as the "notion of bringing vanished species back to life" and as exemplified by the successful cloning of a now extinct Pyrenean ibex); *see also* Nicholas Wade, *Scientists in Germany Draft Neanderthal Genome*, N.Y. TIMES, Feb. 13, 2009, at A12 (discussing the possibility of producing an individual *Homo neanderthalensis* whose genome was fully sequenced).

228 This is under the assumption that archaic *Homo* species may have possessed—and would possess, if individuals of those species were to be de-extinct—mental faculties that make the notions of slavery and involuntary servitude applicable to them in ways similar, if not identical, to members of the species *Homo sapiens*.

229 The sponsors of the Weldon Amendment mentioned such hybrids during the congressional discussions of the Amendment and expressed their intention to include under "human organism" any "human animal hybrid organism formed by fertilizing a nonhuman egg with human sperm or a human egg with non-human sperm, or by combining a comparable number of cells taken respectively from human and nonhuman embryos." *See supra* note 87 and accompanying text.

Notably, attempts to create a human-chimpanzee hybrid, and, later, a human-orangutan hybrid took place in the 1920s as part of research conducted by a Russian scientist by the name of Il'ya Ivanov. *See* Alexander Etkind, *Beyond Eugenics: The Forgotten Scandal of Hybridizing Humans and Apes*, 39 STUD. HIST. PHIL. BIOLOGICAL & BIOMED. SCI. 205 (2008); Kirill Rossiianov, *Beyond Species: Il'ya Ivanov and His Experiments on Cross-Breeding Humans with Anthropoid Apes*, 15 SCI. CONTEXT 277 (2002).

230 The Presidential Commission for the Study of Bioethical Issues has described synthetic biology as "an emerging field of research that combines elements of biology, engineering, genetics, chemistry, and computer science. The diverse but related endeavors that fall under its umbrella . . . [seek to] create new biochemical systems or organisms with novel or enhanced characteristics." *See* PRESIDENTIAL COMMISSION 2010 REPORT, *supra* note 201, at 36. While synthetic biology is currently considered a nascent field of research, it may one day lead to the creation of advanced non-human organisms, potentially with advanced mental faculties. *See, e.g.*, Linda Geddes, *Redesigning Life*, 220 NEW SCIENTIST 29 (2013) (raising the question whether "synthetic biologists [will] ever progress from tinkering with bacteria to radically altering complex organisms – even humans?").

Sentient non-biological beings (artificial intelligence)[231]	No	Yes
A human consciousness preserved outside of a human body (e.g., in a computer; "brain in a vat")[232]	No (not an "organism")	Yes

231 Also known as AI or the "Singularity" (a term coined by mathematician and science fiction author Vernor Vinge in 1993), such sentient beings would be by definition neither organisms nor human. *See* Margaret A. Boden, *Artificial Intelligence*, *in* THE SHORTER ROUTLEDGE ENCYCLOPEDIA OF PHILOSOPHY 71 (Edward Craig ed., 1998) (stating that artificial intelligence attempts to "make computer systems (of various kinds) do what minds can do" and offering examples such as "interpreting a photograph as depicting a face; offering medical diagnoses; using and translating language; learning to do better next time"); VERNOR VINGE, THE COMING TECHNOLOGICAL SINGULARITY: HOW TO SURVIVE THE POST HUMAN ERA (1993) (coining the term "technological singularity").

232 It has been theorized that we may one day be able to preserve the consciousness of a person within or with the assistance of a computer. *See* ANDERS SANDBERG & NICK BOSTROM, FUTURE OF HUMANITY INSTITUTE, OXFORD UNIV., WHOLE BRAIN EMULATION: A ROADMAP, TECHNICAL REPORT #2008-3 (2008), *available at* www.fhi.ox.ac.uk/reports/2008-3.pdf.

A "brain in a vat" (which is currently the sole domain of science fiction) originated as a philosophical idea of a disembodied brain floating in a vat of nutrient fluids that keep the brain alive. The brain may be connected to a computer that creates, via electrical stimuli, a perception of reality in the brain. *See* Tony Brueckner, *Skepticism and Content Externalism*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., Spring 2012), *available at* http://plato.stanford.edu/archives/spr2012/entries/skepticism-content-externalism.