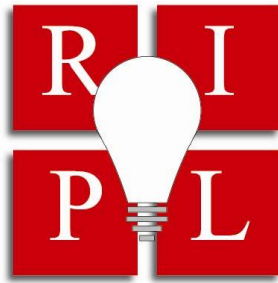


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



DIRECTED TO OR ENCOMPASSING A HUMAN ORGANISM: HOW SECTION 33 OF THE
AMERICA INVENTS ACT MAY THREATEN THE FUTURE OF BIOTECHNOLOGY

AVA CAFFARINI

ABSTRACT

Biotechnology is a rapidly growing field that has pushed the limits of patent eligible subject matter. In response to the expansion of biotechnology, critics have emerged with both economic and moral concerns over the development and patenting of these technologies. On the economic front, critics are wary of the potential development of an “anticommons.” On the moral front, critics are concerned with the potential to erode human dignity and “play God.” Congress has responded to the moral concerns with section 33 of the America Invents Act. Section 33 states that “[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.” This provision was intended to ban the patenting of human beings at any stage of development, including embryos, fetuses, human/non-human chimeras, and clones. However, the vague wording of section 33 and the absence of definitions for “directed to” and “human organism,” give courts wide latitude when construing section 33, possibly leading to a construction that invalidates several biotechnology inventions.

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DIRECTED TO OR ENCOMPASSING A HUMAN ORGANISM: HOW SECTION 33
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BIOTECHNOLOGY

AVA CAFFARINI*

INTRODUCTION

“There is no medicine like hope, no incentive so great, and no tonic so powerful as expectation of something better tomorrow.”¹

To some, biotechnology is a hope for a better tomorrow.² To others, biotechnology is an ethical battleground.³ To all, biotechnology is a cutting edge industry that utilizes living organisms to create products with the potential to revolutionize modern life.⁴ The cutting edge nature of biotechnology carries with it the understanding that many useful inventions will be mired in controversy.⁵ This controversy is both morally and economically focused; some critics object to the patenting of living organisms generally or to experimentation with specific types of organisms,⁶ while others object to biotechnology patents because they drive up the cost of innovation, and threaten to slow scientific research.⁷ Despite public objection, however, biotechnology patents continue to be issued at a constant rate.⁸

* © Ava Caffarini 2013. Juris Doctor Candidate, May 2013. The John Marshall Law School. Bachelor of Science in Molecular and Cellular Biology, May 2010, University of Illinois at Urbana-Champaign. To my mother and father, Angelinn and Joseph Caffarini, for all of their love and support during the turbulent times of law school. To my brother, Joseph, whose love for molecular biology rivals my own. To my editors, Levon Barsoumian and Michael Carrozza, for helping me through this daunting process, and finally, to all of my friends who made law school a significantly more enjoyable experience.

¹ Orison Swett Marden.

² See Andrew Pollack, *F.D.A. Approves a Stem Cell Trial*, N.Y. TIMES, Jan. 23, 2009, at B1 (discussing the first FDA-approved trial on human stem cells).

³ See Jocelyn E. Mackie et al., *Lessons on Ethical Decision Making from the Bioscience Industry*, 3 PLOS MED. 605, 605–10 (2006) (discussing ethical issues in bioscience); Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 469–72 (2003) (remarking on controversial biotechnology inventions).

⁴ See Ashish Swarup Verma et al., *Biotechnology in the Realm of History*, 3 J. PHARMACY & BIOALLIED SCI. 321, 321 (2011).

⁵ See, e.g., J. Suaudeau, *From Embryonic Stem Cells to iPS—An Ethical Perspective*, 44 CELL PROLIFERATION 70, 70–80 (2010) (discussing controversy surrounding stem cell research); Mildred Cho, *Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics*, 28 TRENDS IN BIOTECH. 548, 548–51 (2010) (discussing controversy surrounding gene patents); Bagley, *supra* note 3, at 469–70 (discussing controversy over transgenic animals, and methods of cloning humans).

⁶ See, e.g., Bagley, *supra* note 3, at 469–70 (discussing the controversy over transgenic animals and methods of human cloning).

⁷ See, e.g., Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 662–64 (2004) (discussing the economic problems related to patents and cost).

⁸ Dov Greenbaum, *Academia to Industry Technology Transfer: An Alternative to the Bayh-Dole System for Both Developed and Developing Nations*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 311, 313–20 (2009).

Congress responded to some of these concerns with section 33 of the Leahy-Smith America Invents Act (“AIA”),⁹ which states that “[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.”¹⁰ Although not yet addressed by the courts, section 33 can potentially be construed quite broadly, thereby derailing patent eligibility for a wide range of inventions.¹¹

Part I of this comment provides both legal and historical bases for the controversy surrounding biotechnology patents. Part II analyzes some ways that section 33 may be construed and the implications of those constructions on the future of biotechnology patents. Part III offers a way for legislators to amend section 33 that can avoid invalidating biotechnology patents.

I. BACKGROUND

This section first discusses the patentability of subject matter involved in biotechnology inventions and highlights the arguments some commentators have made, both for and against the patenting of such inventions. The section then proceeds by explaining the history of section 33, and concludes with a brief presentation of the mechanics used in statutory construction.

A. Patent Eligibility of Biotechnological Subject Matter

To be eligible for patent protection, inventions must fall within one of the statutory categories for patent eligible subject matter listed in 35 U.S.C. § 101. Section 101 states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent.”¹² The legislative history of the Patent Act of 1952 provided that subject matter eligibility should extend to “anything under the sun that is made by man.”¹³ Accordingly, courts have consistently construed § 101 very broadly.¹⁴ This has led to patents with extremely diverse subject matter, including

⁹ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.).

¹⁰ *Id.* § 33(a), 125 Stat. at 340.

¹¹ See 149 CONG. REC. E2234–35 (daily ed. Nov. 5, 2003) (statement of Rep. David Weldon) (acknowledging, but not accepting, arguments made by the Biotechnology Industry Organization (BIO) and the Coalition for the Advancement of Medical Research (CAMR) that § 33 would “potentially prohibit[] patents on stem cell lines, procedures for creating human embryos, prosthetic devices, and in short almost any drug or product that might be used in or for human beings”).

¹² 35 U.S.C. § 101 (2012).

¹³ S. REP. NO. 82-1979 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399, 1952 WL 3180.

¹⁴ See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399, 1952 WL 3180) (“Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”); *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130 (2001) (“[T]he language of § 101 is extremely broad. ‘In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”).

patents claiming business methods,¹⁵ software,¹⁶ and even genetically engineered mice.¹⁷

Of particular importance here is the patent eligibility of living organisms. This issue was first addressed in the landmark case *Diamond v. Chakrabarty*.¹⁸ In that case, the United States Supreme Court held that genetically engineered bacteria was patent eligible under § 101 because it was the result of the inventor's handiwork and not a product of nature.¹⁹ The *Chakrabarty* decision marked the beginning of the biotechnology revolution, and there has been a steady increase in the expansion of patent eligible subject matter since.²⁰

Fast forward to recent times. The *Chakrabarty* reasoning—that an inventor's handiwork is patent eligible—is being questioned by the hot debate over whether human genes should be patent eligible subject matter under § 101. In *Association for Molecular Pathology v. United States Patent & Trademark Office* (hereinafter *Myriad*),²¹ the Southern District of New York held that genes were not patent eligible subject matter,²² but the Federal Circuit disagreed.²³ The Supreme Court initially refused to address the matter, and instead, instructed the Federal Circuit to reconsider the issue in light of the Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories*.²⁴ The Federal Circuit again, however, found that human genes are patent eligible under § 101.²⁵ The Supreme Court has now granted certiorari limited to answering the simple question, "Are human genes patentable?"²⁶

B. The Controversy Surrounding Biotechnology Patents

The breadth of patent eligible subject matter under § 101 has introduced a variety of problems into the patent system, and calls for reform have come from

¹⁵ See, e.g., Sys. & Methods to Support Info. Tech. Bus. Decisions, U.S. Patent No. 8,335,692 (filed Oct. 23, 2009).

¹⁶ See, e.g., Command User Interface for Displaying Selectable Software Functionality Controls, U.S. Patent No. 8,255,828 (filed Sept. 30, 2004).

¹⁷ See, e.g., Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (filed June 22, 1984). Despite the breadth of § 101, however, there remains some restrictions on patent eligible subject matter. See *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010). The laws of nature, physical phenomena and abstract ideas, for example, are three categories of subject matter ineligible for patent protection. *Id.* at 3221.

¹⁸ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹⁹ *Id.* at 310.

²⁰ See Peter K. Yu, *Teaching International Intellectual Property Law*, 52 ST. LOUIS U. L.J. 923, 933 (2008) (crediting *Chakrabarty* as the starting point of the biotechnology revolution and discussing the growth of patent eligible subject matter because of *Chakrabarty*).

²¹ *Ass'n for Molecular Pathology v. United States Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

²² *Id.* at 220–32.

²³ *Ass'n for Molecular Pathology v. United States Patent & Trademark Office*, 653 F.3d 1329, 1334 (Fed. Cir. 2011).

²⁴ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012), *petition for cert. denied*, 80 U.S.L.W. 3545 (U.S. Mar. 26, 2012) (No. 11-725).

²⁵ *Ass'n for Molecular Pathology v. United States Patent and Trademark Office* 689 F.3d 1303, 1325–33 (Fed. Cir. 2012).

²⁶ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012), *petition for cert. granted*, 81 U.S.L.W. 3305 (U.S. Nov. 30, 2012) (No. 12-398).

numerous members of the legal community.²⁷ Examples of innovations in biotechnology that have attracted the most negative attention include genetic testing, stem cell research, cloning, and the creation of chimeras.²⁸ Critics of biotechnology patents point to two types of concerns: (1) economic concerns that focus on the creation of a restrictive patent thicket and (2) ethical concerns over the patenting of inventions derived from human cells and human life forms.²⁹ Each concern is now addressed.

1. *The Controversy Over Patent Thickets*

Many believe that patent rights are necessary to spur innovation, especially in the biotechnology industry, because the promise of patent exclusivity encourages investors to fund expensive and risky research.³⁰ Critics with economic concerns, however, point to the growing complexity of the patent landscape as foreshadowing the development of patent thickets.³¹ A patent thicket arises when several parties hold concurrent patent rights in a variety of closely related inventions.³² As a thicket grows and property rights become increasingly fragmented, it becomes more and more difficult to license all of the patents necessary to put the patented inventions to

²⁷ See H.R. REP. NO. 112-98, at 38–39 (2011) (listing various sources calling for patent reform); Jerome H. Reichman, *Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?*, 46 HOUS. L. REV. 1115, 1121 (2009) (“It is widely recognized that the patent system in the United States is emerging from a period of crisis. Among other problems, the cumulative costs of litigation generated by a plethora of weak patents that increasingly pervaded the upstream research dimension threaten to exceed the aggregate returns from patented innovation . . .”).

²⁸ See also M. Mameli, *Reproductive Cloning, Genetic Engineering and the Autonomy of the Child: the Moral Agent and the Open Future*, 33 J. MED. ETHICS 87, 87–93 (2007) (discussing objections to genetic engineering and reproductive cloning); Francoise Baylis & Jason Scott Robert, *Part-Human Chimeras: Worrying the Facts, Probing the Ethics*, 7 AM. J. BIOETHICS 41, 41–45 (2007) (discussing ethical concerns over the creation of chimeras); Hans-Werner Denker, *Potentiality of Embryonic Stem Cells: an Ethical Problem Even with Alternative Stem Cell Sources*, 32 J. MED. ETHICS 665, 665–71 (2006) (discussing ethical concerns surrounding stem cell research); Jon F. Merz & Mildred K. Cho, *What are Gene Patents and Why Are People Worried about Them?*, 8 J. COMMUNITY GENETICS 203, 203–08 (2005) (examining the ethical and practical concerns of patenting genes).

²⁹ See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (discussing the threat of a patent thicket); Joel Lexchin, *One Step Forward, One Step Sideways? Expanding Research Capacity for Neglected Diseases*, 10 BMC INT’L HEALTH & HUM. RTS. 1, 5 (discussing the threat of patent thickets to biotechnology).

³⁰ See Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 ANN. REV. GENOMICS & HUM. GENETICS 383, 392 (2010) (discussing the profitability of Stanford’s patents on recombinant DNA methods); E. Richard Gold et al., *Are Patents Impeding Medical Care and Innovation?*, 7 PLOS MED. 1, 2 (2009) (explaining the importance of drug patents to recoup funds expended during research in the pharmaceutical industry).

³¹ See Cook-Deegan & Heaney, *supra* note 30, at 22–23 (discussing the rise of a potential patent thicket in academic research); Heller & Eisenberg, *supra* note 29, at 698–90 (discussing how a patent thicket can emerge in biotechnology and how this issue it can be addressed from a legal perspective).

³² James M. Buchanan & Yong J. Yoon, *Symmetric Tragedies: Commons and Anticommons*, 43 J.L. & ECON. 1, 1 (2000).

practical use.³³ The result is the under-use of otherwise valuable technology, referred to as an “anticommons.”³⁴ A related concern is that individual patent holders might block the development of new inventions by refusing to license their patented technology.³⁵ This is particularly dangerous because it is nearly impossible to invent around some biotechnology patents.³⁶ There is also serious concern that public access to patented inventions related to healthcare will be limited due to cost.³⁷

Although the growth of patent thickets is a common concern in most fields of biotechnology, as mentioned previously, gene patents have been the focus of more intense academic debate than other types of patents.³⁸ One reason for this is because gene patents are difficult to invent around, making them particularly susceptible to the emergence of a patent thicket.³⁹ As discussed, an emerging patent thicket involving gene patents may make it difficult and expensive to license the necessary patent rights to create a panel of genetic tests for clinical use.⁴⁰ Additionally, there is little incentive for the patent holder of a genetic test to improve upon the already patented test, or to develop tests using different, but analogous technology.⁴¹

In the case of *Myriad*, the claims were directed to “(1) isolated DNA containing all or portions of the *BRCA1* and *BRCA2* gene sequence and (2) methods for ‘comparing’ or ‘analyzing’ *BRCA1* and *BRCA2* gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer.”⁴² While invalidating the claims based on § 101 considerations, the district court judge also largely relied upon policy arguments, including the fear that gene patents would

³³ See David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1684 (2007). The often-repeated concern is that too many patents in upstream research tools will restrict downstream research and product development because it will be too costly and time consuming to license all of the necessary patents. See Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1060 (2008); Adelman & DeAngelis, *supra*, at 1684 (discrediting arguments that there is a patent thicket forming in biotechnology).

³⁴ See Heller & Eisenberg, *supra* note 29, at 698.

³⁵ See *id.*

³⁶ See Cook-Deegan & Heany, *supra* 30, at 23 (citing gene patents specifically as they types of inventions that are difficult to invent around).

³⁷ Ashton Powell et al., *Spinocerebellar Ataxia: Patent and Health Professional Perspectives on Whether and How Patents Affect Access to Clinical Genetic Testing*, 12 J. GENETICS MED. S83, S84, S90–S103 (2010).

³⁸ See E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 J. GENETICS MED. S39, S40 (2010) (noting that there have been many studies on gene patents).

³⁹ See Merz & Cho, *supra* note 28, at 203.

⁴⁰ Brandon L. Pierce et al., *The Impact of Patents on the Development of Genome-Based Clinical Diagnostics: An Analysis of Case Studies*, 11 GENETICS MED. 202, 203 (2009).

⁴¹ See Powell et al., *supra* note 37, at S89–S90. The concern over emerging patent thickets, however, may be disproportionately large when compared to studies documenting the reality of licensing fees. See Eisenberg, *supra* note 33, at 1063–99 (discussing the discrepancy between the fear of a patent thicket and the actual reality of patent licensing); Adelman & DeAngelis, *supra* note 33, at 1681–82 (discussing the lack of evidence to support the existence of patent thickets). A number of studies suggest that the fear of an “anticommons” may in fact be misguided, as there is very little empirical evidence to suggest that patent thickets exist. See Adelman & DeAngelis, *supra* note 33, at 1685. For example, in the case of gene patents, commentators have recognized that patents have been responsible for an increase in price to license gene patents, but there has been no increased difficulty gaining access to genetic tests. See Powell et al., *supra* note 37, at S83.

⁴² *Ass’n for Molecular Pathology v. United States Patent & Trademark Office*, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

lead to the rise of a patent thicket.⁴³ In fact, he accused Myriad of participating in anti-competitive behavior that would aid in the development of a thicket.⁴⁴ The Supreme Court will soon weigh in on these very issues.⁴⁵

2. Moral and Ethical Issues Created by Biotechnology

Biotechnology has also been the center of an ethical debate since *Chakrabarty* expanded patent eligible subject matter to include life forms.⁴⁶ A few weeks after *Chakrabarty* was decided, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report voicing potential moral and ethical issues related to genetic engineering.⁴⁷ The Commission expressed concern about the impact of genetic engineering on humans, including a fear that genetic engineering would change the basic nature of humanity, give humans the ability to direct evolution, and allow humans to "play God" and arrogantly tamper with nature.⁴⁸ The Commission also expressed concerns over the possibility of degrading human dignity by creating human/non-human hybrids.⁴⁹ The majority of objections included in the committee report were focused on moral and social concerns grounded in religious thought.⁵⁰

Since the *Chakrabarty* decision and the Commission Report that followed, objections to various biotechnology inventions have grown louder and more frequent,

⁴³ *Id.* at 209.

⁴⁴ *Id.* at 187. Despite the disproportionate amount of literature to suggest otherwise, the concern of patent thickets in biotechnology is not restricted to gene patents. See Gold et al., *supra* note 30, at 2. Other fields, including pharmaceuticals, stem cell research, biomedical engineering, synthetic biology and medicine share concerns over the rise of patent thickets. See *id.*; John M. Golden, *WARF's Stem Cell Patents and Tensions Between Public and Private Sector Approaches to Research*, 38 J.L. MED. & ETHICS 314, 315 (2010) (discussing how WARF's licensing policies on its stem cell patents are cumbersome and restrictive); Arti Rai & James Boyle, *Synthetic Biology: Caught Between Property Rights, the Public Domain, and the Commons*, 5 PLOS BIOLOGY 389, 390–92 (2007) (discussing how progress in synthetic biology can be slowed by flaws in both biotechnology and software patent law). In pharmaceuticals, the main concern is the prohibitively expensive nature of patented drugs. See Michelle Childs, *Towards a Patent Pool for HIV Medicines: The Background*, 4 OPEN AIDS J. 33, 33–34 (2010). The lack of generic brands for certain drugs allows pharmaceutical companies to increase the price of their product. See *id.*; Li Lui & Hongzhou Lu, *Technology Development Through Pooling ARV Drug Patents: A Vision from China*, 4 OPEN AIDS J. 54, 54–55 (2010) (discussing patent pooling to lower the cost of HIV drugs); see also Gold et al., *supra* note 30, at 1–2 (discussing how patents allow the cost of drugs to remain high). Other critics argue that patents act as a barrier to further research into potential cures for neglected illnesses. See Lexchin, *supra* note 29, at 2–3.

⁴⁵ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012), *petition for cert. granted*, 81 U.S.L.W. 3305 (U.S. Nov. 30, 2012) (No. 12-398).

⁴⁶ See Keay, *Morality's Move in Within U.S. Patent Law: From Moral Utility To Subject Matter*, 40 AIPLA Q.J. 409, 421–30. See also Cook-Degan & Heaney, *supra* note 30, at 6; Anna Lumelsky, *Diamond v. Chakrabarty: Gauging Congress's Response To Dynamic Statutory Interpretation By The Supreme Court*, 39 U.S.F. L. REV. 641, 654–56 (2005).

⁴⁷ NAT'L INFO. RES. ON ETHICS & HUMAN GENETICS, *SPLICING LIFE: A REPORT ON THE SOCIAL AND ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS* (1982), available at <http://bioethics.georgetown.edu/documents/pcemr/splicinglife.pdf>.

⁴⁸ *Id.* at 53–77.

⁴⁹ *Id.* at 58.

⁵⁰ *Id.* at 53–77.

particularly as biotechnology has expanded.⁵¹ Although different inventions in biotechnology raise different ethical concerns, the main arguments still center on the fear that biotechnological innovations will lead to the destruction of human dignity.⁵²

Objections to some inventions, such as gene patents, surgical methods, and pharmaceuticals, rest on a different set of concerns—that patient access to the patented invention will be limited by monopolistic behavior and cost.⁵³ For example, critics who object to method patents involving medical treatments fear that these patents will substantially interfere with medical care by subjecting doctors to liability for patent infringement.⁵⁴ Or, that such patents will shift doctors' resources from patient treatment to monitoring the patent landscape.⁵⁵ Still others fear that these patents will interfere with doctors' ability to effectively treat patients by preventing them from utilizing knowledge disclosed in medical patents, as well as increasing the cost of patient care as a whole.⁵⁶

The patenting of living organisms, especially the patenting of animals and components of the human body, has also received a great deal of negative attention.⁵⁷ Objections to these patents stem from the notion that life is sacred, that patents claiming living organisms violate that sanctity and may lead to the commodification of the human body and the erosion of human dignity.⁵⁸

Perhaps the most criticized development, however, is the patenting of inventions derived from research on human embryos, such as stem cells, human/non-human chimeras and clones.⁵⁹ Stem cells are self-replicating cells found in both adult tissues and developing embryos.⁶⁰ Though similar in function, the two differ in that adult

⁵¹ See, e.g., Rebecca Dresser, *Stem Cell Research as Innovation: Expanding the Ethical and Policy Conversation*, 38 J.L. MED. & ETHICS 332, 332–41 (2010) (discussing the non-traditional ethical considerations that arise as stem cell research expands); see also Cho, *supra* note 5, at 550 (discussing the ethical implications of patenting genes).

⁵² Shawn H.E. Harmon, *Of Plants and People: Why Do We Care About Human Dignity?*, 10 EMBO REP. 946, 946 (2009); see also Richard E. Ashcroft, *Making Sense of Dignity*, 31 J. MED. ETHICS 679, 679 (2005) (discussing the “human dignity” argument made by bioethicists); Dónal P. O'Mathúna, *Bioethics and Biotechnology*, 53 CYTOTECH. 113, 117 (2007) (discussing how biotechnology can change the definition of personhood).

⁵³ See Cook-Degan & Heaney, *supra* note 30, at 6; Tadeusz Tolloczko, *Surgical Patents and Patients—The Ethical Dilemmas*, 11 SCI. & ENGINEERING ETHICS 61, 61–69 (2005) (discussing the opposition to medical procedure patents and the harmful effect of they may have on patient access to treatment); Childs, *supra* note 44, at 33–36 (discussing the potential development of a pharmaceutical patent pool to make HIV medication more affordable to impoverished countries).

⁵⁴ See Petition for Writ of Certiorari at 29–34, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 992001 at 29–34.

⁵⁵ *Id.* at 29–34, 2011 WL 5189089, at *29–34.

⁵⁶ *Id.* at 29–34, 2011 WL 5189089, at *29–34.

⁵⁷ See David B. Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15 HEALTH CARE ANNALS 211, 211–22 (2007) (commentating that the broadness of WARF's patents may slow stem cell research).

⁵⁸ See *id.* at 211–22.

⁵⁹ See *id.* at 211–22; see also Bagley, *supra* note 3, at 469–70 (discussing the ethical implications of the creation of chimeras).

⁶⁰ David G. Zacharias et al., *The Science and Ethics of Induced Pluripotency: What Will Become of Embryonic Stem Cells?*, 86 MAYO CLINIC PROCEEDINGS 634, 635 (2011) (discussion of ongoing controversy surrounding stem cell research).

stem cells can differentiate into only the tissues that they were isolated from,⁶¹ whereas embryonic stem cells can differentiate into any type of tissue under certain physiological conditions.⁶² This characteristic of embryonic stem cells is promising to researchers seeking cures for a variety of illnesses.⁶³ However, research involving embryonic stem cells has received an enormous amount of criticism because the harvesting of these stem cells requires the destruction of a human embryo. Opponents of embryonic stem cell research equate the destruction of an embryo to the destruction of human life—or murder.⁶⁴

C. Section 33 of the AIA

Section 33 of the AIA was Congress's attempt to respond to the moral and ethical concerns just mentioned. What is provided now is a brief explanation of the origins of section 33.

The United States Patent and Trademark Office ("USPTO") has a longstanding policy that prevents the patenting of human beings.⁶⁵ This policy was put to the test in 1997 when a scientist, Stuart Newman, sought to obtain a patent for a human/non-human chimera.⁶⁶ A chimera is an organism that contains cells from two or more genetically distinct sources.⁶⁷ Newman was attempting to obtain a patent to block further research on human/non-human chimeras and force the USPTO to clarify its policy regarding the patent eligibility of human organisms.⁶⁸ The USPTO responded to public outcry over the patent application and issued a press release that stated that a human/non-human chimera may be ineligible for patent protection because of a failure to meet the moral utility requirement under § 101.⁶⁹ Newman never received a patent and his application was finally rejected in 2005.⁷⁰

In response to a similar situation involving a male-female chimera, Representative David Weldon proposed a rider to the Commerce-Justice-State Appropriations bill for fiscal year 2004, which stated that "[n]one of the funds appropriated or otherwise made available under th[e] Act may be used to issue

⁶¹ Antonio Liras, *Future Research and Therapeutic Applications of Human Stem Cells: General, Regulatory and Bioethical Aspects*, 8 J. TRANSLATIONAL MED. 131, 132 (2010).

⁶² See Daniele Lodi et al., *Stem Cells in Clinical Practice: Applications and Warnings*, 30 J. EXPERIMENTAL & CLINICAL CANCER RES. 1, 2 (2011).

⁶³ See Dresser, *supra* note 51, at 332.

⁶⁴ See Giovanni Frazzetto, *Embryos, Cells and God*, 5 EMBO REP. 553, 553–55 (2004) (discussing ethical considerations surrounding stem cell research and the religious basis for these objections, emphasizing the role of the Catholic and Christian faiths in opposing stem cell research); see also Insoo Hyun, *The Bioethics of Stem Cell Research and Therapy*, 120 J. CLINICAL INVESTIGATION. 71, 71 (2010) (comparing the destruction of preimplantation embryos with murder).

⁶⁵ U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (8th ed. Rev. 9, Aug. 2012) [hereinafter MPEP].

⁶⁶ See U.S. Patent Appl. 10/308,135 (filed Dec. 3, 2002).

⁶⁷ Howard Wolinsky, *A Mythical Beast: Increased Attention Highlights the Hidden Wonders of Chimeras*, 8 EUR. MOLECULAR BIOLOGY ORG. REP. 212, 212 (2007).

⁶⁸ Stuart A. Newman, *The Human-Chimera Patent Initiative*, 9 MED. ETHICS 1, 4 (2002).

⁶⁹ See *Media Advisory, 98-06*, U.S. PAT. & TRADEMARK OFFICE (Apr. 1, 1998), <http://www.uspto.gov/news/pr/1998/98-06.jsp>.

⁷⁰ Rick Weiss, *U.S. Denies Patent for a Too-human Hybrid*, WASH. POST, Feb. 13, 2005, at A03.

patents on claims directed to or encompassing a human organism.”⁷¹ The purpose of this section, which came to be known as the “Weldon Amendment,” was to codify existing USPTO policy preventing the patenting of human organisms.⁷² The Weldon Amendment was adopted in subsequent appropriations bills,⁷³ and as the Leahy-Smith America Invents Act began making headway through Congress, the Weldon Amendment was ultimately adopted as section 33.⁷⁴

The Congressional Record, both for the AIA and the Weldon Amendment as it was proposed in 2003, indicates that section 33 was intended only to prevent the patenting of human organisms and nothing else.⁷⁵ The Record includes a lengthy list of biotechnology patents that should remain unaffected by section 33, including stem cell patents, tissue culture patents, research tools, gene patents, and other inventions derived from the human body.⁷⁶ Further, section 33 only impacts patents that were pending on, or filed after the AIA became law on September 16, 2011.⁷⁷ Congress also discussed limitations on the way the phrase, “human organism,” is to be interpreted. Specifically, “human organism” should exclusively include human embryos, human/non-human chimeras, human fetuses, and human beings.⁷⁸ Almost immediately after the AIA was passed, the USPTO recognized the potential problems that section 33 presents, and in response, issued an office-wide memorandum stating that it does not intend to change its patent policy because of the enactment of section 33.⁷⁹

D. Statutory Construction

In practice, the limitations discussed in the legislative history of section 33 will likely do very little to prevent the misinterpretation of the provision. Recent trends in statutory construction emphasize the interpretation of statutory text according to the plain meaning of the words used, independent of extrinsic sources, such as legislative

⁷¹ 149 CONG. REC. H7248 (daily ed. July 22, 2003) (amendment offered by Rep. David Weldon).

⁷² Ryan Hagglund, *Patentability of Human-Animal Chimeras*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 51, 70–71 (2009).

⁷³ 157 CONG. REC. E1177 (daily ed. June 23, 2011) (statement of Rep. Christopher H. Smith) (“I commend Chairman Lamar Smith for including in the manager’s amendment to H.R. 1249, the America Invents Act, a provision that will codify an existing pro-life policy rider included in the CJS Appropriations bill since FY2004.”).

⁷⁴ Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

⁷⁵ See 157 CONG. REC. E1177 (daily ed. June 23, 2011) (statement of Rep. Christopher H. Smith); 157 CONG. REC. E1182 (daily ed. June 23, 2011) (statement of Rep. Lamar Smith); 149 CONG. REC. E2417 (daily ed. Nov. 22, 2003) (statement of Rep. David Weldon); 149 CONG. REC. E2234 (daily ed. Nov. 5, 2003) (statement of Rep. David Weldon). *But see infra* Part II.B (examining in detail Representative Weldon’s statements before Congress regarding to what his amendment applied).

⁷⁶ See 157 CONG. REC. E1183 (daily ed. June 23, 2011) (statement of Rep. Lamar Smith).

⁷⁷ Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(b)(1), 125 Stat. 284, 340 (2011). Despite the debate created by the patents at issue in both *Myriad* and *Prometheus*, neither would be implicated by § 33 as they were issued well before the AIA was enacted.

⁷⁸ 157 CONG. REC. E1178 (daily ed. June 23, 2011) (statement of Rep. David Weldon).

⁷⁹ Memorandum from Robert W. Bahr, Senior Patent Counsel & Acting Assoc. Comm’r for Patent Examination Policy, to Patent Examining Corps (Sept. 20, 2011), *available at* http://www.uspto.gov/aia_implementation/human-organism-memo.pdf.

history.⁸⁰ This method of interpretation, called textualism, attempts to give statutory text a reasonable definition.⁸¹ Textualists reject the use of legislative history, arguing that only the statutory text, and not the legislative history, is the law.⁸² This poses a unique problem for patent law, because courts have traditionally interpreted the Patent Act within the context of legislative history due to its heavily contextual nature.⁸³ We arrive, then, at the million dollar question: How will courts construe section 33 given that some of the important terms do not have a definition within the context of patent law?

II. ANALYSIS

Of the terms used in section 33, two phrases are particularly problematic and would likely be a point of contention for the courts: “directed to” and “human organism.” The vagueness of these phrases may allow them to be construed in ways that could disrupt the patenting of controversial biotechnology inventions. This section begins by considering potential constructions for these phrases, then concludes by hypothesizing about problems that may arise from such constructions.

⁸⁰ See Jonathan R. Siegel, *Textualism and Contextualism in Administrative Law*, 78 B.U. L. REV. 1023, 1025 (1998).

⁸¹ See Daniel P. O’Gorman, *Construing the National Labor Relations Act: The NLRB and Methods of Statutory Construction*, 81 TEMP. L. REV. 177, 199 (2008) (“Textualists try to identify the meaning a reasonable person would give to the text.”); Michael Straubel, *Gender Equity, College Sports, Title IX and Group Rights: A Coach’s View*, 62 BROOK. L. REV. 1039, 1055–56 (1996) (contrasting textualism with intentionalism and stating that “the modern textualist approach can be described as a search for how an ordinary person would understand the law as written, without the aid of extratextual sources”).

⁸² Straubel, *supra* note 81, at 1056 (illustrating textualism with reference to Justice Scalia, who would reason that “legislative history is nothing more than the contrived statements of only a few special interests and therefore not indicative of the prevailing intent of Congress”). Textualists support this position by arguing that the legislative history is frequently as ambiguous as the statute, cannot be considered the aggregation of the actual intention of each individual member of Congress, and has not been through the constitutionally required standards of bicameralism and presentment. See Siegel, *supra* note 80, at 1025.

⁸³ See Jonathan Siegel, *Naïve Textualism in Patent Law*, 76 BROOK. L. REV. 1019, 1020 (2011) (noting a “radical shift in the direction of naïve textualism in the field of patent law” and that for decades “patent law was a paradigm of richly contextualized judicial interpretation”); Peter S. Menell, *Forty Years of Wandering in the Wilderness and No Closer to the Promised Land: Bilski’s Superficial Textualism and the Missed Opportunity to Return Patent Law to its Technology Mooring*, 63 STAN. L. REV. 1289, 1289–1314 (2011) (discussing how the *Bilski* Court fundamentally changed the nature of patent law using a textualist approach to statutory interpretation in a way that would not have otherwise occurred using different approaches); ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARKS 323 (2003) (“[T]he [patent] statute cannot be read in isolation from the array of judicial precedent that has interpreted nearly each of its words.”).

A. “Directed To”

The phrase, “directed to,” is not defined anywhere in the Patent Act.⁸⁴ Therefore, a court will begin the process of statutory construction by using the plain meaning of the undefined phrase.⁸⁵ It is instructive to consider the meaning of each term separately, however, because no dictionary defines the terms together.⁸⁶

Some common definitions of the word, “direct,” are: (1) “to control or conduct the affairs of; manage; govern,”⁸⁷ (2) “to order or instruct with authority; command,”⁸⁸ and (3) “to cause to move, face or go in a desired direction; aim.”⁸⁹ Of these three common definitions, the first two apply more in the business context, as in “a manager *directed* his employee to fill out a timesheet.” The third definition, in particular, “to go in a desired direction; aim,” appears most applicable given section 33’s usage: “no patent may issue on a claim *directed* to . . . a human organism.”⁹⁰

The word “to” has multiple definitions, but most applicable in the context of section 33 would be “in the direction of; toward.”⁹¹ Stringing these most likely definitions together, we can ostensibly replace, “directed to,” with, “aimed toward.” Although these definitions are a good starting point in construing the statute, it is still unclear whether this interpretation of “directed to” is correct. A court would then move on to consider other instances in which these words were used in the AIA, or in the Patent Act and related regulations.⁹²

The word “directed” appears only one other time in the AIA, in section 5, which states that “[a] defense under this section may be asserted only by the person who performed or *directed* the performance of the commercial use.”⁹³ From the context of this sentence, it is obvious that “directed” means “to control or conduct the affairs of,” which is unhelpful in deciphering section 33. The phrase, “directed to,” appears nowhere else in the AIA but section 33. Likewise, the term “directed” is used a

⁸⁴ Patent Act, 35 U.S.C. §§ 1–376 (2012).

⁸⁵ See Michael D. Yanovsky Sukenik, *Distinct Words, Discrete Meanings: The Internet & Illicit Interstate Commerce*, 2011 U. ILL. J.L. TECH. & POL’Y 1, 18–19 (2011); Willison v. Race, 192 B.R. 949, 952 (W.D.Mo.1995) (using the plain meaning rule in the absence of defined terms of a statute).

⁸⁶ See, e.g., Willison v. Race, 192 B.R. 949, 952–53 (W.D.Mo.1995) (construing the phrase “motor vehicle” by defining each term individually).

⁸⁷ THE NEW INTERNATIONAL WEBSTER’S COMPREHENSIVE DICTIONARY OF THE ENGLISH LANGUAGE: DELUXE ENCYCLOPEDIA EDITION 361 (1st ed. 1996).

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011).

⁹¹ WEBSTER’S NEW WORLD DICTIONARY: SECOND COLLEGE EDITION 1493 (2d Ed. 1976).

⁹² See Taniguchi v. Kan Pac. Saipan, Ltd., 132 S. Ct. 1997, 2004–05 (2012) (“[I]t is a ‘normal rule of statutory construction’ that ‘identical words used in different parts of the same act are intended to have the same meaning.’”); Justice Robert P. Young, A Judicial Traditionalist Confronts Justice Brennan’s School of Judicial Philosophy, Address at the William J. Brennan, Jr. Lecture on State Constitutional Law and Gov’t (Oct. 18, 2007), in 33 OKLA. CITY U. L. REV. 263, 280–81 (2008) (stating the way a textualist approaches statutory construction as “[looking] to the statute itself for clues about meaning, to look at its structure, to examine related passages of the same statute . . . that may be *in pari materia* We rely on doctrines such as *noscitur a sociis*.”).

⁹³ Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 5(a), 125 Stat. 284, 298 (2011).

handful of times in the Patent Act, sometimes meaning “to control or conduct the affairs of,” sometimes meaning “aimed at.”⁹⁴

While the differing definitions of the word, “directed,” as provided by common dictionaries and looking to the Patent Act seem to further confuse the matter, the phrase, “directed to,” is a term of art used in patent law. For years, courts have consistently spoken of patent claims being “directed to” certain subject matter.⁹⁵ This is consistent with the construction that defines “directed to” as “aimed toward” certain subject matter. In addition to case law, “directed to” is used in the same manner in the Patent Act,⁹⁶ MPEP,⁹⁷ and the Code of Federal Regulations.⁹⁸ The problem lies in the fact, however, that despite being used in patent parlance, the phrase is never actually defined, leaving open the possibility that a judge may construe it in problematic ways. Further, patent attorneys also disagree on the precise meaning of this often-used phrase.⁹⁹ For purposes of this comment, I will consider “directed to” to mean “aimed toward,” as provided above.

B. “Human Organism”

Determining what is considered a “human organism” goes to the heart of the problem caused by the ambiguities in section 33. Unlike “directed to,” the phrase,

⁹⁴ See, e.g., 35 U.S.C. § 122(b)(2)(B)(iii) (2012) (“[A]n application directed to the invention disclosed in the application”); *id.* § 142 (“When an appeal is taken to the United States Court of Appeals for the Federal Circuit, the appellant shall file in the Patent and Trademark Office a written notice of appeal directed to the Director”); *id.* § 146 (“If there be adverse parties residing in a plurality of districts not embraced within the same state, . . . the United States District Court for the Eastern District of Virginia shall have jurisdiction [over civil actions challenging a derivation proceeding] and may issue summons against the adverse parties directed to the marshal of any district”).

⁹⁵ See, e.g., *C.W. Zumbiel Co. v. Kappos*, 702 F.3d 1371, 1373 (Fed. Cir. 2012) (“The ‘639 patent is **directed to** a carton or box”); *Reese v. Verizon Cal., Inc.*, 498 F. App’x 980, 981 (Fed. Cir. 2012) (“Reese owns U.S. Patent 6,868,150 (the ‘150 patent), **directed to** methods for”); *Kingpak Tech., Inc. v. Kappos*, 498 F. App’x 969, 970 (Fed. Cir. 2012) (“Kingpak’s ‘008 patent is **directed to** a method for manufacturing a computer module”).

⁹⁶ See, e.g., 35 U.S.C. § 122(b)(2)(B)(iii) (“[A]n application directed to the invention disclosed in the application”).

⁹⁷ See, e.g., MPEP, *supra* note 65 § 1504.05 (“Unlike a utility patent application, which can contain plural claims directed to plural inventions, a design patent application may only have a single claim.”); *id.* § 821.04(b) (“Where claims directed to a product and to a process of making and/or using the product”); *id.* § 2106 (“[T]he claimed invention (1) must be directed to one of the four statutory categories, and (2) must not be wholly directed to subject matter encompassing a judicially recognized exception”).

⁹⁸ See, e.g., 37 C.F.R. § 1.141(b) (2013) (“If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product”); *id.* § 1.145 (“If, after an Office action on an application, the applicant presents claims directed to an invention”); *id.* § 1.720(e)(2) (“In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product”).

⁹⁹ See *Patents Directed to Human Organisms*, PATENTLYO (Sept. 9, 2011), <http://www.patentlyo.com/patent/2011/09/patents-directed-to-human-organisms.html> (“The phrase ‘directed to’ is not defined in the Patent Act or the USPTO Implementation Rules found at 37 C.F.R. § 1, *et seq.* However the phrase [is] often used by patent attorneys to describe the coverage of a particular claim and the statutory category. Even amongst patent attorneys, the usage is not uniform.”).

“human organism,” is not a term of art in patent law, was not used anywhere else in the AIA, and appears nowhere in the Patent Act. Further, this phrase is undefined in most dictionaries. In this situation, the court will certainly look to the common definitions of each term separately.

A reasonable definition for “human” is “[o]f, pertaining to, or characteristic of humankind or people; belonging to human kind; of or belonging to the species *Homo Sapiens*.”¹⁰⁰ One definition of “organism” is “any living entity that contains one or more cells.”¹⁰¹ Joining the dictionary definitions of these two words together, a “human organism” could be understood to mean “any living entity containing one or more cells belonging to the species *Homo Sapiens*.”¹⁰²

Also unlike “directed to,” the phrase “human organism,” is infrequently used in case law. There is one Supreme Court case dealing with abortion that used that phrase when discussing “the time at which the fetus becomes a *human organism*.”¹⁰³ Implicit in this usage is the understanding that a fetus is something separate and distinct from a human organism. Unfortunately, this provides courts with little guidance, if any, on what that “something” is.

If a court accepts a definition similar to the dictionary definition discussed above, and finds the words used in section 33 to be clear, the statutory construction exercise is over.¹⁰⁴ But, if the court is looking for further guidance, it may turn to the legislative history.¹⁰⁵

As stated earlier, the language of section 33 was originally proposed by Representative David Weldon in 2003 as an amendment to H.R. 2799, the Commerce-Justice-State Appropriations bill for FY 2004.¹⁰⁶ Responding to criticism from lobbyist groups opposing the amendment, Representative Weldon said it was “absurd” that “patents on stem cell lines, procedures for creating human embryos, prosthetic devices, and . . . any drug or product that might be used in or for human beings” would be affected by the amendment.¹⁰⁷ He argued before Congress that his amendment did nothing more than provide congressional backing for the USPTO’s policy against patenting human beings.¹⁰⁸

¹⁰⁰ SHORTER OXFORD ENGLISH DICTIONARY 1291–92 (6th ed. 2007).

¹⁰¹ See SCOTT FREEMAN, BIOLOGICAL SCIENCE, at G21 (Beth Wilber et al. eds., 4th ed. 2011).

¹⁰² As will be shown shortly, this proposed definition using dictionaries is in direct conflict with the legislative history of the Weldon Amendment. See SHORTER OXFORD ENGLISH DICTIONARY 1291–92 (6th ed. 2007) (defining “human”).

¹⁰³ See *United States v. Vuitch*, 402 U.S. 62, 79 n.2 (1971) (Douglas, J., dissenting) (emphasis added).

¹⁰⁴ See *Milner v. Dep’t of the Navy*, 131 S. Ct. 1259, 1266 (2011) (“We will not take the opposite tack of allowing ambiguous legislative history to muddy clear statutory language.”); *Ratzlaf v. United States*, 510 U.S. 135, 147–48 (1994) (stating that legislative history is meant to eradicate ambiguity, not create it); *Blum v. Stenson*, 465 U.S. 886, 896 (1984); *Burlington N. R. Co. v. Okla. Tax Com’n*, 481 U.S. 454, 461 (1987) (stating that when the words of the statute are unambiguous the court is finished construing the statute).

¹⁰⁵ See *Blum v. Stenson*, 465 U.S. 886, 896 (1984); William Eskridge, *The New Textualism*, 37 UCLA L. Rev. 621, 656–58 (1990).

¹⁰⁶ H.R. 2799, 108th Cong. § 801 (2003) (“None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism.”).

¹⁰⁷ 149 CONG. REC. E2234 (daily ed. Nov. 5, 2003) (statement of Rep. David Weldon).

¹⁰⁸ *Id.* at E2234–35.

Representative Weldon was referring to the USPTO's policy promulgated after the *Chakrabarty* decision that "[a] claim directed to or including within its scope a **human being** will not be considered patentable subject matter under 35 U.S.C. 101."¹⁰⁹ This was later included in section 2105 of the MPEP, stating that "[i]f 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."¹¹⁰

Although Representative Weldon called the argument "absurd" that his amendment would prohibit "procedures for creating human embryos," he explicitly stated that it would "cover [all] human organisms (including human embryos)."¹¹¹ He claimed that "the only difference between [his] amendment and some of the[] USPTO documents is that [his] amendment uses the term 'human organism,' while the USPTO usually speaks of . . . 'human being.'"¹¹² He stated this was because "human organism" has already been defined by Congress in a rider to an appropriations bill, and clearly encompasses human embryos, but not stem-cells.¹¹³ In fact, Representative Weldon argued in favor of his amendment a second time in 2003, stating that it "ha[d] no bearing on stem cell research or patenting genes," but that it "affect[ed] patenting human organisms, human embryos, human fetuses or human beings."¹¹⁴

Due to continuing criticism, the Congressman clarified his amendment a third time, only this time with greater specificity. On December 8, 2003, Representative Weldon spoke before the House and said that his amendment applied 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). Th[e] amendment applie[d] 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.¹¹⁵

The Weldon Amendment was adopted as a "pro-life rider" in all appropriations bills for the Department of Commerce beginning in 2004.¹¹⁶

The legislative history for section 33 of the AIA is much more sparse. Representative Lamar Smith proposed what is now section 33 as an amendment to H.R. 1249,¹¹⁷ which became the AIA. However, during congressional debates, nothing new was said regarding the language of the amendment. Instead, the

¹⁰⁹ *Id.* at E2235.

¹¹⁰ *Id.*; MPEP, *supra* note 65, § 2105.

¹¹¹ 149 CONG. REC. E2235 (daily ed. Nov. 5, 2003) (statement of Rep. David Weldon).

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ 149 CONG. REC. E2417 (daily ed. Nov. 22, 2003) (statement of Rep. David Weldon).

¹¹⁵ 149 CONG. REC. H12840 (daily ed. Dec. 8, 2003) (statement of Rep. David Weldon).

¹¹⁶ *See supra* note **Error! Bookmark not defined.** and accompanying text.

¹¹⁷ 157 CONG. REC. E1177 (daily ed. June 23, 2011) (statement of Rep. Christopher H. Smith); *see also id.* at E1182.

legislative history for the Weldon Amendment was merely admitted into the Congressional Record for section 33.¹¹⁸

To illustrate the problems created by the phrase, “human organism,” consider what a judge would be facing when construing this phrase. As discussed, one possible dictionary definition for “human organism” can be “any living entity containing one or more cells belonging to the species *Homo Sapiens*.”¹¹⁹ The Supreme Court has used “human organism” to mean something separate and distinct from “human fetus.”¹²⁰ The Weldon Amendment and section 33 use only the phrase, “human organism,” yet Representative Weldon explicitly stated this included “human organism, human embryos, human fetuses or human beings.”¹²¹ Given these partially overlapping and contradictory definitions, the judge would be justified in interpreting “human organism” in countless ways. Some ways could construe “human organism” to include the invalidation of patents on human tissue cultures, stem cell lines and potential therapeutic treatments that may arise that utilize these technologies.

C. The Implications of Dangerous Constructions

The hypothetical interpretation of section 33 just discussed poses a troubling meaning, that “[n]o patent shall issue on a claim [aimed toward] or encompassing [any living entity containing one or more cells belonging to the species *Homo Sapiens*].” Given this hypothetical interpretation, the construction of section 33 is no longer vague—it is instead troublingly broad. Although Representative Weldon argued against such a broad construction, a judge construing the statute is free to ignore the legislative history, and accordingly, Weldon’s arguments.¹²²

Hypothetically speaking, a broad construction would have the destructive potential to invalidate patents of any invention designed for consumption by humans. The range of patents that can be invalidated is large, including personalized medicine, pharmaceuticals, genes, prosthetics, artificial organs, research tools for embryonic stem cell research, medical devices, and human derivatives (e.g., hormones, antibodies). This is because the operation of all these inventions are “directed to,” or “aimed toward” humans, potentially falling within the language of section 33.

Gene patents are an excellent example of patents threatened by section 33 because they are “directed to” a human organism. Patents on human genes are used to develop tests for genetic abnormalities in humans.¹²³ In turn, these tests operate

¹¹⁸ See *id.* at E1183 (adopting the legislative history for the Weldon Amendment).

¹¹⁹ See *supra* note 102 and accompanying text.

¹²⁰ See *supra* note 103 and accompanying text.

¹²¹ See *supra* note 114 and accompanying text.

¹²² See, e.g., *United States v. Gonzales*, 520 U.S. 1, 2 (1997) (“[G]iven the straightforward statutory command, there is no reason to resort to legislative history.”); *Ratzlaf v. United States*, 510 U.S. 135, 147–48 (1994) (“[W]e do not resort to legislative history to cloud a statutory text that is clear.”); *Shannon v. United States*, 512 U.S. 573, 583–84 (1994) (stating that the courts must adhere to the statutory text over contradictory statements in the legislative history).

¹²³ See, e.g., U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 5,693,473 (filed June 7, 1995).

to determine whether a person is predisposed for certain genetic disorders. This activity is, arguably, “directed to,” or “aimed toward” humans, and thus falls within the language of section 33.

Proponents of biotechnology patents argue that the impact of invalidating even one biotechnology patent based on section 33 would have enormous negative consequences.¹²⁴ Patents have been instrumental in the development of the biotechnology industry from the *Chakrabarty* decision onward,¹²⁵ and are so central to biotechnology that entire companies have been established because of the economic power that holding key patents provide.¹²⁶ For nascent technology, such as personalized medicine, the invalidation of important patents would be a death knell because the focus of the entire industry is aimed toward developing personalized methods for treating diseases.¹²⁷ Invalidating patents in high-risk, high-cost fields, such as pharmaceuticals, would remove incentives for companies to invest in the development of these technologies, resulting in the slowing of innovation.¹²⁸ Further, patents incentivize the disclosure of new inventions, and removing this incentive may prevent the disclosure of new technology and, in the alternative, the use of that technology as a trade secret.¹²⁹ Without the promise of future patent rights, entire areas of science may remain unexplored because the risk of failure will outweigh the risk of investment.

III. PROPOSAL

Amending section 33 of the AIA is the most efficient way to reduce ambiguity in the language as currently written and to avoid unnecessary litigation over its construction. This section proposes an amendment that defines the terms used in section 33 more precisely. Additionally, this section proposes a construction of section 33 that will have a minimum impact on the patent eligibility of existing biotechnology inventions.

There are a few ways that section 33 could be amended to avoid the pitfalls of a broad construction through the efforts of an activist judge.¹³⁰ First, the phrase, “directed to,” should be removed from the language of section 33. The seemingly

¹²⁴ See NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 20 (2006) [hereinafter NRC RESEARCH PAPER], available at <http://www.ncbi.nlm.nih.gov/books/NBK19865/pdf/TOC.pdf>.

¹²⁵ See *Id.* (discussing the importance of intellectual property rights to biotechnology firms); Stankovic & Stankovic, *The Selfish Patent*, 3 CASE W. RES. J.L. TECH. & INTERNET 195, 197 (2012) (discussing the role that the *Chakrabarty* decision played in developing the biotechnology industry).

¹²⁶ See Amy Landers, *Liquid Patents*, 84 DENV. U. L. REV. 199, 207, 257 (2006).

¹²⁷ Paul Gugliuzza, *IP Injury and the Institutions of Patent Law*, 98 IOWA L. REV. 747, 758 (2013).

¹²⁸ NRC RESEARCH PAPER, *supra* note 124, at 20–25.

¹²⁹ *Id.* at 22.

¹³⁰ See Liza Vertinsky, *Comparing Alternative Institutional Paths to Patent Reform*, 61 ALA. L. REV. 501, 530–31 (2010) (defining judicial activism as “actions taken by judges who ‘legislate’ from the bench by establishing laws that apply broadly to issues not presented in the individual case before them, or by going beyond reasonable interpretations of laws to create their own versions of the law”).

superfluous nature of the phrase, “directed to,” used in conjunction with, “encompassing,” is the very reason why inclusion of this phrase in section 33 is so dangerous; any court interpreting the meaning of the statute cannot simply construe “directed to” to be meaningless.¹³¹ “Directed to” must be given a definition, but unfortunately, any definition that it can be given may also interfere with a variety of biotechnology patents. Therefore, the best option is to simply remove it.

Second, the phrase, “human organism,” should be defined in a manner consistent with the definition used in the Congressional Record. “Human organism” is defined in the Record as “human embryos, human fetuses, human-animal chimeras, ‘she-male’ human embryos, or human embryos created with genetic material from more than one embryo.”¹³² The Record also defined “human organism” as “human embryo, fetus, infant, child, adolescent or adult.”¹³³ To remain consistent with congressional intent, stem cells and other derivatives of the human body not considered organisms, such as tissues and genes, should be explicitly excluded from the definition of “human organism.”¹³⁴

With this proposal in mind, section 33 could be saved if Congress were to amend it to read:

Notwithstanding any other provision of law, no patent may issue on a claim encompassing a human organism.

For purposes of this section, human organism is defined as a human embryo, fetus, infant, child, adolescent, adult, human-animal chimera, she-male human embryos, or human embryos created with genetic material from more than one embryo. For purposes of this section, human organism does not include cells, tissues, organs, or other bodily components that are not themselves human organisms, such as stem cells, stem cell lines, genes, and living or synthetic organs. Nor does human organism include hormones, proteins or other substances produced by human organisms, methods for creating, modifying, or treating human organisms, such as methods for creating human embryos through in vitro fertilization, somatic

¹³¹ See *Bruesewitz v. Wyeth, LLC* 131 S. Ct. 1068, 1094, (2011); *Mac’s Shell Serv., Inc. v. Shell Oil Prods., Co., LLC*, 130 S. Ct. 1251, 1254 (2010).

¹³² 157 CONG. REC. E1184 (daily ed. June 23, 2011).

¹³³ *Id.* at E1180.

¹³⁴ *Id.*

[The Weldon Amendment] should not be construed to affect claims directed to or encompassing subject matter other than human organisms, including but not limited to claims directed to or encompassing the following: cells, tissues, organs, or other bodily components that are not themselves human organisms (including, but not limited to, stem cells, stem cell lines, genes, and living or synthetic organs); hormones, proteins or other substances produced by human organisms; methods for creating, modifying, or treating human organisms, including but not limited to methods for creating human embryos through in vitro fertilization, somatic cell nuclear transfer, or parthenogenesis; drugs or devices (including prosthetic devices) which may be used in or on human organisms.

Id.

cell nuclear transfer, or parthenogenesis, or drugs or devices which may be used in or on human organisms.

CONCLUSION

Section 33(a) of the America Invents Act allows room for a variety of creative constructions in the hands of a judge interested in participating in judicial activism.¹³⁵ In light of the moral controversy surrounding creation and patenting of controversial biotechnology inventions such as human genes, stem cells and human/non-human chimeras, section 33 may easily allow for the limiting of patent eligible subject matter against current precedent, USPTO policy and congressional intent. Misconstruction of this statute may lead to the invalidation of essential biotechnology patents, the slowing of research, and the chilling of innovation in biotechnology. It is imperative that Congress act now to prevent these issues in the future.

¹³⁵ See Vertinsky, *supra* note 130, at 530–31.