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Biotechnology's Great Divide: Strengthening the Relationship Between Patent Law and Bioethics in the Age of CRISPR-Cas9

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Note

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I. INTRODUCTION

In 1953, James Watson and Francis Crick discovered the chemical structure of DNA.[1] Less than 40 years later, results of the first successful gene editing experiment were published in a 1991 edition of *Science*.[2] Then, in 2003, the National Human Genome Sequencing Consortium released the first complete sequence of the human genome.[3] In 2015, researchers in China published the results of the first known use of gene editing technology in human embryos.[4] That technology—the gene

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1. *The Francis Crick Papers*, U.S. NATIONAL LIBRARY OF MEDICINE, NAT'L INSTS. OF HEALTH, https://profiles.nlm.nih.gov/ps/retrieve/Narrative/SC/p-nid/143 (last visited Jan. 20, 2018).

2. N.P. Pavletich & C.O. Pablo, *Zinc Finger-DNA Recognition: Crystal Structure of a Zif268-DNA Complex at 2.1 A*, 252 SCIENCE 809 (1991); *see also Genome Editing: A Brief History*, ALLELE BIOTECHNOLOGY, http://www.allelebiotech.com/genome-editing/ (last visited Jan. 20, 2018).

3. *The Human Genome Project Completion: Frequently Asked Questions*, NAT'L HUMAN GENOME RES. INST., NAT'L INSTS. OF HEALTH, https://www.genome.gov/11006943/human-genome-project-completion-frequently-asked-questions/ (last updated Oct. 30, 2010).

4. Puping Liang et al., *CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes*, 6 PROTEIN & CELL 363 (2015); *see also* David Cyranoski & Sara Reardon, *Chinese Scientists Genetically Modify Human Embryos*, NATURE (Apr. 22, 2015), https://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378#/bl.

editing system CRISPR-Cas9—is now in preparation for its first clinical trial, which is scheduled to commence sometime in 2018.[5] In the 70 years since its conception, the field of biotechnology has expanded exponentially, and has produced countless innovations that have positively impacted human health. Each discovery enables the next, and scientists continue to charge forward—patents in tow—on their quest to modify and improve human existence. In the face of such a concrete public benefit,[6] it's all too easy to forget the ethical shadows looming behind many of these biotechnologies.

Patents function both to fund and incentivize research,[7] and therefore play a huge role in the development of new technology. Yet modern U.S. patent law has long been a stranger to ethics. Although the patent prosecution process involves weighing, measuring, and challenging virtually every facet of an invention[8] in the name of protecting the "patent bargain,"[9] it has not involved even the slightest consideration of the invention's ethical, legal, or societal implications since at least the turn of the century.[10] The Moral Utility Doctrine—a loosely-defined nineteenth century common law doctrine that allowed for judicial consideration of an invention's socially or morally

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5. Chelsea Gohd, *The First CRISPR Clinical Trial Could Begin in 2018*, FUTURISM (Dec. 17, 2017), https://futurism.com/first-crispr-clinical-trial/.

6. Many of these benefits go unappreciated in twenty-first century life, but biotechnology has been responsible for detecting, treating, and curing countless diseases. These health science developments—many building on the innovations that came before them—have improved the lives of individuals with diabetes, genetic diseases, cancers, and many other debilitating or deadly conditions. *See generally Biotechnology Solutions for Everyday Life*, BIOTECH. INNOVATION ORG., https://www.bio.org/articles/biotechnology-solutions-everyday-life (last visited Jan. 23, 2018).

7. *See infra* note 9 and accompanying text.

8. To receive a patent, an invention must be patent-eligible, useful, novel, and nonobvious, in addition to satisfying a host of procedural requirements. *See generally infra* note 40 and accompanying text.

9. The "patent bargain" metaphor is often used to refer to the quid pro quo nature of obtaining a patent, and is generally articulated as follows: a patent is a social contract in which the public provides the inventor with a benefit (exclusive rights to an invention) in exchange for a benefit (the innovation). *See generally* Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After* Eldred, 19 BERKELEY TECH. L.J. 1315, 1316–18, 1328–29 (2004).

10. *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999) (holding that inventions cannot be ruled unpatentable for lack of utility "simply because they have the capacity to fool some members of the public."); *see also infra* note 53 and accompanying text.

"injurious" nature[11]—once filled this void. However, it was "inconsistently and sporadically" applied even before its current dormancy.[12] Further still, the Doctrine was a malleable system of ethical regulation, subject to the convictions of individual judges and, as such, not often reflective of society as a whole.[13] Thus, whatever vestige of the Moral Utility Doctrine may remain available in modern jurisprudence is ill-suited to the novel and complex ethical implications of twenty-first century technology.

Nowhere is this deficiency more apparent than in the field of biotechnology. Recent biotechnological developments present a renewed opportunity to consider the role of ethics in patent law, and generate a modern U.S. patent policy that is both more appropriate and more responsive.[14] For example, gene editing technologies—a discrete but representative subset of biotechnology—have the potential to eradicate certain diseases, but could just as easily be employed to modify to the human genome in ways wholly unrelated to disease.[15] In particular, the

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11. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

12. Andrew Smith, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159, 161 (2003).

13. Common law, in contrast to statutory law, is implemented by judges in individual cases, and therefore tends to be less uniform and evolves over time. *See generally* Giacomo A. M. Ponzetto & Patricio A. Fernandez, *Case Law Versus Statute Law: An Evolutionary Comparison*, 37 J. LEGAL STUD. 379 (2008). This, presumably, would be exaggerated in the case of doctrines that involve moral and ethical considerations, which are highly personal, varied, and volatile.

14. Even at its height, the Moral Utility Doctrine was only used to prevent patents on inventions like gambling devices and deceptive consumer goods. *See infra* notes 47–49 and accompanying text. The ethical concerns that may or may not have been present in such devices are vastly different from those present in biotechnology (the modification of human genomes, for example), rendering existing precedent—*if* still authoritative—largely inapplicable outside of its general premise of judicial ethical oversight.

15. One familiar refrain here is the "designer babies" argument, which refers to parental ability to select certain traits (hair or eye color, height, or perhaps athletic ability) in an embryo prior to implantation. Another frequently-cited concern is germline modification, which not only removes the genetic variant in all future offspring (eliminating the possibility of future individuals' autonomous choice), but could ultimately lead to a reduction in allelic variation in certain populations. For a discussion of these concerns, see generally Jessica Berg, *Editing Human Embryos with CRISPR Is Moving Ahead – Now's the Time to Work Out the Ethics*, THE CONVERSATION (July 28, 2017), http://theconversation.com/editing-human-embryos-with-crispr-is-moving-ahead-nows-the-time-to-work-out-the-ethics-81732.

CRISPR-Cas9 system has made gene editing faster, cheaper, simpler, and more reliable than ever before, thereby expanding both the urgency and the public relevance of these complex ethical repercussions.[16] In the face of technologies like CRISPR,[17] an opportunity to consider these implications and balance them with the technology's potential public benefit is more necessary than ever—in part because of the imminence of these ethically undesirable outcomes, but also because consideration at the patent prosecution stage provides an opportunity to regulate the kind of technologies that often elude *ex post facto* legislation and regulation.[18]

This Note argues for strengthening the relationship between U.S. patent law and ethics, and proposes a schema for utilizing the patent prosecution process as a regulatory mechanism for ethically controversial technologies. Part I of this Note provides a brief introduction to U.S. patent law, the kinds of inventions for which patents can be obtained, and the concept of beneficial utility. This section also details the history and current status of the Moral Utility Doctrine, and concludes with a summary of the current relationship between U.S. patent law and ethics. Part II highlights the issues inherent in continuing to exclude ethical considerations from the patentability inquiry, and discusses potential mechanisms for incorporating those considerations moving forward. Finally, this Note concludes by presenting a scheme of ethical regulation that utilizes principles from the dormant Moral Utility Doctrine, coupled with changes to United States Patent and Trademark Office (USPTO) policy, in order to minimize the societal risks of technologies like CRISPR-Cas9 while continuing to incentivize progress and innovation in biotechnology.

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16. *See generally infra* notes 76–79 and accompanying text.

17. As is common, this Note will use the term "CRISPR" as shorthand for the multi-component CRISPR-Cas9 system.

18. Emergent technologies are often difficult to regulate because of the delays inherent in the legislative process, which can also affect subsequent agency regulation. *See generally* Gary E. Marchant, Douglas J. Sylvester & Kenneth W. Abbot, *What Does the History of Technology Regulation Teach Us About Nano Oversight?*, 37 J.L. MED. ETHICS 724 (2009) (discussing the challenges of regulating emerging technology in the context of nanotechnology).

II. BACKGROUND

A. AN INTRODUCTION TO PATENTABLE SUBJECT MATTER AND 35 U.S.C. § 101

Patent law in the United States can be traced to a grant of congressional authority in the Constitution itself.[19] Acting pursuant to this grant, Congress codified the first body of patent law—colloquially, the "Patent Act"—in 1790,[20] which was amended various times until the codification of the recognizably modern version in 1952.[21] Notions of the concept of "patentability," however, were not incorporated until the 1870 amendment.[22] Patentability—or "subject matter eligibility," as it is sometimes referred to[23]—is perhaps the most basic requirement for obtaining a patent. To be patent-eligible, an invention must be a "new and useful *process, machine, manufacture, or composition of matter*, or any new and useful improvement thereof[.]"[24] On its face, the text of § 101 seems

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19. *See* U.S. CONST. art. I, § 8, cl. 8 (delegating to Congress the power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the *exclusive right* to their respective writings and discoveries") (emphasis added). The presence of this explicit delegation suggests that even at the country's founding, protection of intellectual property was recognized as crucial.

20. 1 Stat. 109 (1790).

21. 35 U.S.C. §§ 8–293 (1952).

22. Patent Act of 1870, Ch. 230, 16 Stat. 198-217 (1870). Specifically, a concept of patentability akin to the current 35 U.S.C. § 101 is found in § 24 of the 1870 version, and allows for patents on "any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof[.]" This exact language is still used in 35 U.S.C. § 101 today: "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" (emphasis added). *See also* Daniel Cole, *Should Section 101 of the Patent Act Be Removed*, IP WATCHDOG (June 23, 2016), http://www.ipwatchdog.com/2016/06/23/section-101-patent-act-removed /id=70230/ ("Section 101 of the patent act was added in 1870 and amended in 1952.").

23. This Note will use the terms "subject matter eligibility" and "patentability" synonymously, as is typical in practice. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2106 (9th ed., rev. Jan. 2018) (using the terms interchangeably throughout examiner guidelines) [hereinafter MPEP].

24. 35 U.S.C. § 101 (emphasis added).

virtually all-encompassing—there is scarcely an invention imaginable that would not be patent-eligible.[25]

As is often the case with statutory interpretation, however, the implicit exceptions to § 101 are substantially more limiting than the text itself. Three categorical exceptions to patentability have been acknowledged by the Supreme Court: laws of nature, natural phenomenon, and abstract ideas.[26] The "law" or "phenomenon" of nature exclusion prevents patents such as methods of medical treatment based on naturally-occurring health correlations,[27] or patents on unaltered living organisms.[28] Contrastingly, the abstract idea restriction often arises in cases concerning business method patents, which are highly

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25. To further illustrate this sentiment, this Note encourages the reader to think about the types of inventions enumerated in the statute—method of conducting business would constitute a "process," any manner of apparatus could constitute a "machine or manufacture," and any molecular creation could constitute a "composition of matter." *Id.* Is an invention that falls outside of these categories even articulable?

26. These exceptions were first succinctly articulated in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) ("This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable."), although the *Diamond* Court does cite earlier decisions as standing for the same proposition. *See, e.g.*, Parker v. Flook, 437 U.S. 584 (1978); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948). Further, these categorical exclusions have been repeatedly affirmed and re-articulated by the Court in modern jurisprudence. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 67 (2012) (holding unpatentable guidelines instructing clinicians to "engage in well-understood, routine, conventional activity . . . [because such] activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law."); Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) ("In [*Mayo*], we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.") (citation removed); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) ("We have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.").

27. *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 67 (2012) (holding unpatentable clinician treatment instructions based on an observed correlation between the concentration of a particular metabolite and drug response). *But see* Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1051 (Fed. Cir. 2016) (holding patentable a method for repeated freeze and thaw cycles of liver cells because it was a patent eligible *application* of a law of nature).

28. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding patentable a bacterium engineered to digest oil products, because it was "markedly different" than anything found in nature).

controversial.[29] All three categories are excluded from patentability because there is not enough of an "inventive concept" present to warrant bestowing intellectual property rights onto the inventor.[30] None, however, are excluded on the basis of moral or ethical considerations.[31]

Other than the recognized judicial exceptions to § 101, there exists one notable statutory exception that applies in the realm of biotechnology:[32] the USPTO cannot grant patents "directed to or encompassing a human organism."[33] Aside from being one of the only *external* statutory exceptions to patentability, this prohibition is also unique in that it is the only exception based on ethical grounds applicable to biotechnology.[34] One effect of

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29. *See, e.g.*, Bilski v. Kappos, 561 U.S. 593, 606 (2010) (holding that a particular business method falls outside of § 101 because it claims an "abstract idea"). In *Bilski*, however, the Court refused to categorically exclude business patents because they could, in theory, be encompassed by the "process" language of § 101. *Id.* at 596.

30. Parker v. Flook, 437 U.S. 584, 594 (1978).

31. Margo A. Bagley, *A Global Controversy: The Role of Morality in Biotechnology Patent Law* 318 (Univ. of Va. Law Sch., Working Paper No. 57, 2007) ("U.S. patent law contains no statutory basis for the United States Patent and Trademark Office (USPTO) or a court to deny patent protection to morally controversial biotech subject matter.") [hereinafter Bagley, *A Global Controversy*].

32. There are a few other statutory exceptions to patentability—namely, for nuclear technology and medical procedures—that *do* exist (and stem at least in part from the Agreement on Trade-Related Aspects of Intellectual Property Rights, *infra* note 66, but they are not germane to the biotechnologies addressed in this Note and therefore are not discussed at length herein). *See generally* WORLD INTELLECTUAL PROP. ORG. STANDING COMM. ON THE LAW OF PATENTS, EXCLUSIONS FROM PATENTABILITY AND EXCEPTIONS AND LIMITATIONS TO PATENTEES' RIGHTS (2010), http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf.

33. Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 199, 118 Stat. 3, 101 (2004). This amendment was later codified into the Patent Act itself. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284, 340 (2011) ("Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.").

34. This prohibition stemmed from backlash to the Supreme Court's decision in *Diamond v. Chakrabarty*, which was the first time the Court held a living organism patentable—in this instance, a bacterium. Diamond v. Chakrabarty, 447 U.S. 303 (1980). However, many individuals became concerned that this could lead to the patenting of multi-cellular organisms and, eventually, humans, and the USPTO issued a notice afterward that explicitly disallowed such patents. Donald J. Quigg, *Animals – Patentability*, 1077 OFFICIAL GAZETTE PATENT & TRADEMARK OFFICE 24 (1987) [hereinafter 1987 USPTO Policy], https://www.uspto.gov/web/offices/com/sol/og/2013/week53/TOCCN/item-137.htm ("A claim directed to or including within its scope a

this ethical basis is that an otherwise ineligible invention—one which *is* directed to a human organism—cannot be "cured" by integrating it with other, patent-eligible subject matter in the same way that other categorically excluded inventions can be.[35] However, it is possible for applicants to circumvent the statute by including in their claims a "disclaim[er] [of] any coverage for human animals,"[36] which renders the prohibition somewhat less rigid than it appears on its face. Section 33 is Congress' only legislative action to date in response to public moral and ethical concerns surrounding biotechnology and has been met with some criticism.[37]

Despite sentiments that the arena of patent-eligible subject matter is shrinking,[38] this "threshold" requirement remains a relatively low bar.[39] Acknowledging the discrete exceptions outlined above, there are no further limitations on the types of biotechnological inventions for which a patent can be obtained.[40] Furthermore, even in instances where an invention falls within the realm of a particular exception, applicants can often employ drafting techniques or modify their inventions to avoid subject

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human being will not be considered to be patentable subject matter under 35 U.S.C. 101.").

35. Dennis Crouch, *Patents Encompassing a Human Organism*, PATENTLYO (Dec. 2, 2012), https://patentlyo.com/patent/2012/12/ex-parte-kamrava.html ("One exception to the cured-by-integration rule involves the patenting of human organisms. Generally speaking, a patent clam [sic] cannot encompasses [sic] a human organism and likewise, a claim encompassing an otherwise unpatentable human organism will not become patentable by integrating elements that are subject matter eligible.").

36. *Id.*

37. *See, e.g.*, Ava Caffarini, *Directed to or Encompassing a Human Organism: How Section 33 of the America Invents Act May Threaten the Future of Biotechnology*, 12 J. MARSHALL REV. INTELL. PROP. L. 768 (2013).

38. *See, e.g.*, Peter S. Menell, *Forty Years of Wondering 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 (2010).

39. Bilski v. Kappos, 561 U.S. 593, 594 (2010).

40. This is not to say that there are no further *substantive* patent requirements—an invention must be useful, novel, and nonobvious (among other things) in order to sustain a patent. Instead, this Note refers only to *categorical* exclusions from patentability, of which there are few. *See Bilski*, 561 U.S. 593 at 594 ("The § 101 eligibility inquiry is only a threshold test. Even if a claimed invention qualifies in one of the four categories, it must also satisfy 'the conditions and requirements of this title.'") (citation omitted).

matter ineligibility.[41] As such, patent-eligible subject matter is relatively free of legal, judicial, and regulatory constraints.

B. THE MORAL UTILITY DOCTRINE

Since 35 U.S.C. § 101 created an expansive definition of patent eligible subject matter, judges once relied on another mechanism for regulating the content of patentable inventions: the "utility" requirement.[42] For an invention to be acceptable on utility grounds, it must have a "specific" and "substantial" use[43]—in other words, the invention must "do what is claimed."[44] This, much like the § 101 subject matter requirement, appears on its face to be a relatively easy condition for a patent application to satisfy, at least in the modern era.[45]

However, historically, many judges recognized a "beneficiality" component to the utility requirement, which provided an opportunity for judicial regulation of patent-eligible subject matter on moral and ethical grounds.[46] This understanding of utility—sometimes referred to as *moral* or *beneficial* utility—stems from the *Lowell v. Lewis* decision in 1817 which stipulated that an invention could not "be frivolous or injurious to the well-being, good policy, or sound morals of society" if it were to receive a patent, per the requirements of 35

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41. *See* Crouch, *supra* note 35.

42. The "utility" requirement is derived from two places in the Patent Act. 35 U.S.C. § 101 ("any new and *useful* process, machine, manufacture, or composition of matter") (emphasis added); 35 U.S.C. § 112 (requiring a patent application's specification to describe "the manner and process of making and *using* [the invention]") (emphasis added).

43. Brenner v. Manson, 383 U.S. 519, 531, 534 (1966).

44. Gene Quinn, *Understanding the Patent Law Utility Requirement*, IP WATCHDOG (Nov. 7, 2015), http://www.ipwatchdog.com/2015/11/07/understanding-the-patent-law-utility-requirement/id=63007/.

45. *See, e.g.*, Lee Petherbridge, *Road Map to Revolution? Patent-Based Open Science*, 59 ME. L. REV. 339, 356 n.90 (2007) ("The utility requirement is still properly understood as very low and generally presents a low bar to patentability."). However, in the wake of *Brenner*, many commentators felt that the utility requirement had, in fact, been elevated for certain classes of inventions. *See, e.g.*, Samantha A. Jameson, *The Problems of the Utility Analysis in* Fisher *and its Associated Policy Implications and Flaws*, 56 DUKE L.J. 311, 313 (2006) ("In *Brenner* . . . the Supreme Court articulated an elevated utility standard for research intermediates.").

46. *See* Margo Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 488–89 (2003) [hereinafter Bagley, *Patent First*].

U.S.C. § 101.[47] This Moral Utility Doctrine served, for a time, as a gatekeeper to subject matter eligibility; despite the "utility" requirement's independent existence from the "subject matter eligibility" requirement, the two functioned together for the purpose of preventing patents on inventions encompassing subject matter that did not meet "judicially identified standards of morality."[48]

For approximately 150 years, the Moral Utility Doctrine precluded patents on immoral and deceptive inventions.[49] However, use of the doctrine substantially declined as time passed and societal values shifted.[50] In *Juicy Whip, Inc. v. Orange Bang, Inc.*—a case now infamous for triggering the decline of the moral utility "requirement"—the Court of Appeals for the Federal Circuit was tasked with evaluating the "usefulness" of a particular style of frozen drink machine, which was designed to mimic a *different* frozen drink machine that was more visually appealing to consumers.[51] As such, the invention's novelty was its deceptive nature.[52] The court held that an invention's deceptiveness should no longer be grounds for patent invalidation on the premise of moral utility.[53] Further, it stipulated that regulating patent issuance on the basis of morality fell within the province of the legislature and not the judiciary,[54] indicating its disapproval for the Moral Utility Doctrine as a whole. From that point forward, courts were

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47. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817). Although Justice Story may have been operating with policy concerns in mind, this opinion suggests that he viewed moral utility as a legitimate statutory requirement—independent from other types of utility. *Id.* ("The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral.").

48. Bagley, *A Global Controversy*, *supra* note 31, at 320.

49. *Id.* For example, the Moral Utility Doctrine was regularly used to prevent individuals from obtaining patents on gambling devices. *See, e.g.*, Schultze v. Holtz, 82 F. 448 (N.D. Cal. 1897) (holding unpatentable a coin-operated gambling device).

50. *See generally* Bagley, *A Global Controversy*, *supra* note 31.

51. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999). The invention was based on the idea that this particular machine could harness the sanitary benefits of one kind of machine while retaining the consumer appeal of the other. *Id.* at 1365–66.

52. *Id.* at 1365–66.

53. *Id.* at 1368.

54. *Id.* ("Of course, Congress is free to declare particular types of inventions unpatentable for a variety of reasons, including deceptiveness.").

reluctant to invalidate a patent on moral utility grounds—if any did at all.[55]

Whether any portion of the Moral Utility Doctrine survived the era of *Juicy Whip* is the subject of debate.[56] In the face of the infamous Rifkin patent application for a human-animal chimera[57]—which was filed in order to draw attention to the potential implications of the Supreme Court's *Bilski* decision—the USPTO issued a "media advisory" that "posited that 'inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.'"[58] Regardless of its official status, however, the doctrine is rarely—if ever—implicated in modern jurisprudence.[59] This dormancy continues today, even in the face of patents on extremely controversial biotechnology.

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55. In terms of precedential weight, the *Juicy Whip* decision *may* only have applied to allegedly deceptive inventions, which would indicate that other kinds of scandalous or immoral inventions were still subject to judicial scrutiny. Regardless of its actual status, the doctrine is no longer invoked. *See* Bagley, *A Global Controversy*, *supra* note 31; *infra* note 56 and accompanying text.

56. There exists substantial uncertainty surrounding the USPTO's current view of the Moral Utility Doctrine, particularly since no direct statement has been made on its status. *See, e.g.*, Smith, *supra* note 12, at 161 ("However, the court's refusal to invalidate the idea of moral utility altogether might signal that the doctrine could be applied in other circumstances, or perhaps, in other patentable subject areas."). *But see* MPEP, *supra* note 23, § 706.03(a) ("A rejection under 35 U.S.C. 101 for lack of utility should not be based on grounds that the invention is frivolous, fraudulent or against public policy."). This inclusion in the MPEP seems to indicate that the USPTO does not support the use of moral utility as grounds for invalidation, although it has not advocated this viewpoint in a more public capacity.

57. The Rifkin patent application sparked extensive debate, as intended. *See, e.g.*, Rick Weiss, *Patent Sought on Making of Part-Human Creatures*, WASH. POST (Apr. 2, 1998), https://www.washingtonpost.com/archive/politics/1998/04/02/patent-sought-on-making-of-part-human-creatures/43e25926-4749-4a12-a342-49678eb2f189/?utm_term=.39ae53be138d.

58. Bagley, *A Global Controversy*, *supra* note 31, at 321 (quoting the USPTO's Media Advisory); *see also* Press Release, U.S. Patent & Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998). However, the author notes that the USPTO has since admitted that it is "without authority" to deny a patent on morality grounds. *Id.*

59. *See* Omar Khan & Richard Crudo, *Scandalous, Immoral and Disparaging Patents in Light of* Tam, LAW 360 (Feb. 25, 2016, 10:11 AM), https://www.law360.com/articles/761308/scandalous-immoral-and-disparaging-patents-in-light-of-tam ("[C]ases denying the protection of the law on the ground of immorality are not of this generation . . . .") (quoting John Gladstone Mills III et al., PATENT LAW FUNDAMENTALS § 11:5 (2015)). After this

C. INTERNATIONAL APPROACHES TO ETHICAL REGULATION OF PATENTS

The U.S. approach to the relationship between ethics and patent law is not the only approach—nor, perhaps, even the most internationally popular. Doctrines similar to moral utility exist in many other jurisdictions.[60] For example, Europe issued the Directive 98/44/EC ("European Biotech Directive") in 1988 in order to respond to changing ethical concerns brought on by the rise of patents on biotechnology.[61] This extensive directive is a much less flexible approach to regulation than common law but clearly stipulates "what is patentable and what is not."[62] Contrastingly—and in a manner perhaps more reminiscent of the Moral Utility Doctrine—China has instituted a blanket prohibition on granting patents for "invention-creations that violate the law or social ethics, or harm public interests."[63] Although these regulations have been met with some criticism,[64]

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decision was issued by the Federal Circuit, the Supreme Court heard an appeal and held that intellectual property rights cannot be denied on the basis of the property's "disparaging" character, citing free speech concerns. Matal v. Tam, 137 S. Ct. 1744, 1753–54 (2017). Notably, in this case the Court was addressing a *different* kind of intellectual property—trademarks, not patents—and interpreting the Lanham Act. Therefore, its analysis does not apply to the context of patent law, even if one were to equate disparagement with ethical affront. Some iteration of this principle could eventually be applied to patents, but without authoritative remarks from the Supreme Court on the issue this Note proceeds under the justified assumption that *Tam* is limited in scope to trademark law only.

60. In other countries, the doctrine is called *ordre public*, which functions similarly to the defunct Moral Utility Doctrine by allowing judicial oversight in the patent process. *See* Joseph Strauss, *Ordre Public and Morality Issues in Patent Eligibility*, *in* INTELLECTUAL PROPERTY IN COMMON LAW AND CIVIL LAW (Toshiko Takenaka ed., 2013); Khan & Crudo, *supra* note 59.

61. *See* Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13–21.

62. Rob J. Aerts, *The Patenting of Biotechnological Inventions in the EU, the Judicial Bodies Involved and the Objectives of the EU Legislator*, EUR. INTELL. PROP. REV. 88 (2014); *see also id.* at 18–19.

63. Patent Law of the People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Mar. 12, 1984, effective Apr. 1, 1985, revised Dec. 27, 2008), art. 5, http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf ("Patent rights shall not be granted for invention-creations that violate the law or social ethics, or harm public interests.").

64. One set of critics of the European Biotech Directive are agriculturalists, because of the restrictions that the directive places on the patenting of live plants. *See, e.g.*, BAVARIAN FARMER'S ASS'N, *Criticism of EU's Bio-Patent*

they provide examples of the various mechanisms by which ethical considerations can play a functional role in the patentability inquiry.

In addition to the varying approaches to ethical governance utilized by other jurisdictions, certain frameworks exist within international patent law—however limited that may be. Multiple international intellectual property agreements recognize morality exceptions to patent subject matter eligibility.[65] One example is the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), which allows member countries to exclude from patentability certain inventions, in order "to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment."[66] Additionally, the European Patent Convention ("EPC") requires its member countries to exclude patents that would be "contrary to '*ordre public*' or morality."[67] The approaches in international treaties may differ, but each indicates at least the recognition of the role that moral and ethical concerns could play in the signatories' patent process.

D. MODERN BIOTECHNOLOGY AS A UNIQUE ETHICAL HAZARD

Biotechnology constitutes an increasingly large proportion of patented inventions—and often produces some of the most high-profile and lucrative patents.[68] Additionally, this

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Directive, FRESH PLAZA (Jan. 29, 2016), http://www.freshplaza.com/article/152706/Criticism-of-EUs-bio-patent-directive.

65. Importantly, some of these are requirements, while others are allowances. In the case of a requirement, member countries *must* prohibit certain types of patents, whereas in instances of an allowance, countries are not required to incorporate any ethical regulation—they are simply allowed to do so if they choose.

66. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

67. The European Patent Convention art. 53, Oct. 5, 1973, 1065 U.N.T.S. 199 (revised at the Convention on the Grant of European Patents Nov. 29, 200). This morality exception can be viewed as an extension of the *ordre public* doctrine, which itself has been implemented by the European Patent Office in a manner very similar to the historical treatment of the Moral Utility Doctrine in the U.S. *See also Case Law of the Boards of Appeal*, EUR. PAT. OFF. (July 27, 2016), https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clr_i_b_2_2_2_b.htm.

68. *See, e.g.*, Antonio Regalado, *Who Owns the Biggest Biotech Discovery of the Century?*, MIT TECH. REV. (Dec. 4, 2014), https://www.technologyreview

technology carries with it unprecedented ethical concerns[69] that will continue to expand as knowledge grows and techniques mature. The boundaries of what exactly *qualifies* as biotechnology, however, can be difficult to discern. Typically, definitions center on an element of "manipulation" of some sort of natural product.[70] These definitions traditionally encompass technology ranging from agricultural products to medical devices.

One category of biotechnology often at the forefront of public discourse is gene editing technology, making it an illustrative context in which to discuss the relationship between ethics and patent law.[71] The term "gene editing" refers to the family of methods that can alter the chemical structure of deoxyribonucleic acid (DNA).[72] DNA is a molecule found in every living cell that contains the biological information required to make proteins, which are required to sustain life.[73] By altering

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.com/s/532796/who-owns-the-biggest-biotech-discovery-of-the-century/ (discussing the three-party patent dispute over CRISPR-Cas9).

69. *See, e.g.*, Ed Silverman, *The 5 Most Pressing Ethical Issues in Biotech Medicine*, BIOTECHNOLOGY HEALTHCARE 41 (2004) (addressing stem cell research, privacy concerns, and bioterrorism, among other concerns).

70. Merriam-Webster defines "biotechnology" as "the manipulation (as through genetic engineering) of living organisms or their components to produce useful usually commercial products (such as pest resistant crops, new bacterial strains, or novel pharmaceuticals); *also*: any of various applications of biological science used in such manipulation." *Biotechnology*, MERRIAM-WEBSTER ONLINE DICTIONARY (2018), https://www.merriam-webster.com/dictionary /biotechnology.

71. Biotechnology spans a variety of applications and subject matter, all of which possess their own set of ethical implications. Therefore, in an effort to present a concise and meaningful analysis, this Note uses gene editing technologies as a representative subset of biotechnology with clear ethical implications. Specifically, this Note focuses on the CRISPR-Cas9 gene editing system because of both its public attention and its widespread use. Further, in confining its discussion to one exemplary technology, this Note attempts to provide a real-world illustration of the implications of a continued failure to incorporate ethical considerations into U.S. patent law, and, later, the benefits of the proposed system of regulation.

72. Merriam-Webster defines "gene editing" as "the use of biotechnological techniques to make changes to specific DNA sequences in the genome of a living organism." *Gene Editing*, MERRIAM-WEBSTER ONLINE DICTIONARY (2018), https://www.merriam-webster.com/dictionary/gene%20editing. As such, gene editing *technologies* would be devices and processes that implement gene editing techniques. *See generally Gene Editing*, HORIZON (2017), https://www.horizondiscovery.com/gene-editing [hereinafter, HORIZON].

73. *See generally What Is DNA?*, GENETICS HOME REFERENCE, NAT'L INSTS. OF HEALTH (Mar. 20, 2018), https://ghr.nlm.nih.gov/primer/basics/dna;

the structure of this molecule—specifically, the order of nucleotides, or "base pairs"—scientists can change the characteristics of the protein that ultimately results.[74] As such, gene editing can, in theory, remedy many clinical conditions for which there is an underlying genetic cause.[75]

Gene editing technologies can be divided into four types, based on their mechanisms of action: zinc finger nucleases ("ZFNs"), transcription activator-like effector nucleases ("TALENs"), meganucleases, and CRISPR-Cas9.[76] All four operate by inducing a natural cellular repair mechanism designed to repair breakages in DNA.[77] The first three of these technologies—ZFNs, TALENs, and meganucleases—are less precise and more labor intensive than the CRISPR-Cas9 system,[78] making CRISPR a much more attractive option to many individuals. As such, the highly accurate and relatively

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Deoxyribonucleic Acid (DNA), NAT'L HUMAN GENOME RES. INST., https://www.genome.gov/25520880/ (last updated June 16, 2015).

74. *See* HORIZON, *supra* note 72. Changing the order of base pairs will change the order of amino acids that are joined during the process of translation. Consequently, these new amino acids alter the characteristics of the resulting protein through changes in molecular folding.

75. To be sure, this is not the only function of gene editing (though the medicinal applications of gene editing are frequently touted as the most exciting). Gene editing technology also has a vast array of other applications, ranging from agriculture to hormone production. *See generally* Sarah Holme, *CRISPR: Emerging Applications for Genome Editing Technology*, GENOMICS RES. (June 26, 2017), https://www.technologynetworks.com/genomics/articles/crispr-emerging-applications-for-genome-editing-technology-288978.

76. Morgan Maeder & Charles Gersbach, *Genome-Editing Technologies for Gene and Cell Therapy*, MOLECULAR THERAPY 430, 432 (2016). These technologies are listed in their order of discovery, with ZFNs being the most established and CRISPR-Cas9 being the most recently discovered.

77. The cellular mechanism referred to here is homology-directed repair. *Id.* at 430. This mechanism operates to repair breakage by using a second homologous strand as a "template" for nucleotide insertion. By inducing DNA breakage at certain points, gene editing technologies can remove and insert particular base pairs, ultimately altering the protein for which the targeted DNA codes.

78. Tomislav Meštrović, *How Does CRISPR Compare to Other Gene-Editing Techniques?*, NEWS MED. (Jan. 13, 2016), https://www.news-medical.net/life-sciences/How-Does-CRISPR-Compare-to-Other-Gene-Editing-Techniques.aspx ("CRISPR/Cas technology has entered the picture as the faster, more straightforward and affordable way for genome-editing in comparison to traditional ZFN and TALENs approaches.").

inexpensive nature of CRISPR-Cas9 made its discovery a monumental scientific development.[79]

Important in the celebration of the CRISPR system's strengths and positive implications, however, is consideration of the ethical concerns that its accessibility may bring. CRISPR has enormous potential to be used in ways society may not be prepared to condone, particularly in the context of human germline editing (where the changes made to DNA would be passed down to that individual's offspring).[80] In addition to questions about equitable access and informed consent, many individuals have a viscerally negative reaction to the use of gene editing in human embryos for moral or religious reasons.[81] Further, although the CRISPR system is safer and more accurate than its predecessors, there remain serious doubts about the accuracy and reliability of gene editing in a healthcare

79. There are three inventors vying for ultimate ownership of the CRISPR-Cas9 system, and, therefore, the credit for this enormous scientific innovation. All three have been awarded in some manner for their contribution to the field of genetics. *See, e.g.*, *Doudna and Charpentier Receive 2017 Japan Prize for CRISPR Contribution*, GENETIC ENGINEERING & BIOTECH. NEWS (Feb. 2, 2017), https://www.genengnews.com/gen-news-highlights/doudna-and-charpentier-receive-2017-japan-prize-for-crispr-contribution/81253814/; *CRISPR Pioneer Awarded $500,000 Lemelson-MIT Prize*, GENOMICS RES. (Sept. 20, 2017), https://www.technologynetworks.com/genomics/news/gene-editing-technology-developer-awarded-500000-lemelson-mit-prize-291932.

80. *See Genome Editing: What Are the Ethical Concerns About Genome Editing?*, NAT'L HUMAN GENOME RES. INST. (Aug. 3, 2017), https://www.genome.gov/27569225/what-are-the-ethical-concerns-about-genome-editing/. The central concern in the context of germline editing is that one individual—the one choosing to engage in gene editing—is thereby making a choice that is enormously consequential for future individuals. This may be less of a concern for some when editing is for solely therapeutic purposes—in other words, to correct a genetic disease—but bioethicists recognize that this creates a "slippery slope" toward non-therapeutic (sometimes called "enhancement") uses. *Id.*; *see also* David Masci, *Human Enhancement: The Scientific and Ethical Dimensions of Striving for Perfection*, PEW RES. CTR. (July 26, 2016), http://www.pewinternet.org/essay/human-enhancement-the-scientific-and-ethical-dimensions-of-striving-for-perfection/.

81. *Genome Editing*, *supra* note 80. Embryonic research is a likely predecessor to widespread clinical use, and therefore negative reactions from the public to such research is likely to slow progress toward therapeutic implementation.

setting.[82] In light of these concerns, clinical use has been widely discouraged by bioethicists until further research is conducted.[83]

In addition to healthcare-related issues, commentators have noted that CRISPR's significant desirability over other gene editing technologies gives it the potential to produce dramatic monopoly effects if patent protected.[84] The accessibility of CRISPR has also increased public interest and media attention, which only heightens the potential for its misuse.[85] Finally, many entities have expressed concerns over the speed with which CRISPR has been implemented and adapted, which has far outpaced any potential regulatory systems.[86] Ultimately, although gene editing in the age of CRISPR-Cas9 has the potential for immense public benefit, the corresponding ethical considerations may hinder stakeholder benefit and public perception if not adequately acknowledged.

E. EXISTING RESTRICTIONS ON GENE EDITING: WHAT ARE THE RULES, AND WHO ARE THE RULEMAKERS?

Although ethics does not play a role in the U.S. patent process, it *does* play some role in other areas of law affecting

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82. *Id.* These safety concerns arise from the potential to induce unintended changes in an individual's DNA, such as "off-target effects (edits in the wrong place) and mosaicism (when some cells carry the edit but others do not)." *Id.*

83. *Id.*

84. John J. Mulvihill et al., *Ethical Issues of CRISPR Technology and Gene Editing Through the Lens of Solidarity*, 122 BRIT. MED. BULL. 17, 25 (2017) ("The idea that a powerful technology, such as CRISPR-Cas9 and the guide DNA can be patented and therefore become the exclusive property of a researcher [or their institution] is part of this debate. If the technology, which was isolated from naturally occurring bacteria [and not invented], can be proprietary, then many people could be denied access to its benefits outside market mechanisms."). A potential counter-argument to the notion of monopoly effects is inherent in the ongoing CRISPR patent battle: if three entities can claim credit for at least a portion of the CRISPR discovery, can a *true* monopoly exist? However, a limited number of individuals controlling a highly impactful technology could produce monopoly-like effects, even though more than one entity controls the technology. *See* Ryan C. Fuhrmann, *3 Groups of Companies That Are Almost a Monopoly*, INVESTOPEDIA (Sept. 2, 2011), https://www.investopedia.com/financial-edge/0911/3-groups-of-companies-that-are-almost-a-monopoly.aspx (providing various examples of "near monopoly conditions"). Further, if the patent battle continues to engender hostility between the patent holders, it could ultimately affect their willingness to engage in licensing.

85. NAT'L ACADS. OF SCIS., ENG'G, & MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE 1 (2017).

86. *Id.*

biotechnology. Current restrictions on gene editing can be divided into two central categories: funding restrictions and market restrictions.[87] In the case of funding restrictions, entities like the National Institutes of Health (NIH) make research grants contingent on adherence to certain conditions, some of which have ethical bases.[88] Contrastingly, Food and Drug Administration (FDA) regulations occur later in a technology's life cycle and are predominantly based on product safety, rather than ethical, concerns.[89]

The NIH provides a significant portion of the funding for research that ultimately results in biotechnologies.[90] Long before modern gene editing techniques existed, the Office of Science Policy created the Recombinant DNA Advisory Committee (RAC),[91] which "provides recommendations to the NIH Director related to basic and clinical research involving recombinant or synthetic nucleic acid molecules."[92] These recommendations shape NIH policy with respect to developing genetic technologies, of which gene editing is no exception. At

87. These categories encompass only actual legal restrictions, and not ethical guidelines. For example, the National Academy of Science promulgates consensus reports on the ethics of gene editing research. *See* HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE, *supra* note 85; *see also Report Highlights*, NAT'L ACAD. OF SCIS. & NAT'L ACAD. OF MED. (2017), http://nationalacademies.org/cs/groups/genesite/documents/webpage/gene_177260.pdf ("Do not proceed at this time with human genome editing for purposes other than treatment or prevention of disease and disability" and "[e]ncourage public discussion and policy debate with respect to somatic human genome editing for uses other than treatment or prevention of disease and disability.").

88. *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, NAT'L INSTS.OF HEALTH (Apr. 28, 2015), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos.

89. Robert M. Califf & Ritu Nalubola, *FDA's Science-Based Approach to Genome Edited Products*, FDA VOICE (Jan. 18, 2017), https://blogs.fda.gov/fdavoice/index.php/2017/01/fdas-science-based-approach-to-genome-edited-products/. This is not to say, however, that the FDA does not recognize that "larger societal considerations should not be overlooked." *Id.*

90. RESEARCH AM., U.S. INVESTMENTS IN MEDICAL AND HEALTH RESEARCH AND DEVELOPMENT 2013–2015 3–4, https://www.researchamerica.org/sites/default/files/2016US_Invest_R%26D_report.pdf (describing how the federal government provided 22.62% of the funding required for U.S. medical research, over 82% of which comes from the NIH).

91. Nelson A. Wivel, *Historical Perspectives Pertaining to the NIH Recombinant DNA Advisory Committee*, 25 HUMAN GENE THERAPY 19, 19 (2014).

92. *Recombinant DNA Advisory Committee*, NAT'L INSTS. OF HEALTH, https://osp.od.nih.gov/biotechnology/recombinant-dna-advisory-committee/.

the recommendation of the RAC,[93] the NIH categorically refuses to approve funding for research that incorporates the genetic modification of human embryos. [94] This—coupled with the longstanding federal prohibition on research in which human embryos are "destroyed"[95] —serves as a considerable barrier to gene editing research and technology development.

In addition to being subject to certain funding restrictions, biotechnology is also highly regulated in the marketplace. In instances where gene editing products are targeted for use in humans, they are "regulated under [the FDA's] existing framework for biological products," which funnels hopeful technologies through the Center for Biologics Evaluation and Research (CBER).[96] Notably, the FDA does not currently approve therapies involving human germline editing.[97] However, in conjunction with the NIH and the RAC, the FDA recently approved the first "clinical protocol" involving the use of CRISPR-Cas9 in human somatic cells.[98] Ultimately, the FDA has appeared to express some hesitancy in regard to the safety of gene editing products, but it has not extensively addressed the ethical concerns related to these technologies.

III. ANALYSIS

The relationship between U.S. patent law and ethics has remained stagnant since the decline of the Moral Utility Doctrine,[99] despite contrasting approaches in other jurisdictions and internationally.[100] After the Federal Circuit's criticism of the doctrine in *Juicy Whip* and its suggestion that the legislature is the appropriate entity to engender a system of ethical regulation

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93. *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, *supra* note 88 ("[The Recombinant DNA Advisory Committee] will not at present entertain proposals for germ line alteration.").

94. Eric S. Lander, *Brave New Genome*, 373 N. ENG. J. MED. 5, 7 (2015); *see also Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, *supra* note 88.

95. Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996) (the "Dickey-Wicker Amendment").

96. Califf & Nalubola, *supra* note 89.

97. *Id.*

98. *Id.*

99. *See* Bagley, *A Global Controversy*, *supra* note 31.

100. *See supra* notes 60–63 and accompanying text.

in patent law,[101] the judicial system has remained virtually silent on the subject. Further, other than incorporating a discrete prohibition on patents directed to "human organisms" in its most recent articulation of the Patent Act,[102] the legislature has also failed to provide definite guidance.[103] The same is true of the USPTO itself.[104] As such, existing U.S. patent law has no opportunity for ethical consideration whatsoever, despite the novel and controversial implications of many emerging biotechnologies.

A. OPPOSITES ATTRACT: WHY ETHICAL CONSIDERATIONS HAVE A PLACE IN PATENT LAW

The time has come for us, as a society, to clarify the relationship between patent law and ethics. The current state of passivity—a combination of the uncertain status of the Moral Utility Doctrine, congressional silence, and USPTO avoidance—has masked a unique opportunity for society to voice its opinion on new technologies by using patent protection to support only those that provide a net benefit. Further, utilizing patent prosecution as a means of ethical regulation is superior to any potential *ex post facto* regulation scheme, because it is both more timely and more flexible.

1. Patents as a Social Contract

Patents are a contract between two entities: the inventor and the rest of society.[105] This contract is implicit in the Patent Act—there are certain requirements that an invention must meet in order to qualify for patent protection, and certain benefits an inventor can receive if the invention meets those requirements. This ensures that an invention provides a *true* benefit to society, while the protection conferred—the exclusive right to make and use an invention for a period of 20 years—

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101. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999); see *supra* notes 51–54 and accompanying text.

102. Leahy-Smith America Invents Act, Pub. L. No. 112–29, § 33, 125 Stat. 284, 340 (2011) ("Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.").

103. Bagley, *Patent First*, *supra* note 47, at 478–79.

104. *Id.* at 477–78.

105. This concept is sometimes called the "bargain metaphor." *See supra* note 9 and accompanying text.

incentivizes inventors to invent.[106] When a balance is appropriately struck, it creates a cycle that benefits both classes of participants—a feature responsible for much of the allure of a patent system.

Necessarily implicit in this system is society's approval of those inventions that receive patent protection. These inventions—in theory—provide enough public benefit to warrant bestowing legal protection thereon,[107] and so society has inherently condoned both their existence and use.[108] A problem arises, however, when the potentially harmful implications of a technology are not adequately weighed against its potential benefits—or, worse yet, aren't even *considered* in the bargaining process. In a system of patent law with no opportunity to consider ethical implications, it is impossible to ensure that the public is *truly* receiving a net benefit in exchange for the inventor's "limited monopoly."[109]

Biotechnologies like the CRISPR-Cas9 system raise the stakes of the patent bargain, both negatively and positively. These technologies are incredibly attractive because of their potential for immense public health benefit,[110] and therefore appear to more than justify their "congressionally mandated price."[111] However, the negative implications of these technologies—and their potential for misuse—are also heightened because of their accessibility, and the presence of

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106. *See generally* Ghosh, *supra* note 9, at 1321–30.

107. *Id.* at 1320 ("In 1966, in *Brenner v. Manson*, the Court redefined the quid pro quo as 'the benefit derived by the public from an invention with substantial utility.'") (citation omitted).

108. In a representative democracy like the U.S., society elects political leaders, who in turn create legislation and policy to reflect the needs of society. Therefore, by way of Congress' passage of the Patent Act and the terms contained therein, society has bestowed its seal of approval on the terms of the patent bargain. This Note, of course, recognizes that legislation is not always a perfect reflection of the values of constituents, but that it is at least *representative* of those values is a necessary assumption in representative democracy.

109. *Id.* at 1320 (citing Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 161 (1989)).

110. *See, e.g.*, Eliza Barclay, *Scientists Successfully Used CRISPR to Fix a Mutation That Causes Disease. This Is Huge.*, VOX (Aug. 2, 2017), https://www.vox.com/science-and-health/2017/8/2/16083300/crispr-heart-disease.

111. Bonito Boats, 897 U.S. at 152. The "price" referred to here is the potential monopoly effect on consumers that stems from a patentee's exclusionary rights.

limited governmental oversight in many research processes.[112] To be sure, it is entirely possible that the benefits of technologies like CRISPR outweigh hypothetical notions of ethical offense, or that the public is willing to accept the associated risks. But if there is no opportunity for these implications to even be *considered* during patent law's intrinsic "negotiation," can it realistically be characterized it as a fair bargain?

If we continue to sacrifice the opportunity to analyze these ethical issues during patent prosecution, we forego an opportunity for public input into a process where the public is a direct stakeholder. Although it is inarguably complicated by politics and attenuated by the U.S. democratic system,[113] the legislative process provides at least some opportunity for public input.[114] Since Patent Act legislation articulates the parameters of the patent bargain and defines the terms of this social contract, refusing an opportunity to fully consider the ethical, legal, and societal implications of emerging biotechnologies at this stage limits the opportunity for the public to weigh in innovations that will shape their future for years to come.

2. Existing Governance Is an Insufficient Ethical Regulatory Mechanism for Emerging Biotechnologies

Emerging technologies are inherently challenging to regulate because they are both difficult for the non-scientific public to understand and rapidly evolving, particularly in the early stages of their development.[115] Existing restrictions on controversial biotechnology are inadequate regulatory mechanisms because of their limited reach and temporally inappropriate relationship to research. Instead, an effective regulatory scheme must be both expansive and readily responsive. The patent prosecution process presents a unique opportunity for proactive ethical regulation that would mitigate

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112. *See Genome Editing: What Are the Ethical Concerns About Genome Editing?*, NAT'L HUMAN GENOME RES. INST. (Aug. 3, 2017), https://www.genome.gov/27569225/what-are-the-ethical-concerns-about-genome-editing/.

113. *See generally supra* note 108.

114. *See generally* Karen S. Czapanskiy & Rashida Manjoo, *The Right of Public Participation in the Law-Making Process and the Role of the Legislature in the Promotion of this Right*, 19 DUKE J. OF COMP. & INT'L LAW 1, 1 (2008) ("By definition, a democratic nation has some mechanism through which leaders hear from the people.").

115. *See* Carolyn Abbot*, Bridging the Gap—Non-State Actors and the Challenges of Regulating New Technology*, 39 J.L. SOC. 329, 357 (2012).

many of the issues associated with playing a game of regulatory "catch-up" to these influential technologies.

Existing infrastructure is insufficient—standing alone—to serve as an ethical regulatory scheme for developing biotechnology. Restricting access to funding undoubtedly discourages *some* prospective researchers, but does not alone provide a sufficient disincentive. Although a portion of healthcare research funding comes from federal sources, the largest portion comes from industry[116]—where grant restrictions are irrelevant. Therefore, research into ethically questionable technologies can continue unheeded in the majority of instances. For example, in 2017, researchers in Portland, Oregon announced that they had "successfully modified the genetic material of a human embryo" using CRISPR technology.[117] This research occurred despite NIH and RAC disapproval—as well as public skepticism[118]—and is likely to become more common as CRISPR technology matures. Clearly, funding restriction has not proven to be an adequate mechanism for voicing governmental or societal opinions on the use of these technologies.[119]

Further, although FDA regulation does prevent products from entering mainstream clinical use—thereby somewhat mitigating their safety risk to consumers—FDA action occurs too late in a technology's lifecycle to be an effective means of ethical regulation.[120] By the time a technology has reached the FDA

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116. RES. AMERICA, *supra* note 90, at 2 ("Industry invested more in R&D than any other sector, totaling $102.7 billion.").

117. Berg, *supra* note 15.

118. Cary Funk, *Americans Divided on Gene Editing, with Parents of Minors More Wary*, PEW RES. CTR. (Aug. 8, 2017), http://www.pewresearch.org/fact-tank/2017/08/08/americans-divided-on-gene-editing-with-parents-of-minors-more-wary/.

119. The logical counter-argument here is that the refusal of patent protection also would not *completely* eliminate the use of these technologies, because not every technology is patented. This is absolutely correct, and this Note does not purport to advocate completely prohibiting research into technologies that carry ethical controversy. However, because a patent is a social bargain, patent law is an important opportunity to voice public opinion. This is the case even if research and further development into a technology continues without patent protection. The patent process does not have to be the *exclusive* mechanism of ethical regulation—there would need to continue to be some market regulation from entities like the FDA—but should be at least a *component* of any regulatory scheme.

120. There is also an argument to be made that the FDA does not—and should not—base its product regulation on anything other than safety. *See*

application stage, extensive research has already been conducted[121] and, therefore, many ethically questionable events may have already occurred. In contrast, patent prosecution occurs at an ideal point in a technology's life cycle for regulation: early enough to mitigate the risk of unethical use, but late enough to allow future applications of a technology to be somewhat apparent.[122] This temporal relationship is unique to patent law, and resolves many issues inherent in an exclusively retroactive system like FDA regulation.

Incorporating ethical regulation into patent prosecution is also superior to industry self-governance in many ways. Although proponents often assert that self-regulation is a desirable mechanism because an inventor—or, in a broader sense, the industry in which the inventor operates—is the most familiar with the ethical risks associated with a technology, often the direct effect of this "regulation" is a simple "warding off more direct government intervention."[123] Although inventor discretion in the licensing process does provide some means of self-regulation—including in the case of CRISPR itself[124]—it

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Califf & Nalubola, *supra* note 89 and accompanying text. Undoubtedly, entities like the RAC and the National Academy of Sciences are better-positioned to make complex bioethical decisions. *See generally* notes 87, 92, and 93.

121. To begin approval proceedings, manufacturers must submit "scientific and clinical data." *About CBER*, FDA (Feb. 26, 2018), https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123340.htm. To have data available to submit, those manufacturers have necessarily engaged in extensive preliminary research activities.

122. In contrast to regulation at the product approval stage, attempting to implement regulation in the basic—or preliminary—stages of research could prove inefficient, because many of the future uses of a technology may not be apparent at that stage. For a brief overview of product development in the healthcare sector, see *Product Development: Positioning New Healthcare Products in the Marketplace*, MARS (Nov. 6, 2014), https://www.marsdd.com/mars-library/product-development-positioning-new-healthcare-products-in-the-marketplace/.

123. Abbot, *supra* note 115, at 345.

124. *See* Christi Guerrini et al., *The Rise of the Ethical License*, NATURE BIOTECH. 22, 22 (2017) (describing how patent licensing allows inventors to self-regulate, by "restrict[ing] socially controversial applications of a technology"). The Broad Institute—one holder of a patent on the CRISPR-Cas9 technology—has undertaken the licensing process "on terms intended to benefit a party not at the negotiating table: the public." *Id.* The Institute has recently licensed its patent to Monsanto, but provided the licensee with restrictions that prohibit the company from: "(i) performing gene drives that spread altered genes quickly through populations, which can alter ecosystems; (ii) creating sterile

would be unwise for the public to rely exclusively on individual restraint in the face of technologies with such potentially large public health effects. Further, in addition to the potential for case-by-case variance in the restraint actually exercised by individual patent holders and industries,[125] enormous monetary incentives are often at play for the owners of these influential technologies.[126] Undeniably, profits of this size could cloud a self-regulator's judgment. Therefore, self-regulation—though a desirable component of or complement to an ethical regulatory scheme[127]—is an insufficient regulatory mechanism when standing alone.

As a whole, addressing ethical concerns during the patent process is a far more consistent, tailored, and efficient manner in which to regulate biotechnology. Funding restrictions only affect the subset of technologies that utilize the particular funding mechanism, whereas patent law reaches a much larger

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'terminator' seeds, which would impose a serious financial burden on farmers who would be forced to buy them each year; and (iii) conducting research directed to the commercialization of tobacco products, which might increase the public health burden of smoking." *Id.*; *see also* Sharon Begley, *Monsanto Licenses CRISPR Technology to Modify Crops — With Key Restrictions*, STAT (Sept. 22, 2016), https://www.statnews.com/2016/09/22/monsanto-licenses-crispr/.

125. This case-by-case variance is also the reason it is unrealistic to expect the majority of developers to abide by the ethical guidelines promulgated by entities like the National Academy of Sciences. *See supra* note 87 and accompanying text. Since these recommendations do not have the force of law—or any force at all, outside of their role in developing grant restriction policies—researchers have little to no *real* incentive to abide by them.

126. The monetary implications of potentially-patentable biotechnologies are often exorbitant. For example, CRISPR-Cas9 has already generated billions of dollars for its patent holders. Katrina Megget, *Money from Genes: CRISPR Goes Commercial*, SCI. AM. (Jan. 22, 2016), https://www.scientificamerican.com/article/money-from-genes-crispr-goes-commercial/ ("Caribou, founded by Crispr pioneer Jennifer Doudna, has raised $15 million; Crispr Therapeutics, set up by Charpentier, has raised $89 million since April 2014, plus $105 million through the deal with Vertex; and Editas, founded by current Crispr patent holder Feng Zhang, has brought in more than $160 million.") Of note, these figures are from early 2016, and therefore the amount of revenue that has actually been generated to date is likely much higher. Incorporating ethical considerations in the licensing process may serve an inventor's own moral framework, but refusal certainly hinders monetary potential. Therefore, it is unrealistic to expect inventors to exercise this sort of discretion with any regularity.

127. Abbot, *supra* note 115, at 344–45.

number of potentially threatening technologies.[128] Additionally, because inventions are evaluated by a USPTO examiner on a case-by-case basis,[129] ethical regulation during the patent prosecution process would be highly individualized. This is enormously beneficial because the ethical issues presented by a biotechnology can vary widely based on its unique implications, rates of accuracy, and potential for misuse. Finally, consideration of the ethical implications would occur soon after the development of the technology,[130] which would allow an external assessment of the ethical risks to be made clear to the inventor early in the research process. Together, these features make patent law an incredibly advantageous ethical regulatory mechanism.

B. POTENTIAL REGULATORY SCHEMES

Incorporating some ethical considerations into the patent prosecution process is both necessary and justified, and there are two principle tools available for crafting a potential regulatory scheme: statutory change and common law revival.[131] While a statutory change is likely to produce more consistent outcomes across technologies, there are drawbacks to rigid legislative

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128. Since patents are so commercially desirable, any inventor that *can* obtain a patent typically chooses to seek one. *See* Megget, *supra* note 126. This creates an incentive for inventors to subject themselves to the attached ethical regulation regardless of their funding source.

129. *See generally Patent Process Overview*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/utility-patent/patent-process-0 (last visited Jan. 20, 2018) (outlining patent application process and noting that USPTO reviews the application once submitted).

130. Since novelty and non-obviousness are both requirements that depend on a lack of the same or similar inventions, an inventor is usually best served by seeking to obtain a patent as early as his or her invention can satisfy the relevant requirements. Therefore, patents are typically sought as early as possible in the inventive process.

131. Of course, both kinds of changes would also necessitate changes to USPTO, as articulated in the Manual of Patent Examining Procedure (MPEP), because of the USPTO's agency status. *See generally About Us*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/about-us (last visited Jan. 21, 2018) ("The United States Patent and Trademark Office (USPTO) is the federal agency for granting U.S. patents and registering trademarks. In doing this, the USPTO fulfills the mandate of Article I, Section 8, Clause 8, of the Constitution that the legislative branch 'promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.'"). *See generally* MPEP, *supra* note 23.

change like stagnancy, or over-inclusiveness. Similarly, although common law provides the flexibility necessary to appropriately evaluate varying technologies, awakening the Moral Utility Doctrine from its state of dormancy would revive many of the negative characteristics associated with its demise.

1. Federal Statutory Changes Promote Uniformity, but Minimize Flexibility

An amendment or addition to the Patent Act would provide a concrete opportunity for ethical consideration in the patent process, and potential overbreadth or under-inclusiveness could be minimized if the amendment was drafted carefully. This sort of statutory change has been proposed at two USPTO roundtable events, but was met with limited congressional support.[132] However, other jurisdictions have successfully incorporated a statutory addition in patent law encompassing ethical considerations—most notably, the European Union—indicating the potential for successful implementation of this mechanism.[133]

A legislative amendment would produce a desirable degree of uniformity, in contrast to an exclusively common law approach.[134] The legislative drafting process would also theoretically be informed by ethical and scientific experts,[135] which could help appropriately tailor the language used and reflect scientific consensus on the ethical risks of a given technology. Further, since any legislative change would presumably be reflected in USPTO policy, the USPTO itself would have an opportunity to provide guidance to and refine the approach of its examiners during the patent prosecution process.[136] Since the USPTO is the entity most familiar with

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132. *See* U.S. PATENT & TRADEMARK OFFICE, PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 59–64 (2017).

133. *See* Directive 98/44/EC, *supra* note 61, at 13–21.

134. *See* Giacomo A.M. Ponzetto & Patricio A. Fernandez, *Case Law Versus Statute Law: An Evolutionary Comparison*, 37 J. LEGAL STUD. 379, 396 (2008); Luca Anderlini et al., *Statute Law or Case Law?* 3 (CESifo, Working Paper No. 2358, 2008).

135. *The Legislative Process*, IND. UNIV. CTR. ON REPRESENTATIVE GOV'T, https://corg.indiana.edu/legislative-process (last visited Apr. 20, 2018) ("When holding a hearing, the committee will usually call *expert witnesses*, occasionally average citizens. . . .") (emphasis added).

136. MPEP, *supra* note 23.

potentially-patentable technology, its direct organizational involvement is a huge benefit.[137]

However, a formal legislative amendment also has drawbacks, and carries the potential for a host of negative effects. Firstly, passage of legislative amendments is an extensive process, and the amount of time needed can vary immensely depending on their nature.[138] As such, the mechanism may be ill-suited to the regulation of dynamic technologies—wherein the relevant ethical implications may change over time, and often rapidly.[139] Such an amendment would also be inapplicable to patents that have already been issued,[140] and therefore has limited regulatory potential concerning technologies that are already in existence, like CRISPR-Cas9. Furthermore, if an extended delay occurred in the passage of the legislative change—either initially or during processes of amendment—the scheme would sacrifice its regulatory capability with respect to any technologies developed during the transitional period.

Additionally, the extent to which a resulting piece of legislation actually reflects public opinion is highly debatable,[141] and therefore what initially seems to be the preeminent strength

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137. USPTO involvement would of course occur with either common law or statutory revision, but it would be substantially more convenient for all involved parties to solicit their involvement during policy development (as would be the case with statutory change) rather than retroactively, as a response to litigation (as would be the case with a purely common law approach).

138. *See generally* ROBERT B. DOVE, ENACTMENT OF A LAW (1997), https://www.congress.gov/resources/download/attachments/19267597/enactlaw.pdf?version=4&modificationDate=1446663432000&api=v2 (discussing in detail the Congressional procedure for enacting a law).

139. *See generally* Abbot, *supra* note 115 (discussing the challenges of regulating new technologies and possible regulatory approaches).

140. Retroactive federal legislation is prohibited by the Constitution itself. *See* U.S. CONST. art. I, § 9, cl. 3 ("No Bill of Attainder or ex post facto Law shall be passed."). In patent law specifically, the effect of this prohibition is evidenced by the America Invents Act itself, which changed many substantive patent requirements and applies only to patents issued on or after March 16, 2013. Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011).

141. Martin Gilens & Benjamin I. Page, *Testing Theories of American Politics: Elites, Interest Groups, and Average Citizens*, 12 PERSP. ON POL. 564, 565 ("The central point that emerges from our research is that economic elites and organized groups representing business interests have substantial independent impacts on U.S. government policy, while mass-based interest groups and average citizens have little or no independent influence."). Gilen and Page's research indicates that, outside of certain influential groups, the ability of public opinion to influence legislation in any meaningful respect is limited.

of this approach may not be as compelling as it initially appears. Legislation would need to incorporate at least a derivative of public opinion on controversial technologies[142] in order to serve its role in protecting the patent bargain. If it is not reflective of public opinion, the function of incorporating consideration of the relevant ethical issues is severely diminished. Further, legislation would be slow to react to changes in public opinion[143]—if it reacted at all—which is a substantial detriment to regulation in light of the speed with which new biotechnologies are produced and patented.

Finally, the legislative drafting necessary would be immensely difficult. In order to avoid unnecessary limitation on innovation, a potential amendment would need to provide the *opportunity* for ethical consideration, without mandating a rigorous course of analysis that would allow denial of a patent on inappropriate grounds.[144] Any potential amendment would also need to employ terms general enough to be applicable to a wide array of technology, but not so general as to be inapplicable to an individual technology.[145] Ultimately, drafting difficulty could prove to be the most insurmountable challenge in utilizing a legislative mechanism alone.[146]

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142. *See, e.g.*, Czapanskiy & Manjoo, *supra* note 114, at 1.

143. *See generally* sources cited *supra* note 134; Gilens & Page, *supra* note 141 and accompanying text.

144. Exactly what constitutes the appropriate grounds for ethical denial or invalidation of a patent is beyond the scope of this Note. For a thought-provoking analysis of some of the relevant considerations, see Bagley, *A Global Controversy*, *supra* note 31, at 532–47.

145. For example, the amendment could add a sentence to the patent eligible subject matter criteria of 35 U.S.C. § 101, that reads: "Patentability may be denied for inventions that have ethical outcomes which are yet unknown or have been established as undesirable." However, even with language as general as this, there is the potential for judicial misuse or expansion. One potential solution would be multiple amendments—each addressing a particular subtype of invention. If this approach were preferred, the European Biotech Directive could provide guidance. *See* European Biotech Directive, *supra* note 61. The European Directive explicitly disallows patents on "mere DNA sequence without indication of a function," as well as "the human body, at any stage in its formation or development, including germ cells," and "plant and animal varieties." *Id.* A similar enumeration approach could be applied to 35 U.S.C. § 101, excluding specifically certain classes of inventions rather than broadly excluding those which are ethically undesirable.

146. *See, e.g.*, Bagley, *Patent First*, *supra* note 46, at 539–45.

2. A Revival of the Moral Utility Doctrine Provides Crucial Flexibility, but Risks Abuse of Judicial Discretion

Many of the strengths of a statutory system would not exist in a common law approach, but the reverse is also true—common law has a unique set of strengths. First and foremost, common law is more individually tailored because of its *ex post* nature,[147] which is a necessary component of any regulatory scheme that hopes to govern in a changing landscape. Further, since common law is implemented on an individualized basis and evolves over time, it mitigates the risk of a sudden and unwarranted shift in the treatment of controversial biotechnologies.[148] Ultimately, a common law regulatory mechanism does not carry the same risks of overbreadth or rigidity, which may make it more suitable to the evolving ethical landscape of biotechnology.

The most desirable characteristic of reinstituting a form of case law governance is its individually-tailored nature.[149] There is no risk of the over- or under-inclusivity inherent in statutory regulation,[150] or of utilizing language that is applicable to only particular classes of technology.[151] Instead, case law systems provide a gradual development of well-tailored doctrine, appropriately suited to individual factual circumstances. Further, evidence suggests that—over time—case law "converges toward more efficient and predictable legal rules."[152] This is of enormous benefit in the realm of biotechnology, where inventors need some level of confidence in their ability to obtain patents in order to justify extensive research and development costs. Therefore, case law could provide a balance of flexibility and predictability as long as future judges are able to avoid the

147. *See, e.g.*, Anderlini et al., *supra* note 134, at 12–13 (discussing the *ex post* nature of case law).

148. *See* sources cited *supra* note 134. Sudden passage of legislation could prove more disruptive to the industry than beneficial to the public.

149. *See, e.g.*, F. Scott Kieff, *The Case for Preferring Patent-Validity Litigation over Second-Window Review and Gold-Plated Patents: When One Size Doesn't Fit All, How Could Two Do the Trick?*, 157 U. PA. L. REV. 1937, 1945 (2009) (discussing the benefit of individualized litigation).

150. *Id.*

151. For example, ethical requirements or prohibitions for agricultural enhancement technologies are likely to differ substantially from those that apply to gene editing technologies, and vice versa.

152. Ponzetto & Fernandez, *supra* note 134, at 379 ("[Case law's] evolution converges toward more efficient and predictable legal rules. . . . [S]tatutes do not share this evolutionary property.").

fate of the old Moral Utility Doctrine and apply a modern version more even-handedly.

Like a purely statutory regime, an exclusively common law approach to ethical consideration is not without its weaknesses. As the *Juicy Whip* court highlighted more than a decade ago, one concern is whether the judiciary even possesses the authority to invalidate patents on ethical or moral grounds—or if that is, in fact, the province of the legislature.[153] If the Federal Circuit's interpretation is correct, relying on case law to regulate biotechnology would be legally insufficient without the involvement of the legislature.[154] Therefore, a statutory component might be a *necessary*—rather than simply beneficial—element of an ethical regulatory system in patent law.

Furthermore, the Moral Utility Doctrine was not applied with any metric of consistency, which produced a complicated doctrine and was arguably at least partially responsible for its resulting disuse.[155] Inconsistent application diminishes the overall clarity of common law rules developed over time, resulting in a loss of one of the greatest potential benefits of a case law system.[156] Convoluted precedent could also confuse potential patent-seekers or patent-issuers, which could then ultimately result in a reduced incentive for innovation.[157] Since appropriate incentivization is crucial to sustaining the balance of the patent bargain, this potential pitfall cannot be overstated.

Additionally, there are certain issues inherent in the *ex post* nature of a purely judicial regulatory scheme—as there are with any *ex post* system.[158] Common law is developed in the

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153. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999).

154. More recently, this sentiment may have been echoed by the Supreme Court. Matal v. Tam, 137 S. Ct. 1744 (2017); *see also* sources cited *supra* note 59 and accompanying text.

155. Smith, *supra* note 12, at 161.

156. Ponzetto & Fernandez, *supra* note 134, at 379 ("[Case law's] evolution converges toward more efficient and predictable legal rules. . . . [S]tatutes do not share this evolutionary property.").

157. It's difficult to imagine that inventors—or, even, *prospective* inventors, would not become frustrated with U.S. patent policy if there was a large degree of unpredictability in the ethical invalidation of patents. Further, sporadic and inconsistent invalidation of issued patents would undoubtedly be incredibly frustrating to the USPTO as a whole, particularly if it was not provided with coherent judicial guidance on how it should amend its patent issuance practices.

158. Anderlini et al., *supra* note 134, at 12–13.

courtroom—in the face of an actual case or controversy[159]—making it inherently retroactive.[160] Patents on technologies that are potentially detrimental to society must be granted and utilized in the real world before a potential challenger can even *attempt* to invalidate them.[161] For this reason, the case law regulatory mechanism falls victim to the plight of other *ex post facto* regulatory attempts, and is forced to play "catch-up" to rapidly-developing technologies rather than provide a preventative solution.[162] In the case of biotechnology—where negative implications could manifest severely and rapidly—this is a tremendous deficit.

Finally, and perhaps most importantly, a modern Moral Utility Doctrine could fall victim to the varying moral and ethical convictions of individual judges—possibly the biggest risk in any potential regulatory scheme, and likely responsible for the original failure of the system.[163] Because of the nature of the patent bargain,[164] incorporating ethics into the patent process should involve some level of consensus—ideally from the public, but at least from some informed and impacted group of people—on where to draw the lines of ethical limitation. Conceptions of ethics and morality can vary widely between individuals, and judges are no exception.[165] Therefore, ethically regulating patent issuance exclusively through case law leaves these determinations subject to immense variability and potential misuse.[166]

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159. U.S. CONST. art. III, § 2, cl. 1.

160. *Id.*

161. For a brief but interesting discussion of the different policy considerations in ex ante and ex post evaluation of an issue, consider Anderlini et al.'s patent litigation example. Anderlini et al., *supra* note 134, at 12–13. ("From an *ex-ante* perspective, as it is standard, the optimal breadth of the patent will be determined taking into account the trade-off between the incentives to invest in R&D, and the social cost of monopoly power exercised by the patent owner. *Ex post*, however, since the R&D investments are sunk, it is always socially optimal to rule in favor of the infringer and thus open the market to competition.").

162. Anderlini et al., *supra* note 134, at 5.

163. *See generally* Smith, *supra* note 12.

164. *See generally* Ghosh, *supra* note 9, at 1316–18, 1328–29.

165. J.M. KIZZA, *Morality and the Law*, *in* ETHICAL AND SOCIAL ISSUES IN THE INFORMATION AGE 15 (2010) ("Although moral values are generally shared values in a society, the degree of sharing these values varies greatly.").

166. *Id.*

C. CRAFTING AN OPTIMAL REGULATORY FRAMEWORK

Rather than employing exclusively legislative change or common law revival, an ideal regulatory scheme would utilize components of both mechanisms in order to maximize flexibility and responsiveness, while minimizing inconsistency. Therefore, ethical regulation would be most effectively accomplished by combining a carefully-crafted statutory amendment—that leaves an appropriate amount of procedural flexibility to the USPTO—with a limited revival of the Moral Utility Doctrine. Such a regulatory scheme would allow for consideration of a technology's ethical implications early in its life cycle without placing undue emphasis on potential negative effects, effectively increasing both public benefit and public protection.

1. Characteristics of an Ideal Schema

In promoting this particular regulatory framework, it is important The ideal approach for ethical regulation in patent law would be to incorporate a broad statutory provision allowing denial of a patent on ethical grounds, while leaving the specific USPTO examiner protocol relatively flexible.[167] This would be most effective if coupled with a *limited* revival of the Moral Utility Doctrine, which would allow for some judicial oversight should the USPTO's interpretation of the statute traverse too far from the current state of society's moral and ethical values.[168] By utilizing the legislative branch, the relevant agency, and the judiciary in tandem, this approach would provide an opportunity for flexible ethical regulation, wherein each component is subject to balancing and supervision by the others.

In drafting the initial federal statute, generality is key. Ideally, Congress could look to the approach taken by the TRIPS Agreement and the EPC, and simply institute the opportunity for considerations in the vein of *ordre public*.[169] Encouraging this level of abstraction limits the opportunity for political pushback

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167. *See* Bagley, *Patent First*, *supra* note 46, at 541.

168. *Id.* ("[T]he judiciary branch . . . is perhaps best suited to engage in line drawing of this sort.").

169. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 66; The European Patent Convention, *supra* note 67 (discussing the broad approaches of two international preeminent intellectual property law treaties to ethical regulations).

from lobbying groups,[170] while still establishing some discrete statutory requirement allowing ethical considerations into the patent examination room. Although very general legislation can be susceptible to misinterpretation, that susceptibility is reduced by coupling the legislation with a clear purpose,[171] as well as judicial and agency-based oversight.[172]

An important component of avoiding the pitfalls of the historical Moral Utility Doctrine is increasing the input of the USPTO in the regulatory process, as well as increasing its discretion in implementing examination guidelines. As the entity with the most intimate knowledge of the technology that it examines, discourse between the USPTO and the judicial branch is essential to the success of this regulatory system.[173] If the governing statute was sufficiently flexible, the USPTO could then tailor the ethical requirements using internal procedure.[174] These internal guidelines would need to be somewhat more

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170. By contrast—as in, if legislation were to be enacted on a technology-by-technology basis—Congress could be subject to immense pressure from lobbying groups backing certain technologies, even if those technologies in fact do present grave ethical risks. Therefore, that approach is politically undesirable. Bagley, *Patent First*, *supra* note 46, at 541 ("Alternatively . . . though likely more hazardous from a political standpoint, Congress could enact specific, subject matter-based legislation.").

171. In particular, a record of legislative history explaining the statutes purpose may be of use in subsequent judicial interpretation. *See* Clarence Miller, *The Value of Legislative History of Federal Statutes*, U. PENN. L. REV. 158 (1925).

172. *But see* Bagley, *Patent First*, *supra* note 46, at 541 (arguing that a statute drafted with general language could, in effect, cause a reversion to the original Moral Utility Doctrine scheme). Undoubtedly, this is a possibility. The only hope for avoiding such a repeat history would be clear communication between Congress and the judiciary as the statute is interpreted (and, perhaps, additional, technology-specific legislation if necessary to clarify), coupled with continued feedback from the USPTO.

173. This relationship could be informal—in large part, in order to respect the talismanic "separation of powers"—but would be essential in avoiding reversion to the old Moral Utility approach.

174. More than likely, this would involve incorporating guidelines for the treatment of the ethical implications of a given technology into the USPTO's Manual of Patent Examining Procedure (MPEP), which "outlines the procedures carried out by the U.S. Patent and Trademark Office." It serves as a handbook for patent examiners during the patent application process, and "describes all of the laws and regulations that must be followed in the examination of U.S. patent applications, and articulates in detail their application to an enormous variety of different factual situations." *Patent Lens*, CAMBIA, http://www.bios.net/daisy/patentlens/2595.html. *See generally* MPEP, *supra* note 23.

technologically specific than the original federal statute in order to be useful, and would ideally be informed by both professional society guidelines[175] and public opinion.[176] Utilizing the relevant agency in this way is beneficial in part because agency policy can be generated and amended more quickly than legislation, and in part because of the USPTO's unique technological expertise. Ultimately, involvement of the USPTO in developing examination procedure would help to offset any of the potential detriments of a very general statutory ethical regulation allowance, and its communication with the judiciary would help minimize the risks of inappropriate or unintended judicial interpretation.

Finally, the ideal system would incorporate some level of reinvigoration of the Moral Utility Doctrine. Since litigation is a necessary and fundamental component of the patent system, judges need a way to evaluate the validity of issued patents on all relevant grounds—including ethical grounds, were the opportunity to be added. Furthermore, judges are uniquely qualified to perform difficult "line drawing," and therefore would play a necessary role in defining the parameters of which inventions are ethically permissible.[177] Additionally, incorporating judicial opinion, by default, incorporates the perspective of the general public, since judges are frequently no

175. *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 85. The National Academy of Science guidelines on gene editing could—and, arguably, *should*—be instructive in amending the MPEP, as they are the preeminent ethical guidelines on gene editing at present. The National Academy of Science recommends abstaining from genome editing for purposes of "enhancement," and cautions against germline editing without "ongoing reassessment and public participation." *See Report Highlights*, *supra* note 87. The USPTO might incorporate these recommendations by instructing examiners to deny claims that could encompass these activities. In practice, this would create a system where the National Academy of Science informs USPTO patentability policy similarly to the way that the Recombinant DNA Advisory Committee (RAC) informs National Institutes of Health research policy. *See generally supra* notes 91–93. In this way, the USPTO would give professional consensus guidelines legal force.

176. Informal (or "notice-and-comment") rulemaking is a mechanism by which the USPTO could incorporate public opinion in this internal policy. *See Notice-and-Comment Rulemaking*, CTR. FOR EFFECTIVE GOV'T (2015), https://www.foreffectivegov.org/node/2578. This style of rulemaking involves proposing a rule in the Federal Register, and responding to comments from the general public. *Id.* Further, Congress could—if it so desired—require the USPTO to entertain even *more* public participation than required by informal rulemaking (or the USPTO itself could choose to do so). *Id.*

177. *See* J.M. Kizza, *supra* note 168.

more knowledgeable about a particular niche technology than the average layperson.[178] In many ways, this is as close to a representation of public opinion as can be realistically achieved in a representative democracy. Therefore—as long as the other components of the proposed policy continue to function in a complementary capacity—a "modern Moral Utility Doctrine" could develop over time without a disproportionate risk of judicial overstep.

2. Necessary Limitations: A Balancing Act

In promoting this particular regulatory framework, it is important to acknowledge the necessary limitations, as well as the policy goals that should govern its implementation. This system is designed to require consideration of a technology's ethical implications, while maintaining some degree of analytical flexibility—an equilibrium that should be continually re-calibrated to reflect society's evolving moral and ethical convictions.[179] Therefore, it will be necessary to re-analyze and re-incorporate public opinion at various points in the future, particularly after watershed developments in a particular field—like the discovery of the CRISPR-Cas9 system.

Additionally, introducing any new considerations into patent prosecution—ethical or otherwise—necessitates a reexamination of the crucial patent law "balancing act." At every turn, we must strive to serve the constitutional policy goal of promoting innovation,[180] while ensuring that the public is adequately benefited and protected.[181] If our ethical restrictions become too severe and patents become too illusive for the inventor, innovation is disincentivized and, ultimately, the public suffers.[182] Similarly, if we continue to operate without any

178. *See, e.g.*, Peter Lee, *Patent Law and the Two Cultures*, YALE L.J. 2 (2010).

179. The patent process truly is a bargain, in which the public is a participant. As such, their inclusion in negotiation should be requisite. *See* Ghosh, *supra* note 9; *see also supra* note 119 and accompanying text. Since public opinion evolves over time, renegotiations are necessary.

180. *See* U.S. CONST. art. I, § 8, cl. 8.

181. For a discussion of this central policy consideration—as well as many others at play in patent law—see Dan Burk & Mark Lemley, *Policy Levers in Patent Law*, VA. L. REV. 1575 (2003).

182. In this instance, society experiences a decreased level of innovation as compared to a less-restrictive patent law environment. Since innovations are often beneficial, this results in a net decrease in public benefit.

ethical constraints at all, the public will also suffer.[183] The appropriate balance of incentive and protection lies somewhere in the middle—it is as elusive as it is desirable, making perpetual reevaluation of a necessary component of any successful patent system.

D. REVISITING CRISPR-CAS9

Proposing an ideal regulatory scheme is significantly easier than employing it in practice. The CRISPR system is an exemplary biotechnology around which to debate patentability because it highlights many of the ethical dilemmas associated with gene editing technology. However, CRISPR also illustrates the complexity of attempting to apply patentability restrictions to technologies that have a wide array of applications. For example, is possible to use CRISPR-Cas9 to edit human embryos,[184] but it can just as easily be used to enhance crop yield[185] or alter flower color.[186] Some of these uses are clearly more contentious than others. Should we deny patent protection to the *entire* technology because of a handful of its applications?

The answer is not simple. Some technologies would almost certainly be barred by the proposed regulatory framework: for example, those encompassing biological weapons.[187] In this case, the patent "balancing act" would tip plainly in favor of societal disapprobation—whatever benefit these technologies provide is

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183. Contrastingly, refusal to restrict patent issuance on ethical grounds allows technologies with potential negative effects to run rampant, and their innovation is encouraged because it appears to be condoned by both society and the government. *See* Bagley, *Patent First*, *supra* note 46, at 535 (indicating that the government places its "*imprimatur* on [a particular technology] via a patent grant").

184. *See, e.g.*, Puping Liang et al., *supra* note 4.

185. *See* Dom Galeon, *Geneticists Have Used CRISPR Gene Editing to Create Crops that Grow More Food*, FUTURISM (Sept. 14, 2017), https://futurism.com/geneticists-have-used-crispr-gene-editing-to-create-crops-that-grow-more-food/.

186. *See* David Nield, *For the First Time, CRISPR Has Been Used to Dramatically Change Flower Colour*, SCIENCEALERT (Sept. 9, 2017), https://www.sciencealert.com/now-scientists-are-using-crispr-to-change-the-colour-of-flowers.

187. *See, e.g.*, U.S. Patent No. 6,523,478 (claiming a "rifle-launched non-lethal cargo dispenser" that can be filled with cartridges containing "chemical/biological agents," among other substances). This patent was actually issued, and was the subject of substantial ethical controversy. *See, e.g.*, Erika Check, *US Army Attacked over Published Patent for 'Bioweapons Grenade'*, NATURE (June 19, 2003), https://www.nature.com/articles/423789a.

unlikely to warrant the risk of their misuse. A more borderline instance might involve a claim encompassing human neural material,[188] wherein the potential medical benefits may or may not outweigh concerns about autonomy and morality. To be sure, this kind of marginal technology presents *some* opportunity for judicial overstep or abuse[189]—a variance in human conviction that no regulatory system can entirely preclude. In the case of CRISPR-Cas9, however, it is unlikely that professional consensus,[190] international approaches,[191] or current public opinion[192] would instruct barring patentability entirely. Instead, subjecting CRISPR to the recommended framework is *still* likely to indicate that it merits patent protection—the technology has

188. The use of human neural material is often debated by bioethicists in the context of chimeras. *See* Allison Harvey & Brian Salter, *Anticipatory Governance: Bioethical Expertise for Human/Animal Chimeras*, 21 SCI. AS CULTURE 291 (2012) (discussing the hypothetical "human neuron mouse," which is "a mouse in which the brain neurons [are] replace [*sic*] with human neural stem cells"). Whether or not the use of human neural material is excluded from patentability by the Patent Act remains uncertain, and hinges on whether the use of such material is seen as creating a claim that is "directed to a human organism." *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284, 340 (2011) ("Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.").

189. This "abuse" refers to judges imparting their own moral and ethical convictions into legal decision-making. In such instances, a judge might invalidate a patent that society would collectively choose to uphold.

190. Although it has issued cautionary statements about certain applications—namely, enhancement and germline modification—the National Academy of Science appears to be supportive of gene editing in certain contexts. *See Report Highlights*, *supra* note 87.

191. For example, even Europe has issued patents that cover CRISPR technology, although a struggle persists as to ownership rights. *See, e.g.*, Kelly Servick, *Broad Institute Takes a Hit in European CRISPR Patent Struggle*, SCI. (Jan. 18, 2018, 3:30 PM), http://www.sciencemag.org/news/2018/01/broad-institute-takes-hit-european-crispr-patent-struggle. In general, the European Union appears to be moving toward relaxing its restrictions on the use of gene editing. *See* Alex Dale, *European Court Supports the Softening of CRISPR Gene Editing Rules*, LABIOTECH (Jan. 22, 2018), https://labiotech.eu/crispr-gene-editing-court/.

192. At present, the public also appears to be generally supportive of gene editing technology. *See* Stephen M. Weissberg et al., *A CRISPR New World: Attitudes in the Public Toward Innovation in Human Genetic Modification*, 5 FRONTIERS IN PUB. HEALTH 1 (2017) ("*Respondents supported genetic modification research*, although demographic variables influenced these attitudes—conservatives, women, African-Americans, and older respondents, while supportive, were more cautious than liberals, men, other ethnicities, and younger respondents.") (emphasis added).

too many ethically permissible applications to warrant total denunciation in the name of a select few, which could be addressed individually.[193] Therefore, this Note does not purport to recommend total condemnation of any technology that implicates ethical concerns. Instead, it simply attempts to encourage discourse—involving *all* participants in the patent bargain—about the ethical risks we are willing to accept in exchange for technological progress.

IV. CONCLUSION

Despite other approaches taken internationally, the current U.S. patent system provides no opportunity to consider the ethical implications of a technology during the patent process. There has never been a statutory basis for doing so,[194] and the common law doctrine that once allowed such considerations to be the basis of patent invalidation—the Moral Utility Doctrine—has been dormant for at least a decade.[195] To date, its status remains uncertain. Current biotechnological developments have brought once-dystopian ethical concerns to the forefront of public discourse, providing a renewed opportunity to establish a relationship between ethics and patent law in the U.S.

The ramifications of a technology are necessary considerations in patent law because patent issuance is a bargaining process— the public must receive a true net benefit in exchange its recognition of a patentee's limited monopoly right. Further, evaluating an emerging technology's ethical implications *during* the patent process—rather than after they have achieved mainstream commercial use—is a uniquely proactive way to regulate rapidly-evolving technologies before they impact the general public. However, effective evaluation of the ethical considerations inherent to new biotechnologies cannot be adequately accomplished by preventative legislation or common law supervision alone. Instead, a blended approach involving a legislative provision that mimics international

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193. For example, a would-be CRISPR patentee could be required to disclaim certain ethically controversial subject matter—such as use of the technology in vertebrate animals—in a similar way that patentees are required to disclaim subject matter encompassing a human organism. *See generally* Crouch, *supra* note 35.

194. Bagley, *Patent First*, *supra* note 46, at 532 ("[T]he United States has never had a statutory morality exception to patentability.").

195. *See supra* notes 47–56 and accompanying text.

approaches and accommodates discretion in agency policy, combined with a limited revival of a modernized Moral Utility Doctrine, strikes the appropriate balance between incentivizing innovation and protecting the public interest. Whether patent protection for CRISPR-Cas9 and its progeny would ultimately be disallowed by this schema is speculative, but it creates a regulatory environment equipped to handle the complex ethical implications of 21st Century biotechnology—making it an ideal approach to U.S. patent law for the years to come.