Gene[ie] in a Bottle: Regulating the Future of Man

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I. INTRODUCTION

Over the past few years, the Broad Institute of Cambridge (Broad Institute) and the University of California at Berkeley (Berkeley) have been involved in heated patent litigation over a new gene-editing technology tool, clusters of regularly interspaced short palindromic repeat CAS9 (CRISPR).[1] CRISPR has the ability to target and edit specific genes, acting as a "molecular scissor."[2] The patent litigation remains controversial because the patent owner of CRISPR will soon be in a very lucrative position as licensor of the technology.[3] Not only will the patent holder have the ability to license the technology but will also have the power to edit specific genes in cells; thereby having the ability to change genes within different cellular bodies such as animals, humans,

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1. Heidi Ledford, *Bitter CRISPR Patent War Intensifies*, NATURE (Oct. 26 2017), http://www.nature.com/news/bitter-crispr-patent-war-intensifies-1.22892.

2. *Research Highlights: CRISPR*, BROAD INST., http://www.broadinstitute.org/research-highlights-crispr (last visited on Mar. 22, 2019); Preetika Rana et al., *China, Unhampered by Rules, Races Ahead in Gene-Editing Trials*, WALL STREET J. (Jan. 21, 2018), http://www.wsj.com/articles/china-unhampered-by-rules-races-ahead-in-gene-editing-trials-1516562360.

3. Ledford, *supra* note 1.

and food.[4] However, there are potential domestic implications to patients and global implications in regards to regulating this new gene technology.[5]

This Comment will explain the patent and regulatory framework that affects genetic technologies today. First, I will discuss gene technologies and why these technologies are patentable, using CRISPR as an example. Second, I will discuss the potential harms of the current patent system and how those harms affect the ability to patent genetic technologies. Next, I will discuss a potential alternative regulatory approach that could make genetic technologies unpatentable and more heavily regulated by the Food and Drug Administration (FDA). Finally, I will provide an argument that will support the idea that the FDA is the best agency to address the legal and ethical challenges facing genetic technology. CRISPR will be used as an example of a genetic technology that would fit into the context of this Comment.

II. PATENTING GENETIC TECHNOLOGY: THE EVOLUTION OF PATENTABLE SUBJECT MATTER IN GENETICS

Patent law is grounded in Article I, Section 8, Clause 8 of the United States Constitution: "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive rights to their respective writings and discoveries."[6] Patents are inventions protected for "the progress of science" under the clause.[7] The law for patents is codified under 35 U.S.C. §§ 100-103.[8] A registered patent is defined as a negative property right, which gives the patent holder the right to exclude others from using that invention for a limited time of twenty years.[9] In order for an invention to qualify for patent protection by the United States Patent and Trademark Office (USPTO), the work of authorship must be considered "patentable subject matter,"[10] nonobvious, independent of a prior work, novel, and a utility.[11]

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4. *Id.*; Jacob S. Sherkow, *CRISPR, Patents, and the Public Health*, 90 YALE J. BIOLOGY & MED. 667, 667-72 (2017).

5. *See* Annalisa Choy, *Rewriting the Human Genome: CRISPR and an International Gene-Editing Standard*, CORNELL INT'L L.J. ONLINE (Nov. 3, 2017), http://cornellilj.org/rewriting-the-human-genome-crispr-and-an-international-gene-editing-standard/; Rana et al., *supra* note 2.

6. U.S. CONST. art. 1, § 8, cl. 8.

7. *See id.* art. 1, § 8, cl. 8.

8. *See* 35 U.S.C. §§ 100-103 (2012).

9. *See id.* § 154.

10. *Id.* § 101.

11. *Id.* §§ 100-103.

Patentable subject matter is defined as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement."[12] Thus, "whoever invent[s] or discover[s]" what is defined as patentable subject matter "may obtain a patent."[13] For example, electronics, pharmaceuticals, and machines are categorized as patentable subject matter.[14] Since the statute uses broad language, courts will interpret these requirements very broadly. Yet, over time courts have narrowed the definition by identifying what it does not include.[15] For example, the laws of nature, natural phenomenons, and abstract ideas like body temperature, wind, or math algorithms were listed by courts as not constituting patentable subject matter.[16]

Genes are no longer considered patentable subject matter.[17] In the past, the USPTO granted patents for specific genes including at least 60,000 patents relating to genes and genetics.[18] This changed in 2013, when the genetic company Myriad Genetics (Myriad) received patent protection for both the BRCA 1 and BRCA 2 genes, the genes most commonly associated with breast cancer.[19] After several claims by Myriad in an effort to protect their patent, one researcher challenged Myriad's patent, thereby forcing the Supreme Court to address the issue of patenting human genes in *Association for Molecular Pathology v. Myriad Genetics Inc*.[20] The biggest concern in the lawsuit was the amount of interested stakeholders involved in the litigation.[21] On one side were "patient groups, scientist[s] and medical associations" who represented the independent researchers wanting access to the genes for testing, and on the other side were patent holders interested in preserving patent property rights.[22] The

12. *Id.* § 101.

13. *Id.*

14. *Patentable Subject Matter: Everything You Need to Know*, UPCOUNSEL, http://www.upcounsel.com/patentable-subject-matter (last visited Feb. 7, 2019).

15. Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980); *Patentable Subject Matter: Everything You Need to Know*, *supra* note 14.

16. *Diamond*, 447 U.S. at 309-10; *Patentable Subject Matter: Everything You Need to Know*, *supra* note 14.

17. Kathlyn Stone, *The Debate About Gene Patents*, BALANCE (Nov. 18, 2018), http://www.thebalance.com/the-gene-patents-debate-2663137.

18. *Id.*

19. Ass'n for Molecular Pathology v. Myriad Genetics Inc., 569 U.S. 576, 579 (2013); Kristin Beale, *The CRISPR Patent Battle: Who Will Be "Cut" Out of the Patent Right to One of the Greatest Scientific Discoveries of Our Generation?*, B.C. INTELL. PROP. & TECH. F. 1, 4 (2015), http://bciptf.org/wpcontent/uploads/2016/02/KBeale-CRISPR.pdf.

20. *Myriad*, 569 U.S. at 580.

21. Stone, *supra* note 17.

22. *Id.*

Court held that human genes are not patentable subject matter because genes are naturally occurring making them not patentable.[23] Since the USPTO previously granted patents for genes, the Court's decision invalidated thousands of patents and tremendously changed the landscape of gene patentability.[24]

Following the Court's decision in *Myriad*, genes were no longer considered patentable subject matter; however, in *Diamond v. Charkrabarty*, the Supreme Court allowed genetic technologies to be patented.[25] In *Charkrabarty*, the Court addressed the patentability of a living organism.[26] It considered the legislative history of the Patent Act of 1952, which states that "anything under the sun that is made by man" can be patented and found that patentable subject matter up to this point had been defined very broadly.[27] Thus, in that same vain, the Court concluded that genetically engineered bacteria was patentable subject matter eligible for patent protection because the bacteria was man-made, rather than originating from nature.[28]

Following the decisions in *Charkabarty* and *Myriad*, came moral and ethical concerns with regards to the growing patent eligibility of genetics and genetic technologies.[29] In response to these concerns, specifically the concerns related to the patentability of human genes, Congress passed section 33 of the Leahy-Smith American Invents Act (AIA) in 2011, which included the following language[30]: "Notwithstanding any other provision of law, no patent may issue on claim directed to or encompassing a human organism."[31] Congress intended the language of section 33 to be interpreted by both the USPTO and courts to prohibit the patentability of

23. 35 U.S.C. § 101 (2012); *Myriad*, 569 U.S. at 580; Beale, *supra* note 19.

24. Beale, *supra* note 19.

25. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980); 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, 771 (2013).

26. *See Chakrabarty*, 447 U.S. at 309.

27. *See id.* at 309; S. REP. NO. 82-1979, at 2439 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2399.

28. *See* Peter K. Yu, *Teaching International Intellectual Property Law*, 52 ST. LOUIS U. L.J. 923, 933 (2008).

29. Stone, *supra* note 17.

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

31. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 340 (2011); Science, State, Justice, Commerce, and Related Agencies Appropriations Act of 2007, H.R. 5672, 109th Cong. § 618 (2006) ("[P]rohibits the use of any of the funds appropriated or otherwise made available under this Act to issue patents on claims directed to or encompassing a human organism.").

human organisms, but still permit patents related to human composition.[32] For example, CRISPR is an illustration of a technology that interacts with human composition, but itself is not human.[33]

Today, genetic technologies are at risk because the USPTO will not grant patents for specific genes after the Court's decision in *Myriad*.[34] However, since gene technologies are not genes themselves, they are not a product of nature;[35] thus, gene technologies are still eligible for patent protection under the *Charkabarty* opinion.[36] For example, scientists and researchers can "alter, control and modify CRISPR to function in animal and human cells, a cellular system in which CRISPR does not naturally function."[37] Furthermore, gene technologies may also benefit from AIA's interpretation because technologies like CRISPR are not considered a human organism but defined as a technology that interacts with human cells.[38] With the current patent system, genetic technologies like CRISPR are patentable but should not be patent protected.[39] Despite their eligibility, the USPTO should avoid patenting gene technologies that are capable of changing specific genes and human organisms because of the high level of risks involved.

III. CRISPR AS A TOOL TO UNDERSTAND GENETIC TECHNOLOGY

CRISPR is adapted from a natural gene editing system found in bacteria; its development has proven to be today's fastest, cheapest, and most efficient gene editing tool.[40] As a tool, CRISPR can edit the genes of humans, animals, and bacteria with surgical precision.[41] It consists of a strand of Ribonucleic Acid (RNA) and Cas9, an enzyme forming a

32. *See* Leahy-Smith America Invents Act § 33; 157 CONG. REC. E1183 (daily ed. June 23, 2011) (statement of Rep. Lamar Smith).

33. *Id.*

34. *See* Ass'n for Molecular Pathology v. Myriad Genetics Inc., 569 U.S. 576, 576 (2013); Beale, *supra* note 19.

35. *See id.*

36. *See* Diamond v. Chakrabarty, 447 U.S. 303, 305, 308 (1980).

37. Beale, *supra* note 19.

38. *See id.*

39. *See id.*

40. *What Are Genome Editing and CRISPR-Cas9?*, NIH U.S. NAT'L LIBR. MED.: GENETICS HOME REFERENCE (Aug. 2017), http://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting.

41. Juliet Childers, *CRISPR Patent Wars: How to Claim a Cure*, EDGY LABS (Jan. 9, 2018), http://edgylabs.com/crispr-patent-wars-how-to-claim-a-cure; Ledford, *supra* note 1; Ed Yong, *What Can You Actually Do with Your Fancy Gene-Editing Technology?*, ATLANTIC (Dec. 2, 2015), http://www.theatlantic.com/science/archive/2015/12/what-can-you-actually-do-with-your-fancy-gene-editing-technology/418377/.

complex with the ability to search and reprogram a single cell.[42] CRISPR is most commonly and notably used for gene therapy in humans, which is the "treatment of disease by modifying the genome of patients' cells."[43]

CRISPR is currently the subject of a patent dispute between the Broad Institute and Berkeley in the Federal Circuit case *Regents of the University of California v. Broad Institute, Inc*.[44] Under the guidance of Jenner Douda and Emmanuelle Charpentier, Berkeley filed its patent application with the USPTO in May 2012.[45] The application detailed the use of CRISPR in various types of cells including non-eukaryotic cells, like bacteria.[46] Several months later, the Broad Institute, led by Feng Zhang, filed an expedited review of its independent patent application for CRISPR in December 2012.[47] In April 2014, the USPTO granted the Broad Institute patent protection for CRISPR, which allows them to use the tool CRISPR for eukaryotic cells like organisms, plants, animals, and humans.[48] Berkeley appealed the USPTO's decision, arguing the Broad Institute's patent interferes with Berkeley's patent application.[49] The USPTO found in favor of the Broad Institute, and Berkeley again appealed its decision.[50] The second appeal took place in April 2018 in front of the Patent Trial and Appeal Board (PTAB).[51] Two months later, on June 19,

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42. Michael A. Stramiello, *CRISPR: The New Frontier of Biotechnology Innovation*, 10 A.B.A. LANDSLIDE NO. 3 (Jan./Feb. 2018), http://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2017-18/january-february/crispr-new-frontier-biotechnology-innovation-digital-feature.html; Zengyou He, *Protein Complex Identifation from AP-MS Data*, SCIENCEDIRECT (2015), http://www.sciencedirect.com/topics/neuroscience/protein-complexes (stating that a complex is a protein complex made up of proteins "that interact with each other at the same time and location and which has essential roles in regulatory process, cellular function and signaling cascades").

43. Stramiello, *supra* note 42; Sherkow, *supra* note 4, at 667.

44. *See* Ledford, *supra* note 1; *see also* Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286 (Fed. Cir. 2018).

45. Jessica Kim Cohen, *UC Berkeley and Broad Institute's Legal Dispute over CRISPR Ownership: A Timeline of Events*, BECKER'S HEALTH IT & CIO REP. (June 21, 2018), http://www.beckershospitalreview.com/data-analytics-precision-medicine/uc-berkeley-and-broad-institute-s-legal-dispute-over-crispr-ownership-a-timeline-of-events.html; Richard Harris, *Scientists Battle in Court over Lucrative Patents for Gene-Editing Tool*, NPR (Dec. 5, 2016), http://www.npr.org/sections/health-shots/2016/12/05/504454201/scientists-battle-in-court-over-lucrative-patents-for-gene-editing-tool; Ledford, *supra* note 1.

46. Cohen, *supra* note 45; Ledford, *supra* note 1.

47. Cohen, *supra* note 45; Harris, *supra* note 45; Ledford, *supra* note 1.

48. Cohen, *supra* note 45; Ledford, *supra* note 1.

49. Cohen, *supra* note 45; Ledford, *supra* note 1.

50. Cohen, *supra* note 45; Ledford, *supra* note 1.

51. Brent Babcock & Kerry Taylor, *The Continuing CRISPR Patent Battle: The Broad Institute Loses a Key European Patent*, MEDCITYNEWS (Jan. 23, 2018), http://medcitynews.com/2018/01/continuing-crispr-patent-battle-broad-institute-loses-key-european-patent/; Ledford, *supra* note 1.

2018, the Court of Appeals for the Federal Circuit granted Berkeley two narrow patents with little commercial value; however, the Broad Institute retains the more lucrative patent for CRISPR.[52]

Patent specialist Kevin Noonan states that institutions like the Broad Institute and Berkeley will typically settle any patent disputes outside the courts; however, when there is a significant amount of money at stake, parties may choose to litigate.[53] This race for patents through litigation is described as "multiple million-dollar companies [] racing to apply CRISPR for use as human therapeutics, [leaving] judges, patent offices, and prize juries clash[ing] over who did what, when, and how important their contribution was or is."[54]

Berkeley's appeals have been crucial to the future of gene-editing technology because CRISPR is considered today's "most lucrative application of gene editing," with significant benefits.[55] The first and foremost benefit is that it is the simplest and most precise gene editing tool in existence.[56] Due to its precision in editing, it can potentially cure diseases such as Alzheimer's and heart disease.[57] The new technology has "groundbreaking" uses, including eliminating cancer cells in one's body.[58] Moreover, several diseases are caused by a malfunction or presence of one specific gene.[59] Inherited diseases that have the ability to affect several generations, like Huntington's Disease or Tay-Sachs, can literally be cut out with the assistance of CRISPR.[60]

Gene-editing technology brings with it significant concerns.[61] One concern in particular is unintended mutations.[62] An unintended mutation

52. Babcock & Taylor, *supra* note 51; Ledford, *supra* note 1.

53. Harris, *supra* note 45; Ledford, *supra* note 1.

54. Frida Holme, *Finally a Win for UC Berkeley: Two CRISPR Patents Awarded*, FRONT LINE GENOMICS (June 20, 2018), http://www.frontlinegenomics.com/news/23997/finally-a-win-for-uc-berkeley-two-crispr-patents-awarded/.

55. Harris, *supra* note 45; Ledford, *supra* note 1.

56. Karen Weintraub, *5 Reasons Gene Editing Is Both Terrific and Terrifying*, NAT'L GEOGRAPHIC (Dec. 3, 2015), http://news.nationalgeographic.com/2015/12/151203-gene-editing-terrific-terrifying-science/.

57. *Id.*; Kristen V. Brown, *Gene Editing Controversy Reminds Us Just How Much Money Influences Science*, GIZMODO (July 6, 2017), http://gizmodo.com/gene-editing-controversy-reminds-us-just-how-much-money-1796493630; Shobita Parthasarathy, *CRISPR Dispute Raises Bigger Patent Issue That We're Not Talking About*, CONVERSATION (Apr. 4, 2016), http://theconversation.com/crispr-dispute-raises-bigger-patent-issues-that-were-not-talking-about-56715.

58. Brown, *supra* note 57; Parthasarathy, *supra* note 57.

59. *See* Brown, *supra* note 57.

60. Parthasarathy, *supra* note 57.

61. *See* Brown, *supra* note 57; Parthasarathy, *supra* note 57.

62. Parthasarathy, *supra* note 57.

can edit DNA in a way that negatively affects future human life.[63] If new genetic technologies can successfully edit individual cells, then they may impact other genes that a user of the technology did not intend to edit.[64] These mutations have the ability to "[r]ewrit[e] life's building blocks," creating "unintended irreversible changes in people that may not emerge for years."[65]

The regulatory decisions of the United States and other international actors have the ability to affect the future of humanity through genetic technologies.[66] Currently, China is using gene-editing technology in humans;[67] however, China has no national regulation or requirements to police these technologies,[68] and the few regulatory systems China does have in place are seemingly flawed.[69] For example, one regulatory procedure is to present the new gene-editing technology to a hospital review board.[70] Yet, this is flawed because one hospital review board took only one afternoon to approve patient trials, while the United States may take several.[71]

The international community is concerned with the implications of China's flawed regulatory systems and the potential negative effects of the country's swift clinical trials.[72] In fact, it has already been reported that fifteen of eighty-six human patients involved in these trials have died.[73] Yet, a Chinese report claims these fatalities were caused by prior illnesses of the patients.[74]

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63. *See* Reenita Das, *Gene Editing with CRISPR-Cas9: The Next Step in Human Evolution Will Be Worth $25 Billion by 2030*, FORBES (Dec. 14, 2017), https://www.forbes.com/sites/reenitadas/2017/12/14/gene-editing-with-crispr-cas9-the-next-step-in-human-evolution-to-be-worth-25-billion-by-2030/#72d03bdf449f.

64. Alex Salkever & Vivek Wadhwa, *When Baby Genes Are for Sale, the Rich Will Pay*, FORTUNE (Oct. 23, 2017), http://fortune.com/2017/10/23/designer-babies-inequality-crispr-gene-editing/.

65. Rana et al., *supra* note 2.

66. *See id.*

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *See* Claire Maldarelli, *China Might Be Winning the CRISPR Race, but We Have the FDA,* POPULAR SCI. (Jan. 30, 2018), http://www.popsci.com/china-crispr-immunotherapy-fda; Rana et al., *supra* note 2.

72. *See* Rana et al., *supra* note 2.

73. *Id.*

74. *Id.*

Genetic technology has the potential to cure diseases, but with an elevated risk of serious consequences.[75] Governments are attempting to minimize these risks through possible regulation reforms.[76] Though some argue that the regulatory framework laid out by the United States has hampered the ability to compete with China, "it's worth the lost race."[77] The potential dangers associated with new technology further emphasizes the importance of proper federal regulation.[78]

IV. PATENT SYSTEM WON'T CUT IT

Modern genetic technologies should not be considered patentable subject matter. The patent system is built for individual inventors and creators; yet, genetic technologies are usually discovered and created by more than one inventor.[79] Now the system is overrun with corporate actors and nuanced university systems like Berkeley and the Broad Institute.[80] It is obvious that Congress did not intend for the patent system to apply to today's complex inventions by groups of individuals.[81] The system does not always match up with modern science, and as a society we should not allow the patent system to "dictate [future] science and innovation."[82]

The patent system currently functions as a first to file system and then the USPTO ensures that each invention meets all the elements for patent protection.[83] By granting a patent holder property rights to genetic technologies, the USPTO is giving the holder regulatory power.[84] The property right provides a patent holder with the power to grant licenses to others to lawfully use the patented invention.[85] In turn, by owning the rights in the patent, the holder has economic control over how the licensee can use the patented invention.[86] For example, a patent holder of a genetic

75. *See* Kevin Curran, *How on Earth Are We Currently Regulating Human Genetic Modification?*, RISING TIDE BIOLOGY (Nov. 23, 2017), http://www.risingtidebio.com/human-gene-therapy-regulations-laws/.

76. *See Id.*

77. Maldarelli, *supra* note 71.

78. *See* Brown, *supra* note 57; Parthasarathy, *supra* note 57.

79. Parthasarathy, *supra* note 57.

80. *Id.*

81. *See* Brown, *supra* note 57; Parthasarathy, *supra* note 57.

82. Rodolphe Barrangou, *Cas9 Targeting and the CRISPR Revolution*, 244 SCI., No. 6185, 707, 708 (May 16, 2014), http://science.sciencemag.org/content/344/6185/707.

83. *See* 35 U.S.C. §§ 101-105 (2012).

84. *See* Childers, *supra* note 41; Parthasarathy, *supra* note 57.

85. Parthasarathy, *supra* note 57.

86. *See* Brown, *supra* note 57; Childers, *supra* note 41; Parthasarathy, *supra* note 57.

technology can control the type of research a licensee can use with the technology.[87]

Patenting genetic technology like CRISPR has the potential to harm public health.[88] The current patent system has the potential to inflate access prices to genetic technology because the cost to license the invention passes on to its consumers.[89] Additionally, these patents could harm future research because they create additional roadblocks for researchers to use cutting edge technology.[90] Instead, the public should be able to use genetic technologies for its benefit; therefore, it should be an open source model instead of the current system.[91]

Granting this patent to either institution will be granting them the property rights necessary to control any research related to the editing of human embryos.[92] As the holder and rights owner of CRISPR, the Broad Institute will be able to regulate who, when, and what research is done by using CRISPR.[93] For example, scientists have voiced an interest in conducting CRISPR research on embryos; however, the patent holder has the ability to limit that research by not licensing it to those scientists or putting restrictions on that type of research.[94] As a society, it does not benefit the future of "progress . . . of . . . sciences" to grant only one person or one university the power to regulate technology as invasive and controversial as CRISPR.[95]

"Should technological breakthroughs of potentially life-changing biotech be hindered due to patent law?"[96] They should not. Regulation of genetic technologies needs to be in a way that "disentangles innovation and public interest from profits,"[97] but unfortunately the process for patenting genetic technologies is driven by profitability.[98] Thus, genetic technologies should not be patentable, but instead should be regulated by

87. *See* Parthasarathy, *supra* note 57.
88. *See* Brown, *supra* note 57; Parthasarathy, *supra* note 57.
89. *See* Brown, *supra* note 57.
90. *Id.*
91. *Id.*
92. *See* Parthasarathy, *supra* note 57; Yong, *supra* note 41.
93. *See* Parthasarathy, *supra* note 57.
94. *See id.*; Yong, *supra* note 41.
95. *See* Brown, *supra* note 57; Childers, *supra* note 41; Parthasarathy, *supra* note 57.
96. *See* Childers, *supra* note 41; *see* Dan L. Buck, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1 (1991).
97. *See* Parthasarathy, *supra* note 57.
98. *See* Barrangou, *supra* note 57.

one agency that is aware of, and concerned with any potential ethical, legal, and societal implications that may result from these inventions.[99]

V. "THE SCIENCE OF REGULATION IS MORE PRECARIOUS THAN THE SCIENCE OF GENE EDITING"[100]

The FDA is an agency within the United States Department of Health and Human Services.[101] The objective of the FDA is to "protect[] the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation."[102] Their regulatory power comes from the Public Health Service Act (PHSA) and the United States Federal Food, Drug and Cosmetic Act.[103] The FDA regulates clinical studies involving genetic technologies and functions as a "gatekeeper" for any drug products before they are commercialized on the market.[104] The FDA's approval process includes three phases to test the toxicity, safety, and effectiveness of a drug to determine whether the drug complies with the FDA's standards.[105] If the drug complies with the standards, the drug will be released into the market; if it does not, then the drug will not enter the market in order to protect consumers.[106]

Currently, the FDA regulates gene technologies when the technologies function as gene therapy.[107] Gene therapies are treated as a

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99. *See* Yong, *supra* note 41.

100. Zachary Brennan, *Human Gene Editing, CRISPR and the FDA: How Will They Mix?*, REG. AFF. PROF. SOC'Y (Dec. 2, 2015), http://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2015/12/human-gene-editing,-crispr-and-fda-how-will-they-mix.

101. Press Release, U.S. Food & Drug Admin., FDA Approves Novel Gene Therapy (Dec. 19, 2017), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589467.htm; *FDA Fundamentals, U.S. Food & Drug Administration*, FDA (Feb. 29, 2018), http://www.fda.gov/aboutfda/transparency/basics/ucm192695.htm.

102. Press Release, U.S. Food & Drug Admin., FDA Approves Novel Gene Therapy (Dec. 19, 2017), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589467.htm; *see also* Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1449 (2013).

103. Evita V. Grant, *FDA Regulation of Clinical Applications of CRISPR-CAS Gene-Editing Technology*, FOOD DRUG L.J. 608, 616 (2016); *see also* Dolin, *supra* note 102, at 1449.

104. Brennan, *supra* note 100; Curran, *supra* note 75; *see* Dolin, *supra* note 102; Grant, *supra* note 103.

105. Maldarelli, *supra* note 71.

106. *Id.*

107. *See* Public Health Service Act § 351, 42 U.S.C. § 262(i)(1) (2016).

biologic under section 351 of the PHSA and the Biologic Price Competition and Innovation Act.[108] A biologic is defined as:

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.[109]

Since gene therapy is not expressly mentioned in the definition of a biologic there has been confusion about whether the FDA has the authority to regulate gene therapies.[110] In *United States v. Regenerative Sciences, LLC*, a biotechnology company claimed the FDA did not have authority to regulate its stem cell treatment, a gene therapy, because it was not a biologic as defined in the PHSA.[111] Instead, Regenerative Sciences argued that it was a medical procedure and not regulated by the FDA.[112] The court analyzed the definition and found both "drug" and "biologic" to be broad terms with a wide-range of meaning based on the plain language of the statute.[113] The court ruled in favor of the FDA, instituting precedent for defining biologic and the term's ability to encapsulate gene therapies.[114]

Following the court's decision in *Regenerative Sciences*, the FDA now had authority to regulate gene therapy and approved its first one in 2017.[115] This approval by the FDA is viewed as monumental, with the FDA Commissioner stating, "[G]ene therapy will become a mainstay in treating, and maybe curing, many of our most devastating and intractable illnesses."[116]

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108. Public Health Service Act § 351, 42 U.S.C. § 262(i)(1); Michael R. McDonald & Irena Royzman, *FDA Approves the First Gene Therapy to Treat an Inherited Disease*, BIOLOGICS BLOG (Jan. 3, 2018), http://www.biologicsblog.com/fda-approves-the-first-gene-therapy-to-treat-an-inherited-disease.

109. Public Health Service Act § 351, 42 U.S.C. § 262(i)(1).

110. 42 U.S.C. § 262(i)(1).

111. United States v. Regenerative Scis., LLC, 741 F.3d 1314, 1318 (D.C. Cir. 2014); McDonald & Royzman, *supra* note 108.

112. *Regenerative Scis.*, 741 F.3d at 1318-19.

113. *Id.* at 1319.

114. *Id.* at 1324; McDonald & Royzman, *supra* note 108.

115. *Regenerative Scis.*, 741 F.3d at 1314-21; Grant, *supra* note 103; Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation, 66 Fed. Reg. 4688 (Jan. 18, 2001) (to be codified at 21 CFR pts. 20, 312, and 601).

116. Melissa Healy, *FDA Approves Gene Therapy to Fix Mutation That Can Lead to Blindness*, L.A. TIMES (Dec. 19, 2017), http://www.latimes.com/science/sciencenow/la-sci-sn-gene-therapy-blindness-20171219-story.html.

Since 2017, the FDA has instituted documents for the public on disease-specific gene therapies.[117] The documents explain the FDA's evaluation of these gene therapies as well as provide guidance for "long term follow up" and "pathways for clinical development."[118] "As gene therapy continues to change, so must the federal framework set up to oversee it,"[119] so the FDA is hopeful that approvals of gene therapy can initiate the change needed to "help[] [the] agency understand what exactly needs to be evaluated."[120]

VI. GIVE THE FDA THE REIGNS

Congress should grant the FDA complete regulatory oversight of genetic technologies and gene therapy. Currently, genetic technologies must be patented and then regulated by the FDA to safely and effectively reach consumers in the marketplace.[121] It is highly inefficient to go through both the patent system and the FDA regulatory scheme because the process elongates the amount of time patients must wait to receive these useful technologies.[122] Instead Congress should focus less on patenting these technologies, so the FDA can strengthen their regulation. With stronger regulation the FDA can better ensure potential life-changing technologies arrive on the market faster and safer.[123]

The FDA is the best regulatory agency to combat any ethical, legal, and health risks associated with new genetic technologies.[124] From a policy standpoint, the FDA should be regulating technology like CRISPR because the Agency was built to consider the similar issues for all products that enter consumers' homes.[125] Additionally, current FDA policies already allow the agency to address each technology on a case-by-case basis using laid out approaches by the FDA.[126]

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117. Press Release, *supra* note 102; S.R. Husain et al., *Gene Therapy for Cancer: Regulatory Considerations for Approval*, 22 CANCER GENE THERAPY 554, 554-63 (June 23, 2015).

118. Husain et al., *supra* note 117; *see* Healy, *supra* note 116.

119. Francis Collins & Scott Gottlieb, *The Next Phase of Human Gene-Therapy Oversight*, NEW ENG. J. MED. (Aug. 15, 2018), http://www.nejm.org/doi/full/10.1056/NEJMp1810628/.

120. Press Release, U.S. Food & Drug Admin., *FDA Approves Novel Gene Therapy to Treat Patient with Rare Form of Inherited Vision Loss* (Dec. 19, 2017), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm589467.htm.

121. Stramiello, *supra* note 42.

122. Jacob S. Sherkow, *Patent Protection for CRISPR: An ELSI Review*, 4 J.L. & BIOSCI. 3 (Dec. 2017), http://academic.oup.com/jlb/article/4/3/565/4706243.

123. Press Release, *supra* note 102; Dolin, *supra* note 102.

124. Brennan, *supra* note 100.

125. *See id.*

126. MARK A HELLER, GUIDE TO MEDICAL DEVICE REGULATION 3 (2015); Husain et al., *supra* note 117.

Further, the FDA already has a regulatory framework in place for monitoring the safety of medical products that can potentially be applied to new therapies.[127] This framework includes several layers of oversight for evaluating new technology, including committee review by the National Institute of Health Committee, the Recombinant DNA Advisory Committee (RAC), and the Center for Biologics Evaluation and Research.[128] Under the current system, RAC considers any "ethical, legal and social implications" of emerging technology but the committees' findings are nonbinding.[129] Instead these layers of oversight should be given more consideration by the FDA so that all of their findings can be binding.[130]

The FDA is better suited to regulate genetic technologies and gene therapies than the USPTO's patent system.[131] While the patent process is reviewing five elements for an invention, the FDA process is reviewing safety, toxicity, and effectiveness, which are more important in regard to developing genetic technology.[132] The current FDA regulatory scheme gives a twelve-year market exclusivity to biologics including gene therapies through the Biologics Price Competition and Innovation Act of 2009 (BPIC Act), which essentially gives the same exclusive financial incentive that patents provide.[133] Whereas, patents give patent holders exclusive property rights for twenty years.[134] Twelve years is a reasonable amount of time to provide financial incentive for inventions as well as promote innovation and competition.[135] Further, the twelve-year market exclusivity does not grant regulatory control to the patent holder like the patent system does.[136]

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127. Collins & Gottlieb, *supra* note 119; *see* Husain et al., *supra* note 117.

128. Marta Carvalho et al., *Regulatory and Scientific Advancements in Gene Therapy: State-of-the-Art of Clinical Application of the Supporting European Regulatory Framework*, NCBI (Oct. 26, 2017), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5662580/; Husain et al., *supra* note 117; Maldarelli, *supra* note 71, *see* Rana et al., *supra* note 2.

129. Husain et al., *supra* note 117.

130. Emily Mullin, *FDA Approves Groundbreaking Gene Therapy for Cancer*, MIT TECH. REV. (Aug. 30, 2017), http://www.technologyreview.com/s/608771/the-fda-has-approved-the-first-gene-therapy-for-cancer/; *see* Curran, *supra* note 75; Husain et al., *supra* note 117.

131. *See* Maldarelli, *supra* note 71.

132. *Id.*

133. *See id.*

134. 35 U.S.C. §§ 100-105 (2012).

135. *See* Maldarelli, *supra* note 71.

136. *See id.*

VII. CONCLUSION

The FDA currently has "700 active investigational new drug applications for gene therapies."[137] Gene therapies will only increase, so it is important for the United States to decide how to best regulate them.[138] Regulating these technologies through the FDA instead of the USPTO will allow the United States to more responsibly protect its citizens.

The decisions on how the United States will regulate these technologies could have grave consequences if not regulated properly. Making these technologies not patentable and giving the FDA the sole authority to regulate will make these technologies easier to access and safer for the future of society.

137. Collins & Gottlieb, *supra* note 119.
138. *Id.*