Morality: An Important Consideration at the Patent Office

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Recent developments in biotechnology have opened new avenues not only for research but also for patenting. However, recent United States Supreme Court decisions such as Association for Molecular Pathology v. Myriad Genetics demonstrate the interpretive difficulties these new technologies raise in patent law. Many scholars, for example, have argued that rather than using the "product of nature" doctrine and focusing on the line between human and natural constructs, the Court in Myriad *should have ruled based on the doctrine's policy goal: protecting the basic tools of scientific and technological work. Not doing so has led to doctrinal confusion, decreased patent protection, and increased uncertainty in industry.*

In addition, recent biotechnological developments also raise increased ethical concerns. These concerns should lead us to reconsider the relationship between patent law and ethics. After reviewing the history of intellectual property protection for biotechnology inventions, this Note considers the policy rationale of promoting "useful" inventions and proposes implementation of a new procedure for ethical review at the United States Patent and Trademark Office.

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INTRODUCTION

In June 2018, an international assembly of researchers published a study examining patents on marine genetic resources.[1] Their paper came to the astounding conclusion that one corporation, German chemicals giant Baden Aniline and Soda Factory (BASF), had registered almost half of all existing patents associated with genes from marine species.[2]

BASF's interest in marine life is not surprising. Many of these animals have unique characteristics that make them commercially valuable. A *New York Times* exposé on the animals behind these patents highlighted that many are "extremophiles," or organisms capable of surviving in harsh environments. One such animal, for instance, is the *Alvinella pompejana*, a type of deep sea worm that can thrive at extreme temperatures.[3] Robert Blasiak, lead researcher on the study, also noted the potentially lucrative area of designer health foods.[4] And, more importantly, by emphasizing the dramatic asymmetry in patent registration, the study raised the question of whether we should be able to patent these genetic sequences at all.[5]

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1. Robert Blasiak et al., *Corporate Control and Global Governance of Marine Genetic Resources*, 4 SCI. ADVANCES 1 (2018).

2. *Id.* at 2.

3. Heather Murphy, *What 13,000 Patents Involving the DNA of Sea Life Tell Us About the Future*, N.Y. TIMES (Sept. 17, 2018), https://www.nytimes.com/2018/09/17/science/patents-marine-dna.html [https://perma.cc/6JB9-8U99].

4. *See* Ryan P. Smith, *Nearly Half the Patents on Marine Genes Belong to Just One Company*, SMITHSONIAN.COM (June 13, 2018), https://www.smithsonianmag.com/science-nature/nearly-half-all-patents-marine-genes-belong-just-one-company-180969325 [https://perma.cc/P22V-ZTMQ] ("And it seems the company is using these marine patents in order to open up avenues of research—potentially lucrative ones. For example, Blasiak notes that BASF has been harnessing the genes of some tiny aquatic lifeforms in an effort to produce designer health foods: 'They've been splicing genes from different microorganisms into grapeseed and canola, then taking the seeds and seeing if they can produce oils that contain omega-3 fatty acids,' he says.").

5. While naturally-occurring genetic sequences are patent-eligible in the European Union, following *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), which is discussed below, they are not patent eligible in the United States. While this may appear to simplify eligibility concerns in the US, it has, in fact, sown judicial uncertainty. *See* Paul Cole, *Patentability of Genes: A European Union Perspective*, COLD SPRING HARBOR PERSP. MED. 2–5 (2015).

Blasiak's publication demonstrates a recent example of the tension between public and private for-profit ideals in patenting. It resurrects concerns flagged at the turn of the century around the completion of the Human Genome Project—concerns that have a pre-history in discussions around the commodification of the animal bodies more generally.[6] The international community has discussed three principal approaches for curtailing gene patents, in addition to a patent system's patent requirements:[7] (1) an equitable "common heritage of mankind principle" that calls for benefit sharing from the exploitation of genetic resources, (2) general exclusion of genetic sequences as patentable subject matter, and (3) "ethical review" within the patent office. The United Nations (UN) is currently considering the first approach. A few months after Blasiak's publication, delegates from members of the UN began treaty negotiations to discuss marine "biological diversity of areas beyond national jurisdiction."[8] By concentrating on international waters, which comprise 46 percent of the Earth's surface, this treaty will address a major gap in current treaty coverage.[9] It also seeks to ensure more equitable ocean stewardship with regard to biodiversity.[10] Several nations have insisted that, like mineral resources in these waters, marine genetic resources should fall under the "common heritage of mankind principle," and be subject to benefit sharing.[11]

The second approach was adopted by the US in 2013 with *Association for Molecular Pathology v. Myriad Genetics* (*Myriad*).[12] In *Myriad*, the Supreme Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible . . . ."[13] However, as discussed below, this 'common-law bar' has proven difficult to apply and counterproductive for biotechnology

6. *See* Timothy Caulfield et al., *Patenting Human Genetic Material: Refocusing the Debate*, NAT. REV. GENET. 227–31 (2000) (identifying both moral concerns such as gene patents infringing human dignity or leading to the commoditization of the human experience, and practical concerns such as patents deterring innovation).

7. For example, US patent requirements—namely regarding subject matter, utility, novelty, non-obviousness, and disclosure—see 35 U.S.C. §§ 101, 102, 103, 112 (2012).

8. G.A. Res. 72/429 (Jan. 19, 2018) (deciding to convene the first intergovernmental conference to write an international legally binding instrument on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction in September 2018).

9. The Nagoya Protocol already protects countries from exploitative bioprospecting. *See About the Nagoya Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/abs/about [https://perma.cc/6DJF-3K9S]; *see also*, Eli Kintisch, *U.N. Talks to Tackle Tough Question: Who Should Benefit from DNA Collected from the High Seas?*, SCIENCE (Sept. 3, 2018) ("Under another U.N. pact, the 2010 Nagoya Protocol, 105 countries have agreed to rules to prevent so-called biopiracy: the removal of biological resources—such as plant or animal DNA—from a nation's habitats without proper permission or compensation. Those rules don't apply in international waters, which begin 200 nautical miles from shore and are attracting growing interest from researchers and companies searching for valuable genes.").

10. *About the Nagoya Protocol*, *supra* note 9.

11. Kintisch, *supra* 9.

12. 569 U.S. 576 (2013).

13. *Id.* at 580.

("biotech") innovation[14]—so much so, that there is bipartisan interest in Congress to amend the patent statute and overrule *Myriad*.[15]

A third approach—and the topic of this Note—is for the patent office to consider the morality of inventions. Several patent systems, including the European system, already evaluate the morality of patent applications, and allow examiners or judges to reject patents on this basis. [16]

Whether considering the morality of inventions at the United States Patent and Trademark Office (USPTO) makes sense depends on how one conceptualizes the purpose of the patent system. As the US Constitution states, the US patent system was created to "promote the Progress of Science and useful Arts."[17] To further this goal, 35 U.S.C. § 154(a)(1) grants the patent owner the right to exclude others from "making, using, offering for sale . . . or importing" the patented invention, generally for up to twenty years.[18] But do patents really achieve this aim? And what, exactly, is covered by the umbrella of the constitutional language?

Patents fit into a larger intellectual property regime whose existence is often questioned. As one commentator writes, "Scholarly justification for the

14. *See* GLOB. INNOVATION POLICY CTR., CREATE: U.S. CHAMBER INTERNATIONAL IP INDEX 35 (6th ed. 2018), http://www.theglobalipcenter.com/wp-content/uploads/2018/02/GIPC_IP_Index_2018.pdf [https://perma.cc/F4F3-FEQT] ("[T]he patentability of basic biotech inventions was compromised by the Supreme Court decisions in the 2013 *Molecular Pathology v. Myriad Genetics* and 2012 *Prometheus Laboratories, Inc v. Mayo Collaborative Services* cases. . . . In 2017, interpretation of the recent Supreme Court decisions in *Myriad*, *Mayo*, and *Alice Corp vs. CLS Bank International* by lower courts and guidance from the USPTO remained inconsistent and difficult to apply."); *see also* Gregory D. Graff et al., *Not Quite a Myriad of Gene Patents*, NATURE BIOTECHNOLOGY 31, 404-10 (2013) (arguing that gene patents were declining before the decision); Michele Wales & Eddie Cartier, *The Impact of* Myriad *on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics*, COLD SPRING HARBOR PERSP. MED. (2015) (arguing that given the Human Genome Project's publishing the human genome and the 20-year patent term, "it was not necessary to make dramatic and sweeping changes in rights" to solve a problem that was close to being a "nonissue").

15. *See* Press Release, Sen. Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act [https://perma.cc/KG55-PVWH].

16. Unlike in the US, the patent laws of the European Union and many European countries contain specific provisions that exclude immoral inventions from patentability. *See* Enrico Bonadio, *Patents and Morality in Europe*, *in* DIVERSITY IN INTELLECTUAL PROPERTY 149 (Irene Calboli & Srividhya Ragavan, eds., 2015). Further, Article 27.2 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement permits member states to exclude inventions from patentability in the name of "morality." Agreement on Trade-Related Aspects of Intellectual Property Rights, pt. II, art. 27, Jan 1, 1995 [hereinafter TRIPS Agreement] *in* Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, 1867 U.N.T.S. 154. As will be discussed, European patent law allows for the patenting of genetic sequences with important caveats. *See* Jessica C. Lai, *Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision*, 5 UC IRVINE L. REV. 1041, 1044–57 (2015) (explaining the restrictions on the patentability of genetic sequences laid out in the Biotech Directive and the European Patent Convention).

17. U.S. CONST. art. 1 § 8, cl. 8.

18. 35 U.S.C. § 154 (a)(1) (2012).

propertization of ideas has tended to resemble martyrdom—an act of faith."[19] Notwithstanding these critiques, patents and intellectual property in general, have taken increased economic and social importance since their Venetian origin in the 15th century.[20] Patents also demonstrate corporate cache. BASF, for example, highlights in its annual reports that it has consistently occupied the top position on the Patent Asset Index since the index was launched in 2009.[21] The emphasis on patents as a measure of success may help explain why the flow of patents issued more than doubled from 2008 to 2017.[22]

Most theoretical writing justifying intellectual property falls into one of four approaches: the utilitarian approach, the Lockean approach, personality theory, and social planning theory. The utilitarian approach is the dominant approach in the US.[23] It focuses property rights on the maximization of net social welfare, balancing exclusive rights that incentivize invention against public enjoyment and use of those inventions.[24]

Some utilitarian scholars argue that patents indeed "promote the progress of science and useful arts" by providing the foundation of the "market for inventions."[25] The patent system does this by converting inventions into transferable intangible assets, promoting disclosure of inventions, and providing standardization in intellectual property.[26] This, in turn, increases transaction efficiencies and competition, reduces costs of searching and bargaining in the market for inventions, and reduces the costs of contracting in the market for inventions.[27]

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19. Ikechi MgBeoji, *Book Review: Justifying Intellectual Property, by Robert P. Merges*, 50 OSGOODE HALL L. J. 291, 292 (2012) (book review).

20. *See generally*, Giulio Mandich, *Venetian Patents (1450–1550)*, 30 J. PAT. OFF. SOC'Y 166 (1948) (examining protections accorded to inventors under Venetian law). Patents have been increasingly relevant, from helping launch life science and software companies in the late 20th century to being at the center of the current US-China trade war. *See e.g.*, NAT'L BUREAU OF ASIAN RESEARCH, UPDATE TO THE IP COMMISSION REPORT: THE THEFT OF AMERICAN INTELLECTUAL PROPERTY (2017); Charlene L. Fu & Curtis S. Chin, *China is Stealing American Intellectual Property. Trump's Tariffs are a Chance to Stop It*, L.A. TIMES (Sept. 17, 2018), https://www.latimes.com/opinion/op-ed/la-oe-fu-chin-the-upside-of-trumps-china-trade-war-20180917-story.html [perma.cc/933Y-L4TR].

21. Blasiak, *supra* note 1, at 3.

22. U.S. PAT. & TRADEMARK OFF., U.S. PATENT STATISTICS CHART CALENDAR YEARS 1963–2015 (2016), https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm [perma.cc/25DX-8K3N] (demonstrating that the number of patents issued doubled from 157,772 in 2008 to 320,003 in 2017); *2017 Patent Trends and Insights,* IFI CLAIMS PAT. SERVS., https://www.ificlaims.com/rankings-trends-2017.htm [perma.cc/EUE4-DF5X].

23. William Fisher, *Theories of Intellectual Property*, *in* NEW ESSAYS IN THE LEGAL AND POLITIC THEORY OF PROPERTY 168, 173–74 (Stephen Munzer ed., 2001).

24. *See id.* at 176–83.

25. Daniel F. Spulber, *How Patents Provide the Foundation of the Market for Inventions*, 11 J. COMPETITION L. & ECON. 271, 272 (2015).

26. *Id.*

27. *Id.*

Others argue, however, that the US patent system does not promote innovation and productivity.[28] To begin, "law lag"—the belief that the law is always falling behind other industries, particularly science and technology—is significant in popular discourse.[29] In addition, there is no evidence that the recent surge in patent issuance has brought about a corresponding surge in useful innovation and productivity.[30] Others note that when trying to correct for patent over-granting and aggressive nonpracticing entities, the Leahy-Smith America Invents Act (AIA)[31]—the first comprehensive patent bill to be enacted since the Patent Act of 1952 (Patent Act)[32]—made matters worse.[33] For example, the AIA created new post-grant proceedings, such as inter-partes review, which have increased the difficulty of asserting patent rights by lowering the requirements for invalidating patents.[34]

Regardless of which side of the debate ultimately proves correct, the utilitarian aim of the patent system remains to encourage progress in the field in which a patent is granted. With the promise of patent protection, BASF, for example, invests billions of dollars into uncertain commercialization endeavors yearly. [35] But the U.S.'s patent system encourages progress imperfectly. [36] And,

28. *See, e.g.*, Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSP. 3, 18 (2013) (arguing that there is no empirical evidence that patents serve to increase innovation and productivity); Jeffrey Funk, *Beyond Patents*, 34 ISSUES SCI. & TECH. 48 (2018) (arguing that patent analysis is a smoke screen that prevents us from measuring innovation).

29. *See, e.g.*, Berger v. New York, 388 U.S. 41, 49 (1967) ("The law, though jealous of individual privacy, has not kept pace with these advances in scientific knowledge."); Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."); J. BENJAMIN HURLBUT, EXPERIMENTS IN DEMOCRACY: HUMAN EMBRYO RESEARCH AND THE POLITICS OF BIOETHICS 141–46 (2017) ("The law lag narrative is common in American discourse about science and technology.").

30. Boldrin & Levine, *supra* note 2828, at 4.

31. Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended at 35 U.S.C. §§ 1–375 (2012)).

32. *See* 157 CONG. REC. S1361, S1380 (daily ed. Mar. 8, 2011) (statement of Sen. Leahy).

33. *See* Russell Slifer, *Five Years After the AIA Created the PTAB*, IPWATCHDOG, http://www.ipwatchdog.com/2017/09/16/five-years-after-the-aia-created-the-ptab/id=87994 [https://perma.cc/RW55-6QZD] (arguing that post-grant proceedings have substituted defendant abuse in district court litigation with patent owner abuse in the Patent Trial and Appeal Board)*; see also* Restoring America's Leadership in Innovation Act of 2018, H.R. 6264, 115th Cong. (2018) (proposing to abolish the PTAB and eliminate both IPRs and PGRs because they "have harmed the progress of science and the useful arts by subjecting inventors to serial challenges to patents").

34. Slifer, *supra* note 33.

35. Blasiak, *supra* note 1, at 3 ("Its annual corporate and financial reports underscore a strategic focus on patents and innovation, which suggests continuity and long-term planning, with 2006 research and development investments already being tied to expectations of two- to fourfold returns in annual sales starting in 2015. Since 2004, BASF has continuously expanded its investments in research and development, reaching a new record of € 1.9 billion in 2017.").

36. In the United States Chamber of Commerce's International IP Index for 2018, the US patent system, which was the top-rated country as recently as 2016 for patent protection, ranked behind eleven other national systems. GLOBAL INNOVATION POLICY CTR., *supra* note 14, at 35. The Index attributed the ratings decline to the ease of challenging patents through post-grant proceedings at the Patent Trial and Appeal Board (PTAB), Supreme Court decisions on patent eligibility, and interpretations of those cases and guidance from the United States Patent and Trademark Office (USPTO). *Id.* at 157. The

as highlighted by the United States Chamber of Commerce's International IP Index for 2018, perhaps nowhere more so than with "basic biotech inventions."[37]

Our patent system was "[d]esigned more than 100 years ago to meet the simpler needs of an industrial era, [and uses] an undifferentiated, one-size-fits-all approach."[38] However, the patent system has developed to be applied differently in different industries.[39] One such variance in patent standards is attributable to the "moral utility doctrine."

The judicially created "moral utility doctrine" served as a gatekeeper of patent subject matter eligibility, allowing the USPTO and the courts to deny patents on morally controversial subject matter under the premise that such inventions were not "useful."[40] This doctrine "rose and fell in the United States within the span of two centuries,"[41] leading one Justice to pronounce that "anything under the Sun that is made by man" is patentable[42] and a judge to subsequently pronounce that the doctrine is dead.[43]

However, the tension that gave rise to the moral utility doctrine—that a system that rewards individuals can harm communities—is not dead. It was apparent in the first recorded reference to patents in Aristotle's *Politics*[44] and continues into the AIA. The AIA expressly excludes patents on specific subject matter categories, namely tax strategies and human organisms.[45] In addition, on

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USPTO released revised guidance for subject matter eligibility in January 2019, which has been favorably received by commentators. *See* Gene Quinn, *Revised Patent Eligibility Guidance Effectively Defines What is an Abstract Idea*, IPWATCHDOG, (Jan. 4, 2019), https://www.ipwatchdog.com/2019/01/04/patent-eligibility-guidance-abstract-idea/id=104754 [perma.cc/BV8G-Q5L8]; Press Release, U.S. Pat. & Trademark Off., U.S. Patent and Trademark Office Announces Revised Guidance for Determining Subject Matter Eligibility (Jan. 4, 2019), https://www.uspto.gov/about-us/news-updates/us-patent-and-trademark-office-announces-revised-guidance-determining-subject [perma.cc/8SZJ-LSPD].

37. GLOBAL INNOVATION POLICY CTR., *supra* note 14, at 8.

38. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002).

39. Sivaramjani Thambisetty, *The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies Like Synthetic Biology* 4 (London Sch. Econ. Law, Working Paper No. 18, 2018) ("Dominant critiques based on normative or foundational views of how patent protection does or does not serve public interest are unable to conclusively justify or determine patentability standards going forward."). Another such variance in patent standards is attributable to the use of a legal construct known as the "person having ordinary skill in the art," to determine obviousness and enablement. Burk & Lemley, *supra* note 38, at 1156.

40. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 476 (2003).

41. *See, e.g.*, Laura A. Keay, *Morality's Move Within U.S. Patent Law: From Moral Utility to Subject Matter*, 40 AIPLA Q. J. 409, 410 (2012).

42. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

43. Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366–67 (Fed. Cir. 1999), *aff'd*, 292 F.3d 728 (Fed. Cir. 2002).

44. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 3–4 (7th ed. 2017) (describing Aristotle's concerns with Hippodamus's proposal for a system that rewards those who discover things useful to the state).

45. *See* Leahy-Smith America Invents Act, Pub. L. 112-29 §§ 14, 33, 125 Stat. 284 (2011) (codified as amended at 35 U.S.C. §§ 101–02 (2012)). Congress has also withdrawn patent protection

its website under "What cannot be patented," the USPTO includes inventions that are "[offensive] to public morality."[46] Some have argued that these developments, along with recent USPTO and court decisions, show that considerations of morality are again rising in US patent law through the restriction of patent eligible subject matter.[47] But Section 101 of the Patent Act does not expressly include such restrictions, stating only that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor . . . ."[48]

This Note explores the debate around when exclusion from patentability is the best social mechanism for addressing "morally offensive" technologies, including defining "morally offensive" technology to begin with. It will argue that, as with European and international patent law, the legislature should restrict subject matter eligibility by explicitly promulgating a process for challenging patents on moral grounds. This would avoid repeating the lower courts' misuse of the moral utility doctrine by which judges base their decisions on subjective moral harms. After all, what constitutes an invention in the US is not clearly delineated, in large part due to the sparseness of legislative guidance on the matter.[49] Thus, legislative clarification regarding the role of morals in the patent process would help rectify this uncertain jurisprudence, particularly when applied to the controversial field of biotechnology. Legislative clarification would also help spark a global conversation around patents and biodiversity. As Blasiak and his co-authors warn regarding marine biodiversity, "[t]he scale of patenting to date suggests the need for a greater sense of urgency to ensure a successful conclusion to the negotiation of a new legal regime."[50] The dramatic asymmetries in patent registration that Blasiak and his co-authors have revealed are much more alarming than similar trends in resource use and industry dominance given their focus on genetic material.

This Note begins with a history of the moral utility doctrine. It then explores the rise of the biotechnology industry, its union with intellectual property, and the role of academia in that union. It continues with an analysis of how courts have approached biotechnology patenting in the US and Europe. It ends by

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from inventions relating to atomic weapons. *See* 42 U.S.C. § 2181(a) (2012) ("No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.").

46. *Patent FAQs*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/help/patent-help#1902 [perma.cc/HT2D-RYYK].

47. *See* Keay, *supra* note 41, at 411.

48. Utility is only one of many requirements for obtaining a patent, and thus only one of many avenues for challenging a patent. There are other substantive requirements—subject matter eligibility, novelty, and non-obviousness—and procedural requirements.

49. Jessica C. Lai, *Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision*, 5 UC IRVINE L. REV. 1041, 1074 (2015).

50. Blasiak, *supra* note 1, at 5.

considering why the morality of inventions should be addressed by the USPTO and with several proposals for implementing ethical review at the USPTO.

I.
HISTORY OF THE MORAL UTILITY DOCTRINE

"There is a common presumption that, until its encounter with biotechnology, patent law was hermetically sealed from external considerations."[51] However, by addressing the early history of patent law and the rise and fall of the moral utility doctrine, this section demonstrates another truth.

The first English patent law, the 1623 Statute of Monopolies, arguably includes moral standards. It expressed prohibitions on patents that were "contrary to law," "mischievous to the state," and "generally inconvenient." Scholars have interpreted the last of these policy phrases in particular to have served as a "broad public benefit test."[52] Later, in the 19th to mid-20th centuries, courts read the US Constitution as taking this moral consideration a step further with the Patent Clause, which authorized Congress to "promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[53] The Supreme Court affirmed that "the clause is both a grant of power and a limitation."[54] The clause limited Congress's patent power "to the promotion of advances in the 'useful arts[]'" to protect against the creation of "patent monopol[ies] without regard to the innovation, advancement or social benefit gained thereby."[55]

Justice Joseph Story is generally credited with introducing the moral utility doctrine in *Lowell v. Lewis*. He asserted: "all that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society."[56] Therefore, the word "useful" is "incorporated into the act in contradistinction to mischievous or immoral."[57] Justice Story further explained his interpretation of the utility requirement in *Bedford v. Hunt* by defining a "useful invention" as "one as may be applied to some beneficial use in society, in contradistinction to an invention, which is injurious to morals, the health, or the good order of society." He continued: "The law, however, does not look to the degree of utility; it simply requires, that it shall be capable of use, and that the use is such as sound morals and policy do not discountenance or

51. Sivaramjani Thambisetty, *Understanding Morality as a Ground for Exclusion from Patentability under European Law*, 12 EUBIOS J. ASIAN & INT'L BIOETHICS 48, 48 (2002).

52. *See* Chris Dent, *"Generally Inconvenient": The 1624* Statute of Monopolies *as Political Compromise*, 33 MELB. U. L. REV. 415, 444-45 (2009); Peter Drahos, *Biotechnology Patents, Markets and Morality*, 21 EUR. INTELL. PROP. REV. 441, 441 (1999).

53. U.S. CONST. art. I, § 8, cl. 8.

54. Graham v. John Deere Co., 383 U.S. 1, 5-6 (1966).

55. *Id.* at 5-6.

56. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.)*; see* PETER MENELL ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2018: VOLUME 1: PERSPECTIVES, TRADE SECRETS AND PATENTS 243-44 (2018).

57. *Lowell*, 15 F. Cas. at 1019.

prohibit."[58] Therefore, while the economy would dictate how much "use" an invention would get, the law's role was to screen out inventions that could be used immorally.

Justice Story's formulation was later used by lower courts to invalidate two main types of patents:[59] gambling devices "injurious to the morals of society" and inventions with a "mischievous tendency" to deceive the public.[60] The first instance of invalidating a patent for gambling devices under the moral utility doctrine likely occurred in 1889 in *National Automatic Device Corp. v. Lloyd*.[61] There, the district court reasoned that because the invention was for a "Toy Automatic Race-Course" used exclusively in gambling establishments, it was "not a useful device, within the meaning of the patent law."[62] Soon after, courts followed suit by applying the moral utility doctrine to patents for a card playing slot machine,[63] a coin return device for slot machines,[64] and a lottery vending machine.[65,66]

In the second line of cases, courts applied the moral utility doctrine to deceptive devices. For example, in 1901 the Eight Circuit invalidated a patent for a medical device called the "Oxydonor" because the patent claim was "at best an imaginary hypothesis" put forth merely to obtain a patent.[67] According to the patentee, diseases were caused by electrical equilibrium disturbances in the body and thus, his electric device could cure all diseases. [68] The court found this claim to be "mere pretense" and an attempt to gain a patent on a simple electric device lacking novelty.[69]

Eventually, the Federal Circuit dealt a fatal blow to the moral utility doctrine in *Juicy Whip, Inc. v. Orange Bang, Inc.*[70] The invention at issue was a post-mix beverage dispenser that was designed to look like a pre-mix dispenser.[71] By displaying a transparent bowl that contained the dispensed

58. Bedford v. Hunt, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) (No. 1,216) (Story, J.).

59. Other types of patents excluded based on morality included artificially spotted tobacco leaves, *Rickard v. Du Bon*, 103 F. 868 (2d Cir. 1900), and faux-seamed women's hosiery, Scott & Williams, Inc. v. Aristo Hosiery Co., 7 F.2d 1003 (2d Cir. 1925).

60. Keay, *supra* note 41, at 412 (internal citations omitted).

61. Nat'l Automatic Device Co. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889).

62. *Id.*

63. Reliance Novelty Co. v. Dworzek, 80 F. 902, 904 (C.C.N.D. Cal. 1897).

64. Schultze v. Holtz, 82 F. 448, 449 (C.C.N.D. Cal. 1897).

65. Brewer v. Lichtenstein, 278 F. 512, 514 (7th Cir. 1922).

66. This is not to say that all inventions used at gambling establishments were held unpatentable. For example, in *Chicago Patent Corp. v. Genco*, the defendant argued that a pinball machine was inherently a "gambling machine without utility and, therefore, beyond protection by the patent laws." 124 F.2d 725, 727 (7th Cir. 1941). But by measuring the ratio of skill to luck, the Seventh Circuit upheld a patent for the pinball machine because the skill in "operating the device [was] not wholly absent." *Id.* at 728.

67. Mahler v. Animarium Co., 111 F. 530, 536-37 (8th Cir. 1901).

68. *Id.* at 534.

69. *Id.* at 535–36.

70. 185 F.3d 1364 (Fed. Cir. 1999).

71. *Id.* at 1365.

beverage (fresh juice), it created the visual impression of being the principal source of the dispensed beverage, whereas the beverage was actually mixed immediately before it was dispensed.[72] The district court found that the invention lacked utility because its purpose was to increase sales by deception.[73] The Federal Circuit, however, reversed.[74] It was not the responsibility of "the Patent and Trademark Office or the courts," the court declared, "to serve as arbiters of deceptive trade practices."[75] Consumer protection in food sales falls into the hands of the Federal Trade Commission and the Food and Drug Administration.[76]

Juicy Whip is emblematic of the transition in US patent jurisprudence to a purely utilitarian approach. A more recent example is the Federal Circuit's decision in *In re Fisher*.[77] There, petitioner adopted Justice Story's formulation of utility, requiring that the claimed invention "not be frivolous, or injurious to the well-being, good policy, or good morals of society," to argue that its claimed invention, five "expressed sequence tags"[78] that encode proteins in maize plants, passed the utility requirement.[79] In rejecting petitioner's claim, the Federal Circuit both narrowed and enlarged the utility inquiry. The court cited *Brenner v. Manson*[80] as rejecting Justice Story's formulation of utility and confirming *Juicy Whips*'s rejection of moral objection standing. At the same time, the court confirmed *Brenner*'s more rigorous utility test, which requires that a patent application disclose "substantial" and "practical" utility for the invention.[81]

Some commentators have blamed the moral utility doctrine's demise on judicial misinterpretation of Justice Story's articulation requirement.[82] Instead of protecting the public from subjective moral harms, Justice Story's real message was that the marketplace is the ultimate arbiter of an invention's utility.[83] However, *Brenner* and *Fisher* expressed concern that conferring patent rights in "upstream" basic research discoveries could create "a monopoly of knowledge"

72. *Id.* at 1365–66.
73. *Id.* at 1366.
74. *Id.* at 1367.
75. *Id.* at 1368.
76. *Id.*
77. 421 F.3d 1365 (Fed. Cir. 2005).
78. Expressed sequence tags are short subsequences of complementary DNA (cDNA), or synthetically created DNA often used for expressing a protein in a cell that doesn't normally express that protein.
79. *In re Fisher*, 421 F.3d at 1369.
80. 383 U.S. 519, 532–33 (1966) (upholding the patent office's determination that an allegedly novel chemical process failed to meet the utility requirement).
81. *In re Fisher*, 421 F.3d at 1371.
82. *See, e.g.*, Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CALIF. L. REV. 421, 436, 448 (1999).
83. "If [the invention] be not extensively useful, it will silently sink into contempt and disregard." Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.N.D. Mass. 1817) (No. 8,568).

and "confer power to block off whole areas of scientific development, without compensating benefit to the public."[84]

Today, the USPTO's Manual of Patent Examining Procedure does not mention morality or ethics anywhere in its section on utility. Instead, the manual cites *Juicy Whip* and expressly states, "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."[85] But, as noted above, the USPTO's website also states that inventions that are "offensive to public morality" may not be patented, leaving open the door for the rejection of patents on moral grounds.[86]

II.
THE RISE OF THE BIOTECHNOLOGY INDUSTRY

To understand why US courts became interested in the patentability of biotechnology during the 1970s and 1980s, it is important to understand the role intellectual property played in biotechnology's commercial exploitation. This section considers the origins of biotechnology, segues into addressing the union of biotechnology with intellectual property and the role academia played in that merger, and closes by presenting the Human Genome Project as an example that demonstrates the importance of this union.

A. Origins of Biotechnology

The early 20th century saw the union of Darwin's theory of evolution with Mendelian genetics, and, soon after, the biological sciences' union and reliance upon computer science.[87] Each of these moments produced a new language with which to understand and describe ourselves and our tools—an evolving vocabulary that recently saw the displacement of "genome engineering" in favor of "gene editing" with the introduction of CRISPR-Cas 9 (CRISPR), the latest tool for genetic manipulation.[88]

While biotechnology generally brings to mind genetic engineering or editing, it can be conceived of broadly as any use of biological organisms or

84. *Brennar*, 383 U.S. at 534.

85. U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE, 706 REJECTION OF CLAIMS [R-07.2015], https://www.uspto.gov/web/offices/pac/mpep/s706.html [perma.cc/QGW8-HUVY] (emphasis in original) (citing Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367–68 (Fed. Cir. 1999)).

86. *Patent FAQs*, *supra* note 46; *see* Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685 (2004) (arguing that the USPTO's history for denying patents appears to be devoid of ethical considerations).

87. John C. Avise, *The Best and the Worst of Times for Evolutionary Biology*, 53 BIOSCIENCE 247, 247–49 (2003).

88. Jennifer Doudna & Siddhartha Mukherjee, In Conversation on The Future of Humans: Gene Editing and the Unthinkable Power to Control, at the Innovative Genomics Institute, University of California, Berkeley (Jan. 18, 2018) (video available at https://www.youtube.com/watch?v=4fjwj92UNn4 [perma.cc/BC7S-LDZM]).

processes in industrial, medical, agricultural, and environmental engineering.[89] The fields of genetics and evolutionary biology grew from the observations and applications of animal and plant breeding.[90] As Charles Darwin wrote, "all my notion [sic] about how species change are derived from long continued study of the works of (& converse with) agriculturists & horticulturists."[91] The transfer of genetic information, however, forms the core of biotechnology, and many scientists at the turn of the 20th century contributed to its elucidation.[92]

Molecular geneticists, however, credit a "little book" as having launched their discipline.[93] In 1943, the Nobel Prize-winning quantum theorist Erwin Schrödinger gave a series of lectures at Trinity College, Dublin, which were later published with the provocative title *What Is Life?*[94] In the "little book," Schrödinger proposed a way of bringing quantum mechanics to bear upon biology.[95] The main implication of *What Is Life* lay in Schrödinger's conviction that the complex phenomenon we know as life "could and would yield to material analysis at molecular levels."[96] His idea inspired a generation of young molecular biologists, most notably James Watson and Francis Crick, who cracked the "code-script,"[97] as Schrödinger called it, and revealed DNA's double helix structure.[98]

As demonstrated by Schrödinger, a quantum physicist, biotechnology is an interdisciplinary affair. His book presented the problem of life as a puzzle posed to no single discipline.[99] As biotechnology evolved from its roots in observation and discovery at the agricultural stage to direct application at the lab bench, the

89. *Biotechnology*, NATURE, https://www.nature.com/subjects/biotechnology [perma.cc/GWR7-GZV8].

90. *Id.* at 321–23 (discussing Gregor Mendel's experiments with pea plants, the basis of his "Laws of Inheritance," and Charles Darwin's Theory of Evolution in relation to biotechnology).

91. Letter from Charles Darwin to Asa Gray (July 20, 1857), http://www.darwinproject.ac.uk/letter/?docId=letters/DCP-LETT-2125.xml;query=all%20my%20notion%20about%20how%20species%20change%20are%20derived%20from%20long%20continued;brand=default [perma.cc/U62J-RYXA].

92. Ashish Swarup Verma et al., *Biotechnology in the Realm of History*, 3 J. PHARM. & BIOALLIED SCI. 321, 321–23 (2011) (Wilhelm Johannsen, for example, coined the term "gene" and T.H. Morgan demonstrated the role of chromosomes in inheritance).

93. JESSICA RISKIN, THE RESTLESS CLOCK 369 (2016).

94. ERWIN SHRÖDINGER, WHAT IS LIFE? THE PHYSICAL ASPECT OF THE LIVING CELL (1944).

95. *Id.*

96. SHEILA JASANOFF, CAN SCIENCE MAKE SENSE OF LIFE? 2 (2019) ("But the moral implications of Schrödinger's essay lay elsewhere, in his conviction that the complex and abundant phenomenon we know as life could and would yield to material analysis at molecular levels.").

97. Watson and Crick relied on x-ray crystallography work by English researchers Rosalind Franklin and Maurice Wilkins. *See* Leslie Pray, *Discovery of DNA Structure and Function: Watson and Crick*, 1 NATURE EDUC. 100 (2008).

98. *What is Life? The Lectures of Physicist Erwin Schrodinger Helped to Change Attitudes in Biology*, 561 NATURE (Sept. 3, 2018), https://www.nature.com/articles/d41586-018-06166-x [perma.cc/2PN2-DKVL].

99. *Id.*

tools from other disciplines like computer science promoted its commercial applicability—but none more so than intellectual property.[100]

B. Union of Intellectual Property with Biotechnology

The 1960s and '70s ushered biotechnology into the modern age.[101] Researchers during this period were trying to make cells replicate and express foreign DNA, as if it were its own DNA.[102] A team headed by Stanley Cohen at Stanford University and Herbert Boyer at the University of California, San Francisco (UCSF), achieved this goal when they transferred frog DNA for resistance to kanamycin into *E. coli* bacteria, and the resulting bacteria replicated and expressed the DNA as if it were its own.[103] Stanford was awarded patents covering the process used in the research in 1980 and the transformed, biological material in 1984.[104]

The income from these patents surpassed $200 million for both Stanford and UCSF, and this initial success rapidly intensified research and commercial development of the new recombinant DNA technology.[105] Private investments into research and development began to rival public funding as private investors anticipated high returns based on intellectual property rights.[106] Perhaps most well-known from these ventures are Genentech—founded in 1976 by venture capitalist Robert Swanson and Herbert Boyer, mentioned above—and Amgen—founded in 1980 by George Rathman, a physical chemist.[107] These companies set off a boom in venture capital investment of biotechnology companies.[108]

Boyer and Rathman symbolize the creation of a new figure, what historian Steven Shapin calls the "entrepreneurial scientist."[109] Not only was biotechnology seen as particularly lucrative, but the US government actively encouraged commercialization of science, going so far as to dub the process a

100. *See* Jacob Sherkow & Henry Greely, *The History of Patenting Genetic Material*, 49 ANN. REV. GENETICS 161, 162 (2015) ("The history of applied molecular biology, therefore, is the history of law applied to biology. One of the most important of these areas of law has been patent law.").

101. *See* Baruch Brody, *Intellectual Property and Biotechnology: The U.S. Internal Experience—Part I*, 16 KENNEDY INST. ETHICS J. 1, 3 (2006).

102. *Id*. at 3.

103. *Id.*

104. Because Stanford was seeking a patent before the Supreme Court's 1980 decision in *Diamond v. Chakrabarty*, Stanford felt it was necessary to seek a process patent. 447 U.S. 303, 309 (1980). In *Chakrabarty*, while considering a recombinant bacterium that could break down crude oil, the Court found that "anything under the sun that is made by man" is eligible for patent protection—living or otherwise. *Id.*

105. Brody, *supra* note 101, at 6. By the end of 2000, American universities received more than $1 billion in annual revenue for licenses and patents, mostly in the area of biotechnology. *Id.*

106. *Id.*

107. *Id.* 7–8.

108. *Id.* 7–9.

109. STEVEN SHAPIN, THE SCIENTIFIC LIFE: A MORAL HISTORY OF LATE MODERN VOCATION 209 (2008).

public service.[110] In the mid- to late 20th century, US leaders believed the country was "surrendering technology leadership to Japan and the east Asian 'tiger' economies."[111]

As part of the US government's efforts to spur the research of American firms, Congress passed the 1980 Tax Reform Act, giving tax credits to corporations funding academic research and development.[112] Technology transfer offices—offices responsible for the commercialization of research—became institutional features of US research universities and, with the passing of the Bayh-Dole Act, university-industry partnerships proliferated.[113] Before Bayh-Dole, the federal government owned, at least in part, inventions created with any federal funding.[114] This arrangement discouraged universities from commercializing their faculty's inventions and dissuaded research in the applied sciences.[115] By allowing institutions themselves to be assignees to and effectively own their faculties' inventions, the Bayh-Dole Act encouraged universities to engage in patentable research.[116] Perhaps most emblematic of this change in attitude is Dean of the University of California, San Diego's Engineering School declaring in the early 2000s that the modern university's "key mission [was] to ensure the effective transfer of research results and discoveries to the sectors of our society, usually the private sector, that can translate such discoveries into products and services for the benefit of society as a whole."[117]

C. Academia and Intellectual Property

Patents have not functioned uniformly across science and engineering disciplines. In fact, a boundary has existed between academic science and the commercial sphere.[118] But with biotechnology, and in particular genomics, attempting to draw a line between science and technology is "empirically elusive."[119] Today, academic laboratories increasingly choose to inscribe their knowledge not only in publications but also in patents. These so-called patent-

110. *Id.*
111. *Id.* at 213.
112. *Id.* at 214–215.
113. *Id.*
114. WENDY H. SCHACHT, CONG. RESEARCH SERV., THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 1 (2012).
115. *Id.*
116. *Id.*
117. SHAPIN, *supra* note 109, at 214.
118. *See, e.g.*, Robert K. Merton, *A Note on Science and Democracy*, 1 J. LEGAL & POL. SOC. 115, 122 (1942) (explaining that science is a communal good and its results should reside in "the public domain").
119. Stephen Hilgartner, *Selective Flows of Knowledge in Technoscientific Interaction: Information Control in Genome Research*, 45 BRIT. J. HIST. SCI. 267, 268 (2012).

paper pairs are "ideas that are captured in two entirely distinctive documents that are traditionally associated with quite separate economic spheres."[120]

The case of the oncomouse is an early example. Mouse geneticists studying cancer were among the first to recognize the potential of molecular biology.[121] In 1982, Timothy Stewart, a post-doctoral researcher in transgenics, and Philip Leder, a leading geneticist at Harvard, created a viable "oncomouse," by injecting cancer-causing cells, or "oncogenes," into mouse eggs. These "transgenic" offspring allowed new insights about the gene's function in the whole organism rather than the cell.[122] Along with publishing their research in *Cell* in 1984, Stewart and Leder applied for patents, the first of which was granted four years later, broadly claiming "a transgenic non-human animal whose germ cells and somatic cells contain an activated oncogene."[123]

The pair then licensed their research to DuPont, a chemicals giant that had made significant investment in the research.[124] While traditionally, industrial owners and licensors transformed patent property rights into financial revenues through contractual relationships with other for-profit firms, DuPont sought the same financial rewards from academic scientists as well.[125]

At that time, academics widely assumed that they were not subject to the rules of the commercial economy.[126] Their assumption was based on the common law "experimental use exception," which protects those who use a patented invention merely "out of curiosity" or for "amusement."[127] DuPont, however, tried to monopolize the use of the oncomouse by destroying the independent academic economy and replacing it with a financial one.[128]

Some scientists responded by operating in the shadows of the commercial credit cycle, while others ignored the law and boycotted the company by breeding their own oncomice.[129] Still others attempted to circumvent the patent by inventing around it.[130] Ultimately, the National Institutes of Health (NIH) advocated on behalf of academics, negotiating with DuPont to prevent the company's patenting practices from disrupting the norms of academic science.[131] The NIH and DuPont entered into a memorandum of understanding that would

120. Fiona Murray, *Patenting Life: How the Oncomouse Patent Changed the Lives of Mice and Men*, *in* MAKING AND UNMAKING INTELLECTUAL PROPERTY: CREATIVE PRODUCE IN LEGAL AND CULTURAL PERSPECTIVE 399, 400 (Mario Biagioli, et al. eds., 2011).
121. *Id.*
122. *Id.*
123. *Id.* at 401 n.4.
124. *Id.* at 403.
125. *Id.*
126. *Id.*
127. *Id.*
128. *Id.* at 403–04.
129. *Id.* at 405.
130. *Id.*
131. *Id.* at 406.

allow NIH-funded academic scientists to use oncomice at no cost for noncommercial purposes.[132]

The oncomouse patent paved the way for future patenting opportunities. Many scientists upset with DuPont for imposing a commercial economy on academics took advantage of the precedent set by the oncomouse patent and started patenting their own mice—albeit for non-commercial purposes.[133] They "us[ed] patents to shape credit and control within the academic economy."[134] Measuring their personal and professional success on patents, scientists no longer thought of patents "as a 'necessary evil' but as an 'important step'" in having a positive, long-term impact.[135]

With this new focus on application rather than research, patents formed an important tool based on exercising control over assets. This transition helped shift the balance in research away from cooperation and towards competition, as is seen in current disputes over such technologies as CRISPR.[136]

D. The Human Genome Project: A Case Study

The controversy around public access to genomic information is an important case study. The Human Genome Project (HGP) originated in the US in 1988.[137] "[B]orn out of the problems of knowledge and justice" produced by radiation exposure during the atmospheric nuclear tests of the 1950s and exposure to mutagenic chemicals, the HGP intended to create "the evidence of things not seen."[138] The US Department of Energy and the International Commission for Protection against Environmental Mutagens and Carcinogens convened experts on DNA analytical methods to determine the technical capacities required to directly detect mutations.[139] The group determined that "a large, complex, and expensive program to improve DNA analysis was

132. *Id.*
133. *Id.*
134. *Id.* at 407.
135. *Id.*
136. Along with a very public battle over the traditional banners of recognition—the so-called "patent-paper pair" and scientific awards—the CRISPR inventors have also commercialized the gene-editing tool. Feng Zhang, the first to use CRISPR in mammalian cells, is cofounder of several CRISPR-based companies. Emmanuelle Charpentier, cofounder of CRISPR Therapeutics, was the first to publish, along with Jennifer Doudna, the invention of the CRISPR gene editor in June 2012. Jennifer Doudna co-founded a CRISPR-based diagnostics company called Mammoth Biosciences. Virginijus Siksnys cofounded the start-up CasZyme. *See e.g.*, Ryan Cross, *CRISPR Researchers Receive Kavli Prize in Nanoscience*, C&EN (June 1, 2018), https://cen.acs.org/biological-chemistry/biotechnology/CRISPR-researchers-receive-Kavli-Prize/96/web/2018/06 [perma.cc/9GB2-JEUR]; Heidi Ledford, *Pivotal CRISPR Patent Battle Won by Broad Institute*, NATURE (Sept. 10, 2018), https://www.nature.com/articles/d41586-018-06656-y [perma.cc/SC8J-K9RC].
137. *What is the Human Genome Project?,* NAT'L HUM. GENOME RES. INST., https://www.genome.gov/12011239/a-brief-history-of-the-human-genome-project [https://perma.cc/BRC3-G5KE].
138. JENNY REARDON, THE POSTGENOMIC CONDITION 25 (2017).
139. Robert Mullen Cook-Deegan, *Alta Summit, December 1984*, 5 GENOMICS 661–63 (1989).

needed."[140] While the founders of the HGP aimed to redress unjust injury and resulting loss of life, they quickly found themselves "embroiled in larger political economic forces that troubled their long-held and cherished beliefs and practices. The so-called secret of life turned out to also promise a pot of gold."[141] The ensuing race between John Sulston, the leader of the public sequencing effort, and Craig Venter, who led the private effort, was chronicled as a war between good and evil, between freedom of information and corporate takeover.[142] The leaders of the HGP publicly celebrated their ethical commitment to the free flow of information and knowledge, encoded as the Bermuda Principles.[143] The Bermuda Principles called for project coordination and the rapid sharing of data for the benefit of science and society.[144] All HGP-funded DNA sequences, for example, were to be released online within twenty-four hours of production.

Great hope for scientific and social advances accompanied the accomplishment of mapping the human genome. President Bill Clinton hailed the human genome sequence, the "blueprint of life," as able to guide humans into a peaceful and prosperous new millennium.[145] Others promised that "[m]edicine would be transformed. Cancer would be cured. Racial ideologies that had torn families apart and killed millions over the course of the 20th century would be defeated."[146]

Yet, fears and questions of morality accompanied the research. As sociologist Jenny Reardon documents in her poignant book, *The Postgenomic Condition*, with the completion of the HGP in 2003, many people were asking, "now that we have the 'human genome' sequence, what does it mean?"[147] What are the uses, significance, and value of the human genome sequence? Along with its promises of precision medicine, the study of human genetics in the 20th century provided the basis for eugenic sterilization, racially motivated immigration laws, and Nazi experimentation.[148] As one commentator asks, "How can we know and act ethically in a world where life becomes information, information becomes capital, and capital is equated with freedom?"[149]

Many HGP participants have argued that "the story that the Human Genome Project sought to liberate the genome for all was an appealing and powerful one, but it ignored on-the-ground realties."[150] For example, the HGP

140. REARDON, supra note 138, at 26.
141. *Id.*
142. *Id.* at 33.
143. *Id.* at 34.
144. *The Bermuda Principles*, DUKE U. LIBR., https://dukespace.lib.duke.edu/dspace/handle/10161/7407 [perma.cc/G29N-7DV9].
145. President Bill Clinton, State of the Union Address (Jan. 27, 2000) (noting that researchers would soon "complete the first draft of the entire human genome, the very blueprint of life").
146. REARDON, *supra* note 138, at 2.
147. *Id.*
148. *Id.* at 5.
149. *Id.*
150. *Id.* at 33.

favored the inclusion of some over the exclusion of others. As one participant noted:

> It made it materially more difficult for minor contributors to the [H]uman Genome Project to meet the Bermuda rules. The Sanger Institute had a one-hundred-person IT [] staff, and it wasn't really a problem for them to funnel their data right into GenBank. It was a serious problem for me, and I resented being told that I should divert other modest resources from what I thought was the best management of our endeavor.[151]

The Bermuda Principle of openness also raised questions about how to achieve the quality of data needed to create genomic knowledge. Many scientists worried about the epistemic value of their research.[152] They noted: "Cultivation and dissemination of knowledge historically and today requires extensive time, money, and attention."[153] As sequencing the human genome required use of expensive machines, "the power to produce genomic information required concentrated wealth, and located the power to produce this information in the labs of the few."[154]

"This meeting of the private property regimes of technological innovation with the Mertonian norm of scientific openness created a formative tension that powerfully shaped genomics from its start."[155] Although openness and sharing of information were fundamental to mapping the genome, ownership still played a key role for preventing duplication and ensuring the whole genome would be sequenced. Those engaged in the sequencing made agreements about who controlled sequencing particular segments of the human genome; agreements that mattered most when those segments were thought to contain important genes.[156] Sequencing machines were not a threat because they threatened to assert property rights over the human genome, but because they threatened to assert private, rather than communal, property, and, as with DuPont and the oncomouse patent, they "placed money, not recognition and academic prestige, at the center of the exchange."[157]

Whether these sequences could be patented, however, was another matter. This question will be further addressed below in light of the decision in *Myriad*,[158] but it is important to flag concerns prevalent while the human genome was being sequenced. Professors Rebecca Eisenberg and Robert Merges wrote an opinion letter for the NIH regarding the patenting of human DNA sequences

151. *Id.* at 33–34.
152. *Id.* at 34.
153. *Id.*
154. *Id.* at 38.
155. *Id.* at 30–31.
156. *Id.* at 32.
157. *Id.*
158. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

and, more specifically, several patent applications assigned to the NIH.[159] Eisenberg and Merges's focus on the utility requirement is telling.[160] By the time the HGP was underway, the USPTO and the courts had turned away from moral utility in favor of *Brenner*'s practical utility requirement.[161] As Eisenberg and Merges write, "in order to satisfy the utility requirement, a patent applicant must not only disclose a specific, practical use for the claimed invention but must also provide a disclosure that enables others working in the same field to use the invention in the described manner without having to do more than routine experimentation."[162]

The USPTO rejected the NIH applications, which sought patent protection for inventions associated with the identification of partial complementary DNA (cDNA)[163] sequences or "expressed sequence tags" (ESTs),[164] in part, on the grounds that a skilled person reading the specification would have to engage in further undue experimentation in order to put the claimed inventions to the suggested uses.[165] In addition, the current uses of the ESTs were vulnerable to challenge under *Brenner v. Manson* "as representing utility only as an object of study in subsequent research rather than showing 'specific benefit . . . in currently available form.'"[166] While some of the genes may prove useful for diagnostic or therapeutic purposes, the specification failed to identify *which* of the genes would be useful.[167]

As this analysis demonstrates, the general concern for the utility requirement lies with premature filing. Eisenberg and Merges observed that "[s]cientists quoted in the popular and scientific press repeatedly expressed an intuition that NIH was claiming too much in light of the very preliminary information that they had disclosed."[168] They concluded that a "utility rejection would present an appealing doctrinal basis for expressing that view."[169]

This analysis demonstrates the concern with the utility requirement at the turn of the 20th century, but, as will be discussed below, the Court later broadened the ability to challenge patents on sequences of DNA in *Myriad*.

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159. Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q. J. 1 (1995).

160. See *id.* at 3 ("Perhaps the issue that has drawn the most attention in public discussions of the patentability of the NIH cDNA sequences is whether these sequences have patentable utility.").

161. *See infra* notes 70–86 and accompanying text (discussing Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999) and *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005)).

162. Eisenberg & Merges, *supra* note 159, at 15.

163. cDNA is synthetically created DNA through a process called revere transcription and is often used for expressing a protein in a cell that doesn't normally express that protein.

164. *See* Eisenberg & Merges, *supra* note 159, at 18.

165. *Id.*

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.* at 19.

III.
BIOTECHNOLOGY AND THE COURTS

More than many other fields, biology has special salience in patent law.[170] Inventions related to biotechnology have captured the public imagination. And not just in the US. As demonstrated in the efforts that gave fruit to the Human Genome Project and CRISPR, the application of biology is an international effort. However, the US and Europe have taken different approaches for life science patents. This section will address each approach in turn, beginning with the US approach.

A. The US Approach

The application of patent law to biology "appears to have given rise to more doctrinal exceptions, statutory carve-outs, and sui generis laws in the US than its sister fields."[171] In fact, "courts are the primary locus of the evolution of patent law."[172] Section 101 of the Patent Act permits any invented or discovered "process, machine, manufacture, or composition of matter" to be eligible for patent protection provided it satisfies the requirements set out in the rest of the statute (namely, novelty, non-obviousness, and disclosure).[173] However, courts have recognized "implicit" exceptions to the provision: "laws of nature, phenomena, and abstract ideas."[174]

The doctrine's prohibition on patenting "products of nature" appears directed mainly toward biological inventions. But for a long time, courts recognized a broad exception for "isolated" or "purified" natural products, an exception stemming from one of the foundational cases in the gene patenting debate, *Parke-Davis & Co. v. H. K. Mulford Co*.[175]

At the turn of the 20th century, researchers observed that extracts from the adrenal gland possessed pharmaceutical properties.[176] In 1900, Japanese chemist Jokichi Takamine, working for American pharmaceutical firm Parke-Davis & Co., identified adrenaline as the extracts' active component.[177] In an effort to protect its research, Parke-Davis secured a patent on the chemical compound itself and sued several of its competitors, who defended on the ground that the patent was invalid because it was a product of nature.[178]

Surprisingly, Judge Learned Hand upheld the patent, finding that the adrenaline claimed in the patent was isolated and purified from its natural

170. Sherkow & Greely, *supra* note 100, at 164.
171. *Id.*
172. Clarisa Long, *The PTO and the Market for Influence*, 157 U. PENN. L. REV. 1965, 1968 (2009).
173. 35 U.S.C. §§ 101, 102, 103, & 112 (2018).
174. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012).
175. Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 99, 102 (S.D.N.Y. 1911).
176. Sherkow & Greely, *supra* note 100, at 164.
177. *Id.*
178. *Id.*

surroundings and, thus, it was not a product of nature.[179] It was "for every practical purpose a new thing commercially and therapeutically."[180] The *Parke-Davis* decision served as the legal basis for the first patents on genetic material: nucleotides.[181] In the first half of the 20th century researchers continued to patent nucleotides and their derivatives. [182] As the research progressed so too did the landscape of biological patents, though these patents were not widely enforced or commercialized.[183]

The Supreme Court decided the next watershed case *Diamond v. Chakrabarty* in 1980. In 1972, Ananda Chakrabarty at General Electric applied for a patent on *Pseudomonas putida*, a bacterium that he had transformed to digest hydrocarbon.[184] It was the first patent application on a recombinant bacterium—and the first on any man-made living thing.[185] The USPTO rejected Chakrabarty's patent application on the grounds that living organisms were not patentable subject matter.[186] The Supreme Court reversed, reciting Congress's intent that "anything under the sun that is made by man" is eligible for patent protection, including a "live, human-made" microorganism.[187] The Court thus shifted the crucial question from whether the organism was living, to whether it was already found in nature, laying the groundwork for the patentability of multicellular organisms and higher forms of life.[188]

The USPTO reiterated *Chakrabarty*'s conclusion that animals were patentable subject matter seven years later in a policy statement.[189] A few days before the release of the policy statement, the USPTO also issued a decision in *Ex parte Allen* that illustrated the concept.[190] Scientists had found that exposing newly-fertilized oyster eggs to extreme water pressure made the oysters sterile and eliminated their normal two-month reproductive cycle during which they are inedible.[191] Thus, oysters treated with the new method could be harvested year-

179. *Parke-Davis*, 189 F. at 103.
180. *Id.*
181. Sherkow & Greely, *supra* note 100, at 165.
182. *Id.*
183. *Id.*
184. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).
185. Sherkow & Greely, *supra* note 100, at 165.
186. *Chakrabarty*, 447 U.S. at 306.
187. *Id.* at 305, 309.
188. *Id.*
189. U.S. Pat. & Trademark Off., *Animals – Patentability*, 1077 OFFICIAL GAZETTE 24 (Apr. 21, 1987) (commissioner notice) ("The Patent and Trademark Office now considers nonnaturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 USC 101."); *see also* Elizabeth Joy Hecht, *Beyond* Animal Legal Defense Fund v. Quigg*: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023 (1992) (exploring whether the USPTO's rule constitutes valid law and whether transgenic animals should be patentable); Danielle K. Miller, *A Patent on the Conscious: A Theoretical Perspective of the Law on Patentable Life*, 2 STAN. J. ANIMAL L. & POL'Y 144 (2009) (exploring legal developments leading to and following the USPTO's announcement of the policy).
190. 2 U.S.P.Q.2d 1425 (1987).
191. *Id.*

round.[192] Although the USPTO rejected the Pacific oyster patent in *Ex parte Allen* on other grounds—the invention was obvious in light of well-known techniques in the field—the Board made clear that "a non-naturally occurring polyploid Pacific coast oyster could have been the proper subject of a patent under 35 U.S.C. 101 if all the criteria for patentability were satisfied."[193]

Although it is rare for USPTO decisions to draw scrutiny, *Allen* entered the mainstream to great furor. United States Senator Mark Hatfield even proposed a moratorium on animal patents and various stakeholders, including farmers and animal rights groups, sued the Patent Office for its policy decision.[194]

A year after the USPTO's policy announcement, it issued the oncomouse patent which raised the stakes even higher, and took on international prominence as the world's first patent for a "higher form of life."[195] The Animal Legal Defense Fund (ALDF) challenged the oncomouse patent grant on behalf of several animal protection groups, farmed animal protection groups, and individual farmers who would be impacted by patenting of animals.[196] ALDF argued that the Patent Commissioner had exceeded his authority in determining that animals were patentable subject matter.[197] The district court dismissed the lawsuit for failure to state a claim[198] and the Federal Circuit dismissed the case for lack of standing.[199] Similar to *In re Fisher*, where the court sidestepped the legal, moral, and ethical issues, the appellate court avoided these issues here, finding no moral objection standing.[200]

And what about patents on humans? In 1987, the USPTO clarified the subject matter doctrine with a moral caveat, explaining, "[A] claim directed to or including within its scope a human being will not be considered to be patentable subject matter."[201] This caveat, however, did not seem to reach inventions composed purely of human material, such as DNA.

Activist Jeremy Rifkin led the march to address the moral quandary around patenting human material. Rifkin had been a vocal opponent of genetic engineering, authoring several amicus briefs on previously mentioned cases through his organization, the New American Movement (later called Peoples

192. *Id.*

193. U.S. PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE, 2105 PATENT ELIGIBLE SUBJECT MATTER — LIVING SUBJECT MATTER [R-08.2017], https://www.uspto.gov/web/offices/pac/mpep/s2105.html [perma.cc/H2MA-Y35Q].

194. Animal Legal Def. Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) (never reaching the substantive issue whether the 1987 rule constituted valid law and holding that plaintiffs lack standing).

195. *See supra* notes 120–136 and accompanying text (discussing the oncomouse case in more depth).

196. *Animal Legal Def. Fund*, 932 F.2d at 922.

197. *Id.* at 924.

198. *In re Quigg*, 710 F. Supp. 728, 732 (N.D. Cal. 1989).

199. *Animal Legal Def. Fund*, 932 F.2d at 939.

200. *Id.*

201. Sander Rabin, *The Human Use of Humanoid Beings: Chimeras and Patent Law*, 24 NATURE BIOTECHNOLOGY 517, 517 (2006).

Business Commission and Foundation on Economic Trends).[202] In December 1997, he gained widespread prominence when he and biology professor Stuart Newman filed a patent application for human-animal chimeras (an animal with both human and non-human cells).[203] Their goal was to use the patent to spark debate about the morality of patent law.[204] Although the USPTO issued a Media Advisory focusing on the possibility of rejecting the application on moral utility grounds, in 2004, the USPTO rejected the patent application in a final office action emphasizing that the claimed invention constituted non-eligible human subject matter.[205]

The most recent Supreme Court case in the field was decided in 2013, *Association for Molecular Pathology v. Myriad Genetics*. In 1990, Mary-Claire King, a researcher at the University of California, Berkeley, discovered that a single gene, BRCA1, was responsible for a large number of early-onset breast cancers.[206] This discovery spurred an international race to locate the gene precisely and to sequence it, which Mark Skolnick at the University of Utah achieved.[207] Roughly thirteen months later, Michael Stratton, a UK researcher, located another gene linked to early onset breast and ovarian cancer, BRCA2.[208] Skolnick again was the first to publish a complete sequence.[209]

Unlike King and Stratton, Skolnick was particularly aggressive about seeking patent protection for his discoveries, which were licensed to Myriad Genetics, a Utah-based diagnostics company that Skolnick and a colleague had founded in 1991.[210] Myriad's focus quickly became clear. Almost immediately after its patents issued, Myriad began to enforce its IP against several high-profile clinicians performing BRCA1 and 2-based cancer risk assessments.[211] Myriad offered expensive licenses to researchers or threatened to sue.[212] This raised the ire of numerous scientific organizations and eventually caught the eye of the American Civil Liberties Union (ACLU), who sued Myriad.[213]

The Supreme Court tackled the issue head-on: "Are human genes patentable?"[214] In June of 2013, the Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated but that c[omplementary] DNA is patent eligible because it is not

202. Keay, *supra* note 41, at 425.
203. *Id.* at 429.
204. *Id.*
205. *Id.* at 432.
206. Sherkow & Greely, *supra* note 100, at 172.
207. *Id.*
208. *Id.*
209. *Id.*
210. *Id.*
211. *Id.*
212. *Id.*
213. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 591 (2013); Sherkow & Greely, *supra* note 100, at 172–73.
214. Sherkow & Greely, *supra* note 100, at 172–73.

naturally occurring."[215] Distinguishing from *Chakrabarty*, the Court declared that while Myriad found an important and useful gene, Myriad did not create anything: "groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[216]

Many applauded the Court for its decision, which goes to the heart of patent law: balancing incentive with access. The Court wrote, "Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes."[217] In essence, these patents would grant one entity the exclusive right to isolate an individual's genetic material and therefore use that analysis in genetic diagnostics. However, in deciding this case under the "product of nature" doctrine, the Court hampered its policy goal, apparently in an attempt to "split the baby."[218]

The Court's distinction between genomic DNA that was extracted from human cells and cDNA that was synthesized in the laboratory is incoherent. As Dan L. Burk observes, "We should begin by recognizing the simple and obvious proposition that genes don't exist in nature. . . . Dividing those networks into conceptual bits such as genes is a practice that is useful to humans, but not one that is somehow mandated by the structure of the universe."[219] Instead of focusing on the public policy rationale of protecting "upstream" or basic research, the court "appears to have confused scientific descriptions, shorthand notations and abstractions representing complex biotechnological products and processes with the biotechnological entities they represent."[220] *Myriad* at once endorses molecules that are structurally different from a native molecule as both patentable and unpatentable and molecules with the same coding information as a native molecule as both patentable and unpatentable.[221]

These misconceptions allow not only for clever claim drafting workarounds but also for unclear doctrine. Because of the lack of clear guidance regarding how to apply the Supreme Court's ruling,[222] the US Chamber of Commerce, among others, has flagged biotech inventions as raising uncertainties regarding

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

216. *Id.* at 577.

217. *Id.* at 585.

218. Some scholars have argued that the Supreme Court's distinction between DNA and cDNA was an attempt at giving something to both the plaintiffs and defendants (i.e., the biotechnology industry that had come to expect patent protection for genetic sequences). *See* Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. 505, 510 (2014).

219. Dan L. Burk, *Edifying Thoughts of a Patent Watcher: The Nature of DNA*, 60 UCLA L. REV. DISCOURSE 92, 95 (2013) [hereinafter Burk, *Edifying Thoughts*].

220. *See, e.g.*, *id.*; Robert M. Schwartz & Timo Minssen, *Life After Myriad: The Uncertain Future of Patenting Biomedical Innovation and Personalized Medicine in an International Context*, 2015 INTELL. PROP. Q. 189 (2015).

221. Burk, *Edifying Thoughts*, *supra* note 219, at 508.

222. The court left open questions such as what counts as a natural product or how much modification is required to render a molecule sufficiently distinct from "naturally" occurring counterparts.

the patentability of products and technologies isolated from natural sources.[223] The Annual Global Index further notes that interpretations by lower courts and the USPTO are inconsistent, are difficult to apply, and create uncertainty for innovators and the legal community.[224] Scholars have noted that between the Supreme Court's *Myriad* decision and its related decision in *Mayo Collaborative Services. v. Prometheus Laboratories, Inc.*, where it barred patents on diagnostic tests that rely on correlations among natural phenomena on the ground that the relationships constitute principles of nature,[225] it will be "difficult to use the patent system to encourage the development of a whole range of therapies and research intermediates useful in developing new therapeutic interventions."[226] Some biotech firms are adopting new strategies for appropriating returns such as experimenting with claiming strategies and relying on trade secrets.[227]

Other scholars have noted that the *Myriad* decision may have been unnecessary given that the empirical evidence that gene patents were tying up basic tools of scientific research and inhibiting innovation was arguable, at best.[228] Focusing on the differences between the subject matter involved in *Chakrabarty* and *Myriad*, one scholar has noted that "[o]ne can question the Justices' indifference to the heightened concerns raised by patents on human genes as opposed to patents on bacterial genes."[229] Even though US patent law is generally agnostic as to where the patented biological products come from, "it is worth thinking about why, when a majority of patents cover genes from non-

223. GLOBAL INNOVATION POLICY CTR., *supra* note 14, at 8; *see also* Jeffrey A. Lefstin et al., *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L. J. 551, 561 (2018) ("The uncertainty and confusion resulting from the Court's recent jurisprudence create significant problems for many companies and investors contemplating research and development projects, as well as for patent prosecutors, patent examiners, and patent jurists. In the decade prior to the *Mayo* decision, the USPTO rarely rejected patents on subject matter grounds, and one could count on one hand the number of judicial § 101 invalidity decisions in any year. Since *Mayo*, the number of § 101 invalidity rulings has skyrocketed, with more than one hundred invalidity determinations per year during the past two years. Courts now routinely confront § 101 invalidity motions at the very outset of, and throughout, many patent cases. The USPTO has issued numerous guidance documents cataloging this rapidly evolving terrain.").

224. GLOBAL INNOVATION POLICY CTR., *supra* note 14, at 8. As noted earlier, the USPTO has released revised guidance for subject matter eligibility in January 2019. *See* Press Release (Jan. 4, 2019), *supra* note 36.

225. 566 U.S. 66, 72, 73 (2012) (holding that such processes "disproportionately [tie up] the use of the underlying natural laws, inhibiting their use in the making of further discoveries").

226. Rochelle C. Dreyfuss et al., *Patenting Nature—A Comparative Perspective*, J. L. & BIOSCIENCES, 550 (2018).

227. *Id.*

228. *See e.g.*, Johnathon Liddicoat et al., *Continental Drift? Do European Clinical Genetic Testing Laboratories Have a Patent Problem?*, EUR. J. HUM. GENETICS (2019) (collecting studies demonstrating both that patents have adversely impacted genetic testing services and that patents rarely hamper and in fact promote academic and commercial research).

229. *See e.g.*, Samantak Ghosh, *Are All Genes Equal?*, 20 BOS. U. J. SCI. TECH. L. 1, 10–14 (2014) (italics omitted).

human sources, the case that finally landed before the Court involved human genes."[230]

In conclusion, the US has dealt with biotechnology patents through evolving caselaw.[231] Europe, by contrast, has dealt with biotechnology largely through its legislature.

B. The European Approach

Although Europe is often painted as having stricter patentability standards than the US, as a consequence of the *Myriad* decision, this is no longer the case, at least when it comes to gene-related technologies.[232] To understand why, it is important to begin by summarizing the different sources of applicable European law and understand how they interact with one another.

Unlike the US, Europe has dealt with policy issues relating to biotechnology at the legislative level. Much of Europe's substantive law on patentability comes from the Strasbourg Convention of 1963, which was the first serious attempt to harmonize the patent laws of the various European countries.[233] Today, Europe's Biotechnology Directive and the European Patent Convention (EPC) specifically regulate whether and how gene-related inventions can be patented.[234] The EPC took effect in 1977, shortly before the European Patent Office (EPO) opened in 1978.[235] The EPO provides for a single grant procedure for all its member states.[236]

After attempting to harmonize the treatment of biotechnology in the 1980s, the EU passed the Biotech Directive in 1998. The original attempt in 1988 emphasized the economic importance of biotech and the concern that differences between European countries could serve as a barrier to the growth of the European biotech industry.[237] However, the European Parliament and its Economic and Social Committee extensively criticized the initial proposal due to lack of ethical considerations, which were subsequently included in the Directive.[238] The Directive therefore represents a compromise between the

230. *Id.* at 2.

231. However, as previously noted, this may change. There is bipartisan interest in Congress to amend the patent statute and overrule *Myriad*. *See* Press Release, Tillis, *supra* note 15.

232. Lai, *supra* note 49, at 1043.

233. *Id.* at 1044.

234. *Id.*

235. *Id.*

236. *Id.*

237. COMM'N OF THE EUROPEAN COMMS., PROPOSAL FOR A COUNCIL DIRECTIVE ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS (1988).

238. The backlash against biotechnology was particularly strong in Germany because of the history of genetic engineering by the Nazis in World War II and militant environmentalists, including the politically powerful Green movement during the 1990s. *See* Nathaniel C. Nash, *Germany Shuns Biotechnology*, N.Y. TIMES (Dec. 21 1994), https://www.nytimes.com/1994/12/21/business/germany-shuns-biotechnology.html [perma.cc/EUP7-W2CN]; *see also* Andreas Schrell et al., *Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany*, 107 ADVANCES BIOCHEMICAL ENGINEERING/BIOTECHNOLOGY 13 (2007) (reviewing the principal

biotech industry and factions opposed to the Directive on moral, environmental, and economic grounds.[239]

Together, the Biotech Directive and the EPC regulate whether and how inventions can be patented. An EU directive such as the Biotech Directive does not itself have direct legal effect as far as its provisions are concerned. Rather, a directive serves as an instruction to member states of the EU to adapt their law by appropriate legislative means to achieve the results specified in the directive.

Unlike the US patent statute, the EPC does not attempt to define what constitutes patentable subject matter. Instead, it clarifies for member states what are not to be regarded as inventions. Article 52 of the EPC defines patentable inventions in a negative sense:

> 1. European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
> 2. The following in particular shall not be regarded as inventions within the meaning of paragraph (1):
>   a. discoveries, scientific theories and mathematical methods;
>   b. aesthetic creations;
>   c. schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
>   d. presentations of information.
> 3. Paragraph (2) shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.[240]

Regarding the life sciences, the most relevant exclusion is new discoveries. Finding a new property of a product is considered to be a mere discovery, but if that property can be put to use in some way, then it is considered to be an invention.[241] This brings us back to the *Myriad* decision. In that case, the US Supreme Court held that simply isolated genetic sequences are not patentable subject matter, regardless of their potential utility. However, according to the Biotech Directive and the EPC, genetic sequences are patentable subject matter

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requirements for biotechnology patents in the signatory states of the European Patent Convention (EPC) and the historical development of biotech-patent legislation in Europe).

239. Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1, 13 (2001).

240. Convention on the Grant of European Patents (European Patent Convention), art. 52, Oct. 5, 1973, 1065 U.N.T.S. 16208 [hereinafter European Patent Convention].

241. Lai, *supra* note 49, at 1042.

so long as the industrial applicability is explicitly clear from the patent application.[242]

One of the purposes of the Directive was to introduce greater certainty into the "ordre public" or morality[243] exception to patentability.[244] Under Article 53 of the EPC, European patents shall not be granted in respect of:

> a. inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
>
> b. plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
>
> c. methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.[245]

The EPC Implementing Regulations clarify that the *ordre public*/morality clause excludes from patentability "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such

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242. 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) pmbl. ¶¶ 20–21 [hereinafter Biotech Directive] ("Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment; [] Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself[.]").

243. *Ordre public* and morality are vague yet distinguishable terms in European patent law. The EPO defined both terms in *Plant Genetic Systems*. It first defined *ordre public*: "the concept of 'ordre public' covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order . . . or to seriously prejudice the environment are to be excluded from patentability as being contrary to 'ordre public.'" Plant Genetic Systems N.V. v. Greenpeace Ltd. (Plant Cells/PLANT GENETIC SYSTEMS), Case T-356/93 - 3.3.4, Eur. Pat. Off. Tech. Bd. App. 5 (Feb. 21, 1995). It then described morality: "[t]he concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality." *Id.* at 6.

244. Bonadio, *supra* note 16, at 149.

245. European Patent Convention, *supra* note 240, art. 53.

processes."[246] As will be discussed below, the EPO appears to still be developing a consistent standard for applying the *ordre public*/morality clause.[247]

The previously discussed oncomouse case clarifies this clause and is useful for contrasting with the US approach. In the US, the court approached the oncomouse patent by addressing its effect on upstream research. By contrast, following opposition, the EPO Board also considered the morality of the patent. In doing so, it decided to allow claims to transgenic mice but not to rodents generally, arguing that the need of humankind to treat disease had to be balanced with avoiding suffering to animals and protecting against uncontrolled dissemination of unwanted genes.[248] No evidence had been submitted to prove that rodents other than mice would provide comparable benefit.[249]

As will be argued below, that Europe has included ethical concerns legislatively is a better approach than the US's wavering judicial approach.

IV.
WHY MORALITY SHOULD BE ADDRESSED BY THE USPTO

Scholars have noted an inherent tension between patent legislation and public interest concerns, such as the protection of human health and dignity, as well as the environment. As a matter of fact, the patent system aims to encourage research and development activities by offering inventors monopolistic rights. But who should be tasked with assessing the morality of those inventions? Should questions of morality be addressed at the patent office? While there is not uniform agreement on the answer to this question, this Note argues that patent offices should be entrusted with the task. But first, we look at arguments against that approach.

A. Why Commentators Disagree

Many commentators argue that patent law is morally neutral and that the grant of a patent is a non-ethical event. The patent system, they argue, does not represent a positive right to work and commercially exploit the invention, but merely provides a legal means by which the patent holder can prohibit another from using the invention. The argument that the patent is "only a negative right" is extended to imply that any restriction upon exploitation of the invention should be dealt with by other regulatory bodies and not through the cumbersome and indirect means of patents laws.

246. *Id.* at Rule 28 Exceptions to Patentability (clarifying art. 53).

247. *See* Ellen-Marie Forsberg & Nico Groenendijk, *RRI and Patenting: A Study of European Patent Governance*, 13 NANOETHICS 83 (2019) (summarizing various tests the EPO has used to determine whether to deny a patent as contrary to *ordre public* or morality).

248. Harvard Coll. v. British Union for the Abolition of Vivisection (Transgenic Animals/HARVARD), Case T-0315/03 – 3.3.08, Eur. Pat. Off. Tech. Bd. App. (July 6, 2004).

249. *Id.*

Professor Robert Merges, for example, takes a historical approach to argue that moral worth is a difficult test of patentability.[250] He notes that moral norms change, citing the example of birth control that "in a period of thirty to forty years, has come from a position of illegality to a position where they are welcomed by some as a means of curbing a population explosion."[251] But not only do moral norms change, he argues, imagining how a technology will be used in the future is a fool's errand.[252] Merges makes a compelling case that public fear is not the best guide—let alone that language and public image can be manipulated.

Analyzing the success of the moral utility doctrine and the EU's morality clause lend credence to Merges's argument that determining the morality of an invention is difficult. Just as the moral utility doctrine saw inconsistent application, some scholars argue that the EPO applies inconsistent legal tests for determining whether an invention is contrary to *ordre public* or morality.[253] This raises concern about the expansiveness of these terms and the goal of a morality clause (e.g., addressing public health and safety, animal welfare, environmental protection, the preservation of genetic diversity, all of the above).

Merges also argues that potential social consequences should be dealt with by other bodies. For example, he cites the creation of the Food and Drug Administration (FDA) as a regulatory body.[254] Because of the existence of the FDA, courts focus more on functional utility rather than clinical safety when medical patents are at issue, avoiding duplication of effort.[255] One court has commented that "[t]o require the Patent Office to make an affirmative finding as to the safety of a drug for human use would work a serious overlapping of the respective jurisdictions of the Patent Office and the [FDA]."[256]

Arguing that the provision is superfluous, those in favor of broad patent protection for biotech inventions made a similar argument when debating the EU's Article 6 morality provision. The grant of a patent does not authorize the patent holder to implement her invention, they argued, it only prohibits third parties from exploiting it.[257]

Thomas Magnani is another opponent to regulating biotechnology at the patent office.[258] At the time of Rifkin and Newman's patent application on a

250. Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051 (1987).

251. *Id.* at 1064–65 (quoting R. CHOATE, CASES AND MATERIALS ON PATENT LAW 76 (3d ed. 1987)).

252. *Id.* at 1065.

253. Gitter, *supra* note 239, at 4 (illustrating confusion on whether the EPO applies the "public abhorrence" or "unacceptability" standard).

254. Merges, *supra* note 250, at 1064.

255. *Id.*

256. Carter-Wallace, Inc. v. Riverton Laboratories, Inc., 433 F.2d 1034, 1039 n.7 (2d Cir. 1970).

257. Gitter, *supra* note 239, at 36 n.272.

258. *See* Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L. J. 443 (1999).

human-animal chimera, Magnani argued that rather than focusing on whether these inventions should be patented, Rifkin and Newman should have focused on whether these inventions should be created at all.[259] Magnani points out that eliminating patent protection for controversial technologies might actually have the opposite of the intended result because without "the limited monopoly granted by the patent law, everyone would be free to make and use a new invention without permission from the original inventor."[260]

B. Why Commentators Agree

In opposition to the scholars referenced above, others have argued that patent law should not be considered isolated, "untouchable," and neutral to moral and *ordre public* issues. The patent system, they argue, is naturally subject to such overriding principles.

Enrico Bonadio, for example, argues that "patent law is not neutral but is subject to moral principles."[261] By isolating the patent system from conversations of morality, we "ignor[e] its very function, which is to stimulate and reward innovation useful to our society—not harmful products and manufacturing processes."[262]

Bonadio's arguments echo those of Justice Story regarding the moral utility doctrine in *Lowell v. Lewis*. While the market decides how "useful" an invention is, the patent system should decide which inventions to incentivize. [263] Bonadio reiterates his point that patent officers and judges "far from being neutral and shutting their eyes to immoral or harmful inventions, must act as social and moral filters and arbiters."[264] As will be explored below, this application is by no means novel. Bioethicists, for example, have been consulted in health care settings for decades.[265]

Bonadio also responds to Magnani's argument that eliminating patent protection for controversial technologies might actually result in more people practicing the controversial technology.[266] He observes that "[t]he prospect of obtaining a patent indeed constitutes an incentive to invest in a particular field of research. Absent the lure of lucrative royalties stemming from patent

259. *Id.* at 459.

260. *Id.*

261. Bonadio, *supra* note 16, at 152.

262. *Id.*

263. *Id.* at 167; *see supra* notes 56–58 and accompanying text (describing Justice Story's framework).

264. Bonadio, *supra* note 16, at 153.

265. *See generally* James Summers, *Principles of Healthcare Ethics*, *in* HEALTH CARE ETHICS: CRITICAL ISSUES FOR THE 21ST CENTURY 41 (Eileen E. Morrison & Elizabeth Furlong eds., 4th ed. 2019) (discussing theories of ethics that provide a practical basis for making practice decisions and proposing a model to assist with making ethics-based decisions).

266. Bonadio, *supra* note 16, at 153.

ownership, very few enterprises would invest human and financial resources in the field in question."[267]

Professor Sivaramjani Thambisetty responds to Merges by arguing that regulatory bodies are not undermined by patent decisions taking into consideration morality.[268] She emphasizes that "the patent office, being the port of first call, has an undeniable onus to assess the desirability of granting property rights and associating legitimacy with a morally objectionable invention."[269] Further, she argues that "the symbolism in the grant of a patent is not an insignificant one."[270] Legislators and other regulatory bodies may be reluctant to impose restrictions on exploitation once a person already holds the patent.[271] Peter Drahos, an Australian academic, summarizes these perceptions by stating that "Patent law is located within and not outside a public ethic of community values and shared economic and social interests."[272]

As deconstructed above, the European Union has taken this approach by excluding from patentability on morality grounds through Articles 53(a) of the EPC—"inventions the commercial exploitation of which would be contrary to 'ordre public' or morality" are not patentable—and 6(a) of the EU Biotech Directive—"inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality." [273] Although, as mentioned above, lack of clear guidance on how to apply the *ordre public*/morality clause has led to inconsistent practice, the evolution of the EPO's decisions demonstrates a viable approach for including morals in a patent system.

Sigrid Sterckx and Julian Cockbain demonstrate the EPO's decisions' evolution regarding its approach to "morality" from a *procedural* approach to morality to a *consequentialist* approach to a *deontological* approach.[274] The definition of morality provided in *Plant Genetic Systems* quoted above demonstrates a procedural approach to morality. In it, morality is defined as "the totality of the accepted norms which are deeply rooted in a particular culture,"[275] which has been called the "public abhorrence" test.[276] Sterckx and Cockbain criticize this approach as "reducing moral judgments to 'counting noses' as in a vote or public opinion poll."[277] While what people happen to regard as contrary

267. *Id.*
268. *See* Thambisetty, *supra* note 51, at 48.
269. *Id.*
270. *Id.*
271. *Id.*
272. Drahos, *supra* note 52, at 447.
273. *See supra* Part III.B.
274. SIGRID STERCKX & JULIAN COCKBAIN, EXCLUSIONS FROM PATENTABILITY: HOW FAR HAS THE EUROPEAN PATENT OFFICE ERODED BOUNDARIES? 295 (2012).
275. Plant Genetic Systems N.V. v. Greenpeace Ltd. (Plant Cells/PLANT GENETIC SYSTEMS), Case T-356/93 - 3.3.4, Eur. Pat. Off. Tech. Bd. App. 15 (Feb. 21, 1995).
276. See Gitter, *supra* note 239, at 21.
277. STERCKX & COCKBAIN, *supra* note 274, at 295.

to morality may be relevant, it is not a viable approach for determining what is contrary to morality. The EPO's approach in the oncomouse case demonstrates the consequentialist approach of balancing the positive and the negative, which has been called the "unacceptability" test.[278] While an improvement over the "hollow" procedural approach, Sterckx and Cockbain maintain that consequentialism is "too limited to 'capture' what matters with regard to morality." The EPO's WARF case, which deals with a patent application relating to primate embryonic stem cells, acknowledges this limitation by asking what the basis is for the view that "some benefits outweigh human dignity."[279] Sterckx and Cockbain maintain that the WARF decision is a positive shift in EPO jurisprudence from a purely utilitarian approach to utilizing a more rigorous *deontological* one.[280] Certain things may be contrary to morality even if they would produce more benefits than disadvantages, such as human dignity and non-commodification. This maturation of the EPO's jurisprudence hints at a viable framework for considering the morality of inventions.

Bonadio further demonstrates how these decisions can make a real impact. In *Oliver Brüstle v. Greenpeace eV*, the CJEU interpreted Article 6(2)(c) of the EU Biotech Directive's prohibition of patents on "uses of human embryos for industrial or commercial purposes[.]"[281] The subject of *Brüstle* was a German patent covering isolated and purified neural precursor cells produced from human embryonic stem cells (HESCs), which had the potential to treat damaged organs in patients with dementia, blindness, and Parkinson's Disease.[282] In the German Federal Patent Court, Greenpeace successfully argued that patenting an invention based on a subsequently destroyed human embryo is unethical.[283] On appeal, the CJEU held that an invention is not patentable if its implementation "requires the prior destruction of human embryos or their prior use as base material."[284] On return to the German Court, the *Brüstle* national patent was granted in an amended form excluding stem cells obtained by destroying human embryos. As Bonadio writes, excluding patentability of HESCs that are obtained by creating and destroying human embryos thus pushes pharmaceutical companies to work with and exploit stem cells without such destruction.[285]

278. See Gitter, *supra* note 239, at 21.

279. Stem Cells/WARF, Case T-1374/04 (I) – 3.3.08, Eur. Pat. Off. Tech. Bd. App. 15 (Nov. 18, 2005).

280. STERCKX & COCKBAIN, *supra* note 274, at 297.

281. Case C-34/10, Brüstle v. Greenpeace eV, 2011 E.C.R. I-0981; Biotech Directive, *supra* note 242, art. 6(2)(c) (establishing "uses of human embryos for industrial or commercial purposes" are not patentable).

282. *Brüstle*, 2011 E.C.R. at I-9864; Bonadio, *supra* note 16, at 154.

283. Bonadio, *supra* note 16, at 154.

284. *Brüstle*, 2011 E.C.R. at I-9876.

285. Bonadio, *supra* note 16, at 167.

C. Considering Morals at the Patent Office

The European approach demonstrates that considering morals at the patent office is not only workable but also desirable. Through such an integrated process, the patent office has the power to grant a stamp of approval and to incentivize invention. A morality provision similar to that in Europe would help create a systematic approach currently lacking in the US and avoid the problems of the moral utility doctrine that saw disorganized application. The European approach, however, only illustrates a first step. As scholars have demonstrated, its approach to applying a morality clause is still maturing.

V.
PROPOSAL

Since the early 1990s, the USPTO has maneuvered to occupy a more central position in making patent law and policy.[286] Indeed, the USPTO's jurisdiction has greatly expanded with the AIA, in particular regarding post-grant proceedings. Patents pose a particular problem, doctrinally and technologically, and also ethically. As proponents of the AIA have noted, the USPTO already has a handle on the first two factors.[287] In contrast to federal judges, the examiners, PTAB judges, and lawyers who wish to practice before the bar of the USPTO are required to have adequate education or experience in a science or engineering discipline.[288]

So why should technically trained patent examiners who have no expertise in social values make ethical judgments? As argued above, the USPTO, as "first port of call" is the most logical place for these judgments to be made.[289] But just as many federal judges with no technical training are not best suited to make decisions regarding the patentability of inventions, patent examiners and PTAB judges without policy guidance may not currently be fully prepared to decide ethical questions on such matters. In our current system, however, they are the people most familiar with the applicable law and the technology, and have the most complete understanding of issues the mainstreaming of the technology would likely create. As this Note has demonstrated, the potential impact of biotechnology inventions on our lives has never been greater.[290] As technology changes, so must the agencies that govern them. The USPTO needs new tools.

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286. Long, *supra* note 172, at 1991.

287. *Id.*

288. U.S. PAT. & TRADEMARK OFF., GENERAL REQUIREMENTS BULLETIN FOR ADMISSION TO THE EXAMINATION FOR REGISTRATION TO PRACTICE IN PATENT CASES BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE 4 (2018), https://www.uspto.gov/sites/default/files/documents/OED_GRB.pdf [perma.cc/C3QB-LZK4].

289. *See* Thambisetty, *supra* note 268, at 48–53.

290. As discussed above, along with being hailed as a path of enlightenment, genomics and molecular biology during the 20th century was also steeped in complex social and cultural contexts, which included partnering with state power in the name of Nazi experimentation, eugenic sterilization, and racially motivated immigration laws. CRISPR is the most recent milestone in the molecular biology

A. Two Approaches for Ethical Review

Among the different approaches Congress and the USPTO could take to begin implementing an ethical review of patent applications, two are immediately clear. The first is that, Congress does not, in fact, need to act. The USPTO could assert that it has plenary rule making power and that section 101 of the Patent Act includes an ethical dimension. Because of "Chevron Deference," courts could defer to this USPTO action.[291]

For the second approach, Congress could amend the Patent Act to include language similar to Article 53(a) of the EPC—"inventions the commercial exploitation of which would be contrary to 'ordre public' or morality" are not patentable—and Article 6(a) of the EU Biotech Directive— "inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality." Congress has, in fact, already begun this process by including in the AIA a provision that expressly excludes patents on specific subject matter categories, namely tax strategies and human organisms.[292] But Congress should include more specific guidance to allow the USPTO and the courts to judge the ethical dimension of inventions.

Under either of these approaches, the USPTO could incorporate ethics committees similar to those provided for under the European Commission's European Group on Ethics in Science and New Technologies. Just as patent examiners are assigned to a particular technology, each technology group would include its own ethics committee. This group could offer expert guidance in a

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revolution. Its use has instigated calls for a more global dialogue, reminiscent of the 1975 International Conference on Recombinant DNA Molecules held at the Asilomar Conference Center in California, which brought together research scientists, lawyers, and ethicists. In a TED talk, a workshop, and in her book *A Crack in Creation: The Uunthinkable Power to Control Evolution,* biochemist and CRISPR co-discoverer Jennifer Doudna has warned that the public discussion of the technology is falling behind its emerging applications. Doudna's concerns were validated by the November 2018 announcement that He Jiankui, a DNA-sequencing expert at the Southern University of Science and Technology in Shenzhen, had orchestrated the birth of the world's first gene-edited babies—allegedly conferring immunity to infection by HIV in one of them. *See e.g.*, *Next Time, Ask First: The Affair of the Gene-Edited Babies Rumbles On*, ECONOMIST (Dec. 15, 2018), https://www.economist.com/science-and-technology/2018/12/15/the-affair-of-the-gene-edited-babies-rumbles-on [https://perma.cc/QPK9-UNK4]. As many have noted, unless the value of the applications of the technology are exposed to public review and inclusively debated, well-intentioned research could move humanity closer to a future it has not assented to and might not want. *See e.g.*, Sheila Jasanoff & J. Benjamin Hurlbut, *A Global Observatory for Gene Editing*, NATURE (Mar. 22, 2018), https://www.nature.com/articles/d41586-018-03270-w [https://perma.cc/C4ZK-LPAK]. Important efforts include the International Summit on Human Gene Editing, held in Washington DC in December 2015, and the Global Observatory for Gene Editing, a project to be launched in Cambridge, Massachusetts in spring 2019. These efforts demonstrate a societal recognition that more ports of ethical review are needed for emerging technology.

291. Some scholars have argued, however, that the USPTO should not be accorded *Chevron* deference when it interprets the Patent Act. *See, e.g.*, Robert P. Merges, *The Hamiltonian Origins of the US Patent System, and Why They Matter Today*, 104 IOWA L. REV 2559, 2561 (2019) ("In practical terms, I am arguing in support of two propositions. First, we should not push for *Chevron* deference to Patent Office interpretations of the Patent Act.").

292. *See* Leahy-Smith America Invents Act, Pub. L. 112-29 §§ 14, 33, 125 Stat. 284 (2018) (codified as amended at 35 U.S.C. §§ 101–02 (2012)).

particular field, updating its guidance as inventors propose new inventions. Through the guidance of the ethics committees, patent examiners and PTAB judges would be capable of assessing the merits of these claims. As with current successful prosecution (i.e., issuance of the patent), these inventions would be entitled to a statutory presumption of ethical validity.[293]

Along with including ethics review at the examination stage, another viable approach as an initial step for implementation is to allow morality challenges during post-grant review (PGR), a post-grant proceeding enacted by the AIA. Considered "the first window" for challenging patent validity, PGR may be sought within the first nine months after a patent is issued by any person who is not the patent owner.[294] At this stage, some consequences of the patent grant would perhaps already be visible. In addition, public interest groups would have standing to challenge (competitors are unlikely to challenge one anothers' inventions as unethical),[295] encompassing all grounds that could be asserted to render a patent invalid or unenforceable.[296] This approach would be very similar to the opposition procedure in Europe, which was used in *Oncomouse*, and permitted valuable feedback from the community.

B. Issues with Implementation

At a general level, some may argue that it is risky and counterproductive to place ethical decision-making powers in the hands of patent examiners, PTAB judges, and federal judges. Some may argue that these individuals, while admittedly knowledgeable about the technical and administrative aspects of the patent process, are ill-suited for making ethical decisions. Admittedly, this would represent a significant change to the existing system. Finding the right balance between ethical standard and guidance provided by Congress and USPTO independence will undoubtedly require a lengthy process of stakeholder vetting. Fortunately, the EU system provides a rough but well-documented roadmap. In addition, this proposal is similar to the one that already exists in hospitals, whereby bioethicists help close the gap between high-level theory and application to the real-world challenges health professionals face in providing patient care. For example, bioethics consults occur in hospitals when a treating physician and patient or a patient and the patient's family disagree on the goals

293. *See* 35 U.S.C. § 282.

294. 35 U.S.C. § 321.

295. *See* Rochelle Cooper Dreyfuss, *Giving the Federal Circuit a Run for Its Money: Challenging Patents in the PTAB*, 91 NOTRE DAME L. REV. 235, 292 (2015) ("[B]ecause standing in court largely limits the class of potential challenges to entities within the same industrial sector as the patent holder, no one raises questions that call the entire industry's holdings into question."); Sapna Kumar, *Standing Against Bad Patents*, 32 BERKELEY TECH. L. J. 87, 92–104 (2018) (arguing that impediments that prevent direct competitors from challenging bad patents include "the high cost of bringing challenges and the risk to the direct competitor's own patents").

296. 35 U.S.C. § 321(b).

of care or course of treatment.[297] During these difficult situations, bioethicists help provide a framework for addressing relevant considerations, generally in the form of principles: patient autonomy, beneficence, nonmaleficence, and justice.[298] While application of these principles can be messy and is invariably fact-specific, the tradition of ethics committees and consults in healthcare—and their proven effectiveness in addressing what literally are often life and death situations—has allowed for a practical approach to applying the reflective equilibrium to this everchanging field.[299]

In addition, given that this will be a new avenue for rejecting and challenging issued patents, a variety of other considerations, such as standing requirements will also have to be considered to minimize unintended consequences, including potential abuse of this new process.[300] The AIA has already expanded the USPTO's ability to reexamine previously issued bad patents.[301] While challenging patents on moral grounds during PGR is a viable option, it is only available during the first nine months after a patent is issued. Other post-grant proceedings, such as inter partes review, restrict the grounds on which a challenge may be brought.[302] Establishing third-party standing to challenge older patents on moral grounds will have to be considered.

The US patent system was created to "promote the progress of science and useful arts." However, with technological innovation accelerating at an unprecedented pace and unclear guidance regarding patentable subject matter—in particular for biotech inventions—it is time to broaden the range of the USPTO to also factor in moral considerations when making determinations on patent applications. It is clear that recent US Supreme Court and Congressional statutes lean in this direction. The scale of patenting in areas like marine biodiversity also suggest the need to spark a more nuanced and global conversation around the ramifications of gene patenting.[303] While this will represent an expansion of the USPTO's current role, with appropriate guidance from Congress, this change would result in greater consistency, predictability, and clarity in the patent process—a result which would positively impact the patent system's fundamental purpose of promoting innovation.

297. *See* Jennie Thomas, *Bioethics Consultations and Resources*, 11 OCHSNER J. 357, 357 (2011).

298. *See id.*

299. *See* Summers, *supra* note 265, at 56.

300. Justice Brennan observed that it has become "a catchall for an unarticulated discretion." Simon v. E. Ky. Welfare Rights Org., 426 U.S. 26, 66 (1976) (Brennan, J., dissenting).

301. *See* Kumar, *supra* note 295, at 119–30.

302. 35 U.S.C. § 311 (2012).

303. *See* Blasiak, *supra* note 1, at 1.