

NATURE’S INVENTIONS: AN EXAMINATION OF PROPOSED LEGISLATIVE SOLUTIONS TO PATENTABLE SUBJECT MATTER

Abstract: The subject matter eligibility doctrine initially existed as a means of limiting the scope of an inventor’s patent claim. Over the past decade, the Supreme Court has broadened the scope of the doctrine to invalidate patents that effectively recite a claim for processes or products that exist in nature. These recent decisions have led to confusion over what inventions qualify as patent eligible under 35 U.S.C. § 101. The Federal Circuit and commentators have implored the legislature to weigh in on the issue and establish clearer guidance for what constitutes patentable subject matter. Two proposed bills introduced in the House and Senate seek to clarify the doctrine by allowing for patents to be granted more broadly to inventions that incorporate biological materials and other routine scientific practices. This Note argues that neither proposed law adequately addresses the underlying policy concerns left unaddressed by the Supreme Court in their recent decisions regarding the patentability of biological materials and processes. Rather than adopt either proposed law, Congress should draft an exclusionary rule for patent eligibility that precludes inventors from claiming a genetic sequence that exists in nature within their patent claim. Such a rule would impose a necessary limit to the scope of patent claims that reinforces the original goals of the subject matter eligibility doctrine.

INTRODUCTION

Interest in the biotechnology (“biotech”) industry has continually grown in recent years due to the rapid development of therapeutics spurred by the COVID-19 pandemic.¹ The biotech industry relies heavily on patent protection for the development of their therapeutics because of the number of regulatory hurdles pharmaceutical companies must overcome for federal approval.² The importance of patents has led to inventors spending millions of dollars to pro-

¹ See Annalee Armstrong, *10 Ways COVID-19 Rocked Biotech—Plus an Honorable Mention for Omicron*, FIERCE BIOTECH (Apr. 4, 2022), <https://www.fiercebiotech.com/special-reports/how-covid-19-rocked-biotech> [<https://perma.cc/6JXR-GWFK>] (explaining that the pandemic spurred the biotech industry to invest in and quickly develop therapeutics for COVID-19).

² See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1580, 1581–82 (2003) (noting that the biotech industry relies on patents to protect investment in new developments).

tect and enforce their patent rights.³ For example, Moderna continues to battle with other companies over the full patent rights to mRNA vaccines for COVID-19.⁴ Sales of the COVID-19 vaccine generated over thirty billion dollars in revenue for Pfizer in 2022 alone, creating an incentive for companies to dispute the rights over the vaccine.⁵

Unlike mechanical inventions, new drugs and therapeutics in the biotech industry rely on products of nature, such as DNA and proteins.⁶ DNA exists in all living organisms, including human beings, and acts as a code that directs cells to build proteins.⁷ DNA consists of nucleotides, or four unique building blocks that can be arranged into different sequences.⁸ Specific DNA sequences, known as genes, dictate different attributes about a person, ranging from a person's physical appearance to their susceptibility to certain diseases.⁹ Living

³ See Carly Klein, *The Complications Around Patenting Biotechnology*, LABIOTECH (Oct. 5, 2020), <https://www.labiotech.eu/in-depth/biotechnology-patents-intellectual-property/> [<https://perma.cc/TX6X-QQQR>] (highlighting that over ten million dollars has been spent in the ongoing dispute over patent rights to CRISPR technology).

⁴ See Aparajita Lath, *COVID-19 Vaccine Patent Infringement? The Battle Between Moderna and Pfizer/BioNTech Continues*, BILL OF HEALTH (Jan. 12, 2023), <https://blog.petrieflom.law.harvard.edu/2023/01/12/covid-vaccine-patents-moderna-pfizer-biontech/> [<https://perma.cc/R8HM-TFCJ>] (summarizing the ongoing infringement claims and defenses in Moderna's lawsuits over their COVID-19 patents). Because Moderna pledged not to enforce its patent rights for the duration of the pandemic, various biotech companies argue that Moderna cannot renege on their promise. See *id.* (highlighting that Moderna pledged not to enforce their patents).

⁵ See Spencer Kimball, *The Covid Pandemic Drives Pfizer's 2022 Revenue to a Record \$100 Billion*, CNBC (Jan. 31, 2023), <https://www.cnbc.com/2023/01/31/the-covid-pandemic-drives-pfizers-2022-revenue-to-a-record-100-billion.html> [<https://perma.cc/FM76-A7M7>] (noting that Pfizer generated billions of dollars in revenue from the COVID-19 vaccine); see also Leroy Leo, *Moderna Meets Forecast with \$18.4 Billion in COVID Vaccine Sales in 2022*, REUTERS (Jan. 9, 2023), [https://www.nasdaq.com/articles/moderna-meets-forecast-with-\\$18.4-billion-in-covid-vaccine-sales-in-2022](https://www.nasdaq.com/articles/moderna-meets-forecast-with-$18.4-billion-in-covid-vaccine-sales-in-2022) [<https://perma.cc/WFT5-YD95>] (highlighting that the COVID-19 vaccine generated nearly twenty billion dollars in revenue for Moderna).

⁶ See Suliman Khan et al., *Role of Recombinant DNA Technology to Improve Life*, INT'L J. GENOMICS, Dec. 8, 2016, at 2, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5178364/pdf/IJG2016-2405954.pdf> [<https://perma.cc/YAJ7-2BDV>] (explaining that recombinant DNA plays an integral role in the development of therapeutics for combatting human disease); Benjamin Leader, Quentin J. Baca & David E. Golan, *Protein Therapeutics: A Summary and Pharmacological Classification*, 7 NATURE REV. DRUG DISCOVERY 21, 21 (2008) (acknowledging the high volume of protein-based therapeutics and their advantages over genetic treatments).

⁷ See *DNA and Disease*, GARVAN INST. MED. RSCH., <https://www.garvan.org.au/research/kinghorn-centre-for-clinical-genomics/learn-about-genomics/dna-base/dna-and-disease> [<https://perma.cc/Y4PN-Q9CJ>] (explaining the function of DNA in living organisms); Rachel Rettner, *What Is DNA?*, LIVE SCI. (Mar. 17, 2023), <https://www.livescience.com/37247-dna.html> [<https://perma.cc/R7EH-FDSU>] (explaining the basic structure of DNA and noting that all living organisms rely on DNA).

⁸ See Rettner, *supra* note 7 (noting that nucleotides serve as the building blocks of DNA and thus all genetic code). A similarly structured molecule, RNA, also exists in living organisms as a short-lived copy of a specific sequence of DNA. See *id.* (explaining that RNA molecules copy the DNA sequence to then direct the cell to generate proteins).

⁹ See *DNA and Disease*, *supra* note 7 (explaining that each person has a genome, or a DNA sequence, that affects their appearance); Odatha W. Kotagama, Chanika D. Jayasinghe & Thelma

things also contain proteins, a vast array of molecules that carry out various functions on a cellular level.¹⁰

Recent developments in biotechnology, such as the discovery of CRISPR-Cas9's ability to directly edit a DNA sequence, open the door to new therapeutics for combatting disease.¹¹ The discovery that CRISPR technology could directly edit human genes led to extensive litigation between the pioneers of the technique over ownership of the patent rights.¹² Throughout the course of the near decade-long battle for patent rights, no party has brought a challenge to the eligibility of CRISPR for patent protection.¹³ Recent Supreme Court

Abeyasinghe, *Era of Genomic Medicine: A Narrative Review on CRISPR Technology as a Potential Therapeutic Tool for Human Diseases*, BIOMED RSCH. INT'L, Oct. 7, 2019, at 1, <https://doi.org/10.1155/2019/1369682> [<https://perma.cc/24NR-QPBJ>] (highlighting that many known diseases originate from mutations to genes within the human genome).

¹⁰ See Nathan Ahlgren, *What Is a Protein? A Biologist Explains*, CONVERSATION (Jan. 13, 2021), <https://theconversation.com/what-is-a-protein-a-biologist-explains-152870> [<https://perma.cc/PPD3-YV6L>] (observing that proteins carry out a vast number of roles in organisms, such as upholding the structure of a person's body). Genes code for the structure of different proteins by using smaller molecules known as amino acids. See Rettner, *supra* note 7 (explaining the process by which RNA and amino acids create proteins).

¹¹ See Kotagama et al., *supra* note 9, at 5–6, 7, 9 (explaining that research into gene editing with CRISPR-Cas9 enabled researchers to determine potential therapeutic treatments for sickle cell anemia as well as the elimination of breast cancer cells). CRISPR refers to “clustered regularly interspaced short palindromic repeats,” short sequences of DNA in an organism that enable a cellular protein to remove short sections of the organism's DNA. See Daphne Ng, *A Brief History of CRISPR-Cas9 Genome-Editing Tools*, BITESIZE BIO (Nov. 10, 2023), <https://bitesizebio.com/47927/history-crispr/> [<https://perma.cc/5AFM-6WHL>] (stating that CRISPR sequences appear naturally in bacteria and enable the organism to remove short sequences of DNA once infected by a virus). Scientists have developed a way of incorporating CRISPR into human DNA and using bacterial proteins to correct mutations in human genes. See Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCIENCE 816, 820 (2012) (demonstrating that a strand of RNA, that contains a copy of an organism's genetic information, can program the Cas9 protein using CRISPR sequences edited into the RNA to modify an organism's genomic sequence). The scientists who first discovered how bacterial proteins could edit DNA sequences earned a Nobel Prize for their work. Heidi Ledford & Ewen Callaway, *Pioneers of Revolutionary CRISPR Gene Editing Win Chemistry Nobel*, 586 NATURE 346, 346 (2020).

¹² See Heidi Ledford, *Major CRISPR Patent Decision Won't End Tangled Dispute*, 603 NATURE 373, 373 (2022) (noting the extensive litigation battle over the licensing rights to CRISPR and technology associated with gene-editing).

¹³ See Deborah Ku, *The Patentability of the CRISPR-Cas9 Genome Editing Tool*, 16 CHI.-KENT J. INTELL. PROP. 408, 422 (2017) (noting that no issues under 35 U.S.C. § 101 arose before federal courts regarding CRISPR patents). Challenges made as to the validity of patents within the field of biotechnology undermine the security of licensing agreements between the patent holder and other companies. See Jon Cohen, *New CRISPR Patent Hearing Continues High-Stakes Legal Battle*, SCIENCE (Feb. 4, 2022), <https://www.science.org/content/article/new-crispr-patent-hearing-continues-high-stakes-legal-battle> [<https://perma.cc/V9WQ-ZBBD>] (acknowledging that companies with licensing arrangements will sustain losses if the patent underlying these arrangements become invalid); see also *Information About Licensing CRISPR Systems, Including For Clinical Use*, BROAD INST., <https://www.broadinstitute.org/partnerships/office-strategic-alliances-and-partnering/information-about-licensing-crispr-genome-edition> [<https://perma.cc/9YK2-LHKR>] (stating that the Broad Institute intends

decisions regarding the eligibility of DNA-based therapeutics have threatened the validity of patents that incorporate genes and other naturally occurring materials into their claims.¹⁴ CRISPR technology's reliance on proteins and cellular materials found in nature threaten the technique's eligibility for patent protection.¹⁵

For a patent application to be successful, the applicant must demonstrate that the claimed invention does not merely embody a natural phenomenon or discovery, but instead applies or embodies that naturally occurring element in a process or device.¹⁶ Although many developments in biotechnology utilize discoveries of naturally occurring processes in cells and other living organisms to develop useful products, these developments run the risk of failing to satisfy eligibility requirements.¹⁷ The current requirements for subject matter eligibility have drawn criticism from members of the biotech and life sciences industry because they exclude many of these new technologies.¹⁸ Unlike other pa-

to negotiate exclusive licenses for its CRISPR patents with companies that seek to develop human therapeutics).

¹⁴ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013) (determining that a patent for naturally occurring products like DNA cannot be valid); see also *Mayo Collaborative Servs. v. Prometheus Lab's, Inc.*, 566 U.S. 66, 72 (2012) (stating that mere application of natural laws, such as ideal concentration of therapeutic drugs, do not satisfy subject matter eligibility requirements). The Supreme Court decisions regarding the eligibility of genetic patent claims raise concerns regarding the validity of patents encompassing genetic elements. See Christopher W. Genheimer, *A Myriad of Solutions? A Guide for Biotech Companies in Response to the Myriad & Mayo Decisions*, 7 ELON L. REV. 431, 431 (2015) (stating that the patent eligibility requirements eliminate protection for developments in genetics such as diagnostic testing).

¹⁵ See Klein, *supra* note 3 (explaining that biotechnology that reflects a discovery in nature and not a manmade creation may fail to satisfy the requirements for patent protection). A decision invalidating the patents for CRISPR technology would undermine years of litigation establishing who first invented the technology, litigation that the parties have spent over ten million dollars on. See *id.* (observing that millions of dollars have been spent over the ownership rights of CRISPR patents). But see Ku, *supra* note 13, at 436 (arguing that the structural differences in the cellular components of CRISPR applied to humans should satisfy the threshold question of eligibility).

¹⁶ See *Mayo*, 569 U.S. at 71 (stating that a claimed patent involving naturally occurring elements must apply the element in some manner for subject matter eligibility); see also 35 U.S.C. § 101 (imposing a requirement that a patent only covers an invention or discovery of a "process . . . or composition of matter").

¹⁷ See Kotagama et al., *supra* note 9, at 2 (highlighting that various bacteria utilize CRISPR without human interferences); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 751 (Fed. Cir.) (affirming that a method for detecting antibodies to test for underlying diseases fails to satisfy patent requirements for subject matter eligibility), *reh'g denied*, 927 F.3d 1333 (Fed. Cir. 2019) (en banc). Public response to the Supreme Court's decisions regarding subject matter eligibility for patents highlights the impact the decisions have had on the life sciences. See U.S. PAT. & TRADE-MARK OFF., PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 34–35 (2017), https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf [<https://perma.cc/9DMB-2SA8>] [hereinafter PTO RESPONSE TO PUBLIC] (observing that subject matter eligibility requirements affect the life sciences because of the subject's close link to natural phenomena).

¹⁸ See PTO RESPONSE TO PUBLIC, *supra* note 17, at 35 (noting that individuals from various biotechnology companies expressed "especially strong" criticism of the subject matter eligibility re-

tent requirements, the legislature has yet to weigh in on the scope of the eligibility requirements.¹⁹

In response to the backlash arising from the subject matter eligibility requirements, members of Congress have begun working toward legislative solutions to the concerns over biotechnology patents.²⁰ House Representative Thomas Massie introduced to the 117th Congress the Restoring America's Leadership in Innovation Act of 2021 (RALIA), which seeks to expand patent eligibility by replacing the current framework for analyzing patentable subject matter with a single statutory rule.²¹ Senator Thom Tillis introduced the Patent Eligibility Restoration Act (PERA) of 2022 to address uncertainty over eligibility of various discoveries and inventions for patent protection.²² PERA would amend 35 U.S.C. § 101 to directly address what “useful process” or “composition of matter” remains eligible for a patent by creating a list of excluded processes and materials.²³ In 2023, Senators Tillis and Chris Coons re-introduced PERA with slight changes to the language of the eligibility exclu-

quirements for patents). Circuit judges have also expressed frustration with the lack of clarity on how to apply the Supreme Court's framework and encouraged Congress to adopt new legislation defining the outer bounds of subject matter eligibility. *See, e.g., Athena* 927 F.3d at 1337 (Hughes, J., concurring) (expressing that necessary distinctions between patents for natural laws and inventions should come from Congress); *id.* at 1363 (Moore, J., dissenting) (expressing that current subject matter eligibility rules prevent diagnostic tests from patent protection despite the statute permitting such protection).

¹⁹ *See infra* notes 33–34 and accompanying text (explaining that subject matter eligibility does not exist as a statutory requirement, but instead as a limitation imposed by the Supreme Court).

²⁰ *See* Malathi Nayak, *Tillis, Coons Vet Patent Eligibility Bill Principles with Stakeholders*, BL (Mar. 26, 2019), <https://news.bloomberglaw.com/ip-law/tillis-coons-vet-patent-eligibility-bill-principles-with-stakeholders> [<https://perma.cc/274F-6J5N>] (reporting that Senators Chris Coons and Thom Tillis convened with members of the pharmaceutical industry to discuss legislative changes to patent eligibility requirements); Press Release, Thom Tillis, *Tillis Introduces Landmark Legislation to Restore American Innovation* (Aug. 3, 2022), <https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation> [<https://perma.cc/7YP8-VH28>] [hereinafter Tillis Press Release] (announcing that Senator Tillis introduced legislation to propose a list of ineligible subject matter for patent protection).

²¹ *See* Press Release, Thomas Massie, *Massie Introduces Patent Reform Legislation Restoring “First to Invent” Protection to Inventors* (Nov. 5, 2021), <https://massie.house.gov/news/documentsingle.aspx?DocumentID=395411> [<https://perma.cc/86Y5-76CM>] [hereinafter Massie Press Release] (announcing the introduction of RALIA to the House of Representatives); KEVIN J. HICKEY, CONG. RSCH. SERV., R45918, *PATENT-ELIGIBLE SUBJECT MATTER REFORM: BACKGROUND AND ISSUES FOR CONGRESS* 40 (2022) (explaining that RALIA abrogates Section 101 jurisprudence of the Supreme Court). RALIA also reverses the change to a first to invent system of granting patents adopted by the America Invents Act. Massie Press Release, *supra*.

²² *See* Tillis Press Release, *supra* note 20 (stating that the Senate received PERA for consideration).

²³ *See* Patent Eligibility Restoration Act of 2022, S. 4734, 117th Cong. § 2 (2022) (amending the text of 35 USC § 101 to grant patents for any “useful process” or “composition of matter” except those subject to a list of exclusions added to the code).

sions.²⁴ Either PERA or RALIA would effectively supersede the framework adopted by the Supreme Court for addressing eligible subject matter, but each bill approaches this change in a different manner.²⁵ This Note argues that legislative action must be taken to clarify the uncertainty surrounding patentable subject matter, and that although PERA better addresses the main concerns with the eligibility requirement than RALIA, any legislative bill must also clearly establish that genes and nucleotide sequences cannot receive patent protection.²⁶

Part I of this Note explores the history of the subject matter eligibility doctrine following the Supreme Court's reexamination of Section 101 and assesses the impact of these decisions on patents for biotechnology.²⁷ Part II addresses both RALIA and PERA amendments to Section 101, as well as their efforts to provide greater guidance to the life sciences industry for patenting technologies that utilize natural biological products.²⁸ Part III suggests that PERA takes necessary steps to clarify subject matter eligibility of biological products, but requires further revisions to properly define what biological materials should remain excluded from patent claims.²⁹

I. THE STATE OF THE SUBJECT MATTER ELIGIBILITY DOCTRINE POST-*MYRIAD*

The Constitution grants Congress the authority to establish exclusive rights on behalf of inventors for their discoveries "to promote the Progress of Science."³⁰ A patent effectively grants its holder a monopoly over their product

²⁴ See Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. § 3 (2023) (creating a carveout for otherwise ineligible processes where the steps "cannot practically be performed without the use of a machine or manufacture"); Press Release, Chris Coons, Senators Coons, Tillis Introduce Patent Eligibility Restoration Act to Revitalize American Innovation (June 22, 2023), <https://www.coons.senate.gov/news/press-releases/senators-coons-tillis-introduce-patent-eligibility-restoration-act-to-revitalize-american-innovation> [<https://perma.cc/76X9-VSTV>] [hereinafter Coons Press Release] (identifying inconsistent application of the eligibility doctrine and widespread criticism as the basis for amending Section 101).

²⁵ See S. 2140, § 3 (adopting a list of ineligible processes and materials); HICKEY, *supra* note 21, at 40 (noting that PERA abrogates the judicially created categories of ineligible subject matter in favor of statutory categories created by the bill); Restoring America's Leadership in Innovation Act of 2021, H.R. 5874, 117th Cong. § 7(a) (2021) (proposing a single statutory rule for excluding materials and processes from eligibility).

²⁶ See *infra* notes 157–208 and accompanying text.

²⁷ See *infra* notes 30–124 and accompanying text.

²⁸ See *infra* notes 125–156 and accompanying text.

²⁹ See *infra* notes 157–208 and accompanying text.

³⁰ U.S. CONST. art. I, § 8, cl. 8. One of the primary goals behind patent laws is the promotion of invention and the creation of new and useful tools by providing exclusive rights to a patent as an incentive for inventors to share their creations. See Burk & Lemley, *supra* note 2, at 1580 (explaining that exclusive rights to an invention outweigh the detriment of limiting public access to these inventions because of the incentive it provides for developing new creations). The development of biotech-

or process for a term of twenty years by preventing “others from making, using, . . . or selling the invention” within the United States.³¹ Inventors include a “claim” within their patent, which establishes the precise scope of an inventor’s monopoly over the machine or process developed.³² The United States Patent Act of 1952 established the statutory requirements applicants must satisfy to receive a patent, including utility or usefulness, novelty, non-obviousness, and sufficient enablement.³³ The Patent Act does not explicitly adopt limitations to what subject matter constitutes a patent eligible invention; rather, the judiciary independently developed rules to limit naturally occurring matter and ideas from patent protection and subsequently read this exclusion into the language of the statute.³⁴

Section A of this Part surveys the early history of patentable subject matter and its purpose of limiting the scope of what inventors could claim in their pa-

nology requires strict adherence to federal regulations, that in turn increases costs in an industry where adapting biological discoveries into useful drugs already entails risk and uncertainty. *See id.* at 1676 (highlighting that biotechnology relies heavily on patent protection because of the significant costs and time devoted to the creation of biotechnology).

³¹ *See* 35 U.S.C. § 154(a)(1)–(2) (establishing that patent holders shall have the exclusive right in the use of their invention for a twenty-year period). Courts have recently considered and rejected patent rights to artificial intelligence systems that generate new and useful inventions. *See* Brandon Furdock, *The State of Patent Eligibility*, CHI.-KENT J. INTELL. PROP.: J. BLOG (Feb. 26, 2023), https://studentorgs.kentlaw.iit.edu/ckjip/the-state-of-patent-eligibility/#_ftnref33 [<https://perma.cc/45QC-LMC5>] (discussing the benefits and drawbacks to granting patent rights to non-human inventors). With the growing prevalence of artificial intelligence in various industries, including biotechnology, amendments to patent law may become necessary to address the scope of patentability for non-human inventions. Alexandra George & Toby Walsh, *Artificial Intelligence Is Breaking Patent Law*, NATURE (May 24, 2022), <https://www.nature.com/articles/d41586-022-01391-x> [<https://perma.cc/SLK5-U6PV>] (arguing for legislative reform “that protects AI-generated inventions”).

³² *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 268 (1977) (explaining that patents do not monopolize the actual thing the inventor created, but rather contain an abstract claim that encompasses an indefinite amount of concrete embodiments of the inventor’s creation).

³³ *See* Genheimer, *supra* note 14, at 433 (noting that the primary policy goal of U.S. patent law aims to reward inventors and incentivize further innovation); 35 U.S.C. § 101 (requiring that inventions or discoveries be “useful” for patent protection, but not explicitly denying patent protection for abstract ideas or natural phenomena); *id.* § 102(a) (limiting the patentability of inventions to those not described or used publicly before the initial filing date of the patent); *id.* § 103 (rejecting patents for inventions that “would have been obvious . . . to a person having ordinary skill in the art . . .”); *id.* § 112(a) (stating that patents require a specification, meaning a written description, to allow a skilled person with familiarity in the field to replicate the invention).

³⁴ *See* Stephanie Bloss, *Taming the Monster: The 2019 Patent Eligibility Guidance Brings Stability Back to Patent Eligibility Doctrine*, 102 J. PAT. & TRADEMARK OFF. SOC’Y 545, 549–50 (2022) (noting that subject matter eligibility stems from “historical precedents” recognizing that ideas or laws of nature cannot receive patents). This limitation prevents patents from blocking innovation because objects in nature exist outside human intervention. *See id.* at 550 (noting that patents for natural phenomena inhibit invention because they restrict the tools of nature that all people inherently have access to); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (stating that natural phenomena “are manifestations of laws of nature, free to all men and reserved exclusively to none”).

tents.³⁵ Section B explores the recent decisions by the U.S. Supreme Court on patentable subject matter as it relates to claims in the biotech industry and the two-step test for determining subject matter eligibility for process patents.³⁶ Section C discusses the response by the lower courts and the United States Patent and Trademark Office (USPTO) to the new two-step test promulgated by the Supreme Court.³⁷ Finally, Section D examines the policy implications behind the subject matter eligibility doctrine and the impact this doctrine has had on the role of patents to incentivize innovation and research in the life sciences industry.³⁸

A. The Origins of Patentable Subject Matter

Prior to the twentieth century, only a few Supreme Court decisions addressed attempts to patent natural phenomena or abstract concepts.³⁹ In these cases, the Court consistently upheld the rule that abstract principles, if not reduced or embodied in some physical manifestation of the principle, could not be patented.⁴⁰ The primary inquiry in early cases examining the eligibility of a patent claim focused on whether the patent claimed an application of the principle in a machine or process rather than the principle in isolation.⁴¹ This rule developed as a means of preventing abuse of the monopoly that patents provide by requiring inventors to limit the scope of their claim to only their inven-

³⁵ See *infra* notes 39–59 and accompanying text.

³⁶ See *infra* notes 60–76 and accompanying text.

³⁷ See *infra* notes 77–101 and accompanying text.

³⁸ See *infra* notes 102–124 and accompanying text.

³⁹ See Asher Hodes, *Diagnosing Patentable Subject Matter*, 26 BERKELEY TECH. L.J. 225, 226 (2011) (acknowledging that during the 1800s, the Supreme Court only addressed the patentability of natural phenomena in five decisions). The rules regarding patentable subject matter derived from an English case, *Boulton v. Bull*, that considered whether a claimed method for building a better steam engine could receive patent protection. See *id.* at 225–26 (noting that *Boulton* first articulated the general rule that principles by themselves could not receive patents).

⁴⁰ See PTO RESPONSE TO PUBLIC, *supra* note 17, at 4 (explaining that principles or abstract concepts cannot receive patent protection because of judicially created rules regarding patent eligibility from the mid-nineteenth century); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112–13 (1854) (rejecting that a patentee may claim the application of electric currents for communication over long distances because the claim would cover all possible applications of the principle, including those the patentee has not reduced to practice); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 176–77 (1853) (rejecting a claim for use of existing machinery used in a new manner to produce higher quality pipes because the claim sought to patent a fundamental idea that pipes could be joined by high pressure rather than a specific process). Despite reference to abstract principles, the Court in *O'Reilly* failed to identify whether the enablement requirement or eligibility derived the limitation against patents for abstract ideas. See Raguraman Kumaresan, Yu v. Apple—*The Abstract Idea Conundrum: It's Time to Either Adopt the Dictionary Definitions or Abandon the Unworkable Abstract Idea Doctrine*, 56 UIC L. REV. 301, 311 (2023) (explaining the lack of consensus on the patent requirement the *O'Reilly* decision relied upon).

⁴¹ See *Le Roy*, 55 U.S. (14 How.) at 175 (stating that inventions consist of the application of natural elements and not the discovery of such elements).

tion.⁴² Many claims over abstract ideas also failed to demonstrate that the patent satisfied the novelty requirement because mere application of a principle to a preexisting machine or device did not constitute a new invention.⁴³ In effect, the rule that principles could not be patented forced prospective patentees to limit the scope of their claimed inventions to what they actually created instead of overly generalizing the claim language.⁴⁴

As technology continued to advance, patents started to push the boundaries of what could be considered a novel use of a natural principle to achieve a new goal and what merely claimed ownership of the underlying principle itself.⁴⁵ For example, the Court refused to recognize an assortment of bacterial strains as a patentable claim because the patent sought to exclude others from using a naturally existing product, the bacteria, rather than the process of mixing the bacterial strains together.⁴⁶ The Court invalidated the patent in part be-

⁴² See *O'Reilly*, 56 U.S. (15 How.) at 113 (affirming that patentees may not claim ideas as opposed to applications because doing so will cripple future inventors from uncovering new properties or discoveries of the concept). Although abstract ideas could not be patented, the Court did recognize that processes, such as in manufacturing, may receive protection, distinguishing natural principles from a means by which the patent holder used a principle to accomplish a task. See PTO RESPONSE TO PUBLIC, *supra* note 17, at 5 (citing *Tilghman v. Proctor*, 102 U.S. 707, 729–30 (1881)) (explaining that a process involves ingenuity in an art or trade, whereas a principle merely claims an observable truth); *cf.* *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 593–94 (1874) (acknowledging that although a process may be claimed, the resulting product from said process may not if it exists as a natural product).

⁴³ See *Am. Wood-Paper Co.*, 90 U.S. (23 Wall.) at 593–94 (explaining that a product of a patented process may not also be patented because its existence predates the process and thus lacks novelty); *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874) (rejecting a patent for the concept of rubber erasers on a pencil in part because application of the idea did not create a novel invention); *Le Roy*, 55 U.S. (14 How.) at 176–77 (explaining that the mere use of preexisting machinery to carry out a new discovery lacks novelty).

⁴⁴ See Alan L. Durham, *Natural Laws and Inevitable Infringement*, 93 MINN. L. REV. 933, 938–39 (2009) (observing that many early cases involving patentable subject matter involved the question of how broadly an inventor may claim the underlying discovery or creation); Hodes, *supra* note 39, at 226 (explaining that patents that incorporated natural laws survived judicial scrutiny when the inventor only claimed a particular method of applying the underlying concept). Patent claims serve the dual role of protecting the inventor's monopoly interest and notifying the public of the claimed technology. See Kelly Casey Mullally, *Patent Hermeneutics: Form and Substance in Claim Construction*, 59 FLA. L. REV. 333, 335 (2007) (acknowledging that patent claims, though created by private parties, significantly impact the public at large if issued).

⁴⁵ See Hodes, *supra* note 39, at 226–27 (observing that jurisprudence of patentable natural laws developed alongside the introduction of new fields of industry, including the use of electromagnetism in machinery and genetically modified organisms).

⁴⁶ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (explaining that the inherent qualities of natural products, like bacteria, exist because of nature and thus cannot be monopolized). The patent did not claim the actual method used to isolate bacterial strains for maximum utility, but instead whether the mixture of various strains could receive protection. *Id.*

cause a discovery, once uncovered, involved an obvious approach to take advantage of the natural law and thus does not involve an inventive concept.⁴⁷

The Court read the limitation that natural products must remain excluded from patentable subject matter into the statutory requirements adopted by the Patent Act of 1952.⁴⁸ The test for eligible subject matter sought to determine whether the claimed invention could be considered a “process” as used in Section 101, or instead an abstract idea.⁴⁹ This interpretation of Section 101 excluded from patentable subject matter any device or machine that merely applied a newly discovered principle or idea, such as a mathematical formula, to an existing invention.⁵⁰

The refusal to permit a patent for discovered features of nature or developed mathematical formulas created tension with one of the underlying goals driving patent law, the promotion and development of useful discoveries and creations.⁵¹ Patents already sacrifice public access to beneficial creations in exchange for an incentive for inventors to develop practical inventions.⁵² The

⁴⁷ See *id.* at 132 (explaining that the use of the bacteria as an inoculant merely applied a discovery of nature in an obvious manner and thus lacked any inventiveness). Patents must be non-obvious for protection, meaning the invention incorporates some novel or inventive element that extends beyond a simple improvement based on known inventions. See Durham, *supra* note 44, at 971 (noting that the focus of the non-obviousness requirement rests on the notable differences between the invention and all other prior creations). The Court, by positing that the inoculant appeared to be an obvious invention in light of the new discovery, suggested that once a discovery becomes known, the discovery must be treated as encompassed in the prior art of the trade. See *Funk Bros.*, 333 U.S. at 132 (acknowledging that the discovery of the ideal mixture of bacteria made production of the inoculant a straightforward task).

⁴⁸ See Genheimer, *supra* note 14, at 433–34 (observing that the Court interpreted Section 101 to exclude natural laws and abstract concepts from eligible subject matter). Section 101 does not explicitly limit what may be patent eligible but instead states that the inventor must create or discover a “useful process . . . or composition of matter . . .” 35 U.S.C. § 101; see *Parker v. Flook*, 437 U.S. 584, 589 (1978) (acknowledging that subject matter eligibility limitations cannot be read literally from the language of Section 101).

⁴⁹ See *Flook*, 437 U.S. at 589 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)) (explaining that principles must be understood as universal truths akin to natural law).

⁵⁰ See Bloss, *supra* note 34, at 550–51 (noting that the dominant test in the late 1900s for assessing patent eligibility involved a determination of whether the invention transformed or altered an object into a useful article or otherwise produced a concrete result); *Flook*, 437 U.S. at 594–95 (explaining that if the only novel feature of a device, such as an alarm clock, is the formula used to determine when to set off the alarm, then the claim effectively places a monopoly on the formula itself). But see *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 310 (1980) (upholding a patent for a strain of bacteria because the strain did not naturally exist, but instead required human intervention to develop and isolate a unique strain with different characteristics from those that exist in nature).

⁵¹ See Durham, *supra* note 44, at 950–51 (positing that landmark discoveries of mathematical formulas deserve greater rewards, not fewer, because of the significance of their contributions to mankind).

⁵² See Burk & Lemley, *supra* note 2, at 1597 (highlighting that a broad consensus exists that patents serve the utilitarian purpose of encouraging invention and progress at the expense of permitted limited monopolies). The difficulty in assigning patent rights involves balancing the need to provide economic incentives for inventors with the need to protect public access to these new creations and

Court justified the new limitations to eligibility as a means of ensuring the scope of patents did not extend too broadly so as to claim applications of a principle which the inventor did not develop.⁵³ The limitation has also been characterized as a means of promoting human ingenuity over mere discovery of a useful natural law.⁵⁴

Shifting the focus of the eligibility requirement to whether the invention applied a natural law or process in some manner appeared to conflict with the main policy objectives of the Patent Act of 1952.⁵⁵ Prior to 1952, each of the patent requirements for new inventions existed in a single section of the statutory code.⁵⁶ The new law sought to clarify the requirements of patentability by separating the individual elements into new statutory sections.⁵⁷ By separating the rule limiting eligibility from the other statutory requirements, like enablement, non-obviousness, and novelty, the revised code made eligibility a rela-

facilitate further innovation. *See id.* at 1599 (explaining that the scope of patent rights lies within a spectrum that weighs the strength of the right against the barriers such rights place against innovation); *see also* Amy Landers, *Patentable Subject Matter as a Policy Driver*, 53 HOUS. L. REV. 505, 511 (2015) (acknowledging that patent law acts as a driver of innovation in the health care industry because the broad protection outweighs the heavy costs associated with the discovery of new treatments and time-consuming regulatory review).

⁵³ *See* Burk & Lemley, *supra* note 2, at 1642–43 (identifying that by excluding abstract ideas from eligibility, future inventors could not claim broad applications of a concept that they failed to reduce to practice); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 134 (1948) (Frankfurter, J., concurring) (arguing that a patent for a mixture cannot claim the properties of said mixture, but must limit its scope by claiming the composition itself); O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1854) (explaining that a patent which covers a principle of science would grant the inventor a monopoly over undiscovered applications of the principle).

⁵⁴ *Compare* Funk Bros., 333 U.S. at 131 (explaining that a claim for a discovered bacterial mixture cannot stand because the claim rests solely on the ingenuity of nature rather than an application of the discovery in some novel way), *with* Diamond, 447 U.S. at 309, 310 (recognizing that a patent for a strain of bacteria may be allowed where the strain owes its existence to the work of the inventor and not nature itself). Many cases involving patent eligibility focused on the degree of human intervention and whether such intervention altered what otherwise occurs naturally. *See* Hodes, *supra* note 39, at 239 (acknowledging that the Federal Circuit relied on the transformation test as a straightforward test for excluding preempted subject matter).

⁵⁵ *See* Diamond, 447 U.S. at 309 (quoting S. REP. NO. 1979, at 5 (1952)) (noting the intent of Congress to allow for “anything under the sun” to satisfy eligibility). Although Section 101 includes no exclusion for discovered phenomena, the Court read an exclusion into the statute. *See* Flook, 437 U.S. at 593 (explaining that the statute carries an implicit understanding that natural laws fall outside the “discovery” contemplated by Section 101).

⁵⁶ *See* David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. 157, 169–70 (2016) (observing that all patent requirements had been originally phrased in one sentence of the statutory code).

⁵⁷ *See id.* at 170–71 (explaining that the Patent Act of 1952 simplified the requirements of patentability by dividing the requirements across different sections of the code). The new language for eligible subject matter in Section 101 aimed to clarify eligibility by enabling any conceivable creation to satisfy eligibility. *See* Bloss, *supra* note 34, at 549 (positing that the revised language broadened the scope of what satisfied the patent eligibility requirement).

tively easy threshold issue to overcome.⁵⁸ Although Congress intended for inventions to satisfy Section 101 with ease, the other patentability requirements would place stronger limits on what inventions could receive protection and serve as a gatekeeper of inventions unworthy of protection.⁵⁹

*B. Mayo, Myriad, and the Supreme Court's Interpretation of
Subject Matter Eligibility*

In 2012, in *Mayo Collaborative Services v. Prometheus Laboratories*, the United States Supreme Court addressed whether a diagnostic test for the ideal concentration of thiopurine drugs applied a natural phenomenon or merely claimed the phenomenon itself.⁶⁰ The patentability of diagnostic testing more broadly remained an unresolved question prior to this decision due to the difficulty in discerning the underlying mathematical and natural processes from the machines and techniques used to apply them.⁶¹ Prometheus Laboratories patented research that identified the correlation that existed naturally between metabolite concentration in an individual's bloodstream and the appropriate dosage of the drug thiopurine to administer based on that concentration.⁶²

⁵⁸ See Maayan Perel, *Reviving the Gatekeeping Function: Optimizing the Exclusion Potential of Subject Matter Eligibility*, 23 ALB. L.J. SCI. & TECH. 237, 242 (2013) (noting that Section 101 acts a weak gatekeeper of what subject matter may even be considered patent eligible).

⁵⁹ See Taylor, *supra* note 56, at 175 (arguing that eligibility must be considered in conjunction with the other requirements for patentability so as to not broaden the reach of Section 101). Congress intended the bar for eligibility to remain low so that even scientific discoveries could qualify for protection. See Jeffrey A. Lefstin, Peter S. Menell & David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 570–71 (2018) (noting that patents should be awarded to scientific discoveries because it would encourage progress in scientific disciplines regardless of whether the scientist applied the principle in an inventive manner).

⁶⁰ See *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72 (2012) (acknowledging that diagnostic testing teeters on the edge of what constitutes an application of natural law rather than a restatement of natural law).

⁶¹ See Durham, *supra* note 44, at 978–79 (recognizing that the Federal Circuit grappled with whether apparatuses that took simple measurements and analyzed an output fell within the natural laws and phenomena exceptions of patent eligibility); Hodes, *supra* note 39, at 242 (acknowledging that patents related to means of performing diagnostic correlations are neither universally eligible or ineligible for protection, but rely in part on the degree of human intervention). Most if not all processes or inventions incorporate naturally occurring products or phenomena, making the line between patents that recite a natural phenomenon and patents that apply it ambiguous. See Durham, *supra* note 44, at 949 (explaining that patented inventions necessarily utilize the tools that nature provides); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 134–35 (1948) (Frankfurter, J., concurring) (arguing against an exception to eligibility for “laws of nature” because all patents, when broken down to their core elements, utilize naturally existing tools).

⁶² *Mayo*, 566 U.S. at 73–74. Thiopurine drugs break down into metabolites once administered to a patient suffering from an autoimmune disease. Hodes, *supra* note 39, at 234–35. Because of severe side effects associated with the drug, including nausea, toxic bone marrow, and pancreatitis, doctors must closely monitor patients to alleviate the side effects. See Ben Warner et al., *A Practical Guide to Thiopurine Prescribing and Monitoring in IBD*, 9 FRONTLINE GASTROENTEROLOGY 10, 13 (2016)

Prometheus Laboratories argued that the Mayo Clinic infringed on their patent by administering the same diagnostic test to their patients, only using a slightly lower threshold for assessing toxicity.⁶³ Nevertheless, the Court struck down the patent, noting that the claim did little more than recite a natural relationship, the optimal dosage of thiopurine in connection to the concentration of blood metabolites.⁶⁴ The Court noted that the only human intervention in applying the test consisted of routine activities already commonly performed by qualified individuals in the field, meaning any inventive concept from the patent existed only in the discovery of the natural relationship and not in application of that relationship.⁶⁵

Just one year later, the Court confronted the issue of whether short segments of DNA isolated from the rest of the human genome, or genes, could be patented.⁶⁶ In 2013, in *Association for Molecular Pathology v. Myriad Genetics*, the United States Supreme Court determined that any segment of DNA as it exists in the human body could not be patented, but that complimentary DNA (cDNA) satisfied eligibility because it required human ingenuity to produce and did not exist as a byproduct of nature.⁶⁷ The Court revoked the patent for the BRCA1 gene because it claimed nothing more than the sequence of nucleotides that naturally exist in the body and not any specific molecule or chemical composition developed by the company.⁶⁸ By contrast, cDNA requires first convert-

(explaining that patients taking thiopurines may suffer several severe symptoms which each require unique treatments).

⁶³ *Mayo*, 566 U.S. at 75.

⁶⁴ *See id.* at 77 (holding that a claim must do more than describe natural phenomena, but instead incorporate some significant human intervention).

⁶⁵ *See id.* at 79 (observing that the patented process involved no human activity beyond that which scientists and other professionals already regularly engage in when examining metabolite levels); *see also Funk Bros.*, 333 U.S. at 132 (explaining that the patent failed to claim more than a naturally occurring interaction between bacteria and otherwise routinely applied steps for making inoculants). By requiring that human application of the natural law extend beyond routine steps, the test for patentable subject matter echoes the novelty requirement by asking whether the steps taken are commonly employed in the industry. *See* 35 U.S.C. § 102 (denying patents that fail to do more than replicate prior art already known and used by the public).

⁶⁶ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013). When an individual inherits a mutated variant of the BRCA1 gene, the risk of breast cancer developing later in life grows significantly. *See The BRCA1 and BRCA2 Genes*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 20, 2023), https://www.cdc.gov/genomics/disease/breast_ovarian_cancer/genes_hboc.htm [<https://perma.cc/P7TZ-427N>] (recognizing that mutations of the BRCA1 gene increases the likelihood of developing breast and ovarian cancers). Genetic testing for mutations in the BRCA1 region of a patient's genome and family history of breast cancer assists doctors in assessing the risk that a patient will develop cancer. *Id.*

⁶⁷ *See Myriad*, 569 U.S. at 580 (highlighting that the eligibility of cDNA rested on the fact that it does not naturally exist within the body).

⁶⁸ *See id.* at 592–93 (explaining that Myriad's patent merely recited the gene locations and not any invented substance). BRCA1 is a genetic sequence found in all humans. *BRCA: The Breast Cancer Gene*, NAT'L BREAST CANCER FOUND., INC., <https://www.nationalbreastcancer.org/what-is-brca/> [<https://perma.cc/3J7P-XBAB>] (Jan. 17, 2024). Genetic mutations to this sequence of DNA correlates

ing the gene sequence to a molecule known as mRNA before using a process known as reverse-transcriptase to convert the mRNA into cDNA.⁶⁹ cDNA satisfied subject matter eligibility because, although the BRCA1 gene provided the nucleotide sequence used to construct cDNA, the molecule can only exist when scientists intervene with naturally occurring processes.⁷⁰

In analyzing the eligibility of biotechnology, the Supreme Court shifted the focus away from the breadth of the claimed invention to the question of whether the inventor intervened enough with natural phenomena to create a product or process.⁷¹ Thus, applications for method patents that involve abstract ideas required some “inventive concept” to make the claimed process patent eligible.⁷² The need for an inventive concept to save a patent claiming a

to higher risks of developing breast cancer, particularly in women. *Id.* A patent claim for a DNA molecule containing the BRCA1 sequence, though not before the Court, would likely be of little value to a patent holder because making slight alterations to the sequence, such as changing single nucleotides, would avoid the patent’s scope entirely. See *Myriad*, 569 U.S. at 593 (acknowledging that patent claims for physical molecules incorporating the gene sequence could be circumvented with little difficulty).

⁶⁹ See Lin Feng et al., *Technique for Strand-Specific Gene-Expression Analysis and Monitoring of Primer-Independent cDNA Synthesis in Reverse Transcription*, 52 *BIO TECHNIQUES* 263, 265 (2012) (detailing the steps to perform cDNA synthesis of genes using reverse transcription). cDNA represents a copy of the gene sequence with the primary difference being the lack of intron sequences, or non-coding regions of DNA that cells excise prior to coding proteins. See *Myriad*, 569 U.S. at 581–82 (explaining that cDNA lacks the introns typically removed when the cell converts DNA into RNA).

⁷⁰ See *Myriad*, 569 U.S. at 595 (noting that cDNA involves work by a lab technician to produce and thus does not exist as a “product of nature”). Although *Myriad* did not seek a process patent for the method of isolating the BRCA1 gene as a DNA molecule, such a patent would likely be deemed invalid because the patent would be obvious considering techniques commonly used by geneticists in the field. See *id.* at 595–96 (explaining that *Myriad*’s method of isolating DNA molecules of the BRCA1 gene involved steps scientists regularly and uniformly performed); *Funk Bros.*, 333 U.S. at 132 (explaining that the creation of an inoculant involved simple, routine steps commonly performed in the industry, thus invalidating the patent).

⁷¹ Compare *Myriad*, 569 U.S. at 580 (holding that only cDNA, and not the gene itself, could receive a patent because cDNA does not exist naturally in the cell), and *Mayo Collaborative Servs. v. Prometheus Lab’s, Inc.*, 566 U.S. 66, 82 (2012) (holding that a patent for measuring the proper drug dosage using blood concentration of naturally occurring metabolites involved nothing more than routine steps in the industry and thus effectively patented the natural law itself), with *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 112–13 (1854) (holding that a patent for a natural principle cannot be sustained because the inventor would monopolize applications of the principle they have not actually created).

⁷² See *Genheimer*, *supra* note 14, at 438 (explaining that a patent requires an “inventive concept” that incorporates non-obvious procedures to carry out the natural principle). Incorporating a non-obvious step into the patented process may also serve an additional purpose in limiting the breadth of the patent to enable iterative innovation. See *Mayo*, 566 U.S. at 86 (explaining that the danger in granting patents for natural laws comes from the barriers it poses to future invention and improvements such a monopoly would ensure). The use of an inventive concept thus provides a bright line rule that can be used to distinguish patents that extend too far. See *Funk Bros.*, 333 U.S. at 133–34 (Frankfurter, J., concurring) (arguing that the true issue with the patent for bacterial inoculants involved claiming all possible strains rather than just those the patentee invented); see also *Hodes*, *supra* note 39, at 242–43 (suggesting that a “human intervention standard” could limit patent scope involving natural processes to not tie up other uses of the principles).

law of nature opens an inquiry into the regular practices of people trained in the industry, a question that overlaps with other patent requirements.⁷³ The Supreme Court established a two-step inquiry to determine whether a claim does more than recite a natural phenomenon in a process patent.⁷⁴ This test involves first identifying the abstract idea more broadly, and second, determining if the claim adds an inventive concept that transforms an otherwise ineligible idea into a patent-eligible application of the natural phenomenon.⁷⁵ For a naturally occurring product to become eligible for a patent, the inventor must manipulate the matter in some manner such that the product becomes something nature does not already produce.⁷⁶

C. The Lower Courts and USPTO Grapple with Subject Matter Eligibility

Following the Supreme Court's guidance on subject matter eligibility, federal courts began to invalidate patents based around genetic testing for failure to incorporate inventive concepts into their claims.⁷⁷ For example, the Federal Circuit struck down a method patent for amplifying and testing DNA in the bloodstream of pregnant women to detect potential genetic defects of the fetus.⁷⁸ The court explained that although the patent did not preclude other us-

⁷³ See *Myriad*, 569 U.S. at 595–96 (noting that a patent for the process of isolating a gene likely cannot be sustained given that the steps used to isolate DNA are fairly routine); *Mayo*, 566 U.S. at 82 (holding that a patent for a natural law cannot be sustained by simply adding routine steps employed in the industry to the process); 35 U.S.C. § 103 (explaining that patents will not satisfy eligibility if the improvement on preexisting inventions appears obvious to an individual with experience in the industry).

⁷⁴ See *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217–18 (2014) (detailing a two-step process for satisfying the requirements of Section 101).

⁷⁵ See *id.* (explaining that patent eligible claims involving natural phenomena require an “inventive concept” that turns the invention into an application of the phenomena); see also *Landers*, *supra* note 52, at 525 (positing that the Supreme Court drew the line in what constituted patentable subject matter based on the question of if the claimed creation could exist absent human intervention).

⁷⁶ See *Genheimer*, *supra* note 14, at 442 (observing that genetic material manipulated in some manner, such as cDNA, likely survives the subject matter eligibility requirements promulgated by the Supreme Court); *Myriad*, 569 U.S. at 580 (stating that cDNA satisfied eligibility because the molecule does not naturally exist, but that DNA based on existing genetic sequences cannot be claimed in a patent).

⁷⁷ See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373, 1376 (Fed. Cir. 2015) (invalidating a patent for testing genetic defects using DNA); *Genetic Veterinary Scis., Inc. v. Canine EIC Genetics, LLC*, 101 F. Supp. 3d 833, 834 (D. Minn. 2015) (determining that a patent for detecting cancer in dogs using genetic testing failed to incorporate an inventive concept).

⁷⁸ See *Ariosa*, 788 F.3d at 1377–78 (explaining that the patent merely claimed routine steps for detecting samples of DNA). The process for amplifying strands of DNA, polymerase-chain reaction (PCR), must also be employed to obtain cDNA strands of known genes. See *Feng et al.*, *supra* note 69, at 263 (detailing the use of PCR to obtain enough copies of the cDNA strand for detection). Thus, mere discovery of a gene sequence, combined with amplification of the DNA region, does not suffice as an inventive concept to warrant patent protection. Compare *Ariosa*, 788 F.3d at 1377 (describing PCR as a conventional technique used by scientists), with *Myriad*, 569 U.S. at 594–95 (determining

es of the DNA incorporated into the claim language, the limited scope did not save the patent from its failure to incorporate an inventive concept.⁷⁹ Patents that claimed DNA primers, or short nucleotide sequences used to create DNA molecules from naturally occurring genes, failed to satisfy eligibility requirements because the primers claimed the same kind of materials as the gene patents invalidated in *Myriad*.⁸⁰

Since the Supreme Court handed down decisions on patent-eligible subject matter, the Federal Circuit has yet to recognize a patent-eligible genetic diagnostic test because such tests fail to employ anything more than conventional steps in the industry.⁸¹ At the time of the *Myriad* decision, the USPTO had granted over twenty thousand patents that included nucleotide sequences into the claim language, with a significant subset of these patents claiming isolated sequences of DNA.⁸² The percentage of patents found invalid for ineligible subject matter more than doubled between 2014 and 2017.⁸³ Many important advances in biotechnology depend upon the discovery of natural processes and products in the human body than can be implemented into therapeutic

that cDNA satisfies patent eligibility requirements because the techniques used in the laboratory involve inventive activity).

⁷⁹ See *Ariosa*, 788 F.3d at 1379 (holding that even though the limited scope of the patent carefully enabled other potential uses of the DNA, the primary question is not the scope of the claims but instead whether the claims cover eligible subject matter). The refusal to grant patents for important discoveries, despite their limited scope, runs contrary to one of the stated goals of subject matter eligibility. See *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1854) (explaining that the danger of allowing patents for principles came from the monopolization such patents held over undiscovered applications of the principle).

⁸⁰ See *In re BRCA1-Based Hereditary Cancer Test Pat. Litig.*, 774 F.3d 755, 760 (Fed. Cir. 2014) (holding that primers cannot be distinguished from genes as patentable subject matter because the sequence of nucleotides exists because of nature and not from man). Method patents for screening for mutations involved the use of PCR and other routine steps performed by scientists researching genes, and thus lacked an inventive concept to satisfy eligibility requirements. See *id.* at 763–64 (holding that the process for detecting mutations and determining risks associated involved nothing more than restating the natural law and asking to apply it).

⁸¹ See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (en banc) (Moore, J., dissenting) (expressing that the current interpretation of Section 101 eliminated diagnostic testing as patentable subject matter). Diagnostic testing claims fail because the novel step across the claims involves the mental step of reading the results and comparing them to a known relationship, or otherwise observing a natural law. See *id.* at 1336 (Lourie, J., concurring) (acknowledging that the only consistent interpretation of Supreme Court decisions resolving issues of patentable subject matter requires invalidating patents for diagnostic tests that merely observe natural laws); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1372 (Fed. Cir. 2018) (explaining that observation of the relationship between the sample and known phenomena does not involve an inventive concept).

⁸² See Gregory D. Graff et al., *Not Quite a Myriad of Gene Patents*, 31 NATURE BIOTECHNOLOGY 404, 406, 408 (2013) (calculating that tens of thousands of patents involved claims over nucleotide sequences).

⁸³ See Lefstin et al., *supra* note 59, at 576–77 (observing that challenges under Section 101 for patent eligible subject matter have increased since the *Mayo* decision).

tics.⁸⁴ But the ingenuity and research necessary to make these discoveries fails to transform them into patentable subject matter.⁸⁵ As a consequence, courts have reluctantly applied the Supreme Court's eligibility test.⁸⁶

Courts have continued to struggle with distinguishing the test for subject matter eligibility with other patent requirements in the statute, such as novelty, non-obviousness, and enablement.⁸⁷ Novelty requires that a patent claim some element or step not made publicly known or available.⁸⁸ The non-obvious requirement also looks to what methods and techniques trained individuals in the industry use, known as the "prior art," when assessing whether the claim rep-

⁸⁴ See PTO RESPONSE TO PUBLIC, *supra* note 17, at 35 (noting that representatives in life sciences rely on isolating products from the body to create biopharmaceutical treatments); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 757 (Fed. Cir.) (Newman, J., dissenting) (noting that despite the importance of diagnostic testing for previously undiagnosable disorders, the patents for the discovery failed the eligibility requirements), *reh'g denied*, 927 F.3d 1333 (Fed. Cir. 2019); see also Richard A. Gibbs, *The Human Genome Project Changed Everything*, 21 NATURE 575, 576 (2020) (explaining that discovery of the genes responsible for underlying diseases presents the first barrier for developing treatments). Despite the importance of gene discovery as a means of treating patients, the efforts taken to determine what genes cause diseases cannot receive patent protection. See *Ass'n for Molecular Pathology. v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013) (holding that genes cannot receive patent protection).

⁸⁵ See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379–80 (Fed. Cir. 2015) (explaining that despite the significance of the discovery of detectable DNA in blood plasma and its impact on medical science, the innovation does not satisfy statutory requirements for patentability); see also *Myriad*, 569 U.S. at 591 (noting that "innovative" discoveries do not satisfy statutory patentability requirements purely by virtue of their impact on the industry).

⁸⁶ Paul R. Gugliuzza & Pyry P. Koivula, *Stepping Out of the Solicitor General's Shadow: The Federal Circuit and the Supreme Court in a New Era of Patent Law*, 64 B.C. L. REV. 459, 508 (2023) (making note of decisions by the Federal Circuit where judges expressed disapproval of the eligibility framework despite applying it to invalidate patents). The Supreme Court has generally demonstrated a lack of interest in revisiting the eligibility doctrine. See *id.* at 463 (highlighting the surprising denial of certiorari of an eligibility case and the Court's lack of interest in reviewing patent decisions); see also Dennis Crouch, *Kavanaugh Signals Openness to Revisiting Patent Eligibility Framework as Supreme Court Declines CareDX Petition*, PATENTLY-O (Oct. 2, 2023), <https://patentlyo.com/patent/2023/10/kavanaugh-revisiting-eligibility.html> [<https://perma.cc/RS8E-8GGJ>] (reporting that of the current Court, only Justice Kavanaugh expressed an interest in revisiting the eligibility of diagnostic patents).

⁸⁷ See *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018) (acknowledging that subject matter eligibility involves fact-sensitive questions that overlaps other patent requirements). The Supreme Court expressly distinguishes the question of eligibility from other requirements, like novelty and obviousness. See *Parker v. Flook*, 437 U.S. 584, 588 (1978) (asserting that the discovery of the formula utilized by the patent satisfies the novelty requirement). Despite this, analyzing subject matter eligibility requires information about routine and conventional steps, evoking similar facts as determining the scope of prior art in the industry. See *Mayo Collaborative Servs. v. Prometheus Lab's, Inc.*, 566 U.S. 66, 79 (2012) (explaining that the patent claimed application of a natural law using routine and conventional activity and thus does not meet the eligibility threshold).

⁸⁸ 35 U.S.C. § 102(a). When assessing the validity of an infringement claim for a design patent, courts will ask whether "in the eye of the ordinary observer . . . [the] two designs are substantially the same." *Int'l Seaway Trading Corp. v. Walgreens Corp.*, 589 F.3d 1233, 1239 (Fed. Cir. 2009) (quoting *Gorham Co. v. White*, 81 U.S. (14 Wall.) 511, 528 (1871)).

resents merely an obvious improvement from what existed before.⁸⁹ Analysis of patentable subject matter implicates similar questions about what methods and techniques other experts utilized in the industry.⁹⁰ Supreme Court decisions on eligibility thus echoed many of the same concerns that other patent law requirements already address.⁹¹ Unlike with challenges to novelty and non-obviousness, however, courts frequently address eligibility on a motion to dismiss because it is viewed as a question of law, making it challenging for courts to independently assess what techniques experts in the field utilized.⁹²

Valid patents for method claims survive challenges to subject matter eligibility by establishing that the subject matter does not direct itself at an abstract idea or natural law, but instead a process or technique under the first part of the two-step inquiry.⁹³ The difficulty with this approach comes from the lack of a clear definition of what can be considered an abstract idea as opposed

⁸⁹ See 35 U.S.C. § 103 (requiring that all claimed inventions not distinguish themselves using obvious improvements that someone with ordinary skill would think to incorporate). “Prior art” refers to all inventions and creations of man developed before the inventor created their patented invention. See Taylor, *supra* note 56, at 194 (explaining that the term “prior art” derived its meaning from archaic language used when the first patent laws passed).

⁹⁰ See *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 890 F.3d 1354, 1355–56 (Fed. Cir. 2018) (en banc) (Moore, J., concurring) (acknowledging that although patent eligibility may typically be addressed as a question of law, it encompasses factual issues that overlap with other requirements, such as novelty). The overlap of issues may be reconciled by incorporating natural law into the scope of prior art, meaning ineligible subject matter also fails to satisfy the novelty requirement. See *id.* at 1360 (Lourie, J., concurring) (explaining that patents for natural phenomena also lack novelty); see also *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 132 (1948) (stating that the discovery of natural qualities of a substance cannot be inventive). But see *Flook*, 437 U.S. at 588, 589–90 (acknowledging that although the underlying mathematical formula satisfies the novelty requirement, the claimed formula was itself ineligible subject matter).

⁹¹ See Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 598–99 (2008) (observing that many decisions regarding subject matter eligibility could have been decided on the grounds of obviousness).

⁹² See Paul Gugliuzza, *The Procedure of Patent Eligibility*, 97 TEX. L. REV. 571, 575–76 (2019) (observing the benefits and downsides to deciding eligibility on a motion to dismiss). Invalidating patents on eligibility grounds may provide a useful procedural benefit in that it allows the court to invalidate patents plainly granted improperly without subjecting the parties to costly discovery on more fact-intensive issues. *Id.* at 587–88. But invalidating patents on a motion to dismiss also presents an additional obstacle to biotechnology patents because courts must rely on the pleadings, rather than explanations from industry experts, to assess eligibility for complex technology. *Id.* at 576.

⁹³ See *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048–49 (Fed. Cir. 2016) (holding that a method patent for freezing liver cells twice to isolate surviving cells directed itself toward a process, not a natural law). The distinguishing feature between method patents that direct themselves toward abstract ideas and those that don’t involves whether the process merely observed a natural phenomenon or instead incorporated the phenomenon’s occurrence to carry out a function other than observation. See *id.* (explaining that the steps of the method patent enabled a desired outcome to occur, the preparation of surviving liver cells). Courts have rarely found a patent directed at an abstract concept under step 1 to include an inventive concept that establishes the claimed invention as patent eligible. Nikola L. Datzov & Jason Rantanen, *Predictable Unpredictability* 69 (Nov. 14, 2023) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4380434 [<https://perma.cc/942C-L3NJ>].

to an application of that abstract idea which avoids simply reciting the principle.⁹⁴ This issue similarly exists with patents that focus on natural phenomenon or natural laws because all inventions, when broken down to their base elements, require some natural substance or natural law to function.⁹⁵ If the claim does direct itself at an abstract idea or natural phenomena, the court must then determine if the claim applied an inventive concept.⁹⁶ Courts look to see whether the claim merely recites well-understood steps in the industry or if it applies these steps in a novel way to determine if the claim survives the eligibility analysis.⁹⁷

To clarify what constitutes patentable subject matter, the USPTO issued memoranda throughout the years to advise the public on successfully navigating the requirements of Section 101, such as the most recent guidance issued in 2019.⁹⁸ The USPTO determines if the claim directs itself toward a natural law by creating categories of unpatentable abstract ideas.⁹⁹ When a claim

⁹⁴ See *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 221 (2014) (explaining that the Court does not need to precisely define what does and does not qualify as abstract). The Court's failure to provide any workable definition has left inventors struggling to determine what inventions even incorporate an abstract idea. See Kumaresan, *supra* note 40, at 304–05 (noting that the lack of a legal definition for abstract ideas has made it difficult for courts to apply the Supreme Court's standard).

⁹⁵ See *Funk Bros.*, 333 U.S. at 134–35 (Frankfurter, J., concurring) (arguing that a rule for limiting patents to those that apply a natural law fail to provide a workable definition for articulating when an invention crosses the line into application rather than mere recitation); Bloss, *supra* note 34, at 575 (explaining that Congress sought to avoid conflation of eligibility requirements with non-obviousness and novelty).

⁹⁶ See *Alice*, 573 U.S. at 221 (explaining that an inventive concept requires the inventor to do more than simply restate the abstract idea with the added step to apply it); see also *Mayo Collaborative Servs. v. Prometheus Lab's, Inc.*, 566 U.S. 66, 72 (2012) (arguing that the claimed method does nothing more than ask a person to use a known natural relationship and apply it in some generic way).

⁹⁷ See *Exergen Corp. v. Kaz USA, Inc.*, 725 Fed. App'x 959, 963–65 (Fed. Cir. 2018) (explaining that an inventive concept requires some step in a method patent that does more than apply routine techniques used in an industry).

⁹⁸ See Bloss, *supra* note 34, at 547 (detailing the efforts taken by the USPTO to address the uncertainty of patents that incorporate abstract ideas). Although courts may invalidate patents issued by the USPTO for failing to satisfy the statutory requirements, such as Section 101, the issuance of a patent grants the holder a presumption that the patent is valid. See 35 U.S.C. § 282(a) (stating that issued patents carry the presumption of validity); *Burk & Lemley*, *supra* note 2, at 1658 (recognizing that the burden rests with the challenger to a patent's validity to demonstrate with “clear and convincing evidence” the invalidity of a patent). Despite the presumption of validity, courts lack an obligation to defer to the guidance provided by the USPTO. See *Ku*, *supra* note 13, at 434 n.283 (explaining that judges have discretion to rely on the USPTO's guidance).

⁹⁹ See 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 52 (Jan. 7, 2019) (organizing groupings of abstract ideas). The three groups of abstract ideas enumerated by the USPTO include mathematical concepts, methods or processes for the organization of human activity, and mental processes. *Id.* Mental processes include any evaluation performed inside of a person's head. *Id.*; see *Mayo Collaborative Servs. v. Prometheus Lab's, Inc.*, 566 U.S. 66, 71 (2012) (explaining that mental processes belong to all as the building blocks of scientific advancement). Federal courts have struck down patents claiming methods for simply observing a biological process. See *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1371 (Fed. Cir. 2018) (holding that the pa-

invokes one of these categories, the applicant must then determine if the claim integrates the idea into the process, or if the claim merely recites the idea.¹⁰⁰ Despite its efforts at clarity, the guidance memoranda struggle to incorporate the ever-changing landscape of the subject matter eligibility doctrine due to the breadth of different industries' patent claims as well as the Federal Circuit's attempts to define bright line rules.¹⁰¹

D. Policy Implications of the Mayo and Myriad Decisions

The Supreme Court's guidance on subject matter eligibility resulted in a sharp increase in the rate at which federal courts invalidated patents on the grounds of claiming abstract ideas or natural laws.¹⁰² Though many commentators have praised the Court's recent decisions as a means of expanding access to medications and information to the public, members of the pharmaceutical industry have criticized the constraints patentable subject matter place on de-

tent served to detect the presence of a nucleotide sequence, meaning the claim served the purpose of observing a natural phenomenon).

¹⁰⁰ See 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. at 52–53 (stating that a patent incorporating one of these three groups must move on to step two). The guidance departs from the use of the Supreme Court's language by asking whether the claim integrates the abstract idea rather than asking whether the claim is "directed to" the abstract concept. See Bloss, *supra* note 34, at 558 (noting that the USPTO subtly changed the wording used to describe the analysis performed on subject matter eligibility based on the precise phrasing used by the Federal Circuit in recent eligibility decisions).

¹⁰¹ See Bloss, *supra* note 34, at 559 (observing that the USPTO continually updates its guidance on patentable subject matter in response to the growing catalogue of federal opinions examining the issue). Courts struggle to distinguish the nuances of different patent claims when assessing subject matter eligibility. Compare *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (reiterating that detection of a natural phenomena recites an abstract idea and thus requires an inventive concept to establish patentable subject matter), and *Lefstin et al.*, *supra* note 59, at 583 (stating that diagnostic testing consistently fails to satisfy subject matter eligibility requirements due to their reliance on observation of natural relationships to diagnose patients), with *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1368–69 (Fed. Cir. 2020) (holding that a patent for measuring disruptions in a heart beat does not observe natural phenomena but rather directs itself at improving the technology used for detection of discrepancies). Part of the confusion stems from the extent to which courts should consider extrinsic evidence when deciding eligibility. See *CardioNet*, 955 F.3d at 1375 (Dyk, J., dissenting) (arguing that the majority imposed an unnecessary limit on developing a factual record for assessing eligibility under Section 101 by limiting the use of extrinsic evidence on a motion to dismiss). Because courts frequently decide issues of eligibility on a motion to dismiss, parties lack the opportunity to present evidence of routine activity in the industry to properly assess eligibility. Gugliuzza, *supra* note 92, at 576.

¹⁰² See *Lefstin et al.*, *supra* note 59, at 576–77 (acknowledging that challenges under Section 101 found increased success). Courts engage in the Section 101 analysis without more deeply considering the underlying policy goals of patent law and how they may affect science driven industries. See *Mayo*, 566 U.S. at 92 (noting that the Court's decision does not rest on the underlying policy rationale for protection of diagnostic testing); Landers, *supra* note 52, at 509 (arguing that courts fail to consider the consequences of the Supreme Court's patent eligibility framework).

veloping sciences.¹⁰³ Despite disagreement over the extent to which biotechnology relies on patent protection for innovation, many recognize that the eligibility requirements have a noticeably stronger impact on biotechnology patents compared to those of other industries.¹⁰⁴ Other requirements also impose significant burdens on patenting inventions in the life sciences, highlighting incongruence in how the system affects biotechnology compared to other patentable inventions.¹⁰⁵

Proponents of the stricter eligibility rules argue that the subject matter eligibility doctrine prevents overly broad patents from tying up future inventors from research and innovation.¹⁰⁶ Nucleotide sequences, for example, appear in almost all organisms, not just human beings.¹⁰⁷ Without the imposition of meaningful limitations on the eligibility of nucleotide sequences, patents could impose significant burdens on scientific research.¹⁰⁸ For example, before the Supreme Court invalidated gene patents, Myriad's patent for the BRCA gene enabled them to charge more than three thousand dollars for their genetic tests

¹⁰³ See Landers, *supra* note 52, at 511–12 (acknowledging that various viewpoints exist as to whether patentable subject matter requirements remove incentives for important research or instead free up different topics of research for the public); PTO RESPONSE TO PUBLIC, *supra* note 17, at 24–25 (stating that the restrictions on patentable subject matter force inventors to limit the scope of their patents and improve claim specificity, increasing the wealth of publicly available information on the subject in disclosures).

¹⁰⁴ See Lefstin et al., *supra* note 59, at 589 (acknowledging that previously patentable inventions receive greater skepticism by patent examiners); PTO RESPONSE TO PUBLIC, *supra* note 17, at 34–35 (explaining that the public generally believed life sciences to have felt the most direct impact in changes to patentable subject matter doctrine); see also *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (en banc) (Moore, J., dissenting) (observing that the Federal Circuit has yet to uphold a patent for diagnostic testing following changes to Section 101).

¹⁰⁵ See Burk & Lemley, *supra* note 2, at 1678–79 (explaining that biotechnology patents encounter difficulty in enforcing literal infringement claims due to how enablement and obviousness requirements limit the scope of molecular patents); see also *Mayo*, 566 U.S. at 92 (explaining that general rules in patent law create unexpected consequences in different industries).

¹⁰⁶ See PTO RESPONSE TO PUBLIC, *supra* note 17, at 24 (explaining that various broad patents granted in the 1990s warranted the stricter eligibility requirements); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (stating that patents for abstract ideas or natural laws prohibit the public from using the tools nature provides for innovation); see also Graff et al., *supra* note 82, at 407 (reporting that patents issued for isolated genes surged in the late 1990s, followed by a steady decline of claims over nucleotide sequences in the subsequent decade).

¹⁰⁷ See Graff et al., *supra* note 82, at 406 (stating that many patents claim nucleotide sequences broadly because of the lack of any limitations on claiming only sequences of named species).

¹⁰⁸ See *Myriad*, 569 U.S. at 580 (refusing to uphold the eligibility of DNA patents except where the sequence does not naturally exist in nature); *Mayo*, 566 U.S. at 71 (explaining that monopolies on broad concepts would inhibit future innovation to an unnecessary degree); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1854) (arguing that patents for abstract principles grant too broad of a monopoly to enable successors to develop technology further). Unlike with challenges to other patent requirements, like non-obviousness, issues with eligibility tend to be resolved at the motion to dismiss stage and thus reduces the economic burden of defending against infringement claims. Gugliuzza, *supra* note 92, at 587–88.

for breast cancer.¹⁰⁹ Invalidation of the gene patents freed up diagnostic testing for BRCA and resulted in lower costs for personal genetic testing, allowing for broader access to important medical tests.¹¹⁰

The two-step analysis adopted by the Court also encourages inventors to state with greater specificity the scope of their invention and the underlying innovations used to advance the field.¹¹¹ This in turn serves the broader public by encouraging that information be shared more freely amongst industry experts in a field that relies heavily on building upon the work of predecessors.¹¹² For example, prior to the Court's decision in *Myriad*, researchers avoided working with the BRCA gene because of the added cost of a licensing arrangement with the patent holder.¹¹³ If scientists needed to receive approval to

¹⁰⁹ See Jorge L. Contreras, Association for Molecular Pathology v. Myriad Genetics: *A Critical Reassessment*, 27 MICH. TECH. L. REV. 1, 18 (2020) [hereinafter Contreras, *Critical Reassessment*] (noting that the monopoly Myriad held over gene patents for BRCA allowed the company to charge thousands of dollars for diagnostic tests).

¹¹⁰ See Michelle Fox, *Genetic Testing Can Assess Your Risk of Getting Cancer. Here Are the Costs Involved*, CNBC (Oct. 31, 2020), <https://www.cnbc.com/2020/10/31/genetic-testing-for-cancer-risks-here-are-the-costs.html> [<https://perma.cc/3PKS-G88C>] (observing that for individuals without health insurance, BRCA genetic testing costed up to three hundred dollars in 2020); see also Riddhi Setty, *Patents for Human Genes, Diagnostic Tests Generate Policy Debate*, BL (Oct. 17, 2022), <https://www.bloomberglaw.com/product/blaw/bloomberglawnews/bloomberg-law-news/X9M1VH7K000000?> [<https://perma.cc/A9JV-UAJ5>] (stating that the prices of genetic testing for breast cancer decreased after invalidation of Myriad's gene patents). Patents for pharmaceutical drugs allows companies to maintain higher costs decades after their invention, placing prohibitive burdens on patients in need of critical care. See Lyrissa Lidsky, *Patent Reform Is Needed to Protect Patients' Access to Life-saving Drugs*, STAT (July 23, 2019), <https://www.statnews.com/2019/07/23/patent-reform-protect-access-lifesaving-drugs/> [<https://perma.cc/Z7XP-9XXJ>] (explaining that even though Herceptin, a breast cancer drug, has sold on the market since 1998, the cost of a single vial in 2019 remained at \$9,600). Despite the prohibitive cost of patient care, patents serve a necessary role in incentivizing companies to invest in discovering new treatments. See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1353–54 (Fed. Cir. 2019) (en banc) (Moore, J., dissenting) (noting that necessary diagnostic testing for cardiovascular disease, breast cancer, and more have been struck down by the Federal Circuit following the *Myriad* decision).

¹¹¹ *Compare* Rapid Litig. Mgmt. Ltd. V. CellzDirect, Inc., 827 F.3d 1042, 1048–49 (Fed. Cir. 2016) (upholding a patent that specified the process without merely reciting discovered principles), *with Mayo*, 566 U.S. at 82 (explaining that the patent fails to contribute enough specificity to the process beyond mere recitation of a natural law and routinely utilized steps in the industry). Patent claims must be made available to the public, meaning that the public must be made aware of the underlying steps and discoveries encompassed within a patent. See Mullally, *supra* note 44, at 349–50 (explaining that patents must specify the subject matter claimed with enough specificity to notify the public of what inventions exist).

¹¹² See Frank Emmert-Streib, Matthias Dehmer & Olli Yli-Harja, *Lessons from the Human Genome Project: Modesty, Honesty, and Realism*, 8 FRONTIERS GENETICS 1, 2 (Nov. 23, 2017), <https://doi.org/10.3389/fgene.2017.00184> [<https://perma.cc/M8F4-NDLK>] (noting that significant advancements in human genetics, such as the human genome project, owed its success to numerous scientists building on the work of one another).

¹¹³ See Jorge L. Contreras, *COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible*, in COVID-19 LAW AND POLICY PLAYBOOK: LEGAL RECOMMENDATIONS FOR A SAFER, MORE EQUITABLE FUTURE 137, 139 (Scott Burris et al. eds., 2021) [hereinafter Contreras, *COVID-19*] (arguing that genes should be a research tool available to all scientists and not locked

research other gene sequences, such as the viral genome responsible for the COVID-19 pandemic, the development of vaccines and therapeutics would likely have been hindered.¹¹⁴

Companies and inventors continue to struggle with the Supreme Court's rules regarding subject matter eligibility.¹¹⁵ The inventive concept standard has been characterized by its subjective nature, owed in part to the difficulty in distinguishing when a claim directs itself toward a patentable invention rather than something more abstract.¹¹⁶ Uncertainty in the eligibility of patents for biotechnology disincentivizes inventors and companies from engaging in research and other innovative work because of the heightened risk that they will receive no return on their investment.¹¹⁷ For example, the pharmaceutical industry relies on patents for drug products to justify the substantial research and development costs associated with drug development.¹¹⁸ Therapeutics like vaccines that utilize natural substances may be at risk of losing any patent protection, thus disincentivizing the industry from researching drug develop-

behind patents); Andrew Pollack, *After Patent Ruling, Availability of Gene Tests Could Broaden*, N.Y. TIMES (June 13, 2013), <https://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html?pagewanted=all> [<https://perma.cc/S5MX-27E4>] (noting that the *Myriad* decision should remove barriers to making genome sequencing more accessible).

¹¹⁴ See Contreras, *COVID-19*, *supra* note 113, at 137 (explaining that the genomic sequence of the virus that initiated the COVID-19 pandemic did not have patent claims encumbering them and thus could be freely researched by scientists); Sandra Park, *The Dangers of Expanding What Can Be Patented in the Age of COVID-19*, ACLU (Oct. 30, 2020), <https://www.aclu.org/news/privacy-technology/the-dangers-of-expanding-what-can-be-patented-in-the-age-of-covid-19> [<https://perma.cc/8EMD-G9FF>] (arguing that the lack of patent claims over viral genomes enabled researchers to research the viruses more freely).

¹¹⁵ See Lefstin et al., *supra* note 59, at 561 (acknowledging that many companies and inventors struggle with securing patents when considering the Supreme Court's decision in *Mayo*).

¹¹⁶ See *id.* (referring to the inventive concept standard as a case by case test); Bloss, *supra* note 34, at 557 (arguing that the Supreme Court failed to adequately define abstract ideas, resulting in the broadening impact of subject matter eligibility on various industries); PTO RESPONSE TO PUBLIC, *supra* note 17, at 29–30 (explaining that public outcry to subject matter eligibility was directed in part toward the lack of concrete definitions for what constituted abstract ideas).

¹¹⁷ See Burk & Lemley, *supra* note 2, at 1581–82 (arguing that development in biotechnology requires stronger incentives than other industries because of uncertainty in reducing research into a marketable product). Despite outcry about the ambiguity of eligible subject matter, recent analysis has shown that appellate courts rarely overturn decisions regarding eligibility. Datzov & Rantanen, *supra* note 93, at 62 (observing that appellate courts affirm the decisions made on issues of eligibility more consistently than decisions addressing other patent requirements).

¹¹⁸ See Landers, *supra* note 52, at 511–12 (noting that the extensive costs for scientific research make the industry suitable for the incentives provided by patent protection). Though most have struggled to identify strong empirical evidence demonstrating that the monopoly afforded by patents improves research and innovation, at least in the pharmaceutical industry, drug development demands the protection that patents afford to be worth investing in. See ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 282–83 (Harv. Univ. Press ed. 2011) (explaining that the pharmaceutical industry only functions because of patents).

ment.¹¹⁹ Without clearer lines between which patents reiterate natural laws and which patents actually apply them, courts are likely to dissuade research and creativity in the sciences because of the financial barriers present in developing important biotechnology like therapeutics and diagnostic kits.¹²⁰

Dissatisfaction with the uncertainty in what constitutes patentable matter and processes has led courts and industry representatives alike to implore Congress to make legislative changes and clarify the limits of eligible subject matter.¹²¹ In 2021, Representative Massie introduced RALIA to the House, a bill that abrogates various Supreme Court decisions that define subject matter eligibility and implements a new standard for assessing eligibility.¹²² Just one year later, Senator Tillis introduced PERA to the Senate, a bill that amends the language of Section 101 by creating statutory exceptions to patentable subject matter.¹²³ These efforts to reform the subject matter eligibility doctrine demonstrate concerns that the doctrine disincentivizes innovation in important industries like biotechnology.¹²⁴

II. LEGISLATIVE SOLUTIONS FOR SUBJECT MATTER ELIGIBILITY

Section A of this Part examines the changes introduced in RALIA and addresses the impact the amendment to Section 101 would likely have on subject

¹¹⁹ See Landers, *supra* note 52, at 514–15 (noting that patents enable startup companies in the biotech industry to obtain financing and protect their investment into research); *mRNA Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.idsociety.org/covid-19-real-time-learning-network/vaccines/mrna-vaccines/> [<https://perma.cc/KD4U-2HTH>] (highlighting that mRNA vaccines utilize the genetic code of an organism to prevent symptoms of COVID-19 infection).

¹²⁰ See Landers, *supra* note 52, at 537–38 (recognizing that all inventions require some prior knowledge, making the line between preemption of natural tools and eligible inventions difficult to discern); *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012) (recognizing that all inventions require natural phenomena to exist). The high costs associated with biotechnology research and development reaffirms the need for patents as incentives to make substantial investments in the industry. See Landers, *supra* note 52, at 511–12 (acknowledging that innovations in industries like healthcare require significant initial investments of time and money).

¹²¹ See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (en banc) (Hughes, J., concurring) (suggesting that Congress draw legislative rules for patent eligibility); PTO RESPONSE TO PUBLIC, *supra* note 17, at 41 (noting that life sciences representatives pushed strongly for legislative changes to subject matter eligibility); Tillis Press Release, *supra* note 20 (noting that all judges of the Federal Circuit have expressed disapproval over the current rules surrounding subject matter eligibility).

¹²² See Massie Press Release, *supra* note 21 (announcing that RALIA reforms various aspects of the U.S. patent system); Restoring America's Leadership in Innovation Act of 2021, H.R. 5874, 117th Cong. § 7(a) (2021) (amending 35 U.S.C. § 101 to create an exception for ineligible subject matter).

¹²³ See Tillis Press Release, *supra* note 20 (explaining that PERA has been introduced to the Senate floor); Patent Eligibility Restoration Act of 2022, S. 4734, 117th Cong. § 2 (2022) (creating statutory exclusions for subject matter not eligible for patent protection). PERA was revised and reintroduced to the Senate in 2023. Coons Press Release, *supra* note 24.

¹²⁴ See Tillis Press Release, *supra* note 20 (arguing that foreign competition technological innovation encourages stronger patent protection in the United States).

matter eligibility doctrine.¹²⁵ Section B of this Part reviews the proposed changes of PERA to subject matter eligibility and explores what impact these changes would have on the eligibility of biotechnology patents.¹²⁶

A. RALIA's Elimination of the Gatekeeping Function of the Subject Matter Eligibility Doctrine

RALIA proposes to make various changes to the U.S. patent system, including the abolishment of the Patent Trial and Appeal Board and promotes the view that patents exist as private property rights.¹²⁷ The bill also seeks to abrogate recent Supreme Court jurisprudence on subject matter eligibility by rejecting the idea that patents require an “inventive concept” to receive protection.¹²⁸ The proposed amendment enables any claimed invention to receive patent protection so long as the invention does not exist independent of any intervention by human activity or “solely in the human mind.”¹²⁹ In addition, the bill strikes from consideration of eligibility any reference to the other requirements of subject matter eligibility, including novelty and non-obviousness.¹³⁰

The exception to patent eligibility proposed by RALIA would likely enable inventors to claim human genes because isolating a gene requires removing the DNA sequence from its natural environment and breaking chemical bonds to form a new molecule.¹³¹ This change in patent eligibility would enable a

¹²⁵ See *infra* notes 127–143 and accompanying text.

¹²⁶ See *infra* notes 144–156 and accompanying text.

¹²⁷ See *What Is the Restoring America's Leadership in Innovation Act?*, US INVENTOR, <https://usinventor.org/massie-innovation-act/> [<https://perma.cc/39CH-W5NG>] (arguing that the current process for obtaining patent rights enables foreign countries to commandeer rights away from American inventors); H.R. 5874, § 9(a) (establishing that patents exist as property rights held by the owner). Patents have been traditionally understood as distinct from traditional property rights because of several unique attributes distinguishing intellectual property rights. See Kitch, *supra* note 32, at 275–76 (noting that comparisons of patents to property rights fails to consider how the two systems operate differently).

¹²⁸ See H.R. 5874, § 7 (replacing rules promulgated by the Supreme Court in favor of a new exception to patent eligibility). The inventive concept is the human activity that transforms a patent claiming a natural phenomenon itself into an application of the phenomena. See *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72–73 (2012) (explaining that a patent claim lacking an inventive concept merely claims the underlying natural law).

¹²⁹ See H.R. 5874, § 7(a) (promulgating a new exception to 35 U.S.C. § 101 for patent eligibility).

¹³⁰ See *id.* (explaining that eligibility must be considered independently from other requirements of patentability). The Supreme Court previously referenced the need to determine what steps in a patent claim do not merely recite routine practices engaged by knowledgeable individuals in the same field. See *Mayo*, 566 U.S. at 79 (holding that the method claim for determining the appropriate dose of thiopurine merely recited conventionally understood practices in the field and thus failed to satisfy eligibility requirements).

¹³¹ See H.R. 5874, § 7(a) (requiring that an eligible invention exist at least in part due to human activity). The Federal Circuit recognized that gene patents for isolated DNA claim molecules that have distinct differences from native DNA found within human cells. See *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1328 (Fed. Cir. 2012), *rev'd sub nom.* *Ass'n for Molecular Pathology*

wide variety of biological materials to receive patent protection.¹³² By creating a less stringent rule for eligibility, RALIA would also allow for greater certainty in what inventions may receive patent protection because the only barriers to patent protection would be the other, well-understood statutory requirements.¹³³ In effect, RALIA eliminates any teeth subject matter eligibility has as a requirement for patent protection and supports the policy that patents should be granted more indiscriminately to promote further innovation.¹³⁴ Limiting the impact that the eligibility doctrine has had on patents also aligns with a common trend in the U.S. patent system to presume that inventions should be eligible for protection.¹³⁵ RALIA effectively wrestles control away from the judiciary to determine what inventions deserve protection by eliminating the only judicially created requirement for patent eligibility.¹³⁶ It also reinforces the idea that patents should be granted to inventors for innovative creations, even if dependent on natural processes.¹³⁷

v. Myriad Genetics, Inc., 569 U.S. 576 (2013) (acknowledging that isolated genes must be synthesized or cleaved to form molecules that do not naturally exist); *see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 593 (2013) (noting that a claim for genetic sequences does not satisfy eligibility requirements merely because the isolated gene fragments do not naturally exist).

¹³² *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1336 (Fed. Cir. 2019) (en banc) (Lourie, J., concurring) (explaining that since the decision in *Mayo*, the Federal Circuit rejected applications of natural laws, such as diagnostic testing, because the human steps to apply the laws did not go beyond routine practices); H.R. 5874, § 7(b) (explaining that the bill abrogates several Supreme Court decisions “to ensure that life sciences discoveries” remain patentable).

¹³³ *See* Risch, *supra* note 91, at 598 (arguing that the limitations imposed by subject matter eligibility could be better addressed through other statutory requirements for patents).

¹³⁴ *See* Perel, *supra* note 58, at 249 (explaining that subject matter eligibility restricts what inventions the PTO must examine more rigorously, thus lowering administrative costs); 35 U.S.C. § 101 (using all-encompassing language to define what inventions satisfy eligibility requirements); *see also* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, at 5 (1952)) (acknowledging that Congress intended for “anything under the sun that is made by man” to satisfy eligibility requirements); Kumaresan, *supra* note 40, at 309 (highlighting that the statutory rule for patent eligibility uses broad language to encompass any conceivable invention).

¹³⁵ *See* Risch, *supra* note 91, at 651–52 (stating that where there exists doubt as to whether a patent should be granted, the patent system should err on the side of granting the protection). Once the PTO grants a patent, the burden rests with a challenger to prove the invalidity of the patent. *See* 35 U.S.C. § 282(a) (stating that patents receive a presumption of validity).

¹³⁶ *See* Risch, *supra* note 91, at 595 (arguing that the judiciary should avoid creating policy for patent law); *see also* Bloss, *supra* note 34, at 549–50 (explaining that subject matter eligibility owes its existence to the judiciary).

¹³⁷ *See* Durham, *supra* note 44, at 950–51 (arguing that important discoveries should not be blocked from the reward of a patent merely because they lean closer to principle than practical application). The expansive scope of RALIA also reinforces the idea that patents should be understood as a kind of property right rather than as a policy incentive. *See* Restoring America’s Leadership in Innovation Act of 2021, H.R. 5874, 117th Cong. § 9(a) (2021) (defining patent rights as comparable to property rights); MERGES, *supra* note 118, at 32–33 (positing that Locke’s theories concerning physical property rights apply well to intellectual property).

RALIA reiterates that an invention does not satisfy eligibility requirements if it exists solely within a person's mind.¹³⁸ At first glance, this exception to eligibility fails to clarify the distinction between abstract ideas and applications of the idea.¹³⁹ The USPTO struggled to offer a satisfactory solution to defining abstract ideas and instead has resorted to compiling an ever growing list of what subject matter the Federal Circuit held to merely exist within the inventor's mind.¹⁴⁰ RALIA's proposed changes do exclude consideration of novelty and non-obviousness when determining whether an invention overcomes the hurdle of patent eligibility.¹⁴¹ RALIA would likely enable patents for diagnostic testing where the only novel step involves observation of a previously undiscovered association between a gene and a disease.¹⁴² This change in how abstract ideas are approached would allow inventors to patent their discoveries by narrowly tailoring their claims.¹⁴³

B. PERA Replaces the Current Eligibility Framework with a Statutory List of Exclusions

PERA redefines subject matter eligibility by creating a list of statutorily excluded processes and matter that cannot be claimed in a patent.¹⁴⁴ With respect to naturally occurring materials, PERA prohibits patents for unmodified materials that appear in nature, including a specific exclusion for human genes

¹³⁸ H.R. 5874, § 7(a) (requiring that claimed inventions exist outside a person's mind to receive protection).

¹³⁹ See *id.* (excluding from the rule a definition for inventions that exist "solely in the human mind"). Courts have previously struggled to define what constitutes an abstract idea when assessing patent eligibility. See Kumaresan, *supra* note 40, at 304–05 (highlighting that abstract ideas lack a concrete definition); *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (acknowledging that all inventions must incorporate abstract ideas or a natural phenomenon to some extent).

¹⁴⁰ See Bloss, *supra* note 34, at 559 (observing that the USPTO compiles eligibility decisions by courts to guide inventors in drafting their claims); 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 52 (Jan. 7, 2019) (creating categories of what qualifies as an abstract idea).

¹⁴¹ Compare H.R. 5874, § 7(a) (excluding from consideration other statutory requirements of patentability from subject matter eligibility), with *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72–73 (2012) (explicitly referencing routine practices in the scientific discipline in deciding to invalidate the method patent).

¹⁴² Compare *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1372 (Fed. Cir. 2018) (explaining that mere observation of a natural phenomenon does not incorporate an inventive concept, thus making the patent invalid), and *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048–49 (Fed. Cir. 2016) (upholding the validity of the patent because the claim did more than simply observe a natural phenomenon), with H.R. 5874, § 7(b) (abrogating Supreme Court decisions to broaden the scope of patents in the life sciences).

¹⁴³ See *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112–13 (1854) (noting that a patent for an idea grants an inventor a monopoly over more than just that which the inventor created or discovered); *Burk & Lemley*, *supra* note 2, at 1642–43 (positing that the judicial restriction against patents for abstract ideas ensured that the claim did not encompass unknown applications of the concept).

¹⁴⁴ See Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. § 3 (2023) (providing a list of exclusions from eligibility).

that exist naturally in a person's body.¹⁴⁵ The bill includes a caveat that any human gene altered by a scientist, including through purification or isolation from the human, may receive protection by a patent.¹⁴⁶ The exclusionary rule in PERA would likely abrogate the decision in *Myriad* and allow patents for isolated human genes.¹⁴⁷

In theory, PERA would enable scientists who uncover new genes to patent only the isolated variant without preventing other scientists from the studying the gene as it exists within the body.¹⁴⁸ A patent for an isolated gene would allow scientists to conduct research on a gene so long as the scientist does not isolate a DNA molecule from the human body.¹⁴⁹ In practice, however, scientists rely on isolated DNA molecules to conduct common research techniques, meaning that the distinction lacks any practical effect.¹⁵⁰ The utility of a patent for an isolated DNA molecule and not the gene sequence itself may also be lacking, because a patent for a DNA molecule could be circumvented by making a single change to the nucleotide sequence.¹⁵¹

PERA also rejects consideration of prior art or well understood techniques that existed before application for the patent.¹⁵² By refusing to consider well understood practices in assessing patent eligibility, PERA rejects the need for

¹⁴⁵ See *id.* (excluding from patent eligibility genes and other naturally occurring substances absent human intervention). The rule mirrors the language of RALIA, which excludes from eligibility any invention that claims a natural substance that has yet to be altered by human hands. See H.R. 5874, § 7(a) (proposing a rule that natural products receive some modification to satisfy subject matter eligibility requirements).

¹⁴⁶ See S. 2140, § 3 (defining modification of a human gene as any alteration performed through human activity).

¹⁴⁷ See Setty, *supra* note 110 (acknowledging that genes extracted from a person's body likely satisfy patent eligibility requirements under PERA because the gene has been isolated). The Supreme Court previously held that merely isolating a DNA fragment from a human body does not satisfy patent eligibility. See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 593 (2013) (holding that the mere isolation of a gene from other genetic material surrounding it does not overcome the requirements of Section 101); see also *In re BRCA1-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 760 (Fed. Cir. 2014) (isolating short nucleotide sequences from human DNA does not satisfy subject matter eligibility).

¹⁴⁸ See S. 2140, § 3 (permitting patents for isolated genes).

¹⁴⁹ See *id.* (denying patents for non-isolated genes).

¹⁵⁰ See *Purpose of Genomic DNA Extraction & Tips for Success*, ZYMO RSCH. (Oct. 3, 2019) <https://www.zymoresearch.com/blogs/blog/purpose-of-gdna-extraction-tips-for-success> [<https://perma.cc/MX96-PNJK>] (explaining that research in the life sciences relies heavily on DNA extraction for conducting research to study genes); *Uses and Applications of DNA Extraction*, SMACGIGWORLD, <https://www.smacgigworld.com/blog/uses-and-applications-of-dna-extraction.php> [<https://perma.cc/FJ38-ZY9G>] (explaining that DNA extraction must be performed for various real-world applications and research techniques).

¹⁵¹ See *Myriad*, 569 U.S. at 593 (acknowledging that a gene patent fails to stop infringers unless the claim included the genetic sequence and not simply the composition of nucleotides within the DNA molecule itself).

¹⁵² See S. 2140, § 3 (explaining that courts should not consider "the state of the applicable art" when assessing patent eligibility).

an inventive concept before granting protection to new inventions or discoveries.¹⁵³ The statutory exclusions to eligible subject matter in PERA recognize an observation by the Supreme Court that different industries require unique approaches to ensure that patents serve the intended purpose of promoting innovation.¹⁵⁴ Congress has previously drafted exclusive rules for patents directed in specialized industries, such as in the growth and preparation of new breeds of plants, to encourage further research in the field.¹⁵⁵ The many unique attributes of the biotech industry compared to traditional mechanical inventions warrant some distinction in the current patent law for delineating what discoveries satisfy the eligibility requirements.¹⁵⁶

III. ADAPTING THE FRAMEWORK OF PERA TO ADDRESS THE LACK OF CLARITY OF SUBJECT MATTER ELIGIBILITY

This Note argues that the structure of PERA better addresses the concerns with subject matter eligibility and its impact on biotechnology, but that the bill must include a clearer prohibition on patents for genes to protect future research and innovation.¹⁵⁷ The current requirements for satisfying patent eligibility run

¹⁵³ Compare *id.* (noting that prior art should not be considered when assessing the eligibility of a claimed invention), with *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72–73 (2012) (requiring that routine and understood steps in the industry be considered before determining if the claimed invention does more than merely incorporate natural phenomena).

¹⁵⁴ See *Mayo*, 566 U.S. at 92 (recognizing that Congress should strike the balance of how patent laws affect different industries by drafting specialized rules for different inventions); Risch, *supra* note 91, at 643 (arguing that courts will fail to focus on the consequences of their rulings for patents in particular industries and that the legislature should tailor specific laws for biotechnology patents).

¹⁵⁵ See *Mayo*, 566 U.S. at 92 (citing statutes that define the rules for patenting plant species). The Plant Patent Act of 1930 addressed eligibility concerns for plant species by granting plant breeders the rights to newly discovered plant breeds. See Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of Its Creation*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 621, 640–41 (2000) (explaining that the Plant Patent Act established that new plant breeds were inventive enough to warrant protection). The Plant Patent Act protected the mere discovery of a new plant breed, even in the absence of inventive human intervention, so that plant breeders would be encouraged to discover new species. See Lefstin et al., *supra* note 59, at 571 (highlighting the goals Congress set out for the Plant Patent Act).

¹⁵⁶ See Klein, *supra* note 3 (explaining that discoveries in biotechnology often have unique attributes compared to other industries such as the ability of patented biological materials to transform and reproduce over time). The ambiguity between a natural law and application of the natural law appears more frequently in biotechnology patents because discoveries focus on interactions between biological products. See Taylor, *supra* note 56, at 235 (arguing that the subjective nature of current subject matter eligibility requirements makes it difficult to determine when biotechnology satisfies these requirements); cf. Landers, *supra* note 52, at 533 (noting that improvements in technology continue to blur any distinction between observational science and manipulation by humans of natural laws or processes).

¹⁵⁷ See Taylor, *supra* note 56, at 235 (arguing that the lack of clarity with respect to patent eligibility comes, in part, from the subjective quality of the Supreme Court's test); Restoring America's Leadership in Innovation Act of 2021, H.R. 5874, 117th Cong. § 7(a) (2021) (proposing a simpler test for eligibility); S. 2140, § 3 (proposing a list of subject matter ineligible for patent protection). Be-

afoul of the legislative intent in crafting Section 101 and the structure of the current patent system.¹⁵⁸ Both RALIA and PERA propose new rules that limit the reach of the eligibility doctrine and enable more discoveries in biotechnology to receive patents.¹⁵⁹ Although these proposed rules clarify eligibility and reinforce legislative intent to allow scientific discoveries to be patentable, a statutory exclusion for genes must be introduced to prevent inventors from tying up future research.¹⁶⁰ Section A of this Part analyzes the reasons why the proposed bills in Congress offer the best solutions for addressing ambiguities in subject matter eligibility that still align with the underlying policy drivers of patent law.¹⁶¹ Section B of this Part addresses the need for a statutory exception to eligibility for gene patents in a revision to Section 101 because of the potential for gene patents to swallow future research in the biotechnology sphere.¹⁶²

A. Reviving the Purpose of Section 101 as the Threshold Step to Patentability

Subject matter eligibility originally prohibited patent holders from claiming more than what they had actually reduced to practice.¹⁶³ Although inventors could patent the application of a natural law or process, the Supreme Court invalidated patents that claimed the underlying principle.¹⁶⁴ But the focus of

cause developments in biotechnology heavily depend on genes, patents should not tie up research into any species' genetic material. *See* Park, *supra* note 114 (arguing that the availability of genes for research enabled scientists to understand and defend against the coronavirus without significant roadblocks).

¹⁵⁸ *See* PTO RESPONSE TO PUBLIC, *supra* note 17, at 29–30 (highlighting the backlash to the Supreme Court's eligibility test due to the lack of an established definition for abstract ideas); Taylor, *supra* note 56, at 175 (explaining that Section 101 should not have to encompass patent requirements found in other sections of the law).

¹⁵⁹ *See* H.R. 5874, § 7(a) (establishing that patent eligibility for new materials only requires some minimal human intervention); S. 2140, § 3 (rejecting consideration of prior art or other patent requirements when determining subject matter eligibility).

¹⁶⁰ *See* Lefstin et al., *supra* note 59, at 570–71 (explaining that Congress sought to allow scientific discoveries to receive patents); Contreras, *Critical Reassessment*, *supra* note 109, at 38–39 (arguing that a patent for genes prohibits any researcher from discovering any number of practical applications of the gene); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112–13 (1854) (noting that the patent claimed all applications of electromagnetism and not merely those that the inventor discovered).

¹⁶¹ *See infra* notes 163–192 and accompanying text.

¹⁶² *See infra* notes 193–208 and accompanying text.

¹⁶³ *See O'Reilly*, 56 U.S. (15 How.) at 113 (stating that patentees cannot claim an idea itself because this would provide a monopoly for more than what the inventor discovered or created); *see also* *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 176 (1853) (noting that a patent claiming a pipe made with a new material effectively claims a property of the material and thus would be invalid).

¹⁶⁴ *See* *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 593–94 (1874) (explaining that a patent may claim the process for extracting a naturally existing product, but discovery of this process does not entitle the inventor to a patent for the product itself); *Durham*, *supra* note 44, at 938–39 (observing that the majority of early subject matter eligibility cases examined how broad of a monopoly an inventor could claim over their discovery); *Burk & Lemley*, *supra* note 2, at

the Court on natural laws and processes distracted from the true purpose of the doctrine; punishing inventors for drafting patent claims that cover more than what the inventor either discovered or created.¹⁶⁵

In recent subject matter eligibility cases, the Supreme Court adopted a two-step inquiry that required patents directed at natural laws or abstract ideas to apply some inventive concept.¹⁶⁶ The requirement that a claim utilize some inventive concept ignores the discovery of the underlying natural law in favor of focusing on whether the human intervention goes beyond routine practices in the field.¹⁶⁷ But this rule discounts the inventiveness of the discovery itself and imposes an additional, unnecessary requirement.¹⁶⁸ The inventive concept also invites courts to consider prior art in the field and what could be considered routine activities.¹⁶⁹ By relying on prior art to consider what inventions satisfy eligibility, the Court introduced redundancy in the patent requirements by overlapping subject matter eligibility with considerations used in determining whether an invention satisfies novelty and non-obviousness requirements.¹⁷⁰ This effectively forces inventions in biotechnology to overcome a

1642–43 (noting that the Court sought to prevent overly broad patents by requiring the claim to specify an embodiment of the abstract idea).

¹⁶⁵ See *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 134–35 (1948) (Frankfurter, J. concurring) (arguing that the majority, by referring to laws of nature to invalidate the patent, confuses the issue rather than merely invalidating the patent for claiming more than what the inventor discovered); *Risch*, *supra* note 91, at 599 (arguing that *Funk Bros.* should have been decided based on non-obviousness rather than subject matter eligibility). Congress endorsed patents for discoveries of nature even when the inventor did little to alter a natural process or product, albeit in specific industries. See *Lefstin et al.*, *supra* note 59, at 571 (explaining that the Plant Patent Act of 1930 allows inventors to claim a discovered plant species).

¹⁶⁶ See *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 217–18 (2014) (explaining that an inventive concept transforms an unpatentable claim into an eligible one); *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 72–73 (2012) (noting that the claim did not involve an inventive concept because it only utilized routine and conventional steps in the industry).

¹⁶⁷ See *Mayo*, 566 U.S. at 77 (explaining that a patent claim incorporating natural laws must also incorporate some additional steps to transform the claim into an application of the law).

¹⁶⁸ See *Durham*, *supra* note 44, at 950–51 (arguing that there should be incentives for people to discover mathematical formulas and other ineligible natural laws). The Supreme Court held that when the inventor discovers a natural law, the underlying law fails patent eligibility. See *Funk Bros.*, 333 U.S. at 131 (explaining that despite the importance of the discovery of properties of the bacterial strains, no patent could be issued). But early cases on subject matter eligibility never required any inventive application of a discovery. See *Lefstin et al.*, *supra* note 59, at 573–74 (arguing that the Supreme Court misunderstood the reasoning of early cases involving patents for principles).

¹⁶⁹ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595–96 (2013) (explaining that because scientists regularly used the techniques Myriad employed in their gene patent, the claim could not overcome subject matter eligibility limitations); *Mayo*, 566 U.S. at 79–80 (explaining that the claim failed to do more than recite routine activity and thus lacked any inventive component).

¹⁷⁰ See *Taylor*, *supra* note 56, at 176–77 (explaining that the non-obvious requirement of Section 103, and not Section 101, should rely upon prior art to determine whether the patent should be granted); *Landers*, *supra* note 52, at 520–21 (observing that current subject matter eligibility considerations overlap with novelty and non-obviousness).

heightened standard of scrutiny even though these contributions deserve and necessitate more robust protection.¹⁷¹

The Court's failure to define abstract ideas or laws of nature has contributed to the growing confusion over what inventions satisfy eligibility, which deters investment into biotechnology.¹⁷² The USPTO also failed to adequately define abstract ideas and instead has turned to simply listing categories of inventions that the Federal Circuit has recognized as patent eligible or not.¹⁷³ The eligibility requirement has predominantly affected inventors seeking to patent new diagnostic tests that utilize relationships between a gene and the likelihood that a mutation will result in disease.¹⁷⁴ The Court has thus unnecessarily discouraged innovation in biotechnology by placing these inventions under the umbrella of natural laws and therefore making them unfit for patent protection.¹⁷⁵

¹⁷¹ See Durham, *supra* note 44, at 950–51 (arguing that discovered formulas should garner more protection because of the impact they can have on innovation, not less). Under the Court's current framework, only patents that direct themselves toward abstract ideas or natural laws must incorporate some inventive concept. See *Alice*, 573 U.S. at 217 (explaining that claims incorporating abstract ideas require an inventive concept). Because an inventive concept discounts routine activity already used in an industry, the test forces inventors to take further steps to distinguish their invention from the routine activity before even addressing the issue of novelty or non-obviousness. See *Mayo*, 566 U.S. at 79 (arguing that conventional activity does not establish an inventive concept when considering the first statutory requirement, eligibility); see also *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 890 F.3d 1354, 1360 (Fed. Cir. 2018) (en banc) (Lourie, J., concurring) (arguing that the two-step analysis complicates eligibility analysis and strikes down biotechnology that make important contributions to industries like hospital care); Klein, *supra* note 3 (explaining that investment decisions in biotechnology often hinge on whether the company possesses patents over their inventions).

¹⁷² See *Alice*, 573 U.S. at 221 (declining to adopt a definition for abstract ideas); Kumaresan, *supra* note 40, at 306 (arguing that ambiguity of what qualifies as abstract will disincentivize people from crafting inventions). The lack of certainty with respect to patent rights exacerbates current deterrents that prevent innovation. See *Burk & Lemley*, *supra* note 2, at 1588 (explaining that stronger patent protection improves investment in the biotech industry); Landers, *supra* note 52, at 514–15 (explaining that biotechnology patents support smaller companies by enabling them to secure financing for future work).

¹⁷³ See Bloss, *supra* note 34, at 559 (explaining that the USPTO regularly updates a list of Federal Circuit opinions that strike down patents for claiming abstract ideas); Kumaresan, *supra* note 40, at 318–19 (explaining that the Federal Circuit has continued to expand the scope of what constitutes an abstract idea to strike down patents in various technological industries).

¹⁷⁴ See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1336 (Fed. Cir. 2019) (en banc) (Lourie, J., concurring) (noting that the current rules regarding subject matter eligibility deny protection for diagnostic tests). A patent for the discovery of a correlation between a natural phenomenon and some external factor does not do more than recite an abstract idea. See *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1372 (Fed. Cir. 2018) (explaining that observations of known relationships fail the eligibility requirement).

¹⁷⁵ See *Parker v. Flook*, 437 U.S. 584, 600 (1978) (Stewart, J., dissenting) (arguing that if the Court seeks to strike down the patent, it should do so on the grounds of novelty and not by importing novelty requirements into eligibility). Biotechnology must incorporate cellular materials in order to advance research. See *PTO RESPONSE TO PUBLIC*, *supra* note 17, at 29 (noting comments from industry experts that biotechnology remains interlinked with naturally occurring products of nature). But the technology's ties to natural substances prohibits even groundbreaking discoveries from protection because the techniques used to implement these discoveries involve routine activity. See *Ariosa Diagnostics, Inc.*

RALIA addresses the primary issues with the Court's current eligibility test by expressly prohibiting courts from considering the other patent requirements when considering the eligibility of an invention for a patent.¹⁷⁶ The bill introduces a new rule that would only allow an invention to satisfy subject matter eligibility if the invention involves human intervention of some kind.¹⁷⁷ PERA also redefines subject matter eligibility by prohibiting, among other things, patents for mental processes that only exist in a person's head and natural products that exist without human intervention.¹⁷⁸ Both bills reinforce the original goal of the Patent Act of 1952, to enable nearly any discovery or invention to satisfy the eligibility requirements of Section 101.¹⁷⁹ By rejecting the more subjective rules promulgated by the Supreme Court, the proposed bills return clarity to the eligibility question and allow more inventions, including those in the biotech industry, to satisfy this initial threshold step.¹⁸⁰

The current framework for subject matter eligibility has led to an increase in the number of patents invalidated by the USPTO.¹⁸¹ Greater scrutiny of biotechnology patents may promote scientific research because scientists will not have to worry about infringement when conducting experiments.¹⁸² Allowing stricter eligibility requirements may also reduce the cost of access to important

v. Sequenom, Inc., 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring) (explaining that the new techniques devised by the inventor should, as a matter of policy, satisfy patent eligibility).

¹⁷⁶ See Restoring America's Leadership in Innovation Act of 2021, H.R. 5874, 117th Cong. § 7(a) (2021) (proposing that eligibility be considered in isolation from other patent requirements).

¹⁷⁷ See *id.* (creating a new exception to subject matter eligibility).

¹⁷⁸ See Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. § 8 (2022) (creating a list of statutorily excluded subject matter from patent eligibility).

¹⁷⁹ See Lefstin et al., *supra* note 59, at 568 (explaining that subject matter eligibility constraints exist due to judicial interpretation of prior cases and not an express intent by Congress to limit the scope of patents); Perel, *supra* note 58, at 242 (noting that prior to recent changes in subject matter eligibility, courts understood Section 101 to serve as a threshold question for eligibility before examining the other conditions of patentability such as novelty); Taylor, *supra* note 56, at 172–73 (explaining that Congress intended for Section 101 to be easily satisfied, but to strike down patents under other provisions of the Patent Act).

¹⁸⁰ See Hodes, *supra* note 39, at 243 (noting that a human intervention standard appears to clarify eligibility without too many potential ambiguities). In contrast to the relatively simple human intervention test, the current subject matter eligibility rules fail to adequately define when an invention merely recites an abstract concept. See Kumaresan, *supra* note 40, at 316–17 (arguing that the reliance on abstract ideas to invalidate patents introduced subjective considerations that only confuse where to draw the line for eligibility).

¹⁸¹ See Lefstin et al., *supra* note 59, at 576 (reporting that district courts regularly struck down patents under Section 101 following Supreme Court rulings on eligibility).

¹⁸² See Perel, *supra* note 58, at 250–51 (noting that the eligibility limitations serve important policy goals of not restricting downstream research as well as the application of newly discovered phenomena). The Supreme Court's attempts at distinguishing claims for laws of nature and claims for applications essentially tried to prevent inventors from too broadly monopolizing their discoveries. See *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012) (explaining that monopolies over discoveries that naturally exist impede the creation of new inventions and important discoveries).

research tools and therapeutics in medicine, exemplified in diagnostic testing becoming more readily available and at a lower cost after invalidation of Myriad's genetic patents.¹⁸³ But focusing on the immediate benefits ignores the need for patents in biotechnology and medicine to incentivize the funding of research.¹⁸⁴ Providing bright-line rules for what categories of inventions qualify for patents will reduce the uncertainty over whether a company or inventor can receive protection for their efforts.¹⁸⁵ Even if particular kinds of inventions should be patent ineligible for policy reasons, the legislature should be the one to address those concerns and draft a rule that balances the need for patent protection and the need for research tools to be freely available.¹⁸⁶

The structure of PERA provides a better framework for creating legislative solutions to patent eligibility because it establishes easier rules to follow than RALIA.¹⁸⁷ Although RALIA provides a relatively low bar for materials by providing patents to anything morphed by human hands, the bill also ex-

¹⁸³ See Landers, *supra* note 52, at 535 (explaining that, in theory, the exclusion of patent claims over abstract ideas enables research in scientific disciplines by reducing access costs to the information and tools to perform research); Compare Contreras, *Critical Reassessment*, *supra* note 109, at 18 (explaining that Myriad could charge over three thousand dollars for BRCA diagnostic testing), with Fox, *supra* note 110 (observing that the cost of BRCA genetic testing has dropped to three hundred dollars for uninsured patients).

¹⁸⁴ See MERGES, *supra* note 118, at 282–83 (highlighting that empirical research shows the need for monopolies in pharmaceutical research and development to justify the cost of producing new medicine); Burk & Lemley, *supra* note 2, at 1676–77 (explaining that development of biotechnology involves development costs and significant delays, making the industry suitable for patent protection).

¹⁸⁵ See Landers, *supra* note 52, at 539 (noting that inventions in certain industries require significant resources and investment before a breakthrough is made); Risch, *supra* note 91, at 606–07 (explaining that “rigorous” application of the requirements for patentability would only exclude a claim if it falls outside a statutory category and not if it exists as a law of nature). The USPTO adopted a similar approach by creating categories of inventions that qualify as abstract ideas rather than laying out a loose definition. See 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 52 (Jan. 7, 2019) (detailing categories of inventions that qualify as abstract); see also Kumaresan, *supra* note 40, at 318 (observing that the USPTO’s guidance on abstract ideas and subject matter eligibility reduced uncertainty in the process of filing for patents).

¹⁸⁶ See *Mayo*, 566 U.S. at 92 (recognizing that Congress should tailor rules for patents based on policy needs within various industries); cf. Fowler, *supra* note 155, at 642 (recognizing that Congress drafted the Plant Patent Act of 1930 to limit its protection to the plant species and not the food or flowers that naturally grew from the species itself). The Court routinely ignored the potential policy impact their rulings may have on industries, instead imploring Congress to design new rules with policy preferences in mind. See *Mayo*, 566 U.S. at 92 (refusing to consider whether diagnostics deserve patents); Landers, *supra* note 52, at 509 (recognizing that the Court failed to grapple with underlying policy considerations in their holdings on subject matter eligibility); see also Risch, *supra* note 91, at 643 (explaining that any attempt by judges to draft rules for particular industries would likely fail to consider all relevant factors that could affect the industry).

¹⁸⁷ Compare Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. § 3 (2023) (designating a list of ineligible matter for patent protection), with Restoring America’s Leadership in Innovation Act of 2021, H.R. 5874, 117th Cong. § 7(a) (2021) (limiting ineligible subject matter to material that “exists in nature independently of . . . human activity” or ideas).

cludes anything that “exists solely in the human mind.”¹⁸⁸ The bill fails to define with precision what an invention inside a person’s head would constitute, instead leaving courts with a vague rule analogous to the Supreme Court’s prohibition on patents for abstract ideas.¹⁸⁹ PERA sidesteps this issue by expressly prohibiting patents for specific categories of subject matter.¹⁹⁰ This model follows the USPTO’s response to uncertainty surrounding patent eligibility and provides inventors with a clear understanding of the limits of patent claims.¹⁹¹ PERA would thus offer more predictability with respect to patent eligibility than RALIA while still allowing Congress to place clearer limits on the scope of patentable subject matter.¹⁹²

B. Maintaining the Supreme Court’s Exclusion of Gene Patents

Unlike RALIA, PERA provides a statutory exclusion for patents over genetic material that naturally exists inside of the human body.¹⁹³ PERA’s exclusion does not necessarily prohibit all patents for nucleotide sequences that match those of naturally occurring genes, because most scientists isolate strands of DNA from an organism to conduct experiments.¹⁹⁴ Thus, PERA effectively ena-

¹⁸⁸ H.R. 5874, § 7(a).

¹⁸⁹ See *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 224–25 (2014) (invalidating a patent for a business method because it merely recited the use of abstract principles to a computer); *Mayo*, 566 U.S. at 71 (noting that patents may not issue to abstract thoughts). The Supreme Court declined to offer a working definition of abstract ideas. See *Alice*, 573 U.S. at 221 (explaining that the case did not require the Court to delineate the contours of what falls under abstract ideas and what does not); see also Kumaresan, *supra* note 40, at 334 (arguing that the expansion of what constitutes as an abstract idea has only driven further uncertainty for inventors).

¹⁹⁰ See S. 2140, § 3 (rejecting eligibility for specific categories of inventions).

¹⁹¹ See 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 50 (Jan. 7, 2019) (noting the pressing need for more predictability for what claims direct themselves at abstract ideas). Many of the categories recognized by the USPTO as excluded inventions overlap with the proposed exceptions under PERA. Compare *id.* at 52 (excluding mathematical formulas and business organization methods from patent eligibility), with S. 2140, § 3 (prohibiting patents for mathematical formulas claimed independent of another device and business processes); see also Perel, *supra* note 58, at 242 (acknowledging that Section 101 originally existed to formally grant eligibility to a wide variety of inventions in the Patent Act of 1952).

¹⁹² See *Mayo*, 566 U.S. at 92 (acknowledging that Congress should provide finer rules for patent eligibility to meet the demands of different industries); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (en banc) (Hughes, J., concurring) (asking that Congress reexamine the eligibility requirement to prevent broad claims while still enabling patents for diagnostic testing); see also Bloss, *supra* note 34, at 577 (observing that the guidance issued by the USPTO stabilized rejections of patents for failing to satisfy the eligibility requirement and positing that this guidance mitigated confusion over what satisfies Section 101).

¹⁹³ Compare S. 2140, § 4 (permitting patents for isolated and enriched human genes), with H.R. 5874, § 7 (lacking any exception for the eligibility of genetic material).

¹⁹⁴ See Setty, *supra* note 110 (observing that PERA allows patents for human genes so long as the genetic material has first been extracted from a person’s body); Jorge Contreras, *Another Legislative Attempt to Revive Gene Patenting*, BILL OF HEALTH (Aug. 4, 2022), <https://blog.petrieflom.law.harvard.edu/2022/08/04/another-legislative-attempt-to-revive-gene-patenting/> [<https://perma.cc/4PJ4->

bles patents for any genetic material that limits its scope to the isolated DNA sequence rather than to the sequence more generally.¹⁹⁵

Although PERA's use of statutorily excluded categories recognizes that gene patents should be limited in scope, the current draft of the bill does not provide enough limits on the patentability of nucleotide sequences and thus opens the door to abuse of the monopoly granted by a patent.¹⁹⁶ The entirety of the human genome has been public knowledge for over twenty years, and sequencing tools have improved to the point where the cost no longer prohibits further.¹⁹⁷ Scientists do not actively seek new genes, but instead try to determine associations between a gene and genetic diseases.¹⁹⁸ In other words, scientific research focuses more on the association of an organism's genetic sequence to traits or diseases, because determining the actual nucleotide sequence does not pose a significant challenge.¹⁹⁹ PERA fails to recognize this distinction and allows for patents of isolated DNA that matches the gene of an organism rather than limiting claim language to an identified association of a genetic sequence with a human trait or disease.²⁰⁰

Part of the difficulty in assessing the patentability of isolated DNA comes from the minor differences between an isolated strand and one that exists naturally in an organism.²⁰¹ The Supreme Court recognized differences between

4MPC] [hereinafter Contreras, *Another Legislative Attempt*] (arguing that PERA reverses the central holding of *Myriad*, that human genes may not be patented merely by isolating the sequence from the body).

¹⁹⁵ See Contreras, *Another Legislative Attempt*, *supra* note 194 (explaining that *Myriad*'s original patent on the BRCA sequence already covered the isolated sequence).

¹⁹⁶ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 585 (2013) (recognizing that *Myriad*'s patent would grant the company the right to prevent others from isolating BRCA genes from any person's genome). Patents on genomic information encourage scientists to avoid research into the genes for fear of infringement. See Contreras, *COVID-19*, *supra* note 113, at 139 (explaining that gene patents inhibit scientific research).

¹⁹⁷ See Gibbs, *supra* note 84, at 575 (explaining that the first draft of the human genome became available by the year 2000); Hodes, *supra* note 39, at 246 (observing that recent technological advancements have enabled scientists to sequence a genome at a relatively low cost).

¹⁹⁸ See Contreras, *Critical Reassessment*, *supra* note 109, at 38 (positing that *Myriad* had discovered a method of analyzing a person's risk for cancer based on the BRCA gene and not the underlying gene itself).

¹⁹⁹ See *id.* at 42 (arguing that *Myriad* should have been allowed a patent to the association between breast cancer and BRCA, but not a patent for the gene). The mere act of isolating DNA from its natural environment should not satisfy the novelty requirement because the genetic information already exists within an organism. See Risch, *supra* note 91, at 616 (arguing that isolated DNA should fail to satisfy the novelty requirement).

²⁰⁰ See Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. § 8 (2022) (granting eligibility to enriched and isolated genetic sequences even when the sequence copies that of the human genome).

²⁰¹ See *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1328 (Fed. Cir. 2012), *rev'd sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) (detailing the chemical differences between DNA as it naturally exists in the human body and isolated strands of DNA).

natural DNA and short sequences of isolated DNA to be trivial when it invalidated Myriad's patents for the BRCA genes.²⁰² The Court's emphasis on the routineness of isolating DNA reinforced the idea that Myriad had not actually invented the gene, but merely discovered the importance of the gene and its link to breast cancer.²⁰³ Although patents for nucleotide sequences likely fail to satisfy requirements for patentability other than subject matter eligibility, a statutory exclusion prevents confusion over how broadly an inventor may design their patent claim for discoveries involving genes.²⁰⁴ The exclusion would not impede patents for diagnostic testing because these inventions would only prohibit others from the application of a gene as a predictor for disease, not the use of the gene itself.²⁰⁵ Preventing genes from becoming locked behind patents will enable researchers to continue exploring genetic information without fear of infringing any patent rights.²⁰⁶ This freedom would allow researchers to continue unlocking the link between human genetic sequences and susceptibility to disease without the added barrier of licensing the right to do so from a patent holder.²⁰⁷ The wider availability of research on genes further enabled

²⁰² See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 593 (2013) (explaining that patents for genes cannot be saved by the differences between naturally occurring DNA and isolated DNA); see also Contreras, *Critical Reassessment*, *supra* note 109, at 31–32 (noting that no substantive differences exist between naturally occurring DNA and isolated DNA because the minor chemical alterations do not change the information carried by each molecule).

²⁰³ See *Myriad*, 569 U.S. at 595–96 (recognizing that the techniques used by Myriad to isolate DNA had been regularly employed by scientists in the field).

²⁰⁴ See Risch, *supra* note 91, at 616 (explaining that simple isolation of DNA from the body does not make the gene itself a novel invention). The complexity of the life sciences makes it challenging for judges unfamiliar with the technology to easily assess whether products of applied molecular biology satisfy the requirements of patentability. See *Myriad*, 569 U.S. at 596 (Scalia, J., concurring) (acknowledging that a lack of understanding of the science behind molecular biology precluded Justice Scalia from affirming the full majority opinion). Commentators have criticized the Supreme Court's holding that cDNA satisfies eligibility because of apparent contradictions in the reasoning used to reach this result. See Contreras, *Critical Reassessment*, *supra* note 109, at 37 (arguing that the reasoning used by the Court to invalidate gene patents should also have applied to patents for cDNA).

²⁰⁵ See Hodes, *supra* note 39, at 261–62 (explaining that diagnostic patents only claim a specific discovery about a gene and therefore do not prevent other research into the gene).

²⁰⁶ See Burk & Lemley, *supra* note 2, at 1613 & n.120 (explaining that DNA should not be locked behind patents because doing so removes from researchers a basic tool for innovation); Hodes, *supra* note 39, at 261–62 (noting that patents for genes and not an association of a disease with a gene preclude even undiscovered applications of the gene in other contexts).

²⁰⁷ See Pollack, *supra* note 113 (explaining that the prohibition on patents for genes facilitates more research that involves genome sequencing). Because a single gene could have multiple diseases affiliated with its mutations, researchers who discover one useful aspect of a gene should not gain a monopoly over all possible uses of the gene. See *id.* (highlighting that a gene associated with hearing loss can also affect susceptibility to skin disease); see also Hodes, *supra* note 39, at 226 (explaining that an inventor who claims an underlying principle for one application of that principle precludes other from further innovation in the field).

researchers to address public health concerns without first confronting the challenges of handling patent rights.²⁰⁸

CONCLUSION

Recent decisions by the Supreme Court on subject matter eligibility have led to confusion among companies and scientists in the biotech industry over the extent to which they may patent their discoveries. The reliance on naturally occurring substances, like DNA, causes greater confusion in the life sciences industry compared to other industries. This confusion has resulted in entire categories of inventions failing to satisfy the eligibility requirement. The unpredictability of patent eligibility hinders the development of biotechnology because of the industry's reliance on patents to incentivize the heavy costs associated with reducing new discoveries to practice. New legislative proposals in the House of Representatives and the Senate seek to eliminate confusion by abrogating recent Supreme Court decisions and replacing them with a clearer rule for satisfying eligibility. The proposed rules would solve the primary concern with subject matter eligibility—the lack of clear guidance on what does and does not satisfy eligibility. Although both bills offer effective solutions for encouraging future biotechnology development, a stricter exclusion of gene patents must be included to prevent the monopoly that patents grant inventors from inhibiting scientific research. Replacing the statutory exclusion of PERA with a stricter exclusion for any nucleotide sequences would effectuate the goal of promoting innovation without tying up the necessary tools for future research in the life sciences industry.

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²⁰⁸ See Contreras, *COVID-19*, *supra* note 113, at 138–39 (arguing that the lack of gene patents for viral and bacterial strains encourage more collaboration and a stronger public response to outbreaks); Armstrong, *supra* note 1 (detailing the efforts biotechnology companies took to respond to the pandemic); see also Emmert-Streib et al., *supra* note 112, at 2 (explaining that innovation in biotechnology occurs when a variety of research groups work independently toward a common goal).