

THE UTILITY OF PATENT ELIGIBILITY

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I. INTRODUCTION

Patent eligibility doctrine is in a state of disarray. Section 101 of the Patent Act defines the scope of patent-eligible subject matter in simple, broad language: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is eligible for patent protection.¹ But after several years of the Federal Circuit and Supreme Court expansively interpreting this statute,² both courts began to slowly establish a set of *ineligible* subject matter areas, adding a gloss over the text of § 101.³ Over time, “laws of nature, natural phenomena, and abstract ideas” became the judicial exceptions to patent eligibility.⁴ Then, beginning in 2012, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,⁵ *Association for Molecular Pathology v. Myriad Genetics, Inc.*,⁶ and *Alice Corp. v. CLS Bank International*⁷ launched the *Mayo/Alice* test for evaluating the § 101 eligibility of inventions directed to one of the judicial exceptions.⁸

There is no shortage of writing on the problems with the *Mayo/Alice* test.⁹ Several patent examiners, practitioners, scholars, and jurists have agreed that patent eligibility doctrine is in urgent need of clarification from either the Court or Congress.¹⁰ For many, a key pressure point is that the *Mayo/Alice* test

1. 35 U.S.C. § 101.

2. 1 PETER S. MENELL, MARK A. LEMLEY, ROBERT P. MERGES & SHYAMKRISHNA BALGANESH, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2021* 177 (2021) (“[B]y the early 2000s, the Federal Circuit had pretty much lowered the patentable subject matter hurdle to a chalk line on the track.”).

3. *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring).

4. *Id.*

5. 566 U.S. 66 (2012).

6. 569 U.S. 576 (2013).

7. 573 U.S. 208 (2014).

8. Talha Syed, *Reconstructing Patent Eligibility*, 70 AM. U. L. REV. 1937, 1959 (2021).

9. Robin C. Feldman, *Rewarding Failure with Patents*, YALE J. HEALTH POL’Y L. & ETHICS 2 n.2 (forthcoming 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4223347 (compiling a long list of scholarly proposals relating to patent eligibility doctrine).

10. *See, e.g.*, David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149 (2017) (arguing in favor of new legislation from Congress to address the lack of clarity for § 101); *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, SCOTUSBLOG (June 27, 2016), <https://www.scotusblog.com/case-files/cases/sequenom-inc-v-ariosa-diagnostics-inc/> (compiling amicus briefs urging the Court to grant certiorari in a controversial § 101 case based on a biotechnology invention). *But see, e.g.*, Jason D. Reinecke, *Is the Supreme Court’s Patentable Subject Matter Test Overly Ambiguous? An Empirical Test*, 2019 UTAH L. REV. 581 (2019) (analyzing the

appears to have specifically narrowed the eligibility of biological and software-based inventions¹¹—two critical areas of innovation, at the heart of what the patent system is designed to promote.¹² Indeed, many litigants are now leveraging the murky § 101 standard to challenge patent validity in these fields.¹³

Since *Alice*, the Court has bowed out of the eligibility problem, leaving district courts and the Federal Circuit to wrestle with § 101 on their own.¹⁴ In 2022, the Court denied yet another petition for certiorari in *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*.¹⁵ *American Axle* saw a district court invalidate a patent claim under § 101,¹⁶ and the Federal Circuit affirm that decision.¹⁷ And while § 101 jurisprudence has wreaked havoc on inventions in the life sciences and computational spaces for the past several years,¹⁸ the asserted patent in *American Axle* uniquely encompassed a *mechanical* device—something canonically thought to be unambiguously patent-eligible subject matter, and somewhat above the § 101 fray.

This Note uses *American Axle* to illustrate the critical problem with the current § 101 eligibility standard, beyond its contemporary restriction of patent eligibility in specific technological areas: the *Mayo/Alice* test asks the wrong questions of patent examiners and courts by (1) placing an emphasis on judicial

application of the *Mayo/Alice* test in several patent eligibility cases, to illustrate that § 101 jurisprudence may not be as unpredictable and dire as others have expressed).

11. See Syed, *supra* note 8, at 1940–42.

12. As per the Intellectual Property Clause of the Constitution, patents are awarded to inventors to “promote the progress of science and the useful Arts.” U.S. CONST. art. 1, § 8, cl. 8.

13. 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, 555–56, 576 (2018). An increasing number of patents are routinely invalidated as ineligible in district courts, with these holdings consistently affirmed by the Federal Circuit. *Id.* at 570, 576.

14. See, e.g., *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 579 U.S. 928 (2016) (denying petition for writ of certiorari); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 140 S. Ct. 855 (2019) (same); *HP Inc. v. Berkheimer*, 140 S. Ct. 911 (2020) (same); *Hikma Pharms. USA Inc. v. Vanda Pharms Inc.*, 140 S. Ct. 911 (2020) (same).

15. 142 S. Ct. 2902 (2022).

16. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 309 F. Supp. 3d 218 (D. Del. 2018).

17. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020).

18. See U.S. PAT. & TRADEMARK OFF., PATENT ELIGIBILITY SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 34–38 (July 2017), https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf [hereinafter USPTO Eligibility Report 2017] (describing criticism of recent § 101 jurisprudence from members of the life sciences and computational communities).

exceptions that are embedded into *all* inventions at some level of abstraction,¹⁹ and (2) inherently overlapping with the other substantive patentability doctrines.²⁰ As an alternative, urgently warranted framework to assess patent eligibility, this Note proposes a revised notion of patent eligibility anchored in *utility* doctrine, tethered to the word “useful” already present in § 101. To this end, Part II provides a history of patent eligibility jurisprudence to contextualize the evolution of the judicial exceptions. Part III summarizes *American Axle* and uses it as a paradigmatic example to analyze the problems with the *Mayo/Alice* test. Part IV proposes a method of assessing patent eligibility under § 101 to supplant the *Mayo/Alice* test, arguing that the word “useful” is sufficient to serve a scope-limiting function within all patent claims.

II. HISTORY OF PATENT ELIGIBILITY JURISPRUDENCE

Section 101 of the Patent Act was viewed originally as a minimum, low-bar threshold to patentability,²¹ as the text of the statute does not explicitly exclude any areas of subject matter from patent protection.²² However, over time, three judicially-added exceptions to § 101 came to be recognized as patent-ineligible: “laws of nature, natural phenomena, and abstract ideas.”²³ Many scholars trace the origins of these ineligible concepts to a set of nineteenth century cases that first disavowed the eligibility of “principles.”²⁴

19. See U.S. PAT. & TRADEMARK OFF., PATENT ELIGIBLE SUBJECT MATTER: PUBLIC VIEWS ON THE CURRENT JURISPRUDENCE IN THE UNITED STATES 16 n.130 (June 2022), <https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf> [hereinafter USPTO Eligibility Report 2022].

20. Many refer to § 102, § 103, and § 112 as the “substantive” patentability doctrines, drawing a line between these concepts and the § 101 standard. See, e.g., Syed, *supra* note 8, at 1960.

21. 35 U.S.C. § 101. Section 101 has explicitly read on a version of the four, present-day *eligible* categories (processes, machines, manufactures, and compositions of matter) since 1793. Syed, *supra* note 8, at 2030–31 (compiling the present-day text of § 101 and all previous versions of the statute in Table 1).

22. Rodney Swartz, *Separating Preemption from the Subject Matter Analysis of 35 U.S.C. § 101*, 61 SANTA CLARA L. REV. 903, 917 (2021). Indeed, the Court has interpreted the use of the word “any” to indicate the intent of Congress for an expansive, liberal approach to patentability, with the other substantive patentability doctrines functioning to more rigorously assess the extent of innovation. See *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

23. *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (2018) (Lourie, J., concurring). These three ineligible subject matter areas are, in their very terms, well-known and regurgitated in countless opinions. Assessing whether (and why) a claim is “directed to” one or more of these “ineligible concepts” is much more elusive.

24. See, e.g., Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 569–70 (2016); Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski’s Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1295–96 (2011); OREN BRACHA, OWNING IDEAS: THE

But in the decades since, these formative cases were misinterpreted, stretched, and applied beyond what courts previously anticipated.

A. EARLY NOTIONS OF INELIGIBLE “PRINCIPLES”

The Court first struggled with the notion of patent ineligibility in the context of so-called “principles.”²⁵ Questions as to the patentability of “principles” lurked in the background of early English patent law,²⁶ but came to a head in an 1841 case from the Court of Exchequer, *Neilson v. Harford*.²⁷ Neilson’s patent was directed to “the improved application of air to produce heat in fires, forges, and furnaces.”²⁸ Wrestling with a tension between (1) the “principle” that hot air more efficiently promotes ignition than cold air and (2) the “application” of injecting that hot air into a furnace, the court articulated that the patent was valid for claiming “not merely . . . a principle, but a machine embodying a principle.”²⁹ This became *Neilson*’s legacy—a principle may be eligible for patent protection to the extent that it is “embodied” or applied in some form.³⁰ But—as others have noted—the true dispute of *Neilson* was, surprisingly, related to the adequacy of *disclosure*, rather than patent eligibility.³¹

In parallel, early American patent jurisprudence had already suggested that patents could only claim “the contrivance or production of something which did not exist before,” which one might interpret as excluding “principles” as ineligible subject matter.³² In 1852, the Court solidified this idea in *Le Roy v. Tatham*,³³ using *Neilson* to more explicitly draw a line of ineligibility.³⁴ The patent in *Le Roy* involved improvements to the manufacture of wrought pipe.³⁵

INTELLECTUAL ORIGINS OF AMERICAN INTELLECTUAL PROPERTY, 1790–1909 261–72 (2016).

25. See BRACHA, *supra* note 24, at 265; Syed, *supra* note 8, at 1961.

26. Lefstin, *supra* note 24, at 578 (describing James Watt’s patent relating to steam engine improvements, and the associated debate over the notion of “patentable manufacture[s] or . . . ‘unorganized principles’” (citing *Boulton & Watt v. Bull*, 126 Eng. Rep. 651, 655 (1795))).

27. 151 Eng. Rep. 1266 (1841).

28. THOMAS WEBSTER, REPORTS AND NOTES OF CASES ON LETTERS PATENT FOR INVENTIONS 273 (1844) (reprinting *Neilson*’s patent). Patents at this primordial stage lacked formal claims, leaving litigants and courts to infer the scope of patented subject matter based on “a holistic examination of the specification and . . . the actual embodiments or experiments carried out by the patentee.” Lefstin, *supra* note 24, at 580.

29. *Neilson*, 151 Eng. Rep. at 1273.

30. See Lefstin, *supra* note 24, at 570.

31. See, e.g., Lefstin, *supra* note 24, at 581–82 (describing how the bulk of the argument in *Neilson* was directed to whether the actual heating apparatus of the invention was sufficiently enabled, a modern § 112 question).

32. *In re Kemper*, 14 F. Cas. 286, 288 (C.C.D.C. 1841); see Lefstin, *supra* note 24, at 594.

33. 55 U.S. 156, 175 (1852).

34. Lefstin, *supra* note 24, at 594.

35. 55 U.S. at 172–73.

As in *Neilson*, the case was much less directed to the fundamental eligibility of “principles,” but rather, what would today be defined as a claim construction issue.³⁶ Again, the Court articulated a philosophical view that would later anchor all of patent eligibility doctrine: “[a] principle is not patentable,” given that principles are “fundamental truth[s] . . . [that] no one can claim . . . [as] an exclusive right,” while “[a] new property . . . *when practically applied* . . . is patentable.”³⁷ And in 1854, in *O’Reilly v. Morse*,³⁸ the Court used *Neilson* to assert that “a principle [is] not patentable,”³⁹ but a “new application of a known principle” is.⁴⁰ This case, like *Neilson*, was not about patent eligibility, but rather, enablement.⁴¹

Thus, *Neilson*, *Le Roy*, and *Morse* came to stand for the notion that some form of “embodiment” or “practical application” could restore eligibility to an otherwise unpatentable “principle.” But three key issues lingered in the background: (1) no court had defined what a “principle” was;⁴² (2) no court had articulated a degree of “embodiment” or “practical application” required to restore eligibility to an otherwise unpatentable principle;⁴³ and (3) every court had proffered a notion of patent eligibility in cases that were truly about something else⁴⁴—enablement (*Neilson*, *Morse*) or claim construction (*Le Roy*). Given this precarious foundation—and potential anchoring in *other* patentability doctrines—courts were bound to later struggle with the meaning of patent ineligibility.

B. THE EMERGENCE OF TWO INELIGIBILITY TRACKS

In the first half of the twentieth century, “principles” remained ineligible, and “practical applications” of those principles remained eligible.⁴⁵ Professor

36. See Lefstin, *supra* note 24, at 595. The claim construction issue was whether the object of the patent was the application of a newly discovered principle or the machinery used in the pipe manufacture. *Id.*

37. *Le Roy*, 55 U.S. at 175 (emphasis added).

38. 56 U.S. 62 (1854).

39. *Id.* at 115.

40. *Id.* at 131.

41. Lefstin, *supra* note 24, at 596–97.

42. See Syed, *supra* note 8, at 1964 (“[W]ithout any clear rationale for *why* unapplied principles are ineligible, it becomes harder to know *what* falls within or outside the restriction.”).

43. See *id.* at 1963–64 (noting the ambiguity in three possible interpretations of *Neilson*, distinctly applied across the patent eligibility cases that followed).

44. See Michael Risch, *America’s First Patents*, 64 FLA. L. REV. 1279, 1283 (2012) (noting the flaws in the reliance on English law to construct U.S. patent law, and that “judicial discussion of principles almost never related to attempts to patent natural phenomena, but instead related to patent construction”).

45. See Lefstin, *supra* note 24, at 609.

Lefstin provides a comprehensive summary of eligibility-oriented case law and commentary during this time period, noting that the basic, minimal eligibility standard established by *Neilson* was left undisturbed.⁴⁶ But these years also watched the elusive concept of a “principle” evolve,⁴⁷ tracking the evolution of the “useful Arts”—the presumed object of the patent system.⁴⁸ The twentieth century welcomed radical progress in science and technology, which spawned areas of subject matter that intersected with “principles” in ways that muddled *Neilson*’s standard beyond comprehension. This history led to the emergence of two tracks of ineligibility: inventions that are (1) too “natural” or (2) too “formulaic.”

1. *Track One: “Natural” Ineligibility*

The “principles” of the nineteenth century trilogy were, at their core, mere correlations that reflected the relationships between factors: *Neilson*, between heated air and ignition efficiency;⁴⁹ *Le Roy*, between heated lead and wrought pipe continuity;⁵⁰ and *Morse*, between galvanic current and distanced character printing.⁵¹ These correlations represent pivotal discoveries and developments of the Industrial Revolution, which spawned inventions that we would now view as highly “mechanical”- and “materials”-oriented,⁵² and thus, for an unknown reason, de facto eligible for patent protection—assuming some degree of “practical application.” But these new industrial processes and machines soon launched an era of unprecedented scientific and technological discovery in newer, different areas, such as agriculture, biotechnology, chemistry, and medicine.⁵³ And in lockstep, interest in patent protection began

46. *See id.* at 609–23.

47. *See id.* at 609 (“pure scientific explanation”) (internal quotation marks omitted), 611 (“scientific or mathematical truth”), 612 (“mental steps or processes” and “purified natural products”), 616 (“process of nature”), 617 (“natural phenomena”), 619 (“natural law”).

48. MENELL ET AL., *supra* note 2, at 36 (noting that “useful Arts,” as written into the Constitution’s Intellectual Property Clause, encompass “what we would today call technology and scientific discovery”).

49. *See* 151 Eng. Rep. at 1273.

50. *See* 55 U.S. at 164.

51. *See* 56 U.S. at 77–78, 114–16.

52. *See* Risch, *supra* note 44, at 1308–10 (listing categories of “historical” patents on mills, steam, plows, pumps, leather, brick, wood, and more, falling into the “mechanical”- and “materials”-oriented category).

53. *See generally* Thomas Philbeck & Nicholas Davis, *The Fourth Industrial Revolution: Shaping a New Era*, COLUMBIA SIPA J. INT’L AFFAIRS (Jan. 22, 2019), <https://jia.sipa.columbia.edu/fourth-industrial-revolution-shaping-new-era> (recounting the impact of the iterative eras of industrial revolution on science and technology).

to grow for a set of resulting inventions that were intertwined with not just “principles,” but now, “nature.”⁵⁴

In 1948, *Funk Brothers Seed Co. v. Kato Inoculant Co.*⁵⁵ brought a “natural” invention before the Court, and generated a new version of eligibility doctrine.⁵⁶ The patentee claimed a composition of matter, comprising a favorable combination of bacterial strains.⁵⁷ This invention involved the exploitation of certain “qualities” of bacterial species; that is, their lack of mutual inhibition.⁵⁸ As in *Neilson*, *Le Roy*, and *Morse*, the patent in *Funk Brothers* intersected with a mere correlation—here, between species-specificity and mutual inhibition. And just like the “principles” of the Industrial Revolution, this correlation is one that might simply be defined as a “fundamental truth.”⁵⁹ But unlike the nineteenth century case trilogy, the Court in *Funk Brothers* fixated on the “natural” element of the correlation. Justice Douglas referred to the bacterial “qualities” of mutual non-inhibition as “natural” in almost every possible permutation: “the work of nature,” a “law of nature,” a “phenomenon of nature,” “nature’s secret,” a “natural principle,” “natural functioning,” and “perform[ance] in [a] natural way.”⁶⁰ He then asserted that such “natural” qualities were “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”⁶¹ Against this nature-oriented backdrop, the Court noted that while the claimed invention was an “application” of a “natural principle”—in fact, one that was also “new and useful”—it did not “satisfy the requirements of *invention or discovery*.”⁶² At first blush, one might think Justice Douglas was reading in “invent[ion] or

54. See MENELL ET AL., *supra* note 2, at 169.

55. 333 U.S. 127 (1948).

56. See Syed, *supra* note 8, at 1965 n.95. While “natural” inventions had previously been discussed, it was only *Funk Brothers* that rose to the level of disturbing *Neilson*’s eligibility standard. See Lefstin, *supra* note 24, at 609–23.

57. *Funk Brothers*, 333 U.S. at 138 n.1 (presenting a representative claim from the asserted patent). At the time of the invention, farmers often inoculated crops with bacterial strains to support plant growth, leveraging the symbiotic, nitrogen-fixing properties of *Rhizobium* species. *Id.* at 128–29. However, a single *Rhizobium* species was typically symbiotic with only certain types of crops, meaning that those growing multiple crop types needed to customize inoculants with different bacterial species. *Id.* Combining multiple *Rhizobium* species into a single inoculant product failed because different bacterial species were mutually inhibitive. *Id.* at 129–30. Uniquely, the claimed inoculant combined a specific set of strains, across bacterial species, that were mutually *non-inhibitive*, and therefore favorable for use in agricultural applications. *Id.* at 130.

58. *Id.*

59. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

60. *Funk Brothers*, 333 U.S. at 130–32.

61. *Id.*

62. *Id.* at 131 (emphasis added).

discover[y]” from the eligibility statute itself.⁶³ But to support this assertion, he cited *Cuno Engineering Corp. v. Automatic Devices Corp.*,⁶⁴ a 1941 case that established a substantive “inventive step” or “non-obvious” requirement for patentability—now codified as § 103.⁶⁵ This grafted an aggressively elevated standard on top of *Neilson’s* original articulation.⁶⁶ The mere application of a “principle”—now, cast as a “natural” concept—would only be patent-eligible if also “inventive.”⁶⁷

Scholars have since noted the drastic impact of *Funk Brothers’* new “inventive application” standard on eligibility doctrine.⁶⁸ And in parallel, a fledgling policy rationale for patent *ineligibility* had also emerged, swirling around the fear of patenting “nature.”⁶⁹ Tellingly, in the *Funk Brothers* concurrence, Justice Frankfurter expressed concerns with the introduction of “vague and malleable terms” such as “‘the work of nature’ and the ‘laws of nature,’” because “[e]verything that happens may be deemed ‘the work of nature,’ and any patentable composite exemplifies in its properties ‘the laws of nature.’”⁷⁰ Still, however, “nature” was irreversibly introduced into the vocabulary of patent ineligibility, where it would remain.

2. *Track Two: “Formulaic” Ineligibility*

As inventions continued to circulate around “nature” at the precipice of the biotechnology revolution, simultaneous developments carried another category of patents into the digital age, introducing a new swath of patent eligibility problems.⁷¹ So, the Court articulated a new type of ineligible subject matter in 1972, in *Gottschalk v. Benson*.⁷² The claims in *Benson* were directed to methods of converting binary coded decimal numbers into pure binary numerals.⁷³ This invention was related to a concept that the Court marked as “ineligible”: the “mathematical procedure,” or “algorithm,” used for the

63. 35 U.S.C. § 101 (“Whoever *invents or discovers* any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”) (emphasis added).

64. 314 U.S. 84 (1941).

65. Syed, *supra* note 8, at 1968–69.

66. Lefstin, *supra* note 24, at 623.

67. *See id.* at 629.

68. *See id.* at 631 (“[C]ommentary in the immediate wake of *Funk Brothers* recognized its true nature . . . [having] demanded inventive application as a condition of patentability.”).

69. Syed, *supra* note 8, at 1965, 1967–68.

70. *Funk Brothers*, 333 U.S. at 134–35 (Frankfurter, J., concurring).

71. *See* MENELL ET AL., *supra* note 2, at 268.

72. 409 U.S. 63, 70–72 (1972).

73. *Id.* at 73–74 (excerpting representative claims from the asserted patent).

conversion.⁷⁴ Citing *Le Roy*, *Morse*, and *Funk Brothers*, the Court invalidated the patent, treating the “algorithm” as an “abstract intellectual concept[]” that was a “basic tool[] of scientific and technological work.”⁷⁵ Herein was a new, more explicit articulation of what the Court perhaps feared most for patents directed to ineligible subject matter: a patent with “no substantial practical application except in connection with a digital computer . . . would *wholly pre-empt* the mathematical formula.”⁷⁶ Interestingly, the Court proposed a method of restoring eligibility to the offending “algorithm” that felt lighter than that of *Funk Brothers*:⁷⁷ “[t]ransformation and reduction of an article ‘to a different state or thing’” might lend eligibility to claims not directed to “particular machines,” e.g., non-physicalized “algorithms.”⁷⁸ This case was the first time that an “abstract idea” was explicitly excluded as ineligible subject matter.⁷⁹

Then, in 1978, the Court expanded *Benson* and the exclusion of algorithms in *Parker v. Flook*.⁸⁰ The claims in *Flook* were directed to methods of updating an alarm limit based on present values.⁸¹ Again, this invention involved a freshly “ineligible” concept: the “mathematical algorithm or formula” used to calculate the updated alarm limit value.⁸² But instead of offering *Benson*’s relaxed “transformation” suggestion to restore eligibility to such an “algorithm,” the Court in *Flook* proposed an “inventive application” standard, much like in *Funk Brothers*.⁸³ And, incorrectly, the Court linked this proposal

74. *Id.* at 65, 67.

75. *Id.* at 67.

76. *Id.* at 71–72 (emphasis added); see also Mark A. Lemley, Michael Risch, Ted Sichelman & R. Polk Wagner, *Life After Bilski*, 63 STAN. L. REV. 1315, 1343, 1339–41 (emphasizing pre-emption considerations in § 101 analyses); Joyce C. Li, *Preemption, Diagnostics, and the Machine-or-Transformation Test: Federal Circuit Refinement of Biotech Method Eligibility*, 32 BERKELEY TECH. L.J. 379, 408 n.194, 408–11 (2017) (same).

77. See Syed, *supra* note 8, at 1971.

78. *Benson*, 409 U.S. at 70. Professor Syed details how the Court’s perception of patent-ineligible subject matter developed against a backdrop of overly “physicalist” concerns, rooted in a fundamental misconception as to the true “object” of a patent right. See Syed, *supra* note 8, 1958–61, 1977–80. This problem is *particularly* salient for digital age inventions that heavily intersected with mathematical formulas and algorithms, given their inherently “intangible” nature. See *id.* at 1969–72.

79. Lefstin, Menell & Taylor, *supra* note 13, at 559 n.29.

80. 437 U.S. 584 (1978).

81. *Id.* at 585.

82. *Id.* at 586.

83. *Id.* at 594; Lefstin, *supra* note 24, at 641 (“[T]he core of *Flook*[] [is] the difference between an unpatentable principle and a patent-eligible invention is invention in the application. But *Flook* took this core from *Funk Brothers*.”).

to *Neilson*.⁸⁴ Together, *Benson* and *Flook* laid the foundation for a second track of ineligible subject matter: “algorithms” or “formulas.”⁸⁵

C. EVOLUTION OF THE *MAYO/ALICE* TWO-STEP TEST

In the early 1980s, the Court redrew the patent eligibility standard yet again, first with a “natural,” then a “formulaic” invention. In *Diamond v. Chakrabarty*, the asserted patent claimed a *Pseudomonas* bacterium expressing at least two types of hydrocarbon-degrading plasmids.⁸⁶ As in *Funk Brothers*, a “natural” concept lurked within: the idea that bacteria are “products of nature.”⁸⁷ Here, for the first time, the Court expressed a version of the modern-day judicial exceptions—“laws of nature, physical phenomena, and abstract ideas”—apparently distilling these three areas out of *Flook*, *Benson*, *Funk Brothers*, *Morse*, and *Le Roy*.⁸⁸ But unlike the elevated standard of *Funk Brothers* and *Flook*, the Court in *Chakrabarty* adopted a relaxed approach, holding that because the patentee’s bacterium had “markedly different characteristics from [bacteria] found in nature”—that is, the carriage of plasmids—the invention was directed to patentable subject matter.⁸⁹ Indeed, Chief Justice Burger went so far as to assert that Congress intended for “anything under the sun that is made by man” to be patentable.⁹⁰ This decision opened up patent eligibility for genetically modified organisms,⁹¹ which for many years would lie at the heart of the biotechnology revolution.

The following year, the Court applied a similarly lowered eligibility standard to a “formulaic” invention. In *Diamond v. Diehr*, the asserted patent claimed methods for molding synthetic rubber compounds.⁹² As in *Benson* and

84. Others have provided far more comprehensive accounts of the *Flook* Court’s mistaken reading of *Neilson*. See, e.g., MENELL ET AL., *supra* note 2, at 286–87; Lefstin, *supra* note 24, at 581–87.

85. See Syed, *supra* note 8, at 1969–72. Notably, the Court also did not clarify how these concepts were distinct from the “natural” correlations of *Neilson*, *Le Roy*, *Morse*, and *Funk Brothers*. Professor Syed notes the confusion in the canonical listing of the three judicial exceptions (laws of nature, natural phenomena, and abstract ideas) in that both “natural phenomena” and “abstract ideas” include concepts within the “laws of nature” category, and instead suggests that these ineligibility categories should be termed “laws of nature, products of nature, and abstract formulas.” *Id.* at 1977–78.

86. 447 U.S. 303, 305 (1980).

87. *Id.* at 306.

88. *Id.* at 309 (citing this exact set of cases).

89. *Id.* at 310 (emphasis added).

90. *Id.* at 309 (relying on the legislative history of the 1952 Patent Act).

91. MENELL ET AL., *supra* note 2, at 287.

92. 450 U.S. 175, 220 n.5 (1981) (excerpting representative claims from the asserted patent).

Flook, the methods involved a “formula.”⁹³ But the Court seemed to slightly step back from the heightened standards of either case, although not quite to the leniency of *Neilson*, *Le Roy*, and *Morse*. First, Justice Rehnquist framed the current version of the three judicial exceptions to patent eligibility—“laws of nature, natural phenomena, and abstract ideas”—citing to *Flook*, *Benson*, and *Funk Brothers*.⁹⁴ He also noted that “novelty” . . . is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter,⁹⁵ apparently overruling the “inventive application” concept of *Funk Brothers* or *Flook*.⁹⁶ And finally, he affirmed a *Benson*-esque “transformation” requirement for “formulaic” inventions, asserting that “[limit[ing]] the use of a formula to a particular technological environment” could not overcome the presumption of ineligibility.⁹⁷ Undoubtedly, *Diehr* introduced immense confusion as to the status of *Flook*.⁹⁸ But just as *Chakerabarty* expanded the eligibility of “natural,” biotechnology-type inventions, *Diehr* did the same for “formulaic,” software-type inventions.

Predictably, biotechnology and software patents exploded in the years following *Chakerabarty* and *Diehr*.⁹⁹ Unfortunately, however, the newly relaxed standards for patent eligibility also inspired an influx of internet-related and business method patents, many of which were met with disdain.¹⁰⁰ This anchored the later enactment of the *Mayo/Alice* test, as the Court attempted to reel in patent issuance with yet another redefined eligibility standard.

After three decades of silence as to patent eligibility, in 2010, the Court granted review of a Federal Circuit case on a “formulaic” business method patent. In *Bilski v. Kappos*,¹⁰¹ the asserted patent claimed a business method for

93. *Id.* at 187.

94. *Id.* at 185.

95. *Id.* at 188–89.

96. MENELL ET AL., *supra* note 2, at 288.

97. *Diehr*, 450 U.S. at 191–92 (stating that an unpatentable principle cannot be transformed into a patentable process without significant “postsolution activity”).

98. *See id.* at 213–16 (Stevens, J., dissenting).

99. *See* MENELL ET AL., *supra* note 2, at 289. This movement arguably spurred the development of startup culture, as expanding patent portfolios lent credibility to early-stage business endeavors, helping many small companies attract investors. *Id.*

100. *Id.*; Syed, *supra* note 8, at 1974. Many have argued that both software and business method inventions should be viewed as categorically incapable of meeting a threshold of patentability. *See, e.g.,* Ognjen Zivojnovic, *Patentable Subject Matter After Alice—Distinguishing Narrow Software Patents from Overly Broad Business Method Patents*, 30 BERKELEY TECH. L.J. 807, 808–09 (2015); Issie Lapowsky, *EFF: If You Want to Fix Software Patents, Eliminate Software Patents*, WIRED (Feb. 25, 2015, 9:00 PM), <https://www.wired.com/2015/02/eff-eliminate-software-patents/>.

101. 561 U.S. 593 (2010).

“managing the consumption risk costs of a commodity,” that is, hedging risks during trading of commodities. The Court invalidated the patent as ineligible subject matter, stating that the claims merely reduced “the basic concept of hedging,” into “a mathematical formula . . . just like the algorithms at issue in *Benson* and *Flook*.”¹⁰² The Court further held that granting such a patent “would pre-empt use of th[e] approach in all fields.”¹⁰³ With this, the Court reilluminated *Benson*’s “pre-emption” fears, and resurrected a higher, pre-*Diebr* standard for assessing the eligibility of “formulaic” inventions. The next four years saw three decisions that solidified this version of the eligibility standard for two “natural” inventions and one “formulaic” invention.

First, in *Mayo*, the asserted “natural” patent was directed to drug dose optimization, specifically, determining the appropriate dosage level of a nucleoside analog to treat inflammatory bowel disease.¹⁰⁴ The Court asserted that the claims recited a “law of nature”—the correlation between the thiopurine drug dosage administered to a patient, the resulting toxic metabolites produced in their body, and the overarching toxicity and/or therapeutic efficacy of treatment.¹⁰⁵ Then, the Court asked “whether the claims do significantly more than simply describe these natural relations,” suggesting a search for a *Funk Brothers*-esque “inventive concept” to “transform an unpatentable law of nature into a patent-eligible application of such a law.”¹⁰⁶ Failing to find one, the Court held that the asserted claims were ineligible under § 101.¹⁰⁷

Then, in *Myriad*, the asserted “natural” patent was directed to BRCA1 genomic DNA (claim 1) and cDNA (claim 2).¹⁰⁸ Based on the Court’s subjective interpretation of what “naturally occurring” meant for the exons and introns of DNA, it held that claim 2—involving cDNA—did “not present the same obstacles to patentability as *naturally* occurring, isolated DNA segments” and was thus eligible under § 101, falling outside of the scope of

102. *Id.* at 611.

103. *Id.* at 612.

104. *Mayo Collaborative Servs. v. Prometheus Lab’s, Inc.*, 566 U.S. 66, 72, 77, 82 (2012).

105. *See id.* at 76.

106. *See id.* at 77, 82.

107. *See id.*

108. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 584 (2013). BRCA1 is a gene that encodes for a protein that researchers have linked to the development of breast cancer. *Id.* The claims of the asserted patent in *Myriad* were not formally construed, so this interpretation is based on the district court’s presumption that claim 1 was directed to “naturally occurring” DNA. *Ass’n for Molecular Pathology v. U.S. Pat. & Trademark Off.*, 702 F. Supp. 2d 181, 217 (S.D.N.Y. 2010).

the judicial exceptions.¹⁰⁹ The “naturally occurring” DNA of claim 1, on the other hand, was deemed to be an ineligible product of nature (encompassed within the “natural phenomena” judicial exception).¹¹⁰ As in *Mayo*, the Court held that the “isolation” of BRCA1 genomic DNA involved the mere *non-inventive* separation of the DNA from its flanking genomic regions, and therefore invalidated claim 1 under § 101.¹¹¹

Finally, in *Alice*, the asserted “formulaic” patent was directed to a business method of mitigating settlement risks by using third-party intermediaries.¹¹² Drawing a parallel to the formulaic business method of *Bilski*, the Court held that the invention was “drawn to the abstract idea of intermediate settlement,” and that there was no “inventive concept” present in its application.¹¹³ Invalidating the claims under § 101, the Court emphasized the foreboding concept of a “fundamental truth”¹¹⁴ and the attendant “pre-emption concern”¹¹⁵ for the final time, and then crystallized the current two-step *Mayo/Alice* test.¹¹⁶

The test is as follows: first, one must determine if the asserted claim is directed to a patent-ineligible concept, i.e., a law of nature, natural phenomenon, or abstract idea (step one).¹¹⁷ If so, the claim is presumptively ineligible for patent protection, unless one can identify some “inventive concept” embodied within the claimed invention that is “sufficient to ensure that the patent in practice amounts to *significantly more* than a patent upon the ineligible concept itself,” beyond “well-understood, routine, conventional activity” (step two).¹¹⁸

After *Alice* in 2014, the Court stepped away from patent eligibility, leaving district courts and the Federal Circuit to apply the *Mayo/Alice* test on their own.¹¹⁹ This has not gone well. Many view the new *Mayo/Alice* test as

109. *Myriad*, 569 U.S. at 594–95 (emphasis added). The *Myriad* Court has received intense criticism of its scientific outlook; however, it was *technically* correct at least in noting that the “natural” genomic DNA of claim 1 is measurably distinct from cDNA. The former contains both coding (exon) and non-coding (intron) regions, and the latter contains only coding (exon) regions and is typically produced by laboratory technicians.

110. *Id.* at 579.

111. *Id.* at 591.

112. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

113. *Id.* at 212.

114. *Id.* at 220.

115. *Id.* at 223.

116. *See id.* at 217–18.

117. *Id.* at 217 (citing *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 77 (2012)).

118. *Id.* at 217–18 (quoting *Mayo*, 566 U.S. at 72–73).

119. Lefstin, Menell & Taylor, *supra* note 13, at 555–56.

antagonistic towards innovation, given the cabined scope of eligibility for certain technologies.¹²⁰ To summarize the problems with the *Mayo/Alice* test: on the one hand, it appears that the test stems from a protracted misunderstanding of the nineteenth century case law on patenting “principles.” On the other, the test seems to capture the Court’s sensible ambivalence towards “natural” or “formulaic” inventions that threaten to “wholly preempt”¹²¹ something that is a “fundamental truth”¹²² or “part of the storehouse of knowledge of all men.”¹²³ Such inventions run the risk of limiting, rather than promoting innovation, and are thus incompatible with the fundamental purpose of the patent system.¹²⁴ Setting this venerable policy rationale aside, however, the *Mayo/Alice* test left the three issues¹²⁵ from *Neilson*, *Le Roy*, and *Morse* unresolved: (1) the meaning of an invention “directed to” a law of nature, natural phenomenon, or abstract idea is unclear (expanding upon the previous, elusive concept of a “principle”); (2) the degree of “inventive application” required to restore eligibility to one of these otherwise unpatentable judicial exceptions is confusing (replacing the previous, undefined degree of “embodiment” or “practical application”); and (3) the entire eligibility standard remains anchored in a “markedly ahistorical reading” of foundational case law (maintaining the nineteenth century confusion of enablement and claim construction case law into eligibility doctrine).¹²⁶

D. IMPACT OF THE *MAYO/Alice* TEST ON “NATURAL” AND “DIAGNOSTIC” INVENTIONS

“Diagnostic” inventions provide a particularly useful case study into the problems of the *Mayo/Alice* test, with *American Axle* emerging as a variant at the end of this grouping. The Court’s § 101 jurisprudence has had a striking impact on patent eligibility in this arena because diagnostic inventions are often perceived as “natural”—a biological correlation is typically leveraged to infer

120. See USPTO Eligibility Report 2022, *supra* note 19, at 21, 25, 28. The now-routine ineligibility of life sciences and computational inventions has spurred patent applicants in both areas to express great frustration with the Court’s § 101 jurisprudence. See Lefstin, Menell & Taylor, *supra* note 13, at 555; USPTO Eligibility Report 2017, *supra* note 18, at 34–38. Beyond the disparate impact on these technological areas, the *Mayo/Alice* test would also arguably render some of the “most famous[ly] patented inventions” ineligible today—that is, “historic” patents mostly comprising mechanical inventions embodied in tangible, physical instruments. See Michael Risch, *Nothing is Patentable*, 67 FLA. L. REV. F. 45, 51–53 (2015) (providing examples in Table 3, such as the electric motor, Morse code, or the light bulb).

121. *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

122. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

123. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

124. U.S. CONST. art. 1, § 8, cl. 8.

125. See discussion *supra* Section II.A.

126. Lefstin, Menell & Taylor, *supra* note 13, at 560.

a physiological “state” (e.g., disease, resistance, responsiveness) based on the presence of a biological “marker” (e.g., a macromolecule such as DNA, RNA, or protein, or a by-product such as a metabolite derived from an administered drug).¹²⁷

Here, several cases follow a similar pattern. An inventor holds a patent on some form of medical diagnostic strategy, which links an underlying “marker” with the identification of some health-relevant “state.” The patent is then challenged for validity under § 101, and like *Mayo* or *Myriad*, it is invalidated due to its intersection with a “natural” concept. And inventors, patent examiners, scientists, and even judges at the Federal Circuit bemoan the resulting invalidity and emphasize that the invention is remarkably innovative. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the invalidated patent claimed “methods of using cffDNA,” including “making a diagnosis of certain fetal characteristics based on the detection of paternally inherited cffDNA”—the marker here is cffDNA; the state is the fetal characteristic.¹²⁸ Many viewed this as an extraordinary invention that merited patent protection.¹²⁹ In *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, the invalidated patent claimed “methods for characterizing a test subject’s risk for cardiovascular disease” by measuring endogenous myeloperoxidase levels—the marker, myeloperoxidase; the state, cardiovascular disease.¹³⁰ Again, many felt that this invention should have been patent-eligible; in fact, the PTO had published a hypothetical example—strikingly similar to the claims at issue in *Cleveland Clinic*—that it deemed patent-eligible.¹³¹ And in *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, the invalidated patent claimed “methods for diagnosing neurological disorders” by detecting anti-muscle-specific tyrosine kinase (MuSK) antibodies—the marker, anti-MuSK antibodies; the state, the

127. Robert M. Califf, *Biomarker Definitions and their Applications*, 243 EXPERIMENTAL BIOLOGY & MED. 213, 213–15. For example, the invasiveness (state) of breast cancer can often be inferred from increased *HER2* oncogene expression (marker). Cristina Grávalos & Amaya Jimeno, *HER2 in Gastric Cancer: A New Prognostic Factor and Novel Therapeutic Target*, 19 ANNALS ONCOLOGY 1523, 1523 (2008); see also N. Lynn Henry & Daniel F. Hayes, *Cancer Biomarkers*, 6 MOLECULAR ONCOLOGY 140 (2012) (describing the identification and use of biomarkers for cancer diagnostics).

128. 788 F.3d 1371, 1373–74 (Fed. Cir. 2015). “cffDNA” refers to cell-free fetal DNA.

129. See, e.g., *id.* at 1380–81 (Linn, J., concurring) (deeming the invention “truly meritorious”).

130. 859 F.3d 1352, 1356 (Fed. Cir. 2017). Myeloperoxidase is an enzyme associated with inflammatory immune responses. Amjad A. Khan, Mohammed A. Alsahli & Arshad H. Rahmani, *Myeloperoxidase as an Active Disease Biomarker: Recent Biochemical and Pathological Perspectives*, 6 MED. SCIS. (BASEL) 1, 1–3 (2018).

131. *Federal Circuit Clarifies PTO Guidance Regarding Subject Matter Eligibility*, MORGAN LEWIS (Apr. 3, 2019), https://www.morganlewis.com/pubs/2019/04/federal-circuit-clarifies-pto-guidance-regarding-subject-matter-eligibility#_ftn4.

neurological disorder.¹³² The “cry for help”¹³³ after *Athena* was even further exaggerated, with eleven amici briefs filed supporting the ultimately unsuccessful certiorari petition.¹³⁴

In all of these cases,¹³⁵ district courts and the Federal Circuit offered similar reasoning in finding ineligibility. Diagnostic methods are necessarily “directed to” laws that judges view as “natural.” To be sure, the concept of a biological marker—the target of medical diagnostics—is theoretically a “natural” one, typically being a macromolecule that is endogenous to the human body and reflective of internal physiology. Thus, all marker-state relationships can be judicially interpreted as “natural” laws under step one of the *Mayo/Alice* test. So, the test proceeds to step two, requiring an “inventive concept” within the invention—where the diagnostics fail. Most diagnostic approaches apply the marker-state relationship to simply assess the state, using routine techniques in the art. And this does not meet the “inventive” standard of the *Mayo/Alice* test.

Of course, a measure of “inventiveness” is already embedded within diagnostic inventions—just not in a format suited to the *Mayo/Alice* test. It is the mere use of the marker-state relationship *to assess the state* that many would deem “inventive”—swallowed entirely by *Mayo/Alice*’s step two.¹³⁶ Thus, medical diagnostic inventions have become presumptively ineligible for patent protection, to the concern of many.¹³⁷ But worse yet is that the medical

132. 915 F.3d 743, 746–47 (Fed. Cir. 2019). Anti-MuSK antibodies are produced in people with conditions such as myasthenia gravis, and are part of an autoimmune response against important endogenous proteins.

133. Petition for Writ of Certiorari, *Athena*, 140 S. Ct. 855 (2020).

134. Dennis Crouch, *Athena v. Mayo: Strong Amicus Support*, PATENTLYO (Nov. 6, 2019), <https://patentlyo.com/patent/2019/11/athena-strong-support.html>.

135. *But see* *Vanda Pharms Inc. v. West-Ward Pharms Int’l Ltd.*, 887 F.3d 1117, 1121 (Fed. Cir. 2018) (providing an exception to the aforementioned set of cases, where the asserted patent claimed “method[s] for treating schizophrenia patients with iloperidone” using patient genotype and cytochrome P450 2D6 metabolic activity—the marker, cytochrome P450 2D6; the state, iloperidone responsiveness). Unlike the other diagnostic cases, the Federal Circuit held that the claims in *Vanda* were patent-eligible, despite a striking parallel between *Vanda* and *Mayo*. *Id.* at 1136.

136. Of course, assessing inventiveness in this way would necessarily involve an examination of the relevant prior art. MPEP § 2141 (9th ed. Rev. 10, June 2020) (providing the examination guidelines for assessing patentability under § 103).

137. *See, e.g.*, Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 *YALE L.J. ONLINE* 341 (2013) (explaining the uncertain impact of *Mayo* on the subject matter eligibility of molecular diagnostic inventions); Philip Merksamer, *Ariosa Diagnostics v. Sequenom: Metastasis of Mayo and Myriad and the Evisceration of Patent Eligibility for Molecular Diagnostics*, 31 *BERKELEY TECH. L.J.* 495 (2015) (arguing that together, *Mayo* and *Myriad* eviscerated eligibility for molecular diagnostics); Lauren Matlock-Colangelo, *Broadly Unpatentable: How Broad Method Claims Have Limited Patentability of Diagnostic Inventions*,

diagnostics and “natural” correlations of *Ariosa*, *Cleveland Clinic*, and *Athena* are not far from those from the nineteenth century era case law in *Neilson*, *Le Roy*, and *Morse*. The correlations of cffDNA with fetal characteristics,¹³⁸ myeloperoxidase with cardiovascular disease,¹³⁹ and anti-MuSK antibodies with neurological disorders¹⁴⁰ are of the same “natural” quality as the correlations of heated air with ignition efficiency,¹⁴¹ heated lead and wrought pipe continuity,¹⁴² and galvanic character with distanced character printing.¹⁴³ *American Axle* shows that such a correlation can also be drawn out of a “mechanical” invention, suggesting that the wrath of § 101 is not as specific to the life sciences as previously framed.

III. *AMERICAN AXLE*

A. CASE SUMMARY

As in *Ariosa*, *Cleveland Clinic*, and *Athena*, the Federal Circuit invalidated yet another “natural” correlation-based invention under § 101 in *American Axle*.¹⁴⁴

119 COLUM. L. REV. 797 (2019) (addressing the issue of overbroad claims in the diagnostic invention space); Li, *supra* note 76 (summarizing Federal Circuit case law relating to biotechnology inventions with a focus on medical diagnostic inventions). Fundamentally, the complaint is that patent protection is critical for diagnostic inventions, albeit not as conclusively as for pharmaceutical products. See Lefstin, Menell & Taylor, *supra* note 13, at 582–83.

138. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373–74 (Fed. Cir. 2015).

139. *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1356 (Fed. Cir. 2017).

140. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 746–47 (Fed. Cir. 2019).

141. *Neilson v. Harford*, 151 Eng. Rep. 1266, 1273 (1841).

142. *Le Roy v. Tatham*, 55 U.S. 156, 164 (1852).

143. *O’Reilly v. Morse*, 56 U.S. 62, 77–78, 114–16 (1854).

144. 967 F.3d 1285 (Fed. Cir. 2020). There is a complex procedural history leading up to the final Federal Circuit opinion in *American Axle*. American Axle & Manufacturing, Inc. (American Axle) first sued Neapco Holdings LLC (“Neapco”) in 2015, for infringement of U.S. Patent No. 7,774,911. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 309 F. Supp. 3d 218 (D. Del. 2018). The district court invalidated the American Axle patent. *Id.* Then, American Axle appealed to the Federal Circuit, which affirmed the district court’s holding. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019). American Axle then petitioned for both a panel rehearing and a rehearing en banc. The Federal Circuit granted the panel rehearing and withdrew the previous opinion. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d 1294 (Fed. Cir. 2020). Issuing a modified opinion after rehearing, the Federal Circuit affirmed the district court decision again, with similar reasoning to the initial opinion and a few key analytical changes. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020). This is the opinion that this Note will focus on. The same day that the refreshed *American Axle* opinion was issued, the Federal Circuit denied the petition for rehearing en banc in an evenly split, 6-6 vote—yielding 5 different

The asserted patent was directed to “an improved method for damping various types of vibrations in a hollow [drive]shaft.”¹⁴⁵ In an automobile, the driveshaft is the part of the vehicle that connects the transmission to the axle shaft and transmits drive torque (rotary power) from the engine to the wheels.¹⁴⁶ This positioning makes driveshafts vulnerable to vibrations that produce undesirable, disruptive noise for passengers.¹⁴⁷ American Axle’s invention addressed this problem with the application of liners to driveshafts to attenuate those vibrations.¹⁴⁸ Liners are susceptible to vibration—just as driveshafts are—but may vibrate at different frequencies, allowing for dampening of the vibration of the driveshafts that they might embrace.¹⁴⁹ Leveraging this concept, the claimed method of manufacture in the asserted patent included a step where variables of the liners (e.g., mass, stiffness) are tuned¹⁵⁰ to alter the ability for the liner to dampen vibration in the driveshaft.¹⁵¹

The Federal Circuit invalidated American Axle’s patent using the *Mayo/Alice* test.¹⁵² Under step one, Judge Dyk identified the claims to be directed to “use of a natural law of relating frequency to mass and stiffness—

opinions written by Judges Dyk, Chen, Newman, Stoll, and O’Malley. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d 1347 (Fed. Cir. 2020). American Axle then filed a petition for certiorari to the Supreme Court, but as in every patent eligibility case since *Alice*, the petition was denied. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 142 S.Ct. 2902 (2022).

145. U.S. Patent No. 7,774,911 col. 2 ll. 40–41. The specification describes three types of vibration that can occur: bending (lateral) mode, torsion mode, and shell mode. *Id.* at col. 1 ll. 42–43.

146. *See id.* at col. 4 ll. 20–31.

147. *See id.* at col. 1 ll. 8–27, 39–43 (noting that driveshafts are typically made of a “relatively thin-walled steel or aluminum tubing and as such, can be receptive to various driveline excitation sources . . . [that] cause the [drive]shaft to vibrate”).

148. Brad M. Scheller, Andrew H. DeVoogd & Matthew A. Karambelas, *SCOTUS Declines to Answer Calls for Clarification in American Axle v. Neapco*, NAT’L L. REV. (July 13, 2022), <https://www.natlawreview.com/article/scotus-declines-to-answer-calls-clarification-american-axle-v-neapco>.

149. *See* U.S. Patent No. 7,774,911 col. 7–8.

150. In the initial claim construction hearing, the court construed the “tuning” terms of U.S. Patent No. 7,774,911 (hereinafter, “the ’911 patent”) to mean “controlling characteristics [of a liner, e.g., mass or stiffness] . . . to match a relevant frequency or frequencies to reduce at least two types of vibration.” Put differently, here, to “tune” a liner refers to altering certain properties of it (e.g., mass, stiffness) for an expected output (e.g., frequency of vibration). *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 15-1168-LPS, 2017 WL 1334733, at *5 (D. Del. Apr. 7, 2017).

151. U.S. Patent No. 7,774,911 col. 10 ll. 10–27. Independent claims 1, 22, and 36 of the ’911 patent were all directed to attenuating two forms of vibration: shell mode and bending mode. *Id.* at col. 10, ll. 10–27, col. 11, ll. 24–36, col. 12, ll. 32–47.

152. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020).

i.e., Hooke’s law.”¹⁵³ The court held that representative claim 22 was “directed to a natural law because it clearly invokes a natural law, and *nothing more*, to accomplish a desired result.”¹⁵⁴ Moving to step two, the court held that the claims failed to identify an “inventive concept,” highlighting again that they did “nothing more” than instruct one to apply Hooke’s law when designing a driveshaft liner to reduce vibration.¹⁵⁵

Judge Moore wrote a fervent dissent, arguing that the claims were in fact not directed to Hooke’s law under step one, nor did they lack an inventive concept under step two.¹⁵⁶ She described the majority’s new explanation for why claim 22 was directed to Hooke’s law as the freshly introduced “nothing more” test, which inappropriately requires appellate judges to “resolve questions of science *de novo* on appeal,” playing the role of scientific experts.¹⁵⁷

B. ANALYSIS OF THE *MAYO/ALICE* TEST IN *AMERICAN AXLE*

American Axle illustrates that current § 101 eligibility doctrine imposes an elevated hurdle for even mechanical devices that are perceived to be “natural.” Is this outcome acceptable? Should *American Axle*’s driveshaft invention—and others like it—be deemed ineligible for patent protection? This Note submits that the *Mayo/Alice* test has narrowed patent eligibility for the wrong types of inventions, by asking the wrong questions of patent examiners and courts. *American Axle* is a useful case to illustrate the flaws in both steps of the *Mayo/Alice* test, justifying its removal and replacement with an alternative standard under § 101. This Section will first present the problems with the *Mayo/Alice* test, as demonstrated by *American Axle*, to advocate for its removal from eligibility doctrine. Part IV will then propose a replacement standard under § 101.

1. Step One of *Mayo/Alice* and the Ineligibility Bars

Step one of the *Mayo/Alice* test sets out an inescapable trap in asking if the asserted claim is directed to a law of nature, natural phenomenon, or abstract

153. *Id.* at 1294. Hooke’s law is a formula used to calculate the force created by a spring (e.g., a driveshaft) that has been displaced. Michael Oliver, *Greasing the Wheels of Patent Law: Clarifying the Judicial Exceptions via American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 29 J. INTELL. PROP. L. 370, 379 (2022). Specifically, it mathematically relates the mass and/or stiffness of an object to its vibration frequency.

154. *American Axle*, 967 F.3d at 1297 (emphasis added).

155. *Id.* at 1298–99.

156. *Id.* at 1305 (Moore, J., dissenting).

157. *Id.* at 1309, 1311 (Moore, J., dissenting).

idea.¹⁵⁸ This “directed to” question can almost always be answered affirmatively. Professor Risch aptly proposes that at some level of abstraction, “every invention will look like an abstract idea or natural phenomenon.”¹⁵⁹ This bears similarity to Judge Newman’s dissent from the denied en banc petition in *American Axle*, stating that so many inventions can simply be “reduc[ed] to mathematical abstractions and algorithms,” or Justice Frankfurter’s concurrence in *Funk Brothers*, asserting that “[e]verything that happens may be deemed ‘the work of nature.’”¹⁶⁰ As detailed in Section II.B, centuries of eligibility jurisprudence led the Court to select laws of nature, natural phenomena, and abstract ideas as the three ineligible concepts, which this Note reclassified as either natural or formulaic. Regardless of the nomenclature for these nebulous ideas, they are interwoven inextricably into most inventions. The invention in *American Axle* simply intersected with yet another “natural” correlation (Hooke’s law), just like the inventions in *Neilson*, *Le Roy*, *Morse*, *Ariosa*, *Cleveland Clinic*, and *Athena*. Like the medical diagnostics, the *marker* in *American Axle* was the liner variable (mass and/or stiffness), correlated with the *state* of vibration intensity. At this level of abstraction, it is hard to imagine an invention without such a correlation.

This Note argues that this problem is enough to warrant the complete removal of the ineligibility bars from the § 101 standard.¹⁶¹ In theory, the Court identified laws of nature, natural phenomena, and abstract ideas to be presumptively ineligible because their standalone patentability runs a greater risk of undue pre-emption, precluding too much valuable follow-on innovation.¹⁶² This, of course, is a very strong policy rationale. But if one can find a law of nature, natural phenomenon, or abstract idea in *any* invention if sufficiently abstracted, what purpose does step one of the *Mayo/Alice* test serve? Notably, the Court never even articulated a persuasive answer to the question of *why* the three ineligible concepts were predisposed to the pre-emption concern.¹⁶³ And while many scholars have proposed alternative, slightly clearer ideological lines along which to partition eligibility¹⁶⁴—*all* the

158. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014) (citing *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 77 (2012)).

159. Risch, *supra* note 120, at 53 (emphasis added).

160. 333 U.S. 127, 134–35 (1948) (Frankfurter, J., concurring).

161. Others have previously proposed and embraced the idea of overruling the ineligibility bars. *See, e.g.*, Risch, *supra* note 120.

162. *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972); *Bilski v. Kappos*, 561 U.S. 593, 611–12 (2010); *Alice*, 573 U.S. at 216 (2014).

163. Syed, *supra* note 8, at 1983 n.175.

164. Several scholars have proposed alternative ways of partitioning eligibility. *See, e.g.*, Lefstin, Menell & Taylor, *supra* note 13, at 563 n.50 (with “the result of human effort”); *id.* at 563–64 n.53 (with “physical or tangible form”); *id.* at 564 (with “practical application”); *id.*

existing suggestions are susceptible to the same fundamental problem. Defining a *concept* or a *category* of concepts as presumptively ineligible forces patent examiners and courts to perform an abstraction analysis without the guiderails of experience in that field (i.e., not from the standard perspective of “one of ordinary skill in the art”).¹⁶⁵ There is no avoiding the inherent subjectivity of such an inquiry; therefore, this Note contends that a line of ineligibility cannot and should not ever be drawn.

2. *Step Two of Mayo/Alice and the Redundant Inquiries*

American Axle also illustrates the futility of step two of the *Mayo/Alice* test, which inevitably bleeds into the substantive patentability doctrines of § 103 and § 112 by requiring an assessment of the prior art (§ 103) or an interrogation into the extent of disclosure (§ 112). It is certainly possible that the invention in *American Axle* was truly undeserving of a patent grant under § 103 or § 112. But in carrying out step two of the *Mayo/Alice* test, the Federal Circuit performed covert § 103 and § 112 analyses without the backbone of either statute to inappropriately invalidate *American Axle*’s patent on § 101 grounds.

a) From § 101 to § 103

As discussed in Section II.B.1, the Court in *Funk Brothers* grafted an “inventive application” standard into § 101, which the *Mayo/Alice* test solidified into the step two search for an “inventive concept.”¹⁶⁶ But the vague notion of inventiveness is also seen in § 103 of the Patent Act, which provides that an invention must not “have been *obvious* . . . to a person having ordinary skill in the art to which the claimed invention pertains.”¹⁶⁷ To assess patents

(with a specified list of categories, e.g., discoveries, scientific theories, mathematical methods, aesthetic creations, schemes, etc.); Patent Eligibility Restoration Act of 2022, S. 4734, 117th Cong. (2022) (with an evaluation of “technological” qualities, specifically proposed by Senator Tillis as a possible legislative reform to § 101); Syed, *supra* note 8, at 1981 (with an assessment of an “applied” rather than “basic” quality of the claimed invention). In contrast, the Court partitioned eligibility across a murky ideological line: things that are “fundamental truth[s]” or “part of the storehouse of knowledge of all men” are ineligible; thus, things that are “non-fundamental” or perhaps even “anything under the sun made by man” are eligible. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

165. MPEP § 2141 (9th ed. Rev. 10, June 2020).

166. *Alice*, 573 U.S. at 217–18 (quoting *Mayo*, 566 U.S. at 72–73).

167. 35 U.S.C. § 103 (emphasis added). Initially—and controversially—the non-obvious standard was viewed as a requirement for inventive, creative genius. *Cuno Eng’g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 90–91 (1941). The 1952 codification of the modern § 103 statute took a step back from the “genius” reference, but left the notion of non-obviousness intertwined with that of inventiveness. *Ryko Mfg. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991).

under § 103, courts compare claimed inventions against “the scope and content of the prior art” and theorize what one of skill in the pertinent art would obviously or non-obviously dream up.¹⁶⁸ And under step two of the *Mayo/Alice* test, the *American Axle* court did just this. In its very terms, step two of the *Mayo/Alice* test invites a prior art inquiry, asking whether the “inventive concept” is beyond “well-understood, routine, conventional activity *already engaged in by the scientific community.*”¹⁶⁹ It is hard to see how one could attempt to answer this question without looking to the prior art, mirroring the exact analysis that § 103 prescribes. Indeed, Judge Dyk focused on the extent to which liner manipulation relied upon techniques that were well-known in the prior art, describing the claimed advance as “simply controlling various *known* characteristics of the liner so as to achieve attenuation of two vibration modes . . . [using methods that were] *well known* in the automotive industry.”¹⁷⁰

In other words, the Federal Circuit affirmed that there was no inventive concept in *American Axle* because the implementation of the driveshaft invention was well-known in the field. There are two issues here. First, carrying out a canonical § 103 analysis under the guise of a § 101 challenge guts the structure of the patent statutes. Second, it forces judges to carry out a § 103 analysis without robust access to the relevant prior art (namely, extrinsic evidence to support the science).¹⁷¹ Rather than carrying out a comprehensive prior art analysis—one that would be supported by litigants defending against a § 103 invalidity challenge—the Federal Circuit judges were left with only the shreds of § 101 arguments.¹⁷² It may well be that the driveshaft invention in *American Axle* did not merit patent protection for a lack of inventiveness over

168. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Secondary considerations such as “commercial success, long felt but unsolved needs, [and] failure of others” are also factored into the § 103 analysis. *Id.*

169. *Mayo*, 566 U.S. at 79–80 (emphasis added).

170. *See American Axle*, 967 F.3d at 1290.

171. *See id.* at 1311 (Moore, J., dissenting). Worse yet, as litigants often bring § 101 challenges at early phases of litigation, this pseudo-§ 103 analysis might occur without claim construction or discovery.

172. To leave open the option of a pseudo-§ 103 analysis under § 101 is to disincentivize litigants from performing their own comprehensive prior art analyses as part of § 103 challenges. And litigants are much better positioned than the court to perform such an analysis. *See Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (C.C.S.D.N.Y. 1991) (noting “the extraordinary condition of law which makes it possible for a man *without any knowledge of even the rudiments of chemistry* to pass upon such questions as these,” in reference to the court needing to rely heavily on expert evidence to understand the technical details of the asserted patent) (emphasis added). If the majority and dissent had been given equivalent access to the prior art, perhaps their respective interpretations of the “inventive concept” (or lack thereof) in *American Axle* would have converged.

the prior art in the automobile manufacturing industry. But if so, the asserted claims should have been invalid under § 103, and not § 101.¹⁷³

b) From § 101 to § 112

As discussed in Section II.A, § 101 and § 112 have been blurred from the start. *Neilson* and *Morse*, two key nineteenth century “eligibility” cases, both hinged on disputes about the adequacy of disclosure—a modern § 112 inquiry.¹⁷⁴ *Neilson* set forth that embodiments or applications of “principles” were patent-eligible, but the patent at issue was truly being challenged for failing to adequately enable the invention.¹⁷⁵ *Morse* then used *Neilson* to reaffirm the importance of applying a “principle” to achieve eligibility, but again, the patent at issue suffered from inadequate disclosure.¹⁷⁶ The core elements of *Neilson* and *Morse* would today be strictly defined as § 112 problems.

To meet the § 112 standard, the specification of a patent must adequately disclose the invention, such that “any person skilled in the art to which it pertains . . . [could] make and use” it in the same way.¹⁷⁷ This statute is now understood to require two distinct elements within the concept of disclosure: written description and enablement.¹⁷⁸ Briefly, the written description doctrine requires that the specification indicate that the inventor was “in possession” of the claimed invention as of the application filing date.¹⁷⁹ The enablement doctrine requires that the patent owner adequately teach and support the entire range of embodiments set out in the patent claims.¹⁸⁰

173. See Brief of Professors Jeffrey A. Lefstin & Peter S. Menell as Amici Curiae in Support of Petitioner for a Writ of Certiorari at 6–7, *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 142 S.Ct. 2902 (2022) (No. 20-891), 2021 WL 859724 [hereinafter Lefstin & Menell Brief].

174. Lefstin, *supra* note 24, at 581–82, 596–97.

175. See *id.* at 580; Lefstin & Menell Brief, *supra* note 173, at 11.

176. See Lefstin, *supra* note 24, at 596–97.

177. 35 U.S.C. § 112(a).

178. These two requirements were deemed to be distinct in 2010. *Ariad Pharms. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc). *Ariad* set out a *quid pro quo* rationale of patent protection: that inventors should only be awarded the exclusionary, negative rights to their inventions if they give the public something in return—more than the mere existence of their invention in the world. *Id.* at 1345; Jacob Adam Schroeder, *Written Description: Protecting the Quid Pro Quo Since 1793*, 21 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 63, 66–67 (2010). A third requirement (best mode) exists within the statute but is now deemed irrelevant for modern patent practice. MENELL ET AL., *supra* note 2, at 262.

179. MENELL ET AL., *supra* note 2, at 273.

180. *Id.* at 263.

The invention in *American Axle* seemed to pose a conventional § 112 problem.¹⁸¹ The court focused on a lack of information as to how to craft the liner and drive shaft, and the absence of “any physical structure or steps for achieving the claimed result.”¹⁸² Bizarrely, Judge Dyk used these deficiencies to conclude that the driveshaft invention lacked an “inventive concept” under step two of the *Mayo/Alice* test, rather than that it more plausibly failed to meet the § 112 enablement standard.

Here, there are another two underlying issues: the implementation of a canonical § 112 analysis shoehorned into a § 101 challenge (1) guts the structure of the patent statutes, and (2) forces judges to carry out a § 112 analysis without the boundaries of the actual statute.¹⁸³ As Judge Newman described in her dissent, the majority’s analysis required the patent claims to go beyond mere definiteness, “inject[ing] a heightened enablement requirement into the § 101 analysis” that failed to adequately refer back to the specification.¹⁸⁴ Section 112—on its own—is better positioned to do the analysis that the *American Axle* court grasped at. And recent decisions even suggest a trend towards intensifying the § 112 requirement,¹⁸⁵ which will more robustly police the “pre-emption” concerns that anchor much of eligibility

181. See Lefstin & Menell Brief, *supra* note 173, at 3 (arguing that *American Axle* “presents an excellent vehicle for clarifying the interplay of § 101 and § 112 of the Patent Act”).

182. 967 F.3d 1285, 1295 (Fed. Cir. 2020).

183. For § 112 written description, the court should have explicitly defined the genus being claimed (liners designed with mass and/or stiffness factored in) and contemplated the entire range of contained species that must be adequately disclosed. For § 112 enablement, the court should have looked to the *specification* to assess the adequacy of disclosure in the driveshaft invention. Instead, the judges all fixated on the plain text of the *claims*, and whether they explained *how* to apply Hooke’s law on their own. See discussion *supra* Section III.A.

184. *American Axle*, 967 F.3d at 1317 (Moore, J., dissenting).

185. See, e.g., *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021) (tightening the written description requirement of § 112 to require more comprehensive disclosure, more rigorously enforcing that an inventor must have possessed the full scope of the claim at the time of filing); *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021) (tightening the enablement requirement of § 112 to require disclosure of all possible embodiments (species) within a genus and more rigorously enforcing that the scope of the claims at issue must be commensurate with the scope of disclosure). To be sure, some have expressed disappointment in what has become of the § 112 standard in recent years, and its potential impact on genus claims. Dmitry Karshedt, Mark A. Lemley & Sean B. Seymore, *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1 (2021). Others have expressed that this is, perhaps, an overstatement. Christopher M. Holman, *After Granting Certiorari in Enablement Case, Supreme Court Declines Opportunity to Address Written Description*, PATENTLYO (Nov. 11, 2022), <https://patentlyo.com/patent/2022/11/certiorari-opportunity-description.html>. Regardless of outlook, recent case law has clearly pushed for a § 112 standard that more rigorously polices claims with functional breadth.

doctrine.¹⁸⁶ So, just as for § 103, perhaps *American Axle*'s invention did not merit patent protection—but under § 112, not § 101.¹⁸⁷

Overall, collapsing the § 103 and § 112 patentability doctrines into § 101, as shown by *American Axle*, creates redundancy between the intentionally partitioned patent statutes and lessens the value of each substantive doctrine for challenging invalidity or defending validity. Twisting § 103 and § 112 questions into § 101 allows litigants and courts to dilute or concentrate the impact of either statute. Removing the *Mayo/Alice* test as an option for covert § 103 or § 112-type inquiries would reinvigorate both doctrines, eliminating the needless and harmful redundancy between the statutes.

IV. A REVISED FRAMEWORK FOR PATENT ELIGIBILITY

Part III uses *American Axle* as a vehicle to argue that steps one and two of the *Mayo/Alice* test are fundamentally flawed. The first step forces a subjective evaluation of “ineligibility” that can capture almost any invention, and the second step forces a betrayal of the partitioned structure of the Patent Act. But if the *Mayo/Alice* test were to be set aside, what could stand in its place? A persuasive solution is to find a sweet spot for the § 101 standard: one that is low enough to avoid an administratively frustrating overlap with § 103 or § 112, but high enough to remain mindful of policy concerns such as whole field pre-emption. That is, the vestiges of the substantive patentability doctrines should be filtered out, but some baseline level of eligibility must be maintained.

To this end, this Note suggests that the existing eligibility inquiry under § 101 should be reoriented to simply focus on utility, stemming from the word “useful” in § 101. That is, the *Mayo/Alice* test ought to be replaced with a utility-oriented eligibility framework, distinct from the current understandings

186. One way of dealing with the pre-emption concern is to treat “laws of nature” as presumptively ineligible for patent protection because claiming such a law might pre-empt its use in all contexts. But a proper evaluation of patent applications under § 112 might render this unnecessary. The enablement requirement of § 112, for example, should theoretically require an inventor to disclose *all possible means* of using a law of nature. That is, if an inventor has such broad claims so as to risk “whole pre-emption” of a law of nature, then they will have to understand it—and all its potential—well enough to describe those pre-empted uses in depth. This, for most laws of nature, is a remarkably high standard to meet—possibly, high enough to disqualify many inventions that are currently dealt with on eligibility grounds. The inherent similarity between the function of § 112 disclosure (in policing claim breadth) and § 101 eligibility (in guarding against pre-emption) is, perhaps, the reason for the inevitable overlap between these doctrines, as seen in *American Axle*. This is distinct from the overlap between § 103 and § 101, which might be better characterized as an artifact of the doctrinal language (the sharing of the word “inventive”).

187. Lefstin & Menell Brief, *supra* note 173, at 7.

of both § 101 eligibility and § 101 utility. This Part will first contextualize this proposal among the existing interpretations of § 101 utility, and then detail the parameters of this Note’s heightened utility-eligibility § 101 standard.

A. EXISTING PERSPECTIVES ON § 101 UTILITY

Currently, patent examiners and courts interpret the word “useful” in the text of § 101¹⁸⁸ to require simply that an invention have some extraordinarily minimal form of “utility.” This is not collapsed into § 101 eligibility, but rather, treated as its own requirement. By many accounts, the modern-day § 101 utility standard is a very low threshold that most inventions easily satisfy.¹⁸⁹ But despite its now-defunct status, the § 101 utility standard initially had much more significance—possibly, in fact, entirely anchoring patent protection in its early days.¹⁹⁰ And in more recent years, specific concerns have spawned efforts to heighten the utility requirement for certain types of patents.¹⁹¹ Together, the history of patent utility and its attendant policy considerations indicate that three existing perspectives on utility are available.¹⁹² This Section will briefly summarize each perspective.

1. *Social and Moral Utility*

An early interpretation of “useful” in § 101 appeared to require “social utility” of inventions.¹⁹³ In the formative years trailing the codification of the 1790 patent regime, patents were treated as a *privilege* that the Patent Board¹⁹⁴ had the power to bestow.¹⁹⁵ In keeping with this privilege-oriented framework, the Board would “weigh the social costs and benefits underlying each grant,”¹⁹⁶ encouraging patent petitions that extolled the virtuous public benefits of

188. 35 U.S.C. § 101 (“Whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”) (emphasis added). The word “useful” has been part of the patent statutes since their first form in the 1790 Patent Act. Syed, *supra* note 8, at 2030–31 (compiling the present-day text of § 101 and all previous versions of the statute in Table 1). It is even woven into the Intellectual Property Clause itself. U.S. CONST. art. 1, § 8, cl. 8 (referring to the “*useful* Arts”) (emphasis added).

189. *See, e.g.,* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999) (“The threshold for utility is not high.”).

190. *See* discussion *infra* Section IV.A.2.

191. *See* discussion *infra* Section IV.A.3.

192. *See* Syed, *supra* note 8, at 2028 (articulating three available perspectives of utility).

193. *See* BRACHA, *supra* note 24, at 188–89, 202–03.

194. The Patent Board of the 1790 Patent Act is the historical analog to the modern PTO. *Id.* at 203–04.

195. *Id.* at 194.

196. *Id.* at 194–97.

inventions.¹⁹⁷ Utility, at this point, was enshrined as a serious patentability requirement.

Later, this “social utility” view shifted into one that was more moral in nature. As recounted by Professor Bracha, the ideological and practical perception of patents transformed from “economic privilege[s] . . . bestowed on inventors” into “inventors’ rights.”¹⁹⁸ Patents went from a discretionary privilege conferred by the Patent Board to an almost presumptive right to be checked by the courts, after issuance.¹⁹⁹ With this, the previous “useful” inquiry—asking, more or less, whether an invention did something *worthwhile for society*—morphed into a more subjective, morally tinged assessment to weed out “mischievous” inventions.²⁰⁰ While popular for some time, neither the social nor moral views of utility currently persist in U.S. patent law.²⁰¹

2. Operable Utility

The value-based assessments of utility were later replaced with an operability view, which remains the prevailing inquiry under present-day § 101 utility for most inventions. Under this perspective, the word “useful” in § 101 is read to suggest simply that an invention “works,” i.e., that it is operable for its disclosed purpose.²⁰² This operability view was ushered in by the statutory

197. *Id.* at 196–99.

198. *Id.* at 188. Some perspectives from this time suggest the embracing of a labor theory-type rationale to catalyze this ideological shift, for example, “a citizen has a right in the inventions he may make, and he considers the law but as the mode by which he is to enjoy the fruits.” *See id.* at 190.

199. *Id.* at 200–02.

200. *See id.* at 203–07 (discussing, among other things, two conflicting constructions of “utility” that emerged in these years: one focused on the “objective social value” of an invention, where a patentee must show a mere “public benefit”; the other focused on a “moralistic framing,” where a patentee must show “that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society”). The “moral utility” perspective can be traced back to Justice Story’s statement deeming inventions that are “injurious to the well-being, good policy, or sound morals of society” to be unpatentable. *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817).

201. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999) (putting the moral requirement of utility, which had begun to rear its head again, to rest: “[t]he requirement of ‘utility’ in patent law is not a directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices”). There is, now, a strong opposition to the notion that questions of morality or general community welfare would permeate the patent laws. *Id.* *But see* Laura A. Keay, *Morality’s Move Within U.S. Patent Law, From Moral Utility to Subject Matter*, 40 AIPLA Q.J. 409 (2012) (noting that § 101 case law represents the infiltration of morality considerations into patent law, once again, without the backbone of historical “moral utility”).

202. Syed, *supra* note 8, at 2028. The canonical example of an invention that would not meet this standard is a perpetual motion machine, which is a physical impossibility. *Id.*

reform leading to the 1836 Patent Act and the establishment of the PTO. The new “utility” of the 1836 Patent Act was not the same as the privilege-anchored version from the 1790 regime.²⁰³ The PTO did not have the Patent Board’s “discretionary powers to grant privileges,” rather, its role was “to certify the satisfaction of standard patentability criteria.”²⁰⁴ With the privilege view put to rest, the social and moral questions were replaced with a quest for uniform patentability.²⁰⁵ Patents, strictly, would be “rights” open to all, with the *market* serving as the arbiter of utility, rather than the PTO.²⁰⁶ So long as the patent met other criteria—now codified as the substantive doctrines of § 102, § 103, and § 112²⁰⁷—the utility of an invention would be naturally assessed based on its demand in the market, such that the inventor would derive value from their patent in proportion to its market utility.²⁰⁸ And with a market-oriented, rights-based view of patent protection, a *substantive* utility requirement was seemingly unwarranted.²⁰⁹ While previously “a central defining feature of patents,” utility became “the exotic periphery of patent law” by the end of the nineteenth century.²¹⁰

3. *Specific, Substantial, and Credible Utility*

A third perspective on utility comes from *Brenner v. Manson*, which added a gloss over the operability view just discussed: utility must be specific, substantial, and credible.²¹¹ These terms are loosely defined, with “specific” suggesting *not vague*, “substantial” suggesting *not throw-away*, and “credible” suggesting *believable for its purpose*,²¹² to be evaluated from the perspective of one of skill in the art.²¹³ The *Manson* Court rationalized this elevated utility standard by citing policy concerns as to the scope of patentability and the notion of pre-

203. BRACHA, *supra* note 24, at 209–13.

204. *Id.* at 209. Professor Bracha describes this shift in perspective as reflective of Jacksonian ideology, which eschewed a former paternalistic implication of the 1790 regime’s utility standard: that the government was appropriately positioned to identify an objective, social utility common to all, and then promote it with the privilege of a patent. *Id.* at 209–12.

205. *Id.* One possible view is that the original casting of the patent right—then, a privilege—only emphasized “use” as a placeholder, before the complete set of patent doctrines took shape.

206. *Id.*

207. *See id.* at 202–03.

208. *See id.* at 212–14 (explaining the market-oriented view of patent valuation).

209. *Id.* at 215. For some time, courts still scrutinized the utility requirement under the 1836 regime, but the utility requirement did eventually decline in importance entirely. *Id.* at 214.

210. *Id.* at 216.

211. 383 U.S. 519, 527–33 (1966); MENELL ET AL., *supra* note 2, at 248.

212. *See id.* at 245–48.

213. MPEP § 2107 (9th ed. Rev. 10, June 2020).

emption—not unlike the case for eligibility.²¹⁴ In evaluating the meaning of “useful” for a patent claiming a steroid,²¹⁵ Justice Fortas focused on the risk of monopolization with a tone mirroring that of *Benson*, *Bilski*, and *Alice*.²¹⁶ Without a showing of use, he opined that “the metes and bounds of [a] monopoly are not capable of precise delineation,” threatening to “confer power to block off whole areas of scientific development, without compensating benefit to the public.”²¹⁷

Manson remains the zenith of § 101 utility. Although all inventions are now formally required to show specific, substantial, and credible utility, these adjectives are rarely a bar to patentability, in perception or practice.²¹⁸ However, *Manson* has at least appeared to have an effect on chemical compositions (e.g., requiring perhaps a feasible therapeutic application for a claimed compound,²¹⁹ even if supported only from *in vitro* testing²²⁰) and biotechnology inventions (e.g., allowing claims directed to coding DNA fragments only if the resultant translated proteins had known functional uses that the inventor could articulate²²¹). The specific application of the *Manson* standard to biotechnology patents was precipitated by the attempted patenting of human genes in the 1990s,²²² which inspired the PTO to “mov[e] toward a

214. Professor Taylor has noted that, at the time of *Manson*, the Court used the utility requirement to address “the very concerns of the Supreme Court in its recent cases addressing patent eligibility.” Taylor, *supra* note 10, at 2189 (2017).

215. The patent in *Manson* claimed a steroid composition but did not specify any use for that composition. Instead, the patent specified the known use of other steroid compositions, which were similar in structure to the claimed composition. 383 U.S. at 533–34.

216. *See id.* at 534–35.

217. *Id.* The *Manson* opinion weighed heavily in favor of the *quid pro quo* rationale to patent protection, where inventors are required to not only adequately disclose their inventions under § 112, but also produce an invention that is “useful” *to some end*, to provide “a significant and presently available benefit to the public.” *See In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

218. *See MENELL ET AL.*, *supra* note 2, at 245–46, 248 (calling *Manson* the “high-water mark” of the utility doctrine and noting that “[m]ost applications of the doctrine have been limited in the hurdles they place before inventors”).

219. *See In re Brana*, 51 F.3d 1560, 1565 (Fed. Cir. 1995).

220. *See Cross v. Iizuka*, 753 F.2d 1040, 1048 (Fed. Cir. 1985).

221. Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 133 (2001).

222. *Chakrabarty*’s permissiveness towards living organism patentability led scientists to begin seeking patent protection on expressed sequence tags (ESTs)—fragments of cDNA, not whole genes—in the early 1990s. Daniel J. Kevles & Ari Berkowitz, *The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics*, 67 BROOK. L. REV. 233, 235–37 (2001). Many disapproved of this trajectory, given the concern that an EST patent landscape would foreclose considerable future research—the pre-emption rationale, again. *Id.* at 237–39. These years also saw the attempted patenting of the *BRC A1* and *BRC A2* genes, which was also met with “overwhelmingly negative” public perception. Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 ANN. REV. GENOMICS & HUM.

stronger requirement for utility.”²²³ And the 2001 Utility Guidelines issued by the PTO effectively pushed the timing of chemical and biotechnology patenting further downstream in the discovery process.²²⁴ In these contexts, specific, substantial, and credible were interpreted to mean that inventors could only claim what they truly had in hand and truly understood on a functional level.²²⁵

B. THE PROPOSED UTILITY-ELIGIBILITY FRAMEWORK

The previous Section describes three currently available perspectives on utility. This Note suggests a fourth construction of utility to replace the existing § 101 eligibility inquiry. The next three Sections will describe the parameters of this fourth utility perspective, clarify how it supports the policy justifications for current eligibility doctrine, and explain its implications for overall patentability.

1. *Scope-Limiting Utility*

There are three layered requirements embedded in this Note’s proposal. The first requirement is that in assessing whether an “invent[ion] or discover[y]” of a “process, machine, manufacture, or composition of matter” is “useful” under § 101,²²⁶ patent examiners and courts should require that *some* finite use or set of uses is delimited by the claims. Specifically, the claimed use or set of uses must not be *infinite* or left out of the claims and only suggested in the specification. This is distinct from the existing standard of operable

GENETICS 383, 389–90 (2010). The most common concern was another depiction of the pre-emption rationale: that gene patents would specifically preclude the development of future sequencing technology and diagnostic tests. Christopher M. Holman, *Debunking the Myth that Whole-Genome Sequencing Infringes Thousands of Gene Patents*, 30 NATURE BIOTECHNOLOGY 240, 240–41 (2012).

223. *In the Crossfire: Collins on Genomes, Patents, and ‘Rivalry,’* 287 SCI. 2396, 2397 (2000) (transcribing an interview with Francis Collins, the head of the National Human Genome Research Institute and leader of the Human Genome Project). Collins referred to the gene patents feared by many as “generation one” applications, where inventors had “just a [DNA] sequence” but “no clue as to what it does.” The PTO’s Utility Guidelines deemed these applications to be insufficiently “specific” to meet the *Manson* standard. Purists may also include, as “generation one” applications, claims directed to sequences with a vague construction of function based on homology—not unlike the steroid composition claims in *Manson*. *Id.*

224. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1097–99 (Jan. 5, 2001).

225. See Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines and DNA Patents*, 16 BERKELEY TECH. L.J. 123, 132 (2001) (explaining the stringency of the newer utility examination guidelines on certain types of inventions).

226. 35 U.S.C. § 101 (“Whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”) (emphasis added).

utility under § 101, which does require that inventions “work” for their disclosed purposes,²²⁷ but does not require setting out those disclosed purposes *in the claims*.²²⁸ That is, under the current § 101 utility standard, applicants can satisfy the low-bar utility requirement through a merely qualitative suggestion of use in the specification. The instant proposal, instead, is a quantitative requirement of use, embedded into the claims.

The second requirement of this proposal makes clear the implications of placing a set of uses in the claim language itself. In this Note’s framework, the scope of the exclusionary patent right would be limited to the uses laid out in the application’s claims (of course, also accommodating for equivalents and after-arising technology, to be interpreted from the specification).²²⁹ And in keeping with the current standards under § 112, these uses would need to be commensurate with the scope of the material disclosed in the patent specification, which would require both adequate disclosure and the contemplation of all embodiments. Currently, § 112 doctrine requires only claims containing means-plus-function language to be interpreted in this way.²³⁰

The third and final requirement answers a lingering question within this framework—what are the qualities of an adequate “use” for the purposes of limiting claim scope? Scope-limiting uses must be “specific, substantial, and credible,” as per *Manson*. On its own, this requirement does not signal a change in existing § 101 utility doctrine—patent examiners are already advised to apply *Manson*’s adjectives to all inventions.²³¹ However, when integrated with the other two requirements, this would push the *Manson* standard outside of merely chemical and biotechnology patents, where its application currently has the most force. This casting of “use” is closer in meaning to the “practical application” requirement of *Neilson*, *Le Roy*, and *Morse*, rather than the “inventive application” requirement of *Funk Brothers*, *Flook*, *Mayo*, *Myriad*, and

227. Syed, *supra* note 8, at 2028.

228. See *infra* note 247 and accompanying text (explaining the current standard of utility applied to claim language, with the example of standalone composition of matter claims).

229. Recall that the “right” conferred by a patent is a negative, exclusionary one, to exclude others from making, using, or selling the invention—specifically, the invention as “defined and limited by the language in that patent’s claims.” *Corning Glass Works v. Sumimoto Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Here, that language will specifically include the clearly articulated set of uses that the applicant lays out.

230. See MPEP § 2181 (9th ed. Rev. 10, June 2020). At least one Note has, similarly, proposed that claims directed to one of the judicial exceptions could be treated as means-plus-function claims (as an alternative to the *Mayo/Alice* test). See, e.g., Nicholas Stroger, *An Automatic Means-Plus-Function Limitation for Otherwise Unpatentable Subject Matter*, 22 WAKE FOREST J. BUS. & INTELL. PROP. L. 243 (2022).

231. See MPEP § 2107 (9th ed. Rev. 10, June 2020).

Alice.²³² This Note proposes to simply replace “practical application” with a requirement for an explicit use or set of uses, not required to be “practical” or “inventive,” but “specific, substantial, and credible.”

2. Innovation Policy Justifications

Why is this scope-limiting utility framework a viable substitute for the existing § 101 eligibility inquiry? Is this proposal enough to replace the ineligibility bars on laws of nature, natural phenomena, and abstract ideas? To answer these questions, it is useful to think back to the innovation policy rationale anchoring the existence of the § 101 eligibility standard itself. Part II of this Note traced the history of patent eligibility jurisprudence, revealing that the strongest justification for the ineligibility bars was expressed in *Benson*,²³³ *Bilski*,²³⁴ and *Alice*.²³⁵ the threat of pre-emption. The § 101 eligibility standard, ideally, is a bulwark against inventions that are novel, non-obvious, and adequately disclosed, yet also pre-empt the use of a critical, pseudo-universal concept in other inventions.²³⁶ In theory, these “pre-emptive” inventions threaten to impede more innovation than they would promote, betraying the fundamental purpose of the patent system.

This Note agrees with the importance of the pre-emption rationale, as patents that tie up “building blocks”²³⁷ and monopolize entire technological fields are a deterrent to innovation. But the *Mayo/Alice* test does not suffice to address the pre-emption rationale. The nuances of this argument aside, borne out in the preceding Parts—the *Mayo/Alice* test asks the wrong questions and is fundamentally unclear. The proposed scope-limiting framework, instead, addresses the pre-emption rationale with more clarity.²³⁸ The Court’s pre-emption fears were arguably tailored to disallowing claims that “substantially encompass” an ineligible concept. But, as others have noted, what really should be disallowed are claims that fail to “impose[] a meaningful limit” on

232. See discussion *supra* Part II.

233. 409 U.S. 63, 71–72 (1972).

234. 561 U.S. 593, 611–12 (2010).

235. 573 U.S. 208, 223 (2014).

236. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

237. Syed, *supra* note 8, at 1967–68 & 1967 n.105 (describing the “building block” rationale that emerged from the Court’s eligibility jurisprudence, getting to the heart of the pre-emption concern).

238. Again, arguably, the *Manson* opinion swirled around this same policy rationale. Justice Fortas justified the heightened utility standard applied to the invention in *Manson* against pre-emption concerns. 383 U.S. at 534–35.

the concept.²³⁹ Requiring an explicit articulation of scope-limiting uses to be set out in the patent claims themselves does just this—it imposes a meaningful limit. Thus, this casting of utility-eligibility improves upon the *Mayo/Alice* test by shifting the burden of assessing that “meaningful limit” away from patent examiners and courts and toward applicants, who themselves must write their uses into their claims with precision. And in doing so, the proposed model avoids the ineligibility bar question entirely by uniformly imposing this standard across all inventions.²⁴⁰

3. *Implications of and Potential Improvements to the Proposal*

It bears emphasizing that this Note is not the first to call attention to the utility requirement as a vehicle for patent reform. Many have specifically looked to § 101 utility in the context of patent eligibility, albeit not with the exact boundaries of the instant framework.²⁴¹ Compared to these other

239. See David V. Sanker & Jillynne Quinn, *A Quantitative Approach to Overcoming § 101 Rejections*, PAT. LAW. 17 (2021), <https://www.morganlewis.com/-/media/files/publication/outside-publication/article/2021/a-quantitative-approach-to-overcoming-101-rejections-the-patent-lawyer.pdf?rev=bf8e7a96c0e44e058c09c24a04855099&hash=BED99736E739B6E7F1E590386001A633>. David Sanker and Jillynne Quinn have proposed a “quantitative approach” to evaluating § 101, painting the eligibility question as one that should compare: (1) the realm of options included in the ineligible concept; with (2) the realm of options included in the *claim* relating to the ineligible concept. *Id.* This, in effect, is a search for a meaningful limit—a patent-eligible invention should simply be one in which the realm of options covered by the claim is “meaningful[ly] limit[ed],” compared to the realm of imaginable options covered by the ineligible concept itself. *Id.* The “meaningful limit” language was proposed by the PTO as a useful way of thinking about patent eligibility. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 4 (Jan. 7, 2019), <https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf> (“A claim that integrates a judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a *meaningful limit* on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.”) (emphasis added).

240. For a possible exception to this standard, see discussion *infra* Section IV.B.3.

241. See, e.g., Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046 (2014) (proposing the entire deletion of the utility requirement, with an argument resembling that of this Note regarding the current eligibility standard—that it is redundant with the other patentability doctrines); Robin C. Feldman, David A. Hyman, W. Nicholson Price II & Mark J. Ratain, *Negative Innovation: When Patents Are Bad for Patients*, 39 NATURE BIOTECHNOLOGY 914, 914–15 (2021) (highlighting the vulnerabilities of pharmaceutical patents to negative innovation—where patent law incentivizes innovation into directions that are net harmful to the public—and suggesting that the utility standard should be heightened for pharmaceutical patents to require that they “actually improve social welfare relative to the prior art,” for example, by “requir[ing] certification of likely improvement, followed by a demonstration that the improvement had materialized, on pain of losing the patent”); Michael Risch, *A Surprisingly Useful Requirement*, 19 GEO. MASON L. REV. 17 (2011) (arguing that the utility standard should be more harmoniously woven into the other substantive patentability doctrines); Sean M. O’Connor, *The Lost “Art” of the Patent System*, 2015 U. ILLINOIS L. REV. 1397, 1476 (2015)

proposals, the instant scope-limiting utility standard does not clearly expand or contract the overall stringency of § 101.²⁴² Instead, it treats a different set of inventions as patent-eligible. For some inventions—those that are vulnerable to characterization as “natural” or “formulaic,” which currently succumb to the *Mayo/Alice* test—this proposal makes § 101 a lower bar. As discussed in Section IV.B.1, requiring applicants to claim a specific, substantial, and credible set of uses is a lower standard than the “inventive application” requirement of *Mayo/Alice*, closer to the “practical application” requirement of nineteenth century eligibility case law. This Note has already advanced several arguments to support this outcome. Briefly, again, § 103 and § 112 can adequately police most inventions challenged under § 101, and the imposition of the proposed framework would still impose a meaningful limit to guard against pre-emption concerns. All the “natural” and “diagnostic” inventions discussed in Section II.D—deemed ineligible under § 101—would likely satisfy this Note’s version of § 101 utility-eligibility, given their specific, substantial, and credible uses²⁴³ in the context of fetal characteristic analysis,²⁴⁴ cardiovascular disease risk assessment,²⁴⁵ and neurological disorder diagnosis.²⁴⁶ The same is true for the invention in *American Axle*, which articulated a use for the invention in the specific, substantial, and credible context of driveshaft assembly.

For other inventions—those that do not intersect with the so-called ineligibility concepts, do not traditionally claim a set of uses, and have not yet been discussed by this Note—this proposal would radically elevate the § 101 hurdle. Replacing the *Mayo/Alice* test with the instant framework means that

(describing that limiting the scope of patent-eligible subject matter those inventions that “progress or advance the use of natural materials or forces for *practical (useful)* ends” would remove the need for judicial exceptions, in an argument based on a historical reconstruction of the target “art” of the patent system) (emphasis added); Taylor, *supra* note 10, at 2188–89 (proposing, among other types of amendments to repair eligibility doctrine, that the utility requirement be elevated to require that inventors describe the use of an invention in the claims, rather than merely the specification); Syed, *supra* note 8, at 2029, 2033–35 (suggesting that the word “useful” in § 101 might illustrate a “subject-matter delimiting” role for patent utility doctrine, wherein “useful” connotes “applied,” and that only practical, downstream applications of knowledge should be patent-eligible subject matter, rather than basic, unapplied knowledge).

242. See *supra* note 241.

243. Of course, one of skill in the art would need to perceive the data in each patent as credible to satisfy this analytical standard.

244. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

245. *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017).

246. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 746–47 (Fed. Cir. 2019).

all inventions would be subjected to the same level of scrutiny. Even inventions that are not “directed to” ineligible concepts would require an explicit articulation of scope-limiting, specific, substantial, and credible uses. In this sense, the proposed utility-eligibility framework needs further refinement. On the one hand, the current § 112 disclosure requirements are, as is, tailored to serve this function—inventors should theoretically not be able to claim uses of an invention that are not yet understood or even anticipated. But on the other hand, many patentees benefit from claims untethered to uses—for example, claims directed to entirely novel, synthetic small molecules.²⁴⁷ Thus, there are perhaps some technological areas that need to be somehow exempted from this Note’s proposal, suggesting a degree of unavoidable exceptionalism in eligibility doctrine that merits further research and discussion.²⁴⁸

V. CONCLUSION

This Note proposes a revised framework for § 101, replacing the current eligibility standard with a heightened utility requirement: that patents must lay out a finite set of specific, substantial, and credible uses in their claims,

247. See generally Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEXAS L. REV. 503 (2009) (explaining how pharmaceutical firms view strong composition of matter patents as essential in the drug development process). The current § 101 eligibility and utility standards, even with the guidelines of *Manson*, would allow a composition claim directed to that small molecule itself, with no express articulation of its use(s) (i.e., “A compound of formula X, or a pharmaceutically acceptable salt thereof,” with nothing more). That is, an applicant’s discovery of new chemical matter is currently sufficient under § 101 for them to tie up all future uses of it. Under this Note’s framework, such a claim would be invalid—the applicant would be entitled to claim only the uses of that small molecule that they understand enough to satisfy *Manson*’s specific, substantial, and credible standard (i.e., an allowed claim would need to recite “A compound of formula X, or a pharmaceutically acceptable salt thereof, for [one or more specific, substantial, and credible uses].”). To be sure, viewed against the reward-incentivization framework of the patent system, it is unfair and perhaps even entirely unnecessary to entitle a patent applicant to yet-uncontemplated uses of a discovery, simply because they were the one to discover it. Further, the PTO’s notion of a “meaningful limit” and the Court’s consistent articulation of the pre-emption fear indicates a concern for claims of this nature. See generally Sanker & Quinn, *supra* note 239 (describing the “meaningful limit” issue).

248. See, e.g., Dan L. Burk & Mark A. Lemley, *Biotechnology’s Uncertainty Principle*, 54 CASE W. RES. L. REV. 691 (2004) (arguing that patent law is unavoidably mired in technology specificity, perhaps warranting distinct legal standards for distinct technological areas, e.g., “a consciously designed . . . patent policy” that would be specific to biotechnology). But see, e.g., R. Polk Wagner, *Exactly Backwards: Exceptionalism and the Federal Circuit*, 54 CASE W. RES. L. REV. 749 (2004) (arguing that Federal Circuit case law does not indicate as pervasive a degree of technology exceptionalism as argued by Professors Burk and Lemley, and that as a matter of policy, allowing or encouraging such exceptionalism is prone to several issues).

commensurate with the scope of disclosure in the patent specification. But this proposal leaves much room for further refinement, in having dealt primarily with inventions of the “natural” and not “formulaic” variety, not analyzing the implications of the utility-eligibility framework for software or business method patents, and not fine-tuning *Manson’s* “specific, substantial, and credible” standard outside of the chemical and biotechnology contexts.

Earlier, this Note laid out three issues that were left open by *Neilson*, *Le Roy*, and *Morse*, and then aggravated by *Mayo*, *Myriad*, and *Alice*. The revised framework for § 101 addresses each one, as follows: (1) it is no longer relevant what principles, laws of nature, phenomena, or abstract ideas are, nor what it means for an invention to be directed to them; (2) the degree of “application” required of an invention is simply a finite set of specific, substantial, and credible uses, explicitly laid out in the claims of a patent; and (3) some deference has been given to both the early nineteenth century eligibility case law and the § 101 jurisprudence that followed it, retaining the original “application” standard but also paying respect to the later pre-emption concerns. Perhaps a heightened form of utility is the antidote to patent eligibility doctrine’s disarray.

