
Response

The Influence of *Alice*

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INTRODUCTION

Alice's decimating influence on patents and patent applications has been far-reaching, metastasizing to cover a host of diverse industries.¹ Its long shadow looms over every stage of a patent's life cycle—from prosecution to litigation and the administrative post-grant process at the patent office.² The fact that *Alice* concerned only the

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1. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014). The claim concerned a method of mitigating “settlement risk,” the risk a party to an agreed-upon financial exchange would default on its obligations. *See id.* at 214. The Court found the claims invalid because they were tied to a patent-ineligible abstract idea. *Id.* at 218; *see* Jay P. Kesan & Runhua Wang, *Eligible Subject Matter at the Patent Office: An Empirical Study of the Influence of Alice on Patent Examiners and Patent Applicants*, 105 MINN. L. REV. 527, 532 (2020) (“[L]ower court decisions post-*Alice* show that none of the patent claims in any technology area are spared from review under the *Alice* framework.”); Eileen McDermott, *The Patent System is ‘Desperate’: American Axle Implores High Court to Take Up Eligibility Fight*, IPWATCHDOG (Jan. 5, 2021), <https://www.ipwatchdog.com/2021/01/05/patent-system-desperate-american-axle-implores-high-court-take-eligibility-fight/id=128729> [<https://perma.cc/2MMZ-6D9V>] (quoting Petitioner’s brief arguing that “[t]he Federal Circuit has pushed Section 101 well beyond its gate-keeping function to invalidate industrial manufacturing processes historically eligible for patent protection.”); Kurt Prange, *Blockchain & Business Methods: How Business Method Patents May Be Redeemed by Furthering Blockchain Innovation*, 18 COLO. TECH. L.J. 185, 188 (2020) (“*Alice* sent shockwaves of uncertainty through the patent law community.”); Jasper L. Tran, *Two Years After Alice v. CLS Bank*, 98 J. PAT. & TRADEMARK OFF. SOC’Y 354, 358 (2016) (invalidation rate of sixty-six percent following *Alice*); Bijal Vakil, *Congress Attempts to Remove Ambiguity in Favor of Patent Holders*, 31 INTELL. PROP. & TECH. L.J. 21, 21 (2019) (“[D]istrict courts too often use *Alice* to invalidate patents on the pleadings, without consideration of the patent’s claims or underlying technologies.”).

2. *See* Kesan & Wang, *supra* note 1, at 533 (“The *Alice* test impacts the entire lifecycle of a patent, including patent application preparation, patent prosecution in

threshold requirement of patent eligible subject matter did not stop lower courts from using statutorily distinct requirements such as novelty, nonobviousness and enablement as convenient proxies upon which to conclude the invention covered patent ineligible subject matter as well.³ Their interpretation runs counter to orthodoxy that §101 functions only as a threshold inquiry, and those other elements of patentability should be separately determined.⁴ The concern with *Alice* is not simply that its standards are too narrow but rather that *Alice*'s standards are virtually indiscernible.⁵

In their article, Professor Jay Kesan and Dr. Runhua Wang ("the Authors") offer a penetrating look at *Alice*'s influence on software, business methods and bioinformatics, all key technologies powering our modern economy.⁶ The Authors examined data from a staggering 4.48 million patent office actions and patentee responses before and

the U.S. Patent and Trademark Office (PTO), and patent enforcement in the courts and in post-issuance proceedings in the PTO."); *id.* ("A negative consequence of blurring the eligibility and prior art distinctions in patent law is increased transaction costs in both patent litigation and patent examination as patent eligibility counterclaims (or through motions to dismiss under Rule 12(c)) and PTO Sec. 101 rejections play an increasingly important role."); Prange, *supra* note 1, at 189 ("The standard is malleable and unpredictable. Patent drafters are often left guessing what a patent examiner, a Patent Trial and Appeal Board (PTAB) judge, or the courts will consider to be an 'abstract idea' and when the claims may be deemed patent-eligible for adding 'significantly more.'").

3. See Kesan & Wang, *supra* note 1, at 541 ("Many scholars note that the Supreme Court in *Alice* decided the issue of patent eligibility under § 101 by bleeding into the novelty and non-obviousness requirements under §§ 102 and 103."); Interval Licensing LLC v. AOL, Inc., 896 F.3d 1335, 1354–55 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part) ("There is little consensus among trial judges (or appellate judges for that matter) regarding whether a particular case will prove to have a patent with claims directed to an abstract idea, and if so whether there is an 'inventive concept' in the patent to save it.").

4. Christopher J. Hamersky, Note, *Fiddling with Federal Circuit Precedent: The Commercial and Qualitative Impact of Recent Supreme Court Reversals on the U.S. Patent System*, 30 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 935, 979 (2020) ("As a relatively objective matter, the question of abstract ideas really must be addressed before these other issues.").

5. Kesan & Wang, *supra* note 1, at 539. ("[T]here are significant concerns regarding what 'abstract idea' means in *Alice*, and how to apply the *Alice* test to overcome this hurdle to patent eligibility."); *id.* at 529 ("It has been difficult to define what the three categories of exclusions mean in practice, partly because the meanings of these exclusions are unclear. As a result, courts have struggled to specify legal tests to operationalize these exclusions."); Rebecca Lindhorst, Note, *Two-Stepping Through Alice's Wasteland of Patent-Eligible Subject Matter: Why the Supreme Court Should Replace the Mayo/Alice Test*, 69 *CASE W. RES. L. REV.* 731, 762 (2019) ("The test fails to provide objective guidelines and leaves the patent-eligibility determination to the subjective opinion of a judge or patent examiner.").

6. See Kesan & Wang, *supra* note 1, at 535.

after *Alice*.⁷ Some findings track conventional wisdom, such as *Alice*'s impact on depressing applicant success rates.⁸ Other findings paint a vastly different picture.

Consider the Authors' observation that applicants in different technology areas employed markedly different strategies with different degrees of success in overcoming *Alice*.⁹ Notably, the Authors report *Alice* "places the highest costs of patenting on bioinformatics."¹⁰ Their numbers show bioinformatics applications received more *Alice*-based rejections, and applicants were relatively less successful in overcoming those rejections.¹¹ By comparison, business methods patent applications "learned from *Alice*" and became more successful over time.¹²

This Response proceeds as follows. Part I briefly sets out the relevant law on patent eligibility. Part II contextualizes the Authors' key findings on bioinformatics applications against that legal framework. Part III considers whether Congress, the courts, and the U.S. Patent and Trademark Office (USPTO) can be agents of change to alleviate *Alice*'s baleful influence on patent law.

I. ALICE'S LONG SHADOW

Patents play an important role in stimulating the economy.¹³ According to Section 101 of the Patent Act, "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is patent-eligible.¹⁴ To this broad mandate, the Supreme Court carved out exceptions such as "laws of nature" and "abstract ideas" to prevent patenting of "basic tools of scientific and technological work."¹⁵ It also recognized applying exceptions too broadly would undermine the purpose of patent law since "all

7. *See id.* at 556.

8. *See id.*

9. *Id.* at 534.

10. *Id.* at 535.

11. *Id.*

12. *Id.*

13. *Econ. & Statistics Admin. and USPTO, Intellectual Property and the U.S. Economy: 2016 Update*, USPTO (2016), <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf> [<https://perma.cc/FR9U-KQ9Y>] ("IP-intensive industries continue to be a major, integral and growing part of the U.S. economy.").

14. 35 U.S.C. § 101.

15. *See Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *see also Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) ("[P]art of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.").

inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”¹⁶ For this reason, claims directed to applying a judicial exception may be patent-eligible.¹⁷ Accordingly, “an invention is not rendered ineligible for patent simply because it involves an abstract concept.”¹⁸ Specifically, the Court distinguished between “patents that claim laws of nature, natural phenomena, and abstract ideas [and] those that claim patent-eligible applications of those concepts.”¹⁹

In *Alice*, the Court attempted to articulate a two-part test operationalizing this dichotomy: (1) whether the claims were directed to judicially created exceptions to patent eligibility and (2) if so, whether the claim elements individually and in combination, sufficiently provided an “inventive concept” that ensures the patent constitutes “significantly more” than a patent on the underlying judicial exception to avoid claiming, for instance, the abstract idea itself.²⁰

Donald Chisum explained that *Alice* sought to provide a “safe harbor from Section 101 abstract idea scrutiny . . . if the claimant establishes[d] that the claim is directed to a solution of a technological problem.”²¹ According to the Court, claims directed to one of the judicial exceptions must contain “additional elements that ‘transform the nature of the claim’ into a patent-eligible application.”²² Activities that are “well-understood, routine, [or] conventional” to a person of ordinary skill in the art would not transform a claim directed to a judicial exception into eligible subject matter unless claim elements, considered as a whole, “transform the nature of the claim’ into a patent-eligible application.”²³

Reasonable minds can differ whether an invention is “directed to” undefined judicial exceptions like an “abstract idea”²⁴ or an “inventive

16. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012).

17. *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

18. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014).

19. *See id.*

20. *Id.* at 212, 225.

21. Donald S. Chisum, *The Supreme Court’s Alice Decision on Patent Eligibility of Computer-Implemented Inventions: Finding an Oasis in the Desert*, PATENTLYO (June 23, 2014), <https://patentlyo.com/patent/2014/06/eligibility-implemented-inventions.html> [<https://perma.cc/4RZH-VQXT>].

22. *Id.* at 216.

23. *Id.* at 211.

24. *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016) (contending that the Federal Circuit must compare challenged claims to precedent since the U.S. Supreme Court has yet to define “abstract idea.”).

concept.”²⁵ For instance, though “labor” or “investment” in developing technology is generally insufficient to qualify, the Federal Circuit has used economic investment to justify its conclusion that the claimed invention was not “conventional, routine, and well-understood” under *Alice*.²⁶ Unfortunately, *Alice* itself provides no operative anchor for an inherently subjective inquiry based primarily on the patent claims at issue and the court’s views of those claims.²⁷ This subjectivity has led Administrative Patent Judge Hung Bui to lament that “[s]ince *Alice*, . . . the Federal Circuit, the district courts, and the United States Patent & Trademark Office (USPTO) have all struggled to implement the Supreme Court’s *Alice* two-step framework in a predictable and consistent manner.”²⁸

A. THE PRICE OF INDETERMINACY

Alice has disturbed judges at the nation’s patent court.²⁹ Federal Circuit Judge Newman wrote a concurrence in part and dissent in part when *Alice* came before the Federal Circuit, warning “[t]he uncertainty of administrative and judicial outcome and the high cost of resolution are a disincentive to both innovators and competitors.”³⁰ In her partial dissent to the Federal Circuit’s *Alice* decision *en banc*, Judge Moore wrote ominously of “death of hundreds of thousands of patents, including all business method, financial system, and software patents.”³¹

To understand these concerns, it is important to realize patents provide inventors and investors with the assurance that they have the

25. Austin Paalz, *Patent Wars: The Attack of Blockchain*, 28 TEX. INTELL. PROP. L.J. 241, 260 (2020) (“Even though *Alice Corp.* created a more detailed test for the courts to follow than what they previously had to rely on, the difficulties of determining patent eligible subject matter have remained—as have the inconsistencies of the courts.”).

26. *Exergen Corp. v. Kaz USA, Inc.*, 725 F. App’x 959, 966 (Fed. Cir. 2018).

27. See Paalz, *supra* note 25, at 259 (“There is relative flexibility built into the test for patent examiners or the courts to conclude that a claim is either subject matter eligible or ineligible to be patented.”).

28. Hung H. Bui, *A Common Sense Approach to Implement the Supreme Court’s Alice Two-Step Framework to Provide “Certainty” and “Predictability”*, 100 J. PAT. & TRADE-MARK OFF. SOC’Y 165, 165 (2018).

29. See Daryl Lim, *I Dissent: The Federal Circuit’s “Great Dissenter,” Her Influence on the Patent Dialogue, and Why It Matters*, 19 VAND. J. ENT. & TECH. L. 873, 876 (2017).

30. *CLS Bank Int’l v. Alice Corp. Pty.*, 717 F.3d 1269, 1321 (Fed. Cir. 2013) (Newman, J., concurring in part and dissenting in part).

31. *Id.* at 1313 (Moore, J., dissenting in part).

freedom to operate³² and that patent protection is important for industries like biotechnology which typically invests hundreds of millions of dollars on clinical trials.³³ Brenda Simon observed startups apply for patents despite questions about their validity and enforcement costs as a signaling device to attract investors.³⁴ David Taylor's empirical work shows the equation's flip side, reporting that investments by venture capitalists and private equity investors diminish when firms fail to obtain patent protection.³⁵

Scholars have called *Alice* "the most radical redefinition of patent-eligible subject matter in U.S. history,"³⁶ delivering "a shock to patent practitioners and the inventive community."³⁷ Jeffrey Lefstin observed that post-*Alice*, "there is now less clarity on the basic question of patent eligibility than at almost any other time in American patent law."³⁸ Under the hood, patent examiners and judges use Section 101 to screen out weak patents, including by incorporating anticipation, obviousness, and disclosure requirements into the analysis.³⁹ Robert Sachs reported that the USPTO rejected applications early and often during the prosecution process.⁴⁰ Kristen Osenga explained that lower

32. See Tom Ewing & Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. 1, 25 (2012); Brenda M. Simon, *Patents, Information, and Innovation*, 85 BROOK. L. REV. 727, 770 (2020).

33. See Alexander M. Walker, *Silencing Innovation: The Patent Eligibility of Sirna Therapeutics*, 21 MINN. J.L. SCI. & TECH. 333, 351 (2020) (arguing that "patent protection [is] arguably more important to pharmaceutical developers than other industries.").

34. Simon, *supra* note 32, at 771 ("[P]atents provide an additional source of useful information that can be communicated to potential investors and partners at an early stage.").

35. David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019 (2020); Hallie Wimberly, Comment, *The Changing Landscape of Patent Subject Matter Eligibility and Its Impact on Biotechnological Innovation*, 54 HOUSTON L. REV. 995, 1008 (2017).

36. Jeffrey A. Lefstin & Peter S. Menell, *Restoring the Legislative Framework for Patenting Applications of Scientific Discoveries 2* (U.C. Berkeley Pub. L. Research Paper No. 2767904, 2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2767904 [<https://perma.cc/F28P-YDN7>].

37. Jason Rantanen, *Patent Protection for Scientific Discoveries: Sequenom, Mayo, and the Meaning of § 101*, PATENTLYO (Apr. 22, 2016), <http://patentlyo.com/patent/2016/04/protection-scientific-discoveries.html> [<https://perma.cc/S4MU-HGJX>].

38. Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 N.C. J.L. & TECH. 647, 649 (2015).

39. Matthew G. Sipe, *Patent Law 101: The View from the Bench*, 88 GEO. WASH. L. REV. ARGUENDO 21, 32 (2020).

40. See Robert Sachs, *Two Years After Alice: A Survey of the Impact of a "Minor Case" (Part 1)*, BILSKI BLOG (June 16, 2016), <https://www.bilskiblog.com/2016/06/two-years-after-alice-a-survey-of-the-impact-of-a-minor-case> [<https://perma.cc/4UDX-NBHW>] (summarizing § 101 rejections at the Patent Office following *Alice*).

courts might leverage on *Alice* “as an easy way to dispose of cases and avoid difficult questions, invalidating patents and affirming rejections of patent applications issued by the Patent Office in short order.”⁴¹ For their part, the Authors note that “the risk of preemption is the increased association between the frequency of receiving [subject matter] rejections and the frequency of receiving [enablement/written description] rejections in both initial and final decisions from the PTO after *Alice*.”⁴²

USPTO’s statistics reveal a large decline in the number of business method patents it issued, fewer than half than the number it issued just before *Alice*.⁴³ More broadly, Section 101 invalidations have become the most common basis for invalidating patents, accounting for a marked increase in USPTO rejections,⁴⁴ as well as a third of all invalidated patents in general.⁴⁵ The decimation post-*Alice* was dramatic, with “over one hundred patents [that were] invalidated for claiming ineligible subject matter, more than the total number of patents invalidated under Section 101 in the past five years.”⁴⁶

Failing to address and clarify patent eligibility threatens America’s leadership in innovation globally. *Alice* harms national competitiveness as businesses look overseas in search of more consistent standards, taking the know-how with them.⁴⁷ As it turns out, Chinese and European patent offices routinely approve applications denied in the United States based on Section 101.⁴⁸ There is still another form

41. Kristen Osenga, *Patent-Eligible Subject Matter ... Still Wielding the Wrong Weapon - 12 Years Later*, 60 IDEA 104, 123 (2020).

42. See Kesan & Wang, *supra* note 1, at 598.

43. James Bessen, *What the Courts Did to Curb Patent Trolling—for Now*, THE ATLANTIC (Dec. 1, 2014), https://www.theatlantic.com/business/archive/2014/12/what-the-courts-did-to-curb-patent-trolling-for-now/383138/?single_page=true [<https://perma.cc/GGQ6-7QD5>].

44. Hannah Mehrle, *Forum Shopping Within the United States Patent and Trademark Office*, 70 CASE W. RES. L. REV. 791, 794–95 (2020) (“Following the Supreme Court’s decisions in *Alice* and *Mayo*, examiners in some art units, such as the business-methods and biotechnology art units, are much more likely to reject applications because the application consists of an abstract idea or a law of nature than before these decisions.”).

45. See Stephen Yelderman, *Prior Art in the District Court*, 95 NOTRE DAME L. REV. 837, 854 (2019); see also *id.* at 888 (noting a significant jump post-*Alice*).

46. See generally Daniel Taylor, Comment: *Down the Rabbit Hole: Who Will Stand Up for Software Patents After Alice*, 68 ME. L. REV. 217, 247 (2016).

47. Nicole Bruner, *Interpreting Gobbledegook Under 35 U.S.C. S 101: Does the 2019 Patent Eligibility Guidance Clarify Past Confusion?*, 9 AM. U. BUS. L. REV. 281, 311 (2020).

48. See Brief of United States Senator Thom Tillis, Honorable Paul R. Michel, and Honorable David J. Kappos, as Amici Curiae in Support of Petition by American Axle & Manufacturing, Inc. for a Writ of Certiorari Directed to the U.S. Court of Appeals for the

of extraterritorial harm that could result. John Duffy warned foreign countries might import *Alice* into their domestic patent law to eviscerate American companies' patents.⁴⁹ Beyond these baleful effects, there is yet another—one that drives inventors away from disclosing their inventions and toward secrecy.

B. TOWARD SECRECY

The Authors fret about *Alice*'s dampening effect on innovation, warning *Alice* will drive inventors to "trade secret law instead of relying on the current patent regime."⁵⁰ Indeed, one impact is that *Alice* has made trade secrets an attractive alternative to patent rights.⁵¹ First, when the invention contains features that are not easily discerned, such as AI, these features mitigate trade secrets' comparative weakness vis-à-vis patents permitting independent invention or reverse engineering.⁵² Second, apart from Section 101 obstacles, some inventions may have difficulty meeting patent disclosure requirements.⁵³ Third, trade secret claims occur with increasing frequency in

Federal Circuit at 4, *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, (No. 20-891) (March 1, 2021).

49. Brief of Amicus Curiae Int'l Bus. Mach. Corp. in Support of Neither Party at 8–14, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014) (No. 13-298) ("Some of those countries may not be pre-disposed to supporting patent rights, especially patent rights held by foreign patentees. Those countries might be quite willing to embrace, vigorously, a judge-made exclusionary principle that has the acknowledged capability to 'swallow all of patent law' if judges and other decision-makers do not 'tread carefully' in applying it.").

50. Kesan & Wang, *supra* note 1, at 530.

51. See, e.g., Samuel J. LaRoque, Comment, *Reverse Engineering and Trade Secrets in the Post-Alice World*, 66 U. KAN. L. REV. 427, 431–35 (2017); Sonia K. Katyal, *The Paradox of Source Code Secrecy*, 104 CORNELL L. REV. 1183, 1191–1236 (2019).

52. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 475–76 (1974) ("A trade secret law, however, does not offer protection against discovery by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering, that is by starting with the known product and working backward to divine the process which aided in its development or manufacture."); see also Jeanne C. Fromer, *Machines as the New Oompa-Loompas: Trade Secrecy, the Cloud, Machine Learning, and Automation*, 94 N.Y.U. L. REV. 706, 723 (2019) ("It is also essentially impossible to reverse engineer these data because they are not discernable from any commercially available software based on machine learning, precisely because they are not contained within the software and because any predictive model built on these data is likely to be too complex to convert back into even a rough approximation of the underlying data.").

53. See Michael Mattioli, *Disclosing Big Data*, 99 MINN. L. REV. 535, 553 (2014) ("[A]n expert cannot decipher just how a set of data was assembled with nothing more to work from than the data itself.").

criminal cases where they are less likely to face challenges.⁵⁴ Fourth, post-Defend Trade Secrets Act, trade secrets enjoy federal reach and other important benefits.⁵⁵ The secrecy cloaks product errors and limits the ability of experts to provide insights to the court.⁵⁶ In criminal cases, judges have deferred to trade secret claims by companies by denying defendants access to the “secret” information.⁵⁷

Trade secrets can also make business deals difficult. Whereas patent law has an inbuilt, one-year grace period to file for a patent, trade secret owners need to rely on unpopular non-disclosure agreements⁵⁸ and be prepared to detail other measures they took to protect their know-how during marketing, negotiations, and other interactions that require them to share the details of their technology.⁵⁹ Echoing the Authors, Simon’s work indicates bioinformatics may be disproportionately hurt by this shift to secrecy, as the technology’s value becomes difficult to quantify properly.⁶⁰ Moreover, the timeline for obtaining a return on investment is relatively limited; she notes that decreased patent availability “can hinder information exchange, reducing opportunities to secure financing and ultimately the ability to bring a medical device invention to the market.”⁶¹

The Authors argue that reestablishing “reliable and reasonable expectations regarding the law governing patent eligibility can help investors minimize economic loss and maximize economic

54. See Rebecca Wexler, *Life, Liberty, and Trade Secrets: Intellectual Property in the Criminal Justice System*, 70 STAN. L. REV. 1343, 1396–99 (2018).

55. 18 U.S.C. § 1836 (2018).

56. Andrew D. Selbst, *Negligence and AI’s Human Users*, 100 B.U. L. REV. 1315, 1365–66 (2020) (“If litigants hire experts, an engineer from one company will not know anything about how the model in another company was constructed because the data and the testing is all kept secret, and knowing the algorithm or even the source code without the data is not useful.”).

57. See Natalie Ram, *Innovating Criminal Justice*, 112 NW. U. L. REV. 659, 672–73 (2018).

58. See Simon, *supra* note 32, at 768 (“Negotiations can be challenging because most investors will not sign nondisclosure agreements, yet they want to know about the market and regulatory opportunity.”); *id.* (“[I]f too much information about the technology is provided to potential investors, ‘the cat’s out of the bag.’”).

59. See *id.* (“In light of recent changes in the availability and scope of patent protection for software-related inventions, emerging companies now may have to describe what they have done to protect their trade secret and whether their technology is reproducible.”).

60. *Id.* (“The challenges of obtaining intellectual property protection for software associated with medical devices can also make valuation difficult.”).

61. *Id.* at 770.

efficiency.”⁶² To achieve this goal, the Authors pin their hopes on Congress.⁶³ Like the Authors, major patent stakeholders have called for patent eligibility reform. For instance, the American Bar Association (ABA) stressed, “[l]egislative reform [of patent eligibility] is needed to restore predictability to the patent system and maintain incentives to invest in future technologies and discoveries.”⁶⁴ Similarly, the Intellectual Property Owners Association (IPO) also commented that it remains “concerned that the courts will continue to issue conflicting decisions on subject matter eligibility . . .,” and suggested that “the best approach is . . . one that restores patent eligibility law in line with the foundational principles set forth in the 1952 Patent Act.”⁶⁵ Part III, *infra*, considers avenues and agents for change.

While the turmoil *Alice* caused has been well documented, its impact on patent applicant behavior at the patent office remains relatively obscure. It is here that the paths of *Alice* and the Authors converge. The Authors examined data from a staggering 4.48 million patent office actions and patentee responses before and after *Alice*.⁶⁶ The most remarkable aspect of the Authors’ study is their finding on bioinformatics patent applications, which they single out as *Alice*’s greatest casualty.

II. WHY BIOINFORMATICS?

Empirical research can help illuminate bedrock truths that lie under the topsoil of conventional wisdom. The Authors’ work does so here. Part A highlights their key findings regarding *Alice*’s decimating

62. See Kesan & Wang, *supra* note 1, at 531 (“[F]inanciers and venture capitalists rely on the predictability of the patent laws and the availability of patent protection to assess the economic viability of the innovations in which they might invest.”); Hamersky, *supra* note 4, at 964 (“*Alice Corps. v. CLS Bank International*, together with *eBay*, are arguably the two cases most responsible for weakening the U.S. patent system as a whole given that they ushered in two of the most sweeping changes.”); see also *id.* at 972 (“Supreme Court cases like *Alice* and *eBay* changed the very fundamentals of patent practice, including patentability standards, critical components of litigation, and standards of proof among others.”).

63. See Kesan & Wang, *supra* note 1, at 529 n.4 (“[P]atent eligibility is still a continuing problem unaddressed by the Supreme Court which perhaps opens the door for Congress to act.”).

64. Stuart Meyer, *No Shortage of Opinions on New USPTO Eligibility Guidance*, LAW360 (Apr. 12, 2019), <https://www.law360.com/articles/1149320/noshortage-of-opinions-on-new-uspto-eligibilityguidance> [https://perma.cc/ZJL8-EKDP].

65. Ryan Davis, *USPTO Patent Eligibility Rules Still Too Vague, IP Groups Say*, LAW360 (Mar. 11, 2019), <https://www.law360.com/articles/1137387/usptopatent-eligibility-rules-still-too-vague-ip-groups-say> [https://perma.cc/M7LU-XM27].

66. See Kesan & Wang, *supra* note 1, at 556.

impact on bioinformatics patent applications. Part B swivels the lens to examine the impact of two pre-*Alice* Supreme Court precedent in setting the stage for the eventual impact that the Authors report.

A. THE BIOINFORMATICS MASSACRE

The Authors found bioinformatics “most likely to be initially and finally rejected under § 101 compared to other technology areas before *Alice*.”⁶⁷ They report that patent examiners rejecting bioinformatics applications increased from 24% to 61%, and final decisions increased from 18% to 72%.⁶⁸ In contrast, business method application office action rejection rates shrank from 31% to 9%, and final rejection rates increased from 9% to 45%.⁶⁹ Software application office actions rose from 1% to 2%; final decisions rose from 6% to 10%.⁷⁰

Consistent with the discussion in Part I, the Authors deduce that the root cause was indeterminate rules, observing *Alice* failed spectacularly as bioinformatics applicants were “not clearly instructed by the Supreme Court in its *Alice* decision, even though they reacted to the law and adjusted their patent preparation and filing strategies,” making “cautious adjustments by modifying the disclosures and claims.”⁷¹ Unfortunately, applicants’ efforts at modifying disclosures and claims proved futile. Allowance rates did not rise, and instead, “they merely spent more money on patent applications that would not be approved.”⁷²

Over time, applicants “became pessimistic” and gave up, filing seventy-four percent fewer bioinformatics patent applications.⁷³ By comparison, the Authors observe that while business method

67. *Id.* at 589; *see also id.* at 588 (Bioinformatics received “the most initial or final § 101 rejections compared to business methods and software” applications).

68. *Id.* at 559.

69. *Id.* at 561.

70. *Id.* Compare Colleen Chien & Jiun Ying Wu, *Decoding Patentable Subject Matter*, PATENTLY-O PATENT L.J. (Oct 16, 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id (observing business methods, bioinformatics, and software experiencing a relatively higher degree of abandoned patent applications post-*Alice*.), with Paul R. Gugliuzza & Mark A. Lemley, *Can a Court Change the Law by Saying Nothing?*, 71 VAND. L. REV. 765, 790 (2017) (observing biotechnology applications patents withstanding eligibility challenges better post-*Alice* compared to IT patents).

71. *See* Kesan & Wang, *supra* note 1, at 595, 594.

72. *Id.* at 595.

73. *Id.* at 593.

application rejection initially rose,⁷⁴ and applications fell,⁷⁵ post-*Alice* applications showed more success overcoming subject matter rejections, suggesting some learning had taken place there.

The costs of *Alice*, the Authors warn, go beyond the applicants. *Alice*'s indeterminacy has increased the cost to patent examiners by failing to instruct them on the appropriate standard to apply in examining the applications before them.⁷⁶ Unsurprisingly, *Alice* has made it more difficult to attract bioinformatics-related investments as well. As the Authors surmise, "what is worse is that *Alice* may have not only added more application or prosecution costs in the business of bioinformatics, but the case may have also restricted applicants' access to investors and capital through the market."⁷⁷

As Part I discussed, conventional wisdom teaches that lower court patent eligibility decisions became infected with novelty, non-obviousness, and disclosure deficiencies.⁷⁸ However, the Authors report a more nuanced result with bioinformatics applications. While the association with enablement/written description rejections increased post-*Alice*, subject matter rejections associated with novelty, nonobviousness, and definiteness rejections decreased post-*Alice*.⁷⁹ The Authors helpfully deduce that overcoming enablement/written description objections may help them overcome subject matter rejections.⁸⁰

B. THE *MYRIAD*/*MAYO* FACTOR

Scholars like Craig Nard recognize *Alice* affects both software and biotechnology patents.⁸¹ That much is conventional wisdom. It is worth a pause for thought, however, to ask "why"? *Alice*'s impact on software is foreseeable. The invention in the case concerned a

74. *Id.* at 597 ("The decrease in patent applications for business methods was incremental and a sharp decrease occurred when the PTO decided to implement the *Alice* decision.").

75. *Id.*

76. *Id.* at 599 ("[T]he law is not clear enough to instruct examiners and patent applicants and merely creates costly uncertainties.").

77. *Id.* at 595.

78. *See supra* Introduction.

79. *See Kesan & Wang, supra* note 1, at 598.

80. *Id.*

81. Craig Allen Nard, *Patent Law's Purposeful Ambiguity*, 87 TENN. L. REV. 187, 190 (2019) ("Few would argue that the application of *Alice* and *Mayo* did not lead to increased invalidity rates, particularly in the computer-implemented arts and biotechnology.").

computer-implemented, electronic escrow service for facilitating financial transactions.⁸² But why biotechnology?

As it turns out, the relationship between bioinformatics applications and the properties of DNA also makes it prone to eligibility issues.⁸³ Before *Alice*, the Supreme Court ruled on the patent eligibility of nucleotide sequences in *Mayo* and *Myriad*.⁸⁴ *Mayo*'s claims involved a correlation between metabolite levels and the likelihood of harm or ineffectiveness from a particular drug dosage.⁸⁵ The Court found the claims directed to a law of nature and failed to add "significantly more" to the underlying law of nature itself, and was hence invalid.⁸⁶ Commentators saw this as the Supreme Court's salvo against "problematic patents."⁸⁷

Since *Mayo*, courts have found claims directed to diagnostic methods centering on observed correlations between a natural characteristic and a disease state, coupled with routine or conventional technical means for detection to be patent ineligible.⁸⁸ Nicole Bruner observed that *Alice* relied on *Mayo* "to restrict eligible subject matter to the furthest point in the history of business method patents."⁸⁹ While it is true that courts have upheld "method of treatment" claims, bioinformatics inventions are unlikely to benefit since "treatment" claims may be difficult to enforce against rival bioinformatics companies not treating the disease or directing end-users to do so.⁹⁰

In *Myriad*, the patents conferred an exclusive right to isolate BRCA1 and BRCA2 genes and synthetically create BRCA cDNA.⁹¹ Since isolation is necessary to conduct genetic testing, those patents would

82. See *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 212 (2014).

83. See Walker, *supra* note 33, at 343 ("Nucleotide technologies present a difficult case for patent eligibility because of the close relationship between biotechnology and the natural properties of DNA."). See also Diane Gershon, *Recombinant DNA Technology*, 348 NATURE 92, 92-93 (1990).

84. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013).

85. *Mayo*, 566 U.S. at 73-75.

86. *Id.* at 72-73.

87. See Prange, *supra* note 1, at 197 ("The Supreme Court's *Mayo* and *Alice* decisions continued the trend of combating problematic patents.").

88. See generally, Evan Diamond, Julia Kolibachuk, & Vanessa Yen, *Federal Circuit Continues Trend of Finding Diagnostic Inventions to Be Patent-Ineligible*, 32 No. 2 INTELL. PROP. & TECH. L.J. 13 (2020).

89. See Bruner, *supra* note 47, at 287.

90. See, e.g., *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1363-64 (Fed. Cir. 2017) (finding diagnostic claims patent-ineligible).

91. See Kesan & Wang, *supra* note 1, at 585.

likely monopolize BRCA1 and BRCA2 genes' diagnostic applications.⁹² The Court held that the mere act of isolating DNA was also not sufficiently transformative, though it did recognize artificially altering natural genes such as cDNA could confer patent eligibility.⁹³ In its wake, prominent biotechnology research and diagnostics industries decried the harm caused by patent validity's indeterminacy in these fields.⁹⁴

The Supreme Court's jurisprudence interlacing software and biotechnology underscored its concern over the hegemony of basic research tools like bioinformatics.⁹⁵ Bioinformatics is essentially a hybrid of software and biotechnology patents, and by its very nature, it is caught in *Alice* and *Myriad/Mayo's* twin jaws. Indeed, the Federal Circuit applied *Alice* in at least one high-profile case to find bioinformatics inventions patent-ineligible under Section 101. Thus in *Ariosa Diagnostics*, it held a claim amplifying and detecting the paternally inherited cell-free fetal DNA (cffDNA) ineligible because the method was a well-understood, routine, or conventional activity at the filing date.⁹⁶

In sum, *Alice* wreaked disproportionate havoc on bioinformatics patents. The impact was keenly felt by applicants, who first tried to adapt their strategic response to examiner objections, but many eventually gave up. Patent examiners, as well as the lower courts, struggled to employ *Alice's* indeterminate guidance. Such confusion threatens both the economy-boosting effects of maintaining a functional patent system and faith in the judiciary to produce reliable, consistent outcomes.

92. *Id.*

93. *Id.* at 586–87.

94. See Sean Sheridan, *How Mayo, Myriad and Alice May Impact Patent Valuations*, CHARLES RIVER ASSOCIATES (Mar. 4, 2015), <http://www.crai.com/sites/default/files/publications/How-Mayo-Myriad-And-Alice-May-Impact-Patent-Valuations.pdf> [<https://perma.cc/TY6M-5G45>] (noting the drop in patent value due to legal uncertainty).

95. Skye Cho, *The Current Application of the Myriad and Mayo/Alice Rulings on Patent Eligibility: Inconsistent Results and Contradistinguishing Biotechnology Products*, 38 CARDOZO ARTS & ENT. L.J. 183, 197 (2020) (“Although the patent claim at issue in *Alice Corp. Pty. Ltd. v. CLS Bank International* was not related to biotechnology, it is central to the understanding of the Supreme Court's current framework for determining the patentability of a claim.”).

96. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (Claims were “generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon.”); Yen et al., *supra* note 88 (“With respect to ‘diagnostic’ inventions involving, *e.g.*, the detection of diseases or genetic conditions using newly-discovered biological phenomena, the *Mayo/Alice* two-step test has almost universally been applied by the Federal Circuit to find claims patent-ineligible under § 101.”); Cho, *supra* note 95, at 201 (“[N]o one was amplifying and detecting cffDNA at the time of the ‘540 patent because no one knew cffDNA existed.”).

Unpredictability in the patent system is harmful to the economy, the patent system as a whole, and to inventors, business entities, investors, potential infringers, and other interested parties who need to understand what can and cannot be patented. The Authors argue that the answer lies with Congress. Looking at the USPTO and the courts' situation, it would be easy to see why they might think so.

III. AGENTS OF CHANGE

Who are the agents of change, and is change more imaginary than real? Part A examines the courts' efforts to apply *Alice*, explaining how the Federal Circuit is gridlocked, and the Supreme Court has refused to act. Part B examines the USPTO's efforts to undo the excesses of *Alice* and how their efforts may be themselves undone by the courts. Part C examines how bipartisanship may, in theory, provide a legislative fix, but for the fact that stakeholders themselves have chilled legislative momentum to abrogate *Alice*.

A. THE COURTS

Since *Alice*, the Federal Circuit and district courts issued over a thousand decisions involving patent eligibility, declaring hundreds of patents and no doubt thousands of patent claims ineligible under *Alice*.⁹⁷ Between 1982 and 2012, Federal Circuit opinions citing Section 101 averaged about four per year. Post-*Alice*, this figure rose to 24 per year.⁹⁸ Unfortunately, results in similar subject matter in one case may turn out abstract, and in another, not abstract.⁹⁹ This difference of opinion illustrates the widespread confusion *Alice* caused, seen recently by the evenly divided 6-6 split at the Federal Circuit denying a rehearing en banc in *American Axle*.¹⁰⁰ The court's failure to obtain even a majority illustrates percolation in the lower courts is unhelpful.

Worse, the Federal Circuit exacerbated the flaws in its Section 101 analysis in that case with the panel hearing the appeal inserting a new requirement into Section 101 that claims had to be self-enabling, thereby shifting the inquiry under Section 112 to Section 101.¹⁰¹ It found that because a claim lacked sufficiently specific steps or

97. Brief Of New York Intellectual Property Law Association as Amicus Curiae In Support of Petitioner at 15, *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, (No. 20-891) (Jan. 25, 2021).

98. Brief of United States Senator Thom Tillis et al., *supra* note 48, at 19.

99. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 52 (Jan. 7, 2019).

100. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 966 F.3d 1347 (Fed. Cir. 2020).

101. *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 939 F.3d 1355 (Fed. Cir. 2019).

structure for achieving its method, it must be directed to a natural law and nothing more.¹⁰² This conclusion blurs the lines between a patent's claims and its written description. Section 101 does not require claims to demonstrate how the applicant possessed the invention and or disclose how to make and use it. That conclusion would make the written description and enablement superfluous.

Dissenting from the denial for rehearing en banc, Judge Newman surmised that: "The court's rulings on patent eligibility have become so diverse and unpredictable as to have a serious effect on the innovation incentive in all fields of technology. . . . [T]he victims are the national interest in an innovative industrial economy, and the public interest in the fruits of technological advance."¹⁰³

In addition to *American Axle* with three dissenting opinions, *Sequenom*, *Aatrix*, *Berkheimer*, and *Athena*, citing *Alice*, each featured multiple opinions.¹⁰⁴ When the Federal Circuit, an appeals court created to develop consistent interpretations and applications of patent law, is itself divided on how to apply Supreme Court subject matter eligibility precedent, a fundamental aspect of the U.S. patent system is at risk. Patentees, alleged infringers, and innovators working to design around the patented technology cannot properly assess risks, evaluate investments, and make decisions based on a useful, clear, and consistently applicable patent-eligibility test.

The Supreme Court has been asked to revisit various aspects of the patent eligibility standard scores of times since it granted remands under *Alice*.¹⁰⁵ The Solicitor General of the United States and solicitors at the USPTO encouraged the Justices to revisit *Alice*, particularly in biomedical-related inventions.¹⁰⁶ The Court refused every single

102. *Id.* at 1366–67.

103. *Id.* at 1357 (Newman J., dissenting).

104. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121 (Fed. Cir. 2018); *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019).

105. See Brief of United States Senator Thom Tillis et al., *supra* note 48, at 23 ("While important innovations go unprotected, the Court has declined granting petitions for certiorari in dozens of cases that presented the opportunity to clarify patent eligibility law."); Clark D. Asay, *Artificial Stupidity*, 61 WM. & MARY L. REV. 1187, 1206–07 (2020) ("[T]he *Alice* decision's lack of concrete guidance on this question means that subsequent case law on the question will remain in a state of some uncertainty, at least until and if the Supreme Court again decides to step in.").

106. Brief for the United States as Amicus Curiae at 14, *Hikima Pharm. USA, Inc. v. Vanda Pharm., Inc.*, 140 S. Ct. 911 (2020) ("[I]t is arguably unclear whether even a method of treating disease with a newly created drug would be deemed patent-eligible.").

opportunity.¹⁰⁷ The Authors note this too, observing that “the U.S. Supreme Court has recently chosen not to revisit this topic by denying certiorari in a series of cases involving patentable subject matter in both the software and biotechnology fields.”¹⁰⁸

The USPTO has recognized subject matter eligibility precedent has grown increasingly difficult to apply consistently. To provide consistency in patent examinations, it generated two sets of patent examination guidelines.¹⁰⁹ Its attempt to derive a uniform set of guidelines to prevent inconsistent results indicates the need to clarify Section 101. To an extent, the USPTO succeeded. Practitioners observed a “noticeable decline” in rejections.¹¹⁰ But is there more than meets the eye to this result?

B. THE USPTO

The Authors found the USPTO’s implementation of *Alice* initially caused more rejections in bioinformatics, business methods, and software than applications filed pre-*Alice*. They observed that “[t]he direction of the PTO implementation effect is consistent with the *Alice* decision, but the PTO’s implementation had a stronger effect than the *Alice* decision itself.”¹¹¹

At the same time, the Authors do give credit to the USPTO for its efforts in taking on the additional review step detailed in their January 2019 guidelines, which the USPTO issued after the period in their study (2012 – 2016). The Authors note that “[b]oth the additional procedure and the additional indication about reciting ‘abstract ideas’ in the justification add transaction costs to the PTO.”¹¹² The need to clarify its approach just four years after the 2014 guidelines represents “an increase in administrative transaction costs at the PTO.”¹¹³ These costs were triggered by the USPTO’s decision “to take on the burden to clarify the law through the revised Step 2 and the added second

107. See Brief of United States Senator Thom Tillis et al., *supra* note 48, at 23 (“This Court has repeatedly refused to revisit Section 101 jurisprudence.”).

108. See Kesan & Wang, *supra* note 1, at 528.

109. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019).

110. Peter J. Prommer & Ravinderjit Braicha, *More Certainty on Limits To Early Section 101 Challenges – How will This Impact Patent Owners and Applicants?*, 32 No. 5 INTELL. PROP. & TECH. L.J. 12, 13 (2020) (“[A]n owner of a patent that may still be prone to Section 101 issues at least now has a better chance to carry forward an enforcement action well beyond the pleadings and summary judgement stages.”).

111. See Kesan & Wang, *supra* note 1, at 599.

112. See *id.* at 601.

113. *Id.*

review procedures pertaining to the elements that are not listed in the revised Guidance,¹¹⁴ thereby shifting the burden from applicants to the USPTO. What follows is a discussion of these efforts.

The USPTO has indeed been proactive in ameliorating *Alice*'s baleful effects through its examination guidelines.¹¹⁵ Then-Director Iancu identified patent eligibility as "the most important issue of substantive patent law" that "must be addressed now."¹¹⁶ In line with that imperative, the USPTO had acted *inconsistently* with *Alice* to save patent applications. In January 2019, the USPTO issued revised guidelines allowing claims to recite a judicial exception if the exception is integrated into a practical application.¹¹⁷ The January guidelines directed examiners to find claims found eligible if abstract ideas presented had a practical application.¹¹⁸ Examiners must determine whether the claim recites a judicial exception; if it does not, the claim is eligible for patenting.¹¹⁹ If it does, examiners evaluate whether that exception is integrated into a practical application.

Additionally, examiners must consider the claim as a whole but should not evaluate whether additional claim elements are well-understood, routine, or conventional.¹²⁰ Those questions are only relevant if the claim is not a practical application of a judicial exception.¹²¹ The January Guidance also gave broad illustrations of practical application commentators noted were "never before viewed as patentable, such as an algorithm to gather data."¹²²

The USPTO's restatement of *Alice* in effect considered whether claim elements were routine, conventional, or well-known later. In contrast, *Alice* considered this sooner, resulting in a determination that claims were directed to an abstract idea. This subtle but important change allowed examiners to look at each step to determine if

114. *Id.*; *see also id.* ("The increased administrative transaction cost could be a result of shifting the increased transaction costs in the market that is borne by patent applicants and investors to the PTO.").

115. *See Prange, supra* note 1, at 189 ("The USPTO publishes updated guidelines based on case law applying the *Alice/Mayo* standard, in an attempt to add clarity and consistency to its examination procedures.").

116. *See Vakil, supra* note 1, at 22.

117. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019).

118. *Id.* at 6.

119. Kesan & Wang, *supra* note 1, at 585.

120. *See id.* at 589.

121. *See id.*

122. Samuel Scholz, *A Siri-Ous Societal Issue: Should Autonomous Artificial Intelligence Receive Patent or Copyright Protection?*, 11 CYBARIS AN INTELL. PROP. L. REV. 81, 99–100 (2020).

claims were eligible before determining if it contained an inventive concept, allowing claims that might have failed *Alice*.¹²³ By limiting “abstract ideas” to those directed towards mathematical concepts, certain methods of organizing human activity, mental processes, and software applications were treated more favorably. Indeed, software application allowance spiked from 50.8% to 60.9%.¹²⁴

In October 2019, the USPTO issued a second set of guidelines.¹²⁵ It purported not to change the January guidelines substantively but merely clarify how examiners should apply them.¹²⁶ Notably, examiners had to bring an application to their technology director’s attention if the claim is rejected for citing an abstract idea outside mathematical concepts, methods of organizing human activity, and mental processes, in effect limiting the discretion of examiners to reject applications except in the clearest of cases.¹²⁷ In turn, the technology center director must validate the rejection, which triggers an opportunity for patent applicants to request an interview with the examiner to help identify eligible subject matter.¹²⁸

The Patent Trial and Appeal Board (PTAB), the USPTO’s internal administrative review process, also reversed examiners deviating from the guidelines to find more inventions patent-eligible.¹²⁹ The guidelines guidance drew mixed reviews. Osenga noted that “[t]he biggest complaint being lodged against the 2019 Guidelines is that they do not look like the *Alice/Mayo* test, which is in my opinion probably one of the guidelines’ biggest strengths.”¹³⁰

One final observation is in order. The Authors are skeptical of the efficacy of USPTO’s cumulative efforts, opining that any gains in clarity

123. *Id.* at 99 (“The addition of the second prong allows some material that would have originally failed under step 2A to achieve subject matter eligibility.”).

124. See Raymond Millien, *As Congress Contemplates Curbing Alice, more than 60% of Issued U.S. Patents Are Software Related*, IPWATCHDOG (Nov. 5, 2019), <https://www.ipwatchdog.com/2019/07/02/congress-contemplates-curbing-alice-60-issued-u-s-patents-software-related/id=110920/> [https://perma.cc/TN8Z-3ZBH].

125. U.S. PATENT AND TRADEMARK OFFICE, OCTOBER 2019 PATENT ELIGIBILITY GUIDANCE UPDATE 9 (2019), https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf [https://perma.cc/2QNX-QLDU].

126. *Id.* at 52.

127. *Id.*

128. *Id.*

129. See, e.g., Aseet Patel & Craig Kronenthal, *First PTAB Reversals Under New Subject Matter Eligibility Guidance*, IPWATCHDOG (Feb. 14, 2019), <https://www.ipwatchdog.com/2019/02/14/first-ptab-reversals-new-subject-matter-eligibility-guidance> [https://perma.cc/RC8C-VGQM].

130. See Osenga, *supra* note 41, at 130.

“could be limited by the PTO itself,” and provide two reasons.¹³¹ First, the Authors blame the 2014 Guidelines, “which has provided more detailed tests than the *Alice* test itself, increased the transaction costs in the market, as shown in our empirical results.”¹³² The 2019 guidelines serve to blunt that criticism. Second, courts may disregard the 2019 Guidance in determining how they apply *Alice*.¹³³ This criticism still has its sting.

Daniel Cahoy observed that “the PTO’s efforts are a good example of the uphill battle an interpreter faces. The agency has put forth several guidance documents that consist primarily of different examples of what seems to be eligible and what is not based on court decisions.”¹³⁴ However, the Federal Circuit has disavowed the guiding value of USPTO guidelines, making it clear that while it “respect[s] the [Patent Office’s] expertise,” it was “not bound by its guidance,” “especially regarding the issue of patent eligibility.”¹³⁵ More recently, in *cxLoyalty, Inc.*, the Federal Circuit reiterated this position in a precedential opinion.¹³⁶ It noted that the Guidance did not carry the force of law and did not bind its patent eligibility analysis.¹³⁷

In short, while the USPTO arguably provided more structure to *Alice*, giving applicants a clearer idea of what constitutes an abstract idea, the Federal Circuit, with its deep divisions, continues to adhere to a more abstract and inconsistent interpretation of *Alice*. The court’s attitude significantly limits the stabilizing effects of USPTO guidelines beyond its examiner corps.¹³⁸ The 2019 guidelines, which set a lower bar for eligibility findings, have also injected unpredictability in the process as courts that apply a higher bar interpretation of *Alice* will

131. See Kesan & Wang, *supra* note 1, at 601.

132. *Id.*

133. *Id.* at 602 (“[T]he Revised Guidance may not affect how the courts determine patent eligibility or how they apply *Alice* because the judicial system is also a critical player in continuously creating uncertainties in patent eligibility. It is hard, however, to predict how the PTO’s justification addressing the uncertainties of patentability will be perceived on review by the judicial system.”).

134. Daniel R. Cahoy, *Patently Uncertain*, 17 NW. J. TECH. & INTELL. PROP. 1, 36 (2019).

135. *Cleveland Clinic Found. v. True Health Diagnostics*, 760 F. App’x 1013, 1020 (Fed. Cir. 2019).

136. *cxLoyalty, Inc. v. Maritz Holdings Inc.*, 986 F.3d 1367, 1376 n.1 (Fed. Cir. 2021).

137. *Id.*

138. See also Bruner, *supra* note 47, at 287 (“Examiners relied on the Manual of Patent Examining Procedure (“MPEP”) and case law for determinations of eligibility under the *Alice/Mayo* test, whereas courts are bound by federal precedent.”).

weed out patents properly approved by the USPTO according to its guidelines.¹³⁹

C. CONGRESS

If the judicial exclusion of “abstract ideas” has proven too abstract to be useful to courts, the Authors argue that Congress is the place to fix it.¹⁴⁰ Some judges and scholars agree, pointing to how Congress can rectify *Alice* by imposing clearer definitions and limit room for subjectivity.¹⁴¹ Others had pointed to the USPTO guidelines as a blueprint for change.¹⁴² Those who share the Authors’ optimism have reason to cheer.¹⁴³

2019 saw a bipartisan Congressional effort to address *Alice*.¹⁴⁴ Draft legislation proposed by Senators Chris Coons (D-Del.) and Thom Tillis (R-N.C.) would extend patent eligibility to “any invention or discovery that provides specific and practical utility in any field of

139. See, e.g., *Univ. of Fla. Rsch. Found., Inc. v. GE*, 916 F.3d 1363, 1368–69 (Fed. Cir. 2019) (invalidating claims found by the USPTO to recite an improvement over prior art systems by allowing the real-time sharing of information in a standardized format independent of an original format).

140. See *Kesan & Wang*, *supra* note 1, at 528. (“In the next year or two, Congress is once again likely to be under pressure to address eligible subject matter reform.”).

141. See, e.g., *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, A. J., concurring) (stating that patent eligibility law “needs clarification by higher authority, perhaps by Congress.”); *Taylor*, *supra* note 35, at 2094 (“Congress should amend 35 U.S.C. § 101 such that the ‘abstract idea’ category under the judicial exception is severely limited, thereby vitiating subjectivity.”); see also *Bruner*, *supra* note 47, at 310 (“Tensions between abstract ideas and the eligibility of business method patents stress the need for Congress to define what subject matter constitutes an abstract idea and to specify standards within that definition.”); *id.* at 311 (“[35] U.S.C. § 101 should provide more defined standards for when to reject an invention that has a statutory class.”).

142. See *Kesan & Wang*, *supra* note 1, at 542 (“[R]egardless of whether the Supreme Court further defines what constitutes an ‘abstract idea’ in the future, until then, practitioners may use the PTO’s Guidance to determine the scope of eligible subject matter.”); *Bruner*, *supra* note 47, at 311. (“In setting forth consistent standards, Congress should adopt guidance similar to standards set forth in the 2019 PEG under PTO Director Andrei Iancu’s mission to bring eligibility in closer light with current technology.”).

143. See *Osenga*, *supra* note 41, at 131 (describing it as “hav[ing] much more momentum than previous efforts at reforming patent eligibility.”).

144. See, e.g., Press Release, *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act* (May 22, 2019), <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act> [<https://perma.cc/SLY5-4TG9>]; *Osenga*, *supra* note 41, at 131 (“[E]specially welcome after the Federal Circuit essentially spurned the Patent Office’s 2019 Guidelines.”).

technology through human intervention.”¹⁴⁵ It mandates that “§ 101 is to be construed in favor of eligibility.”¹⁴⁶ The bill proposes to repeal *Alice* and its predecessors and progeny, including those blending in novelty, nonobviousness, and disclosure considerations into patent-eligible subject matter jurisprudence.¹⁴⁷

Additionally, the bill removes the word “new,” and ties “useful” to human intervention, and provides an exhaustive list of ineligible subject matter, namely “fundamental scientific principles; products that exist solely and exclusively in nature; pure mathematical formulas; economic or commercial principles; and mental activities.”¹⁴⁸ Finally, eligibility shall be determined without regard to how the invention was made, whether individual claim limitations are well-known or routine, and clarifying that patent eligibility should not be a proxy for other patentability requirements.¹⁴⁹

As the democratic expression of the people’s will, Congress’s job is to legislate and decide what society deems worthy of patent protection. It is especially true in an area as technical as subject matter eligibility. Moreover, as Part III.A., *supra*, shows, courts are ill-equipped to answer this question. Unfortunately, this most recent effort fizzled out in the face of an impasse between the pharmaceutical and tech industries.¹⁵⁰ In the words of Senator Tillis, “[l]ast year, Senator Coons and I led an extensive effort to lay out a framework for Section 101 reform. At the end of the day, that process stalled because stakeholders

145. The May 22, 2019 draft bill is available at <https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26> [<https://perma.cc/DH3V-YGYJ>].

146. *See id.*

147. *See id.* (noting that eligibility shall be determined without regard to how the invention was made, whether individual claim limitations are well-known or routine, and clarifying that patent eligibility should not be as a proxy for other patentability requirements).

148. *See* Press Release, *supra* note 144 (Stating “(a) Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. (b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.”).

149. *See id.* (“[T]he manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112.”).

150. AEIdeas, *1 Year Later, Patent Eligibility Reform No Further Along*, AEI (August 14, 2020), <https://www.aei.org/technology-and-innovation/1-year-later-patent-eligibility-reform-no-further-along> [<https://perma.cc/LJ88-9ZTF>].

refused to compromise. They let the great and perfect get in the way of the good.”¹⁵¹

CONCLUSION

Rules need to be clear if they are to be followed. The Authors present a comprehensive analysis of the dynamics in patent prosecution post-*Alice*. This Response has focused on *Alice*'s indeterminacy, its disproportionate impact on bioinformatics and the institutions that could affect change. The enterprise of developing a coherent understanding of patent-eligible subject matter is in the works. In our endeavors, we can be grateful to the Authors for their valuable insights that illuminate *Alice*'s influence on patent examiners and patent applicants at USPTO.

151. See Gene Quinn, *Senator Thom Tillis: If IP Stakeholders Can't Find Consensus, Congress Can't Help*, IPWATCHDOG (May 5, 2020) <https://www.ipwatchdog.com/2020/05/05/senator-thom-tillis-ip-stakeholders-cant-find-consensus-congress-cant-help/id=121262> [<https://perma.cc/22H7-SNYM>].