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Rulemaking § 101

ABSTRACT. The doctrine of subject-matter eligibility, as developed from 35 U.S.C. § 101, ensures that no one can stifle innovation by gaining a monopoly over an abstract idea, natural phenomenon, or law of nature. By excluding abstract ideas and laws of nature from patent protection, the doctrine ensures that no one can stifle innovation by gaining a monopoly over something as fundamental as the law of gravity. But recent decisions by the Supreme Court and the Federal Circuit have muddied the distinction between patentable and unpatentable subject matter. The resulting doctrinal confusion around subject-matter eligibility has prompted innovators to warn of serious consequences to investment and also spurred a notoriously ossified Congress to consider bipartisan reforms.

Enter the United States Patent and Trademark Office (USPTO). Although this office lacks the formal authority to promulgate substantive rules on subject-matter eligibility, it has nonetheless broadened its use of guidance documents in that area as a means of addressing this crisis. This Note chronicles the USPTO's use of these guidance documents across time, as well as how federal courts and the Patent Trial and Appeal Board have come to rely on them. It argues that these guidance documents, for all their regulatory utility, closely resemble legislative rules. Looking ahead, this Note encourages Congress to grant the USPTO rulemaking authority over patentability. Until it does so, the USPTO's recent guidance threatens to push the boundaries of its current authority and run afoul of the Administrative Procedure Act.

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INTRODUCTION

In April 2018, the United States Patent and Trademark Office (USPTO) issued the *Berkheimer* memo to its patent-examining corps.¹ The memo, written in response to a recent high-profile decision from the Federal Circuit,² provides guidance to patent examiners on policing the line between patentable and unpatentable subject matter and supporting their determinations. Just nine months later, the Patent Office spoke again on the subject by publishing “Revised 2019 Patent Subject Matter Eligibility Guidance” in the Federal Register.³

Practitioners were quick to note that these documents represented “a big departure from current practice”⁴ and “a drastic course correction for how patents . . . are examined.”⁵ Some practitioners, for instance, pointed to a drop in the rate at which patent examiners were rejecting patent applications as a direct result of the *Berkheimer* memo,⁶ while others asserted that the 2019 guidance made it “easier and faster for Examiners to find claims eligible.”⁷

These developments look from a distance to be the products of traditional agency rulemaking. Indeed, the Patent Office solicited feedback from regulated parties on these documents in a manner that resembled notice-and-comment rulemaking under the Administrative Procedure Act (APA).⁸ The only problem

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1. Memorandum from Robert W. Bahr, Deputy Comm’r for Patent Examination Policy, to Patent Examining Corps, Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*) (Apr. 19, 2018), <https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF> [<https://perma.cc/VF5K-88KG>] [hereinafter *Berkheimer* Memo].
 2. *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018).
 3. See 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019).
 4. Christopher C. Johns, *Berkheimer Memorandum: A Big Shift, in Fact*, FINNEGAN: PROSECUTION FIRST BLOG (Apr. 24, 2018), <https://www.finnegan.com/en/insights/blogs/prosecution-first/berkheimer-memorandum-a-big-shift-in-fact.html> [<https://perma.cc/C3YP-JJYS>].
 5. Philip M. Nelson & Jordan M. Cox, *New 101 Guidance from USPTO – What Does It Change?*, KNOBBE MARTINS: IP PRACTICE (Jan. 8, 2019), <https://www.knobbemartins.com/news/2019/01/new-101-guidance-uspto---what-does-it-change> [<https://perma.cc/AZ58-SQGX>].
 6. Dennis Crouch, *Updates from USPTO Public Meeting from Aug 2, 2018*, PATENTLYO (Aug. 2, 2018) <https://patentlyo.com/patent/2018/08/updates-from-uspto-public-meeting-from-aug-2-2018.html> [<https://perma.cc/A8FN-MHRA>]. Of course, correlation does not equal causation, and I note these empirical conclusions as an example of the perception of the *Berkheimer* memo and not necessarily for any conclusion of causality.
 7. Nelson & Cox, *supra* note 5.
 8. See Request for Comments on Determining Whether a Claim Element Is Well-Understood, Routine, Conventional for Purposes of Subject Matter Eligibility, 83 Fed. Reg. 17536 (Apr. 20, 2018); 84 Fed. Reg. 50, *supra* note 3.

with this picture is that the USPTO lacks the statutory authority to promulgate legislative rules on patentability.⁹

This Note highlights the degree to which these guidance documents have allowed the Patent Office to shape the law of subject-matter eligibility. Unlike the majority of scholarship on subject-matter eligibility,¹⁰ which casts the USPTO in a passive role,¹¹ this Note argues that the Patent Office has long played an indispensable role in adapting the law of subject-matter eligibility to technological change.¹² But in arguing that much of this guidance resembles legislative rulemaking, this Note also raises questions about whether the USPTO is defying both its authorizing statute and the procedural safeguards enumerated in the APA. This Note thus adds to the emerging discussion about the proper role of the Patent Office within the modern administrative state and provides an additional case study on its competence to engage in both legislative and interpretive rulemaking.¹³

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9. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (“Congress has not vested the Commissioner [of the USPTO] with any general substantive rulemaking power . . .”). An academic debate is emerging over whether the Leahy-Smith America Invents Act of 2011 entitles the USPTO’s Patent Trial and Appeals Board to *Chevron* deference on substantive questions of patentability. See *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc) (disagreeing in a sharply divided series of opinions on the level of *Chevron* deference afforded when reviewing a PTAB decision on burden shifting in inter partes review). Compare Stuart Minor Benjamin & Arti K. Rai, *Administrative Power in the Era of Patent Stare Decisis*, 65 DUKE L.J. 1563 (2016) (arguing that while the USPTO has failed to request *Chevron* deference for Patent Trial and Appeal Board (PTAB) interpretations it may nonetheless be entitled to it), and Christopher J. Walker, *Chevron Deference and Patent Exceptionalism*, 65 DUKE L.J. ONLINE 149 (2016) (largely supporting Benjamin & Rai’s conclusions), with John M. Golden, *Working Without Chevron: The PTO as Prime Mover*, 65 DUKE L.J. 1657 (2016) (largely contesting them). In any case, these debates largely concern the PTAB, while I focus on the ability of the USPTO to affect the substantive law of patentability via rulemaking, not adjudication.
 10. See, e.g., sources cited *infra* Section I.A.
 11. Two notable exceptions are John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041 (2011) (arguing that the USPTO is the entity most institutionally competent to shape eligibility doctrine and surveying some of the office’s pre-2011 guidance initiatives) and Melissa F. Wasserman, *The PTO’s Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379 (2011) (arguing that institutional features of the USPTO lead it to expand substantive standards of patentability and citing as examples some of the Office’s pre-2011 guidance initiatives).
 12. See Wasserman, *supra* note 11, at 390–391 (arguing that the USPTO has long developed substantive law in order to apply existing legal standards to new technology).
 13. See, e.g., Stuart Minor Benjamin & Arti K. Rai, *Who’s Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269 (2007); David E. Boundy, *Agency Bad Guidance Practices at the Patent and Trademark Office: A Billion Dollar Problem* 2018 PATENTLY-O PATENT L.J. 20 (focusing on USPTO guidance but not guidance involving subject-matter eligibility); Golden, *supra* note 11; Christopher J. Walker & Melissa Wasserman, *The New*

The USPTO's recent guidance initiatives can only be understood in light of the problem they were trying to solve. It is well established that patents can only be granted on new inventions. Less known is that courts have read § 101 of the Patent Act¹⁴ to categorically preclude entire classes of inventions from patent protection, even if they are genuinely novel.¹⁵ While scholars have debated the theoretical underpinnings of this reading, the most discussed rationale for the policy is ensuring that firms cannot obtain oppressive monopolies on ideas as broad and foundational as the law of gravity or the very building blocks of nature, like the naturally existing human genome.¹⁶

Line-drawing in the area of patentable subject matter has substantial implications for litigants. Slight changes in the doctrine can bar entire fields of study from using the patent process. Indeed, many of the most dynamic and impactful areas of scientific research struggle to prove that their discoveries claim patentable subject matter. For example, the Supreme Court's decision in *Alice Corp. v. CLS Bank International*, which held that computer-implemented processes for risk hedging are unpatentable subject matter,¹⁷ has been estimated to render invalid over eighty percent of existing software patents.¹⁸ Similarly, the Court's decision in *Mayo Collaborative Services v. Prometheus Labs*, which classified a method for measuring drug dosages as unpatentable subject matter,¹⁹ "cast a shadow of uncertainty over the validity of patents on diagnostic inventions."²⁰

It is no exaggeration, therefore, to say that the viability of entire fields of research and innovation hinges on the courts' ability to provide clear lines for patent protection. But the courts have failed the scientific community. One prominent commentator has described the courts' attempts to provide clear

World of Agency Adjudication, 107 CALIF. L. REV. 141 (2019) (focusing on USPTO adjudication rather than rulemaking); Wen Xue, Note, *Obviousness Guidance at the PTO*, 5 NYU J. INTEL. PROP. & ENT. L. 306 (2016) (focusing on guidance under § 103 rather than § 101).

14. 35 U.S.C. § 101 (2018).

15. PETER MENELL, MARK A. LEMLEY & ROBERT P. MERGES, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2017*, at 277 (2017) (noting that "we find the contours of [patentable subject matter] doctrines not in the text of the Patent Act but in the two centuries of jurisprudence that has ebbed and flowed with technological advances, perspectives on scientific discovery, and concerns about whether the patent system encourages or stifles new inventions").

16. See *infra* Section I.A.

17. 573 U.S. 208 (2014).

18. Jasper L. Tran, *Software Patents: A One-Year Review of Alice v. CLS Bank*, 97 J. PAT. & TRADE-MARK OFF. SOC'Y 532, 540 (2015).

19. 566 U.S. 66, 77 (2012).

20. Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J.F. 341, 342 (2013).

limits to patentable subject matter as a “march of failures,”²¹ and another has characterized the courts’ performance as fairly poor.²² In the rare instances in which courts have drawn lines, “those lines quickly eroded or had to be abandoned as unworkable.”²³ The consequences of this failure may be severe. “The Supreme Court’s recent treatment of the law of patent eligibility has introduced an era of confusion, lack of administrability, and, ultimately, risk of under-investment in research and development.”²⁴

The courts’ struggles in this area can be explained, in part, by their general discomfort with judicial policy-making.²⁵ After all, the principal justification for patent law’s restrictions on subject-matter eligibility is a concern for social welfare. Ideally, these restrictions balance the social benefits of incentivizing innovation with the social costs of allowing a monopoly on foundational ideas.²⁶ This kind of policy decision—balancing the societal costs and benefits of particular policy choices—falls most naturally within the province of Congress. Yet Congress has historically been hesitant to engage with issues of patentable subject matter.²⁷ This hesitance is exemplified most clearly by Congress’s abolition of the Office of Technology Assessment, an arm of the legislature that was once competent to make such judgments.²⁸ And while the newly revived Senate Judiciary Subcommittee on Intellectual Property has shown some interest in patent eligibility,²⁹ it is an open question whether the body will produce viable

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21. John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 623 (2009).
 22. Golden, *supra* note 11, at 1075.
 23. DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 157 (2009).
 24. David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2149 (2017).
 25. See Golden, *supra* note 11, at 1085 (“Moreover, at least partly because of concerns of legitimacy, democracy, and separation of powers, present-day U.S. courts tend to handcuff themselves to ways of approaching subject-matter eligibility that are unlikely to produce optimal social results.”).
 26. See *id.* at 1070-74 (showing via a mathematical model that the social costs of patenting inventions with very many uses outweigh the social benefits).
 27. *Id.* at 1091.
 28. See Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 21 (2008) (“[W]ith the abolition of the Office of Technology Assessment . . . in the mid-1990s, the ability of Congress to secure unbiased advice on questions of innovation policy is limited.”).
 29. I engage with the reform initiative in Section I.C, which provides helpful insight into issues with the current doctrine that motivated renewed legislative interest. In brief, the subcommittee released a bipartisan and bicameral preliminary draft bill in May 2019, followed by three sessions of hearings, which included forty-five witnesses.

legislation. An additional consideration is that, even if Congress succeeded in legislative reform, it may not meaningfully improve on judicial action—in part because it may move too slowly relative to technological change.³⁰

Against this backdrop, some have proposed that the Patent Office is a natural candidate to clean up this subject-matter eligibility mess.³¹ Indeed, the very members of Congress tasked with legislating on this issue have praised the USPTO's "heroic efforts" in promulgating guidance on § 101.³² The proposal to delegate to the Patent Office has been made most forcefully by John Golden, who has argued that Congress should give the USPTO substantive rulemaking authority over subject-matter eligibility.³³

Golden's 2011 article provides a theoretical foundation for the value of subject-matter-eligibility analysis and the desirability of leaving those decisions with the USPTO.³⁴ But even as Golden tackles important normative questions of what an ideal Patent Office should do, he places less emphasis on what the Patent Office has actually been doing.³⁵ While the article references several of the Patent Office's guidance initiatives, they are offered primarily as evidence of the

30. See Golden, *supra* note 11, at 1091.

31. This proposal fits nicely into a broader debate over the merits of giving the USPTO substantive rulemaking authority and a growing literature that marshals traditional tenants of administrative law in considering the proper role and function of the USPTO. See Benjamin & Rai, *supra* note 13; John M. Golden, *The USPTO's Soft Power: Who Needs Chevron Deference?*, 66 SMU L. REV. 541 (2013).

32. Senator Chris Coons, the ranking member of the Senate Judiciary Committee's Subcommittee on Intellectual Property, opened the June 4th, 2019 hearing with a statement that praised USPTO Director Andrei Iancu's attempt to clarify § 101 by issuing guidance. See *Oversight of the United States Patent and Trade Office: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 116th Cong. 1 (2019) [hereinafter *Oversight Hearing*] (statement of Andrei Iancu, Director, USPTO), <https://www.judiciary.senate.gov/imo/media/doc/Iancu%20Testimony.pdf> [<https://perma.cc/9G6J-S49A>].

33. Golden, *supra* note 11, at 1043.

34. *Id.*

35. Indeed, in this Note, I respond to a later call by Golden to fill in this gap. See Golden, *supra* note 31, at 543 ("Instead of spilling more ink on what additional powers the USPTO should or could have, commentators and policymakers might better spend their time analyzing what the USPTO should do with the power it already has.").

USPTO’s institutional competence.³⁶ To date, the existing scholarship on the topic has spent too little time on the Patent Office’s current role.³⁷

To fill that gap, this Note identifies six discrete rulemaking initiatives over the last twenty-five years, which I term “major guidance moments.”³⁸ This research should dispel any notions that the USPTO’s recent actions are unprecedented. The Office has been issuing guidance on § 101 for decades. At the same time, the increasing frequency of these moments—half of them occurred in the last five years alone—show how subject-matter eligibility rulemaking has expanded to fill the void left by the Supreme Court’s recent doctrinal revival.³⁹ A close examination of the USPTO’s guidance practices sheds light on its competence as a rulemaker. Although major guidance initiatives are announced in the *Federal Register* and comments are encouraged, the depth of engagement with these comments vary greatly across guidance initiatives.

Guidance from the USPTO wields considerable force. As Nicholas Parrillo has documented, regulated parties often follow guidance even though it is formally nonbinding.⁴⁰ Moreover, Article III courts and the Patent Trial and Appeal Board (PTAB) may place considerable reliance on the “non-substantive” words the Patent Office has written in making their own eligibility determinations.⁴¹ On paper, the Federal Circuit has declined to accord the USPTO’s subject-matter guidance much formal deference.⁴² However, I point to

36. Golden, *supra* note 11, at 1106 (“Recent USPTO initiatives on subject-matter eligibility demonstrate both the agency’s already-existing rulemaking capacity, and its ability to act quickly . . .”). Further, subject-matter-eligibility guidance at the time of that foundational article was infrequent. Much has changed in the subsequent nine years, as I explain below.

37. A foundational course correction was set in motion by Melissa Wasserman, who showed how the USPTO has used its existing powers, including guidance, to expand substantive standards of patentability. See Wasserman, *supra* note 11. This Note builds on her important work by (i) honing in on subject-matter-eligibility guidance as a detailed case study; (ii) critically examining the Federal Circuit’s doctrine that classifies these guidance documents as interpretive rules; and (iii) focusing its analysis on recent USPTO guidance in the years since Wasserman’s article was published—a time period that I believe represents a new and notable era in subject-matter-eligibility rulemaking.

38. Of course, counting exercises are of extremely limited utility in legislation and regulation. See generally Jodi L. Short, *The Trouble with Counting: Cutting Through the Rhetoric of Red Tape Cutting*, 103 MINN. L. REV. 93 (2018).

39. See Wasserman, *supra* note 11, at 393 (arguing that the USPTO had responded to the beginnings of this doctrinal revival with guidance that fills the legal void).

40. See generally Nicholas R. Parrillo, *Federal Agency Guidance: An Institutional Perspective*, ADMIN. CONFERENCE OF THE U.S. (Sept. 18, 2017), <https://www.acus.gov/sites/default/files/documents/parrillo-agency-guidance-draft-report.pdf> [<https://perma.cc/Z7CH-BQZ7>].

41. See Golden, *supra* note 31.

42. See *infra* Section III.C.

substantial evidence that federal district courts regularly treat the guidance as persuasive evidence. Further, the PTAB regularly cites this guidance, which purports to bind all Patent Office officials, to uphold claim rejections on appeal.

Rules that alter rights and obligations require additional procedural protections under the APA.⁴³ But unlike most agencies, the USPTO may only promulgate rules governing the office's own internal procedures⁴⁴ or nonbinding interpretive or guidance documents.⁴⁵ Documents that toe this line into the territory of legislative rulemaking—in other words, that *make law*—would not simply require the agency to go back and “do it again” with more procedures; it would instead run afoul of the authority granted to the USPTO by Congress.⁴⁶

Recognizing that the line between legislative and nonlegislative rulemaking is famously blurry,⁴⁷ I critically examine the USPTO's guidance, focusing in particular on the most recent guidance released in 2019. I conclude that under the prevailing precedent set out in *Animal Legal Defense Fund*,⁴⁸ the Federal Circuit would most likely classify the office's guidance as interpretive. At the same time, I argue that this test misses the mark. The unique realities of the patent system make it a somewhat poor fit for the paradigm of legislative versus nonlegislative rules as applied by the Federal Circuit. The nature of § 101—more closely resembling the common law than a statutory scheme—complicates the traditional dichotomy between interpreting a statute and creating new policy. Moreover, the trade-offs inherent in subject-matter eligibility make a focus on patent rejections misguided. Rules that expand subject-matter eligibility necessarily affect the rights and obligations of others by granting monopolies on abstract ideas or laws of nature. But the parties to individual examinations will never object to the increased patentability because the applicants are benefiting and the examiners are bound by the guidance. Offending patents, therefore, will

43. 5 U.S.C. § 553 (2018).

44. As one topical example, the Federal Circuit held in *Tafas v. Doll* that USPTO rules limiting an applicant's ability to file continuation applications (and requests for continuing examination) were procedural rules, and thus fell within the USPTO's authority. *Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009).

45. A notable exception may be the narrow but potentially more substantive grant of rulemaking authority in inter partes review by the America Invents Act. See *Cuozzo Speed Technologies v. Lee*, 136 S. Ct. 2136 (2016).

46. Others have discussed the USPTO's use of guidance relative to its authority in general or in other contexts. See, e.g., David E. Boundy, *Agency Bad Guidance Practices at the Patent and Trademark Office: A Billion Dollar Problem*, 2018 PATENTLY-O PATENT L.J. 20; Wen Xue, *supra* note 13.

47. For information on the difficulty of classifying rules as interpretive or legislative, see sources cited *infra* Section IV.A.

48. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991).

stand unless and until they are invalidated by impacted third parties in litigation or at the PTAB.⁴⁹

Even under current doctrine, the breadth and substance of the USPTO's guidance documents often push the boundaries of what one might call interpretation. This observation, discussed extensively below and coupled with the fact that these guidance documents both bind examiners and carry weight on appeal, has led me to conclude that this guidance appears to be closer to legislative rulemaking than previously acknowledged.⁵⁰

Part I of this Note provides a brief primer on patent subject-matter eligibility, surveying the confusion stemming from the Court's doctrine. From there, Part II sets out the results from my search of the *Federal Register* and the USPTO website for documents relating to subject-matter eligibility. Part III reviews citations to these documents by federal court and PTAB opinions to analyze how much adjudicators rely on USPTO guidance. Finally, Part IV analyzes the treatment of these documents as nonlegislative rules exempt from notice and comment.

I. SUBJECT-MATTER ELIGIBILITY: A PRIMER

In this Part, I provide the theoretical and historical backdrop that motivated the USPTO's recent guidance initiatives. In Section I.A, I address two simple questions: where does the subject-matter eligibility requirement come from, and what is its fundamental purpose? In Section I.B, I chronicle recent attempts by the Supreme Court and the Federal Circuit to set the goalposts of subject-matter eligibility. Finally, in Section III.C, I show how the courts' efforts have failed to provide clear and effective guidelines, as evidenced by recent congressional hearings on the topic.

A. *The History and Function of Subject-Matter Eligibility*

The oft-cited Intellectual Property Clause of the Constitution gives Congress the power to “promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective

49. Cf. Wasserman, *supra* note 11, at 404-05 (arguing that judicial review is “unidirectional” because, unlike for patent denials, there is no immediate appeal of patent grants, although granted patents may still be challenged in subsequent litigation).

50. Cf. *id.* at 389 (concluding similarly that the USPTO “develops views of substantive law that are binding on its own employees” and “is often setting de facto substantive law because many of its determinations remain unchallenged,” but not applying these conclusions to inform doctrinal questions of legislative and interpretive rulemaking).

writings and discoveries.”⁵¹ Congress, in exercising this enumerated power,⁵² has set out the standards for patent protection in 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, subject to the conditions and requirements of this title.”⁵³

This provision lays out four categories of patent-eligible subject matter: (i) processes, (ii) machines, (iii) manufactures, and (iv) compositions of matter. And yet, due to the brevity and breadth of this language, the modern concept of subject-matter eligibility is best understood to be a product of the U.S. Supreme Court and the Federal Circuit.⁵⁴

One of the Court’s most famous decisions in this area, which pulled together its early jurisprudence on patent-eligible subject matter,⁵⁵ is *Diamond v. Chakrabarty*.⁵⁶ In that case, the Court granted a patent on a “new bacterium with markedly different characteristics from any found in nature,” citing to a committee report for the 1952 Patent Act to find that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”⁵⁷ At the same time, the Court warned that “anything under the sun”

51. U.S. CONST. art. I, § 8, cl. 8.

52. While the current text of 35 U.S.C. § 101 comes from the modern 1952 Patent Act, similar language – “any new and useful art, machine, manufacture, or composition of matter” – appeared in the first patent statutes. See MENELL ET AL., *supra* note 15, at 277.

53. The language of § 101 has been held to generate several distinct requirements for patentability, including actual inventorship, utility, and a bar on double patenting. See MPEP § 2104 (§ 101 “has been interpreted as imposing four requirements”). For the purposes of this Note, I focus only on its conditions for patent-eligible subject matter. Still, searches for rulemaking on § 101 often touch on the other requirements contained therein and can bias any measures of subject-matter-eligibility discussion in various sources unless carefully handled, as I discuss *infra* Part II.

54. See MENELL ET AL., *supra* note 15.

55. For a more thorough treatment of the early subject-matter-eligibility doctrine, see MENELL ET AL., *supra* note 15, at 277. Many of these cases preceded the 1952 Patent Act, including *O’Reilly v. Morse*, 56 U.S. 62 (1854), which held that Morse could patent his specific telegraph application but not the very concept of using electromagnetism to transmit characters at distances, and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), which rejected as unpatentable the idea of combining different strains of bacteria to apply to plants. This trend continued in the decades after the modern Patent Act, including *Gottschalk v. Benson*, 409 U.S. 63, 64, 73 (1972), which rejected as unpatentable a series of mathematical calculations to convert “binary-coded decimal (BCD) numerals into pure binary numerals,” and *Parker v. Flook*, 437 U.S. 584 (1978), which rejected as unpatentable a process for using a mathematical algorithm to update alarm limits during catalytic conversion.

56. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

57. *Id.* at 309–10 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

apparently had some limits, alluding to its earlier line of cases where “[t]he laws of nature, physical phenomena, and abstract ideas have not been held patentable.”⁵⁸

The Court also summarized the key motivating factor behind limiting patents to certain categories of subject matter: it would be absurd—not to mention impracticable—to grant Newton a patent for gravity,⁵⁹ and thereby give him a right to exclude others from dropping apples on the ground. Subject-matter eligibility thus implicates a key tension at the heart of patent law: at what point does a monopoly stop promoting innovation and start impeding it? While patents are expected to increase innovation through monetary incentives, a patent on an idea as foundational as a law of nature could have the perverse effect of crowding out waves of productive innovation.⁶⁰

In recent years, scholars have spilled considerable ink debating the role and proper bounds of subject-matter eligibility.⁶¹ The traditional justification for subject-matter-eligibility boundaries is a theory of gatekeeping.⁶² As the industry-based arguments suggest, § 101 has been considered “predominantly coarse-grained and categorical,” dealing with broad areas rather than the specifics of particular patents—quite unlike the finer-grain requirements of novelty or nonobviousness.⁶³ The Patent Office itself has referred to subject-matter eligibility as “merely a coarse filter.”⁶⁴ As Golden has demonstrated via a theoretical model, such a coarse filter can effectively prevent the patenting of

58. *Id.* at 309.

59. *Cf. id.* (“Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.”).

60. See Golden, *supra* note 11, at 1069 (summarizing and citing claims by various commentators that patents on general ideas like gravity may “impede development or exploitation of a wide array of uses,” or “decrease incentives and increase costs for follow-on innovations that develop the ultimately desired practical applications”).

61. See, e.g., Thomas F. Cotter, *A Burkean Perspective on Patent Eligibility, Part II: Reflections on the (Counter) Revolution in Patent Law*, 11 MINN. J.L. SCI. & TECH. 365 (2010); Golden, *supra* note 11; Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315 (2011); Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017); Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591 (2008); Joshua D. Sarnoff, *Patent-Eligible Inventions After Bilski: History and Theory*, 63 HASTINGS L.J. 53 (2011).

62. Lemley et al., *supra* note 61, at 1326 (“The traditional way academics think about patentable subject matter is as a gatekeeper . . .”).

63. Golden, *supra* note 11, at 1061.

64. Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43,926 (July 27, 2010).

innovations that are “socially inappropriate” for patenting from a welfare perspective, even if they are newly conceived.⁶⁵

Some have put forward alternative justifications for eligibility doctrine. Joshua Sarnoff, for example, has argued that the doctrine is rooted in a historical desire to keep basic science in the public domain.⁶⁶ Others have instead described the abstract idea doctrine as “an overclaiming test,” which “makes the scope of the resulting patent clearer and leaves room for subsequent inventors to improve upon – and patent new applications of – the same basic principle.”⁶⁷

Others have gone further, advocating the elimination of judicial exceptions entirely.⁶⁸ These calls are often based in a pure policy argument: that current eligibility doctrine disincentivizes inventions that should be promoted.⁶⁹ In their place, the argument often goes, rigorous application of the statutory requirements of patentability – explicit § 101 categories, utility, novelty, obviousness, and specification – can satisfactorily address controversial questions of patentability, such as business methods.⁷⁰ The defenders of this statutory approach describe it as a scalpel, compared to the “machete” of current, judicially created doctrine.⁷¹

Still, others have defended subject-matter-eligibility hurdles on procedural rather than substantive grounds.⁷² Because of its broad nature, courts have often held subject-matter eligibility to be a pure question of law, allowing dismissal of suits on § 101 grounds at the motion-to-dismiss stage.⁷³ While recent Federal Circuit opinions have stressed that decisions on eligibility may sometimes require factual findings,⁷⁴ the primarily legal nature of § 101 supports “a key

65. Golden, *supra* note 11, at 1073.

66. Sarnoff, *supra* note 61.

67. Lemley et al., *supra* note 61, at 1315.

68. See, e.g., Risch, *supra* note 61.

69. See, e.g., Madigan & Mossoff, *supra* note 61 (arguing that the judicial exceptions in current doctrine disincentivize valuable research, including medical research, and presenting a data set of patents rejected at the USPTO but permitted in China or the European Patent Office).

70. Risch, *supra* note 61, at 609.

71. *Id.* at 591.

72. See Paul R. Gugliuzza, *The Procedure of Patent Eligibility*, 97 TEX. L. REV. 571 (2019).

73. See Gugliuzza, *supra* note 72, at 601 (“[T]he reason courts are able to decide eligibility at the ‘threshold’ via a motion to dismiss or for judgment on the pleadings is that they often view it as a question of law involving no factual considerations.”).

74. See *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1128 (Fed. Cir. 2018) (finding that factual questions precluded a motion to dismiss); *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370 (Fed. Cir. 2018) (finding that factual questions precluded summary judgment).

policy justification for the very existence of the eligibility requirement: providing a means to quickly and cheaply dispose of infringement claims that obviously lack merit.”⁷⁵

B. Recent Doctrinal Attempts to Flesh Out § 101

As the academy has wrestled with the proper balancing of subject-matter eligibility, the Supreme Court and the Federal Circuit have likewise grappled with this issue on the ground.⁷⁶ The last decade, in particular, has seen courts tackle this issue with increased frequency and vigor, following an era in which “patentable subject matter was effectively a dead letter.”⁷⁷ After a definitive statement in 1981 in *Diamond v. Diehr* that three categories—“laws of nature, natural phenomena, and abstract ideas”—are not patentable,⁷⁸ the Supreme Court remained silent on the issue for nearly three decades.⁷⁹ During this period, the Federal Circuit was left unencumbered to scale back the limitations of § 101 and widen the range of patentable inventions.⁸⁰ On the business-method side, *State Street Bank v. Signature Financial Group*⁸¹ affirmed the patentability of business methods; *AT&T v. Excel*⁸² extended this holding further to explicitly include process claims by themselves.

That all changed in 2010, when the Supreme Court reentered the conversation in *Bilski v. Kappos*.⁸³ In *Bilski*, the Supreme Court upheld the Federal Circuit’s en banc rejection of a claim for a method of hedging risk.⁸⁴ The opinion added confusion to the issue of eligibility by rejecting the “test relied

75. Gugliuzza, *supra* note 72, at 580.

76. Here I primarily concentrate on the key tensions that have arisen in the doctrine over the last decade. For a more comprehensive survey of each judicial move since the 1952 Patent Act, see generally MENELL ET AL., *supra* note 15, at 276.

77. Lemley et al., *supra* note 61, at 1318.

78. 450 U.S. 175, 185 (1981).

79. MENELL ET AL., *supra* note 15, at 277 (“The Supreme Court was silent on patentable subject matter from 1981 to 2010.”).

80. *Id.* at 284 (“In the ensuing three decades, the Federal Circuit gradually eroded patent eligibility limitations.”).

81. *State St. Bank & Tr. Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

82. *AT&T Corp. v. Excel Commc’ns, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999).

83. 561 U.S. 593 (2010).

84. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff’d sub nom. Bilski v. Kappos*, 561 U.S. 593 (2010). While this decision simply affirmed the below Federal Circuit decision, rather than flipping the direction of precedent, *Bilski v. Kappos* represented a revival of Supreme Court interest in (constraining) eligibility.

upon below”⁸⁵ without providing additional guidance on why the invention was unpatentable.⁸⁶ Two years later, the Court decided *Mayo Collaborative Services v. Prometheus Labs*, which held that a method of treating a patient with a certain drug dosage to avoid side effects was not patent eligible.⁸⁷ Two years after that, the Court decided *Alice v. CLS Bank*, which reaffirmed *Mayo* and characterized its holding as the following two-step inquiry.⁸⁸ First, courts “determine whether the claims at issue are directed at one of those patent-ineligible concepts,” such as laws of nature, natural phenomena, and abstract ideas.⁸⁹ From there, courts search for an “inventive concept,” evaluating “the elements of each claim both individually and ‘as an ordered combination’ to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application.”⁹⁰

Unfortunately, this existing body of case law has hardly satisfied its key constituents. The word used often to describe the doctrine and its operation today is: “mess.”⁹¹ A report summarizing roundtable discussions on the state of the law noted that several participants conceded that “the *Mayo/Alice* standards lack coherence—often boiling down to a subjective ‘I know it when I see it’ standard.”⁹²

85. This was the machine-or-transformation test, which held that “A claimed process is . . . patent-eligible under § 101 if (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *In re Bilski*, 545 F.3d at 954. The Supreme Court rejected this as the exclusive test of patentability but noted it could nonetheless be an “important clue.” *Bilski*, 561 U.S. at 604.

86. Lemley et al., *supra* note 61, at 1318-19.

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

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

89. *Id.* at 218.

90. *Id.*

91. See, e.g., James Busch, *Making Sense of the Mess Caused by Alice, and Evaluating a Contingent Fee Patent Matter for Subject Matter Eligibility*, JAMES DAVID BUSCH, <https://www.jdbip.com/blog/2018/11/7/making-sense-of-the-mess-caused-by-alice-and-evaluating-a-contingent-fee-patent-matter-for-subject-matter-eligibility> [<https://perma.cc/XH4V-GTZN>].

92. Jeffrey A. Lefstin et al., *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 592 (2018).

C. *The Effects of the Current Doctrinal “Mess” and Emerging Congressional Interest in Reform*

In light of the current state of the case law, some have called for legislative reform to § 101.⁹³ Within the last year, rumblings of legislative interest in § 101 have grown on Capitol Hill. While no bill has yet made its way to the floor, nascent congressional interest is an important marker of the level of discontent and pressure exerted by key interest groups – evidenced by testimony in recent hearings.

On May 22, 2019, two U.S. Senators and three Representatives publicly released a “bipartisan, bicameral draft bill that would reform Section 101 of the Patent Act.”⁹⁴ This release was the culmination of rumblings of renewed congressional interest in § 101 that had been building for several months.⁹⁵ In February, Senators Thom Tillis and Chris Coons had revived, for the first time in over a decade, the Senate Judiciary Subcommittee on Intellectual Property.⁹⁶ Just one month into the subcommittee’s tenure, it held an oversight hearing with USPTO Director Iancu,⁹⁷ during which subject-matter eligibility was the very first substantive issue raised by the director in his written statement.⁹⁸

The draft bill itself takes up only one page,⁹⁹ but its potential impact is profound. The draft bill proposes replacement text for § 101, which subsumes the existing text of § 101 into a newly created subsection (a), but leaves that existing text largely identical. The only change is the deletion of the word “new”

93. See, e.g., Taylor, *supra* note 24 (proposing legislative reforms to correct the Supreme Court’s recent doctrine).

94. Press Release, Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), <https://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework> [<https://perma.cc/4G5V-9LCY>].

95. Immediately preceding this draft bill release, the same group of legislators released an early framework for reform in April, which was followed by a roundtable. *Id.*

96. See Press Release, Sen. Thom Tillis, Tillis & Coons to Lead Senate Judicial Subcommittee on Intellectual Property (Feb. 7, 2019), <https://www.tillis.senate.gov/2019/2/tillis-coons-to-lead-senate-judiciary-subcommittee-on-intellectual-property> [<https://perma.cc/VKC7-A9JR>]; Malathi Nayak, *Senate Judiciary Revives Intellectual Property Panel*, BLOOMBERG L. (Feb. 7, 2019, 5:24 PM), <https://news.bloomberglaw.com/ip-law/senate-judiciary-revives-intellectual-property-panel> [<https://perma.cc/3MU4-MJQ5>].

97. See *Oversight Hearing*, *supra* note 32.

98. *Id.* at 2.

99. Thom Tillis et al., *Draft Bill to Amend Section 101 of the Patent Act* (May 22, 2019) <https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26> [<https://perma.cc/8CJ5-ZLYX>].

preceding the word “useful.” This change reaffirms that questions of “newness” are to be dealt with elsewhere in the Patent Act, notably § 102.¹⁰⁰ The proposed text also adds a new subsection (b), which makes clear that eligibility is to be determined holistically, thus codifying a principle reminiscent of the Supreme Court’s analysis in *Diehr*.¹⁰¹ This change should be expected to skew toward patentability because elements that might, on their own, appear ineligible might be rendered eligible when considered alongside other claim limitations.

The largest changes to subject-matter eligibility come under the heading “Additional Legislative Provisions.” The effects of these provisions are large and fairly straightforward. First, a new presumption in favor of eligibility will act to limit the bite of § 101 across the board. Second, a new paragraph explicitly and wholly abrogates the entire field of judicial exceptions carved out by the Supreme Court over many decades. And third, the final paragraph removes the factual elements at play in *Berkheimer* from the § 101 analysis. Taken together, these changes, on their face, skew heavily in the direction of expanding eligibility, taking a step back toward making patentable “anything under the sun” created by humankind.¹⁰² At the same time, the draft language also makes some changes that might pump the brakes slightly on the enlarged § 101.¹⁰³

Setting aside the merits of the specific reform proposal, the hearings were stark in their indictment of the current doctrine. A former Chief Judge of the Federal Circuit declared that the uncertainty over § 101 is the number-one issue facing the patent system today.¹⁰⁴ A former director of the Patent Office lamented that the current state of the law might be undermining technologies that are

100. 35 U.S.C. § 102 (setting forth the requirement of novelty).

101. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981) (“In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.”).

102. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

103. For example, it modifies the requirements of § 112 in a way that might narrow the scope of some patent claims that would be allowed on previously ineligible subject matter. Cf. *The State of Patent Eligibility in America, Part I: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary*, 116th Cong. 5 (2019) [hereinafter *Hearing I*] (statement of Robert Armitage, IP Consultant), <https://www.judiciary.senate.gov/imo/media/doc/Armitage%20Responses%20to%20QFRs.PDF> [https://perma.cc/6VCB-GDSH] (“If the § 101 hurdle to securing valid patent rights is to be lowered by abrogating the ‘implicit exception’ jurisprudence, it is essential for Congress to assure that the remaining hurdles stand tall enough. This includes the § 112(a) disclosure requirement that would invalidate overly broad claims absent the ability of proposed § 112(f) to protect them from such invalidation by confining their breadth to the scope of the supporting disclosure laid out in the patent.”).

104. *Hearing I*, *supra* note 103, at 3 (testimony of Judge Paul R. Michel).

critical to national security.¹⁰⁵ Some have separated out the negative impact for the two main affected areas: confusion in software and incorrect ineligibility determinations in biosciences.¹⁰⁶ In his testimony, David Taylor reported the results of a survey in which venture-capital and private-equity investors indicated that many who knew about the Supreme Court’s eligibility cases saw a negative investment effect¹⁰⁷ and that the importance of patentability for investment varied greatly by sector (highest in life sciences).¹⁰⁸

The claim of aggregate investment shocks meshes well with anecdotal evidence provided by key industry players. A representative of IBM claimed that the “current lack of clarity undercuts the potential of the information technology industry.”¹⁰⁹ Qualcomm came armed with anecdotes of the difficulty of patenting 5G innovations, noting that a “[I]ack of predictability and uncertainty over patent rights, as we currently face today, makes it risky to develop and invest in new technology.”¹¹⁰ These concerns were echoed in the medical diagnostics field as well, with Peter O’Neill of the Cleveland Clinic stating that “the uncertainty of patent protection makes it less likely we and other inventors will make the investments to make new advances commercially available.”¹¹¹

It is uncertain whether and when the recent congressional interest in subject-matter eligibility will result in statutory change. Still, the recent hearings have served to underscore the depth of the problem. Clearly, there is broad consensus that subject-matter-eligibility doctrine, as it stands, is threatening innovation in the United States. It is in this unenviable landscape that the USPTO finds itself, and it is against this backdrop that the office has decided to promulgate its recent guidance.

105. *Hearing I, supra* note 103, at 2 (testimony of David J. Kappos).

106. *Hearing I, supra* note 103 (testimony of David O. Taylor).

107. *Id.* at 7 (“Almost 40% of the investors who knew about at least one of the Court’s eligibility cases indicated that the Court’s decisions had somewhat negative or very negative effects on their firm’s existing investments, while only about 15% of these investors reported somewhat positive or very positive effects.”).

108. *Id.* at 6 (“[O]n average each industry would see reduced investment [if from elimination of patents], but the impact on particular industries would be different. And the life sciences industries are the ones most negatively affected.”).

109. *The State of Patent Eligibility in America: Part III, Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 116th Cong. 6 (2019) (testimony of Manny Schecter, Chief Patent Counsel, IBM) [hereinafter *Hearing III*].

110. *Hearing III, supra* note 109, at 6 (testimony of Laurie Self, Senior Vice-President and Counsel, Government Affairs, IBM).

111. *Hearing III, supra* note 109 (responses to Questions of Peter O’Neil, Executive Director, Cleveland Clinic).

II. THE USPTO'S USE OF GUIDANCE DOCUMENTS

In response to this increasingly confusing case law, the Patent Office has attempted to promulgate guidance that clarifies the patentability determination under § 101. In this Part, I catalog the recent universe of USPTO guidance on subject-matter eligibility and summarize its more prominent contours. First, a brief note on what, exactly, constitutes “guidance.” Guidance encompasses “virtually any agency statement that is applicable to a general class of persons but does not rise to the status of a legislative rule.”¹¹² As a practical matter, “guidance—and lots of it—is a necessity for an agency that wishes to control its field personnel and keep the public informed about how to comply with the agency’s program.”¹¹³ The volume of guidance “greatly exceeds that of notice-and-comment regulation” and may take the form of things labeled orders, notices, memoranda, manuals for agency staff or stakeholders, frequently asked questions, letters or the like.¹¹⁴ In short, the scope and scale of agency guidance is vast.

The primary compilation of USPTO guidance on patentability is the Manual of Patent Examining Procedure (MPEP).¹¹⁵ The relevant section of the MPEP, § 2106, provides a flowchart, descriptions, examples, and interpretations of case law.¹¹⁶ The MPEP appears to serve a largely archival function, however. Both of the guidance documents that motivated my research effort—the *Berkheimer* memo and the 2019 guidance update—indicated that their text superseded the language currently existing in the MPEP and would be finalized and incorporated therein in a subsequent revision. Furthermore, a brief review of the USPTO website reveals materials that can rightly be considered guidance—slides, FAQs and the like—that are not included in the MPEP’s pages.

I focus on two sources of Patent Office guidance.¹¹⁷ In Section II.A, I examine guidance narrowly defined: formal documents published or referenced in the

112. JERRY L. MASHAW ET AL., *ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW SYSTEM CASES AND MATERIALS* 651 (2014).

113. *Id.*

114. *Id.* (quoting Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 804-5 (2001)).

115. See generally James E. Ruland, *Chapter 2100 of the Manual of Patent Examining Procedure—A Means for Persuasion*, 6 TEX. INTELL. PROP. L.J. 49, 52, 57 (1997) (detailing how MPEP Chapter 2100 and its constituent sections aid patent practitioners and examiners, despite the Chapter’s frequent conflicts with Federal Circuit precedent).

116. MPEP § 2106 (8th ed. rev. 7, 2008).

117. This search method comes with a host of caveats. The electronically available *Federal Register* only dates back to 1994, so I cabin my study as covering the last twenty-five years. In an effort

Federal Register. In doing so, I aim to capture the most significant of the USPTO's guidance—the *Berkheimer* memo and the 2019 guidance, which were published in the *Federal Register*—as well as guidance for which the Patent Office sought public comment in a notice-and-comment-like fashion. Second, recognizing that not all guidance is published in the *Federal Register*, I scour the USPTO website in Section II.B to catalog other materials contained in designated subject matter or archival webpages. In Section II.C, I synthesize my findings into six major guidance “moments” and examine their motivating circumstances, principal objectives, and resemblance to notice-and-comment rulemaking. Finally, in Section II.D, I briefly synthesize observations from this Part to draw generalizations and conclusions about the USPTO's guidance practices.

A. *The Federal Register*

Appendix Table A1 displays all of the documents returned via a Boolean search of the *Federal Register*.¹¹⁸ While keyword selection is an imperfect tool, I chose keywords that were based on the language the Patent Office actually uses.¹¹⁹ In sum, the search returned seventy-three documents, with posting

to reach back farther, I also reviewed the “more important notices and rule changes” published in the USPTO's *Official Gazette* between 1964 and 1998. The one notice I found dealing with eligibility was from 1996 and already captured by my earlier search methods, which somewhat validated my search methods. At the same time, other notices on subject-matter eligibility could have been published before the electronically available *Federal Register*—or published only in the *Official Gazette*—and not deemed “more important” by the archival compiler. Lastly, the Patent Office might update the MPEP without announcing its changes in the *Federal Register* or its website. My assumption there is that such changes—made without publication or seeking public comment when doing so was done for other changes—are unlikely to be the kind of far-reaching, quasisubstantive rules that I primarily seek to grapple with in this Note.

118. *Reader Aids, Federal Register*, <https://www.federalregister.gov/reader-aids/videos-tutorials/utilizing-complex-search-terms> [<https://perma.cc/MB7T-SZAV>]. This search was performed on January 7, 2019, and the results are current as of that date. The date of search fell within a government shutdown, and the *Federal Register* website contained a banner noting that the website would not be updated, so conceivably this search is only current as of the start of the government shutdown. But the search produced documents as recent as January 7, suggesting that the government—or an automated program—was indeed keeping it current. The Appendix accompanying this Note is available on the *Yale Law Journal* website at <https://www.yalelawjournal.org/note/rulemaking-101>.

119. First, I used the exact citation to the U.S. Code (“35 U.S.C. 101”). Having reviewed the *Berkheimer* memo, I next included the language the USPTO used: “subject matter eligibility.” Finally, on a brief review of other USPTO documents, I noted that the U.S. Code section was frequently only referred to as “Sec. 101,” and that the term “statutory subject matter” sometimes took the place of “subject matter eligibility.” Of course, other variants of the U.S. Code citation and subject-matter eligibility are sometimes used. These two terms were included because they were in a few occasions used to completely displace the other two terms. In a

dates ranging from September 1994 to January 2019.¹²⁰ These documents collectively span over fourteen hundred pages in the *Federal Register*, and just over five percent of the total documents that the USPTO released.

I coded nineteen documents as responsive, meaning that on review I determined that the document engaged substantively with subject-matter eligibility. Ten documents are requests for written comments, three documents are extensions of the written comment period, three documents convened a public roundtable or forum, one document expanded such a forum to a second location, and two documents issued “final” guidance with no request for further comment. Of the total, fourteen responsive documents were centered squarely around the issue of subject-matter eligibility. Of the remaining responsive documents, three discuss subject-matter eligibility at length within the broader (and narrower) context of computer-implemented inventions, one discusses eligibility in the broader context of international harmonization of patent laws, and one engages with (and rejects) calls for changes to subject-matter eligibility made by comments responding to a notice on utility guidance.

Interestingly, the five responsive documents that only touch upon subject matter through another topic were all published on or before 2001. In the last seventeen years, each document that has engaged substantively with the issue of subject-matter eligibility has been created squarely around this issue. This perhaps signifies a conscious choice by the USPTO to address subject matter by itself.

Figure 1 shows the number of documents in the *Federal Register* that contain search keywords and that are responsive relative to the total USPTO docket for each year. While the total number of *Federal Register* documents filed by the USPTO over the last twenty-five years appears to be on a steady incline,¹²¹ the

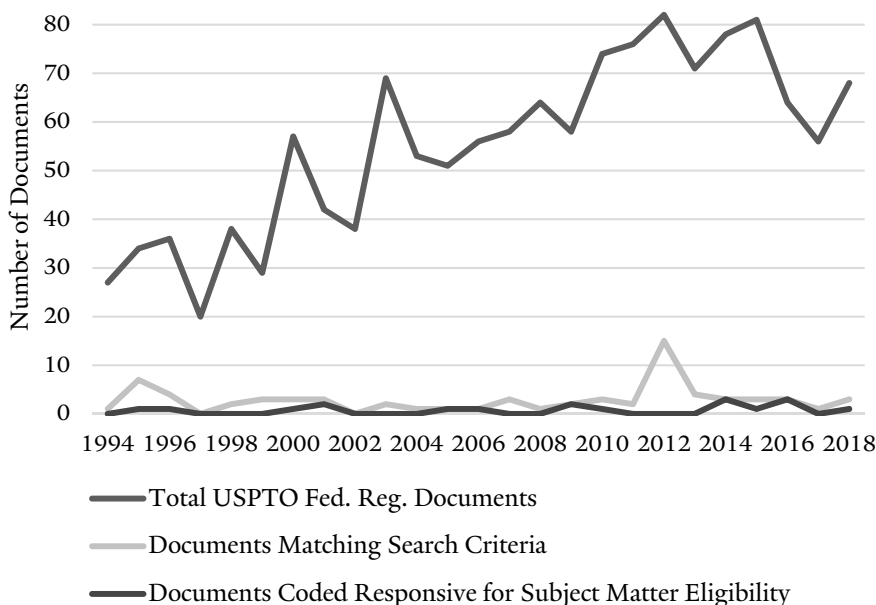
first cursory review of the results, I noticed that a final guidance document referred to a request for comment, but the request for comment itself did not come up in the search. The request for comment used “Sec. 101” and “statutory subject matter” in place of my first two search terms, so I included these in my final search. Doing so increased my initial search results by five documents, that is, from sixty-eight to seventy-three. The final keyword search was: “35 U.S.C. 101” | “Sec. 101” | “subject matter eligibility” | “statutory subject matter.” It is very unlikely that any relevant document—that is, one that discusses patent subject-matter eligibility under § 101—would fail to include one of these terms somewhere in its text.

120. I should note that some of the notices in the *Federal Register* were explicit that their guidance replaced any guidance in the MPEP. Other notices stated an intention to update the MPEP with the new guidance in due course. I suspect that the MPEP functions in this way as something like the U.S. Code; it is revised periodically to incorporate new documents put out by the USPTO.

121. This observation could suggest that the USPTO’s use of guidance, rulemaking, or both has increased across the board in recent years and, while beyond the scope of this Note, raises questions for future research.

same is not true for the subset of documents dealing with subject matter, which appear relatively flat,¹²² with short bursts of a few documents separated by years with no such documents.¹²³

FIGURE 1.
SECTION 101 / SUBJECT-MATTER ELIGIBILITY DOCUMENTS IN THE *FEDERAL REGISTER* OVER TIME



122. Several back-of-the-envelope statistical tests lend some support to this observation. A linear time trend is not significant as a predictor of whether a USPTO *Federal Register* document will be subject-matter responsive. Still, a handful of years appear anomalous compared to the overall rate of subject-matter documents: tests of proportionality suggest that the rate of subject-matter document issuance was significantly different ($p < 0.1$) from the population in 2001, 2014, and 2016. Of course, these years might be anomalous for other reasons than a general trend in use of the *Federal Register* for subject-matter guidance—such as concurrence with large exogenous events such as court decisions.

123. The increased discussion of § 101 and/or subject-matter eligibility in 2012—without a corresponding increase in actual substantive engagement with the subject—can be attributed to a large swath of rulemaking that followed the America Invents Act, Pub. L. No. 112-29, 125 Stat. 204 (2011), where § 101 and subject-matter eligibility were noted in passing as potential grounds for postgrant review and covered business-method review.

that were coded as exact duplicates of earlier entries).¹²⁸ The number of relevant documents on the SME website is several times greater than that in the *Federal Register*.¹²⁹

The remaining documents have many flavors but generally fall within one of several broad buckets. Some are memos to the examining corps that lay out new examination guidance, such as the *Berkheimer* memo. Comments to at least some of these memos, likewise, are maintained on their own separate pages. Other documents take the form of these memos to the examining corps but serve only to summarize recent case holdings, without distilling any guidance or instructions for examiners. The most voluminous bucket contains examiner training materials.¹³⁰

C. Major Guidance “Moments”

In the previous Sections, I described the set of *Federal Register* and USPTO documents that concern subject-matter eligibility. These sources are closely linked together. A guidance document posted on the USPTO website, for example, might be summarized in the *Federal Register*. Subsequently, the USPTO might post a separate page on its website for training materials relating to the same guidance document.

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128. Unlike the *Federal Register*, distinctions between documents are a bit blurrier – one bullet-pointed item (such as “Abstract Ideas Workshop II”) might actually lead to several downloadable files. I tended to group such sets of files together as one distinct unit and noted how they were actually chunked out by file, if at all. If one were to count each file separately, the number of “documents” contained on the SME website would be several times greater than my initial tally of fifty-six – well into the hundreds.
129. Further, the set of documents on the USPTO’s website are fairly disjointed from the *Federal Register*, begging the question of how the Patent Office decides which subject-matter-eligibility documents merit public notice or would benefit from public comment. Five documents are effectively identical to those in the *Federal Register*: they link to the *Federal Register* itself or perform substantially the same function (i.e., both point to the revised MPEP). Five additional documents are not identical but are closely related to *Federal Register* entries; that is, the documents are the actual guidance memos that are announced (but not provided) in the *Federal Register*, or the *Federal Register* is used to announce events that are chronicled on the SME website.
130. Virtually every memo or guidance is accompanied by a set of examples. Sometimes, these examples form part of a training unit alongside audio presentations, PowerPoint slides, and worksheets with answer keys. Still other documents are compendia of events that happened at the USPTO, reproducing the agenda and the slides for each speaker and sometimes providing a written report, full transcript, or summary of the proceedings. Finally, a variety of documents attempt to summarize or catalog the swath of other types of materials, including indices of examples and cases and short summaries of or quick-reference sheets for longer guidance documents.

To make sense of these linkages, I now group together documents for the major § 101 guidance initiatives. Each grouping, or “moment,” represents one discrete change in the USPTO’s subject-matter-eligibility guidance and all the relevant documents that came from it. Because the electronic *Federal Register* that forms a large part of this search begins in 1994 and the documents on the USPTO website are all more recent than that, I focus on the last twenty-five years.¹³¹ In total, I identify six such moments over that period. In the Sections that follow, I provide brief summaries of the main priorities of each moment. I reserve a more detailed legal analysis of the substance of the USPTO’s rulemaking initiatives for Part IV, where I use the most recent initiative as a case study.

1. 1996 Examination Guidelines for Computer-Related Inventions

On June 2, 1995, the USPTO posted a “Request for Comments on Proposed Examination Guidelines for Computer-Implemented Inventions” in the *Federal Register*.¹³² The proposed guidelines were contained within the *Federal Register* notice, and referenced supporting legal analysis that was “being prepared.”¹³³ Less than a year later, the office published a “final version” of the guidelines in March 1996.¹³⁴

In the request for comment, the Patent Office justified the need for guidance: “These guidelines respond to recent changes in the law that governs the patentability of computer-implemented inventions, and set forth the official policy of the Office regarding inventions in this field of technology.”¹³⁵ The

131. The scope of this study begins with the start of the electronically available *Federal Register* in 1994. In addition, I reviewed the USPTO’s “compilation of the more important notices and rule changes, which have been published in the *Official Gazette* from July 1, 1964, through December 31, 1998.” *The Consolidated Listing of Official Gazette Notices*, USPTO, <https://www.uspto.gov/web/offices/com/sol/og/con/ogcon.htm> [<https://perma.cc/KPA4-57KL>].

132. Request for Comments on Proposed Examination Guidelines for Computer-Implemented Inventions, 60 Fed. Reg. 28,778 (June 2, 1995).

133. The legal analysis was later issued in October of that same year. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, LEGAL ANALYSIS TO SUPPORT PROPOSED EXAMINATION GUIDELINES FOR COMPUTER-IMPLEMENTED INVENTIONS (Oct. 3, 1995), in 1180 Off. Gazette U.S. Pat. & Trademark Office TMOG 14 (Nov. 7, 1995).

134. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, EXAMINATION GUIDELINES FOR COMPUTER-RELATED INVENTIONS, in 1184 Off. Gazette U.S. Pat. & Trademark Office OG87 (Mar. 26, 1996) [hereinafter 1996 Guidelines].

135. Request for Comments on Proposed Examination Guidelines for Computer-Implemented Inventions, 60 Fed. Reg. 28,778 (June 2, 1995).

Office is almost certainly referring to the Federal Circuit's decisions in *Alappat*¹³⁶ and *Lowrey*,¹³⁷ which upheld the patentability of computer inventions previously deemed unpatentable by the USPTO.

The guidelines are aimed to “clarify the Office’s position on certain patentability standards related to this field of technology.”¹³⁸ The guidelines explicitly endorse a particular test for analyzing claims directed “solely” to a process for solving algorithms,¹³⁹ admonish that business method claims should be treated “like any other process claims,” and set forth a series of steps for examiners to follow when examining computer-related inventions.¹⁴⁰

Especially notable about the final guidance is its responsiveness to public comment on the earlier version: “The Office received forty-six comments The Office has carefully considered all of the comments, and a number of changes have been made in response.”¹⁴¹ Although several of these comments were nonsubstantive, such as changing the title, others were as expansive as “clarifying the legal requirements for statutory subject matter.”¹⁴² At the same time, the office explicitly rejected two requests, including “(1) determining that claims for data structures per se and computer programs per se are statutory subject matter, [and] (2) determining that claims for non-functional descriptive material embodied on computer-readable media are statutory subject matter.”¹⁴³ Later portions of this guidance justified the Office’s decision not to adopt such wide-ranging presumptions of eligibility.¹⁴⁴ Indeed, the level of engagement with these comments looks much like the deliberation that would be expected when promulgating a legislative rule under notice and comment.

136. *In re Alappat*, 33 F.3d 1526, 1544-45 (Fed. Cir. 1994) (holding that the claimed invention was a patentable machine rather than an ineligible “mathematical algorithm”).

137. *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994) (reversing the USPTO’s rejection of a claim for a data structure).

138. 1996 Guidelines, *supra* note 134, at 87.

139. The endorsement of this test, known as the “Freeman-Walter-Abele test,” is perhaps a signal that the USPTO guidance is lagging behind the Federal Circuit, as the cases motivating this guidance had begun to move away from this test. See John E. McGlynn, *Patent Law—Patentable Subject Matter and Computer Software Inventions—In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994), 14 TEMP. ENVTL. L. & TECH. J. 135, 148 (1995) (“Conspicuously missing from the Federal Circuit’s analysis is an application of the Freeman-Walter-Abele test.”).

140. 1996 Guidelines, *supra* note 134, at 87, 99.

141. *Id.* at 87.

142. *Id.*

143. *Id.*

144. *Id.* (“The first two suggestions are addressed in detail in Section IV.B.I(a)-(c).”)

2. 2005 Interim Guidelines

Nearly a decade passed before the USPTO again turned to the *Federal Register* to seek comment on § 101. This time, the generically titled “Interim Guidelines for Examination of Patent Applications for Patent”¹⁴⁵ were published in the *Official Gazette* of the Patent Office, with a concurrent request for comments published in the *Federal Register*.¹⁴⁶ The timing is important: this guidance did not come on the heels of a legislative change or a court decision in need of interpretation.¹⁴⁷ As motivation for the guidance, the document references the USPTO’s 1996 computer-related invention guidelines¹⁴⁸ and the Federal Circuit’s 1998 decision in *State Street Bank*,¹⁴⁹ both from nearly a decade earlier. “Since this time,” the guidance contends, “the USPTO has seen increasing numbers of applications outside the realm of computer-related inventions that raise issues.”¹⁵⁰ On its face, therefore, the USPTO is invoking its interpretive power *sua sponte*, not in response to ambiguity in a recent statute or court decision but as a shift in *policy* in response to waves of newly questionable applications.

After reading the application and “consider[ing] the breadth of [101],” examiners are instructed first to “determine whether the claimed invention falls within an enumerated statutory category.”¹⁵¹ However, the guidance notes that there are sometimes instances that are “potentially confusing as to which

145. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 Off. Gaz. Pat. & Trademark Office 142 (Nov. 22, 2005) [hereinafter 2005 Guidance].

146. Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005).

147. While Crouch notes that this document was released “[i]n the wake of the Lundgren case,” Dennis Crouch, *USPTO Releases New Business Method Guidelines: Requires “Physical Transformation” or “Concrete and Tangible Result,”* PATENTLY-O (Oct. 27, 2005), https://patentlyo.com/patent/2005/10/uspto_releases_.html [<https://perma.cc/D8BH-HFE7>], in which the Board of Patent Appeals and Interferences rejected the “technological arts” test for business-method patents, Dennis Crouch, *Patent Board Eliminates “Technological Arts” Requirement for Business Method Patents*, PATENTLY-O (Oct. 17, 2005), https://patentlyo.com/patent/2005/10/patent_board_cl.html [<https://perma.cc/KJ4T-HSRZ>], the document does not reference the case and was likely actually written far before that case came down.

148. 2005 Guidance, *supra* note 145, at 142; Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. 7,478 (Feb. 28, 1996).

149. 2005 Guidance, *supra* note 140, at 142; *State St. Bank & Tr. Co. v. Signature Fin. Grp.*, 149 F.3d 1368 (Fed. Cir. 1998).

150. 2005 Guidance, *supra* note 145, at 142.

151. *Id.* at 144-45 (capitalization altered).

category of patentable subject matter it belongs in”¹⁵² and that examiners need not worry too much about picking out one of the four categories. Instead, “[t]he burden is on the USPTO to set forth a *prima facie* case of unpatentability,”¹⁵³ so the examiner must provide an explanation only if “it is more likely than not that the claimed subject matter falls outside all of the statutory categories.”¹⁵⁴

Next, the guidance directs examiners to determine whether the claimed invention falls within judicial exceptions to § 101: “abstract ideas, natural phenomena, and laws of nature.”¹⁵⁵ Much of the text is devoted to practical applications, claiming that “methods and products employing [subject matter covered by the judicial exceptions] to provide a real-world function may well be [eligible].”¹⁵⁶ To surmount a judicial exception by virtue of a practical application, an invention must either (i) “transform[]’ an article or physical object to a different state or thing” or (ii) “otherwise produce[] a useful, concrete and tangible result.”¹⁵⁷ In a later annex, the Office explicitly rejects as improper various eligibility tests—including the test earlier endorsed in the 1996 guidance.¹⁵⁸

While the “interim guidelines” were accompanied by a call for comments in the *Federal Register*, this initiative differs markedly from 1996 in its subsequent steps. As best I can find, the USPTO never released a “final” version of the guidance that responded to any comments raised¹⁵⁹ or clarified whether the guidance would be changed in any way before eventual incorporation into the MPEP. Perhaps signifying an increased confidence by the Patent Office that their guidelines were not legislative rules, the initiative no longer as closely followed the full notice-and-comment process.

152. *Id.* at 145.

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.* In support of this proposition, the guidance cites *Diehr*, which held that an “application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection,” *Diamond v. Diehr*, 450 U.S. 175, 187 (1981), and *Gottschalk v. Benson*, which rejected a formula claim because it “has no substantial practical application,” 2005 Guidance, *supra* note 145, at 146, (citing *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972)).

157. 2005 Guidance, *supra* note 145, at 146.

158. *Id.* at 150.

159. At least one comment was submitted. See Letter from the American Bar Association to Linda Therkorn (July 27, 2006), https://www.americanbar.org/content/dam/aba/migrated/intelprop/executive_m/Letter_to_Linda_Therkorn_letterhead.PDF [https://perma.cc/5898-UF96].

3. 2009/2010 Interim Guidance in Light of *Bilski*

The next moment occurred four years later, with the issuance of “Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility” and an associated request for comments in 2009.¹⁶⁰ Once again, the timing of this guidance moment bears note. The Patent Office—mindful of the fact that the Supreme Court had granted cert—nonetheless responded quickly to the Federal Circuit’s decision in *Bilski*, providing “instructions to examiners pending a final decision from the Supreme Court in *Bilski*.”¹⁶¹ A revised version of the guidance document incorporating the Supreme Court’s decision was then posted ten months later—within one month of the Court’s decision. This timeline shows that the USPTO is nimble in its ability to react to changes in the law to provide guidance.

After summarizing the holding in *Bilski*, the guidance focuses on providing a series of examples and factors that speak in favor or against patentability including “inquiries from the machine-or-transformation test, which remains a useful investigative tool, and inquiries gleaned from Supreme Court precedent.”¹⁶²

This guidance does not alter the procedure for evaluating claims under § 101, nor does it mandate any particular test or analysis. Instead, it provides a cheat sheet of many factors that examiners might want to consider—emphasizing that the list is not exhaustive and nothing on it is dispositive—in making a finding on whether a claim is directed to an abstract idea.

The 2010 guidance notes that the Office “received and considered the comments” from the earlier 2009 notice without engaging with any specifically.¹⁶³ Despite an articulated “inten[t] to issue final guidance after evaluating the public comments,”¹⁶⁴ I can find no such final guidance that was

160. Request for Comments on Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility, 74 Fed. Reg. 47,780 (Sept. 17, 2009).

161. *Id.*

162. Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43,924 (July 27, 2010).

163. *Id.* at 43,923.

164. Press Release, U.S. Patent & Trademark Office, USPTO Issues Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos* (July 27, 2010), <https://www.uspto.gov/about-us/news-updates/uspto-issues-interim-guidance-determining-subject-matter-eligibility-process> [<https://perma.cc/66BK-QXD6>]. *But see* Request for Comments on Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility, 74 Fed. Reg. 47,780, 47,781 (Sept. 17, 2009) (“Persons submitting written comments should note that the USPTO may not provide a ‘comment and response’ analysis

issued. The Office thus continued the 2006 trend of requesting comments but not subsequently engaging them.

4. 2014 Interim Guidance and 2015/2016 Updates

Another four years passed before the next moment.¹⁶⁵ While the guidance no longer requested comments in its title, it did so in its text. This guidance, issued in December, supplemented and synthesized two other documents released earlier in the year: a March response to *Myriad* and *Mayo*, and a June response to *Alice*.¹⁶⁶

The guidance puts forth a two-part analysis for judicial exceptions, evidenced by a flowchart. The flowchart splits the subject-matter-eligibility analysis into two major steps. In the first step, an examiner determines whether the claim is to one of the four categories explicitly set out in § 101. The next step is split into two substeps. Step 2A asks whether the claim is “directed to a law of nature, a natural phenomenon or an abstract idea (judicially recognized exceptions).” Step 2B then asks whether “the claim recite[s] additional elements that amount to significantly more than the judicial exception.”¹⁶⁷

Effectively, therefore, the Patent Office’s framework first asks whether a claim fits in the statutory categories of 35 U.S.C. § 101. Then, steps 2A and 2B implement the two-step test set out in *Mayo* and *Alice*. In these broad strokes, the Patent Office’s guidance neatly maps onto the relevant statute and case law. To describe step 2A, the guidance lists several examples of laws of nature, natural phenomena, and abstract ideas. Each item in the list is accompanied by a judicial citation, and the list is stressed to be nonlimiting.¹⁶⁸ Additional analysis is provided for natural products that might now require a “markedly different characteristics analysis,” after *Myriad*.¹⁶⁹ Step 2B deals with the “inventive concept” put forth by *Alice* and stresses that “[i]t is important to consider the claim as whole,” and “[e]very claim must be examined individually.”¹⁷⁰ The guidance then provides examples of language that has been held sufficient or

of such comments as notice and an opportunity for public comment are not required under 5 U.S.C. 553(b) or any other law.”).

165. See 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1).

166. *Id.*

167. *Id.* at 74,621.

168. *Id.* at 74,622.

169. *Id.* at 74,622-23.

170. *Id.* at 74,624.

insufficient to satisfy the inventive step, each with a specific judicial citation. Despite careful explication of this process, the guidance also notes that examiners may bypass it entirely in their discretion.¹⁷¹

The guidance concludes by applying the analysis to the fact patterns in several Supreme Court cases and then summarizing recent Supreme Court and Federal Circuit cases.¹⁷² As with previous guidance, it requested comments and noted that “[i]mplementation of examination guidance on eligibility will be an iterative process continuing with periodic supplements based on developments in patent subject matter eligibility jurisprudence and public feedback.”¹⁷³

In July 2015, the USPTO made good on its promise to consider public comments with an update posted to its website. It stated that over sixty comments had been received and “carefully reviewed.”¹⁷⁴ From these comments, the Office synthesized and responded to six main themes.¹⁷⁵

In rejecting the call in some comments to move the markedly different characteristics (MDC) analysis from step 2A to 2B, the guidance makes a surprising admission: that its ordering of doctrine into steps can have real-world impacts on claim eligibility, noting that “[i]f the MDC analysis was moved to Step 2B as suggested, however, then the conclusion for claim 5 [of provided example 17] might change because the Step 2B additional pathway to eligibility would no longer exist for claims directed to ‘product of nature’ exceptions.”¹⁷⁶

In response to comments complaining of lack of clarity on abstract ideas, the update sought to “ensure that a claimed concept is not identified as an abstract idea unless it is similar to at least one concept that the courts have identified as an abstract idea.”¹⁷⁷ The update then listed four such abstract ideas: fundamental economic practices, certain methods of organizing human activity, an idea of itself, and mathematical relationships/formulas.¹⁷⁸

171. *Id.* at 74,625 (“For purposes of efficiency in examination, a streamlined eligibility analysis can be used for a claim that may or may not recite a judicial exception but, when viewed as a whole, clearly does not seek to tie up any judicial exception such that others cannot practice it. Such claims do not need to proceed through the full analysis herein as their eligibility will be self-evident.”).

172. *Id.* at 74,629-32.

173. *Id.* at 74,619 (citation omitted).

174. *July 2015 Update: Subject Matter Eligibility*, U.S. PAT. & TRADEMARK OFF. 1, <https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf> [<https://perma.cc/MH8V-JXXE>].

175. *Id.*

176. *Id.* at 2-3.

177. *Id.* at 3.

178. *Id.* at 4-5.

The update noted that the eligibility inquiry has been held by courts to be a matter of law and thus instructed examiners that evidence was not needed to support findings of “well-understood, routine or conventional” elements—judicial notice based on the knowledge of those in the art or prior court cases is adequate.¹⁷⁹

Less than one year later, the guidance was updated again in May 2016.¹⁸⁰ This time styled as a “memorandum to the Patent Examining Corps,” it focused on the *process* of rejecting a claim as ineligible under the recent guidance.

5. 2018 Berkheimer Memorandum

The next moment, and the one that motivated this Note, came in direct response to the Federal Circuit’s February 2018 decision in *Berkheimer*.¹⁸¹ In that case, the court held that the determination whether a claim element is well understood, routine, or conventional—relevant to Step 2 of the *Mayo/Alice* test—is a question of fact, which could preclude summary judgment.¹⁸²

Within two months, the USPTO issued a memorandum to the examining corps¹⁸³ and solicited public comment.¹⁸⁴ While recognizing that “standards in civil litigation are generally inapplicable during the patent examination process,” the USPTO nevertheless concluded that the holding in *Berkheimer* is informative.¹⁸⁵ The memorandum instructed examiners that they could no longer reject a claim under step 2 of the *Mayo/Alice* test—step 2B of the guidance framework—without making a clear factual finding supported by evidence. In doing so, the Office went beyond *Berkheimer* to specify four categories of evidence, at least one of which would be required to support any rejection. Doing so, obviously, makes it more difficult for an examiner to support a conclusion of a well-understood or routine element and therefore more difficult to reject claims as ineligible.

179. *Id.* at 7.

180. Again, the update was announced but not reproduced in the *Federal Register*. May 2016 Subject Matter Eligibility Update, 81 Fed. Reg. 27,381 (May 6, 2016) (to be codified at 37 C.F.R. pt. 1).

181. *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018).

182. *Id.* at 1368, 1370.

183. *Berkheimer* Memo, *supra* note 1.

184. Request for Comments on Determining Whether a Claim Element Is Well-Understood, Routine, Conventional for Purposes of Subject Matter Eligibility, 83 Fed. Reg. 17,536 (Apr. 20, 2018).

185. *Berkheimer* Memo, *supra* note 1, at 2.

6. 2019 Revised Patent Subject-Matter-Eligibility Guidance

Finally, the sixth moment occurred in January 2019. On January 7th, 2019, the USPTO put a notice in the *Federal Register* entitled “2019 Revised Patent Subject Matter Eligibility Guidance.”¹⁸⁶ The notice was classified as “[e]xamination [g]uidance; [r]equest for comments,” and set a deadline for written comments of March 8, 2019.¹⁸⁷ Unlike some previous notices in the *Federal Register*, the notice did not simply footnote the existence of a new guidance document or link to the USPTO website. Instead, the entire text of the guidance was contained in the *Federal Register*.

The breadth of the 2019 guidance document appears expansive, speaking to both steps 2A and 2B of the Patent Office’s § 101 examination framework.¹⁸⁸ The major substantive changes to prior guidance come in step 2A, with step 2B referenced in its residual capacity for claims that do not satisfy the revised step 2A. As described in the summary to the notice, the guidance “revises . . . [s]tep 2A of the USPTO’s Subject Matter Eligibility Guidance in two ways.”¹⁸⁹ I discuss each of these in turn.

First, the guidance “explains that abstract ideas can be grouped.”¹⁹⁰ As a justification for this grouping, the notice stated that the Office’s previous practice of summarizing court opinions as they come in had “become impractical [as] [t]he Federal Circuit has now issued numerous decisions identifying subject matter as abstract or non-abstract in the context of specific cases, and that number is continuously growing.”¹⁹¹ In addition, the notice observed that “similar subject matter has been described both as abstract and not abstract in different cases . . . [making precedent] increasingly more difficult for examiners to apply.”¹⁹² These two statements are staggering in their implications. Effectively, the Patent Office is stating that the cases being decided in the courts are too numerous and too contradictory for its examiners to apply consistently. In their place, the Patent Office has decided to step in and provide clear, bright-line groupings of abstract ideas. The guidance presents three such groupings:

186. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019).

187. *Id.* at 50.

188. USPTO, *Manual of Patent Examining Procedure*, U.S. DEP’T COM. § 2106 (9th ed., rev. Jan. 2018), <https://www.uspto.gov/web/offices/pac/mpep/index.html> [<https://perma.cc/T5Z8-UEFK>].

189. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. at 50.

190. *Id.*

191. *Id.* at 52.

192. *Id.* (footnote omitted).

“[m]athematical concepts,” “[c]ertain methods for organization human activity,” and “[m]ental processes.”¹⁹³

Importantly, the guidance does not cite any statute or judicial opinion as the source of this grouping. Instead, it states that the guidance “extracts and synthesizes key concepts identified by the courts as abstract ideas.”¹⁹⁴ To be clear, each of the groups is *individually* well supported by string cites to cases where claims were held to be patent eligible. But the groupings themselves—the contention that there are three types of abstract ideas, that they can be described by these three titles, and that anything in one of those three buckets as described by the USPTO qualifies as an abstract idea—are purely a creation of the Patent Office.

Second, the guidance “explains that a patent claim . . . is not ‘directed to’ the judicial exception if the judicial exception is integrated into a practical application of the judicial exception.”¹⁹⁵ Effectively, this revises step 2A into “a two-prong inquiry.”¹⁹⁶ The first prong is the typical inquiry into whether or not a claim’s matter recites a judicial exception (with the abstract-ideas determination now using the new groupings). The second prong asks whether the claim is directed to such a judicial exception. That is, the guidance creates a carve-out where a claim might *recite* a judicial exception but is not *directed to* that exception, in particular if it integrates it into a practical application.

This two-pronged approach appears novel. Under the previous guidance incorporated in the MPEP, determinations of “practical applications” occurred interchangeably with determinations of an inventive concept in step 2B. In fact, the summary of the analysis in the MPEP instructs examiners to “evaluate what more such claims recite to provide an inventive concept (Step 2B) (also called a practical application) to the judicial exception.”¹⁹⁷

D. The USPTO’s Guidance Practices

Reduced to only the most substantive examples, two conclusions can be drawn from my grouping into six guidance moments. First, any perception of the USPTO’s recent guidance as completely unprecedented or revolutionary would be mistaken. The USPTO has been publishing guidance documents engaging with the substance of subject-matter eligibility for decades, well before the recent revival of the Supreme Court’s doctrine on the subject. Second, the

193. *Id.* (footnotes omitted).

194. *Id.*

195. *Id.* at 50.

196. *Id.* at 54.

197. USPTO, *supra* note 188, § 2106.

frequency of such guidance has increased substantially in the recent era of judicial activity and confusion. Of these six major guidance moments, four have occurred within the last decade and three have occurred within the last five years. Despite documents discussing subject-matter eligibility appearing in the *Federal Register* for several decades, the era of substantive changes in subject-matter eligibility appears to have just begun in earnest.

Further, much attention has been given in recent years to best practices for agency-guidance action.¹⁹⁸ Compliance or noncompliance with these goalposts can evaluate the USPTO's demonstrated competence in rulemaking¹⁹⁹ and inform judgments of whether to expand the Office's rulemaking power. Here, the Office has demonstrated a practice of posting its most notable guidance documents in the *Federal Register* and seeking comment. Its responsiveness to these comments, however, has varied greatly.²⁰⁰ While some documents were put forth in draft form and then re-released in updated form with detailed and meaningful responses to issues raised in comments, others were simply left in their "interim" form and comments were never addressed at all. Further, the Office's practices could be improved with respect to consistency. Although the substance of guidance was often contained within the *Federal Register*, some documents were posted only in the *Official Gazette* or on the USPTO website. Nonetheless, on balance, the agency has shown itself to be a competent and nimble rulemaker, responding quickly to changes in technology and altering its approach when presented with compelling comments from regulated parties.

III. COURTS' USE OF GUIDANCE

In this Part, I consider how reviewing courts have used the subject-matter-eligibility guidance. The use of guidance by administrative and judicial decision-makers informs legal analysis of whether the rule is improperly substantive by determining its ability to "bind" the agency and regulated parties.²⁰¹ As a corollary, strong deference to the guidance by reviewing courts or patent applicants could suggest that the USPTO is having its cake and eating it too:

198. See, e.g., Parrillo, *supra* note 40.

199. Cf. Boundy, *supra* note 13, at 33-43 (performing a similar analysis on USPTO's guidance actions); Wasserman, *supra* note 11, at 400 (arguing that "because the PTO's views on substantive law have a significant effect on patent policy, the process by which the PTO crafts these rules should come under more scrutiny").

200. See Wasserman, *supra* note 11, at 395 (finding that while the USPTO sometimes publishes guidance for notice and comment, it is more often the case that the guidance is the result of a "black box" with only limited public participation).

201. See *infra* Part IV.

receiving the core benefits of substantive rulemaking without any of the procedural costs. This same dynamic, of course, could also be framed in a positive light, showing that the USPTO is able to assist the patent system with its technical expertise without requiring substantive rulemaking authority or formal *Chevron* deference.²⁰²

A. *The Federal Circuit*

The distinction between rules and guidance is significant, in part, because only rules receive *Chevron* deference.²⁰³ When the Patent Office speaks under a rule, its decisions and interpretations are accorded substantial weight by reviewing courts. By contrast, courts consider guidance only to the extent that it is persuasive.²⁰⁴ This dynamic creates a trade-off for regulators across the administrative state. In exchange for clearing the procedural requirements that accompany notice-and-comment rulemaking, these regulators can benefit from a greater degree of deference. But this system can also break down. If the Patent Office were able to issue rules without notice-and-comment rulemaking but still receive substantial deference in its interpretation of those rules, it would cut corners under the conventional account of administrative law. It is therefore of great interest with what degree of deference reviewing courts treat the Patent Office's guidance documents on subject-matter eligibility.

The Federal Circuit has specifically held that because the USPTO lacked substantive rulemaking power, “the rule of controlling deference set forth in *Chevron* does not apply.”²⁰⁵ The Federal Circuit, when it most recently spoke on the issue, appeared unwilling to give deference to the USPTO's subject-matter-eligibility guidance, which would in fact be consistent with its classification as a nonsubstantive rule. In a hot-off-the-presses case from April 2019, the Cleveland Clinic appealed the district court's cancellation of its patent claims under § 101, and argued that the district court erred by not giving “appropriate deference to subject matter eligibility guidance published by the PTO.”²⁰⁶ The guidance at issue here appears to be related to the “May 2016 Subject Matter Eligibility Update,”²⁰⁷ which is one of the major guidance “moments” cataloged in Part II.

202. See generally Golden, *supra* note 9.

203. *Id.*

204. Cf. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

205. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

206. *Cleveland Clinic Found. v. True Health Diagnostics LLC*, No. 2018-1218, slip op. at 12 (Fed. Cir. Apr. 1, 2019).

207. May 2016 Subject Matter Eligibility Update, 81 Fed. Reg. 27,381 (May 6, 2016).

More specifically, the appellants appear to be referring to Example 29 in the “Subject Matter Eligibility Examples: Life Sciences” document published on the USPTO website to accompany the May 2016 guidance update (and also indexed in the Appendix to this Note).²⁰⁸ In response, the Federal Circuit panel stated:

While we greatly respect the PTO’s expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.²⁰⁹

This rejection of deference is particularly biting, as the appellants were not requesting *Chevron* deference, but rather a weaker *Skidmore*²¹⁰ deference – and the Federal Circuit was unwilling to even grant that. This signal does, however, come with a host of caveats.²¹¹ This particular opinion was nonprecedential.²¹² To the extent that other Federal Circuit precedent does not explicitly command district courts not to accord *Skidmore* deference to USPTO subject-matter guidance, various district courts could still choose to do so. Further, the deference rejected here was to a very narrow USPTO statement: a hypothetical example in a list of life-sciences examples accompanying the May 2016 update. This leaves open the door, at least in theory, that the Federal Circuit could prove

208. *Cleveland Clinic*, slip op. at 13. The Appendix accompanying this Note is available on the *Yale Law Journal* website at <https://www.yalelawjournal.org/note/rulemaking-101>.

209. *Id.*

210. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

211. First, the rejection of deference does not necessarily mean that the Federal Circuit is opposed to the USPTO putting out guidance. To the contrary, the Federal Circuit has seemed to nod approvingly at the issuance of subject-matter-eligibility guidance. See *Myspace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1262 n.20 (Fed. Cir. 2012) (“Ultimately, the solution to solving the puzzle of § 101 will require close collaboration between the courts and the Patent and Trademark Office (PTO), the latter providing an initial forum for understanding what can and cannot be patented. How best to structure that collaboration so as to maximize efficiency and fairness for both inventors and competitors remains to be seen. The PTO has begun the process – see ‘Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*.’ 75 Fed. Reg. 43,922 (July 27, 2010).”).

212. *But cf. In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (establishing a precedential holding, discussing the PTO’s 2001 § 101 Utility Guidelines (not subject-matter guidelines) and noting that they are “not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute” (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002))).

more deferential to the USPTO's main guidance documents, or the broader statements contained therein. Clearly, though, this is a strong signal that the Federal Circuit does not intend to accord the USPTO's subject-matter-eligibility guidance general deference.

Curiously, this signal is in tension with another signal given by the Federal Circuit—in a precedential opinion—just one month earlier.²¹³ In a March opinion, the Federal Circuit wrote:

Under [USPTO eligibility guidance], a claim to a practical application of a natural product to treat a particular disease is patent eligible. The parties dispute the persuasiveness of this document and the weight we should afford it under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). The issue before us is a matter of law and the result is clear, thus this is not a case in which *Skidmore* deference would affect the outcome.²¹⁴

While not actually according deference and not deciding the level of weight that might be appropriate (not to mention having been buried in a footnote), this statement appears to suggest that *Skidmore* deference for subject-matter-eligibility guidance might be appropriate. At the moment, the Federal Circuit's position on deference to the USPTO's guidance on § 101 seems uncertain. Still, the nascent signals suggest that the guidance would receive, at best, *Skidmore* deference—suggesting that in any case the Patent Office's statements on subject-matter eligibility will fall short of the weight traditionally given to true notice-and-comment promulgated rules.

B. District Courts

Many federal district courts deal with issues of § 101 eligibility, and although the Federal Circuit has seemed to foreclose formal *Chevron*-level deference, they may still rely on the Patent Office's guidance as a resource. Indeed, one can find examples of several district courts doing just that in recent years. For example, the Northern District of California wrote in one case that the Patent Office's guidance was “not binding” but nonetheless “persuasive.”²¹⁵

213. See Dennis Crouch, *Eligibility Train Wreck Continues Its Skid: Skidmore Deference for the PTO on Eligibility*, PATENTLYO (Apr. 3, 2019), <https://patentlyo.com/patent/2019/04/eligibility-continues-deference.html> [https://perma.cc/7Z9S-XQM9].

214. Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC, 918 F.3d 1338, 1346 n.2 (Fed. Cir. 2019).

215. Finjan, Inc. v. Blue Coat Sys., Inc., No. 13-cv-03999, 2015 WL 7351450, at *9 (N.D. Cal. Nov. 20, 2015), *rev'd on other grounds*, 879 F.3d 1299 (Fed. Cir. 2018).

Another judge, while seemingly pushing back on the assertion that the court treated guidance as binding, affirmed the guidance's role in the ultimate analysis. On this point, the judge wrote that, although the agency's guidelines were "not necessarily controlling," he used them "as a resource to help support [his] legal research and to validate [his] analysis."²¹⁶ Similar examples abound in district courts across the country.²¹⁷ Patent law is notoriously technical, and the judicial precedent on subject-matter eligibility has made things more difficult. To the extent the Patent Office can provide even an iota of clarity, it is no wonder that its guidance will permeate judicial decision-making— even if ostensibly viewed as nonbinding.

C. *The PTAB*

The federal courts are not the only courts that matter in the modern era of patent law. The Patent Trial and Appeal Board (PTAB), an administrative court staffed with administrative patent judges, has been growing in importance since its creation in 2011.²¹⁸ Searches of published PTAB documents for terms indicating reference to one of the USPTO's subject-matter-eligibility guidance initiatives returns over one thousand documents.²¹⁹ While many of these documents are initiating a post-grant review of the patent such as a Covered

216. *Magna Elecs., Inc. v. Valeo, Inc.*, No. 13-11376, 2017 WL 9471686, at *10 n.12 (E.D. Mich. Apr. 10, 2017).

217. See, e.g., *Aatrix Software, Inc. v. Green Shades Software, Inc.*, No. 3:15-cv-164-HES-MCR, 2016 WL 1375141, at *5 (M.D. Fla. Mar. 30, 2016) (citing the 2014 guidance), *rev'd on other grounds*, 882 F.3d 1121 (Fed. Cir. 2018); *HealthTrio, LLC v. Aetna, Inc.*, No. 12-cv-03229-REB-MJW, 2015 WL 4005985, at *6 (D. Colo. June 17, 2015) ("These two cases, and the PTO's guidance relying on them, suggest . . ."); *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 83 F. Supp. 3d 774, 783 (N.D. Ill. 2015) ("Though the parties cite limited caselaw detailing the meaning of 'directed to' patent-ineligible subject matter, the PTO recently issued its 2014 Interim Guidance . . . that defines *Alice* step 1 as requiring that a law of nature, natural phenomenon or abstract idea be 'recited (*i.e.*, set forth or described) in the claim.'"), *rev'd on other grounds*, *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016); *Graff/Ross Holdings LLP v. Fed. Home Loan Mortg. Corp.*, No. 07-796 (RJL)(AK), 2010 WL 6274263, at *5 (D.D.C. Aug. 27, 2010) ("The USPTO, however, has issued 'Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*.' Although this guidance is not binding on the courts, it can be viewed for persuasive authority." (citation omitted)).

218. See generally Walker & Wasserman, *supra* note 13 (situating PTAB adjudication in the larger realm of agency adjudication within administrative law).

219. I performed a Westlaw search within PTAB opinions for the following: advanced: "subject matter" AND ("interim guidance" OR "interim guidelines" OR "july 2015 update" OR "subject matter eligibility update" OR "eligibility guidance" OR "interim examination instructions").

Business Method Review, some are also decisions on appeal from examiner actions.

In fact, the PTAB has already published *dozens* of such decisions that cite to the 2019 guidance. In one such decision, the PTAB panel noted that it was “sustain[ing] the Examiner’s rejection of this claim under 35 U.S.C. § 101 as being directed to non-statutory subject matter in light of *Alice*, its progeny, and the Revised 101 Guidance (Memorandum).”²²⁰ In another decision, the PTAB appeared to not just pay lip service to the existence of the 2019 guidance but to treat its key changes as authoritative and binding.²²¹

The fact that the PTAB appears bound by the USPTO’s guidance is notable, as it could potentially be used to gain backdoor deference for the agency’s interpretive rules.²²² For example, the PTAB could embrace the guidance’s interpretation in a precedential opinion, which might then receive deference by future reviewing courts. Indeed, in *Facebook v. Windy City Innovations*,²²³ the government has recently requested that the Federal Circuit accord *Chevron* deference to a precedential PTAB opinion, though its reasoning in that case is grounded in the text of the America Invents Act and not directly applicable to the statutory provisions governing subject-matter eligibility.²²⁴

IV. THE SUBSTANCE OF THE USPTO’S “NON-SUBSTANTIVE” GUIDANCE

Congress has not vested the Commissioner of the USPTO with the general power to promulgate substantive rules.²²⁵ As such, absent a specific grant of

220. *Ex parte* Das, No. 2018-002948, 2019 WL 1874307, at *6 (P.T.A.B. Mar. 28, 2019).

221. *Ex parte* Root, No. 2018-002631, 2019 WL 1874306, at *2 (P.T.A.B. Mar. 28, 2019) (“Per Office Guidance, this first inquiry has two prongs of analysis: (i) does the claim recite a judicial exception (e.g., an abstract idea), and (ii) if so, is the judicial exception integrated into a practical application. 84 Fed. Reg. at 54. Under the Office Guidance, if the judicial exception is integrated into a practical application, see *infra*, the claim passes muster under § 101. 84 Fed. Reg. at 54-55.”).

222. Thanks are due to Chris Walker for bringing this point to my attention.

223. *Facebook, Inc. v. Windy City Innovations, LLC.*, 953 F.3d 1313 (Fed. Cir. 2020) (Nos. 18-400, 18-1401, 18-1402, 18-1403, 18-1537, 18-1540, 18-1541).

224. Brief for the United States as Amicus Curiae, *Facebook*, 953 F.3d 1313 (Nos. 18-400, 18-1401, 18-1402, 18-1403, 18-1537, 18-1540, 18-1541); see also Dennis Crouch, *Does the PTAB Precedential Opinion Panel (POP) get Chevron Deference?*, PATENTLYO (Sept. 18, 2019), <https://patentlyo.com/patent/2019/09/precedential-opinion-deference.html> [https://perma.cc/K73X-D2E9].

225. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996).

rulemaking authority in a particular context,²²⁶ the Patent Office may promulgate only those rules governing the office's own internal procedures,²²⁷ and nonbinding interpretive or guidance documents.²²⁸ Given this backdrop, if any of the guidance documents discussed above met the criteria for substantive rulemaking, they would run afoul of the USPTO's delegated authority and—to the extent the rule was promulgated without proper notice-and-comment procedures—the APA.²²⁹ The Patent Office would thus be exerting power greater than intended by Congress, and, more broadly, eschewing the APA's carefully designed rules and processes for holding agencies accountable to the public.

In this Part, I critically analyze the substance of the subject-matter-eligibility guidance documents put out by the USPTO. In Section IV.A, I provide a brief primer on substantive rulemaking and highlight areas in which the state of patent law complicates the traditional substantive-versus-interpretive-rule paradigm. In Section IV.B, I examine *Animal Legal Defense Fund*,²³⁰ the foundational case that attempted to mete out the boundaries between substantive rulemaking and nonsubstantive guidance in the area of subject-matter eligibility. In Section IV.C, I move forward in time to *Mikkilineni*,²³¹ which examines a 2009 guidance document and appears to be the most recent time the Federal Circuit has squarely addressed this issue. Finally, having distilled the rules from these two cases, I apply them to the most recent iteration of the Patent Office's subject-matter-eligibility guidance in Section IV.D to argue that although the 2019 guidance would most likely survive as an interpretive rule under the Federal Circuit's permissive doctrine, it appears to be quite substantive.

226. One recent example is the narrow grant of substantive rulemaking authority in the inter partes review context under the America Invents Act. See *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (rejecting the contention that the inter partes review rulemaking authority conferred by the America Invents Act is limited to procedural rules).

227. For example, the Federal Circuit in *Tafas* held that USPTO rules limiting an applicant's ability to file continuation applications (and requests for continuing examination) were procedural rules and thus fell within the USPTO's authority. *Tafas v. Doll*, 559 F.3d 1345, 1364 (Fed. Cir. 2009).

228. See generally KEITH WERHAN, *PRINCIPLES OF ADMINISTRATIVE LAW* 274 (2d ed. 2014) ("Because legislative rules are legally binding, agencies may issue such rules only if Congress has authorized them to do so.").

229. 5 U.S.C. § 553 (2018).

230. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991).

231. *Mikkilineni v. Stoll*, 410 F. App'x 311 (Fed. Cir. 2010).

A. Substantive Rulemaking and the Traditional Paradigm

On paper, the rules for rulemaking are straightforward. The APA sets forth the procedures that an agency must follow when engaging in rulemaking in § 553.²³² This Section covers all rulemaking, except for rulemaking falling within narrow subject-matter categories,²³³ those classified as “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice”;²³⁴ or when an agency explicitly reports a finding of “good cause” to abstain from procedures that are “impracticable, unnecessary, or contrary to the public interest.”²³⁵ The APA thus draws a line in the sand between rules that require conformity to rulemaking procedures because they are substantive²³⁶ and those escaping procedural requirements because they are merely procedural or, alternatively, interpretive rules or statements of policy (often jointly referred to simply as “guidance”).²³⁷

In practice, however, the line between guidance and substantive rulemaking is anything but clear. Pronouncements by the Supreme Court have been too general to be of much use, such as the Supreme Court’s statement, made in 1995 and reiterated as recently as 2015, that “the critical feature of interpretive rules is that they are ‘issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers.’”²³⁸ In that case, the Supreme Court noted that “[t]he term . . . interpretive rule is not further defined by the APA, and its precise meaning is the source of much scholarly and judicial debate,” and promptly declined to “wade into that debate.”²³⁹ Other courts and commentators have been blunter. The D.C. Circuit has famously referred to the distinction between legislative and interpretive rules as “enshrouded in

²³². 5 U.S.C. § 553 (2018).

²³³. *Id.* § 553(a).

²³⁴. *Id.* § 553(b)(A).

²³⁵. *Id.* § 553(b)(B).

²³⁶. Rules subject to the APA’s procedures are referred to alternatively as “legislative” or “substantive.” When referring to cases or materials, I typically adopt the terminology of the source; otherwise I tend to use the term “substantive” to comport with the Federal Circuit’s terminology in the on-point cases. *See infra* Sections IV.B-C.

²³⁷. MASHAW ET AL., *supra* note 112, at 651 (“Interpretive rules and general statements of policy (a.k.a. policy statements) are known collectively as *guidance*.” (footnote omitted)).

²³⁸. *Perez v. Mortgage Bankers Ass’n*, 135 S. Ct. 1199, 1204 (2015).

²³⁹. *Id.* (internal quotation marks and footnote omitted).

considerable smog,”²⁴⁰ and commentators have similarly concluded that the line between legislative rules and policy statements is blurry.²⁴¹

As one leading article on the subject declared, “There is perhaps no more vexing conundrum in the field of administrative law than the problem of defining a workable distinction between legislative and nonlegislative rules.”²⁴² Nonetheless, courts and the academy have labored to provide a collection of clues to assist in distinguishing between guidance and substantive rulemaking.²⁴³

Notably, certain characteristics of the patent system and doctrine today complicate the application of the traditional paradigm to the case of subject-matter eligibility. First, the stakes are much higher. Empirical literature on agency guidance often focuses on agencies’ choice to use guidance instead of traditional rulemaking.²⁴⁴ The USPTO, however, has no such choice. Congress, for its part, has made the decision not to vest the agency with power over the substantive rules of patentability. Therefore, a loose finding that a substantive rule is interpretive will not merely save the agency some procedural homework—it will allow it to operate in an area where it has no authority to legislate.

Second, the source of the subject-matter-eligibility doctrine renders the “interpretive” portion of interpretive rulemaking at best a legal fiction. While agencies issuing interpretive rules are traditionally assumed to interpret an enabling statute or their own regulations, the Patent Office ostensibly has no substantive regulations to interpret. And the statute—simply listing four categories of subject matter—bears little resemblance to the doctrine that has evolved today. All of the guidance described in the previous Parts attempts to

240. *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1108 (D.C. Cir. 1993) (quoting *Gen. Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc)).

241. See, e.g., Connor N. Raso, *Strategic or Sincere? Analyzing Agency Use of Guidance Documents*, 119 YALE L.J. 782, 791 (2010).

242. David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 278 (2010). Similar frustrations abound in the patent context. See generally Sarah Tran, *Administrative Law, Patents, and Distorted Rules*, 80 GEO. WASH. L. REV. 831 (2012) (focusing on procedural rules and arguing that the Federal Circuit’s jurisprudence on substantive USPTO rulemaking is wrongly decided, incoherent, and creates perverse incentives for the USPTO to keep the public out of its decisions).

243. See generally William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321 (2001) (attempting to define nonlegislative rules and the open questions surrounding that definition).

244. See, e.g., Raso, *supra* note 241, at 787 (noting and empirically rebutting the idea that agencies strategically choose guidance to avoid notice-and-comment rulemaking); Roberta Romano, *Does Agency Structure Affect Agency Decisionmaking? Implications of the CFPB’s Design for Administrative Governance*, 36 YALE J. ON REG. 273 (2019) (empirically examining the Consumer Financial Protection Bureau and other financial regulators’ choice to use notice-and-comment rulemaking versus guidance).

interpret things like “abstract ideas” or “laws of nature,” which do not appear on the face of § 101 and could not be divined by any process reasonably called “interpretation.” Rather, the USPTO is effectively interpreting federal common law.²⁴⁵ Further, to the extent the USPTO bases its guidance on an interpretation of a Federal Circuit panel decision that contradicts an earlier holding, the USPTO may not even be correctly interpreting the current state of the law.²⁴⁶ Allegiance to the statute is therefore a poor benchmark for the interpretive nature of a particular rule.

Third, and most importantly, the very nature of the trade-offs inherent in subject-matter eligibility belie the “rights and obligations” framework. That is, under a traditional inquiry, a court would ask whether a rule had an adverse impact on a regulated party’s rights in order to help determine whether it is a legislative or nonlegislative rule.²⁴⁷ In the patent context, this would generally require a rule that made it more difficult to obtain patent protection; rules that made it easier to obtain a patent would not be considered substantive simply because they limited examiner discretion.²⁴⁸ But the very nature of subject-matter eligibility is that it involves a trade-off between short-term incentives and follow-on innovation. Granting a patent on a fundamental law of nature both enhances the rights of the patent recipient and allows her to enforce that patent broadly against others.

To return to an earlier example, a rule expanding eligibility to include the law of gravity would have no adverse effect on Newton’s rights, but it would seriously curtail the rights of those wishing to drop apples on the ground. Even contained within the patent system, enhancing eligibility presents a first-bite problem: the rights of the first inventor are enhanced, but the ability of countless other inventors to patent their inventions are adversely affected.

245. Cf. Duffy, *supra* note 21, at 621 (noting that “an entirely different methodology for deciding patentable subject matter questions has treated the area as one of federal common law”).

246. I am grateful to Josh Sarnoff for bringing this point to my attention. The theory is that because Federal Circuit holdings may only be overruled by the Federal Circuit sitting en banc, the earliest panel decision controls in the event of a conflict. See *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 719 F.3d 1305, 1316 (Fed. Cir. 2013) (en banc) (“Panel opinions are, of course, opinions of the court and may only be changed by the court sitting en banc.”). Any USPTO guidance that purports to adopt a conflicting later-in-time panel holding, therefore, may not in fact be faithfully interpreting the law of the Federal Circuit.

247. See, e.g., *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 929 (Fed. Cir. 1991) (stating that a restriction of discretion only renders a rule substantive when there is “adverse effect of that limitation on an individual’s rights and obligations”).

248. See *id.* at 929–30. Notably, the court in *Animal Legal Defense Fund* considers and rejects theories of adverse impact to third parties that are similar to some of the rationales advanced in this Section. See *id.*

In this way, the area of subject-matter eligibility implicates one of the primary downsides of allowing agencies the “short cut” of interpretive rules. As David Franklin notes, when an agency sets a minimum criterion for enforcement or announces a deregulatory policy or interpretation, there is unlikely to be a “later enforcement action in which the agency’s views can be tested.”²⁴⁹ In the patent context, the raised bar for enforcement actions is analogous to the reduced claim rejections that come with expanding patentable subject matter. Further, expanded patentability can also be categorized as deregulatory; in no small sense, it relaxes constraints on government-sponsored monopolies. And similar to the absence of an enforcement action, the lack of a rejection means that there will be no case appealing a rejection to test the office’s views on patentability.²⁵⁰

In addition, expanded patent eligibility “can have substantial practical effects on regulated entities”²⁵¹—here the regulated entities are those seeking a government-sponsored monopoly via the patent system. And at the same time, expanded patent eligibility can have substantial practical effects “on the intended beneficiaries of regulation.”²⁵² In the broadest sense, the intended beneficiaries here are members of the public, or at least consumers of the patent good, who are served by a producer with some form of monopoly power and are subject to the price effects that go along with it.²⁵³ More narrowly, the intended beneficiaries are other innovators, as discussed above, who would be crowded

249. Franklin, *supra* note 242, at 309.

250. See Wasserman, *supra* note 11, at 404. Of course, patent law is an area of strong *private* challenges to patent rights, and patents that are allowed on questionable expansions of subject-matter eligibility may be challenged by private litigants in district court. Still, in contrast to the strong incentives for a rejected applicant to appeal the challenge, the mechanisms for selecting disputes for litigation suggest that many such patents will never be challenged: litigated patents are only a fraction of the total number of issued patents, and an extremely small number of patent cases ever reach a substantive verdict. See generally Colleen V. Chien, *Predicting Patent Litigation*, 90 TEX. L. REV. 283 (2011) (finding different characteristics for litigated patents); Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won’t Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 943 (2004) (suggesting that litigation will not correct patent office errors because of “often grossly skewed incentives to challenge and defend issued patents”); Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved – An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237, 274 (2006) (providing an overview of litigation outcomes).

251. See Franklin, *supra* note 242, at 309.

252. See *id.*

253. Cf. Wasserman, *supra* note 11, at 420 (discussing how enhanced eligibility standards could increase costs to consumers but not drawing a direct link to the theory behind interpretive rulemaking).

out by a patent on a fundamental building block of their field.²⁵⁴ In either the broad or narrow conception, the cost is clear: a lack of administrative-law checks on subject-matter eligibility can expand the rights of certain innovators at the expense of others without first taking the latter's views into account.

B. *The 1987 Guidance and Animal Legal Defense Fund*

In *Animal Legal Defense Fund (ALDF)*, appellants challenged the USPTO's issuance of a 1987 notice²⁵⁵ addressing the patentability of living organisms issued in the wake of the Supreme Court's decision in *Chakrabarty*²⁵⁶ and a subsequent decision by the Board of Patent Appeals and Interferences in *Allen*.²⁵⁷ That notice read in relevant part:

[T]he Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity," such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter. . . . A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101.²⁵⁸

The Federal Circuit held that "[t]he genesis and effect of the Notice demonstrates that it represents no change in the law effected by the Commissioner and that, in reality, it is merely 'interpretative' of prior decisional

254. Cf. *id.* (discussing the "dynamic costs" of expanded eligibility to future innovators but not drawing a direct link to the theory behind interpretive rulemaking).

255. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 922 (Fed. Cir. 1991). Note that the ground for affirmance was technically standing. Because one alleged injury here was the deprivation of participation in rulemaking, the court engaged substantively with the issue of whether APA procedures for rulemaking was required. *Id.* at 926-27 ("Whether there is any viability in such allegation of injury by reason of the alleged procedural defect, namely, the Commissioner's failure to provide public notice and comment procedures in adopting the rule, depends on the resolution of an issue of law: Was the Commissioner required to comply with section 553 before issuing the Rule?" (footnote omitted)).

256. *Id.* at 927-28; see *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (holding that a patent may be granted on a "new bacterium with markedly different characteristics from any found in nature").

257. *Ex Parte Allen*, No. 86-1790, 1987 WL 123816 (B.P.A.I. Apr. 3, 1987) (holding that a patent may be granted on a genetically modified strain of oysters).

258. Donald J. Quigg, *Animals – Patentability*, 1077 Off. Gaz. Pat. & Trademark Office 24, USPTO (Apr. 7, 1987) (quoting *Diamond*, 447 U.S. at 309).

precedent.”²⁵⁹ In reaching this conclusion, the court placed particular emphasis on the fact that “[t]he language used by the Commissioner in the Notice largely tracks the above history and the language of *Allen*.”²⁶⁰

The court thus concluded that “[t]he notice clearly corresponds with the interpretations of section 101 set out by the Board in *Allen* and *Hibberd*, in reliance on *Chakrabarty*, with the only caveat being the statement that section 101 does not extend to humans.”²⁶¹ This caveat is an important one: because the appellants base their injury on injury to animals, they do not raise the issue of the additional limitation to nonhumans. The court chose to sidestep that issue entirely: “[T]he question whether section 553 requirements extend to that part of the Rule which precludes the patentability of humans is not in issue and we do not address it.”²⁶² This dictum expressly left open the possibility that language in a notice that goes beyond restating a court’s holding—in this case language that excludes humans from an otherwise patentable class—would exceed the USPTO’s authority.

The court then rejected several arguments that would classify the rule as substantive, finding that they were each inapplicable to this case. First, the argument that the notice is substantive merely because it changes course on a longstanding USPTO policy “at best merely ignores the Board’s intervening interpretation of section 101 [in interference cases].”²⁶³ The court likewise rejected the argument that the notice is substantive merely because it takes away the “‘discretion’ of PTO examiners to enter a rejection based on section 101 of claims directed to non-naturally occurring multicellular animals.”²⁶⁴ A limitation on discretion, the court held, only deems a rule substantive when there is an “adverse effect of that limitation on an individual’s rights and obligations.”²⁶⁵

In the instant case, the effect of the part of the notice in question is to expand § 101 eligibility. As the court noted, “if mandatory, [the notice] means that the examiner will refrain from issuing a section 101 rejection, but patent applicants are not ‘adversely affected’ by an examiner’s failure to enter a rejection.”²⁶⁶ This logic, however, left as an open question whether notices that tend to restrict § 101

259. *ALDF*, 932 F.2d at 927.

260. *Id.* at 928.

261. *Id.*

262. *Id.* at 928 n.9.

263. *Id.* at 928.

264. *Id.* at 929.

265. *Id.*

266. *Id.* at 930.

eligibility might lead to adversely affected applicants, and a determination that the notice is substantive.

C. *The 2009 Guidance and Mikkilineni*

The Federal Circuit recently addressed this question²⁶⁷ in the 2010 nonprecedential decision *Mikkilineni v. Stoll*.²⁶⁸ In that case, applicant M.R. Mikkilineni appealed a nonfinal rejection of a patent for a method of falling asleep.²⁶⁹ In a meeting, the examiner assigned to the application told the applicant's attorney that he was "required to reject the claims as nonstatutory subject matter" by the 2009 Interim Patent Subject-Matter Eligibility Examination Instructions.²⁷⁰ The guidelines, in relevant part, provide that "[p]urely mental processes in which thoughts or human based actions are 'changed' are not considered an eligible transformation."²⁷¹ Mikkilineni filed suit in the Eastern District of Virginia, alleging that the USPTO violated the notice-and-comment requirements of the APA, and the district court granted the USPTO's motion to dismiss.²⁷²

On appeal, the Federal Circuit considered whether "the Interim Guidelines are substantive rules improperly promulgated without notice and comment rulemaking."²⁷³ In a per curiam opinion, the court rejected this contention. Instead, it held that the USPTO's 2009 guidelines are "interpretive, rather than substantive, and are thus exempt from the notice and comment requirements of

267. Note that the issue was also raised most recently in 2016, with a similar result. *In re Smith*, 815 F.3d 816, 819 (Fed. Cir. 2016) ("Finally, we cannot address Applicants' argument that the PTO's 2014 Interim Guidance on Patent Subject Matter Eligibility ('Interim Eligibility Guidance') exceeds the scope of § 101 and the Supreme Court's *Alice* decision. Applicants' challenge to the Guidelines is not properly before us in this appeal.>").

268. 410 F. App'x 311 (Fed. Cir. 2010).

269. *Id.* at 311.

270. *Id.*

271. Andrew H. Hirshfeld, *Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101*, U.S. PAT. & TRADEMARK OFF. 5 (Aug. 24, 2009), https://www.uspto.gov/sites/default/files/patents/law/comments/2009-08-25_interim_101_instructions.pdf [<https://perma.cc/PCD6-X7AL>]; see also Request for Comments on Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility, 74 Fed. Reg. 47,780 (Sept. 17, 2009) (requesting comments on the Interim Examination Instructions).

272. *Mikkilineni v. Stoll*, No. 1:09CV141, 2010 WL 9554632, at *1 (E.D. Va. Apr. 30, 2010), *aff'd*, 410 F. App'x 311 (Fed. Cir. 2010).

273. *Mikkilineni*, 410 F. App'x at 312.

§ 553 of the APA.”²⁷⁴ In its opinion, the court relied almost entirely on the previous precedent of *ALDF*.²⁷⁵

In fact, the part of the 2009 notice at issue in *Mikkilineni* did lead to a rejection of an application, a fact that the court did not distinguish from *ALDF* in its opinion. Nor did that opinion consider how closely the 2009 guidance tracks *Bilski*, the decision on which that guidance was based.²⁷⁶ Instead, the opinion seemed to defer to the USPTO’s categorization of its own document, noting that:

The USPTO’s Request for Comments explicitly states both (1) that the guidelines are “based on the USPTO’s current understanding of the law and are believed to be fully consistent with binding precedent,” and (2) that the guidelines “do not have the force and effect of law”; thus, “[r]ejections are and will continue to be based upon substantive law.”²⁷⁷

This argument is wholly unconvincing. Agencies surely cannot render clearly substantive rules “interpretive” merely by appending language that the rules “do not have the force and effect of law” and are “based upon substantive law.”²⁷⁸ At least by the text of its opinion, it is unclear whether the Federal Circuit thoroughly and carefully reviewed the nature of the rule.

D. The 2019 Guidance

As has now become typical, the 2019 notice contained a slew of disclaimers aimed at removing it from the ambit of § 553 of the APA. It stated, for example, that “[t]his guidance does not constitute substantive rulemaking and does not have the force and effect of law” and that it “was developed as a tool for internal USPTO management and does not create any right or benefit, substantive or procedural, enforceable by any party against the USPTO.”²⁷⁹

274. *Id.* at 313.

275. *Id.* (“Our decision in *Animal Legal Defense Fund* is almost directly on point.”).

276. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

277. *Mikkilineni*, 410 F. App’x at 312-13.

278. Indeed, the D.C. Circuit has explicitly rejected the use of similar “boilerplate” language as insufficient to render something a nonsubstantive rule. See *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (2000).

279. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 51 (Jan. 7, 2019) [hereinafter 2019 Guidance].

In short, the guidance purports to hit nearly every major exception to notice-and-comment rulemaking.²⁸⁰ It is simultaneously a general policy statement, an interpretive rule, and an internal management document.²⁸¹ These statements are similar to those endorsed by the court in *Mikkilineni* but should not be viewed as talismanic. We must inquire into the substance of the guidance document and its effects.

First, recall that the guidance sets out groupings of abstract ideas. Individually, each grouping of abstract ideas seems to describe fairly well categories of claims that relevant case law has found to be abstract ideas. Importantly, though, the USPTO goes further by claiming that these groupings *effectively exhaust the universe of abstract ideas*. The guidance affirmatively states, “claims that do not recite matter that falls within these enumerated groupings of abstract ideas should not be treated as reciting abstract ideas.”²⁸² Whereas the relevant case law has imposed an “if” statement (if a claim recites X then it recites an abstract idea), the Patent Office has transformed it into an “only if” statement (a claim recites an abstract idea *only if* it recites matter falling into one of three categories). While there is one exception – in “rare circumstance[s]” a claim may still be rejected as a nongrouped “tentative abstract idea” with approval from the Technology Center Director²⁸³ – the guidance creates a clear presumption that only matter within the three enumerated categories should support claim rejections as abstract ideas.

Second, recall that the guidance created two prongs within Step 2A. In some sense, this change could be viewed as a change in form, not substance. At a base level, the 2019 guidance shifts a practical-application analysis that would

280. *Id.* (“This guidance does not constitute substantive rulemaking and does not have the force and effect of law. The guidance sets out agency policy with respect to the USPTO’s interpretation of the subject matter eligibility requirements of 35 U.S.C. 101 in view of decisions by the Supreme Court and the Federal Circuit. The guidance was developed as a tool for internal USPTO management and does not create any right or benefit, substantive or procedural, enforceable by any party against the USPTO. Rejections will continue to be based upon the substantive law, and it is those rejections that are appealable to the Patent Trial and Appeal Board (PTAB) and the courts. All USPTO personnel are, as a matter of internal agency management, expected to follow the guidance. Failure of USPTO personnel to follow the guidance, however, is not, in itself, a proper basis for either an appeal or a petition.”).

281. For the purposes of this inquiry, I do not attempt to draw distinctions between these categories. As a leading casebook notes, some courts distinguish between policy statements and interpretive rules while others do not; the authors note that on their review, whether the court distinguishes these categories or not “has never made a difference to the outcome of a case.” MASHAW ET AL., *supra* note 112, at 652 n.5.

282. 2019 Guidance, *supra* note 279, at 53.

283. *Id.* at 57 n.42.

previously have happened in Step 2B to Step 2A prong 2. The guidance acknowledges this fact, stating, “while some of the considerations listed below were discussed in prior guidance in the context of Step 2B, evaluating them in revised Step 2A promotes early and efficient resolution of patent eligibility.”²⁸⁴ There is some reason to believe, however, that the substance of the inquiry may be changing along with its placement. The guidance cautions, “[r]evised Step 2A specifically excludes consideration of whether the additional elements represent well-understood, routine, conventional activity.”²⁸⁵ In other words, the analysis of whether an element is routine (as supported in ways described by the *Berkheimer* memo) now comes after a determination whether those elements integrate into a practical application. To the extent that examiners were only considering routine elements in Step 2B to determine practical applications, segmenting the analysis in this way might allow more claims to be deemed eligible based on nonroutine elements.

How substantive is the 2019 guidance under the test set forth in *ALDF*? The crux of this inquiry is whether the rule is properly interpretive, that is, whether it interprets recent precedent without adding any substantive changes. First, the shifting of the “practical application” test from Step 2B to Step 2A, and the associated creation of “prongs” in Step 2A, appears to be an organizational change to help examiners apply the doctrine efficiently. It does not appear on its face to be a change in the substantive rules of patentability. Still, this change could be substantive to the extent the reordering leads to changes in rejections on the ground. While an as-yet unanswered empirical question in relation to the 2019 guidance, the USPTO’s own July 2015 guidance showed how a similar reordering (moving the “markedly different characteristics analysis” from Step 2A to Step 2B) could result in differences in claim rejections.²⁸⁶ A similar result could follow from the reordering in the 2019 guidance.

The 2019 guidance’s creation of abstract-idea categories presents a weaker case for pure interpretation. The 2019 guidance’s imposition of an “only if” requirement appears to place a substantive limit on the scope of abstract ideas that does not appear to be in other judicial decisions. This grouping makes the question of whether or not the guidance document is substantive a very close call: by implicitly deciding that all subject matter outside of the new three groupings are patentable, the guidance document takes a step beyond merely interpreting precedent. At the same time, limiting the restrictive holdings of court cases to their facts could in fact be viewed as faithful to the text of § 101. Because no “judicial exceptions” appear on the face of § 101, the statute implies that “anything under

284. *Id.* at 55.

285. *Id.*

286. See *supra* text accompanying note 176.

the sun” could be patentable. Thus, the fealty of the interpretation to the text it purports to interpret is disputable.

The remaining arguments advanced by the *ALDF* court are less likely to result in a reviewing court judging the 2019 guidance to be substantive. As I have shown earlier in this Note, the 2019 guidance will bind patent-office actors and limit their discretion. It will similarly operate, in a practical matter if not a technical one, to affect the outcomes in many appeals. However, under the reasoning of *ALDF*, the 2019 guidance would almost certainly be saved because it is decidedly proapplicant. By limiting the scope of abstract ideas and allowing for even routine elements to support a practical application, the Patent Office appears to be making it easier for claims to be allowed under § 101. Therefore, any constraint on examiner discretion would appear to counsel against rejections and preclude any “adverse effect . . . on an individual’s rights and obligations.”²⁸⁷ Even if an examiner cited the 2019 guidance en route to a rejection, the decision in *Mikkilineni* suggests that this would likely not matter. Thus, if the Federal Circuit were to consider an APA challenge to the 2019 guidance, it would most likely hold that it is an interpretive rule.

In this Part, I have shown that the Federal Circuit’s current case law skews in favor of finding eligibility guidance to be nonsubstantive; if the 2019 guidance was challenged under this precedent it would likely survive. That said, this Section articulates reasons to question whether this test is the proper one. The USPTO has meaningfully changed the law of subject-matter eligibility. Indeed, the 2019 guidance by its text has created a substantive and procedural safe harbor. Patent examiners who might have otherwise rejected certain patent claims for covering abstract ideas are now foreclosed from doing so. Although this safe harbor may benefit certain patent applicants, its adverse effects will trickle down, punishing other innovators who make use of the same abstract idea.

CONCLUSION

Congress and the courts have failed to draw clear lines around subject-matter eligibility. With the muddled doctrine threatening the landscape of innovation in the United States, the Patent Office has attempted to fill this void with recent guidance initiatives. Although these initiatives reflect an admirable intent, reviewing courts should scrutinize them closely to ensure that the Patent Office has not exceeded its authority by promulgating substantive rules. More precisely, courts should grant the Patent Office’s guidance *Skidmore*-level deference to the extent that it is persuasive, while retaining a willingness to strike down guidance documents that overstep either the Office’s statutory authority or the APA.

²⁸⁷. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 929 (Fed. Cir. 1991).

The Federal Circuit's current doctrine does not apply the necessary scrutiny but instead operates as little more than a rubber stamp on any eligibility guidance the Patent Office labels interpretive. This doctrine places an outsized weight on the Office's own characterization of its guidance, which hides that the guidance is both binding on the Office and often treated as authoritative by reviewing judges on appeal, giving it a greater force of law than claimed. Further, the 2019 guidance would likely be upheld under the current doctrine because it skews toward increasing patent issuances rather than rejections, even though it introduces new elements into the eligibility inquiry that could hardly be called interpretive of existing doctrine. The status quo is thus untenable from the standpoint of democratic legitimacy and accountability.

Still, this Note should not be read as an admonition to the Patent Office to remain permanently silent on subject-matter eligibility. To the contrary, the USPTO's historical practice has shown it to be, at times, a profoundly competent rulemaker, responding quickly to changes in the status quo and meaningfully updating its rules to conform to persuasive comments. At the same time, the agency's practice — unrestricted by § 553 and associated judicial review — has been inconsistent, as "interim" guidelines were allowed to remain in place for years while comments were largely ignored. Grants of substantive rulemaking power would give the agency greater power to clean up the mess that courts have created and would provide sticks to rein in its poorer guidance practices.

A corollary of this recommendation is that current congressional reform efforts are incomplete. In endeavoring to make the difficult policy judgments required to balance various short- and long-term incentives, Congress is playing precisely the right role. But recent history suggests that any clarity that comes from new statutory language is likely to be short-lived. Throughout the decades surveyed in this Note, cycles of new technologies and difficult court cases have blurred the lines of patentable subject matter. Congress would be wise to consider a structural change along with its policy judgment: giving the Patent Office substantive rulemaking authority over subject-matter eligibility. With this authority, the Patent Office could continue to fulfill the clarity-enhancing role it has thus far been performing through recent guidance — this time with the traditional checks of the administrative state.