**Flook Says One Thing, Diehr Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter**

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**ABSTRACT**

In a series of recent cases, the U.S. Supreme Court has made clear that there are substantial constraints on the categories of actions and materials for which patent protection may be afforded. But the Court has not provided clear instruction on how to implement these constraints. The Court can do better, and this Essay describes how the Court can perform judicial housecleaning that improves the state of the law on patentable subject matter. The Essay indicates the plausibility of judicial adoption of these proposals by showing how they comport with reasonable understandings of recent Supreme Court opinions and with concerns that Supreme Court Justices have voiced during oral argument.

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**INTRODUCTION**

Defining the bounds of patentable subject matter has become one of patent law’s hottest issues. In a series of recent cases, the U.S. Supreme Court has made clear that there are substantial constraints on the categories of actions and materials for which patent protection may be afforded. But the Court has not provided clear instruction on how to implement these constraints. The result has been uncertainty about the subject-matter eligibility of broad swaths of key kinds of modern innovation, including biomedical substances derived from naturally occurring organisms, approaches to medical treatment in-
volving new diagnostic knowledge, and computer-related functions resulting primarily from new software. Commentators have bemoaned the problems this uncertainty and lack of clarity create for potential innovators and patent-system administrators. For some, the resulting morass suggests the correctness of arguments that judicially developed limitations on patentable subject matter should largely be abandoned in favor of rigorous policing of patentability requirements such as non-aesthetic utility, novelty, and nonobviousness.

I have previously suggested that such a morass is a relatively predictable result of leaving definition of the bounds of patentable subject matter to the courts. An administrative agency such as the U.S. Patent and Trademark Office (“USPTO”) might do a better job than the courts if the agency were armed with a sufficient level of substan-

Says Yes and No, 32 HEALTH AFF. 1343, 1345 (2013) (inquiring whether the U.S. Supreme Court’s holding in Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013), that merely isolated DNA is not patentable, “threaten[s] the patentability of other purified forms of naturally occurring molecules”).


4 See Kevin Emerson Collins, Bilski and the Ambiguity of “An Unpatentable Abstract Idea,” 15 LEWIS & CLARK L. REV. 37, 59 (2011) (“While a claim to a computer programmed with a newly invented mathematical operation is a clear example of an invention based on a principle, truth, or law that is too abstract . . . to be patent eligible under [Supreme Court precedent], precisely what changes are necessary to transform the embodiment into a patentable application of an invention is far from clear.”).


6 See Risch, supra note 5, at 606–07.

7 John M. Golden, Patentable Subject Matter and Institutional Choice, 89 TEX. L. REV. 1041, 1044 (2011) (“The federal judiciary’s historic struggles with subject-matter issues suggest a lack of judicial facility for resolving problems in this area.”).
tive rulemaking authority—a level of authority that the USPTO currently appears to lack.\footnote{Id. (“[A]mong potential institutional candidates . . . the USPTO appears the only one likely to have the expertise and the incentive . . . to deal with subject-matter eligibility questions promptly, effectively, and with adequate protection of developed expectations.”).}

This Essay focuses on how the courts—in particular, the U.S. Supreme Court—might do better with questions of patentable subject matter despite institutional limitations. Part I discusses recent developments in the law. Accepting as a given that the courts will continue to hold that laws of nature, natural phenomena, and abstract ideas are excluded from subject-matter eligibility, Part II proposes ways in which the Supreme Court can perform judicial housecleaning that improves the state of the law with respect to these exclusions. Further, Part II indicates the plausibility of judicial adoption of these proposals by showing how they comport with reasonable understandings of recent Supreme Court opinions and with concerns that Supreme Court Justices have voiced during oral argument. Although statements from Justices during oral argument are not legally authoritative, this Essay demonstrates how they can shed light on the Court’s opinions, at the very least by indicating arguments and concerns to which those opinions respond.

I. FROM EXPANSION TO QUAGMIRE

About a decade ago, highly expansive views of subject-matter eligibility had such strong support in a two-decade trend in the case law that one could wonder whether, other than some requirement of “human ingenuity,”\footnote{Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (describing a patent-eligible microorganism as “a product of human ingenuity”).} any truly meaningful limitations on patentable subject matter remained.\footnote{Cf. Margo A. Bagley, Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law, 45 WM. & MARY L. REV. 469, 485 (2003) (“‘Anything under the sun that is made by man’ has been the mantra for the unprecedented expansion in patent-eligible subject matter articulated by the Supreme Court over the past twenty-plus years.”); Andrew F. Knight, A Potentially New IP: Storyline Patents, 86 J. PAT. & TRADEMARK OFF. SOC’Y 859, 870 (2004) (arguing “the proposition that storyline claims—drafted either as the methods necessary to create the useful, tangible entertainment forms containing those storylines, or as the articles of manufacture (e.g., electronic or printed media) actually containing those storylines—are patentable subject matter”).}

The Supreme Court had opened the 1980s...
with two opinions that embraced expansive language, and the Court had not struck down a patent claim for lack of subject-matter eligibility since the 1970s. Moreover, the United States’ leading judicial expositor of patent law since the early 1980s, the U.S. Court of Appeals for the Federal Circuit, had essentially reduced analysis of subject-matter eligibility to a question of whether the invention was associated with a “useful, concrete and tangible result”—an inquiry that could be hard to distinguish from the requirement that a patentable invention be useful. When, in 2001, the Supreme Court revisited subject-matter eligibility for the first time since 1981, the Court showed little inclination to change course: in holding that plants could be the subject matter of standard utility patents, the Court reaffirmed that the scope of patentable subject matter “is extremely broad.”

What a difference a decade makes! By 2006, at least three members of the Supreme Court were suggesting that broad reconsideration of the law on patentable subject matter was necessary. Since then, the Supreme Court has held that patent claims fail requirements of

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12 Diamond v. Diehr, 450 U.S. 175, 192 (1981) (“[W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.”); Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) (“Congress plainly contemplated that the patent laws would be given wide scope.”).


15 See Katherine J. Strandburg, Much Ado About Preemption, 50 HOU. L. REV. 563, 567 (2012) (“The Federal Circuit’s test [for subject-matter eligibility] set a very low bar, asking only whether a claimed invention produced a ‘useful, concrete, and tangible result’ (and emphasizing usefulness).”). Compare Janice M. Mueller, Patent Law 343 (4th ed. 2013) (“[E]ven if an invention is of the proper type or category, it is only ‘potentially’ patentable because it must still satisfy the remaining statutory criteria of utility, novelty, and nonobviousness . . . .” (footnotes omitted)), with State Street, 149 F.3d at 1375 (“The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to . . . but rather on the essential characteristics of the subject matter, in particular, its practical utility.”) (emphasis omitted)).


17 Id. at 130.

subject-matter eligibility in four straight opinions: *Bilski v. Kappos*,\(^{19}\) *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,\(^{20}\) *Association for Molecular Pathology v. Myriad Genetics, Inc.*,\(^{21}\) and *Alice Corp. Pty. Ltd. v. CLS Bank International.*\(^{22}\)

Meanwhile, judges of the Federal Circuit have begun policing limits on patentable subject matter more aggressively, at least on occasion arguably even more aggressively than the Supreme Court might have intended. In 2008, nine of the Federal Circuit’s twelve active judges joined an en banc opinion in *In re Bilski*\(^{23}\) that not only rejected decade-old circuit precedent holding that a “useful, concrete, and tangible result” sufficed to establish the subject-matter eligibility of a process claim,\(^{24}\) but also held that a process claim generally must involve a machine or transformation of matter in order to be patent eligible.\(^{25}\)

The Supreme Court believed that the Federal Circuit majority had taken this course reversal too far. In *Bilski*, the Court affirmed the Federal Circuit’s holdings that specific patent claims lacked patentable subject matter,\(^{26}\) but the Court rejected the Federal Circuit’s newly adopted machine-or-transformation test on the ground that adoption of this test would constitute “‘read[ing] into the patent laws limitations and conditions which the legislature has not expressed.’”\(^{27}\) The Court noted that it had previously “explicitly declined” to hold that, to meet the requirement of subject-matter eligibility, a process

\(^{19}\) *Bilski v. Kappos*, 130 S. Ct. 3218, 3229–30 (2010) (holding that patent claims for “the concept of hedging risk and the application of that concept to energy markets” failed requirements of subject-matter eligibility because they were “attempts to patent abstract ideas”).

\(^{20}\) *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297–98 (2012) (holding that method claims requiring the administering of a drug and the determination of metabolite levels did not “qualify as patent-eligible processes that apply natural laws” (emphasis omitted)).

\(^{21}\) *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013) (“[W]e hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.”).


\(^{24}\) *Id.* at 959–60 (holding that “the ‘useful, concrete and tangible result’ inquiry is inadequate”).

\(^{25}\) *Id.* at 956 (“At present . . . and certainly for the present case, we . . . reaffirm that the machine-or-transformation test, properly applied, is the governing test for determining patent eligibility of a process under § 101.”).

\(^{26}\) *Bilski*, 130 S. Ct. at 3230 (“[A]ll members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea.”).

\(^{27}\) *Id.* at 3226 (quoting *Diamond v. Diehr*, 450 U.S. 175, 182 (1981)).
had to satisfy the machine-or-transformation test. In the Court’s view, the fundamental question with respect to subject-matter eligibility of a process claim was whether the claim fell within the reach of “three specific exceptions to [the Patent Act’s] broad patent-eligibility principles: laws of nature, physical phenomena, and abstract ideas.”

The Court then held that all claims at issue in *Bilski* were “not patentable processes because they [were] attempts to patent abstract ideas.”

But the Supreme Court’s opinion in *Bilski* left much undecided and unexplained. As Justice Stevens lamented in a lengthy concurring opinion, the Court’s opinion in *Bilski* provided little instruction about what degree or aspects of generality in a patent claim cause it to cross over into the forbidden zone of unpatentable abstractness. Without guidance, such questions tend naturally to be a conundrum because patent claims are meant to generalize from specific embodiments of an invention, “abstracting” those key aspects that distinguish the claimed invention from the prior art.

Since the Supreme Court issued its *Bilski* decision in 2010, the law of subject-matter eligibility has plunged into a seemingly ever widening maelstrom of uncertainty. The Supreme Court itself has felt a need to intervene in this area again and again. On June 19, 2014, the Supreme Court issued its third merits opinion on patentable subject matter since, and not including, its June 2010 opinion in *Bilski*. Like *Bilski*, two of the Court’s subsequent decisions have held specific patent claims to fail the requirement of subject-matter eligibility without establishing new categorical lines. In *Mayo*, the Court held that specific claims relating to assessment of a course of medical treatment...

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28 *Id.* at 3227.
29 *Id.* at 3225 (internal quotation marks omitted).
30 *Id.* at 3229–30.
31 *Id.* at 3236 (Stevens, J., concurring in the judgment) (“The Court . . . never provides a satisfying account of what constitutes an unpatentable abstract idea.”); see also Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1350 (2011) (discussing the extent to which the Supreme Court’s opinion in *Bilski* “provided little information on how to determine whether particular subject matter is statutory”).
32 See Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1145 (2008) (“Typically, patentees begin with a broad claim reciting as few properties as possible to yield the broadest claim permissible in light of the prior art and the patentee’s disclosure.”).
were unpatentable.\textsuperscript{34} In \textit{Alice}, the Court held that specific claims for “a computer-implemented scheme for mitigating ‘settlement risk’ (i.e., the risk that only one party to a financial transaction will pay what it owes)” were also unpatentable.\textsuperscript{35} In the Court’s other post-\textit{Bilski} decision—\textit{Myriad}—the Court ruled more categorically that claims to isolated but otherwise naturally occurring DNA are unpatentable\textsuperscript{36} but that claims to complementary DNA that omit portions of naturally occurring sequences are, generally speaking, patent eligible.\textsuperscript{37} But even in \textit{Myriad}, the Court carefully emphasized limits to its decision, highlighting, for example, that, at least outside deliberations relating to complementary DNA, the Court had not “consider[ed] the patentability of DNA in which the order of the naturally occurring nucleotides has been altered.”\textsuperscript{38}

In short, the Court’s interventions have been deliberately limited in ways that have left members of the patent community uncertain about how to proceed.\textsuperscript{39} This could have been a significantly positive feature of the Court’s interventions, rather than a bug, if the remainder of the patent community, in particular the Federal Circuit, had been able to use the opportunity provided by the Court’s limited decisions to arrive at a new overall formulation of subject-matter eligibility law that was substantially informed by the community’s expertise.\textsuperscript{40}

\textsuperscript{34} \textit{Mayo}, 132 S. Ct. at 1296–97 (holding that certain claims relating to assessment of the effectiveness or toxicity of a course of treatment did not “qualify as patent-eligible processes that apply natural laws” (emphasis omitted)).

\textsuperscript{35} \textit{Alice}, 134 S. Ct. at 2351–52.

\textsuperscript{36} \textit{Myriad}, 133 S. Ct. at 2120 (“We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.”).

\textsuperscript{37} \textit{Id.} at 2119 (holding that “cDNA is not a ‘product of nature’ and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA”).

\textsuperscript{38} \textit{Id.} at 2120.


\textsuperscript{40} See John M. Golden, The Supreme Court as “Prime Percolator”: A Prescription for Ap-
Indeed, the Court’s opinion in *Bilski* concluded with a virtual invitation to the Federal Circuit to develop “other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.” But, in the wake of the Court’s *Bilski* and *Mayo* decisions, the Federal Circuit lost any semblance of unity on the topic.

Presumably to try to restore some order, the Federal Circuit granted en banc hearing of a case later heard by the Supreme Court under the name *Alice Corp. Pty. Ltd. v. CLS Bank International*. As indicated above, *Alice* involved a patent for a way to conduct financial transactions. Claims in that patent described the alleged innovation in three different ways: (1) as a process for conducting a transaction using a computer system, (2) as software saved on a computer-readable medium that would be useful in conducting a transaction, and (3) as a computer system used to aid in a transaction. The Federal Circuit’s effort to use review of these patent claims to clarify the state of

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42 *See, e.g.*, Accenture Global Servs., GmbH v. Guidewire Software, Inc., 728 F.3d 1336, 1346 (Fed. Cir. 2013) (Rader, C.J., dissenting) (criticizing the majority for “re[lying] significantly on the framework proposed by the plurality opinion in *CLS Bank*”); Ultramercial, Inc. v. Hulu, LLC, 722 F.3d 1335, 1354 (Fed. Cir. 2013) (Lourie, J., concurring) (writing separately because of a belief that, instead of reasoning as the majority had, “we should concise[ly] and faithfully follow the Supreme Court’s most recent guidance regarding patent eligibility . . . and should track the plurality opinion of five judges from this court in *CLS Bank*”). *Compare* Alexsam, Inc. v. *IDT Corp.*, 715 F.3d 1336, 1348 (Fed. Cir. 2013) (Mayer, J., dissenting) (arguing that questions of subject-matter eligibility “must be addressed before this court can consider subordinate issues related to obviousness and infringement”), *with* Dealertrack, Inc. v. *Huber*, 674 F.3d 1315, 1335 (Fed. Cir. 2012) (Plager, J., concurring in part and dissenting in part) (contending that the court should have “insist[ed] that litigants, and trial courts, initially address patent invalidity issues” such as novelty, nonobviousness, claim definiteness, and adequate disclosure before addressing subject-matter eligibility); *compare* Classen Immunotherapies, Inc. v. *Biogen Idec*, 659 F.3d 1057, 1073 (Fed. Cir. 2011) (Rader, C.J., concurring) (lamenting that “[s]ubject matter eligibility . . . has become the ‘substantive due process’ of patent law”), *with* *id.* at 1075–76 (Moore, J., dissenting) (“I believe that the claims at issue are to a fundamental scientific principle so basic and abstract as to be unpatentable subject matter . . . .”).


44 *CLS Bank Int’l v. Alice Corp.*, 717 F.3d 1269, 1274 (2013) (en banc) (Lourie, J., concurring) (“[T]he patents relate to a computerized trading platform used for conducting financial transactions in which a third party settles obligations between a first and a second party so as to eliminate ‘counterparty’ or ‘settlement’ risk.”), *aff’d*, 134 S. Ct. 2347 (2014).

45 *Id.* (describing claims at issue as involving “methods of exchanging obligations,” “data processing systems,” and “computer-readable media containing a program code for directing an exchange of obligations”).
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the law was largely a failure.\textsuperscript{46} With ten judges sitting en banc, the Circuit could only agree on a one-paragraph per curiam opinion reporting the Circuit’s affirma mce of the district court’s rulings that all three forms of claims fail the requirement of subject-matter eligibility.\textsuperscript{47} The per curiam opinion included no rationale and affirmed the district court with respect to the computer-system claims only because the circuit judges were “equally divided.”\textsuperscript{48} Reasoning in relation to the Circuit’s holdings appeared only in a fractured set of five opinions, none of which commanded a majority.\textsuperscript{49} Although Judge Lourie’s concurring opinion for half of the en banc Circuit’s ten judges emphasized points of majority agreement among the opinions,\textsuperscript{50} an opinion by then Chief Judge Rader specifically emphasized that nothing in the Circuit judges’ reasoning had precedential effect.\textsuperscript{51}

The Supreme Court’s later decision in Alice provided precedential resolution of a number of key issues in the case but left many questions about subject-matter eligibility unanswered. The Court’s members unanimously agreed that all three of the forms of claims at issue—the process claims, the computer-readable medium claims, and the computer system claims—failed to be subject-matter eligible because they were drawn “to a patent-ineligible abstract idea.”\textsuperscript{52} Moreover, although the Court’s opinion avoided using the word “software,”

\textsuperscript{46} Seong-hee Lee, Software Patent Eligibility: A Call for Recognizing and Claiming Concrete Computer Programs, 95 J. PAT. & TRADEMARK OFF. SOC’Y 402, 402–03 (2013) (“The latest attempt by the en banc Federal Circuit to clarify software patent eligibility has been largely unsuccessful and only demonstrated that the court is deeply fractured on the issue of software eligibility.”).

\textsuperscript{47} CLS Bank, 717 F.3d at 1273 (per curiam) (reporting holdings that certain computer-related method and media claims failed requirements of subject-matter eligibility and the affirmance by an “equally divided court” of the district court’s similar holding in relation to “system claims”).

\textsuperscript{48} Id.

\textsuperscript{49} See id. at 1273 (Lourie, J., concurring) (opinion for five-judge plurality); id. at 1292 (Rader, C.J., concurring in part and dissenting in part) (opinion for four-judge plurality except for Part VI); id. at 1313 (Moore, J., dissenting in part) (opinion for four-judge plurality); id. at 1321 (Newman, J., concurring in part and dissenting in part) (opinion for Judge Newman alone); id. at 1327 (Linn, J., and O’Malley, J., dissenting) (opinion for Judges Linn and O’Malley alone).

\textsuperscript{50} See id. at 1274 n.1 (Lourie, J., concurring) (noting, for example, that “seven of the ten members, a majority of this en banc court have agreed that the method and computer-readable medium claims before us fail to recite patent-eligible subject matter”).

\textsuperscript{51} See id. at 1292 n.1 (Rader, C.J., concurring in part and dissenting in part) (observing that, as “[n]o portion of any opinion issued today other than our Per Curiam Judgment garnered a majority,” “nothing said today beyond our judgment has the weight of precedent”).

\textsuperscript{52} Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2352 (2014) (“We hold that the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention.”).
the Court sent a strong signal by failing to respond positively to invitations to declare computer software to be generally unpatentable,\(^{53}\) thereby suggesting that continued calls to exclude software in general from subject-matter eligibility most likely need to be directed at Congress, rather than the courts.

Nonetheless, as with prior subject-matter eligibility opinions, the Supreme Court deliberately limited the scope of its decision. The Court explicitly declined to “labor to delimit the precise contours of the ‘abstract ideas’ category.”\(^{54}\) Instead, despite knowing that the Federal Circuit had failed to coalesce around a new understanding of subject-matter eligibility law in the wake of \textit{Bilski} and \textit{Mayo}, the Court largely relied on \textit{Mayo} for its analytical framework.\(^{55}\) The Court further relied on analogy to the specific facts of \textit{Bilski} for the conclusion that the claims at issue involved an abstract idea.\(^{56}\) Unsurprisingly, therefore, a patent community puzzled by those decisions has not found \textit{Alice} entirely enlightening.\(^{57}\)

\(^{53}\) See, e.g., Brief for Red Hat, Inc. as Amicus Curiae Supporting Respondents at 7, Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347 (2014) (No. 13-298) (“This case offers an opportunity to restore the historical and well-founded boundaries for patentable subject matter that exclude abstract ideas of the type generally involved in software from patent eligibility.”); Brief for Software Freedom Law Center et al. as Amici Curiae Supporting Respondents at 11, Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347 (2014) (No. 13-298) (“A computer program, no matter what its function, is nothing more or less than a collection of abstract ideas comprising one or more algorithms.”).

\(^{54}\) \textit{Alice}, 134 S. Ct. at 2357.

\(^{55}\) Id. at 2355 (describing \textit{Mayo} as having “set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts”).

\(^{56}\) Id. at 2357 (stating there was no need to “labor to delimit the precise contours of the ‘abstract ideas’ category” because there was “no meaningful distinction between the concept of risk hedging in \textit{Bilski} and the concept of intermediated settlement at issue here”).

I am not surprised by the continuing confusion surrounding judicial efforts to enforce meaningful limits on patentable subject matter. As indicated above, in prior work I argued that general questions of subject-matter eligibility are relatively ill-suited for judicial resolution. The courts’ continuing struggles have only reinforced my lack of confidence. Moreover, the USPTO’s visible struggles to make sense of the courts’ rulings have strengthened my sense that, at least absent congressional action to clarify subject-matter eligibility directly, the USPTO will have trouble improving the situation as long as it has only “interpretive authority bound to preexisting judicial precedent.”

A look at a recent USPTO effort to provide guidance highlights the frustrating circles in which the courts’ jurisprudence has caused the USPTO to turn. In eighteen pages of guidelines released in March 2014, approximately three months before the Supreme Court issued its opinion in *Alice*, the USPTO issued new instructions to examiners that focused on when, in accordance with the Supreme Court’s decision in *Mayo*, a claim should be held to be excluded from subject-matter eligibility because it effectively seeks to patent a law of nature or natural phenomenon. Inauspiciously, the guidelines lead off with the somewhat circular instruction that a claim should be considered to satisfy subject-matter eligibility “if the claim as a whole recites something significantly different” from a “judicial exception” from subject-matter eligibility. The guidelines’ efforts to explain what makes for a “significant difference” lead immediately to an even clearer instance of circularity: the guidelines explain that a “significant difference” exists if, for example, “(1) the claim includes elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way, e.g., by adding significantly more to the judicial exception; and/or (2) the claim includes features or steps that demonstrate that the claimed subject matter is markedly different from what exists in nature.” In short, the USPTO’s initial attempt to

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58 See *supra* text accompanying notes 7–9.
59 *Golden,* *supra* note 7, at 1110–11.
60 U.S. PATENT & TRADEMARK OFFICE, GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS 1 (2014) [hereinafter “2014 USPTO GUIDANCE”], available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf (“The Office is issuing the following guidance for use in subject matter eligibility determinations of all claims . . . reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products.” (emphasis omitted)).
61 *Id.* at 3–4 (emphasis omitted).
62 *Id.*
indicate when claimed matter is sufficiently distinct from a law of nature or natural phenomenon amounts to saying that there is a sufficient distinction when there is a significant difference and that there is a significant difference when the claim contains “significantly more” than the law of nature or natural phenomenon or “is markedly different” from it. Other than establishing that “significant” and “marked” are meant to be essentially synonymous, it is unclear what this initial verbiage accomplishes.

The next segment of the guidelines arguably makes matters worse. The guidelines proceed to indicate that assessing whether claimed subject matter is significantly different from a law of nature or natural phenomenon requires a totality-of-circumstances analysis in which examiners should consider at least twelve enumerated factors and then somehow weigh these and any other “relevant factors” against one another. Some of the factors primarily kick the can farther down the road: the first factor largely reiterates the “marked difference” standard already discussed, and later instruction loops back to the guidelines’ initial “significant difference” language. In the guidelines’ words, “a marked difference must be a significant difference, i.e., more than an incidental or trivial difference.” Although other listed factors and notes, including discussion of specific hypothetical claims, might be more helpful, the main impression left by the USPTO’s long but nonexhaustive list of factors is that subject-matter eligibility analysis has become a quagmire that a USPTO bound to an unwieldy set of judicial precedents will have great difficulty clearing up.

63 Id. at 4–5 (listing twelve factors, indicating that they are “not intended to be exclusive or exhaustive,” and stating that “[t]he determination of eligibility . . . is a conclusion reached by weighing the relevant factors, keeping in mind that the weight accorded each factor will vary based upon the facts”).

64 Id. at 4 (listing as a factor favoring subject-matter eligibility a finding that the patent claim in question “is a product claim reciting something that . . . is determined to be non-naturally occurring and markedly different in structure from naturally occurring products”).

65 Id. at 5.

66 See id. at 4 (observing that satisfaction of a machine-or-transformation test is a useful clue for subject-matter eligibility); id. at 5 (clarifying that a “marked difference” from a natural phenomenon can be generated “as a result of routine activity or via human manipulation of natural processes”).

67 The USPTO’s brief instructions to examiners in the immediate wake of the Supreme Court’s decision in Alice do not alter this impression as they largely just extend the reach of problems under the 2014 USPTO GUIDANCE by recognizing that the basic analytical approach for claims involving laws of nature or natural phenomena should also apply to claims involving abstract ideas. See generally Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, U.S. Patent & Trademark Office, to Patent Examining Corps: Prelimi-
II. THE POTENTIAL FOR SUBJECT-MATTER ELIGIBILITY HOUSEKEEPING

Assuming no action by Congress either to provide further direction on subject-matter eligibility or to give the USPTO the interpretive authority necessary to overcome judicial precedent, what can the Supreme Court do to help extricate the law from its current quagmire? Assuming the Court wishes to continue to leave much development of legal details to the Federal Circuit, district courts, and USPTO, the Court can aid the process of percolation below by performing some housecleaning with respect to its own opinions and specific language within them. This Part of the Essay discusses some ways in which the Court might productively proceed.

The discussion here focuses on patent claims for processes that in some way invoke a so-called “law of nature.” Although the significance of the Court’s 2014 decision in Alice will also be considered for such claims, the most on-point recent Supreme Court precedent is that of Mayo, in which the patent at issue disclosed threshold levels of metabolites in a person’s blood that correlated with whether a drug the person was taking was having therapeutic or toxic effect. More specifically, the Court held that the following claim fails the requirement of subject-matter eligibility:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ red blood cells indicates a need to increase the
amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10⁸ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.⁷⁰

On its face, this claim requires two actions: (1) administration of a drug to treat a particular type of condition and (2) measurement of a metabolite of that drug, 6-thioguanine, in the patient’s blood. The claim further specifies a form of “natural law”—namely, that metabolite levels above or below specified amounts indicate that the drug dosage should be decreased or increased, respectively.

The Court concluded that the claim failed the requirement of patentable subject matter because its effect was “simply to tell doctors to apply the [natural] law somehow when treating their patients.”⁷¹ The Court arrived at its conclusion after performing what the Court’s opinion in Alice later characterized as a two-step analysis that applies generally to subject-matter exclusions: (1) “determine whether the claims at issue are directed to one of those patent-ineligible concepts,” namely, laws of nature, natural phenomena, and abstract ideas; and (2) if a claim is directed to such a concept, determine whether the claim nonetheless embodies “an ‘inventive concept’—i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’”⁷²

This Essay does not seek either to contest or to confirm the wisdom of the Supreme Court’s basic holdings in its recent decisions. Instead, it looks for ways of understanding those decisions that will facilitate legal application and development going forward. The accepted goal is to improve the law on subject-matter eligibility within constraints signaled by the Court’s recent decisions. As suggested above, the Supreme Court can take action to facilitate this aim. In

⁷⁰ Id. (quoting U.S. Pat. No. 6,355,623 col. 20 ll. 9–25 (filed Apr. 8, 1999) (issued Mar. 12, 2002) (internal quotation marks omitted)).
⁷¹ Id. at 1299–1300.
⁷² Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2355 (2014) (alteration in original) (quoting Mayo, 132 S. Ct. at 1294); see also Mayo, 132 S. Ct. at 1296–97 (first concluding that “Prometheus’ patents set forth laws of nature” and then considering whether “the patent claims add enough . . . to allow the processes they describe to qualify as patent-eligible processes that apply natural laws” (emphasis omitted)); Kevin Emerson Collins, Prometheus Laboratories, Mental Steps, and Printed Matter, 50 HOU. L. REV. 391, 402 (2012) (describing Mayo as featuring a two-step analysis).
particular, this Part argues that, if and when the Court addresses questions of subject-matter eligibility again, its written opinions should (1) be more willing to criticize and distinguish language in the Court’s prior opinions; (2) either abandon or better define the “inventive concept” and “inventive act” language that has appeared in a number of the Court’s opinions on subject-matter eligibility; and (3) continue to emphasize that much of the Court’s subject-matter analysis has been of a “safety-valve” nature, addressed primarily to what the Court has understood to be relatively clear instances of overreach in which alleged distinctions between the claimed invention and a patent-ineligible law of nature seem much more liable to being the product of the patent draftsman’s art than a true reflection of what any reasonable observer would consider to be the practical or technological nature of the claimed invention.

Moreover, the Essay suggests that, at least collectively, the Supreme Court Justices are already aware of the need for doing all of the above. Careful parsing of the Court’s opinions and transcripts of oral arguments indicates that, despite relative inexpertise in patent law, members of the Court understand many of the relevant problems with the jurisprudence on patentable subject matter that the Court has constructed. Further, the Essay contends, statements by the Justices in opinions and during oral argument indicate that they are likely at the very least to be open to considering the steps proposed.

A first point is that, in order to improve the clarity of the Court’s pronouncements on subject-matter eligibility, the Justices should be clearer about how they are using their prior opinions. In particular, when the Court cites opinions containing statements that are in apparent tension with one another, the Court should do more to explain how it is resolving the apparent tensions. Alternatively, if the Court is not seeking to reconcile such prior statements, the Court should indicate which statements it believes are no longer worth following. Commentators have repeatedly noted that Supreme Court opinions relating to patentable subject matter feature a confusing mishmash of principles and holdings, at least some of which appear inconsistent or just plain wrong.\(^73\) The Court’s oft-cited\(^74\) 1948 majority opinion in

\(^{73}\) See, e.g., Menell, supra note 5, at 1290 (noting “the murky and conflicting reasoning of the Benson-Flook-Diehr trilogy from the 1970s and early 1980s” (footnote omitted)); Arti K. Rai, Diagnostic Patents at the Supreme Court, 18 MARQ. INT’L PROP. L. REV. 1, 5 (2014) (observing that “the Court’s decisions have often been quite unhelpful” with respect to clarifying the bounds of and rationales for exclusions from patentable subject matter); Joshua D. Sarnoff, Patent Eligible Medical and Biotechnology Inventions After Bilski, Prometheus, and Myriad, 19 TEX. INT’L PROP. L.J. 393, 394 (2011) (discussing the “conflicting doctrinal standards for eligi-
Funk Brothers Seed Co. v. Kalo Inoculant Co.\textsuperscript{75} has been subjected to especially heavy criticism,\textsuperscript{76} and some writers have questioned whether it should be considered a subject-matter eligibility case at all.\textsuperscript{77} Nonetheless, the Court has regularly cited the case as if there

\textsuperscript{75} Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).


were no question about its authority in relation to questions of subject-matter eligibility.78

A natural result of the Supreme Court’s efforts to paper over conflicting aspects of its precedents is conflict within individual opinions themselves. For tension within a single opinion, one can look to the Court’s 1980 opinion in Diamond v. Diehr.79 This opinion emphasizes the principle that, in an assessment of subject-matter eligibility, claims “must be considered as a whole,” it being “inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.”80 At the same time, Diehr advocates an “anti-principle” that reveals some willingness to dissect claims: Diehr instructs that inclusion of “insignificant post-solution activity” in a claim “will not transform an unpatentable principle into a patentable process.”81 In support of this anti-principle, Diehr cites the Court’s 1978 opinion in Parker v. Flook,82 in which the opinion for the Court had suggested the possibility of at least partial dissection of claims into old and new elements for purposes of subject-matter eligibility analysis.83 In Flook, the Court rejected “[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process,” saying that such an idea “exalts form over substance.”84 In short, there are clear tensions within the language of single opinions such as that for the Court in Diehr, as well as between the differing language and holdings of Diehr and its predecessor Flook.85 This tension might be unsurprising once one recognizes that, whereas Justice Stevens was the author of the Court’s majority opinion in Flook and the author of a four-Justice dissent in Diehr,86 Justice Rehnquist was

78 See Myriad, 133 S. Ct. at 2117 (citing Funk); Mayo, 132 S. Ct. at 1294 (same); Bilski, 130 S. Ct. at 3225 (same); Sichelman, supra note 76 (noting citation of Funk in Supreme Court opinions from 1972 on).
80 Id. at 188–89 (“The ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”).
81 Id. at 191–92.
83 See id. at 588 (“The question is whether the discovery of this feature makes an otherwise conventional method eligible for patent protection.”); see also id. at 600 (Stewart, J., dissenting) (criticizing the Court majority for “importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness”).
84 Id. at 590.
85 See Eisenberg, supra note 3, at 343 (describing Diehr and Flook as cases that “reach opposing conclusions on similar facts and are difficult to reconcile”).
86 Compare Diehr, 450 U.S. at 193 (Stevens, J., dissenting), with Flook, 437 U.S. at 585.
the author of the Court’s majority opinion in Diehr and one of three dissenters from the Court’s majority opinion in Flook.87

Members of the current Supreme Court are not oblivious of vagaries and equivocations in their precedents on subject-matter eligibility. During oral arguments, Supreme Court Justices have recognized problems in understanding and applying their case law. In the 2011 oral argument for Mayo, Justice Breyer bluntly observed, “If you look at the Court’s cases, they seem to say[,] Flook, one thing, and[,] Diehr, another thing.”88 In the 2014 oral argument for Alice, Justice Breyer acknowledged limitations of his own recent opinion for the Court in Mayo, saying to counsel, “[Y]ou realize I couldn’t figure out much in [Mayo] to go beyond what I thought was an obvious case, leaving it up to you and your colleagues to figure out how to go further.”89 More subtly, Justice Ginsburg suggested concerns with the clarity of the Court’s prior opinions by questioning an attorney as follows: “The Federal Circuit in this case split in many ways, and it had our decisions to deal with. You said, given Bilski and Mayo, this is an easy case. What is the instruction that escaped a good number of judges on the Federal Circuit?”90 Meanwhile, Justice Scalia has expressed some discomfort with the task of delineating the bounds of precedent-based exclusions from subject-matter eligibility, repeatedly observing that exclusions of laws of nature and natural phenomena threaten to swallow wide swaths of otherwise patent-eligible matter because all alleged inventions can be expected to operate according to so-called natural laws.91

All too predictably, however, such awareness of deficiencies in the case law has not shone brightly in the Supreme Court’s written opinions. In accordance with the law that the Supreme Court does not “admit to inconsistency if it can help it,”92 the Court’s opinions

87 Compare Diehr, 450 U.S. at 177, with Flook, 437 U.S. at 598 (Stewart, J., dissenting).
90 Id. at 42.
have tended to present its prior opinions, including opinions more than a century old, as part of a “seamless web” rather than as the confusing agglomeration of conflicting parts that experts commonly find them to be. This approach to presentation of the Court’s ostensibly reasoning might have the virtue of comporting with the notion that judges should decide cases on the assumption “that the law is structured by a coherent set of principles.” But confusion within the patent community is a predictable result when, without distinguishing “bad” from “good” dicta, the Court cites as equally authoritative any of the current menagerie of opinions on subject-matter eligibility scattered over more than a century.

What can the Supreme Court do to provide a less muddled message? Although the Court might justifiably want to avoid the trauma of overturning precedent, the Court seems more than capable of clearing doctrinal underbrush that does not implicate prior case outcomes. For example, the Court could clarify what recent opinions in Mayo, Myriad, and Alice mean by terms such as “inventive concept,” “inventive application,” “inventive way,” and “inventive act.”

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94 See Ghosh, supra note 39, at 348 (describing the Mayo Court as making an “obvious departure from Diehr” but nonetheless “attempt[ing] to paint a picture of consistency with Diehr”); Menell, supra note 5, at 1300 (describing the Bilski majority’s one-paragraph summary of the Court’s precedent on patentable subject matter as “blithely sweep[ing] the fundamental interpretive problem of patentable subject matter—what grounds and guides the contours of the exclusions—under the rug”).

95 Cf. Schauer, supra note 73, at 175 (“[T]he view that judicial opinions are largely about making a decision that was the product of choice and discretion appear as if it had been compelled by earlier cases and other legal materials . . . is almost certainly the conventional wisdom.”).

96 RONALD DWORKIN, LAW’S EMPIRE 243 (Frank Kermode ed., 1986).

97 Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2355 (2014) (describing analysis under the subject-matter exclusions as first featuring an inquiry into “whether the claims at issue are directed to one of those patent-ineligible concepts” and, if so, then involving “a search for an ‘inventive concept’”); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012) (stating that Supreme Court precedents require “that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself”); id. at 1299 (concluding that, in the process claimed in Flook, “putting [a mathematical] formula to the side, there was no ‘inventive concept’ in the claimed application of the formula”).

98 Alice, 134 S. Ct. at 2358 (describing the innovation at issue in Diamond v. Diehr, 450 U.S. 175 (1981), as involving “an inventive application of [a mathematical] formula”); Mayo, 132 S. Ct. at 1299 (describing the process claimed in Diehr as including steps that “transformed the process into an inventive application of [a mathematical] formula”).
These terms derive from language in earlier Court opinions and describe a feature of a claim that can turn otherwise patent-ineligible subject matter into a form of legally cognizable invention. But perhaps in part because of their historical lineage, these terms are ill-defined and ripe for modern misinterpretation. Use of this “inventive” terminology invites confusion with one or another of patent law’s other established uses for the term “invention.” In patent parlance, the term “invention” can refer to any of the following:

1. The class of products or processes described by a patent’s enumerated claims.
2. Historical events like conception or reduction to practice that establish the legally relevant date of “invention” and the identities of a patent’s legally relevant “inventors.”
3. A product or process that satisfies, *inter alia*, patentability requirements of utility, novelty, and nonobviousness.

99 *Mayo*, 132 S. Ct. at 1300 (describing the addition of a heated chamber before a furnace as “an inventive way” of applying the principle that it was desirable to preheat air before blowing it into a furnace).

100 Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2114 (2013) (describing the “central dispute among [Federal Circuit] panel members” as having been “whether the act of isolating DNA . . . is an inventive act that entitles the individual who first isolates it to a patent” (second emphasis added)); see also id. at 2117 (“[S]eparating [a] gene from its surrounding genetic material is not an act of invention.”).


102 See *supra* notes 97–100.

103 *In re Kathawala*, 9 F.3d 942, 946 (1993) (“It is a truism that a claim defines an invention . . . .”); Lefstin, *supra* note 32, at 1145 (“In modern parlance, the claim, ‘the invention,’ and ‘the patent’ are essentially synonymous.”); cf. Peter S. Menell, Matthew D. Powers & Steven C. Carlson, *Patent Claim Construction: A Modern Synthesis and Structured Framework*, 25 Berkeley Tech. L.J. 711, 750 (2010) (“When the patentee uses descriptive terms such as ‘the invention’ or ‘the present invention’ to describe what is claimed, then those descriptive embodiments may be definitional.”).

104 See *Pfaff* v. Wells Elecs., Inc., 525 U.S. 55, 60 (1998) (“The primary meaning of the word ‘invention’ in the Patent Act unquestionably refers to the inventor’s conception rather than to a physical embodiment of that idea.”); see also *Mueller*, *supra* note 15, at 232 (noting that a patent applicant can show an invention date that precedes an alleged prior-art reference by establishing early enough dates of reduction to practice or conception followed by diligence in reducing to practice).

105 Sewall v. Walters, 21 F.3d 411, 415 (Fed. Cir. 1994) (“Determining ‘inventorship’ is nothing more than determining who conceived the subject matter at issue . . . .”); *Mueller*, *supra* note 15, at 220–21 (“For a person to be properly named as an inventor on a patent, he must generally contribute to the conception of the invention.”).

106 See, e.g., Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1093 n.317 (2014) (“Recall that under the current patent statute an invention must be useful (§ 101), novel (§ 102), nonobvious (§ 103), and directed to patentable subject matter (§ 101).”).

Particularly given the last two listed meanings for “invention” and the Supreme Court’s penchant for uncritical citation of pre-1952 case law, the Court’s use of “inventive” terminology in the subject-matter eligibility context can leave members of the patent community legitimately in doubt about the extent to which the Court’s use of that language signals a return to pre-1952 forms of reasoning.

Members of the Supreme Court appear fully capable of appreciating the concerns that its “inventive” terminology creates. In Mayo, the Court rejected the Solicitor General’s recommendation that subject-matter and “invention” analysis be combined in a particularly graphic way—namely, by treating laws of nature as non-novel (i.e., known even before any alleged human discovery) for purposes of patent law’s novelty and nonobviousness analyses.108 At the oral argument in Mayo, Justice Breyer explicitly criticized such an approach, saying that it “not only runs into conflict with prior cases, but . . . doesn’t make much sense because really the novel thing is often the law of nature.”109 Justice Breyer’s opinion for the Court in Mayo reiterated that criticism, saying that the Government’s proposed approach was “not consistent with prior law,” was unsupported by the text of specific statutory provisions on novelty and nonobviousness, and risked rendering “all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.”110 The Court’s rejection of the Government’s recommendation suggests that, although the Court has acknowledged that “the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap,”111 the Court

107 Rich, supra note 92, at 34 (“As compared to finding or not finding ‘invention,’ § 103 was a whole new way of thinking and a clear directive to the courts to think that way.”). See generally MERGES & DUFFY, supra note 77, at 624 (“Section 103 of the 1952 Act was the first legislative attempt to structure judicial thinking about obviousness.”).

108 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1304 (2012) (noting that U.S. Patent Act §§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections).

109 Transcript of Oral Argument at 17, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (No. 10-1150); see also id. at 28 (suggesting that treating laws of nature as non-novel for purposes of novelty and nonobviousness analysis “maybe . . . goes too far . . . because we know that a lot of work goes into these laws of nature”).


111 Id. at 1304.
has also taken the position that these inquiries are distinct in principle. The Court should be able to recognize how talk of the necessity of an “inventive act” or “inventive concept” when discussing subject-matter eligibility can muddy the waters.

The Court’s later invocation of the notion of an “inventive act” in Myriad does not indicate the contrary. In Myriad, the Court did not define the phrase but seemed to use it as a sort of stand-in for an act or series of acts that starts with a naturally occurring substance or thing such as a bacterium and ultimately yields something “with markedly different characteristics,” such as the oil-eating bacteria that the Court had previously found to be patentable subject matter. In the Court’s view, even according to what Myriad’s patents suggested was important about their claimed inventions, the difference between naturally occurring DNA and the isolated sequences of DNA recited by some of the patents’ claims was inconsequential and, therefore, apparently not “markedly different.” According to the Court, failure to write these claims in terms of specific chemical compositions, instead of their genetic sequences, suggested that these sequences, not the absence or presence of covalent bonds to surrounding genetic material, should be the fundamental focus of concern. Hence, the absence of those bonds in the claimed versions of isolated DNA did not make them “markedly different” from naturally occurring non-isolated DNA, and merely isolated DNA was therefore unpatentable.

In contrast, for reasons that a relatively cursory section of the Court’s opinion left somewhat mysterious, the Court held that Myriad’s claims for complementary DNA (cDNA) satisfied the requirement of subject-matter eligibility because, generally speaking, cDNA does not include certain DNA sequences appearing in naturally occurring DNA and is thus meaningfully “distinct from the DNA from which it was derived.” The Myriad opinion did not make much effort to explain what made cDNA’s distinction from naturally occurring DNA meaningful whereas merely isolated DNA’s distinction was

112 Id. (observing that the § 101 and § 102 inquiries “need not always” overlap and that sections such as §§ 102 and 103 of the Patent Act were “not equipped to do” the same work as § 101).

113 Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013) (internal quotation marks omitted).

114 See id. (“Myriad’s patent descriptions highlight the problem with its claims.”).

115 Id. at 2118 (observing that the relevant “claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes”).

116 See id. at 2117 (“In this case, . . . Myriad did not create anything.”).

117 Id. at 2119.
not.\textsuperscript{118} For purposes here, the key point is that, despite Myriad’s suggestion that the presence or absence of an “inventive act” is crucial, analysis of whether there is such an act does not appear to be “invention” analysis in the nature of the novelty and nonobviousness analyses.\textsuperscript{119} Instead, the question of whether there is an “inventive act” for purposes of subject-matter eligibility seems largely to be code for the question of whether there is a “marked difference” between the claimed invention and excluded subject matter, in this case a naturally occurring sequence of DNA.\textsuperscript{120} As in Mayo, the Court appears to have believed that the fundamental question is whether the “claims add enough” to excluded subject matter to bring themselves within the scope of subject-matter eligibility.\textsuperscript{121}

Alice appears to confirm that the Court’s language regarding an “inventive concept” or “inventive act” is a kind of judicial term of art in the subject-matter eligibility context. When there is excluded matter in a patent claim, the question of whether there is a sufficient “inventive concept” or “inventive act” appears fundamentally to equate to the question of whether there is something else sufficient to bring the claim within the bounds of subject-matter eligibility. Under this understanding, the use of terms such as “inventive concept” or “inventive act” merely signals that this inquiry into sufficiency is at issue, and the terms do not signal any necessary connection to questions of novelty or nonobviousness. In apparent accordance with this understanding, the Court’s opinion in Alice emphasized equivalence between the term “inventive concept” and such sufficiency by observing that the Court had “described step two of [the Mayo framework] as a search for an ‘inventive concept’—i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon [patent-ineligible subject matter] itself.’”\textsuperscript{122}

True, Mayo features language that understandably generates questions about the extent to which the Court envisions novelty and nonobviousness analyses as parts of the assessment of subject-matter eligibility.\textsuperscript{123} In discussing what makes for a sufficient addition to a

\textsuperscript{118} Id.
\textsuperscript{119} Id. at 2119 n.9.
\textsuperscript{120} Id. at 2116–17.
\textsuperscript{121} Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1297 (2012).
\textsuperscript{123} See Bernard Chao, Finding the Point of Novelty in Software Patents, 28 BERKELEY TECH. L.J. 1217, 1220 (2013) (“The Supreme Court used a kind of point-of-novelty analysis in
law of nature, Mayo at times suggests that a process focused on a law of nature must contain something other than “well-understood, routine, conventional activity” in combination with the law of nature or its understanding. \(^{124}\) Perhaps the strongest statement of this sort comes in a passage in which Mayo quoted the Court’s earlier opinion in Flook to make the following point: “[P]ost-solution activity that is purely conventional or obvious . . . can[not] transform an unpatentable principle into a patentable process.”\(^{125}\) At least in isolation and absent attachment of narrowing significance to the term “post-solution activity,” this language suggests that there must be novelty or nonobviousness outside the patent-ineligible subject matter in a patent claim.

But other language in Mayo suggests that the Court only intended to embrace a qualified version of the assertion derived from Flook. The Court’s Mayo opinion later characterizes the Flook language as encapsulating a view “that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”\(^{126}\) The language emphasized in this quotation explicitly narrows the circumstances to which the proposition from Flook is applied. The adverb “simply” and the verb “appending” both suggest that the Court envisioned the proposition from Flook as applying to a relatively limited class of essentially trivial combinations of excluded subject matter and “conventional steps.” In this formulation, the Flook proposition does not rule out subject-matter eligibility for all combinations of excluded matter with “conventional steps.” Likewise, the qualifying language “specified at a high level of generality” suggests that some forms of more narrowly specified “conventional steps” might support a finding of subject-matter eligibility.

The Court’s reasoning in support of the specific holding in Mayo similarly suggests that, although inclusion of “unconventional steps” might suffice to establish subject-matter eligibility,\(^ {127}\) the Court did

\(^{124}\) Mayo, 132 S. Ct. at 1294 (explaining that “the process claims at issue” failed requirements of subject-matter eligibility by noting, “[i]n particular, the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field”).

\(^{125}\) Id. at 1299 (alterations in original) (quoting Parker v. Flook, 437 U.S. 584, 589–90 (1978)) (internal quotation marks and citation omitted).

\(^{126}\) Id. at 1300 (emphasis added).

\(^{127}\) Id. at 1300 (explaining how patentable subject matter in a prior case featured “several
not believe that every combination of a law of nature with otherwise merely conventional steps necessarily fails the requirement of subject-matter eligibility. The Court provided four consecutive, enumerated paragraphs that laid out its reasoning.128

The first three paragraphs addressed separate limitations of the relevant patent claims.129 The first indicated the Court’s view that the claims’ step of “administering” a drug amounted to no more than a sort of field limitation that the Court had previously indicated does not generally suffice to establish subject-matter eligibility.130 In explanation of this view, the Court said (1) that “the ‘administering’ step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs”; (2) that this audience was not new as doctors had “used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims”; and (3) that, “[i]n any event, the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.”131 In the second paragraph, the Court addressed the “‘wherein’ clauses” in the claims and characterized these as “simply tell[ing] a doctor the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient.”132 The third paragraph noted that the claims’ final, additional part, a step calling for determination of metabolite levels, was “well-understood, routine, conventional activity previously engaged in by scientists who work in the field.”133

If the Court believed that the conventionality of a claim’s non-excluded subject matter suffices to establish lack of subject-matter eligibility, the Court presumably would have stopped the explanation of its holding at the end of these three paragraphs. The first three explanatory paragraphs had established the Court’s view that the claims in question involved nothing other than indisputably conventional

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128 Id. at 1297–98 (providing reasoning in four paragraphs starting with the words “First,” “Second,” “Third,” and “Fourth,” respectively).
129 Id.
130 Id.; Diamond v. Diehr, 450 U.S. 175, 191 (1981) (stating that the principle that a “mathematical formula as such is not accorded the protection of our patent laws . . . cannot be circumvented by attempting to limit the use of the formula to a particular technological environment”).
132 Id.
133 Id. at 1297–98.
steps that appeared in combination with a law of nature. But the Court apparently believed, contrary to at least one plain-language understanding of the earlier-quoted language from *Flook*, that this understanding of the claims was insufficient to establish lack of subject-matter eligibility. Evidently because the Court believed more needed to be said, the Court’s explanation continued:

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.\(^{134}\)

For certain patent law practitioners and academics, the language of this fourth paragraph undoubtedly sounds gratingly resonant of concerns with “synergy” in the context of analyzing a claim for nonobviousness.\(^ {135}\) For present purposes, however, the key point is that, in this fourth paragraph, the Court is examining something other than whether any of a process claim’s steps are unconventional. This point is reinforced by the fourth paragraph’s citation of *Diehr*, complete with its lengthy parenthetical quotation of *Diehr’s* statement that “a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.”\(^ {136}\) In *Diehr’s* terms, the conventionality or unconventionality of such steps might affect whether they merely constitute “insignificant . . . activity” formally appended to unpatentable subject matter, but insignificance or significance for purposes of the subject-matter eligibility might be established on grounds other than such steps’ conventionality or unconventionality.\(^ {137}\) In short, the fourth paragraph of the *Mayo*

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134 *Mayo*, 132 S. Ct. at 1298 (citation omitted) (citing *Diehr*, 450 U.S. at 188 (“[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.”)).

135 *Compare* KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 416–17 (2007) (noting that, in analyzing questions of nonobviousness for purposes of a prior case, the Court had concluded a combination of “two pre-existing elements” “did not create some new synergy”), with Rich, *supra* note 92, at 43 (“As for synergism, I don’t know what Justice Douglas meant by it as applied to mechanical devices.”).

136 *Diehr*, 450 U.S. at 188.

137 *Id.* at 191–92 (stating that “insignificant post-solution activity will not transform an unpatentable principle into a patentable process” without specifying how significance is determined).
Court’s explanation of its specific holding indicates that, although the conventionality or unconventionality of the separate steps appended to unpatentable subject matter can be relevant to subject-matter eligibility, such element-by-element conventionality or unconventionality is not necessarily determinative.138 As the Court later stated explicitly when applying and restating the Mayo “framework” in Alice, courts adjudicating subject-matter eligibility must also consider “all claim elements . . . in combination,” consistent with “the general rule that patent claims must be considered as a whole.”139

More subtly, the Court’s opinion in Mayo might also suggest a specific way by which subject-matter eligibility may be established without inclusion of an unconventional step. The Court’s opinion observed that the patent claims at issue did not specify any subsequent course of treatment and thus “tie up the doctor’s subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations.”140 The Court’s language thereby touched on a distinction that at least two Justices, Justices Sotomayor and Kagan, highlighted at oral argument—a distinction between patent claims that specify a course of treatment, a classic form of practical application of technical knowledge, and claims, like those at issue, that do not specify any course of treatment but instead essentially just specify a test and associate information with that test.141 Justice Kagan particularly emphasized this distinction. At one point, Justice Kagan noted that what the claims at issue did not do “is say at a certain number, you should use a certain treatment; at another number, you should use another treatment,” and she openly wondered why the claims did not include such a treatment step given that a claim including such a step “clearly would have been patentable. Everybody agrees with that.”142 Unless one assumes Justice Kagan was playing devil’s advocate, she seems to have signaled a view that it is uncontroversial that claims that specify courses of

138 Mayo, 132 S. Ct. at 1298.
139 Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2355 n.3 (2014) (internal quotation marks omitted).
140 Mayo, 132 S. Ct. at 1302.
141 See, e.g., Transcript of Oral Argument at 47, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (No. 10-1150) (recording Justice Kagan’s statement, “And I think that the difference people are noting or some people are noting is that this is not a treatment protocol”); id. at 59–60 (recording a question from Justice Sotomayor expressing concern about the status of “treatment patents”).
142 Id. at 47.
treatment involve the sort of “particular applications of [natural] laws” that the Mayo Court believed are generally patent eligible. 143

The Court’s later opinion in Alice appears to have provided more explicit grounding for the view that a post-diagnostic treatment step can provide a ready route to subject-matter eligibility. First, the Court offered a distinct explanation for the result in Diehr, a case in which the Court found in favor of the subject-matter eligibility of claims for a method of curing rubber in accordance with a mathematical formula. 144 Mayo had explained the result in Diehr vaguely and arguably even grudgingly: according to Mayo, the claims at issue in Diehr were patent eligible “because of the way the additional steps of the process integrated the equation into the process as a whole”; because there was no suggestion that those additional steps or their combination “were in context obvious, already in use, or purely conventional”; and because those steps “apparently added to the formula something that in terms of patent law’s objectives had significance.” 145 Alice emphasized that the patent claims in Diehr were patent eligible because they “used [their] equation in a process designed to solve a technological problem” and thereby “improved an existing technological process.” 146

Subsequent discussion in Alice reinforced the hint that “solv[ing] a technological problem” could be a key to patent eligibility. The Court’s opinion later explained the patent ineligibility of the claims in Alice in part by pointing to their failure even to “purport to improve the functioning of [a] computer” or to “effect an improvement in any other technology or technical field.” 147 In short, as Donald Chisum has suggested, 148 Alice suggests that “solv[ing] a technological problem” is one way to establish the presence of “an ‘inventive concept’—i.e., an element or combination of elements that is sufficient to ensure

143 Mayo, 132 S. Ct. at 1302. Of course, even if specifying a course of treatment can make a patent claim subject-matter eligible, the degree to which that course of treatment needs to be specified is another question on which the courts will likely need to opine. Cf. 2014 USPTO GUIDANCE, supra note 60, at 15–17 (discussing three hypothetical examples of claims involving a treatment step in accordance with an observation that exposure to light can help with a patient’s “mood disorder”).


147 Id. at 2359.

that the patent in practice amounts to significantly more than a patent upon [patent-ineligible subject matter] itself.” If changing a course of patient therapy is understood to entail “solv[ing] a technological problem,” one can then explain why Justice Kagan was apparently so confident that the addition of a detailed therapeutic step to Prometheus’ claims would have rendered them patent eligible.

In sum, the Court’s recent opinions and oral-argument colloquies provide substantial evidence that the Justices are more than capable of the judicial housecleaning advocated above. If and when the Court revisits questions of patentable subject matter, the Court’s issued opinions should take more care in quoting and implicitly endorsing language in oft-cited precedents. Further, the Court can and should make clear that the qualifications that the Mayo opinion places on Flook’s language about conventionality are both deliberate and meaningful: unconventionality of appended steps can suggest their significance to the subject-matter eligibility analysis, but conventionality of those steps does not necessarily establish their insignificance. The eligibility analysis is fundamentally intended to be pragmatic, and, in this spirit, Alice has indicated that subject-matter eligibility may be established by showing that a patent claim involves solution of “a technological problem.” Ultimately, subject-matter eligibility analysis is to be grounded in a bottom-line principle stated in Mayo: “If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.”

The Court’s invocation of concerns about crafty drafting leads to this Part’s final suggestion. This suggestion is that, in future opinions, the Court should emphasize that the fundamental focus of modern subject-matter eligibility case law has been to curtail a relatively extreme subset of potential patent claims that may justifiably be viewed as entailing efforts to achieve the equivalent of patenting a law of nature, natural phenomenon, or abstract idea. As the concern with abusively artful claim drafting suggests, the subject-matter exclusions seem primarily intended to operate as safety valves that are triggered

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149 Alice, 134 S. Ct. at 2355 (internal quotation marks omitted).
150 Id. at 2358.
152 Cf. Golden, supra note 7, at 1061 (arguing that subject-matter eligibility doctrines “are largely intended to provide doctrinal safety valves that provide official decision makers with some room—but substantially limited room—to ensure that the substance of subject-matter restrictions is not gutted through strategic claim drafting”).
by claims that push on certain aspects of patentable subject matter’s peripheries. As with a great variety of safety-valve doctrines that might otherwise generally unsettle large areas of law, explicit emphasis on how the subject-matter eligibility exclusions are directed at relatively extreme situations can help address concerns about the exclusions’ scope and administrability, restraining and thereby making more manageable their application by reminding judges and patent examiners that the exclusions from subject-matter eligibility such as that for laws of nature are not meant to come close to swallowing patent law’s whole. Just as contract law has survived the existence of unconscionability doctrine despite its fuzziness and its posited threats to personal autonomy or judicial administrability, patent law can survive the subject-matter exclusions as long as courts and administrators are committed to keeping them reasonably contained.

CONCLUSION

Because of patent law’s fundamental relation to innovation, patent law’s “steady state” might naturally be one of disruptive flux. A form of such disruption has recently come to previously dormant is-

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153 See, e.g., Mark P. Gergen, John M. Golden & Henry E. Smith, The Supreme Court’s Accidental Revolution? The Test for Permanent Injunctions, 112 COLUM. L. REV. 203, 227 (2012) (“The traditional undue-hardship defense acts not as a no-injunction default but instead as a form of safety valve, enabling courts to deny injunctive relief under circumstances where such relief appears very unlikely to serve the public interest or, perhaps more specifically, a goal of maximizing net private interests.”); Stewart E. Sterk, Freedom from Freedom of Contract: The Enduring Value of Servitude Restrictions, 70 IOWA L. REV. 615, 654 (1985) (“Given the [changed conditions] doctrine’s narrow scope, combined with an appropriate judicial hesitation to interfere with servitudes that embody their own limitations, the uncertainty costs imposed by the changed conditions doctrine may be a small price to pay for a safety valve against continuation of obsolete restrictions.”) (footnote omitted)); cf. E. ALLAN FARNSWORTH, CONTRACTS § 4.28, at 302 (4th ed. 2004) (“On the whole, judges have been cautious in applying the doctrine of unconscionability, recognizing that the parties often must make their contract quickly, that their bargaining power will rarely be equal, and that courts are ill-equipped to deal with problems of unequal distribution of wealth in society.”); John F. Manning, Textualism and the Equity of the Statute, 101 COLUM. L. REV. 1, 118 (2001) (contending that “the absurdity doctrine provides an important, albeit limited, safety valve” for textualist statutory interpretation).

154 See FARNSWORTH, supra note 153, at 299–300 (“That the term [“unconscionability”] is incapable of precise definition is a source of both strength and weakness.”).

155 See Richard A. Epstein, Unconscionability: A Critical Reappraisal, 18 J.L. & Econ. 293, 315 (1975) (contending that “when the doctrine of unconscionability is used in its substantive dimension, . . . it serves only to undercut the private right of contract in a manner that is apt to do more social harm than good”).

156 See FARNSWORTH, supra note 153, at 302 (noting that, “[o]n the whole, judges have been cautious in applying the doctrine of unconscionability”).

sues of subject-matter eligibility. The Supreme Court has played a prime role in these developments but has also complicated further progress by uncritically reiterating or citing a tangle of principles and precedents that have long left patent-law experts scratching their heads.

There is reason to hope that the judiciary—and the Supreme Court in particular—can do better. Oral argument transcripts suggest that members of the Supreme Court appreciate many of the difficulties with their case law. The Justices appear to understand the desirability of clarifying aspects of that law, including by signaling that subject-matter eligibility analysis focuses primarily on policing the patent system’s peripheries, generally leaving to requirements such as novelty, nonobviousness, and adequate disclosure the task of policing its core. So far, the substance of the Court’s opinions has lacked much of the sharpness and self-awareness that the Justices have displayed at oral argument. In its written work product, the Court can do better. Through more critical appraisal of the Court’s prior opinions and more careful use of apparent terms of judicial art such as “inventive concept,” the Court can do more to promote the capacity of the patent community, including the lower courts and USPTO, to fill in the gaps that the Court’s jurisprudence inevitably and often deliberately leaves.

on patent law’s administrative institutions and forced repeated, dramatic change in the U.S. patent system’s early decades”).

See supra text accompanying notes 12–17.

See supra text accompanying notes 32–42. See generally Lon L. Fuller, The Morality of Law 39 (rev. ed. 1969) (listing among “distinct routes to disaster” “a failure to make rules understandable,” “the enactment of contradictory rules,” and “a failure of congruence between the rules as announced and their actual administration”).