



Flaws in the Supreme Court's §101 Precedent and Available Ways to Correct Them

By Judge Paul Michel & John Battaglia / April 27, 2020

Amid the crush of patent-eligibility case law, *see* 35 U.S.C. §101, patent lawyers and even courts can lose sight of the key principles and precedents that serve as the foundation of the eligibility analysis. Or they may not have appreciated in the first place the underlying bases for these §101 cases and whether, for example, those cases accord with precedents they cite from decades before. In any event, this article addresses these foundational Supreme Court precedents for §101 and the *Mayo-Alice* ineligibility regime that dominates the patent landscape today. In particular, we trace the Court's precedents from nearly 50 years ago, with an emphasis on key cases separated by some 30 years but tied together by the Court's representation that it has faithfully followed (and not overruled) any such precedent. After analyzing the precedent in this light, with due emphasis on the Supreme Court's decisions in *Diamond v. Diehr*, 450 U.S. 175 (1981) and *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), the article briefly examines the U.S. Patent and Trademark Office's 2019 Patent Eligibility Guidance on §101—the Article II branch's response to the §101 sea change wrought by the Article III courts. Finally, based on these authorities, the article offers a mix of points and observations for patent litigators and judges to consider as they continue to shape §101's eligibility law.

I. The Multi-Step, "Conventional," and Eligible Claims in *Diehr* (1981)

Diamond v. Diehr is the main case from a nine-year period (1972-1981) in which the Supreme Court addressed §101 on four precedential occasions. In *Diehr*, the Court specifically addressed the patent eligibility of a claimed multi-step process for curing synthetic rubber. 450 U.S. at 177. The claimed steps recited use of both a well-known mathematical equation (the "Arrhenius equation") and a "digital

computer” to implement it, “in conjunction with” multiple steps for heating the rubber, determining the “amount of time” for opening the rubber mold, and removing the rubber therefrom. *Id.* at 177-78. The PTO examiner, however, rejected the claims as ineligible for patent protection under 35 U.S.C. §101. *Id.* at 180-81. The examiner reasoned that the steps in the claim “carried out by a computer” were ineligible under the Court’s precedent, and that all the other steps on rubber-curing were “*conventional* and necessary to the process and *cannot be the basis of patentability.*” *Id.* at 178 (emphases added throughout unless otherwise noted). The PTO’s appellate board affirmed the examiner but the Court of Customs and Patent Appeals (CCPA) reversed. *Id.*

In an opinion that still carries wide precedential value today, the Supreme Court affirmed, confirming the patent-eligibility of the *Diehr* claims. Notwithstanding the “judicially created” or “implied” exceptions to §101, *Diehr* emphasized that the same interpretation principles applied to the patent-eligibility statute as with any other provision: The “common and ordinary meaning” of the words used therein applied, and “courts could not read into the patent laws limitations and conditions which the legislature has not expressed.” *Id.* at 182 (citation omitted). *Diehr* also reiterated that it must interpret §101 mindful of Congress’s intent that “statutory subject matter includes *anything under the sun that is made by man.*” *Id.* at 182 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); S. Rep. 1979, 82nd Cong. 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82nd Cong., 2nd Sess. 6 (1952)). And it referred to the “historical purposes of the patent laws and §101 in particular,” *Diehr*, 450 U.S. at 181, indicating courts must interpret §101 consistent with the Founders’ vision for “liberal[ly]” encouraging “ingenuity,” *Chakrabarty*, 447 U.S. at 308-09 (“The [Patent] *Act embodied Jefferson’s philosophy that “ingenuity should receive a liberal encouragement.”*) (quoting 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871)).

Given this wide patent-eligibility berth, *Diehr* recognized that a “claim drawn to subject matter otherwise statutory,” i.e., eligible, does *not* become ineligible

“simply because it uses a mathematical formula, computer program, or digital computer.” *Id.* at 187. Indeed, *Diehr* **rejected** the notion that having even “**several [claimed] steps**” on a “mathematical equation and a programmed digital computer” (i.e., ineligible subject matter) necessarily rendered the claim ineligible. *Id.* at 185. Instead, *Diehr* recounted classic examples for the three longstanding but “implied exceptions” to § 101’s eligibility criteria, illustrating that patent protection doesn’t extend to an abstract idea “**of itself**,” or for a law of nature or natural phenomenon “itself.” *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. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”

Id. (“An idea of itself is not patentable,” “A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented ...”) (citations omitted).

A. *Diehr* Distinguishes *Flook* (1978) and *Benson* (1972).

Moreover, *Diehr* explained that the Court’s then-recent precedents on these §101 exceptions stood “for no more than these [same] long-established principles.” *Id.* Indeed, in each of *Parker v. Flook*, 437 U.S. 584, 587 (1978) and *Gottschalk v. Benson*, 409 U.S. 63, 64, 72 (1972), the PTO examiner indisputably found and the parties **agreed** that the respective claims there were “in practical effect on the **formula itself**” for computing an “updated alarm limit” (*Flook*) and, “in practical effect ... on [an] **algorithm itself**” “for converting binary-coded” numbers (*Benson*). In each case, the Supreme Court concluded that claims such as these were ineligible. *Id.* The dispute and analysis in those cases focused then on a point which no one disputes today, *viz.*, whether an algorithm “itself” was ineligible subject matter. *E.g., Benson*, 409 U.S. at 67-72.

“In contrast,” said the Court, *Diehr*’s multi-step claims “do **not** seek to patent a mathematical formula or other patent-ineligible concept. Instead, they seek protection for a [multi-step] process of curing rubber:

[Diehr’s claimed] process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process [for curing rubber] Obviously, one does not need a “computer” to cure natural or synthetic rubber, but if the computer use ... significantly lessens the possibility of “overcuring” or “undercuring,” the process as a whole does not thereby become unpatentable subject matter.

Id. at 187. Accordingly, the Court repeatedly described *Diehr*’s claims as drawn **not** to an ineligible concept, such as an equation, but instead to a “**physical and chemical process for molding**” and curing rubber products. 450 U.S. at 180, 184. As it reasoned, this claimed rubber-molding process in turn related to the “[i]ndustrial processes ... which have historically been eligible to receive the protection of our patent laws.” *Id.* And it concluded that “[b]ecause we do not view [the *Diehr*] claims as an attempt to patent a mathematical formula, but rather to be **drawn to an industrial process for the molding of rubber products**, we” uphold the claims’ eligibility. *Id.* at 192-93.

B. Diehr Uses “Directed to,” “Drawn to,” and “Recited” When Referring to the Narrow Scope of Claims Subject to a §101 Implied Exclusion, unlike *Flook*

Beyond the analysis above, *Diehr* used arguably more restrictive phrases than *Flook* when describing the claimed matter subject to the §101 “exceptions.” For example, whether purposefully or not, *Diehr* used the terms “**drawn to**,” “**directed to**,” and “**recited**” interchangeably, indicating again that a claim was subject to an implied §101 exclusion if written on, essentially on, or “in practical effect on” an abstract idea “**itself**,” or law of nature or natural phenomena itself. *See, e.g.*, 450 U.S. at 181 (recounting procedural history and *Diehr*’s multi-

step rubber-molding claim as a “*claim drawn*” to subject matter otherwise statutory does not become nonstatutory because a computer is involved. [Diehr’s] *claims were not directed to* a mathematical algorithm [although “several steps” recited its use] or an improved method of calculation but rather *recited* an improved process for molding rubber articles”); *id.* at 186 (summarizing *Flook*, *supra*, as having “*claims ... drawn to* a method for computing an ‘alarm limit’”); *see also id.* at 187. To that same end, *Diehr* instructed that courts conducting this §101 analysis must consider a patent’s “*claims ... as a whole*” and especially “a process claim because 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.” *Id.* at 188.

On the other hand, the *Flook* decision itself used a range of terms, both narrow and broad, when referring to the claimed matter subject to a §101 judicial exclusion—terms such as what the claims “*cover,*” “*are directed essentially to,*” “*involved in,*” and “*describe.*” *See, e.g.,* 437 U.S. at 586 (“The [Flook] claims *cover* any use of [Flook’s] formula ... *involved in* a process comprising the catalytic chemical conversion of hydrocarbons. They do not, however, *cover* every conceivable application of the formula.”); *id.* at 587 (recounting that PTO examiner found that “a patent on this method ‘would in practical effect be a patent on the formula or mathematics *itself*’” and that the “examiner concluded that the *claims did not describe* a discovery that was eligible for patent protection”); *id.* at 590 (describing the “algorithm” or “mathematical formula *involved in*” *Gottschalk v. Benson, supra*, and that recited the formula “itself”); *id.* at 595 (quoting with approval the CCPA’s analysis that “if a *claim is directed essentially* to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory”) (citation omitted). *Benson* similarly used “*cover*” and “*involved*” to refer to ineligible claims whose body recited only the algorithm itself, as further reflected in the opinion’s appendix and by the PTO examiner’s “itself” fact-finding. 409 U.S. at 64, 68, 71-72.

C. Under *Diehr*, §102-103 and What was “Well-known” and Conventional are “Irrelevant” to Whether the Claimed Subject Matter is §101 Eligible.

Diehr reached one other key holding, still extant today. Examining §101’s text and legislative history, *Diehr* held that considerations of what claim elements “were *well known and in common use*” before the claimed invention—or whether those claims were “novel” or “non-obvious”—had “*no relevance* in determining whether the subject matter of a claim” was §101-eligible. *Id.* at 189-90.

As *Diehr* explained, those sections on patentability, such as §102 on “novelty,” addressed what was “well known” and conventional. *Id.* And the PTO could still determine “later” that the claims didn’t deserve patent protection because they couldn’t meet the “statutory conditions of novelty under §102 or non-obviousness under §103. But rejection on either of these grounds [doesn’t] affect the determination” that the claims recite patent-eligible subject matter under §101. *Id.* at 191. Consistent with this holding, the *Diehr* majority made no mention of an “inventive concept” analysis, first raised in *Flook, supra*, that perforce required analysis of what was “well-known,” “conventional,” and new or obvious.

D. Justice Stevens’ Dissent Highlights that *Diehr* Rejected *Flook’s* “Inventive Concept” Test and Limited the “Implied” Exceptions to §101.

As the author of *Flook, supra*, Justice Stevens’ lengthy dissent in the *Diehr* case is telling for several reasons. First, while tracing the history of presidential commissions, the PTO’s, the CCPA’s, and the Court’s treatment of computer technology, his dissent made clear that the *Diehr* majority had overruled and even “*trivialize[d]*” *Flook* and *Benson, supra*. See *Diehr*, 450 U.S. at 205.

Specifically, said Justice Stevens, *Flook* had “clarified” *Benson* such that its §101 analysis “was *not* limited” to claims that “wholly preempt[]” an algorithm or that claim an “algorithm *itself*.” *Id.* at 204. But as the dissent admitted, the parties in those cases agreed, and the PTO indisputably found, that the respective claims-at-issue were “in practical effect” on such an “algorithm *itself*.” See, e.g., *id.* at 211-14.

Second, Justice Stevens urged that his *Flook* opinion had explained the “correct” §101 test for assessing the eligibility of a patent claim “employing” an algorithm—*viz.*, the “*inventive concept*” test *not* used or even mentioned by the *Diehr* majority. 450 U.S. at 204. As he noted, the CCPA had not “enthusiastically received” *Flook*’s “inventive-concept” test, with the CCPA decisions saying *Flook* had “erroneously commingled distinct statutory provisions which are conceptually unrelated.” *Id.* at 204. And he expressly faulted the *Diehr* majority for “fail[ing] to focus upon what *Diehr* claims to have discovered” and invented. *Id.* at 212-13, n.36.

Third, in proceeding to apply (or “commingle”) the “irrelevant” inventive-concept test nonetheless, Justice Stevens assessed what was known at the time about the rubber-curing process. *Id.* at 208. In so doing, he found it “difficult to believe” that *Diehr*’s rubber-curing patent application disclosed anything “novel.” *Id.* Despite this, Justice Stevens turned and criticized the *Diehr* majority for “completely disregard[ing]” the “distinction between the [eligibility] issue” under §101 and whether the invention “is in fact novel” under §102. *Id.* at 211-12.

II. Justice Breyer’s 2006 *Corp.* Dissent from the Supreme Court’s DIG

Diehr thereafter stood as the Court’s last word on §101 for essentially 30 years. That timeframe may reflect that *Diehr* had stabilized §101 law and “liberally” promoted investment and innovation. It may also reflect that the Court was content to leave the issue to the new “patent” court that went into existence the year after *Diehr*; namely, the Federal Circuit.

Whatever the reason, in 2006, Justice Breyer issued a notable 14-page dissent in a §101 case that the Court dismissed as improvidently granted, reasoning the petition had not specified §101 as the basis of its appeal. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 134 (2006) (Breyer, J., dissenting). Joined by Justices Stevens and Souter, Breyer urged that “clarification of the scope of patentable subject matter” presented “an important” question of “public interest,” requiring a Court decision “sooner rather than later.” *Id.* Beyond

that, Breyer emphasized his views on the §101 merits, liberally citing *Diehr* and *Flook, supra*, and presaging the analysis that was to come in his 2012 *Mayo* opinion. His dissent urged, for example:

- That the claimed diagnostic test in *Corp.* merely alerted doctors to the “natural phenomena” of the “*correlation* between homocysteine and vitamin deficiency,” *id.* at 134-35;
- Doctors could “*use any test at all*” to obtain these results and, per the claims, merely had to consider or “think about them” when treating patients, at 136-37;
- If permitted to stand, §101 and patents such as these would allow a greater patent thicket to develop—one where “*too much* patent protection can impede rather than ‘promote’” “the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements,,” at 126-27 (emphasis in original).

Given this, Justice Breyer’s dissent concluded that the claimed invention is “invalid, no matter how narrowly one reasonably interprets that ‘natural phenomena’ doctrine.” *Id.* at 134-37. His extensive foray into the merits said nothing about claims needing to demonstrate an “inventive concept” to prove §101-eligible. That made sense. After all, while joining Breyer’s dissent here, Justice Stevens had also repeatedly made clear in his own *Diehr* dissent some 25 years earlier that the *Diehr* majority opinion itself had abrogated the “inventive concept” test.

III. The Next Generation of §101 Cases: *Bilski’s* Machine-or-Transformation “Clue”

The Court, of course, and Justice Breyer in particular eventually got their §101 chance, leading to the controlling *Mayo-Alice* regime today. But it first decided *Bilski*, holding in a splintered 5-4 decision that the Federal Circuit’s “machine-or-transformation” test for a process claim was merely an “important

clue” to §101 eligibility, **not** the lone test. *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010). Writing for the majority, Justice Kennedy indicated this test might not widely apply in the “Information Age,” although it suggested that claims to “inventions grounded in a physical or other tangible form” may well qualify under §101. *See id.* at 3227. Otherwise, *Bilski* emphasized that the “ordinary meaning” of the Patent Act’s terms applied; that “[a]ny suggestion” to the contrary “in this Court’s case law” has served only to explain the existence of the three “implied” §101 exceptions; and that, given this ordinary-meaning principle, the Act didn’t permit the machine-or-transformation test to stand as the only test for assessing eligibility. *Id.* at 3226-27. The Court nevertheless applied the machine-or-transformation test, affirmed the ineligibility judgment, but offered no controlling test or guidance. *See, e.g., id.* at 3231.

A. After 30+ Years, *Mayo* Dramatically Changes the Law on U.S. Patent-Eligibility—All While Claiming It was Following Precedent.

But Justice Breyer’s unanimous 2012 opinion in *Mayo* did supply a controlling §101 framework—and dramatically changed the U.S. patent laws as a consequence.

Citing *Flook*, *Mayo* first indicated it must interpret the Act (and judicial “exceptions” thereto) skeptically, with notions that the patent “draftsman” could evade the §101 exceptions merely by adding conventional elements or other such “post-solution activity” to a claim. *See, e.g.,* 132 S. Ct. at 1294. *Mayo* otherwise said nothing about the “ordinary meaning” principle that *Bilski* and *Diehr* emphasized, although it recognized that the “exclusivity” of the patent laws provides the “monetary incentives” to invest and “invent[.]” *Id.* at 1305.

Moreover, *Mayo* emphasized it was **not** overruling or yielding to “any temptation to depart from” the Court’s §101 precedents, including the two cases “**most directly on-point**”: *Diehr* and *Flook*. 132 S. Ct. at 1298, 1302. From the outset, however, *Mayo* pronounced that the §101 cases “insist” on an assessment of a

claim's *"inventive concept,"* citing *Flook*—i.e., the very "inventive concept" case that Justice Stevens himself recognized, in dissent, had been *"trivialized"* and overruled (at least in part) by the *Diehr* majority. 132 S. Ct. at 1294.

Mayo also expanded the sweep of its "inventive concept" test to patent claims beyond those that were merely on an ineligible concept "itself"—as was characterization of the claims-at-issue in *Benson* and *Flook, supra*. See, e.g., *id.* at 211-14 (citing *Flook*, 437 U.S. at 586; *Benson*, 409 U.S. at 71-72.)

Indeed, *Mayo* now required that a patentee demonstrate an "inventive concept" for *any claim* that *"focuses on"* such an ineligible idea or natural law. 132 S. Ct. at 1294. And for all such claims, held *Mayo*, a patentee must show how the "other elements or combination of elements" in the claim *"amounts to significantly more* than a patent upon the natural law" or ineligible idea itself—i.e., an "inventive concept." *Id.*

A. Mayo's Treatment of Diehr's "Conventional" Findings and Holdings

In justifying these changes to §101 law, *Mayo* not only disregarded the *Diehr* holdings described above, but also mis-described *Diehr's* core facts and analysis, described below.

First, according to Justice Breyer in *Mayo*, *Diehr* had *"nowhere suggested"* that the multiple steps recited in the *Diehr* claim for rubber curing "were in context *obvious, already in use, or purely conventional.*" 132 S. Ct. at 1299. But the PTO in *Diehr* expressly found that the claimed rubber-curing steps there were *"conventional* and necessary to the process and *cannot be the basis of patentability"*—findings left undisturbed on appeal. 450 U.S. at 178.

Second, *Mayo* alleged *Diehr* had applied the *Mayo-Flook* "inventive concept" test, rather than abrogated it. More specifically, Justice Breyer in *Mayo* alleged that, in *Diehr*, the "other [claim] steps *apparently added* [something inventive] to the formula" in the claimed rubber-curing process and must have thereby "transformed [*Diehr's* claimed] process into an *inventive application.*" 132 S. Ct. at

1299. But *Diehr* repeatedly undercuts this *Mayo* assertion as well, holding that *Diehr*'s multi-step claims were *not* "an attempt to patent a[n] [ineligible] mathematical formula, but rather [were claims] ***drawn to an industrial process for the molding of rubber products***," 450 U.S. at 192-93, or to a "physical and chemical process for molding" and curing rubber products, *id.* at 180, 184. In other words, the multi-step claims in *Diehr* were *not* "drawn to" a formula or any other ineligible concept in the first place, precluding any need to reach the "inventive concept" test—even if *Diehr* had not rejected it. *See, e.g., id.* Moreover, Justice Stevens' *Diehr* dissent recognized the *Diehr* majority had overruled this "inventive concept" test.

Third, and relatedly, *Mayo* ignored *Diehr*'s unqualified holding that an analysis of the prior art, novelty, obviousness, and what elements of the claim "were well known and in common use" is "***irrelevant***" to §101.

Citing *Flook* again, *Mayo* instead analyzed the prior art and considered what was "***conventional and obvious***" and "***well-understood, routine, and conventional***"—the term of art now applicable to the "inventive concept" step of the two-step *Mayo-Alice* test. *See* 132 S. Ct. at 1297-98. As *Mayo* conceded, the §101 eligibility analysis may "overlap" after all with the §102 "novelty" analysis. *Id.* at 1304.

B. Mayo's New §101 Test and Application to Diagnostic Testing Claims

On the merits of its new §101 test, *Mayo* also rejected as ineligible the claimed diagnostic test for "administering" thiopurine drugs to a "subject" and measuring the body's reaction in the bloodstream to determine whether doctors should "increase" or "decrease" a therapeutic drug for auto-immune disease. *Id.* at 1297. As it explained, the claims merely described the natural "***correlation***" between the body's reaction to an administered compound ("thiopurine"), meaning the claims were "***focused***" on a natural law. *Id.* at 1296-97. And their recitation of additional steps on "administering" the drug and of measuring the results—"through whatever [test or] way the doctor or the laboratory wishes"—

were *not* “inventive,” but merely an instruction to make doctors aware of this natural relation and take this information *“into account when treating his patient.”* *Id.* at 1298. And as in *Lab. Corp., supra*, Justice Breyer emphasized that the *Mayo* ruling would cut against the “vast thicket of exclusive rights” that otherwise “might impede the flow of information that might permit, indeed spur, invention” *Mayo*, 132 S. Ct. at 1304.

The *Bilski* “machine-or-transformation” test didn’t change this outcome, held *Mayo*. That test is merely an eligibility “clue” and couldn’t supplant the “natural law” exception to §101. *Id.* at 1303. Notably, *Mayo* also addressed with approval but distinguished a well-known “English case,” *Nielson*, that had upheld the eligibility of claims where a “very valuable” machine had specifically applied the natural law or principle at issue. *Id.* at 1299-1300 (citation omitted). Cases dating back to *O’Reilly v. Morse* in 1854 have similarly evaluated cases abroad for determining §101-eligibility issues. *See, e.g.*, 56 U.S. 62, 112-21 (1854).

***C. Alice* Refines *Mayo* and Applies the “Directed to” Eligibility Framework**

With *Mayo* having restored (and even expanded) various *Flook*-based principles, the Court’s 2014 opinion in *Alice* then refined *Mayo* to fashion the familiar two-part “framework” used in all §101 cases today; namely, (1) whether the claims-at-issue *“are directed to”* a *patent-ineligible concept*, i.e., an abstract idea, law of nature, or natural phenomenon; and (2) if so, whether the additional claim elements, when considered “individually or as an ordered combination,” demonstrate an *“inventive concept,”* i.e., elements “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Alice Corp. Pty Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014). As in *Mayo*, *Alice* cautioned that courts must *“tread carefully in construing this exclusionary principle, lest it swallow all of patent law.”* *Id.* at 2354. To that point, *Alice* reiterated that “an invention is *not* rendered ineligible for [a] patent simply because it involves an abstract concept.” *Id.* (citation omitted).

In referring to this framework, *Alice* appears to be the first of the §101 cases that repeatedly used “**directed to**,” as opposed to phrases such as “drawn to,” “cover,” “directed essentially to,” “describes,” “involved in,” and the like, as used in *Diehr*, *Flook*, and *Benson*, *supra*. Otherwise, *Alice* itself, like the other recent §101 precedents, used various “directed to” stand-ins when referring to it—such as “drawn to” and “involves”—thus appearing to make its meaning and boundaries more difficult to discern. *See, e.g., id.* at 2353, 2356. More concretely, *Alice* held that the two-part ineligibility test applied to “abstract ideas” that included well-known business methods—methods such as the claimed scheme at issue there for “mitigating ‘settlement risk,’ i.e., the risk that only one party to an agreed-upon financial exchange will satisfy its obligation.” *Id.* at 2352, 2356 (describing “intermediated settlement” as a “fundamental economic practice long prevalent in our system of commerce”). *Alice* otherwise declined to “delimit the precise contours of the ‘abstract ideas’ category,” adding there existed “no meaningful distinction” between this “settlement” practice and the abstract idea of “risk-hedging” in *Bilski*, *supra*. 134 S. Ct. at 2357.

As to step two of its framework, *Alice* held that such abstract or presumptively ineligible claims couldn’t demonstrate an “inventive concept” merely because a “**generic computer**” helped implement them. *E.g., id.* at 2358. That analysis might differ, however, said *Alice*, if “for example” the claims “purport to **improve the functioning of the computer itself**,” or **improve “any other technology or technical field.”** *Id.* at 2359-60. But the *Alice* “intermediated settlement” claims there did no such thing, the Court concluded, as it used “some unspecified, generic computer.” *Id.*

D. The PTO issues its Guidance on §101—and “Additional” Guidance in Response.

As is well-known, the *Mayo-Alice* framework has effectuated a massive change in patent law, leading to numerous rulings that have rendered ineligible claims at (for example) the Rule 12(b) motion-to-dismiss stage, the summary-judgment stage, and stages in between and after (including appeal). While litigation has

sought to change this course, the Executive Branch has not stood by silent. Following a 2016 memorandum, the PTO in January 2019 issued a revised Patent Eligibility Guidance (“PEG”) on how its examiners would conduct the §101 analysis. In so doing, the PTO made plain that it was seeking to improve the “predictability,” “stability,” and “consistency” in the patent-eligibility analysis—goals that many have opined have been sacrificed since *Mayo* and that have in turn undermined the invest-and-innovate objectives of U.S. patent law. As part of this January 2019 Guidance, the PTO detailed its view of the *Mayo-Alice* process or “prongs” to follow and identified numerous examples for each of the three main “Judicial Exceptions” to §101 (i.e., the implied exceptions for “abstract ideas,” natural laws, and natural phenomena), as well as judicial cases that the Office considered helpful or not helpful.

In April 2019, the Federal Circuit held that this §101 Guidance and the examples therein didn’t bind the court, require *Skidmore* deference, or otherwise save the patentee’s case from the trial court’s Rule 12(b)(6) dismissal on §101 grounds. *See Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 2018-1218, at *12-14 (Fed. Cir. April 1, 2019) (non-prec.). Among other reasons, the PTO’s Guidance didn’t have formal rulemaking effect and the court had to consistently apply its own Article III precedent. *Id.* As a result, the court again held ineligible another claimed diagnostic test—one that it found nearly indistinguishable from the diagnostic tests described in its other §101 precedent. *Id.*

Thereafter, in mid-October 2019, the PTO issued its additional PEG on §101. This PEG continues to set forth the procedure and analysis that the PTO examiners should follow in applying the Office’s view of §101 and the *Mayo-Alice* “prongs” and “Judicial Exceptions” thereto. Unlike the January 2019 PEG, however, this Guidance no longer takes the case-comparison approach taken earlier, given concerns that judicial rulings on §101 have now become too numerous and too inconsistent to predictably and uniformly apply. Accordingly, and as the authors

here respectfully agree, this Guidance takes a step back and instead applies the “firmly rooted” precedents and principles on § 101 by the Supreme Court.

IV. The Supreme Court’s §101 Precedents—Practical Points and Observations for Patent Litigators and Judges

With this precedential foundation, we believe that the controlling §101 case law lends itself to consideration of the following points and observations—for patent litigators and judges alike.

1. **Use the Statute and Principles of Statutory Interpretation.** While seemingly case law driven, bear in mind that §101 and the application of the “implied exceptions” thereto still often depend on interpreting and applying those statutory sources, both textual and “implied.” Thus, parties and judges would do well to recall, for example, the “ordinary meaning” principles applicable to the §101 text, what it says, and what it does *not* say, as the Court emphasized in *Bilski* and *Diehr, supra*. Similarly, parties can point to Congress’s “*anything under the sun*” intent as to the breadth of eligibility under §101—and conversely, to the narrowness of the implied exceptions thereto, *see, e.g., Diehr; Chakrabarty, supra*. The same goes for the precedents’ discussion on the goals of the U.S. Constitution and patent laws in wanting to promote “*monetary incentives*” to invent, *Mayo, supra*, and to “*liberally encourage*” invention, as explained by the Founders and Thomas Jefferson (the author of the first U.S. patent statute), *Chakrabarty*, 447 U.S. at 308-09. So too with the *Mayo-Alice* cautionary instruction that courts must “*tread carefully*” in applying this two-part framework, given risks that the “implied exceptions” might “*swallow up*” all of patent law. Those looking to narrow the exceptions might also reference other interpretative principles that reflect the law’s skeptical view of “implied” statutory terms—principles such as those that disfavor “implied” statutory repeals of sovereign immunity, for example, or that disfavor the “implied” preemption of state laws. Cutting the other way is the *Mayo-Alice* emphasis on applying these exceptions with a skeptical eye for

the “*draftsman’s art*,”e., the notion that patent drafters will write claims in a way to obscure their reliance on an ineligible subject.

2. **The Scope of the “*Directed to*” Formulation.** Unlike (it seems) the Supreme Court’s recent §101 case law, the Federal Circuit has sought to impose some rigor on the “*directed to*” test now routinely used in light of *Alice*. But both that Federal Circuit guidance on saying “directed to” means putting a “focus on the claimed advance,” see, e.g., *Training Techs. Int’l v. IBG LLC*, 921 F.3d 1378, 1384 (Fed. Cir. 2019), and the Supreme Court’s varying formulations (e.g., “recited,” “drawn to,” “cover,” “directed essentially to,” “focus on,” “involved in,” “described”), have quite arguably rendered the “directed to” formulation overly subjective and panel-dependent at the Federal Circuit.

But it doesn’t have to be that way, and shouldn’t. After all, patent lawyers and judges alike could just focus more (so to speak) on the particular cases that more concretely illustrate what “directed to” (or whatever formulation the cases uses) may properly encompass. This includes the Supreme Court’s cases in *not* just *Mayo* and *Alice*, but also the “most directly on-point precedents” that *Mayo* emphasized it was honoring; namely, *Diehr* and *Flook*, *supra*, as well as *Benson*. As detailed above, *Flook* and *Benson* reflect that the proper scope for determining whether a claim is directed to an ineligible concept is whether the claim is essentially on the abstract idea, natural law, natural phenomenon “*itself*”—a formulation that approximates the “*per se*” standard for, e.g., British European patent laws.

Other litigants and courts at a different stage—say, for an en-banc rehearing petition—may consider whether the Supreme Court precedents specifically foreclose debate on the “*directed to*” meaning itself, as opposed to its precedents merely illustrating and informing that phrase. As the Court has long held, a point of law, merely “assumed” in an opinion, not “squarely addressed,” is *not* authoritative, and leaves the next court (or panel) “free to address the issue on the merits.” *Brecht v. Abrahamson*, 507 U.S. 619, 631 (1993). As discussed earlier, the Court’s §101 precedents don’t appear to “squarely

address” the meaning of this now-ubiquitous §101 phrase, meaning the Federal Circuit can still likely expound on the “directed to” scope accordingly.

3. **Applying *Diehr* as “Good Law” in All Respects—*Or* as Modified by *Mayo*.** As also detailed above, the Court in *Mayo* expressly purported to adhere to *Diehr* and other precedents, without acknowledging that it had modified *Diehr* in critical respects. Accordingly, those looking to apply *Diehr*’s full slate of holdings across-the-board (for example) could still plausibly do so, in our view, given *Mayo*’s assertion that it merely followed the “directly on-point” *Diehr*. And it appears that some lawyers and judges have taken this approach recently in the Federal Circuit, urging for example that *Diehr*’s “*irrelevant*” holding for §101 eligibility bars consideration of what was “conventional” and “standard” (or not “new” and “obvious”) for both steps of the *Mayo–Alice* framework. *See, e.g., Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 761-62 (Fed. Cir. 2019) (Newman, J., dissenting). And that approach, to be sure, may gather force by virtue of certain jurisprudential commands. The Supreme Court, for example, has instructed in strident and even emphatic terms that lower courts are not to overrule the Court’s precedential holdings, even when it appears that the basis for that holding has eroded, or the holding itself seemed “unsounded when decided,” “moth-eaten,” or “increasingly wobbly.” *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997). The bottom line is that a court such as the Federal Circuit must still apply those holdings and leave it to the “Court’s prerogative alone to overrule,” modify, or uphold its own precedents. *Id.* Otherwise, parties looking to apply or distinguish a *modified Diehr* decision could so do by reference to the case law analysis set forth herein and what *Mayo* has done with *Diehr* and §101.
4. ***Bilski*’s Machine-or-Transformation Test and Other *Bilski* Principles are Available.** *Bilski*’s machine-or-transformation test remains good law, albeit as an “important clue” to eligibility only. And *Bilski* itself, following that “clue” and without any other test to follow at the time, upheld the Federal Circuit’s application of it accordingly. Further, *Bilski* made clear that “inventions

grounded in a physical or other tangible form” may qualify under §101 as well—a point that may become more important as the §101 case law attempts to expand beyond, for example, computer-implemented business methods and diagnostic tests—and into processes that might seem “mechanical” or “physical” and previously thought unlikely to fail under the *Mayo-Alice* See, e.g., *AAM v. Neapco Holdings*, 939 F.3d 1355, 1365-68 (Fed. Cir. 2019) (applying *Mayo-Alice* two-part test to a claimed process for manufacturing specific auto parts), *rhr’g* and *rhr’g en banc petition pending*. That said, based on a quick review of Federal Circuit §101 precedents since *Bilski*, few if any cases appear to have adopted the machine-or-transformation test, whether as a dispositive point or an “important” clue to eligibility.

5. Eligibility Standards in Foreign Jurisdictions—e.g., China, Europe,

England. Patentees facing this §101 issue also shouldn’t forget to reference foreign patent laws—and specifically, the more-favorable foreign patent laws on the patent eligibility for diagnostic testing, business methods and software, for example—in countries such as England, China, or the European Union. For more than 150 years, the Supreme Court has favorably evaluated cases from foreign jurisdictions—England, for example—in assessing whether a U.S. patent claim has qualified as statutorily eligible for patent protection. See, e.g., *Mayo*, 132 S. Ct. at 1299-1300 (assessing English *Nielson* case on eligibility issue); *O’Reilly*, 56 U.S. at 112-17 (1854) (same).

Accordingly, the precedent invites reference by courts and litigators alike to foreign jurisdictions whose patent-eligibility criteria may inform the “implied” judicial exceptions under U.S. patent law. Patent owners, for example, may urge that, as to the scope and meaning of the *Mayo-Alice* “directed to” ineligibility step (i.e., *Alice* step one), England and Europe apply a narrow “per se” test—as in, a claim is ineligible for patent protection if it claims an abstract idea “*per se*.” They may fairly argue for example that this English “per se” test comports with the Supreme Court’s *Flook* and *Benson* holdings, where the implied §101 exceptions similarly applied to claims that were essentially or in “practical effect” on the idea, natural law or phenomenon “*itself*.” Similarly, some of the

world's other large patent systems, such as China's and Europe's, have eligibility criteria that purportedly afford more patent protection than U.S. law to diagnostic testing and computer-implemented business methods. Notably, these foreign cases are also *not* directly informing a U.S. statutory text *per se* (if you will), namely, 35 U.S.C. §101, but rather the "implied" or judicially created exceptions to the statute. Thus, it seems to us that there would be no principled objection, as in years past, with using foreign law to inform such a judicially created ineligibility standard, as opposed to the U.S. Constitution or a federal statute.

6. ***Alice's "Examples" of Eligible Claim Elements That Recite an Improvement in the Functioning of Computer Technology or in Other "Technology or Technical Fields."*** *Alice* said that the ineligible computer-implemented idea there for "mitigating 'settlement risk'" *could* have withstood *Alice's* test in other circumstances, as noted above. Specifically, the claims could have demonstrated an "inventive concept" if its claim elements reflected an *"improved functioning of a computer or in any other technology or field."*¹³⁴ S. Ct. at 2359-69. Patent litigators and Federal Circuit panels didn't miss this *Alice* suggestion, as they have often raised this exception-to-the-exception for "improved computer functioning" or improved technical areas. *See, e.g., DDR Holdings, LLC v. Hotels.com*, 773 F.3d 1245 (Fed. Cir. 2014); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016). Litigators and judges will surely continue to raise or explore the issue, particularly given the growing precedent that now backs it.
7. **The Scope or Meaning of Exceptions for an "Abstract Idea, Law of Nature, Natural Phenomenon."** As with other decisions, *Alice* declined to define the "precise contours" of an "abstract idea," and other decisions over time (both recent and dated) have split on whether the ineligible concept at issue did indeed constitute, for example, a "law of nature." *See, e.g., AAM*, 939 F.3d at 1365-68. In any event, given the breadth by which courts and parties alike have invoked the *Mayo-Alice* framework, the issue whether the cited "ineligible concept" is

“directed to” an “*abstract idea*” or “*natural law*,” for example—or whether the claim is directed to all or only a portion of such an ineligible “idea” or “law,” or maybe none at all—will continue to present itself for consideration by both sides.

8. **Judicial Deference or Disregard of the PTO Agency’s §101 Guidance?** As recounted above, the Federal Circuit recently held in *Cleveland Clinic v. True Health* that the PTO’s §101 Guidance didn’t bind the court or trump its case law. As an application of first principles, *Cleveland Clinic, supra*, may well represent the type of rulings that the Federal Circuit will continue to issue in response to Guidance-supported §101 arguments. As others have pointed out, the Patent Office didn’t appear to promulgate these Guidance documents pursuant to the formal notice-and-comment rulemaking procedures required by the Administrative Procedures Act for “substantive” legal rules (e.g., rules that change the requirements for patentability). *See, e.g.*, 5 U.S.C. §553(c). Further, as described therein, *Cleveland Clinic* did *not* present *inter alia* the *Chevron*-type ambiguity with the statute that might otherwise permit consideration of the “reasonableness” of the agency’s (the PTO’s) views or response on the topic. Instead, the Federal Circuit affirmed the trial court’s ruling even insofar as it held that the PTO’s §101 Guidance didn’t merit the lesser *Skidmore*

So, the reasonable and practical question here becomes, and especially for patentee-advocates: Why bother citing to such agency Guidance at all, particularly at a time when notions of deference to government agencies have waned? And the answer is, first, that as a co-equal branch of government, the Executive Branch and the PTO therein certainly have the power and even the duty to issue its views on these important questions, including critical questions about the §101 laws and their meaning. After all, the PTO has as much a hand (maybe more) in interpreting and applying these statutory patentability requirements on a day-by-day basis as the federal courts. Moreover, the PTO’s Guidance here appears as an extensive and detailed notice that the agency has

provided to the public about how it will interpret and apply a statute (§101). As the Supreme Court has held, *agency interpretative documents* such as these do *not* require notice-and-comment rulemaking or other formal APA procedures. *E.g., Perez v. Mort. Bankers Ass'n*, 135 S. Ct. 1199, 1204, 1206 (2015) (interpretative rules “advise the public of the agency’s construction of the statutes and rules which it administers”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating 5 U.S.C. §553 and 35 U.S.C. §2(b)(2)(B) do not require notice-and-comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice”). In other words, producing an agency interpretive document such as the PEG represents a valid and responsible exercise of the agency’s power.

Moreover, as *Cleveland Clinic* suggests, the PTO’s views on §101 warrant a degree of respect for the expertise they offer on often-difficult and arcane patent-law subjects, principles, and doctrines. Judge Lourie’s opinion in *Cleveland Clinic* thus appropriately referred to how the Federal Circuit “*greatly respects the PTO’s expertise on all matters relating to patentability*, including *patent eligibility*,” even though not bound by it. *Cleveland Clinic*, 2018-1218, at *13-14. The Supreme Court’s *Skidmore* principle, moreover, may afford “*some deference*” to “informal agency interpretations of ambiguous statutory” provisions, depending on the degree of “the agency’s *care, its consistency, formality, and relative expertness*,” and the “*persuasiveness of the agency [PTO’s] position*.” *E.g., id.* (citation omitted).

Accordingly, as reflected in *Cleveland Clinic, supra*, our sense is that practitioners and courts should appropriately re-raise and re-consider the PTO’s 2019 PEG and the “expertise” it offers on §101 and the *Mayo-Alice* framework—or otherwise be prepared to address it if opposed to their interpretation. By appearances and depth-of-analyses alone, the 2019 Guidance documents reflect that the Patent Office prepared them with due care, consistency, formality, and expertise—as one might expect for any patent issue addressed by the Patent Office, but most especially for a §101 issue of such overwhelming concern to the U.S. patent system. Generally speaking, then, it seems to us that the more a party or “side”

can enlist the relevant expert agency—such as the PTO—to support its position on a particular §101 issue, the more likely over time that position may gain currency and become part of the law itself. And that seems all the truer still when, as discussed above, the debate on the issue could ultimately turn on a fair reading of the Supreme Court’s core §101 precedents.

Conclusion

Undoubtedly, the additional observations and points for ongoing consideration in patent litigation today are near-endless, and at minimum would surely include additional discussions on the scope of (for example) the “preemption” concerns that underlie the patent-eligibility criteria itself. Be that as it may, the broader point here is that lawyers and judges in the field still have considerable room to argue and address a multitude of key patent-law issues. They are of course fundamental not only to clients and parties, but to all the country—and its well-being and safety.

THE AUTHORS

***Judge Paul Michel** became a private citizen on June 1, 2010 for the first time since he graduated from law school at the University of Virginia in 1966. Upon graduating from law school he became an Assistant District Attorney in Philadelphia, thus embarking upon the career of a public servant from 1966 to his retirement from the United States Court of Appeals for the Federal Circuit in 2010. Michel served on the Federal Circuit, which is the main patent appeals court in the United States, from 1988 to 2010, serving as Chief Judge from 2004 to 2010.*

***John Battaglia** is an accomplished first-chair trial lawyer, appellate lawyer, and former US Justice Department lawyer who has successfully tried to verdict a broad array of civil and criminal cases. While the subject matter of his cases over the past 22-plus years has ranged from immigration to intellectual property, from guns, drugs, and violence to advanced electrical engineering, pharmaceuticals, and ice-hockey equipment, Mr. Battaglia's area of particular interest and expertise is patent litigation. Mr. Battaglia has successfully argued cases before the U.S. Courts of Appeal for the Federal, Second, Sixth, Seventh, and Ninth Circuits. He argued and*

prevailed in In re Papst Licensing Digital Camera Patent Litig. (Fed. Cir. 2015), a case involving numerous adverse issues and the first Federal Circuit case to address the impact of the Supreme Court's decision in Teva v. Sandoz. For that victory, the legal press dubbed Mr. Battaglia and his team a "Legal Lion."