No. 18-817

In the Supreme Court of the United States

HIKMA PHARMACEUTICALS USA INC., ET AL.,
PETITIONERS

v.

VANDA PHARMACEUTICALS INC.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Section 101 of the Patent Act provides that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," is eligible for a patent. 35 U.S.C. 101. The question presented is as follows:

Whether methods of using drugs to treat medical conditions are patent-eligible processes under Section 101.

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This brief is filed in response to the order of this Court inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. The Constitution authorizes Congress "[t]o promote the Progress" of "useful Arts, by securing for limited Times to * * * Inventors the exclusive Right to their * * * Discoveries." U.S. Const. Art. 1, § 8, Cl. 8. Exercising that authority, Congress has directed that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. 101.

By "defin[ing] the subject matter that may be patented," *Bilski* v. *Kappos*, 561 U.S. 593, 601 (2010), Section 101 confines patents to particular types of innovations. To obtain a patent, an inventor "must also satisfy" additional Patent Act requirements, "includ[ing] that the invention be novel, nonobvious, and fully and particularly described." *Id.* at 602 (citing 35 U.S.C. 102-103, 112 (2006)). Those requirements complement Section 101 but serve different functions. The novelty requirement, for example, ensures that a patent applicant cannot obtain exclusive rights for another's previous discovery.

An invention thus might satisfy the Act's other requirements but not Section 101, or vice versa. See *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 483 (1974) ("[N]o patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter."). For example, a new way of structuring real-estate transactions might be novel and nonobvious, but it would not be patent-eligible under Section 101 because it would not be the *type* of innovation that has traditionally been viewed as falling within the "useful Arts." Conversely, an application for a patent on Alexander Graham Bell's telephone would satisfy Section 101, but it would fail today for lack of novelty.

b. Although Section 101's text is "expansive," *Diamond* v. *Chakrabarty*, 447 U.S. 303, 308 (1980), it is not limitless, *ibid.* The Court has long recognized, for example, that "phenomena of nature" are not patent-eligible if materially unaltered by humankind. *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (citing *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 175 (1853)). A "nonnaturally occurring manufacture or composition of matter," such as a newly created "micro-organism," is

patent-eligible, but "a new mineral discovered in the earth or a new plant found in the wild is not." *Chakrabarty*, 447 U.S. at 308-309 (citation omitted). Newly discovered "'manifestations of . . . nature,'" such as Newton's "law of gravity" or Einstein's "law that $E=mc^2$," likewise are not patent-eligible. *Id.* at 309 (citation omitted).

Until 2010, the Court's decisions recognizing that such discoveries are not patent-eligible were best understood as interpreting the specific terms ("process, machine, manufacture, [and] composition of matter," 35 U.S.C. 101) contained in Section 101's list of patent-eligible inventions, based in part on history and statutory context. See *Diamond* v. *Diehr*, 450 U.S. 175, 184 (1981) ("process"); *Corning* v. *Burden*, 56 U.S. (15 How.) 252, 267 (1854) ("machine"); *American Fruit Growers, Inc.* v. *Brogdex Co.*, 283 U.S. 1, 11 (1931) ("manufacture"); *Chakrabarty*, 447 U.S. at 308 ("composition of matter"). The terms "machine" and "manufacture" clearly refer to products constructed through human effort. And while the term "composition of matter" might be construed in isolation to encompass newly discovered naturally occurring organisms, the Court has long held that "patents cannot issue for the discovery of the phenomena of nature," *Funk Bros.*, 333 U.S. at 130-131, and it has construed current Section 101 to carry forward that traditional understanding, see *Chakrabarty*, 447 U.S. at 308-310.

The Court likewise has interpreted "process" in Section 101 based on traditional usage of that term and its precursor ("art") in the patent context. *Diehr*, 450 U.S. at 182-184 (citation omitted). It took as its touchstone "[i]ndustrial processes" of "the types which have historically been eligible to receive the protection of our patent

laws." *Id.* at 184. That approach aligned with the placement of "process" (or "art") alongside "machine," "manufacture," and "composition of matter." See *The Telephone Cases*, 126 U.S. 1, 533-534 (1888); see also Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 196 (2012). It also avoided the "comical" result that Section 101 would encompass "[a] process for training a dog, a series of dance steps, [or] a method of shooting a basketball." *Bilski*, 561 U.S. at 624 (Stevens, J., concurring in the judgment).

The Court's recent decisions, however, have applied a different approach. In *Bilski*, the Court held that patent claims for a method of hedging financial risk in energy markets were not patent-eligible under Section 101. 561 U.S. at 601-604, 606-608, 609-613. But the Court did not ground that conclusion in traditional patent-law understandings of the term "process," or in the Framers' conception of the "useful Arts." It stated instead that "process" and Section 101's other terms should bear their general-purpose "dictionary definitions," but that Section 101 is nevertheless limited by three "exceptions" that "are not required by the statutory text": "'laws of nature, physical phenomena, and abstract ideas.'" *Id.* at 601, 603 (citation omitted). The Court held that the method-of-hedging claims at issue were patent-ineligible "attempts to patent abstract ideas." *Id.* at 609; see *id.* at 609-613.

In *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), the Court applied *Bilski*'s new approach and held that "patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high" were patent-ineligible attempts to claim a natural law.

Id. at 72; see *id.* at 77-92. The Court stated that the claims "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of [the] drug will prove ineffective or cause harm." *Id.* at 77. It concluded that the claims did not "do significantly more than simply describe these natural relations," but instead merely instructed practitioners "to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field." *Id.* at 77, 79. The Court contrasted those claims with "a typical patent on a new drug or a new way of using an existing drug," which might "confine [its] reach to particular applications of those laws." *Id.* at 87; see *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 589-596 (2013) (holding that DNA sequences isolated from human genome were patent-ineligible "product[s] of nature," but that synthetically created DNA sequences not found in nature were patent-eligible).

The Court subsequently described *Mayo*'s approach as a two-step inquiry. First, a court determines whether a claim is "directed to" a "law[] of nature, natural phenomen[on], or abstract idea[]." *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (citation omitted). "If so," the court then "ask[s], 'what else is there in the claims,'" considering "the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Ibid.* (quoting *Mayo*, 566 U.S. at 78-79) (brackets omitted); see *id.* at 217-227 (concluding that "a computer-implemented scheme for mitigating 'settlement risk' * * * by using a third-party intermediary" was a patent-ineligible attempt to claim an abstract idea).

2. a. This case concerns claims for methods of using human-made drugs to treat medical conditions. In 2009, respondent (Vanda) obtained approval from the Food and Drug Administration (FDA) to market Fanapt (iloperidone), an antipsychotic drug, to treat schizophrenia. Pet. App. 4a. Petitioners (collectively, Hikma) filed an Abbreviated New Drug Application (ANDA) with the FDA, seeking approval to market a generic version of iloperidone. *Id.* at 5a. Because Vanda owned several patents listed "in connection with Fanapt[] in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the 'Orange Book,'" Hikma was required to include in the ANDA so-called "Paragraph IV" certifications representing that Vanda's patents either were invalid or would not be infringed. *Id.* at 4a-5a; see *id.* at 5a-6a, 60a; see also 21 U.S.C. 355(j)(2)(A)(vii)(IV).

b. Vanda sued Hikma for infringement of U.S. Patent No. 8,586,610, which claims a "method for treating a patient" suffering from schizophrenia with iloperidone. Pet. App. 3a, 5a-6a (citation omitted). The patent notes that some patients have a variation (genotype) of a particular gene (CYP2D6) that results in poor metabolization of iloperidone, which in turn can lead to a dangerous heart condition called QTc prolongation. *Id.* at 2a-3a. The claimed method first requires performance of a genetic test to "determin[e] whether the patient is a CYP2D6 poor metabolizer." *Id.* at 3a-4a (citation omitted). If so, the claim directs the administration of "iloperidone * * * in an amount of 12mg/day or less." *Id.* at 4a (citation omitted). If instead "the patient does not have a CYP2D6 poor metabolizer genotype," the claim directs the administration of iloperidone "in an

amount that is greater than 12 mg/day, up to 24 mg/day." *Ibid.* (citation omitted).

The district court found that Hikma's proposed products would infringe Vanda's patent. Pet. App. 51a-92a. It also rejected Hikma's contention that the patent claimed a patent-ineligible natural law. *Id.* at 73a-78a. The court held that the claims are directed to a natural law but are patent-eligible because they include "more than a mere instruction to apply a natural relationship." *Id.* at 78a; see *id.* at 73a-78a.

3. The court of appeals affirmed. Pet. App. 1a-50a.

a. The majority concluded at the first *Mayo/Alice* step that Vanda's claims are patent-eligible because they "are not directed to" a patent-ineligible natural law. Pet. App. 30a; see *id.* at 28a-35a. It held that, unlike the claims in *Mayo*, the claims here are "directed to a novel method of treating a disease." *Id.* at 31a. The majority explained that, although "[t]he inventors recognized the relationships between iloperidone" and genetically linked side effects, they had not claimed the relationship itself, but instead had "claimed an application of that relationship" that requires the administration of a specific dosage, "depending on the result of a genotyping assay." *Id.* at 32a.

b. Chief Judge Prost dissented. Pet. App. 43a-50a. She concluded that the claims here "set[] forth a natural relationship—namely, the relationship between the CYP2D6 genotype and the likelihood that a dosage of iloperidone will cause QTc prolongation"—and lack any "inventive concept." *Id.* at 47a, 49a. Chief Judge Prost also stated that, "[w]hatever weight can be ascribed to" *Mayo*'s suggestion that "a new way of using an existing drug" may be patent-eligible, lower courts "remain beholden" to what she described as *Mayo*'s contrary "holding." *Id.* at 49a.

c. The Federal Circuit denied rehearing en banc without recorded dissent.

DISCUSSION

The court of appeals correctly held that the relevant claims of Vanda's patent constitute patent-eligible subject matter under 35 U.S.C. 101. Those claims encompass methods of medical treatment. Historically, such methods were well understood to be patent-eligible.

The decision below, however, implicates important and recurring questions on which the Court's recent Section 101 decisions have fostered substantial uncertainty. In particular, *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), has sent conflicting signals. Language in that opinion indicates that the Court did not intend to overturn the well-settled understanding that method-of-medical-treatment claims typically are patent-eligible. But the decision's logic arguably implies the opposite. The disagreement between the majority and dissenting opinions below reflects that internal inconsistency.

Although *Mayo* is the most immediate source of confusion, the uncertainty ultimately stems from the broader framework articulated in the Court's recent Section 101 decisions. The Court's reconceptualization in *Bilski* v. *Kappos*, 561 U.S. 593 (2010), of inherent, long-recognized limitations on Section 101's affirmative scope as freestanding, atextual "exceptions," *id.* at 601, has given rise to an array of difficult questions. The confusion created by this Court's recent Section 101 precedents warrants review in an appropriate case.

This case, however, is not an optimal vehicle for bringing greater clarity because the court of appeals majority arrived at the correct result. In cases involving medical-diagnostic methods, by contrast, the Federal Circuit's

recent decisions suggest that the court might well have reached different outcomes if it were not bound by the *Mayo* framework. The Court should await a case in which lower courts' confusion about the proper application of Section 101 and this Court's precedents makes a practical difference.

1. This case concerns the patent-eligibility of a method of using a drug to treat a medical condition. Historically, it was well understood that such methods were patent-eligible. But the Court's recent Section 101 decisions leave the proper analysis of such claims unclear.

a. A method of treating a medical condition with an existing drug—such as Vanda's claimed method of using iloperidone to treat schizophrenia—is a patent-eligible process. Methods of practicing the medical arts have long been considered "eligible to receive the protection of our patent laws." *Diamond* v. *Diehr*, 450 U.S. 175, 184 (1981); see Gov't Amicus Br. at 15-16, *Mayo*, *supra* (No. 10-1150). And the Patent Act defines "process" to "include[] a new use of a known process" or "composition of matter." 35 U.S.C. 100(b). Since the enactment of the Patent Act in 1952, the United States Patent and Trademark Office (USPTO) has granted tens of thousands of patents that included at least one method-of-treatment claim.

More recent congressional action confirms that historical understanding. In 1984, Congress enacted the Hatch-Waxman Act's generic-drug regime, see Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, Tit. I, § 101, 98 Stat. 1585, which referred to patents that "claim[] a use for [a] drug." 21 U.S.C. 355(b)(2)(A)(iv) and (j)(2)(A)(vii). Congress also amended the Patent Act to make the submission of a

generic-drug application "for a drug claimed in a patent or the use of which is claimed in a patent" an act of infringement. 35 U.S.C. 271(e)(2)(A). Congress subsequently limited the infringement remedies that are available against "medical practitioner[s]" with respect to the "performance of a medical activity that constitutes an infringement," including "the practice of a patented use of a composition of matter in violation of such patent." 35 U.S.C. 287(c)(1) and (2)(A)(ii). Those provisions assume that claims for methods of medical treatment, including methods that involve the administration of drugs to patients, are potentially patent-eligible.

b. The *Mayo* Court contrasted the claims at issue in that case with "a typical patent on a new drug or a new way of using an existing drug," which the Court described as "confin[ing] [its] reach to particular applications of [natural] laws." 566 U.S. at 87. Consistent with the settled understanding described above, the Court thus appeared to take as its premise that methods of medical treatment are patent-eligible. Nevertheless, as evidenced by the dissenting opinion below, it is arguably unclear how the longstanding and entirely correct rule that method-of-treatment claims are patent-eligible can be reconciled with mechanical application of *Mayo*'s two-step framework.

i. The *Mayo* Court applied a new and capacious understanding of patent-ineligible "laws of nature." It identified the natural law claimed by the patent as "relationships," expressed in precise mathematical terms, "between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." 566 U.S. at 77. That articulation of the natural law is significant in two respects.

First, the *Mayo* Court concluded for the first time that a phenomenon can be a law of nature even if it exists *because of*, not *apart from*, human invention. The Court had previously described "the relevant distinction" under Section 101 as one "between products of nature * * * and human-made inventions." *Diamond* v. *Chakrabarty*, 447 U.S. 303, 313 (1980). The Court had concluded that Section 101's predecessor did not encompass phenomena that exist in nature, "like the heat of the sun, electricity," "the qualities of metals," or the tendency of particular bacteria to inhibit other bacterial species' growth. *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). By contrast, this Court and others had viewed as patent-eligible under Section 101 and its statutory predecessors processes that depend on natural phenomena but also involve human intervention—for example, a process of curing rubber that relies on inherent chemical properties of a substance extracted from rubber trees, *Diehr*, 450 U.S. at 184 & n.8 (citing *Tilghman* v. *Proctor*, 102 U.S. 707 (1881)), or a process of extracting aluminum from compounds found in nature by applying electric current to exploit aluminum's natural properties, see, *e.g.*, *Electric Smelting & Aluminum Co.* v. *Pittsburg Reduction Co.*, 125 F. 926, 929 (2d Cir. 1903).

The *Mayo* Court departed from that prior usage by describing as "laws of nature" biological responses of the human body to conditions that arise solely from human intervention. The thiopurine drugs involved in *Mayo* do not exist in nature, and the administration of such drugs to a patient likewise requires "a human action." 566 U.S. at 77. The court nevertheless stated that "the relation" between a patient's metabolite levels and

the recommended thiopurine-drug dosage for that patient "exists in principle apart from any human action" because it is "a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes." *Ibid.*

Second, the *Mayo* Court defined the natural law it identified at an extremely high level of specificity. 566 U.S. at 77. The Court held that one claim "set forth [a] law[] of nature" by "stat[ing] that if the levels of 6–TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8×10^8 red blood cells, then the administered dose is likely to produce toxic side effects." *Ibid.* (emphasis omitted). That highly particularized relationship contrasts starkly with laws of nature the Court had previously identified, such as Newton's "law of gravity." *Chakrabarty*, 447 U.S. at 309. When highly specific relationships of that sort are treated as laws of nature, it becomes more difficult for a patent applicant to show that its invention goes substantially beyond an instruction to "apply the law."

The treatment method claimed in Vanda's patent depends on the perceived relationship between the results of a genetic test used to "determin[e] whether the patient is a CYP2D6 poor metabolizer," and the appropriate dosage of iloperidone for that patient. Pet. App. 3a-4a (citation omitted); see pp. 6-7, *supra*. Both the genetic test and a patient's reactions to administration of iloperidone depend on human intervention. But if mechanical application of *Mayo*'s approach leads to the conclusion that the metabolizing of a drug, as in *Mayo*, is an "entirely natural process[]"—merely illustrating a natural law that "exists in principle apart from any human action," 566 U.S. at 77—the same would arguably be true of the biological reactions involved in Vanda's

process. And if the precise mathematical correlations in *Mayo* qualify for this purpose as "laws of nature," *ibid.*, the same would arguably be true of the highly particularized relationships on which Vanda's treatment method is premised.

ii. As noted, the *Mayo* Court distinguished "a typical patent on a new drug or a new way of using an existing drug" that "confine[s] [its] reach to particular applications of [natural] laws" from the claims at issue in that case, which did not prescribe any particular course of action based on information yielded by testing. 566 U.S. at 87; see *id.* at 86 (describing claimed process as merely "tell[ing] a treating doctor * * * to consider * * * measurements in light of the statistical relationships"). Yet the Court also suggested that, in determining whether a process claims a patent-eligible application of a natural law—or instead has the practical effect of claiming the natural law itself—steps that consist of applying conventional technologies or activities should be disregarded. 566 U.S. at 79. The Court concluded that the claims at issue were patent-ineligible because, apart from stating a natural law, they merely instructed practitioners to "engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field." *Ibid.* The Court stated that such "[p]urely 'conventional or obvious'" steps are "normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Ibid.* (citation omitted); see *Alice Corp. Pty. Ltd.* v. *CLS Bank Int'l*, 573 U.S. 208, 221-224 (2014). Thus, while the process claimed in Vanda's patent concludes with a concrete treatment step, it is unclear whether that step would render the process patent-eligible under the Court's reason-

ing in *Mayo*, or whether that step would instead be discounted as routine, conventional activity because it is not independently new.

Indeed, it is arguably unclear whether even a method of treating disease with a *newly created* drug would be deemed patent-eligible under a mechanical application of *Mayo*'s two-part test. The proposition that a specified dosage of a new drug has therapeutic benefits for a particular class of patients would seem to constitute a "law of nature" under *Mayo*'s expansive conception of that term. And once that therapeutic benefit has been identified, an instruction to administer the drug in the specified dosage to the relevant patients might be viewed as nothing more than routine and conventional activity. The patent-eligibility of such method-of-treatment claims has long been settled, and the *Mayo* Court did not suggest that it intended such an avulsive effect on established practices. The potential for rote application of the *Mayo* two-step framework to call into question such bedrock understandings of the patent system, in a way that the *Mayo* Court clearly did not envision, suggests that the *Mayo* framework warrants reconsideration.

c. The majority and dissenting opinions in this case illustrate the conflicting strands within the *Mayo* opinion. The majority reconciled its holding with *Mayo* by drawing a sharp distinction between processes that include specific treatment steps and those that direct the practitioner merely to consider test results. Pet. App. 31a-34a. It highlighted *Mayo*'s language distinguishing the claims there from "a typical patent on a new drug or a new way of using an existing drug." *Id.* at 32a (quoting *Mayo*, 566 U.S. at 87). The majority thus marshaled

very weighty evidence that the *Mayo* Court did not intend to preclude the patenting of method-of-treatment claims like those at issue here.

Conversely, the dissent explained how *Mayo*'s two-step framework casts doubt on the general patent-eligibility under Section 101 of method-of-treatment processes. See Pet. App. 45a-49a. Chief Judge Prost highlighted *Mayo*'s expansive view of natural laws—encompassing not merely "the bare fact of [a] relationship" between a metabolite in the body and the appropriate dosage of a drug, "but also the precise levels of concentration in question." *Id.* at 45a. The dissent also emphasized that, under *Mayo*, an instruction "to apply the natural law in a routine and conventional manner" is insufficient to render a process claim patent-eligible. *Id.* at 48a. And while the dissenting judge noted *Mayo*'s language contrasting the claims at issue there from typical method-of-treatment drug claims, she concluded that "the holding of *Mayo* * * * requires us to find [Vanda's] claims directed to a natural law at step one," and she found "no inventive concept in the claims once the natural law at issue is properly understood in view of *Mayo*." *Id.* at 49a.

d. The current uncertainty as to the proper application of the *Mayo* framework has considerable practical consequences for various types of medical innovations. See, *e.g.*, *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc.*, 809 F.3d 1282, 1285 (Fed. Cir. 2015) (Lourie, J., concurring in the denial of rehearing en banc) ("It is * * * said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern."). Commentators have echoed that concern. See, *e.g.*, Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine is*

Undermining U.S. Leadership in Innovation, 24 Geo. Mason L. Rev. 939, 948-949 (2017) (noting "destructive potential" of *Mayo* and subsequent "high invalidation rates in the biotech and pharmaceutical industries"). Some have observed that *Mayo* and subsequent decisions have "sent shock waves through the research, technology, business, and patent communities," prompting many to express "hope[] that [this] Court would provide fuller and clearer guidance on patent eligibility standards." Jeffrey A. Lefstin et al., *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 Berkeley Tech. L.J. 551, 555-556 (2018). They and others have likened *Mayo*'s analysis to an elusive "I-know-it-when-I-see-it" standard. *Id.* at 561; accord *McRO, Inc.* v. *Sony Computer Entm't Am., LLC*, 55 F. Supp. 3d 1214, 1220 (C.D. Cal. 2014), rev'd on other grounds, 837 F.3d 1299 (Fed. Cir. 2016).

In light of *Mayo* and the Court's other recent decisions, the USPTO has issued guidance regarding Section 101 to its more than 8500 patent examiners and administrative patent judges. *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (Jan. 7, 2019). But the agency's ability to provide direction is constrained by the lack of clarity in judicial precedent. The USPTO's guidance observes that "[p]roperly applying the *Alice/Mayo* test in a consistent manner has proven to be difficult"; "has caused uncertainty in this area of the law"; has made it difficult for "inventors, businesses, and other patent stakeholders to reliably and predictably determine what subject matter is patent-eligible"; and "poses unique challenges for the USPTO" itself. *Id.* at 50, 52.

2. The present difficulties in applying Section 101 ultimately derive in substantial part from the *Bilski* Court's reconceptualization of the limits on Section 101's coverage as freestanding "exceptions," 561 U.S. at 601, rather than as context-sensitive interpretations of the provision's terms.

a. As the concurring Justices in *Bilski* explained, Section 101's statutory and historical context provides sound bases for construing the specific terms it contains. But the *Bilski* Court declined to interpret Section 101's terms in light of that context, instead hewing to general-purpose "dictionary definitions." 561 U.S. at 603. It then recast decades of precedent recognizing internal limits on Section 101's reach as "exceptions" that the Court acknowledged "are not required by" Section 101's language. *Id.* at 601. That approach decoupled the Section 101 analysis from the statutory text and context, necessitating an alternative methodology for ascertaining the scope of the exceptions and identifying claims that implicate them.

Mayo and later decisions demonstrate the difficulty of that task. *Mayo* "set forth a framework" that *Alice* distilled to two "step[s]." *Alice*, 573 U.S. at 217. First, courts must ask "whether the claims at issue are directed to one of th[e] patent-ineligible concepts." *Ibid.* Second, "[i]f so," courts must "ask, 'what else is there in the claims,'" while effectively disregarding activities that are "'well-understood, routine, [and] conventional.'" *Id.* at 217, 225 (quoting *Mayo*, 566 U.S. at 73, 78) (brackets omitted). Both steps have proven problematic.

The instruction that courts inquire at the first step whether a patent is "directed at" a law of nature, natu-

ral phenomenon, or abstract idea provides little guidance. "[A]ll inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. If an invention's dependence on one of those concepts were fatal, untold numbers of innovations would be patent-ineligible. That risk is exacerbated by *Mayo*'s expansive understanding of "natural laws" as encompassing phenomena that can occur only through human intervention, and as including even precisely quantified relationships between chemical substances and specific results within the human body.

The second step is similarly ambiguous. Within a single post-*Mayo* opinion, the Court variously articulated that step as a query regarding "what else is there in the claims"; an examination of "whether the additional elements transform the nature of the claim into a patent-eligible application"; "a search for an inventive concept"; an inquiry into any "additional features to ensure that the claim is more than a drafting effort designed to monopolize" the abstract idea or natural law; a review of whether the claims do "more than simply stating the abstract idea while adding the words 'apply it'"; an evaluation of whether a patent does more than merely "limit the use of an abstract idea to a particular technological environment"; and a determination whether additional features are "well-understood, routine, conventional activit[ies]" previously known to the industry. *Alice*, 573 U.S. at 217-218, 221, 223, 225 (brackets, citations, and internal quotation marks omitted).

The Court's description of the second step also causes the Section 101 inquiry to overlap with the application of other Patent Act provisions. To the extent *Mayo* deemed "well-understood, routine, conventional

activities previously known to industry" inadequate to satisfy the second step, 566 U.S. at 73, 79-80, 82, the analysis imports considerations already addressed by the novelty and nonobviousness requirements of Sections 102 and 103. Particularly as applied to process claims, that approach departed from previously settled law in two distinct respects.

First, the Court had previously emphasized that "[t]he '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." *Diehr*, 450 U.S. at 188-189. Tying patent-eligibility to novelty and nonobviousness ignores the distinct purposes those statutory requirements have traditionally served. Second, to the extent *Mayo*'s approach screens out routine activity and considers only those discrete steps that are independently new, it replaces the traditional statutory focus on the invention "as a whole," *id.* at 188; see, *e.g.*, 35 U.S.C. 103, with a more demanding test. The Court had previously observed that analyzing the claimed invention "as a whole" is particularly important "in 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 was made." *Diehr*, 450 U.S. at 188. An approach that disregards "routine" or "conventional" steps in applying Section 101 to a process claim threatens the patent-eligibility of numerous valuable innovations that incorporate existing steps into new and useful processes.

b. The *Bilski* Court resorted to superimposing atextual exceptions because it viewed Section 101's text as placing insufficient limits on the range of patent-eligible

inventions. But positing a choice between atextual exceptions and adopting the broadest possible reading of Section 101's terms creates a false dichotomy. Under traditional norms of statutory interpretation, courts construing Section 101 should "begin with the language" but should also bear in mind the provision's history and context. See *Diehr*, 450 U.S. at 182. That context includes the fact that Section 101 implements the Intellectual Property Clause, "the main object" of which is "'to promote the progress of science and useful arts.'" *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829) (Story, J.) (quoting U.S. Const. Art. I, § 8, Cl. 8); see *Golan* v. *Holder*, 565 U.S. 302, 324 (2012).

Section 101's original precursor clearly evoked that purpose by "defin[ing] statutory subject matter as 'any new and *useful art*, machine, manufacture or composition of matter, or any new or useful improvement thereof.'" *Diehr*, 450 U.S. at 182 (quoting Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318-321) (brackets omitted; emphasis added). Congress's replacement of "art" with "process" in 1952 did not alter the provision's purpose or scope. See *id.* at 182-184. Current Section 101's retention of the word "useful" to limit the types of processes, etc., that may be patented confirms Congress's continued adherence to the patent laws' traditional role in promoting the "useful Arts." Cf. *The Telephone Cases*, 126 U.S. 1, 533 (1888). Terms in Section 101 that might sweep more broadly in other contexts should be read against that backdrop. See *United Sav. Ass'n of Tex.* v. *Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988) ("A provision that may seem ambiguous in isolation is often clarified by the" statutory context, including where "only one of the permissible meanings produces a substantive effect that is compatible with the

rest of the law."); *Bilski*, 561 U.S. at 624 (Stevens, J., concurring in judgment) (explaining that, although the term "process" standing alone might encompass "[a] process for training a dog, a series of dance steps, [or] a method of shooting a basketball," context and historical understanding preclude that interpretation of the term as it appears in Section 101).

To be sure, borderline cases will arise in which text, history, and tradition provide no clear answer to the question whether particular claimed processes are patent-eligible under Section 101. But unlike the Court's more recent attempts to articulate and apply atextual exceptions to Section 101's coverage, the Court's pre-*Bilski* approach of interpreting Section 101's terms in light of statutory context, history, and constitutional purpose involved the application of traditional tools of statutory construction to the language that Congress enacted. That interpretive method placed courts on familiar judicial terrain, even if it did not make every case an easy one.

3. This case, however, is not an optimal vehicle to address the confusion stemming from this Court's recent Section 101 decisions. Despite that uncertainty, the court of appeals majority reached the correct result in concluding that the method of medical treatment claimed in Vanda's patent is patent-eligible subject matter. A decision from this Court resolving the internal tension within *Mayo* and reaffirming that Section 101 encompasses methods of medical treatment would have little practical effect in this case. Nor does the decision below cast doubt on the patent-eligibility of a wide swath of medical technologies.

The Court instead should provide additional guidance in a case where the current confusion has a material effect on the outcome of the Section 101 analysis. For example, *Mayo* has had particularly significant practical effects with respect to medical-diagnostic methods. See *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352-1353 (Fed. Cir. 2019) (Moore, J., dissenting from the denial of rehearing en banc) ("Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible."), petition for cert. pending, No. 19-430 (filed Oct. 1, 2019). In contrast to this case, where rehearing was denied without recorded dissent, the Federal Circuit's recent order denying rehearing en banc in *Athena* was accompanied by multiple separate opinions articulating different understandings of *Mayo* and seeking clarification from this Court. See *id.* at 1337 (Hughes, J., concurring in the denial of rehearing en banc) ("welcom[ing] further explication of eligibility standards in the area of diagnostics patents"); *id.* at 1335 (Lourie, J., concurring in the denial of rehearing en banc); *id.* at 1339 (Dyk, J., concurring in the denial of rehearing en banc); *id.* at 1344-1348 (Chen, J., concurring in the denial of rehearing en banc); *id.* at 1352 (Moore, J., dissenting from the denial of rehearing en banc); *id.* at 1363-1368 (Newman, J., dissenting from the denial of rehearing en banc); *id.* at 1370-1371 (Stoll, J., dissenting from the denial of rehearing en banc); *id.* at 1371 (O'Malley, J., dissenting from the denial of rehearing en banc).

Those various opinions provide substantial grounds for inferring that, if the Federal Circuit were not bound by the current Section 101 framework, that court might have reached different outcomes in *Athena* itself and in other diagnostic-method cases. Whether in *Athena* or in

another such case, further guidance from this Court is amply warranted.

CONCLUSION

The petition for a writ of certiorari should be denied. In the alternative, if the Court grants the petition for a writ of certiorari in *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs., LLC*, No. 19-430 (filed Oct. 1, 2019), the petition in this case should be held pending the Court's decision in *Athena* and then disposed of as appropriate.

Respectfully submitted.

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