

No. 18-817

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IN THE  
**Supreme Court of the United States**

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HIKMA PHARMACEUTICALS USA INC., ET AL.,  
*Petitioners,*  
v.  
VANDA PHARMACEUTICALS USA, INC.,  
*Respondent.*

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On Petition for a Writ of Certiorari to the United  
States Court of Appeals for the Federal Circuit

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**BRIEF OF AMICI CURIAE  
INTELLECTUAL PROPERTY AND  
INNOVATION PROFESSORS,  
ENGINE ADVOCACY, AND  
THE R STREET INSTITUTE  
IN SUPPORT OF PETITIONERS**

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## INTEREST OF AMICI CURIAE

Amici curiae are 17 professors at law schools and universities throughout the United States, who study intellectual property and innovation, and two public interest organizations.<sup>1</sup> Amici have no personal interest in the outcome of this case. They share a professional academic and organizational interest in seeing patent law develop in a way that best furthers the purposes of the patent system and most benefits society.<sup>2</sup>

Amicus Engine Advocacy is a non-profit technology policy, research, and advocacy organization that bridges the gap between lawmakers and startups across the nation to support the development of entrepreneurship. Part of amplifying startup concerns includes highlighting the unique challenges startups face when confronted with abusive patent litigation.

Amicus the R Street Institute is a non-profit, non-partisan public-policy research organization. R Street's mission is to engage in policy research and educational outreach that promotes free markets as well as limited yet effective government, including

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<sup>1</sup> Pursuant to Rule 37.2(a), counsel for both parties received notice of intent to file this brief at least 10 days before its due date. The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund its preparation or submission. No person other than the amici or their counsel made a monetary contribution to the preparation or submission of this brief.

<sup>2</sup> A full list of amici intellectual property and innovation professors is contained in the Appendix.

properly calibrated legal and regulatory frameworks that support economic growth and individual liberty

### SUMMARY OF ARGUMENT

The Federal Circuit’s decision below directly conflicts with this Court’s patentable subject matter precedent by upholding patent claims to routine, conventional applications of a law of nature. If allowed to stand, the decision will eviscerate this Court’s unanimous and repeated determinations that such claims lack the “inventive concept” that is required of patentable subject matter. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l.*, 573 U.S. 208, 217 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012). The divided Federal Circuit panel held the claims at issue here were not “directed to” a law of nature because they claim a “specific method of treatment.” Pet. App. 35a. This interpretation of the term “directed to” is incompatible with the Court’s usage in *Alice*, 573 U.S. 208. It is also directly at odds with the Court’s invalidation of the method-of-treatment claims at issue in *Mayo*, 566 U.S. 66, on patentable subject matter grounds.

The *Mayo* decision reaffirmed the principle that patentability requires more than simply directing a practitioner to apply an otherwise ineligible natural law in a “routine, conventional” way. 566 U.S. at 73. The panel in this case sought to distinguish *Mayo* on the grounds that the patent at issue explicitly recites the step of adjusting a drug dose in applying a natural law, whereas the dose adjustment was merely implicit in the claims invalidated in *Mayo*. This distinction is untenable, as it depends on the “draftsman’s art,” *Alice*, 573 U.S. at 224, and ignores this Court’s

repeated ruling that mere specificity is not sufficient to transform a natural law into patent eligible subject matter. *Mayo*, 566 U.S. at 88-89 (citing *Parker v. Flook*, 437 U.S. 584 (1978)).

The Federal Circuit is obligated to follow this Court's guidance by elaborating the limits on 35 U.S.C. § 101 patent eligible subject matter in a manner that conforms with the legal interpretation and rationale set out in this Court's precedents. The decision below shirks that duty. This Court has adopted a two-step framework for analyzing patentable subject matter in order to ensure that patents are awarded only to claims that add an "inventive concept" to the underlying natural law. The Federal Circuit majority's interpretation of this analysis would render this framework toothless because *no* method of treatment applying a discovered law of nature would *ever* be considered "directed to" that law of nature, regardless of whether the claim adds only "well-understood, routine, conventional activity" to the otherwise-ineligible subject matter. *Mayo*, 566 U.S. at 73.

The harmful consequences of this decision are real and immediate. The U.S. Patent and Trademark Office (USPTO) has issued guidance that explicitly adopts the reasoning of the majority's holding and instructs examiners that "method of treatment" claims that apply natural relationships should be considered *per se* eligible subject matter so long as integrated into a practical application—such as a treatment claim—even if that application is uncreative, routine, or conventional, once the ineligible discovery has been made. This guidance, like the decision below, ignores the standards of § 101 articulated by this Court for

patentable subject matter in general and for medical treatment patents in particular.

Moreover, the reasoning of the decision below need not apply only to medical treatment patents. It is thus likely that the decision's erroneous interpretation of "directed to" will be extended to other classes of patents, enabling clever patent drafters to avoid the critical second step of this Court's patent eligible subject matter analysis.

The decision below is exceptionally important. The Federal Circuit's and USPTO's disregard of *Mayo* and *Alice* are unmistakable and growing. Review and correction by this Court are vital now, before the harmful effects of the decision and its implementation by the USPTO become widespread. Only immediate review will prevent thousands of ineligible patents from being improperly issued and improperly upheld in the courts below and remaining in effect until some potential future opportunity for this Court to consider and invalidate them.

Left uncorrected, the Federal Circuit's decision and the USPTO guidance based on it will allow the piecemeal appropriation of the public domain. Patent law carefully limits the subject matter of patents to ensure the existence of a robust and unrestricted public domain for routine and conventional uses of the laws of nature, even if those laws are newly discovered. Patents must not be allowed to monopolize the basic ideas and natural laws that provide the foundation for medical innovation, research and treatment. If they do, downstream innovation will be hampered or blocked and vital medical practices and decisions will face undue interference.

This case is an excellent vehicle for the Court to correct the Federal Circuit's and USPTO's departure from *Mayo* and *Alice* and to restore the vitality of this Court's test for § 101 eligibility. The case presents a clean issue of law without any meaningful factual dispute or complexity. The relevant issue is squarely presented by the language in the patent at issue below and by the similarity of these claims to those invalidated in *Mayo*.

## ARGUMENT

### **I. The Federal Circuit's Decision Effectively Overturns This Court's Precedents, Thwarts the Proper Development of Patent Eligibility Law, and Will Lead to Countless Improperly Issued Patents**

The patent that a divided panel of the Federal Circuit upheld in this case is precisely the type of patent this Court held was ineligible under 35 U.S.C. § 101 in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). The majority's attempts to distinguish the two patents and to explain its departure from *Mayo's* clear precedent are unavailing, but now are the law of the Circuit and thus the law of the land for all patent cases unless and until overruled in a future case. Until then, the *Vanda* precedent will permit many patents to issue and to remain in force that should not. And rather than further develop and clarify § 101 law in accordance with this Court's prior decisions, the Federal Circuit has instead created a limit on § 101 that is plainly inconsistent with this Court's decisions and with the Patent Act.

### A. The Decision Below Directly Conflicts With *Mayo*

In *Mayo*, the Court held to be ineligible subject matter a method-of-treatment claim (based on diagnosing a natural correlation) that left implicit the final step of adjusting the dose of the administered drug (as presumably it would be malpractice not to do). See 566 U.S. at 74 (“A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder . . . .”) (quoting U.S. Patent No. 6,355,623 Col. 20, ll. 10-11 (filed Apr. 8, 1999)). The Court explained that “[t]o transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words ‘apply it.’” *Mayo*, 566 U.S. at 72 (citing *Gottschalk v. Bensen*, 409 U.S. 63, 71-72 (1972)); see also *Alice Corp. Pty. Ltd. v. CLS Bank Int’l.*, 573 U.S. 208, 221 (2014) (“*Mayo* made clear that transformation into a patent-eligible application requires ‘more than simply stat[ing] the [abstract idea or law of nature] while adding the words ‘apply it.’”))

This Court in *Mayo* treated the patent at issue as nothing “more than an instruction to doctors *to apply* the applicable laws when treating their patients.” *Mayo*, 566 U.S. at 79. (emphasis added); see also *id.* at 82 (“the effect is to simply tell doctors *to apply* the law somehow when *treating* their patents.”) (emphasis added). This Court cannot have meant to say that the claim at issue would have been valid had it explicitly recited the words “apply it,” i.e., the discovered correlation, “by adjusting the dose,” rather than having left the dosage adjustment implicit from the language of the claim. But that is precisely the

interpretation of *Mayo* the divided panel below adopted and which is now precedent for the Federal Circuit. The majority's decision therefore categorically excludes every method-of-treatment claim that the Patent Office has issued or will issue in the future from the required scrutiny for an "inventive concept" that is more than mere application.

The patent at issue in the present case does nothing more than (as in *Mayo*) state a law of nature regarding correlations between a patient's genotype and the dosage of an anti-schizophrenia drug, determine the presence or absence of that correlation, and then (unlike in *Mayo*) add the words "then internally administer." U.S. Patent No. 8,586,610 Col. 17, ll. 14, 17 (filed Sept. 30, 2005) ('610 patent). Nothing could be closer to simply adding the words "apply it" than taking a natural relationship pertaining to drug dosages and *explicitly* instructing a healthcare provider to administer it for treatment according to that correlation.

If this is enough to convert the ineligible claim of *Mayo* into an eligible invention, then *Mayo* has been neutered and patents will now issue when the only advance they reflect is the discovery of a law of nature. *But see Mayo*, 566 U.S. at 86-87 ("The [laws of nature at issue] tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, *they tie up the doctor's subsequent treatment decision . . .* in light of the inference he has drawn using the correlations.") (emphasis added).

The patent at issue in *Mayo* effectively covered the use of a natural law for treatment—and the Court recognized it to do so. *Mayo*, 566 U.S. at 82 ("the effect

is to simply tell doctors to apply the law somehow when *treating* their patents.”) (emphasis added). The ’610 patent is no different. The Federal Circuit’s reasoning that the patent was eligible because it was a treatment claim and thus “not *Mayo*,” Pet. App. 31a, cannot be squared with this Court’s decision.

Merely explicitly reciting in the claim a direction to a practitioner to use a natural law in this manner is insufficient to render claimed subject-matter eligible. “Such a result would make the determination of patent eligibility ‘depend simply on the draftsman’s art.’” 573 U.S. at 224 (quoting *Parker v. Flook*, 437 U.S. 584, 593 (1978)). Rejecting these admonitions, the decision below sought to distinguish *Mayo* on the grounds that the *Mayo* patent was not directed “to the application of a drug to treat a particular disease” even though that patent in fact covered the application of a drug to treat certain diseases. Pet. App. 32a. Rather, the actual difference between the two patents is that the claims in the ’610 patent explicitly say to apply the law of nature by adjusting the dosage based on it, where the patent in *Mayo* left that last step implicit—which is a mere drafting difference.

The dissent below highlighted the inconsistencies in the majority’s reasoning, recognizing that “reciting specific metes and bounds in the claims did not prevent the Supreme Court from concluding those claims set forth a natural law in *Mayo*,” and that the same principle adopted by this Court in *Mayo* applies in the current controversy. Pet. App. 47a (Prost, C.J., dissenting). In other words, the claimed invention in *Mayo* was clearly “directed to” an abstract law of nature despite being clearly focused on diagnosis for treatment using that law, and that claimed invention

supplied no “inventive concept . . . 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 Intern.*, 573 U.S. 208, 217-18 (2014) (quoting *Mayo*, 566 U.S. at 72-73). The fact that the ’610 patent also focuses on a natural discovery’s use in treatment does not prevent it from being directed at a law of nature. Nor does the fact that the doctor performs the only reasonable (and ethically required) next step (that the claim in *Mayo* only implied should occur) prevent that “treatment” step from being “well-understood, routine, conventional activity.” *Mayo*, 566 U.S. at 73.

The only differences between the ’610 patent and the *Mayo* patent are “drafting effort[s],” Pet. App. 47a (Prost, C.J., dissenting) (alteration in original), and the ’610 patent “claims no more than instructions directing [doctors] to apply the natural law in a routine and conventional manner,” *id.* The ’610 patent accordingly is directed at an unpatentable law of nature in precisely the same manner that the *Mayo* patent was. This blatant departure from the Court’s precedent warrants immediate review.

**B. The Federal Circuit Is Failing to Fulfill Its Obligation to Develop This Court’s Law and the Patent Office Is Improperly Following the Federal Circuit’s Precedent Rather Than This Court’s Directions**

This Court specifically encouraged the Federal Circuit to continue to clarify the limits of § 101 eligibility when earlier rejecting the Federal Circuit’s

effort to create a “bright line” test of eligibility. As the Court explained: “[w]e by no means foreclose the Federal Circuit’s development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.” *Bilski v. Kappos*, 561 U.S. 593, 613 (2010). However, the Federal Circuit decision in this case imposed a restriction on the limits of § 101 that is plainly “inconsistent” with the text of the Act as interpreted by this Court. *Id.*

As explained above, the Federal Circuit has failed to develop the law properly and elaborate the constraints of § 101 patent eligibility in a way that is consistent with this Court’s guidance. It is the role of the appellate courts to develop the law beyond the broad guidance this Court provides, but the Federal Circuit has shirked that obligation. Instead, the majority’s decision below directly contradicts this Court’s precedents and forecloses any meaningful development of precedents to further explain what “well-understood, routine, conventional activity” means in regard to claimed applications of discoveries of laws of nature that are directed to such discoveries and used for medical treatment.

The Federal Circuit has previously acknowledged the need to develop greater clarity regarding the limits of § 101. *See, e.g., Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1353 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part). *Cf. Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie and Newman, JJ., concurring in denial of rehearing en banc) (“the law needs clarification by higher authority”). But in this case the Circuit has effectively abandoned the effort to

apply this Court's guidance, rather than build upon it. Under the holding of the majority below, *no* method of treatment applying a discovered law of nature can *ever* be considered "directed to" that law of nature, much less be determined to add only routine and conventional activity to the otherwise-ineligible subject matter.

Worse yet, based on this decision, the USPTO has issued guidance to its patent examiners that makes the improper consequences of the decision below crystal clear. The USPTO has instructed examiners, based on that decision, that "method of treatment' claims that practically apply natural relationships should be considered patent eligible." Robert W. Bahr, Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals*, USPTO 2 (June 7, 2018), <https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF> [hereinafter Bahr memo], accord 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) (Issuing the content of the Bahr memo as USPTO guidance); *see also* Bahr memo at 2-3 ("The USPTO's current subject matter eligibility guidance and training examples are consistent with the Federal Circuit's decision in *Vanda*, with the understanding that: (1) 'method of treatment' claims that practically apply natural relationships should be considered *patent eligible* under Step 2A of the USPTO's subject matter eligibility guidance; and (2) it is not necessary for 'method of treatment' claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered *patent eligible* under 35 U.S.C. § 101.") (emphasis in original). Where a natural correlation between a human diagnostic

condition and a treatment is discovered, there is no reasonable way to apply that correlation other than to adjust treatment accordingly. Every method of treatment is a practical application. Under the USPTO's guidance, no claimed invention directed to treatment based on merely applying an ineligible discovery will ever be considered ineligible subject matter.

The decision below and the Bahr memo bypass the correct reading of § 101 for medical treatment patents. But the court's and the agency's reasoning will not stop there, and both the Federal Circuit and the USPTO will extend that reasoning to other classes of patents. In fact, the USPTO has just issued further guidance doing just that. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50. That guidance instructs examiners that "a claim is not 'directed to' a judicial exception if the judicial exception is integrated into a practical application of that exception." *Id.* That guidance is not limited to medical treatment claims applying laws of nature, nor even to the applications of ineligible "abstract ideas" that are the focus of most of the rest of the guidance. But the problem in *Mayo* was not that the claim was not directed to a practical application of the ineligible discovery; it was that the practical application of that ineligible discovery (diagnosis based on applying the correlation, as well as the "obvious" and "conventional" next step of treatment) "add[ed] nothing to the laws of nature" that was not "[p]urely 'conventional or obvious' [post]-solution activity." *Mayo*, 566 U.S. at 79 (quoting *Flook*, 437 U.S. at 590).

In short, the disregard of *Mayo* (and *Alice*) by the Federal Circuit and the USPTO is palpable and

growing. Review and correction by this Court is vital *now*, before the harmful effects of the decision, its extension in other cases, and its implementation by the USPTO become widespread, and thus before thousands of patents issue that should not and that will require this Court to later correct and invalidate them.

## **II. Review Is Exceptionally Important Because the Decision Below Will Effectively Authorize Patents on Natural Laws, Constricting the Public Domain**

As this Court explained 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.

.....

These statements [from this Court's precedents] reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work."

*Mayo*, 566 U.S. at 78, 86. This concern is no less weighty when the "scientific and technological work" is medical practice than when it is physics research.

Patent law carefully limits the subject matter of patents to ensure the existence of a robust public domain free from restriction for routine and conventional uses of the laws of nature, even if those

laws are newly discovered. If patents are allowed to monopolize the basic ideas and natural laws that provide the foundation for medical innovation by claiming practical but uncreative applications of those discoveries, then downstream innovation will be hampered or blocked and patents will be allowed to unduly interfere with medical practices and decisions. This is as true for the diagnostic evaluations that precede treatment dosage adjustments as it is for the treatments themselves; both “tie up the doctor’s [] treatment decision[s]” and “tie up too much future use of laws of nature.” *Id.* at 86-87.

Further, this Court’s discussions of preemption do not counsel a different result. As the Court recognized in *Alice*, “we rejected the argument that ‘implement[ing] a principle in some specific fashion’ will ‘automatically fal[l] within the patentable subject matter of § 101’” *Alice*, 573 U.S. at 222 (quoting *Flook*, 437 U.S. at 593) (alterations in original). The Court has explained that “*Flook* stands for the proposition that the prohibition against patenting abstract ideas ‘cannot be circumvented by attempting to limit the use of [an idea] to a particular technological environment.’” *Bilski*, 561 U.S. at 610-11 (quoting *Diamond v. Diehr*, 450 U.S. 175, 191-92 (1981)). And medical treatment, like catalytic cracking of hydrocarbons, *Flook*, 437 U.S. at 585, or the curing of rubber, *Diehr*, 450 U.S. at 177, is simply a particular technological environment—just one that matters even more to society.

The Court in *Mayo*, moreover, specifically rejected the argument that patentability should depend on the scope of pre-emption. The Court noted that “even a narrow law of nature . . . can inhibit future research”

and that “our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow.” *Mayo*, 566 U.S. at 88-89. Thus, the possibility that some unknown, alternative use of a newly discovered correlation (beyond the obvious and conventional application of the law of nature in medical treatment) might be found in the future (and thus that the treatment claim might not preempt *all* possible applications of an ineligible discovery) should not evade this Court’s prohibitions on finding such claimed, practical applications to be ineligible. Rather, by tying up the obvious and conventional treatment, such patents would “disproportionately t[ie] up the use of the underlying natural laws” and would make such future alternative applications less likely to be invented, by limiting uses to those that are licensed from the patent holder (who may also impose restrictions on any data generated from those uses). *Mayo*, 566 U.S. at 73.

If left unreviewed, the Federal Circuit’s reasoning and its adoption by the USPTO in its guidance to patent examiners will result in the issuance of numerous patents that are in fact ineligible under *Mayo*. Those patents will wrongfully appropriate the public domain through *piecemeal* claiming of what are effectively natural laws without any additional inventive creativity, rather than seeking to swallow the public domain whole by claiming the natural law itself. To do so would thereby prohibit all applications (including those that are as yet unknown and thus undisclosed). As explained to the Court in *Mayo*, “large swaths of the public domain that should remain free for public use and creative investigation could be subjected to a plethora of patent rights.” Brief of Nine

Law Professors as Amici Curiae in Support of Petitioners at 7, *Mayo*, 566 U.S. 66 (No. 10-1150) (discussing how § 101 prevents the “piecemeal encroachment” of patent claims into the public domain).

The effect of the *Vanda* majority’s decision and now the USPTO’s approach will be what this Court was cautioned about and rejected in *Mayo*. The danger of patents foreclosing downstream innovation and public use of natural laws “become[s] acute when a patented process amounts to no more than an instruction to ‘apply the natural law’ . . . .” *Mayo*, 566 U.S. at 86. The patent system exists to reward *inventive* creativity, not ineligible discoveries or creative claim drafting.

Even if this Court is later presented with another opportunity to correct the *Vanda* majority’s deviation from *Mayo*’s clear requirement for an “inventive concept,” the passage of time in the interim will have resulted in many improvidently granted patents that will cause significant damage to the public domain and to the public itself. The decision below should be reviewed now to avoid those harms.

### **III. This Case Is an Excellent and Timely Vehicle to Correct the Federal Circuit’s Error**

This case presents an excellent and timely vehicle for the Court to correct the Federal Circuit’s error and to reinforce the correct test for § 101 eligibility. The issue of law is straightforward and not muddied by any meaningful factual dispute or complexity; it is squarely presented by the language in the ’610 patent and its similarity to the patent in *Mayo*.

Indeed, it is precisely the clarity of the departure from *Mayo* that highlights the need to correct the Federal Circuit’s and the USPTO’s mistaken determinations that the *Mayo* decision authorized method-of-treatment claims (or any other claims) that *practically* apply ineligible subject matter to be considered eligible subject matter, without *any* evaluation of whether that application reflects an “inventive concept” that is not merely “well-understood, routine, conventional activity.” *Mayo*, 566 U.S. at 72-73 (quoting *Flook*, at 594). The decision below authorizes any and all claims that apply ineligible discoveries to a practical purpose—without *any* evaluation that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself,” allowing all such claims to issue for “insignificant postsolution activity.” *Mayo*, 566 U.S. at 73 (quoting *Diehr*, 450 U.S. at 594).

The legal question is so crisply defined that the Court need only consider the first step of the *Mayo-Alice* eligibility framework and simply clarify that treatment claims like diagnostic claims (or any other claims practically applying ineligible subject matter, whether explicitly recited in the claim or not) may be “directed to” ineligible discoveries.

The decision below categorically precludes that understanding, and thus precludes any further inquiry into whether and when the claims add “more” than merely “insignificant, post-solution activity.” The clarity of the legal issue is further demonstrated by the stark divide in the reasoning between the majority and the dissenting opinions below; only one of those

opinions can correctly have interpreted what this Court has said in *Mayo* and *Alice*.

### CONCLUSION

The divided Federal Circuit decision below is inconsistent with this Court's precedents. Review now by this Court is exceptionally important to prevent the proliferation of patents from issuing and being upheld that would swallow the public domain either in large blocks or small pieces, harming the public and future innovation. The Court should grant certiorari to correct the Federal Circuit's departure and to prevent the significant harms that the decision below and the USPTO's embrace of it will cause.

Respectfully submitted,

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January 28, 2019

**APPENDIX**

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