

No. 17-997

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**In the Supreme Court of the United States**

THE CLEVELAND CLINIC FOUNDATION, ET AL.,  
*Petitioners,*

v.

TRUE HEALTH DIAGNOSTICS, LLC,  
*Respondent.*

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

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**BRIEF FOR *AMICUS CURIAE*  
RAYMOND A. MERCADO  
IN SUPPORT OF PETITIONERS**

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Adam K. Mortara  
*Counsel of Record*  
BARTLIT BECK HERMAN  
PALENCHAR & SCOTT LLP  
54 W. Hubbard St.  
Chicago, IL 60654  
(312) 494 4400  
adam.mortara@bartlit-beck.com  
*Counsel for Amicus Curiae*

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**BRIEF FOR *AMICI CURIAE*  
RAYMOND A. MERCADO, PH.D.**

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**STATEMENT OF INTEREST OF *AMICUS*  
*CURIAE*<sup>1</sup>**

*Amicus* Raymond A. Mercado, Ph.D., is a political scientist and patent law scholar who has written on

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<sup>1</sup> Pursuant to Supreme Court Rule 37.2(a), *amicus curiae* files this brief with consent from all parties. Petitioners and Respondent have consented to the filing of this brief, although Respondent received notice fewer than 10 days before the due date for this brief. Pursuant to Supreme Court Rule 37.6, the undersigned further affirms that no counsel for a party authored this

the law of patentable subject matter under 35 U.S.C. § 101 at issue in this case, and is interested in the wholesome development of the law. See Raymond A. Mercado, *Resolving Patent Eligibility and Indefiniteness in Proper Context: Applying Alice and Aristocrat*, 20 Va. J.L. & Tech. 240 (2016).

### SUMMARY OF ARGUMENT

No sooner had Petitioners stepped through the courthouse doors than they were thrown back out again, their patents declared invalid on the pleadings. Cert. Pet. at 15. The phenomenon of “pleading invalidations” raised by Petitioners in their second question presented is by now familiar to inventors throughout the nation, as patents are being routinely held invalid under § 101 at the pleadings stage, without any fact-findings to support such rulings.<sup>2</sup> The

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brief in whole or in part, and no person or entity other than *amicus curiae* or its counsel made a monetary contribution specifically for the preparation or submission of this brief.

<sup>2</sup> See, e.g., *Intellectual Ventures II LLC v. FedEx Corporation*, 2017 WL 6002762, at \*2 n. 1 (E.D. Tex. Dec. 1, 2017) (“[r]esolving validity issues at the Rule 12 stage can also tempt courts, sometimes improperly, to conclude that certain concepts are conventional or routine by way of judicial notice or treating this potentially factual question as a purely legal one.”); see also Timothy R. Holbrook & Mark D. Janis, *Patent-Eligible Processes: An Audience Perspective*, 17 Vand. J. Ent. & Tech. L. Rev. 349, 362, 382 (2015) (observing that courts are deciding eligibility with “virtually nothing to guide and focus the judicial imagination,” a “dynamic [that] becomes particularly salient when considering the procedural posture of these cases – motions to dismiss under Rule 12(b)(6) or 12(c)” and arguing against the courts’ “problematic” practice of “kick[ing] the hypothetical person of ordinary skill in the art to the curb in favor of a discretionary analysis [by the court] that need not be constrained to establish qualifying

reason for this phenomenon is plain: the Federal Circuit is hopelessly divided on whether the § 101 inquiry is a purely *legal* question ripe for resolution on the pleadings, or whether § 101 analysis involves substantial *factual* issues that would rarely, if ever, be appropriate for resolution on the Rule 12 stage. Compare, e.g., *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1338 (Fed. Cir. 2017) (“Patent eligibility under § 101 is an **issue of law** that we review without deference.”) (emphasis added); *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 912 (Fed. Cir. 2017) (deciding § 101 question “at the motion to dismiss stage based on intrinsic evidence from the [patent’s] specification without need for extraneous fact finding outside the record”), with *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 2018 WL 843288, at \*5 (Fed. Cir. Feb. 14, 2018) (“While the ultimate determination under § 101 is a question of law, like many legal questions, there can be subsidiary fact questions which must be resolved en route to the ultimate legal determination . . . Whether the claim elements or the claimed combination are well-understood, routine, [and] conventional [at *Mayo/Alice* Step Two] is a **question of fact.**”) (emphasis added); *Berkheimer v. HP Inc.*, 2018 WL 774096, at \*5 (Feb. 8, 2018) (“The question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the

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prior art evidence”); Raymond A Mercado, *Resolving Patent Eligibility and Indefiniteness in Proper Context: Applying Alice and Aristocrat*, 20 Va. J.L. & Tech. 240, 250, 257 (2016) (observing that “[s]ince *Alice*, the trend has been for eligibility to be resolved on the pleadings or via motions to dismiss” and arguing that “[c]ourts are improperly resolving these cases in a vacuum, substituting their own perspective for that of the skilled artisan and ignoring critical fact issues.”).

relevant field [at *Mayo/Alice* Step Two] is a **question of fact**” (emphasis added).

This Court must grant certiorari here to resolve the conflict within Federal Circuit case law on a question critical to the *procedure* of patent eligibility analysis, namely whether the test for eligibility under § 101 this Court set forth in *Mayo/Alice* necessarily involves questions of fact. Otherwise, the “deep conflicts in the case law about whether eligibility is a question of law, fact, or a little of both” will continue to plague the lower courts.<sup>3</sup>

While there was, briefly, some certainty indicating the factual nature of the § 101 inquiry in *Ultramercial Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339 (Fed. Cir. 2013), that case was shortly thereafter *vacated* on other grounds by this Court in *WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014) (GVR in light of *Alice*). Since that time, the Federal Circuit’s case law on this issue has been muddled and uncertain, sometimes characterizing the § 101 issue as purely legal, at other times emphasizing the underlying factual questions. Yet the Federal Circuit has refused to go *en banc* to deal with this issue—including in this case, which brought the question squarely before the court on petition for rehearing. Pet.App.48a.

In the vacuum of uncertainty prevailing since *Ultramercial* was vacated, the phenomenon of “pleading invalidations” has mushroomed. According to one scholar, “[t]he number of pleadings-stage dismissals

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<sup>3</sup> Paul R. Gugliuzza, *The Procedure of Patent Eligibility*, at 25, Paper Presented at the Chicago IP Colloquium at the Chicago-Kent College of Law (Jan. 23, 2018), available at <http://chicagoip.com/files/2018/01/Gugliuzza.pdf>.

on eligibility grounds has dramatically increased” in recent years.<sup>4</sup> “Before the recent reemergence of the eligibility requirement, pleading-stage motions to invalidate patents were basically unheard of.”<sup>5</sup> Now they are the dominant vehicle for challenging eligibility under § 101. As of mid-2017, more than 70% (278 out of 392) of district court decisions on eligibility have been rendered on the pleadings or on motions to dismiss, as in this case.<sup>6</sup> The consequence of such “early resolution of validity via the eligibility requirement may” be the “decreased accuracy” of judicial rulings on patent validity—“[s]pecifically, courts may be using the eligibility requirement of § 101 to invalidate meritorious inventions,” as here.<sup>7</sup> More importantly—as a number of district courts, PTAB judges, and commentators have all recognized—the practice of holding patents invalid under § 101 on the pleadings is flatly inconsistent with this Court’s decision in *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*,

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<sup>4</sup> Paul R. Gugliuzza, *Quick Decisions in Patent Cases*, 106 Georgetown L.J. \_\_, at \*36, (forthcoming 2018), available at <https://ssrn.com/abstract=2987289>; see also Mercado, *supra* note 2, at 258 (“[s]ince Alice, the trend has been for eligibility to be resolved on the pleadings or via motions to dismiss, rather than at the summary judgment stage. As of January 2016, roughly 59% of eligibility decisions were being rendered at the beginning of litigation, via judgment on the pleadings or a motion to dismiss. This is an extraordinary procedural revolution in patent litigation.”).

<sup>5</sup> Gugliuzza, *supra* note 3, at 33.

<sup>6</sup> See Robert Sachs, #Alicestorm: April Update and the Impact of TC Heartland on Patent Eligibility, BILSKIBLOG (Jun. 1, 2017) available at <http://www.bilskiblog.com/blog/2017/06/alicestorm-april-update-and-the-impact-of-tc-heartland.html>

<sup>7</sup> Gugliuzza, *supra* note 4, at 39.

566 U.S. 66 (2012), which articulated a test for eligibility under § 101 that requires significant factual inquiries.

As argued *infra*, under any fair reading of *Mayo*, the current trend of pleading invalidations is untenable, and a misapplication of the law. Step Two of the test for § 101 eligibility set forth in *Mayo* necessarily raises historical questions regarding the state of the art at the time of invention that cannot be resolved on the pleadings in all but the rarest of cases. Rather, courts will need a well-developed record to decide these issues. They will need evidence of the state of the art to compare with the claimed invention, and they will often need expert testimony so that they can understand such evidence from the perspective of the person of ordinary skill in the art, long the objective baseline in patent law. *Mayo*'s search for what was "well-understood, routine, [and] conventional" to "researchers in the field" at the time of invention is a quintessentially factual inquiry, and requires proper evidentiary support. *Mayo*, 566 U.S. at 73. The current explosion of "pleading invalidations," which evades this inquiry entirely or substitutes judicial hindsight for historical evidence, is inconsistent with *Mayo*. Indeed, by preventing patent owners from presenting factual evidence in support of validity, deciding eligibility on the pleadings also raises serious Seventh Amendment issues of the sort this Court is currently considering in *Oil States Energy Services LLC v. Greene's Energy Group, LLC*, cert. granted, 137 S.Ct. 2239 (Jun. 12, 2017).<sup>8</sup>

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<sup>8</sup> See generally Jesse D.H. Snyder, *Have We Gone Too Far: Does the Seventh Amendment Compel Fact-Finding Before Reaching a Decision on Patent-Eligible Subject Matter?*, 14 Chi.-

Therefore this Court must grant certiorari on Petitioners' second question presented to clarify that § 101 necessarily involves factual determinations inappropriate for resolution on a motion to dismiss, as in this case.

However, Petitioners' first question presented also raises an important and recurring issue on which this Court should grant certiorari.

*Mayo* specifically declined to specify when a patent claiming known techniques adapted for a *new* use might be eligible under § 101. *See Mayo*, 566 U.S. at 87 (“We need not, and do not, now decide whether were the steps at issue here less conventional” the claims would be eligible under § 101, noting that “[u]nlike, say a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws.”). As a result, the boundary between clearly ineligible patents that “simply state the law of nature while adding the words ‘apply it,’” and valid patents that confine their reach to a “particular application” of a natural law, remains uncertain after *Mayo*.

The Federal Circuit has simply been unable to articulate a clear test for determining when a “particular application” of a natural law is patentable. This could not be more evident than in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), on which the Federal Circuit relied heavily in this case to justify its result. But as the dissenting judge in *Ariosa*

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Kent J. Intell. Prop. 436 (2015) (arguing that “threshold fact-finding is necessary before rendering a patent invalid” on eligibility grounds).

observed, while “*Mayo*’s declaration that a claim to a ‘new way of using an existing drug’ is patentable, *Mayo*, 132 S.Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*’s sweeping test,” *Ariosa*, 788 F.3d at 1381 (Linn, J., dissenting) (citing Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343-44 (2013)). At least, the Federal Circuit has not been unable to develop case law reading *Mayo* in such a way as would permit such meritorious inventions.

The same is true here as in *Ariosa*: the Federal Circuit in this case was unable to articulate a principle of patent-eligibility whereby Petitioners’ *new* uses of known techniques would be patentable under *Mayo*.

“[D]espite the number of cases that have faced these questions and attempted to provide practical guidance [on eligibility doctrine],” Federal Circuit Judge Linn recently wrote, “great uncertainty yet remains. And the danger of getting the answers to these questions wrong is greatest for some of today’s most important inventions in computing, medical diagnostics, artificial intelligence, the Internet of Things, and robotics, among other things.” *Smart Systems Innovations, LLC v. Chicago Transit Authority*, 873 F.3d 1364, 1378 (Fed. Cir. Oct. 18, 2017) (Linn, J., dissenting in part and concurring in part).

This Court should grant certiorari on both questions presented in this case to provide badly needed guidance. It should clarify (in addressing Petitioners’ second question presented) that the § 101 inquiry under the test this Court set forth in *Mayo* necessarily involves factual determinations that make eligibility under § 101 inappropriate for resolution on a motion



to dismiss in all but the rarest of cases. And (in addressing Petitioners' first question presented) it should clarify the boundary it left open in *Mayo*: when a *new* use for known techniques is patent-eligible. To the extent Petitioners' claims involve natural laws, this Court should provide guidance as to when patent claims that "confine their reach to particular applications of [natural] laws" are patent-eligible. *Mayo*, 566 U.S. at 87.

## ARGUMENT

### I. THIS COURT SHOULD GRANT CERTIORARI AS TO PETITIONERS' SECOND QUESTION PRESENTED TO RESOLVE THE FEDERAL CIRCUIT SPLIT AND CLARIFY THAT THE § 101 INQUIRY UNDER *MAYO/ALICE* IS DEPENDENT ON ISSUES OF FACT.

Under this Court's current two-part test for § 101 eligibility in *Mayo/Alice*, "[f]irst, we determine whether the claims at issue are directed to one of those patent-ineligible concepts," such as an "abstract idea." *Alice*, 134 S.Ct. at 2355. Then, "[a]t *Mayo* step two, we must examine the elements of the claim to determine whether it contains an 'inventive concept,' or whether the claims merely cover 'well-understood routine, and conventional activit[ies] previously known to the industry.'" *Id.* at 2257-2259 (quotation omitted).

Step Two of this Court's current test for eligibility necessarily involves issues of fact because it is impossible to determine whether a claim recites "well-understood, routine, [and] conventional" activity without knowing what was "conventional" at the time of invention. Commentators, including the Federal Circuit's Judge Moore—author of the *Aatrix* and *Berkheimer* opinions characterizing § 101 as dependent on factual

issues—have asked “how should a court determine what is well-known” under *Mayo*?<sup>9</sup> But, as one district court thoughtfully applying Step Two of *Mayo* explained, “it is the state of the art [at the time of invention] that provides the objective baseline for the analysis,” “[l]ike other provisions of the statute,” and “Section 101 should be no exception.”<sup>10</sup> Determining the state of the art at the time of invention, and then comparing it to the patent to ascertain whether the patent claims more than merely “conventional” activity, necessarily involves factual issues. It requires receiving evidence as to the state of the art, and often expert testimony, so that the court is in a position to view the field of invention through the lens of the person of ordinary skill in the art. The district court in *Ameritox* undertook the § 101 analysis in this way, deferring its decision until “the court [became] well versed in the state of the art at the time of the invention.”<sup>11</sup> Having received into evidence “the seminal reference in the art,” “indicative of routine and well-known techniques at the time of the invention in the urine testing world,” the court was prepared to conclude that the patented method “was anything but routine and commonplace in the urine drug testing protocols” of the prior art, and properly upheld its eligibility under the test set forth in *Mayo*.

The courts below should have followed a similar fact-based § 101 inquiry in this case, but did not. Rather,

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<sup>9</sup> Kimberly A. Moore, Timothy R. Holbrook & John F. Murphy, *Patent Litigation and Strategy* 643 (4<sup>th</sup> ed. 2013).

<sup>10</sup> *Ameritox, Ltd. v. Millennium Health, LLC*, 88 F.Supp.3d 885, 915 (W.D. Wis. Feb. 19, 2015).

<sup>11</sup> *Id.* at 914.

they “construed facts *against*” Petitioners, “even though the Pleadings clearly alleged that each of the MPO Testing Patents claim[ed] innovative methods and a specific application of MPO.” *See* Cert. Pet. at 32; Pet.App.54a. And they “purported to take judicial notice of the PTO file histories, but ignored facts about the state of the art,” refusing to develop the factual record in such a way as would shed light on what the skilled artisan would have understood as “conventional” at the time of invention. Cert. Pet. at 32-33. Rather, the courts “incorrectly determined that the techniques claimed in the MPO Testing Patents for detecting MPO mass and MPO activity were conventional or routine.” Cert Pet. at 31.

As the *Ameritox* court perceptively warned, rendering § 101 decisions untethered to a proper evidentiary record in this way frequently results in a “hindsight bias” about the supposed “conventionality” of an invention.<sup>12</sup> Unfortunately, district courts are engaging in this sort of “hindsight bias” all too often,<sup>13</sup> rendering eligibility decisions without factual support and

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<sup>12</sup> *Id.* at 914.

<sup>13</sup> *See Intellectual Ventures II LLC*, 2017 WL 6002762, at \*2 n. 1 (“[r]esolving validity issues at the Rule 12 stage can also tempt courts, sometimes improperly, to conclude that certain concepts are conventional or routine by way of judicial notice or treating this potentially factual question as a purely legal one.”); *see also* Holbrook & Janis, *supra* note 2, at 362 & 382 (observing that courts are deciding eligibility with “virtually nothing to guide and focus the judicial imagination,” a “dynamic [that] becomes particularly salient when considering the procedural posture of these cases – motions to dismiss under Rule 12(b)(6) or 12(c)” and arguing against the courts’ “problematic” practice of “kick[ing] the hypothetical person of ordinary skill in the art to the curb in favor of a discretionary analysis [by the court] that need not be constrained to establish qualifying prior art evidence”); *see also*

divorced from the perspective of the person of ordinary skill in the art, which is the standard throughout patent law.<sup>14</sup> As one district court has observed “[r]esolving validity issues at the Rule 12 stage can also tempt courts, sometimes improperly, to conclude that certain concepts are conventional or routine by way of judicial notice or treating this potentially factual question as a purely legal one.”<sup>15</sup> The same court went on to complain that “[f]raming the [§ 101] question as a legal one also sidesteps and undermines the presumption of validity” and noted that “[g]uidance from the Federal Circuit regarding the specific factual inquiries underlying a § 101 determination is badly needed.”<sup>16</sup> Unfortunately, guidance from the Federal Circuit has not been forthcoming. Instead, the best the Federal Circuit has managed to do is issue a split decision in this area, in which the majority attempts to make an authoritative statement of the law and the

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Mercado, *supra* note 2, at 250 & 257 (arguing that “[c]ourts are improperly resolving these cases in a vacuum, substituting their own perspective for that of the skilled artisan and ignoring critical fact issues.”).

<sup>14</sup> See, e.g., *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128-30 (2014) (holding that definiteness under § 112 “is to be evaluated from the perspective of someone skilled in the relevant art” and “the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters *post hoc*”); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 36-37 (1966) (holding claims obvious under § 103 after comparing them to “the prior art as it stood at the time of the invention” and concluding that “the differences between them and the pertinent prior art would have been obvious to a person reasonably skilled in the art.”).

<sup>15</sup> *Intellectual Ventures II LLC*, 2017 WL 6002762, at \*2 n. 1.

<sup>16</sup> *Id.* (citation omitted).

dissent accuses it of “contradict[ing] our case law that patent ineligibility under § 101 is a question of law.” *Aatrix*, 2018 WL 843288, at \*7 (Reyna, J., concurring-in-part and dissenting-in-part).

Under a proper, fact-based § 101 analysis that follows the procedure this Court outlined in *Mayo*, if a defendant challenging eligibility wishes to argue that a “combination of elements is conventional, [that party] must supply some evidence to convince the trier of fact to accept its version of events,” for “[t]o ignore this concern would provide a ‘blank check’ to all those who challenge patents without sufficient legal or evidentiary basis.”<sup>17</sup> Given the overlap between novelty and Step Two of *Mayo*,<sup>18</sup> “the concern of hindsight bias has as much relevance to a § 101 challenge as it does a § 103 challenge.”<sup>19</sup> Needless to say, in the *Ameritox* case, the district court operating on these principles deferred its decision on § 101 until the summary judgment stage, by which time it had developed a substantial record.<sup>20</sup>

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<sup>17</sup> *Ameritox*, 88 F.Supp.3d at 915.

<sup>18</sup> *Mayo* “recognize[d] that “the § 101 patent-eligibility inquiry and” the “§ 102 novelty inquiry might sometimes overlap.” *Mayo*, 132 S.Ct. at 1304. Of course, the § 102 novelty inquiry said to overlap with § 101 has long been understood to be a “question of fact for the jury.” *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619 (Fed. Cir. 1985), *cert. dismissed*, 474 U.S. 976 (1985).

<sup>19</sup> *Ameritox*, 88 F.Supp.3d at 915.

<sup>20</sup> *Id.* (“having had the benefit of claims construction and viewing the claims through the lens of the skilled addressee, the court is well versed in the state of the art at the time of the invention.”)

With the benefit of a full factual record, a district court may regard itself as “well versed in the state of the art at the time of the invention” and ready to engage in a proper § 101 analysis.<sup>21</sup> If, after such a record has been developed, “there is nothing in the art that demonstrates that such a combination [of claimed structures or method steps] was well-known” and if a defendant “failed to offer any evidence that someone in the scientific community would even have ‘thought’ to combine the claimed elements,” “[t]his provides indicia” that the patent is “inventive for § 101 purposes.”<sup>22</sup> But in the absence of such a record, no indicia of inventiveness, or lack thereof, are to be found. As one district court faced with a motion challenging eligibility on the pleadings asked, “how, on this record, would the Court be in a position to conclusively determine” whether the claim involved merely “conventional activities?”<sup>23</sup> There, the court realized it had no facts with which to under take Step Two of the § 101 analysis under *Mayo*, and properly deferred that decision. Unfortunately, that is the exception to current practice, not the rule. The posture of the current case is by far the most common,<sup>24</sup> and this Court must grant certiorari to curb this growing trend, which is inconsistent with *Mayo*.

Commentators reacting to this Court’s reformulation of the test for eligibility in *Mayo* realized early

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<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 915.

<sup>23</sup> *Kaavo Inc. v. Amazon.com Inc.*, 2016 WL 6562038, at \*11 (D. Del. Nov. 3, 2016).

<sup>24</sup> See *supra* note 6 and accompanying text.

that it requires factual inquiries, which was one reason why the current trend of “pleading invalidations” was not immediately foreseen. For example, one commentator writing soon after *Mayo* remarked: “[t]he fear is that *Mayo* has opened a Pandora’s Box of patentable subject matter defenses. I believe those fears are unwarranted.”<sup>25</sup> That confidence, however, was premised on a reading of *Mayo* recognizing that the new test for eligibility “**requires that courts view evidence of prior art** as part of the patentable subject matter analysis.”<sup>26</sup> More recently, another writer has echoed the same interpretation, noting that “[d]etermining the prevailing practices of a particular community [under *Mayo*] would seem to be a factual inquiry, not a legal one.”<sup>27</sup>

While some members of the Federal Circuit agree with these readings of *Mayo* (see *Berkheimer*, 2018 WL 774096, at \*5; *Aatrix*, 2018 WL 843288, at \*5), others disagree. For example, Judge Reyna worries that this approach “shoehorn[s] a significant factual component into the *Alice* § 101 analysis” and risks “the introduction of an inexhaustible array of extrinsic evidence, such as prior art, publications, other patents, and expert opinion.” *Aatrix*, 2018 WL 843288, at \*7 (Reyna, J., concurring-in-part and dissenting-in-part). Such evidence—and the “full blown factual inquiry” it supports, *id.* at \*7—is not to be feared, as it will lead to more accurate decisions in this confused

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<sup>25</sup> Bernard Chao, *Moderating Mayo*, 107 Nw. U. L. Rev. 423, 432 (2012) (emphasis added).

<sup>26</sup> *Id.* at 435; see also Mercado, *supra* note 2, at 326.

<sup>27</sup> Gugliuzza, *supra* note 3, at 44.

area of the law.<sup>28</sup> Moreover, it is what is *required* by Step Two of the test this Court articulated in *Mayo*.

As mentioned above, the factual nature of the inquiry required by *Mayo* was initially made clear in the Federal Circuit’s decision in *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335 (Fed. Cir. 2013), but that decision was soon *vacated* by *WildTangent, Inc. v. Ultramercial, LLC*, 134 S.Ct. 2870 (2014). However, the Federal Circuit seems to have interpreted this Court’s GVR in *Ultramercial* as impugning the entirety of that decision, and made no attempt to resurrect its reasoning. Yet there is no reason to interpret that vacatur as anything but an instruction from this Court for further consideration in light of *Alice*. *Ultramercial* had made clear, through a careful reading and reflection on the implications of *Mayo*, that “the analysis under § 101, while ultimately a legal determination, is rife with underlying factual issues” and that “[a]lmost by definition, analyzing whether something was ‘conventional’ or ‘routine’ involves analyzing facts.” *Id.* at 1339. *Ultramercial*’s expectation, reading *Mayo*, was that “it will be rare that a patent infringement suit can be dismissed at the pleading stage for lack of patentable subject matter . . . Rule 12[] dismissal for lack of eligible subject matter will be the exception, not the rule.” *Id.* at 1338-39. None of these things was contradicted by this Court’s decision in *Alice*. Unfortunately, the Federal Circuit has made no effort since *Ultramercial* to resolve this issue with similar clarity, and declined the opportunity to go *en banc* in this case, though Petitioners sought rehearing

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<sup>28</sup> See Mercado, *supra* note 2, at 326 (“Had *Mayo*’s approach been followed more carefully, the present chaos in eligibility doctrine might not have occurred.”)



on this question. *See* Pet.App.48a. If this Court does not grant certiorari in this case, the uncertainty will continue to plague the lower courts, and the trend of pleading invalidations will likely continue, in contravention of *Mayo*.<sup>29</sup>

Numerous commentators agree that § 101 analysis under *Mayo* requires a factual inquiry.<sup>30</sup> “[E]xplicitly acknowledging the factual components of the eligibility analysis would nudge courts to more carefully apply the *Twombly* and *Iqbal* framework,” and “dismissal would be appropriate only if there is no plausible argument that the patent satisfies the eligibility requirement.”<sup>31</sup> Another scholar has compared eligibility to claim construction—with respect to which this

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<sup>29</sup> Not only are district courts in need of guidance on this issue, but the PTO also adjudicates § 101 during contested validity proceedings, where the relevance of factual evidence to the § 101 inquiry is as uncertain as ever. As a panel of judges from the PTO’s Patent Trial and Appeal Board recently explained, attempting to make sense of the extant confusion, “if the question of patent-eligibility is a question of law based on underlying facts, then underlying facts have the potential of controlling the ultimate determination.” *IBQ LLC v. Trading Technologies International, Inc.*, 2017 WL 3394060, at \*12-13 (PTAB Aug. 7, 2017) (disagreeing with “the view that the question of patent-eligibility is a pure question of law” and basing its decision on factual “evidence of what was routine and conventional”).

<sup>30</sup> *See, e.g.*, Gugliuzza, *supra* note 3, at 44-45; Holbrook & Janis, *supra* note 2, at 377 n. 143; Mercado, *supra* note 2, at 330-31; Snyder, *supra* note 8, at 450-54.

<sup>31</sup> Gugliuzza, *supra* note 3, at 45.

Court has recognized “subsidiary fact-finding is sometimes necessary”<sup>32</sup>—and to obviousness under § 103.<sup>33</sup> Two others have questioned “the designation of the eligibility inquiry as a question of law” and suggested that “courts might be better off recognizing that eligibility determinations as well may turn on matters that are best deemed to be underlying technical facts.”<sup>34</sup>

All of these considerations were present in the Federal Circuit’s now-vacated *Ultramercial* opinion, which may serve as a fruitful starting point for this Court’s decision in this case. There is no reason to interpret this Court’s GVR in *Ultramercial* as a repudiation of that decision in its entirety—particularly when it is more consistent with *Mayo* than the Federal Circuit’s decision in this case.

“[T]he current fad of ineligibility motions has . . . gotten ahead of itself,” one district court has observed, and “courts should make such determinations on a proper record.” *Verint Systems Inc. v. Red Box Recorders Ltd.*, 2016 WL 7156768, at \*1 (S.D.N.Y. Dec. 7, 2016). To ensure this, the Court must grant certiorari, and clarify that Step Two of the analysis of § 101 eligibility under *Mayo* is dependent on underlying factual determinations that cannot be resolved on the pleadings.

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<sup>32</sup> *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 838 (2015).

<sup>33</sup> Mercado, *supra* note 2, at 330-31.

<sup>34</sup> Holbrook & Janis, *supra* note 2, at 377 n. 143.

**II. THIS COURT SHOULD ALSO GRANT CERTIORARI AS TO PETITIONERS' FIRST QUESTION PRESENTED TO CLARIFY WHEN A NEW USE OF A KNOWN METHOD IS PATENT-ELIGIBLE**

As mentioned above, *Mayo* specifically declined to specify when a patent claiming known techniques adapted for a *new* use might be eligible under § 101. *See Mayo*, 566 U.S. at 87. But as Judge Linn dissenting in *Ariosa* observed, while “*Mayo*’s declaration that a claim to a ‘new way of using an existing drug’ is patentable, *Mayo*, 132 S.Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*’s sweeping test,” at least as narrowly interpreted by the *Ariosa* majority. *Ariosa*, 788 F.3d at 1381 (Linn, J., dissenting) (citation omitted). And indeed, as the result of the Federal Circuit’s narrow reading of *Mayo* in *Ariosa* and in this case, many claims to new uses of known techniques have been invalidated.

Guidance from this Court is badly needed as to the boundary between clearly ineligible patents that “simply state the law of nature while adding the words ‘apply it,’” and valid patents that confine their reach to a “particular application” of a natural law. If this Court does not grant certiorari in this case, the Federal Circuit’s narrow reading of *Mayo* will prevail, and many more meritorious patents will be struck down.

*Ariosa*, which was the principal authority the Federal Circuit relied on in this case, “has not been well

received, and rightly so.”<sup>35</sup> Commentators have criticized it for too “narrowly appl[ying]” this Court’s “inventive concept standard” in *Mayo*, and the “Federal Circuit’s opinion [in *Ariosa*] has now made the *Mayo* standard as overwhelmingly restrictive as the judges feared it to be.”<sup>36</sup> “The repercussions . . . have already begun to manifest themselves,” and among them is the invalidation of Petitioners’ patents in this case.<sup>37</sup> “As the Federal Circuit continues to strike down patents on inventions aimed at discoveries of novel and useful phenomena in the life sciences, the incentive to invent in these areas is likely to dry up.”<sup>38</sup>

The Federal Circuit has simply been unable to provide reasonable guidance in § 101 doctrine—not least on the issue raised by Petitioners in their first question presented: when a new use of a known technique becomes patent-eligible. *See, e.g., CG Technology Development, LLC v. Bwin.Party (USA), Inc.*, 2017 WL 58575, at \*2 (D. Nev. Jan. 4, 2017) (“Commentators have noted the lack of clarity in the test for abstractness challenges under § 101.”) (citing authorities); *TNS Media Research LLC v. TIVO Research and Analytics, Inc.*, 2016 WL 6993768, at \*1 (S.D. N.Y. Nov. 29, 2016) (referring to caselaw interpreting this Court’s current test under § 101 as “somewhat confused”).

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<sup>35</sup> Jared Koch, *The ‘Inventive Concept’ After Mayo: Where Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *Went Wrong*, 96 Neb. L. Rev. 221, 245 (2017).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

The former Director of the PTO David Kappos has stated that decisions “on the issue [of § 101 eligibility] are a ‘real mess’ and threaten patent protection for key U.S. industries.”<sup>39</sup> “[W]e’re now seeing real chaos,” Kappos has said, because “[w]e’re dealing with a litmus test, an ‘I know it when [I] see it’ test” under *Mayo/Alice*.<sup>40</sup> “Patent protection for biotechnology and software inventions is more robust in other countries like China and Europe” than in the United States, according to Kappos, who finds it “a disturbing trend for the U.S. to take those two areas, which are the crown jewel of the innovation economy, and provide less protection for them than other countries.”<sup>41</sup>

It is time for this Court, therefore, to provide additional guidance for when a new use of a known method might be patent-eligible and, to the extent the Court finds that Petitioners’ patents involve natural laws, provide guidance as to when a particular application of a natural law is permissible under § 101.

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<sup>39</sup> Ryan Davis, *Kappos Calls For Abolition Of Section 101 Of Patent Act*, LAW360 (Apr. 12, 2016), available at <https://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act>

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

**CONCLUSION**

For the foregoing reasons, the Court should grant the petition.

Respectfully submitted,

Adam K. Mortara  
BARTLIT BECK HERMAN  
PALENCHAR & SCOTT LLP  
54 W. Hubbard St.  
Chicago, IL 60654  
(312) 494 4400  
adam.mortara@bartlit-beck.com

*Counsel for Amicus Curiae*  
Raymond A. Mercado, Ph.D.