

No. 17-997

IN THE
Supreme Court of the United States

THE CLEVELAND CLINIC FOUNDATION AND CLEVELAND
HEARTLAB, INC.,

Petitioners,

v.

TRUE HEALTH DIAGNOSTICS LLC,

Respondent.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

**SECOND SUPPLEMENTAL
BRIEF OF PETITIONERS**

CALVIN P. GRIFFITH
SUSAN M. GERBER
JONES DAY
North Point, 901 Lakeside
Ave.
Cleveland, OH 44114
(216) 586-3939

LAWRENCE D. ROSENBERG
Counsel of Record
JONES DAY
51 Louisiana Ave., NW
Washington, DC 20001
(202) 879-3939
ldrosenberg@jonesday.com

Counsel for Petitioners

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES.....	ii
SECOND SUPPLEMENTAL BRIEF OF PETITIONERS	1
I. THE OPINIONS IN <i>BERKHEIMER</i> AND <i>AATRIX</i> CONFIRM THAT THE FEDERAL CIRCUIT'S APPROACH TO SECTION 101 ISSUES IS IRRECONCILABLY FRACTURED	3
A. The Majority Of Federal Circuit Judges To Express An Opinion Would Not Find Patents Ineligible On The Pleadings Whenever Material Facts Are In Dispute	3
B. The <i>Berkheimer</i> and <i>Aatrix</i> Opinions Show That The Case Below Was Wrongly Decided.....	6
II. IN LIGHT OF <i>BERKHEIMER</i> AND <i>AATRIX</i> , THIS CASE PRESENTS A PARTICULARLY GOOD VEHICLE FOR THIS COURT TO ADDRESS THE FEDERAL CIRCUIT'S DIVIDED APPROACH TO SECTION 101 JURISPRUDENCE.....	8
CONCLUSION	10

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Aatrix Software, Inc. v. Green Shades Software, Inc.</i> , 882 F.3d 1121 (Fed. Cir. 2018)	1
<i>Aatrix Software, Inc. v. Green Shades Software, Inc.</i> , No. 2017-1452, 2018 WL 2436813 (Fed. Cir. May 31, 2018)	<i>passim</i>
<i>Alice Corp. Pty. Ltd. v. CLS Bank Int’l</i> , 134 S. Ct. 2347 (2014)	3
<i>Berkheimer v. HP Inc.</i> , 881 F.3d 1360 (Fed. Cir. 2018)	1
<i>Berkheimer v. HP Inc.</i> , No. 2017-1437, 2018 WL 2437140 (Fed. Cir. May 31, 2018)	<i>passim</i>
<i>Mayo Collaborative Servs. v. Prometheus Labs., Inc.</i> 566 U.S. 66 (2012)	3
<i>Nautilus, Inc. v. Biosig Instruments, Inc.</i> , 134 S. Ct. 2120 (2014)	4

**SECOND SUPPLEMENTAL
BRIEF OF PETITIONERS**

Petitioners submit this second supplemental brief to bring to the Court's attention two very recent decisions from the Federal Circuit that bear directly on the issues raised in the petition and that support granting certiorari in this case. Petitioners previously showed that the Federal Circuit's decisions earlier this year in *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018) and *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1128 (Fed. Cir. 2018), expressly stated that the question whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a ***factual*** determination. Moreover, whether a particular technology is well-understood, routine, and conventional *goes beyond what was simply known in the prior art. Id.* Those decisions hold that where, as here, the pleadings and intrinsic record contain facts showing that the claimed inventions are innovative, that the prior art taught away from the claimed inventions, and that the Patent Office carefully examined the claims and found them to be novel and non-obvious methods, the inherent factual issues should prevent dismissal on the pleadings. Supp.Br.5-7; Reply.Br.3-9.

The appellee in each of those cases sought rehearing *en banc*, and yesterday, the Federal Circuit denied rehearing in both cases. *Berkheimer v. HP Inc.*, No. 2017-1437, 2018 WL 2437140 (Fed. Cir. May 31, 2018); *Aatrix Software, Inc. v. Green*

Shades Software, Inc., No. 2017-1452, 2018 WL 2436813 (Fed. Cir. May 31, 2018).¹ The court issued a *per curiam* denial of rehearing, but also issued two separate concurrences supporting denial of rehearing and one dissenting opinion. Four judges joined only the *per curiam* order without joining one of the other opinions or separately writing to express their views.

These opinions are significant because they confirm that the Federal Circuit is irreconcilably fragmented in its views on subject matter eligibility, and they further highlight the current uncertainty and unpredictability in the Federal Circuit's Section 101 jurisprudence. This conflict cannot be resolved without the intervention of a "higher authority," such as this Court, as is evidenced by the Federal Circuit's repeated refusal to consider the issues *en banc*. Indeed, Judge Lourie's concurrence urges a higher authority to take action: "Section 101 issues certainly require attention beyond the power of this court." *Berkheimer*, 2018 WL 2437140, at *4. This case presents an ideal vehicle for this Court to take the action needed to resolve the conflicting views among the judges of the Federal Circuit, bring certainty to the law, and redress the errors committed below that deprived Petitioners of their valuable patent rights.

¹ The *per curiam* orders, concurrences, and dissent in *Berkheimer* and *Aatrix* are essentially identical. For simplicity's sake, Petitioners have cited only the opinions from *Berkheimer* in this supplemental brief.

I. THE OPINIONS IN *BERKHEIMER* AND *AATRIX* CONFIRM THAT THE FEDERAL CIRCUIT’S APPROACH TO SECTION 101 ISSUES IS IRRECONCILABLY FRACTURED.

A. The Majority Of Federal Circuit Judges To Express An Opinion Would Not Find Patents Ineligible On The Pleadings Whenever Material Facts Are In Dispute.

In their prior briefs, Petitioners showed that the Federal Circuit is hopelessly divided over how to implement this Court’s directions in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) and *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014). Pet.24-26; Supp.Br.6-7; Reply.Br.6-9. The Federal Circuit’s denials of rehearing in *Berkheimer* and *Aatrix* confirm the polarization within the court, which the Federal Circuit does not seem be able to resolve on its own. The highly fragmented state of the Federal Circuit’s jurisprudence begs for this Court’s intervention.

First, a plurality of the court—Judges Moore, Dyk, O’Malley, Taranto, and Stoll—are of the view that underlying factual issues permeate the eligibility analysis, and the presence of factual disputes prevents a court from declaring patents ineligible on the pleadings or on summary judgment. *Berkheimer*, 2018 WL 2437140, at *1-4. In their concurring opinion, those judges analogized Section 101 to other validity challenges and concluded that “[w]hile the ultimate question of patent eligibility is one of law, it is not surprising that it may contain underlying issues of fact.” *Id.* at *1. Moreover, this opinion emphasized the importance of evaluating patent

eligibility from the “perspective of the ordinarily skilled artisan” as opposed to the perspective of a “reasonable judge.” *Id.* at *1, n.1. *Cf.*, *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128 (2014).

They also explained that this Court “in *Alice* asked whether the claimed activities were ‘previously known to the industry,’ and in *Mayo* asked whether they were ‘previously engaged in by researchers in the field.’” *Berkheimer*, 2018 WL 2437140 at *1. Accordingly, when considering whether the claims recite innovative steps, they framed the inquiry as involving “a question of historical fact[.]” *Id.* at *2, n.3. Those judges also emphasized that in *Aatrix*, dismissal on the pleadings was improper because the patentee’s complaint included “concrete allegations ... that individual elements and the claimed combination are not well-understood, routine, or conventional activity.” *Id.* at *3. They explained, “[w]e cannot adopt a result-oriented approach to end patent litigation at the Rule 12(b)(6) stage that would fail to accept as true the complaint’s factual allegations and construe them in the light most favorable to the plaintiff, as settled law requires.” *Id.* at *3.

Second, another segment of the court, Judges Lourie and Newman, espoused the view that the *Alice/Mayo* two-step test is overly-complicated and ill-advised. *Id.* at *4-6. They urged that “steps that utilize natural processes, as all mechanical, chemical, and biological steps do, should be patent-eligible, provided they meet the other tests of the statute, including novelty, nonobviousness, and written description.” *Id.* at *5. And, while they

recognized that “[a] claim to a natural law itself should not be patentable,” they asserted that “claims to using such processes should not be barred at the threshold of a patentability analysis by being considered natural laws, as a method that utilizes a natural law is not itself a natural law.” *Id.* Those judges concluded, however, that after *Mayo/Alice*, what began “as a simple § 101 analysis” is now “a complicated multiple-step consideration of inventiveness (‘something more’), with the result that an increasing amount of inventive research is no longer subject to patent.” *Id.*

Nevertheless, while clearly uncomfortable with the complex analysis that has been engrafted onto the eligibility inquiry, they apparently feel handcuffed to do anything other than affirm the host of rulings that have declared worthy inventions ineligible for patent protection. *Id.* at *4 (“And the panel, and the court, are bound to follow the script that the Supreme Court has written for us in § 101 cases.”) They do not see a possibility for the Federal Circuit to resolve the “current § 101 dilemma.” To the contrary, they implore a “higher authority” to take action: “Resolution of patent-eligibility issues requires higher intervention, hopefully with ideas reflective of the best thinking that can be brought to bear on the subject.” *Id.* at *6.

Third, one judge, Judge Reyna, is leading the charge to eliminate *any* consideration of factual issues from the Section 101 analysis, arguing that eligibility is a “threshold test” and an “issue of law.” *Id.* at *6-11. He interprets step two of the *Alice* test as an inquiry that “is predominately a legal question focused on *the claims*.” *Id.* at *7 (emphasis in

original). He contended that “[t]he inventive concept cannot merely be alleged; rather, ‘the *claim* ha[s] to supply a ‘new and useful’ application of the idea in order to be patent eligible.” *Id.* (emphasis in original & citation omitted). Thus, as he did in this case, Judge Reyna would deny eligibility in every case unless it is obvious from the claims themselves, divorced from any facts alleged in the pleadings or evidence from the intrinsic record, that the claims include innovative steps that were not conventional or well-known in the art at the time of the invention.

Fourth, the remaining judges who participated in the decision to deny rehearing, Chief Judge Prost and Judges Wallach, Chen and Hughes, expressed no specific views on the matter, having joined only the *per curiam* order.

B. The *Berkheimer* and *Aatrix* Opinions Show That The Case Below Was Wrongly Decided.

The views expressed by the judges of the Federal Circuit shed significant light on the errors committed below in this case, errors that can only be corrected by this Court. Here, the question of what was innovative at the time of the invention is riddled with factual issues. The claimed invention utilized techniques for detecting and comparing MPO that were not known in the art for this purpose. Indeed, the specification provides evidence that at the time of the inventions, skilled artisans suspected MPO could have a role in predicting CVD, but no method had been developed to meaningfully measure MPO and exploit it as a viable biomarker. Patent.App.16, 6:63-67 (“Immunohistochemical methods have demonstrated that MPO is present in human

atherosclerotic lesions. However, MPO has not yet been shown to be present at increased levels in blood samples from individuals with atherosclerosis.”) As discussed in Petitioner’s prior briefs, the prior art tried to detect and measure MPO using other conventional techniques so it could be meaningfully used as a biomarker, but those efforts failed. Pet.7-11; Reply.Br.3-5, 9-12. Indeed, those prior art methods taught away from the claimed inventions. *Id.* Detecting MPO using the techniques disclosed in Petitioners’ patents for the purpose of predicting the risk of CVD was not known in the art before Petitioners’ inventions, as the pleadings alleged. Pet.App.54a.

Thus, had the decision below been rendered after *Berkheimer* and *Aatrix*, and particularly if the panel below included the judges who believe the eligibility inquiry must take into consideration underlying factual issues, the district court’s decision below would likely have been reversed. Further, given Judge Reyna’s strong opinion that eligibility should be determined solely in light of the patent claims without regard to any other evidence presented, it is no surprise that the decision he authored below failed to take into account the facts in the pleadings and intrinsic record that established the innovativeness of the claimed methods, or, at a bare minimum, raised genuine issues of material fact that should not have been resolved against the patentee on the pleadings.

II. IN LIGHT OF *BERKHEIMER* AND *AATRIX*, THIS CASE PRESENTS A PARTICULARLY GOOD VEHICLE FOR THIS COURT TO ADDRESS THE FEDERAL CIRCUIT'S DIVIDED APPROACH TO SECTION 101 JURISPRUDENCE.

In the face of the clear conflict within the Federal Circuit on these issues, and the Federal Circuit's inability to deal with and resolve the conflicts, this case is a particularly good vehicle for this Court's consideration of the issues presented for at least four reasons.

First, the pleadings, specification, and intrinsic record contain facts that show the techniques claimed in the patents were used in an unconventional way, and, indeed, were taught away from by the prior art. Pet.7-11; Reply.Br.3-5, 9-12; Pet.App.54a. Those genuine issues of material fact were erroneously resolved against the patentee. This case provides an ideal opportunity for this Court to address the proper role of underlying facts in the Section 101 inquiry.

Second, this is a life sciences case, and the subject matter involves concrete methods for detecting, measuring, and comparing MPO levels in a bodily sample to predict the risk of CVD. The subject matter is more tangible than methods claimed in abstract idea cases, such as *Berkheimer* and *Aatrix*.²

² The plurality concurrence cites several decisions finding claims ineligible on the pleadings or at summary judgment that were decided after the panel decisions in *Berkheimer* and *Aatrix*. 2018 WL 2437140, at *3. Notably, each of those decisions involved an abstract idea and computer technology; none of

Moreover, the inventions at issue here are critical to protect public health.

Third, this case cleanly presents the issue of patent eligibility without the presence of other complicating questions of invalidity. Each of the patents at issue was thoroughly vetted for novelty and nonobviousness by the Patent Office. Moreover, the '552 patent was scrutinized twice more by the Patent Office in two separate reexamination proceedings. Pet.13-14. Unlike other cases where questions of anticipation and obviousness might be murky, these patents have cleared the validity hurdles on several occasions.

Fourth, this Court is Petitioners' last resort to regain their valuable patent rights. The outcome below is inconsistent with the Federal Circuit's more recent rulings in *Berkheimer* and *Aatrix*. Indeed, the author of the decision below, Judge Reyna, appears to be the strongest supporter of an approach that considers Section 101 issues in a legal vacuum without regard to underlying factual issues, which was applied in this case to strip Petitioners of their valuable patent rights, on the pleadings, without any development of the record. This Court is the only tribunal with the ability to remedy the injustice rendered by the courts below.

(continued...)

them involved a life sciences invention such as those at issue here.

CONCLUSION

Petitioners respectfully request that the Court grant certiorari in this case.

JUNE 1, 2018

Respectfully submitted,

LAWRENCE D. ROSENBERG

Counsel of Record

JONES DAY

51 Louisiana Ave., NW

Washington, DC 20001

(202) 879-3939

ldrosenberg@jonesday.com

CALVIN P. GRIFFITH

SUSAN M. GERBER

JONES DAY

North Point, 901 Lakeside

Avenue

Cleveland, OH 44114

(216) 586-3939

Counsel for Petitioners