

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**

SUPPLEMENTAL BRIEF OF PETITIONERS

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SUPPLEMENTAL BRIEF OF PETITIONERS

Petitioners submit this supplemental brief to bring to the Court's attention two recent precedential decisions from the Federal Circuit that bear on the issues raised in the petition and that support granting certiorari in this case. Below, both the district court and the Federal Circuit misapplied this Court's ground-breaking decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), and invalidated Petitioners' patents for diagnostic methods involving laboratory techniques that had been adapted in a new way and for a new purpose. The district court determined eligibility on the pleadings, over Petitioners' objections, and refused to allow further development of the record, expert testimony, or claim construction. The decision below conflicts with the Federal Circuit's decisions in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016) and *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017), and now also with the two new decisions discussed herein.

The first of the two new decisions is *Berkheimer v. HP Inc.*, --- F.3d ---, No. 2017-1437, 2018 WL 774096, at *5 (Fed. Cir. Feb. 8, 2018). In that case, Judge Moore, joined by Judges Taranto and Stoll, reversed the district court's grant of summary judgment that the patent-in-suit was invalid for claiming ineligible subject matter. The panel ruled that the eligibility determination should not have been decided on summary judgment because the facts underlying the eligibility determination were in dispute. The panel explained:

While patent eligibility is ultimately a question of law, the district court erred in concluding there are no underlying factual questions to the § 101 inquiry. *Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a **factual** determination.* Whether a particular technology is well-understood, routine, and conventional *goes beyond what was simply known in the prior art.* The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.

Berkheimer, 2018 WL 774096, at *6 (emphasis added). There, like in this case, the record showed the inventor's improvements over the state of the art. The panel held that "to the extent [such improvements] are captured in the claims, [they] create a factual dispute regarding whether the invention describes well-understood, routine, and conventional activities[.]" *Id.* In this case, the courts below, like the district court in *Berkeimer*, adjudged the patents invalid even though the issue of whether the claims "perform well-understood, routine, and conventional activities to a skilled artisan is a genuine issue of material fact[.]" *Id.*, at *7. There is thus a clear conflict between the Federal Circuit's decision below in this case and *Berkeimer*.

The second of the new decisions is *Aatrix Software, Inc. v. Green Shades Software, Inc.*, No. 2017-1452, 2018 WL 843288, at *2 (Fed. Cir. Feb. 14, 2018). There, the Federal Circuit reversed the district

court’s Section 101 dismissal on the pleadings where the plaintiff had requested claim construction and sought leave to amend its complaint to allege additional facts showing patent eligibility. *Id.*, at *3. Judge Moore, writing for herself and Judge Taranto, stated that patent eligibility may be determined on the pleadings “only when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law.” *Id.*, at *2. Judge Moore explained that “plausible factual allegations may preclude dismissing a case under § 101 where, for example, ‘nothing on th[e] record ... refutes those allegations as a matter of law or justifies dismissal under Rule 12(b)(6).” *Id.* In that case, however, the court found that the proposed amended complaint “supplie[d] numerous allegations related to the inventive concepts,” “describe[d] the development of the patented invention,” and “present[ed] specific allegations directed to ‘improvements and problems solved by the Aatrix patented inventions.”” *Id.*, at *4. The majority concluded that dismissal was improper because the allegations and supporting evidence raised factual questions as to “[w]hether the claim elements or the claimed combination are well understood, routine, conventional ... cannot be answered adversely to the patentee based on the sources properly considered on a motion to dismiss, such as the complaint, the patent, and materials subject to judicial notice.” *Id.*, at *5.

Judge Reyna—who authored the decision below in this case and the Federal Circuit’s controversial decision in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015)—dissented in

part. He explained that he “disagree[s] with the majority’s broad statements on the role of factual evidence in a § 101 inquiry.” *Id.*, at *6. In his view, “the § 101 inquiry is a legal question.” *Id.* He predicted that if “the 12(b)(6) procedure is converted into a full blown factual inquiry on the level of § 102, § 103, and § 112 inquiries ... [it] would turn the utility of the 12(b)(6) procedure on its head[.]” *Id.*, at *7. Judge Reyna’s dissent largely concedes what Petitioners argued in the Petition—the current detrimental practice of dismissing claims and declaring patents invalid on the pleadings with no procedural safeguards would not be invoked if courts were required to fully consider the underlying facts before invalidating patents on Section 101 grounds. Rather, dismissal on the pleadings would occur only in appropriate cases where there were, in fact, no material factual issues.¹

In this case, Petitioners pled facts showing that the claimed inventions were innovative, including

¹ Last Friday, the Federal Circuit issued a nonprecedential decision in *Automated Tracking Solutions, LLC v. The Coca-Cola Co.*, No. 2017-1494 (Fed. Cir. Feb. 16, 2018), which reaffirmed that “[p]atent eligibility under § 101 is a question of law that may contain underlying issues of fact.” Slip Op. at 6. In that case, unlike here, the *patentee* selected representative claims for the eligibility analysis, all of which claimed only conventional methods used in a conventional way. At oral argument, the patentee’s counsel conceded that the claims analyzed were representative and that the claimed antenna did not differ from conventional RFID antennas. Given these concessions and because the patentee failed to plead or assert any material facts to support its position, the panel affirmed the district court’s dismissal on the pleadings.

that the prior art taught away from the claimed inventions and the United States Patent and Trademark Office carefully examined the patents and concluded that the patents claimed novel and non-obvious methods for detecting and quantifying myeloperoxidase (“MPO”) in blood samples to predict the risk of cardiovascular disease (“CVD”). Pet.App.44a. Moreover, like in *Aatrix*, Petitioners identified claim terms requiring construction, showed how expert testimony was required to resolve the factual disputes, and explained how the claimed inventions were innovative. The Federal Circuit’s decision to affirm dismissal in this case notwithstanding the facts alleged in the complaint and the parties’ factual disputes about the innovativeness of the inventions directly conflicts with the Federal Circuit’s decision in *Aatrix*. See 2018 WL 843288, at *6 (“In light of the allegations made by *Aatrix*, the district court could not conclude at the Rule 12(b)(6) stage that the claimed elements were well-understood, routine, or conventional.”).

The Federal Circuit’s recent decisions in *Berkheimer* and *Aatrix* amply demonstrate the need for this Court’s further review. *First*, the new cases make clear that this case was wrongly decided. Before the district court and the Federal Circuit, Petitioners argued that many material facts about the claimed inventions were in dispute, including whether the allegedly representative claims were, in fact, representative of all of the claims, and asserted that claim construction and expert testimony were necessary to evaluate eligibility. Petitioners’ arguments were dismissed out of hand, but *Berkheimer* and *Aatrix* hold that dismissal or

summary judgment on Section 101 grounds is improper if the patentee raises genuine issues of material fact. Under *Berkheimer* and *Aatrix*, the district court's decision should have been reversed.

Second, these new cases show that the Federal Circuit is hopelessly divided on how to implement this Court's decision in *Mayo*. On one end of the spectrum, Judges Reyna, Wallach and Lourie asserted in this case that resolving eligibility on the pleadings is not just permitted, but encouraged. Pet.App.13a (This court has "repeatedly affirmed § 101 rejections at the motion to dismiss stage, before claim construction or significant discovery has commenced."). Judge Reyna was joined by Judge Wallach in *Ariosa* in affirming that the patent-in-suit claimed ineligible subject matter. And, Judge Reyna dissented in *Aatrix* to argue that a "full blown factual inquiry" should not be allowed in the Section 101 analysis because it would, in his view, turn the "utility" of dismissals on the pleading "on its head." 2018 WL 843288, at *7.

On the other end of the spectrum, Judges Moore, Taranto, Stoll, and Newman hold that the eligibility analysis is not a pure question of law because the issue of whether the invention is sufficiently innovative must be evaluated in light of the scientific and historic facts. *Berkheimer*, 2018 WL 774096, at *5 ("The question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact."); *see also* *BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1354 (Fed. Cir. 2016) (Newman, J., concurring) (urging courts to analyze patentability rather than

eligibility when issues raised by step 2 of the Alice test and the prior art are coextensive); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1294 (Fed. Cir. 2015) (Newman, J. dissenting) (criticizing decision finding patent ineligible on breakthrough invention that “is novel and unforeseen, and is of profound public benefit.”).

Not only is the Federal Circuit hopelessly divided on these fundamental points, it shows no prospect of reaching consensus in the near future. When the Federal Circuit decided *Ariosa*, the patentee sought rehearing en banc. The court declined to hear the case en banc, but that decision to deny rehearing produced three concurrences (Judges Linn, Lourie and Dyk) and one dissent (Judge Newman). Since then, the Federal Circuit has not taken any Section 101 case en banc, despite having had many opportunities to do so, including this case. The Federal Circuit’s fractured approach to handling Section 101 issues has created confusion in the industry and chilled innovation because inventors and investors cannot predict whether new discoveries in this field will ultimately be protected. This case cries out for this Court’s review.

Moreover, in the face of the clear conflict within the Federal Circuit on these issues, and the Federal Circuit’s apparent unwillingness to deal with and resolve the conflicts, this case is a particularly good vehicle for this Court’s consideration of the issues presented. The pleadings 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, yet those material factual issues were resolved against

the patentee. Both the substantive and procedural questions set forth in the Petition are squarely presented by this case.

CONCLUSION

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

FEBRUARY 21, 2018 Respectfully submitted,

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