Case Nos. 14-1139, 14-1144

United States Court of Appeals for the Federal Circuit

ARIOSA DIAGNOSTICS, INC., AND NATERA, INC.
Plaintiffs-Appellees,

AND

DNA DIAGNOSTICS CENTER, INC.,
Counterclaim Defendant-Appellee,

v.

SEQUENOM, INC., AND SEQUENOM CENTER FOR MOLECULAR MEDICINE, LLC
Defendants-Appellants,

AND

ISIS INNOVATION LIMITED,
Defendant.

On Appeal From The United States District Court For The Northern District Of California In Case Nos. 3:11-cv-06391 And 3:11-cv-00132, Judge Susan Illston

RESPONSE OF APPELLEE ARIOSA DIAGNOSTICS, INC. TO APPELLANTS' PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Plaintiff/Counterclaim Defendant-Appellee Ariosa Diagnostics, Inc. certifies as follows:

1. The full name of every party or amicus represented by us is:

   Ariosa Diagnostics, Inc.

2. The name of the real party in interest represented by us is:

   Not applicable.

3. All parent corporations and any public companies that own 10 percent or more of the stock of the parties represented by us are:

   Ariosa Diagnostics, Inc. is a wholly-owned subsidiary of Roche Molecular Systems, Inc., which is a wholly-owned subsidiary of Roche Holdings, Inc. and an indirect subsidiary of Roche Holding Ltd. Novartis AG, a publicly held company, owns more than 10% of the voting shares of Roche Holding Ltd. Novartis AG has no representation on Roche Holding Ltd.'s board of directors and does not in any way control Roche Holding Ltd. or any of its subsidiaries.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or are expected to appear in this Court are:

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INTRODUCTION

On June 12, 2015, a panel of this Court composed of Judges Reyna, Linn, and Wallach unanimously affirmed the Northern District of California's determination that the asserted claims of U.S. Patent No. 6,258,540 (the "'540 patent") "are not directed to patent eligible subject matter and are, therefore, invalid." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015) (the "Panel Opinion"). In doing so, the panel faithfully applied Supreme Court precedent. In fact, despite his misgivings about the Supreme Court's interpretation of 35 U.S.C. § 101, Judge Linn concurred with the panel's decision because this Court is bound by that precedent—which Judge Linn did not suggest the panel had misapplied. As a result, there is no reason for this appeal to be reheard *en banc* and, moreover, no basis on which this Court should disturb the panel's conclusion.

The panel's affirmance was based on its application of the claims of the '540 patent to the "framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts" set forth by the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). *Id*. at 1375; *see also Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (describing and summarizing the *Mayo* framework). In particular, the panel's analysis focused on independent claim 1 as representative of the '540 patent; all but two of the other

asserted claims depend from claim 1. Claim 1 purports to broadly cover using routine laboratory methods to detect naturally-occurring paternally-inherited nucleic acid of fetal origin in maternal serum or plasma. The claim reads in its entirety as follows:

> 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
>
> amplifying a paternally inherited nucleic acid from the serum or plasma sample and
>
> detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

'540 patent col. 23, l. 61-67; Panel Op. at 1373-74. After analyzing claim 1, as well as the other asserted claims and the specification of the '540 patent (Panel Op. at 1373-74, 1376), the panel applied the *Mayo* framework and concluded that (i) those claims "are directed to naturally occurring phenomena," *id*. at 1376, and (ii) those claims do not contain an "inventive concept sufficient to 'transform' the claimed naturally occurring phenomena into a patent-eligible application." *Id*. at 1376-78.

The panel's analysis is exactly what the Supreme Court has mandated and its conclusion is controlled by the Supreme Court's directive that a "process that focuses upon the use of a natural law" must "also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient

to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo*, 132 S. Ct. at 1294. It is also controlled by the Supreme Court's conclusion that the need for an "inventive concept" is not satisfied by combining that natural law with additional steps that "consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id*. at 1298.

Indeed, the method set forth in claim 1 of the '540 patent does not contain any such "other elements or a combination of elements." Rather, setting aside the amplification (*i.e.*, copying) step—which even Appellants concede is not, in itself, inventive—the language of claim 1 is circular and devoid of content: "A method for *detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample* from a pregnant female, which method comprises . . . *detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample*." The claim recites a method for detecting naturally-occurring paternally inherited nucleic acid whose *only* step (aside from making more copies of the nucleic acid) is detecting the naturally-occurring paternally inherited nucleic acid. This is little more than a claim to the natural phenomenon itself—and thus it is hardly surprising that the panel found this claim fails to recite anything "sufficient to

ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo*, 132 S. Ct. at 1294.[1]

Nonetheless, Appellants seek *en banc* review and argue that the panel misinterpreted *Mayo* and ruled inconsistently with other Supreme Court decisions in a manner that "threatens dire consequences for biomedicine as a field and patent law as a whole." Pet. at 7. Despite this "sky-is-falling!" rhetoric, however, Appellants have not identified a single instance in which the panel misinterpreted *Mayo* or in which the Panel Opinion is contrary to any Supreme Court decision, including *Association for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107 (2013) and *Diamond v. Diehr*, 450 U.S. 175 (1981). To the contrary, it is Appellants—not the panel—that misinterpret *Mayo*, misapply *Myriad*, and misread *Diehr*.

Nor have Appellants demonstrated that either *Mayo* or the panel's decision precludes meritorious inventions—*i.e.*, inventions that in fact "add *enough* to their statements of the [natural law or phenomenon] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." *Mayo*, 132 S. Ct. at

[1] It is noteworthy that the amplification step was added at the insistence of the PTO to address enablement concerns—having enough copies of cffDNA in the sample to detect—and not by the inventors as a meaningful limitation on the scope of the claim or to distinguish anything in the prior art. A1036-37 (17:18-18:4). But for the last-minute intervention of the PTO, claim 1 truly would have been devoid of any limitation whatsoever on the use of the natural phenomenon at issue.

1297 (emphasis in original). Countless inventions might do so, but the claims of the '540 patent do not. Indeed, it is telling that Appellants' Petition never once quotes the claim language of the '540 patent—instead relying on theoretical arguments based on Appellants' own view of Supreme Court precedent and hyperbolically dire predictions of the impact of the Panel's decision. Yet as Judge Linn's concurrence demonstrates, when the asserted claims of the '540 patent are actually applied to that precedent, this Court must conclude that the claims are "not directed to patent eligible subject matter and are, therefore, invalid." Panel Op. at 1378; 1380.

Accordingly, as discussed in detail below, the panel in this appeal properly applied controlling Supreme Court precedent and there is no reason for *en banc* review. Appellants' petition should be denied.

ARGUMENT AGAINST REHEARING EN BANC

The panel reached several factual and legal conclusions, almost all of which Appellants do not contest. For example, Appellants do not contest that the existence of cell-free fetal DNA ("cffDNA") in maternal serum and plasma is a natural phenomenon that, on its own, is not patent-eligible subject matter. Panel Op. at 1376. Appellants also do not contest that the claimed method in the '540 patent is directed to that natural phenomenon. *Id*. In addition, Appellants do not contest that the "amplification" and "detection" steps of the asserted claims were "well-understood, conventional and routine" at the time the patent was filed, *id*. at

1377, nor do they disagree with the panel's review of the patent's specification and prosecution history. *See id*. at 1377-78. And, as a result, Appellants do not contest that the "only subject matter new and useful as of the date of the application [for the '540 patent] was the discovery of the presence of cffDNA in maternal plasma or serum." *Id*. at 1377.

Finally, Appellants do not deny that the two-part test established in *Mayo*, as reaffirmed in *Alice*, required the panel to first "determine whether the claims at issue are directed to a patent-ineligible concept" and, if the answer is yes, then "next consider the elements of each claim both individually and 'as an ordered combination' to determine whether additional elements 'transform the nature of the claim' into a patent-eligible application"—which is the precise analysis the panel conducted. Panel Op. at 1375 (*quoting Mayo*, 132 S. Ct. at 1297-98).

Conceding the foregoing, Appellants' only legal argument (as opposed to their dire policy-based prognostications) in favor of rehearing *en banc* is that *Mayo*, *Myriad* and *Diehr* must be read as teaching that "a combination of known steps that incorporates or is motivated by an unpatentable natural phenomenon is nonetheless patentable if that combination 'considered as a whole' was not routine before the patent disclosed it." Pet. at 10. Yet Appellants' misreading of those precedents amounts to nothing short of a wholesale revision of the Supreme Court's two-part test for determining whether a claim recites patent-eligible subject matter.

Indeed, Appellants seek to replace the Supreme Court's two-part test with a fundamentally different inquiry. They would have this Court focus on whether a combination of known steps has ever been routinely applied to an unpatentable natural phenomenon. Appellants' reformulation of the patent-eligibility standard would thus collapse the Supreme Court's two-part test into a one-part test that would be satisfied by *any* patent claim reciting a newly discovered natural phenomenon (because it would never be "routine" to apply "a combination of known steps" to a previously unknown natural phenomenon). And that is the entire point of Appellants' reformulated patent-eligibility inquiry—to secure patent protection for a previously unknown natural phenomenon even when combined with "well-understood, routine, conventional activity already engaged in by the scientific community." *See Mayo*, 132 S. Ct. at 1298. That is not the law, and Appellants' suggestion that this Court rewrite the Supreme Court's standard for patent-eligibility is contradicted by, and thus finds no support in, the well-settled cases this Court is required to follow and apply.

A. Appellants' Argument is Contrary to *Mayo* and *Myriad*

The core of Appellants' argument amounts to their disagreement with *Mayo*, the recent Supreme Court case that the panel opinion faithfully applied. The Supreme Court in *Mayo* could not have been clearer in ruling that, in order to transform unpatentable subject matter "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.'" *Id.* at 1294. And consistent with that rule, the Court held "that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Id*. at 1300. But that is precisely what the applicants did in the asserted claims of the '540 patent. Just as it is not sufficient to "simply state the law of nature while adding the words 'apply it,'" *id*. at 1294, it is not sufficient to simply identify naturally occurring cffDNA in maternal serum or plasma and instruct one to "copy it" and "detect it."

Appellants propose a rule under which the first person to claim a process in which any steps are added to a newly discovered natural phenomenon can obtain a patent because, "considered as a whole," combining the new discovery with those steps was not "routine"—because no one had done it before. Pet. at 10-11. *Mayo* says the opposite. In *Mayo*, the Supreme Court considered whether the patent claims at issue "add *enough* to their statements of the [natural law or phenomenon] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." *Mayo*, 132 S. Ct. at 1297. The Supreme Court concluded that considering the process as an ordered combination "adds nothing to the laws of nature that is not already present when the steps are considered separately." *Id*. at 1298.

Appellants fail to recognize that the patentability of the claims in *Mayo* did not turn on whether the natural phenomenon recited in the claims was newly discovered. Rather, *Mayo* held that the prohibition on patenting a natural phenomenon cannot be overcome by combining that phenomenon with additional steps that "consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id.* at 1298. Nowhere did *Mayo* suggest, let alone hold, that this rule does not apply to a newly discovered natural phenomenon. Indeed, it would make no sense to apply a different rule, with a different outcome, to a newly discovered natural phenomenon. The teaching of *Mayo* is that patent claims reciting "well-understood, routine, conventional activity" do not "add *enough* to their statements of the [natural law or phenomenon] to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." *Id.* at 1297-98. To adopt a different test for a newly discovered natural phenomenon would permit the patenting of a method that does *not* amount "to significantly more than a patent upon the natural law itself." *Id.* at 1294. Yet that is precisely what Appllants seek to accomplish with the '540 patent.

Having no basis to justify patent protection under *Mayo*, Appellants attempt to rely on *Myriad's* statement that "the first person with knowledge" of a natural

phenomenon is in a better position to claim applications of that knowledge. *See* Pet. at 11-12 (citing *Myriad*, 133 S. Ct at 2120). Notably, this is the only language from *Myriad* that Appellants cite. But the language adds nothing to their argument. Even if Drs. Lo and Wainscoat were "in an excellent position" to claim an application of their discovery of cffDNA in maternal serum and plasma, *they did not do so*. Instead, they procured broad claims that merely point to that discovery and instruct one to "copy" the DNA and "detect" the DNA. Indeed, in language from *Myriad* that Appellants omit, the Supreme Court noted that:

> Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents[,] ... widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach....

133 S. Ct. at 2119-20 (internal quotation marks omitted).

The Supreme Court's "had Myriad created" language is mirrored in the District Court's conclusion here that "had the inventors of the '540 patent created an innovative method of performing DNA detection while searching for paternally inherited cffDNA, such as a new method of amplification or fractionation, those claims would be patentable." A0017 (17:5-7). As with the inventors in *Myriad*, however, and unlike the inventors in *Diehr*, Drs. Lo and Wainscoat created no such innovative method and added nothing to their discovery "sufficient to ensure that the

patent in practice amounts to significantly more than a patent upon the natural law itself." *Mayo*, 132 S. Ct. at 1294.

B. Appellants' Argument is Contrary to *Diehr*

Appellants argue that the panel's "core error lies in ignoring *Diehr* and so misunderstanding what it means for a method's steps to be 'routine,' 'conventional,' or 'well-understood.'" Pet. at 7. *Diehr* thus lies at the heart of Appellants' contention that simply adding any method steps to a newly discovered natural phenomenon renders that discovery patentable. *Diehr* says no such thing.

The claimed invention in *Diehr* was "a process for molding raw, uncured synthetic rubber into cured precision products" using "a mold for precisely shaping the uncured material under heat and pressure and then curing the synthetic rubber in the mold so that the product will retain its shape and be functionally operative after the molding is completed." 450 U.S. at 177. Because the process utilized a mathematical formula (the Arrhenius equation), the Supreme Court addressed whether the claimed process was impermissibly "directed to a mathematical algorithm or an improved method of calculation" or instead "recited an improved process for molding rubber articles by solving a practical problem which had risen in the molding of rubber products." *Id*. at 181. The Court concluded it was the latter, and thus was patentable under Section 101. *Id*. at 191.

The distinction between the patentable process claimed in *Diehr* and unpatentable process claimed in the ’540 patent is evident from an analysis of the respective processes themselves—an analysis Appellants do not perform. Specifically, in *Diehr*, the patent claimed a “process of constantly measuring the actual temperature inside the mold” and then feeding these temperature measurements “into a computer which repeatedly recalculates the cure time by use of the Arrhenius equation. . . . According to the respondents, the continuous measuring of the temperature inside the mold cavity, the feeding of this information to a digital computer which constantly recalculates the cure time, and the signaling by the computer to open the press, are all new in the art.” *Id*. at 178-79. The Supreme Court concluded that “Arrhenius’ equation is not patentable in isolation, but when a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is at the very least not barred at the threshold by § 101.” *Id*. at 188; *see also id*. (“While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”) (*quoting Mackay Radio & Telegraph Co. v. Radio of America*, 306 U.S. 86, 94 (1939)).

The asserted claims of the ’540 patent are fundamentally different. They “start and end with a naturally occurring phenomenon” and the method steps between those end points are “conventional, routine, and well understood applications in the

art." Panel Op. at 1378. As noted above, independent claim 1 is entirely circular, reciting a method of detecting DNA, comprising the steps of copying the DNA and then detecting the DNA—all through routine, conventional techniques. The panel also considered the other asserted claims and reached the same conclusion. Panel Op. at 1378. Indeed, Appellants themselves did not rely on any purported points of additional novelty in these other claims. Unlike the claims in *Diehr*, the claims of the '540 patent do not reflect any "inventive concept" that *transforms* the unpatentable natural phenomenon of cffDNA in maternal serum and plasma into a patent-eligible *application* of that phenomenon. *See* Panel Op. at 1376.[2]

To circumvent the holding of *Diehr*, Appellants focus on one paragraph of that opinion in which the Court wrote that, "[i]n determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process

[2] Amici make arguments that are variations on the theme advanced by Appellants. For example, Professors Lefstin and Menell suggest that the Panel Opinion would invalidate claims *Mayo* found patentable, such as the *Neilson* patent. Not so. As *Mayo* expressly held, Neilson's claimed process "included not only a law of nature but also several unconventional steps . . . that confined the claims to a particular, useful application of the principle." *Mayo*, 132 S. Ct. at 1300. Here, the '540 patent includes no such inventive concept, and the Panel Opinion is both consistent with *Mayo* and would not affect meritorious inventions such as Neilson's.

may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Diehr*, 450 U.S. at 188. But this language does not support Appellants' contentions or salvage the claims of the '540 patent: While it is true that claims should be "considered as a whole," the claims still must "transform" unpatentable subject matter "into patentable applications" of that subject matter. *Mayo*, 132 S. Ct. at 1298 (acknowledging *Diehr*, but concluding that "the three steps as an ordered combination *adds nothing to the laws of nature* that is not already present when the steps are considered separately.") (emphasis added). *Mayo* teaches that combining routine scientific activity with a natural phenomenon fails to transform unpatenable subject matter into a patentable application of that subject matter. *Id.*

Moreover, contrary to Appellants' suggestion, Mayo *did not* "strongly reaffirm" Appellants' incorrect reading of *Diehr*. Rather, *Mayo* specifically concluded that *Diehr* (1) "found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole;" and (2) "nowhere suggested that all [the] steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional." *Mayo*, 132 S. Ct. at 1298-99. For these reasons, *Mayo* found that the steps in *Diehr* "added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the

formula." *Mayo*, 132 S. Ct. at 1298-99. This analysis of *Diehr* is entirely consistent with *Mayo's* articulation of the governing standard: "We must determine whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws," and determine whether "a process that focuses upon the use of a natural law also contain[s] other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Id*. at 1294.

That is the standard the panel faithfully applied in this case and that the panel concluded the asserted claims of the '540 patent could not meet because "appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept." Panel Op. at 1378. The panel committed no error in its application of Supreme Court precedent and, accordingly, there is no basis for *en banc* review.

CONCLUSION

For the foregoing reasons, Appellants' petition should be denied.

Dated: October 19, 2015

Respectfully submitted,

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