2014-1139, -1142, -1144

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

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

v.

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

ISIS INNOVATION LIMITED,
Defendant.

Appeals from the United States District Court for the
Northern District of California in case numbers 3:11-cv-06391-SI,
3:12-cv-00132-SI, Judge Susan Y. Illston

BRIEF OF AMICUS CURIAE JYANT TECHNOLOGIES INC. IN SUPPORT OF PETITION FOR REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

Counsel for Amicus Curiae JYANT Technologies, Inc. certifies the following:

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

JYANT Technologies, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

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

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Date: August 27, 2015

/s/ Matthew J. Dowd
Signature of counsel

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

IDENTITY AND INTEREST OF AMICUS CURIAE[1]

JYANT Technologies, Inc. (pronounced "giant"), located in Marietta, Georgia, is an early-stage biotechnology/pharmaceutical development company. JYANT leverages its strong proprietary intellectual property position to develop new therapies with companion diagnostics to bring medical products to the market faster. JYANT's patented technologies provide ground-breaking solutions to diagnosis and treat cancers and inflammatory diseases through the use of anti-chemokine and anti-chemokine receptor antibodies. JYANT has also developed a novel nano-compounding manufacturing methodology that allows for the targeted delivery of anti-cancer agents. Patent protection is critical to ensure the resources needed for its continued research and development. The Court's decision in the present appeal threatens to wreak havoc on patent law, and JYANT urges the Court to rehear this case *en banc*.

SUMMARY OF THE ARGUMENT

The panel's decision is an errant attempt to navigate the murky jurisprudence of subject matter patent eligibility. Without question, the

[1] No party or party's counsel authored this brief in whole or in part, or contributed money intended to fund preparing or submitting the brief.

Supreme Court's efforts have fallen short of clear guidance for distinguishing between a patent-ineligible "law of nature, natural phenomenon, and abstract idea" and an eligible "new and useful process, machine, manufacture, or composition of matter." Notwithstanding the lack of judicial clarity, the panel's decision relies on a misreading of the precedent, and it must be corrected.

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), the Court recognized that applications using non-patentable human genes may be patentable. In *Diamond v. Diehr*, 450 U.S. 175, 188 (1981), the Court explained that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." In *Funk Brothers Seed Co. v. Kalo Co.*, 333 U.S. 127 (1948), the Court countenanced an earlier appellate decision that affirmed the patent-eligibility of a nonobvious, practical application of the natural phenomenon of anaerobic bacteria processing sewage. The panel's holding here fundamentally misreads these precedents.

The panel's opinion also ignores the purpose of the patent laws: "To promote the Progress of . . . useful Arts." U.S. Const. art. I, § 8, cl. 8. Patent protection for novel and nonobvious diagnostic methods furthers that objective. Importantly, patent protection for useful diagnostic tests does not preempt future research. On the contrary, it encourages the dissemination of ideas and enables others to invent improved or alternative diagnostic methods. For these reasons, the nonobviousness requirement of 35 U.S.C. § 103—and not the eligibility requirement of § 101—is the proper test for assessing the patentability of new diagnostic methods.

Finally, the panel's reasoning threatens to abolish wide swaths of existing and future intellectual property. Almost every diagnostic test, whether medical, chemical, or agricultural, relies on some natural phenomenon. Those tests frequently apply known tools, such as reagents or procedures, to solve a specific problem. PCR itself—the basis of the 1993 Nobel Prize—used known reagents and protocols in a novel combination to produce a revolutionary result. Under the panel's reasoning, many diagnostic methods—no matter how novel and

nonobvious—would be ineligible for patent protection without any consideration of the merits of the invention under § 103.

ARGUMENT

I. THE PANEL'S DECISION CONTRAVENES PRECEDENT AND IGNORES THE PURPOSE OF THE PATENT CLAUSE

The panel opinion purports to apply the framework set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), but the *Mayo* framework must be understood in the correct context of precedent, which the panel overlooked. Taken in context, *Mayo* does not require the invalidation of a diagnostic method claim simply because it uses known techniques to achieve a useful result based on new scientific knowledge.

In *Myriad*, the Court rejected claims directed to the naturally-occurring human genes. Applied here, *Myriad* ostensibly foreclosed claims directed to the naturally occurring, cell-free fetal DNA, but the inventors here do not seek such claims.

The *Myriad* Court expressly recognized that methods implementing the human genes may qualify for patenting. The Court explained that the issue being decided "[did] not involve patents on new applications of knowledge about" the human genes. 133 S. Ct. at 2120.

The unanimous Court also quoted Judge Bryson's apt observation that, "[a]s the first party with knowledge of the [gene] sequences, Myriad was in an excellent position to claim applications of that knowledge." *Id.* The Court specifically noted that many of the "unchallenged claims are limited to such applications." *Id.*

Even before *Myriad*, the Court in *Diehr* applied similar reasoning in affirming the patent-eligibility of a method for curing rubber. The claim at issue in *Diehr* covered a method of operating a rubber-molding press, and the innovative aspect was using the Arrhenius equation to calculate "when to open the press and remove the cured product." 450 U.S. at 177–78. Each physical step was known, but the claim, assessed as a whole, was to the patent-eligible improvement of using a particular algorithm together with known steps to achieve an improved result.

Consistent with *Diehr* and *Myriad*, the claimed method here—analyzed as a whole—uses known tools in a novel manner based on a unique scientific insight. The invention's improvement is to use known techniques, such as blood fractionation, PCR, and detection, to achieve a useful result in an improved manner.

The panel's error here is further underscored by *Funk Brothers'* affirmation of *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (2d Cir. 1908). In *Funk Brothers*, the Court approvingly cited *Cameron Septic Tank* as an example of an "application of the law of nature to a new and useful end." 333 U.S. at 130. Claim 1 in *Cameron Septic Tank* covered a "process of purifying sewage, which consists in subjecting the sewage under exclusion of air, of light and of agitation to the action of anaerobic bacteria until the whole mass of solid organic matter contained therein becomes liquefied, and then subjecting the liquid effluent to air and light." 159 F. at 454. The Second Circuit explained that neither the individual steps nor the anaerobic bacteria used in the process were new. *Id.* at 456.

Rather, the invention's innovative feature was the particular implementation of old steps to achieve the new result. *Id.* The Second Circuit firmly rejected the infringer's contention that the method claims "are void because the process they cover 'is a process of nature, and one which cannot be covered by any one.'" *Id.* at 462. When the Supreme Court in *Funk Brothers* cited *Cameron Septic Tank* with approval, *see* 333 U.S. at 130, the Court necessarily agreed that conventional tools,

employed in a novel combination configured to utilize a natural phenomenon, can be patent-eligible.

Furthermore, the claims here do not present the preemption risk of which the Supreme Court has frequently warned. The method's ultimate utility is analyzing fetal DNA to determine characteristics of the fetus, such as gender, Rh type, and certain genetic abnormalities. The claims do not prevent others from making those very same determinations using traditional means for analyzing fetal DNA. The claims therefore do not present the preemption concern the *Myriad* Court considered with the patenting of human genes, which might have tied up the basic informational building blocks of the human genome.

The further flaw of the panel's analysis is how it avoids an obviousness determination under § 103 by skipping to a cursory conclusion on patent eligibility under § 101. Section 103 provides an analytical framework with which a court can objectively determine whether a claimed diagnostic test is a significant enough advance so as to warrant patent protection. *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Section 101 offers no such objective framework. Instead, it employs undefined terms such as "abstract" and "preemption."

Furthermore, patent protection creates the necessary incentive to develop and disseminate groundbreaking diagnostic technologies. *See* Joe Fore Jr., et al., *The Effects of Business Practices, Licensing, and Intellectual Property on Development and Dissemination of the Polymerase Chain Reaction: Case Study*, 1 J. of Biomedical Discovery & Collaboration 7 (2006) ("Without patent protection, and the possibility of rights to future revenue, it seems less likely that Cetus would have devoted any of the necessary resources that contributed to PCR's development."). Unlike § 101, the obviousness inquiry ensures the proper balance of patent protection to provide the necessary incentive for continued innovation.

II. THE PANEL'S RATIONALE CASTS DOUBT ON THE PATENTABILITY OF NUMEROUS TYPES OF INVENTIONS

The panel's incorrect application of the law threatens to undermine patent protection for a wide variety of inventions, including diagnostic tests. No informed application of § 101 should decimate the very legal protection that incentivizes the development of so many useful tools that improve the human condition.

Indeed, patent protection has facilitated the development of medical diagnostic tests of all type, thus improving the standard of care

in the vast majority of medical decisions. *See* Jim Kling, *Will Pharmaceutical Companies or Diagnostics Manufacturers Earn More From Personalized Medicine?*, 8 EMBO Reports 903, 904 (2007) (reporting that "approximately 70% of the decisions made by physicians in the USA are based on the results of a diagnostic test"). Diagnostic tests are ubiquitous, and they provide guidance for the detection and medical treatment of conditions and diseases such as infectious diseases, HIV infection, cancers, inflammatory disorders, stroke, Alzheimer's, and many others. All of these tests, at their base, are specific applications relying on some natural phenomenon. Moreover, absent patent protection, companies will be less inclined to invest in research for diagnostic tests.

Under the panel's reasoning, the invention of PCR itself would likely be patent-ineligible, even though it revolutionized biotechnology and was the basis for the 1993 Nobel Prize. PCR used pre-existing materials, *e.g.*, DNA, primers, DNA polymerase, and deoxynucleoside triphosphates, along with known heating and cooling steps. PCR exploited the natural phenomenon of how DNA replicates to create a

revolutionary process, yet no one could reasonably contend that PCR is not eligible for patent protection.

The invention at issue here can be considered a new, specific use of existing technology, such as PCR. Considering the claims as whole, they should be patent-eligible. The merits of the claimed invention ought to be considered under the proper analytic framework of § 103.

III. CONCLUSION

For the above reasons, JYANT Technologies, Inc. respectfully submits that the Court should grant the petition for rehearing *en banc*.

Date: August 27, 2015

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the page-length limitation of Federal Circuit Rule 35(g). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft® Word and 14-point Century type.

/s/ Matthew J. Dowd

Matthew J. Dowd

Dated: August 27, 2015

CERTIFICATE OF SERVICE

I hereby certify that on this day, August 27, 2015, the foregoing was electronically filed and therefore served electronically via the court's ECF/CM system all counsel of record.

/s/ Matthew J. Dowd

Matthew J. Dowd

Dated: August 27, 2015