No. 15-1182

In The Supreme Court of the United States

SEQUENOM, INC.,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC., and DNA DIAGNOSTICS CENTER, INC.,

Respondents.

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

BRIEF OF *AMICI CURIAE* POPULATION DIAGNOSTICS, INC., AVANT DIAGNOSTICS, INC., PERSONALIS, INC., LINDA BRUZZONE, AND ERIN MARIE MADING IN SUPPORT OF PETITIONER

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amicus curiae Population Diagnostics, Inc., a gene discovery company, is accelerating the delivery of personalized medicine and diagnostic and therapeutic products to enable safe, low-cost, and more effective patient healthcare. Population Diagnostic's gene-based tests allow for early, pre-symptomatic disease detection; aid in the development of novel medications; and assist physician management of conditions such as autism, Alzheimer's disease, Parkinson's disease, endometriosis, and peanut allergy. Population Diagnostics has a strong interest in informing this Court that patent protection is necessary for development of diagnostic tests.

Amicus curiae Avant Diagnostics, Inc., is a medical technology company based on the completion of the human genome-sequencing project. Avant develops specialized, cutting-edge diagnostic tests. Avant's OvaDx® Pre-Symptomatic Ovarian Cancer Screening Test is a blood test that identifies ovarian cancer at an early stage, allowing for early intervention when therapy is most likely to be effective. Avant has a

[1] Notice of the intention to file this brief was given to the parties at least ten days prior to the due date hereof. Counsel for all parties have consented to the filing of this brief, and their consents have been lodged with the Clerk of this Court. No counsel for any party had any role in authoring this brief, and no person other than the named *amici* and their counsel has made any monetary contribution to the preparation and submission of this brief. *See* Rule 37.

strong interest in informing this Court that patent protection underpins the commercialization of diagnostic tests, including the commercialization-in-progress of Avant's own diagnostic tests.

Amicus curiae Personalis, Inc., is a pioneer in genome-guided medicine. Personalis provides researchers and clinicians with accurate DNA sequencing and interpretation. Personalis' ACE (Accuracy and Content Enhanced) Technology supplements a standard exome or genome, substantially increasing its medically relevant coverage and accuracy. Through a comprehensive approach, Personalis provides genomic data and interpretation of the highest accuracy. Personalis has a strong interest in informing this Court that patent protection is an important component of the business strategy of Personalis and other companies specializing in genome-guided medicine.

Amicus curiae Linda Bruzzone is the author of a recently released book entitled, *My Father's Daughter: A Story of Survival, Life, and Lynch Syndrome Hereditary Cancers*. Ms. Bruzzone is a cancer survivor, and a Founder and former President of Lynch Syndrome International ("LSI"). LSI is a 501(c)(3) not-for-profit, all-volunteer organization dedicated to supporting those at high risk for hereditary cancers of Lynch syndrome ("LS"), advocating for people with LS, and providing the general public and medical professionals with awareness and education concerning LS. Ms. Bruzzone has a strong interest in informing this Court that diagnostic tests save lives and

that, without patent protection, life-saving diagnostic tests will not be developed.

Amicus curiae Erin Marie Mading is the mother of five children. Ms. Mading's three youngest children died of cancer before reaching age 18. Son Cody died of cancer in 2010 at age 17, after being misdiagnosed with the genetic condition Neurofibromatosis Type 1. Daughter Averi died of a brain tumor at age 17, after being incorrectly suspected of having a genetic condition called Familial Adenomatous Polyposis. Youngest daughter, Isabella ("Bell"), died of a brain tumor at age 10, after being diagnosed with cancer at age 9. Ms. Mading has a strong interest in informing this Court both that it is critically important to have readily available, accurate, life-saving diagnostic tests that catch diseases early in the development process and that the availability of these tests depends on their ability to be patented.

ARGUMENT

I. The Lower Courts and the USPTO Apply the *Alice/Mayo* Test Inflexibly to Invalidate Any Claim Involving a Judicial Exception, Thereby Thwarting Development of Critical Diagnostic Tests and Increasing the Risk of Needless Deaths

Diagnostic tests save lives in many ways. They detect often hidden conditions, such as infections (*e.g.*, HIV) and metabolic abnormalities (*e.g.*, diabetes), and

flag these conditions for treatment. They detect aggressive diseases (such as Lynch syndrome cancers) at very early stages, when treatment is most likely to be effective. And they ensure that only patients who can benefit from a drug are given the drug, thereby minimizing the chance of patients being disabled or killed by adverse drug reactions.[2]

Furthermore, diagnostic tests rein in healthcare costs. Diagnostic tests ensure that patients and payers purchase only therapies that will work for patients, lowering costs and avoiding side effects. They save money because early treatment is often more cost-effective. They also pare costs by preventing unnecessary medical procedures.

But the development and commercialization of diagnostic tests cost money. Without patent protection, diagnostic test companies cannot recoup the sizable investment of time and capital required for commercialization. As a result, life-saving diagnostic tests will not be commercialized, patients will not have access to diagnostic tests, and needless deaths will follow.

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[2] Adverse drug reactions ("ADRs") are responsible for "the death, hospitalization, or serious injury of more than 2 million people in the United States each year, including more than 100,000 fatalities." ADRs are the fifth leading cause of death in the United States. *Adverse Drug Reactions*, Public Citizen's Health Research Group (2016), available at http://www.worstpills.org/public/page.cfm?op_id=4 (last accessed April 12, 2016).

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), this Court held claims to a specific, simple diagnostic test to be ineligible for a patent. The *Mayo* claims were not representative of the rich variety and complexity of diagnostic innovation. Nevertheless, lower courts and USPTO are applying *Mayo* with a broad brush to invalidate claims far removed from those in *Mayo*. Despite this Court's caution against rigid application of the concerns and principles enunciated in this Court's decisions,[3] rigid application is precisely what has resulted.

II. This Court's Guidance Is Needed to Prevent Reflexive Invalidation of Diagnostic Method Patent Claims

Most diagnostic methods rely on and are built around a judicial exception to patentability,[4] so most diagnostic method claims *involve* a judicial exception.

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[3] "[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* ("*Alice*"), 134 S. Ct. 2347, 2354 (2014) (citation omitted).

[4] The "judicial exceptions" to patentability were explained in *Gottschalk v. Benson*, 409 U.S. 63 (1972), as follows: "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Id.* at 67. Since diagnostic methods involve observation and quantification of phenomena of nature, most diagnostic methods involve a judicial exception.

But that does not mean that such claims are *directed to* a judicial exception. And there is the rub.

Under the two-part *Alice/Mayo* test, a court must first ask "whether the claims at issue are *directed to* one of those patent-ineligible concepts"; if so, then the court must ask, "[w]hat else is there in the *claims* before us?"[5]

Judges and the USPTO are taking the following approach when applying the *Alice/Mayo* test: if a claim contains a judicial exception, judges and patent examiners reflexively invalidate the claim. That is, any claim that merely *involves* a judicial exception is simply equated by this approach with a claim *directed to* a judicial exception. Moreover, once a judicial exception is identified in a claim and is asserted to be what the claim is "directed to," the remaining claim elements are either: (i) ignored; (ii) examined individually *in isolation* and found *in isolation* to be conventional; or (iii) examined as a combination – independent of their combined effect with the judicial exception – and again found to be conventional. In none of this analysis is the claim considered *as a whole*.

This Court has repeatedly rejected overbroad, preclusive, bright-line tests in patent law.[6] Reflexive

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[5] *Alice*, 134 S. Ct. at 2355 (citation omitted) (emphasis added).

[6] Appreciating the danger in applying bright-line tests at the interface of law and rapidly evolving technology, this Court

(Continued on following page)

invalidation of any diagnostic method claim that contains a judicial exception thwarts the intent underlying *Alice* and *Mayo*. Such a reflexive approach indiscriminately invalidates patent-eligible diagnostic claims and, ultimately, will result in more patient deaths. This Court should grant certiorari and hold that a reflexive, inflexible approach is not consistent with *Alice* and *Mayo*.

Neither of the two questions forming the *Alice*/*Mayo* test requires the jettisoning of rudimentary patent law tools, such as claim construction and fact finding. Indeed, it is difficult to see how the questions can be answered without construing contested claim terms and considering the relevant facts. Yet lower courts and the USPTO treat claim construction as optional, and often treat facts as irrelevant, because patent eligibility is said to be a pure question of law.

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has repeatedly rejected use of bright-line tests in patent law. Recent examples include:

i) overturning the teaching, suggestion, or motivation test, *see KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398 (2007);

ii) overruling the machine-or-transformation test, *see Bilski v. Kappos*, 561 U.S. 593 (2010);

iii) rejecting the insolubly indefinite standard for indefiniteness, *see Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014); and

iv) disposing of the Federal Circuit's *Brooks Furniture* fee analysis awarding attorney fees as an "overly rigid" formula that "superimposes an inflexible framework onto statutory text that is inherently flexible," *see Octane Fitness, LLC v. ICON Health & Fitness, Inc*., 134 S. Ct. 1749, 1756 (2014).

This Court's holding can provide useful guidance by instructing the lower courts and patent examiners to honor the plain wording of the *Alice/Mayo* test.[7] The guidance can simply require that judges and patent examiners – instead of analyzing claim elements *in isolation* – conduct a reasoned and thorough evaluation of what the claim *as a whole* is directed to. This guidance, simple as it may be, has several advantages. It adheres to the plain wording of the *Alice/Mayo* test. It sorts § 101[8] eligible claims from § 101 ineligible claims. And by restoring integrity to § 101 evaluations, it provides reasonable predictability for valid diagnostic method claims and will thereby save patient lives.

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[7] *See* Ryan Davis, *Kappos Calls For Abolition Of Section 101 Of Patent Act*, Law360 (April 12, 2016) ("The former director of the U.S. Patent and Trademark Office on Monday called for the abolition of Section 101 of the Patent Act, which sets limits on patent-eligible subject matter, saying decisions like *Alice* on the issue are a 'real mess' and threaten patent protection for key U.S. industries. . . . David Kappos, now a partner at Cravath Swaine & Moore LLP, said . . . that the U.S. Supreme Court's high-profile Section 101 decisions in *Mayo*, *Myriad* and *Alice*, *and the way lower courts have interpreted them*, have made it too difficult to secure patents on biotechnology and software inventions. The high court's decisions were aimed at barring patents on abstract ideas, natural phenomena and laws of nature, but they have been interpreted so broadly that important inventions may no longer be patent-eligible, Kappos said. Parts of patent law besides Section 101 can be used to limit what is patent-eligible without hindering patents on legitimate innovations, he said." (emphasis added)).

[8] 35 U.S.C. § 101.

CONCLUSION

The Court should grant certiorari in order to provide guidance requiring lower court judges and patent examiners to evaluate claims as a whole and in the context of relevant facts when conducting a § 101 analysis. Such evaluation will restore integrity to § 101 analysis, preserve valid diagnostic method claims, and save patient lives.

Respectfully submitted,

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