No. 17-___

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

PETITION FOR A WRIT OF CERTIORARI

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 Petitioner

QUESTIONS PRESENTED

In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), the inventors identified an element existing in nature and claimed known methods to detect that element for a purpose already known in the art. This Court held that patent invalid for claiming ineligible subject matter, but cautioned that "too broad an interpretation of this exclusionary principle could eviscerate patent law." *Id.* at 71. This Court further noted, for example, that "a new drug or a new way of using an existing drug" could be patent-eligible under 35 U.S.C. § 101 ("Section 101"). *Id.* at 87.

In this case, the patents were fully examined by the United States Patent and Trademark Office ("PTO") and found to be novel and not obvious, including for one of the patents, confirmation after two *ex parte* reexaminations. The PTO further found that the prior art taught away from the claimed inventions. Notwithstanding that the inventions were groundbreaking and a significant advancement over the prior art, the district court declared them invalid at the pleading stage. It gave the patents a cursory review, and refused to construe any claim terms. It took 55 separate claims—each claiming a distinct invention with many different limitations—and analyzed them as if all of the claimed inventions were a single method with two simplistic steps. The court did not permit evidentiary submissions or development of the record, and while the district court purported to take judicial notice of the prosecution history, it ignored the PTO record in its analysis. The Federal Circuit affirmed the lower court, invalidating valuable patent rights in a new

and nonobvious diagnostic method using known techniques to detect an element in blood, but where the inventors had discovered that adapting known techniques for an entirely new purpose yielded medically-relevant data not known in the prior art and, in fact, taught away from by the prior art.

The questions presented are:

1. Whether the court below erred in holding, contrary to *Mayo,* that a method involving natural phenomena is ineligible for patent protection if it claims known techniques that have been adapted for a new use and purpose not previously known in the art.

2. Whether *Mayo* authorizes a district court to invalidate valuable patent rights on the pleadings when there are disputed questions of fact, a disputed question of claim construction or scope, and/or an undeveloped evidentiary record, notwithstanding the presumption of patent validity and settled procedural and Seventh Amendment safeguards that ordinarily prevent the resolution of such disputed questions on the pleadings.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners are The Cleveland Clinic Foundation and Cleveland HeartLab, Inc.

The Cleveland Clinic Foundation has no parent corporation, and no publicly held company owns 10% or more of the Cleveland Clinic Foundation's stock.

Cleveland HeartLab, Inc. was recently acquired and is now a wholly-owned subsidiary of Quest Diagnostics, Inc., which is a publicly held company. Prior to the acquisition, Cleveland HeartLab, Inc. had no parent corporation, and no publicly held company owned 10% or more of Cleveland HeartLab, Inc.'s stock.

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INTRODUCTION

In recent years there has been substantial controversy and tumult over Section 101 law.[1] After this Court's ground-breaking decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), follow-on cases in the life sciences area involving DNA—such as, *Association for Molecular Pathology v. Myriad Genetics*, *Inc.*, 569 U.S. 576 (2013), and more recently, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (June 27, 2016)—have created substantial uncertainty and a "bumpy road ahead for pharmaceutical and diagnostic inventors in obtaining patent protection for their discoveries." Thobe*, supra*, at 1048. Indeed, "the broad application of the newly created exceptions to patentability has damaged many innovators[,] … provoked uncertainty in entire industries[,] … [and] 'seems to lead to the *reduction ad absurdum* that most biotechnology processes are patent-ineligible.'"[2]

The decision below conflicts with this Court's precedents and takes a step in the wrong direction in

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[1] Megan Thobe, *A Call To Action: Fixing The Judicially-Murkied Waters Of 35 U.S.C. § 101*, 50 Ind. L. Rev. 1023, 1031-33 (2017) (describing scholars, industry groups, and judges that have expressed concern over current Section 101 jurisprudence, including the ABA, AIPLA, numerous legal scholars, and several judges of the Federal Circuit).

[2] Naira Rezende Simmons, *Why The Supreme Court Should Use* Ariosa v. Sequenom *To Provide Further Guidance On 35 U.S.C. § 101 Patent Eligibility*, 16 Chi.-Kent J. Intell. Prop. 112, 115-116 (2016)

the evolution of Section 101 law that will dramatically undermine research and innovation in life sciences and laboratory medicine. It should be reviewed by this Court for at least four reasons.

First, the Federal Circuit's decision conflicts with *Mayo* and other decisions of this Court. Here, even though the claimed diagnostic methods involved laboratory techniques that had been adapted *in a new way and for a new purpose,* the courts below held the subject matter was ineligible for patent protection despite this Court's precedent including, for example, the statement in *Mayo*, that "a new drug or a new way of using an existing drug" could be patent-eligible under Section 101. 566 U.S. at 87. They failed to apply this Court's admonition to avoid "too broad an interpretation of this exclusionary principle" lest it "eviscerate patent law." *Id.* at 71.

Second, the decision below conflicts with two other Federal Circuit decisions, *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). In *Rapid Litigation*, like here, the inventors observed a natural phenomenon, applied that observation by adapting known techniques in novel ways to create new and improved methods. But there, unlike here, the Federal Circuit found the patent claimed patent-eligible subject matter. In *Thales*, the Federal Circuit applied *Rapid Litigation* and held that an improved technique for measuring movement of an object on a moving platform was patent eligible because it, like here, *applied* the natural law/phenomena. 850 F.3d at 1349. This case thus created an intra-circuit split with *Rapid Litigation*

and *Thales* that has generated further uncertainty and unpredictability in the application of Section 101 law. It is a recurring problem that the Federal Circuit shows no signs of fixing.

Third, the decisions below encourage district courts to analyze eligibility challenges on the pleadings, with no development of the factual record, even though this Court's two-step test in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), is permeated with underlying factual inquiries. Pet.App.13a (This court has "repeatedly affirmed § 101 rejections at the motion to dismiss stage, before claim construction or significant discovery has commenced."). Here, Petitioners The Cleveland Clinic Foundation and Cleveland HeartLab, Inc. (collectively, "the Clinic") requested many procedural safeguards, but the district court denied every request. It refused to construe disputed claim terms, failed to allow appropriate development of the record, and ultimately resolved facts against the non-moving party. Affirming the district court's cursory review on an undeveloped record, the Federal Circuit similarly misapprehended the claimed methods and their advancement of the prior art. It affirmed invalidation of the Clinic's valuable patent rights without any procedural or Seventh Amendment safeguards or deference to the statutory presumption of patent validity.

As former Federal Circuit Chief Judge Michel recently testified before Congress, misunderstanding of this Court's precedents has placed inventors and patent holders at risk, while dramatically reducing the incentives and capital needed for innovation. Paul R. Michel, *The Impact of Bad Patents on*

American Business, Testimony, House Judiciary Committee, Subcommittee on Courts, Intellectual Property and the Internet at 5 (July 13, 2017) (noting that uncertainty in this area "is choking off funding for bio-tech firms just when they are on the cusp of breakthrough discoveries that would revolutionize human health and longevity."). Robust patent protection remains central to this Nation's economic growth and international competitiveness, *id.* at 2, but the Federal Circuit has done nothing to address the problem. To the contrary, it is affirming district court invalidations at an alarming rate, often by Rule 36 summary affirmance, such that one study reports that the Federal Circuit has found patents invalid in 92.3% of cases post-*Alice* for claiming ineligible subject matter.[3] The study concluded that "patentees are, in fact, overwhelmingly losing in the Federal Circuit on patentable subject matter. And they are overwhelmingly losing in decisions that affirm a finding of invalidity by the tribunal below." *Id.*

Fourth, by excluding important and life-saving discoveries, the Federal Circuit's decision will very likely chill innovation to the detriment of scientific development and public health needs. Strong patent protection is critical to innovation. *Bilski v. Kappos*, 561 U.S. 593, 613 (2010) (Stevens, J., concurring in the judgment). Companies that fund research are

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[3] Paul R. Gugliuzza & Mark A Lemley, *Can a Court Change the Law by Saying Nothing?*, 71 Vanderbilt L. Rev. (forthcoming 2018); Stanford Public Law Working Paper; Boston Univ. School of Law, Public Law Research Paper. Available at SSRN: https://ssrn.com/abstract=3015459 at 28-29.

risk-averse and rely on patents to return their investments in new technologies. But the current application of Section 101, especially in the field of biotechnology, has left innovators uncertain whether their discoveries can be protected. Judges, legal scholars, and industry representatives have expressed serious concerns about the apparent weakening of patent protection after *Mayo*. The issues presented here are critical, recurring, and will not be resolved without this Court's intervention.

Review of Section 101 is urgently needed, and this case is an ideal vehicle for this Court's review. Here, the inventors discovered the claimed methods through years of research. The PTO carefully examined the patents multiple times and found the groundbreaking inventions novel and not obvious. The Section 101 issues are cleanly presented, and the patents involve diagnostic methods that implicate substantial public health concerns.

OPINIONS BELOW

The district court's opinion granting respondent's motion to dismiss (Pet.App.24a) appears at 2016 WL 705244. The Federal Circuit's decision affirming the lower court (Pet.App.1a) was reported at 859 F.3d 1352.

JURISDICTION

The Federal Circuit entered judgment on June 16, 2017, and denied petitioner's timely motion for rehearing and rehearing en banc on August 31, 2017. *See* Pet.App.1a, Pet.App.48a. On November 17, 2017, Justice Roberts extended the time to file a certiorari petition until January 16, 2018. *See* No.

17A554. This Court has jurisdiction under 28 U.S.C. § 1254(1).

PROVISIONS INVOLVED

Relevant statutory provisions are reproduced at Pet.App.50a-52a.

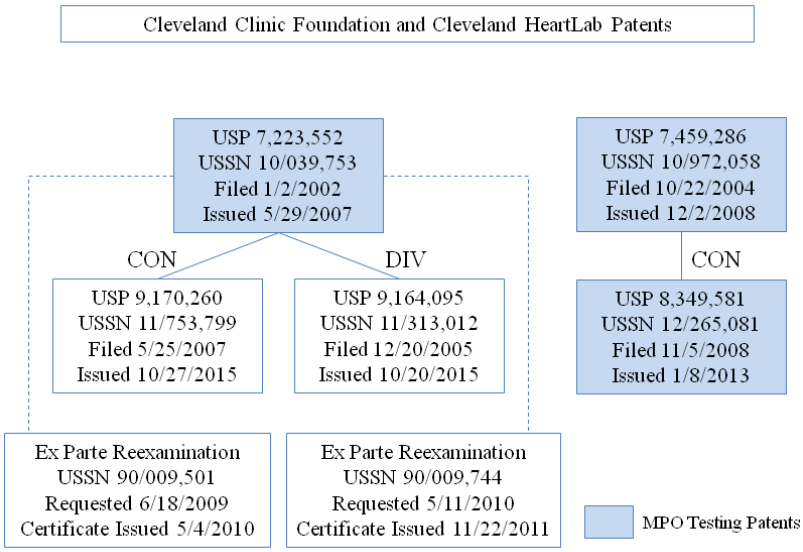
STATEMENT

The Cleveland Clinic is a nationally-recognized top medical center in the United States and in the world. It is particularly well known for its advances in the treatment of cardiovascular disease ("CVD"). It operates the largest heart program in the United States, ranked No. 1 for 23 years. It is also a premier research facility with an integrated research community and an emphasis on disease-focused research. With more than 175 principal investigators and annual research expenditures exceeding $250 million, it is one of the largest private research facilities in the country.

Stanley Hazen, MD, PhD—Department Chair/Section Head at the Clinic and an inventor of the patents here—is a renowned researcher. He has published over 200 peer-reviewed articles in top tier journals, invited reviews, and book chapters in the fields of atherosclerosis, oxidation and inflammation chemistry, and cardiovascular disease. He was named a Distinguished Scientist by the American Heart Association for 2017 and elected to the prestigious National Academy of Medicine in 2016.

A. The Inventors Discovered Groundbreaking Techniques That Can Predict The Risk Of Cardiovascular Disease.

The patents are United States Patents 7,223,552 ("the '552 patent"), 7,459,286 ("the '286 patent"), and 8,349,581 ("the '581 patent") (collectively, the "MPO Testing Patents").



The MPO Testing Patents teach and claim various methods for detecting the presence of an enzyme—myeloperoxidase ("MPO")—that the body releases when an artery wall is damaged or becomes inflamed, and, upon finding MPO in the blood, analyzing the medically-relevant data obtained to predict the risk of cardiovascular disease ("CVD").

1. Before the MPO Testing Patents, the state of the art included three approaches for detecting MPO and attempting to use it to predict CVD. The first

approach detected MPO in an atherosclerotic plaque or lesion as described in Daugherty. Patent.App.99-106. This approach was invasive and required a surgical extract. *Id.* While MPO detected by this method could be correlated with the risk of CVD, the approach was not practical for human clinical testing.

The second approach was known as myeloperoxidase intracellular index or "MPXI." This method, described in Biasucci, indirectly detected the presence of MPO by interrogating neutrophils (*i.e.*, white blood cells) found in blood. Patent.App.107. MPXI had its own diagnostic purpose for cancer patients, but Dr. Hazen's team found it was *not* predictive of CVD. Patent.App.119-128.

The third approach, described in Tereletskaya, detected MPO in the blood. Patent.App.116. While the detection method was an "activity" assay, more akin to the methods claimed in the MPO Testing Patents, Tereletskaya explains it yielded results that were *not* predictive of CVD. Patent.App.117. Using those methods, MPO levels for patients who suffered myocardial infarction had significantly *lower* MPO levels than the control group. *Id.* Thus, Tereletskaya teaches away from the inventions claimed in the MPO Testing Patents.

2. The inventors theorized that MPO could play an important role in identifying patients at risk for CVD. While there were a large number of analytical methods available to the inventors that could potentially detect MPO in the blood, it was unknown in the art which of those potential methods, if any, would be *suitable* for detecting MPO while preserving any potential correlation of MPO to CVD.

Consider test strips to determine the level of chlorine in a swimming pool. If the test strip is not made with appropriate reagents capable of returning a meaningful response, it would not be suitable. For example, the reagents found on a diabetic test strip are perfectly suited to detect blood sugar, but they would not work on a chlorine test strip.

In their search for a suitable technique, the inventors first investigated MPXI. They studied many subjects (in some studies, thousands) to try to relate MPXI to MPO content and MPO activity in the blood stream. Patent.App.119-128. They determined, however, "that MPXI is not a measure of MPO content or activity, and is not a useful risk indicator of cardiovascular disease risks." Patent.App.120.

Once the inventors ruled out MPXI, they began investigating other methods. *Id.* They had to determine which techniques would actually work to detect MPO in the blood and identify method(s) using such technique(s) (if any, given the failure with MPXI) to generate results that provided medically relevant information. Through their extensive research efforts, they discovered that the techniques disclosed in the MPO Testing Patents are suitable.

The patents disclose that MPO activity can be detected using a colorimetric-based assay or in situ peroxidase staining using flow cytometry-based methods. Patent.App.17-18.[4] MPO mass "is readily determined by an immunological method, *e.g.*,

[4] These methods are disclosed in each of the MPO Testing Patents; only the '552 patent has been cited for simplicity's sake.

ELISA." Patent.App.18. In addition to directly detecting MPO in the blood (MPO mass and activity), they discovered that MPO could be usefully detected by analyzing the oxidation products that result when MPO reacts in the blood. Patent.App.18-21; *see also* Patent.App.22-28 (disclosing detailed instructions for detecting MPO-generated oxidation products and practical application of these techniques).

The patents also disclose kits with specific assays that "have appropriate sensitivity with respect to predetermined values selected on the basis of the present diagnostic tests." Patent.App.16. These kits "differ from those presently commercially available for MPO." *Id.* They include "different cut-offs, different sensitivities at particular cut-offs, as well as instructions or other printed material for characterizing risk based upon the outcome of the assay" to make them suitable for the methods claimed in the patents. *Id.*

The inventors also created innovative methods for deriving a value or range of values ("predetermined" or "control" values) using the discovered detection techniques that, when compared to the detected MPO mass or MPO activity, predict whether that individual is at risk of developing or having CVD. Patent.App.23-25. These methods include compiling MPO data from the general population and then segregating the data based upon whether the subjects are "apparently healthy" or whether they have previously exhibited symptoms of atherosclerosis or suffered an acute adverse cardiovascular event. *Id.* The methods customize statistical techniques to evaluate the data and determine the value or range of values for

the claimed comparison step. Patent.App.24-28; Patent.App.43.

Thus, while MPO exists naturally in the body, all of the claimed steps—detecting MPO in the blood, measuring it in a meaningful way, comparing it to a statistically-determined control value obtained using the claimed techniques, and predicting the risk of CVD—were the result of human ingenuity *and* were new to the art.

3. While the MPO Testing Patents stem from the same foundational research, each patent claims multiple, different inventions. The '552 patent claims inventive methods for predicting the risk of CVD by determining the levels of MPO activity, MPO mass, or both in certain bodily samples; comparing the detected MPO activity, MPO mass, or both with a group of subjects diagnosed as not having the disease; and identifying the test subjects at risk of having CVD if the test shows elevated levels of MPO activity, MPO mass, or both as compared to a predetermined value. Patent.App.28.

The dependent claims of the '552 patent add further limitations, requiring that MPO activity or mass is determined by particular techniques: "an assay which employs a peroxidase substrate and flow cytometry," (Claims 2, 19, 22), an "immunological technique," (Claims 7, 20, 23), "exposing said blood leukocytes to a peroxidase substrate and subjecting the substrate exposed blood leukocytes to flow cytometry" and correlating the MPO in the blood leukocytes "with one more flow cytometry parameters," (Claim 12), and determining MPO "by an assay which employs an antibody that binds to myeloperoxidase and flow cytometry," (Claim 13).

Patent.App.28-29. Dependent claims 8 and 9 limit the predetermined values to a single normalized or representative value or a range of normalized or representative values. Patent.App.28.

The '286 and '581 patents claim another set of distinct inventions. Patent.App.48-49; Patent.App.64. These patents also claim inventions where MPO is detected in urine. Patent.App.49; Patent.App.64. Some of the inventions claimed in the '286 patent require the step of determining levels of troponin in the patient's blood and comparing that level to determine whether it is normal or elevated (Claims 13-15, 23). Patent.App.48-49 Claim 18 measures specific MPO-generated oxidation products in the bodily sample, and another invention detects MPO mass, MPO activity, MPO-generated oxidation products, in combination, to predict risk when compared to the control value. Patent.App.49.

The claims of the '581 patent add still further limitations to determine the level of specific MPO-generated lipid peroxidation products and compare the level(s) to a control value. Patent.App.64.

4. The claimed methods were carefully scrutinized by the PTO. During prosecution of the '552 patent, the examiner rejected the claims as anticipated by prior art references. Patent.App.73. Those rejections were overcome by making clear that the claimed methods were measuring MPO in blood, serum, plasma, or circulating leukocytes. *Id.* The PTO accepted that the prior art "does not disclose, teach or suggest determining levels of MPO in any of these bodily samples." *Id.* The '552 patent issued May 29, 2007.

In the first reexamination, the PTO again examined the claims of the '552 patent. The examiner concluded that while the patient populations described in the prior art "indicate various levels of cardiovascular disease," none of the control subjects in the prior art could be "classified 'as not having the disease' as required by the patented claims." Patent.App.92. Indeed, the examiner found that the prior art *taught away* from the claimed inventions:

> [T]he trend does not indicate that the patients with high MPO activity [measured by MPXI] were also those with atherosclerotic cardiovascular disease. … [T]here is no basis for the artisan to conclude that MPO levels are associated with or an indication of atherosclerotic disease as the unstable angina and acute myocardial infarction patients with greater indications of atherosclerotic disease exhibit lower levels of MPO activity.

Patent.App.92-93.

In the second reexamination of the '552 patent, the examiner confirmed again the validity of the claims, accepting that MPXI is not a measure of and does not correlate with MPO detected free-flowing in the bloodstream. Patent.App.97.

The examiner issued similar prior art rejections during prosecution of the '286 patent. Patent.App.82-83. The Clinic overcame the rejections, Patent.App.75-84, and the '286 patent issued on December 2, 2008. In allowing the '581 patent, the examiner again confirmed that the

closest prior art reviewed did not teach the claimed methods. Patent.App.86. The '581 patent issued on January 8, 2013.

B. This Litigation.

1. On November 12, 2015, the Clinic filed suit in the Northern District of Ohio, alleging that Respondent, True Health Diagnostics LLC ("TH"), was infringing the MPO Testing Patents. TH moved to dismiss the case, asserting that the patents are invalid because the correlation between MPO in the bloodstream and the risk of having or developing atherosclerotic CVD was allegedly naturally occurring. Notwithstanding the many independent and dependent claims in the MPO Testing Patents, each defining a separate invention, TH contended that six claims were representative and the district court was not required to evaluate all 55 claims separately.

The Clinic opposed TH's motion and requested several important procedural safeguards, including taking judicial notice of the prosecution histories, because they showed the innovative aspects of the claimed methods. Pet.App.25a; Pet.App.28a-30a. The Clinic explained that the patents cover *non-routine* techniques for detecting and measuring MPO and that the inventors discovered a specific way to "see" MPO in the bloodstream before the onset of symptoms of CVD. Pet.App.38a. The Clinic stressed that "no one asserted claim is representative of the others" because the dependent claims in the MPO Testing Patents each add inventive matter that must be separately considered. Pet.App.30a. While the Clinic had previously proffered constructions of MPO activity and MPO mass, it also identified several

other terms—"immunological technique," "comparing levels," and "determining levels"—that would require construction in order to resolve TH's motion to dismiss. Pet.App.28a.

2. The district court denied each of the requested safeguards and granted TH's motion to dismiss. Pet.App.28a-30a. The court first decided that claim construction was unnecessary. Pet.App.29a. The court also rejected Plaintiffs' argument that it must address each claim in each patent separately, and analyzed all three of the MPO Testing Patents collectively, without distinguishing between the patents or any of the claims in the MPO Testing Patents. Pet.App.29a-30a. Citing the two-part *Alice* test, 134 S. Ct. at 2354, the district court held that the MPO Testing Patents are invalid because they claim ineligible subject matter in the form of a law of nature. Pet.App.36a-37a. The district court's cursory analysis failed to acknowledge that the techniques disclosed in the patents, while previously used in other contexts, had not been previously used for the purpose of detecting MPO activity and MPO mass in a way that is medically relevant for predicting the risk of CVD. The district court declared the patents invalid and dismissed the case.

3. The Clinic timely appealed to the Federal Circuit. The Federal Circuit analyzed the patents under this Court's two-step *Alice* framework. Pet.App.14a. In its analysis, the Federal Circuit barely acknowledged *Mayo,* even though that case involved diagnostic methods, just as this case involves diagnostic methods. Instead, the Federal Circuit based its analysis on its largely inapposite

decision in *Ariosa*, a case involving naturally-occurring DNA, which was authored by the same judge that authored the decision in this case.

At step one of the *Alice* test, the Federal Circuit determined that "[t]he claims of the testing patents are directed to multistep methods for observing the law of nature that MPO correlates to cardiovascular disease." Pet.App.15a. The court stated that the "inventions are 'based on the discovery that patients with cardiovascular disease have significantly greater levels of leukocyte and [MPO],' and they do not purport to alter MPO levels in any way[.]" *Id.* (internal citations omitted). Extrapolating from this, the Federal Circuit determined that the "Clinic's invention thus involves 'seeing' MPO already present in a bodily sample and correlating that to cardiovascular disease." *Id.* It then concluded, based on alleged similarities with *Ariosa*, that "the method starts and ends with naturally occurring phenomena with no meaningful non-routine steps in between." Pet.App.16a.

The Federal Circuit distinguished its prior decision in *Rapid Litigation* by characterizing the inventions in that case as being "directed to a new and useful laboratory technique for preserving [liver cells]" while mischaracterizing the Clinic inventions as "us[ing] well-known techniques to execute the claimed method." Pet.App.16a-17a. Focusing on statements that "known testing methods could be used to detect MPO," and that commercially-available kits for detecting MPO existed, Pet.App.17a, the Federal Circuit ignored a crucial point: while the patents employed conventional techniques, the inventors adapted those techniques

for an entirely new purpose not known in the prior art, and, in fact, taught away from by the prior art. *See, e.g.,* Patent.App.16 ("lmmunohistochemical 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."); *id.* (explaining that kits designed for the patented methods differed from then-available commercial kits, which lacked sensitivity and consistent calibration).

At step two of the *Alice* test, the Federal Circuit considered whether the claims "contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application." Pet.App.17a. Contrary to *Mayo*, the Federal Circuit stated that the analytical techniques to detect MPO in the blood and statistical methods to derive predetermined or control values were "known," Pet.App.18a, while ignoring the inventors' important and previously unknown discovery that those techniques could be adapted in a new way to provide medically-relevant data that was predictive of the risk of CVD. It incorrectly reasoned that the claimed methods "require only conventional MPO detection methods and compare those values to predetermined or control values derived from conventional statistical methods." Pet.App.19a. Based on these faulty premises, the Federal Circuit concluded that the claims "do not sufficiently transform the natural existence of MPO in a bodily sample and its correlation to cardiovascular risk into a patentable invention." Pet.App.19a.

The Federal Circuit's erroneous application of the *Alice* test was exacerbated because the district court failed to provide any procedural safeguards. There was no factual development of the record below, no claim construction, and facts alleged in the complaint and in the PTO record showed that the inventions were not well-known or routine as of the priority date of the '552 Patent. Patent.App.92-93; Patent.App.107-112; Patent.App.113-118. Yet, the Federal Circuit concluded that the MPO detection methods claimed in the patents are "conventional." Pet.App.19a. Before the Federal Circuit, the Clinic argued that the district court erred when it failed to analyze all the claims (or at least establish that the ones analyzed were in fact representative); failed to construe disputed claim terms; and failed to allow development of the record and expert testimony. Pet.App.13a. The Federal Circuit rejected these arguments, concluding (wrongly) that each claim element raised for separate consideration "merely recites known methods of detecting MPO or MPO derivatives and applies the correlation between these biomarkers and cardiovascular health." *Id.* Not only did the Federal Circuit affirm the district court's conclusions, it endorsed the district court's procedure of resolving eligibility on the pleadings: "[W]e have repeatedly affirmed § 101 rejections at the motion to dismiss stage, before claim construction or significant discovery has commenced." *Id.*

REASONS FOR GRANTING THE WRIT

This case raises the issue whether the discovery of a *new application* of *known techniques* resulting in a *novel and non-obvious* method for diagnosing the risk of heart disease is patent-eligible subject matter

under Section 101. It further raises whether an assessment of patent eligibility can or should be made at the pleading stage, particularly when there are disputes of fact, disputes about the scope and meaning of the claim terms, and no development of the evidentiary record. While nothing in this Court's jurisprudence suggests that district courts should be resolving patent-eligibility on the pleadings under these circumstances, since *Mayo*, there have been an avalanche of district court decisions that do just that—decisions that have been affirmed in scores of Federal Circuit cases. These determinations have resulted in the invalidation of hundreds of valuable patents, each one a vested private property right, with no opportunity for fact finding, claim-construction briefing, expert testimony, trial by jury on disputed facts, or any of the other protections usually afforded before issued patents are declared invalid. *See, e.g.,* Michel, *supra*, at 5; Gugliuzza, *supra*, at 28-29.

This Court should grant review in this case. The decision below conflicts with this Court's precedents, and it has created an intra-circuit split at the Federal Circuit. Moreover, the district court refused any procedural safeguards before it invalidated the patents, and the Federal Circuit not only affirmed the result, but it endorsed the procedural shortcuts. This decision, if left unchecked, will create confusion and uncertainty that will chill innovation to the detriment of private enterprise as well as public health.

I. THE DECISION BELOW CONFLICTS WITH THIS COURT'S PRECEDENTS.

Section 101 specifies four categories of inventions or discoveries that are eligible for patent protection: processes, machines, manufactures, and compositions of matter. 35 U.S.C. § 101. "The term 'process' means process, art or method, and includes *a new use of a known process*, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b) (emphasis added). This Court explained that "[i]n choosing such expansive terms … modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope[,]" and a categorical rule denying patent protection for "inventions in areas not contemplated by Congress … would frustrate the purposes of the patent law." *Diamond v. Chakrabarty*, 447 U.S. 303, 308, 315 (1980). Over the years, this Court's treatment of Section 101 has remained constant—the judicially-created exceptions to patent-eligible subject matter are laws of nature, physical phenomena, and abstract ideas, but "a process is not unpatentable simply because it contains a law of nature or mathematical algorithm." *Parker v. Flook*, 437 U.S. 584, 590, 593 (1978).

A. This Court's Precedents Hold That New Applications Or Discoveries Involving Known Techniques Are Patent Eligible.

This Court has consistently held that *new* methods that apply a law of nature or mathematical formula are patent-eligible. For example, in *Diamond v. Diehr*, 450 U.S. 175, 177 (1981), the patent claimed a previously unknown method for curing rubber using a mathematical formula. This Court explained that

"an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection" and concluded that the claimed method was patent eligible. *Id*. at 187, 192-193. The Court emphasized the importance of considering the invention as a whole, rather than "dissect[ing] the claims into old and new elements and then ... ignor[ing] the presence of the old elements in the analysis." *Id*. at 188.

Years later, in *Alice,* this Court reiterated that the claims in *Diehr* were "patent eligible because they improved an existing technological process." 134 S. Ct. at 2358. The Court explained that "[a]t some level, all inventions … embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," but *applications* of abstract concepts "to a new and useful end," are nonetheless eligible for patent protection. *Id.* at 2354 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).)

In the life sciences area, the Court consistently applied these principles. In *Mayo*, the patent involved methods for measuring certain metabolites in blood, the levels of which correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. *Mayo*, 566 U.S. at 72. This Court held that the patent claimed ineligible subject matter because the claims identified an element existing in nature, involved *known* methods to detect that element, and the purpose was already *known* in the art. *Id*. at 79-80. But, this Court cautioned that while "phenomena of nature, ... mental processes, and abstract intellectual concepts" are not patent-eligible, "too broad an interpretation of this exclusionary principle could

eviscerate patent law." *Id.* at 71. Indeed, "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." *Id.* at 79 (quoting *Diehr*). For example, "a new drug or a new way of using an existing drug" could be patent-eligible under Section 101. *Id*. at 87.

The Court's decision in *Myriad* comports with these principles. 569 U.S. at 576. There, the Court found claims to human-made cDNA were patent eligible, even though the claims were "based upon" the discovery of a naturally-occurring location and "sequence of two human genes." *Id.* at 579. In finding other claims directed to naturally-occurring DNA were *not* patentable, the Court distinguished the processes used by Myriad to isolate DNA because they were well understood in the art at the time of Myriad's patents, and any scientist engaged in the search would likely have used a similar approach. *Id*. at 595-96.

B. The Federal Circuit Failed To Follow This Court's Precedents When It Held The MPO Testing Patents Ineligible.

In this case, the Federal Circuit failed to apply this Court's precedents and expanded its prior rulings, by holding that the MPO Testing Patents claim patent-ineligible subject matter, even though the patents claim conventional techniques *adapted for an entirely new purpose not known in the prior art* (in fact here taught away from by the prior art). In reaching this conclusion, the Federal Circuit did *not* analyze and apply *Mayo* and other cases from this

Court, but instead foisted the inapposite (and faulty) analysis from *Ariosa* onto this case.

1. *Ariosa* is fundamentally different from the circumstances here. "Laws of nature are exact statements of physical relationships, deduced from scientific observations of natural phenomena[,]" but "methods that utilize laws of nature do *not* set forth or claim laws of nature." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1285 (Fed. Cir. 2015) (Lourie, J., concurring in denial of rehearing en banc) (emphasis added). In *Ariosa*, the claims involved a method to detect paternally-inherited fetal DNA, a substance that exists in nature, in maternal blood that would show fetal characteristics, such as gender. Here, the patents claim methods for predicting the risk of CVD, which is not a law of nature. Medical diagnosis includes an element of human ingenuity different from what was involved in *Ariosa*.

Moreover, in *Ariosa*, the patent claimed methods "like PCR to amplify and detect cffDNA [that] w[ere] well-understood, routine, and conventional activity in 1997." 788 F.3d at 1377. In contrast, here, the methods discussed and claimed in the patents were known for other purposes, but were adapted for the first time by the inventors to detect and measure MPO free flowing in the blood to obtain medically relevant information relating to the risk of CVD. And, the MPO Testing Patents go further because they claim a method for deriving controls and cutoffs using the claimed laboratory techniques to obtain data and then apply statistical models—again known in other contexts, but not in this context—to determine values that can be compared to specific

results from a patient sample to evaluate the risk of CVD.

2. Not only did the Federal Circuit improperly apply *Ariosa* to this case, it largely ignored *Mayo,* with which this case conflicts. There, the patent was held ineligible because the claims were directed to natural phenomena and everything else claimed in the patent was well known in the art. *Mayo*, 566 U.S. at 79-80. But here, the Federal Circuit should have found that while the inventions claimed in the MPO Testing Patents involved conventional techniques, the discovery of using those techniques for an entirely new purpose not known in the prior art and actually taught away from by the prior art is patent-eligible subject matter. This Court should grant certiorari to correct the Federal Circuit's erroneous application of Section 101, reign in its expansive interpretation of *Mayo*, and stop its evisceration of valuable patent rights, particularly in the life sciences arena.

II. THIS CASE CREATED AN INTRA-CIRCUIT SPLIT WITH *RAPID LITIGATION* AND *THALES* THAT CANNOT BE RESOLVED WITHOUT THIS COURT'S INTERVENTION.

Even though this case is just like *Rapid Litigation* and *Thales*, the Federal Circuit did not follow its prior decisions, and its attempt to distinguish *Rapid Litigation* from this case has created an intra-circuit split and still further confusion in the law of Section 101.

In *Rapid Litigation*, the inventors discovered the natural phenomenon that hepatocytes are capable of surviving multiple freeze-thaw cycles. 827 F.3d at

1047. "But that [discovery] is not where they stopped, nor is it what they patented." *Id.* at 1048. Rather, they claimed applications of that knowledge: "They employed their natural discovery to create a new and improved way of preserving hepatocyte cells for later use." *Id.*

The same is true here. The Clinic inventors discovered the relationship of MPO in the blood to CVD, but they did not stop with that discovery. As a result of intensive research, they discovered which analytical techniques were suitable for detecting and measuring MPO in the blood, quantified the resulting data so that it was meaningful and correlated with the risk of developing CVD, and used the results to diagnose the risk of CVD. As the Federal Circuit correctly explained in *Rapid Litigation*, applying known techniques to new problems is inventive and not routine: "That each of the claims' individual steps (freezing, thawing, and separating) were known independently in the art does not make the claim unpatentable. … '[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.'" *Id.* at 1051 (quoting *Diehr*, 450 U.S. at 188).

Instead of following *Rapid Litigation*, however, the Federal Circuit attempted to distinguish it, and, as a result, has created substantial uncertainty in the law. And that uncertainty is compounded by the Federal Circuit's decision in *Thales*. There, unlike in this case, the Federal Circuit did follow *Rapid Litigation*. The claims in *Thales* involved principles of physics and mathematical equations that were

adapted for methods for measuring movement of an object on a moving platform. 850 F.3d at 1349. The Federal Court held the claims were patent eligible because "[j]ust as a natural law can be utilized to create an improved laboratory technique for preserving liver cells, [*Rapid Litigation*] at 1048, so can the application of physics create an improved technique for measuring movement of an object on a moving platform." *Id.* When the inventions of the MPO Testing Patents are properly understood and characterized, they, like the claims in *Rapid Litigation* and *Thales*, are clearly directed to techniques adapted for a new and useful purpose in detecting MPO to predict the risk of CVD. If this intra-circuit split is left uncorrected, it will result in even more confusion and uncertainty in the law. Given that the Federal Circuit denied rehearing in this case, this Court is the only one in a position to address the split and provide the clarity and certainty that is needed.

III. THE FEDERAL CIRCUIT DECIDED THIS CASE WITHOUT ANY PROCEDURAL SAFEGUARDS AND IS ACTIVELY ENCOURAGING ELIGIBILITY DETERMINATIONS ON THE PLEADINGS.

More and more, the district courts and the Federal Circuit have been giving short shrift to the question of patent eligibility and have been invalidating patent rights at an alarming rate. More than 70% of district court decisions on patent eligibility have been rendered on the pleadings or on a motion to dismiss. Robert Sachs, *#Alicestorm: April Update and the Impact of TC Heartland on Patent Eligibility*, BILSKIBLOG (June 1, 2017) available at http://www.bilskiblog.com/ blog/2017/06/ alicestorem-

april-update-and-the-impact-of-tc-heartland.html. This study reported the invalidation rate under the *Mayo-Alice* test in federal courts is 67.6%. *Id.* But another study reports that the Federal Circuit has found patents invalid for claiming ineligible subject matter in 92.3% of post-*Alice* cases when Rule 36 decisions are included in the calculation. Gugliuzza, *supra*, at 28-29.

A. Analyzing Patent Eligibility Often Involves Questions Of Fact, And May Need Expert Testimony And Claim Construction.

1. The analysis of patent eligibility using the *Alice* framework is permeated with factual inquiries. *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1056 (Fed. Cir. 1992) (Newman, J.) (stating that the eligibility analysis "may require findings of underlying facts specific to the particular subject matter and its mode of claiming"). "[T]he analysis under § 101, while ultimately a legal determination, is rife with underlying factual issues" and "[a]lmost by definition analyzing whether something was 'conventional' or 'routine' involves analyzing facts." *Ultramercial, Inc. v. Hulu*, LLC, 722 F.3d 1335, 1339 (Fed. Cir. 2013) vacated by *WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014) (GVR). As this Court recognized in *Mayo*, "the § 101 patent-eligibility inquiry" and the "§ 102 novelty inquiry might sometimes overlap." 132 S. Ct. at 1304.

"[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). Indeed, to be

sustained, "[a] dismissal under Rule 12(b)(6) … must be correct as a matter of law when the allegations of the complaint are taken as true." *Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems, Inc.*, 988 F.2d 1157, 1160 (Fed. Cir. 1993) (vacating dismissal and remanding). When deciding a case on the pleadings, the court may not resolve disputed issues of fact against the plaintiff. Under the framework created by this Court in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), a district court must consider whether there is a plausible scenario in which the plaintiff could prevail, rather than simply ruling on the patent's inventiveness without giving the patentee the benefit of the doubt. Unfortunately, the latter seems to have become the prevailing practice when courts determine patent eligibility under Section 101.

2. Not only does the Section 101 analysis involve factual inquiries, the subject matter can be highly technical. Expert testimony may be required, for example, to determine the level of skill in the art at the time, and to understand the background science or the meaning of a term in the relevant art. *Teva Pharmaceuticals USA, Inc. v. Sandoz Inc*., 135 S. Ct. 831, 841 (2015) (explaining the need to look beyond the intrinsic record to interpret a patent: "a patent may be 'so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning.'").

Yet, like here, expert testimony is often excluded from the patent eligibility analysis. For example, in one recent case, the patentee, anticipating a Section

101 challenge, attached expert testimony to its complaint, but the district court excluded it as being "inapplicable to legal conclusions"; that decision was subsequently affirmed in a Rule 36 summary affirmance by the Federal Circuit. *Appistry, Inc. v. Amazon.com, Inc.*, 195 F. Supp. 3d 1176, 1183 (W.D. Wash. July 19, 2016), aff'd 676 F. App'x 1008 (Fed. Cir. Feb. 10, 2017).

3. Further, the Section 101 inquiry may require construction of claim terms. The Federal Circuit explained that "it will ordinarily be desirable—and often necessary—to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter." *Bancorp Servs., LLC v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1273–74 (Fed. Cir. 2012).

4. Finally, by evaluating patent eligibility on a motion to dismiss, the patentee is deprived of its Seventh Amendment right to trial by jury when factual issues are resolved at the pleadings stage. As this Court explained, the "thrust of the [Seventh] Amendment was to preserve the right to jury trial as it existed in 1791[.]" *Curtis v. Loether*, 415 U.S. 189, 193 (1974). Factual issues relating to patent validity have been tried to juries under the common law since early in the 17th Century. *See, e.g., Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (Story, J. Circuit Justice) (charging jury that the plaintiff must show that its invention is "a useful invention"); *Kneass v. Schuylkill Bank*, 14 F. Cas. 746, 748 (C.C.D. Pa. 1820) (same). Because patent validity questions were tried to juries in 1791, and the

Seventh Amendment protects the right to a jury trial as it existed in 1791, it violates the Seventh Amendment to subject patentees to summary invalidation of their patents when there are unresolved factual disputes.

B. District Courts And Commentators Have Expressed Concern That Section 101 Decisions Are Being Made On An Undeveloped Record Without Appropriate Procedural Safeguards.

Many district courts have expressed concern about resolving factual issues at the motion to dismiss stage on an undeveloped record and without expert testimony. *Verint Systems Inc. v. Red Box Recorders Ltd.*, 226 F. Supp. 3d 190, 192-93 (S.D.N.Y. 2016) (explaining "the current fad of ineligibility motions in patent cases has, in certain respects, gotten ahead of itself" and noting that "courts should make such determinations on a proper record"); *Kaavo Inc. v. Amazon.com, Inc.*, Nos. 15-638-LPS-CJB, 15-640-LPS-CJB, 2016 WL 6562038, at *11 (D. Del. Nov. 3, 2016) (asking "how, on this record, would the Court be in a position to conclusively determine" whether, under the second step of *Alice* that the claim involved merely "conventional activities?"); *Invue Sec. Prods. Inc. v. Mobile Tech, Inc.*, No. 3:15-cv-00610-MOC-DSC, 2016 WL 1465263, at *2 (W.D.N.C Apr. 14, 2016) (noting that numerous courts have declined to rule on eligibility at the pleading stage, "finding claim construction and additional factual development necessary to resolution of the invalidity question").

As one commentator aptly stated, when eligibility is decided on the pleadings without benefit of factual

evidence, " [c]ourts are improperly resolving these cases in a vacuum, substituting their own perspective for that of the skilled artisan and ignoring critical fact issues." Raymond A. Mercado, *Resolving Patent Eligibility And Indefiniteness in Proper Context: Applying* Alice *and* Aristocrat, 20 Va. J. L. & Tech. 240, 250 (2016).

C. The Federal Circuit And District Court Resolved Factual Issues Against The Patentee And Contrary To The Facts Alleged In The Patents And Pleadings.

Here, the Federal Circuit incorrectly determined that the techniques claimed in the MPO Testing Patents for detecting MPO mass and MPO activity were conventional or routine. Pet.App.13a ("Each limitation Cleveland Clinic raises, however, merely recites known methods of detecting MPO or MPO derivatives and applies the correlation between these biomarkers and cardiovascular health.") It reached these conclusions even though the prosecution history from the PTO showed that at the time of the inventions, skilled artisans knew that MPO could be detected in atherosclerotic lesions and in white blood cells, but when elevated levels of MPO were analyzed from those sources, there was no correlation with CVD. Patent.App.92-93; Patent.App.107-112; Patent.App.113-118. And, at least one prior art method taught away from the Clinic's inventions because MPO levels detected using that method in patients who had suffered myocardial infarction were significantly lower than MPO levels for the control group. Patent.App.117. Before the claimed inventions, skilled artisans did not know that

detecting and measuring MPO mass or activity in the blood would be predictive of CVD.

The district court invalidated the MPO Testing Patents without affording any procedural safeguards. *First*, the district court construed facts against the Clinic even though the pleadings clearly alleged that each of the MPO Testing Patents claim innovative methods and a specific application of MPO. *See, e.g.,* Pet.App.54a, ¶ 14 ("The '552 Patent's claims include using MPO to assess CVD risk and "determining levels of [MPO] activity, [MPO] mass, or both," which were not known, well-known or routine as of the priority date of the '552 Patent. The patent claims a specific application of MPO and not MPO itself."); *see also id.*, ¶¶ 15-16 (alleging same for the other MPO Testing Patents). *Second*, the district court purported to take judicial notice of the PTO file histories, but ignored the facts about the state of the art. *See* pages 12-13, *supra.* The court further ignored statements from the patents that explained the claimed inventions were novel in light of the state of the art at the time of the invention. *Id.* *Third*, the district court refused to construe claim terms "immunological technique," "determining," "comparing," and "predetermined levels." Pet.App.29a; Pet.App.40a. A proper construction of "immunological technique" and "determining" would have defined the limits of the claims and clarified the specific tests and assays the inventors discovered that were suitable for the task. Similarly, if "comparing" had been properly construed, it would have become clear that the district court misunderstood and undervalued the "predetermined/control value" mechanism when it

concluded that the "control samples are in turn derived from basic statistical techniques and can vary in form." Pet.App.37a-38a. *Fourth*, in deciding eligibility on the pleadings, the district court prevented additional expert testimony and development of the factual record that would have shown the state of the art at the time of the invention and what a skilled artisan would have understood as conventional at that time. And, of course, deciding eligibility at the pleading stage eliminates the patentee's right to a trial by jury on that issue.

Had the district court granted the Clinic's request for these basic procedural safeguards, the district court and the Federal Circuit would have been in a position to make meaningful findings about the state of the art and whether the claimed techniques were routine or conventional for this purpose. But without any development of the record, the district court made erroneous assumptions and wrongfully invalidated the Clinic's valuable patent rights.

IV. THE CURRENT APPLICATION OF SECTION 101 ELIGIBILITY WILL CHILL INNOVATION.

The MPO Testing Patents disclose groundbreaking tools for diagnosis of one of America's most prevalent and life-threatening conditions, CVD. However, the Federal Circuit's decision below, as well as its inconsistent application of Section 101 in the life sciences arena, will likely chill innovation in this area to the detriment of public health. Indeed, the fields of biotechnology and medical diagnostics have already suffered significant losses of funding as a result of *Mayo* and its progeny. Michel, *supra*, at 5. In fact, here, relying upon the MPO Testing Patents,

investors funded development of a clinical MPO test and a created a specialty lab that later became Cleveland HeartLab. Without the patents, however, those investors might not have been motivated to make this life saving technology available to the public.

1. Strong patent protection and predictable application of patent law is critical to innovation. As Justice Stevens noted, "[i]n the area of patents, it is especially important that the law remain stable and clear." *Bilski*, 561 U.S. at 613 (Stevens, J., concurring in the judgment).

Unfortunately, after *Mayo*, there has been great uncertainty in the courts' application of Section 101, particularly in the fields of biotechnology. Judge Linn recently noted that the Federal Circuit's application of the Section 101 test "is indeterminate and often leads to arbitrary results." *Smart Sys. Innovations, LLC v. Chicago Transit Authority*, 873 F.3d 1364, 1377 (Fed. Cir. 2017) (Linn, J., dissenting). He explained that "[d]espite the number of cases that have faced these questions and attempted to provide practical guidance, great uncertainty yet remains." *Id*. at 1378. Indeed, "the danger of getting the answers to these questions wrong is greatest for some of today's most important inventions in computing, medical diagnostics, artificial intelligence, the Internet of Things, and robotics, among other things." *Id*. *See also BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1353 (Fed. Cir. 2016) (Newman, J., concurring in the result) ("[T]he emphasis on eligibility has led to erratic implementation in the courts.").

Uncertainty in the application of Section 101 at the Federal Circuit was clearly demonstrated when the court was asked to re-hear *Ariosa*. While the court declined to re-hear the case, three judges wrote separately to express their significant concerns. Judge Newman dissented because she found that the panel's decision had improperly extended this Court's precedent. *Ariosa* 809 F.3d at 1294 (Newman, J., dissenting) (noting that the panel's decision failed to consider the admonitions in *Mayo*). Judge Lourie explained that, in his view, "neither of the traditional preclusions of laws of nature or of abstract ideas ought to prohibit patenting of the subject matter in this case." *Id*. at 1284. He noted that "the whole category of diagnostic claims is at risk [and] that a crisis of patent law and medical innovation may be upon us[.]" *Id*. at 1285. And Judge Dyk warned that the consequence of "a too restrictive test … may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena." *Id*. at 1287.

2. The interested public has expressed concern about the chilling effect of the current Section 101 law. *See, e.g.,* Simmons, *supra*, at 115-116 (Fall, 2016) ("[T]he broad application of the newly created exceptions to patentability has damaged many innovators[,] … provoked uncertainty in entire industries[,] … [and] 'seems to lead to the *reduction ad absurdum* that most biotechnology processes are patent-ineligible.'"); Dr. Alice O. Martin, *Further Erosion of Patent Protection for Diagnostics: The Federal Circuit Denies En Banc Rehearing In Ariosa*

Diagnostics, Inc. v. Sequenom, Inc., 44 AIPLA Q.J. 437, 451 (Summer 2016) (noting that many pending diagnostic applications and patents harken to pre-*Mayo,* pre-*Myriad*, and pre-*Ariosa* days, and "[t]he retroactive application of these decisions has caught applicants and patentees by surprise and changed the assumptions under which the innovations were developed.").

In its recent report, the PTO reported that some industry representatives "opined that an overly broad interpretation of the judicial exceptions to patent eligibility is likely to have an adverse impact on U.S. innovation," and one urged that it could even "eviscerate patent law." Patent Eligible Subject Matter: Report On Views And Recommendations From The Public, https://www.uspto.gov/sites/default/files/documents/101-Report_ FINAL.pdf at 32. The PTO reported that "nearly all participants from the life science industry expressed concern" about the current Section 101 jurisprudence, "which reportedly ha[s] seriously harmed thousands of companies through patent invalidations or the prospect thereof." *Id*. at 35.

Legal scholars have expressed similar concerns. *See, e.g.,* Thobe, *supra*, at 1041 (noting uncertainty "could dampen life-altering innovation in the medical field, raising the need for more clarity regarding the judicially-created exceptions to § 101. "); Simmons, *supra*, at 128 (noting the refusal to recognize groundbreaking discoveries as patent-eligible "baffles almost anyone that has been taught to think of an invention as a ground breaking, innovative or even brilliant discovery"); Gugliuzza, *supra*, at 15-16 (noting that lawyers, scholars, and even some judges

have criticized the caselaw as confusing and unpredictable and they "worry that the restriction of patent eligibility threatens innovation, particularly in the fields of biotechnology and medical diagnostics."). Indeed, Judge Michel testified before Congress that "the law has created unacceptable chaos for inventors, innovators, business, and investors. Legal chaos is the exact opposite of what the U.S. economy needs." Paul R. Michel, *The Impact of Bad Patents on American Business,* Supplemental Testimony, House Judiciary Committee, Subcommittee on Courts, Intellectual Property and the Internet at 18 (Sep. 12, 2017).

Here, the work that resulted in the MPO Patents was expensive, took years of research, and involved exploring possible solutions that ultimately did not work. Without strong and reliable patent protection, support for research and development in this area is at risk to the detriment of the industry and public health in general.

3. This case presents an ideal vehicle for this Court to review the Federal Circuit's expansive application of Section 101 and its highly detrimental practice of invalidating valuable patent rights, particularly in the fields of medical diagnostics and biotechnology, on an incomplete record, by resolving disputed issues of fact and claim construction against the patentee. Here, the PTO carefully examined the inventiveness of the patents, including two reexaminations, and found the inventions to be novel and not obvious. The district court invalidated the Clinic's valuable patents rights solely on the basis of Section 101; thus, the legal issues are cleanly presented for this Court's review. Moreover, because

the field of medical diagnostics is an area where innovation is important to protect public health, this case represents not just the Clinic's private interests but important public interests as well. And as medical and biotechnology discoveries must be publicly disclosed to obtain regulatory approval, the need for patent protection is particularly acute in this field because trade secret protection is not a viable alternative. Simmons, *supra*, at 126.

CONCLUSION

The petition should be granted.

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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