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 *AMICUS CURIAE* COALITION FOR 21ST CENTURY MEDICINE IN SUPPORT OF SEQUENOM, INC.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the Coalition for 21st Century Medicine (the "Coalition") represents more than two dozen of the world's most renowned molecular diagnostic companies, clinical laboratories, and patient advocacy groups, as well as researchers, physicians, and venture capitalists involved in the industry,[2] all of whom agree that continuous diagnostic innovation is essential to help patients and healthcare professionals make better, more informed treatment decisions and continue to improve patient outcomes. Coalition members make significant investments in the research, development, and clinical validation of molecular diagnostic technologies and rely on strong patent protection for those investments.

The incentives to innovate provided by the patent system depend above all on predictability. Only with the knowledge that patents will provide some period of exclusivity will innovators continue to make the massive investment of time and resources needed to develop innovative diagnostic tests and deliver these life-changing products to patients in need.

A string of panel decisions by the Federal Circuit, of which the present case is exemplary, have extended this Court's narrow holdings in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct.

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[1] This brief was not authored, in whole or in part, by counsel to a party; no party or counsel to a party made a monetary contribution intended to fund the preparation or submission of the brief; and no one other than the Coalition, its members, or its counsel made such a monetary contribution.

[2] Coalition for 21st Century Medicine website, http://www.twentyfirstcenturymedicine.org/ (last accessed April 17, 2016).

1289 (2012), *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013), and *Alice Corp. Pty. Ltd. v. CLS Bank Intl.*, 134 S. Ct. 2347, 2352 (2014) to virtually exclude the vital molecular diagnostics industry from the patent system. This has, in turn, injected a worrisome level of arbitrariness into examination at the U.S. Patent and Trademark Office ("USPTO") and made it nearly impossible for stakeholders to enforce patents in the lower courts. The Coalition submits this brief[3] to help the Court understand the impact of its subject matter eligibility jurisprudence—but more particularly the impact of the aggressive extension of that jurisprudence by lower courts and the USPTO—on a molecular diagnostics industry in which predictability and stability of patent rights are paramount.

[3] All parties to this case filed a blanket consent to the filing of *amicus* briefs. In accordance with Supreme Court Rule 37, the Coalition gave each of the parties at least 10 days advance notice of its intent to file this brief.

SUMMARY OF THE ARGUMENT

It is critical to the survival of innovation in the molecular diagnostics industry that this Court take the unique opportunity presented by this case to mandate a correction in the seemingly limitless expansion of *Mayo*, *Myriad* and *Alice* currently applied by the lower courts and the USPTO. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) ("*Ariosa I*"), a panel of the Federal Circuit invalidated under 35 U.S.C. § 101 and this Court's *Mayo* trilogy claims to a ground-breaking laboratory process for such vague reasons as "[t]he method therefore begins and ends with a natural phenomenon." *Id.* at 1376. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282 (Fed. Cir. 2015) ("*Ariosa II*"), the en banc Federal Circuit affirmed *Ariosa I* over a vigorous dissent, with three concurring judges complaining about an incorrect outcome they felt was compelled by *Mayo*.

The Federal Circuit's expansive interpretation of the *Mayo* trilogy has led to "perhaps unintended" harmful consequences to the molecular diagnostics industry. *Ariosa I*, 788 F.3d at 1380 (Linn, J., concurring). District courts bound by Federal Circuit precedent are striking down claims to clearly meritorious inventions within patents statutorily presumed valid at the earliest pleadings stages. The USPTO, attempting in good faith to apply Federal Circuit precedent, has issued examination guidelines that make meaningful patent protection in the life sciences nearly impossible.

Meanwhile, opportunistic free-riders, recognizing the weakness in patent protection, have copied products and ruined markets at the expense of innovators and, ultimately, the patients they seek to serve. Ar-

guments against the value of patents and a narrative of patents blocking innovation, which may well have basis in certain contexts within certain industries, have been blindly applied to a molecular diagnostics industry where patent protection is absolutely required.

Perhaps the best evidence that this Court must take this case to clarify the *Mayo* trilogy comes from the opinions in *Ariosa* itself. In his concurrence in *Ariosa I*, Judge Linn found the claimed process was not routine and yet still felt compelled by *Mayo* to strike down the claims:

> The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here *no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers.

Ariosa I, 788 F.3d at 1381 (Linn, J., concurring) (emphasis in original). Judge Lourie expressed the same helplessness in his concurrence in *Ariosa II*:

> [I]t is undisputed that before this invention, the amplification and detection *of cffDNA from maternal blood*, and use of these methods for prenatal diagnoses, were *not* routine and conventional. But applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.

Ariosa II, 809 F.3d at 1286 (Lourie, J., concurring) (emphasis in original).

When copyists are taking advantage of an eviscerated patent system to commandeer products and markets, when the experts at the USPTO are struggling through numerous attempts to apply ever metastasizing "exceptions" to patent eligibility, and when judges at the Federal Circuit feel compelled against their conscience to strike down patents on ground-breaking technological advances, it is time for this Court to step in and set the record straight.

ARGUMENT

I. Subject Matter Eligibility Has Put the Life Sciences and Diagnostic Industries in a Desperate State

The "limited judicial exceptions" from patent-eligibility articulated by this Court in *Mayo* have, contrary to this Court's own warnings, been extended by lower courts to being on the verge of swallowing up an entire life-saving industry. *Alice*, 134 S. Ct. at 2354 ("[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law."). The "exceptions" have truly, and tragically, become the rule, as the vast majority of patent applications in molecular diagnostics receives a *Mayo* rejection. A recent empirical analysis confirmed what life science innovators sensed: "Only 15.9% of the office actions issued pre-*Mayo* had rejections under section 101 for subject matter eligibility. In contrast, 86.4% of the office actions issued post-*Mayo* had rejections under section 101 for subject matter eligibility." Chao & Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 Patently-O Patent Law Journal 10 (*available at* http://patentlyo.com/media/2016/04/Chao.2016.Perso

nalizedMedicine.pdf) (last accessed April 16, 2016) Of the applications forced into the *Mayo* rejection trap, only a select few emerge as issued patents and even these typically do so by adding unnecessarily restricting claim scope.

The very nature of molecular diagnostics means innovation in this field, more than any other, is intertwined with what occurs in nature. The most fundamental idea behind molecular diagnostics is to measure the inner workings of a patient's body—his or her genes, proteins, etc.—and draw clinical conclusions that enable more personalized treatment. This is the very core of "precision medicine," which President Obama highlighted with the introduction of his Precision Medicine Initiative:

> Until now, most medical treatments have been designed for the "average patient." … Precision Medicine, on the other hand, is an innovative approach that takes into account individual differences in people's genes, environments, and lifestyles.

Precision Medicine Initiative website, https://www.whitehouse.gov/precision-medicine (last accessed April 14, 2016).

Thus, this most vital of industries is particularly vulnerable to the improper interpretation currently given to this Court's § 101 jurisprudence. The resulting denial of protection stifles further investment needed to bring potentially life-saving products to patients.

Sequenom's story of huge investment misappropriated by a free-rider is not an anomaly under the current legal environment, but will shortly and surely become the norm. That is, until the current des-

perate hope amongst innovators for relief from this Court runs out, the pipeline of life-saving technologies dries up, and the free-riders have nothing left to take.

A. A Cautionary Tale from the Experience of the Coalition

In addition to the example related in Sequenom's petition, Coalition companies can point to specific instances where the interpretation of the *Mayo* trilogy by lower courts and the USPTO has failed to "promote the progress of … useful arts," U.S. Const., Art. I, §8, cl. 8, and instead promoted misappropriation of intellectual property. The following example is particularly illustrative but, sadly, not unique.

Several years ago, a team of scientists at one Coalition member company set out to develop a diagnostic test to predict patient response to specific cancer drugs. Through expensive clinical studies, keen insight and an approach that reversed the conventional wisdom of how to develop new diagnostics, they succeeded. But initial development of the test was merely the first critical step in the long, expensive, and risky road toward delivering a quality test doctors would order and insurance companies would pay for. At the same time *Mayo* was working its way up to this Court, the company filed a series of patent applications disclosing the invention in the hopes of obtaining protection against copying.

Banking on such future protection, the company invested in further study and validation of this new test. Numerous trials, involving thousands of patients and costing millions of dollars, were performed to build the scientific evidence required for adoption by medical societies and reimbursement by third

party payors (*e.g.*, Medicare). Completed studies have shown the test to accurately predict response, allowing doctors to decide who should endure and who can forgo toxic chemotherapy. It is important for the Court to understand that even if a diagnostic test is proven clinically useful, it will not become widely available to patients unless insurance companies, HMOs, etc. reimburse it. And this process of convincing payors to reimburse a test takes years and a lot of money, which few companies will invest if free-riders can readily take advantage. Petitioner's Brief, 6.

Several years later, the first patent application filed on this groundbreaking technology is still mired at the USPTO. The claims recite a new and greatly improved process for detecting a specific biological phenomenon, including an entirely new way of analyzing data from complex laboratory assays, and administering a specific drug to a specific patient population identified through such analysis. An international examination found these claims novel and non-obvious, which qualified the application for expedited review in the USPTO under a program meant to harmonize and increase consistency in international patent searching and determinations of patentability. *See, e.g.*, Press Release, U.S. Patent and Trademark Office, *USPTO and JPO to Implement Patent Prosecution Highway on Full-Time Basis*, *available at* http://www.uspto.gov/about-us/news-updates/uspto-and-jpo-implement-patent-prosecution-highway-full-time-basis (last accessed April 14, 2016). Instead—after three rounds of prosecution, multiple iterations of guidance from the USPTO, and Federal Circuit decisions such as *Ariosa*—the application has been rejected under *Mayo*.

This is where a story of frustration turns into one of injustice. The primary utility of the test is to predict patient response to a decades-old drug that is a cornerstone of chemotherapy regimens. The drug is not patented, so no pharmaceutical company has any incentive to support the test for this application or share in the cost of development and dissemination. The Coalition member company must shoulder this burden alone.

This is the precise scenario the patent system was designed by the Founders and Congress to address by providing an innovator who is building a new market a limited period of protection from predatory competition. Others are welcome to devise different ways of predicting response to this drug, or of different ways of measuring the natural phenomenon measured by the innovator's test. But an appropriately tailored patent should be available to protect this company's test.

Instead, while the core patent is stuck at the USPTO, an opportunistic corporation has launched a copy of the original test. And, much like Ariosa in the present case, this free-rider has already stated its intention not to do any clinical work, opting instead to merely wait and do an analytical equivalence study against the innovator's product. This, in turn, has forced the innovator to review the advisability of continued support for this program, which may prevent investment in necessary clinical studies. Patients may never benefit from an inexpensive chemotherapy that could save their lives. Ultimately, a lack of patent protection, and the piracy it engenders, presents the very real danger of choking off the market for an important new test before it even has the chance to get started.

B. Key Lessons from Industry Experience

This story of misappropriation offers some critical lessons on how the current interpretation of *Mayo*, if not corrected by this Court, will devastate the molecular diagnostics industry.

First, the development time line in molecular diagnostics is long. From first discovery studies to launch of a validated test was over six years. And the day when anyone will actually pay for the test (*i.e.*, when the innovator can *hope* to *start* to recoup its massive and continually growing investment) is still likely years away. This is similar to the extended time frame for drug development. *See, e.g.*, Tufts Center for the Study of Drug Development, *Cost of Developing a New Drug* (November 18, 2014) (*available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf (last accessed April 16, 2016).

Second, the scale of capital investment in life sciences and in molecular diagnostics is huge. The investment by the innovator described above is already in the millions of dollars and, if the test is to reach the full market of patients who could benefit, will accelerate significantly. This again is more similar to the pharmaceutical industry than to other industries, *e.g.*, software and electronics.

These time frames and scales of investment are very different from the industries in which many decisions interpreting and applying *Mayo* are made. Within the *Mayo* trilogy itself, *Alice* involved software, where development timelines, initial and continuing capital outlays, and product life cycles are typically much smaller. *See, e.g.*, Michael Griffith,

The Lifecycle of a Mobile App, a User's Perspective, UXMatters.com, http://www.uxmatters.com/mt/archives/2011/10/the-lifecycle-of-a-mobile-app-a-users-perspective.php (last accessed April 17, 2016) ("The average user doesn't open a mobile app more than twenty times, and people use only one third of the apps they download beyond 30 days."); Carter Thomas, *How much does it cost to develop an app?*, BlueCloudSolutions.com blog, http://www.bluecloudsolutions.com/blog/cost-develop-app/# (last accessed April 17, 2016) (estimating total costs for app development in the range of a few thousand dollars to a couple hundred thousand). This makes intuitive sense since Silicon Valley was largely built on the paragon of the "garage inventor." We routinely envision an individual literally sitting in his own garage writing code in his spare time on a laptop computer he purchased at the mall for $500, incentivized by the pay-off of a mildly successful smart phone app for finding funny cat videos on the Internet.

The diagnostic industry is fundamentally different. Initial discovery studies typically require collecting hundreds of biological specimens (costing hundreds or thousands of dollars apiece), processing those specimens on highly specialized equipment (which often costs millions of dollars), and interpreting the data using sophisticated statistical analysis and computer modeling. When something potentially significant emerges from such a study, it must be validated in even larger, longer, and more expensive trials. If validated, millions of dollars must be invested in building the infrastructure to run the test at a large scale. Further time and investment are required for regulatory approval and educating indi-

vidual doctors, medical societies, and third party payors about the utility of the test. Molecular diagnostics simply cannot be a "garage industry."

Finally, incorrect interpretation of *Mayo* has put the U.S. out of step with the rest of the world and possibly in violation of its treaty obligations. *See also*, Pet. Br., 32-33. The original patent application for the innovator's invention described above was found patentable by the international search authority and the European Patent Office, only to be declared categorically ineligible for patenting in the U.S. based on a bad interpretation of *Mayo*.

II. Lower Courts and the USPTO Have Incorrectly Interpreted and Dramatically Extended the *Mayo* Trilogy

The most unfortunate aspect of the current state of affairs is how unnecessary it is. Nothing in the Patent Act or binding precedent from this Court required or even permitted us to arrive at this no-man's land. *Mayo*, *Myriad* and *Alice* undoubtedly changed what some have called the nearly unlimited contours of what could formerly be patented. But lower courts and the USPTO have extended these cases beyond all bounds by focusing on isolated dicta and ignoring the rest of § 101 law, including the statute itself and older Supreme Court decisions expressly endorsed in the *Mayo* trilogy. Only this Court, uniquely in this case, can reverse the spiral of ineligibility under which life science innovators, and ultimately *patients*, are suffering.

A. *Mayo*, *Myriad* and *Alice* Are Narrow

This Court's trilogy of recent § 101 cases—*Mayo*; *Myriad*, and *Alice*—is quite narrow in both facts and holdings. In *Mayo* this Court struck down claims to

what had been practiced for years because the claims merely added a statement of pre-existing but newly-discovered fact:

> The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent eligible processes that *apply* natural laws? We believe that the answer to this question is no.

132 S. Ct. at 1297 (emphasis in original). In *Myriad*, the Court could not have more plainly emphasized the narrow reach of the decision:

> We *merely hold* that genes and the information they encode are not patent eligible under § 101 *simply because* they have been isolated from the surrounding genetic material.

133 S. Ct. at 2120 (emphasis added). *Alice* rejected claims because the supposed invention was the mere computer implementation of longstanding economic activities:

> We hold that the claims at issue are drawn to the abstract idea of intermediated settlement, and that *merely requiring generic computer implementation* fails to transform that abstract idea into a patent-eligible invention.

134 S. Ct. at 2352 (emphasis added).

B. Federal Circuit Interpretation of the *Mayo* Trilogy Is Expansive, With No Apparent Limits to What Will Be Ineligible for Patenting

Applying these narrow Supreme Court decisions, the Federal Circuit has invalidated all claims challenged under § 101 in every case before it except one. *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245 (Fed. Cir. 2014). While the majority of those cases involve computer software and business methods, four cases involve molecular diagnostics—*In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014); *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014) ("*Ambry*"); *Ariosa*; and *Genetic Techs. Ltd. v. Merial L.L.C.*, 2016 U.S. App. LEXIS 6407 (Fed. Cir. Apr. 8, 2016) ("*Genetic Technologies*"). To put *Ariosa* in perspective, and to fully understand how much the Federal Circuit has diverged from the *Mayo* trilogy, a careful chronicling of these four cases is warranted.

First, in *Roslin*, the court extended *Myriad* to dispatch claims to a monumental achievement in biotechnology, the successful cloning of a sheep. The *Roslin* panel came to the remarkable conclusion that a *cloned* sheep generated in a *laboratory* is ineligible for patent protection under the *product* of *nature* doctrine. *Roslin*, 750 F.3d at 1337. It is hard to imagine that when this Court explicitly stated in *Myriad* that it "merely" held isolated genes ineligible, it intended a completely artificial agricultural product to be considered a "product of nature."

Next in *Ambry*, the Federal Circuit ignored this Court's statement in *Myriad* that "the first party with knowledge of [a natural phenomenon]" should

be "in an excellent position to claim applications of that knowledge." *Myriad*, 133 S. Ct. at 2120. The court instead invalidated claims to a laboratory process whose general features were routine, but whose details were adapted to apply new knowledge of a natural phenomenon. *Ambry* thus extended *Mayo*'s discussion of "well-understood, routine, conventional activity *previously* engaged in by researchers in the field," *Mayo*, 132 S. Ct. at 1294 (emphasis added), to apply to something the court felt *would have been* routine to implement *after* learning of the natural phenomenon. *Ambry*, 774 F.3d at 764 ("Nothing is added by identifying the techniques to be used in making the comparison because those comparison techniques were the well-understood, routine, and conventional techniques that a scientist *would have* thought of when instructed to compare two gene sequences.") (emphasis added).

In *Ariosa*, discussed in detail below, the Federal Circuit struck down claims to a laboratory process whose combination of physical details all judges agreed was not routine or conventional, merely because the specific novel combination was *inspired* by the inventors' discovery of a natural phenomenon.

Finally, after Sequenom filed its petition and less than two weeks before the submission of this brief, *Genetic Technologies* affirmed a district court decision invalidating a claim to a new diagnostic process whose eligibility under *Mayo* is at least as clear as Sequenom's. In a detailed but deeply flawed analysis under step one of the *Mayo* framework, the court followed directly in *Ariosa*'s footsteps, and cited extensively to *Ariosa*, to hold that the claims were "directed to" a law of nature simply because the new laboratory process was inspired by it. *Genetic Tech-*

nologies, slip op. 13-14. At step two, the panel again followed (and cited) *Ariosa* in ignoring important details of the claimed laboratory process that differ from what was routine—*e.g.*, the panel framed the claims as relating to "amplifying" and "analyzing" *generally* rather than considering *specifics* of the design of reagents used and how data from the chemical reactions are analyzed. *Genetic Technologies*, slip op. 13-14.

C. *Ariosa* Is Plainly Contrary to the Facts and Holding of *Mayo*

Sequenom's petition catalogues the numerous deficiencies in *Ariosa I*, and the Coalition agrees with Sequenom's analysis. The Court taking this case on the merits will enable deeper exploration of the implications of these and other deficiencies, including those raised by numerous commentators. *See, e.g.*, Center for the Protection of Intellectual Property Blog, *Federal Circuit Threatens Innovation: Dissecting the Ariosa v. Sequenom Opinion*, http://cpip.gmu.edu/2015/06/23/federal-circuit-threatens-innovation-dissecting-the-sequenom-v-ariosa-opinion/ (last accessed April 19, 2016). The Coalition takes this opportunity to briefly highlight just one of the central problems with the Federal Circuit's decision.

Under *Ariosa*, if one could, *after* learning of a newly-discovered law of nature, use routine skill to devise a novel process *applying* that law of nature, then a claim directed to that novel process is invalid. In other words, innovators in molecular diagnostics who want a patent must make *two independent inventions*—a new way of applying a biomarker to a diagnostic problem *and* an entirely new way of phys-

ically detecting that biomarker. This new rule is clearly inconsistent with *Mayo*.

The *Mayo* patentee did not take a newly-discovered law of nature and use it to devise a new or modified process. Nor were the claims invalid merely because individual elements of the claimed process were routine. Instead the *entire* process, in every detail and considered as a whole, was routine. This Court rejected the claims because all that was added by the patentee to this conventional process was a *statement of fact*. *See, e.g.*, *Mayo* at 1298 ("[T]he claims *inform* a relevant audience about certain laws of nature […]") (emphasis added); *id.* at 1297 ("[A] patent that simply *describes* that relation sets forth a natural law.") (emphasis added); *id.* ("The question before us is whether the claims do significantly more than *simply describe* these natural relations.") (emphasis added); *id.* ("[D]o the patent claims add enough to their *statements* of the correlations […]?") (emphasis added).[4]

This case is readily distinguishable since Sequenom's process was, when considered as a whole, neither routine nor conventional. As in *Mayo*, it is helpful to rigorously compare the claimed process against what was routine (as shown in Figure 1 below):

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[4] Similarly in *Alice*, the only difference between the claimed process and the fundamental economic practice of intermediated agreements was implementation on a computer. 134 S. Ct. at 2360.

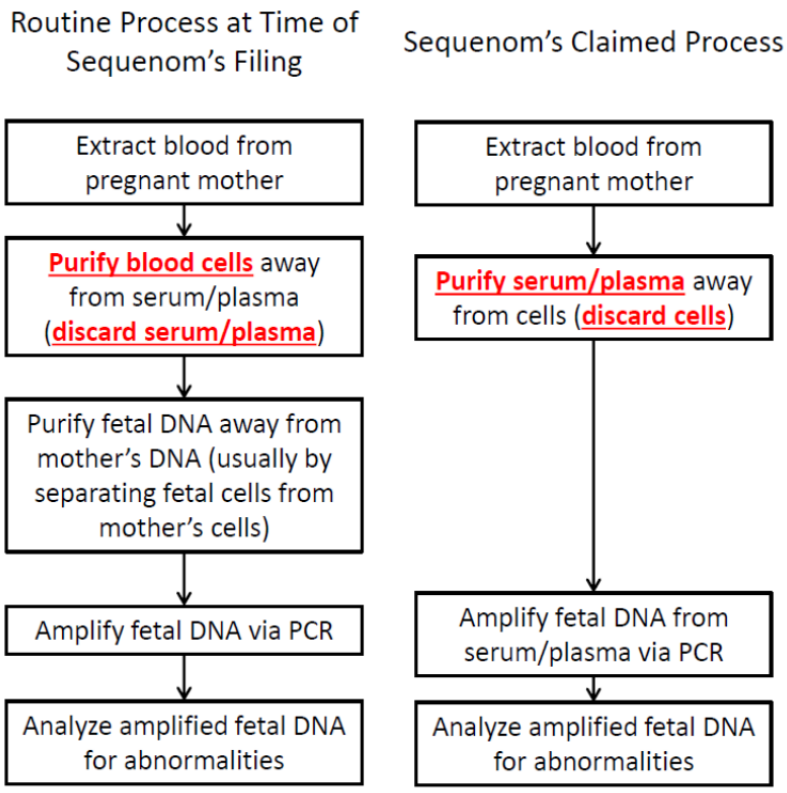

Figure 1

Though Sequenom's ground-breaking discovery of cell-free fetal DNA *inspired* the modifications highlighted in Figure 1, Sequenom critically *did not* claim cell-free fetal DNA *itself*. *Ariosa II*, 809 F.3d at 1286 (Lourie, J., concurring) ("[N]o one asserts that a claim directed to the mere existence of cffDNA is patent-eligible. But neither of the representative claims here merely recites a law of nature, a natural phenomenon, or an abstract idea"). And, unlike in

Mayo, the differences highlighted in Figure 1 are not mere *statements* of a law of nature. They are instead modifications to the *analytical details* and *steps* of the process itself—*e.g.*, separating plasma/serum from blood cells and, instead of discarding it as was routine at the time, using this serum/plasma as a new input material for the rest of the laboratory process. The flow chart in Figure 2 below illustrates this critical difference between this case and *Mayo* by comparing the "well understood, routine, conventional" process "previously engaged in by scientists" to the process claimed in *Mayo*:

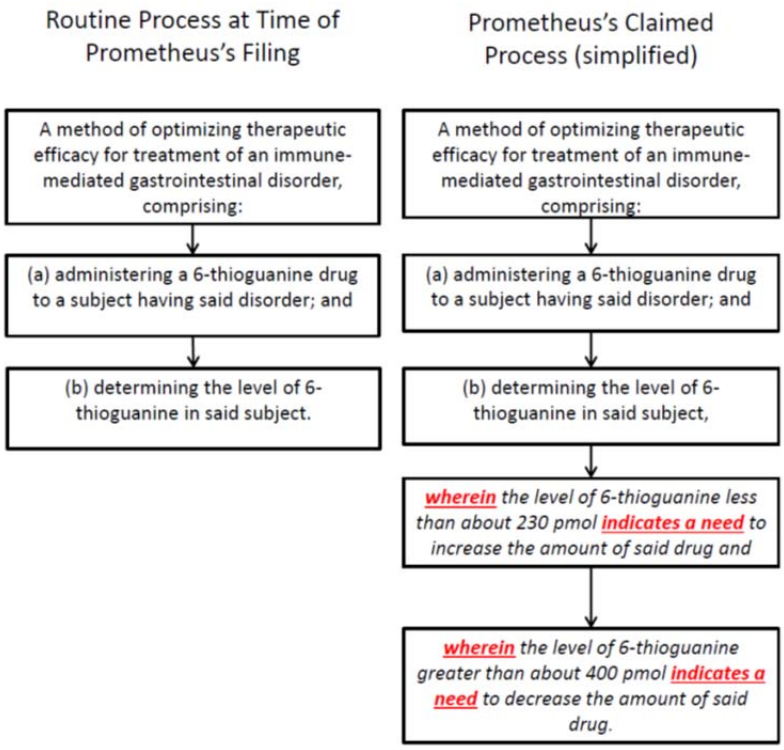

Figure 2

The implications of these differences between *Mayo* and *Ariosa* go beyond mere factual distinctions and instead show how broadly, and to what inappropriate factual circumstances, the Federal Circuit has applied *Mayo*. Indeed, at least five Federal Circuit judges were quite vocal in expressing their concern over *Ariosa*.

In *Ariosa I*, Judge Linn bemoaned the fact that, in his view, *Mayo* required him to reject what he felt was patent eligible:

> I join the court's opinion invalidating the claims of the '540 patent only because I am bound by the sweeping language of the test set out in [*Mayo*]. […] This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.

Ariosa I, 788 F.3d at 1380. In *Ariosa II*, Judges Lourie and Moore echoed Judge Linn's sentiment and expressed concern about impact on the diagnostic industry:

> It is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.

Ariosa II, 809 F.3d at 1285. Even Judge Dyk, author of *Ambry*, *Roslin*, and *Genetic Technologies*, admitted:

> I worry that method claims that apply newly discovered natural laws and phe-

> nomena in somewhat conventional ways are screened out by the *Mayo* test.

Ariosa II, 809 F.3d at 1289-90.

Judge Newman's dissent in *Ariosa II* perhaps best frames this case for review by this Court. While she criticizes *Mayo*, she correctly perceives that the real problem is not so much *Mayo* itself but instead erroneous and overbroad *application* of *Mayo*. For Judge Newman, Sequenom's claims are patent eligible in full view of *Mayo* and *Myriad*:

> I agree with my colleagues that this case is wrongly decided. However, I do not share their view that this incorrect decision is required by Supreme Court precedent. The facts of this case diverge significantly from the facts and rulings in [*Mayo*] and in [*Myriad*]. […] Precedent does not require that all discoveries of natural phenomena or their application in new ways or for new uses are ineligible for patenting; *the Court has cautioned against such generalizations*.

Ariosa II, 809 F.3d at 1293-4 (emphasis added).

D. The Federal Circuit's Incorrect Interpretation of the *Mayo* Trilogy Has Rippled Through District Courts and the USPTO

District courts have amplified the Federal Circuit's signal to a troubling degree, including invalidating patents under *Mayo* at the pleadings stage. *See, e.g.*, *Endo Pharms., Inc. v. Actavis Inc.*, 2015 U.S. Dist. LEXIS 127104 (D. Del. Sept. 23, 2015). In *Genetic Technologies*, for example, the Federal Circuit affirmed dismissal of a case under Rule 12(b)(6).

It is notable that, as sole support for his contention that "[w]e have repeatedly recognized that in many cases it is possible and proper to determine patent eligibility under 35 U.S.C. § 101 on a Rule 12(b)(6) motion," Judge Dyk cited only three Federal Circuit decisions all issued after *Mayo*. *Genetic Technologies*, slip op. at 7. Thus, patentees cannot even pass the low bar of being able to state a claim for which relief can be granted, and are denied an already meager summary judgment forum to defend a patent whose *statutory presumption of validity* was recently reaffirmed by this Court, *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91 (2011), all because a court has determined on the pleadings that a novel laboratory process is "directed to" a law of nature.

Striking down claims because they are vaguely "directed to" a law of nature is the central theme of all of these cases, and is one of the primary stumbling blocks to the USPTO as it has tried its best to apply the Federal Circuit's interpretation of the *Mayo* trilogy. With each case from this Court the USPTO has issued revised guidance for day-to-day examination of patents. And each guidance document, while an improvement over the last, has been met with widespread dissatisfaction amongst the innovation community.[5] In the first iteration of such guidance, for example, the USPTO directed examiners to reject any patent claim merely "involving" a law or phenomenon of nature and trained examiners

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[5] Public comments in response to the USPTO's guidance have been overwhelmingly critical. *See, e.g.*, *Comments on 2014 Interim Guidance on Patent Subject Matter Eligibility*, USPTO website, http://www.uspto.gov/patent/laws-and-regulations/comments-public/comments-2014-interim-guidance-patent-subject-matter.html (last accessed April 15, 2016).

on an example under which gun powder was apparently patent ineligible because it is a mixture of three naturally occurring substances. U.S. Patent and Trademark Office Letter to Examiners, *Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products*, *available at* http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf (last accessed April 15, 2016).

Later iterations of the guidance facially reversed course on both of these points in response to vociferous criticism, but the practical effect has been the same: following the Federal Circuit's lead, as it must, the USPTO is issuing *Mayo* rejections for effectively any claims even "involving" biotechnology. Chao & Mapes, 2016 Patently-O Patent Law Journal 10. And once a claim has been branded as "directed to" a phenomenon of nature under step one of *Mayo*, which will be true for essentially every molecular diagnostic claim, the USPTO is also following the Federal Circuit in ignoring specific process details that (1) distinguish the claim from what came before and (2) ensure the claim is to an application of the phenomenon rather than to the phenomenon itself. The USPTO has promised detailed examples to clarify how to examine life science patents, but Coalition members have heard from USPTO personnel that the office is waiting for the ultimate outcome of this case to provide such guidance. The present lack of clarity at the highest level has resulted in near paralysis of the system at the USPTO.

III. Patents Prevent Piracy, not Progress

Some question the desirability of patents in life sciences. It is important for the Court to understand,

however, that these questions are often based on self-serving, *post hoc* arguments made by imitators to excuse commandeering the investment of innovators. This case again provides a far from unique example.

In the proceedings below, Ariosa picked up the drumbeat from previous successful § 101 challengers, raising the tired specter of "[t]he risk of stifling future innovation." *See, e.g.*, Ariosa's Opposition to Sequenom's Cross-Motion for Summary Judgment, Docket No.238, 1 (Sept. 23, 2013) ("The reason for this rule is self-evident: Any other rule would allow a patentee to disproportionately tie up the use of a natural phenomenon, thereby stifling innovation. And that is precisely what Sequenom seeks to do in this case."). This is indeed a consistent concern underlying this Court's § 101 decisions. A careful study of the *Mayo* trilogy and the present case, however, shows the limits of this theme.

Mayo involved claims that recited a process *identical* to what was routine in the art, the only difference being a statement of pre-existing but previously unknown fact. Add to this the fact the patentee admitted the claims covered doctors *thinking*, and one understands the Court's concern that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." *Mayo*, 132 S. Ct. at 1294.

Taking a page from Mayo's winning playbook, the centerpiece of the *Myriad* plaintiffs' case was the allegation that Myriad's patents blocked biomedical research. Impassioned arguments from world-renowned scientists played into the narrative of anti-innovation patents and understandably swayed the

Court. *Myriad*, 133 S. Ct. at 2120 (Scalia, J., concurring) (Expressly relying on "the expert briefs presented here.").

By the time *Alice* reached the Court, the proven strategy of attacking patents for hindering progress was readily applied against a so-called "patent troll."[6] With a non-practicing entity, which sold no product, suing a bank for practicing centuries-old escrow transactions on a computer, it is no wonder this Court worried that patents on "the buildin[g] block[s] of human ingenuity […] would risk disproportionately tying up the use of the underlying ideas." *Alice*, 134 S. Ct. at 2354 (internal quotation marks and citations omitted).

In this case, however, the patent challenger has stretched this well-worn argument over "a bridge too far." Ariosa has exposed how dangerous it is for courts and agencies to react too strongly to a logical, though largely hypothetical, policy concern. The Court can in *Ariosa* see past the rhetoric and claims of phantom harm to innovation. Here, one company (Sequenom) sued another company (Ariosa) for *copying* its product. Here, Ariosa has openly admitted that part of its plan was to free-ride on Sequenom's extensive investment in establishing an entirely new market. *See, e.g.*, Pet. Br., 6 ("Ariosa candidly told its investors that it would 'draft on Sequenom's efforts to go after the same geographies,' and its Chairman testified about Ariosa's 'strategies of being

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[6] James Bessen, *What the Courts Did to Curb Patent Trolling—for Now*, TheAtlantic.com, *available at* http://www.theatlantic.com/business/archive/2014/12/what-the-courts-did-to-curb-patent-trollingfor-now/383138/ (last accessed April 2, 2016.) ("Alice Corporation is a patent troll […].").

a fast follower and letting your competitor educate the market around advantages to cell-free DNA.'") (internal citations omitted).

This case calls into question the entire premise of patents blocking innovation. All Sequenom's patent, if upheld by this Court, would prevent Ariosa from doing is copying Sequenom's product and "drafting on" Sequenom's investment. The Coalition reiterates that this is precisely what the patent system was meant to do, and yet this is what errant interpretation of this Court's *Mayo* trilogy is preventing that carefully designed system from doing.

CONCLUSION

For the reasons stated above, Sequenom's petition for certiorari should be granted.

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