United States Court of Appeals for the Federal Circuit

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
Plaintiffs-Appellants

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, MAYO CLINIC,
Defendants-Appellees

2017-2508

Appeal from the United States District Court for the District of Massachusetts in No. 1:15-cv-40075-IT, Judge Indira Talwani.

ON PETITION FOR REHEARING EN BANC

ADAM GAHTAN, Fenwick & West, New York, NY, filed a petition for rehearing en banc for plaintiffs-appellants. Also represented by ERIC M. MAJCHRZAK, VANESSA PARK-THOMPSON; ANDREW JOSEPH KABAT, EMMETT J. MCMAHON, Robins Kaplan LLP, Minneapolis, MN; DIMITRIOS T. DRIVAS, White & Case LLP, New York, NY.

JONATHAN ELLIOT SINGER, Fish & Richardson, PC, San

Diego, CA, filed a response to the petition for defendants-appellees. Also represented by JOHN CAMERON ADKISSON, ELIZABETH M. FLANAGAN, PHILLIP GOTER, DEANNA JEAN REICHEL, Minneapolis, MN.

MELISSA A. BRAND, Biotechnology Innovation Organization, Washington, DC, for amici curiae Biotechnology Innovation Organization, CropLife International, Pharmaceutical Research and Manufacturers of America, Wisconsin Alumni Research Foundation. Also represented by HANSJORG SAUER. Amicus curiae Biotechnology Innovation Organization also represented by BRIAN PAUL BARRETT, Eli Lilly and Company, Indianapolis, IN. Amicus curiae Pharmaceutical Research and Manufacturers of America also represented by DAVID EVAN KORN, Pharmaceutical Research and Manufacturers Association of America, Washington, DC.

MATTHEW JAMES DOWD, Dowd Scheffel PLLC, Washington, DC, for amici curiae Richard A. Epstein, Christopher Michael Holman, Adam Mossoff, Kristen J. Osenga, Michael Risch, Ted M. Sichelman, Brenda M. Simon. Also represented by ROBERT JAMES SCHEFFEL.

SHERRY M. KNOWLES, Knowles Intellectual Property Strategies, LLC, Atlanta, GA, for amici curiae Freenome Holdings Inc., Achillion Pharmaceuticals, Inc. Also represented by MEREDITH MARTIN ADDY, AddyHart P.C., Atlanta, GA.

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges.*

LOURIE, *Circuit Judge*, with whom REYNA and CHEN, *Circuit Judges*, join, concurs in the denial of the petition for rehearing en banc.

HUGHES, *Circuit Judge*, with whom PROST, *Chief Judge*, and TARANTO, *Circuit Judge*, join, concurs in the denial of the petition for rehearing en banc.

DYK, *Circuit Judge*, with whom HUGHES, *Circuit Judge*, joins, and with whom CHEN, *Circuit Judge*, joins as to Parts IV, V, and VI, concurs in the denial of the petition for rehearing en banc.

CHEN, *Circuit Judge*, concurs in the denial of the petition for rehearing en banc.

MOORE, *Circuit Judge*, with whom O'MALLEY, WALLACH, and STOLL, *Circuit Judges*, join, dissents from the denial of the petition for rehearing en banc.

NEWMAN, *Circuit Judge*, with whom WALLACH, *Circuit Judge*, joins, dissents from the denial of the petition for rehearing en banc.

STOLL, *Circuit Judge*, with whom WALLACH, *Circuit Judge*, joins, dissents from the denial of the petition for rehearing en banc.

O'MALLEY, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

O R D E R

A petition for rehearing en banc was filed by appellants Athena Diagnostics, Inc., Oxford University Innovation Ltd., and the Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V. A response to the petition was invited by the court and filed by appellees Mayo Collaborative Services, LLC and Mayo Clinic. Several motions for leave to file amici curiae briefs were filed and granted by the court. The petition for rehearing, response, and amici curiae briefs were first referred to the panel that heard the appeal, and thereafter, to the circuit judges who are in regular active service. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

1) The petition for panel rehearing is denied.
2) The petition for rehearing en banc is denied.
3) The mandate of the court will issue on July 10, 2019.

FOR THE COURT

July 3, 2019
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

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LOURIE, *Circuit Judge*, with whom REYNA and CHEN, *Circuit Judges*, join, concurring in the denial of the petition for rehearing en banc.

I concur in the court's decision not to rehear this case en banc. In my view, we can accomplish little in doing so, as we are bound by the Supreme Court's decision in *Mayo*. Some of us have already expressed our concerns over current precedent. *E.g.*, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 753 n.4 (Fed. Cir. 2019); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015) (Lourie, J., concurring in the

denial of rehearing en banc); *id.* at 1287 (Dyk, J., concurring in the denial of rehearing en banc).

If I could write on a clean slate, I would write as an exception to patent eligibility, as respects natural laws, only claims directed to the natural law itself, *e.g.*, $E=mc^2$, F=ma, Boyle's Law, Maxwell's Equations, etc. I would not exclude uses or detection of natural laws. The laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is patentable.

But we do not write here on a clean slate; we are bound by Supreme Court precedent. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the claims at issue were held by the Court to be directed to the relationship between the concentration of metabolites in the blood and the likelihood that a drug dose will be ineffective, which it referred to as a law of nature. 566 U.S. 66, 74–75, 77 (2012). The other steps—administering a drug and detecting the level of a specific metabolite—added only "[p]urely 'conventional or obvious' '[pre]-solution activity'" that was "not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Id.* at 79 (second alteration in original) (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)); *see Bilski v. Kappos*, 561 U.S. 593, 610–11 (2010) ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.'" (quoting *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981))); *Flook*, 437 U.S. at 590 ("The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance."). Because the claims recited only what the Court called a natural law together with well-understood, conventional activity, the Court concluded the claims were ineligible under § 101. *Mayo*, 566 U.S. at 73, 79–80.

In applying *Mayo*, we have accordingly held claims focused on detecting new and useful natural laws with conventional steps to be ineligible. *E.g.*, *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1363 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016). In *Cleveland Clinic*, the claims recited a specific assay to detect the protein MPO, the enzyme-linked immunosorbent assay. 859 F.3d at 1357–58, 1362. *Ariosa* similarly involved a specific technique to amplify and detect DNA, the polymerase chain reaction. 788 F.3d at 1377. But in both cases, the patents' specifications described these techniques as well-understood and conventional. *Cleveland Clinic*, 859 F.3d at 1355; *Ariosa*, 788 F.3d at 1377. We concluded that using these routine assays to detect new natural phenomena did not transform the claims into patent eligible applications. *Cleveland Clinic*, 859 F.3d at 1362–63; *Ariosa*, 788 F.3d at 1376–77.

In contrast, new method of treatment patents do not fall prey to *Mayo*'s prohibition. *E.g.*, *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1136 (Fed. Cir. 2018). Nor have unconventional arrangements of known laboratory techniques, even if directed to a natural law. *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1051 (Fed. Cir. 2016). But this case involves neither scenario. Athena's claims recite observing a natural law using a radioimmunoassay that the specification describes as "standard" and "known per se in the art." U.S. Patent 7,267,820 col. 3 ll. 33–37, col. 4 ll. 10–12. The claims do not recite a new method of treatment or an unconventional combination of steps to detect the natural law. The only unconventional aspect is the inventors' discovery of what the Supreme Court would call the natural law—the correlation between MuSK autoantibodies and the neurological disorder *myasthenia gravis*—but we cannot premise eligibility solely on the natural law's novelty. *Mayo*, 566 U.S.

at 73 (concluding that "the steps in the claimed processes (*apart from the natural laws themselves*) involve well-understood, routine, conventional activity previously engaged in by researchers in the field" (emphasis added)); *Flook*, 437 U.S. at 591–92 ("[T]he novelty of the mathematical algorithm is not a determining factor at all" and "is treated as though it were a familiar part of the prior art."). Under Supreme Court precedent, I do not believe that specific yet purely conventional detection steps impart eligibility to a claim that otherwise only sets forth what the Court has held is a natural law. That is the situation presented in *Ariosa*, *Cleveland Clinic*, and now *Athena*. Accordingly, as long as the Court's precedent stands, the only possible solution lies in the pens of claim drafters or legislators. We are neither.

Amici and others have complained that our eligibility precedent is confused. However, our cases are consistent. They have distinguished between new method of treatment claims and unconventional laboratory techniques, on the one hand, and, on the other hand, diagnostic methods that consist of routine steps to observe the operation of a natural law, a clear line. Beyond that, I do not see a way clear to distinguish *Mayo* in a useful, principled, fashion. Software is another matter, but such patents are not before us here.

I therefore concur in the decision of the court not to take this case en banc because I do not believe we can convincingly distinguish *Mayo* in this case.

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HUGHES, *Circuit Judge*, with whom PROST, *Chief Judge,* and TARANTO, *Circuit Judge,* join, concurring in the denial of the petition for rehearing en banc.

The multiple concurring and dissenting opinions regarding the denial of en banc rehearing in this case are illustrative of how fraught the issue of § 101 eligibility, especially as applied to medical diagnostics patents, is. I agree that the language in *Mayo*, as later reinforced in *Alice*, forecloses this court from adopting an approach or reaching a result different from the panel majority's. I also

agree, however, that the bottom line for diagnostics patents is problematic. But this is not a problem that we can solve. As an inferior appellate court, we are bound by the Supreme Court.

I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications. Such an explication might come from the Supreme Court. Or it might come from Congress, with its distinctive role in making the factual and policy determinations relevant to setting the proper balance of innovation incentives under patent law.

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DYK, *Circuit Judge*, with whom HUGHES, *Circuit Judge,* joins, and with whom CHEN, *Circuit Judge,* joins as to Parts IV, V, and VI, concurring in the denial of the petition for rehearing en banc.

I

In the realm of abstract ideas, the *Mayo*/*Alice* framework has successfully screened out claims that few would contend should be patent eligible, for example, those that merely apply well-known business methods and other

processes using computers or the Internet.[1] The *Mayo*/*Alice* framework has thus proven to be both valuable and effective at invalidating overly broad, non-inventive claims that would effectively "grant a monopoly over an abstract idea." *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (quoting *Bilski v. Kappos*, 561 U.S. 593, 611–612 (2010)). As the Supreme Court has recognized, the concern with such patents is that they would "'inhibit further

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[1] *See, e.g., Trading Techs. Int'l, Inc. v. IBG LLC*, 921 F.3d 1378, 1384–85 (Fed. Cir. 2019) (invalidating claims directed to "providing a trader with additional financial information to facilitate market trades" using "a generic computer"); *SAP Am., Inc., v. Investpic, LLC*, 898 F.3d 1161, 1167–69 (Fed. Cir. 2018) (invalidating claims directed to "the selection and mathematical analysis of [investment] information, followed by reporting or display of the results" using "off-the-shelf computer technology"); *Credit Acceptance Corp. v. Westlake Servs.*, 859 F.3d 1044, 1054–57 (Fed. Cir. 2017) (invalidating claims directed to "processing an application for financing a purchase" using "generic computer components"); *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–55 (Fed. Cir. 2016) (invalidating claims directed to "collecting information, analyzing it, and displaying certain results" using "off-the-shelf, conventional computer, network, and display technology"); *Intellectual Ventures I LLC v. Capital One Bank*, 792 F.3d 1363, 1369–70 (Fed. Cir. 2015) (invalidating claims directed to tailoring advertising to individual customers using a "generic web server with attendant software"); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715–16 (Fed. Cir. 2014) (invalidating a claim directed to "using advertising as an exchange or currency" "on the Internet"); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014) (invalidating a claim directed to "creating a contractual relationship" through "online transactions" using "generic" computer functionality).

discovery by improperly tying up the future use of' these buildings blocks of human ingenuity." *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 85 (2012)). At the same time, our § 101 precedent has allowed room for claims that do more than recite conventional applications of abstract concepts.[2]

II

Despite assertions to the contrary, the doctrines of novelty under § 102, obviousness under § 103, and enablement and written description under § 112 cannot adequately guard against the dangers of overclaiming. In *Mayo*, the Supreme Court rejected the argument that "other statutory provisions"—specifically §§ 102, 103, and 112—could adequately "perform th[e] screening function" served by § 101. 566 U.S. at 89. Although the Court recognized that the § 101 patent eligibility inquiry "might sometimes overlap" with considerations of novelty and non-obviousness under §§ 102 and 103, it concluded that "to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do." *Id.* at 90. Those sections and § 112 do not adequately address "the risk that a patent on the [natural]

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[2] *See, e.g.*, *Ancora Techs., Inc. v. HTC Am., Inc.*, 908 F.3d 1343, 1348–49 (Fed. Cir. 2018) (holding that claim to a specific technique for improving computer security against unauthorized use of a program was not directed to an abstract idea); *Finjan, Inc. v. Blue Coat Sys., Inc.*, 879 F.3d 1299, 1303–04 (Fed. Cir. 2018) (holding that claims to a "behavior-based virus scan" allowing for more flexible and nuanced virus filtering were not directed to an abstract idea); *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336–38 (Fed. Cir. 2016) (holding that claims to self-referential tables that allowed for more efficient launching and adaptation of databases were not directed to an abstract idea).

law would significantly impede future innovation." *Id.* at 90–91; *see also* Mark Lemley et al., *Life After* Bilski, 63 Stan. L. Rev. 1315, 1329–32 (2011) (outlining differences between §§ 101 and 112). Nor do these other provisions typically allow early stage resolution of the "threshold" issue of patent eligibility, *Bilski*, 561 U.S. at 602, necessary to avoid the costs of lengthy litigation. Thus, § 101 serves an important purpose not served by these other provisions in the Patent Act.

A simple example in the area of diagnostic patents illustrates this point. If the first person to identify the relationship between a genetic abnormality and a disease had sought a broad patent on a method of searching for genetic abnormalities and determining their relationship to disease, the claims would have been neither anticipated nor obvious. Nor is it likely that they would they have been invalid for lack of enablement (since a representative species was disclosed) or written description (the overall conception being in the mind of the inventor). The only barrier to such broad patent claiming is § 101.

In fact, one of the diagnostic patents that we have held unpatentable under § 101 had exactly that problem of overbreadth. In *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 (Fed. Cir. 2014), we held that genetic testing claims were directed to the "patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations" of the gene. *Id.* at 763. We noted the breadth of the claims, explaining that they "are not restricted by the purpose of the comparison or the alteration being detected," nor "limited to the detection of risk of breast or ovarian cancer." *Id.* at 763–64. Indeed, the claims encompassed "comparisons for purposes other than detection of cancer." *Id.; see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373–74, 1378 (Fed. Cir. 2015) (invalidating claims to methods of detecting cffDNA in maternal serum or plasma that encompassed any diagnosis of any disease). What was

claimed was a broad concept, and we therefore held the claims ineligible under § 101, though the claims may well have survived challenge under §§ 102, 103, and 112.

III

The problem with § 101 arises not in implementing the abstract idea approach of *Alice*, but rather in implementing the natural law approach of *Mayo*. Although *Mayo*'s framework is sound overall, I share the concerns expressed by my dissenting colleagues that the *Mayo* test for patent eligibility should leave room for sufficiently specific diagnostic patents. But it is the Supreme Court, not this court, that must reconsider the breadth of *Mayo*.

Although the Supreme Court's decision in *Mayo* did not make all diagnostic claims patent ineligible, as we previously held in *Ariosa*, 788 F.3d at 1376–77, *Mayo* left no room for us to find typical diagnostic claims patent eligible, absent some inventive concept at *Mayo* step two. The panel here correctly concluded that *Mayo* controls.

The inventors of U.S. Patent 7,267,820 ("the '820 patent") discovered that myasthenia gravis ("MG"), a neurological disorder, can be diagnosed by detecting the presence of MuSK autoantibodies in bodily fluid. *See Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 747 (Fed. Cir. 2019). At *Mayo* step one, the claims are directed to a natural law: "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid" and certain neurological diseases like MG. *Id.* at 750. This is similar to the correlation between "concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm," which the Supreme Court held "sets forth a natural law" in *Mayo*, 566 U.S. at 77.

So too as in *Mayo*, at step two, the additional steps of the claims here, though "set forth with some specificity," *Athena*, 915 F.3d at 752, "only require standard techniques

to be applied in a standard way" and thus do not supply the requisite inventive concept, *id.* at 753. The specification explains that "[t]he actual steps of detecting autoantibodies in a sample of bodily fluids may be performed in accordance with immunological assay techniques known per se in the art." *Id.* at 753–54 (alteration in original). Similarly, in *Mayo*, adding steps "to determine the level of the relevant metabolites in the blood" was held "not sufficient to transform an unpatentable law of nature into a patent-eligible application" because those steps were "well known in the art." 566 U.S. at 79. Therefore, the panel here correctly held that under the *Mayo* framework, the claims are not patent eligible under § 101. *Athena*, 915 F.3d at 746, 756. And the Supreme Court has instructed us to follow its precedent until the Court itself chooses to expressly overrule it.[3]

IV

It is nonetheless appropriate to point out that there is tension between *Mayo* and the Supreme Court's later decision in *Association for Molecular Pathology v. Myriad*

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[3] *See, e.g.*, *Hohn v. United States*, 524 U.S. 236, 252–53 (1998) ("Our decisions remain binding precedent until we see fit to reconsider them, regardless of whether subsequent cases have raised doubts about their continuing vitality."); *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) ("The Court of Appeals was correct in applying that principle despite disagreement with [the precedent], for it is this Court's prerogative alone to overrule one of its precedents."); *Rodriguez de Quijas v. Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989) ("If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions.").

Genetics, Inc., 569 U.S. 576 (2013), and that the holding of *Mayo* may be overbroad. The language of § 101 does cover "discover[ies]," 35 U.S.C. § 101, and there is no doubt that determining the relationship between specific genetic abnormalities and specific diseases constitutes an important discovery with proven utility. There is much to be said for the patentability of claims to such discoveries, if not drafted overbroadly. And *Myriad* suggests that such discoveries may be patent eligible. There, the patent applicant discovered a previously unknown natural phenomenon: the location and sequence of the BRCA1 and BRCA2 genes and their connection to cancer. *Myriad*, 569 U.S. at 582–83. Although the Court held ineligible the claims to naturally occurring DNA sequences, it suggested that "new *applications* of knowledge about the BRCA1 and BRCA2 genes" could be eligible and referred to various "unchallenged claims" discussed in Judge Bryson's concurrence to our court's decision below. *Id.* at 596 (emphasis in original) (citing *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, Inc.*, 689 F.3d 1303, 1349 (Fed. Cir. 2012) (Bryson, J. concurring)). One of these "unchallenged claims" was claim 21 of Myriad's U.S. Patent No. 5,753,441, which covered a method of detecting (using conventional methods) any of several specific mutations in the BRCA1 gene, newly discovered by the patent applicant and shown to increase a person's risk of developing particular cancers (a far narrower claim than the claims held unpatentable in *BRCA1- & BRCA2*).

By suggesting that such a claim could be patent eligible, *Myriad* thus recognized that an inventive concept can sometimes come from the discovery of an unknown natural phenomenon and its application for a diagnostic purpose. This appears to be in tension with *Mayo*. Under *Mayo*, a natural phenomenon itself, no matter how narrow and specific, cannot supply the requisite "inventive concept." *See Mayo*, 566 U.S. at 77–78, 88–89.

Thus, it would be desirable for the Supreme Court to refine the *Mayo* framework to allow for sufficiently specific diagnostic patent claims with proven utility. In the life sciences, development of new diagnostic methods is often based on researching complex biological systems. The inventive concepts in this area may lie primarily in the application of a natural law.

V

At the same time, *Mayo*'s central concern was both important and consistent with the Patent Act. There is a substantial risk that overbroad claims involving natural laws may "preempt the use of a natural law" and thus "inhibit further discovery by improperly tying up the future use of laws of nature." *Id.* at 72, 85. In other words, there is a risk that granting overbroad patents could reward a mere concept rather than the work subsequently done by the actual inventor. The risks associated with such overbreadth are shown by the examples discussed earlier.

In my view, the *Mayo* framework should be refined in limited respects. First, at step one of *Mayo*, the natural law cannot be claimed as such. *See Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). As *Mayo* noted, "Einstein could not patent his celebrated law that $E=mc^2$." 566 U.S. at 71 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)); *see also Parker v. Flook*, 437 U.S. 584, 591 (1978). Nor could a patent claimant "simply recite a law of nature and then add the instruction 'apply the law,'" such as if Einstein had claimed "a process consisting of simply telling linear accelerator operators to refer to the law." *Mayo*, 566 U.S. at 78. Where the natural law itself is so broadly claimed, there is no reason to address step 2 (the inventive concept). The claims are simply ineligible.

At the same time, "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.* at 71. Thus, a sufficiently specific "application of a law of nature or mathematical

formula to a known structure or process may well be deserving of patent protection." *Id.* (emphasis in original) (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)).

For there to be a patent eligible application of a natural law, there must be a "discover[y]," 35 U.S.C. § 101, and the claims must recite a specific application of that "discovery" with established utility. Otherwise, the natural law may be entirely preempted, even as to those aspects where the patent claimant has done no more than claim a broad conception. Requiring a specific application mitigates against the risk of granting patents too early—that is, before the patent applicant has devised a specific application of the natural law—and thereby prevents monopolization of the "basic tools of scientific and technological work." *Mayo*, 566 U.S. at 71 (quoting *Benson*, 409 U.S. at 67); *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966) (noting that before a claimed invention is sufficiently "refined and developed," granting a patent "may confer power to block off whole areas of scientific development"); *see generally* Lemley, *supra*, at 1337–38 (arguing for a focus on claim scope under § 101 and noting that overly broad claims "make later improvements more costly or even impossible").

The Supreme Court's opinion in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854), the foundation of the Court's jurisprudence on patent eligibility, appears to make this very distinction. There, the Court allowed Morse's narrower claims, which were tied specifically to his discovery: the telegraph. *See id.* at 112.[4] The Court reasoned that Morse

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[4] For example, Morse's second claim recited "the employment of the machinery called the register or recording instrument, composed of the train of clock-wheels, cylinders, and other apparatus, or their equivalent, for removing the material upon which the characters are to be imprinted, and for imprinting said characters,

"discover[ed] a method by which intelligible marks or signs may be printed at a distance" and that "for the [particular] method or process thus discovered, he is entitled to a patent." *Id.* at 117. But the Court held unpatentable Morse's claim to all "marking or printing [of] intelligible characters, signs, or letters, at any distances" via electric currents, because "the claim is too broad, and not warranted by law." *Id.* at 112–13. As in *Mayo*, the Court was particularly concerned about preempting use of the natural phenomenon: "For aught that we now know some future inventor, in the onward march of science, may discover a [different] mode of writing or printing at a distance by means of the electric or galvanic current . . . . But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee." *Id.* at 113.

More recent opinions of the Supreme Court are also consistent with a focus on claims that sweep too broadly. In *Benson*, the Court observed that the claims were "so abstract and sweeping as to cover both known and unknown uses of" the mathematical formula at issue, and so held the claims ineligible. 409 U.S. at 67–68. Similarly, in *Flook*, the claims to "a formula for computing an updated alarm limit" could "cover a broad range of potential uses" and were also held ineligible. 437 U.S. at 586. By contrast, in *Diehr*, the Court held eligible claims that used a well-known mathematical equation in a process of curing synthetic rubber. 450 U.S. at 191–92. The patent claimants did "not seek to pre-empt the use of th[e] equation," but rather sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process" for curing rubber. *Id.* at 187. Thus, the

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substantially as set forth in the foregoing description of the second principal part of my invention." *Morse*, 56 U.S. at 85.

Supreme Court's precedents support a requirement of specific application as part of the patent eligibility inquiry as to natural laws.

To ensure against overbroad claims, the scope of the § 101 natural law exception is necessarily informed by the utility requirement of § 101. The utility requirement has its origins in the constitutional grant of Congressional authority, which contemplated that the "discoveries" entitled to patents would be limited to those of proven utility. *See* U.S. Const. art. I, § 8, cl. 8; Sean M. O'Connor, *The Overlooked French Influence on the Intellectual Property Clause*, 82 U. Chi. L. Rev. 733, 792–93 (2015). And the statutory requirement of utility has been held by the Supreme Court to require that the claimed invention have established utility, not merely the prospect of future utility. *Brenner*, 383 U.S. at 534–36. In *Brenner*, the Supreme Court held that a patent claiming an allegedly novel process for making certain known steroids was ineligible for lack of utility. *Id.* The Court reasoned that without a showing of utility, "the metes and bounds of th[e] monopoly are not capable of precise delineation," and "[s]uch a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public." *Id.* at 534. "Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." *Id.* at 534–35. It follows that the scope of patents involving the application of natural laws should not extend beyond established utility, and that claims that extend further are not patent eligible. Under this approach, because of their breadth, the claims in *Mayo* would not be eligible at step one. *See Mayo*, 566 U.S. at 87 (explaining that the claim steps were "set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways").

However, if the claim is sufficiently tied to a specific and useful application of a natural law at *Mayo* step one, that application itself should serve as the necessary inventive concept at *Mayo* step two. Yet at step two, the application must be more than determining the precise correlation of a known relationship using prior art processes, as was the case in *Mayo* itself. In *Mayo*, "scientists already understood that the levels in a patient's blood of certain metabolites, including [those involved in the claims] were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective." *Id.* at 73–74. And "scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds." *Id.* at 79. "But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness." *Id.* at 74. Thus, *Mayo*'s claims only involved determining the precise correlations of a law of nature that was already well known. The asserted application of the natural law was therefore no more than determining "the precise correlations between metabolite levels and likely harm or ineffectiveness" of a drug dosage and thus was patent ineligible.

Requiring specific and useful application for the entire scope of the claim at *Mayo* step one, and more than determining precise correlations of a known natural law using prior art processes at *Mayo* step two, would ensure that the claims truly recite an "inventive application" of the natural law that should be eligible under § 101. This approach would help ensure that the reward of a patent goes to those who have actually done the work to develop a specific application of a natural law, not those who are the first to the patent office with broad, conceptual claims lacking proven utility in many applications.

VI

Finally, this case may involve claims that could be patent eligible under this suggested approach. First, claims 7–9 do not claim the natural law itself—the relationship between MuSK autoantibodies and MG, a rare neurological disorder—but rather claim specific methods of diagnosing neurological disorders like MG by detecting MuSK autoantibodies. *See Athena*, 915 F.3d at 747.[5] Second, unlike in

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[5] Claims 7–9 depend from claim 1, not at issue in this appeal, which recites:

> 1. A method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [MuSK].

'820 patent, col. 12, ll. 31–35.

Claim 7 recites:

> 7. A method according to claim 1, comprising
>
> contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid, immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
>
> monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
>
> wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to [MuSK].

Id. col. 12, l. 62–col 13, l. 5 (indentation added).

Mayo, this case involves a "discovery" of the relationship, not mere determination of the precise correlations of a known natural law using prior art processes. As the panel noted, "[p]rior to the[] discovery [by the named inventors], no disease had been associated with MuSK." *Id.*

Because at least some of the claims here recite specific applications of the newly discovered law of nature with proven utility, this case could provide the Supreme Court with the opportunity to refine the *Mayo* framework as to diagnostic patents.

Claim 8 depends from claim 7 and recites that the label is a radioactive label. *Id.* col. 13, ll. 6–7. Claim 9 depends from claim 8 and further recites that the radioactive label is 125I. *Id.* col 13, ll. 8–9.

United States Court of Appeals for the Federal Circuit

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
Plaintiffs-Appellants

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, MAYO CLINIC,
Defendants-Appellees

2017-2508

Appeal from the United States District Court for the District of Massachusetts in No. 1:15-cv-40075-IT, Judge Indira Talwani.

CHEN, *Circuit Judge,* concurring with denial of the petition for rehearing en banc.

"Congress plainly contemplated that the patent laws would be given wide scope." *Bilski v. Kappos*, 561 U.S. 593, 601 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). As the Court observed, "Congress took this permissive approach to patent eligibility to ensure that 'ingenuity should receive a liberal encouragement.'" *Id.* Consistent with that mandate, the Court in *Diamond v. Diehr*, 450 U.S. 175 (1981) adopted a relatively narrow and more

administrable version of the judicial exceptions to the statutory text of 35 U.S.C. § 101 compared to what the Court articulated three years earlier in *Parker v. Flook*, 437 U.S. 584 (1978). Under *Diehr*'s "claim as a whole" principle, which does not divide the claim into new versus old elements, Athena's claims, particularly claims 7 and 9, likely would have been found to be directed to a patent-eligible process comprising a set of technical, transformative steps to test a patient for a particular medical condition. But in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), the Court set forth an inventive concept/point of novelty framework, which is a more far-reaching, aggressive version of the judicial exceptions to the statute and is largely incompatible with *Diehr*'s core rationale. At the same time, nothing in *Mayo* suggests that it sought to repudiate *Diehr*'s analysis. While I believe our court would benefit from the Supreme Court's guidance as to whether it intended to override central tenets of *Diehr*, *Mayo*'s reasoning is clear and we are bound by it. Because that analysis requires the affirmance of the district court's decision to invalidate Athena's claims, I concur with this court's decision to deny the petition for rehearing en banc.

I. *FLOOK* AND *DIEHR*

In *Flook*, the Court articulated the notion that something else beyond an algorithm or law of nature recited in a claim must provide the key "inventive concept" to make a claim patent-eligible. 437 U.S. at 594. There, the claims recited a formula for computing an updated alarm limit, a number that signals the presence of an abnormal temperature, pressure, and flow rate combination indicating inefficiency or perhaps danger during catalytic conversion processes. *Id.* at 585. While the Court recognized that "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm," *id.* at 590, it also declared that "the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application." *Id.* at 594. Because the

recited field of use of catalytic conversion of hydrocarbons was "well known," and the formula received no credit in the analysis, the Court concluded that Flook's claim "contains no patentable invention." *Id*. The Court indicated that it had considered the claim "as a whole," but it did so by reviewing the claim on an element-by-element basis in search of something new and inventive, discounting the formula as "assumed to be within the prior art." *Id*. In so doing, the Court found no novel "inventive concept" in the claim. *Id*.

The Court advanced a very different analytic approach for the judicial exceptions in *Diamond v. Diehr*, 450 U.S. 175 (1981), one that is difficult to reconcile with much of *Flook*'s reasoning. The Court held patent-eligible under § 101 a claim for a process of constantly measuring the temperature inside a molding press to determine when to remove a cured rubber product. *Id.* at 192–93. The relationship between temperature and cure relied on a known mathematical equation, but the Court found that, when the overall patent claim was considered as a whole, the respondents did "not seek to patent a mathematical formula," but instead "[sought] protection for a process of curing synthetic rubber." *Id.* at 187. Rejecting a point of novelty inquiry for § 101, the Court stated: "The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Id*. at 188–89; *id.* at 193 n.15 ("The fact that one or more of the steps in [a claimed] process may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter *eligible* for patent protection under § 101.") (emphasis in original); *see also id*. at 190 ("The question therefore of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject

matter.'" (quoting *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979))).

Furthermore, *Bilski* recognized the interplay between *Diehr* and *Flook*, pointing out that *Diehr* "established a limitation on the principles articulated in [*Gottschalk v.*] *Benson* and *Flook*" in that "*Diehr* emphasized the need to consider the invention as a whole, rather than 'dissect[ing] the claims into old and new elements . . . in the analysis.'" *Bilski*, 561 U.S. at 611 (quoting *Diehr*, 450 U.S. at 188). Thus, as recently as *Bilski*, the Court understood *Diehr* as requiring consideration of the claim as a whole, including any mathematical formula or scientific principle, in the § 101 inquiry, and as rejecting any dissection of the claim in search of novel or unconventional components.

Aside from reaffirming the result in *Flook*, the *Diehr* Court addressed *Flook*'s takeaway meaning at two different points in the opinion. First, *Diehr* observed: "Our recent holdings in *Gottschalk v. Benson*, *supra*, and *Parker v. Flook*, *supra*, both of which are computer-related, stand for no more than [the] long-established principles" that "[e]xcluded from such patent protection are laws of nature, natural phenomena, and abstract ideas." 450 U.S. at 185 (citing *Flook* and other cases describing the judicial exceptions, *e.g.*, "[a] principle[] in the abstract . . . cannot be patented."). Second, *Diehr* explained the defect in the *Flook* claim in the following way: "A mathematical formula does not suddenly become patentable subject matter simply by having the applicant acquiesce to limiting the reach of the patent for the formula to a particular technological use . . . . All the application provided was a 'formula for computing an updated alarm limit.'" *Id.* at 192 n.14 (quoting *Flook*, 437 U.S. at 586). The *Diehr* Court thus regarded the *Flook* claim as merely reciting a formula that would be applicable in an industrial process, but not reciting an

industrial process itself.[1] Aside from these two points, *Diehr* did not restate any other principles expressed in *Flook*.

That *Diehr* established a limitation on *Flook* and rejected the point of novelty/inventive concept approach to patent eligibility is underscored by the protests within the *Diehr* dissent. *See Diehr,* 450 U.S. at 204–16. "Proper analysis," in the dissent's view, "must start with an understanding of what the inventor claims to have discovered—or phrased somewhat differently—what he considers his inventive concept to be." *Id.* at 212. Because the claim had "no other inventive concept" other than the addition of a mathematical algorithm to the otherwise conventional claimed process for curing rubber, the dissent would have found the *Diehr* claim ineligible. *Id.* at 213–14. The *Diehr* majority responded: "In order for the dissent to reach its conclusion it is necessary for it to read out of respondents' patent application all the steps in the claimed process which it determined were not novel or 'inventive.' That is not the purpose of the § 101 inquiry and conflicts with the proposition recited above that a claimed invention may be entitled to patent protection even though some or all of its elements are not 'novel.'" *Id*. at 193 n.15.

Given *Diehr*'s evident disagreement with *Flook*'s analysis, *Diehr*, as the later opinion, was widely understood to be the guiding, settled precedent on § 101 for three decades. *See*, *e.g.*, *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1057 n.4 (Fed. Cir. 1992)

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[1] Citing *Flook*, the *Diehr* Court also stated that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process." *Id*. at 191–92. What that meant (pre-*Mayo*) was not clear, but, at the time, it could be read to refer to the fact that *Flook*'s claim did nothing more than "limit the use of the formula to a particular technological environment." *Id*. at 191.

("Although commentators have differed in their interpretations of *Benson, Flook,* and *Diehr,* it appears to be generally agreed that these decisions represent evolving views of the Court, and that the reasoning in *Diehr* not only elaborated on, but in part superseded, that of *Benson* and *Flook*.") (citing R.L. Gable & J.B. Leaheey, *The Strength of Patent Protection for Computer Products,* 17 Rutgers Computer & Tech. L.J. 87 (1991); D. Chisum, *The Patentability of Algorithms,* 47 U. Pitt. L. Rev. 959 (1986)); *see also* Edward W. Roush, Jr., *Patent Law-Patentable Subject Matter-Manufacturing Process Which Includes Use of Mathematical Formula and Computer Program Constitutes Patentable Subject Matter*, 13 St. Mary's L.J. 420, 428–29 (1981) ("The *Diehr* Court's holding is entirely consistent with title 35, section 101 subject matter standards. Although both the majority and dissent acknowledged that *Diehr* presented a section 101 statutory subject matter question, the dissent improperly injected considerations of section 102 novelty into its analysis. The majority in *Flook* employed the same rationale.").

II. *MAYO* AND *ALICE*

Three decades after *Diehr*, *Mayo* provided a framework for the judicial exceptions that strongly tracked the reasoning of *Flook* and the *Diehr* dissent. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012). The claims in *Mayo* were for a method of optimizing the treatment of an immune-mediated gastrointestinal disorder comprising two physical steps: (1) administering a synthetic drug to a patient, and (2) determining the concentration level of certain metabolic byproducts in the patient's bloodstream. The claims also included two "wherein" clauses, reciting that the measured level indicates whether the patient has received a safe and effective dose. *Id.* at 74–75. The Court found that the "wherein" clauses incorporate a law of nature: the relationship between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or

cause harm. *Id.* at 78. Because the two physical steps were well-known in the prior art, the *Mayo* Court characterized these claims as adding to that law of nature nothing more than "well-understood, routine, conventional activity." *Id.* at 73, 79–80.

Citing primarily to *Flook*, as well as *Bilski*, the Court stated that its prior decisions "insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself." *Id.* at 72–73. Because, in the Court's view, "the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field," the claims lacked any inventive concept. *Id.* at 73. Moreover, the Court did not share the concerns *Diehr* expressed as to preserving a doctrinal distinction between §§ 101 and 102; instead, the Court noted: "We recognize that, in evaluating the significance of additional steps [beyond the law of nature] the § 101 patent eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap." *Id.* at 90. *Mayo*'s rationale thus follows the point of novelty/inventive concept reasoning of *Flook* and the *Diehr* dissent.

As such, *Mayo* is in considerable tension with *Diehr*'s instruction to consider claims "as a whole" and *Diehr*'s disapproval of dissecting claims into elements and ignoring non-novel elements in the § 101 analysis. 450 U.S. at 188. The *Mayo* Court indicated that it considered the claimed steps "as an ordered combination," but it excluded the law of nature from that review and concluded that the "ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately." 566 U.S. at 79. In other words, after setting aside the law of nature, "any additional steps consist[ed] of well-understood, routine, conventional activity already engaged in by

the scientific community; and those steps, when viewed as a whole, add[ed] nothing significant beyond the sum of their parts taken separately." *Id.* at 79–80. The Court found support for this understanding of the judicial exceptions in *Flook*, observing that, for the *Flook* claim, the steps of monitoring a catalytic conversion process "were all 'well known,' to the point where, putting the formula to the side, there was no 'inventive concept' in the claimed application of the formula." *Id*. at 82. That type of "ordered combination" review ("putting the formula to the side"), however, is fundamentally different from *Diehr*'s "claim as whole" principle, which does not carve out the judicial exception from the patent eligibility inquiry, nor does it dismiss elements that lack novelty.[2] *See Diehr*, 450 U.S. at 188–93.

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[2] Both *Mayo* and *Flook* rely on an 1841 English case, *Neilson v. Harford*, 1 Web. P. C. 295 (1841), as supporting an "inventive concept" requirement in which a law of nature is treated as something well-known. *Mayo*, 566 U.S. at 82–83; *Flook*, 437 U.S. at 592. There is reason to believe, however, that the decision in *Neilson* did not turn on such a premise. *See Tilghman v. Proctor*, 102 U.S. 707, 723–25 (1880) (describing *Neilson*'s reasoning as drawing "the true distinction between a mere principle . . . and a process by which a principle is applied to effect a useful result."); *see also* Brief of Professors Jeffrey A. Lefstin and Peter S. Menell as *Amici Curiae* in Support of Petition for Writ of Certiorari at 15–21, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.* (2016) (No. 15-1182) (Lefstin and Menell Br.). Moreover, no Supreme Court patent eligibility case for a process claim prior to *Flook* relied on an inventive concept inquiry or assumption that a scientific discovery should be regarded as well-known. *See*, *e.g.*, *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Expanded Metal Co. v. Bradford*, 214 U.S. 366 (1909); *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1 (1888); *Tilghman*, 102 U.S. ; *Cochrane v. Deener*, 94 U.S. 780

In *Alice*, the Court reaffirmed this reversion to *Flook*, reiterating that, if the claims at issue are directed to laws of nature, natural phenomena, or abstract ideas, then we must ask "what else is there in the claims before us?" And in doing so, we must "consider the *elements* of each claim individually and 'as an ordered combination' to determine whether the *additional* elements 'transform the nature of the claim' into a patent-eligible application." *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014) (quoting *Mayo*, 566 U.S. at 78–79) (emphases added). As in *Mayo*, *Alice* described the second step of this analysis "as a search for an 'inventive concept'" that discounts the law of nature or abstract idea from that inquiry. *Id.* (quoting *Mayo*, 566 U.S. at 72–73); *see also id.* at 221 ("A claim that recites an abstract idea must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to

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(1876); *Corning v. Burden*, 56 U.S. 252 (1853); *Le Roy v. Tatham*, 55 U.S. 156 (1853) ("A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained." (quoting *Household Coal & Iron Co. v. Neilson*, 1 Web. P. C. 673, 683 (1843))); *see also O'Reilly v. Morse*, 56 U.S. 62, 114–15,118 (1853) (quoting same passage from *Neilson* quoted in *Mayo* and *Flook*, and then stating that "we see nothing" in *Neilson* "which would sanction the introduction of any new principle in the law of patents" and relying on "established principles in the American courts"). Importantly, *Diehr*'s reasoning, which post-dates *Flook* and was controlling authority for 30 years, is incompatible with the inventive concept approach.

monopolize the [abstract idea].'" (quoting *Mayo*, 566 U.S. at 77)).[3]

When it comes to applying the judicial exceptions, it bears noting that the *Mayo* analytical approach is considerably harder to apply consistently than the *Diehr* framework, and more aggressive in its reach. Consider the claim in *Mayo*. If that claim had recited just the single step of administering a synthetic drug to a patient, that single-step claim would be patent-eligible, but lack novelty under § 102. And if that claim added a second step for determining the subsequent level of a non-naturally occurring metabolite in a patient, that claim also would pass muster under § 101, but lack novelty. But when the claim further recites a relationship between a metabolite level and its efficacy in a patient, that claim suddenly would be invalid under § 101 for violating the law of nature exception. In other words, steps 1 and 2 now get pushed aside and declared insignificant, and the last step is designated as the "focus" of the claim, *i.e.*, the heart of the invention. The notion that adding claim language can convert an otherwise patent-eligible claim into a patent-ineligible claim is counterintuitive and a very difficult thing to explain to 8,000 patent examiners.[4] Moreover, the process of

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[3] The *Alice* Court, like *Mayo* and *Flook*, states that its approach is consistent with the rule that patent claims must be considered as a whole, because it considers the claim elements separately as well as in combination. *Alice*, 573 U.S. at 218 n.3. But, as explained *supra*, this approach is wholly unlike *Diehr*'s understanding of evaluating the claim "as a whole."

[4] That is not to say that the *Mayo* claim should have been upheld as valid. The "wherein" clauses simply identified a mental inference from practicing a prior art process, which is insufficient to distinguish the claim from the prior art. *See* Brief for United States as *Amicus Curiae*, at

determining what the claim is "really about" when the claim is viewed in pieces, rather than as a whole, can be highly subjective and impressionistic. This approach puts courts and examiners in the position of assigning value judgments to individual limitations, designating some as "significant" and others as "insignificant," and hoping everyone else reaches the same conclusion as to whether the claim contains a truly meritorious inventive contribution as opposed to a judicial exception embellished with insignificant window dressing. And all this just to resolve the threshold question of whether an invention is eligible for the patent system.

As written, *Mayo* requires a patent claim to have an inventive concept apart from the recitation of a natural law. That requirement has consequences that go beyond the facts of *Mayo* and is certainly clear enough that we are obliged to follow it. But, as explained above, *Mayo*'s framework is in tension on its face with *Diehr*, which was equally clear in requiring that a patent claim be considered as a whole, without putting aside any natural law or otherwise dissecting a claim into new versus old elements. Moreover, nothing in *Mayo* suggests that it sought to repudiate anything in *Diehr*; it instead suggests that it sought to maintain continuity with the Court's prior cases in this area. As for *Flook*, the Court in *Bilski* acknowledged that *Diehr* had "established a limitation" on *Flook* by "emphasiz[ing] the need to consider the invention as a whole, rather than 'dissect[ing] the claims into old and new elements . . . in the analysis.'" *Bilski*, 561 U.S. at 611 (quoting *Diehr*, 450 U.S. at 188). Importantly, *Mayo* does not say that it nullified this key "limitation" expressed in *Diehr*. Furthermore, as Judge Dyk points out in his concurrence, the Court's opinion in *Ass'n for Molecular Pathology v. Myriad Genetics,*

26–28, *Mayo v. Prometheus*, 566 U.S. 66 (2012) (No. 10-1150).

Inc., 569 U.S. 576 (2013), which issued after *Mayo*, could be read as potentially maintaining an open door for diagnostic claims such as Athena's, because they may be regarded as applications of knowledge of discovered natural laws. *See* Dyk Concurrence at 7. *Myriad* thus could suggest that *Mayo* should not go as far as its language indicates.

Through it all, there is a serious question today in patent law as to what extent *Diehr* remains good law in light of *Mayo*. We are not in a position to resolve that question, but the Supreme Court can. Resolution of the present confusion is important because if *Mayo* in fact overruled the principles in *Diehr* (as reiterated in *Bilski*), then that would be a significant incursion on the settled expectations that had existed for 30 years since *Diehr*. Relying on the *Diehr* framework, the Patent Office examined and granted many patents for medical diagnostic methods, establishing settled expectations in those granted property rights, and prompted companies and research institutions to organize their conduct and choices accordingly. Many of these diagnostic claims, including the ones at issue here, do not hold up well against *Mayo*'s more searching, claim dissection scrutiny.

III. ATHENA'S CLAIMS

Judge Newman, Judge Moore, the petitioner, and the *amici* raise several valid concerns. But I believe the reasoning underlying recent Supreme Court decisions compels us to affirm the district court's invalidity determination here. While *Diehr* long established that we must evaluate "the claim as a whole" for § 101 purposes, that principle has been considerably undermined, for we've been recently instructed to ask for claims such as Athena's, "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?" *Mayo*, 566 U.S. at 77 (emphases in original). Moreover, "[p]urely

'conventional or obvious' '[pre]-solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Id.* at 79.

It appears to me that, per *Mayo*, because the association of an antibody and a medical disorder is deemed to be a law of nature rather than an application of a law of nature, detecting that law of nature, by using data gathering steps or devices that can be said to be basic, conventional, or obvious, fails § 101. This is in contrast to examples, such as *Diehr* and *Neilson*, in which, as characterized by *Mayo*, the claimed inventions included unconventional steps beyond reliance on an abstract scientific principle. *Mayo*, 566 U.S. at 80–81, 83–84. In other words, the Supreme Court has made clear that detecting a law of nature (without more than conventional steps for accessing the law of nature) does not qualify as a patent-eligible application of a law of nature.

Here, the inventors of Athena's U.S. Patent No. 7,267,820 discovered an association between the disorder *myasthenia gravis* and the presence of muscle specific tyrosine kinase (MuSK) autoantibodies in a patient's blood. At issue are claims 7–9 reciting:

> 1. A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).
>
> [. . .]
>
> 7. A method according to claim 1, comprising
>
> contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid,

> immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
>
> monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
>
> wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to [MuSK].

8. A method according to claim 7 wherein said label is a radioactive label.

9. A method according to claim 8 wherein said label is 125I.

'820 patent, col. 12 ll. 31–35, col. 12 l. 62 – col. 13 l. 9.

We must accept that the association between the antibody and the disorder is a law of nature. Here, as in *Mayo*, data first must be gathered in order to access and observe the newly-discovered law of nature, and the claimed steps "simply tell doctors to gather data from which they may draw an inference in light of the correlations." *Mayo*, 566 U.S. at 79. That claims 7 and 9 do not preempt all ways of observing the law of nature isn't decisive, as none of the steps recited therein add anything inventive to the claims. Claim 7's label-adding and immunoprecipitating steps are conventional, standard techniques in the art of detecting the presence of a law of nature such as a protein; the panel majority opinion notes that these steps do not recite any improvement in the underlying immunoassay technology. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 751 (Fed. Cir. 2019).

Claim 9 recites use of a particular label, but one that was standard to use in the art. This cannot provide the inventive concept under *Mayo*. As an analogy, we would

not find that a claim directed to an abstract idea of communicating information through a device passes muster under § 101 simply because it limits the claimed device to, say, a Samsung Galaxy® smartphone. Nor would the *Mayo* claim be considered to possess an inventive concept if it had recited that the initial step of "administering a drug" be performed in a conventional way, such as orally or intravenously.

One amicus brief points out that § 101 provides that "[w]hoever invents or discovers" a new or useful process, manufacture, machine or composition of matter may be entitled to a patent, and that § 100(a) defines "invention" to mean "invention or discovery." Brief of Freenome Holdings Inc. and Achillion Pharm., Inc. as *Amici Curiae* in Support of Neither Party, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (2019) (No. 17-2508). Section 100 also defines "process" to include "a new use of a known process, machine, manufacture, composition of matter, or material." § 100(b). Arguably, Athena's invention is a claim for a new use (diagnosing *myasthenia gravis*) of a known composition of matter (MuSK autoantibodies). Moreover, given that the dual "invention or discovery" structure consistently has been part of every Patent Act since 1790, this statutory provision suggests that at least some discoveries, including Athena's "discovery" of how to diagnose *myasthenia gravis*, have always been contemplated as patentable subject matter. *See* Lefstin and Menell Br. at 4–14. However, I am not aware of the Supreme Court ever addressing the meaning of "discovers" in § 101 separately from "invents," and it must be the Supreme Court, and not this court, that speaks to that statutory question, because the Court already proclaimed that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the section 101 inquiry." *Myriad*, 569 U.S. at 591.

In sum, I do not think the claims here can withstand *Mayo*'s scrutiny.[5] But perhaps when read "as a whole" under *Diehr*, claims such as claims 7 and 9 in this case could be viewed as methods of testing for a specific medical condition, employing a sequence of steps that physically transform materials. By no means do the claims cover a natural principle in the abstract. Rather, this sounds like a contribution to the "useful arts" stated in Article I, Section 8, Clause 8 of the U.S. Constitution. That those physical, transformative steps may apply conventional techniques for locating an antibody in a sample would not be disregarded in the threshold inquiry of whether the claimed invention qualifies as subject matter eligible for the patent system.

New methods for diagnosing medical conditions, as a general matter, intuitively seem to be the kind of subject matter the patent system is designed for: to encourage the risky, expensive, unpredictable technical research and development that people would not otherwise pursue in the hope that *if* they discover something of great medical value, then they will be protected and rewarded for that successful effort with a patent. This category of invention, after all, is not the same as methods of entering into contracts, or horse whispering, or speed dating or other methods that animated many of the concerns underlying *Bilski*. The kind of lab work undertaken in discovering new diagnostics

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[5] While this court is bound by *Mayo*, I do not believe this court has turned *Mayo* into a "per se rule" that bars all medical diagnostic claims from patent protection. Moore Dissent at 4. Diagnostic claims grounded in novel, non-obvious techniques that render a given diagnosis possess an inventive concept continue to be granted. As to the difference in outcomes so far in our § 101 decisions between diagnostic and treatment claims, I agree with the analysis in Judge Lourie's concurrence. Lourie Concurrence at 3–4.

and performing the steps of such claimed inventions can only be described as being technical in nature. For several decades before *Mayo*, this has been the basis for why the Patent Office granted patents for many medical diagnostics—not just for the law of nature in the abstract, but as applied in the real-world medical context to diagnose patient health conditions. In any meaningful sense, this represents a practical application of the discovered law of nature, that is, it is applied science in every sense of that term. And it should be patentable subject matter in a well-functioning patent system.

CONCLUSION

The most recent Supreme Court opinions are clear in my view on how to address claims like Athena's. Even though Athena's claims likely would be found patent-eligible under *Diehr*'s framework, it is not an inferior court's role to dodge the clear, recent direction of the Supreme Court. Accordingly, I concur with denial of the petition for rehearing *en banc*.

United States Court of Appeals for the Federal Circuit

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
Plaintiffs-Appellants

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, MAYO CLINIC,
Defendants-Appellees

2017-2508

Appeal from the United States District Court for the District of Massachusetts in No. 1:15-cv-40075-IT, Judge Indira Talwani.

MOORE, *Circuit Judge*, with whom O'MALLEY, WALLACH, and STOLL, *Circuit Judges*, join, dissenting from the denial of the petition for rehearing en banc.

This is not a case in which the judges of this court disagree over whether diagnostic claims, like those at issue in *Athena*, should be eligible for patent protection. They should. None of my colleagues defend the conclusion that claims to diagnostic kits and diagnostic techniques, like those at issue, should be ineligible. The only difference among us is whether the Supreme Court's *Mayo* decision

requires this outcome. The majority of my colleagues believe that our hands are tied and that *Mayo* requires this outcome. I believe *Mayo* does not. The Patent Act renders eligible the invention or discovery of any new and useful process. 35 U.S.C. § 101. And the patent system exists to promote exactly this sort of specific, targeted application of a life-saving discovery, which is characterized by extraordinarily high initial market entry costs. The claims in this case should be held eligible, and they are distinguishable from *Mayo*.

DIAGNOSTICS ARE PER SE INELIGIBLE

Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible. *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013 (Fed. Cir. 2019) ("*Cleveland Clinic II*"); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019); *Roche Molecular Sys., Inc. v.* CEPHEID, 905 F.3d 1363 (Fed. Cir. 2018); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017) ("*Cleveland Clinic I*"); *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015); *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014); *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65 (Fed. Cir. 2012).[1] Despite the

[1] The district courts are following our lead, holding diagnostic methods ineligible. *See, e.g.*, *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 356 F. Supp. 3d 925 (N.D. Cal. 2018); *Genetic Veterinary Scis., Inc. v. LABOklin GmbH & Co.*, 314 F. Supp. 3d 727 (E.D. Va. 2018); *Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distribution, Inc.*, No. 15–170–GMS, 2017 WL 3867649 (D. Del. Sept. 5, 2017); *Esoterix Genetic Labs. LLC v. Qiagen Inc.*, No. 14–CV–13228–ADB, 2016 WL 4555613 (D. Mass. Aug. 31, 2016); *Esoterix*

significance of these diagnostic inventions and the high costs of developing them, we have held, because of *Mayo*, every one of these life-changing inventions and discoveries ineligible. For example, we held a method for assessing a patient's risk of having cardiovascular disease by detecting a specific enzyme, based on the discovery of the correlation between the enzyme and the disease, ineligible. *Cleveland Clinic I*, 859 F.3d at 1363. Cardiovascular disease is the number one cause of death in the United States, killing more than 600,000 people per year, and costing over $200 billion annually.[2] The diagnostic invention in *Cleveland Clinic I* allowed for early diagnosis of cardiovascular disease and had a better predictive value than the clinically used risk factors employed by physicians at the time. There can be no argument but that such early diagnoses will save lives and reduce future treatment costs. But because of *Mayo*, such claims were held ineligible. We also held ineligible claims to a method of screening for alterations in genes linked to hereditary breast and ovarian cancer. *In re BRCA1*, 774 F.3d at 765. It is estimated that breast cancer will kill more than 40,000 people in 2019.[3] Again, there is no reasonable dispute that early diagnoses save lives and future medical costs. To be clear, the method claims were *not* to the gene itself which is found in nature, but rather to a use of the discovered correlation between

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Genetic Labs. LLC v. Qiagen Inc., 133 F. Supp. 3d 349 (D. Mass. 2015); *Genetic Veterinary Scis., Inc. v. Canine EIC Genetics, LLC*, 101 F. Supp. 3d 833 (D. Minn. 2015).

[2] CTRS. FOR DISEASE CONTROL AND PREVENTION, *Heart Disease Fact Sheet* (Aug. 23, 2017), https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_heart_disease.htm.

[3] NAT'L CANCER INSTITUTE, *Cancer Stat Facts: Female Breast Cancer*, https://seer.cancer.gov/statfacts/html/breast.html.

certain mutations and breast cancer for diagnostic purposes. *In re BRCA1*, 774 F.3d at 758. We held ineligible a method for detecting tuberculosis, one of the world's deadliest diseases.[4] *Roche*, 905 F.3d at 1374. And claims to diagnostic methods related to fetal health, characteristics, and genetic disorders, such as Down syndrome, fared no better. *Ariosa*, 788 F.3d at 1378; *PerkinElmer*, 496 F. App'x at 73. The *Ariosa* method of detecting fetal abnormalities based on a simple blood test was an absolute game changer. Prior to the *Ariosa* discovery, such abnormalities were detected with higher cost and higher risk procedures such as amniocenteses which had the potential to harm all involved. That brings us to the *Athena* claims, which are directed to a method of diagnosing patients with an autoimmune disease using a protein that had never before been associated with the disease. *Athena*, 915 F. 3d at 747. One of every five patients with the autoimmune disease experienced symptoms but did not produce the type of autoantibodies previously associated with the disease, and thus were unable to be diagnosed and properly treated at an early stage. *Id.* The claimed diagnostic method in *Athena* solved that problem through a specific, narrowly tailored diagnostic process but was nonetheless held ineligible. None of these diagnostic claims survived because we concluded we had no choice because of *Mayo*.

We have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible. That per se rule is "too broad an interpretation of this exclusionary principle [which] could eviscerate patent law." *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 71 (2012). The Supreme Court has repeatedly cautioned against rigid or per se rules. *See, e.g.*, *Halo Elecs., Inc. v.*

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[4] CTRS. FOR DISEASE CONTROL AND PREVENTION, *Tuberculosis (TB) Data and Statistics* (Dec. 31, 2018), https://www.cdc.gov/tb/statistics/default.

Pulse Elecs., Inc., 136 S. Ct. 1923, 1932 (2016) (rejecting test which "is unduly rigid"); *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 551 (2014) (rejecting test as "unduly rigid"); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419–20 (2007) (cautioning against "[r]igid preventative rules"); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002) (preferring that rules be interpreted "in a flexible way, not a rigid one"); *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 (1997) (declining to adopt a "rigid rule"); *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980) (declining to create a rule that "inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable *per se*").

In his opening statement during The State of Patent Eligibility in America Senate hearings, Senator Coons recognized that "for medical diagnostics, . . . [there is] a presumption against eligibility that is nearly impossible to overcome." *The State of Patent Eligibility in America, Part I: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary*, 116th Cong. 15:36–45 (2019) (opening statement of Sen. Coons). And testimony from industry representatives confirmed that industry members and scholars think "it is unclear whether diagnostic methods are patentable in any meaningful way." *See, e.g.*, *The State of Patent Eligibility in America, Part II*, 116th Cong. 7 (2019) (written testimony of Hans Sauer, Ph.D., Deputy General Counsel and Vice President for Intellectual Property, Biotechnology Innovation Organization (BIO)).

Our fervor for clarity and consistency has resulted in a per se rule that excludes all diagnostics from eligibility. I do not agree with my colleagues that *Mayo* requires that all of these claims in all of these cases be held ineligible. But that is where we are.

I do not fault my colleagues, who under protest have concluded that they have no choice but to hold the claims in *Athena* ineligible because of *Mayo*. *See Athena*, 915 F.3d at 753 n.4 ("[W]hether or not we as individual judges might agree or not that these claims only recite a natural law . . . the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature."); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1287 (Fed. Cir. 2015) (Lourie, J., concurring with denial of reh'g en banc) ("[I]t is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility . . . [b]ut I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court."). There is surely some broad language in *Mayo* which could lead to this conclusion. I, however, think we have extended *Mayo* too far. Reading the entirety of *Mayo* and the subsequent *Myriad* decision, the Supreme Court did not intend *Mayo* to be the "sweeping" decision my colleagues have concluded it is. *See, e.g.*, *Ariosa*, 788 F.3d at 1380 (Linn, J., concurring) ("I join the court's opinion invalidating the claims . . . only because I am bound by the sweeping language of the test set out in [*Mayo*]."); *Ariosa*, 809 F.3d at 1290 n.3 (Dyk, J., concurring) (stating that we must "respect the sweeping precedent of *Mayo*"); *see also id.* at 1289 ("[T]here is a problem with *Mayo* insofar as it concludes that inventive concept cannot come from discovering something new in nature . . . . *Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself."). It is the role of this court to both faithfully follow *Mayo* and to determine its reach when facts and circumstances differ. I dissent from my colleagues' refusal to rethink our interpretation of *Mayo*.

DIAGNOSTICS DESERVE PATENT INCENTIVES

"Diagnosis is the foundation of medicine," and diagnostic techniques and kits when narrowly claimed are precisely the type of innovation the patent system exists to promote.[5] Diagnostic techniques, while accounting for less than 2.5% of healthcare expenses, "guide[] approximately 66% of clinical decisions."[6] Diagnostics are an essential category of medical technologies, critical to treating illnesses and saving lives. Diagnostic medicine saves lives and money through early detection and reduces the need for high cost pharmaceuticals or curative procedures, but developing diagnostic kits and techniques is expensive and time consuming. Development of a new diagnostic test is estimated to cost up to $100 million and to take nearly 10 years.[7]

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[5] NAT'L RESEARCH COUNCIL, TOWARD PRECISION MEDICINE: BUILDING A KNOWLEDGE NETWORK FOR BIOMEDICAL RESEARCH AND A NEW TAXONOMY OF DISEASE, Epilogue, (2011) https://www.ncbi.nlm.nih.gov/books/NBK92141/.

[6] UP Rohr et al., *The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report*, PLOS ONE (March 2016), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0149856.

[7] I. Okeke et al., *Diagnostics as Essential Tools for Containing Antibacterial Resistance*, 14 DRUG RESISTANCE UPDATES 95, 101 (April 2011), https://www.sciencedirect.com/science/article/pii/S1368764611000185?via%3Dihub; s*ee also Mystery Solved! What is the Cost to Develop and Launch a Diagnostic*, DIACEUTICS (Jan. 15, 2013), https://www.diaceutics.com/?expert-insight=mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic (2013) (The average cost of developing a diagnostic in the U.S. is $50–75 million with development of expansion

Diagnostics economically depend on strong patent protection. Because they are typically characterized as "very expensive to develop but relatively cheap to reproduce," patent protection is required to make it financially viable for continued investment in their development.[8] As Senator Tillis explained in his opening statement during The State of Patent Eligibility in America Senate hearings, "[w]hy would anyone in their right mind risk millions if not billions of dollars to develop a product when they have no idea if they're eligible for protection? From a business perspective, it simply isn't worth the risk for many endeavors."[9] Without the possibility of patent protection to recoup the high costs of research and development associated with diagnostic techniques and kits, the impact can only be that there will be fewer advances in diagnostic medicine.[10] Industry leaders make clear that absent dependable patent

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assays on existing platforms costing $10–15 million and development of new platforms costing over $100 million.).

[8] A. Krattiger, *Promoting Access to Medical Innovation*, WORLD INTELLECTUAL PROPERTY ORGANIZATION (Sept. 2013), https://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html.

[9] *The State of Patent Eligibility in America, Part I*, 116th Cong. 3:32–47 (2019) (opening statement of Sen. Tillis).

[10] *The State of Patent Eligibility in America, Part II*, 116th Cong. 1–2 (2019) (written testimony of Rick Brandon, Associate. General Counsel, University of Michigan representing Association of American Universities) ("[I]nventors and investors often require the protection of a period of exclusivity in order to assume the substantial risk of investing the significant resources needed in order to bring a product to the public. In the case of products that require FDA approval, including diagnostics, this can take years and millions of dollars. The public benefits from both

protection, companies will not move forward with diagnostic innovations.[11] As investors routinely recognize, once patent protection over medical technologies is lost, these innovations essentially become gifts to society and the companies that developed them cannot recoup the time and money they spent to do so.[12] It is these life-saving fields though, with such high costs to the initial market investor, where patent protection is critical.

The importance of diagnostics and their cost-reducing effects on patient treatment cannot reasonably be questioned. We are hard-pressed to identify facets of modern medicine that do not employ or rely on diagnostics. Diagnostics are "crucial in mitigating the effect of disease outbreaks."[13] For example, had diagnostic techniques been

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public disclosure and a greater assurance of new products and services.").

[11] *The State of Patent Eligibility in America, Part III*, 116th Cong. 3 (2019) (written testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations) (The "[a]bility to get protectable intellectual property (usually in the form of a patent) is the first, and most influential factor in our assessment. If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point.").

[12] M. Rosenblatt, The Real Cost of "High-Priced" Drugs, HARVARD BUSINESS REVIEW (Nov. 17, 2014), https://hbr.org/2014/11/the-real-cost-of-high-priced-drugs; *The State of Patent Eligibility in America, Part I*, 116th Cong. 1–2 (2019) (written testimony of Patrick Kilbride, Senior Vice President of the Global Innovation Policy Center at the U.S. Chamber of Commerce).

[13] M. Perkins et al., *Diagnostic Preparedness for Infectious Disease Outbreaks*, 390 SCIENCEDIRECT 2211

developed *before* the 2015 Ebola outbreak, and applied to patients early enough, the population-attack rate of Ebola could have been reduced from 80% to 0%. *Id.* Ebola is only one example. "Poor diagnostic preparedness has [also] contributed to significant delays in the identification of . . . Lassa Fever, yellow fever, and Zika."[14] Disease epidemics are not the only life-threatening conditions to which diagnostics provide a meaningful response. Diagnostics are pivotal to addressing the advent and increase in drug-resistant infections. Current estimates project that by 2050, drug-resistant infections will "lead to 10 million people dying every year and . . . would cost the world up to 100 trillion" dollars.[15] Diagnostic tests are a critical component of the answer to this problem. Methicillin-Resistant Staphylococcus Aureus ("MRSA") is an example of an antibiotic-resistant infection that burdens American hospitals in terms of morbidity, mortality, and healthcare costs.[16] Its treatment, and the outcome of that treatment, depends on appropriate diagnosis and antibiotic administration. *Id.* And the effects of diagnostics in improving the detection and treatment of cancer, human immunodeficiency virus,

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(2017), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31224-2/fulltext.

[14] C. Kelly-Cirino et al., *Importance of Diagnostics in Epidemic and Pandemic Preparedness*, 4 BMJ GLOBAL HEALTH (2019), https://gh.bmj.com/content/4/Suppl_2/e001179.

[15] J. O'Neill, *Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations*, THE REV. ON ANTIMICROBIAL RESISTANCE, 6 (Dec. 2014).

[16] K. Bauer et al., *An Antimicrobial Stewardship Program's Impact with Rapid Polymerase Chain Reaction Methicillin-Resistant Staphylococcus Aureus/S. aureus Blood Culture Test in Patients with S. aureus Bacteremia*, 51 CLINICAL INFECTIOUS DISEASES 1074 (2010).

as well as *in vitro* care should not be overlooked. *See* Rohr, *supra* note 6. For example, diagnostics improved medical approaches to cancer care, and will continue supporting progress in a field that cost an estimated $125 billion in the United States in 2010.[17] Development of diagnostics plays a central role in American medical innovation as we face increasingly robust medical challenges, with a goal to save lives and improve the quality of those lives.

Not only do diagnostics save lives, they reduce the cost of treatment. The diagnostic industry drives medical costs down, not up. People suffering from illness or disease will do whatever they can to find a cure. Proper diagnoses allow for earlier detection of illness and targeted treatment. But without proper diagnosis, patients have to endure numerous unsuccessful and costly treatments. Both the financial burden of continued testing and treatment and the emotional and physical tolls associated with suffering from symptoms, but not knowing the cause, can be reduced or even prevented thanks to diagnostics. And when there are specific advances, discoveries, or inventions in the diagnostics industry, they must be eligible for patent protection.[18]

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[17] A. Mariotto et al., *Projections of the Cost of Cancer Care in the United States: 2010-2020,* 103 J. NAT'L CANCER INST. 117, 122 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3107566/.

[18] *See* R. Davis, *Senate Scrutinizes Patent Bill's Effect on Drug Prices, Genes*, LAW360 (June 6, 2019), https://www.law360.com/ip/articles/1164262/senate-scrutinizes-patent-bill-s-effect-on-drug-prices-genes?nl_pk=c4844ff4-19ab-48d7-b2f9-9fa06ce87648&utm_source=newsletter&utm_medium=email&utm_campaign=ip (discussing Senator Tillis' explanation that patent eligibility uncertainty "has undermined investment in new medical research and could prevent new drugs from being created, making it a moot point how much they cost").

Unless one opposes the notion of patent protection entirely, it cannot be reasonably disputed that claims to diagnostic kits and techniques, like pharmaceuticals, which require enormous initial investments in terms of both time and money, are the reason we suffer the promise of a monopoly. As many have explained, without patent protection, there will be little incentive for companies to invest the monumental amount of time and money necessary to develop diagnostic kits, tools and techniques. A recent article, co-written by Paul Michel, former Chief Judge of the Federal Circuit, and David Kappos, former Director of the PTO, states:

> This uncertain patent climate has a chilling effect on innovation in biosciences to the detriment of public health. . . . [I]nvestors are less interested in funding costly new biomarker diagnostic research. As a result, diseases will go undiagnosed, and patients will suffer the consequences. . . . Investment in diagnostics goes to the core of containing spiraling health care costs, improving patient outcomes and treating illnesses before they become debilitating to suffering Americans.[19]

This sentiment was echoed by industry leaders during The State of Patent Eligibility in America Senate hearings held on June 4–5 & 11, 2019. *See The State of Patent Eligibility in America, Part II*, 116th Cong. 6–7 (2019) (written testimony of Hans Sauer, Ph.D., Deputy General Counsel and Vice President for Intellectual Property, BIO) ("Absent the ability to protect their discoveries with valid patents . . .

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[19] D. Kappos & P. Michel, *Supreme Court Patent Decisions are Stifling Health Care Innovation*, MORNING CONSULT (Oct. 29, 2018), https://morningconsult.com/opinions/supreme-court-patent-decisions-stifling-health-care-innovation/.

companies would lack the necessary incentive to make the risky, expensive, and time-consuming investments in research and development often required to bring new technologies to market."); *The State of Patent Eligibility in America, Part II*, 116th Cong. 9 (2019) (written testimony of Henry Hadad, President, IPO) ("[C]onfusion about what is patent-eligible discourages inventors from pursuing work in certain technology areas, including discovering new genetic biomarkers and developing diagnostic and artificial intelligence technologies. [This] uncertainty disincentivizes the enormous investment in research and development that is necessary to fuel the innovation cycle."); *The State of Patent Eligibility in America, Part I*, 116th Cong. 14:46–15:05 (2019) (opening statement of Sen. Coons) ("I worry that this continuing lack of clarity . . . has led to reduced investment in the expensive and intensive research and development necessary to develop next generation cures . . . ."); *The State of Patent Eligibility in America, Part III*, 116th Cong. 1:22:12–1:22:35 (2019) (testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations) ("The work of translating discovery into commercial products requires [patent] protection to justify the investment into those discoveries. And absent clarity . . . we are not moving forward diagnostic discoveries to translate them into commercial products the way we would do otherwise."); *The State of Patent Eligibility in America, Part III*, 116th Cong. 1:42:12–1:42:28 (2019) (testimony of Corey Salsberg, Vice President and Global Head Intellectual Property Affairs for Novartis) ("Make no mistake about section 101, this is the gateway to the patent system. So what that means in practical terms is it's a guide as to which fields of technologies can support sustained investment, and which ones likely cannot, and that's why we have such deep concerns about the status quo."); *The State of Patent Eligibility in America, Part III*, 116th Cong. 1 (2019) (written testimony of Robert Deberardine, Chief Intellectual Property Counsel, Johnson & Johnson) ("It is only because of the United States patent system, and the

predictability that it has historically provided, that we have been able to make the investments, conduct the research, and take the risks required to develop these treatments. And only with predictability will we be able [to] solve today's most challenging healthcare problems and develop the groundbreaking treatments of tomorrow. Unfortunately, the patent system in the United States today is anything but predictable.").

The math is simple, you need not be an economist to get it: Without patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline. To put it simply, this is bad. It is bad for the health of the American people and the health of the American economy. And it is avoidable depending on our interpretation of the Supreme Court's holding in *Mayo*. I have no doubt that my colleagues agree with the sentiments herein that diagnostics are important, and that patent protection of such diagnostics is critical to incentivizing their very existence. The only point upon which we disagree is over the breadth of the *Mayo* holding.

ATHENA'S SPECIFICALLY CLAIMED METHOD IS ELIGIBLE

While *Mayo* did not require the result the panel reached in this case, the panel could not disregard our binding precedent of cases like *Ariosa, Cleveland Clinics,* and *Roche* which have interpreted *Mayo* as requiring this per se rule. Thus, the only hope was en banc action.

It is my view that § 101 and *Mayo*, when read together and in their entireties, compel the holding that the claims in *Athena* are eligible. Under the Patent Act, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. Our decisions have ignored the truth that claims to specific, narrow processes, even if those processes involve natural laws, are not directed to the natural laws

themselves. And contrary to the "elementary principle that . . . [we must] 'give effect, if possible, to every clause and word of a statute,'" our § 101 jurisprudence has largely ignored Congress' explicit instruction that a discovery can be the basis for a patentable invention. *King v. Burwell*, 135 S. Ct. 2480, 2498 (2015) (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)). Section 101 refers to both "invent[ion] or discover[y]," and § 100(a) expressly defines invention as any "invention or discovery." We have misread *Mayo* and how it fits within the framework of the judicially-created exceptions to § 101 for laws of nature, natural phenomena, and abstract ideas.

Laws of nature, natural phenomena, and abstract ideas are considered "the basic tools of scientific and technological work." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (quoting *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)). The Supreme Court excepted these categories from § 101 to ensure that patent law does not "'inhibit further discovery by improperly tying up the future use of' these building blocks of human ingenuity." *Id.* (quoting *Mayo*, 566 U.S. at 85). Accordingly, "patents cannot issue for the discovery" of a law of nature. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). Nor can a claim to the law of nature become patentable by simply "adding the words 'apply it.'" *Mayo*, 566 U.S. at 72 (citing *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972)). But "an *application* of a law of nature . . . to a known structure or process may well be deserving of patent protection." *Id.* at 71 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)). We have chosen to ignore the legal space between these principles in favor of a swiftly executing, per se rule that all diagnostic claims are ineligible. That conclusion is incorrect.

By distinguishing between claims that recite a law of nature and simply add the words "apply it," and claims that

recite a concrete application of a law of nature, the Supreme Court suggests we should consider the level of specificity in the claims to determine whether the claim is even directed to the natural law. *See Alice*, 573 U.S. at 223 ("[I]f a patent's recitation of a computer amounts to a mere instruction to implement an abstract idea on a computer, that addition cannot impart patent eligibility.")); *Mayo*, 566 U.S. at 72 ("[T]o transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'"); *Diehr*, 450 U.S. at 192 ("[W]hen a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract. . . . [W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.").

The law of nature at issue in *Mayo* was the "relationship between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." 566 U.S. at 77. Importantly, this relationship was not a new discovery. "At the time the discoveries embodied in the patents were made, scientists already understood that the levels in a patient's blood of certain metabolites . . . were correlated with the likelihood that a particular dosage of thiopurine drug could cause harm or prove ineffective." *Id.* at 73. While the inventors characterized the precise correlation, they could not be said to have discovered the relationship in the first place.

The Court began its analysis with the statement that "[i]f a law of nature is not patentable, then neither is a pro-

cess reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." *Id.* at 77–78. It examined the limitations of the representative claim, which recited:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> > (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
> >
> > (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
> >
> > wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
> >
> > wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Id. at 74–75.

This claim in its entirety did nothing more than describe the natural relationship between metabolite concentrations and the effective dose of a thiopurine drug. *Id.* at 77. "Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims d[id] not confine their reach to particular applications of those laws." *Id.* at 87. The claimed steps were set forth in "highly general language covering all processes that make use of the correlations . . . including later discovered processes

that measure metabolite levels in new ways." *Id.* at 87. Due to their breadth, the Supreme Court concluded that upholding the claims "would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries." *Id.* at 73; *see also id.* at 87 (holding that "the basic underlying concern that these patents tie up too much future use of laws of nature" reinforced the holding of ineligibility). "[S]imply appending conventional steps, *specified at a high level of generality*," to the law of nature did not make that law patentable. *Id.* at 82 (emphasis added).

The breadth and generality of the *Mayo* claims led to their demise, as they recited nothing more than the natural law. We have since ignored these considerations, treating every claim that includes a law of nature as directed to that law, even if the claim as a whole recites a specific way of applying that law of nature to a new and useful end. We should not ignore the considerations related to claim breadth articulated in *Mayo* in our § 101 analysis.

The *Athena* claims differ significantly from the *Mayo* claims. In 1960, before the invention claimed in U.S. Patent No. 7,267,820 ("the '820 patent"), scientists identified a specific category of autoantibodies that bind to and interfere with the acetyl choline receptor (AChR)—which is responsible for the transmission of signals from neurons to muscle cells—cause *Myasthenia gravis* ("MG"). '820 patent at 1:24–26. The presence of these anti-AChR antibodies thus indicates that the patient suffers from MG. However, 20% of patients who manifested MG-like symptoms did not have the anti-AChR antibodies. *Id.* at 1:34–40. It was unknown if this 20%, "have the same or a distinct and separate MG condition," *id.* at 1:41–42, and there was "no basis for providing an immediate clinical diagnosis for such patients," *id.* at 4:20–22.

The inventors of the '820 patent discovered that a different type of autoantibody that binds to and interferes

with muscle-specific tyrosine kinase (MuSK)—another receptor also known to help transmit signals from neurons to muscles—can also cause MG. *Id.* at 1:54–61 ("The present inventors surprisingly found that many of the 20% of MG patients which do not exhibit any autoantibodies to AChR, instead have IgG antibodies . . . indicating that they are afflicted with a form of MG which has a different etiology . . . ."). The inventors in *Athena* discovered that these MG sufferers produced the anti-MuSK antibody, and created a process for diagnosing MG using methods that detect the presence of that antibody. These methods had never before been used to diagnose MG. Claims 7 and 9, on which the majority focused in *Athena*, require the use of specific laboratory techniques to diagnose a patient based on the natural law that 20% of people having MG produce autoantibodies to the MuSK protein. Claim 7 recites:

> 1. A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).
>
> 7. A method according to claim 1, comprising contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid, immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex, wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to muscle specific tyrosine kinase (MuSK).

'820 patent at Claims 1, 7.

The claims provide for a method of diagnosing patients with MG using the following concrete steps: (1) contacting the patient's bodily fluid with labeled MuSK, MuSK epitope, or other antigenic determinant that binds any anti-MuSK antibodies that may be present in the bodily fluid; (2) immunoprecipitating any resulting complexes from the bodily fluid; and (3) detecting the presence of the anti-MuSK antibody by monitoring for the label, whereby the presence of the label indicates a diagnosis of MG. *Id.* These steps are not set out at the "high level of generality" that concerned the Court in *Mayo*, and they specifically confine their reach to a specific application of the relationship between anti-MuSK antibodies and MG. While the combination of steps in *Mayo* amounted to little "more than an instruction to doctors to apply the applicable laws when treating their patients," 566 U.S. at 79, claim 7 in *Athena* is a single, specific method for applying the applicable law.

Indeed, the majority in this case repeatedly acknowledged that the claims in *Athena*, unlike the claims in *Mayo*, contain specific, concrete steps applying the law of nature. *See, e.g.*, *Athena*, 915 F.3d at 751 ("The claims at issue here involve both the discovery of a natural law and certain concrete steps to observe its operation."). As the majority further acknowledged, claim 9, which depends on claim 7, "leaves open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps." *Id.* at 752. In fact, the '820 patent identifies alternate methods for detecting antibodies, such as MuSK-related antibodies. *See* '820 patent at 3:33–4:12. The claims do not "broadly preempt the use of a natural law," and do not prevent any scientist from using the natural law in association with other common processes. *Mayo*, 566 U.S. at 72; *see Myriad*, 569 U.S. at 595–96. The concreteness and specificity of the claims in *Athena* moves them from reciting a law of nature to a particular application of a law of

nature. The claims are not directed to a natural law or phenomenon.

The inventiveness of the claimed discovery in the process steps should also be considered when assessing eligibility. New and useful discoveries, such as the before unknown relationship between anti-MuSK autoantibodies and MG, when applied in a "process," should pass muster as eligible under the statutory text of § 101. Our decision to entirely disregard the discovery incorporated in the claims is a misapplication of the statute. This is not to say that a claim on the discovery of a law of nature itself or a natural phenomenon should be eligible. I agree it should not. But to wholly ignore the inventiveness of the discovery when assessing patent eligibility closes our eyes to the statute enacted by Congress. Athena discovered that 20% of people suffering from MG generate autoantibodies that bind to a MuSK protein. Its claims recite concrete steps to detect the presence of autoantibodies to MuSK to diagnose MG. These antibody/MuSK complexes had never been used by prior art MG diagnostic tests. In contrast, the claims in *Mayo* recited a generic "determining" step, with no laboratory test at all specified by the claims, and the specification itself stated that the methods were "well-understood, routine, and conventional activity already engaged in by the scientific community." 566 U.S. at 79. Moreover, the Court explained that scientists had routinely performed that very step on thiopurine metabolites, the metabolite being detected in the claim. *Id.* at 78. This is not at all the case in *Athena*. The claims are directed to a new and useful process of specific, concrete steps for diagnosing MG using a particular immunoassay that had never been previously used to diagnose MG. The claims should be held patent eligible under § 101 and *Mayo*.

I do not believe that the Supreme Court intended *Mayo* to be the sweeping decision it has become. Indeed, it warned us that "too broad an interpretation of" its judicial

exceptions to eligibility "could eviscerate patent law" because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. I do not understand *Mayo* to render ineligible a claim which covers a specific, concrete application of a natural law simply because such a claim is diagnostic as opposed to therapeutic. Both should be eligible. The last word on this from the Supreme Court came in *Myriad* where the Court made clear "patents on new applications of knowledge about BRCA1 and BRCA2 genes" could be eligible. 569 U.S. at 596. To the extent that this Court has read *Mayo* so broadly that it precludes exactly that sort of patent, we have erred. Doing so leaves *Mayo* at odds with the patent statutes and the later *Myriad* decision.

CONCLUSION

"It's important for the judiciary to first recognize that there is a problem that needs to be addressed . . . 101 remains the most important substantive patent law issue in the United States today. And it's not even close." R. Davis, *Courts Can Resolve Patent Eligibility Problems, Iancu Says*, LAW 360 (Apr. 11, 2019) (quoting U.S. Patent and Trademark Office Director Iancu). In the wake of *Mayo*, we have painted with a broad brush, suggesting that improved diagnostic techniques are not patent eligible. *Mayo* did not go so far, and given the import of diagnostic techniques, we should reconsider this case and clarify our precedent. Because my colleagues have declined to do so, there are no more options at this court for diagnostic patents. My colleagues' refusal deflates the Amici's hopeful suggestion that our precedent leaves the eligibility of a diagnostic claim in front of the Federal Circuit "uncertain." It is no longer uncertain. Since *Mayo*, every diagnostic claim to come before this court has been held ineligible. While we believe that such claims should be eligible for patent protection, the majority of this court has definitively concluded that the Supreme Court prevents us from so holding. No

need to waste resources with additional en banc requests. Your only hope lies with the Supreme Court or Congress. I hope that they recognize the importance of these technologies, the benefits to society, and the market incentives for American business. And, oh yes, that the statute clearly permits the eligibility of such inventions and that no judicially-created exception should have such a vast embrace. It is neither a good idea, nor warranted by the statute. I dissent.

United States Court of Appeals for the Federal Circuit

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
Plaintiffs-Appellants

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, MAYO CLINIC,
Defendants-Appellees

2017-2508

Appeal from the United States District Court for the District of Massachusetts in No. 1:15-cv-40075-IT, Judge Indira Talwani.

NEWMAN, *Circuit Judge,* with whom WALLACH, *Circuit Judge*, joins, dissenting from denial of the petition for rehearing en banc.

The majority of the court has voted not to rehear this case en banc. I write again in dissent because of the importance of medical diagnosis and the critical role of the patent system in achieving new diagnostic methods. Diagnostic methods are costly in research and development, from scientific discovery through federal approval, and are of substantial public benefit—exemplified by Athena's

method of diagnosing *Myasthenia Gravis* in persons previously undiagnosable. The patent system provides the economic foundation for the cycle of experimental study, clinical evaluation and proof, and implementation in commerce. This foundation applies to diagnosis as well as to treatment.

The panel majority held that the new diagnostic method in U.S. Patent No. 7,267,820 ("the '820 patent") was not eligible for patenting under section 101 of the Patent Act. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019) (Newman, J., dissenting). The panel majority stated that "the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature," and therefore methods for determining previously unknown correlations for diagnostic purposes are not patent-eligible. *Id.* at 753 n.4.

The majority's position is a flawed interpretation of the Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012). The Court did not hold that methods of diagnosis are subject to unique patent-eligibility rules. We have mistakenly enlarged the Court's holding, in substance and in application. Rehearing en banc is warranted.

I summarize the reasons for concern:

I

The Supreme Court's Mayo decision did not convert diagnostic methods into laws of nature

Until Athena's invention of the diagnostic method described in the '820 patent, some 20% of patients suffering from *Myasthenia Gravis* were not capable of being diagnosed. The '820 patent describes and claims a multi-step method wherein for such patients the presence in bodily fluid of autoantibodies to a protein, muscle-specific tyrosine kinase (MuSK), is detected by "binding of a MuSK or

its epitope, together with a revealing label, to the autoantibodies in the serum or bodily fluid." '820 patent, col. 3, l. 66–col. 4, l. 2. The '820 patent explains that "[t]he present inventors surprisingly found that many of the 20% of MG patients which do not exhibit any autoantibodies to AChR [acetyl choline receptor] instead have IgG [immunoglobulin] antibodies directed against the extracellular N-terminal domains of MuSK." *Id.*, col. 1, ll. 54–57.

These antibodies and their reaction with the MuSK protein were not known, nor the use of this procedure to diagnose *Myasthenia Gravis*. The separate chemical steps of radioactive labelling, reaction of an antibody with a protein, separation of the reaction product, and analysis of radioactivity, are described in the specification as conducted by conventional methods. However, the panel majority held that this new diagnostic method is not patent-eligible, stating that "claims 7–9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law." *Athena*, 915 F.3d at 751. This statement is a misapplication of the patent statute, and a misperception of the Court's decision in *Mayo*.

At issue are patent claims 7–9, shown with claim 1 from which they depend:

> 1. A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).
>
> 7. A method according to claim 1, comprising
>
> contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid,

> immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
>
> monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
>
> wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to muscle specific tyrosine kinase (MuSK).
>
> 8. A method according to claim 7 wherein said label is a radioactive label.
>
> 9. A method according to claim 8 wherein said label is 125I [iodine isotope 125].

The reaction between the specified antibodies and the MuSK protein was not previously known, and the specified claim steps had not previously been performed, separately or in combination. This method of diagnosing *Myasthenia Gravis* and related disorders is conceded to be new and unobvious.

The '820 patent specification teaches that each claim step is conducted by conventional procedures, that is, procedures for creating a radioactively labelled compound, reacting an antibody with a protein, separating any antibody-protein complex, and monitoring the radioactivity of the product. The panel majority holds that since the separate steps are "conventional," they do not count in the section 101 analysis, leaving claims 7–9 with only the general "concept" of "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases like MG." *Athena*, 915 F.3d at 750. The panel majority concluded that "[t]he '820 patent thus describes the claimed invention principally as a discovery of a natural law, not as an

improvement in the underlying immunoassay technology." *Id.* at 751.

The Court in *Mayo* admonished against "too broadly preempt[ing] the use of a natural law." 566 U.S. at 72. Claims 7–9 claim a new multi-step method of diagnosis; it is incorrect to omit from the claims the steps by which the method is performed, leaving only the "concept" of the general purpose. En banc review is needed to provide consistent and correct application of statute and precedent to methods of medical diagnosis.

II

Statute and precedent require that the claimed invention is considered as a whole

The Court explained this principle in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007):

> [I]nventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418–19. The Court had explored this principle in *Diamond v. Diehr*, 450 U.S. 175 (1981):

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole.

Id. at 188. The Court stressed that:

> It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.

Id. The Court further explained that this rule applies to patent eligibility as it does to patentability:

> The "novelty" of any element or steps in a process, or even of the process itself, is of no relevance in

> determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

Id. at 188–89; *see also, e.g.*, *Parker v. Flook*, 437 U.S. 584, 594 (1978) ("[A] patent claim must be considered as a whole."); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344 (1961) ("[I]f anything is settled in the patent law, it is that the combination patent covers only the totality of the elements in the claim and that no element, separately viewed, is within the grant.").

This established rule does not evaporate when the subject matter is a diagnostic method. The *Mayo* Court did not effect such a change. The Court reiterated in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014), that "an invention is not rendered ineligible for patent simply because it involves an abstract concept" in some of its claim elements. There is no support in the Court's precedent for our abandonment of the invention-as-a-whole in determining eligibility under section 101.

The purpose of section 101 is to provide a broad statutory scope to inventive activity. *See Bilski v. Kappos*, 561 U.S. 593, 605 (2010) ("Section 101 is a dynamic provision designed to encompass new and unforeseen inventions." (internal quotation marks omitted)); *Diehr*, 450 U.S. at 187 ("[A]n *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."). In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the Court observed that "Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable," *id.* at 316, and that the legislative history of the 1952 Patent Act showed that "Congress intended statutory subject matter to 'include anything under the sun that is made by man,'" *id.* at 309 (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)). The *Mayo* Court cautioned that

> too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.

566 U.S. at 71.

The Federal Circuit has respected this long-standing principle in contexts other than for diagnostic methods. *See, e.g.*, *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299, 1313 (Fed. Cir. 2016) ("[C]ourts must be careful to avoid oversimplifying the claims by looking at them generally and failing to account for the specific requirements of the claims." (internal quotation marks omitted)). However, we have strayed in our rulings on diagnostic methods; our flawed analysis is summarized by the majority in *Athena*, 915 F.3d at 753 n.4 ("We have since confirmed that applying somewhat specific yet conventional techniques . . . to detect a newly discovered natural law does not confer eligibility under § 101.").

When viewed on correct law and precedent, Athena's diagnostic method meets the requirements of section 101. The appropriate analysis of patentability is under sections 102, 103, and 112; not section 101.

III

The Court in Mayo did not create a section 101 distinction between diagnostic methods and therapeutic methods

In *Mayo* the Court discussed the method at issue in that case, and concluded 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." 566 U.S. at 73. The Court did not hold that every diagnostic method ties up a natural law, and the *Athena* panel majority acknowledged that "we agree that claim 9 leaves open to the public other ways of

interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps." 915 F.3d at 752.

Athena's diagnostic method is not a law of nature; it is a novel man-made method of diagnosis of a neurological disorder. The Athena diagnostic method, a multi-step method performed by a combination of specific chemical and biological steps, was unknown in the prior art. The Court in *Mayo* did not exclude such methods from eligibility for patenting.

Following is an outline of this court's inconsistent rulings between diagnosis and treatment of disease:

A. Methods of diagnosis, held ineligible under section 101

1. *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 (Fed. Cir. 2014). The claimed invention is a method for screening for genes linked to inherited breast and ovarian cancer, by analyzing for certain mutations in the DNA. The court held the claims ineligible under section 101 as directed to a law of nature, and also held that identifying genetic mutations is an ineligible abstract idea.

2. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). The claimed invention is a method for detecting paternally-inherited fetal abnormalities by analyzing the blood or serum of a pregnant female. The court held the claims ineligible under section 101, while recognizing that "detecting cffDNA in maternal plasma or serum that before was discarded as waste material is a positive and valuable contribution to science." *Id.* at 1380.

3. *Genetic Technologies Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016). The claimed invention is a method for detecting a coding region of DNA based on its relationship to non-coding regions, by amplifying genomic DNA with a primer spanning a non-coding sequence in genetic

linkage to an allele to be detected. The court stated that "the patent claim focuses on a newly discovered fact about human biology," *id.* at 1376, and that this is a law of nature and is ineligible subject matter under section 101.

4. *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017). The claimed invention is a method for diagnosing risk of cardiovascular disease by analyzing for the enzyme myeloperoxidase ("MPO"). The court held that even though prior methods for detecting MPO were inferior, the discovery of how to directly analyze for MPO, and discovery of the relation to the risk of cardiovascular disease, although "groundbreaking, 'even such valuable contributions can fall short of statutory patentable subject matter.'" *Id.* at 1363 (quoting *Ariosa*, 788 F.3d at 1380).

5. *Roche Molecular Systems, Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018). The claimed invention is a method for detecting the pathogenic bacterium Mycobacterium tuberculosis ("MTB"), based on nucleotide content and a novel method of analysis. The court stated that the method is new, unobvious, and "both faster and more accurate than the traditional MTB detection methods," *id.* at 1366, but held that the method is ineligible under section 101.

6. *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 760 F. App'x 1013 (Fed. Cir. 2019). The claimed invention is the novel immunoassay to detect the correlation between blood MPO levels and cardiovascular disease. The court held that the claims are for a law of nature and ineligible under section 101.

In all of these diagnostic cases the claims were held ineligible under section 101, whether or not the method of diagnosis was new and unobvious, and independent of patentability under sections 102, 103, and 112.

B. Methods of treatment, held eligible under section 101

1. *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016). The claimed invention is a "method of producing a desired preparation of multi-cryopreserved hepatocytes [liver cells]." *Id.* at 1047. The court stated that "the natural ability of the subject matter to undergo the process does not make the claim 'directed to' that natural ability," *id.* at 1049 (emphasis omitted), and "[t]his type of constructive process, carried out by an artisan to achieve 'a new and useful end,' is precisely the type of claim that is eligible for patenting," *id.* at 1048 (quoting *Alice*, 573 U.S. at 217).

2. *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018). The claimed invention is a method of treating schizophrenia with the known drug iloperidone, where the dose is adjusted based on whether the patient is a "CYP2D6 poor metabolizer." *Id.* at 1121. The method uses genetic testing to determine CYP2D6 metabolism. The court held that this is "a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome," *id.* at 1136, and is eligible under section 101.

3. *Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019). The claimed invention is a method of increasing athletic performance by administering beta-alanine in larger quantities. The court held the method eligible under section 101, although the mechanism was a natural effect.

4. *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019). The claimed invention is a method of treating patients with oxymorphone, based on the discovery that patients with impaired kidney function need less oxymorphone for pain relief. The court stated that the method was patent-eligible, for "the claims

here are directed to a *treatment* method, not a detection method." *Id.* at 1356 (emphasis in original).

IV

The amici curiae advise on the consequences of our rulings[1]

The major biotech industry organizations advise that our court's application of *Mayo* "has caused great uncertainty to the industry, and . . . has called into doubt innumerable biotech patents." Biotechnology Innovation Organization (BIO) Br. at 3. BIO discusses the inconsistency of our section 101 rulings, and points out that "[t]he panel decision reflects a troubling divergence in this court's section 101 jurisprudence between software and biotech inventions," explaining that in software cases the threshold analysis focuses on whether the claims contain a technical improvement over the prior art, whereas this aspect is absent from our biotech analyses. *Id.* at 9.

The *amici* discuss the adverse effect of our section 101 rulings on advances in medical diagnosis. Seven Law Professors state that "diagnostic tests form[] the basis of 60%–70% of all medical treatment decisions," and "[d]iagnostic tests have immense benefits for patient care and greatly reduce associated costs, including decreasing hospitalization and avoiding unnecessary treatment." Profs. Br. at 11 (citing *The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care* (July 2005), *available at*

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[1] *Amicus curiae* briefs were filed by the Biotechnology Innovation Organization, Pharmaceutical Research and Manufacturers of America, Croplife International, Wisconsin Alumni Research Foundation, Seven Law Professors, and Freenome Holdings Inc. and Achillion Pharmaceuticals, Inc.

https://dx.advamed.org/sites/dx.advamed.org/files/resource/Lewin%20Value%20of%20Diagnostics%20Report.pdf).

The Law Professors state that "[t]he economics of the R&D and commercialization of innovative diagnostic tests reflect the core economic justification for the patent system: The marginal cost of making a diagnostic test is relatively low, but the *ex ante* R&D costs can be enormous," stating that the cost of commercializing a diagnostic test is between $50-$100 million. *Id.* at 11–12 (citing Diaceutics Group, *Mystery Solved! What is the Cost to Develop and Launch a Diagnostic?* (2013), *available at* https://www.diaceutics.com/?expert-insight=mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic). The Law Professors state that by "creat[ing] an unduly restrictive patent eligibility doctrine under § 101, the majority decision and many other court decisions send the wrong message to innovators that groundbreaking diagnostic tests born of the biotechnological arts in the modern biopharmaceutical industry are virtually per se unpatentable under § 101." *Id.* at 13.

Amici curiae Freenome Holdings and Achillion Pharmaceuticals suggest that our jurisprudence contravenes "promot[ing] the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8. These *amici* point to the judicial duty to construe section 101 to include both inventions and discoveries, and that discovery of a new diagnostic method is within the constitutional purpose.

I repeat that "the public interest is poorly served by adding disincentive to the development of new diagnostic methods. This is a severe criticism; and when presented by the entire industry, and stressed by thoughtful scholars, it warrants judicial attention." *Athena*, 915 F.3d at 762 (Newman, J., dissenting).

The need for en banc action

The judicial responsibility is to provide clear and consistent law in conformity with statute. Our holdings on medical diagnostics contravene the admonition that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." *Chakrabarty*, 447 U.S. at 308.

The legislative plan is for an incentive system that supports advances in useful technologies by enabling innovators to benefit economically. The patent statute requires that the new knowledge is disclosed to the public, where it adds to the body of knowledge and, in turn, may be studied and built upon. No benefit has been suggested by excluding medical diagnostic methods from the patent incentive system.

This case presents an opportunity for judicial review and judicial remedy. Although diagnostic methods are not the only area in which section 101 jurisprudence warrants attention, Federal Circuit precedent is ripe for reconsideration specific to diagnostic methods, to correct our application of the *Mayo* decision and to restore the necessary economic incentive. As summarized by Senators Chris Coons and Thom Tillis, co-chairs of the Senate Subcommittee that is conducting hearings on proposed remedial legislation, "courts have clouded the line to exclude critical medical advances like life-saving precision medicine and diagnostics," and "studies showed that investors familiar with the current lack of clarity invest less in critical research and development in areas like medical diagnostics." The Senators stated that "[e]ven some witnesses advocating against broad reform conceded that there are problems with the current system, particularly in the life sciences." *Report available at* https://www.law360.com/articles/1171672/what-coons-and-tillis-learned-at-patent-reform-hearings (June 21, 2019).

From my colleagues' denial of en banc review, I respectfully dissent.

United States Court of Appeals for the Federal Circuit

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., MAX-PLANCK-GESELLSCHAFT ZUR FORDERUNG DER WISSENSCHAFTEN E.V.,
Plaintiffs-Appellants

v.

MAYO COLLABORATIVE SERVICES, LLC, DBA MAYO MEDICAL LABORATORIES, MAYO CLINIC,
Defendants-Appellees

2017-2508

Appeal from the United States District Court for the District of Massachusetts in No. 1:15-cv-40075-IT, Judge Indira Talwani.

STOLL, *Circuit Judge,* with whom WALLACH, *Circuit Judge,* joins, dissenting from the denial of the petition for rehearing en banc.

In a series of cases since the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), we have established a bright-line rule of ineligibility for all diagnostic claims. *See, e.g., Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015) (rejecting a diagnostic claim because the "only subject matter new and useful as of the date of

the application was the discovery of the presence of cffDNA in maternal plasma or serum"). This rule as applied to the facts of this case dictated that the majority panel find the claimed invention ineligible. But, because this court's bright-line rule is based on an over-reaching and flawed test for eligibility, a test that undermines the constitutional rationale for having a patent system—promoting the progress of science and useful arts—the court should take this opportunity to correct its erroneous rule. So, while I stand by the panel decision in this case, I write separately to dissent from the denial of en banc rehearing because the question of the eligibility of diagnostic inventions is exactly the type of exceptionally important issue that warrants full consideration by this court.

Federal Rule of Appellate Procedure 35 directs us to order rehearing en banc when "the proceeding involves a question of exceptional importance." Fed. R. App. P. 35(a)(2). A question is of exceptional importance if it creates "important systemic consequences for the development of the law and the administration of justice." *Watson v. Geren*, 587 F.3d 156, 160 (2d Cir. 2009). As Judge Newman and Judge Moore aptly describe, a wholesale bar on patent eligibility for diagnostic claims has far-reaching and long-ranging implications for the development of life-saving diagnostic methods. The eligibility of life-saving inventions is not only one of the most important issues of patent law, but of human health. Thus, the importance of the issue here mandates that we consider it en banc.

Interpreting *Mayo*, our prior opinions seem to take for granted that the Supreme Court has foreclosed all avenues of patent protection for diagnostic claims. As Judge Moore points out, we have held every diagnostic claim in every case before us ineligible. Dissent Op. at 2 (Moore, J.). Our inflexible following of *Mayo* has created flawed decisions that are inconsistent with the precepts of *Mayo* and our patent system as a whole. The *Mayo* test was guided by broad-sweeping principles that are not applicable to every

individual diagnostic claim. For example, *Mayo* emphasizes that patent eligibility cannot apply to "processes that too broadly preempt the use of a natural law." 566 U.S. at 72. Certain diagnostic claims, such as the ones at issue in this case, are so narrowly tailored that preemption is not a reasonable concern.

Given the importance of this question, I would urge the en banc court to take the opportunity to entertain the thoughtful argument and fully developed record that such review would provide, and reconsider this critically important issue. As Congress's recent interest in § 101 legislation has demonstrated, there are a variety of stakeholders that consider this issue to be vitally important. En banc rehearing would not only permit us to have a more extensive view of the various considerations underlying *Mayo*, but it would also allow us to create judicial doctrine geared toward the practical application of *Mayo*'s principles. At the very least, en banc review would help the court develop an articulable standard for its § 101 jurisprudence moving forward.

In my view, by consistently bypassing en banc review of a critical issue that goes to the heart of this court's jurisdiction, we are abdicating our responsibility. For this reason, I respectfully dissent.

United States Court of Appeals for the Federal Circuit

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Appeal from the United States District Court for the District of Massachusetts in No. 1:15-cv-40075-IT, Judge Indira Talwani.

O'MALLEY, *Circuit Judge*, dissenting from the denial of the petition for rehearing en banc.

I agree with all aspects of Judge Moore's thoughtful dissent. Indeed, I agree with all my dissenting colleagues that our precedent applies the Supreme Court's holding in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) too broadly. I write separately, however, because I believe that confusion and disagreements over patent eligibility have been engendered by the

fact that the Supreme Court has ignored Congress's direction to the courts to apply 35 U.S.C. sections 101, *et seq* ("Patent Act") as written. Specifically, the Supreme Court has instructed federal courts to read into Section 101 an "inventive concept" requirement—a baffling standard that Congress removed when it amended the Patent Act in 1952. I encourage Congress to amend the Patent Act once more to clarify that it meant what it said in 1952.

I begin with some historical perspective. After World War II, federal courts were invalidating patents at breakneck speed. Lawrence Baum, *The Federal Courts and Patent Validity: An Analysis of the Record*, 56 J. Patent Office Soc'y 758, 760 tbl. 1 (1974) (showing that federal appellate courts, on average, invalidated patents at a rate of 77% between 1941–1945), 777 tbl. 5 (showing that the Supreme Court invalidated patents at a rate higher than 81% from 1921–1973, except during 1953–1964 when the Court did not issue any decisions on patent validity). As Justice Jackson wrote, it seemed the only valid patent was "one which [the Supreme Court] ha[d] not been able to get its hands on." *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting). This was due, in large part, to what became known as the "invention requirement"—itself "invented" by the Supreme Court rather than Congress or the Constitution. Applying this requirement meant asking whether a patent evidenced "invention."

Prominent jurists of that time remarked that the requirement was unworkable. Judge Learned Hand opined that, under this requirement, "'invention' became perhaps the most baffling concept in the whole catalogue of judicial efforts to provide postulates for indefinitely varying occasions." *Lyon v. Bausch & Lomb Optical Co.*, 224 F.2d 530, 536 (2d Cir. 1955). According to Judge Giles Rich, because inventiveness "is an unmeasurable quantity having different meanings for different persons," the invention requirement "left every judge practically scott-free to decide this

often controlling factor according to his personal philosophy of what inventions *should* be patented." Giles S. Rich, *The Vague Concept of Invention as Replaced by Sec. 103 of the 1952 Patent Act*, 46 J. Patent Office Soc'y 855, 865 (1964) (internal quotations and citations omitted). If the invention requirement and its criticisms sound familiar, that is because they are.

Congress attempted to address these criticisms by amending the Patent Act to replace the ill-defined and judicially-created invention requirement with the more workable anticipation and obviousness tests codified in Sections 102 and 103. Patent Act of 1952, Pub. L. No. 82-593, § 103, 66 Stat. 792, 798 (1952); *see, e.g.*, H.R. 4061, 80th Cong. (1947) (as introduced to the H. Comm. on the Judiciary, July 1, 1947) ("A BILL To establish a criterion of invention with respect to patent applications and issued patents[.]"); Nat'l Patent Planning Comm'n, The American Patent System, June 18, 1943, H.R. Doc. 78-239, at 10 ("One of the greatest technical weaknesses of the patent system is the lack of a definitive yardstick as to what is invention."); *id.* at 5 ("The most serious weakness in the present patent system is the lack of a uniform test or standard for determining whether the particular contribution of an inventor merits the award of the patent grant. . . . The difficulty in applying this statute arises out of the presence of the words 'invented' and 'discovered.' Novelty alone is not sufficient, nor is utility, nor is the final accomplishment. There must also be present some mysterious ingredient connoted in the term 'invented.'").

But although Congress so amended the Act decades ago, we continue to apply the invention requirement today under a new name—the "inventive concept" requirement. Early cases applying § 101 after the 1952 amendment, such as *Parker v. Flook*, 437 U.S. 584 (1978), drew heavily from cases decided under the "invention" requirement. *Compare Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (concluding that the "aggregation of

species" at issue "fell short of invention" because "[i]f there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end"), *with Flook*, 437 U.S. at 591 ("*Mackay Radio* and *Funk Bros.* point to the proper analysis for this case."). *Flook* therefore forged a two-part test, with respect to § 101, that is seemingly indistinguishable from the one that had been applied in many "invention" cases over twenty-five years earlier. First, *Flook* treated the natural law as part of "the prior art." *Flook*, 437 U.S. at 594. Second, *Flook* asked whether what remained—apart from the prior art, *i.e.* the natural law—constituted "invention." *Id.* ("Respondent's process is unpatentable under § 101, not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention."); *see also Diamond v. Diehr*, 450 U.S. 175, 204 (1981) ("Under this procedure, the algorithm is treated for § 101 purposes as though it were a familiar part of the prior art; the claim is then examined to determine whether it discloses 'some other inventive concept.'") (quoting *Flook*, 437 U.S. at 594)). Against this backdrop, the search for an inventive concept—now enshrined in the § 101 inquiry via *Mayo*—calls back to the invention requirement that Congress quite deliberately abrogated through the Patent Act of 1952.

In fact, the disagreement here centers on whether the additional limitations in the claims, either individually or as an ordered combination, satisfy the inventive concept requirement. *Compare* Lourie Op. at 4 ("Under Supreme Court precedent, I do not believe that specific yet purely conventional detection steps impart eligibility to a claim that otherwise only sets forth what the Court has held is a natural law." (internal quotations omitted)), *with* Moore Op. at 20 ("These [additional] steps are not set out at the 'high level of generality' that concerned the Court in *Mayo*,

and they specifically confine their reach to a specific application of the relationship between anti-MuSK antibodies and MG."). Had the Supreme Court not disregarded Congress's wishes for a second time, perhaps the outcome in this case would be different. *See* Lourie Op. at 2 ("If I could write on a clean slate, . . . I would not exclude uses or detection of natural laws."). Indeed, claims directed to uses of natural laws rather than the natural laws themselves would be eligible under § 101 as written. Because the Supreme Court judicially revived the invention requirement and continues to apply it despite express abrogation, I dissent to encourage Congress to clarify that there should be no such requirement read into § 101; to clarify that concepts of novelty and "invention" are to be assessed via application of other provisions of the Patent Act Congress designed for that purpose.