



Federal Bar Association

Northern District of Ohio Chapter

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Winter 2023

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5 – 4 – 3 – 2 – 1 ... just like that, 2022 is at an end.

Happy New Year to you all and welcome to 2023!

There is something very special about starting a new year. Here in Ohio, there is that crisp bite in the air and the purity of new-fallen snow. There are those quiet first days of the year, often spent with friends and family. And then – with just that brief time of quiet and respite to mark the occasion – off we all go, back to the bustle of our busy lives and careers.

I ask you now to go back in your minds to those first few moments and days of the new year. What did you hope 2023 would bring? Did you set any goals or make any plans?

Knowing that New Year's resolutions are notoriously easy to make and hard to keep, I thought it would be fun to give you my thoughts on how our chapter might help you to accomplish some of your resolutions this year.

Did you resolve to mentor others? On February 1st, our Mentoring and Law Student Committee hosted a happy hour to kick off our 2023 Mentoring Program. If you did not sign up to be a mentor this time around, keep an eye out for more opportunities to interact with our local law students, including our popular Summer Associate Reception at the House of Blues this summer!

Did you resolve to get out and meet new people? Every month, our Younger Lawyers Committee hosts a Roundtable event where a small group of younger lawyers can meet and engage with one of our local judges. In the spring, we will be hosting social events in both Toledo and Cleveland to welcome our many new(er) judges. And our members-only Summer Social is always a great opportunity to meet and reconnect with others in our legal community.

Did you resolve to learn a new skill? Plans are underway for a variety of interesting and informative seminars in the coming year. And don't worry, our popular Trial Academy is returning in the fall with another intensive hands-on introduction to litigation and trial skills.

Did you resolve to honor our servicemembers and veterans? If you did not attend our *Speaking Truth to Power* ethics seminar in December, featuring retired General Officers and Judge Advocates, do not fret. You can count on more valuable programs from our Veterans' Committee this year, including the return of our Wills for Vets legal assistance program.

Did you resolve to give back to your community? Our Civics Committee finished out 2022 with a bang, celebrating the birthday of the Bill of Rights at a local Cleveland elementary school. But they have bigger plans for the spring, with opportunities for members to get involved in bringing civics education to local high schoolers throughout this District.

Whatever your goals for 2023 may be, we are glad to have you as a part of our legal community, and we look forward to seeing what we all can accomplish together this year.



INTRODUCTION TO FEDERAL PRACTICE AND NEW LAWYER TRAINING PROGRAM

P.J. Sullivan*

On November 21, 2022, the FBA's Northern District of Ohio Chapter held an Introduction to Federal Practice seminar as well as a New Lawyer Training CLE for newly admitted lawyers. Following the Introduction to Federal Practice seminar, 55 new lawyers joined the Northern District of Ohio Bar. The Chapter would like to extend a special thank you to Chief Judge Patricia A. Gaughan for hosting the programs in her courtroom.

The Chapter would also like to thank our distinguished speakers for volunteering their time and sharing their insights:

- Introduction to Federal Practice:
 - Magistrate Judge Darrell A. Clay
 - Ms. Sandy Opacich, Clerk of Court
 - Ms. Michelle D. Sztul, Deputy-in-Charge
 - Ms. Sarah Nintcheff, Career Law Clerk to Chief Judge Gaughan
 - Ms. Ellen Siebensschuh, Career Law Clerk to Judge Pamela A. Barker
 - Mr. James Jones, Courtroom Technology Coordinator, Northern District of Ohio
- New Lawyer Training:
 - Ms. Cathleen Bolek, Principal, Bolek Besser Glesius
 - Mr. Matthew Besser, Principal, Bolek Besser Glesius
 - Ms. Dolores (Lola) Garcia, Partner, Ulmer & Berne LLP
 - Mr. Kevin Vogel, Judicial Attorney, Ohio Court of Appeals for the Eighth District

The Chapter would also like to thank Ms. Gudrun Swoboda, Administrative Assistant to the Clerk and Chief Deputy, and Ms. Jeanette Schinness, Administrator for the FBA-NDOH Chapter, for their assistance in coordinating and facilitating the event.



* P.J. Sullivan is an associate in the Cleveland office of Jones Day and a member of the Board of Directors of the Northern District of Ohio Chapter of the FBA.

FBA News**BILL OF RIGHTS BIRTHDAY PARTY**

In what has become a tradition for the FBA Northern District of Ohio Chapter, the Civics Committee of the FBA-NDOH visited the third grade class at Campus International School to celebrate the December 15th Birthday of the Bill of Rights. The organizers of the event were Matthew Gurbach and Warren McClurg, the Chapter's Civics Committee co-chairs, and the presenters were Judge Philip Calabrese of the U.S. District Court for the Northern District of Ohio, Judge Emily Hagan of the Cuyahoga County Court of Common Pleas, and Jim Satola, a Law Clerk to Senior Judge Donald Nugent of the U.S. District Court for the Northern District of Ohio.

The presenters gave a broad overview of the ten amendments that make up the Bill of Rights and answered lots of questions from a very active and engaged third-grade class ... ending, as always, with birthday cupcakes.



CIVIL STANDING ORDER UPDATES FOR THE NEW YEAR**Judge J. Philip Calabrese****U.S. District Court for the Northern District of Ohio**

At the beginning of 2023, I updated my Civil Standing Order (which is available on the Court's website at: <https://www.ohnd.uscourts.gov/content/judge-j-philip-calabrese>) to keep up with changes to my approach to managing civil cases and to try to head off problems I have encountered on the bench. Substantively, the thrust of the revisions aims to frontload the parties' investigation and conferring about the case, both to identify any issues that require the Court's involvement as soon as possible and to facilitate resolution, whatever form that takes. Additionally, the updated Standing Order is reordered to better track the progression of a case from filing to judgment and corrects a few typographical errors and the like. Beyond that, I want to call attention to three changes or clarifications in the amended Standing Order.

First, the Northern District recently amended Local Rule 3.13 to require disclosure of the identity and citizenship of the members of each LLC, partnership, or similar entity. Quite often, I have seen even sophisticated counsel overlook this requirement, which is necessary for determination of jurisdiction in a diversity case. The updated Standing Order goes beyond the amendment to Local Rule 3.13 by making clear that an entity's principal place of business must also be disclosed. (See Section 2.) The consequences for the Court and the parties of getting jurisdiction wrong are severe. This updated provision aims at avoiding those costs if at all possible.

Second, too often parties do not take deadlines, such as a discovery cut-off or amendment deadline, seriously. My practice is *not* to continue trial dates once scheduled, and the updated Standing Order extends that practice to pretrial deadlines as well. (See Section 5.H.) Constant adjustments to deadlines creates a tremendous amount of work behind the scenes, and that work should be focused on the important and meaningful rulings that cases require, not processing paperwork. They also lead the progress of cases to stall, resulting in greater costs and inefficiencies. We all know that life sometimes interferes. In those limited circumstances, good cause will often justify adjusting a deadline. But going forward, when parties commit to deadlines for dispositive motions, discovery cut-offs, and other significant pretrial events, they should not expect those dates to change absent a showing of good cause.

Third, I remain committed to providing opportunities for less-experienced lawyers to get time in court arguing motions or examining witnesses. That provision of my Standing Order remains unchanged. As amended, the Standing Order makes clear that this provision applies to all proceedings, including objections to a report and recommendation from a Magistrate Judge, including in a social security appeal. (See Section 19.A.) Providing opportunities for lawyers to examine their first witness or have their first or second argument in court have been among the more memorable and rewarding parts of serving on the bench. I strongly encourage lawyers and their clients to take advantage of these opportunities, which will often be in their interest.

Finally, if considering threatening sanctions against an opposing counsel or client, please think again. Such threats are rarely warranted or appropriate, considerably interfere with the resolution of a dispute, and consume inordinate judicial resources. However, if you persist in this approach, the updated Standing Order includes a reference to a recent opinion summarizing my view on how and when pursuing sanctions may be appropriate. (See Section 18.)

In the FBA's next newsletter, I will explain the thinking behind the changes to the updated Rule 26(f) Report to help me and the parties prepare for the initial case management conference.

CWRU STUDENT CHAPTER REPORT

The Case Western Reserve University student chapter of the Federal Bar Association is pleased to look back on a successful Fall of 2022. Membership more than doubled and many of the new members are 1L students who will help to carry the chapter forward in years to come.

We are particularly proud to have put together a successful and well-attended panel of CWRU alumni who have held federal clerkships. More than forty students attended the event, which introduced them to federal clerkships and demonstrated the value of the FBA in connecting students to the broader legal community.

The event was held at the law school on November 17th and was successful thanks to the three excellent speakers who took time out of their busy schedules to educate and inspire young law students.

James Satola, who has clerked for both Judge Donald C. Nugent and Judge John Manos, spoke eloquently about his transition to a clerkship directly out of law school. In particular, he discussed how the personal connections he developed in that experience altered the course of his professional development for the better.

Koko Etokebe, who had recently begun clerking for Magistrate Judge Jennifer Dowdell Armstrong, provided excellent pointers on finding and developing quality mentors in law school. Her story served as an excellent example of the importance of mentorship in obtaining clerkship positions with the federal judiciary.

Kyle Cutts, a former clerk for Judge Jay S. Bybee of the U.S. Court of Appeals for the Ninth Circuit and currently a Class Action and Appellate Partner at BakerHostetler, provided excellent insight when he discussed the way his clerkship informed his pro bono practice. After seeing a number of petitions as a clerk, Kyle increased his focus on post-conviction appeals in the following years.

The panel provided a diverse, thoughtful, and relatable array of insights and experiences. Their experiences as both Case students and federal clerks had an inspirational impact on all who attended.

The new board of the CWRU student chapter thanks all the speakers for their valuable participation and looks forward to organizing more events in the coming months. We would also like to take this opportunity to introduce ourselves:

Our Treasurer, Aanya Myrie-Silburn, is a 2L international law fellow and SBA senator. She spends her free time working with the Black Law Students Association, Mock Trial Team, and the Yemen Accountability Project.

Our Secretary, Kelsey Moore, decided to go to law school because she enjoys problem solving and wanted to sharpen her advocacy skills. Last summer she interned at the U.S. District Court for the Northern District of Ohio with the Honorable Christopher A. Boyko. She tutors first-year legal writing, and she is on Law Review and the Mock Trial Team. Outside of school, she enjoys hiking, biking, and making music.

Our Vice President, Michael O'Donnell, is a first-generation law student who has found a great community at CWRU law. He was excited to bring in panelists who could provide insight into how work in the federal courts can fit into a career plan. He looks forward to planning future events that benefit CWRU law students and strengthen the relationship between the school and the Greater Cleveland legal community.

FBA News

Our President, Ben Foote-Huth, is a third-year law student who has found his life's pursuit in the law. He is an Honors Fellow and Upper-Level Writing Tutor, an Articles Editor on Law Review, and regularly volunteers at the Northeast Ohio Worker Center's Wage Theft Clinic. He was an extern at the U.S. District Court for the Northern District of Ohio with the Honorable Benita Y. Pearson in 2021, and for the Office of the General Counsel at the MetroHealth System in 2022. His Note—*Biomarkers as Subject Matter: A Tailored Solution for Patent Ineligibility in Medical Diagnostics*—was selected for publication in Issue 1 of Volume 73 of the Case Western Reserve Law Review (an abridged version appears elsewhere in this issue). He is an avid fan of the Cleveland Cavaliers and enjoys running with friends in his free time.

Clerk's Corner**CLERK'S CORNER**

Sandy Opacich

Clerk of Court, U.S. District Court for the Northern District of Ohio

Happy New Year! Hoping that 2023 is off to a good start for everyone. Following is a brief update from the Ohio Northern District Court Clerk's Office.

Effective December 1, 2022, our Local Rules and forms were updated to reflect the following amendments to the Federal Rules of Civil and Criminal Procedure:

- **Civil Rule 7.1 Disclosure Statement**

The amendment requires a disclosure statement to be filed by a nongovernmental corporation that seeks to intervene. In a diversity action, a party or intervenor must file the disclosure statement and identify the citizenship of every individual or entity whose citizenship is attributed to that party or intervenor. A party, intervenor, or proposed intervenor must file the disclosure statement with its first appearance, pleading, petition, motion, response, or other request. The amendment also removes the requirement to file two copies of the disclosure statement.

- **Criminal Rule 16(a)(1)(G)(ii) and (b)(1)(C)(ii) Discovery and Inspection**

The amendment requires the Court to set a time for the government and defendant to disclose expert witnesses to the opposing party. The deadline set must be "sufficiently before trial to provide a fair opportunity" for each party to meet the other side's expert evidence.

Our Help Desk regularly receives inquiries from attorneys as to how to change their address in CM/ECF. Please note the following:

- Attorneys admitted to practice in the U.S. District Court for the Northern District of Ohio are required to submit a written notice of change of name, business address and/or email address to the Clerk upon a change in address pursuant to Local Civil Rule 83.5(i) and Local Criminal Rule 57.5(i).
- While written notice is required under Local Rules, in order to effectuate the change within CM/ECF, attorneys must **submit the changes through PACER**.
- You must [log in](#) with your upgraded PACER account to make changes:

Log in to [Manage My Account](#).

Click the Maintenance tab.

Click Update Address Information

Once the update is submitted and approved by the Court, you will be notified that the update has been accepted.

For more information on these topics and other best practices, please access our website:

<https://www.ohnd.uscourts.gov/attorney-best-practices>

As always, please call our Help Desk at 800-355-8498 anytime you have a question or would like assistance.

BIOMARKERS AS SUBJECT MATTER: A TAILORED SOLUTION FOR PATENT INELIGIBILITY IN MEDICAL DIAGNOSTICS

Benjamin Foote-Huth*

I. Biomarkers, Eligibility, and Medical Diagnostics

Central to medical diagnostics is the concept of biomarkers.¹ In the words of one researcher, “[T]he perfect sources of diagnostic information are the molecular contents of sweat, saliva, urine, and feces, naturally excreted every day and packed with information.”²

Estimates put the cost of developing and bringing to market a new biomarker-based diagnostic method at more than \$100 million.³ The risk and expense inherent in the process lead investors to seek patentable innovations.⁴ Unfortunately, the current legal landscape has led one judge on the Federal Circuit to describe biomarker-based diagnostic claims as “per se ineligible.”⁵

The Supreme Court has interpreted the language of section 101 of the Patent Act to implicitly exclude laws of nature, natural phenomena, and abstract ideas.⁶ These three judicial exceptions restrict the four otherwise broad categories of statutorily eligible subject matter: “[P]rocess, machine, manufacture, [and] composition of matter.”⁷ These exceptions were then dramatically expanded with the Court’s development of the *Mayo/Alice* test—described more thoroughly in the following section—which has resulted in the current problematic landscape.

Most experts agree that medical diagnostics ought to be patent eligible.⁸ However, the Supreme Court appears comfortable with the status quo, and proposals for legislative change are overbroad and have difficulty achieving consensus. This problem should be resolved with a specific legislative exemption from the current eligibility test.

* Articles Editor, Case Western Reserve Law Review, and president, Case Western Reserve University School of Law Student Chapter of the FBA. This is an abridged version of the author’s Note, which is forthcoming in issue 1 of Volume 73 of the Law Review and appears here with the permission of the Case Western Reserve Law Review.

¹ Lmar M. Babrak et al., *Traditional and Digital Biomarkers: Two Worlds Apart?*, 3 Digit. Biomarkers 92, 93 (2019).

² Jennie Dusheck, *Diagnose This: A Health-Care Revolution in the Making*, Stan. Med., <https://stanmed.stanford.edu/2016fall/the-future-of-health-care-diagnostics.html> (last visited Sept. 17, 2022).

³ Doug Dolginow, Katherine Tynan, Noel Doheny & Peter Keeling, *Mystery Solved! What is the Cost to Develop and Launch a Diagnostic?*, Diaceutics (Jan. 15, 2013), <https://www.diaceutics.com/articles/mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic>.

⁴ Henry G. Grabowski, Joseph A. DiMasi & Genia Long, The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation, 34 Health Affs. 302, 302 (2015).

⁵ *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, 927 F.3d 1333, 1352–54 (Fed. Cir. 2019) (Moore, J., dissenting from the denial of rehearing en banc) (collecting cases).

⁶ *Ariosa Diagnostics, Inc. v. Sequeunom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015).

⁷ *Id.* (quoting 35 U.S.C. § 101).

⁸ Jeffrey A. Lefstin, Peter S. Mennell & David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 Berkeley Tech. L.J. 551, 595 (2018).

II. The *Mayo/Alice* Test

The current test for patent eligibility originated with the Supreme Court's 2012 decision *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*⁹

Mayo involved a challenge to the validity of a patent containing a biomarker.¹⁰ The claims in *Mayo* described a specific range of metabolites that correlated with proper dosage of an administered drug. If the measurements were above this range, the patient was likely to suffer harmful side effects—if they fell below the range, the drug was likely to be ineffective.¹¹ Thus, the central inventive concept was the discovery of a correlation that existed naturally and independently from this formulation, but which were not previously available for utilization.

While the claims in *Mayo* are indeed a discovered process, they also centrally involve a law of nature: the naturally existent correlation between thiopurine metabolism and effective dosage. The Supreme Court held that the claims in *Mayo* amounted to a patent on this correlation in toto,¹² stating that the additional steps in the claimed patent failed to “add [anything] of significance to the natural laws themselves.”¹³

Mayo was joined two years later by *Alice Corp. v. CLS Bank International*,¹⁴ and together they inform the *Mayo/Alice* test for patent subject matter eligibility.¹⁵ The *Mayo/Alice* test instructs courts to look for a law of nature or abstract concept in a patent's claims.¹⁶ If these elements are found, then the court must determine whether anything else within the claims is novel and unconventional in such a way that the claims as a whole amount to more than the unpatentable abstract concept or law of nature.¹⁷

If the Supreme Court's goal was to narrow the gateway of patent eligibility with this test, then it worked. In the two years following *Alice*, the Federal Circuit invalidated patents challenged for eligibility at a rate of 91.9 percent.¹⁸ A study of medical diagnostic patents between 2007 and 2016 found an eligibility rejection rate of 15.9 percent before *Mayo* and 86.4 percent after.¹⁹

The Federal Circuit expressed unanimous concern over this state of affairs with its denial of en banc review in *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*.²⁰ This denial contained an unprecedented eight separate opinions that uniformly lamented the *Mayo/Alice* test's clear preclusion of patent eligibility in the case at hand as well as the patent eligibility problem in medical diagnostics at large.²¹

⁹ 566 U.S. 66 (2012).

¹⁰ See *id.* at 73–74.

¹¹ *Id.*

¹² *Id.* at 73.

¹³ *Id.* at 87.

¹⁴ 573 U.S. 208 (2014).

¹⁵ Thomas Damarico, *Subject Matter Eligibility Roundup in 2021*, Lexology (Mar. 3, 2022), <https://www.lexology.com/library/detail.aspx?g=167104c6-0bb3-4de8-9616-4e74905e45b4>.

¹⁶ Elizabeth Flanagan, Deanna Reichel & Jonathan Singer, *Section 101: Cert. Denied . . . Now What?*, Fish & Richardson (Apr. 3, 2020), <https://www.jdsupra.com/legalnews/section-101-cert-denied-now-what-68426/>.

¹⁷ *Id.*

¹⁸ Jasper L. Tran, *Two Years After Alice v. CLS Bank*, 98 J. Pat. & Trademark Off. Soc'y 354, 358 (2016).

¹⁹ Bernard Chao & Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 Patently-O Pat. L.J. 10, 12 (2016).

²⁰ 927 F.3d 1333 (Fed. Cir. 2019); Kevin Richards, Cong. Rsch. Serv., LSB10344, *Judges Urge Congress to Revise What Can Be Patented* 2–3 (2020).

²¹ Richards, *supra* note 20, at 4.

While several of the opinions in *Athena* called for help from Congress or clarification from the Supreme Court, Judge Dyk's concurrence propounded a more specific response. He noted a distinction between the claims in *Mayo*—which did not confine their application to a specific utility—with those in *Athena*, which laid out their application with high specificity and involved the discovery of an entirely novel biomarker.²² He wrote, “For there to be a patent eligible application of a natural law, there must be a ‘discover[y]’ . . . and the claims must recite a specific application of that ‘discovery’ with established utility.”²³ This practical application test has the support of other notable analysts.²⁴

III. The Practical Application Test

If preemption of “the basic tools of scientific . . . work” is the primary concern addressed by the natural law exception, then why not provide eligibility only to those claimed processes that stake out a sufficiently specific practical application?²⁵ This is the central concept of the practical application test.

This concept was acknowledged but rejected in *Mayo*.²⁶ The Court reasoned that a narrow natural law equates to a narrow value in application.²⁷ It is worth noting that patients with difficult-to-diagnose conditions might perceive a different level of value in any such discovery. In any event, broad elimination of the patent incentive has an impact beyond the scale of any one discovery. The accumulated loss of many diagnostic discoveries—though each may be narrow in scope—creates a compounding impact.

The Court also cited a danger in “interpreting patent statutes in ways that make patent eligibility ‘depend simply on the draftsman’s art.’”²⁸ This argument is specious; it is the law’s duty to guide drafters in a desired direction.²⁹ The Court need only analyze the language of the claims in any particular patent to understand whether they include a sufficiently specific practical application. The *Mayo/Alice* test already requires courts to look at the claimed steps in a process to determine whether those other than the natural law amount to more than “well-understood, routine, conventional activity previously engaged in by scientists who work in the field.”³⁰ Are courts and judges really more “institutionally well suited” to determine what constitutes standard practice in a niche scientific field than whether the language of particular claims stake out a confined application?³¹

By mid-2019, the Supreme Court denied more than 40 petitions for certiorari on the issue of section 101 eligibility. The Court remains comfortable denying eligibility³² to various innovative, lifesaving, diagnostic processes. If there is to be a change in patent eligibility for medical diagnostics, it will have to come from Congress.

IV. The Second Tillis-Coons Proposal

In May of 2019, following Senate hearings on an earlier proposal, a legislative draft to reform eligibility standards was released.

²² *Athena*, 927 F.3d at 1342–43 (Dyk, J., concurring in denial of rehearing en banc).

²³ *Id.* at 1341.

²⁴ See, e.g., *Patentable Subject Matter Reform: Hearing on The State Of Patent Eligibility in America Before the S. Subcomm. On Intell. Prop.*, 116th Cong. 2 (2019) (statement of Mark A. Lemley, Dir. of the Stanford University School of Law Program in Law, Science & Technology) [hereinafter Lemley Testimony]; David O. Taylor, *Amending Patent Eligibility*, 50 U.C. Davis L. Rev. 2149, 2206–07 (2017).

²⁵ *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 71 (2012) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

²⁶ *Id.* at 88–89.

²⁷ See *id.*

²⁸ *Id.* at 72 (quoting *Parker v. Flook*, 437 U.S. 584, 593 (1978)).

²⁹ See Taylor, *supra* note 24, at 2174.

³⁰ *Mayo*, 566 U.S. at 79.

³¹ *Id.* at 89.

³² Eileen McDermott, *Todd Dickinson: SCOTUS Has Denied 42 Section 101 Petitions Since Alice, So It’s Up to Congress*, IP Watchdog (June 4, 2019, 3:10 PM), <https://www.ipwatchdog.com/2019/06/04/todd-todd-dickinson-congress-must-act-because-scotus-has-denied-42-section-101-petitions-since-alice/id=109957/>.

³³ See, e.g., *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 576–80 (2013); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373–74 (Fed. Cir. 2015); *Roche Molecular Sys., Inc. v. Cepheid*, 905 F.3d 1363, 1365 (Fed. Cir. 2018).

This proposed amendment to the Patent Act became known as the Second Tillis-Coons Proposal.³⁴ Among other alterations, it explicitly forbids the application of implicit judicial exceptions such as those the Supreme Court previously read into the statute.³⁵ Unsurprisingly, this proposal was met with mixed reactions.³⁶ Those in the life sciences were pleased with the dramatic increase in eligibility the new language would supply.³⁷ Others—particularly those in the software industry—were understandably concerned with a potential increase in “unmeritorious patent litigation.”³⁸

Professor Mark Lemley of Stanford Law School acknowledged the negative impact of the *Mayo/Alice* test on medical diagnostics but praised *Alice* for alleviating a pandemic of “patent trolls” that plagued the software industry. Since the *Mayo/Alice* test made a broader array of patents subject to patent eligibility analysis—a matter of law—more ill-fated patents became resolvable on a motion to dismiss.³⁹ Statistical analyses demonstrate the benefit of the *Mayo/Alice* test in reducing the type of bad faith patent litigation associated with the term ‘patent trolls.’⁴⁰ Lemley argued any approach to protecting medical diagnostics should “focus narrowly on identified problems in the medical diagnostics business, rendering significant new medical discoveries patentable when they have a practical application.”⁴¹

This is the wisest approach to patent eligibility reform at this time. The plurality of stakeholders in the patent system makes it difficult to reach consensus, but the desire for patent eligibility for medical diagnostics has broad support.⁴² While the debate continues over other subject matter, an amendment should be made to restore eligibility to medical diagnostics.

V. A Tailored Amendment for Medical Diagnostics

A statutory amendment could add “biomarkers” to the four listed categories of subject matter in section 101. The term “biomarkers” refers explicitly to the types of correlations the Court has found to constitute natural laws. To apply the natural law exception to “biomarkers” outright following such an amendment would ban a whole category of subject matter that Congress explicitly made eligible.

The scope of this addition could be confined by defining “biomarkers” in 35 U.S.C. § 100. Such a definition could take the form of the following insertion:

The term “biomarker” means a correlation between a measurable substance in a human subject and the likelihood of a certain disease or disorder, utilized in a process with at least one technical step occurring separate from the human body, narrowly claimed through a practical application.

³⁴ See Press Release, Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>.

³⁵ Kevin J. Hickey, Cong. Rsch. Serv., R45918, Patent Eligible Subject Matter Reform in the 116th Congress 36 (2019) (citing Bruce M. Wexler, Yar R. Chaikovsky, Philip Ou, Alexandra Cho & Iman Kholdebarin, *Senate Hearing on “The State of Patent Eligibility in America”: Analysis of Viewpoints on Looming Section 101 Change*, Paul Hastings (June 25, 2019), <https://www.paulhastings.com/insights/client-alerts/senate-hearing-on-the-state-of-patent-eligibility-in-america-analysis-of-viewpoints-on-looming-section-101-change>).

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ See Mark A. Lemley & Samantha Zyontz, *Does Alice Target Patent Trolls?*, 18 J. Empirical Legal Stud. 47, 67, 89 (2021).

⁴⁰ See Lemley Testimony, *supra* note 24.

⁴² See *id.*

The intention of the language “narrowly claimed” is to avoid the implication that the Court must make judgments—such as determining the relative breadth of a natural law—for which it is not institutionally well suited. Instead, the claims of the patent are required to stake out a process beyond the natural law, through which it is applied to a specific disease or disorder. The language that requires a technical step separate from the human body is inspired by Article 53 of the European Patent Convention (“EPC”).⁴³ The EPC excludes medical diagnostics “practised on the human . . . body,” but allows them when they are performed through a process that occurs at least partially outside of the body.⁴⁴ This language prevents the possibility of supplying eligibility for physical structures or processes of the human body such as metabolic pathways or genetic alleles. Altogether, these changes to 35 U.S.C. §§ 100 and 101 would achieve the goal of returning subject matter eligibility to medical diagnostics while preserving the *Mayo/Alice* test’s application to those areas of subject matter—such as software patents—where it has demonstrated real utility.

⁴³ Convention on the Grant of European Patents art. 53, Nov. 29, 2000, <https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/ma1.html>.

⁴⁴ *Guidelines for Examination: Diagnostic Methods*, Eur. Pat. Off., https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_2_1_3.htm (Mar. 1, 2022).

MEMBERSHIP INFORMATION

Here's How to Renew your membership:

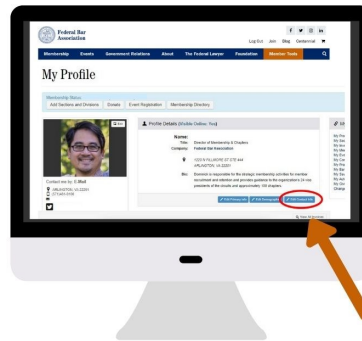
- 1) Log in to www.fedbar.org with your email and password.
- 2) Confirm your contact information in "My Profile."
- 3) Click **PAY NOW** next to your national membership invoice (located mid-page in My Profile). During checkout, please consider a donation to the [FBA Foundation](#).

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Annual Meeting and Convention Memphis, TN

Thursday, September 21– Saturday, September 23, 2023
The Peabody Memphis
149 Union Avenue, Memphis, TN 38103

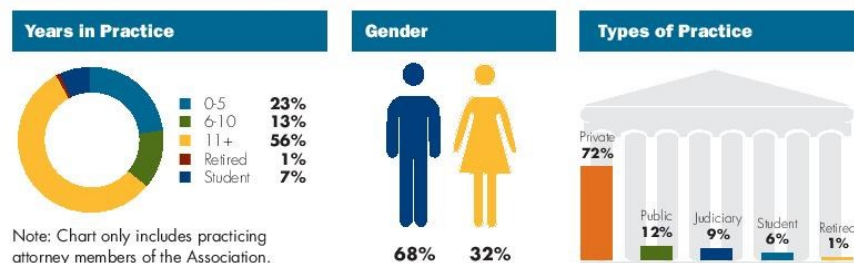
More information to be posted Spring 2023.

Federal Bar Association

Benefits of Membership

Joining the FBA entitles you to membership within the national organization as well as within your local FBA chapter. Members receive a host of special benefits designed to uphold the mission of the FBA and support each member's career within the federal legal system. Association activities and member benefits are organized into five primary categories.

You're in Good Company



Advocacy

The organization's headquarters are located outside of Washington, D.C., in Arlington, Va., giving it the proximity necessary to remain engaged on behalf of its members.

- government relations efforts as defined by the FBA Issues Agenda
- annual Capitol Hill Day
- monthly updates on recent government relations developments

Networking and Leadership

The FBA is large enough to have an impact on the federal legal profession, but small enough to provide opportunities for networking and leadership. The FBA is governed by a 15-member, elected, Board of Directors and numerous volunteer members.

- more than 95 chapters across all federal circuits
- 22 practice area sections
- five career divisions
- volunteer leadership opportunities within each chapter, section, and division

Education

The FBA offers more than 700 credit hours of continuing legal education (CLE) at both the national and local level throughout the year.

- national CLE conferences
- bimonthly CLE webinars
- local chapter-sponsored CLE events

Publications and Communication

As part of your membership, you will receive and have access to:

- FBA website (www.fedbar.org)
- The Federal Lawyer magazine (10x per year)
- bimonthly eNewsletter
- section, division, and chapter newsletters (printed)
- Judicial Profile Index (archived)

Legal Career Center

The Legal Career Center is an online resource for both employers looking to hire and job seekers looking for a position within the federal legal community. Employers have the option of posting jobs available to the FBA Legal Career Center only, or to the Legal Job Exchange Network that reaches thousands of potential candidates through the network of partner job boards. Job seekers have free access and can use the Legal Career Center to post resumes, search for jobs, and prepare for interviews, as they launch their careers.

Member-Only Advantages

- Member Plus affinity program
- online membership directory
- optional public directory listing
- online specialty items catalog
- discounted rates for CLE, networking events, publications, and other services

Become a Sustaining Member

Support

Sixty dollars of every sustaining membership is used to support educational programs and publications of the FBA.

Save

Sustaining members save five percent on national event registrations and publications orders, and are recognized annually in *The Federal Lawyer* and at FBA events.

Sustaining Members also receive one free CLE webinar per year—a \$99 value!



Federal Bar Association

Make your mark within the federal legal community.

Sign up for membership today at www.fedbar.org/join.

Contact the FBA at (571) 481-9100 or membership@fedbar.org for more information.

FBA-NDOH Calendar of Events:**February 15, 2023 FBA-NDOH Board Meeting****March 15, 2023 FBA-NDOH Board Meeting****April 19, 2023 FBA-NDOH Board Meeting*****We add events to our calendar often so please check our website for upcoming events that may not be listed here.*****Federal Bar Association**

Northern District of Ohio Chapter

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**Federal Bar Association****STATEMENT OF THE FEDERAL BAR ASSOCIATION BOARD OF DIRECTORS ON JUDICIAL INDEPENDENCE**

Judicial independence, free of external pressure or political intimidation, lies at the foundation of our constitutional democracy. An independent judiciary needs to remain free of undue influence from the legislative and executive branches and to remain beholden only to the maintenance of the rule of law and the protection of individual rights and personal liberties. We affirm the right to challenge a judge's ruling for reasons based in fact, law or policy. However, when robust criticism of the federal judiciary crosses into personal attacks or intimidation, it threatens to undermine public confidence in the fairness of our courts, the constitutional checks and balances underlying our government and the preservation of liberty.

The Federal Bar Association is comprised of over 19,000 public and private sector lawyers practicing in our federal courts, hailing from all fifty states and the U.S. Territories. The Federal Bar Association is a non-partisan professional organization created to promote the sound administration of justice and integrity, quality and independence of the judiciary.

INTER ALIA is the official publication of the Northern District of Ohio of the Federal Bar Association.

If you are a FBA member and are interested in submitting content for our next publication please contact Stephen H. Jett, Prof. Jonathan Entin, James Walsh Jr. or Benjamin Reese no later than April 15, 2023

Next publication is scheduled for Spring 2023

FBA-NDOH Officers**President-**

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SOLACE

Support of Lawyers/Legal Personnel - All Concern Encouraged

Our Chapter supports the FBA's SOLACE program, which provides a way for the FBA legal community to reach out in small, but meaningful and compassionate ways, to FBA members and those related to them in the legal community who experience a death, or some catastrophic event, illness, sickness, injury, or other personal crisis. For more information, please follow this link:

<http://www.fedbar.org/Outreach/SOLACE.aspx>