September 24, 2024

The Honorable Dick Durbin
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Durbin and Ranking Member Graham:

In light of the Committee's upcoming markup of S. 2140, the Patent Eligibility Restoration Act (PERA), on September 26, 2024, we write to underscore the repeated calls for legislative reform that have come from numerous judges of the Court of Appeals for the Federal Circuit, the appellate court with jurisdiction over appeals of patent-related controversies from trial-level forums.[1]

We are both former judges of this court who were troubled by this area of patent law during our tenure.[2] Since then, we have publicly pressed the urgent need for reform,[3] especially given the types of meritorious inventions this area of law is rendering ineligible. This includes, for example, inventions allowing for the detection of certain medical conditions for the first time, or with dramatically improved techniques. It even includes relatively straightforward mechanical inventions that have always been considered within the realm of patentability, but which now must be viewed as "abstract" and therefore ineligible. It also includes vast areas of computer-related inventions.

It is especially noteworthy that so many sitting judges have called for patent eligibility reform in published judicial opinions.[4] In 2019, this sentiment was expressed by all 12 active judges when they declined to rehear a case where the panel had invalidated, under 35 U.S.C. § 101, a patent for method of diagnosing a rare cause of certain neurological diseases,

[1] This jurisdiction includes appeals from district court patent cases, exclusion order cases based on patent infringement at the International Trade Court, the Patent Trial and Appeal Board post grant proceedings, and denials of patent applications by the U.S. Patent and Trademark Office. 28 U.S.C. § 1295.

[2] Judge Michel served as a judge on the Federal Circuit from 1988-2004 and its chief judge from 2004-2010. Judge O'Malley served as a judge on the Federal Circuit from 2010-2022 and as a judge for the Northern District of Ohio from 1994-2010.

[3] This includes our work as Board Members for C4IP. See also Paul Michel & Kathleen O'Malley, *Congress Needs to Clean Up the Supreme Court's Mess on Patents*, THE HILL (March 13, 2024), https://thehill.com/opinion/4530270-congress-needs-to-clean-up-the-supreme-courts-mess-on-patents/.

[4] This includes one of the authors of this letter before she left the bench, Judge O'Malley.

allowing for earlier diagnosis and treatment.[5] As Chief Judge Moore wrote, "There is very little about which all twelve of us are unanimous, especially when it comes to § 101. We were unanimous in our unprecedented plea for guidance."[6]

But expressions of concern and calls for reform started earlier and have continued afterward. For example:[7]

- ***"I believe the law needs clarification by higher authority, perhaps by Congress***, to work its way out of what so many in the innovation field consider are § 101 problems. Individual cases, whether heard by this court or the Supreme Court, are imperfect vehicles for enunciating broad principles because they are limited to the facts presented. Section 101 issues certainly require attention beyond the power of this court."[8]
- "The court's rulings on patent eligibility have become so diverse and unpredictable as to have a serious effect on the innovation incentive in all fields of technology. The victim is not only this inventor of this now-copied improvement in driveshafts for automotive vehicles; ***the victims are the national interest in an innovative industrial economy, and the public interest in the fruits of technological advance***. . . . I write to emphasize the far-reaching consequences of the court's flawed Section 101 jurisprudence."[9]
- "[T]here is no particular incentive for the Supreme Court to immerse itself again in this intellectual morass. The Court, unlike this court, is not called upon daily to address the consequences of an incoherent doctrine that has taken on a life of its own. It will take a special effort by the judges and the patent bar to gain the Court's attention. Failing that,

[5] Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333 (Fed. Cir. 2019) (denying petition for rehearing en banc) (separate opinions included calls to the Supreme Court, Congress, or both, from Chief Judge Moore, and Judges Newman, Lourie, Dyk, Prost, O'Malley, Reyna, Wallach, Taranto, Chen, Hughes, and Stoll). *See also id.* at 1353-54 (describing the invention) (Moore, C.J., O'Malley, Wallach, Stoll, J., dissenting from the denial of rehearing en banc) ("One of every five patients with the autoimmune disease experienced symptoms but did not produce the type of auto-antibodies previously associated with the disease, and thus were unable to be diagnosed and properly treated at an early stage. The claimed diagnostic method in *Athena* solved that problem through a specific, narrowly tailored diagnostic process but was nonetheless held ineligible.").

[6] Am. Axle & Mfg. v. Neapco Holdings LLC, 977 F.3d 1379, 1382 (Fed. Cir. 2020) (concurring in denial of petition to stay mandate); *see also id.* ("As the nation's lone patent court, we are at a loss as to how to uniformly apply § 101. All 12 active judges of this court urged the Supreme Court to grant certiorari in *Athena* to provide us with guidance . . . . [A]s we acknowledged in our decisions in *Athena*, that holding was at heart a reticent application of *Mayo* to similar claims.").

[7] Emphasis added in the following quotations.

[8] Berkheimer v. HP Inc., 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring from denial of rehearing en banc); Aatrix Software, Inc. v. Green Shades Software, Inc., 890 F.3d 1354, 1360 (Fed. Cir. 2018) (Lourie, J., and Newman, J., concurring from denial of rehearing en banc).

[9] Am. Axle & Mfg. v. Neapco Holdings LLC, 966 F.3d 1347, 1357 (Fed. Cir. 2020) (Newman, J., Moore, C.J., O'Malley, Reyna, Stoll, J., dissenting in the denial of rehearing en banc).

a legislative fix is a possibility, though waiting for that may be the ultimate test of patience."[10]

- "Since *Mayo*, every diagnostic claim to come before this court has been held ineligible. . . . ***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."[11]
- "In the current state of Section 101 jurisprudence, inconsistency and unpredictability of adjudication have destabilized technologic development in important fields of commerce. ***Although today's Section 101 uncertainties have arisen primarily in the biological and computer-implemented technologies, all fields are affected***."[12]

Notwithstanding these entreaties, the Supreme Court has declined every petition for review that was filed after the last of its recent four decisions, issued in 2014.[13] By implication, the onus now falls squarely on Congress to act.

Taking action now is critical — doing nothing puts the United States's technological leadership at risk. Our commercial competitors in Europe and Asia face no eligibility restrictions, putting U.S. universities, research entities, small businesses, inventors, and other entities at a serious disadvantage.[14] U.S. leadership in advanced technologies is also threatened, often in favor of our principal strategic rival, China, which likewise has no such patent eligibility restrictions.[15] Nor do our economic competitor nations countries suffer the uncertainty over eligibility that plagues the U.S. patent system.

[10] Interval Licensing LLC v. AOL, Inc., 896 F.3d 1335, 1355 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part); *see also id*. ("We are left with a process for finding abstract ideas that involves two redundant steps and culminates with a search for a concept—inventiveness—that some 65 years or so ago was determined by Congress to be too elusive to be fruitful. Is it any wonder that the results of this process are less than satisfactory?").

[11] *Athena*, 927 F.3d at 1363 (Fed. Cir. 2019) (Moore, C.J., O'Malley, J., Wallach, J., Stoll, J.) (dissenting from denial of rehearing en banc).

[12] Yu v. Apple Inc., 1 F.4th 1040, 1049 (Fed. Cir. 2021) (Newman, J., dissenting).

[13] Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).

[14] See Kevin Madigan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/; Kevin Madigan & Adam Mossoff, *Turning Gold to Lead: How Patent Eligibility Doctrine is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939 (2017).

[15] See Preetika Rana, *Your Cancer Drugs May Soon Be Discovered in China*, WALL STREET JOURNAL (Apr. 11, 2017), https://www.wsj.com/articles/china-emerges-as-powerhouse-for-biotech-drugs-1491816607; Jackie Snow, *China's AI Startups Scored More Funding Than America's Last Year*, MIT TECHNOLOGY REVIEW (2018), https://www.technologyreview.com/2018/02/14/145616/chinas-ai-startups-scored-more-funding-than-americas-last-year/; *see also* Elizabeth Chien-Hale, *A New Era for Software Patents in China*, LAW360 (May 25, 2017), https://www.law360.com/articles/924934/a-new-era-for-software-patents-in-china.

No wonder, then, that U.S. venture capital funding is increasingly flowing away from research-intensive technology toward less risky domestic markets, such as entertainment and hospitality, and away from domestic technology investments toward foreign nations, including China.[16]

We have been heartened to see the diligent work the Senate Judiciary Committee has already done on this issue, with its numerous hearings and the introduction of the bipartisan, bicameral Patent Eligibility Restoration Act of 2023. This markup is the next critical juncture — long awaited by inventors, investors, business leaders, university technology transfer heads, CEOs of hospitals, laboratories, research institutions, engineering firms, and patent practitioners, among many others. We firmly believe that the analytical process set forth in PERA provides a workable, justiciable framework, unlike the current two-part test established under *Bilski, Myriad, Mayo*, and *Alice*. PERA also corrects the excesses of the current jurisprudence that are undermining the patent system's incentive system in critical areas of the innovation economy. Its passage should put the United States back on track to remain the world leader in innovation.

Thank you for your leadership in bringing PERA before the Committee, and we hope the bill will be reported favorably. We would be happy to provide any further assistance the Committee might need.

Sincerely,

Judge Paul Michel, Board Member, Former Judge of the U.S. Court of Appeals for the Federal Circuit (1988-2010)

Judge Kathleen O'Malley, Board Member, Former Judge of the U.S. Court of Appeals for the Federal Circuit (2010-2022)

cc:

Sen. Alex Padilla, Member, Senate Committee on the Judiciary
Sen. Amy Klobuchar, Member, Senate Committee on the Judiciary
Sen. Chris Coons, Member, Senate Committee on the Judiciary
Sen. Chuck Grassley, Member, Senate Committee on the Judiciary
Sen. Cory Booker, Member, Senate Committee on the Judiciary

[16] *See, e.g.*, David Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019 (2020); *The State of Patent Eligibility in America: Part III: Hearing Before the S. Subcomm. on Intellectual Property of the S. Comm. of the Judiciary*, 116th Cong. (2019) (written testimony of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) ("Financial supporters of new products put significant weight on intellectual property rights, including patents, when issuing support. Those financial supporters are following federal court cases like ours, and weighing whether a patent is likely to withstand a court challenge. The absence of that financial backing can make it nearly impossible to bring products to market.").

Sen. John Cornyn, Member, Senate Committee on the Judiciary
Sen. John Kennedy, Member, Senate Committee on the Judiciary
Sen. Jon Ossoff, Member, Senate Committee on the Judiciary
Sen. Josh Hawley, Member, Senate Committee on the Judiciary
Sen. Laphonza Butler, Member, Senate Committee on the Judiciary
Sen. Marsha Blackburn, Member, Senate Committee on the Judiciary
Sen. Mazie Hirono, Member, Senate Committee on the Judiciary
Sen. Mike Lee, Member, Senate Committee on the Judiciary
Sen. Peter Welch, Member, Senate Committee on the Judiciary
Sen. Richard Blumenthal, Member, Senate Committee on the Judiciary
Sen. Sheldon Whitehouse, Member, Senate Committee on the Judiciary
Sen. Ted Cruz, Member, Senate Committee on the Judiciary
Sen. Thom Tillis, Member, Senate Committee on the Judiciary
Sen. Tom Cotton, Member, Senate Committee on the Judiciary