



The Medical Device Manufacturers Association (MDMA) and the Alliance of U.S. Startups and Inventors for Jobs (USIJ) write to express our strong support for the Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL Act), the Patent Eligibility Restoration Act (PERA), and the Inventor Diversity for Economic Advancement Act (IDEA Act) and we urge the Senate Judiciary Committee to pass all three bills at the September 19, 2024 markup and promote their passage in the full Senate.

Our organizations collectively represent over 300 startups, venture investors, research organizations and innovative companies working in fields including medical devices, mobile technologies, clean energy, cybersecurity and biotechnology.

We commend the work done by the Subcommittee on Intellectual Property to conduct substantive and constructive legislative hearings on these critical pieces of legislation that will support and promote innovation and economic growth in the U.S. The PREVAIL Act and PERA will both make critical improvements to the U.S. patent system by restoring balance to the process of considering patent validity, and by providing clarity to the question of patent eligibility. In addition, the IDEA Act will better harness the potential of all Americans to pursue opportunities in STEM fields and promote patent activity by underrepresented groups.

The PREVAIL Act addresses several shortcomings in the American Invents Act (AIA), the comprehensive revision to the Title 35 of the U.S. Code enacted into law in 2011. Since the enactment of the AIA we have seen large incumbent companies leverage the post-issuance challenge procedures to the validity of previously issued patents, the Inter Partes Reviews and Post Grant Reviews set forth in 35 U.S.C. §§ 315 *et seq.* and 325 *et seq.*, respectively, to render the patent system largely unavailable to innovative and disruptive inventors, startups, small companies and their investors, all of whom require stable, predictable and reliable patents to justify the risks inherent in investing time and resources in new technologies and new products.

There are several provisions of the PREVAIL Act that we strongly support, including: (i) the imposition of a standing requirement to determine with certainty the real parties in interest that challenge valid U.S. patents; (ii) limiting abuse of the joinder provisions that currently allow time-barred challengers to avoid the bar by joining some other petition; (iii) limiting the ability of defendants to complicate litigation by maintaining parallel challenges to the validity of the same patent in both the IPR process and district court litigation involving the same parties; (iv) refusals to entertain petitions that rely on prior art the PTO has previously considered barring “exceptional circumstances;” (v) raising the legal standard for invalidating an issued patent by requiring clear and convincing evidence of invalidity instead of a preponderance of the evidence as is currently

the case; (vi) prohibiting further challenges following a final decision by the PTAB or a district court judge that a patent is not invalid, thus making better use of the concepts of *res judicata* and collateral estoppel to achieve finality, and (vii) addressing the issues raised by serial and parallel petitions and proceedings.

In addition to serious challenges at PTAB for American inventors, entrepreneurs and investors, all of the active judges on the U.S. Court of Appeals for the Federal Circuit have cited their own confusion regarding U.S. law on patent eligibility, and former USPTO Directors have said the state of patent eligibility is in “disarray” and it is leading to “deep uncertainty.” PERA would address this fundamental challenge by eliminating all prior judicial exceptions to eligibility and replacing them with a clearly articulated and limited set of exclusions. Under PERA, U.S. law would draw clear lines regarding what is not patent eligible, this includes: pure mathematical formulas and mental processes, unmodified genes in the human body and unmodified natural material existing in nature. PERA also excludes substantially economic, financial, business, social, cultural, or artistic processes, even when followed by language like “do it on a computer,” as long as such processes can be practically performed without the use of a machine.

The net effect of PERA is to strike a decade of judicial tinkering that has needlessly turned the question of patent eligibility into a confusing mess and harmed the U.S. versus our economic competitors. While the U.S. has spent a decade holding back innovations in areas such as fintech, diagnostic solutions and medical devices while trying to figure out whether they are “abstract” or not, our competitors are moving forward and protecting these inventions. China in particular has leapt well ahead of the U.S. by extending patent protection for a broader range of inventions by focusing on the concrete features of the invention while we spin our wheels arguing about whether something is “abstract” or not.

The IDEA Act directs the USPTO to voluntarily collect demographic data from patent applicants and publish reports on the findings, while making the data publicly accessible for independent research. The goal is to address disparities faced by underrepresented groups in securing patent rights, ensuring that all Americans have an equal opportunity to innovate. We support the IDEA Act because it promotes transparency and inclusivity, helping to identify and address barriers that prevent equitable access to the patent system, ultimately fostering a more diverse and innovative economy.

Our members rely heavily on stable and reliable patent protection as a foundational prerequisite for making long term investments of capital and time commitments to high-risk businesses developing new technologies.

We continue to advocate strongly for the passage of the PREVAIL Act, PERA and the IDEA Act so that our members and others can confidently innovate, invest, and compete on a level playing field, ensuring that the U.S. remains a global leader in technological advancements and economic growth.

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