



Andrei Iancu, Co-Chair
David Kappos, Co-Chair
Judge Paul Michel (Ret.), Board Member
Judge Kathleen O'Malley (Ret.), Board Member
Frank Cullen, Executive Director

June 10, 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,

On behalf of the Council for Innovation Promotion, we are writing to express our strong support for the PREVAIL Act and to address several myths being advanced by the bill's misinformed critics.

The Council for Innovation Promotion is a bipartisan coalition chaired by two former directors of the U.S. Patent and Trademark Office. Our board includes two retired judges from the Court of Appeals for the Federal Circuit, former Chief Judge Paul Michel and Judge Kathleen O'Malley. We aim to promote U.S. innovation and global economic competitiveness by championing strong intellectual property (IP) rights. Robust patents and other IP protections enable, rather than impede, access to life-saving medicines and other socially beneficial inventions.

The PREVAIL Act would make several much-needed changes to the Patent Trial and Appeal Board's procedures for adjudicating patent validity disputes. For example, the legislation would eliminate the duplication that occurs when cases that have already been taken up by a district court are brought before the Patent Trial and Appeal Board -- or vice versa. Allowing challenges to be pursued in multiple venues at once puts enormous burdens on innovators, particularly small businesses, trying to defend their IP rights.¹ This duplication of effort also burdens the judicial system with needless repetition.

Unfortunately, the PREVAIL Act has been met with fierce criticism from those who do not understand basic realities of the U.S. patent system.²

¹ https://c4ip.org/why-c4ip-supports-the-prevail-act/#new_tab

² <https://www.congress.gov/bill/118th-congress/senate-bill/2220/text?s=1&r=6>

For instance, according to the bill's opponents, the PREVAIL Act would make it easier for life sciences firms to file "weak" and duplicative patents for brand-name medicines in order to make it harder for generic competitors to enter the market.

But this makes little sense. The PREVAIL Act allows competitors to challenge the patent, at their choice, in Court or at the Patent Office. If the patent is indeed invalid, that challenge should succeed to remove the patent. The PREVAIL Act does prevent the same party from challenging the same patent twice, but why would a competitor need multiple challenges to invalidate a "weak" patent?

Further, for the United States Patent and Trademark Office to grant a patent in the first place, an invention must meet strict requirements for novelty, usefulness, and non-obviousness. This is a difficult standard to meet; around half of patent applications are ultimately denied.³ Filing patents for life sciences innovations can be even riskier. Drugs and medical devices have the lowest patent approval rate of any category of technology, with the majority of applications rejected, according to a recent analysis in the *Yale Journal of Law & Technology*.⁴ And if the Patent Office makes a mistake despite this rigorous examination, then either the district court or the PTAB can correct that mistake. There is no need to have multiple tribunals looking at the same question. Indeed, if the district court or the PTAB themselves make a mistake, the Court of Appeals can also correct it.

Second, opponents of the PREVAIL Act have repeatedly implied that the bill would somehow raise drug prices. But this claim is unfounded as well. The reality is that pharmaceutical patents represent a vanishingly small share of all PTAB challenges.

Indeed, almost all the petitions to come before the Patent Trial and Appeal Board between 2012 and 2021 came from Big Tech -- specifically from major firms like Apple, Google, and Facebook.⁵ By contrast, only 4% of PTAB petitions filed from September 2012 through March 2023 related to small-molecule drug patents, while a mere 2% of petitions concerned patents for biologics.⁶ It is dishonest to act as if the PTAB is a forum that primarily adjudicates pharmaceutical patent disputes. The reality is that the PREVAIL Act would have no impact on drug prices.

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<https://patentlawyer.io/understanding-the-patent-rejection-rate/#:~:text=According%20to%20the%20U.S.%20Patent.amendments%20during%20the%20examination%20process.>

⁴ https://yiolt.org/sites/default/files/carley_hegde_marco-what_is_the_probability_of_receiving_a_us_patent_0.pdf, p. 212

⁵ <https://innovationalliance.net/from-the-alliance/infographic-big-tech-companies-are-biggest-users-of-ptab-2012-2022/>

⁶ https://www.uspto.gov/sites/default/files/documents/orange_book_biologics_study_update_thru_march_2023_.pdf?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term= p. 3

Third, some critics insist that the PREVAIL Act would somehow favor large corporations at the expense of smaller inventors. In fact, the opposite is true. For years, a number of large, established corporations have abused patent validity proceedings by actively litigating the same patent in two venues at once.⁷ This strategy of parallel litigation only serves to run up huge legal bills and stretch the resources of small inventors with limited resources. The PREVAIL Act would crack down on this unfair practice by prohibiting petitioners from filing redundant patent challenges in two venues simultaneously.

Abuse of PTAB proceedings disproportionately harms small companies, most of whom cannot afford to fight multi-front, multi-million-dollar legal battles against the world's most powerful corporations. In practice, many small companies have no choice but to forgo enforcing their patent rights or settle for artificially depressed royalties, which effectively enables large firms to "efficiently infringe" on their competitors' IP with impunity. Among other reforms, the PREVAIL Act would restore balance to this system by making it harder for large firms to weaponize the system against smaller rivals with multiple, duplicative attacks on the same patent.

We at the Council for Innovation Promotion believe that a strong, reliable patent system is a basic precondition for a prosperous, innovative economy. The PREVAIL Act would reform the PTAB to help make the current IP system fairer and more balanced for all participants, including both patent holders and those seeking to incorporate patented inventions into their own products.

Thank you for your attention to this pressing issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Cullen', is positioned below the word 'Sincerely,'.

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)

cc:

Sen. Alex Padilla, Member, Senate Committee on the Judiciary
Sen. Amy Klobuchar, Member, Senate Committee on the Judiciary

⁷ <https://c4ip.org/why-c4ip-supports-the-prevail-act/>

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
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