September 6, 2023

The Honorable Xavier Becerra
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

The Council for Innovation Promotion believes that if our nation truly aims to drive innovation and boost our economic competitiveness, we need to promote and protect strong intellectual property rights here at home. For too long, the interests of predictable and enforceable patent rights have been sacrificed in efforts to resolve public policy challenges and commercial differences wholly unrelated to patent law. It is for this reason we read with profound concern a recent letter from advocacy groups urging you to oppose ongoing efforts to promote efficiency, predictability, and fairness in the patent system.

In their August 8th letter, Public Citizen and other advocacy groups take advantage of the political climate surrounding drug pricing to advance the extreme agenda of a handful of giant corporations. The letter is deeply misleading, and it is disappointing that groups supposedly acting in the public's interest are advocating policies that would ultimately harm American citizens by depriving them of future life-saving innovations. First, the letter's authors present a false choice between access to life-saving medicines and robust patent rights. These two policy priorities are not mutually exclusive. In fact, they're mutually reinforcing and dependent on one another.

It costs upwards of $3 billion to develop a single new drug, accounting for the cost of failures. The process can take more than a decade, and just 12% of drug candidates entering clinical development are ultimately approved by the FDA.

Innovators cannot make such large, risky investments without secure intellectual property rights. Patents provide innovators a period of market exclusivity during which they can recoup outlays on research and development and earn a return. After patents expire -- generally just 10 to 12 years after a drug enters the market -- generic competition drives down prices considerably.

The letter writers list drugs that would supposedly be made cheaper by weakening patents. But they fail to mention that those medicines would not exist in the first place without strong, enforceable patent rights.

Second, the authors assume that drug patents account for a substantial portion of disputes brought before the Patent Trial and Appeal Board.

This is untrue. Life-science cases represent only a tiny share of patents challenged before the PTAB. From September 2012 through March 2023, just 4% of PTAB petitions challenged small-molecule drug patents, and just 2% challenged patents for biologic drugs. Small-molecule patents make up a *declining* share of patents challenged in recent years, contrary to the narrative that weak or invalid drug patents are a growing problem.

Similarly, the authors' insinuation that drug patents are especially likely to be invalid is false. The PTAB can only institute trials for petitions that are reasonably likely to succeed. The institution rate for drug patents is substantially lower than the average rate across all industries, according to USPTO data indicating that drug patents are less likely to be invalid than other categories of patents.

Third, the authors falsely suggest that proposed reforms, including codifying the PTAB practice of denying trials for patents that have already undergone substantial litigation in federal courts "could shield a plethora of invalid patents from review." This current practice is known as the *Fintiv* rule. Despite the authors' claims, there's no evidence that *Fintiv* denials are a significant factor in the drug patent ecosystem. The PTAB invoked the *Fintiv* rule to deny drug patent challenges only four times from March 2020 through October 2021.

Fourth, the letter advances the false notion that reforming the PTAB would hamper innovation and disproportionately hurt small inventors. In fact, the opposite is true. Large, established firms frequently use PTAB proceedings to challenge smaller competitors' patents, using their enormous wealth to run up costs for these start-ups. Nearly all of the top 20 PTAB petitioners from 2012 to 2022 were Big Tech companies. Apple alone filed 904 petitions, followed by Samsung with 898. These companies alone dwarf the 1,268 total petitions filed during the same fiscal years against all bio-pharma patents.

Moreover, over the past decade, industry giants have repeatedly weaponized PTAB proceedings -- or the threat of them -- against small inventors without the means to defend themselves. Shortcomings in the PTAB process and existing law make this abuse an easy and straightforward strategy.

For instance, large firms or groups of firms -- including those without legal standing -- can currently bring multiple PTAB proceedings against one patent holder. Similarly, corporations can file multiple PTAB challenges against the same patent -- even when the complaints could have been combined into one petition -- subjecting the patent holder to maximum cost and administrative burden.

These and other abusive practices make PTAB reforms essential. Bipartisan legislation like the PREVAIL Act, co-sponsored by Senator Chris Coons (D-Del) and Thom Tillis (R-N.C.), would bring fairness and transparency to PTAB proceedings while restoring confidence in the value of patents for good faith innovators.

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Lastly, we are disturbed by the letter's suggestion that the U.S. Patent and Trademark Office does not "conduct rigorous scrutiny of every patent application, arriving at accurate conclusions of patentability, and thus ensuring patents are granted solely to genuinely novel and useful inventions."

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In short, the claim that the PREVAIL Act threatens Americans' access to affordable prescription drugs is contradicted by the facts.

We appreciate the opportunity to provide input. Please don't hesitate to contact us with any questions.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion

September 6, 2023

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, DC 20001

Dear Administrator Brooks-LaSure,

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Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion

September 6, 2023

The Honorable Robert Califf
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

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Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion

September 6, 2023

The Honorable Kathi Vidal
U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

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Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion

September 7, 2023

The Honorable Gina Raimondo
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, D.C. 20230

Dear Secretary Raimondo,

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