Congress of the United States
Washington, DC 20510

September 16, 2021

Mr. Andrew Hirshfeld
Performing the Functions and Duties of Director
U.S. Patent and Trademark Office
600 Dulany St.
Alexandria, VA 22314

Dear Mr. Hirshfeld:

Americans urgently need relief from the soaring cost of prescription drugs. Millions of Americans rely on prescription drugs to provide relief from chronic ailments and help them cope with life-threatening medical conditions. While the patent system plays a critical role in incentivizing innovation in the prescription drug market, aspects of the system have also allowed drug companies to engage in anti-competitive practices that drive up the cost of drugs and keep competitors from entering the market. We are concerned that one important tool to help thwart these abuses of the patent system – the inter partes review (IPR) process – has been weakened by administrative changes that are not grounded in statute. Specifically, the U.S. Patent and Trademark Office (USPTO) has, in recent years, begun frequently denying petitions for IPR for reasons not based on the merits, which has made it more difficult to curtail anti-competitive practices by prescription drug companies.

The rise of discretionary denials of IPRs for non-merits-based reasons robs generic drug and biosimilar companies of a key venue to challenge the validity of brand manufacturer patents that are primarily designed to extend the manufacturer's monopoly on a drug. Far too often, brand manufacturers create "patent thickets," comprising dozens of questionable, back-to-back patents, and engage in "product hopping," by which they block generic competition by leveraging follow-on patents on minor and insignificant changes to the original product to artificially extend the term of their patent protection. Patent thickets and product hopping do not represent innovation, but instead serve primarily to shut out competition from other manufacturers and allow for the kind of monopoly pricing that drives up healthcare costs and blocks access for American consumers who depend upon these drugs. Once these patents are issued, it is expensive for consumers or competitors like generic drug companies to challenge their validity, further cementing the hold brand manufacturers have over the market.

The IPR process, as designed by Congress, is intended to provide a lower-cost and faster alternative to litigation. The process serves as a means to challenge the validity of patents that should not have been issued, including those used for product hopping. Since the decision in *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020, designated as precedential May 5, 2020) – which established as precedent certain agency policies on discretionary denials – there has been a disturbing rise in discretionary denials of IPR petitions. By some accounts, following *Fintiv*, 19 percent of IPR petitions were denied in 2020 for reasons that had nothing to do with the merits, compared to only 5 percent in 2016. A record number of petitions were denied without a merits-based decision during the first quarter of 2021. Without a sufficiently strong IPR system to serve as a check against questionable patents, brand manufacturers will continue to wield patent thickets that are nearly impossible to challenge and

engage in product hopping, further burdening the American people with needlessly high drug prices. Indeed, weakening the IPR system encourages abuse of the patent system generally and has a grave impact on numerous industries beyond drugs or healthcare, such as the semiconductor, telecommunications, and automotive industries.

The purpose of the patent system is to create incentives that promote the progress of science and the useful arts for the benefit of the public, not to indefinitely extend monopolies that quash competition and harm American consumers. As long as discretionary denials of IPRs under *Fintiv* continue, the public will lose one of the few tools available that can help address the root cause of high prescription drug prices and drive competition in the marketplace. We encourage you to reassert the USPTO's role in reviewing drug manufacturers' anticompetitive practices, including by ending the policies that have caused the spike in discretionary denials of patent challenges.

Sincerely,

Patrick Leahy
United States Senator

Darrell Issa
Member of Congress

Ron Wyden
United States Senator

Anna G. Eshoo
Member of Congress

Debbie Stabenow
United States Senator

Tom Tiffany
Member of Congress

Elizabeth Warren
United States Senator

Pramila Jayapal
Member of Congress

Richard Blumenthal
United States Senator

Victoria Spartz
Member of Congress

Bobby L. Rush
Member of Congress