The Honorable Thom Tillis
United States Senate
113 Dirksen Senate Office Building
Washington, DC, 20510

The Honorable Christopher Coons
United States Senate
218 Russell Senate Office Building
Washington, DC, 20510

Dear Senator Coons and Senator Tillis:

The undersigned write this letter to express serious concerns about S. 2082, the STRONGER Patents Act of 2019. This bill will undermine vital reforms that Congress overwhelmingly passed in the America Invents Act (AIA) after years of careful bipartisan consideration, debate and negotiation. We thank you for holding a hearing on this important matter,[1] and urge the Subcommittee to consider strengthening – not weakening – the *inter partes* review (IPR) process.

IPR is a critical check on the United States Patent and Trademark Office (USPTO). Examiners at the USPTO are given just nineteen hours, on average, to review patents.[2] This necessarily results in the granting of invalid patents. Worse, if the patent system is not carefully calibrated, then bad actors are actually encouraged to bombard the patent office with patent applications.

Abuse of the patent system can be costly for Americans, especially vulnerable patient populations who must take certain medications. For example, AbbVie filed over 240 patent applications for a single drug, Humira, and received over 110 granted patents.[3] This patent thicket allowed AbbVie to keep biosimilars out of the market until 2023, when other countries have had access to more affordable competing versions since 2018. Cutting through these thickets will allow generic drug competition sooner, saving patients and the healthcare system billions of dollars.[4] By making it harder for us to cut through Big Pharma's patent thickets, the STRONGER Patents Act will keep prescription drug prices high at a time when Congress desperately needs to take actions to cut drug prices for American patients and taxpayers.

The AIA created a fair and successful program that allows the public to help identify patents that may have been granted in error and provides a process by which the USPTO can take a second look at those patents. This IPR system is faster and less expensive than the courts. It also uses subject matter experts within the USPTO to maintain patent quality by reviewing the work of their patent examiners. This decreases the burden on the judicial system and market participants and provides benefits that are passed down to consumers.

[1] https://www.judiciary.senate.gov/meetings/innovation-in-america-how-congress-can-make-our-patent-system-stronger
[2] https://www.nber.org/papers/w20337.pdf#page=9
[3] http://www.i-mak.org/wp-content/uploads/2018/09/i-mak.humira.report.final_.0917.pdf
[4] http://www.affordableprescriptiondrugs.org/app/uploads/2019/07/brand_gamesmanship_july_2019.pdf

This streamlined system has been a tremendous success. In its first five years, IPR saved approximately $2.31 billion in deadweight loss by reducing the cost of determining patent validity.[5] IPR has also been used to invalidate patents that were weaponized against small businesses and governments. IPR was used by the non-profit Electronic Frontier Foundation to successfully challenge a patent that claimed to cover all forms of podcasting.[6] The owner of this patent, Personal Audio LLC, was asserting this patent against individuals and small businesses for creating podcasts. IPR allowed them to continue their business without harassment. IPR was also successfully used by the Los Angeles Metropolitan Transportation Authority to challenge a patent that claimed to own the toll technology used by LA Metro.[7] The USPTO found the patent to be invalid. A generic company recently invalidated a number of patents covering Lantus®—an insulin product that nets Sanofi-Aventis $15 million per day and has been the subject of numerous price hikes that far exceed inflation.[8] IPR is a proven tool in saving the public money from the improper use of invalid patents to engage in rent seeking or anticompetitive behavior.

The STRONGER Patents Act would weaken this beneficial program in several ways. First, the bill will only allow a single petitioner to seek review of a patent claim. This means that once the Patent Trial and Appeal Board (PTAB) has instituted a review of a patent, no other party can ever ask for another review no matter the circumstances of the first review. This creates an avenue for bad actors to subvert the system through collusive petitioning: where a friendly party files a weak initial petition intended to fail so that it immunizes the patent from future challenges.

Second, the bill has several provisions that make the filing of an IPR petition extremely unattractive to the public. The bill adopts a higher standard of proof used by courts out of deference to the competence of the USPTO. The USPTO's PTAB, as subject matter specialists, do not have a need to defer to their agency's own competence. The bill defines real party in interest broadly so that stockholders and crowdfunders might be included.

Third, the bill overturns the Supreme Court decision in *eBay v. MercExchange*[9] by requiring an automatic injunction upon the finding of a court of infringement of a patent. This case was considered instrumental in reeling in patent trolls,[10] and has had an important procompetitive impact for many areas, including the healthcare industry, where injunctions have been limited for several cases involving important medical devices and diagnostic tests.[11]

Finally, the bill creates a standing requirement that deprives the public of the ability to participate in the IPR process. The assertion of invalid patents can create a tremendous

[5] https://www.patentprogress.org/2017/09/14/inter-partes-review-saves-over-2-billion/
[6] https://www.eff.org/cases/eff-v-personal-audio-llc
[7] https://norcalrecord.com/stories/512490356-federal-judge-dismisses-patent-infringement-claim-against-la-metro-as-moot
[8] https://www.statnews.com/2018/12/07/patent-abuse-rising-drug-prices-lantus/.
[9] eBay Inc. v. Mercexchange, LLC, 547 U.S. 388 (2006).
[10] https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?&article=1311&context=jipl
[11] https://www.keionline.org/us-injunction-medical

cost to the public, and it is important that this right to participate is preserved. Under the bill, the Electronic Frontier Foundation would not have had standing to challenge a patent that had a broad negative impact on podcasting. The standing requirement also prevents companies from testing patents before going to market and incurring development expenses. This actually creates an incentive for patent holders to wait until products are developed and profitable before asserting their rights to gain maximum leverage. The mere threat of patent trolling has a measurable effect on the ability of startups to attract investors. A study of anti-troll laws enacted in 32 U.S. states found that states with such measures had an increase in venture capital funding within the state. Such legislation was found to increase high-tech startup employment by 4.4%, and allowed startups with stronger patents to better leverage them to increase funding.[12]

IPR is far too important to patients and small and medium sized businesses to diminish it in this manner. If anything, IPR should be strengthened. Currently, IPR only allows the challenge the patents that are not new or non-obvious under Sections 102 and 103 of the Patent Act. This leaves many grounds for invalidity to the courts and prevents the USPTO from reviewing patents more fully in the IPR process. We recommend that the Subcommittee consider ways to make IPR more robust.

Sincerely,

Association for Accessible Medicines
Blue Cross Blue Shield Association
Campaign for Sustainable Rx Pricing
Citizen Outreach
Coalition Against Patent Abuse
Coalition to Protect Patient Choice
Consumer Action
Electronic Frontier Foundation
End AIDS Now
Health GAP
Innovation Defense Foundation
Knowledge Ecology International
Lincoln Network
Marina Tsaplina, Patient Advocate for #insulin4all
Niskanen Center
Patients for Affordable Drugs
Public Citizen
R Street Institute
SEIU
Social Security Works
Society for Patient Centered Orthopedics
Treatment Action Group (TAG)
U.S. PIRG

[12] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2887104&download=yes

CC: Senate Judiciary Committee Members
CC: Chairman Lindsey Graham and Ranking Member Dianne Feinstein