The Honorable Dick Durbin
Chair, Senate Judiciary Committee
711 Hart Senate Building
Washington, D.C. 20510

The Honorable Chuck Grassley
Ranking, Senate Judiciary Committee
135 Hart Senate Building
Washington, D.C. 20510

The Honorable Patrick Leahy
Chair, IP Subcommittee
437 Russell Senate Building
Washington, D.C. 20510

The Honorable Thom Tillis
Ranking, IP Subcommittee
113 Dirksen Senate Building
Washington, D.C. 20510

Dear Sens. Durbin, Grassley, Leahy, and Tillis:

We are groups who work in a variety of ways on issues of health, science, technology, and access to knowledge and medicines who support the intentions of the Restoring America Invents Act ("RAIA") to strengthen *inter partes review* ("IPR") and increase patent quality. Patent quality is extremely important in the drug industry, where patent thickets[1] have been found to thwart the availability of lower-cost generic and biosimilar medicines.[2] We support the goals expressed in the current draft of RAIA and urge the committee to advance a bill that restores the intentions of the America Invents Act to create a faster and lower cost path to challenge patents that are preventing competition on vital medications.

Generic and biosimilar medications are essential to increase the competition needed to bring about price savings to make our health care system financially sustainable. Competition saved consumers $338 billion in 2020 alone.[3] Generics represent 90% of prescriptions filled, yet account for only 18.1% of drug spending. Unfortunately, anticompetitive abuses of the patent system are preventing some of this competition - especially in the biosimilars industry.

Restoring a strong *inter partes review* ("IPR") process, the goal of RAIA, will improve access to a less expensive and swifter process to challenge low quality drug patents resulting in improved access to lower cost medications. Challenging patents in court is extremely expensive and time consuming. Litigation costs for challenging drug patents range from $900,000 to $5,000,000, depending on the amount of money at risk, and take years to conclude.[4] IPRs are significantly less expensive, costing an average of $400,000 through appeal,[5] and are required by statute to take only 18 months to reach a final decision. This makes IPRs more attractive, and, for example, it has been successfully used by the generic company Mylan to invalidate a device patent blocking competition for Sanofi's insulin drug Lantus.[6]

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[1] Patent thicketing is a strategy where a drug company files a large number of patent applications later in a drug's life in the hopes that blocking patents will issue and generic and biosimilar competition will be delayed.
[2] Silverman, Ed, "Patent thickets are thwarting U.S. availability of lower-cost biosimilar medicines, study finds", *STAT News*, 18 Jan. 2022, https://www.statnews.com/pharmalot/2022/01/18/patent-biosimilar-abbvie-biologic/.
[3] https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[4] https://www.ipwatchdog.com/wp-content/uploads/2021/08/AIPLA-Report-of-the-Economic-Survey-Relevant-Excerpts.pdf
[5] *Id.*
[6] https://www.prnewswire.com/news-releases/mylan-invalidates-sanofis-lantus-solostar-device-patents-in-ipr-proceedings-301067927.html

Vigilant challenges of low-quality drug patents will only make our patent system more effective to its purpose by preventing low-quality patents from blocking competition while high-quality patents are allowed to stand. This is important as drug companies are increasingly turning to follow-on patents, applied for after the drug is on the market, to block competition. For example, a House Oversight investigation found that AbbVie was pursuing these later filed patents as part of a strategy to thwart generic and biosimilar entry after predicting biosimilar entry for Humira starting in 2017.[7] Competition still hasn't occurred, although biosimilars are expected in 2023. This strategy is being copied for other drugs and by other companies. A study of patent infringement lawsuits against generic manufacturers found that patent thickets are successfully blocking competition, and most involved patents unrelated to the active drug ingredient (42% for manufacturing processes, 35% for methods of use, and 24% for formulations).[8]

The prevalence of invalid patents has been well-documented, and a strong IPR system offers an efficient process to cull those from the system. One study found that approximately 27% of all patents would be found at least partially invalid if challenged.[9] Another study found that 46% of patents challenged for validity are ultimately found invalid.[10] This patent quality problem provides a pathway for some companies to use the patent system to pursue anti-generic and biosimilar strategies.

We support the goals of RAIA to provide a swifter, less expensive way to challenge the validity of patents, which should result in greater drug price competition. The American public is united in its call for solutions to high drug prices, and RAIA is a common-sense and bipartisan bill that will lower drug prices.

Signed,

Coalition Against Patent Abuse
Prescription Justice
Right to Health Action
Doctors for America
Institute for Liberty
U.S. PIRG (Public Interest Research Group)
Health Care Voices
Public Citizen
Patients for Affordable Drugs
T1 International
Social Security Works
Office of the Health Care Advocate, Vermont Legal Aid
Knowledge Ecology International
The Society for Patient Centered Orthopedics
Niskanen Center

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[7] https://oversight.house.gov/news/press-releases/chairwoman-maloney-releases-staff-report-and-new-documents-showing-abusive-drug

[8] https://www.nature.com/articles/s41587-021-01170-5.epdf

[9] Miller, Shawn Patrick, Where's the Innovation? An Analysis of the Quantity and Qualities of Anticipated and Obvious Patents (February 10, 2012). Available at SSRN: https://ssrn.com/abstract=2029263

[10] Allison, John R. and Lemley, Mark A., Empirical Evidence on the Validity of Litigated Patents (July 1, 1998). American Intellectual Property Law Association (AIPLA) Quarterly Journal, Vol. 26, p. 185, 1998, Available at SSRN: https://ssrn.com/abstract=118149