May 7, 2024

Senator Richard Durbin
Chairman, Committee on the Judiciary
711 Hart Senate Office Building
Washington, DC 20510

Dear Chariman Durbin,

As organizations dedicated to serving the public interest, we express our strong support for the inter partes review proceedings established by Congress in the America Invents Act of 2011. We are opposed to legislative proposals that threaten to impair the accessibility and efficiency of these proceedings because such proposals ensure wrongly granted patents continue driving drug prices to unjustifiable heights. We are also concerned about the specific threat posed by S.2220—the Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL).[1]

History of Inter Partes Review Proceedings

Inter partes review (IPR) proceedings are central to the proper administration of the patent system. These proceedings enable any member of the public to ask a panel of technical and legal experts—administrative patent judges at the Patent Trial and Appeal Board (PTAB)—to evaluate whether a patent was erroneously issued and is therefore invalid. If the PTAB decides the patent is invalid, the patent is cancelled, and can no longer prevent competition and its beneficial effects.

Congress created IPR proceedings for three key reasons: (1) the U.S. Patent and Trademark Office (USPTO) gets so many patent applications that errors are inevitable; (2) these errors lead to the issuance of invalid patents that cause significant harm to the American public patients, researchers, and consumers; and (3) the only other system for challenging invalid patents—federal court—is financially and legally out of reach for many people, especially those who are most vulnerable to litigation costs and price hikes.

Given these circumstances, Congress wisely saw and acted upon the need for more accessible and efficient mechanisms for challenging wrongly granted patents and mitigating their harmful effects.

Evidence of Post-IPR Drug Price Reductions

The mechanisms that Congress created are vitally important to the pharmaceutical sector, where patents often serve as formidable barriers to research, competition, and access to medicine. By facilitating the cancellation of wrongly granted patents, IPRs facilitate the removal of these barriers when they are unjust, thus opening the door to research and competition that improve the quality and affordability of medical care.

[1] https://www.coons.senate.gov/download/prevail-act-bill-text.

Empirical evidence confirms that IPR proceedings that lead to the cancellation of invalid patents lead to more competition and lower prices for prescription drugs. One study identifies specific IPRs that led to steep and swift reductions in drug prices, including the following examples:[2]

- 97% decrease in the price of prasugrel, a treatment for cardiovascular disease;
- 80% to 98% drop in the price of abiraterone acetate, a prostate cancer treatment;
- 75% reduction in the price of glatiramer acetate, a treatment for multiple sclerosis;
- 75% declines in the prices of rivastigmine patches, used to treat dementia; and
- 50% reduction in the price of buprenorphine, a treatment for opioid addiction.

Another recent study further validates IPR's effectiveness as a mechanism for correcting erroneously granted patents on biologic drugs, and thus facilitating the entry of more affordable biosimilars.[3] Evidence also demonstrates the price-insulating effect of restricting access to IPR proceedings: for example, following the PTAB's refusal to review patents on an injectable schizophrenia treatment, the price of a single dose remains alarmingly high at over $2,000.[4]

PREVAIL's Threat to the IPR System

While many aspects of PREVAIL are concerning, two categories of changes would be especially detrimental to the IPR system's effectiveness in reducing drug prices.

First, PREVAIL would prohibit many individuals and groups who can currently ask the PTAB to review patents from doing so. This prohibition would have the biggest effect on people who are already excluded from filing suits in federal court because they lack legal standing, such as medical patients, consumers, and researchers. Under PREVAIL, these groups and individuals would have no way to challenge wrongly granted patents that stand in the way of potentially fruitful research or more affordable generic and biosimilar alternatives.

Second, PREVAIL would prevent PTAB judges from canceling many wrongly granted patents that they can cancel now by substantially increasing evidentiary requirements. While current law allows PTAB judges to cancel patents based on a "preponderance" (or predominant weight) of evidence, PREVAIL would prohibit them from doing so unless the evidence rises to the higher "clear and convincing" standard. Practically speaking, this would prevent PTAB judges from making decisions based on their objective assessments of the evidence, and force them to put a heavy thumb on the scale in favor of patent owners.

---

[2] Duan, Charles, *On the Appeal of Drug Patent Challenges*, 2 AM. U. L. REV. 1177, 1203–04 (2023), available at: https://ssrn.com/abstract=4406404 or http://dx.doi.org/10.2139/ssrn.4406404.

[3] Van de Wiele, V.L., Kesselheim, A.S. & Tu, S.S. *Biologic patent challenges under the America Invents Act*, Nature Biotechnology 42, 374–377 (2024), https://doi.org/10.1038/s41587-024-02156-9.

[4] Decision Denying Institution of *Inter Partes* Review, *Mylan Labs.* v. *Janssen Pharmaceutica NV*, IPR2020-00440, Paper 17 (P.T.A.B. Sept. 16, 2020), https://s3-us-west-1.amazonaws.com/ptab-filings%2FIPR2020-00440%2F17; Drug Patent Watch, *Drug Price Trends for Invega Sustenna*, https://www.drugpatentwatch.com/p/drug-price/drugname/index.php?query=INVEGA+SUSTENNA (last visited Apr. 24, 2024).

Conclusion

Given the body of empirical evidence demonstrating the IPR system's impact on drug prices, it is perhaps unsurprising that pharmaceutical companies are pushing for changes that would dismantle it, as PREVAIL would. These changes may benefit big pharmaceutical companies, but they will hurt patients and payers by ensuring that wrongly granted patents keep driving drug prices to excessive and unjustifiable heights.

We respectfully implore you to protect the current IPR system from proposals that would curtail the public's capacity to challenge and the PTAB's capacity to cancel wrongly granted patents.

Sincerely,

ACA Consumer Advocacy

American Economic Liberties Project

Beta Cell Action

Citizen Action/Illinois

Families USA

I-MAK

Interfaith Center on Corporate Responsibility

NETWORK Lobby for Catholic Social Justice

New York StateWide Senior Action Council

Patients for Affordable Drugs Now

People's Action

Progressive Maryland

Public Citizen

Public Interest Patent Law Institute

R Street Institute

Salud y Farmacos

Seventh Generation Interfaith Coalition for Responsible Investment

T1International, USA

WV Citizen Action Group