April 26, 2023

The Honorable Darrell E. Issa
Chairman, Subcommittee on Courts,
Intellectual Property, and the Internet
U.S. House of Representatives
2108 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry "Hank" C. Johnson
Ranking Member, Subcommittee on Courts,
Intellectual Property, and the Internet
U.S. House of Representatives
2240 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Issa and Ranking Member Johnson,

The undersigned organizations write to express grave concerns about new restrictions that U.S. Patent & Trademark Office (USPTO) Director Kathi Vidal recently proposed. These changes would have significant adverse impacts on patients, consumers, researchers, and others who contribute to and depend on technological advances. We urge you to protect the provisions of the America Invents Act that are at risk.

Ten years have passed since Congress passed the America Invents Act (AIA) with overwhelming bipartisan support, but the need for efficient and affordable proceedings to challenge invalid patents is greater than ever. The USPTO is granting more patents per year than ever,[1] most of them are granted to foreign entities,[2] and most patent cases are brought by patent assertion entities that make money off litigation instead of developing, manufacturing, or selling products.[3] Meanwhile, Americans pay higher prices for medications than our counterparts around the world and income disparities continue to widen.[4]

Nevertheless, the USPTO is proposing restrictions that serve one purpose: ensuring the USPTO rejects meritorious petitions requesting review of patents that should never have been granted. Congress created these administrative review proceedings in the AIA to give the public a quicker, cheaper, and more accessible mechanism for challenging wrongly granted patents than the only other mechanism for such challenges–district court litigation. Shielding invalid patents from review will ensure that the American people continue paying higher prices, including for life-saving medications, while depriving researchers and small businesses of freedom to develop and commercialize their own inventions, ensuring less innovation and less competition. While

[1] USPTO, *U.S. Patent Statistics Chart*, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (388,900 patents were granted in 2020 and 391,103 in 2019.).
[2] *Id.* (Foreign entities have received more than 50% of utility patent grants per year since 2008.).
[3] Non-practicing entities were responsible for nearly 60% of all district court patent cases in 2022. Unified Patents, *2022 Patent Dispute Report,* https://www.unifiedpatents.com/insights/2023/1/4/2022-patent-dispute-report.
[4] "[I]n 2020, estimated retail prices for 20 selected brand-name prescription drugs were more than 2 to 4 times higher [in the U.S.] than prices in Australia, Canada, and France." U.S. Gov't Accountability Office, *Prescription Drug Spending*, https://www.gao.gov/prescription-drug-spending (last visited Apr. 24, 2023).

protecting invalid patents may benefit a small number of brand pharmaceutical companies, those benefits will come at the expense of American patients and consumers.

We urge you, as representatives of the American people, to ensure that AIA proceedings can continue to serve their intended purpose: enabling meritorious challenges of invalid patents that should never have been granted so that the patent system fosters more competition and innovation than it deters.

Specifically, we urge you to ensure that the USPTO does not override provisions of the AIA establishing that:

- **"Any person" can petition for review:** Congress deliberately allowed "any person" to petition for review, yet the USPTO is proposing to deny petitions, regardless of merit, if filed by those without standing to sue in district court. Standing requirements will shut out individuals and organizations challenging patents for the benefit of others–for example, to clear out patent thickets impeding access to medicine or medical devices. These requirements will not improve patent quality or promote innovation; they will simply protect invalid patents from meritorious challenges.

- **To institute review, petitioners need only show a "reasonable likelihood" that a granted patent is invalid:** Congress established this standard, yet the PTO is effectively proposing to raise the threshold to require petitions that are "compelling" on the merits. It is not clear what this means, but it clearly requires more than Congress intended, thus protecting invalid patents that should be reviewed under the AIA as written.

- **The USPTO can consider meritorious petitions even if district courts have considered other grounds of invalidity.** Congress protected patent owners by prohibiting petitioners from challenging patents on the same (or even similar) grounds raised in district court. The USPTO is now proposing to deny petitions whenever a district court has issued a decision on a patent's validity—even if the decision was based on an issue that cannot be raised in an AIA proceeding and despite the fact that district courts impose a higher burden of proof on challengers. This, too, would do nothing but insulate invalid patents from review and give their owners undue profits.

The benefits of AIA proceedings cannot be overstated. In 2015, the Congressional Budget Office determined that less drastic restrictions on AIA proceedings than those proposed now would cost U.S. taxpayers over $1 billion in higher drug prices. Individual examples demonstrate the immense impact the cancellation of invalid patents can have on drug prices.

For example, AIA proceedings led to the cancellation of an invalid patent on Rivastigmine, a treatment for Alzheimer's disease.[5] Generic competition came quickly after the cancellation, and as a result, prices dropped up to 75%.[6] Similarly, when AIA proceedings led to the cancellation of patents on Zytiga, a treatment for prostate cancer, a generic version soon became available for 98% less (costing as little as $2 per dose compared to $88 for the brand).[7]

When the PTO denies petitions for reasons unrelated to their merits, competition is blocked and drug prices stay sky-high. One such denial thwarted generic manufacturer Mylan's petition for review of patents on Invega Sustenna, an injectable treatment for schizophrenia.[8] Three years later, with no generic competition, the average retail price of Invega Sustenna is over $2,000 for one dose.[9] If not for restrictions like those the USPTO now seeks to codify, the patents inflating the cost of this treatment would have been canceled or confirmed on the merits. By denying petitions for reasons unrelated to their merits, the USPTO strengthens invalid patents and weakens the public's trust in the patent system.

The PTO is proposing far-reaching restrictions that will be fatal to meritorious challenges that the AIA was designed, not only to allow, but encourage people to bring. These changes may please a small number of patent owners, but they will hurt countless Americans, who will experience higher prices, less competition, and less innovation as a result. The PTO should focus on promulgating and enforcing regulations that allow it to deny meritless patent applications instead of meritorious patent challenges.

We urge Congress to ensure the provisions of the AIA creating administrative review proceedings can continue to protect the American people from the harm invalid patents inflict.

Sincerely,

Public Citizen
Public Innovation Project
Public Interest Patent Law Institute
Public Interest Research Group
R Street Institute
Michigan United
Michigan People's Campaign

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[5] Charles Duan, *On the Appeal of Drug Patent Challenges,* Am. Univ. L. Rev. (forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4406404, at 23.
[6] *Id.*
[7] *Id.* at 31.
[8] 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.
[9] 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, 2022).