August 8, 2023

The Honorable Lawrence A. Tabak
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Acting Director Tabak:

As organizations committed to the public interest, we are deeply concerned about high prescription drug prices in the United States given the excessive burdens they place on patients and our health care system. We applaud the Biden Administration for recognizing this urgent crisis and calling for assertive legislative and administrative measures to lower drug prices, as President Biden's Executive Order on Lowering Drug Prices for Americans has done.

Our strong support for the Administration's efforts in this area, however, intensifies our concern regarding proposals from the U.S. Patent and Trademark Office (USPTO) and certain legislative representatives. If enacted, these proposals would compromise the Administration's capacity to accomplish its goal of lowering drug prices. Given the projected impact of these proposals on this critically important goal, we request your intervention in the inter-agency clearance process for the USPTO's Advance Notice of Proposed Rulemaking, published on April 20, 2023 ("USPTO Proposal"), and in the formulation of any Statement of Administration Policy on the Promoting and Respecting Economically Vital American Innovation Leadership Act ("PREVAIL Act"), introduced by Senators Chris Coons (D-DE) and Thom Tillis (R-NC) and Representatives Ken Buck (CO-04) and Deborah Ross (NC-02).

Because invalid patents have a significant impact on drug prices, proposals aimed at restricting access to proceedings for eliminating invalid patents raise serious policy concerns. These proposals include those in the USPTO Proposal, which aims to codify a host of new limitations on meritorious efforts to challenge invalid patents through administrative proceedings, and in the PREVAIL Act, which threatens to impose even more restrictive measures that could shield a plethora of invalid patents from review. By restricting the availability and efficacy of administrative patent review proceedings, these proposals would embolden patent owners to initiate unfounded lawsuits predicated on patents undeserving of their grant. Ultimately, this would obstruct public access to essential medical care and thwart the Administration's efforts to drive down drug prices.

The Need for Patent Review Proceedings

You may already appreciate that unsustainably high drug prices in the U.S. are primarily a consequence of the power which government-issued monopolies, such as patents, give brand-name pharmaceutical companies. This inflated pricing generally reflects monopoly power more than the actual costs associated with manufacturing or labor. Regrettably, it has become commonplace for these companies to extend exclusivity periods for pharmaceuticals significantly beyond their intended duration. They achieve this by securing patents on trivial or obvious variations of existing treatments. Ideally, the USPTO would conduct rigorous scrutiny of every patent application, arriving at accurate conclusions of patentability, and thus ensuring patents are granted solely to genuinely novel and useful inventions.

Reality, however, paints a different picture. With an overwhelming inflow of over 600,000 patent applications each year, the USPTO finds itself grappling with a near-impossible task. Inevitably, mistakes happen. Academic research shows that between 27% and 40% of granted patents are found invalid when challenged, suggesting that an estimated 100,000 invalid patents are erroneously granted annually. These errors overwhelmingly favor foreign companies that receive the majority of U.S. patents. Simultaneously, they disproportionately increase prices borne by American consumers, as is especially evident in the realm of pharmaceuticals.

The Public's Right to Petition for Review of Invalid Patents

Because the public's ability to challenge invalid patents is of paramount importance, Congress authorized any person, other than the patent owner, to ask the USPTO's Patent Trial and Appeal Board (PTAB) to review a granted patent and cancel it if it is found invalid.[1] These proceedings are unique in allowing the validity of a patent to be contested in an adversarial proceeding outside of federal court. They are vital mechanisms for clearing patent thickets that artificially inflate drug prices and eliminating invalid patents that obstruct access to essential, life-saving medications. Consequently, a wide array of entities have used them to challenge invalid patents, including public interest organizations, generic drug manufacturers, and brand-name pharmaceutical companies.

The Role of Patent Reviews in Lowering Drug Prices

In 2015, the Congressional Budget Office projected that even less severe access restrictions than those currently under consideration could cost taxpayers over $1 billion in higher drug prices alone. This prediction is validated by real world examples of successful patent challenges that have led to dramatic reductions in drug prices. For instance, the invalidation of a patent on an Alzheimer's disease treatment

[1] 35 U.S.C. § 311(a).

opened the for generic competition, triggering a 75% decrease in the price of that treatment. Similarly, invalidating patents on a prostate cancer treatment allowed patients to access generic alternatives that cost 98% less. On the other hand, the USPTO's decision not to review patents on an injectable schizophrenia treatment has impeded the introduction of generic alternatives, keeping the price of a single dose alarmingly high at over $2,000.

Key Concerns with Pending Proposals

We are particularly concerned about the aspects of these proposals that would:

- **Prevent the public from challenging invalid patents in administrative review proceedings.** In the America Invents Act, Congress broadly empowered "a person who is not the owner of a patent" to petition for review,[2] yet the USPTO is proposing to deny petitions, regardless of their merit, unless the petitioner has been sued or threatened with litigation. These requirements would shut out patients, researchers, and pioneering manufacturers as well as entities challenging patents on their behalf. For example, a doctor or patient advocacy group could not challenge a drug patent impeding life-saving research.

- **Raise the threshold for instituting a review proceeding so that strong petitions fail.** To institute a review proceeding, Congress required petitioners to show a "reasonable likelihood" of invalidity for at least one patent claim.[3] However, the USPTO's proposal would upend this statutory requirement by replacing it with a more stringent "compelling merits" test. Such a change would lead to the denial of numerous deserving petitions that meet the statutory threshold Congress established.

- **Require denial of meritorious petitions based on unrelated district court litigation.** Review proceedings are already barred if a petitioner previously challenged the patent on the same or similar grounds in a district court or the PTAB.[4] Now, the USPTO Proposal aims to prohibit review proceedings whenever a district court or the USPTO has issued *any* decision on a patent's validity—even if the petitioner never previously challenged the patent or the prior decision concerned an entirely different issue, including one that could not have been raised at the PTAB. For instance, if a generic drug manufacturer unsuccessfully argued in court that a patent was invalid due to its failure to enable others to make the claimed invention, a medical research consortium could not challenge the patent at the PTAB by proving its obviousness in light of published work by those researchers. Declining to review patents simply because of failed attempts at challenges on other grounds is fundamentally flawed. Patents cannot be deemed permanently valid against all future challenges—they can only be classified as "not invalid" based on the specific arguments and evidence presented in the challenge.[5]

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[2] *Id.*

[3] 35 U.S.C. § 314(a) & (e).

[4] 35 U.S.C. § 315(e)(1).

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- **Prohibit review based on invalidity evidence that the USPTO never previously considered.** Before the USPTO grants a patent, it is supposed to review the entire universe of prior scientific and technical knowledge relevant to the invention to ensure that the invention is, in fact, novel. This evidence is referred to as "prior art." Patent applicants, obligated to disclose relevant prior art, often provide voluminous amounts, aware that USPTO personnel cannot possibly sift through it all. Nevertheless, pending proposals seek to prohibit challenges based on prior art that was submitted to the USPTO, regardless of whether it was ever actually considered. This would shield patents from invalidating prior art and encourage applicants to overload USPTO examiners with even larger quantities of prior art. This would not only protect invalid patents that exist now, but also decrease the efficacy of patent examination and thereby increase the issuance of invalid patents in the future.

- **Prevent the USPTO from correcting its own mistakes.** Granted patents are presumed valid because patent examiners are expected to use their technical expertise to evaluate applications accurately. For that reason, challengers in court have to prove invalidity with "clear and convincing" evidence.[6] The PREVAIL Act's proposal to import this heavy burden of proof into administrative patent reviews threatens their core objective: allowing the USPTO to correct its own mistakes. Indeed, the administrative patent judges who oversee patent review proceedings adhere to the same technical prerequisites as patent examiners so that they can correct their mistakes. That is also why review proceedings are significantly more thorough than examination: decisions are made by three-judge panels—in contrast to examination where a single examiner makes patent issuance decisions—and through an adversarial process in which the petitioner participates—in contrast to examination where applicants engage with examiners directly without any third-party involvement.

These administrative and legislative proposals aim to impose far-reaching restrictions that would erode the efficacy of patent review proceedings, nullifying their potential role in efforts to reduce drug prices. These changes would profit a select few patent owners—many of which are brand-name pharmaceutical companies—at the expense of patients, generic drug manufacturers, and governmental entities such as Medicare, which bear the brunt of unjustly inflated drug prices. Worryingly, these proposals would primarily benefit the owners of *invalid* patents, who failed to satisfy statutory requirements for patent protection and contributed nothing to the advancement of medical science or improvement of public health. Such proposals would exacerbate our country's ongoing health care crisis, ensuring Americans continue paying more than the rest of the world for prescription drugs. This means that access to medicine in this country will remain insufficient and inequitable, particularly for the poorest and most vulnerable patients.

As allies of this Administration in its efforts to alleviate the financial strains borne by Americans who depend on prescription drugs, we respectfully implore you—as the heads of executive agencies tasked with advancing the Administration's policies on drug prices—to actively oppose pending proposals that would curtail the capacity of generic drug manufacturers, researchers, doctors, patients, and public interest organizations to challenge invalid pharmaceutical patents. Given the projected impact of these proposals on drug prices, we specifically request your intervention in the inter-agency clearance process for the

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Thank you in advance for your consideration.

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Public Interest Patent Law Institute
R Street Institute
T1 International
U.S. Public Interest Research Group
United Vision for Idaho

August 8, 2023

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf:

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Thank you in advance for your consideration.

Sincerely,

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Patients for Affordable Drugs
Public Citizen
Public Innovation Project
Public Interest Patent Law Institute
R Street Institute
T1 International
U.S. Public Interest Research Group
United Vision for Idaho

August 8, 2023

The Honorable Denis R McDonough
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Secretary McDonough:

As organizations committed to the public interest, we are deeply concerned about high prescription drug prices in the United States given the excessive burdens they place on patients and our health care system. We applaud the Biden Administration for recognizing this urgent crisis and calling for assertive legislative and administrative measures to lower drug prices, as President Biden's Executive Order on Lowering Drug Prices for Americans has done.

Our strong support for the Administration's efforts in this area, however, intensifies our concern regarding proposals from the U.S. Patent and Trademark Office (USPTO) and certain legislative representatives. If enacted, these proposals would compromise the Administration's capacity to accomplish its goal of lowering drug prices. Given the projected impact of these proposals on this critically important goal, we request your intervention in the inter-agency clearance process for the USPTO's Advance Notice of Proposed Rulemaking, published on April 20, 2023 ("USPTO Proposal"), and in the formulation of any Statement of Administration Policy on the Promoting and Respecting Economically Vital American Innovation Leadership Act ("PREVAIL Act"), introduced by Senators Chris Coons (D-DE) and Thom Tillis (R-NC) and Representatives Ken Buck (CO-04) and Deborah Ross (NC-02).

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August 8, 2023

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Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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Because invalid patents have a significant impact on drug prices, proposals aimed at restricting access to proceedings for eliminating invalid patents raise serious policy concerns. These proposals include those in the USPTO Proposal, which aims to codify a host of new limitations on meritorious efforts to challenge invalid patents through administrative proceedings, and in the PREVAIL Act, which threatens to impose even more restrictive measures that could shield a plethora of invalid patents from review. By restricting the availability and efficacy of administrative patent review proceedings, these proposals would embolden patent owners to initiate unfounded lawsuits predicated on patents undeserving of their grant. Ultimately, this would obstruct public access to essential medical care and thwart the Administration's efforts to drive down drug prices.

The Need for Patent Review Proceedings

You may already appreciate that unsustainably high drug prices in the U.S. are primarily a consequence of the power which government-issued monopolies, such as patents, give brand-name pharmaceutical companies. This inflated pricing generally reflects monopoly power more than the actual costs associated with manufacturing or labor. Regrettably, it has become commonplace for these companies to extend exclusivity periods for pharmaceuticals significantly beyond their intended duration. They achieve this by securing patents on trivial or obvious variations of existing treatments. Ideally, the USPTO would conduct rigorous scrutiny of every patent application, arriving at accurate conclusions of patentability, and thus ensuring patents are granted solely to genuinely novel and useful inventions.

Reality, however, paints a different picture. With an overwhelming inflow of over 600,000 patent applications each year, the USPTO finds itself grappling with a near-impossible task. Inevitably, mistakes happen. Academic research shows that between 27% and 40% of granted patents are found invalid when challenged, suggesting that an estimated 100,000 invalid patents are erroneously granted annually. These errors overwhelmingly favor foreign companies that receive the majority of U.S. patents. Simultaneously, they disproportionately increase prices borne by American consumers, as is especially evident in the realm of pharmaceuticals.

The Public's Right to Petition for Review of Invalid Patents

Because the public's ability to challenge invalid patents is of paramount importance, Congress authorized any person, other than the patent owner, to ask the USPTO's Patent Trial and Appeal Board (PTAB) to review a granted patent and cancel it if it is found invalid.[19] These proceedings are unique in allowing the validity of a patent to be contested in an adversarial proceeding outside of federal court. They are vital mechanisms for clearing patent thickets that artificially inflate drug prices and eliminating invalid patents that obstruct access to essential, life-saving medications. Consequently, a wide array of entities have used them to challenge invalid patents, including public interest organizations, generic drug manufacturers, and brand-name pharmaceutical companies.

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In 2015, the Congressional Budget Office projected that even less severe access restrictions than those currently under consideration could cost taxpayers over $1 billion in higher drug prices alone. This prediction is validated by real world examples of successful patent challenges that have led to dramatic reductions in drug prices. For instance, the invalidation of a patent on an Alzheimer's disease treatment

[19] 35 U.S.C. § 311(a).

opened the for generic competition, triggering a 75% decrease in the price of that treatment. Similarly, invalidating patents on a prostate cancer treatment allowed patients to access generic alternatives that cost 98% less. On the other hand, the USPTO's decision not to review patents on an injectable schizophrenia treatment has impeded the introduction of generic alternatives, keeping the price of a single dose alarmingly high at over $2,000.

Key Concerns with Pending Proposals

We are particularly concerned about the aspects of these proposals that would:

- **Prevent the public from challenging invalid patents in administrative review proceedings.** In the America Invents Act, Congress broadly empowered "a person who is not the owner of a patent" to petition for review,[20] yet the USPTO is proposing to deny petitions, regardless of their merit, unless the petitioner has been sued or threatened with litigation. These requirements would shut out patients, researchers, and pioneering manufacturers as well as entities challenging patents on their behalf. For example, a doctor or patient advocacy group could not challenge a drug patent impeding life-saving research.

- **Raise the threshold for instituting a review proceeding so that strong petitions fail.** To institute a review proceeding, Congress required petitioners to show a "reasonable likelihood" of invalidity for at least one patent claim.[21] However, the USPTO's proposal would upend this statutory requirement by replacing it with a more stringent "compelling merits" test. Such a change would lead to the denial of numerous deserving petitions that meet the statutory threshold Congress established.

- **Require denial of meritorious petitions based on unrelated district court litigation.** Review proceedings are already barred if a petitioner previously challenged the patent on the same or similar grounds in a district court or the PTAB.[22] Now, the USPTO Proposal aims to prohibit review proceedings whenever a district court or the USPTO has issued *any* decision on a patent's validity—even if the petitioner never previously challenged the patent or the prior decision concerned an entirely different issue, including one that could not have been raised at the PTAB. For instance, if a generic drug manufacturer unsuccessfully argued in court that a patent was invalid due to its failure to enable others to make the claimed invention, a medical research consortium could not challenge the patent at the PTAB by proving its obviousness in light of published work by those researchers. Declining to review patents simply because of failed attempts at challenges on other grounds is fundamentally flawed. Patents cannot be deemed permanently valid against all future challenges—they can only be classified as "not invalid" based on the specific arguments and evidence presented in the challenge.[23]

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[20] *Id.*

[21] 35 U.S.C. § 314(a) & (e).

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- **Prohibit review based on invalidity evidence that the USPTO never previously considered.** Before the USPTO grants a patent, it is supposed to review the entire universe of prior scientific and technical knowledge relevant to the invention to ensure that the invention is, in fact, novel. This evidence is referred to as "prior art." Patent applicants, obligated to disclose relevant prior art, often provide voluminous amounts, aware that USPTO personnel cannot possibly sift through it all. Nevertheless, pending proposals seek to prohibit challenges based on prior art that was submitted to the USPTO, regardless of whether it was ever actually considered. This would shield patents from invalidating prior art and encourage applicants to overload USPTO examiners with even larger quantities of prior art. This would not only protect invalid patents that exist now, but also decrease the efficacy of patent examination and thereby increase the issuance of invalid patents in the future.

- **Prevent the USPTO from correcting its own mistakes.** Granted patents are presumed valid because patent examiners are expected to use their technical expertise to evaluate applications accurately. For that reason, challengers in court have to prove invalidity with "clear and convincing" evidence.[24] The PREVAIL Act's proposal to import this heavy burden of proof into administrative patent reviews threatens their core objective: allowing the USPTO to correct its own mistakes. Indeed, the administrative patent judges who oversee patent review proceedings adhere to the same technical prerequisites as patent examiners so that they can correct their mistakes. That is also why review proceedings are significantly more thorough than examination: decisions are made by three-judge panels—in contrast to examination where a single examiner makes patent issuance decisions—and through an adversarial process in which the petitioner participates—in contrast to examination where applicants engage with examiners directly without any third-party involvement.

These administrative and legislative proposals aim to impose far-reaching restrictions that would erode the efficacy of patent review proceedings, nullifying their potential role in efforts to reduce drug prices. These changes would profit a select few patent owners—many of which are brand-name pharmaceutical companies—at the expense of patients, generic drug manufacturers, and governmental entities such as Medicare, which bear the brunt of unjustly inflated drug prices. Worryingly, these proposals would primarily benefit the owners of *invalid* patents, who failed to satisfy statutory requirements for patent protection and contributed nothing to the advancement of medical science or improvement of public health. Such proposals would exacerbate our country's ongoing health care crisis, ensuring Americans continue paying more than the rest of the world for prescription drugs. This means that access to medicine in this country will remain insufficient and inequitable, particularly for the poorest and most vulnerable patients.

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Some or all of the undersigned would greatly appreciate the opportunity to arrange a meeting with you and department staff working on these issues to discuss our concerns and answer your questions. Please contact Alex Moss at alex@piplius.org to schedule a meeting.

Thank you in advance for your consideration.

Sincerely,

ACA Consumer Advocacy
Generation Patient
Patients for Affordable Drugs
Public Citizen
Public Innovation Project
Public Interest Patent Law Institute
R Street Institute
T1 International
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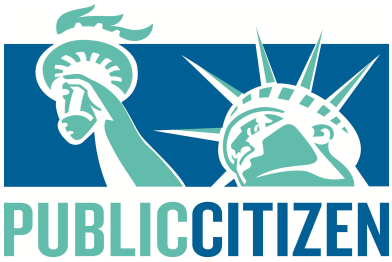
United Vision for Idaho



August 8, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Becerra:

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Public Innovation Project
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R Street Institute
T1 International
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United Vision for Idaho