



Treatment Action Group

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Under Secretary of Commerce for Intellectual Property and Director
U.S. Patent and Trademark Office

600 Dulany Street, Madison East, Concourse Level
Alexandria, VA 22314

December 3, 2020

RE: Request for Comments, Docket No. PTO-C-2020-0055

Jim Aquino
Dick Dadey
Nick Debs
Joy Episalla
Kevin Goetz
Roy M. Gulick, MD, MPH
Jameel Jiwani
Richard Lynn, PhD
Robert Monteleone
Eddie Pelto
David Sigal
Mrinal Vikram

Dear Mr. Iancu:

Treatment Action Group (TAG) writes in strong opposition to the U.S. Patent and Trademark Office (USPTO) moving forward with proposed rulemaking that would harm patients taking HIV, hepatitis C (HCV), and tuberculosis (TB) preventative or therapeutic medications. We are gravely concerned that the increased use by the Patent Trial and Appeal Board (PTAB) of discretionary denials will result in delaying generic and biosimilar competition, foster patent and other monopolies with minimal returns into funding the R&D in these diseases, and raise the cost of prescription medications for people living with or at risk of HIV, HCV, and TB in the US, with implications globally and especially for those subject to discriminatory treatment denials.

EXECUTIVE DIRECTOR

Mark Harrington

TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, TB, and HCV. TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV.

Patent abuses and blocking patent challenge costs lives. We submit our comments following World AIDS Day, in which over 700,000 Americans have died since the start of the pandemic in 1981, with over 1 million currently living with or at risk of HIV ^[1]. While new HIV infections in the overall general population had been declining, they have spiked and are disproportionately rising in Black and Latinx men who have sex with men, Black womxn, and transgender womxn of color. Patent barriers have prevented the swift roll out of pre-exposure prophylaxis (PrEP) to prevent HIV transmission within these communities. Despite having an effective HCV cure, high list prices protected by patent monopolies have resulted in treatment rationing and restrictions that delay treatment initiation, particularly for uninsured people or people on Medicaid plans in the US, and have been used as an excuse to deny needed treatment to people who use drugs. As a result, of the nearly 3 million Americans with HCV, 85% remain untreated seven years after the cure became available.^[2] These delays become longer as companies file numerous



Treatment Action Group

secondary patents and other evergreening strategies that do not fit patentability criteria.

The recent changes the USPTO has made in its approach to discretionary denials—that is, denials based on something other than the actual merits of the petition—are obstructing Congress's efforts to reduce the harms caused by low-quality patents. Discretionary denials have been increasing, as a result.^[3] Instead of continuing down this path by codifying current policies and practices, the PTO should re-prioritize patent quality and restore focus in the *inter partes* review system towards resolving the problems of erroneously-granted patents.

Rather, *inter partes* review serves as a streamlined process for eliminating invalid drug patents and helps to lower prescription drug prices. **Although *inter partes* review is a comparatively new process, it has led to significant price savings in several instances.** For example, prices for an important drug used to treat opioid use disorder, Suboxone (buprenorphine and naloxone), fell by 50% compared to its peak originator brand price after a successful *inter partes* review challenge combined with other litigation.

We strongly object to the how the USPTO has discretionarily denied multiple *inter partes* review petitions that were used to present full challenges to patents in view of not adhering to word limits, rather than objective consideration of the content in these petitions. Relevant to our areas of work in HIV, HCV and substance user health, the availability of overdose prevention treatments has become costly for health budgets and impedes wide rollout of community distribution of Narcan (naloxone nasal spray). In *Nalox-1 Pharmaceuticals, LLC v. Opiant Pharmaceuticals, Inc. et al.*, IPR2019-00694, -00695, -00696, the petitioner similarly filed multiple petitions to ensure the Board had a full record and all but one was denied. Narcan is priced at US\$126 for two doses, and a high price due only to the injector patent which was challenged. The active ingredient, naloxone, is available for approximately US\$30 as a generic. Thus, had the *Nalox-1 inter partes* review been successful, patients, community-based organizations, and health departments could have saved a great deal of money, and more harm reduction and other public health programs could increase its distribution to save lives. (In 2018, opioid related overdose took the lives of over 60,000 Americans^[4]).

In summary, TAG urges the USPTO to reject any efforts to do away with the *inter partes* review system, and subsequently pursue policies to strengthen its ability to address patent abuse and monopolies. We look forward to actions taken by USPTO to protect the lives of millions of people affected by HIV, HCV, and TB here and abroad.

Respectfully submitted,

Bryn Gay
HCV Project Director
Treatment Action Group

[1] <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>

[2] <https://www.i-mak.org/2017/10/25/first-ever-us-patent-challenges-gilead-hepatitis-c/>

[3] <https://www.unifiedpatents.com/insights/2020/10/21/ptabdistrict-court-trial-date-denials-spiraling-upward-ptab-discretionary-denials-third-quarter-report>

[4] <https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates>



Treatment Action Group

Responses to USPTO Questions

For the reasons above, TAG urges the USPTO not to codify the policies and practices mentioned in the Request for Comments. Instead, TAG encourages the USPTO to discontinue its recent efforts which have weakened the *inter partes* review system and made it harder to challenge invalid, unmerited patents. A summary of our responses to the USPTO questions per the public comment are as follows:

1. *Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in General Plastic, Valve I, Valve II and their progeny, for deciding whether to institute a petition on claims that have previously been challenged in another petition?* **No. As noted above, serial petitions can serve important purposes for complex patent disputes where some parties are likely to settle or otherwise fail to prosecute IPR petitions fully. Codifying those precedents in rules would prevent the Board from flexibly distinguishing precedent where necessary to address novel and unexpected situations where serial IPR petitions could be appropriate.**
2. *Alternatively, in deciding whether to institute a petition, should the Office (a) altogether disregard whether the claims have previously been challenged in another petition, or (b) altogether decline to institute if the claims have previously been challenged in another petition?* **No to both. While prior petitions may bear some relevance to whether to institute future ones, the proposal of (b) would deny IPR petitions based on potentially unrelated, incomplete prior ones, thereby preventing IPR from being an effective alternative to litigation.**
3. *Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in the Consolidated Trial Practice Guide, for deciding whether to institute more than one petition filed at or about the same time on the same patent?* **No. Multiple petitions may be necessary for a variety of reasons as described above, and failure to grant them could deny the Board sufficient evidence or the best arguments to consider with respect to any given patent, leading to incomplete or erroneous outcomes.**
4. *Alternatively, in deciding whether to institute more than one petition filed at or about the same time on the same patent, should the Office (a) altogether disregard the number of petitions filed, or (b) altogether decline to institute on more than one petition?* **The Office should institute enough petitions to ensure that a full record of prior art and arguments is available before it. Preliminary assessments of whether prior art is “duplicative” can easily turn out to be wrong. Furthermore, the Office should not use an unrelated third party’s IPR proceeding as reason to deny a petition,**



Treatment Action Group

since there is no guarantee that the unrelated third party will prosecute its challenge fully.

5. *Should the Office promulgate a rule with a case-specific analysis, such as generally outlined in *Fintiv* and its progeny, for deciding whether to institute a petition on a patent that is or has been subject to other proceedings in a U.S. district court or the ITC?* **No. The *Fintiv* factors are insufficient and open to manipulation by forum shopping, therefore codifying those factors would render IPR less effective and improperly contrary to its congressional purpose. Furthermore, even if those factors are correct, codifying them would prevent the Board from further applying the case law method to refine those factors to adapt to new litigation strategies and factual situations.**

6. *Alternatively, in deciding whether to institute a petition on a patent that is or has been subject to other proceedings in district court or the ITC, should the Office (a) altogether disregard such other proceedings, or (b) altogether decline to institute if the patent that is or has been subject to such other proceedings, unless the district court or the ITC has indicated that it will stay the action?* **The Office should generally grant petitions even with co-pending litigation. The very purpose of IPR was to be a lower-cost alternative to litigation; denying IPR petitions in view of litigation subverts that very purpose.**