## **BEFORE THE**

# United States Patent and Trademark Office 600 Dulany Street Alexandria, Virginia 22313

IN THE MATTER OF:	
Notice of Brown and	) )
Notice of Proposed	) Docket No.: PTO-C 2020-0055
Rulemaking	)
	) Document Citation: 85 FR 66502
On Codification or Modification of	)
<b>Current Policies and Practices on Trials</b>	)
<b>Before the Patent Trial and Appeal Board</b>	)
	_)

# COMMENT OF CENTER FOR INDIVIDUAL FREEDOM

IN SUPPORT OF MODIFICATION OF CURRENT POLICIES AND PRACTICES ON TRIALS

BEFORE THE PATENT TRIAL AND APPEAL BOARD

December 3, 2020

#### I. Introduction

The Center for Individual Freedom (hereinafter "CFIF") is a non-profit, non-partisan organization with over 300,000 grassroots supporters and activists across the United States.

CFIF was established in 1998 for the purpose of safeguarding and advancing Constitutional rights and free market principles, as well as ensuring continued American welfare, innovation, prosperity, leadership and worldwide preeminence.

As a central part of that mission, CFIF advocates for public policies that preserve our nation's legacy of strong intellectual property (IP) protections, including patent rights. In that vein, the Proposed Rulemaking under consideration by the United States Patent and Trademark Office (USPTO) offers important improvements to the way in which the Patent Trial and Appeal Board (PTAB) would review patent challenges. On that basis, CFIF respectfully submits this Comment in support of the Proposed Rulemaking, insofar as it contemplates modification of current policies and practices on patent challenges and trials.

#### II. Discussion

First and foremost, we must recognize the foundational truth that the United States stands unrivaled as the most inventive, scientifically prolific, creative, prosperous, influential and powerful nation in human history for one salient reason in particular: our legacy of protecting patent and other IP rights like not other nation. Our Founding Fathers held IP rights in such central regard that they deliberately and specifically protected them in the text of Article I of the Constitution, which reads, "The Congress shall have the Power ... [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

The Founders recognized that strong patent rights serve both a utilitarian purpose in incentivizing innovation and also safeguarding the natural human right of allowing inventors to enjoy the fruits of their labor and creativity. Reflecting on the Founders' wisdom, one-time patent attorney and president Abraham Lincoln later observed, "The patent system added the fuel of interest to the fire of genius."

Experience has borne out Lincoln's observation, as no nation before or since even approaches America's record of scientific invention, from lifesaving pharmaceuticals to aeronautics to computer and internet technology.

In recent years, however, we've witnessed ominous signs in relation to America's patent rights legacy.

Specifically, our traditional position atop global rankings of patent protection has receded in recent years. That decline is directly attributable in large part to administrative patent system changes occurring during the Obama Administration, including PTAB decisions that resulted in elimination of at least one existing patent in almost 80% of petitions brought before it.<sup>1</sup> Also playing a role were judicial branch decisions interpreting federal laws in ways that weakened patent certainty, patent enforcement and substantive patent protections.

That's the bad news. The good news is that more recent executive branch decisions in the current administration successfully interrupted that disturbing slide in America's standing in global patent protection rankings. Those more recent decisions have brought greater emphasis on the importance of strong patent rights to the American economy, including prevention of patent violation by foreign actors, thereby rejuvenating incentivization of American patent innovation and invention. For that we wish to recognize and applaud the current administration and USPTO for interrupting that slide and reemphasizing the importance of strong patent rights.

See, e.g., https://www.uschamber.com/sites/default/files/023331 gipc ip index 2018 opt.pdf

The instant Proposed Rulemaking can successfully extend that reemphasis on strong patent protections, to the extent that it can modify current policies and practices on patent challenges and trials.

Perhaps most importantly, applicable practices must offer both patent holders and patent challengers greater predictability. All parties must possess greater assurance whether challenges will be permitted or denied on the basis of substantive law and policy, as well as objectivity and neutrality, not subjectivity or arbitrary discretion. Clarity in rules and procedures is critical, and variance and unpredictability in use of weighted factors must be minimized. Furthermore, determinative criteria should be published clearly in the Code of Federal Regulations (CFR) to the maximum degree possible.

To accomplish that end, multiple petitions must be restricted. Petitioners, real parties in interest and privy of petitioner should be confined to one petition per patent at issue.

Additionally, each patent should be subject to one trial, not multiple bites at the proverbial trial apple. A 90-day filing window from earlier petitions against for patent challenges should also be instituted, and any petitioners filing within that 90-day period against a subject patent should be allowed to join instituted trials. Only a showing of extraordinary circumstances should merit exceptions from these provisions relating to multiple petitions, as reviewed and sanctioned by the Director, Commissioner and Chief Judge.

Accomplishing that end also requires changes regarding proceedings in other tribunals.

The PTAB should disallow institution of duplicative proceedings, and petitions should be refused when challenged patents are concurrently asserted in district courts against petitioners, real parties in interest or privies of the petitioner, where the courts have neither

stayed the underlying cases nor issued orders contingent upon institution of review. In the same vein, petitions should be denied when challenged patents are concurrently asserted in district courts against petitioners, real parties in interest or privies of petitioners with trial set for within 18 months of petition filing dates. Finally, petitions should be denied when challenged patents have been determined not invalid following final determination involving petitioners, real parties in interest or privies of petitioners.

Furthermore, entities that benefit from invalidation of patents and that make monetary payment to petitioners challenging patents should be considered privy, subject to applicable estoppel provisions. Privy should also be interpreted to include parties to agreements with petitioners or real parties in interest related to the validity or infringement of patents in question, where at least one of the parties to underlying agreements would stand to benefit from findings of unpatentability.

In terms of economic impact, we believe that regulations must acknowledge and account for the disproportionately greater degrees of harm to independent inventors and small businesses from commencement of challenges, as related to litigation costs and legal representation demands.

Finally, we would like to address the misplaced assertion that modification of current policies and practices on trials before the PTAB might somehow result in delayed entry of generic pharmaceutical competitors or increased prescription drug costs for American consumers. To the contrary, strong and reliable patent rights are a primary reason for the fact that the U.S. accounts for approximately two-thirds of all new drugs introduced worldwide, far ahead of any competitor, and that American consumers quickly access new drugs to a far

higher degree than consumers in other advanced nations.<sup>2</sup> Accordingly, procedural changes that strengthen patent rights will safeguard Americans' access to lifesaving drugs, not undermine it.

# III. Conclusion

For the reasons set forth herein, CFIF and its 300,000 activists and supporters support the Proposed Rulemaking to modify current policies and practices on trials before the PTAB.

Respectfully submitted,

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The United States vs. Other Countries: Availability of Cancer Medicines Varies, Pharmaceutical Research and Manufacturers of America (PhRMA), January 2019, <a href="https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/P