

VIA ELECTRONIC TRANSMISSION

May 1, 2024

President Joseph R. Biden
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear President Biden:

Intellectual property (IP) protections are a cornerstone of American enterprise and have been since our Nation's founding. The Constitution grants Congress the power "to promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries."¹

Patents give inventors exclusive rights in their discoveries for a defined period, permitting them to sell products covered by those rights, as well as to assign or license those rights. In exchange for a patent's exclusive right, an inventor must fully disclose the technical details of the invention to the public so that others can use the disclosure to expand innovation. When a patent expires, its information is dedicated to the public for anyone to use without any obligation to the inventor. The certainty and reliability of a patent's exclusive right gives investors the confidence to dedicate billions of dollars to innovation, thereby preserving America's status as the world's innovation leader.

This system has worked for over two centuries. Today, IP-intensive industries make up nearly half of all domestic economic activity and are the reason America leads in a variety of high-tech sectors.² America, however, is losing ground because unlike our competitors and adversaries, the United States has failed to recognize the importance of IP in securing its own economic interests and technological competitiveness. In addition to stealing American IP, the Chinese Communist Party and other adversaries have strengthened their own patent systems over the last several decades, hoping to out-compete and out-innovate the United States.³

In order for the U.S. to remain globally competitive, I urge you to reject attacks on the U.S. patent system. For example, advocate groups and even some policymakers have called on your Administration to use section 1498 as an affirmative tool to address drug pricing issues.⁴ Their arguments, however, mistakenly claim that section 1498 allows the government to impose price controls on patents drug products. In addition, the Department of Justice is urging a federal district court to expand the application of section 1498 to products and services made by private companies that were purchased by the government for transfer to private entities and for use by private individuals.

¹ U.S. Const., art. I, § 8, cl. 8.

² [https://www.uspto.gov/ip-policy/economic-research/intellectual-property-and-us-economy#:~:text=Intellectual%20property%20\(IP\)%20protection%20affects.investments%20in%20innovation%3B%20supporting%20startup.](https://www.uspto.gov/ip-policy/economic-research/intellectual-property-and-us-economy#:~:text=Intellectual%20property%20(IP)%20protection%20affects.investments%20in%20innovation%3B%20supporting%20startup.)

³ [https://ipwatchdog.com/2020/11/03/china-legislature-approves-increases-statutory-patent-damages-maximum-5x-punitive-damages-intentional-infringement/id=126990/.](https://ipwatchdog.com/2020/11/03/china-legislature-approves-increases-statutory-patent-damages-maximum-5x-punitive-damages-intentional-infringement/id=126990/)

⁴ [https://www.commondreams.org/news/sanders-alzheimer-s-drug.](https://www.commondreams.org/news/sanders-alzheimer-s-drug)

There is no justification in the text, legislative history, or case law for that reading of the statute. As such, I thought it important to make clear that efforts to use section 1498 in this way would do great harm to our innovation ecosystem and have little discernible effect on drug prices.

Congress enacted section 1498 in 1910 to ensure wartime readiness during World War I.⁵ It provides that when the government uses a patented invention without authorization, the patent owner may sue for “reasonable and entire compensation.”⁶ In other words, section 1498 is a remedial statute intended to make clear that patent owners are entitled to compensation for government takings under the Fifth Amendment.

Despite the unambiguous statutory language, advocate groups have incorrectly argued that the government can use section 1498 to disregard patents on drug products and to induce generic pharmaceutical companies to manufacture patented medicines.⁷ The New York Times’ editorial board and several senators have embraced this argument, urging Health and Human Services Secretaries from both your administration and the prior administration to use section 1498’s “government patent use power” on innovative new medicines.^{8,9} Further, the Department of Justice is currently seeking to advance that same position, arguing that, when the government purchases a drug for use by American civilians, that constitutes infringement “by and for” the government.¹⁰

In fact, nothing in the statute confers such a power to the government. Relying on section 1498 to willfully infringe privately owned patents could result in immense harm to the patent system across technologies. Moreover, using section 1498 would not significantly reduce drug costs because, as courts have repeatedly recognized, the law requires the government to provide “reasonable and entire compensation” for any infringement conducted “by or for” the government.¹¹ Indeed, the pending private lawsuit the Department of Justice has sought to intervene in may result in a multi-billion-dollar award that American taxpayers would have to pay.

The statutory requirement that the infringement be “by and for” the government makes clear that section 1498 is limited to government use, not merely purchase or manufacturing by the government for use by the American public. Affirmatively authorizing patent infringement by a third party, as advocates propose your Administration do, is likewise clearly outside the plain meaning of the text. The statutory (and Constitutional) requirement that the government pay the patent owner “reasonable and entire compensation” mitigates any cost savings. At best, then, use of section 1498 would transfer costs from private insurance companies or private infringers to American taxpayers.

⁵ See Act of July 1, 1918, ch. 114, 40 Stat. 704, 705 (1918); Act of October 31, 1942, Pub. L. 768, Section 6, 77th Cong. 2d Sess., 56 Stat. 1013, 1014 (1942).

⁶ 28 U.S.C. § 1498.

⁷ Kapczynski, Amy and Kesselheim, Aaron S., ‘Government Patent Use’: A Legal Approach to Reducing Drug Spending, *Health Affairs* 35:5 (May 2016), available at: https://law.yale.edu/sites/default/files/documents/faculty/papers/kapczynski_govpatentuse.pdf.

⁸ How the Government Can Lower Drug Prices, *NY Times* June 20, 2018, available at: <https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html>.

⁹ <https://www.warren.senate.gov/oversight/letters/warren-urges-biden-administration-to-lower-prescription-drug-prices-using-existing-executive-authority>; <https://www.help.senate.gov/chair/newsroom/press/news-sanders-urges-biden-administration-to-act-to-lower-price-of-alzheimers-treatment>.

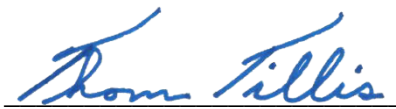
¹⁰ Statement of Int., Dep’t. of Just., *Arbutus Biopharma Corp. v. Moderna, Inc.*, 1:22-cv-00252-MSG (D. Del. 2023) (filed Feb. 14, 2023).

¹¹ <https://www.law.cornell.edu/uscode/text/28/1498#:~:text=Whenever%20an%20invention%20described%20in,United%20States%20Court%20of%20Federal>; Letter from Jonathan Barnett, et al., to Sen. Bernie Sanders, et al. (Sept. 28, 2023), at 10-12 (available at <https://s3.amazonaws.com/media.hudson.org/Letter+to+Congress++Bayh-Dole+and+1498+Not+Basis+for+Price+Controls+on+Drugs.pdf>).

Weakening patent rights through section 1498 will have deleterious effects on American innovation and economic competitiveness. If inventors and investors can't be confident that a patent confers reliable and predictable rights, American investment in R&D in IP-intensive industries – including life sciences, renewable energy, and artificial intelligence – will decline precipitously.

Our IP system has consistently rewarded inventors for their valuable contributions to our collective well-being. It has made America the most innovative nation in history based on a legal regime that sustains and encourages that innovation. Use of section 1498 would undermine that regime. Thus, I strongly urge your Administration to reject such a policy.

Sincerely,



Thom Tillis
United States Senator