EXHIBIT 11

Section 1498(A) is Not a Rx to Reduce Drug Prices

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ABSTRACT

On June 20, 2018, *The New York Times* published an editorial captioned "How the Government Can Lower Drug Prices," announcing that "a possible solution involves an obscure part of federal law known as Section 1498. The provision acts as a sort of eminent domain for patented inventions allowing the government to circumvent patent protections if the patent holder is compensated. In the case of a pharmaceutical, the Department of Health and Human Services (HHS) can authorize a drug maker to produce a low-cost generic version, which it would then buy in bulk."[1] The authority cited by *The New York Times* for this proposition was a 2016 law review article published in the *Yale Journal of Law & Technology* (Yale Article).[2]

Fast forward to March 23, 2021. Within weeks of President Biden's inauguration, Senator Bernie Sanders delivered the Opening Statement at a Senate Committee on Health, Education, Labor, and Pensions Subcommittee hearing citing *The New York Times* editorial as support for the introduction of S. 909, the Prescription Drug Price Relief Act of 2021, proposed legislation that would authorize the HHS Secretary to infringe on pharmaceutical patents or require pharmaceutical patent owners to enter compulsory licenses at royalty rates established by HHS should those patent owners be found to have charged excessive rates for the drug in question.[3]

On February 17, 2022, Senators Elizabeth Warren and Angus S. King, Jr., with Congressman Lloyd Doggett, wrote a letter to HHS Secretary Xavier Becerra urging

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[1] *How the Government Can Lower Drug Prices*, N.Y. TIMES: EDITORIALS (June 20, 2018), https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html.

[2] Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016).

[3] Prescription Drug Price Relief Act of 2021, S. 909, 117th Cong. (2021); *Why Does the U.S. Pay the Highest Prices in the World for Prescription Drugs*, *Hearing Before the Subcomm. on Primary Health and Ret. Sec.*, 116th Cong. (Mar. 23, 2020), https://www.help.senate.gov/hearings/why-does-the-us-pay-the-highest-prices-in-the-world-for-prescription-drugs (opening statement of Senator Bernie Sanders).

him to use "existing executive authority" to lower drug prices.[4] On March 24, 2022, eight public interest groups forwarded the HHS Secretary a "Petition To Make Drugs More Affordable," citing the Yale Article.[5] On April 22, 2022, Senator Warren again wrote to the HHS Secretary attaching an April 22, 2022 letter from "over 25 legal and public health experts" describing 28 U.S.C. § 1498 as the "government patent use power," i.e., a "tool" that can be used "to intervene when patients and public health are harmed by excessive drug prices."[6] The chief author of this letter is none other than one of the authors who penned the 2016 Yale Article. And, on June 23, 2022, eight Senators and 103 members of Congress sent a letter to the HHS Secretary to "utilize . . . government use compulsory licensing under 28 U.S.C. 1498 . . . to lower prescription drug prices."[7] In light of the close margins in the 118th Congress, continued pressure on the executive branch to exert 28 U.S.C. § 1498 (a) should be expected.

In *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928), however, the United States Supreme Court held that the "intention and purpose of Congress in the act of 1918 [(the predecessor to Section 1498)] was to stimulate contractors to furnish what was needed for [World War I], without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents." In 1949, Congress amended the Act of 1918 to precisely limit Section 1498(a) solely as a waiver of sovereign immunity to provide a private party with standing and a judicial forum in which to sue the government for patent infringement.[8] No federal court, however, has held that the government has an absolute *right* to infringe privately held patent rights and therefore, historically, they have narrowly and strictly construed Section 1498(a), as we discuss below.

I. INTRODUCTION

This Article argues that the authors of the Yale Article have misled some legislators and members of the public to believe government infringement of pharmaceutical

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[4] Letter from Senator Elizabeth Warren, Senator Angus S. King, Jr., and Congressman Lloyd Doggett to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (Feb. 17, 2022), https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20(2).pdf.

[5] Letter from Action Center on Race & the Economy, Center for Popular Democracy Action, Indivisible, People's Action, PrEP4All, Public Citizen, Social Security Works, and T1International, to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. 3 n. 9 (Mar. 24, 2022), https://www.citizen.org/article/make-meds-affordable-petition/ (introducing and including petition).

[6] Letter from Senator Elizabeth Warren to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (Apr. 22, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.22%20Letter%20to%20Becerra%20on%20Drug%20Pricing%20Executive%20Authorities.pdf; Letter from Amy Kapczynski, JD, Aaron S. Kesselheim, MD, JD, MPH, Christopher J. Morten, JD, PhD, David Herman, Christopher Umanzor, to Senator Elizabeth Warren (Apr. 22, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf.

[7] Letter from Elizabeth Warren et al. to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (June 23, 2022), https://www.warren.senate.gov/imo/media/doc/Bicameral%20Letter%20Urging%20HHS%20to%20Lower%20Drug%20Prices%20FINAL1.pdf.

[8] 28 U.S.C. § 1498(a); *see* Brennan et al., *supra* note 2, at 301 n.128; *see generally* Sean M. O'Connor, *Taking, Tort, or Crown Right? The Confused History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145 (2012).

patent rights is sanctioned by Section 1498(a) and will reduce drug prices. First, we take issue with the Yale Article for its failure to cite empirical evidence that government infringement of pharmaceutical patents will lower drug prices. Next, we critique the Yale Article's proposal that HHS engage in the unprecedented misuse of executive authority to infringe on pharmaceutical patents, ignoring the history and limited scope of Section 1498(a), as reflected in decades of case law. Consequently, we believe that any unilateral executive action authorizing infringement of pharmaceutical patents or compelling owners of pharmaceutical patents to license them at royalty rates set by HHS, or another federal agency, should be nullified by the federal courts. If not, Section 1498(a) will require the government to pay pharmaceutical patent owners "reasonable and entire compensation" as damages, including lost profits. And those damages will be paid from congressional appropriations. As such, the misuse of Section 1498(a) is not a Rx for reducing drug prices, but in effect is a tax imposed on American citizens.

II. NO EMPIRICAL EVIDENCE SHOWS THAT GOVERNMENT INFRINGEMENT OF PHARMACEUTICAL PATENTS WILL REDUCE DRUG PRICES

The Yale Article states with alarm that the cost of pharmaceuticals in the United States is "soaring," but admits the "increase in prescription spending can be attributed almost entirely to recently approved drugs that treat the Hepatitis C virus (HVC)."[9] The drug at issue was HARVONI™, a breakthrough patented pharmaceutical developed and manufactured by Gilead Sciences, Inc. (Gilead). The Yale Article asserts, based on inferences and assumptions, that "Gilead's prices vastly exceed the cost of producing these drugs."[10] The Yale Article accurately reports the initial list price of HARVONI™ was approximately $100,000 for a twelve-week regimen.[11] This initial price, however, was reduced by 46% within twelve months; by 2018, Gilead released its own generic drug, EPCLUSA™.[12] The myopic focus on the introductory price of these drugs, hyped by the Yale Article as an example of "one of the most pressing domestic policy issues in the United States today,"[13] however, did not take into account that new competition on the horizon could have a significant downward effect on these drug prices—which happened.

In 2017, the U.S. Food and Drug Administration (FDA) approved AbbVie, Inc.'s MAVYRET™, which reduced HCV treatment time to eight weeks at an estimated wholesale cost of $26,400.[14] A few months later, MAVYRET™ weekly new

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[9] Brennan et al., *supra* note 2, at 277.

[10] *Id.* at 278.

[11] *Id.* at 277.

[12] Richard Staines, *Gilead Launches Generics of Own Hepatitis C Drugs in US to Cut Health Costs*, PHARMAPHORUM (Sept. 25, 2018), https://pharmaphorum.com/news/gilead-launches-generics-of-own-hepatitis-c-drugs-in-us-to-cut-health-costs/.

[13] Brennan et al., *supra* note 2, at 277.

[14] Ned Pagliarulo, *AbbVie Surprised Investors with its Hepatitis C Success. Will it Last?* BIOPHARMADIVE (Aug. 2, 2018), https://www.biopharmadive.com/news/abbvies-surprised-investors-mavyret-hepatitis-c-success-will-it-last/529158/; *see also* Press Release, AbbVie, AbbVie Receives U.S. FDA Approval of MAVYRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1-6) in as Short as 8 Weeks, https://news.abbvie.com/news/abbvie-receives-us-fda-

prescriptions "outpaced" Gilead's HARVONI™ and EPCLUSA™.[15] As a result of these drugs, Hepatitis C virus-caused disease has steadily declined, leaving a "smaller and smaller pool of patients."[16] While the Yale Article was published in 2016 and subsequently did not have the benefit of this information, we are skeptical of the authors' contention that the price of HVC drugs raises "the problem that economists have long identified with patent-based drug pricing: the potential for massive social 'deadweight' losses that stem from supra-marginal cost pricing"[17] that must be remedied by the government's infringement of these patented pharmaceuticals. The *raison d'être* advanced for the federal government "breaking" pharmaceutical companies' patent rights is the promise of "significant social gains to be had from bringing compensation in line with the risk-adjusted cost of developing a drug."[18] Of course, these "social gains" are not identified, nor how the government will determine the "risk-adjusted cost of drug development," nor who within the government will decide when these "significant social gains" require infringing a patent issued by the United States Patent and Trademark Office (USPTO), the sole federal agency authorized by Congress "[t]o promote the Progress of Science . . . by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries."[19]

The Yale article also did not account for the subsequent development that both list and net prices of pharmaceuticals, primarily those composed of small-molecule drugs, began to fall around the time of its publication; a trend that has continued.[20] Biologics have become "the driver behind overall drug spending in the United States in recent years.[21] In inflation-adjusted terms, biologic drug spending increased from $291 to $435 per capita from 2014 to 2018, while small-molecule drug spending fell from $689 to $610 per capita during this same period."[22]

The following chart, based on data obtained and compiled by Drug Channels Institute, an organization that collects and reports on approximately 1,000 brand-name

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approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.

15 Pagliarulo, *supra* note 14.

16 *Id.*

17 Brennan et al., *supra* note 2, at 279.

18 *Id.* at 282.

19 U.S. CONST. art. I., § 8, cl. 8.

20 A "small-molecule drug" is composed of "organic compounds affecting molecular pathways by targeting important proteins. These compounds have a low molecular weight, making them penetrate cells easily." Qingxin Li & CongBao Kang, *Mechanics of Action for Small Molecules Revealed by Structural Biology in Drug Discovery*, 21 INT'L. J. MOLECULAR SCI. 5262 (2020).

21 *What Are "Biologics" Questions and Answers*, U.S. Food and Drug Admin. (Feb. 6, 2018), https://www.fda.gov./about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (defining a "biologic drug" as being composed of "sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues." Biologic drugs are not easily identified or characterized and are extremely sensitive to environmental factors such as heat and microbiological contamination); *see also Why Does the US Pay the Highest Prices in the World for Prescription Drugs*? *Hearing Before the Subcomm. on Primary Health and Retir. Sec.*, 117th Cong. 2 (Mar. 23, 2021) (statement of Alex Brill, Resident Fellow, American Enterprise Institute) (pointing to biologics as the current driver of overall drug spending in the United States) [hereinafter Statement of Brill].

22 Statement of Brill, *supra* note 21 at 2.

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