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The U.S. Government's Apparent Co-Ownership of Patents Protecting Remdesivir

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Table of Contents

I.	Executive Summary	2
II.	Authors' Note	3
III.	Introduction.....	3
A.	Remdesivir and the COVID-19 pandemic	3
B.	Chemistry of Remdesivir.....	5
IV.	The U.S. government appears to legally co-own the key patents on remdesivir itself.....	7
A.	U.S. Patent Nos. 9,724,360 and 9,949,994 are the U.S. patents that disclose and claim remdesivir.	8
B.	The '360 and '994 patents and other publications all explain that Gilead and U.S. government scientists worked together to invent remdesivir.	8
C.	U.S. government scientists' contributions likely make them co-inventors of the '360 and '994 patents.....	10
1.	U.S. government scientists may qualify as co-inventors of remdesivir itself.....	10
2.	U.S. government scientists likely qualify as co-inventors of methods of using remdesivir.....	12
D.	If U.S. government scientists co-invented the '360 and '994 patents, then the U.S. government is presumed co-owner of these patents and likely holds important legal rights.....	13
V.	In addition, the U.S. government appears to hold other relevant patent rights on remdesivir.....	15
A.	The "genus patents": U.S. Patent Nos. 8,008,264, 8,012,941, 8,318,682, and RE46,762	15
B.	The "soon-to-be patent on treatment of COVID": U.S. Patent Application No. 16/265,016.....	16
VI.	Conclusion: Some thoughts on the way forward	17

I. Executive Summary

Some preliminary evidence suggests the antiviral drug remdesivir can accelerate recovery from COVID-19, although (as of writing) there is no clear evidence it can actually save the lives of people with COVID-19. Given its promise, remdesivir has been given emergency use authorization by the Food and Drug Administration and is currently being used in hospitals around the world. Remdesivir is manufactured by Gilead Sciences, Inc. (“Gilead”) and is widely perceived as being “owned” by Gilead.¹

However, our analysis indicates that the U.S. government likely has a legal right to claim co-ownership of remdesivir—or at least co-ownership of the core U.S. patents that cover the chemical structure of remdesivir—as well as methods of using the remdesivir to treat various diseases. This is because U.S. government scientists working with United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Centers for Disease Control and Prevention (CDC) appear to have contributed in various ways to the “invention” of remdesivir—perhaps to the selection of the compound as a drug candidate, and more clearly to the discovery of remdesivir’s antiviral properties. Based on their intellectual contributions, these government scientists should probably be named as co-inventors on these patents.

If these U.S. government scientists are indeed inventors of the patents on remdesivir, then, under U.S. patent law, the patents are presumed co-owned by the U.S. government. If remdesivir proves safe and effective in treating COVID-19, as the world hopes it will, the U.S. government could exercise its patent rights to lower prices and expand access to remdesivir, if need be.

This report poses a critical question—if the U.S. government co-invented remdesivir, with substantial investment by the American public in its development, why should Gilead alone profit and control who can manufacture it?

¹ See, e.g., Brown, M. Fact check: *China doesn't own patent for coronavirus treatment remdesivir*. USA TODAY. 15 May 2020. URL: <https://www.usatoday.com/story/news/factcheck/2020/05/15/fact-check-china-doesnt-own-patent-covid-19-treatment-remdesivir/5194192002/> (“Gilead Sciences, which owns the U.S. patent for promising COVID-19 treatment remdesivir, solely maintains the intellectual property rights to the drug.”).

II. Authors' Note

The PrEP4All Collaboration is an all-volunteer collaboration of activists, scientists, and healthcare providers dedicated to igniting political action to put life-saving HIV—and now COVID-19—medications into the hands of everyone who needs them. Visit PrEP4All on the web at prep4all.org.

James Krellenstein is an infectious disease activist focusing on scaling up effective interventions to dramatically reduce the spread of infectious diseases in the United States. He is a co-founder of the PrEP4All Collaboration and the COVID-19 Working Group. His writing has been published in *The New York Times* and *The Guardian*, and his work has been featured in *The New York Times*, *The Washington Post*, *NBC News*, *Kaiser Health News*, *Vice*, *NPR*, *STAT*, *BuzzFeed News*, and *The Daily Beast*. In addition to his work on HIV and COVID, James has worked as a research assistant in molecular biology and pharmacology at the Yale University School of Medicine, the Mount Sinai School of Medicine and the CUNY Medical School. He holds degrees in physics as well as natural science and mathematics.

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III. Introduction

A. Remdesivir and the COVID-19 pandemic

The COVID-19 pandemic is the largest public health crisis the world has faced since the outbreak of 1918 pandemic influenza more than a century ago. With over 4.4 million confirmed cases and over 300,000 deaths across the globe, the need for effective treatments, pharmaceutical prophylactics and vaccines grows every day. Unfortunately, no drug or vaccine is currently approved by the United States (“US”) Food and Drug Administration (“FDA”) for the treatment or prevention of COVID-19.

Remdesivir, a drug manufactured by Gilead Sciences, Inc. (“Gilead”), is being investigated in multiple clinical trials to evaluate whether it is safe and effective in treating COVID-19. While one clinical trial, which terminated early due to under-enrollment, showed no statistically significant improvement in COVID-19 patients treated with remdesivir compared to placebo,² another trial was reported (via press release) to have shown a statistically significant reduction in time to recovery patients who received remdesivir compared to placebo.³ While it is currently not known whether remdesivir is safe and effective in treating COVID-19, the U.S. FDA granted an emergency use authorization to the drug on May 1, 2020.⁴

There are significant concerns about access to remdesivir. While Gilead has donated all of its existing stock of remdesivir to governments across the world, the company’s and its suppliers’ abilities to provide enough drug to meet the world’s demand has stirred some doubt,⁵ even by Gilead’s own estimates.⁶ Already, widespread shortages of remdesivir are being reported across the United States.⁷

Another significant barrier to access may be the price the company decides to charge for the drug. Although remdesivir is a cheap drug to produce at scale—production costs are estimated at less than USD \$1 per day of treatment⁸—Gilead has an unfortunate history of charging remarkably high prices for life-saving antiviral drugs. Two examples:

- Gilead charges over \$20,000 per patient per year for HIV prevention drugs that costs pennies per pill to manufacture, a practice that the late U.S. Representative Elijah Cummings described as “outrageous, making [Gilead] \$36 billion while there are literally hundreds of thousands of people who need this drug.”⁹

² Wang, Y et al. *Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial*. THE LANCET (2020). [https://doi.org/10.1016/s0140-6736\(20\)31022-9](https://doi.org/10.1016/s0140-6736(20)31022-9).

³ National Institutes of Allergy and Infectious Diseases. NIH Clinical Trial Shows Remdesivir Accelerates Recovery from Advanced COVID-19. 29 April 2020. Accessed on 14 May 2020. URL: <https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19>

⁴ U.S. FDA. Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization for Potential COVID-19 Treatment. 1 May 2020. Accessed on 14 May 2020. URL: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment>

⁵ See, e.g., Chatsko M. *Gilead Sciences Races to Manufacture Remdesivir, but Chemistry Has Speed Limits*. THE MOTLEY FOOL. 22 April 2020. Accessed on 19 May 2020. URL: <https://www.fool.com/investing/2020/04/22/gilead-sciences-races-to-manufacture-remdesivir-bu.aspx>

⁶ Gilead Sciences. Q1 2020 Earnings Results. Slide 20. 29 April 2020. Accessed on 15 May 2020. URL: <http://investors.gilead.com/static-files/af4599eb-4fb8-4cf7-96a1-38caf477e9b4>

⁷ See, e.g., Flanagan, C. *Gilead’s Virus Drug Seen in Short Supply for Americans*. BLOOMBERG NEWS. 11 May 2020. Accessed on 15 May 2020. URL: <https://www.bloomberg.com/news/articles/2020-05-11/gilead-s-covid-19-drug-seen-in-short-supply-for-americans>

⁸ Hill A et al. *Minimum costs to manufacture new treatments for COVID-19*. J VIRUS ERADICATION. Online 9 April 2020. [http://viruseradication.com/journal-details/Minimum costs to manufacture new treatments for COVID-19/](http://viruseradication.com/journal-details/Minimum%20costs%20to%20manufacture%20new%20treatments%20for%20COVID-19/)

⁹ *HIV Prevention Drug: Billions in Corporate Profits After Millions In Taxpayer Investments Hearing Before the Committee in Oversight and Reform*, 116th Cong. 2. URL: <https://docs.house.gov/meetings/GO/GO00/20190516/109486/HHRG-116-GO00-Transcript-20190516.pdf>.

- After acquiring a hepatitis C drug from another company that “expected to profitably sell [...] in the United States for \$36,000” for a standard course of treatment,¹⁰ Gilead set the initial price more than twice as high—\$84,000—straining public health budgets around the country.¹¹ Senators Charles Grassley and Ron Wyden investigated and concluded that Gilead’s “pricing strategy was focused on maximizing revenue—even as the company’s analysis showed a lower price would allow more patients to be treated.”¹²

B. Chemistry of Remdesivir

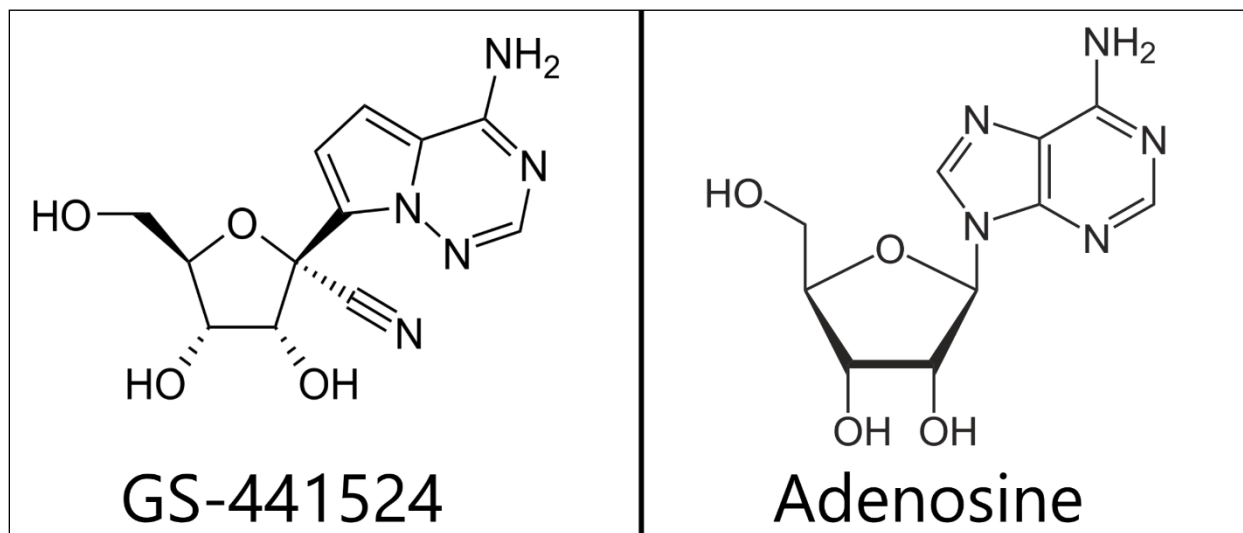


Figure 1: GS-441524 is an analogue of the naturally occurring nucleoside -- the "A" in the genetic code. Note the structural similarity between the two.

The development of remdesivir can be traced back to 2008, to a program at Gilead to develop drugs to treat hepatitis C. One of the molecules generated in that program, now known as GS-441524, was shown to inhibit hepatitis C virus replication in test tube models,¹³ but it was not developed further as a treatment for hepatitis C virus infection. GS-441524 is a *nucleoside analogue*, a type of drug that has a similar or “analogous” structure to nucleosides—the molecular building blocks of DNA and RNA. When a viral protein incorporates the nucleoside

¹⁰ Press Release. Senators Ron Wyden and Charles Grassley, Senators Seek Details on Sovaldi Pricing. (11 July 2014) URL: <https://www.grassley.senate.gov/news/news-releases/senators-seek-details-sovaldi-pricing>.

¹¹ Pollack A. *Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to \$10.3 Billion*. THE NEW YORK TIMES. 3 Feb 2015. URL: <https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html>

¹² Committee on Finance, United States Senate. “The Price of Sovaldi and its Impact on the U.S. Healthcare System”. December, 2015. Accessed on 16 May 2015. URL: [https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf)

¹³ Cho A et al. *Synthesis and antiviral activity of a series of 1'-substituted 4-aza-7,9-dideazaadenosine C-nucleosides*. BIOORG MED CHEM LETT. 2012 Apr 15;22(8):2705-7. doi: 10.1016/j.bmcl.2012.02.105. Epub 2012 Mar 8.

analogue molecule, rather than a naturally occurring nucleoside, the ability of the virus to copy its genetic code is halted, and viral replication is inhibited.¹⁴

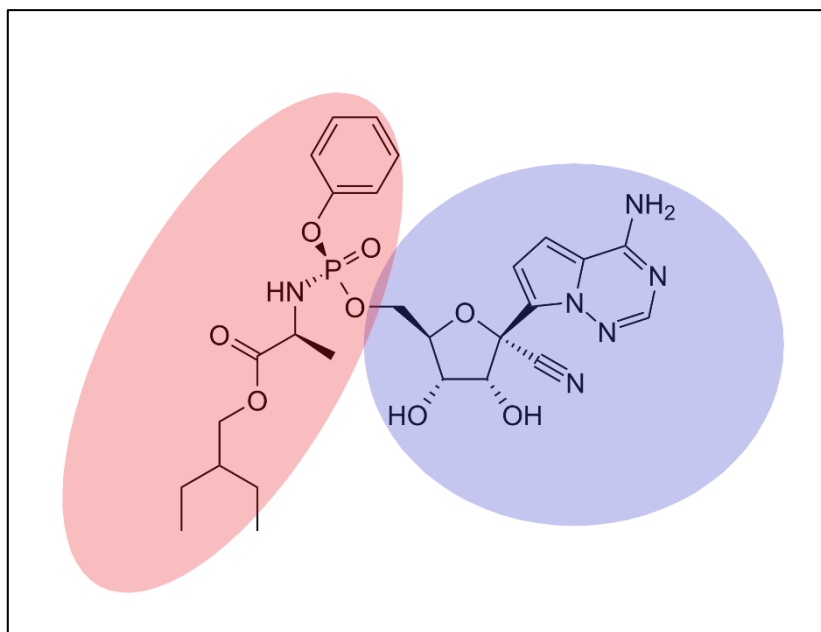


Figure 2: The structure of remdesivir. The region of the remdesivir molecule that is based on GS-441524 is shaded in blue, and the prodrug region is shaded in red.

Remdesivir is a *prodrug* of GS-441524. Prodrugs are pharmacologically inactive compounds that can be efficiently absorbed and then converted by the body into the active drug compound. During remdesivir’s development, Gilead referred to remdesivir by its code name, “GS-5734.”¹⁵

The development of effective prodrugs is often an essential step in drug development. For example, the anti-HIV compounds tenofovir disoproxil¹⁶ (found in Viread, Truvada, Atripla, Complera and Stribild) and tenofovir alafenamide¹⁷ (found in Vemlidy, Descovy, Genvoya, Odefsey, and Biktarvy) are different prodrugs of the same molecule, tenofovir. Although Gilead

¹⁴ See, e.g., Eastman RT et al. *Remdesivir: A Review of Its Discovery and Development Leading to Emergency Use Authorization for Treatment of COVID-19* ACS CENT. SCI. 2020, DOI: 10.1021/acscentsci.0c00489

¹⁵ “GS-5734” is still commonly used by Gilead and others as a synonym for “remdesivir.” See, e.g., “Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Severe Coronavirus Disease (COVID-19),” NCT04292899, entry on ClinicalTrials.gov, <https://clinicaltrials.gov/ct2/show/NCT04292899>.

¹⁶ See, e.g., Shaw JP et al. *Metabolism and pharmacokinetics of novel oral prodrugs of 9-[(R)-2-(phosphonomethoxy)propyl]adenine (PMPA) in dogs*. PHARM RES. 1997 Dec;14(12):1824-9.

¹⁷ See, e.g., Eisenberg EJ, He GX, Lee WA. *Metabolism of GS-7340, a novel phenyl monophosphoramidate intracellular prodrug of PMPA, in blood*. NUCLEOSIDES NUCLEOTIDES NUCLEIC ACIDS. 2001 Apr-Jul;20(4-7):1091-8.

A. U.S. Patent Nos. 9,724,360 and 9,949,994 are the U.S. patents that disclose and claim remdesivir.

We are aware²⁰ of two—and only two—U.S. patents that disclose and claim the precise molecular structure of remdesivir: U.S. Patent Nos. 9,724,360 (the “’360 patent”) and 9,949,994 (the “’994 patent”). For example, Claim 1 of the ’360 patent covers remdesivir exactly.²¹ Claim 13 of the ’994 patent covers a group of 17 compounds, of which one is remdesivir.

B. The ’360 and ’994 patents and other publications all explain that Gilead and U.S. government scientists worked together to invent remdesivir.

As an Ebola virus epidemic began breaking out in West Africa in 2014, Gilead, in collaboration with the U.S. Centers for Disease Control and Prevention (CDC) in Atlanta, GA and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) in Fort Detrick, MD, began a program to evaluate whether any existing molecules in Gilead’s library could inhibit Ebola virus replication.²² A library of approximately one thousand compounds were first tested against multiple families of RNA viruses. Compounds which showed promise in the first screens were then tested against Ebola virus at CDC and USAMRIID labs.²³ It was this subsequent screening process, done by Gilead scientists and U.S. government scientists with a mixture of private and taxpayer money at multiple federal laboratories that led to the invention of remdesivir.²⁴

The ’360 and ’994 patents were first filed by a group of Gilead inventors in 2014 and 2015. They are currently owned by Gilead and Gilead alone. Yet the patents repeatedly reference scientific contributions of scientists outside Gilead, at USAMRIID and CDC. The ’360 patent, for example, states that “[t]he antiviral activity of selected compounds [including remdesivir] was measured against ebolavirus (EBOV) strain Zaire conducted in biosafety level-4 containment (BSL-4) at the US Army Medical Research Institute for Infections Disease [*sic*] (USAM-RIID),”²⁵ and that additional studies of antiviral activity “were conducted in biosafety level-4 containment (BSL-4) at the Centers for Disease Control and Prevention.”²⁶

²⁰ One of the authors (J.K.) performed a systemic search of patent applications using World Intellectual Property Organization’s (WIPO) PATENTSCOPE search engine for filings that disclosed the chemical structure of GS-441524 (InChI Key: BRDWIEOJOWJCLU-LTGWCKQJSA-N) and remdesivir (InChI Key: RWWYLEGWBNMMLJ-YSOARWBDSA-N).

²¹ The chemical structure depicted in claim 1 is that of remdesivir. *Compare, e.g.*, Gilead’s “FACT SHEET FOR HEALTH CARE PROVIDERS: EMERGENCY USE AUTHORIZATION (EUA) OF REMDESIVIR (GS-5734™),” at 29. https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fact-sheet-for-hcps_01may2020.pdf.

²² Siegel D et al. *Discovery and Synthesis of a Phosphoramidate Prodrug of a Pyrrolo[2,1-f][triazin-4-amino] Adenine C-Nucleoside (GS-5734) for the Treatment of Ebola and Emerging Viruses*, J MED CHEM. 2017 Mar 9;60(5):1648-1661. doi: 10.1021/acs.jmedchem.6b01594. Epub 2017 Feb 14.

²³ *Id.*

²⁴ *Id.*

²⁵ ’360 patent 129:34-38; *see also* ’994 patent 132:65-133:2.

²⁶ ’360 patent 126:3-5; *see also* ’994 patent 129:38-40.

Various publications, many authored or co-authored by Gilead employees, corroborate the patents and confirm that U.S. government scientists contributed to the invention of remdesivir:

- In a 2015 press release, Gilead stated that remdesivir “was discovered as part of Gilead’s program to screen compounds in its libraries for activity against a range of potential emerging viruses, including Ebola. In collaboration with the Centers for Disease Control and Prevention (CDC) and the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the company identified [remdesivir’s] *in vitro* activity against the Ebola virus.”²⁷
- A 2015 article in a trade journal stated that “the company [Gilead] and USAMRIID finally struck upon an effective dose” of remdesivir against Ebola in the spring of 2015.²⁸
- A 2016 press release from USAMRIID described “continuing collaborations between USAMRIID and Gilead Sciences,” with further contributions from “[s]cientists at the Centers for Disease Control and Prevention (CDC).”²⁹ According to USAMRIID’s press release, CDC scientists initially “identified the precursor to” remdesivir—GS-441524—“which led to the effort by Gilead and USAMRIID to further refine, develop and profile” remdesivir.³⁰ The joint public-private research team was “[l]ed by USAMRIID Science Director Sina Bavari” and “demonstrate[d] the compound’s antiviral activity against several pathogens, including Ebola virus.”³¹
- A 2016 paper entitled “Therapeutic efficacy of the small molecule GS-5734 [remdesivir] against Ebola virus in rhesus monkeys,” jointly published by scientists affiliated with Gilead, CDC, and USAMRIID, stated that a USAMRIID scientist, Travis K. Warren, “designed and supervised activities associated with efficacy evaluations, and interpreted study results,” while a mix of Gilead and U.S. government scientists collectively “designed experiments, evaluated results, and provided project oversight.”³²
- A 2017 paper jointly published by scientists affiliated with Gilead, CDC, and USAMRIID is explicit that remdesivir would not have been recognized as an antiviral compound without the contributions of the government scientists: “The partnership with government organizations, including CDC and USAMRIID, that generated the screening

²⁷ Press Release. Gilead Sciences, Gilead Provides Update on Investigational Compound, GS-5734, for the Treatment of Ebola Virus Disease, Oct. 21, 2015. URL: <https://www.businesswire.com/news/home/20151021005958/en/Gilead-Update-Investigational-Compound-GS-5734-Treatment-Ebola>. The press release used the term “GS-5734” to refer to remdesivir. As noted above, GS-5734 was Gilead’s internal name for remdesivir.

²⁸ Jarvis LM. *What We’ve Learned From The Race For An Ebola Cure*. CHEMICAL & ENGINEERING NEWS (Nov. 16, 2015), <https://cen.acs.org/articles/93/i45/ve-Learned-Race-Ebola-Cure.html>.

²⁹ *USAMRIID’s Small-Molecule Antiviral Shows Efficacy Against Ebola*. GLOBAL BIODEFENSE (Mar. 7, 2016), <https://globalbiodefense.com/2016/03/07/usamriids-small-molecule-antiviral-shows-efficacy-against-ebola/>.

³⁰ *Id.*

³¹ *Id.*

³² Warren TK et al. *Therapeutic efficacy of the small molecule GS-5734 against Ebola virus in rhesus monkeys*, NATURE. 2016 Mar 17;531(7594):381-5. doi: 10.1038/nature17180. Epub 2016 Mar 2.]

data and conducted the rhesus efficacy studies was critical to the successful identification of” remdesivir.³³

C. U.S. government scientists’ contributions likely make them co-inventors of the ’360 and ’994 patents.

Under U.S. patent law, the substantial intellectual contributions of USAMRIID and CDC scientists suggest they should be acknowledged as co-inventors of the ’360 and ’994 patents. A missing inventor should be added to a patent when she has collaborated with the patent’s named inventors, “contributed to the conception of the invention,” “made a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and did more than merely explain to the real inventors well-known concepts and/or the current state of the art.”³⁴

The evidence quoted above indicates that the intellectual contributions of scientists at USAMRIID and CDC likely meet this legal standard. There are two distinct ways in which USAMRIID and CDC scientists could qualify as co-inventors of the ’360 and ’994 patents, which we present below. The first is uncertain. The second seems rather clear.

1. U.S. government scientists may qualify as co-inventors of remdesivir itself

First, USAMRIID scientists may qualify as co-inventors of the compound itself. The public record is not entirely clear as to whether government scientists contributed to the chemical synthesis of remdesivir: for example, USAMRIID’s 2016 press release describes remdesivir as “USAMRIID’s small molecule” and discusses a joint “effort by Gilead and USAMRIID to further refine, develop and profile” GS-441524 (remdesivir’s predecessor compound),³⁵ but the 2016 *Nature* paper published by Gilead and U.S. government authors states simply that remdesivir was “synthesized at Gilead Sciences, Inc.”³⁶ and a 2015 publication describes Gilead scientists as having “come up with a prodrug of a nucleoside inhibitor, now called GS-5734,” in 2014.³⁷ If USAMRIID or CDC scientists did contribute to the synthesis of remdesivir, they may qualify as co-inventors of the compound on that basis.

But even if we assume that Gilead scientists synthesized remdesivir without help from USAMRIID or CDC, government scientists may still have contributed significantly to the legal “conception” of the compound—and thus its legal “invention”—if they conceived, developed, and executed the methods through which remdesivir’s bioactivity was detected, enabling the collaborative team to select remdesivir as the most promising drug candidate among the many

³³ Siegel et al., *supra* note 22.

³⁴ *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001) (alteration, citation, and internal quotation marks omitted). *See also Falana v. Kent State Univ.*, 669 F.3d 1349, 1357 (Fed. Cir. 2012).

³⁵ Global BioDefense, *supra* note 29

³⁶ Warren TK et al., *supra* note 32.

³⁷ Jarvis LM, *supra* note 28.

compounds tested. We are not aware of a Federal Circuit decision that addresses this precise legal question.

However, in a broadly similar district court case, a scientist at Brigham Young University contended that he had contributed to Pfizer scientists' invention of the drug celecoxib (brand name Celebrex) because he identified its bioactivity (inhibition of COX-2) and should therefore be named co-inventor on several of Pfizer's patents on the active compound.³⁸ The court held that "an inventor of a method may be entitled to joint inventorship on a patent that discloses only compounds if (1) the plaintiff conceived of a method; (2) that is outside the exercise of ordinary skill; and (3) is in fact used to create the compounds in the patent."³⁹ The court concluded that the contributions of the BYU scientist (Daniel Simmons) could suffice to merit co-inventorship, based on BYU's evidence "(1) that Simmons discovered COX-2 and conceived of a method for determining whether a compound was COX-2 selective; (2) that Simmons's contribution was greater than the exercise of ordinary skill; and (3) that Pfizer used Simmons's method in developing its own COX-2 inhibitor."⁴⁰ Pfizer had argued that Simmons's intellectual contribution—"a method for testing existent compounds for COX-2 selectivity rather than a method for synthesizing" celecoxib—was insufficient to merit co-inventorship, but the court disagreed.⁴¹ The court held that "[r]egardless of whether Simmons synthesized a new compound that could inhibit COX-2, or simply discovered that COX-2 existed and that an existent compound could inhibit it, his contribution would have the same effect in the end: providing the capability to develop COX-2 selective NSAIDs."⁴² The district court denied Pfizer's motion for summary judgment on the issue of inventorship,⁴³ and Pfizer ultimately settled with BYU for \$450,000,000 before the court could reach an ultimate judgment on inventorship.⁴⁴

BYU v. Pfizer is a modest precedent in any event, as it did not decide the ultimate question of inventorship and is non-binding district court authority. But under the reasoning of the *BYU v. Pfizer* decision, CDC and USAMRIID scientists may qualify as co-inventors of remdesivir itself because they may have "(1) conceived of a method; (2) that is outside the exercise of ordinary skill; and (3) is in fact used to create the compounds in the patent." According to USAMRIID's press release, the CDC "contributed by performing initial screening of the Gilead Sciences compound library to find molecules with promising antiviral activity," and USAMRIID scientist Sina Bavari led the research team that "used cell culture and animal

³⁸ *Brigham Young Univ. v. Pfizer, Inc.*, No. 2:06-CV-890 TS, 2012 WL 1015002, at *3 (D. Utah Mar. 22, 2012).

³⁹ *Id.* at *4.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Tom Harvey, *Pfizer, BYU settle Celebrex lawsuit for \$450M*, The Salt Lake Tribune (May 2, 2012), <https://archive.slttrib.com/article.php?id=54024947&itype=cmsid>.

models to demonstrate [remdesivir's] antiviral activity against several pathogens, including Ebola virus.”⁴⁵

More information would be helpful to determine whether these (and other) contributions of the CDC and USAMRIID scientists contributed sufficiently to conception to make them legal co-inventors. For example, the record that we have reviewed does not answer the important question of whether the assays used by CDC and USAMRIID scientists to identify remdesivir's promising activity were merely routine or instead qualified as “outside the exercise of ordinary skill.”⁴⁶ Members of the Gilead, USAMRIID, and CDC scientific teams may be able to shed more light on their respective roles and thus help to resolve the question of whether any U.S. government scientists made sufficient intellectual contributions to make them co-inventors of remdesivir itself. If so, these scientists should be named co-inventors of the '360 and '994 patents.

2. U.S. government scientists likely qualify as co-inventors of methods of using remdesivir.

Regardless of whether CDC or USAMRIID scientists meet the legal standard for co-inventorship of remdesivir itself, they likely qualify as co-inventors of the '360 and '994 patents because they contributed significantly to other claims of those patents: claims directed to methods of treating Ebola and other viruses by administering a therapeutically effective amount of remdesivir.⁴⁷ The public record seems to suggest strongly that Gilead and U.S. scientists worked together to uncover remdesivir's antiviral activity and develop methods of using remdesivir against Ebola and other viruses. If anything, the record shows that government scientists led this part of the collaborative team's work.

Gilead's own press release states that it was “[i]n collaboration with the Centers for Disease Control and Prevention (CDC) and the United States Army Medical Research Institute of Infectious Diseases (USAMRIID),” that “the company identified GS-5734 *in vitro* activity against the Ebola virus.”⁴⁸ USAMRIID's press release states that a joint Gilead-USAMRIID team led by Sina Bavari of USAMRIID “demonstrate[d] the compound's antiviral activity against several pathogens, including Ebola virus” and that “cell culture studies, led at USAMRIID by Veronica Soloveva” concluded that remdesivir was “active against a broad spectrum of viral pathogens,” including “Middle East Respiratory Syndrome (MERS) virus [a

⁴⁵ Global BioDefense, *supra* note 29.

⁴⁶ Perhaps these assays were outside the exercise of ordinary skill, given the dangers and difficulties associated with working with the Ebola virus.

⁴⁷ *See, e.g.*, '360 patent claim 7 (claiming, *inter alia*, a method of treating an Ebola virus infection by administering a therapeutically effective amount of remdesivir); '994 patent claim 6 (claiming, *inter alia*, a method of treating a Filoviridae infection by administering a therapeutically effective amount of remdesivir). (Filoviridae is the family of viruses that includes Ebola. *See* '994 patent 1:23.)

⁴⁸ Gilead press release, *supra* note 27.

type of coronavirus], Marburg virus, and multiple variants of Ebola virus.”⁴⁹ The 2016 *Nature* paper co-authored by Gilead, CDC, and USAMRIID scientists states that three CDC scientists (Michael K. Lo, Mike Flint, and Laura K. McMullan) “designed and executed the initial *in vitro* antiviral testing against [Ebola] and analysed data” while six USAMRIID scientists (Veronica Soloveva, Rouzbeh Zamani, Cary J. Retterer, Dima Gharaibeh, Tara Kenny, and Brett P. Eaton) “designed and executed cell-based infection assays and analysed these data.”⁵⁰ No Gilead scientists are mentioned in the 2016 *Nature* paper as having worked on these tests of remdesivir’s antiviral activity. This is consistent with the ’360 and ’994 patents themselves, which, as noted above, state that studies of remdesivir’s antiviral activity were conducted in CDC and USAMRIID laboratories.

If it is true, as the record seems to show, that CDC and/or USAMRIID scientists first identified remdesivir’s antiviral activity and conceived, on their own or in collaboration with Gilead scientists, methods of using remdesivir to treat viral infections, then these government scientists have made significant contributions to conception and are legally co-inventors of method claims of the ’360 and ’994 patents.⁵¹ And if these scientists are co-inventors of even one claim of the ’360 and ’994 patents, then, under U.S. patent law, they are legal co-inventors of the entire patents. “All inventors, even those who contribute to only one claim or one aspect of one claim of a patent, must be listed on that patent.”⁵² It therefore seems likely that U.S. government scientists should legally be deemed co-inventors of the ’360 and ’994 patents.

D. If U.S. government scientists co-invented the ’360 and ’994 patents, then the U.S. government is presumed co-owner of these patents and likely holds important legal rights.

If, as we suggest, USAMRIID and/or CDC scientists are true legal co-inventors of the ’360 and ’994 patents, the legal consequence is that the U.S. government is presumed to co-own these patents, along with Gilead. “[A] joint inventor as to even one claim enjoys a presumption of ownership in the entire patent.”⁵³ Patent law generally requires the patent document to indicate the true inventorship of a patent.⁵⁴ If U.S. government scientists met the legal requirements to merit co-inventor status, then they should legally be recognized as such.

⁴⁹ Global BioDefense, *supra* note 29.

⁵⁰ Warren TK et al., *supra* note 32.

⁵¹ *Supra* note 47.

⁵² *Vapor Point LLC v. Moorhead*, 832 F.3d 1343, 1348-49 (Fed. Cir. 2016).

⁵³ *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1465–66 (Fed. Cir. 1998).

⁵⁴ *See, e.g.*, 37 C.F.R. 1.41(a) (“An application must include, or be amended to include, the name of the inventor for any invention claimed in the application.”).

Patent inventorship cannot be waived or modified by contract.⁵⁵ It is, however, possible to change *ownership* by contract. There could exist a contract between Gilead and the U.S. government that compels the U.S. government to forfeit any ownership rights in these patents.⁵⁶ We do not know whether such an agreement exists in this case. In our view, CDC and USAMRIID should disclose any relevant agreements with Gilead, if they exist.

The '360 and '994 patents confer important legal rights over remdesivir—legal rights to exclude everyone but the patent owner from making, importing, using, or selling remdesivir in the U.S. without the patent owner's permission.⁵⁷ If Gilead is sole owner of the patents, then it alone holds these legal rights. But if the U.S. government co-owns these patents along with Gilead, then circumstances change. First, the U.S. government could itself make, import, use, or sell remdesivir without permission from or payment to Gilead (setting aside, for a moment, the question of other patents and intellectual property rights over remdesivir—more on those in the following section and in the Conclusion).⁵⁸ Second, the U.S. government could freely license its patent rights to remdesivir to Gilead's competitors—e.g., to generic manufacturers—without Gilead's consent.⁵⁹

If it is indeed true that USAMRIID and CDC scientists qualify as co-inventors, and those scientists were close collaborators with Gilead, the question arises of how the USAMRIID and CDC inventors were left off the '360 and '994 patents. Justin Hughes and Arti Rai recently concluded and reported that U.S. government scientists probably co-invented separate patents on therapeutic uses of remdesivir (on which more below).⁶⁰ Hughes and Rai have written that “given Gilead's public-minded stances on Covid-19 to date, we think one should assume a good-faith omission.”⁶¹ Given the apparently close, collegial collaboration between Gilead, USAMRIID, and CDC, we too assume a good faith omission.⁶² And we agree with Hughes and

⁵⁵ See, e.g., *Koehring Co. v. Etnyre and Co.*, 254 F. Supp. 334, 359 (D.D.C. 1966) (“The statutory requirement as to inventorship cannot be waived”); 3 *Moy's Walker on Patents* § 10:7 (4th ed.) (outside of interference proceedings, the law does “not open the door to the contractual transference of inventorship generally”).

⁵⁶ See *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248 (Fed. Cir. 1993) (“[I]nventorship and ownership are separate issues. . . . [T]he patent right initially vests in the inventor who may then, barring any restrictions to the contrary, transfer that right to another, and so forth.”).

⁵⁷ 35 U.S.C. § 271.

⁵⁸ 35 U.S.C. § 262 (“In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.”).

⁵⁹ *Schering Corp. v. Roussel-UCLAF SA*, 104 F.3d 341, 344 (Fed. Cir. 1997) (“Each co-owner's ownership rights carry with them the right to license others, a right that also does not require the consent of any other co-owner.”).

⁶⁰ Justin Hughes & Arti Rai. *Acknowledging the public role in private drug development: lessons from remdesivir*, STAT (May 8, 2020), <https://www.statnews.com/2020/05/08/acknowledging-public-role-drug-development-lessons-remdesivir/>.

⁶¹ *Id.*

⁶² In the event that some of the named inventors acted in bad faith and intentionally omitted CDC or USAMRIID scientists from the list of inventors, knowing that they qualified as co-inventors, a court could nonetheless correct the patents' inventorship and join the missing government scientists as co-inventors, so long as the government scientists themselves have acted in good faith. If “some or all of the original applicants to have acted with an

Rai that Gilead could work with the U.S. government to correct the record and add any missing USAMRIID or CDC scientists as co-inventors of the patents.⁶³

V. In addition, the U.S. government appears to hold other relevant patent rights on remdesivir.

It is common for multiple—even many—different patents to cover a single prescription drug.⁶⁴ The drug’s active compound (also known as the “active pharmaceutical ingredient”), its formulation, methods of using the drug, processes for manufacturing the active compound, and processes for manufacturing the formulation are all separately patentable. However, the “core” or “primary” patents covering the active compound itself tend to be the most commercially important.⁶⁵

Besides the ’360 and ’994 patents, we are aware of a few other commercially critical U.S. patents and patent applications on remdesivir. These can be divided into two groups: (A) patents covering large groups (“genera”) of compounds that encompass remdesivir and (B) a soon-to-issue patent on the method of using remdesivir to treat coronavirus infections. As Hughes, Rai, and Silverman recently reported,⁶⁶ U.S. government scientists appear to have co-invented the latter soon-to-issue patent, making the U.S. government its presumed co-owner.⁶⁷

A. The “genus patents”: U.S. Patent Nos. 8,008,264, 8,012,941, 8,318,682, and RE46,762

We are aware of four U.S. patents owned by Gilead—U.S. Patent Nos. 8,008,264, 8,012,941, 8,318,682, and RE46,762—that broadly claim very large groups (“genera”) of distinct chemical compounds. The claimed genera encompass remdesivir, meaning that the owner of these “genus patents” can use these patents to exclude others from making, importing, using, or selling remdesivir without permission.

offensive state of mind,” but “the other applicants or inventors to have proceeded innocently,” “[c]orrection remains available even if these already-named persons acted with deceptive intent.” 3 Moy’s Walker on Patents § 10:60 (4th ed.); see also *Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551, 1556 (Fed. Cir. 1997) (“[T]he district court’s reading of section 256 as limited to cases where both named and unnamed inventors acted without deceptive intent is too restrictive. Section 256 merely precludes any deceptive intention in the inventor that seeks to be restored to a rightful place in the patent.”).

⁶³ See 35 U.S.C. § 256; 37 C.F.R. § 1.324.

⁶⁴ I-MAK, OVERPATENTED, OVERPRICED: HOW EXCESSIVE PHARMACEUTICAL PATENTING IS EXTENDING MONOPOLIES AND DRIVING UP DRUG PRICES. (2018) URL: <https://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/>.

⁶⁵ See, e.g., Hemphill CS, Sampat BN. *Evergreening, patent challenges, and effective market life in pharmaceuticals*, J HEALTH ECON. 2012 Mar;31(2):327-39. doi: 10.1016/j.jhealeco.2012.01.004. Epub 2012 Feb 9. <https://www.sciencedirect.com/science/article/abs/pii/S0167629612000057?via%3Dihub>

⁶⁶ Ed Silverman, The U.S. government contributed research to a Gilead remdesivir patent — but didn’t get credit, STAT (May 8, 2020), <https://www.statnews.com/pharmalot/2020/05/08/gilead-remdesivir-covid19-coronavirus-patents/>; Hughes & Rai, *supra* note 60.

⁶⁷ *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d at 1465–66.

In 2008 and 2009, Gilead first filed the patent applications that matured into these patents, apparently before remdesivir itself had been synthesized and its antiviral properties appreciated.⁶⁸ However, under U.S. patent law, the patents may nonetheless cover remdesivir.

B. The “soon-to-be patent on treatment of COVID”: U.S. Patent Application No. 16/265,016.

We are aware of one U.S. patent application, U.S. Patent Application No. 16/265,016 (the “’016 application”), that is owned by Gilead and that covers methods of treating infectious COVID-19 and other coronaviruses. The ’016 application was published as U.S. Patent Application Publication No. US 2019/0255085 A1 and claims methods of treating *coronaviridae* infection⁶⁹ by administering remdesivir and related compounds. The ’016 application is not yet a patent, but, as of May 15, 2020, the USPTO had officially “allowed” the application for issuance as a patent, and Gilead had paid the issuance fee, suggesting the application is a “soon-to-be patent” on treatment of COVID, likely to issue as a patent within the next few months.

On May 8, 2020, Hughes, Rai, and Silverman reported that U.S. government scientists working with USAMRIID and CDC should probably have been named co-inventors of the soon-to-be patent on treatment of COVID.⁷⁰ Hughes and Rai wrote that “[o]ur own review of [remdesivir’s] development indicates that one or more government researchers should probably have been listed as inventors.”⁷¹ Hughes and Rai point to some of the same evidence we present above (§ IV.B), which “suggests that several U.S. government scientists contributed to the patented invention.”⁷²

If it is true that that U.S. government scientists co-invented the ’016 patent, the legal consequence is the same as with the ’360 and ’994 patents: barring some unknown agreement to the contrary, the U.S. government can claim co-ownership of this patent application, and thus a right to control who uses remdesivir to treat COVID-19.

⁶⁸ Gilead’s own fact sheet on remdesivir corroborates the fact that remdesivir was not invented until after 2009. It states that “research that led to remdesivir began as early as 2009” and that Gilead “continued to explore various uses for remdesivir following its discovery, including antiviral profiling in 2013 and early 2014 that suggested the potential for remdesivir to have broad spectrum antiviral activity.” Gilead, Development of Remdesivir, https://www.gilead.com/-/media/gilead-corporate/files/pdfs/covid-19/gilead_rdv-development-fact-sheet-2020.pdf.

⁶⁹ *Coronaviridae* is a family of viruses that includes the coronaviruses, including SARS-Cov-2, the strain of coronavirus that causes COVID-19.

⁷⁰ Silverman, *supra* note 66; Hughes & Rai, *supra* note 60.

⁷¹ Hughes & Rai, *supra* note 60.

⁷² *Id.*

VI. Conclusion: Some thoughts on the way forward

There is no dispute that the invention of remdesivir was the result of a collaboration between Gilead Sciences and the U.S. government, dependent on the use of federal laboratories and the insights of U.S. government scientists, all funded by the American public. Gilead's own press release and co-authored publications attest to these facts.

More than half a decade after remdesivir was discovered, the U.S. government continues to play a pivotal role in the development of the drug, with the first clinical trial showing a possible benefit of remdesivir therapy in COVID-19 patients being funded by the United States National Institute of Allergy and Infectious Diseases (NIAID).⁷³

The pharmaceutical industry has repeatedly told the public that the high prices charged for brand-name drugs are necessitated by the industry's massive investments in research and development.⁷⁴ Yet many experts believe that industry-sponsored estimates of the costs of drug development are broad overestimates,⁷⁵ and industry does not shoulder the costs of drug development alone. Indeed, Americans effectively pay at least twice for prescription drugs—once as their tax dollars fund R&D of new drugs and again at the pharmacy—and many patients are now at their breaking point.⁷⁶ When the American public's investment of tax dollars in biomedical research plays a critical role in the discovery and/or commercial development of a drug and thereby effectively socializes some of the risks of R&D—as it did in the case of remdesivir—we think it reasonable to argue that the pharmaceutical industry cannot expect to privatize all of the drug's profits.

If it is true, as we argue above, that the U.S. government co-invented remdesivir and yet failed to assert its rights over the drug, this would not be the first time. Time and again, the U.S. government has allowed private industry to monopolize and charge very high prices for life-saving drugs that public dollars created, in whole or in part, and over which the government holds powerful legal rights.⁷⁷

⁷³ NIAID, *supra* note 2. *see also* Public Citizen, *The Real Story of Remdesivir*. (7 May 2020). URL: <https://www.citizen.org/article/the-real-story-of-remdesivir/?eType=EmailBlastContent&eId=9bdafb07-71bb-41dc-8726-f80183f3f648>.

⁷⁴ *See, e.g.*, PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicine* (2015). URL: http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

⁷⁵ *See* Marcela Vieira, Knowledge Network on Innovation and Access to Medicines. *Research Synthesis: Costs of Pharmaceutical R&D*. (January 2020). URL: <https://www.knowledgeportalia.org/cost-of-r-d>.

⁷⁶ *See, e.g.*, Sainoto M. *Medication or housing?: why soaring insulin prices are killing Americans*. (23 Sept 2019). THE GUARDIAN. <https://www.theguardian.com/society/2019/sep/23/diabetes-americans-soaring-insulin-prices>.

⁷⁷ *See, e.g.*, Thomas JR. *March-In Rights Under the Bayh-Dole Act*. Congressional Research Service. (2016) URL: <https://fas.org/sgp/crs/misc/R44597.pdf>.

The parallels between the invention of remdesivir and the invention of HIV pre-exposure prophylaxis (HIV PrEP) are striking. A once-a-day pill (e.g., tenofovir disoproxil/emtricitabine, sold by Gilead under the brand name Truvada), HIV PrEP is one of the most effective methods of HIV prevention known, reducing the risk of HIV transmission by 99%.⁷⁸ HIV PrEP was invented by government scientists at the CDC⁷⁹ and was later shown to be safe and effective by multiple U.S. government-funded clinical trials.⁸⁰ The U.S. government obtained multiple U.S. patents on its invention, beginning in 2015,⁸¹ but for nearly half a decade allowed Gilead to infringe on its patents even as Gilead's high prices kept HIV PrEP out of reach for many patients⁸² and as over a hundred thousand Americans were newly diagnosed with HIV infection.⁸³ Yet, in late 2019, CDC and the Department of Health and Human Services (HHS) did eventually exercise their patent rights on behalf of the American people and bring a patent infringement lawsuit against Gilead.⁸⁴ (We and PrEP4All had advocated that CDC and HHS bring this suit.⁸⁵) The U.S. government's lawsuit, if used wisely, could bring down the price of HIV PrEP and expand access to PrEP to hundreds of thousands of Americans currently at risk of HIV.⁸⁶

CDC and USAMRIID appear now to have an opportunity to exercise a different set of patent rights to expand access to remdesivir and, perhaps, help defeat COVID-19: their rights over the patents on remdesivir that we have described above. CDC, USAMRIID, and all of HHS must do everything they can to ensure universal, equitable, global access to remdesivir, should the drug prove safe and effective.

So, what is the path forward? Ideally, Gilead will, of its own initiative, commit to low-cost pricing and ensure that there is universal, equitable, global access to remdesivir, with robust worldwide manufacturing. Already Gilead has voluntarily licensed its intellectual property to

⁷⁸ See, e.g. Anderson PL et al. *Emtricitabine-tenofovir Concentrations and Pre-Exposure Prophylaxis Efficacy in Men Who Have Sex With Men*. SCI TRANSL MED. 2012 Sep 12;4(151):151ra125. doi: 10.1126/scitranslmed.3004006.

⁷⁹ See, e.g., U.S. Patent No. 9,044,509.

⁸⁰ See, e.g. Grant RM et al. *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex With Men*. N ENGL J MED. 2010 Dec 30;363(27):2587-99. doi: 10.1056/NEJMoa1011205. Epub 2010 Nov 23.

⁸¹ Christopher Rowland, *An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions*. Washington Post (Mar. 26, 2019), https://www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html.

⁸² Walensky RP, Paltiel AD. PrEP School: A Field Manual For The Battle Over HIV Prevention Drug Pricing. HEALTH AFFAIRS (2019). URL <https://www.healthaffairs.org/doi/10.1377/hblog20190826.11005/full/>

⁸³ Centers for Disease Control and Prevention. *HIV Surveillance Report, 2018 (Updated)*; vol. 31. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2020.

⁸⁴ McNeil D, Mandavilli A. *Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says*. (Nov 8, 2019) THE NEW YORK TIMES. URL: <https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html>

⁸⁵ Press Release. Yale Law School, GHJP Joins PrEP4All in Calling on CDC To Use Its Patents for PrEP. (March 27, 2019) URL: <https://files-profile.medicine.yale.edu/documents/c87d1300-7026-4af8-b0f8-178fd16ac2ff0>

⁸⁶ Morten CJ, Kapczynski A. *United States v. Gilead: Can a Lawsuit Yield Better Access To PrEP?* (November 18, 2019). HEALTH AFFAIRS. URL: <https://www.healthaffairs.org/doi/10.1377/hblog20191118.218552/full/>

competitor manufacturers in 127 countries,⁸⁷ though many access-to-medicines experts argue that these voluntary licenses do not do enough to ensure global access.⁸⁸ Public Citizen has argued that Gilead could and should price remdesivir at \$1 per patient per day—a price at which Gilead would still earn a reasonable profit.⁸⁹ We hope that Gilead learns from its past mistakes and commits this time to global fair pricing.

But the U.S. government must make clear that access to remdesivir is not a voluntary choice but a requirement. In the event that access challenges in the United States arise as a result of Gilead’s decisions regarding licensing, manufacturing, distribution, or pricing, the U.S. government can and must take swift action to protect public health. Under an existing federal law codified at 28 U.S.C. § 1498, the U.S. government has the right to “use” or “manufacture” any patented technologies, at will, without the permission of the patent owner.⁹⁰ The patent owner may then take the United States to court to claim “reasonable and entire compensation” for use of any valid, infringed patents the government does not have rights to, compensation typically set by the court as a reasonable royalty.⁹¹

Under 28 U.S.C. § 1498, HHS has the power to authorize generic manufacturers to make and distribute low-cost remdesivir, quickly introducing competition into the U.S. market in the event that Gilead overcharges or is unable to meet demand.⁹² The U.S. government always holds the “government patent use” power under section 1498, even when it funded none of the R&D on the patented technology and owns or co-owns none of the relevant patents. But if it is true, as we suggest above, that the U.S. government co-owns the key patents on remdesivir itself, as well as the separate (soon-to-be-) patent on treating COVID-19 with remdesivir, then section 1498 becomes more appealing from the government’s (and public’s) perspective: the “reasonable and

⁸⁷ Silverman E. *Gilead signs licenses for generic companies to make and sell remdesivir in 127 countries*. (May 12, 2020) STAT. URL <https://www.statnews.com/pharmalot/2020/05/12/gilead-generics-remdesivir-covid19-coronavirus-licenses/>

⁸⁸ *See, e.g.*, Public Citizen, *Remdesivir Should Be in the Public Domain; Gilead’s Licensing Deal Picks Winners and Losers*. (May 12, 2020) URL: <https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/>

⁸⁹ Public Citizen, *Remdesivir Should Be in the Public Domain; Gilead’s Licensing Deal Picks Winners and Losers*. (May 4, 2020). URL: <https://www.citizen.org/news/gilead-should-price-remdesivir-at-1-per-day/>

⁹⁰ 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 (2017); *see also* Christopher Morten & Charles Duan, *Who’s Afraid of Section 1498?: Government Patent Use as Versatile Policy Tool*, guest post on Written Description (April 24, 2020), <https://writtendescription.blogspot.com/2020/04/whos-afraid-of-section-1498-government.html>.

⁹¹ *Id.*

⁹² If Gilead obtains FDA approval of remdesivir, Gilead may obtain a separate form of intellectual protection granted by the FDA known as “data exclusivity” or “marketing exclusivity.” Should HHS decide to help a generic manufacturer bring a generic version of remdesivir to market, any FDA-granted exclusivity would need to be dealt with separately, as section 1498 applies only to patents.

entire compensation” the government will owe for use of any patents the government turns out to co-own will be zero.⁹³

We note that even government patent use under section 1498 would not and should not preclude Gilead from being financially rewarded, and celebrated, for its genuine contributions to the inventorship and development of remdesivir. Should HHS decide to use 1498 to accelerate generic competition and expand the supply of remdesivir, Gilead would still receive “reasonable and entire compensation” under the law.⁹⁴ And Gilead’s scientists should be praised for their central roles in developing this potentially life-saving compound—as should the CDC, USAMRIID, and NIAID scientists who have also made vital contributions.

A final note: the analysis presented in this report is based solely on a limited amount of publicly available information. There is much we still do not know about the discovery and development of remdesivir. To understand more fully the inventorship and ownership of the patents that cover various aspects of remdesivir, we need more information. In our view, the CDC and USAMRIID should disclose all agreements between themselves and Gilead that governed their collaboration. Patients, policymakers, and the public all have a right to know whether the U.S. government holds significant legal rights to this potentially vital drug.

⁹³ The Court of Federal Claims (CFC), where section 1498 claims are adjudicated, appears capable of determining the inventorship of U.S. patents. *See, e.g., Univ. of S. Fla. v. United States*, 146 Fed. Cl. 274, 281 (2019); *Garrett Corp. v. United States*, 422 F.2d 874, 881 n.5 (Ct. Cl. 1970). Should HHS authorized generic manufacture of remdesivir and should Gilead and the United States litigate at the CFC, the court should be able to investigate any inventive contributions of CDC and USAMRIID inventors.

⁹⁴ *Supra* note 90.