

9-25-2021

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Recommended Citation

Caleb Holland, *"PrEP"aring for a Challenge to Government-Owned Patents*, 70 *Cath. U. L. Rev.* 493 (2021).
Available at: <https://scholarship.law.edu/lawreview/vol70/iss3/11>

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Cover Page Footnote

Caleb Holland is a J.D. graduate of The Catholic University of America Columbus School of Law with a background in health science, completing his B.S. in Biology and graduate certificate in Global Health at Old Dominion University. The author would like to thank Luis E. Zambrano Ramos for his advice and guidance, and the Catholic University Law Review for its invaluable support in editing this Comment.

“PREP”ARING FOR A CHALLENGE TO GOVERNMENT-OWNED PATENTS

Caleb A. Holland⁺

The word “patent” traces its origin to the Latin word “patere”—to be open.¹ Indeed, the underlying impact of a patent system is that it promulgates the open exchange of information to disseminate new ideas into the public sphere.² The concept of a government-owned patent, however, can run contrary to this ideal. While the number of government-owned patents has waned in recent years, the United States Government was granted over 1,000 utility patents in 2019 alone.³ Interestingly, despite owning such a prodigious patent estate, it surprisingly does not often sue for patent infringement.⁴ To understand why, it is necessary to understand the nature of an American patent — from its Constitutional origins, to judicial interpretations, and finally to modern statutory refinements. In addition to understanding patents, one needs to have an appreciation of the unique status the United States government holds as an entity that both issues and owns patents. Public policy norms and historical traditions have constrained much of what the government has chosen to do with its patents, but a recent confrontation between the Department of Health and Human Services and pharmaceutical company Gilead Sciences, Inc. is challenging those norms and traditions.⁵ In refusing to accept a license for usage of the CDC-owned patent

⁺ Caleb Holland is a J.D. graduate of The Catholic University of America Columbus School of Law with a background in health science, completing his B.S. in Biology and graduate certificate in Global Health at Old Dominion University. The author would like to thank Luis E. Zambrano Ramos for his advice and guidance, and the *Catholic University Law Review* for its invaluable support in editing this Comment.

1. 1 JOHN GLADSTONE MILLS III ET AL., PAT. L. FUNDAMENTALS § 1:1 (2d ed. 2020).

2. *Effective Use of Government-Owned Rights to Inventions: Publication Versus Patenting*, 55 GEO. L. J. 1083, 1084 (1967) [hereinafter *Publication Versus Patenting*] (“The purpose of the patent laws is primarily to channel significant inventions swiftly into the mainstream of the economy.”).

3. See Captain Steven R. Fuscher, USAF, *How the Government Obtains Patent Rights Under the ASPR and FPR Patent Rights Clauses – Part I: When Is the Government Entitled to Patent Rights?*, 20 A.F.L. REV. 209, 209 (1978) (explaining that between 1970 and 1975 alone, the U.S. Government received 52,996 invention disclosures from approximately \$100 billion dollars in research and development); see also U.S. Patent and Trademark Office, *Patenting by Organizations (Utility Patents) 2019, Part A1- Table A1-1b, Breakout by Ownership Category* (2019). https://www.uspto.gov/web/offices/ac/ido/oeip/taf/topo_19.htm#PartA1_1b

4. See Thomas Lizzi, *From Benevolent Administration to Government Employee Inventions, Human Genomes, and Exclusive Licensing: Is Governmental Ownership of Patents Constitutional?*, 34 DUQ. L. REV. 299, 300–01 (1996).

5. Complaint at 3, *United States v. Gilead Scis., Inc.*, No. 1:19-cv-02103-UNA (D. Del. filed Nov. 6, 2019).

for PrEP, Gilead could be testing the limits of what the government is willing to do with its patents.

This Comment will examine the nature of government-owned patents and attempt to answer the question why the government has heretofore been reticent to exercise its patent rights against infringers. Finally, this Comment will look specifically at the case of *United States v. Gilead Sciences, Inc.* and provide observations as to potential implications that could result from the suit, and ultimately will probe whether or not the federal government can or should take action when its patent rights are infringed.

I. BACKGROUND AND PRIOR LAW

A. *The Origins of Patents in the United States*

One of the earliest known acquisitions of patent rights by the United States federal government dates back to 1812, with an Act of Congress that appropriated sixty thousand dollars for the purchase of technology related to the lighting of lighthouses.⁶ Since that time the government has acquired thousands of patents through similar modes of acquisition, as well as by acquiring rights and licenses through the theory of “shop right”⁷ and by directly filing for patents in its name on behalf of its employees.⁸ But what does the government do with its patent estate? What *can* the government do with its patents? To understand these questions, one must examine the nature of a patent right, as well as the different scenarios that could implicate the government’s patents.

The ability to patent is so important to our society that its roots trace back to the Constitution.⁹ Congress was given the enumerated power to “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[.]”¹⁰ This clause is commonly known as the “Intellectual Property Clause.”¹¹ Patents and copyrights as we know them in the United States are Congress’ way of exercising this Constitutional prerogative.¹² It is helpful to understand that a patent is, at bottom, a contract between the patent-holder and

6. Act of March 2, 1812, ch. 34, 2 Stat. 691.

7. JOHN GLADSTONE MILLS III ET AL., PAT. L. BASICS § 12:10 (Nov. 2020) (explaining that “[t]he Supreme Court developed the concept of shop right as a form of equitable compensation for situations where the employer has financed an employee’s invention by providing wages, materials, tools, and a work place.”).

8. See Lizzi, *supra* note 4, at 305–06.

9. U.S. CONST. art. I, § 8, cl. 8.

10. *Id.*

11. David L. Lange, *The Intellectual Property Clause in Contemporary Trademark Law: An Appreciation of Two Recent Essays and Some Thoughts About Why We Ought to Care*, 59 SPG L. & CONTEMP. PROBS. 213, 213 (1996); see also *Allen v. Cooper*, 140 S. Ct. 994, 1001 (2020).

12. *Publication Versus Patenting*, *supra* note 2, at 1084.

the government.¹³ In exchange for the rights attendant to owning a patent, the inventor must disclose information to the public.¹⁴ Therefore, while securing to inventors the ability to profit from their achievements is certainly a collateral effect of patents—and additionally incentivizes the patenting of new inventions and discoveries—it is arguably not the primary purpose of a patent.¹⁵ Ultimately, society is the key benefactor of patents; new information begets new discovery and, therefore, society progresses.

Patents have been described as limited monopolies,¹⁶ but this definition does not take into account the appropriate nuance of patents. While patents are traditionally viewed as property, they do not fall neatly within the paradigm of either real or personal property.¹⁷ The key to understanding this is to recognize that the essential element of a patent is the property right of exclusion.¹⁸ To illustrate, assume that one invents, uses, and markets a new product. That inventor did not need a patent to grant them the ability to invent, use, or market that product. In fact, one cannot even obtain a patent until the product has itself been sufficiently realized to qualify for the patent.¹⁹ Instead, obtaining a patent provides the patent-holder with the critical right to prevent (i.e., exclude) others from making and marketing the same invention.²⁰ Therefore, owning a patent does not actually grant the patent-holder the “positive” rights to create and use, but rather the “negative” right to exclude others from making the same invention.²¹ This exclusionary right seems, on some level, to be at odds with “promot[ing] the [p]rogress of [s]cience and useful [a]rts.”²² However, this is reconciled when viewed in light of the way patents function overall to bring forth new information into the public consciousness.

Philosophical distinctions notwithstanding, patents have common elements that have been outlined by statute.²³ While the intricacies of patent law are numerous and generally beyond the scope of this article, it is still useful to have a basic understanding of these fundamental elements. Inventions are patent-eligible if they fall into at least one of four categories: “processes or methods;

13. *Id.*

14. *Id.*

15. *Id.*

16. See Lizzi, *supra* note 4, at 302 (citing PETER D. ROSENBERG, PAT. L. BASICS §1.03 (1993)).

17. Sean M. O’Connor, *Taking, Tort, or Crown Right?: The Confused Early History of Government Patent Policy*, 12 JOHN MARSHALL REV. INTELL. PROP. L. 145, 146 (2012).

18. *Id.* at 147.

19. Lizzi, *supra* note 4, at 303–04 (providing the requirements of patentability).

20. *Publication Versus Patenting*, *supra* note 2, at 1084–85 (“The most active use of a patent occurs through the exercise of . . . exclud[ing] others from making, using, or selling the invention.”).

21. O’Connor, *supra* note 17, at 147.

22. U.S. CONST. art. 1, § 8.

23. 35 U.S.C. § 101.

[]machines or apparatuses; []manufactures; and []compositions of matter.”²⁴ Within these categories, patent applications must satisfy the statutory conditions of utility, novelty, and non-obviousness of the subject matter.²⁵ The Supreme Court has carved out three exceptions to patentability: laws of nature; physical phenomena; and abstract ideas.²⁶ The patents examined later in this Comment are presumed valid for the sake of argument.

B. Patents vs. Copyrights

Notably lacking in the above-mentioned history and purpose of patents is the ability, right, or authority of the government to grant patents to itself or to otherwise acquire patent rights. In fact, a significant number of commenters have suggested that there is no constitutional basis for the government to own patents at all.²⁷ This quirk of the law is even more puzzling considering that government ownership of the other part of the intellectual property clause – copyrights – has been thoroughly examined and addressed by United States

24. Elizabeth D. Lauzon, Annotation, *Patentability Under 35 U.S.C.A. § 101 Which Excludes Laws of Nature, Physical Phenomena, and Abstract Ideas*, 5 A.L.R. Fed. 3d. Art. 4 § 2 (2015) (ALR is updated weekly).

25. See 35 U.S.C. §§ 101–103. § 103 states:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. §103. See generally, U.S. PAT. & TRADEMARK OFF., *General Information Concerning Patents*, (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents>.

26. Because “[l]aws of nature, natural phenomena, and abstract ideas are ‘the basic tools of scientific and technological work[.]’” the Supreme Court has expressed concern that monopolizing these tools by granting patent rights may impede innovation rather than promote it. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014). See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71(2012). However, the Court has also emphasized that an invention is not considered to be ineligible for patenting simply because it involves an abstract concept. *Alice Corp.*, 573 U.S. at 217 (citing *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)); see also *Thales Visionix, Inc. v. United States*, 850 F.3d 1343, 1349 (Fed. Cir. 2017) (“That a mathematical equation is required to complete the claimed method and system does not doom the claims to abstraction.”). Accordingly, the Court has said that an application of an abstract idea, law of nature, or natural phenomenon may be eligible for patent protection. *Alice Corp.*, 573 U.S. at 217 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). U. S. PAT. & TRADEMARK OFF., *2106 Patent Subject Matter Eligibility [R-10.2019]*, <https://www.uspto.gov/web/offices/pac/mpep/s2106.html>.

27. See *Publication Versus Patenting*, supra note 2, at 1088; Frank J. Willie, *Government Ownership of Patents*, 12 *FORDHAM L. REV.* 105, 111 (1943); see generally Lizzi, supra note 4, at 299.

law.²⁸ As a matter of public policy, the government has, originally through judicial decision and eventually through statutory enactment, determined that there must be some restriction on ownership of copyrights in government publications.²⁹ In sum, the courts found that because “such material as the laws and governmental rules and decisions must be freely available to the public and made known as widely as possible . . . there must be no restriction on the reproduction and dissemination of such documents.”³⁰ In regard to state government documents, the courts determined that while statutes and decisions were not eligible for copyright, the added material such as “headnotes, syllabi, annotations, indexes, etc.” was deemed eligible.³¹ The courts did not have occasion to determine whether copyright eligibility also applied to the federal government.³² This idea of a distinction between government related documents that were and were not copyrightable has been referred to as the “public policy rule”³³ which essentially means that government publications were not eligible for copyright.³⁴ Congress first codified this position with the Printing Act of 1895.³⁵ Today, the prohibition still exists as a provision of the Copyright Act of 1976,³⁶ codified in Title 17 of the United States Code.³⁷ The end result of this policy is that, with few exceptions,³⁸ nearly anyone may copy, disseminate, or otherwise use documents or data produced by federal agencies, with no need for a license, notice, or royalties.³⁹

What is important to note about the government’s position on copyrights is that the branches of government recognized early in our nation’s history that public policy demanded limitations on the government’s use of the intellectual property clause of the Constitution. Government-owned patents, on the other

28. See generally STAFF OF S. COMM. ON PAT., TRADEMARKS, AND COPYRIGHTS, 86TH CONG., COPYRIGHT LAW REVISION: STUDIES PREPARED FOR THE SUBCOMM. ON PATENTS, TRADEMARKS, COPYRIGHT IN GOVERNMENT PUBLICATIONS 27 (Comm. Print 1961).

29. *Id.* at 27. See also 17 U.S.C. § 105(a) (“Copyright protection under this title is not available for any work of the United States Government”)

30. STAFF OF S. COMM. ON PAT., TRADEMARKS, AND COPYRIGHTS, 86TH CONG., COPYRIGHT LAW REVISION: STUDIES PREPARED FOR THE SUBCOMM. ON PATENTS, TRADEMARKS, COPYRIGHT IN GOVERNMENT PUBLICATIONS 27 (Comm. Print 1961).

31. *Id.* at 28.

32. *Id.*

33. *Id.*

34. *Id.* at 29.

35. *Id.*

36. Robert M. Gellman, *Twin Evils: Government Copyright and Copyright-Like Controls Over Government Information*, 45 SYRACUSE L. REV. 999, 1024–25 (1995).

37. 17 U.S.C. § 105 (“Copyright protection under this title is not available for any work of the United States Government, but the United States Government is not precluded from receiving and holding copyrights transferred to it by assignment, bequest, or otherwise.”).

38. For exceptions, see e.g. 15 U.S.C. § 290e; U.S. COPYRIGHT OFFICE, INTRODUCTION TO THE THIRD EDITION OF THE COMPENDIUM OF U.S. COPYRIGHT OFFICE PRACTICES 30–31(3d ed. 2017).

39. See Gellman, *supra* note 36, at 1026.

hand, did not receive such attention. One possible explanation for this is that, while not mandated by statute, the traditional policy of the United States has been to issue an applicant a non-exclusive, royalty-free license to a patent if requested.⁴⁰ It has been speculated that this benign position has resulted in a lack of challenges to government patent ownership.⁴¹

C. What Does the Government Patent, and How Does it do it?

The United States spends significant amounts of tax-payer dollars on research and development in various industries and fields of study. The most recently available data at the time of writing indicates that the United States government spent over 580 billion dollars on these endeavors in 2018 alone.⁴² Some of the earliest examples of government patent ownership relate to war-related technology.⁴³ Indeed, even today the majority of research and development spending is devoted to national defense, with health, space, general science, energy, agriculture, and national resources & environment constituting the remainder.⁴⁴ The fruit of this research is often patented in some form or another.⁴⁵ It is not surprising, therefore, that the government is consistently one of the largest patent holders in the United States.⁴⁶

Appreciating the role of research and development in government patents is critical for the purposes of this Comment because it directly precipitated the two main theories that exist today regarding government-owned patents.⁴⁷ The debate over the government's role in patenting government-financed inventions traces back to the 1800s.⁴⁸ However, the significance of this debate certainly grew in proportion to the substantial increase in government spending on research and development during and after the Second World War.⁴⁹

40. *Publication Versus Patenting*, *supra* note 2, at 1091.

41. Lizzi, *supra* note 4, at 299. It is also worth noting that issues surrounding copyrights are tangential to free speech issues, which is another possible reason why copyrights have been given more attention than patents. Further, it is possible that copyrights had to be dealt with because of the universal need for citizens to be aware of the law. No such universal need exists with patents, which could also explain why copyrights have been restricted differently than patents.

42. JOHN F. SARGENT, JR., CONG. RSCH. SERV., R44307, U.S. RESEARCH AND DEVELOPMENT FUNDING AND PERFORMANCE: FACT SHEET (2020).

43. O'Connor, *supra* note 17, at 154–55 (In 1836, Congress authorized the purchase of two patents from Captain William H. Bell, both relating to cannon technology. In 1846, Congress authorized the purchase of a machine called a “manger stopper” for “all ships of war or other vessels belonging to the United States”).

44. Sargent, *supra* note 42, at 2.

45. *Publication Versus Patenting*, *supra* note 2, at 1083.

46. *See supra* note 3.

47. Josh Lerner, *Patent Policy Innovations: A Clinical Examination*, 53 VAND. L. REV. 1841, 1852 (2000).

48. *Id.*

49. *Id.*

D. How the Government Acquires Patent Rights

Patents are statutorily treated as personal property.⁵⁰ This includes the right of assignment and the ability to grant and convey, in whole or in part, any interest in a patent to the United States government.⁵¹ While the government may utilize one of these methods to acquire patent rights, perhaps the most common method of attainment is through inventions developed by its employees.⁵² The concept of “shop right” is a common law doctrine developed by the United States Supreme Court, which provides that when an employer has provided the means—i.e., tools, materials, wages, etc.—for developing an invention, that employer is entitled to some form of equitable compensation.⁵³ That “compensation” is usually manifested as a vested right to an “irrevocable, equitable license to use the invention.”⁵⁴ Shop right has been extended to the federal government.⁵⁵ It is important to note that a shop right is not by definition confined to the employee-employer relationship; the full nature of the relationship considering all facts and circumstances are taken into account to determine the existence of a shop right.⁵⁶

Aside from shop right, there are other ways under common law that an employer can come to own or at least rightfully use an employee’s patent.⁵⁷ The baseline assumption is that the rights to an invention belong to the inventor, and “[a]bsent an agreement to the contrary, an employer does not have rights in an invention ‘which is the original conception of the employee alone.’”⁵⁸ This is premised on the fact that “original conception” excludes the usage of an employer’s resources; in other words, if an employer provided the necessary means to bring an invention to fruition, they facilitated the invention in such a way as to preclude a finding of “original conception of the employee alone.”⁵⁹ In these instances, the employer is entitled to an irrevocable, royalty-free license.⁶⁰ Two other common exceptions exist to the general rule, which says

50. 35 U.S.C. § 261 (“Subject to the provisions of this title, patents shall have the attributes of personal property.”).

51. *Id.*

52. See Lizzi, *supra* note 4, at 305.

53. MILLS III ET AL., *supra* note 7.

54. *Id.*

55. Lizzi, *supra* note 4, at 305 (citing *United States v. Dubilier Condenser Corp.*, 289 U.S. 178 (1933) stating that the federal government has the common law right, i.e. shop right, to an employee’s inventions).

56. *Id.* at 304.

57. See Paul Spiel, *Express Employee Patent Assignments: Staying True to Intellectual Property’s Credo of Rewarding Innovation*, 99 J. PAT. & TRADEMARK OFF. SOC’Y 79, 84 (2017).

58. *Bd. of Trs. of the Leland Stan. Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776, 777 (2011) (explaining that “[s]ince 1790, patent law has operated on the premise that rights in an invention belong to the inventor.”).

59. See Spiel, *supra* note 57, at 84.

60. MILLS III ET AL., *supra* note 7.

that inventors own their inventions.⁶¹ These include an express contract, in which consideration would be paid to the inventor in return for the invention, and, relatedly, in the circumstance where an employee has been hired to exercise his “inventive faculties” for a specific project.⁶²

As noted above, the common law doctrine of shop right extends to the federal government as an employer.⁶³ However, a combination of executive orders and statutory enactments laid the groundwork for the current paradigm of how the government handles inventions by its employees.⁶⁴ Two reports, commissioned by President Franklin Roosevelt shortly after the start of the Second World War, articulate the debate.⁶⁵ The first report, created by the National Patent Planning Commission (the “Commission”), recognized that the traditional position of the government was to issue non-exclusive, royalty-free licenses stemming from patents held by non-defense agencies.⁶⁶ The report noted that some government-owned patents should be commercialized and made available to the public; however, the policy of freely granting licenses acted as an impediment to that commercialization.⁶⁷ The Commission believed that, if substantial capital and investment were required on the part of a private business, that business would be less likely to incur those expenses if they could not be guaranteed the commercial advantage of an exclusive license.⁶⁸ The Commission’s recommendation was not to fully endorse granting exclusive licenses, but to posit that licensing practices should be allowed to vary among the different government agencies.⁶⁹ This selective granting of licenses has far reaching implications, which will be discussed further in the Comment.

A second report by the Department of Justice argued that exclusive licenses should be forbidden, except in extraordinary circumstances.⁷⁰ The report pointed out that innovations funded by the public should be for the benefit of the public.⁷¹ If a license was granted which created a purely private monopoly, the public could be asked to pay for—or even be denied access to—technology which was already publicly funded.⁷² Three years after the release of the Department of Justice report, in 1950, President Truman issued Executive Order

61. See Spiel, *supra* note 57, at 84.

62. *Id.*

63. Lizzi, *supra* note 4, at 305.

64. *Id.* at 299.

65. Lerner, *supra* note 47, at 1852–53 (citing H.R. Doc. No. 79-22 (1945)).

66. *Id.*

67. *Id.* at 1853.

68. H.R. Doc. No. 79-22, at 5–6 (1945).

69. *Id.* at 7.

70. Lerner, *supra* note 47, at 1853.

71. *Id.*

72. *Id.*

10096.⁷³ The Order established new policy that called for the government to obtain:

[T]he entire right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.⁷⁴

Importantly, under this Order the government reserved the right to grant licenses “for all governmental purposes.”⁷⁵ While statistical analysis of licensing government patents in the immediate aftermath of this Order is lacking, commenters have noted that the frequency of awarding exclusive licenses to contractors and government employees is perhaps higher than would be expected given the recommendations of the Commission and Department of Justice reports.⁷⁶

Congress has worked to strike a balance between encouraging innovation and protecting government rights. The Bayh-Doyle Act, passed in 1980, gave small businesses and nonprofit organizations, including universities, the right to patent inventions made with federal funds.⁷⁷ Section 200 of Title 35 of the United States Code says, in part, “[i]t is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . .” and “to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions”⁷⁸ Another example of Congress applying statutory conditions on the patent system can be found in the Invention Secrecy Act.⁷⁹ As noted above, a significant portion of patents are in the realm of national defense. Unsurprisingly, some of the information and discoveries contained in those patents could be damaging to national security were it to enter into the wrong hands. Congress passed the Invention Secrecy Act of 1951 to allow the United States Patent and Trademark Office (“USPTO”) the ability to order certain inventions be kept secret.⁸⁰ As patent applications are reviewed upon initial receipt at the USPTO, the Commissioner of Patents can order that the invention be kept secret if it is determined that publication or disclosure of the invention

73. Exec. Order No. 10096, 3 C.F.R. 76–78 (1950).

74. *Id.* at 76.

75. *Id.*

76. Lerner, *supra* note 47, at 1853.

77. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3018 (1980) (codified as 35 U.S.C. §§ 200–206).

78. *Id.*

79. Invention Secrecy Act, 35 U.S.C. §§ 181–88.

80. James Maune, *Patent Secrecy Orders: Fairness Issues in Application of Invention of Secrecy Act*, 20 TEX. INTELL. PROP. L.J. 471, 472 (2012).

(i.e., granting a patent for the invention) “would be detrimental to national security.”⁸¹ As of 2010, over 5,000 United States patents were subject to a secrecy order in some form.⁸² In this we see an example of Congress bending the overall policy goal of the patent system — promoting progress of science and useful arts — to yield to a different goal of protecting national security.

E. Relationship Between the Federal Government and Patent Infringement

Patent infringement is the equivalent of a violation of one’s right to exclude. When a private party seeks remedy for patent infringement by another private party, several options are available.⁸³ These include money damages, including royalties and interest, and an injunction.⁸⁴ Are these same remedies available when the government is a party in the infringement action? Is the answer different depending on if the government is a plaintiff or a defendant?

An infringement of rights is an action in tort, rather than in property.⁸⁵ However, as stated above, patent rights do have qualities of real and personal property.⁸⁶ It follows, then, that if the *government* infringes on a *privately-owned* patent, and subsequently renders the only meaningful component of a patent—the right to exclude—meaningless, this is effectively a taking under the Fifth Amendment.⁸⁷ Still, courts in the United States have ruled that government infringement of patents is not a “taking” because of 14 U.S.C. § 1498, something commonly referred to as the “Government Use Statute.”⁸⁸ This statute provides that the only remedy patent-holders may seek against the government will be fair compensation in the Court of Federal Claims.⁸⁹ Prior to this statute, the status of remedies for government infringement was murky: patent grants were not truly established as property rights until 1870 in the

81. *Id.*

82. *Id.*

83. Lizzi, *supra* note 4, at 304–05.

84. *Id.*

85. O’Connor, *supra* note 17, at 146–47.

86. *See infra* Sec. I.

87. O’Connor, *supra* note 17, at 151.

88. *Id.*

89. 28 U.S.C. § 1498(a) (providing that “[w]hen an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license . . . the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”).

Supreme Court case of *Seymour v. Osborne*,⁹⁰ and sovereign immunity precluded suit against the United States, absent consent from Congress.⁹¹

The "Government Use Statute" tracks closely with the English doctrine of "Crown Right," which allows the British Government to practice any patent that it grants.⁹² A key difference, however, is that the Government Use Statute requires fair compensation, whereas Crown Right does not.⁹³ For this reason, the Supreme Court has consistently rejected Crown Right in the United States.⁹⁴ An 1878 decision by the United States Court of Claims is enlightening in this regard, as it pointed out that the United States did not view patents as favors or privileges that can be granted or withdrawn on the whim of a sovereign, but rather as rights to be secured with the attendant condition of just compensation for unjust appropriation.⁹⁵ The first case brought against the United States for patent infringement was the case of *Pitcher v. United States* in 1863, but that case was ultimately unsuccessful due to lack of jurisdiction.⁹⁶

Today, significant debate persists over the government as an actor in the patent system. The overall landscape is much clearer today than it was in 1863, but government patent policy in general is still very much evolving.⁹⁷ Key to this Comment is the fact that there are virtually no cases in which the government has sued a private actor for infringement of a government-owned patent, particularly in the pharmaceutical context.⁹⁸ One extremely rare exception can be found in a case brought before the United States International

90. *Seymour v. Osborne*, 78 U.S. 516, 533 (1870) (stating "inventions secured by letters patent are property in the holder of the patent, and as such are as much entitled to protection as any other property, consisting of a franchise, during the term for which the franchise or the exclusive right is granted.").

91. *See, e.g., Schillinger v. United States*, 155 U.S. 163, 166 (1894) (stating "[t]he United States cannot be sued in their courts without their consent").

92. O'Connor, *supra* note 17, at 151.

93. *Id.*; 28 U.S.C. § 1498(a).

94. O'Connor, *supra* note 17, at 152.

95. *Id.* at 164 (quoting *McKeever v. United States*, 14 Ct. Cl. 396, 421 (1878)).

96. *Id.* at 156–57 (citing *Pitcher v. United States*, 1 Ct. Cl. 7 (1863)). In sum, the case was over a machine utilized by a prison warden to have inmates manufacture brooms. At the time, patent infringement was treated as a tort, and the United States could not be sued for tortious acts. Pitcher attempted other arguments based on the Takings Clause and a theory of implied contract, but the court was unpersuaded. *Id.*

97. *Id.* at 204 (explaining that several nuances and unresolved issues still exist in government patent policy).

98. Christopher Rowland, *An HIV Treatment Cost Taxpayers Millions. The Government Patented it. But a Pharma Giant is Making Billions.*, WASH. 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 (explaining that the current standoff between the CDC and Gilead is "extraordinary" and that intellectual-property disputes between the government and private pharmaceutical companies are rare).

Trade Commission (“ITC”) in 1984.⁹⁹ There, the ITC, on its own motion, instituted an investigation to determine if certain Swedish and American companies had violated Section 337 of the Tariff Act of 1930 by importing products that infringed on patents owned by the Department of Agriculture.¹⁰⁰ A split Commission recommended that the investigation be terminated on a technicality, and thus the case was never decided.¹⁰¹ However, even if this case had been decided on the merits and found in favor of the government, the primary remedy available to the ITC is to direct Customs to stop any products from coming into the country.¹⁰² Whether or not this would have resulted in significant implications to the patent system is unclear.

F. Constitutional Infirmary of Government Owned Patents

To fully understand the footing of the government when it comes to what it can and cannot do with its patents, it is helpful to understand the constitutional arguments against government ownership of patents in the first place. As stated above, patents are contracts with the government.¹⁰³ For the “consideration” of public disclosure of an invention, the government grants the patent-owner the right to exclude others from making that invention for a limited time.¹⁰⁴

99. *Certain Apparatus for Flow Injection Analysis & Components Thereof*, Inv. No. 337-TA-151, USITC Pub. (Nov. 1984) (Final).

100. *Id.* at *1, *4. The ITC is one of the few places where patent challenges can be heard. *About Unfair Import Investigations*, USITC, https://www.usitc.gov/intellectual_property/about_section_337.htm (last visited January 11, 2021). According to the ITC website:

Unfair import (a.k.a Section 337) investigations conducted by the U.S. International Trade Commission most often involve claims regarding intellectual property rights, including allegations of patent infringement and trademark infringement by imported goods. Both utility and design patents, as well as registered and common law trademarks, may be asserted in these investigations. Other forms of unfair competition involving imported products, such as infringement of registered copyrights, mask works or boat hull designs, misappropriation of trade secrets or trade dress, passing off, and false advertising, may also be asserted.

Id. This provision essentially states that importation of goods into the United States using unfair trade practices are unlawful. 19 U.S.C. § 1337(a).

101. *Certain Apparatus for Flow Injection Analysis & Components Thereof*, Inv. No. 337-TA-151, USITC Pub. at *4 (Nov. 1984) (Final) (finding that the investigation had to be vacated because the investigation was based on the original claims and the claims of the reexamined patent did not match the claims in the original patent).

102. *About Unfair Import Investigations*, *supra* note 100. The key here is to note that the ITC has limited enforcement capabilities: “The primary remedy available in Section 337 investigations is an exclusion order that directs Customs to stop infringing imports from entering the United States. In addition, the Commission may issue cease and desist orders against named importers and other persons engaged in unfair acts that violate Section 337. Expedited relief in the form of temporary exclusion orders and temporary cease and desist orders may also be available in certain exceptional circumstances.”

103. See *Publication Versus Patenting*, *supra* note 2, at 1084.

104. Lizzi, *supra* note 4, at 302–03.

Therefore, to best serve the public policy goal behind granting patents, it follows that the disclosure be made available to the public as soon as possible.¹⁰⁵

If the government becomes the party to which that right is granted, that relationship reduces to one party: the government has now made a contract with itself.¹⁰⁶ This implicates a myriad of issues of contract law, including the sovereign merger doctrine, which essentially states that if a right issued by a sovereign returns to the sovereign it is extinguished.¹⁰⁷ In other words, “the patent becomes a nullity by the very incidence of governmental ownership.”¹⁰⁸

Even if we assume that the patents are legally valid, credible arguments can be made that the government having the power to exclude (i.e., the essential right bestowed upon a patent holder) does not serve the public policy interest of the patent system envisioned by the Framers.¹⁰⁹ First, the purpose behind granting a right to exclude is to reward and incentivize inventors to invent new things.¹¹⁰ The government already has a Constitutional mandate to spend money for the public good, so this incentive is largely irrelevant to the government as a patent holder.¹¹¹ Second, the sheer size and resources of the government apparatus may have the effect of stifling innovation from private companies who do not wish to compete with the government in acquiring or utilizing a contested patent.¹¹² Finally, the government exercising ownership of patents can have the effect of restricting or removing information from the public domain, limiting free access to information that was paid for with public funds.¹¹³

105. Willie, *supra* note 27, at 106. (“Public policy would seem compellingly to require that an invention, as soon as it is made and disclosed, should be available to the public.”). *Id.*

106. Lizzi, *supra* note 4, at 317–18 (explaining five reasons based on contract law principles why government-owned patents are unconstitutional: (1) there must be two parties to a contract; (2) “contract merger doctrine,” which states that if the “promise returns to the hands of the promisor . . . the contract is extinguished”; (3) “the federal government lacks the capacity to” make a valid patent contract “of its own issue”; (4) unenforceability of illegal contracts, i.e., that the Intellectual Property Clause disallows government patent ownership and thus any such patent would be a contract for an illegal purpose; (5) sovereign grant merger doctrine, i.e. the patent “is void because the patent rights are extinguished upon their return to the hands of the sovereign which issued them and cannot constitute the valuable consideration necessary to sustain a valid contract.”).

107. *Id.* at 316 (The idea of sovereign merger was spoken about by a former Commissioner of Patents as early as 1928 and was traced back to Thomas Paine).

108. Lizzi, *supra* note 4, at 316.

109. *Id.* at 312 (explaining that government ownership of patents inhibits the “progress of the useful arts” in several significant ways); *see also* 35 U.S.C. § 271(a) (“Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

110. Lizzi, *supra* note 4, at 312.

111. *Id.*

112. *Id.* at 312–13.

113. *Id.* at 313–14.

G. Case Study: PrEP, Truvada, Gilead, and DHHS.

Amid the recent furor over high prescription drug prices in the United States, one drug in particular has been highlighted by advocacy groups pushing for reform.¹¹⁴ Truvada is a medication manufactured by pharmaceutical company Gilead Sciences, Inc.¹¹⁵ Truvada is the brand name for a single pill that contains two medications: 300 mg of TDF (tenofovir disoproxil fumarate) and 200 mg of FTC (emtricitabine).¹¹⁶ TDF and FTC are drugs used to treat persons infected with HIV to prevent the development of AIDS (acquired immunodeficiency syndrome).¹¹⁷ Truvada was approved by the FDA in 2004 for HIV treatment, but recently has been used not only to treat persons with HIV, but also as a prophylactic drug that can prevent new HIV infections.¹¹⁸ This concept has been called pre-exposure prophylaxis, or “PrEP”.¹¹⁹ The need for such a drug cannot be understated. Globally, almost 38 million people are living with HIV with 1.7 million individuals newly infected in 2018 alone.¹²⁰ In the United States, roughly 1.2 million people live with HIV and approximately 14 percent (one in seven) of those do not know that they are infected.¹²¹ Since the beginnings of the epidemic in the early 1980s, over 700,000 people have died from AIDS in the United States.¹²² The first drug approved by the FDA for treating AIDS came in 1987, with a drug known as azidothymidine (AZT).¹²³ However, HIV replicates quickly, and mutations in the virus led to pharmaceutical resistance.¹²⁴ Over the next several years, numerous medications were developed which eventually led to the advent of combination therapy, which allowed for durable suppression of HIV to undetectable levels

114. Rowland, *supra* note 98.

115. Drug Database: *Emtricitabine / Tenofovir Disoproxil Fumarate*, U.S. DEPT. OF HEALTH & HUMAN SERVS. (Feb. 10, 2020) <https://clinicalinfo.hiv.gov/en/drugs/emtricitabine-tenofovir-disoproxil-fumarate/patient>.

116. *See supra* note 115.

117. *Id.*

118. *Id.* *See also* U.S. Food & Drug Admin., *Drug Approval Package*, TRUVADA (Emtricitabine and Tenofovir Disoproxil Fumarate) Tablets, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_TruvadaTOC.cfm.

119. *Id.*

120. *HIV Basics: Overview: Data & Trends: U.S. Statistics*, DEPT. OF HEALTH & HUM. SERVS. (June 30, 2020), <https://www.hiv.gov/hiv-basics/overview/data-and-trends/global-statistics>.

121. *Id.*

122. *The HIV/AIDS Epidemic in the United States: The Basics*, KAISER FAM. FOUND. (Mar. 25, 2019), <https://www.kff.org/hivaids/fact-sheet/the-hivaids-epidemic-in-the-united-states-the-basics/>.

123. *Antiretroviral Drug Discovery and Development*, NAT'L INST. OF ALLERGY AND INFECTIOUS DISEASES (Nov. 26, 2018), <https://www.niaid.nih.gov/diseases-conditions/antiretroviral-drug-development>.

124. *See generally* Stanford University HIV Drug Resistance Database, Primer on HIV Resistance (last updated Sept. 23, 1999), <https://hivdb.stanford.edu/pages/documentPage/primer.html>

by using two or three drugs simultaneously.¹²⁵ One of those drugs is Truvada, which was approved by the FDA in 2004 for the treatment of HIV.¹²⁶ By and through a series of experiments conducted by the CDC in the mid-2000s, it was discovered that the components of Truvada were effective at *preventing* HIV infection.¹²⁷ Based on those CDC studies, Gilead received approval from the FDA in 2012 to sell Truvada as a PrEP regimen.¹²⁸ PrEP is remarkably effective at preventing HIV transmission from sex and injection drug use: when taken consistently, PrEP reduces the risk of HIV infection from sex by 99%, and by at least 74% from injection drug use.¹²⁹ The potential impact on the spread of HIV is enormous, and in fact has already been documented in other countries. For example, Australia introduced a program of government-funded Truvada/PrEP for high-risk Australian men in New South Wales, and experienced a twenty-five percent drop in new HIV diagnoses in just one year — reaching the lowest number of new diagnoses in the area since recording began in 1985.¹³⁰ According to Gilead's sales reports, sales of HIV and HBV products (including Truvada's newer version, Descovy) topped \$14.2 billion in 2017 alone, representing a significant portion of Gilead's total product revenue for the year.¹³¹ The current monthly cost for a daily supply of Truvada approaches \$2,000.¹³² This represents a 45% increase since Truvada was first approved for PrEP in 2012.¹³³ Reports indicate that these same pills cost only \$6 per month outside of the United States.¹³⁴

125. *Id.*

126. *FDA in Brief: FDA continues to encourage ongoing education about the benefits and risks associated with PrEP, including additional steps to help reduce the risk of getting HIV*, U.S. FOOD & DRUG ADMIN. (July 1, 2019), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-continues-encourage-ongoing-education-about-benefits-and-risks-associated-prep>.

127. Complaint at 1, *United States v. Gilead Scis., Inc.*, No. 1:19-cv-02103-UNA (D. Del. filed Nov. 6, 2019).

128. *Truvada FDA Approval History*, DRUGS.COM, <https://www.drugs.com/history/truvada.html> (last visited Mar. 7, 2021).

129. *PrEP Effectiveness*, CTR. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html> (last updated Nov. 3, 2020).

130. Nina Avramova, *PrEP can 'significantly' reduce HIV rates across populations, study says*, CNN (Oct. 17, 2018, 3:00 PM), <https://www.cnn.com/2018/10/17/health/hiv-reduction-men-prep-australia-intl-study/index.html>.

131. Press Release, Gilead, *Gilead Sciences Announces Fourth Quarter and Full Year 2017 Financial Results* (Feb. 6, 2018), <https://www.gilead.com/news-and-press/press-room/press-releases/2018/2/gilead-sciences-announces-fourth-quarter-and-full-year-2017-financial-results>.

132. Shefali Luthra & Anna Gorman, *Rising Cost of PrEP to Prevent HIV Infection Pushes it Out of Reach for Many*, NPR (June 30, 2018, 6:00 AM), <https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many>.

133. *Id.*

134. *See GHJP Joins PrEP4All in Calling on CDC to Use Its Patents for PrEP*, YLS TODAY (Mar. 27, 2019), <https://law.yale.edu/yls-today/news/ghjp-joins-prep4all-calling-cdc-use-its-patents-prep>.

H. Patent Conflicts Between the United States and Gilead

The United States has recently filed a civil suit against Gilead under 35 U.S.C. § 271 *et seq.* for infringement of four patents held by the CDC.¹³⁵ The government contends that these patents collectively represent the CDC's groundbreaking work in discovering PrEP, i.e., that a combination of TDF and FTC (i.e., Truvada) could be taken to prevent HIV infection.¹³⁶ It is undisputed that Gilead developed Truvada, i.e., the combination of TDF and FTC into a single pill.¹³⁷ The issue in the suit is over the fact that Gilead markets and sells Truvada as a medication for PrEP, which (allegedly) violates the patents held by the CDC.¹³⁸ The CDC claims that it has repeatedly tried to work with Gilead to develop a licensing agreement whereby Gilead can market Truvada as PrEP for a reasonable licensing fee.¹³⁹ Not only has Gilead refused to enter into such an agreement, but they assert that the CDC's patents are invalid.¹⁴⁰ While no court or review board has yet made such a determination, industry commenters have evaluated the patents and found no reason to believe that, if subjected to legal challenge, the patents in question would be found invalid.¹⁴¹ This Comment will assume for the purposes of the overarching argument relating to government usage of government-held patents that the patents would be held valid.

Gilead's patent on pharmaceutical combinations of TDF and FTC (i.e., Truvada) runs through 2021, and as such there is no currently available generic in the United States market.¹⁴² Outside of the United States, however, one company sells generic equivalents in several countries including "Canada, Germany, France, Australia, and the United Kingdom[.]"¹⁴³ As further evidence that a challenge to the CDC's patents would be unsuccessful, a challenge was made by generic drug manufacturer Mylan to the international counterpart to the

135. Complaint at 3, *United States v. Gilead Scis., Inc.*, No. 1:19-cv-02103-UNA (D. Del. filed Nov. 6, 2019) (The four patents are U.S. Patent Nos. 9,044,509, 9,579,333, 9,937,191, and 10,335,423. The patents are referred to collectively as "the Patents-in-Suit").

136. *Id.* at 1.

137. *Id.* at 10.

138. *Id.* at 2–3.

139. *Id.* at 57–59.

140. Eric Sagonowsky, *Gilead loses first PrEP patent challenge but vows to defend against HHS lawsuit*, FIERCEPHARMA (Feb. 7, 2020, 8:35 AM), <https://www.fiercepharma.com/pharma/gilead-loses-first-prep-patent-challenge-but-vows-to-defend-against-hhs-lawsuit>.

141. Christopher Morten, *Statement on CDC's Patents for PrEP*, YALE GLOB. HEALTH JUST. P'SHIP 2 (Mar. 12, 2019), https://law.yale.edu/sites/default/files/area/center/ghjp/documents/ghjp_mortenstatement.pdf.

142. Gilead recently announced it had struck a deal with generic drug maker Teva to bring a generic Truvada to market one year ahead of schedule, at some time in 2020. As of the time of this writing no generic is yet available in the United States market. See Richard Morgan, *HIV prevention drugs illustrate just how bad pharmaceutical patents are for our health*, NBC NEWS (Dec. 1, 2020), <https://www.nbcnews.com/think/opinion/hiv-prevention-drugs-illustrate-just-how-bad-pharmaceutical-patents-are-ncna1249428>.

143. Complaint at 56, *United States v. Gilead Scis., Inc.*, No. 1:19-cv-02103-UNA (D. Del. filed Nov. 6, 2019).

CDC's patents-in-suit before the European Patent Office.¹⁴⁴ The CDC's European patent survived the challenge and is still in force today.¹⁴⁵ As a result, Mylan entered into a settlement agreement with the CDC and agreed to pay the CDC royalties.¹⁴⁶ Another pharmaceutical manufacturer, TAD Pharma GmbH, has taken a similar license "to sell a generic equivalent to Truvada for PrEP in Germany."¹⁴⁷ The details of these settlement licensing agreements are not known, but the payment amounts collected from Mylan have been described as "small."¹⁴⁸ Still, advocacy groups point out that the CDC extracting licensing fees from foreign manufacturers makes a low-cost generic drug more expensive in countries abroad.¹⁴⁹ This is particularly unpalatable given that the only manufacturer allowed to sell to American consumers is, as of now, *not* paying a licensing fee and charging much higher prices than the foreign manufacturers who *do* pay the fees.¹⁵⁰

Advocacy groups have been calling for the CDC to leverage its patents for PrEP for the benefit of the American people.¹⁵¹ Specifically, the PrEP4All Collaboration ("PrEP4All") has joined with the Yale Global Health Justice Partnership (GHJP) with a call for the CDC to force Gilead to pay a royalty and to use the proceeds to promote public access to PrEP.¹⁵² PrEP4All and GHJP have outlined several elements that should be included in any agreement between Gilead and the CDC:

- Payment by Gilead of royalty revenues not just for future use of the CDC's patents for PrEP but also for past infringement.
- A licensing structure under which Gilead continues to pay royalties, even in the event that Gilead obtains FDA approval for PrEP with a newer branded product, Descovy (emtricitabine and tenofovir alafenamide) tablets.
- A bar prohibiting Gilead from increasing the price of Truvada or Descovy as a result of the licensing agreement.
- Transparent payment of royalties by Gilead and transparent investment of the royalty revenue by CDC.

144. Morten, *supra* note 141, at 7.

145. *Id.*

146. Ed Silverman, *AIDS activists skewer CDC for conflicting stance on collecting HIV drug royalties*, (Apr. 10, 2019), <http://web.archive.org/web/20190411172712/https://www.statnews.com/pharmalot/2019/04/10/aids-cdc-hiv-patents-royalties/>.

147. Complaint at 57, *United States v. Gilead Scis., Inc.*, No. 1:19-cv-02103-UNA (D. Del. filed Nov. 6, 2019).

148. Ed Silverman, *supra* note 146.

149. *Id.*

150. *Id.*; see also Luthra, *supra* note 132.

151. *GHJP Joins PrEP4All in Calling on CDC to Use Its Patents for PrEP*, *supra* note 134.

152. *Id.*

- Use of CDC's royalty revenue to fund "wrap-around" services and programs, such as laboratory tests and clinical care, that enable vulnerable Americans to access PrEP.
- Provision by the CDC of low-cost PrEP, whether low-cost branded Truvada or a generic alternative, to public health programs and clinics serving vulnerable communities.¹⁵³

A March 2019 Washington Post article highlighted some of the reasons why the government has been slow to aggressively act against Gilead for infringement.¹⁵⁴ After years of collaboration, an interdependence has developed between government research and private drug companies.¹⁵⁵ The government historically has sought to encourage commercialization of its research, not stifle the dissemination of new medical breakthroughs by bringing patent infringement lawsuits.¹⁵⁶ While the companies may be making a profit, at the end of the day they are producing lifesaving drugs on which millions of Americans rely. Importantly, however, it should be noted that the government routinely *licenses* these discoveries.¹⁵⁷

President Trump announced in his 2019 State of the Union address a goal of eradicating HIV/AIDS by 2030.¹⁵⁸ Dr. Anthony Fauci of the National Institute of Allergy and Infectious Diseases later elaborated that the administration would rely on two strategies to accomplish this goal: "antiretroviral medications and the increased use of preventative drugs", e.g., Truvada for PrEP.¹⁵⁹ President Trump subsequently called for \$291 million dollars in his proposed 2020 budget to fund the initiative, \$140 million of which would go, in part, to providing treatment and medications used for PrEP.¹⁶⁰ This represents an eighteen percent increase in the CDC's HIV prevention funding above the previous fiscal year.¹⁶¹ It is important to note that in addition to concerns over drug prices, education

153. *GHJP Joins PrEP4All in Calling on CDC to Use Its Patents for PrEP*, YLS TODAY (Mar. 27, 2019), <https://law.yale.edu/yls-today/news/ghjp-joins-prep4all-calling-cdc-use-its-patents-prep>.

154. Rowland, *supra* note 98.

155. *Id.*

156. *Id.*

157. *Id.*

158. *In State of Union, Trump Announces Plan to Target HIV Hot Spots in Ambitious Goal to Reduce New Infections*, KHN MORNING BRIEFING (Feb. 6, 2019), <https://khn.org/morning-breakout/in-state-of-union-trump-announces-plan-to-target-hiv-hot-spots-in-ambitious-goal-to-reduce-new-infections/>.

159. *Id.*

160. Lena H. Sun, *Trump budget calls for \$291 million to fund HIV initiative*, WASH. POST (Mar. 11, 2019), <https://www.washingtonpost.com/health/2019/03/11/trump-budget-calls-million-fund-hiv-initiative/>.

161. *Id.*; *CDC HIV Prevention Funding, FY 1981 – FY 2020 Budget Request (BR)*, KAISER FAM. FOUND. (Mar. 11, 2019), <https://www.kff.org/hiv/aids/slide/cdc-hiv-prevention-funding-fy-1981-fy-2020-budget-request-br/>.

programs for both patients and healthcare providers are equally critical in the overall effort to end the HIV/AIDS epidemic. For example, the American South had 20,000 new HIV diagnoses in 2017 — more than the remaining regions of the United States combined.¹⁶² A combination of “stigma, poverty, inadequate access to health care and lingering racial bias” is to blame for this surprising statistic.¹⁶³ Still, the issue of education and awareness is directly linked to drug prices. For example, Virginia Medicaid pays \$54.04 per pill (over \$1600 per month) of Truvada.¹⁶⁴ That takes away from the funding available to provide the educational programming necessary for outreach. Even President Trump’s \$291 million dollars in allocated funding comes as part of an overall package that *reduces* total funding to Medicaid.¹⁶⁵

For its part, Gilead makes several contentions in rebuttal, namely that the government’s PrEP patents are either invalid or at least do not reflect Gilead’s own contributions to the research, and that Gilead has been active in finding solutions to high prices and other barriers to widespread PrEP usage in high-risk populations.¹⁶⁶ Gilead points out that they offer discount coupons for uninsured patients to reduce their monthly costs, and that it has spent almost \$140 million dollars since 2012 on grants and programs to promote education and raise awareness.¹⁶⁷

II. A WAY FORWARD: QUESTIONS AND IMPLICATIONS

The government’s recent action to sue Gilead for infringement raises several questions. Assuming the patent is valid, what kind of damages can the government expect to recover? Will it be enough to make a meaningful impact in the fight against the HIV/AIDS epidemic, either by funding the purchase of Truvada for usage as PrEP or by establishing enough education and outreach programs to make a meaningful difference? If so, what kind of impact could be expected on the relationship between the CDC and drug manufacturers which have previously worked together in partnership? In other words, if the government were to win the suit, would it result in pharmaceutical companies being less willing to market potentially life-saving drugs to new consumers, ultimately slowing progress in health research and discovery? And finally, does this challenge put the entire government-owned patent paradigm under a spotlight that might expose the entire system to accusations of unconstitutionality?

162. Lenny Bernstein, *This HIV pill saves lives. So why is it so hard to get in the Deep South?*, WASH. POST (Mar. 11, 2019), https://www.washingtonpost.com/national/health-science/this-hiv-pill-saves-lives-so-why-is-it-so-hard-to-get-in-the-deep-south/2019/03/11/a221a784-354a-11e9-854a-7a14d7fec96a_story.html.

163. *Id.*

164. Rowland, *supra* note 98.

165. Bernstein, *supra* note 162.

166. Rowland, *supra* note 98.

167. *Id.*

The 1947 Department of Justice report warned against the concern of double billing taxpayers — once for the research, and again to buy the fruits of that research.¹⁶⁸ This is a crucial component of the argument that advocacy groups make to encourage the government to engage in enforcement actions against Gilead — that the taxpayer has paid for the research that discovered PrEP and pharmaceutical companies (like Gilead) unjustly reap the benefit of that taxpayer investment.¹⁶⁹ Title 35 of the United States Code specifically states that it is the “*objective* of Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development[.]”¹⁷⁰ However, this comes with the crucial caveat that the patent system also “meet the needs of the Government and protect the public against . . . the unreasonable use of inventions[.]”¹⁷¹

If the government prevails in its suit and is able to extract damages and fees from Gilead, that money could be used for lifesaving programs and medications. This also means that in some ways the patent system remains virtually unscathed: a party who infringes upon a patent is liable for damages. There is certainly room for the argument that the government should be treated as a private patent holder, and that the “government-owned” aspect doesn’t impact whether or not a valid patent was infringed. However, the reality is that the government as a patent owner is unique. Were the government to act on its patents to exclude others, they could be defeating the purpose sought by our country’s Framers of promoting progress and the advancement of society.¹⁷²

In truth, the relationship between government health research and private pharmaceutical companies is a well-established relationship. It has only been recently, with enormous spikes in drug prices, that public outrage has led to a close examination of this system. This might suggest that if the government were to disturb the system by suddenly taking patents on offense, the relationship could become seriously unbalanced. A disruption could result in negative health outcomes for millions of Americans across a broad range of health issues, from high blood pressure to cancer. However, if the current system is no longer working, a realignment of the relationship may be necessary for long-term benefits and for the advancement of health research into the future.

Finally, by taking a protective stance over its patent collection, the government is in effect removing publicly funded inventions from the reach of the public. However, as shown by the fact that the CDC routinely licenses its patents for nominal fees,¹⁷³ it seems unlikely that any seismic shift in the landscape would result. The key is in crafting a licensing agreement that encourages companies to be reasonable in their pricing schemes while also

168. Lerner, *supra* note 47, at 1853; *see infra* Sec. I.D.

169. *Our Story*, PREP4ALL, <https://www.prep4all.org/our-story> (last visited March 17, 2021).

170. 35 U.S.C. § 200 (emphasis added).

171. *Id.*

172. *See infra* Sec. I.F.

173. *See infra* Sec. I.

ensuring that the public is not unfairly charged for inventions and discoveries for which they have already paid. It is a novel idea for the government to wield its patent estate for public policy goals, but one that has enormous potential. If the government prevails in its suit against Gilead, it is almost guaranteed that we would see more of these actions in the future. Such power is also rife with potential for abuse, and advocates should be mindful that if the government succeeds in this case it will theoretically have the power to selectively withhold licenses from certain individuals in the name of policy goals. As the guiding ideology of our political system is subject to change every two to four years, the possibility of corruption and uncertainty could have a net negative effect on progress in various fields of study.

III. CONCLUSION

The government is one of the largest owners of United States patents, yet surprisingly does not often sue private parties for infringement. One reason for this is that the legality of the patent estate remains somewhat unsettled. Issues stemming from the language of the Constitution itself underlie concerns ranging from contract theory to untenable public policy positions. More obviously, however, there simply hasn't been occasion for any court to consider the issue. This may change, however, if the government prevails in its first-of-its-kind suit against Gilead. Ultimately, it remains to be seen how the courts will treat a challenge brought by the government for infringement, but surely these issues and more will inform the court's thinking and possibly even its decision.

