IN THE UNITED STATES COURT OF FEDERAL CLAIMS

GILEAD SCIENCES, INC., Plaintiff, v. THE UNITED STATES OF AMERICA, Defendant.	Case No. _____

COMPLAINT

Plaintiff Gilead Sciences, Inc. ("Gilead"), through its undersigned counsel, hereby alleges as follows:

NATURE OF THE CASE

1. This is an action for breach of contract arising out of the violation of four Material Transfer Agreements (the "MTAs") and a Clinical Trial Agreement (the "CTA") by the United States of America (the "Government"), acting through the Centers for Disease Control and Prevention ("CDC").

2. Gilead brings this suit because the Government is asserting patents that it secretly obtained in violation of the collaboration agreements that Gilead entered into and executed in good faith.

3. Gilead has been at the forefront of scientific efforts to identify and develop effective treatments for HIV for over three decades. As a result of Gilead's investments in research and development, Gilead has helped change HIV from a death sentence to a manageable and preventable condition for over a million Americans. Gilead has consistently developed innovative, first of their kind HIV treatment and prevention therapies, including Truvada® and

Truvada® for PrEP, and has brought to market more than a dozen products that have been approved by the U.S. Food and Drug Administration ("FDA") for the treatment and prevention of HIV.

4. Throughout its history and continuing through today, Gilead has collaborated in good faith with CDC on various research studies relating to the use of antiretroviral agents for prevention of HIV-1. As part of these collaborations, Gilead scientists have shared their significant expertise in the field of HIV with CDC researchers, including by providing ideas and guidance, and Gilead has provided CDC with millions of dollars of pharmaceuticals—at no cost to CDC—to further the scientific community's efforts to end the HIV epidemic.

5. This case arises out of a specific series of interactions and two sets of contracts in that ongoing collaboration.

6. First, beginning in 2004, Gilead and CDC entered into numerous MTAs, pursuant to which Gilead agreed to provide CDC with significant quantities of Gilead compounds free of charge. The Government, in return, "agree[d] to promptly notify" Gilead of "any Inventions" under the MTAs, which the agreements defined as "any inventions, discoveries and ideas that are made, conceived or reduced to practice." The Government likewise agreed "to give serious and reasonable consideration to [Gilead's] request for a non-exclusive or exclusive license on commercially reasonable terms under [the U.S. Public Health Service]'s intellectual property rights in or to any Inventions."

7. In compliance with its obligations under the MTAs, Gilead repeatedly delivered the compounds that CDC requested in a timely manner. On information and belief, CDC utilized the compounds that Gilead provided in the studies contemplated by the MTAs, as well as in other, related studies.

8. Second, Gilead and the Government, acting through CDC, also entered into a Clinical Trial Agreement with an effective date of November 18, 2004. This agreement set forth the terms under which Gilead would provide antiviral products free of charge for a clinical trial about HIV prevention in Botswana. The Government agreed, among other things, "to put the results of the Trial, patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC." "For clarity," the CTA provided, "CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial."

9. In compliance with its obligations under the CTA, Gilead provided to CDC compounds and placebos at no cost. On information and belief, CDC utilized the compounds that Gilead provided in the Botswana trial contemplated by the CTA.

10. The Government breached its obligations under both the MTAs and the CTA.

11. On February 3, 2006, CDC filed Provisional Patent Application No. 60/764,811 (the "'811 Provisional") with the U.S. Patent and Trademark Office ("PTO") related to purported inventions that CDC made in the course of the research conducted under the MTAs, and using the compounds that Gilead provided under the MTAs. On January 31, 2007, non-provisional patent Application No. 11/669,547 (the "'547 Application") was filed, claiming priority to the '811 Provisional. On information and belief, CDC relied on information derived from the Botswana clinical trial to make decisions concerning the prosecution of the '547 Application.

12. U.S. Patent No. 9,044,509 (the "'509 Patent") issued from the non-provisional '547 Application on June 2, 2015. Three other U.S. patents—U.S. Patent Nos. 9,579,333 (the "'333 Patent"), 9,937,191 (the "'191 Patent"), and 10,335,423 (the "'423 Patent"; together with the '509 Patent, the '333 Patent, and the '191 Patent, the "HHS Patents")—that claim priority to

the same provisional and non-provisional applications have since issued. On information and belief, the HHS Patents are owned by the Government, represented by the U.S. Department of Health and Human Services ("HHS").

13. In spite of the express terms of the MTAs requiring CDC to "promptly notify" Gilead of any claimed "Inventions" arising out of the research conducted under the MTAs and the clear terms of the CTA expressly providing that "CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial," CDC not only filed patent applications seeking patent protection for purported "Inventions" derived from the use of the compounds Gilead supplied under the MTAs and CTA, but also failed to disclose to Gilead the purported invention(s) claimed in the '811 Provisional and in the applications that eventually issued as the HHS Patents. Instead, the Government waited more than eight years—at least until October 2014—to attempt to provide the contractually required notice to Gilead.

14. Gilead has suffered, and will continue to suffer, damages because of the Government's breaches of the MTAs and the CTA.

15. While the Government was secretly seeking patent protection on work covered by the MTAs and CTA, the Government—acting through the FDA, which is one of HHS's subsidiary agencies—encouraged Gilead to seek, and Gilead ultimately sought, approval from the FDA to market its groundbreaking HIV-treatment drug, Truvada®, for HIV-1 pre-exposure prophylaxis ("PrEP"). The FDA approved Truvada® for PrEP on July 16, 2012.

16. In spite of CDC having recommended Truvada® for prophylaxis in its clinical guidelines since 2005, as well as its knowledge of Gilead's marketing and sale of Truvada® for PrEP as of 2012, the Government waited until at least October 2014 to attempt to notify Gilead of the patent application, and until March 11, 2016 to assert that Gilead required a license under

the HHS Patents in order to continue marketing Truvada® for PrEP. By that time, Gilead had already invested substantial amounts in educating at-risk patient populations about the potential benefits of Truvada® for PrEP, and some of those at-risk patient populations had already come to rely on Truvada® for prophylaxis to attempt to minimize their potential for contracting HIV-1.

17. On November 6, 2019, the Government filed suit against Gilead in the U.S. District Court for the District of Delaware alleging infringement of the HHS Patents. In that suit, the Government acknowledges that the HHS Patents resulted from the research that CDC conducted pursuant to at least one of the MTAs. *See* Del. Compl., D.I. 1, ¶ 119-127, *United States v. Gilead Scis., Inc.*, C.A. No. 19-2103-MN (D. Del. filed Nov. 6, 2019) (the "Delaware Litigation"). Gilead denies that the HHS Patents are valid, enforceable, or infringed.

18. In the Delaware Litigation, the Government is seeking royalties on Gilead's sales of Truvada® from June 2, 2015 to present and on sales of Descovy®, a separate Gilead product that is also approved for PrEP, from October 3, 2019 to present, along with an ongoing royalty for future sales of both products. Gilead's Truvada® and Descovy® products are breakthrough therapies for the treatment and prevention of HIV that have enjoyed extraordinary commercial success. Accordingly, the damages the Government is seeking are in the millions of dollars.

19. The Government deliberately took actions that allowed it to obtain invalid and/or unenforceable patents. By delaying its contractually required notification to Gilead of the purported invention(s) described in the '811 Provisional, the '547 Application, and the HHS Patents, for more than eight years, the Government breached its contracts with Gilead. It is now bringing a lawsuit alleging patent infringement, which cannot be allowed to stand and needs to be defended. Further, now that the Government has granted patents and Gilead has been

approved to market Truvada® for PrEP, the Government is in a position to seek excessive royalties.

20. Had CDC fulfilled its contractual obligations under the MTAs to promptly notify Gilead of the purported invention(s) described in the '811 Provisional and in the applications that resulted in the HHS Patents at or around the time of filing those applications, Gilead would have had the opportunity to consider its options, including providing CDC and/or the PTO with information showing why any such patent would be invalid. Gilead also would have had the option to change its application for FDA approval to market Truvada® for PrEP.

21. Had CDC fulfilled its contractual obligations under the CTA to not seek patent protection on alleged inventions derived from the Botswana trial, the HHS Patents never would have issued.

22. In the unlikely event the HHS Patents are ultimately upheld, Gilead is also entitled to monetary damages in the amount of the difference between the royalties to which the Government claims it is entitled and the cost, on commercially reasonable terms, of a non-exclusive license to the purported invention(s) described in the '811 Provisional and in the applications that resulted in the HHS Patents, in or around the time of filing those applications.

PARTIES

23. Plaintiff Gilead Sciences, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

24. Defendant is the United States of America acting on behalf of HHS, by virtue of its administrative control of CDC, which is headquartered at 1600 Clifton Road NE, Atlanta, Georgia 30329.

JURISDICTION AND VENUE

25. This Court has exclusive subject-matter jurisdiction over this action under the Tucker Act, 28 U.S.C. § 1491(a)(1), because this action involves claims for damages greater than $10,000 against the Government founded upon express contracts with the Government.

26. This Court has jurisdiction to resolve the Government's breach of the MTAs and the CTA. For example, in *Institut Pasteur v. United States*, the Federal Circuit held that the Court of Claims properly had jurisdiction over contracts concerning "facilitation of the transfer of research materials among scientists engaged in a collaborative research effort." 814 F.2d 624, 628 (Fed. Cir. 1987). In that case, the Government entered into a material transfer agreement with the Institut Pasteur for research materials related to HIV—much like the MTAs at issue in this case. And, as in this case, the Government was alleged to have breached its MTA with the Institut Pasteur by improperly seeking to patent the results of work that it conducted under the MTA.

27. Among its affirmative defenses in the Delaware Litigation, Gilead asserts that the claims of the HHS Patents are unenforceable against Gilead because of the equitable doctrine of unclean hands due to, among other things, the Government's breaches of the MTAs and CTA. Gilead's unclean hands defense does not bar this Court's jurisdiction under 28 U.S.C. § 1500.

FACTUAL ALLEGATIONS

I. Gilead is an Established Leader in HIV Research

28. Founded in 1987, Gilead is a pioneer in the development of effective treatments for HIV. As a result of its efforts, Gilead has brought to market more than a dozen products that have been approved by the FDA for the treatment and prevention of HIV.

29. In 1991, Gilead licensed the rights to a portfolio of nucleotide compounds from the Rega Institute for Medical Research and the Institute of Organic Chemistry and Biochemistry. These nucleotide compounds—including a compound called tenofovir ("TFV")—would go on to serve as the foundation of the company's transformative HIV treatment and prevention development program.

30. TFV could not be administered orally, so Gilead's early discovery work turned to the invention of a prodrug for tenofovir that could be formulated in a pill. After extensive research and development work, Gilead scientists synthesized a compound called tenofovir disoproxil fumarate ("TDF"), which had superior properties in early testing. Gilead selected TDF for further development, and, following promising results in Gilead-sponsored pre-clinical and clinical trials, the company moved forward with seeking FDA approval for TDF as a treatment for HIV.

31. After TDF was approved by the FDA in 2001, Gilead began marketing the drug for HIV treatment under the brand name Viread®. Upon its approval and marketing, Gilead's Viread® product was viewed as an incredibly meaningful improvement over other treatments in the market due to its efficacy and superior safety profile.

32. Following the launch of Viread® in 2001, doctors commonly prescribed Viread® tablets in combination with GlaxoSmithKline's Epivir® product (lamivudine or "3TC") and a third agent to treat HIV because, by then, it was accepted that combination therapy for HIV infections with multiple drugs would be more effective in suppressing HIV, which was capable of frequent mutations. Seeing an opportunity to reduce the number of pills a patient was required to take daily, and thus improve adherence and overall patient health, Gilead began

searching for a compound to pair with TDF to create a combination pill that would ease this burden on patients.

33. Through these efforts, Gilead identified emtricitabine ("FTC"), a compound discovered by researchers at Emory University and licensed to Triangle Pharmaceuticals, as a potentially effective partner for TDF with a superior profile—longer half-life, increased potency, and less resistance—as compared to 3TC. Gilead subsequently acquired Triangle Pharmaceuticals, along with the rights to FTC and the substantial investment in clinical development made by Triangle, and finished developing FTC for clinical use.

34. In July 2003, the FDA approved FTC for use in combination with other antiretroviral agents for HIV treatment. Gilead has since marketed FTC under the brand name Emtriva®.

35. Gilead scientists also worked to develop a co-formulation of TDF and FTC that could be administered as a single pill, leading to Gilead's Truvada® product. Truvada® was approved by the FDA in August 2004 as one of the first fixed-dose combination tablets for HIV treatment.

36. In January 2005, CDC issued guidelines recommending the use of certain antiretroviral regimens for post-exposure prophylaxis, including a combination of FTC and TDF as a preferred regimen. Ex. 1, at 11 (Jan. 21, 2005 Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States). In September 2005, CDC issued updated guidelines more explicitly recommending the use of Truvada® for post-exposure prophylaxis, in "situations in which [health care professionals] have been exposed to a source person who either has or is considered likely to have HIV infection." Ex. 2, at 10-11 (Sept. 30, 2005 Updated U.S. Public Health Service Guidelines for the

Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis).

37. Gilead scientists also developed tenofovir alafenamide ("TAF"), which demonstrated promising antiviral activity. Recognizing TAF's potential, Gilead undertook efforts to bring TAF to market. Gilead has since launched several commercially successful TAF-based therapies. Gilead's Descovy® product, which is a fixed-dose combination of TAF hemi-fumarate and FTC, is one such therapy.

38. Gilead's portfolio of HIV products, including Truvada® and Descovy®, have been instrumental in helping people with HIV live longer and healthier lives, especially when compared to the earliest days of HIV treatment. With modern antiretroviral therapies such as Truvada® and Descovy®, median life expectancy for patients living with HIV now approximates that of the general population.

39. Gilead has a long history of working with the scientific community to promote basic scientific and clinical research on HIV, HIV treatment, and HIV prevention. In addition to the significant research and development work Gilead itself has conducted, it has collaborated with the CDC on many studies related to HIV.

40. For example, prior to 1995, Gilead—primarily through the work of then-Head of Research & Development, Norbert Bischofberger—led an effort to assist two NIH-funded studies conducted at the University of Washington. In addition to providing free TFV for use in the studies (which did not require oral administration of the active ingredient), Gilead helped design the study methodology, provided dosing guidance, and participated in analysis of the results. One of the studies—which demonstrated that TFV was effective as both a pre- and post-exposure prophylactic in response to "systemic" exposure to the virus in monkeys—was

published in *Science* magazine in 1995, with Bischofberger credited as a co-author. Ex. 3 (Che-Chung Tsai et al., *Prevention of SIV Infection in Macaques by (R)-9-(2-Phosphonylmethoxpropyl)adenine*, 270 SCIENCE 1197 (1995)). The results of the second study—which demonstrated tenofovir's efficacy as a gel-based prophylactic in response to vaginal exposure to HIV in monkeys—were later presented at a scientific meeting in Japan in May 1996.

41. Following Bischofberger et al.'s seminal study, Gilead continued to support HIV prevention and treatment investigations by CDC and other researchers throughout the 1990s and 2000s, including through the MTAs and CTA described herein. Gilead's efforts to support research in the treatment, prevention, and cure of HIV continue still today.

II. Gilead's Collaboration Agreements with the CDC

42. As part of their long-standing research collaborations, Gilead and CDC have entered into many material transfer and related agreements over the past three decades. This case is about the Government's breach of four specific MTAs related to the early-stage preclinical work described in the patent applications that resulted in the HHS Patents and a contemporaneous clinical trial agreement.

A. The Material Transfer Agreements

43. Beginning in 2004, CDC researchers sought Gilead's assistance with certain experiments that the CDC proposed to conduct relating to prophylaxis in macaques, including asking Gilead to supply free pharmaceuticals and active compounds for use in the experiments. Gilead discussed these studies with the CDC researchers at length and provided feedback and advice concerning study design, and Gilead ultimately agreed to provide the material that the CDC researchers requested.

44. In connection with these various studies, CDC and Gilead entered into four separate MTAs and at least eight amendments of those various MTAs between 2004 and 2014.

45. Under each of the MTAs described in the table below, Gilead agreed to provide TFV, TDF, and/or FTC to CDC at no cost, to be used in HIV-1 research. Each MTA describes the study for which the free material would be used. And under each of the four MTAs, the Government "agree[d] to promptly notify" Gilead of "any Inventions" under the applicable MTA, which each MTA defined as "any inventions, discoveries and ideas that are made, conceived or reduced to practice." In each MTA, the Government likewise agreed "to give serious and reasonable consideration to [Gilead's] request for a non-exclusive or exclusive license on commercially reasonable terms under PHS's intellectual property rights in or to any Inventions." Ex. 4 ¶ 8; Ex. 5 ¶ 8; Ex. 6 ¶ 8, Ex. 7 ¶ 8.

CDC Ref. No.	**Effective Date**	**Studies**	**Material Transferred**
NCHSTP-C043072 (the "'072 MTA") (Ex. 4)	Jun. 21, 2004	Project 1: Evaluation of Tenofovir pre-exposure prophylaxis (PREP) for the prevention of simian human immunodeficiency virus (SHIV) infection in a low-dose rectal challenge model in *Macaca mulatta*. Project 2: In-vitro evaluation of development of Tenofovir resistance in $SHIV_{SF162P3}$ and pattern of amino acid changes in RT over time under drug pressure.	TDF TFV
NCHST-V053433 (the "'433 MTA") (Ex. 5)	Jan. 7, 2005	Using cervical and colorectal explant models to evaluate antiretroviral drugs for the prevention of HIV-1 infection.	TFV
Amendment to '072 MTA	Jan. 24, 2005	Oral Chemoprophylaxis With Tenofovir Disoproxil Fumarate to Evaluate Vaginal SIV Transmission	TDF

		in a Rhesus Macaque Repeat-Virus Exposure Model.	
NCHSTP-V053471 (the "'471 MTA") (Ex. 6)	Jan. 31, 2005	Pre-exposure prophylaxis with FTC in combination with one or two drugs for the prevention of simian human immunodeficiency virus (SHIV) infection in a repeat low-dose challenge model in *Macaca mulatta*.	FTC
NCHSTP-V053649 (the "'649 MTA") (Ex. 7)	Apr. 25, 2005	Evaluation of Multidrug Chemoprophylaxis for the Prevention of Simian Human Immunodeficiency Virus Infection Using the Repeat-Exposure Macaque Model.	TFV
First Amendment to '471 MTA	Around Feb. 2006	*See '471 MTA, above.*	FTC
Second Amendment to '471 MTA	Mar. 6, 2006	*See '471 MTA, above.*	TDF
Additional material provided pursuant to '471 MTA	Around Sept. 2006	*See '471 MTA, above.*	FTC TDF
First Amendment to '649 MTA (Ex. 8)	Apr. 30, 2008	Antiretroviral prophylaxis against HIV/SIV/SHIV in animal models.	TFV
Second Amendment to '649 MTA (Ex. 9)	Jan. 27, 2010	Development and evaluation of topical prophylaxis interventions in animal models.	FTC TDF TFV
Third Amendment to '649 MTA (Ex. 10)	Jun. 12, 2012	Conducting efficacy and pharmacokinetic studies in monkey models with oral TDF and FTC alone or in combination with elvitegravir or other drugs. Conducting combination intervention studies with oral PrEP and vaccines to explore potential synergistic or additive effects of partially effective vaccines and PrEP modalities.	FTC TDF
Fourth Amendment to '649 MTA (Ex. 11)	Jun. 20, 2013	Development and evaluation of a novel drug delivery system for systemic pre-exposure prophylaxis with TRUVADA® (emtricitabine/tenofovir disoproxil fumarate), a combination of	TFV

		EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate[)], also known as PrEP based on an injectable organic solution of biodegradable poly(lactic acid)/poly(ethyleneglycol)(PLA/PEG) copolymers and active pharmaceutical ingredients (API).	
Fifth Amendment to '649 MTA (Ex. 12)	Aug. 4, 2014	Recipient seeks to formulate other tenofovir prodrug, TDF, to investigate if instability is specific to Tenofovir Alafenamide Fumarate (TAF) or related to tenofovir.	TDF

46. Gilead performed its obligations under each of the MTAs and amendments described above and delivered the free pharmaceuticals to CDC in a timely manner. On information and belief, CDC used these Gilead-provided materials in the course of its HIV research that was recited in the HHS Patents.

47. The CDC investigators identified on some of these MTAs include inventors named on the face of the HHS Patents. For example, the '471 and '649 MTAs identified Dr. Walid Heneine as the investigator; Dr. Heneine is one of the individuals identified as an inventor on the face of the HHS Patents. Likewise, the '433 MTA identified CDC Scientist Thomas Folks as a co-investigator of the study described in the '433 MTA; Thomas Folks is one of the individuals identified as an inventor on the face of the HHS Patents.

48. At no time during any of the communications in the course of executing the parties' obligations under the MTAs or MTA amendments was there any mention by CDC of any purported invention that had been conceived or reduced to practice or any plan to seek patent protection as a result of the research performed under the MTAs and/or the amendments. Several of the MTA amendments occurred after the CDC's filing of the '811 Provisional and/or the '547 Application, but the CDC still did not notify Gilead that it had in fact filed those

applications when the amendments were being executed or when it requested additional free material from Gilead.

B. The Clinical Trial Agreement

49. Gilead and CDC also entered into other agreements related to HIV-1 research in the 2000s. For example, Gilead and the Government, acting through CDC, entered into a CTA with an effective date of November 18, 2004 (Ex. 13).

50. Under the CTA, Gilead agreed to provide 8,500 bottles each of TDF and a matching placebo to CDC at no cost to be used in a clinical trial titled "Study of the Safety and Efficacy of Daily Tenofovir Disoproxil Fumarate ('TDF') for the Prevention of HIV Infection in Heterosexually-Active Young adults in Botswana." In addition, Gilead agreed to be responsible for distributing the drug materials to the study sites.

51. The clinical trial described in the original CTA, TDF1, was registered with ClinicalTrials.gov as trial number NCT00111150. CDC is listed as the trial's sponsor, and Gilead is identified as a "Collaborator[ ]."

52. In exchange for Gilead's agreement to supply and distribute drugs under the CTA, CDC agreed, among other things, "to put the results of the Trial, patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC." "For clarity," the CTA provided, "CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." Ex. 13 ¶ 7.

53. Gilead and the Government, acting through CDC, entered into three amendments to the CTA between October 3, 2006 and January 12, 2012.

54. Gilead and the Government, acting through CDC, entered into a first amendment to the CTA with an effective date of October 3, 2006. Ex. 14 (the "CTA-01 Amendment").

55. The CTA-01 Amendment modified the study drug to be supplied for the Botswana clinical trial described in the original CTA from TDF to Truvada® tablets, which Gilead also agreed to provide free of charge. The Government has alleged in its District of Delaware complaint that the Botswana protocol was changed to study Truvada® (oral combination FTC/TDF) based, at least in part, on the results of the study that was the subject of the '471 MTA and amendments. Del. Compl. ¶¶ 140-141, 160-162; Ex. 15, at 2 (Michael C. Thigpen et al., *Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana*, 367 NEW ENGL. J. MED. 423, 424 (2012)). The clinical trial described in CTA-01 was registered with ClinicalTrials.gov as trial number NCT00448669 (TDF2). CDC is listed as the trial's sponsor, and Gilead as a "Collaborator[ ]." Gilead agreed to supply 8,500 bottles of Truvada® tablets and 8,500 bottles of matching placebos at no cost to study sites for the Botswana clinical trial, with Gilead bearing responsibility for distributing the drugs to the participating sites.

56. Gilead and the Government, acting through CDC, entered into two more amendments to the CTA, CTA-02, with an effective date of November 24, 2008 (Ex. 16), and CTA-03, with an effective date of January 12, 2012 (Ex. 17), pursuant to which it agreed to supply additional amounts of Truvada at no cost for use in the Botswana clinical trial.

57. All told, as a result of the CTA and its amendments, Gilead agreed to provide 37,080 bottles of Truvada and matching placebos, the value of which Gilead estimates to be well in excess of $6.7 million.

58. Each of the CTA amendments specified that the original CTA "shall be unchanged and shall remain in full force and effect in accordance with its terms" "[e]xcept as expressly amended herein"; none of the amendments changed the terms of the original CTA in

which "CDC agree[d] not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial."

59. Gilead performed its obligations under the CTA and delivered the Truvada® and placebos in a timely manner as required by the original CTA and its amendments. On information and belief, CDC used or directed the use of these Gilead-provided materials in the course of the Botswana clinical trial.

60. At no time during any of these communications between Gilead and CDC concerning the CTA and its amendments thereto, was there any mention by CDC of any purported invention that had been conceived or reduced to practice or any plan to seek patent protection, in contravention of the express terms of the CTA or otherwise, nor any notice provided to Gilead that CDC had in fact filed the '811 Provisional and '547 Application during this time period.

III. CDC's Research Under the Agreements

61. On information and belief, over the course of 2005 and 2006, CDC conducted research studies on HIV prevention using a combination of FTC with either TFV or TDF. These studies were the same studies described in the MTAs or directly built upon the studies described in the MTAs.

62. On February 3, 2006, CDC filed the '811 Provisional (Ex. 18), with the PTO claiming compositions and methods of preventing HIV infections using a plurality of antiretroviral compounds. Upon information and belief, the purported inventions claimed in the '811 Provisional were based on studies that CDC conducted under the MTAs.

63. The '811 Provisional described the results of a study in which a group of six Rhesus macaques were injected subcutaneously with 22 mg/kg TFV and 20 mg/kg FTC once

daily, as contemplated in the ’649 MTA. The macaques were also subjected to weekly rectal exposures with a low dose of SHIV, as contemplated in the ’649 MTA, except for the method of exposure to SHIV (rectal, as opposed to vaginal). The study found that the subcutaneous TFV/FTC combination provided a high level of protection against repeated virus challenges. A presentation slide submitted as part of the ’811 Provisional further reported that “Macaque models show that tenofovir [alone] can provide substantial protection against … mucosal virus exposures,” like the rectal exposures used in the study.

64. On information and belief, the study described in the ’811 Provisional was performed by CDC researchers using FTC that Gilead provided to CDC under the ’471 MTA and/or the first amendment to the ’471 MTA.

65. On information and belief, the study described in the ’811 Provisional was performed by CDC researchers using TFV that Gilead provided to CDC under the ’072 MTA, the ’649 MTA, and/or the ’433 MTA.

66. The ’811 Provisional included 17 proposed patent claims, including the following:

> 8. A method of preventing HIV transmission in a subject, comprising administering to the subject a therapeutically effective amount of a composition comprising a plurality of antiretroviral compounds in sufficient amounts to prevent viral infection in the subject.
>
> 15. A method of antiviral chemoprophylaxis, comprising administering to the subject a therapeutically effective amount of a composition comprising a plurality of antiviral compounds in sufficient amounts to prevent viral infection in the subject.
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> 17. A method of preventing HIV transmission in a subject, comprising administering to the subject a chemoprophylatically [*sic*] effective amount of a composition comprising a plurality of antiretroviral compounds.

Ex. 18, at 24, 25.

67. On January 31, 2007, the ’547 Application, (Ex. 19) was filed claiming priority to the ’811 Provisional.

68. The study described in the ’811 Provisional was not described in the ’547 Application.

69. Instead, Examples 7 and 8 of the ’547 Application described a study in which Rhesus macaques were divided into three study groups of six macaques each and treated with three different daily prophylaxis regimens. Animals in the first group were treated subcutaneously with 20 mg/kg FTC alone; animals in the second group received orally a combination of FTC (20 mg/kg) and TDF (22 mg/kg); and animals in the third group were injected subcutaneously with 22 mg/kg TFV and 20 mg/kg FTC. Ex. 19, at 21-23. According to the ’547 application, the study concluded that each of the three prophylaxis regimens was “protective to a degree with a clear dose-response relationship being observed.” Ex. 19, at 22.

70. On information and belief, the study described in Example 7 of the ’547 Application was performed by CDC researchers using compounds that Gilead provided to CDC under one or more of the ’471 MTA or the first amendment to the ’471 MTA.

71. On information and belief, the study described in Example 7 of the ’547 Application was performed using TFV that Gilead provided to CDC free of charge under one or more of the MTAs and pursuant to the Government’s obligation to “promptly notify” Gilead of “any Inventions.” For example, on information and belief, the FTC used in the Example 7 study was provided by Gilead to the CDC under the ’471 MTA or the first amendment to the ’471 MTA; the TFV used in the Example 7 study was provided by Gilead to the CDC under one or more of the ’072 MTA, the ’649 MTA, or the ’433 MTA; and the TDF used in the Example 7

study was provided by Gilead to the CDC under one or more of the ’072 MTA, the first amendment to the ’072 MTA, and/or the second amendment to the ’471 MTA.

72. The ’547 Application included 21 proposed patent claims, including the following:

> 1. A process of protecting a primate host from a self-replicating infection by an immunodeficiency retrovirus comprising: administering to the primate host a combination of a pharmaceutically effective amount of a nucleoside reverse transcriptase inhibitor and a pharmaceutically effective amount of a nucleotide reverse transcriptase inhibitor prior to exposure to the immunodeficiency retrovirus.
>
> 13. The process of claim 1 wherein said nucleoside reverse transcriptase inhibitor is emtricitabine [i.e., FTC] and said nucleotide reverse transcriptase inhibitor comprises tenofovir [TFV] or a tenofovir ester [e.g., TDF].
>
> 15. A process for controlling retrovirus transmission within a population comprising: administering to a subpopulation at high risk for contracting an immunodeficiency retroviral infection a combination of a pharmaceutically effective nucleoside reverse transcriptase inhibitor and a pharmaceutically effective amount of a nucleotide reverse transcriptase inhibitor prior to an exposure to a source of immunodeficiency retrovirus so as to preclude the immunodeficiency retrovirus from becoming self-replicating in a member of said subpopulation administered said combination.

Ex. 19, at 28, 30.

73. The ’547 Application issued as the ’509 Patent. All of the HHS Patents that have issued to date claimed priority to the ’547 Application and the ’811 Provisional.

74. On information and belief, the purported inventions disclosed in the ’811 Provisional, the ’547 Application, and all of the other applications that issued as the HHS Patents were made, conceived, or reduced to practice as a result of the studies described in the MTAs. *See, e.g.*, Del. Compl. ¶ 121 (“The earliest MTA ***related to the research leading to the Patents-***

in-Suit was signed in December 2004 by Dr. Heneine, and later by Dr. Mick Hitchcock, Gilead's then Vice President of Medical Affairs, in response to Dr. Heneine's email request for a transfer of FTC to CDC." (citing the '471 MTA, which was fully executed by Gilead on January 31, 2005)) (emphasis added).

75. In spite of the plain language of the MTAs requiring CDC "to promptly notify" Gilead of "any Inventions" made under those MTAs, CDC failed to notify Gilead of the purported invention(s) described in the '811 Provisional, the '547 Application, and the later applications that resulted in the HHS Patents when they were made, or even when the '811 Provisional was filed with the PTO in 2006. Instead, CDC waited approximately eight years—until October 2014 at the earliest—to provide the contractually required notice to Gilead of the purported invention(s) described in the '811 Provisional and/or the '547 Application.

76. On February 1, 2008, CDC sent Gilead a draft of an article entitled *Prevention of Rectal SHIV Transmission in Macaques by Daily or Intermittent Prophylaxis with Emtricitabine and Tenofovir*. The draft listed several CDC researchers as authors, including Dr. Heneine and Dr. J. Gerardo García-Lerma. The paper generally described the macaque study described in the '649 MTA. Nowhere in the draft article was there any disclosure of the '811 Provisional or the '547 Application, let alone any disclosure of any purported "Invention" by CDC researchers. Under the "Competing Interests" note, the draft included a single sentence stating that five of the authors (Dr. García-Lerma, Dr. Heneine, Ron A. Otten, Robert Janssen, and Thomas M. Folks) were "named in a US Government patent application related to methods for HIV prophylaxis." The note did not provide any additional information regarding the purported "Invention," nor identify the referenced application or indicate that the application was directly related to the studies reported in the article.

77. Four days later, on February 5, 2008, the article was published in *PLoS Medicine*. Ex. 20 (J. Gerardo García-Lerma et al., *Prevention of Rectal SHIV Transmission in Macaques by Daily or Intermittent Prophylaxis with Emtricitabine and Tenofovir*, 5 PLOS MEDICINE (2) 291 (2008) ("Garcia-Lerma (2008)").

78. On information and belief, decisions made during prosecution of the '811 Provisional, the '547 Application, and the HHS Patents also derive from the trials described in the original CTA and its subsequent amendments. As the Government has stated in its complaint, the results of the Botswana trial demonstrated the effectiveness of the alleged inventions. *See, e.g.*, Del. Compl., ¶¶ 140-141, 160-162.

79. During the time period that Gilead and the Government were parties to the CTA and its subsequent amendments, the Government never notified Gilead that it had filed the '811 Provisional or the '547 Application in direct contravention of the terms of the CTA "not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial" and "to put the results of the Trial, patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC."

IV. Gilead Obtained FDA Approval to Market Truvada® for PrEP in 2012

80. During development of Truvada®, Gilead was focused on bringing to market new and improved treatments for HIV for patients who were facing a death sentence from their infections. Nonetheless, based on the work of Dr. Bischofberger in 1995 (described earlier), among others, and based on the mechanism of action of reverse transcriptase inhibitors like tenofovir, it was clear to Gilead as early as the mid-1990s that tenofovir had potential prophylactic uses.

81. In January 2011, over a year before Gilead obtained FDA approval to market Truvada® for PrEP, the CDC provided interim guidelines that explicitly directed physicians to prescribe the use of Truvada® for pre-exposure prophylaxis. Ex. 21, at 4 (Jan. 28, 2011 Interim Guidance: Preexposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men). According to CDC at that time, the Truvada® product was one of the preferred medications for prophylactic use.

82. In 2012, and with the encouragement and support of the Government (including the FDA), Gilead obtained approval from the FDA to market Truvada®, which contains TDF and FTC—the compounds that Gilead provided to CDC—for HIV-1 PrEP. Had CDC fulfilled its contractual obligations to promptly notify Gilead of the purported invention(s) described in the '811 Provisional and in the applications that resulted in the HHS Patents in or around 2006, Gilead would have had the opportunity to consider its options, including providing CDC and/or the PTO with information showing why any such patent would be invalid. Gilead also would have had the option to change its application for FDA approval to market Truvada® for PrEP.

V. Gilead's First Notice of the Government's Alleged Inventions Related to Prophylaxis

83. On October 1, 2014, HHS published a notice in the *Federal Register* of "Government-Owned Inventions; Availability for Licensing." Ex. 22, 79 Fed. Reg. 59,277 (Oct. 1, 2014). Among these purported inventions was one titled "Inhibition of HIV Infection Through Chemoprophylaxis Using Emtricitabine and Tenofovir." The notice described this purported invention as follows:

> The invention is directed to prophylactic administration of emtricitabine (FTC) in combination with tenofovir or its prodrug, tenofovir disoproxil fumarate (TDF), to protect against transmission of human immunodeficiency virus (HIV) infection. Also disclosed are other nucleoside reverse transcriptase inhibitors

> (NRTIs) and nucleotide reverse transcriptase inhibitors (NtRTIs) that, when administered in combination, protect against HIV infection. CDC researchers demonstrated that daily pre-exposure prophylaxis (PrEP) with a combination of antiretroviral NRTI and NtTRI drugs, including FTC and TDF, significantly increases the level of protection against HIV transmission.

Ex. 22, at 1-2.

The *Federal Register* notice listed the "Inventors" as "Walid Heneine, Thomas Folks, Robert Janssen, Ronald Otten, J. Gerardo Garcia-Lerma (all of CDC)"; cited two García-Lerma publications, including García-Lerma (2008); and disclosed the following "Intellectual Property":

- U.S. Provisional Application No. 60/764,811 filed 3 Feb 2006.
- U.S. Patent Application No. 11/669,547 filed 31 Jan 2007.
- PCT Application No. PCT/US2007/002926 filed 01 Feb 2007.
- European Patent No. 2015753 issued 01 May 2013.
- German Patent No. 2015753 issued 01 May 2013.
- French Patent No. 2015753 issued 01 May 2013.
- U.K. Patent No. 2015753 issued 01 May 2013.
- Australian Patent No. 2007212583 issued 25 Mar 2013.
- Canadian Patent Application No. 2641388 filed 01 Aug 2008.
- Indian Patent Application No. 7408/DELNP/2008 filed 01 Jul 2008.

Ex. 22, at 2.

84. As of October 1, 2014, the Government had not provided notice of the existence of any of the patents or patent applications listed in the *Federal Register* to Gilead.

85. On October 23, 2014, Laura T. Prestia from the National Institutes of Health's Office of Technology Transfer ("NIH/OTT") sent separate, substantively identical emails about the purported invention described in the *Federal Register* notice to Vice President of Biology Dr. Linda Higgins and Associate Director of Corporate Development Dr. Jay Parrish at Gilead. Ex. 23 (Oct. 23, 2014 email from L. Prestia to J. Parrish and T. Kirby). The body of those emails said:

> In light of your recent and ongoing interest in and success with Truvada, your company appears to be an ideal partner for a technology developed by Dr. Walid Heneine at the Centers for Disease Control and Prevention (CDC).
>
> Dr. Heneine's group has shown that daily pre-exposure prophylaxis (PrEP) with emtricitabine in combination with tenofovir disoproxil fumarate (Truvada) significantly increases the level of protection against HIV transmission. This finding was discovered following repeated virus challenges with macaque monkeys. The CDC is pursuing U.S. and foreign patent protection for this technology.
>
> An abstract with more information can be found in the Federal Register. Also, Dr. Heneine has co-authored publications in PLoS Medicine and *Science Translational Medicine*, describing the above discovery.
>
> Please contact me if I can be of further assistance.

86. These two October 23, 2014 emails were the first communications that the Government sent to Gilead concerning the purported invention(s) described in the '811 Provisional or the '547 Application.

VI. The Government Actively Concealed the Relationship Between the '811 Provisional/'547 Application and the MTAs

87. Gilead and CDC engaged in numerous HIV research collaborations between the Government's filing of the '811 Provisional on February 3, 2006, and these October 23, 2014

emails. At no point during these collaborations did the Government or anyone acting on its behalf notify Gilead of the existence of the ’811 Provisional, the ’547 Application, or the relationship between these applications and the MTAs and the CTA.

88. For example, approximately one month after the filing of the ’811 Provisional, Gilead and CDC entered into the second amendment to the ’471 MTA on March 6, 2006. This amendment related to follow-on studies to the work described in the ’811 Provisional and to studies that, on information and belief, are expressly described in Examples 7 and 8 of the ’547 Application. This amendment did not modify the requirement in the original ’471 MTA for CDC to promptly notify Gilead of any alleged inventions, discoveries and ideas that are made, conceived or reduced to practice under the agreement.

89. Nonetheless, during its communications with Gilead related to the second amendment to the ’471 MTA, CDC made no mention of its filing of the ’811 Provisional one month earlier.

90. The CDC also failed to notify Gilead that it had filed the ’811 Provisional during Dr. Heneine’s communications with Gilead seeking additional FTC and TDF for HIV PrEP studies in August and September 2006. Despite writing on August 31, 2006 that “[w]e [CDC] continue to be excited about the promise of this research and I know you all at Gilead share this excitement with us,” Dr. Heneine failed to notify Gilead that CDC was seeking patent protection on the work that resulted from this collaboration. Ex. 24, at 2 (Sept. 21, 2006 email from Walid Heneine to Martha Vazquez).

91. Dr. Heneine’s signature appears on the ’471 MTA under the heading “AGREED AND ACCEPTED BY:”. Ex. 6, at 5. On information and belief, Dr. Heneine knew of CDC’s

obligation to notify Gilead that CDC was seeking patent protection on the subject matter of the ’811 Provisional.

92. On information and belief, Dr. Heneine knew that he was listed as an inventor on the ’811 Provisional and was aware that it was filed based on research conducted using materials provided by Gilead under, at least, the ’471 MTA.

93. On information and belief, Dr. Heneine intentionally and actively concealed the existence of the ’811 Provisional from Gilead.

94. Gilead executed ten different amendments to its collaboration agreements with CDC between 2006 and 2014, including but not limited to: the first and second amendments to the ’471 MTA in February and March 2006; the first amendment to the CTA on October 3, 2006; a first amendment to the ’649 MTA on April 30, 2008; a second amendment to the CTA on or around November 24, 2008; a second amendment to the ’649 MTA on January 27, 2010; a third amendment to the CTA on January 12, 2012; and the third, fourth, and fifth amendments to the ’649 MTA on June 12, 2012, June 20, 2013, and August 4, 2014.

95. In executing these agreements and amendments, Gilead relied on the CDC’s repeated reaffirmance of its commitment to notify Gilead of any inventions under the MTAs, and its commitment not to seek intellectual property protection on work related to studies using Gilead drugs in the CTA, between 2006 and 2014. Gilead reasonably concluded that the CDC was abiding by its agreements.

VII. Gilead’s Continued Development in Innovative HIV Treatments, TAF, Descovy®, and Descovy® for PrEP

96. Since FDA approval of Truvada®, Gilead has continued its groundbreaking research on HIV treatment and prevention.

97. On April 4, 2016, Gilead obtained FDA approval for its Descovy® product for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.

98. The Descovy® product is a two-drug combination of FTC and TAF hemi-fumarate. TAF, which was invented by Gilead scientists, has been shown to more efficiently deliver tenofovir to target cells at a much lower dose while maintaining similar efficacy to TDF.

99. Gilead sponsored a clinical trial called DISCOVER to bring the benefits of TAF to patients who can benefit from pre-exposure prophylaxis.

100. Based in part on the results of the DISCOVER clinical trial, FDA approved the Descovy® product for PrEP on October 2, 2019. Specifically, FDA approved the Descovy® product for use "in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex"; the approval also required that "[i]ndividuals must have a negative HIV-1 test immediately prior to initiating DESCOVY for HIV-1 PrEP." Ex. 25, at 1 (Descovy® Highlights of Prescribing Information, Oct. 2019).

VIII. The Government's Assertion of the HHS Patents Against Gilead

101. On March 11, 2016, Dr. Tara L. Kirby, CDC Team Supervisor, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, wrote to Dr. Parrish in the Corporate Development group at Gilead, stating in part that:

> The matter I wanted to discuss with you is an invention from CDC's Division of HIV/Aids Prevention Surveillance and Epidemiology, our reference number E-195-2013/0. We have recently obtained issued patents for this invention in a number of jurisdictions, including the United States (USPN 9,044,509), and we believe that your marketed drug, Truvada, may be covered by these patents. For your ease of reference, I have attached a copy of

> the issued U.S. patent, as well as a listing of our patent filings relating to this invention.
>
> We would be happy to discuss an amicable resolution to this matter. This invention is available for licensing on a non-exclusive basis, so I have attached a copy of our standard license application form for your review and consideration.

Ex. 26, at 1 (Mar. 11, 2016 email from J. Parrish to E. Hartrum, L. Bhatt, L. Morgan, and M. Edwards). Dr. Kirby attached a copy of the '509 Patent, a document showing the countries in which the Government had sought or was seeking patent protection claiming priority to the '811 Provisional, and a license application.

102. Gilead and the Government discussed the Government's licensing demand throughout the 2016 to 2019 period. During the discussions, Gilead informed the Government of its breach of the MTAs and its belief that the HHS Patents are not valid. Ultimately, the parties were not able to reach any resolution.

103. Both before and during this negotiation period, the Government sought additional patents related to the purported invention(s) described in the '811 Provisional and the '547 Application, including patents purporting to cover Gilead's innovative TFV prodrug, TAF.

104. On April 6, 2015, the Government filed U.S. Patent Application No. 14/679,887 (the "'887 Application"). The '887 Application claimed priority to the '547 Application and the '811 Provisional. On February 28, 2017, the Patent Office issued the '333 Patent from the '887 Application.

105. On January 13, 2017, the Government filed U.S. Patent Application No. 15/406,344 (the "'344 Application"). The '344 Application claimed priority to the '887 and '547 Applications and the '811 Provisional. On April 10, 2018, the Patent Office issued the '191 Patent from the '344 Application.

106. On March 6, 2018, the Government filed U.S. Patent Application No. 15/913,750 (the "'750 Application"). The '750 Application claimed priority to the '344, '887, and '547 Applications and the '811 Provisional. On July 2, 2019, the Patent Office issued the '423 Patent from the '750 Application.

107. On November 6, 2019—thirteen years after the CDC purportedly invented its prophylaxis methods and seven years after the FDA approved Gilead's Truvada® product for PrEP—the Government filed its complaint against Gilead and one of its subsidiaries in the Delaware Litigation. The Government's complaint accuses Gilead of infringing certain claims of the HHS Patents by selling and promoting its Truvada® and Descovy® products for PrEP. The Government seeks damages from Gilead for past and future sales of Gilead's Truvada® and Descovy® products, as well as enhanced damages and attorney fees.

108. Gilead has asserted several defenses to the Government's complaint, including that the HHS Patents are not valid and/or not enforceable. Among other reasons, certain prior art that was not disclosed during prosecution of the '509 and '333 Patents anticipates and/or renders obvious all claims of the '509 and '333 Patents. Moreover, on December 2, 2019, the Government disclaimed claims 12 and 14-18 of the '509 Patent and claims 12 and 14-17 of the '333 Patent. On information and belief, the Government made these disclaimers because it recognized that material prior art had not been disclosed to the Patent Office during prosecution of these patents.

109. By delaying its notification to Gilead of the purported invention(s) described in the '811 Provisional, the '547 Application, and the HHS Patents until at least October 23, 2014, after providing interim guidelines in January 2011 that explicitly directed use of the Truvada® product for PrEP, after Gilead had invested in development of and obtained FDA approval for

use of its Truvada® product for PrEP, and after the market for PrEP had been well-established for several years based on the Government's and Gilead's promotion of its Truvada® product for PrEP, the Government deliberately took actions that would prejudice Gilead.

110. Had the Government performed its contractual obligation under the MTAs to promptly notify Gilead of the purported invention(s) described in the '811 Provisional, the '547 Application, and the HHS Patents, Gilead would have had the opportunity to consider its options, including providing CDC and/or the PTO with information showing why any such patent would be invalid. Gilead also would have had the option to change its application for FDA approval to market Truvada® for PrEP. Further, the Government's actions increased the cost of a potential license and exposed Gilead to the risk of patent-infringement damages. They also have required Gilead to expend substantial attorneys' fees to analyze the patents and prior art, and respond to the Delaware Litigation.

COUNT I:
BREACH OF THE '072 MTA

111. Gilead incorporates by reference all the allegations set forth in the preceding paragraphs.

112. Gilead and CDC entered into a valid and enforceable contract, the '072 MTA (Ex. 4), on June 21, 2004.

113. On or around January 24, 2005, Gilead and CDC executed an amendment to the '072 MTA.

114. Gilead performed its obligations under the '072 MTA and amendment.

115. The Government failed to perform its obligations under the '072 MTA and amendment because the Government did not promptly notify Gilead of the purported invention(s) described in the '811 Provisional, the '547 Application, and the HHS Patents, which

were made, conceived, and/or reduced to practice in the course of the research conducted under the ’072 MTA and amendment.

116. The Government’s failure to promptly notify Gilead of the purported invention(s) described in the ’811 Provisional, the ’547 Application, and the HHS Patents is a material breach of the ’072 MTA and amendment.

117. As a direct and proximate result of the Government’s delay in notifying Gilead of its purported invention and of the issuance of the ’509 Patent on June 2, 2015, and after the Government’s demands that Gilead license the ’509 Patent beginning on March 11, 2016, Gilead has incurred unnecessary attorneys’ fees, including but not limited to investigating the Government’s claims, defending itself against meritless claims of patent infringement in the Delaware Litigation, and negotiating with CDC over the dispute, in an amount over $10,000. In addition, Gilead has suffered reputational harm due to the Delaware Litigation in an amount to be determined at trial.

COUNT II:
BREACH OF THE ’433 MTA

118. Gilead incorporates by reference all the allegations set forth in the preceding paragraphs.

119. Gilead and CDC entered into a valid and enforceable contract, the ’433 MTA (Ex. 5), on January 7, 2005.

120. Gilead performed its obligations under the ’433 MTA.

121. The Government failed to perform its obligations under the ’433 MTA because the Government did not promptly notify Gilead of the purported invention(s) described in the ’811 Provisional, the ’547 Application, and the HHS Patents, which were made, conceived, and/or reduced to practice in the course of the research conducted under the ’433 MTA.

122. The Government's failure to promptly notify Gilead of the purported invention(s) described in the '811 Provisional, the '547 Application, and the HHS Patents is a material breach of the '433 MTA.

123. As a direct and proximate result of the Government's delay in notifying Gilead of its purported invention and of the issuance of the '509 Patent on June 2, 2015, and after the Government's demands that Gilead license the '509 Patent beginning on March 11, 2016, Gilead has incurred unnecessary attorneys' fees, including but not limited to investigating the Government's claims, defending itself against meritless claims of patent infringement in the Delaware Litigation, and negotiating with CDC over the dispute, in an amount over $10,000. In addition, Gilead has suffered reputational harm due to the Delaware Litigation in an amount to be determined at trial.

COUNT III:
BREACH OF THE '471 MTA

124. Gilead incorporates by reference all the allegations set forth in the preceding paragraphs.

125. Gilead and CDC entered into a valid and enforceable contract, the '471 MTA (Ex. 6), on January 31, 2005.

126. On or around February 2006, Gilead and CDC executed a first amendment to the '471 MTA.

127. On or about March 6, 2006, Gilead and CDC executed a second amendment to the '471 MTA.

128. Gilead performed its obligations under the '471 MTA and amendments.

129. The Government failed to perform its obligations under the '471 MTA and amendments because the Government did not promptly notify Gilead of the purported

invention(s) described in the ’811 Provisional, the ’547 Application, and the HHS Patents, which were made, conceived, and/or reduced to practice in the course of the research conducted under the ’471 MTA and amendments.

130. The Government’s failure to promptly notify Gilead of the purported invention(s) described in the ’811 Provisional, the ’547 Application, and the HHS Patents is a material breach of the ’471 MTA and amendments.

131. As a direct and proximate result of the Government’s delay in notifying Gilead of its purported invention and of the issuance of the ’509 Patent on June 2, 2015, and after the Government’s demands that Gilead license the ’509 Patent beginning on March 11, 2016, Gilead has incurred unnecessary attorneys’ fees, including but not limited to investigating the Government’s claims, defending itself against meritless claims of patent infringement in the Delaware Litigation, and negotiating with CDC over the dispute, in an amount over $10,000. In addition, Gilead has suffered reputational harm due to the Delaware Litigation in an amount to be determined at trial.

COUNT IV:
BREACH OF THE ’649 MTA

132. Gilead incorporates by reference all the allegations set forth in the preceding paragraphs.

133. Gilead and CDC entered into a valid and enforceable contract, the ’649 MTA (Ex. 7), on April 25, 2005.

134. Between April 30, 2008, and August 4, 2014, Gilead and CDC executed five amendments to the ’649 MTA.

135. Gilead performed its obligations under the ’649 MTA and amendments.

136. The Government failed to perform its obligations under the ’649 MTA and amendments because the Government did not promptly notify Gilead of the purported invention(s) described in the ’811 Provisional, the ’547 Application, and the HHS Patents, which were made, conceived, and/or reduced to practice in the course of the research conducted under the ’649 MTA and amendments.

137. The Government’s failure to promptly notify Gilead of the purported invention(s) described in the ’811 Provisional, the ’547 Application, and the HHS Patents is a material breach of the ’649 MTA and amendments.

138. As a direct and proximate result of the Government’s delay in notifying Gilead of its purported invention and of the issuance of the ’509 Patent on June 2, 2015, and after the Government’s demands that Gilead license the ’509 Patent beginning on March 11, 2016, Gilead has incurred unnecessary attorneys’ fees, including but not limited to investigating the Government’s claims, defending itself against meritless claims of patent infringement in the Delaware Litigation, and negotiating with CDC over the dispute, in an amount over $10,000. In addition, Gilead has suffered reputational harm due to the Delaware Litigation in an amount to be determined at trial.

COUNT V:
BREACH OF THE CTA

139. Gilead incorporates by reference all the allegations set forth in the preceding paragraphs.

140. Gilead and CDC entered into a valid and enforceable contract, the CTA (Ex. 13), on November 18, 2004.

141. On or around October 3, 2006, Gilead and CDC executed the CTA-01 Amendment (Ex. 14).

142. On or around November 24, 2008, Gilead and CDC executed the CTA-02 Amendment (Ex. 16).

143. On or around January 12, 2012, Gilead and CDC executed the CTA-03 Amendment (Ex. 17).

144. Gilead performed its obligations under the CTA and amendments.

145. By seeking patent protection on alleged inventions deriving from the Botswana trial, and by seeking to license the regimen that was studied in the clinical trial, the Government materially breached the CTA and its subsequent amendments.

146. As a direct and proximate result of the Government's breach of the CTA, and after the Government's demands that Gilead license the '509 Patent beginning on March 11, 2016, Gilead has incurred unnecessary attorneys' fees, including but not limited to investigating the Government's claims, defending itself against meritless claims of patent infringement in the Delaware Litigation, and negotiating with CDC over the dispute, in an amount over $10,000. In addition, Gilead has suffered reputational harm due to the Delaware Litigation in an amount to be determined at trial.

PRAYER FOR RELIEF

Wherefore, Gilead prays for an order and judgment:

A. Finding that the Government breached the '072, '433, '471, and '649 MTAs and the CTA;

B. Awarding Gilead monetary relief for the damages suffered to date and for the damages Gilead continues to suffer as a result of the Government's breach of the MTAs and their respective amendments and the CTA, in an amount to be determined at trial, but not less than $10,000;

C. Awarding Gilead pre-judgment and post-judgment interest, together with any and all further costs, disbursements, and reasonable attorneys' and expert fees;

D. Granting such other and further relief as the Court deems just and proper.

Dated: April 24, 2020

Respectfully submitted,

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