IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff/Counterclaim Defendant,	)	
	)	
v.	)	
	)	
GILEAD SCIENCES, INC.,	)	C.A. No. 19-2103 (MN)
	)	
Defendant/Counterclaim Plaintiff,	)	
	)	
and GILEAD SCIENCES IRELAND UC,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

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January 28, 2021
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

On May 29, 2020, Defendants Gilead Sciences, Inc. ("Gilead") and Gilead Sciences Ireland UC ("Gilead Ireland") (collectively, "Defendants") filed their Second Amended Answer and Affirmative Defenses and Gilead's Second Amended Counterclaims (D.I. 21) ("the Second Amended Answer"). Before the Court are a motion to strike (D.I. 29) the equitable defenses raised in the Second Amended Answer and a motion to dismiss (D.I. 30) Gilead's counterclaims of noninfringement and invalidity, which were filed by the United States of America ("Government" or "Plaintiff") on June 26, 2020. Both motions were fully briefed, (D.I. 29, 30, 35, 36, 40, 41), and the Court heard argument on October 30, 2020, (D.I. 60). For the reasons set forth below, Plaintiff's motion to strike and motion to dismiss will be DENIED.

I. BACKGROUND

A. Factual Background[1]

The Government alleges that the Department of Health and Human Services (HHS) is, by virtue of its administrative control of the Centers for Disease Control and Prevention (CDC), the owner of U.S. Patent Nos. 9,044,509 ("the '509 Patent"), 9,579,333 ("the '333 Patent"), 9,937,191 ("the '191 Patent") and 10,335,423 ("the '423 Patent") (collectively, "the Patents-in-Suit"). (D.I. 1 ¶ 10, 12). The Patents-in-Suit relate to two-drug regimens, known as pre-exposure prophylaxis (PrEP), which were developed by researchers at CDC in the mid-2000s and effectively prevent new HIV infections. (*Id.* ¶ 2, 5). These regimens consist of (1) emtricitabine (FTC) and (2) tenofovir or a tenofovir prodrug. (*Id.* ¶ 2). Truvada and Descovy, medications developed by Gilead, each contain FTC and a tenofovir prodrug. (*Id.* ¶¶ 47–49, 54). Gilead received approval

[1] Unless otherwise indicated, the facts recited are those alleged by Defendants in the Second Amended Answer. The Court, as it must at this stage, takes them as true.

from the U.S. Food and Drug Administration (FDA) to sell Truvada as a PrEP regimen on July 16, 2012. (D.I. 21 at 94 ¶ 14). Descovy was approved as a PrEP regimen by the FDA on October 3, 2019. (D.I. 1 ¶ 57).

Between 2004 and 2008, Gilead and CDC executed several Material Transfer Agreements ("MTAs"), pursuant to which Gilead provided CDC with FTC, tenofovir, and tenofovir disoproxil fumarate (TDF)[2] for use in CDC research. (*Id.* ¶ 120; *see, e.g.*, D.I. 1, Ex. 30). Pursuant to amendments to an MTA executed in 2005, Gilead continued to provide materials to CDC until 2014. (D.I. 21 at 73 ¶¶ 31–32).

Under the terms of the MTAs, CDC was to "promptly disclose to [Gilead] all results, data, and other information or materials derived from" any materials and confidential information provided by Gilead, as well as to "promptly notify [Gilead] of any Inventions." (D.I. 1 ¶¶ 122–23). In addition to the MTAs, the Government and Gilead entered into a Clinical Trial Agreement ("CTA"). (D.I. 21 at 75 ¶ 37). Under the CTA, Gilead agreed to provide antiviral products for a clinic trial about HIV prevention in Botswana, and the Government agreed "to put the results of the Trial, patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC" as well as "not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." (*Id.*).

CDC filed U.S. Provisional Patent Application No. 60/764,811 ("the '811 Provisional") on February 3, 2006. (D.I. 1 ¶ 128). On January 31, 2007, CDC filed U.S. non-provisional patent Application No. 11/669,547 ("the '547 Application"), claiming priority to the '811 Provisional. (*Id.*). All Patents-in-Suit claim priority to the '811 Provisional and '547 Application.

[2] TDF is a tenofovir prodrug. (D.I. 1 ¶ 49).

The inventions described in the ’811 Provisional and the ’547 Application were the result of the studies described in the MTAs, for which Gilead provided drugs to CDC. (D.I. 21 at 74 ¶ 36). The Government relied on information derived from the Botswana trial contemplated in the CTA to make decisions concerning prosecution of the ’547 Application. (*Id.* at 75 ¶ 37). The Government breached its obligations under the MTAs and CTA because it “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).” (*Id.* at 75 ¶ 38). Further, the Government did not provide notice of the claimed inventions until October 2014 at the earliest and did not assert that Gilead required a license under the Patents-in-Suit until March 11, 2016. (*Id.*).

During prosecution of the Patents-in-Suit, the Government allegedly, knowingly, and willfully failed to provide material information to the Patent Office relating to the inventiveness of the claimed inventions. (*Id.* at 77 ¶ 45). In August 2019, Gilead filed petitions for *inter partes* review of claims 1–18 of the ’509 Patent, *see* Petition, No. IPR2019-01453 (P.T.A.B. Aug. 21, 2019), and claims 1–17 of the ’333 Patent, *see* Petition, No. IPR2019-01454 (P.T.A.B. Aug. 21, 2019) (collectively, “the IPR Petitions”). Among the prior art asserted in the IPR Petitions were CDC’s 2005 guidelines on post-exposure prophylaxis (PEP)[3] (“the CDC-PEP Guidelines”). (D.I. 21 at 78 ¶ 47; *see* D.I. 21, Ex. J). The CDC-PEP Guidelines were published on January 21, 2005, more than one year before the February 3, 2006 filing of the ’811 Provisional. (D.I. 21 at 79 ¶ 49; *see also* D.I. 1 ¶ 128). Two of the named inventors of the Patents-in-Suit, Robert Janssen and Ronald Otten, were identified as “federal consultants” for the CDC-PEP

[3] Post-exposure prophylaxis is a regimen for preventing HIV infection which involves taking antiretroviral drugs shortly after a potential exposure that presents a substantial risk for such infection. (D.I. 1 ¶ 64).

Guidelines. (D.I. 21 at 78 ¶ 47). The CDC-PEP Guidelines identified a combination of TDF and FTC as "one of two 'preferred' backbone combinations" for use in PEP and noted that Truvada is an oral formulation containing a combination of TDF and FTC. (*Id.* at 78 ¶ 48).

The Government did not disclose the CDC-PEP Guidelines to the Patent Office during prosecution of the '509 Patent and '333 Patent, and the examiners did not consider the CDC-PEP Guidelines. (*Id.* at 79 ¶ 52). Individuals with a duty to disclose material information during prosecution, such as named inventors and prosecuting attorneys, allegedly failed to disclose the CDC-PEP Guidelines during prosecution of the '509 Patent and '333 Patent. (*Id.* at 82 ¶ 62). Defendants allege that claims 12–18 of the '509 Patent and claims 12–17 of the '333 Patent are anticipated by the CDC-PEP Guidelines, and that reference renders all challenged claims of the '509 and '333 Patents obvious. (*Id.* at 79 ¶ 53). Furthermore, claim 12 and dependent claims 12–18 of the '509 Patent and claim 12 and dependent claims 14–17 of the '333 Patent do not specify that the two-drug regimen must be administered prior to an actual or potential exposure to HIV, which is a key difference between PEP and PrEP. (*Id.* at 80 ¶¶ 54–55).

The Government also did not disclose the CDC-PEP Guidelines in its initial application for what would later issue as the '191 Patent, and did not alert the examiner to the alleged materiality of the reference even when it eventually disclosed the CDC-PEP Guidelines two months after the original filing. (*Id.* at 80 ¶ 59). After that disclosure, the examiner rejected claims in reliance on the CDC-PEP Guidelines, "noting that [the reference] disclosed the use of Truvada® for PEP purposes and that it would have been obvious to treat uninfected individuals 'who are exposed to or at risk of exposure to HIV' with Truvada®." (*Id.* at 82 ¶ 61 (citing D.I. 21, Ex. O at 5–6)). Following this rejection, the patent application was amended to include a limitation confining the claim to pre-exposure administration. (*Id.* at 82 ¶ 61 (citing D.I. 21, Ex. P at 3)).

In addition, the Government allegedly encouraged the prescription and public use of Truvada for PrEP purposes even before the FDA approved Truvada for that purpose in 2012. (*Id.* at 67 ¶ 5). In January of 2011, CDC issued guidelines that identified "1 tablet of Truvada . . . daily as part of [b]eginning [a] PrEP medication regimen." (*Id.* (internal quotations omitted)). The Government "actively encouraged [Gilead] to seek FDA approval for the PrEP indication for Truvada," (*id.*), and Truvada had already been publicly used for PrEP "before the inventions of the [Patents-in-Suit] and/or more than one year before the earliest priority date to which each claim of the [Patents-in-Suit] is entitled," (*id.* at 96 ¶ 20). The Government alleges that Truvada had earned Gilead more than $3 billion from global sales in 2012, (D.I. 1 ¶ 174; D.I. 1, Ex. 63 at 3), and more than $6.7 billion from domestic sales since the '509 Patent was issued in mid-2015, (*id.* ¶ 255).

B. Procedural Background

On November 6, 2019, the Government filed this suit against Defendants. The Government alleges that Gilead's actions with respect to Truvada and Descovy for PrEP constitute willful infringement of the '509 Patent and the '423 Patent. (D.I. 1 ¶¶ 282–85, 307–10). It further alleges that Gilead's actions with respect to Truvade for PrEP constitute willful infringement of the '333 Patent and the '191 Patent. (*Id.* ¶¶ 291–94, 299–302).

Defendants filed their Answer and Affirmative Defenses and Gilead's Counterclaims (D.I. 7) on January 23, 2020. In that filing, Defendants did not directly address sovereign immunity. (D.I. 7 at 70 ¶¶ 3–4). Pursuant to a joint stipulation, (D.I. 11), Defendants filed their First Amended Answer and Affirmative Defenses and Gilead's First Amended Counterclaims (D.I. 13) on March 27, 2020. On May 15, 2020, the Government filed a Motion to Strike equitable affirmative defenses (D.I. 16) and a Motion to Dismiss for failure to state a claim and lack of

subject matter jurisdiction (D.I. 17). Pursuant to another joint stipulation, (D.I. 19), Defendants filed the Second Amended Answer on May 29, 2020.

The Second Amended Answer pleads fifteen affirmative defenses: failure to state a claim for relief, non-infringement, invalidity, unclean hands, inequitable conduct, derivation, safe harbor, acquiescence and/or estoppel, implied waiver, no willfulness, no exceptional case, no recovery of costs, failure to mitigate, no standing, and no constitutional authority. (D.I. 21 at 66–90 ¶¶ 1–86). Defendants allege that the Government has waived its immunity from equitable defenses for three reasons. First, because the Government has acted in a proprietary capacity, rather than a sovereign capacity, by obtaining and asserting patent rights. (*Id.* at 77 ¶ 43, 84 ¶ 67, 86 ¶ 72, 88 ¶ 79, 89 ¶ 84). Second, because the Government engaged in affirmative misconduct. (*Id.* at 77 ¶ 43, 84 ¶ 67, 86 ¶ 72, 88 ¶ 79, 89 ¶ 84). Third, because immunity from equitable defenses would result in serious injustice to Defendants because it would "expose Defendants to greater potential liability as a direct result of [Gilead's] efforts to work with the Government to mitigate the HIV crisis and promote public health." (*Id.* at 77 ¶ 43, 84 ¶ 67, 86 ¶ 72, 88 ¶ 79, 89 ¶ 84).

In the Second Amended Answer, Gilead also asserts numerous counterclaims: declaratory judgment of non-infringement of the '509 Patent (Count I), declaratory judgment of invalidity of the '509 Patent (Count II), declaratory judgment of non-infringement of the '333 Patent (Count III), declaratory judgment of invalidity of the '333 Patent (Count IV), declaratory judgment of non-infringement of the '191 Patent (Count V), declaratory judgment of invalidity of the '191 Patent (Count VI), declaratory judgment of non-infringement of the '423 Patent (Count VII), and declaratory judgment of invalidity of the '423 Patent (Count VIII).

The Second Amended Answer alleges that sovereign immunity has been waived for two reasons. First, that because Gilead's counterclaims "arise from the same transactions that gave rise to the Government's suit, seek relief of the same kind or nature as the Government's suit (i.e., a finding on whether the claims of the [Patents-in-Suit] are valid and infringed), and do not seek an amount of relief that is in excess of the Government's claims (i.e., because they seek only declaratory relief)," the counterclaims sound properly in recoupment. (D.I. 21 at 92 ¶ 5). Second, that because the counterclaims "seek only declaratory relief, not money damages; because HHS, CDC, and/or their employees acted unlawfully in their official capacities in obtaining the [Patents-in-Suit], which claim subject matter that is not patentable; and because HHS and/or its employees acted unlawfully in their official capacities in asserting that Gilead infringes the claims of the [Patents-in-Suit] and demanding that Gilead license the [Patents-in-Suit]," (*id.* at 93 ¶ 6), the counterclaims fall within the scope of 5 U.S.C. § 702, which provides that an action "seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States," 5 U.S.C. § 702. Gilead alleges that, either or both of these waivers are sufficient to give this Court subject matter jurisdiction over the counterclaims brought in the Second Amended Answer. (*See id.* at 92 ¶ 4).

On June 26, 2020, the Government filed the present Motion to Strike (D.I. 29) and Motion to Dismiss for lack of subject matter jurisdiction (D.I. 30). The Motion to Strike is directed at Gilead's equitable affirmative defenses, which the Government specifies as Defendants' Fourth Affirmative Defense (Unclean Hands), Fifth Affirmative Defense (Inequitable Conduct), Eighth Affirmative Defense (Acquiescence and/or Estoppel), Ninth Affirmative Defense (Implied Waiver), and Thirteenth Affirmative Defense (Failure to Mitigate). (D.I. 29 at 19 n.9).

II. LEGAL STANDARD

A. Standard Pursuant to Rule 12(f)

A court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "An affirmative defense is insufficient if it is not recognized as a defense to the cause of action." *U.S. ex rel. Spay v. CVS Caremark Corp.*, No. 09-4672, 2013 WL 1755214, at *1 (E.D. Pa. Apr. 24, 2013) (quoting *Total Containment, Inc. v. Environ Prods., Inc.*, No. 91–7911, 1992 WL 208981, at *1 (E.D. Pa. Aug. 19, 1992)). Motions to strike are generally "disfavored." *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 356 (D. Del. 2009) (citing *Seidel v. Lee*, 954 F.Supp. 810, 812 (D.Del.1996)). The Third Circuit has cautioned that "a court should not grant a motion to strike a defense unless the insufficiency of the defense is 'clearly apparent.'" *Cipollone v. Liggett Grp., Inc.*, 789 F.2d 181, 188 (3d Cir. 1986). "When ruling on a motion to strike, the [c]ourt must construe all facts in favor of the nonmoving party and deny the motion if the defense is sufficient under law." *Symbol Techs.*, 609 F. Supp. 2d at 356 (quoting *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 697 F.Supp. 1360, 1362 (D.Del.1988)) (internal quotations omitted).

B. Standard Pursuant to Rule 12(b)(1)

"Sovereign immunity not only protects the United States from liability, it deprives a court of subject matter jurisdiction over claims against the United States." *Richards v. United States*, 176 F.3d 652, 654 (3d Cir. 1999). "If the court determines . . . it lacks subject matter jurisdiction, the court must dismiss the action." Fed. R. Civ. P. 12(h)(3). A plaintiff bears the burden of establishing subject matter jurisdiction. *Lincoln Ben. Life Col. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). Motions brought under Rule 12(b)(1) for lack of subject matter jurisdiction may present either a facial or factual challenge to the court's jurisdiction. *Id.* A challenge is facial

when a motion to dismiss is filed prior to an answer and asserts that the complaint is jurisdictionally deficient on its face. *Cardio-Medical Assoc., Ltd. v. Crozer-Chester Medical Center*, 721 F.2d 68, 75 (3d Cir. 1983). In reviewing a facial challenge under Rule 12(b)(1), the standards relevant to Rule 12(b)(6) apply. *Lincoln*, 800 F.3d at 105 ("In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff").

C. Standard Pursuant to Rule 12(b)(6)

When presented with a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), district courts conduct a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the Court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210–11. Second, the Court determines "whether the facts alleged in the complaint are sufficient to show . . . a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)).

"To survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Dismissal under Rule 12(b)(6) is appropriate if a complaint does not contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570); *see also Fowler*, 578 F.3d at 210. A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The Court is not obligated to accept as true "bald assertions" or

"unsupported conclusions and unwarranted inferences." *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997); *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997). Instead, "[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.*, 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted).

III. DISCUSSION

A. Motion to Strike

The Government repeatedly asserts that "[w]hen the United States seeks relief in its courts, the general rule is that it is not subject to ***any*** equitable defenses." (D.I. 29 at 3 (emphasis in original), D.I. 40 at 1). Although the Government has in the past advocated for such a "sweeping rule," the Supreme Court has declined to adopt one. *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 423 (1990); *see Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 60 (1984) ("We have left the issue open in the past, and do so again today."); *see also Burnside-Ott Aviation Training Ctr., Inc. v. United States*, 985 F.2d 1574, 1581 (Fed. Cir. 1993) (rejecting interpretation of *Richmond* as standing for "the proposition that equitable estoppel will not lie against the government for any monetary claim"). Rather, the general rule is that when the United States brings suit in its sovereign capacity, it is not subject to equitable defenses. *United States v. Georgia-Pac. Co.*, 421 F.2d 92, 100–01 (9th Cir. 1970). When the government acts in its proprietary capacity, however, equitable defenses may be asserted. *Id.* at 100–01, 100 n.17 (collecting cases); *United States v. Banks*, 115 F.3d 916, 919 (11th Cir. 1997); *United States v. Philip Morris Inc.*, 300 F. Supp. 2d 61, 72, 75 (D.D.C. 2004). Even when the government acts in its sovereign capacity, courts have suggested that equitable defenses may be permitted when

authorized by a clear expression of Congress, *see Banks*, 115 F.3d at 919 (discussing application of statute of limitations to claims brought by the federal government in its sovereign capacity), or when supported by proof of the traditional elements of estoppel as well as affirmative misconduct by the United States, *see Richmond*, 496 U.S. at 421–22, *ATC Petroleum, Inc. v. Sanders*, 860 F.2d 1104, 1111 (D.C. Cir. 1988).

Defendants argue that equitable defenses may be asserted in this case for two reasons. First, they contend that the defenses are expressly authorized by the Patent Act. (D.I. 35 at 10 (citing 35 U.S.C. § 282)). Second, they argue that in bringing this suit the Government has acted in a proprietary capacity and has thereby opened the door to equitable defenses. (*Id.* at 12).

The parties acknowledge that, for purposes of the motion to strike, the four enforceability defenses – unclean hands, inequitable conduct, acquiescence and/or estoppel, and implied waiver – rise and fall together, and the affirmative defense of failure to mitigate has separate considerations. (D.I. 60 at 43:4–7, 46:7–8). Therefore, this Court will address the enforceability defenses collectively.

1. Express Authorization Under 35 U.S.C. § 282

Defendants contend that enforceability defenses may be asserted against the Government because § 282 specifies that certain defenses, including unenforceability, "shall be defenses in any action involving the validity or infringement of a patent." (D.I. 35 at 10 (quoting 35 U.S.C. § 282(b)(1))). Defendants reason that because this is a case for patent infringement, it falls within the scope of "any action involving the . . . infringement of a patent." (*Id.* (quoting 35 U.S.C. § 282(b)(1))). In response, the Government suggests that this reading of § 282 "hinges on a misreading of the law" and points to the Supreme Court's analysis in *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, 137 S. Ct. 954 (2017), to argue that § 282

incorporates a pre-existing common law rule barring equitable defenses against the government. (D.I. 40 at 2–3).

The Court agrees that Defendants' proposed interpretation of § 282, which would allow equitable defenses in *all* patent actions brought by the government, is too broad. As with any statute, there is a presumption that the 1952 Congress passed § 282 "against the background of general common-law principles." *SCA Hygiene*, 137 S. Ct. at 966 (2017). And the general principle that equitable defenses could not be asserted against the United States "in a suit brought by them as a sovereign government [was] established past all controversy or doubt" in 1888. *United States v. Beebe*, 127 U.S. 338, 344 (1888). Although that rule had not been explicitly applied in patent cases, "[p]atent law is governed by the same common-law principles . . . as other areas of civil litigation." *SCA Hygiene*, 137 S. Ct. at 964 (citation omitted). There is nothing in the text of § 282 to suggest that Congress intended to vitiate the long-established rule for all patent infringement actions brought by the government, regardless of whether the government acts in its sovereign or proprietary capacity. Thus, § 282 alone cannot allow Defendants to assert enforceability defenses.

2. Sovereign Versus Proprietary Capacity

When the government carries out "its unique governmental functions for the benefit of the whole public," it acts in its sovereign role. *Georgia-Pac. Co.*, 421 F.2d at 101. On the other hand, when the government "divests itself of its sovereign character as to [a] particular transaction . . . [it] submits to the same law as governs individuals under like circumstances" and is said to act in its proprietary capacity. *Id.* There is no clear rule distinguishing sovereign from proprietary actions, but there are several trends in the case law that are instructive here. Courts looking at cases involving real property have held that the United States acts in its sovereign capacity when

it brings a suit "to enforce and maintain its policy respecting lands which it holds in trust for all the people." *Utah Power & Light Co. v. United States*, 243 U.S. 389, 409 (1917). In the contract context, the government acts as a private party, and is therefore subject to the same laws as other litigants. *Georgia-Pac. Co.*, 421 F.2d at 101. Finally, courts have carved out an exception for the United States Postal Service, reasoning that because it is uniquely structured to be "a nearly self-sustaining enterprise competitive with other commercial ventures," only the traditional elements of estoppel need be shown. *Azar v. U.S. Postal Serv.*, 777 F.2d 1265, 1271 (7th Cir. 1985).

Here, Plaintiff suggests that because Congress passed the Bayh-Dole Act expressly authorizing the federal government to "apply for, obtain, and maintain patents . . . on inventions in which the Federal Government owns a right, title, or interest" and then act "to protect and administer rights to federally owned inventions," such action is always necessarily taken in a sovereign capacity. (D.I. 29 at 9 (quoting 35 U.S.C. § 207(a))). Applying for, obtaining, and enforcing patents, however, are not "unique governmental functions," *Georgia-Pac. Co.*, 421 F.2d at 101, and are routinely performed by private research entities.[4]

Moreover, the distribution rules for royalty payments confirm that actions under the Bayh-Dole Act are not categorically sovereign. Royalties are paid first to the inventor(s) of the licensed technology, then are used to provide incentives to other laboratory employees, and then may be used by the relevant agency's laboratories to reward employees, to "further scientific exchange

[4] Indeed, there is some evidence that the Bayh-Dole Act was intended to allow the government to manage its intellectual property more like private entities, such as universities. Prior to the Bayh-Dole Act, the government could grant only nonexclusive licenses for its patents, and less than 4% of the government's patent portfolio had been successfully licensed. S. Rep. No. 96-480, at 2 (1979). Universities, meanwhile, could offer exclusive licenses and had been able to successfully license 33% of their patent portfolios. *Id.* By passing the Bayh-Dole Act, Congress authorized the government to grant "nonexclusive, exclusive, or partially exclusive licenses," 35 U.S.C. § 207(a)(2), and thus to act more like a private entity with respect to its patent portfolio.

among the laboratories," for "education and training of employees [and] other activities that increase the potential for transfer of the technology of the laboratories," for "payment of expenses incidental to the administration and licensing of intellectual property," or, more generally, for "scientific research and development consistent with the . . . missions and objectives of the laboratory." 15 U.S.C. § 3710c(a)(1). Royalties are paid into the Treasury only if the initial payments received are very large or if, after all research expenditures, there are still funds remaining after two years. 15 U.S.C. § 3710c(a).[5]

This does not mean that ***all*** action taken under the Bayh-Dole Act is of a proprietary nature. It is possible that, under certain circumstances, the Government could be found to act in a sovereign capacity when it obtains and asserts patent rights. *See Portmann v. United States*, 674 F.2d 1155, 1160–1161 & 1161 n.17 (7th Cir. 1982) (noting that, despite the general rule, some government contracts are exercises of sovereign responsibility). The allegations concerning the Government's actions in this case, however, are that it has acted in a proprietary capacity.

The Government argues that, under the Bayh-Dole Act, it is called to "protect the public against nonuse or unreasonable use of inventions," 35 U.S.C. § 207(a), not to "act in a proprietary capacity, concerned only with extracting all the profits the market can bear at the expense of consumers." (D.I. 29 at 10). It does not, however, argue that this case is one involving nonuse or even unreasonable use. Nor could it.

The '811 Provisional and '547 Application to which the Patents-in-Suit claim priority were filed in 2006 and 2007, respectively. (D.I. 1 ¶ 128). At that time, the Government was already

[5] Much like the Postal Service is "a nearly self-sustaining enterprise competitive with other commercial ventures," *Azar*, 777 F.2d at 1271, agencies that license patents are meant to use the royalties to recoup their investment and reward their researchers. *See* S. Rep. No. 96-480, at 3.

aware that Truvada was used for PEP. (*See* D.I. 21 at 78 ¶¶ 47–48). Even before Gilead received FDA approval to market Truvada for PrEP, the Government identified Truvada as "part of [b]eginning [a] PrEP medication regimen." (*Id.* at 67 ¶ 5). The Government "actively encouraged [Gilead] to seek FDA approval for the PrEP indication for Truvada." (*Id.*). In the same year that approval was granted, the Government alleges that Gilead earned more than $3 billion dollars from global sales of Truvada. (D.I. 1 ¶ 174). Nonetheless, the Government purportedly did not provide notice of the claimed inventions until October 2014 and did not assert that Gilead required a license for the Patents-in-Suit until March 11, 2016. (D.I. 21 at 75 ¶ 38). In the intervening years, the Government could not have been concerned about nonuse of a federally-funded invention.

Indeed, the Government is aware that Defendants have developed Truvada and Descovy into "a multibillion dollar market," (D.I. 60 at 58:6), and Gilead has earned more than $6.7 billion from domestic sales of Truvada since the '509 Patent was issued, (D.I. 1 ¶ 255). As the Government acknowledged during argument, "where the product was ultimately very successful, the government is seeking to license this." (D.I. 60 at 63:3–4). Thus, the Government is acting in furtherance of one of the goals of every private research entity, as well as of the Bayh-Dole Act: "to stimulate a greater return on the billions of dollars spent each year by the Government on its research and development programs." S. Rep. No. 96-480, at 3.

Even if the facts in this case did not clearly point towards proprietary action, the allegations in the Second Amended Answer, taken as true, rise to the level of affirmative misconduct necessary to permit equitable defenses in this case. The Government asserts that equitable defenses are permitted only upon a showing of "affirmative, egregious government misconduct." (D.I. 29 at 14). Here, Defendants have alleged that the Government breached its contractual obligations under the MTAs and CTA when it failed to disclose to Gilead the inventions underlying the Patents-in-

Suit. (D.I. 21 at 75 ¶ 38). Defendants have also alleged that at least two of the Patents-in-Suit were obtained because government employees knowingly withheld material information from the Patent Office during prosecution, despite a duty to disclose such information. (*Id.* at 79 ¶¶ 52–53, 82 ¶ 62). The alleged violations of the duties of disclosure and candor, as well as the potential fraud on the Patent Office, are examples of affirmative government misconduct, and sufficient to permit Defendants' unenforceability defenses.

Thus, because the Government has acted in a proprietary capacity in bringing this suit and because there has been a showing of affirmative misconduct, the four enforceability defenses – unclean hands, inequitable conduct, acquiescence and/or estoppel, and implied waiver – are legally sufficient and will not be stricken.

3. Failure to Mitigate

Defendants have also asserted an affirmative defense of failure to mitigate, explaining that if the Government intends to seek damages measured by harm it has sustained, rather than a reasonable royalty, this defense is proper because the Government has acted in a proprietary capacity. (D.I. 35 at 20). The Government argues that its "efforts to patent and license innovative PrEP regimens to commercial entities like Gilead and, in turn, to enforce its patents when necessary to protect the public's investment and interest in its inventions" should be "free from the second-guessing Gilead's defense requires." (D.I. 29 at 17). In support, the Government cites cases holding that a defense of failure to mitigate cannot be asserted against the Federal Deposit Insurance Corporation (FDIC) based on its dealings with failing financial institutions. (*Id.* (citing *FDIC v. Mijalis,* 15 F.3d 1314, 1324 (5th Cir. 1994); *FDIC v. Oldenburg*, 38 F.3d 1119, 1121–22 (10th Cir. 1994); *FDIC v. Bierman*, 2 F.3d 1424, 1441 (7th Cir. 1993))). The FDIC, however, is a unique institution and "special public policy considerations distinguish banking cases from

ordinary tort cases where these affirmative defenses are normally available." *Oldenburg*, 38 F.3d at 1121. As explained above, in this case the Government has acted in a proprietary capacity, and therefore this case does not have the same "special public policy considerations."

Moreover, the insufficiency of Defendants' failure to mitigate defense is not "clearly apparent" so as to warrant striking the defense. *See Cipollone*, 789 F.2d at 188. The Government's damages theory is unclear at this stage and, to the extent it will seek damages measured by harm it has sustained, Defendants have alleged sufficient facts to sustain the defense. Defendants have pleaded that, despite filing the '811 Provisional in 2006, (D.I. 1 ¶ 128), and "actively encourage[ing Gilead] to seek FDA approval for the PrEP indication for Truvada," (D.I. 21 at 67 ¶ 5), the Government did not provide notice of the claimed inventions under October 2014 and did not assert that Gilead required a license for the Patents-in-Suit until March 11, 2016, (*Id.* at 75 ¶ 38). At this early stage of litigation and when faced with a "disfavored" motion to strike, *Symbol Techs.*, 609 F. Supp. 2d at 356, these allegations are sufficient to permit the assertion of the failure to mitigate defense.

B. Motion to Dismiss

The Government argues that Gilead's counterclaims of noninfringement and invalidity for each of the Patents-in-Suit should be dismissed because Gilead has failed to establish a legally sufficient waiver of sovereign immunity. (D.I. 30 at 2). In response, Gilead contends that (1) 5 U.S.C. § 702 waives the Government's sovereign immunity for Gilead's requests for declaratory relief, (D.I. 36 at 2 (citing 5 U.S.C. § 702)), and (2) under the doctrine of recoupment, the Government has waived sovereign immunity for counterclaims that arise from the same issues of fact and law as the Government's own claims, (*id.* at 6).

1. Waiver Under 5 U.S.C. § 702

Section 702 provides:

> A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. . . .

5 U.S.C. § 702. The Federal Circuit considered § 702 in the context of a patent case in *Delano Farms Co. v. California Table Grape Commission*, 655 F.3d 1337 (Fed. Cir. 2011). In *Delano*, the plaintiffs had licensed three patented varieties of grapevines from the California Table Grape Commission, which had been granted the right to sublicense the patents by the patent owner, the United States Department of Agriculture ("USDA"). *Id.* at 1340. The plaintiffs subsequently brought an action in the United States District Court of the Eastern District of California, seeking a declaratory judgment that all three patents were invalid because of prior use and one patent was unenforceable because of inequitable conduct during prosecution. *Id.* The Commission and USDA moved to dismiss the declaratory judgment claims, arguing that, as the patentee, the USDA was an indispensable party but could not be joined due to sovereign immunity. *Id.* at 1341. The Federal Circuit concluded that, although the underlying patent dispute was not within the category of agency actions for which the APA prescribes a right to judicial review, it nonetheless fell within the waiver of sovereign immunity in § 702. *Id.* at 1344. The court held that:

> [S]ection 702 . . . waives sovereign immunity for non-monetary claims against federal agencies, subject to the limitations in subsections (1) and (2). It is not limited to "agency action" or "final agency action," as those terms are defined in the APA. We therefore conclude that the waiver of sovereign immunity in section 702 is broad enough to allow Delano to pursue equitable relief against the USDA on its patent law claims.

Id.

Defendants argue that *Delano* applies to Gilead's counterclaims of non-infringement and invalidity. (D.I. 36 at 3). The Government, however, contends that *Delano* is inapposite for two reasons. First, the Government argues that Gilead has not pleaded that "an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority," 5 U.S.C. § 702, and that Gilead's counterclaims are therefore "far different substantively" from the claims which established a waiver of sovereign immunity in *Delano*. (D.I. 30 at 9). Second, the Government argues that HHS's actions are not subject to judicial review under § 702 because they were "committed to agency discretion by law" and therefore fall within an exception to the Administrative Procedure Act. (*Id.* at 12 (quoting 5 U.S.C. § 701(a)(2))). The Government asserts that the *Delano* court did not address the question of whether § 701(a)(2) precludes review of governmental actions related to patent rights, but directs this Court's attention to *Southern Research Institute v. Griffin Corporation*, in which the Eleventh Circuit held that an agency's discretion to assign or transfer federal patent rights was so broad as to be unreviewable. (*Id.* at 13 (citing *S. Research Inst. v. Griffin Corp.*, 938 F.2d 1249, 1255 (11th Cir. 1991)).

The Court agrees with Defendants. The claims at issue here are comparable to those at issue in *Delano* and the Second Amended Answer has sufficiently pleaded that "an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority," 5 U.S.C. § 702. The *Delano* plaintiffs had alleged that a government employee and named inventor had committed an invalidating prior use of the patented grape varieties and subsequently failed to inform the Patent Office of that use. *Delano*, 655 F.3d at 1340–41. In the present case, Gilead has alleged that government employees applied for the Patents-in-Suit despite their knowledge of the CDC-PEP Guidelines, which constitute material prior art that would have

invalidated "all challenged claims of the '509 Patent and '333 Patent." (D.I. 21 at 79 ¶ 52–53). Gilead has further alleged that individuals with a duty to disclose material information during patent prosecution, such as inventors and prosecuting attorneys, failed to make such disclosures during the prosecutions of both the '509 and '333 Patents. (*Id.* at 82 ¶ 62). According to Gilead, the named inventors failed to make these disclosures to the Patent Office despite the fact that two of the named inventors of the Patents-in-Suit were identified as "federal consultants" for the CDC-PEP Guidelines. (*Id.* at 78 ¶ 47). Thus, Defendants' allegations here are comparable to those made by the plaintiffs in *Delano*.

Despite the Government's reliance on *Southern Research*, the question of sovereign immunity in this case is resolved by the Federal Circuit's decision in *Delano*. Sovereign immunity issues in patent cases are governed by Federal Circuit law "in light of the special important of ensuring national uniformity on such questions." *Delano*, 655 F.3d at 1343 (citing *Pennington Seed, Inc. v. Produce Exch. No. 299*, 457 F.3d 1334, 1338 (Fed. Cir. 2006)). The *Delano* court stated that the APA "waives sovereign immunity for any action stating a claim against the United States (or its officers or employees) and seeking relief other than money damages," *id.* at 1344, and relied on the legislative history of the statute to conclude that waiver of sovereign immunity was not meant to be limited to actions arising under the APA itself or under statutes directed at the review of "agency action," *id.* at 1345. That decision is binding on this Court.

To the extent that the Government argues that *Delano* does not govern this case because the Federal Circuit did not address whether § 701(a)(2) precludes review of governmental actions in obtaining and maintaining patents, (D.I. 30 at 13), it is equally true that *Southern Research* did not address the application of § 701(a)(2) to an agency's decision to ***obtain*** a patent beyond a brief

mention in a footnote, *see Southern Research*, 938 F.2d at 1254 n.9. Thus, *Delano* applies to Gilead's counterclaims and Gilead has established a waiver of sovereign immunity.

Having concluded that sovereign immunity has been waived under 5 U.S.C. § 702, the Court does not reach the remaining argument under the doctrine of recoupment.

IV. CONCLUSION

For the foregoing reasons, the Government's motion to strike and motion to dismiss are DENIED. An appropriate order will follow.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff/Counterclaim Defendant,	)	
	)	
v.	)	
	)	
GILEAD SCIENCES, INC.,	)	No. 19-2103 (MN)
	)	
Defendant/Counterclaim Plaintiff,	)	
	)	
and GILEAD SCIENCES IRELAND UC,	)	
	)	
Defendant.	)	

ORDER

At Wilmington this 28th day of January 2021:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. Plaintiff's Motion to Strike (D.I. 29) is DENIED.

2. Plaintiff's Motion to Dismiss (D.I. 30) is DENIED.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge