UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA,
Plaintiff–Counterclaim Defendant,

v.

GILEAD SCIENCES, INC.
Defendant–Counterclaim Plaintiff,

AND GILEAD SCIENCES IRELAND UC,
Defendant.

Civil No. 1:19-cv-02103-MN

UNITED STATES' REPLY IN SUPPORT OF ITS MOTION TO STRIKE

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Plaintiff United States of America (Government or United States) submits this reply in support of its Motion to Strike the equitable defenses raised in the Second Amended Answer and Counterclaims of Defendants Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead). D.I. 29.

ARGUMENT

I. AS A GENERAL RULE, WHEN THE UNITED STATES SEEKS RELIEF IN ITS COURTS, IT IS NOT SUBJECT TO ANY EQUITABLE DEFENSES

When the United States seeks relief in its courts, the general rule is that it is not subject to any equitable defenses. Gilead suggests that this well-established rule is no rule at all and disparages longstanding jurisprudence supporting the rule as a "hodgepodge of unrelated cases." D.I. 35 at 1. But Gilead cannot escape that courts have clearly accepted and applied the precise rule Gilead claims does not exist. *See* D.I. 29 at 4–5, 12–19. Likewise, legal scholars have long recognized the existence of this general rule.[1]

Because Gilead's opposition provides no basis for disturbing or avoiding this accepted rule, nor its application to all of Gilead's asserted equitable defenses, none are unavailable against the Government and the Court should strike them.

[1] *See* Deborah Walrath, Note, *Estopping the Federal Government: Still Waiting for the Right Case*, 53 Geo. Wash. L. Rev. 191, 191 (1984). ("Traditionally, courts have not permitted estoppel of the federal government no matter how compelling the circumstances."); Michael Braunstein, *In Defense of a Traditional Immunity - Toward an Economic Rationale for Not Estopping the Government*, 14 Rutgers L.J. 1, 8 (1982) (noting "the clarity of the Supreme Court's rule against estopping the Government"); *accord Phelps v. Fed. Emergency Mgmt. Agency*, 785 F.2d 13, 19 (1st Cir. 1986) ("As far as we have been able to determine, the Supreme Court has never shown hospitality toward claims of estoppel against the Government."); *W. Augusta Dev. Corp. v. Giuffrida*, 717 F.2d 139, 141 (4th Cir. 1983) ("[U]nder both traditional principles of estoppel and the recent liberalizing trend, a government agency is not estopped merely because its actions, if taken by a private party, would have worked an estoppel.") (citations omitted).

II. THE GENERAL RULE IS NOT AFFECTED BY 35 U.S.C. § 282

Gilead's principal argument is that, because 35 U.S.C. § 282 states that "unenforceability" "shall be" a defense "in any action involving the . . . infringement of a patent," D.I. 35 at 1, the statute expressly authorizes Gilead's equitable defenses. This argument, however, hinges on a misreading of the law. Despite relying on *SCA Hygiene Prod. Aktiebolag v. First Quality Baby Products, LLC*, 137 S. Ct. 954, 967 (2017), D.I. 35 at 8–9, Gilead ignores the Supreme Court's explanation of section 282 and its rejection of the same overly-textual position Gilead advances.

Before *SCA*, the Federal Circuit had held that section 282 "codif[ied]" equitable defenses, such as laches, "as a defense to all patent infringement claims," enabling a defendant to raise a laches defense even if the claim was brought within the six-year statutory damages window set forth in 35 U.S.C. § 286. 137 S. Ct. at 962.[2] The Supreme Court, however, rejected that reading of section 282, and its holding rebuts Gilead's overly simplistic interpretation here. To determine the scope of section 282, *SCA* examined the "most prominent feature[s] of the relevant legal landscape at the time of enactment of the Patent Act," looking for "general rule[s]" that shed light on the scope of the Act, 137 S. Ct. at 963, as "Congress legislates against the background of general common-law principles." *Id*. at 966. The Court found that section 282 was limited by the common law principle that laches cannot "bar a claim for damages incurred within a limitations period specified by Congress." *Id.* at 963. Thus, inclusion of equitable defenses is not absolute, and the Court clearly envisioned that common law rules still apply to patent cases.

[2] Gilead's position regarding the inclusion of all unenforceability defenses in section 282 is identical to the now-rejected position the Federal Circuit took as to laches. *Compare* D.I. 35 at 10–11 *with SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 807 F.3d 1311, 1323 (Fed. Cir. 2015).

There is no question that in 1952, when the Patent Act was passed, there was a well-developed general rule that equitable defenses were unavailable against the Government when it brought suit in its sovereign capacity. "[T]he immunity of the sovereign from these [equitable] defenses is historic. Unless expressly waived, it is implied in all federal enactments." *Bd. of Cty. Comm'rs v. United States*, 308 U.S. 343, 351 (1939); *United States v. California*, 332 U.S. 19, 40 (1947) ("The Government . . . is not to be deprived of those interests by the ordinary court rules designed particularly for private disputes"). Accordingly, the Government's immunity to Gilead's equitable defenses is not prohibited by section 282.[3] To the contrary, the statute incorporates the general rule barring equitable defenses against the Government.

Similarly, Gilead's insistence that "[t]his is a patent infringement case, and that distinction matters," D.I. 35 at 1 (emphasis original), cannot save its equitable defenses. "[P]atent law is governed by the same common-law principles, methods of statutory interpretation, and procedural rules as other areas of civil litigation." *SCA*, 137 S. Ct. at 964 (citation omitted). And the general rule barring equitable defenses against the Government when acting as the sovereign continues today. *See, e.g., United States v. Philip Morris, Inc.*, 300 F. Supp. 2d 61, 66 (D.D.C. 2004) (collecting cases). *SCA* only reinforces the rule's existence, its broad application, and the conclusion that "[i]f Congress examined the relevant legal landscape when it adopted 35 U.S.C. § 282, it could not have missed [Supreme Court] cases endorsing this general rule." *SCA*, 137 S. Ct. at 963–64; *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1536 (2017).

[3] Gilead concedes that one of its equitable defenses, failure to mitigate, is not an unenforceability defense, and thus not subject to section 282. D.I. 35 at 20. Notably, the Government is unaware of any court recognizing this defense in patent cases prior to the decision in *IMX, Inc. v. E-Loan, Inc.*, 748 F. Supp. 2d 1354, 1361 (S.D. Fla. 2010).

Gilead's assertions that "[n]othing in the legislative history of Section 282 suggests any intention to exempt the government from unenforceability defenses" misses the point. D.I. 35 at 11. Properly understood, the question is whether the legislative history in any way supports the view that Congress sought to subject the Government in patent cases to defenses traditionally unavailable against it. *See Rios v. Nicholson*, 490 F.3d 928, 931 (Fed. Cir. 2007) (stating Congress must clearly intend to abrogate common law rule). It does not. Thus, section 282 does not prohibit application of the general rule barring equitable defenses against the Government in this action.[4]

Gilead also raises *Delano Farms Company v. California Table Grape Commission*, 655 F.3d 1337 (Fed. Cir. 2011), as an instance where "the government did not claim exemption from unenforceability or inequitable conduct." D.I. 35 at 11–12. *Delano*, however, involved a declaratory judgment action brought against the U.S. Department of Agriculture (USDA) and its patent licensees. 655 F.3d at 1340. As such, it was not a claim for inequitable conduct *per se*, unmoored from agency action; rather, Delano Farms asserted it suffered a legal wrong due to agency action, where the alleged USDA "action" was that the agency undertook invalidating, public distributions that it did not subsequently disclose to the Patent Office. *Id.* at 1349–50 & n.6. In addition, *Delano* was decided before *SCA*, which clarified the scope of section 282 and further limited its application.

III. THE GOVERNMENT BRINGS THIS SUIT IN ITS SOVEREIGN CAPACITY

Gilead's opposition also disputes the sovereign capacity of the Government in bringing this lawsuit. Specifically, Gilead asserts that equitable defenses are prohibited only where they implicate "sovereign-immunity and separation-of-powers concerns," which Gilead broadly

[4] Gilead's fears of potential governmental revival of patents previously held unenforceable due to inequitable conduct, D.I. 35 at 11, is far beyond the facts of this case.

characterizes as "constitutional concerns." D.I. 35 at 14. Gilead argues that this action does not implicate those concerns, *id.*, and that it is more akin to suits against the Postal Service or seeking contract enforcement. *Id*. at 15–16.

A. The Government's Claims Meet the Requirements for a Sovereign Action

Although Gilead is correct that cases where the Government brings suit in its sovereign capacity, as here, *may* raise sovereign immunity, separation of powers, and constitutional concerns, such issues are *not necessary* for the action to be one brought in the Government's sovereign capacity. Indeed, Gilead identifies many "public-protection actions" that are sovereign actions including actions to quiet title in federal property. D.I. 35 at 14–15. Gilead claims that the Government's suit is not a sovereign act but, instead, one to "set the rights and liabilities of two parties." *Id*. at 16. Yet, Gilead fails to provide any appreciable distinction that would separate the nature of the current action from a Government action to quiet title.

In any event, Gilead's own description of what constitutes a sovereign action is instructive. Gilead defines "public-protection actions" as actions where "[1] the government was acting to [2] prevent or seek remedies for [3] violations of federal statutory prohibitions." *Id*. at 15. That well describes the current action where [1] the Government has brought suit [2] to seek a remedy [3] for Gilead's willful infringement of the Government's patents in violation of 35 U.S.C. § 271. *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1937 (2016) (Breyer, J., concurring) ("Patent infringement, of course, is a highly undesirable and unlawful activity."). Thus, this is a sovereign "public-protection action" under Gilead's own definition. And it is clear that the Government is acting in its sovereign capacity when it is protecting public property. U.S. CONST. art. 4, § 3, cl. 2 ("Congress shall have Power to dispose of and make all needful Rules and Regulations respecting the Territory or other Property belonging to the United States." (emphasis added)). Patents, in turn, "have the attributes of personal property," 35 U.S.C. § 261. Allowing

Gilead to proceed with its defenses would permit them to "dispose of" the property of the United States, primarily by rendering the patents unenforceable.

B. Gilead's Analogies to the Postal Service and to Contract Enforcement Are Misplaced

Gilead's Postal Service analogy is inapt, as the Postal Service is a uniquely structured agency explicitly "launched . . . into the commercial world and endowed [] with authority to 'sue or be sued,'" in its own name, unlike regular agencies. *Franchise Tax Bd. v. United States Postal Serv.*, 467 U.S. 512, 518 (1984). Indeed, the Supreme Court has noted that the Postal Service's waiver of sovereign immunity is "broad" with legislative history that indicates that Congress "[had not] intended to preserve sovereign immunity with respect to the Postal Service" and had hoped it would "be run more like a business than had its predecessor, the Post Office Department." *Id*. at 519–20.

In contrast, the protection of federal innovation provided for in the Bayh-Dole Act neither broadly waives immunity nor attempts to run federal innovation as a business. The Act instead empowers the agencies across the federal government to "protect and administer rights to federally owned inventions on behalf of the Federal Government," according to statutorily announced policy objectives. 35 U.S.C. § 207(a)(3) (emphasis added).[5] D.I. 35 at 10 n. 5. The Postal Service cases cited by Gilead, *Portmann v. United States*, 674 F.2d 1155 (7th Cir. 1982) and *Azar v. U.S. Postal Service*, 777 F.2d 1265, (7th Cir. 1985), are thus inapposite.

Gilead's analogy to contract enforcement is similarly flawed. Gilead asserts that the Government is "acting as a private party would—like suing to enforce a contract between it and a

[5] Gilead apparently disputes that ability. It purports to have found an alleged (but unidentified) jurisdictional defect in this case, yet attempts to "reserve[ ] the right to press that objection at an appropriate time," D.I. 35 at 10 n.5, inviting a potential waste of judicial (and governmental) resources.

third party," D.I. 35 at 15 (quotation omitted), but ignores that contract law is private law. When it contracts, the Government necessarily "steps off the throne [when it] engages in purchase and sale of goods, lands, and services, transactions such as private parties, individuals or corporations also engage in among themselves." *Kania v. United States*, 227 Ct. Cl. 458, 464 (1981). It brings suit here to prevent unlawful infringement of property rights held in trust by the Government for the public's benefit. The Government does so precisely because Gilead refused to enter into a contract (license) for these patents. D.I. 1 at ¶ 232, 241.

Gilead heavily relies on *United States v. Georgia-Pacific Company*, 421 F.2d 92 (9th Cir. 1970), to assert that equitable defenses should not apply to the Government here by analogy to contractual enforcement. D.I. 35 at 15, 16, 18. But Gilead's position ignores the volitional conduct of the Government in entering into such a contract. *Georgia-Pacific* noted that "[w]hen the government enters into a contract with an individual or corporation, it divests itself of its sovereign character as to that particular transaction and takes that of an ordinary citizen and submits to the same law as governs individuals under like circumstances." 421 F.2d at 101 (emphasis added, quotation omitted). The Government did not "enter into" Gilead's willful infringement, or broadly "divest" itself of its sovereign character by seeking patent protection. Longstanding, binding precedent holds that "[a] patent is not a contract," *In re Yardley*, 493 F.2d 1389, 1395 (CCPA 1974). Protection of federally-owned intellectual property is simply not analogous to contractual enforcement.

Gilead states, and the Government generally agrees, that "[w]hether the government is exempt from equitable doctrines thus turns on what the government is doing, which agency is doing it, and what principles constrain its actions." D.I. 35 at 16. Here, the Government is acting to protect the public's property according to statutory directives to both obtain and protect

intellectual property. Just as the protection of public lands is a sovereign function even though "[t]he Government has with respect to its own land the rights of an ordinary proprietor . . . [and] may deal with such lands precisely as an ordinary individual may deal with his [] property," *Light v. United States*, 220 U.S. 523, 536 (1911), the fact that private parties can obtain and enforce patent rights does not detract from the sovereign nature of the activities here.

C. The Bayh-Dole Act Authorizes the Government to Protect Intellectual Property Rights to Federally-Owned Inventions

Gilead disputes that statutory authority establishes that all aspects of the Government's protection of intellectual property are sovereign acts, asserting that the Bayh-Dole Act only provides "authorization" to "perform the function of a tech transfer program." D.I. 35 at 17–18. But Gilead ignores that section 207(a)(3) "authoriz[es the] government to 'protect and administer rights to federally owned inventions.'" *Id*. (emphasis added). The present action is a core government function because it is "a suit brought . . . as a sovereign Government to enforce a public right, or to assert a public interest." *United States v. Beebe*, 127 U.S. 338 (1888). And while Gilead asserts that this action does not "protect the public fisc," D.I. 35 at 18, money recovered by the Government in this action, rightfully owed to the United States and unlawfully retained by Gilead, is presumptively public money. *Humanitarian Law Project v. Reno*, 205 F.3d 1130, 1136 (9th Cir. 2000) ("[F]undamentally, money is fungible."). Gilead itself admits that funds from licensing do find their way "to the Treasury" by statute, after first funding other public entities and purposes. D.I. 35 at 16 (citing 15 U.S.C. § 2701c(a)). Further, "the intended beneficiaries of the Bayh–Dole Act are the institutions themselves and the government," not

"research scientists."[6] *Platzer v. Sloan–Kettering Inst. for Cancer Research*, 787 F.Supp. 360, 364–65 (S.D.N.Y.1992).

And, notably, the Government is not, as Gilead suggests, "acting like any other patent holder in the tech-transfer marketplace." D.I. 35 at 18. Gilead refused to license the Government's patents, compelling the Government's enforcement action here. The public's rights should not be imperiled by normal estoppel or equitable concerns: exclusion of equitable defenses against the Government serves "the great public policy of preserving the public rights, revenues, and property from injury and loss, by the negligence of public officers." *United States v. Hoar*, 26 Fed. Cas. 329, 330 (C.C.D. Mass. 1821).

D. The Government's Decision to Not Pursue An Injunction Further Confirms Its Role as a Sovereign

Gilead complains that the Government has failed to explain its choice not to seek injunctive relief demonstrates sovereign action. *Id*. at 19. But the Government clearly stated that it "deliberately has not sought injunctive relief [] given the potential public health harm."[7] D.I. 29 at 11. In other words, the Government has obligations, as the sovereign, to consider implications beyond this case or this infringement, including public health concerns, that necessarily inform and restrain its actions. Such considerations, as applied here, properly reflect the Government's sovereign capacity.

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[6] The government submits, however, that whether royalties go to the Treasury or to research scientists is irrelevant. The royalties are owed to the United States, and once received may be used as Congress sees fit. Congress chose to use some revenue to fund further research and other revenue to reward the inventors. Those choices were well within Congress's prerogative and do not diminish their public nature.

[7] Other Gilead allegations of Government misconduct also fall within Government efforts to promote public health, such as efforts to conduct HIV prevention research, and to promote HIV pre- and post-exposure prophylaxis (PrEP and PEP) by issuing guidelines and encouraging Gilead to pursue a PrEP indication. D.I. 35 at 3-6.

Nor has the Government been "derelict in its duties" to enforce its patents. D.I. 35 at 18. The Government is now doing exactly what Gilead asserts it has not been doing. Moreover, Gilead simply presumes, without any basis, that many other private actors have willfully infringed federal patents, as Gilead has, but did not face a suit.

IV. GILEAD'S RECITATION OF FACTUAL ALLEGATIONS DOES NOT GIVE LEGAL SUFFICIENCY TO ITS DEFENSES

While Gilead provides a lengthy recitation of the allegations pled in its affirmative defenses, D.I. 35 at 2–9 and 19, the Government's Motion relates solely to the legal sufficiency of Gilead's defenses in view of the Government's immunity. Accordingly, the sufficiency or veracity of Gilead's factual allegations are irrelevant to the Government's Motion. Likewise, consideration of such issues are generally unnecessary for a Rule 12 motion. *Dorothy Covey v. City of Phila.*, No. 06-CV-3649, 2007 U.S. Dist. LEXIS 17734, at *8 (E.D. Pa. Mar. 13, 2007).

V. THE SCHEDULING ORDER DID NOT CONTROL THE FILING OF THIS MOTION

Gilead also asserts that the Government violated the Scheduling Order by filing its Motion. D.I. 35 at 9. Gilead neglects to mention that it stipulated, and the Court ordered, that the Government's original Motion to Strike was "deemed withdrawn without prejudice to the Government's right to renew [that] motion in the context of the amended pleading." D.I. 20 (emphasis added). That Order preceded the Scheduling Order. To the extent the Scheduling Order, filed a day before the Government's renewed Motion, was intended to supersede the Court's prior order, the Government requests the Court to hear the Motion to Strike on its merits, alongside the pending Motion to Dismiss.

CONCLUSION

For the reasons stated, the Government requests the Court grant its Motion and strike Gilead's equitable defenses.

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