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 DISMISS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Plaintiff United States of America (Government or United States) submits this Reply in support of its Motion to Dismiss Defendant Gilead Sciences, Inc.'s, (Gilead's) Counterclaims (D.I. 30).

INTRODUCTION

Gilead admits that the Government did not waive its sovereign immunity to Gilead's Counterclaims simply "by bringing this action." D.I. 21 at 92 (¶ 5). Even so, Gilead asserts the sovereign immunity waivers of 5 U.S.C. § 702 and recoupment both subject the Government, by virtue of bringing any action, to any related counterclaims—like any other party. In reality, neither waiver is limitless, nor do they operate to waive the Government's immunity by their mere invocation in Gilead's Counterclaims. The Government, accordingly, is immune from Gilead's Counterclaims.

First, Gilead improperly reads *Delano Farms v. California Table Grape Comm'n*, 655 F.3d 1337 (Fed. Cir. 2011), to waive immunity to all patent-related declaratory actions against the United States brought under the Administrative Procedure Act (APA). This reads out the absolute requirement under 5 U.S.C. § 702 that the claim, as pled, demonstrate that the claimant "suffer[ed] [a] legal wrong" and that wrong resulted from an "act[ ] or fail[ure] to act in an official capacity or under color of legal authority." Gilead's Counterclaims lack such allegations, and Gilead ignores that such allegations were present in the *Delano Farms* claims. Additionally, the section 701(a)(2) analysis in *Southern Research Institute v. Griffin Corporation*, 938 F.2d 1249 (11th Cir. 1991) strongly indicates that the Government has broad, unreviewable discretion in obtaining and maintaining patents on Government inventions and stands squarely against permitting a counterclaim plaintiff to use *Delano* to reflexively subject the Government to the waiver of section 702.

Second, Gilead continues to misapply the test for recoupment by removing the required "same kind or nature" and "amount" prongs. Because the Government seeks money damages and Gilead seeks affirmative, declaratory relief, the relief the parties seek is not of the same kind or nature. Likewise, the case law indicates that the "amount" prong will only be satisfied by monetary counterclaims.

In sum, Gilead's cited precedent supports the Government's position and undermines Gilead's own arguments. The Government has not waived its immunity here. Accordingly, Gilead's Counterclaims should be dismissed for lack of jurisdiction.

ARGUMENT

I. GILEAD'S COUNTERCLAIMS SHOULD BE DISMISSED FOR FAILURE TO ESTABLISH A WAIVER OF SOVEREIGN IMMUNITY

A. Gilead Concedes That the United States Does Not Waive Its Immunity Simply by Bringing This Suit.

Though Gilead's Counterclaims state that they "are compelled by Federal Rule of Civil Procedure 13(a) and are therefore adverse claims that have arisen out of the same transaction which gave rise to the Government's suit," D.I. 21 at 92 (¶ 5), and that "[t]he Government waived its sovereign immunity . . . by bringing this action," *id*., Gilead now does not contest that "sovereign immunity is not automatically waived because a claim is compulsory." D.I. 36 at 7 n.10. Even so, this admission is belied by Gilead's application of section 702 and the recoupment doctrine to its Counterclaims, in which Gilead improperly fails to provide any meaningful limitations to either waiver of sovereign immunity, making them coextensive with Rule 13.

B. Gilead Improperly Reads *Delano Farms* as Waiving Sovereign Immunity to All Patent-Related Declaratory Judgments.

Gilead principally argues that the Federal Circuit in *Delano Farms v. California Table Grape Comm'n*, 655 F.3d 1337 (Fed. Cir. 2011) "effectuated a broad waiver of sovereign

immunity for non-monetary claims" through section 702 of the APA. D.I. 36 at 3. *Delano* states that section 702 "waives sovereign immunity for non-monetary claims against federal agencies," including "declaratory relief against the United States on a cause of action arising under the Patent Act." *Id*. at 1344. Nevertheless, as Gilead concedes, such a claim must "arise[] under the APA or 'agency action.'" D.I. 36 at 3 (citing *Delano Farms*, 655 F.3d at 1344).

As previously discussed, D.I. 30 at 10–12[1], section 702 provides a waiver of sovereign immunity only for actions "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 . . . ." Gilead ignores the requirement of a legal wrong resulting from agency action (or inaction[2]) and instead suggests that a section 702 action must only "concern[] 'agency action.'" D.I. 36 at 3 (emphasis added). Gilead further broadens the reach of section 702 by suggesting that it can apply to "any action stating a claim against the United States (or its officers or employees) and seeking relief other than money damages." *Id*. (quoting *Delano Farms*, 655 F.3d at 1344) (emphasis added). Gilead strains to expand the scope of section 702 because its pleadings say nothing about any alleged Government action (or inaction) that has caused a "legal wrong" that might support the asserted waiver of section 702. *See* D.I. 36.

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[1] Gilead's opposition never addresses the fact that the substance and nature of its allegations differ greatly from the allegations at issue in *Delano*, provided as Exhibit 6 (D.I. 30-6) to the Government's motion.

[2] Gilead ignores (and apparently contests) that allegations of unlawful agency inaction can meet the requirements of section 702, further evidencing that its interpretation is erroneous. D.I. 36 at 5–6 n.9. In *Delano*, the claimant specifically pled, *inter alia*, that the public use by private growers formed the basis of unlawful agency inaction because the U.S. Department of Agriculture (USDA) allegedly did "not report[] these prior public uses and sales when applying for patents on the new varieties." D.I. 30-6 at 7 (¶ 21).

Gilead relies on the footnote statement in *Delano* that "USDA's act of obtaining ownership of the patents makes it subject to the declaratory judgment action seeking to invalidate the patents or hold them unenforceable." *Id*. at 3 (quoting *Delano Farms*, 655 F.3d at 1344 n.6). But this does not remove, as Gilead asserts, the requirement that a "legal wrong because of agency action" must underlie any section 702 claim based on the Government's acts in obtaining patents, as is clear from the relevant pleadings in *Delano*. D.I. 30 at 11 (discussing D.I. 30-6).

Unlike the pleadings at issue in *Delano*, Gilead's Counterclaims lack any hint of underlying wrongful government action[3] and instead generally challenge agency decisions "in obtaining the [Department of Health and Human Services (HHS)] Patents, which claim subject matter that is not patentable," D.I. 30 at 12 (quoting D.I. 21 at 93 (¶ 6)). Accordingly, the Counterclaims lack a sufficient grounding in the waiver of 5 U.S.C. § 702.

Gilead further asserts that section 701(a)(2)'s exception to the section 702 waiver for actions committed to agency discretion by law does not apply to its Counterclaims. D.I. 36 at 4–6. Specifically, Gilead argues that *Southern Research Institute v. Griffin Corporation*, 938 F.2d 1249, 1254 n.9 (11th Cir. 1991), is "neither applicable nor persuasive." D.I. 36 at 4. In Gilead's view, the case "might suggest that a party cannot challenge an agency's decision to seek patent protection by filing for a patent . . . ." *Id.* at 5 (emphasis in original).

[3] Gilead's counterclaims also call for affirmative declaratory relief "that the HHS Patents are unenforceable." D.I. 21 at 92, ¶ 3. Presumably this is a typographical error from Gilead moving its claims of unenforceability into its defenses.

But what Gilead relies upon to assert a waiver of the Government's immunity for its Counterclaims is, in fact, the HHS decision to seek and obtain patents.[4] Gilead, however, points to patentability and infringement standards, not agency action standards, as a basis to judge its challenges under 35 U.S.C. §§ 102, 103, 112 and 281. D.I. 36 at 5.[5] It is clear that none of those Patent Act statutes nor the "well established legal standards under the Patent Act," *id.*, involve any analysis of a legal wrong resulting from agency action. If any standard is to apply, the appropriate statute is 35 U.S.C. § 207(a)(1), which authorizes the Government to "apply for, obtain, and maintain patents . . . on inventions," where inventions are defined as "any invention or discovery which is or *may be* patentable," *id.* § 201(d) (emphasis added).[6] Consistent with *Southern Research*, this language indicates that the Government has broad, permissive discretion, such that no meaningful standard can be applied.[7]

Furthermore, section 702 of the APA does not apply if "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). Gilead's parallel opposition to the Government's motion to strike admits that "the decision to sue for infringement, if authorized at all, is committed

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[4] And this is the only action Gilead may attempt to ground its claim in, as it admits in its Opposition to the Government's Motion to Strike, D.I. 35, that "the decision to sue for infringement . . . is committed to agency discretion." *Id.* at 17.

[5] *Delano Farms* provides no support for this view of APA standards. Indeed, in *Delano*, the district court dismissed APA claims directed to the validity of the patents. The district court dismissed those claims because the Patent Act precluded APA review; Delano Farms did not appeal as to those claims. 655 F.3d at 1341.

[6] The permissive "may be patentable" indicates that the Government can, and should, seek to protect federal inventions broadly with no fear that improperly issued patents can form a basis for challenging agency action *post hoc*. *Southern Research*, 938 F.2d at 1254 n.9.

[7] While Gilead notes that the *Delano* parties included a discussion of section 701(a) in their briefing, D.I. 36 at 4 n.8, this specific issue was not the subject of appeal or cross-appeal at the Federal Circuit, and thus that Court's decision does not resolve it.

to agency discretion . . . ." D.I. 35 at 17. Gilead's admission that the decision to sue for infringement is discretionary forecloses section 702 as a means for waiving the Government's sovereign immunity to permit counterclaims in this infringement suit.

In conclusion, there is no pleading to support waiver of the Government's sovereign immunity via the APA. Gilead's counterclaims should be dismissed accordingly.

C. Gilead Continues to Incorrectly Apply the Test for Recoupment, Vitiating the "Same Kind" of Relief and "Amount" Requirements

Gilead's arguments regarding recoupment similarly distort the scope of the waiver provided. Gilead correctly states that a permissible recoupment counterclaim must: "(1) arise[] from the same transaction or occurrence as the [Government's] suit; (2) seek[] relief of the same kind or nature; and (3) seek[] an amount not in excess of the [Government's] claim." D.I. 36 at 7 (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus. Inc.*, 72 F. Supp. 2d 547, 550 (W.D. Pa. 1999)). But Gilead fails to properly establish that its counterclaims "seek relief of the same kind or nature" or "seek an amount not in excess of the Government's claim." Instead, Gilead effectively renders those two prongs meaningless, leaving the Rule 13 "same transaction or occurrence" test as the only standard.

Most notably, Gilead generally (and wrongly) asserts that "[a]side from *Delano*, this Court's jurisdiction is further confirmed by the principle that when the government chooses to bring its claims in district court, it waives sovereign immunity for counterclaims that arise from the exact same issues of fact and law, as [Gilead's] counterclaims do." D.I. 36 at 1. Based on this flawed understanding of sovereign immunity, which mirrors the "same transaction and occurrence" test, Gilead improperly asserts that its claims seek relief of the same kind and nature as the Government's Complaint.

Unlike Gilead's Counterclaims, which set forth eight counts that each seek a declaratory judgment, *e.g.*, D.I. 21 at 103–4 (Count I), the Government brings four counts alleging willful infringement of federally owned patents, each alleging that "Gilead has injured the Government and is liable to the Government for infringement" and that "[t]he Government is entitled to recover from Gilead all damages that the Government has sustained as a result of Gilead's infringement." *See, e.g.*, D.I. 1 at ¶ 288.

The present case is an action at law for damages, not an action for declaratory relief. *Arachnid, Inc. v. Merit Indus.*, 939 F.2d 1574, 1579 (Fed. Cir. 1991). That the Government's Complaint seeks a "judgment declaring that that Gilead has infringed . . . one or more claims of the Patents-in-Suit" is not sufficient to turn an action for money damages into one of declaratory relief. This prayer for relief simply requests a predicate finding sufficient to support a judgment in the Government's favor on issues of infringement, willful infringement, and enhanced damages. *See Manildra Milling Corp. v. Ogilvie Mills, Inc.*, Nos. 92-1462, -1480, 30 U.S.P.Q.2D (BNA) 1012, 1017 (Fed. Cir. June 22, 1993) (non-precedential).

The *Mylan* decision expressly characterized the relief sought in that Abbreviated New Drug Application (ANDA) case as one in which both "Government and defendants seek a declaratory judgment determining the validity/invalidity and infringement/non-infringement of the [asserted] patent," because, in that case, "the Government [sought] both an injunction and a declaratory judgment; defendants [sought] only a declaratory judgment on the same subject matter." *United States Dep't of Health & Human Servs. v. Mylan Pharm. Inc.*, No. CV 10-5956 (WHW), 2011 WL

13238650, at *3 (D.N.J. July 13, 2011).[8] Here, the Government seeks no such declaratory judgment.[9]

The monetary nature of the Government's claim is critically important in evaluating the availability of a counterclaim in recoupment. Gilead cites *Regents of Univ. of N.M. v. Knight*, 321 F.3d 1111, 1125 (Fed. Cir. 2003), D.I. 36 at 9, for the proposition that "[r]ecoupment counterclaims are limited to counterclaims of the 'same kind or nature' and, if monetary, are limited to the amount of the principal claims against which they constitute recoupment." (Emphasis added). Gilead reads this "if monetary" to imply that non-monetary claims may be raised against monetary claims to defeat them. But *FDIC v. Hulsey*, 22 F.3d 1472 (10th Cir.1994), cited by the Federal Circuit, explicitly rejects Gilead's reading, stating that "compulsory counterclaims must seek relief of the same kind or nature. This has been interpreted to mean that if the plaintiff is seeking monetary relief, the defendant's counterclaims must also seek monetary relief to qualify as claims in recoupment." *Id*. at 1487 (emphasis added).[10]

It logically follows that the "amount" prong of the recoupment test must also be limited to monetary claims. *See United States v. Washington*, 853 F.3d 946, 968 (9th Cir. 2017); *United States v. U.S. Fid. & Guar. Co.*, 309 U.S. 506, 511 (1940); D.I. 30 at 6–7. Gilead largely ignores

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[8] The Government discussed why *Mylan* was wrongly decided in its original brief, D.I. 30 at 8. Regardless, as set forth in that motion and *infra*, *Mylan* does not control here.

[9] Gilead asserts that the government's complaint in *Mylan* sought monetary relief "in the event of an at-risk launch." D.I. 36 at 9, n.12. But this argument only highlights that the only pled relief was a judgment based on an artificial act of infringement under 35 U.S.C. § 271(e)(2) based on the filing of ANDAs with paragraph IV certifications. *See* D.I. 30 at 8. The monetary relief was conditioned on infringing sales that had not occurred (and had not been pled). *See* D.I. 30-5 (requesting relief only "[i]f Defendants commercially manufacture, use, offer to sell, or sell . . . within the United States, or import the Defendants' Products into the United States").

[10] Gilead also cites *Hulsey* in its brief, D.I. 36 at 7 n. 10, but fails to mention this contrary holding.

the rationale of these cases. Instead, it focuses on a statement by the Third Circuit that "although equitable recoupment most often arises in the context of offsetting monetary claims, as in tax or bankruptcy cases, it is not necessarily limited to those situations." D.I. 36 at 9 (citing *In re Frescati Shipping Co.*, 886 F.3d 291, 312 (3d Cir. 2018), *aff'd sub nom. CITGO Asphalt Ref. Co. v. Frescati Shipping Co.*, 140 S. Ct. 1081 (2020)). But this ruling did not directly address the breadth of the "amount" prong and effectively endorsed the Government's view of the "same kind or nature" prong. Specifically, the Third Circuit cited *Oneida Indian Nation of New York v. New York*, 194 F. Supp. 2d 104, 136-37 (N.D.N.Y. 2002), which "allow[ed] an equitable recoupment defense in the context of offsetting requests for declaratory judgments in a land rights case," *Frescati*, 886 F.3d at 312 (emphasis added). Contrary to Gilead's arguments, *Frescati* specified that it was not considering the "amount" prong, analyzing only (i) "whether CARCO possesses a 'claim' against [the United States], rather than a generalized request for the court to balance the equities," and (ii) "whether CARCO seeks relief of the same kind as the United States." *Id*. at 311.

Accordingly, the mixing-and-matching of relief that Gilead advocates for is not permitted or endorsed. In short, it violates the most basic principle of recoupment doctrine, which is that "'recoupment is in the nature of a defense' to defeat a plaintiff's claims, not a vehicle for pursuing an affirmative judgment." *Ute Indian Tribe of the Uintah & Ouray Reservation v. Utah*, 790 F.3d 1000, 1011 (10th Cir. 2015) (Gorsuch, J.) (quoting *Bull v. United States*, 295 U.S. 247, 262 (1935)).[11] Gilead's affirmative defenses of non-infringement and invalidity would defeat the Government's claims; its Counterclaims seek affirmative, declaratory judgments on those issues.

[11] Gilead's opposition admits it seeks an affirmative judgment, separate from the Government's action. D.I. 36 at 13. This raises the unacceptable specter of keeping the Government in court without its consent. *Quinault Indian Nation v. Pearson*, 868 F.3d 1093, 1099 (9th Cir. 2017).

Accordingly, because the Government seeks money damages, Gilead may not bring non-monetary, declaratory-judgment claims as recoupment.

CONCLUSION

Gilead's failure to identify and plead a sufficient express and unequivocal waiver of sovereign immunity warrants dismissal of its Counterclaims under Rule 12(b)(1).

Respectfully submitted,

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