IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA, Plaintiff & Counterclaim-Defendant, v. GILEAD SCIENCES, INC. and GILEAD SCIENCES IRELAND UC, Defendants & Counterclaim Plaintiff.	C.A. No. 19-02103-MN

GILEAD SCIENCES, INC.'S OPPOSITION TO THE GOVERNMENT'S MOTION TO DISMISS COUNTERCLAIMS

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Abbreviation	Full Form
Br.	United States' Motion to Dismiss (D.I. 30)
Compl.	Complaint (D.I. 1)
Ans.	Gilead's Second Amended Answer (D.I. 29, pages 2-66)
Countercl.	Gilead Sciences, Inc.'s Second Amended Counterclaims (D.I. 29, pages 91-110)
GSI	Gilead Sciences, Inc.

I. INTRODUCTION

By taking the rare step of suing a private company for patent infringement and seeking damages, the government is demanding to be treated like a private party for purposes of asserting and licensing its patents for profit. At the same time, however, it claims that Defendant Gilead Sciences Inc. ("GSI")[1] is not permitted to respond with standard counterclaims for declaratory judgments of non-infringement and invalidity because of its sovereign immunity.[2] But binding Federal Circuit authority is clear that 5 U.S.C. § 702 ***waives*** the government's sovereign immunity for GSI's "request for declaratory relief against the United States on a cause of action arising under the Patent Act." *Delano Farms Co. v. Calif. Table Grape Comm'n*, 655 F.3d 1337, 1343-44 (Fed. Cir. 2011). The government's efforts to avoid *Delano* are defeated by the Federal Circuit's detailed analysis and, in any event, would need to be directed to the *en banc* Federal Circuit, not to this Court. Aside 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 GSI's counterclaims do. Accordingly, GSI[3] respectfully submits that the government's motion should be denied.

[1] Abbreviations are collected and fully defined in the table of abbreviations, *supra* p. vi.

[2] The government asserts immunity not only from counterclaims, but also from defenses. *See* United States' Motion to Strike, D.I. 29. As explained in this memorandum and Defendants' Opposition to the Government's Motion to Strike, which is being filed concurrently, the government overstates its immunity in both contexts.

[3] Defendant Gilead Sciences Ireland UC has not brought counterclaims and is not a party to the government's motion.

II. ARGUMENT

An "assertion of sovereign immunity constitutes a facial challenge to the Court's subject matter jurisdiction." *Dixon-Gibson v. Del. Dep't of Labor*, No. 11-884-LPS, 2012 WL 3526934, at *1 (D. Del. Aug. 15, 2012). "In reviewing a facial challenge under Rule 12(b)(1), … the Court must accept all factual allegations in the [pleading] as true." *Samsung Elecs. Co. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008); *see also Licata v. U.S. Postal Serv.*, 33 F.3d 259, 260 (3d Cir. 1994).

The government's motion should be denied for two independent reasons. ***First***, as the Federal Circuit has held, Congress's enactment of section 702 of the Administrative Procedure Act waived the government's sovereign immunity for certain claims seeking declaratory relief, including declaratory judgment claims arising under the Patent Act. *Delano*, 655 F.3d at 1343-44. ***Second***, as the district court held (and twice reaffirmed) in *U.S. Department of Health & Human Services v. Mylan Pharmaceuticals Inc.*, Civ. No. 10-5956 (WHW), 2011 WL 13238650, at *2 (D.N.J. July 13, 2011), the government waives its sovereign immunity over mirror-image declaratory judgment counterclaims by filing a patent infringement suit.

A. Binding Federal Circuit Precedent Holds That Section 702 Of The Administrative Procedure Act Waived Sovereign Immunity For Declaratory Judgments Related To Patents.

The government's motion is easily resolved by the Federal Circuit's binding decision in *Delano*, which held that "section 702 of the APA 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."[4] 655 F.3d at 1344.

[4] Federal Circuit law governs the question of whether there is jurisdiction over a government defendant in a patent case. *Delano*, 655 F.3d at 1343 (citing the "special importance of ensuring national uniformity" in patent litigation).

Section 702 of the APA provides as follows:

> 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]

5 U.S.C. § 702.[6] In *Delano*, the Federal Circuit ruled that the language in section 702 referring to "[a]n action … seeking relief other than money damages" effectuated a broad waiver of sovereign immunity for non-monetary claims, regardless of whether such a claim arises under the APA or concerns "agency action." *Delano*, 655 F.3d at 1344. Rather, it waives sovereign immunity over "any action stating a claim against the United States (or its officers or employees) and seeking relief other than money damages." *Id*. Accordingly, the Federal Circuit held that a licensee's declaratory judgment claims for patent invalidity against the government were not barred by sovereign immunity: "***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.*** Such an action arises under the Patent Act." *Id*. at 1349 n.6. *Delano*'s holding and reasoning apply fully to GSI's counterclaims here.[7]

[5] The waiver of section 702 is subject to two limitations that are not implicated here: "Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought." 5 U.S.C. § 702.

[6] Emphases added unless otherwise noted.

[7] The government does not argue that counterclaims of patent non-infringement should be treated any differently from counterclaims for patent invalidity; and, in any event, nothing in the reasoning of *Delano* would permit such a conclusion.

The government's effort to evade *Delano*'s clear holding and reasoning fail. The government primarily relies on dicta in a footnote in the Eleventh Circuit's decision in *Southern Research Institute v. Griffin Corp*. Br. 13 (citing 938 F.2d 1249, 1254 n.9 (11th Cir. 1991)). Unlike *Delano*, *Southern Research* is not binding on this Court and is neither applicable nor persuasive. *Southern Research* involved a plaintiff's challenge to the government's decision to give another party an exclusive license to the government's patent rights. *Id.* at 1250-51. The Eleventh Circuit ruled that the Bayh-Dole Act, 35 U.S.C. § 207(a)(1) and (2), gives federal agencies broad discretion to decide whether to license patents. *Id.* at 1254. Specifically, the court held that the Bayh-Dole Act "admits of no considerations by which we could fairly gauge the propriety of ***a refusal to so grant such rights***," such that "Congress has committed ***the refusal to assign or transfer*** patent rights to the discretion of the various federal agencies that acquire those rights in a manner putting such ***discretionary refusal beyond judicial review***." *Id.* at 1254-55. According to the Eleventh Circuit, such a decision was unreviewable under the APA because the statute was "'drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion,'" *id.* at 1254 (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)), and consequently it fell under an exception to the sovereign immunity waiver of section 702—specifically, 5 U.S.C. § 701(a)(2), which creates an exception for "agency action … committed to agency discretion." *Id.*[8]

Unlike the plaintiff in *Southern Research*, however, GSI is not challenging a discretionary licensing decision, nor any other decision as to which the courts lack a "meaningful

[8] The government wrongly asserts that the Federal Circuit in *Delano* did not consider Section 701(a)(2). In fact, the parties expressly argued the application of Section 701(a)(2) in their briefs. *See* Brief of Appellants at 33, *Delano*, 655 F.3d 1337 (Fed. Cir. 2011) (No. 2010-1546), 2010 WL 5560225 at *33; Brief of Appellees the United States at 20, *Delano*, 655 F.3d 1337 (Fed. Cir. 2011) (No. 2010-1546), 2011 WL 585726, at *26.

standard against which to judge" the lawfulness of the government's actions. *Heckler*, 470 U.S. at 830. Rather, GSI challenges the validity and non-infringement of patent claims—issues that are subject to well-established legal standards under the Patent Act, as interpreted over decades by the Supreme Court, the Federal Circuit, and this Court. The government's actions here, therefore, do not meet the strict "no meaningful standard" test required to establish that a decision is committed to agency discretion with the meaning of 5 U.S.C. § 701(a)(2).

Notably, the Eleventh Circuit in *Southern Research* did not consider whether a court's ability to decide the validity and non-infringement of patents was somehow impaired by the fact that the patents were owned by the government. To the extent the government suggests otherwise, Br. 13-14, it overreads the Eleventh Circuit's observation in a footnote that it is not "mandatory" for the government to exercise its power to apply for, obtain, or maintain patents under the Bayh-Dole Act just because it is authorized to do so. *Southern Research*, 938 F.2d at 1254 n.9. The mere fact that the government has a choice does not mean that there is "no meaningful standard" for a court to apply when the government does act. At most, this footnote's dicta might suggest that a party cannot challenge an agency's decision to ***seek*** patent protection by filing for a patent; it does not suggest that once patent claims have been issued, obtained, maintained, and asserted in litigation, a court would have no meaningful basis on which to decide whether the claims were validly issued or whether the defendant's accused behavior infringes them. On the contrary, those are decisions that federal district courts and the Federal Circuit make every day—and they are decisions the government is already asking this Court to make in deciding whether GSI infringes its asserted patent claims.[9]

[9] The government's attempt to rewrite *Delano* by limiting it to situations in which the government itself "undertook the actions that establish the invalidity" of the challenged patent also fails. Br. 11. Nothing in the *Delano* decision indicates that the Federal Circuit understood

Accordingly, section 701(a)(2)'s exception for matters committed to agency discretion does not apply to GSI's counterclaims, and section 702's broad waiver of sovereign immunity for non-monetary claims against the government applies fully here. *Delano*, 655 F.3d at 1349. The government's motion therefore may, and should, be denied on that ground alone.

B. The Government Waived Its Sovereign Immunity Over GSI's Defensive, Mirror-Image Counterclaims By Filing Suit.

Independently, the Third Circuit has recognized that "when the United States ... institutes a suit, it thereby submits itself to the jurisdiction of the court, but, as to claims against the sovereign, the latter's submission to a court's jurisdiction, because of its suit, draws in only such adverse claims as have arisen out of the same transaction which gave rise to the sovereign's suit." *In re Monongahela Rye Liquors, Inc.*, 141 F.2d 864, 869 (3d Cir. 1944). Such counterclaims are not barred by sovereign immunity regardless of whether the government has specifically waived immunity by statute. *Livera v. First Nat'l State Bank of N.J.*, 879 F.2d 1186, 1196 (3d Cir. 1989) ("[A] defendant may assert by way of recoupment ***any claim*** arising out of the same transaction or occurrence as the original claim in order to reduce or defeat the government's recovery.") (emphasis in original); *see also* Wright & Miller, 6 Fed. Prac. & Proc. Civ. § 1427 (3d ed. Apr. 2020 update) ("Despite the sovereign-immunity doctrine and the language of Rule 13(d), when the United States institutes an action, defendant may assert by way of recoupment any claim arising out of the same transaction or occurrence as the original claim in order to reduce or defeat the government's recovery."). As another district court in this Circuit has recognized, the government waives sovereign immunity for declaratory judgment

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its decision in those terms. *See Delano*, 655 F.3d at 1349. Indeed, the public use allegations that were adjudicated focused primarily on actions taken by ***private*** growers. *See Delano Farms Co. v. Calif. Table Grape Comm'n*, 778 F.3d 1243, 1247 (Fed. Cir. 2015).

counterclaims for non-infringement and invalidity under the recoupment doctrine by bringing a patent infringement suit. *Mylan*, 2011 WL 13238650, at *2 (applying Third Circuit law to deny government's motion to dismiss non-infringement and invalidity counterclaims on sovereign immunity grounds).

Courts in this Circuit require three elements to find a waiver of sovereign immunity over a counterclaim under *Livera* and *Monongahela*: The counterclaim "may be based on any type of claim so long as it (1) arises from the same transaction or occurrence as the plaintiff's suit; (2) seeks relief of the same kind or nature; and (3) seeks an amount not in excess of the plaintiff's claim." *Pension Benefit Guar. Corp. v. White Consol. Indus. Inc.,* 72 F. Supp. 2d 547, 550 (W.D. Pa. 1999) (citing *Livera*, 879 F.2d at 1195-96). GSI's counterclaims satisfy each requirement.

First, the government does not dispute that GSI's counterclaims arise from the same transaction or occurrence as the government's suit—they are counterclaims for invalidity and non-infringement of the same patents asserted by the government, and the assertion of such counterclaims is standard in patent litigation.[10] Br. 5 ("[I]t is not disputed that Gilead's claims arise from the same transaction or occurrence…."). The government's infringement claims and GSI's non-infringement counterclaims concern identical issues of fact, and the government's

[10] The government argues that sovereign immunity is not automatically waived because a claim is compulsory. Br. 4-5. GSI does not argue otherwise, and it does not need to. GSI's position is simply that counterclaims that meet the compulsory-counterclaims test must also "arise from the same transaction" for purposes of the first element in the recoupment test—a point the government does not dispute. *F.D.I.C. v. Hulsey*, 22 F.3d 1472, 1487 (10th Cir. 1994) ("Under the first requirement, claims in recoupment are compulsory under Fed.R.Civ.P. 13(a) because they arise out of the same transaction or occurrence that is the subject matter of the opposing party's claim.") (cited at Br. 5 n.2); *see also Mylan*, 2011 WL 13238650 at *4 (in patent infringement action, declaratory judgment counterclaims of non-infringement and invalidity "would easily meet the requirements for compulsory counterclaims" and, as such, were "allowed to stand").

requested relief cannot be granted if the patents' claims are, in fact, invalid. Therefore, the issue of invalidity will necessarily need to be decided for this Court to adjudicate the government's claim of infringement. *Weatherchem Corp. v. J.L. Clark, Inc*. 163 F.3d 1326, 1335 (Fed. Cir. 1998).

Second, GSI's counterclaims seek relief of the same kind or nature as the government's claims. Both the government and GSI seek declaratory relief. The government expressly seeks a declaration that GSI has infringed the asserted patents, and GSI seeks a declaration that it has not done so and that the patents are invalid.[11] *Compare* Compl. at 75 ("WHEREFORE, the United States prays for a judgment in its favor and against Gilead and respectfully requests… [a] judgment declaring that Gilead has infringed, either literally or under the doctrine of equivalents, one or more claims of the Patents-in-Suit."), *with* Countercls. at 109, Prayer for Relief. The *Mylan* court considered an analogous situation; in that case, the government sought both declaratory and injunctive relief for patent infringement, and the defendants sought declarations of non-infringement and invalidity. *Mylan*, 2011 WL 13238650, at *1. The *Mylan* court rejected the government's argument that the parties sought different kinds of relief: "That the Government, as plaintiff, requests ***additional*** relief of a different nature is irrelevant to the dismissal of defendants' request for declaratory judgment. The mirror-image claims for declaratory judgment on the same issue satisfy the criteria for recoupment." *Id.* at *3.

Even if the government's claims were limited to monetary relief (which they are not), GSI's counterclaims would still be proper. The Third Circuit recognizes that recoupment is not

[11] Like the government, GSI also seeks reasonable attorneys' fees and costs pursuant to 35 U.S.C. § 285. *See* Compl. at 75; Countercls. at 110. Such a request is authorized by statute. *See* 28 U.S.C. § 2412(b) ("[A] court may award reasonable fees and expenses of attorneys, in addition to [certain] costs …, to the prevailing party in any civil action brought by or against the United States….").

limited to monetary counterclaims. "[A]lthough 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." *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); *see also Regents of Univ. of N.M. v. Knight,* 321 F.3d 1111, 1125 (Fed. Cir. 2003) ("Recoupment 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 in original). Applying Third Circuit law, the *Mylan*[12] court rejected exactly the argument the government makes here, namely "that defendants' counterclaims cannot be asserted in recoupment because they request declaratory rather than monetary relief." *Mylan*, 2011 WL 13238650, at *3. Holding that the defendants' declaratory judgment counterclaims were permissible recoupment claims, the court explained:

> While the cases among the circuits are somewhat mixed on this issue, the Court believes that the Third Circuit has endorsed a broad interpretation of the doctrine. In *In re Monongahela Rye Liquors*, the Circuit held that the nature of a recoupment defense arises out of some feature of the transaction upon which the plaintiff's action is grounded. 141 F.2d at 869 (citing *Bull v. United States*, 295 U.S. 247, 262 (1935)). The Third Circuit has also stated that, "when the United States institutes an action, a defendant may assert by way of recoupment ***any claim*** arising out of the same transaction or occurrence as the original claim in order to reduce or defeat the government's recovery." *Livera v. First Nat'l State Bank*, 879 F.2d 1186, 1196 (3d Cir. 1989) (emphasis in

[12] The government attempts to distinguish *Mylan* because "monetary damages were not at issue" in that case. Br. 8. First, that is not true—the government's complaint sought "a Judgment awarding Plaintiffs monetary relief together with interest" in the event of an at-risk launch. Complaint, D.I. 1 at 7, *United States v. Mylan Pharms. Inc.*, No. 2:10-cv-5956, 2010 WL 4853242 (D.N.J. Nov. 15, 2010). Second, even if that were true, it is immaterial; the government cites no authority suggesting that the recoupment exception to sovereign immunity is broader if the government seeks only injunctive relief.

> original) (citing *United States v. U.S. Fid. and Guar. Co.*, 309 U.S. 506 (1940)).

Id. Accordingly, it does not matter that GSI's counterclaims do not affirmatively seek money; it suffices that, if they succeed, they will "***defeat***" the government's desired recovery. *Id.* (quoting *Livera*, 879 F.2d at 1196).[13]

Notably, the government cites ***no*** case holding that declaratory judgment counterclaims about the validity or non-infringement of asserted patents are barred by sovereign immunity. Instead, the government asks this Court to ignore Third Circuit precedent in favor of non-binding case law from the Ninth Circuit that applied a narrower definition of recoupment in cases outside of the patent context. Br. 4-5. But the government's Ninth Circuit case involved counterclaims that were "based on facts that [were] … far-flung" from the plaintiff's affirmative claims. *Quinault Indian Nation v. Pearson for Estate of Comenout*, 868 F.3d 1093, 1098 (9th Cir. 2017). Accordingly, applying Third Circuit law to deny the government's motion here would not contradict the result in *Quinault*; the counterclaims at issue in *Quinault* would not have met the Third Circuit's test for recoupment.[14]

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[13] The government also cites *United States v. Levering*, 446 F. Supp. 977, 978 (D. Del. 1978) to suggest that recoupment counterclaims must seek monetary relief to be permissible. Br. 7. In *Levering*, the government brought claims for fraud in the acquisition of funding for mortgages insured by the Federal Housing Authority, and the defendant counterclaimed for malicious prosecution. 446 F. Supp. at 978. The court rejected the counterclaim on multiple grounds, among them that the counterclaims did not arise from the same transaction. *Id*. at 979. *Levering* nowhere held that recoupment claims must be monetary.

[14] The government also cites a footnote from *Bolduc v. Beal Bank, SSB*, 167 F.3d 667, 672 (1st Cir. 1999), in which the First Circuit rejected recoupment claims because they did not arise out of the same transaction. Br. 6-7. There, the court noted that recoupment claims are "classically" permitted to reduce or eliminate damages in cases where damages are asserted. *Bolduc*, 167 F.3d at 672 n.4. The First Circuit did not hold that other types of relief are completely barred in recoupment.

To the extent the Court looks beyond the Third Circuit, numerous other courts have also recognized the applicability of the recoupment exception where counterclaims seek declaratory relief. *See, e.g.*, *United States v. Tsosie*, 92 F.3d 1037, 1043 (10th Cir. 1996) (allowing counterclaim for declaratory judgment regarding ownership of property under recoupment exception); *Rupp v. Omaha Indian Tribe*, 45 F.3d 1241, 1245 (8th Cir. 1995) (same); *Cayuga Indian Nation of N.Y. v. Village of Union Springs*, 293 F. Supp. 2d 183, 185, 195 (N.D.N.Y. 2003) (allowing counterclaim where plaintiff filed action seeking only declaratory and injunctive relief); *Wyandotte Nation v. City of Kansas City*, 200 F. Supp. 2d 1279, 1285-86 (D. Kan. 2002) (allowing counterclaim to quiet title under recoupment exception). As one court stated, "claims in recoupment are not limited to claims for monetary damages, and a claim for declaratory relief may, in fact, be deemed a claim for recoupment as long as it arises out of the same subject as the original cause of action and is based on issues asserted in the complaint." *Cayuga*, 293 F. Supp. 2d at 194.

Likewise, courts in other circuits have similarly and consistently found counterclaims analogous to the ones GSI asserts here to be based in recoupment.[15] In *Wyandotte*, plaintiff Wyandotte Nation, a federally recognized Indian tribe, sought a declaratory judgment quieting title to land, monetary damages for trespass, and injunctive relief. *Wyandotte*, 200 F. Supp. 2d at 1282. Defendants counterclaimed against the tribe seeking to quiet title. *Id.* at 1283. The court

[15] Many of the cases discussing the recoupment exception arise in the context of tribal sovereign immunity, which "is generally coextensive with that of the United States." *Wyandotte*, 200 F. Supp. 2d at 1285 (quoting *Jicarilla Apache Tribe v. Andrus*, 687 F.2d 1324, 1344-45 (10th Cir. 1982)).

found that the tribe waived its sovereign immunity as to the quiet title counterclaim under the doctrine of recoupment:

> In this case, by asking the court to quiet title, plaintiff ***necessarily submits for the court's consideration*** the question of whether defendants have title to the land. This court may not award the relief plaintiff seeks—a declaratory judgment quieting title in the tribe—without also determining the quality of title held by defendants the Modeers. The quiet title counterclaim brought by the Modeers is not an attempt to subject the plaintiff to greater liability or obligations beyond those which plaintiff already has sought the court to adjudicate by bringing a quiet title action in the first place. Thus, equitable recoupment provides that plaintiff has waived its sovereign immunity as to the quiet title counterclaim.

Id. at 1285; *see also Tsosie*, 92 F.3d at 1043 (finding sovereign immunity waived where the government brought an action for ejectment and trespass, because counterclaim for declaratory judgment of occupancy rights is "based on issues asserted by the United States in its complaint"); *United States v. Steinmetz*, 763 F. Supp. 1293, 1300 (D.N.J. 1991) (counterclaim seeking a declaration of property ownership held to be a claim in recoupment, where the Government sought a declaration of title, ownership, and possession of property). The *Wyandotte* and *Steinmetz* courts allowed the declaratory judgment counterclaims to proceed because they did not subject the plaintiff to greater liability or obligations beyond those which plaintiff already asked the court to adjudicate, but denied counterclaims requesting monetary relief because they sought relief beyond the scope of plaintiffs' equitable claims. *See Wyandotte*, 200 F. Supp 2d at 1285-86; *Steinmetz*, 763 F. Supp. at 1300.

Third, GSI does not seek an amount in excess of the government's claims. The government seeks millions of dollars in damages as well as declaratory relief. GSI's claims do not seek any amount of money, much less an amount in excess of the government's claims; rather, GSI simply requests a declaration that the asserted patents are not valid and not infringed. GSI seeks only certainty that this dispute between the parties will reach final resolution regarding

the validity and infringement of the asserted patents. GSI's counterclaims are therefore not in excess of the government's claims.

The government's position is apparently that GSI's counterclaims ***cannot*** be claims in recoupment because they seek an affirmative judgment.[16] Br. 7. But, as explained above, GSI's counterclaims seek relief of the same type as the government's own request for declaratory relief, and the Court must reach the merits of the validity and infringement issues to decide the government's claims. In other words, by bringing this action against GSI, the government necessarily submitted for this Court's determination the question of whether ***or not*** GSI infringes the asserted patents and whether ***or not*** the HHS Patents are valid. This Court may not award the government the relief it seeks—i.e., a declaratory judgment that GSI has indirectly infringed certain claims of the asserted patents—without also determining whether GSI's actions are non-infringing and whether the HHS Patents are invalid. *See, e.g.*, *Mylan*, 2011 WL 13238650, at *4; *cf. Wyandotte*, 200 F. Supp. 2d at 1285-86 (allowing declaratory judgment counterclaims to proceed because they did not subject the plaintiff to greater liability or obligations beyond those which plaintiff had already asked the court to adjudicate). The government's assertion of its patents raises the same controversy addressed by GSI's declaratory judgment claims. Therefore,

[16] The government selectively quotes a Tenth Circuit decision to suggest that any claim that can be considered "affirmative relief" against a sovereign is impermissible. Br. 7. But the Tenth Circuit's holding was far more limited. The "affirmative relief" that the Tenth Circuit found to be beyond the scope of recoupment included a "demand, among other things, [for] ***the affirmative relief of an injunction barring the Tribe from bringing lawsuits against county officials in federal or tribal courts***." *Ute Indian Tribe of the Uintah & Ouray Reservation v. Utah*, 790 F.3d 1000, 1011 (10th Cir. 2015). The asserted counterclaim was thus a significant encroachment on the tribe's sovereign rights and went far beyond an attempt to defeat the tribe's affirmative claim, which merely sought an injunction against the prosecution of its members for offenses on tribal lands.

GSI's claims do not seek affirmative relief beyond resolution of the government's claims—they seek only "to reduce or defeat the government's recovery." *Livera*, 879 F.2d at 1196.

The government's main response to the *Mylan* decision is to argue that it was "[w]rongly [d]ecided" and that the government "specifically disagrees" with it. Br. 8. But as explained above, *Mylan* was based on a sound application of Third Circuit law to the unusual situation in which the government brings a patent-infringement case. The government eventually acquiesced in the *Mylan* court's decision: *Mylan* was the first in a series of related ANDA cases that the government filed against different generic pharmaceutical companies seeking to sell generic versions of the HIV antiviral darunavir. As in the *Mylan* action, the government moved to dismiss the defendants' counterclaims in the next two actions, expressing its specific disagreements with the *Mylan* decision in its briefing.[17] The court denied both follow-on motions.[18] The defendants asserted counterclaims in three more actions after that, and the government did not move to dismiss in any of them.[19] And that is consistent with how the government acted in the only other case that GSI is aware of in which the government has asserted its patents. In *EPA v. Micrology Laboratories, LLC*, No. 3:09-cv-69 (N.D. Ind. filed Feb. 19, 2009), the government asserted patent-infringement claims, and the defendant asserted non-infringement, invalidity, and unenforceability counterclaims. The government merely

[17] Reply Brief in Support of Mot. to Dismiss, Dkt. No. 24, *United States v. Teva Pharms. USA, Inc.*, No. 2:11-cv-01461 (D.N.J. filed July 25, 2011); Mot. to Dismiss Def.'s Countercls., Dkt. No. 9, *United States v. Lupin Ltd.*, No. 2:11-cv-3995 (D.N.J. filed Sept. 16, 2011).

[18] Order, Dkt. No. 25, *United States v. Teva Pharms. USA, Inc.*, No. 2:11-cv-01461 (D.N.J. July 25, 2011); Order, Dkt. No. 16, *United States v. Lupin Ltd.*, No. 2:11-cv-3995 (D.N.J. Sept. 26, 2011).

[19] *U.S. Dep't of Health & Human Servs. v. Lupin Ltd.*, No. 2:13-cv-4039 (D.N.J. filed June 27, 2013); *U.S. Dep't of Health & Human Servs. v. Cipla Ltd.*, No. 2:14-cv-5135 (D.N.J. filed Aug. 15, 2014); *U.S. Dep't of Health & Human Servs. v. Aurobindo Pharma USA, Inc.*, No. 3:17-cv-6911 (D.N.J. filed Sept. 8, 2017).

answered, without filing a motion to dismiss the counterclaims on sovereign immunity grounds. Put simply, the government's position that it is immune from declaratory judgment counterclaims in patent cases is a theory that the government has only sporadically—and never successfully—pursued. This Court, like the *Mylan* court, should reject it.

III. CONCLUSION

GSI respectfully requests that the Court deny the government's motion to dismiss GSI's counterclaims.

Dated: July 24, 2020

/s/ Frederick L. Cottrell, III
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