

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

**THE UNITED STATES and
THE ADMINISTRATORS OF THE
TULANE EDUCATIONAL FUND,
Plaintiffs**

CIVIL DOCKET

VERSUS

NO. 16-13987

**CYTOGEL PHARMA, LLC,
Defendant**

SECTION: "E"

ORDER AND REASONS

Before the Court is the Refiled Motion of Plaintiff the Administrators of the Tulane Educational Fund ("Tulane") and Counterclaim-Defendant Dr. James E. Zadina, in which Plaintiff the United States of America joins, to Dismiss Defendant's First Amended and Restated Counterclaims Pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.¹ Defendant Cytogel Pharma, LLC ("Cytogel") opposes this motion.² In this Order and Reasons, the Court addresses only Tulane and Dr. Zadina's argument that the Court must dismiss Counts 2 and 3 of Cytogel's First Amended and Restated Counterclaims pursuant to Rule 12(b)(1) because the Court lacks subject matter jurisdiction.³ For the reasons that follow, Tulane and Dr. Zadina's motion to dismiss Counts 2 and 3 as to them is **DENIED**.

BACKGROUND

In the 1990s, Dr. Zadina and his colleagues at Tulane University developed synthetic opioid peptides related to endomorphins, which are opioid peptides found naturally in the human body.⁴ Based on their research, Tulane obtained two patents, U.S.

¹ R. Doc. 75.

² R. Doc. 83

³ The Court does not address in this Order and Reasons Tulane and Dr. Zadina's motion to dismiss Counts 1 and 4-13 of Cytogel's First Amended and Restated Counterclaims pursuant to Rule 12(b)(6).

⁴ R. Doc. 1 at 4-5, ¶ 14-16; R. Doc. 68 at 7, ¶ 16.

Patent Nos. 5,885,958 (“the ’958 Patent”) and 6,303,578 (“the ’578 Patent”), claiming these synthetic opioid compounds.⁵ On December 1, 2003, Tulane licensed the ’958 Patent and the ’578 Patent to Cytogel.⁶ After Tulane and Cytogel signed the Licensing Agreement, Dr. Zadina began performing consulting work for Cytogel pursuant to a Consulting Agreement.⁷ He advised Cytogel on the development of Cyt-1010, a synthetic opioid peptide similar in structure to the compounds covered by the ’958 Patent and the ’578 Patent, for commercial use as an analgesic.⁸

Dr. Zadina was a joint employee of Tulane and the Department of Veterans Affairs (“VA”).⁹ He and his colleague Dr. Laszlo Hackler developed new synthetic opioid compounds for Tulane and the VA.¹⁰ Drs. Zadina and Hackler applied for a patent for these compounds and assigned their ownership rights in the pending patent to Tulane and the VA.¹¹ The application resulted in U.S. Patent No. 8,716,436 B2 (“’436 Patent”), which issued on May 6, 2014 and lists Drs. Zadina and Hackler as co-inventors.¹² Cytogel alleges that Dr. Zadina secretly developed the compounds covered by the ’436 Patent while acting as a consultant to Cytogel.¹³ Cytogel asserts the compounds covered by the ’436 Patent are related to Cyt-1010 and result from Dr. Zadina’s consulting work.¹⁴ As a result, Cytogel claims ownership of the ’436 Patent.¹⁵

⁵ R. Doc. 1 at 5–6, ¶ 17–19; R. Doc. 68 at 7, ¶ 16.

⁶ R. Doc. 1 at 6, ¶ 20; R. Doc. 68 at 7, ¶ 17.

⁷ R. Doc. 1 at 6–9, ¶ 24–36; R. Doc. 68 at 8, ¶ 19.

⁸ R. Doc. 1 at 6, ¶ 20–21; R. Doc. 68 at 10, ¶ 30.

⁹ R. Doc. 1 at 3, ¶ 10–11; R. Doc. 68 at 5, ¶ 10.

¹⁰ R. Doc. 1 at 9–10, ¶ 38–41; R. Doc. 68 at 16–19, ¶ 45–56.

¹¹ R. Doc. 1 at 11–12, ¶ 43–47; R. Doc. 68 at 18, ¶ 54.

¹² R. Doc. 1 at 11–12, ¶ 43–47; R. Doc. 68 at 19, ¶ 57.

¹³ R. Doc. 68 at 20, ¶ 61.

¹⁴ *Id.* at 16–17, ¶ 45–50.

¹⁵ *Id.* at 26, ¶ 78.

On August 19, 2016, Tulane and the United States filed the instant action.¹⁶ They seek declaratory judgments of ownership and inventorship of the '436 Patent.¹⁷ On September 7, 2016, Cytogel filed counterclaims against the Tulane and the United States and joined Dr. Zadina as a defendant to those counterclaims.¹⁸ Cytogel brought Counts 2 and 3 of its counterclaims against Tulane, Dr. Zadina, and the United States for infringement of the '958 and '578 Patents pursuant to 35 U.S.C. § 271.¹⁹

On November 7, 2016, the United States moved to dismiss Counts 2 and 3 of Cytogel's counterclaims, among other claims, because 35 U.S.C. § 271(a) does not waive sovereign immunity against the federal government.²⁰ Cytogel did not oppose the motion.²¹ The same day, Tulane and Dr. Zadina filed a Motion to Dismiss All of Cytogel's Counterclaims Pursuant to Rule 12(b)(6) or, in the Alternative, for a More Definite Statement Under Rule 12(e), in which the United States joined.²² On February 6, 2017, the Court granted the United States' motion in part, dismissing Counts 2 and 3 as to the United States.²³ On March 28, 2017, the Court granted Tulane and Dr. Zadina's Motion for a More Definite Statement Pursuant to Rule 12(e).²⁴

Cytogel filed its First Amended and Restated Counterclaims on April 11, 2017.²⁵ Pursuant to the Court's order of February 6, 2017, Cytogel brings Counts 2 and 3 of its counterclaims against Tulane and Dr. Zadina, not against the United States.²⁶ Otherwise,

¹⁶ R. Doc. 1.

¹⁷ *Id.*

¹⁸ R. Doc. 6.

¹⁹ R. Doc. 68 at 4, ¶ 6.

²⁰ R. Doc. 31 at 16–17.

²¹ R. Doc. 46 at 12 n.10.

²² R. Doc. 34.

²³ R. Doc. 59. The Court noted Dr. Zadina and Tulane did not argue Counts 2 and 3 should be dismissed with respect to them and, as a result, the Court did not address this argument. *Id.* at 3 n. 13. The Court's Order and Reasons of March 28, 2017, which vacated in part its Order and Reasons of February 6, 2017, did not vacate the portion dealing with Counts 2 and 3 of Cytogel's counterclaims. R. Doc. 67.

²⁴ R. Doc. 67.

²⁵ R. Doc. 68.

²⁶ *Id.* at 4, ¶ 6.

Counts 2 and 3 of Cytogel's First Amended and Restated Counterclaims are substantially identical to Counts 2 and 3 of Cytogel's initial Counterclaims.²⁷ Cytogel alleges Drs. Zadina and Hackler used the compounds covered by the '958 and '578 Patents to develop the '436 Patent, violating Cytogel's Licensing Agreement with Tulane.²⁸ Cytogel brings these claims for patent infringement pursuant to 35 U.S.C. § 271.²⁹

On May 2, 2017, Tulane and Dr. Zadina, joined by the United States, filed the instant Motion to Dismiss Defendant's First Amended Counterclaims Pursuant to Rules 12(b)(6) and 12(b)(1).³⁰ Tulane and Dr. Zadina argue Counts 2 and 3 of Cytogel's counterclaims should be dismissed "for the same reasons" the Court dismissed the claims against the United States.³¹ Tulane and Dr. Zadina argue Cytogel's infringement claim against them includes an assertion the United States also infringed the patent.³² They argue, as a result, sovereign immunity bars not only Cytogel's claim against the United States but also its claim against Tulane and Dr. Zadina.³³ Cytogel opposes this motion.³⁴ Cytogel argues sovereign immunity does not extend to Tulane and Dr. Zadina.³⁵

On July 23, 2018, Cytogel filed its Second Amended and Restated Counterclaims.³⁶ Counts 2 and 3 of Cytogel's Second Amended and Restated Counterclaims are substantially identical to Counts 2 and 3 of Cytogel's First Amended and Restated Counterclaims.³⁷ As a result, the Court construes the instant motion as a motion to

²⁷ *Id.* at 26–28, ¶ 80–87.

²⁸ *Id.*

²⁹ *Id.*

³⁰ R. Doc. 75.

³¹ R. Doc. 75-1 at 31.

³² *Id.*

³³ *Id.*

³⁴ R. Doc. 83.

³⁵ *Id.* at 6–9.

³⁶ R. Doc. 220.

³⁷ *Id.* at 29–31, ¶ 83–90.

dismiss Counts 2 and 3 of Cytogel's Second Amended and Restated Counterclaims pursuant to Rule 12(b)(1).

LAW AND ANALYSIS

“Federal courts are courts of limited jurisdiction; without jurisdiction conferred by statute, they lack the power to adjudicate claims.”³⁸ A motion to dismiss under Federal Rules of Civil Procedure 12(b)(1) challenges a federal court's subject-matter jurisdiction.³⁹ Under Rule 12(b)(1), “[a] case is properly dismissed for lack of subject matter jurisdiction when the court lacks the statutory or constitutional power to adjudicate the case.”⁴⁰ “Lack of subject-matter jurisdiction may be found in the complaint alone, the complaint supplemented by the undisputed facts as evidenced in the record, or the complaint supplemented by the undisputed facts plus the court's resolution of the disputed facts.”⁴¹

Cytogel brings Counts 2 and 3 of its counterclaims against Tulane and Dr. Zadina pursuant to 35 U.S.C. § 271.⁴² Sections 271(b) and 281 of Title 35 of the United State Code create a private right of action for patent infringement.⁴³ Section 271(h) waives sovereign immunity for states,⁴⁴ but the statute contains no provision waiving sovereign immunity for the federal government.⁴⁵ Because sovereign immunity is not waived, the Court dismissed Cytogel's claims under 35 U.S.C. § 271 against the United States.⁴⁶

³⁸ *In re FEMA Trailer Formaldehyde Products Liab. Litig. (Mississippi Plaintiffs)*, 668 F.3d 281, 286 (5th Cir. 2012).

³⁹ See Fed. R. Civ. P. 12(b)(1).

⁴⁰ *Home Builders Ass'n of Miss., Inc. v. City of Madison, Miss.*, 143 F.3d 1006, 1010 (5th Cir. 1998) (internal quotation marks and citation omitted).

⁴¹ *In re FEMA*, 668 F.3d at 287.

⁴² *Id.* at 4, ¶ 6.

⁴³ 35 U.S.C. §§ 271(b), 281.

⁴⁴ 35 U.S.C. § 271(h) (“Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.”).

⁴⁵ See *United States v. Sherwood*, 312 U.S. 584, 586 (1941) (“The United States, as sovereign, is immune from suit save as it consents to be sued.”); *United States v. King*, 395 U.S. 1, 4 (1969) (“[W]aiver [of sovereign immunity] cannot be implied but must be unequivocally expressed.”).

⁴⁶ R. Doc. 59.

In its Motion to Dismiss, the United States argued, because Dr. Zadina and Tulane were parties to a federal funding agreement, they are government contractors shielded from liability.⁴⁷ The Court disagrees. The Fifth Circuit extends sovereign immunity to government contractors when “performance of a discretionary function is at issue” and the government “approved ‘reasonably precise’ specifications” for the contractor’s work.⁴⁸ This “government contractor defense” applies to government contractors producing goods for the government, not to researchers like Drs. Zadina and Hackler working under federal funding agreements. Sovereign immunity under the statute does not extend to Tulane and Dr. Zadina. As a result, the Court has jurisdiction over Cytogel’s claims against Tulane and Dr. Zadina under 35 U.S.C. § 271.

In their motion, Tulane and Dr. Zadina argue this Court lacks subject matter jurisdiction over claims brought under 28 U.S.C. § 1498, which grants the United States Court of Federal Claims jurisdiction for patent claims against the federal government.⁴⁹ Cytogel bring Counts 2 and 3 against Tulane and Dr. Zadina under 35 U.S.C. § 271, not 28 U.S.C. § 1498.⁵⁰ Tulane and Dr. Zadina’s argument based on the Court’s lack of jurisdiction under 28 U.S.C. § 1498 is inapposite.

28 U.S.C. § 1498 does not foreclose Cytogel’s right to bring suit against Tulane and Dr. Zadina under 35 U.S.C. § 271. 28 U.S.C. § 1498 allows a patent owner to bring suit against the United States when a patented invention is “used or manufactured by or for the United States.”⁵¹ This includes use or manufacture “by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or

⁴⁷ R. Doc. 31-2 at 21.

⁴⁸ *Kerstetter v. Pac. Sci. Co.*, 210 F.3d 431, 435 (5th Cir. 2000) (citing *Boyle v. United Tech. Corp.*, 487 U.S. 500, 511 (1988)).

⁴⁹ R. Doc. 75-1 at 31.

⁵⁰ R. Doc. 68.

⁵¹ 28 U.S.C. § 1498(a).

consent of the Government.”⁵² In *Astronet Technologies Inc. v. BAE Systems, Inc.*,⁵³ the Federal Circuit affirmed the dismissal of a patent infringement suit against a government contractor manufacturing equipment for use by the Transportation Security Administration. The court found 28 U.S.C. § 1498 to be the patent owner’s exclusive remedy and noted the statute was enacted “to stimulate contractors to furnish what was needed’ by the government ‘without fear of becoming liable themselves” for patent infringements.⁵⁴ That rationale does not apply in this case. Cytogel does not allege Tulane and Dr. Zadina infringed a patent while furnishing goods to the federal government. Rather, it alleges Drs. Zadina and Hackler infringed patents for which Cytogel held a license while developing a new compound for their employers Tulane and the VA.⁵⁵ 28 U.S.C. § 1498 is not Cytogel’s exclusive remedy against Tulane and Dr. Zadina for patent infringement.

Even if Counts 2 and 3 of Cytogel’s counterclaims had been brought under 28 U.S.C. § 1498, the Court would reject Tulane and Dr. Zadina’s argument because they cannot raise a defense under 28 U.S.C. § 1498 in a motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. When the United States is a defendant in a patent infringement claim, section 1498 serves as a jurisdictional bar.⁵⁶ In contrast, “with respect to suits to which the United States is *not* a party, [28 U.S.C. § 1498 is applied] as a codification of a defense and not as a jurisdictional statute.”⁵⁷ In such cases, “the district court cannot dismiss t[he] action under Federal Rule of Civil Procedure

⁵² *Id.*

⁵³ 802 F.3d 1271 (Fed. Cir. 2015).

⁵⁴ *Id.* at 1277 (citing *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928)).

⁵⁵ R. Doc. 68.

⁵⁶ See 28 U.S.C. § 1498(a); *Crater Corp. v. Lucent Technologies, Inc.*, 255 F.3d 1361, 1364 (Fed. Cir. 2001) (explaining that section 1498(a) gives “the United States Court of Federal Claims *exclusive* jurisdiction over patent infringement suits against the government.” (emphasis added)).

⁵⁷ *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990) (citing *Sperry Gyroscope Co. v. Arma Eng’g Co.*, 271 U.S. 232, 235-36 (1926)).

12(b)(1). If appropriate, a defense arising under 1498(a) should be resolved by summary judgment under Rule 56 rather than a motion to dismiss under Rule 12.”⁵⁸ As a result, even if Counts 2 and 3 of Cytogel’s counterclaims had been brought under 28 U.S.C. § 1498, the Court would not dismiss them pursuant to Rule 12(b)(1).

Based on the allegations in Cytogel’s First Amended and Restated Counterclaims,⁵⁹ the Court finds it has subject matter jurisdiction over Counts 2 and 3 of Cytogel’s counterclaims, which allege Tulane and Dr. Zadina infringed the ’958 Patent and the ’578 Patent under 35 U.S.C. § 271.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that the Refiled Motion of Plaintiff the Administrators of the Tulane Educational Fund and Counterclaim-Defendant Dr. James E. Zadina, in which Plaintiff the United States of America joins, to dismiss Counts 2 and 3 of Defendant Cytogel Pharma LLC’s First Amended and Restated Counterclaims against Tulane and Dr. Zadina pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure be and hereby is **DENIED**.⁶⁰

New Orleans, Louisiana, this 17th day of September, 2018.



SUSIE MORGAN
UNITED STATES DISTRICT JUDGE

⁵⁸ *Toxogon Corporation v. BNFL, Inc.*, 312 F.3d 1379, 1382 (Fed. Cir. 2002) (citations omitted).

⁵⁹ R. Doc. 68.

⁶⁰ R. Doc. 223.