

**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

For the reasons that follow, the Court on its own motion **ORDERS** that Count 2 of the Complaint of Plaintiffs the Administrators of the Tulane Educational Fund ("Tulane") and the United States¹ and Count 14 of Defendant Cytogel Pharma, LLC's ("Cytogel") Second Amended and Restated Counterclaims² are **DISMISSED WITHOUT PREJUDICE** as to *pending* patent applications.³

Pursuant to Rule 42(b) of the Federal Rules of Civil Procedure, the Court on its own motion further **ORDERS SEPARATE TRIALS** of the causes of action in the Complaint and the causes of action in Cytogel's Second Amended and Restated Counterclaims as follows:

- (1) the trial currently scheduled to begin on December 3, 2018 will deal with Count 1 of the Complaint and all claims in Cytogel's Second Amended and Restated Counterclaims other than Count 14, and
- (2) the second trial, to be scheduled at a later date, will deal with Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims.

¹ R. Doc. 1.

² R. Doc. 220.

³ Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims now deal only with the inventorship of U.S. Patent No. 8,716,436 B2 ("the '436 Patent").

BACKGROUND

In the 1990s, Dr. Zadina, Dr. Laszlo Hackler, and their 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. 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

Drs. Zadina and Hackler were joint employees of Tulane and the Department of Veterans Affairs (“VA”).⁹ They developed new synthetic opioid compounds and applied for patents for these compounds.¹⁰ They assigned their ownership rights in the pending patents to Tulane and the VA.¹¹ Dr. Hackler died in 2013.¹² The patent application for the compounds developed by Drs. Zadina and Hackler resulted in U.S. Patent No. 8,716,436 B2 (“the ’436 Patent”), which issued on May 6, 2014 and lists Drs. Zadina and Hackler as co-inventors.¹³ Tulane and the VA also jointly own U.S. Patent Application No. 14/268,057 (“the ’057 Application”), U.S. Patent Application No. 14/845,813 (“the ’813

⁴ R. Doc. 1 at 4–5, ¶ 14–16; R. Doc. 220 at 9, ¶ 16.

⁵ R. Doc. 1 at 5–6, ¶ 17–19; R. Doc. 220 at 9, ¶ 16.

⁶ R. Doc. 1 at 6, ¶ 20; R. Doc. 220 at 9, ¶ 17.

⁷ R. Doc. 1 at 6–9, ¶ 24–36; R. Doc. 220 at 10, ¶ 19.

⁸ R. Doc. 1 at 6, ¶ 20–21; R. Doc. 220 at 13, ¶ 31.

⁹ R. Doc. 1 at 3, ¶ 10–11; R. Doc. 220 at 7, ¶ 10.

¹⁰ R. Doc. 1 at 9–10, ¶ 38–41; R. Doc. 220 at 18–21, ¶ 45–56.

¹¹ R. Doc. 1 at 9–12, ¶ 38–47; R. Doc. 220 at 20, ¶ 55.

¹² R. Doc. 1 at 3, ¶ 10.

¹³ R. Doc. 1 at 11–12, ¶ 43–47; R. Doc. 220 at 21, ¶ 57.

Application”), U.S. Patent Application No. 14/974,249 (“the ’249 Application”),¹⁴ and U.S. Patent Application No. 15/450,259 (“the ’259 Application”),¹⁵ claiming compounds developed by Drs. Zadina and Hackler.

Cytogel alleges Dr. Zadina secretly developed the compounds covered by the ’436 Patent while acting as a consultant to Cytogel.¹⁶ Cytogel asserts the compounds covered by the ’436 Patent are related to Cyt-1010 and result from Dr. Zadina’s consulting work.¹⁷ As a result, Cytogel claims ownership of the ’436 Patent.¹⁸ Cytogel does not allege Dr. Hackler acted as a consultant to Cytogel or had access to Cytogel’s confidential information.

On August 19, 2016, Tulane and the United States filed the instant action.¹⁹ They bring two claims: Count 1 for a declaratory judgment of ownership of the ’436 Patent and the ’057, ’813, and ’249 Applications and Count 2 for a declaratory judgment of inventorship of the ’436 Patent and the same three pending patent applications.²⁰ On September 7, 2016, Cytogel filed thirteen counterclaims against the Tulane and the United States and joined Dr. Zadina as a defendant to those counterclaims.²¹ Cytogel filed its First Amended and Restated Counterclaims on April 11, 2017,²² and its First Amended and Restated Affirmative Defenses and Second Amended and Restated Counterclaims on July 23, 2018.²³

¹⁴ R. Doc. 1 at 11, ¶ 43.

¹⁵ R. Doc. 220 at 23, ¶ 65.

¹⁶ R. Doc. 220 at 18–20, ¶ 45–50.

¹⁷ *Id.*

¹⁸ *Id.* at 29, ¶ 81.

¹⁹ R. Doc. 1.

²⁰ *Id.*

²¹ R. Doc. 6.

²² R. Doc. 68.

²³ R. Doc. 220.

Cytogel's Second Amended and Restated Counterclaims include as a fourteenth counterclaim a claim for correction of inventorship of the '436 Patent, the '259 Application, and related applications.²⁴ Cytogel alleges the listing of Dr. Hackler as an inventor of the '436 Patent, the '259 Application, and related applications "is erroneous because he did not significantly contribute to the conception of the claimed invention."²⁵ Cytogel requests that the Court order Dr. Hackler to be removed as an inventor of the '436 Patent, the '259 Application, and related applications pursuant to 35 U.S.C. § 256.²⁶

On August 13, 2018, Tulane and Dr. Zadina filed a motion to dismiss Count 14 the instant motion.²⁷ Cytogel opposes the motion.²⁸

LAW AND ANALYSIS

I. This Court does not have jurisdiction over claims to declare the inventorship of pending patent applications.

"Federal courts are courts of limited jurisdiction; without jurisdiction conferred by statute, they lack the power to adjudicate claims."²⁹ "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."³⁰ Courts may consider questions of subject matter jurisdiction *sua sponte*.³¹

²⁴ *Id.* at 47–51, ¶ 169–181. In its Second Amended and Restated Counterclaims, Cytogel for the first time includes the '259 Application in its list of related Pending Patent Applications. *Id.*

²⁵ *Id.* at 47, ¶ 170.

²⁶ *Id.* at 50–51, ¶ 180.

²⁷ R. Doc. 235.

²⁸ R. Doc. 252.

²⁹ *In re FEMA Trailer Formaldehyde Products Liab. Litig. (Mississippi Plaintiffs)*, 668 F.3d 281, 286 (5th Cir. 2012).

³⁰ *In re FEMA*, 668 F.3d at 287.

³¹ *See, e.g., Perez v. Region 20 Educ. Serv. Ctr.*, 307 F.3d 318, 333 n.8 (5th Cir. 2002).

35 U.S.C. § 256(b) grants federal courts jurisdiction over claims to correct inventorship “[w]henver through error a person is named in an *issued* patent as the inventor.”³² The Fifth Circuit has held that “notwithstanding the inherently federal nature of inventorship, district courts must dismiss premature questions of inventorship for lack of jurisdiction.”³³ “[U]ntil a patent has actually issued, any questions of inventorship are not justiciable outside the Patent and Trademark Office.”³⁴

In Count 2 of the Complaint, the United States and Tulane seek a declaratory judgment affirming the inventorship of the pending '057, '813, and '249 Applications. In Count 14 of its Second Amended and Restated Counterclaims, Cytogel requests that the Court order Dr. Hackler to be removed as an inventor of the pending '259 Application. Patents have not issued for the '057, '813, '249, and '259 Applications. As a result, this Court has no jurisdiction to review their inventorship. The Court dismisses for lack of subject matter jurisdiction the portions of Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims dealing with the pending '057, '813, '249, and '259 Applications.

II. This Court has discretion to order a separate trial of Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims, both of which deal with the inventorship of the '436 Patent.

Rule 42(b) provides that “[f]or convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims.”³⁵ Whether to order a separate trial of different issues, “even a patent trial, is always a question committed to the sound

³² 35 U.S.C. § 256(b) (emphasis added).

³³ *Camsoft Data Sys., Inc. v. S. Elecs. Supply, Inc.*, 756 F.3d 327, 336 (5th Cir. 2014).

³⁴ *Id.*

³⁵ FED. R. CIV. P. 42(b).

discretion of the trial court, and the court is expected to exercise its discretion on a case-by-case basis.”³⁶ Courts have broad discretion to order separate trials, and they must balance the equities in doing so.³⁷ The Court is mindful that in ordering separate trials, the “issue to be tried [separately] must be so distinct and separable from the others that a trial of it alone may be had without injustice.”³⁸

Count 2 of the Complaint and Count 14 of Cytogel’s Second Amended Counterclaims deal only with the inventorship of the ’436 Patent. Drs. Zadina and Hackler are currently listed as joint inventors of the ’436 Patent and the Pending Patent Applications.³⁹ Tulane and the United States seek a declaratory judgment upholding their inventorship, and Cytogel seeks the removal of Dr. Hackler and the listing of Dr. Zadina as the sole named inventor of the ’436 Patent.⁴⁰

The parties agree Dr. Zadina is properly listed as an inventor of the ’436 Patent. Cytogel alleges Dr. Hackler “did not significantly contribute to the conception of the claimed invention.”⁴¹ Tulane and Dr. Zadina argue there is evidence corroborating Dr. Hackler’s inventorship.⁴² The only contested issue is Dr. Hackler’s contribution. Dr. Hackler is not a party to the case, and this issue is distinct from all the other claims. The other claims deal with ownership of the ’436 Patent and the interactions between Dr. Zadina, Tulane, and Cytogel. The issue of inventorship is distinct and separable from issues of ownership and tort claims, and a trial on the inventorship issue alone may be

³⁶ *Laitram Corp. v. Hewlett-Packard Co.*, 791 F. Supp. 113, 114 (E.D. La. 1992)

³⁷ *See id.* (citing *Willemijn Houdstermaatschaap BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1434 (D. Del. 1989)).

³⁸ *Swofford v. B & W, Inc.*, 336 F.2d 406, 415 (5th Cir.1964).

³⁹ *Id.*

⁴⁰ R. Doc. 220 at 47–51, ¶ 169–81.

⁴¹ *Id.* at 47, ¶ 170.

⁴² R. Doc. 235-1 at 12–17.

had without injustice. Ordering separate trials serves the convenience of the Court, expedites the case, and economizes judicial resources. The Court finds ordering separate trials does not prejudice any party.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Count 2 of the Complaint of Plaintiffs the Administrators of the Tulane Educational Fund (“Tulane”) and the United States⁴³ and Count 14 of Defendant Cytogel Pharma, LLC’s (“Cytogel”) Second Amended and Restated Counterclaims⁴⁴ be and hereby are **DISMISSED WITHOUT PREJUDICE** as to U.S. Patent Application No. 14/268,057 (“the ’057 Application”), U.S. Patent Application No. 14/845,813 (“the ’813 Application”), U.S. Patent Application No. 14/974,249 (“the ’249 Application”), and U.S. Patent Application No. 15/450,259 (“the ’259 Application”).

IT IS FURTHER ORDERED that there be **SEPARATE TRIALS** in the instant action as follows:

- (1) the trial currently scheduled to begin on December 3, 2018 will deal with Count 1 of the Complaint and all claims in Cytogel’s Second Amended and Restated Counterclaims other than Count 14, and
- (2) the second trial, to be scheduled at a later date, will deal with Count 2 of the Complaint and Count 14 of Cytogel’s Second Amended and Restated Counterclaims.⁴⁵

IT IS FURTHER ORDERED that the Motion to Grant Plaintiffs’ Declaratory Judgment Claims 1 and 2 and Dismiss Cytogel’s Patent Ownership Counterclaim and Inventorship Counterclaim (Counts 1 and 14) filed by Tulane, Dr. Zadina, and the United

⁴³ R. Doc. 1.

⁴⁴ R. Doc. 220.

⁴⁵ Both of these claims deal only with the inventorship of the ’436 patent.

States⁴⁶ be and hereby is **DENIED AS MOOT** as to the inventorship of *pending* patent applications and **DENIED WITHOUT PREJUDICE** as to Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims.

New Orleans, Louisiana, this 20th day of September, 2018.



SUSIE MORGAN
UNITED STATES DISTRICT JUDGE

⁴⁶ R. Doc. 273.