

**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 a Motion for Partial Summary Judgment on Counts 2 and 3 of Defendant Cytogel Pharma, LLC's ("Cytogel") Second Amended and Restated Counterclaims, filed by Plaintiff the Administrators of the Tulane Educational Fund ("Tulane") and Counterclaim-Defendant Dr. James E. Zadina.¹ Cytogel opposes.² For the reasons that follow, the motion is **DENIED**.

BACKGROUND³

In the 1990s, Dr. Zadina and his colleagues at Tulane University researched and developed opioid compounds 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 compounds.⁵ On December 1, 2003, Tulane executed a Licensing Agreement on the patents in favor of Cytogel.⁶

¹ R. Doc. 274.

² R. Doc. 313.

³ The facts in this section are undisputed unless noted otherwise.

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. Tulane and Dr. Zadina filed the Licensing Agreement on the record. R. Doc. 279-6. Cytogel's opposition to the instant motion cites and quotes the version of the Licensing Agreement Tulane and Dr. Zadina filed. R. Doc. 313 at 5 n.1. Cytogel does not contest the contents of the Licensing Agreement as filed.

In the Licensing Agreement, Tulane granted Cytogel “an exclusive, worldwide license under the Patent Rights . . . to research, use make, have made, import, sell and offer for sale any Licensed Product(s) within the Field.”⁷ The “Patent Rights” are defined as the rights to the ’958 and ’578 Patents.⁸ “Licensed Product” is defined as “any product incorporating, embodying, otherwise making use of or described in the patents within the Patent Rights.”⁹ The “Field” is defined as “the use of the Licensed Product for medical use in humans and animals.”¹⁰

After Tulane and Cytogel signed the Licensing Agreement, Dr. Zadina, who was an employee of Tulane and the Department of Veterans Affairs (“VA”), began performing consulting work for Cytogel pursuant to a Consulting Agreement.¹¹ Dr. Zadina advised Cytogel on the development of Cyt-1010, a synthetic opioid peptide covered by the ’958 and ’587 Patents, for commercial use as an analgesic.¹² Cytogel alleges Dr. Zadina accessed confidential data and information relating to Cyt-1010 and used this information to further his own secret work on the development of compounds that would compete directly with Cyt-1010.¹³

From September 8, 2010 onward, Cytogel “disengaged from” Dr. Zadina.¹⁴ On August 22, 2012, Dr. Zadina and his colleague at Tulane Dr. Laszlo Hackler formally assigned to Tulane and the VA their ownership rights to a patent application they filed for a group of synthetic opioid compounds.¹⁵ On May 6, 2014, the resulting patent, U.S.

⁷ R. Doc. 279-6 at 6, ¶ 2.1.

⁸ *Id.* at 22.

⁹ *Id.* at 5, ¶ 1.6.

¹⁰ *Id.* at 5, ¶ 1.5.

¹¹ R. Doc. 1 at 6–9, ¶ 24–36; R. Doc. 220 at 10, ¶ 19.

¹² R. Doc. 1 at 5, 6, ¶ 16, 20–21; R. Doc. 220 at 13, ¶ 32.

¹³ R. Doc. 220 at 22, ¶ 61.

¹⁴ R. Doc. 233-1 at 9, ¶ 19; R. Doc. 285 at 7, ¶ 19.

¹⁵ R. Doc. 1 at 12, ¶ 47; R. Doc. 220 at 20, ¶ 55.

Patent No. 8,716,436 B2 (“the ’436 Patent”), issued.¹⁶ Cytogel alleges the compound claimed in the ’436 Patent is a “modified version of Cyt-1010 and plainly designed to compete with [Cyt-1010] as a potential pharmaceutical treatment.”¹⁷

On August 19, 2016, the United States and Tulane filed suit against Cytogel for declaratory judgments of ownership and inventorship of the ’436 Patent.¹⁸ On September 7, 2016, Cytogel filed thirteen counterclaims against Plaintiffs Tulane and the United States, joining Dr. Zadina as Counterclaim-Defendant.¹⁹ On July 23, 2018, Cytogel filed its Second Amended and Restated Counterclaims, which included a fourteenth counterclaim.²⁰ At issue in this motion are Counts 2 and 3 of Cytogel’s Second Amended and Restated Counterclaims, which Cytogel brings against Tulane and Dr. Zadina. In these Counts, Cytogel alleges Tulane and Dr. Zadina infringed the ’958 and ’578 Patents by making and using Cyt-1010 and a compound called EM-1, which are covered by the ’958 and ’578 Patents, to test the ’436 Patent compounds.²¹ Tulane and Dr. Zadina admit researchers in Dr. Zadina’s laboratory conducted experiments using Cyt-1010 and EM-1 as comparator compounds for the ’436 Patent compounds.²²

Tulane and Dr. Zadina filed the instant motion on September 10, 2018.²³ They argue the scope of the Licensing Agreement is limited to medical use, and their use of Cyt-1010 and EM-1 as comparator compounds for the ’436 Patent compounds does not constitute medical use.²⁴ Tulane and Dr. Zadina also argue Cytogel lacks standing to bring

¹⁶ R. Doc. 233-1 at 9, ¶ 20; R. Doc. 285 at 7, ¶ 20.

¹⁷ R. Doc. 220 at 23, ¶ 64.

¹⁸ R. Doc. 1.

¹⁹ R. Doc. 6.

²⁰ R. Doc. 220.

²¹ *Id.* at 29–31, ¶ 83–90.

²² R. Doc. 313-1 at 11–12, ¶¶ C2, C4, C6.; R. Doc. 371-1 at 29–32, ¶¶ C2, C4, C6.

²³ R. Doc. 274.

²⁴ R. Doc. 274-3 at 8–10.

claims for infringement of the '958 and '578 Patents and that Cytogel has no evidence of infringement or damages.²⁵ Cytogel opposes.²⁶

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate only “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”²⁷ “An issue is material if its resolution could affect the outcome of the action.”²⁸ When assessing whether a material factual dispute exists, the Court considers “all of the evidence in the record but refrain[s] from making credibility determinations or weighing the evidence.”²⁹ All reasonable inferences are drawn in favor of the non-moving party.³⁰ There is no genuine issue of material fact if, even viewing the evidence in the light most favorable to the non-moving party, no reasonable trier of fact could find for the non-moving party, thus entitling the moving party to judgment as a matter of law.³¹

“[A] party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact.” To satisfy Rule 56’s burden of production, the moving party must do one of two things: “the moving party may submit affirmative evidence that negates an essential element of the nonmoving party’s claim” or “the moving party may demonstrate to the Court that the nonmoving party’s evidence is insufficient to establish an essential element of the nonmoving party’s claim.” If the moving party fails to carry this burden, the motion must

²⁵ *Id.* at 11–14, 17–18.

²⁶ R. Doc. 313.

²⁷ FED. R. CIV. P. 56; *see also Celotex*, 477 U.S. 317, 322–23 (1986).

²⁸ *DIRECTV, Inc. v. Robson*, 420 F.3d 532, 536 (5th Cir. 2005).

²⁹ *Delta & Pine Land Co. v. Nationwide Agribusiness Ins. Co.*, 530 F.3d 395, 398–99 (5th Cir. 2008); *see also Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150–51 (2000).

³⁰ *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994).

³¹ *Hibernia Nat. Bank v. Carner*, 997 F.2d 94, 98 (5th Cir. 1993) (citing *Amoco Prod. Co. v. Horwell Energy, Inc.*, 969 F.2d 146, 147–48 (5th Cir. 1992)).

be denied. If the moving party successfully carries this burden, the burden of production then shifts to the non-moving party to direct the Court's attention to something in the pleadings or other evidence in the record setting forth specific facts sufficient to establish that a genuine issue of material fact does indeed exist.³²

If the dispositive issue is one on which the non-moving party will bear the burden of persuasion at trial, the moving party may satisfy its burden of production by either (1) submitting affirmative evidence that negates an essential element of the non-movant's claim, or (2) affirmatively demonstrating that there is no evidence in the record to establish an essential element of the non-movant's claim.³³ If the movant fails to affirmatively show the absence of evidence in the record, its motion for summary judgment must be denied.³⁴ Thus, the non-moving party may defeat a motion for summary judgment by "calling the Court's attention to supporting evidence already in the record that was overlooked or ignored by the moving party."³⁵ "[U]nsubstantiated assertions are not competent summary judgment evidence. The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his or her claim. 'Rule 56 does not impose upon the district court a duty to sift through the record in search of evidence to support a party's opposition to summary judgment.'"³⁶

³² *Celotex*, 477 U.S. at 322–24.

³³ *Id.* at 331–32 (Brennan, J., dissenting).

³⁴ *See id.* at 332.

³⁵ *Id.* at 332–33. The burden would then shift back to the movant to demonstrate the inadequacy of the evidence relied upon by the non-movant. Once attacked, "the burden of production shifts to the nonmoving party, who must either (1) rehabilitate the evidence attacked in the moving party's papers, (2) produce additional evidence showing the existence of a genuine issue for trial as provided in Rule 56(e), or (3) submit an affidavit explaining why further discovery is necessary as provided in Rule 56(f)." *Id.* at 332–33, 333 n.3.

³⁶ *Ragas v. Tenn. Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998) (citing *Celotex*, 477 U.S. at 324; *Forsyth v. Barr*, 19 F.3d 1527, 1537 (5th Cir. 1994) and quoting *Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915–16 & n.7 (5th Cir. 1992)).

LAW AND ANALYSIS

I. Cytogel has standing to bring Counts 2 and 3 of its Second Amended and Restated Counterclaims.

“The doctrine of standing limits federal judicial power and has both constitutional and prudential components.”³⁷ “Constitutional standing requires only that a plaintiff must have suffered an injury in fact, that there be a causal connection between the injury and a defendant's conduct, and that the injury be redressable by a favorable court decision.”³⁸ Exclusive patent licensees have constitutional standing to bring infringement suits when, as in this case, they were injured by a party that used the subject of the license.³⁹ However, exclusive patent licensees lack prudential standing to bring suit against infringers when the patent owner is not a party to the suit.⁴⁰ “The presence of the owner of the patent as a party is indispensable, not only to give jurisdiction under the patent laws, but also in most cases to enable the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in the one action, or by satisfying one adverse decree to bar all subsequent actions.”⁴¹

When a patent owner is a party to the suit, “the policy concerns motivating the need for a patent owner to be joined in an infringement suit with its licensee—principally, from the standpoint of an accused infringer, avoidance of multiple lawsuits and liabilities, and, from the standpoint of the patentee, ensuring that its patent is not invalidated or held unenforceable without its participation—are . . . met.”⁴² Although in a typical patent infringement suit, a patent owner would be a co-plaintiff with the exclusive licensee,

³⁷ *Media Techs. Licensing, LLC v. Upper Deck Co.*, 334 F.3d 1366, 1369 (Fed.Cir.2003).

³⁸ *Evident Corp. v. Church & Dwight Co.*, 399 F.3d 1310, 1313 (Fed. Cir. 2005) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)).

³⁹ *See, e.g., id.*

⁴⁰ *Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 468, 46 S. Ct. 166, 169, 70 L. Ed. 357 (1926).

⁴¹ *Id.*

⁴² *Evident*, 399 F.3d at 1314.

courts have found the prudential standing requirement that the patent owner be a party to the suit satisfied when the patent owner is joined to the suit in any way.⁴³

In this case, Tulane granted Cytogel an exclusive license to use the '958 and '578 Patent compounds within a field defined in the Licensing Agreement.⁴⁴ As an exclusive licensee, Cytogel has constitutional standing to bring patent infringement suits. Cytogel also has prudential standing to bring suit against Tulane because Tulane is a party to the suit. Tulane cannot be joined as a co-plaintiff to Cytogel's patent infringement counterclaims because Tulane is a Counterclaim-Defendant. As a Counterclaim-Defendant, Tulane is able to defend its interest in the '958 and '578 Patents. There is also no risk of multiple lawsuits regarding the alleged infringement. As a result, Cytogel has prudential standing to bring suit for infringement of the '958 and '578 Patents.

II. The Licensing Agreement leaves the scope of the license granted to Cytogel ambiguous, and genuine issues of material fact exist regarding whether Tulane and Dr. Zadina's use of Cyt-1010 and EM-1 was among the rights reserved by Tulane under the Licensing Agreement.

The parties agree that the evidence Cytogel presents of infringement of the '958 and '578 Patents relates entirely to Dr. Zadina's use of the licensed compounds to test the '436 Patent.⁴⁵ Tulane and Dr. Zadina argue, based on their interpretation of the Licensing Agreement, that this use does not constitute evidence of patent infringement.⁴⁶ Cytogel argues, based on its interpretation of the Licensing Agreement, that the alleged use does constitute evidence of infringement.⁴⁷

⁴³ See, e.g., *id.* (holding an exclusive licensee had prudential standing to bring suit when patent owner was joined as third-party defendant).

⁴⁴ R. Doc. 279-1 at 6, ¶ 2.1.

⁴⁵ R. Doc. 274-1 at 5, ¶ 10; R. Doc. 313-1 at 3, ¶ 10.

⁴⁶ R. Doc. 274-3 at 15.

⁴⁷ R. Doc. 313 at 11-14.

In its Order of October 25, 2018, this Court found there were genuine issues of material fact as to the scope of the Licensing Agreement.⁴⁸ The Court noted the Licensing Agreement does not define “medical use” or “research” and is “ambiguous regarding whether the license covers preclinical and Phase I studies.”⁴⁹ As a result, the Court denied Tulane and Dr. Zadina’s motions for summary judgment on Count 6.⁵⁰ For the reasons fully laid out in that Order, the Court finds genuine issues of material fact as to the intent of the parties with respect to the scope of license granted to Cytogel. Genuine issues of material fact exist regarding whether Tulane and Dr. Zadina’s use of Cyt-1010 and EM-1 falls within the scope of the rights reserved by Tulane under the Licensing Agreement.

III. Because Cytogel has requested injunctive relief and damages based on Counts 2 and 3 of its Second Amended and Restated Counterclaims, Tulane and Dr. Zadina are not entitled to judgment as a matter of law on the claims because they argue damages have not been proven.

Tulane and Dr. Zadina argue that, because Cytogel’s damages expert did not provide a calculation of damages based on the alleged infringement of the ’958 and ’578 Patents, Cytogel has no evidence of damages related to Counts 2 and 3 of its Second Amended and Restated Counterclaims.⁵¹ They argue they are entitled to judgment as a matter of law on the claims.⁵²

The parties dispute whether Cytogel has shown it suffered damages resulting from the alleged infringement. Tulane and Dr. Zadina allege Cytogel did not provide a damages calculation or damage amount relating to Counts 2 and 3 in response to an

⁴⁸ R. Doc. 395 at 12.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ R. Doc. 274-3 at 17–18.

⁵² *Id.*

interrogatory.⁵³ Cytogel states its interrogatory response incorporated its expert reports, including the report of Dr. Gregory K. Bell, who estimated Cytogel's damages amount.⁵⁴

Tulane and Dr. Zadina have filed a motion in limine challenging the admissibility of Dr. Bell's testimony.⁵⁵ The Court has not yet ruled on whether Dr. Bell will be allowed to testify. Regardless of whether Dr. Bell's testimony is admitted, the Court notes Cytogel requests damages and injunctive relief with respect to its patent infringement claims.⁵⁶ Cytogel's infringement claims arise under 35 U.S.C. § 271. Under 35 U.S.C. § 283, this Court may grant injunctions relating to these claims "in accordance with the principles of equity to prevent the violation of any right secured by patent." As a result, this Court has the equitable authority to grant Cytogel's requested injunctive relief with respect to Counts 2 and 3. Tulane and Dr. Zadina are not entitled to summary judgment on Counts 2 and 3 on the basis that Cytogel has not shown damages.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that the Motion for Partial Summary Judgment on Counts 2 and 3 of Defendant Cytogel Pharma, LLC's Second Amended and Restated Counterclaims, filed by Plaintiff the Administrators of the Tulane Educational Fund and Counterclaim-Defendant Dr. James E. Zadina, be and hereby is **DENIED**.⁵⁷

New Orleans, Louisiana, this 2nd day of November, 2018.



SUSIE MORGAN
UNITED STATES DISTRICT JUDGE

⁵³ R. Doc. 274-1 at 8, ¶ 23.

⁵⁴ R. Doc. 313-1 at 7, ¶ 23.

⁵⁵ R. Doc. 283.

⁵⁶ R. Doc. 220 at 52, ¶ J (requesting the Court to "enjoin Tulane, VA, and Dr. Zadina . . . from further infringement of the '958 and '578 Patents.")

⁵⁷ R. Doc. 274.