

**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 in Limine on the Admissibility of the Expert Testimony of Defendant Cytogel Pharma, LLC's ("Cytogel") Expert Dr. Stephen G. Davies, 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 **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

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.³ 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.⁴ On December 1, 2003, Tulane licensed the patents to Cytogel.⁵

After Tulane and Cytogel signed a 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.⁶ Dr. Zadina advised

¹ R. Doc. 286.

² R. Doc. 315.

³ R. Doc. 1 at 4-5, ¶ 14-16; R. Doc. 220 at 9, ¶ 16.

⁴ R. Doc. 1 at 5-6, ¶ 17-19; R. Doc. 220 at 9, ¶ 16.

⁵ R. Doc. 1 at 6, ¶ 20; R. Doc. 220 at 9, ¶ 17.

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

Cytogel on the development of Cyt-1010, a synthetic opioid peptide covered by the '958 and '587 Patents, for commercial use as an analgesic.⁷ 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-1010.⁸

From September 8, 2010 onward, Cytogel “disengaged from” Dr. Zadina.⁹ 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.¹⁰ On May 6, 2014, the resulting patent, U.S. Patent No. 8,716,436 B2 (“the '436 Patent”), issued.¹¹ 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.”¹²

On August 19, 2016, the United States and Tulane filed suit against Cytogel for declaratory judgments of ownership and inventorship of the '436 Patent.¹³ On September 7, 2016, Cytogel filed thirteen counterclaims against Plaintiffs Tulane and the United States, joining Dr. Zadina as Counterclaim-Defendant.¹⁴ On July 23, 2018, Cytogel filed its Second Amended and Restated Counterclaims, which included a fourteenth counterclaim to correct the inventorship of the '436 Patent.¹⁵

Dr. Davies prepared two expert reports for Cytogel. One report addresses ownership and inventorship of the '436 Patent and infringement of the '958 and '578

⁷ R. Doc. 1 at 5, 6, ¶ 16, 20–21; R. Doc. 220 at 13, ¶ 32.

⁸ *Id.* at 22, ¶ 61.

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

¹⁰ R. Doc. 1 at 12, ¶ 47; R. Doc. 220 at 20, ¶ 55.

¹¹ R. Doc. 233-1 at 9, ¶ 20; R. Doc. 285 at 7, ¶ 20.

¹² R. Doc. 220 at 23, ¶ 64.

¹³ R. Doc. 1.

¹⁴ R. Doc. 6.

¹⁵ R. Doc. 220.

Patents.¹⁶ The other report is a rebuttal report to the report of Cytogel's expert Dr. Jane V. Aldrich, who prepared a report on the relationship between Cyt-1010 and the '436 Patent compounds.¹⁷

Tulane and Dr. Zadina filed the instant motion on September 10, 2018.¹⁸ They seeks to prevent Dr. Davies from testifying at trial on the following five issues: (1) the inventorship of the '436 Patent, (2) Dr. Zadina's motivation (3) the infringement of the '958 and '578 Patents, (4) Cyt-1010's status as a "lead compound," and (5) the date of inventorship of the '436 Patent.¹⁹ Cytogel opposes.²⁰

On September 20, 2018, the Court, on its own motion, ordered that there be a separate trial for Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims, which involve inventorship of the '436 Patent.²¹

RULE 702 STANDARD

Rule 702 of the Federal Rules of Evidence permits an expert witness with "scientific, technical or other specialized knowledge" to testify if such testimony "will help the trier of fact to understand the evidence or to determine a fact in issue," so long as (1) "the testimony is based upon sufficient facts or data," (2) "the testimony is the product of reliable principles and methods," and (3) "the expert has reliably applied the principles and methods to the facts of the case."²² Furthermore, Rule 703 provides: "An expert may

¹⁶ Tulane and Dr. Zadina filed Dr. Davies' expert report on the record. R. Doc. 286-4. Cytogel's opposition to the instant motion cites and quotes the version of Dr. Davies' expert report Tulane and Dr. Zadina filed. R. Doc. 315 at 9 n.15. Cytogel does not contest the contents of Dr. Davies' expert report as filed.

¹⁷ Tulane and Dr. Zadina filed Dr. Davies' rebuttal report on the record. R. Doc. 286-5. Cytogel's opposition to the instant motion cites and quotes the version of Dr. Davies' rebuttal report Tulane and Dr. Zadina filed. R. Doc. 315 at 10 n.18. Cytogel does not contest the contents of Dr. Davies' rebuttal report as filed.

¹⁸ R. Doc. 286.

¹⁹ R. Doc. 286-1.

²⁰ R. Doc. 315.

²¹ R. Doc. 298.

²² FED. R. EVID. 702.

base an opinion on facts or data in the case that the expert has been made aware of or personally observed.”²³ Rule 703 continues:

If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.²⁴

As a general rule, questions relating to the bases and sources of an expert’s opinion affect the weight of the evidence rather than its admissibility, and should be left for the finder of fact.²⁵ “Unless wholly unreliable, the data on which the expert relies goes to the weight and not the admissibility of the expert opinion.”²⁶ Thus, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”²⁷ The Court is not concerned with whether the opinion is correct, but whether the preponderance of the evidence establishes that the opinion is reliable.²⁸ “It is the role of the adversarial system, not the court, to highlight weak evidence.”²⁹

LAW AND ANALYSIS

The Court notes Tulane and Dr. Zadina do not argue Dr. Davies’ testimony should be excluded based on his qualifications. The Court has reviewed Dr. Davies’ qualifications as outlined in his expert reports³⁰ and finds he has the scientific, technical or other specialized knowledge to testify to the technical questions at issue in the instant matter.

²³ FED. R. EVID. 703.

²⁴ *Id.*

²⁵ See *Primrose Operating Co. v. Nat’l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004).

²⁶ *Rosiere v. Wood Towing, LLC*, No. 07-1265, 2009 WL 982659, at *1 (E.D. La. Apr. 8, 2009) (citing *United States v. 14.38 Acres of Land*, 80 F.3d 1074, 1077 (5th Cir. 1996)) (emphasis added); *Wolfe v. McNeil-PPC, Inc.*, No. 07-348, 2011 WL 1673805, at *6 (E.D. Pa. May 4, 2011).

²⁷ *Pipitone*, 288 F.3d at 250 (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993) (internal quotation marks omitted).

²⁸ See *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012).

²⁹ *Primrose*, 382 F.3d at 562.

³⁰ R. Docs. 286-4, 286-5.

I. Because the first trial in this case does not deal with issues of inventorship of the '436 Patent, Dr. Davies' testimony on inventorship is not relevant.

Tulane and Dr. Zadina argue the Court should exclude Dr. Davies' testimony on inventorship of the '436 Patent because Dr. Davies' testimony is not based on firsthand knowledge of the factual issues relevant to inventorship.³¹ Cytogel argues Dr. Davies' analysis would be helpful to a factfinder.³² The Court notes this issue is relevant only to Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims, which are the only claims involving inventorship of the '436 Patent. The Court has ordered a separate trial for those counts.³³ As a result, the Court grants Tulane and Dr. Zadina's motion to exclude Dr. Davies' testimony on inventorship at the first trial in this case. To the extent the motion relates to Dr. Davies' testimony at the second trial, the Court denies Tulane and Dr. Zadina's motion without prejudice, to be refiled, if appropriate, at the time of that trial.

II. Dr. Davies' testimony on whether the '436 Patent resulted or emerged from information provided by Cytogel is relevant, reliable, and helpful to a factfinder.

Dr. Davies' expert report includes a comment that "Dr. Zadina was influenced to produce the ['436 Patent compound], and was further motivated to test [the compounds] by his consultation with Cytogel."³⁴ Cytogel argues this supports his opinion that the "'436 Patent compounds "resulted and emerged from information obtained from Cytogel."³⁵ Tulane and Dr. Zadina argue the Court should exclude Dr. Davies' testimony on Dr. Zadina's mental processes in finding he was "motivated" to invent the '436 Patent

³¹ R. Doc. 286-1 at 10.

³² R. Doc. 315 at 6-7.

³³ R. Doc. 298.

³⁴ R. Doc. 286-5 at 60, ¶ 104.

³⁵ *Id.*

compounds by information he obtained from Cytogel.³⁶ Expert opinions may not be based on “subjective belief or unsupported speculation.”³⁷ “Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.”³⁸ Dr. Davies is not allowed to testify about Dr. Zadina’s motivation.

The majority of Dr. Davies’ opinions parallel the language of the Consulting Agreement.³⁹ The Court denies Tulane and Dr. Zadina’s motion in limine on this issue. Dr. Davies will be permitted to give his opinion that the ’436 Patent compounds resulted and emerged from information obtained from Cytogel. At trial, Dr. Davies should couch his testimony in the language of the Consulting Agreement rather than speculate about Dr. Zadina’s motivation.

III. Dr. Davies’ testimony on whether Tulane and Dr. Zadina infringed the ’958 and ’578 Patents is relevant, reliable, and helpful to a factfinder.

Dr. Davies’ expert report includes a section that concludes Dr. Zadina, Tulane, and the VA⁴⁰ infringed the ’958 and ’578 Patents.⁴¹ He bases his conclusion on his review of the ’958 and ’578 Patents, his review of the ’436 Patent, his being informed Cytogel held an exclusive license to the ’958 and ’578 Patents, deposition transcripts, and correspondence between Dr. Zadina and researchers in his laboratory.⁴² Tulane and Dr. Zadina argue the Court should exclude Dr. Davies’ testimony on infringement because

³⁶ R. Doc. 286-1 at 9–10.

³⁷ *Daubert*, 509 U.S. at 599.

³⁸ *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004); *see also DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998) (holding expert “could not testify as an expert that [a party] had a particular motive.”) (emphasis in original).

³⁹ R. Doc. 223-3 at 3–4, ¶ 7–8 (“Consultant acknowledges that any inventions, processes, methods, techniques, formulae, compounds, designs, improvements, writings, tradenames, trademarks, copyrights, patents, trade secrets and other intellectual properties that may *result or emerge* from materials or information provided by Cytogel, its employees or other consultants, or on the premises of Cytogel, or as a result of the consulting process, shall remain the sole and exclusive property of and for the benefit of Cytogel.”) (emphasis added).

⁴⁰ Cytogel does not bring claims for infringement of the ’958 and ’578 Patents against the VA. R. Doc. 220.

⁴¹ R. Doc. 286-5 at 66–69, ¶ 112–20.

⁴² *Id.* at 66–69, ¶ 112–15, 118–19.

they allege the patent license was not exclusive, and Cytogel does not have the right to enforce the '958 and '578 Patents against Tulane.⁴³

Questions relating to the bases and sources of an expert's opinion affect the weight of the evidence rather than its admissibility and should be left for the finder of fact.⁴⁴ The Court finds the issues Tulane and Dr. Zadina raise go to the weight and not the admissibility of his testimony. Tulane and Dr. Zadina may raise these issues on cross-examination. The Court also finds Dr. Davies' testimony on the alleged infringement will help the factfinder understand the similarities between and among Cyt-1010, EM-1, and the '436 Patent compounds and how Cyt-1010 and EM-1 were used in developing the '436 Patent compounds. As a result, the Court denies Tulane and Dr. Zadina's motion on this issue. Dr. Davies' testimony on alleged patent infringement will be allowed.⁴⁵

IV. Dr. Davies' testimony on whether Cyt-1010 is a "lead compound" is relevant, reliable, and helpful to a factfinder.

Dr. Davies' expert report includes a section describing the process for identifying a "lead compound" in medicinal chemistry.⁴⁶ As the report explains, when researchers study potential pharmaceutical compounds, they conduct testing to identify leading candidates for further research, which they label "lead compounds."⁴⁷ The report states Cytogel identified Cyt-1010 as a lead compound through preclinical testing.⁴⁸ Dr. Davies concludes Dr. Zadina, when developing the '436 Patent, relied on the testing Cytogel conducted to identify Cyt-1010 as a lead compound and thereby "avoided costly trial and error."⁴⁹ Tulane and Dr. Zadina assert, based on Dr. Davies' deposition testimony, that

⁴³ R. Doc. 286-3 at 4-5.

⁴⁴ See *Primrose Operating Co.*, 382 F.3d at 562.

⁴⁵ The Court notes Dr. Davies will not be permitted to give legal opinions at trial.

⁴⁶ R. Doc. 286-5 at 17-20, ¶ 43-48.

⁴⁷ *Id.*

⁴⁸ *Id.* at 58-59, ¶ 100-01.

⁴⁹ *Id.* at 60-66, ¶ 102-11.

the data that establish Cyt-1010 as a lead compound is contained in the '958 Patent,⁵⁰ which was developed by Dr. Zadina for Tulane before Tulane and Cytogel signed the Licensing Agreement.⁵¹ Tulane and Dr. Zadina argue this shows Dr. Davies' testimony is self-contradictory and unreliable.⁵²

Tulane and Dr. Zadina do not challenge Dr. Davies' explanation of how lead compounds are identified. The Court finds Dr. Davies' testimony on this subject, along with Dr. Davies' conclusion that Cytogel identified Cyt-1010 as a lead compound, will help the jury determine the extent to which Dr. Zadina's work with Cytogel may have contributed to his development of the '436 Patent compounds.⁵³ Tulane and Dr. Zadina's arguments regarding alleged contradictions in Dr. Davies' testimony are best raised on cross-examination. As a result, the Court denies Tulane and Dr. Zadina's motion to exclude Dr. Davies' testimony on Cyt-1010's identification as a lead compound through preclinical testing and Dr. Zadina's alleged reliance on this testing.

V. Dr. Davies' testimony regarding the date of inventorship of the '436 Patent is relevant, reliable, and helpful to a factfinder.

Dr. Davies' expert report includes a chart on the timing of Dr. Zadina's research.⁵⁴ The chart lists 2005 as the date for Dr. Zadina's first conceived the idea for the '436 Patent compounds.⁵⁵ The chart proceeds to list the approximate dates of several of Cytogel's tests on Cyt-1010 between 2006 and 2009 and the approximate dates of Dr. Zadina's synthesizing or testing '436 Patent Compounds between 2007 and 2010.⁵⁶ Based on the timeline, Dr. Davies concludes Dr. Zadina's consulting work for Cytogel informed his

⁵⁰ R. Doc. 286-3 at 12.

⁵¹ R. Doc. 1 at 5-6, ¶ 17-19; R. Doc. 220 at 9, ¶ 16.

⁵² R. Doc. 286-3 at 12.

⁵³ R. Doc. 286-5 at 58-59, ¶ 100-01.

⁵⁴ *Id.* at 64-65, ¶ 110.

⁵⁵ *Id.*

⁵⁶ *Id.*

development of the '436 Patent.⁵⁷ When asked about the chart at deposition, Dr. Davies testified that the date of invention of the '436 Patent compounds was 2005, when Dr. Zadina first conceived of his idea.⁵⁸

Based on this deposition testimony, Tulane and the United States asserted, in their Motion for Partial Summary Judgment of Patent Ownership, that the '436 Patent was invented in 2005, before the 2006 effective date of the Consulting Agreement.⁵⁹ They argued that, as a result, the Consulting Agreement cannot, as a matter of law, assign the '436 Patent to Cytogel.⁶⁰ In opposition, Cytogel argued Dr. Davies based the 2005 date in his expert report on Dr. Zadina's testimony, which is contradicted by other evidence.⁶¹ The Court found this to be a genuine issue of material fact and denied summary judgment on the issue.⁶²

In the instant motion, Tulane and Dr. Zadina argue Dr. Davies' testimony about the alleged 2005 invention date of the '436 Patent Compounds contradicts his testimony about all testing Cytogel and Dr. Zadina conducted later than 2005.⁶³ They argue that, as a result, Dr. Davies' testimony on the subject is unreliable.⁶⁴

The Court finds Dr. Davies' analysis of the timeline, in light of his technical expertise, will help a jury understand how Cytogel's studies compare and relate to Dr. Zadina's research. Tulane and Dr. Zadina's arguments regarding Dr. Davies' testimony at deposition are best raised on cross-examination. As a result, the Court denies Tulane and

⁵⁷ *Id.* at 65–66, ¶ 111.

⁵⁸ R. Doc. 286-7 at 23–24.

⁵⁹ R. Doc. 270-3 at 7–8.

⁶⁰ *Id.*

⁶¹ R. Doc. 307-1 at 6, ¶ 13.

⁶² R. Doc. 398 at 9.

⁶³ R. Doc. 286-3 at 12–13.

⁶⁴ *Id.*


Dr. Zadina's motion to exclude Dr. Davies' testimony on the date of inventorship of the '436 Patent.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Motion in Limine on the Admissibility of the Expert Testimony of Defendant Cytogel Pharma, LLC's Expert Dr. Stephen G. Davies, filed by Plaintiff the Administrators of the Tulane Educational Fund and Counterclaim-Defendant Dr. James E. Zadina be and hereby **GRANTED IN PART** to the extent it relates to Dr. Davies' testimony on inventorship at the first trial in this case. The motion is **DENIED IN PART WITHOUT PREJUDICE** to the extent it relates to Dr. Davies' testimony on inventorship at the second trial in this case. The Administrators of the Tulane Educational Fund and Dr. Zadina may refile the relevant portion of the motion at the time of the second trial.

IT IS FURTHER ORDERED that the motion be and hereby is **DENIED IN PART** as to all other issues.

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



SUSIE MORGAN
UNITED STATES DISTRICT JUDGE