United States, et al v. Cytogel Pharma, LLC Doc. 404

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 to Limit the Expert Testimony of Plaintiffs' Expert Dr. Jane V. Aldrich, filed by Defendant Cytogel Pharma, LLC.[1] Plaintiffs the United States of America and the Administrators of the Tulane Educational Fund ("Tulane") and Counterclaim-Defendant Dr. James E. Zadina oppose in part.[2] For the reasons that follow, the motion is **GRANTED**.

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

[1] R. Doc. 277.
[2] R. Doc. 327.
[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.

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consulting work for Cytogel pursuant to a Consulting Agreement.[6] 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.[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]

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

Dr. Aldrich prepared two expert reports for Plaintiffs. One addresses "how knowledge of the solubility analgesic properties, and other aspects of the endomorphin and endomorphin-analog compounds of [the '958 and '578 Patents], namely through research of the CYT-1010 compound, would, in [Dr Aldrich's] opinion, not inform the design of the endomorphin analogs of the '436 Patent."[16] The other is a rebuttal report to the report of Cytogel's expert Dr. Stephen G. Davies, who prepared a report on ownership and inventorship of the '436 Patent and Infringement of the '958 and '578 Patents.[17]

Cytogel filed the instant motion on September 10, 2018.[18] Cytogel seeks to prevent Dr. Aldrich from testifying at trial on topics of inventorship and patent infringement.[19] Tulane, Dr. Zadina, and the United States do not oppose this portion of the motion.[20] Cytogel also seeks to prevent Dr. Aldrich from testifying as to her experiences with collaboration on patents.[21] Tulane, Dr. Zadina, and the United States oppose this portion of the motion.[22]

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.[23]

LAW AND ANALYSIS

Federal Rule of Evidence 702 permits an expert witness with "scientific, technical or other specialized knowledge" to testify if such testimony "will help the trier of fact to

[16] R. Doc. 227-2 at 3, ¶ 2.
[17] R. Doc. 277-3.
[18] R. Doc. 277.
[19] R. Doc. 277-1.
[20] R. Doc. 327 at 2–3.
[21] R. Doc. 277-1 at 6–7.
[22] R. Doc. 327 at 3–5.
[23] R. Doc. 298.

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."[24] Furthermore, Federal Rule of Evidence 703 provides: "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed."[25] 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.[26]

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.[27] "Unless wholly unreliable, the data on which the expert relies goes to the weight and not the admissibility of the expert opinion."[28] 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."[29] The Court is not concerned with whether the opinion is correct, but whether the preponderance of the evidence establishes that the opinion is reliable.[30] "It is the role of the adversarial system, not the court, to highlight weak evidence."[31]

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[24] FED. R. EVID. 702.
[25] FED. R. EVID. 703.
[26] *Id.*
[27] *See Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004).
[28] *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).
[29] *Pipitone*, 288 F.3d at 250 (quoting *Daubert*, 509 U.S. at 596) (internal quotation marks omitted).
[30] *See Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012).
[31] *Primrose*, 382 F.3d at 562.

Cytogel moves to keep Dr. Aldrich from testifying at trial on patent inventorship and patent infringement.[32] As to inventorship, Cytogel states Dr. Aldrich's initial report "appeared to approach the issue."[33] As to infringement, Cytogel states "Dr. Aldrich had an opportunity to rebut" the expert opinion of Cytogel's expert Dr. Stephen G. Davies.[34] Tulane, Dr. Zadina, and the United States do not oppose this portion of the motion.[35] As a result, Dr. Aldrich will be precluded from addressing issues of patent inventorship and infringement at trial.

Cytogel moves to keep Dr. Aldrich from testifying about collaboration in patent invention.[36] In her rebuttal expert report, Dr. Aldrich notes her "experience of working in a collaborative environment when developing new compounds" and states, based on similar experiences, that she "see[s] nothing to indicate that Dr. Zadina's testimony that he collaborated with Dr. Hackler is incorrect."[37] Cytogel argues this testimony is "anecdotal" and neither reliable nor relevant.[38] Tulane, Dr. Zadina, and the United States oppose this portion of the motion, arguing the testimony "assists in qualifying Dr. Aldrich as an expert, and would also assist the jury in understanding generally how research . . . typically proceeds in Dr. Aldrich's field."[39] The Court finds this testimony is not necessary to qualify Dr. Aldrich as an expert and would not be helpful to the jury at the first trial in

[32] R. Doc. 277-1.
[33] *Id*. at 5.
[34] *Id*. at 9.
[35] R. Doc. 327 at 2–3.
[36] R. Doc. 277-1 at 6–7.
[37] R. Doc. 277-3 at 7, ¶ 7–8.
[38] R. Doc. 277-1 at 6–7.
[39] R. Doc. 327 at 4.

this matter. As a result, Cytogel's motion is granted. Dr. Aldrich's testimony on collaboration in patent invention will be excluded.[40]

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that the Motion in Limine to Limit the Expert Testimony of Plaintiffs' Expert Dr. Jane V. Aldrich, filed by Defendant Cytogel Pharma, LLC, be and hereby is **GRANTED**.

New Orleans, Louisiana, this 31st day of October, 2018.

SUSIE MORGAN
UNITED STATES DISTRICT JUDGE

[40] To be clear, Dr. Aldrich may not testify at the first trial in this matter, on Count 1 of the Complaint and Counts 1–8 and 10 of Cytogel's Second Amended and Restated Counterclaims, regarding whether Dr. Zadina's testimony that he collaborated with Dr. Hackler is correct.