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"(1)**

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. Gregory K. Bell, filed by Plaintiffs the United States of America and 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**.[3] The Court **DENIES AS MOOT** the Motion in Limine on the Admissibility of the Expert Testimony of Cytogel's expert Dr. William K. Schmidt[4] and the Motion in Limine on the Admissibility of the Expert Testimony of Cytogel's expert Dr. William A. Clementi,[5] filed by Tulane, Dr. Zadina, and the United States.

[1] R. Doc. 283.
[2] R. Doc. 309.
[3] Cytogel belatedly and offhandedly requested an evidentiary hearing in connection with this motion. R. Doc. 439-1 at 3. The parties have had ample time and opportunity to brief this issue and to discuss it with the Court on several occasions. Cytogel is not entitled to an evidentiary hearing, and it is within the Court's discretion to determine whether one is needed. The Court finds an evidentiary hearing is not necessary on this motion.
[4] R. Doc. 268. On November 12, 2018, Cytogel acknowledged that, if Dr. Bell is not allowed to testify, Dr. Schmidt's testimony will not be offered. R. Doc. 437 at 2 n.1.
[5] R. Doc. 281. Tulane, Dr. Zadina, and the United States represent that Dr. Clementi's opinions "are provided in rebuttal to the opinions of Dr. Schmidt." R. Doc. 320 at 7. Because Dr. Schmidt will not testify at trial, Dr. Clementi's rebuttal opinion will be unnecessary.

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.[6] 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.[7] On December 1, 2003, Tulane licensed the patents to Cytogel.[8]

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, eventually executing a Consulting Agreement.[9] 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.[10] 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.[11]

On July 9, 2010, United States Provisional Patent Application 61/363,039 ("the Provisional Application") was filed.[12] On September 8, 2010, Tulane sent Cytogel an email stating Dr. Zadina had designed a "new family of peptides."[13] From that date 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

[6] R. Doc. 1 at 4–5, ¶ 14–16; R. Doc. 220 at 9, ¶ 16.
[7] R. Doc. 1 at 5–6, ¶ 17–19; R. Doc. 220 at 9, ¶ 16.
[8] R. Doc. 1 at 6, ¶ 20; R. Doc. 220 at 9, ¶ 17.
[9] R. Doc. 1 at 6–9, ¶ 24–36; R. Doc. 220 at 10, ¶ 19.
[10] R. Doc. 1 at 5, 6, ¶ 16, 20–21; R. Doc. 220 at 13, ¶ 32.
[11] R. Doc. 220 at 22, ¶ 61.
[12] R. Doc. 271-4 at 4, ¶ 8; R. Doc. 321-1 at 4, ¶ 8.
[13] R. Doc. 271-4 at 5, ¶ 14; R. Doc. 321-1 at 5, ¶ 14.
[14] R. Doc. 233-1 at 9, ¶ 19; R. Doc. 285 at 7, ¶ 19.

rights to a patent application[15] that incorporated and claimed the benefit of the Provisional Application.[16] On May 6, 2014, the resulting patent, U.S. Patent No. 8,716,436 B2 ("the '436 Patent"), issued, with Tulane and the VA as owners.[17] 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."[18]

On November 8, 2010, the Food and Drug Administration ("FDA") placed a partial hold on clinical testing of Cyt-1010, pursuant to 21 C.F.R. § 312.42(b)(1)(iv).[19] In May 2016, Cytogel responded to the FDA's partial hold on clinical testing of Cyt-1010.[20] On June 3, 2016, the FDA imposed a full hold on clinical testing of Cyt-1010, pursuant to 21 C.F.R. § 312.42(b)(2)(i).[21] On August 29, 2018, Cytogel submitted a "Formal Dispute Resolution Request" to the FDA to appeal the Full Clinical Hold issued on June 3, 2016.[22] On October 16, 2018, the FDA granted the appeal in part and denied the appeal in part.[23] Cyt-1010 is now subject to a Partial Clinical Hold.[24] On October 31, 2018, Cytogel filed a supplemental memorandum to inform the Court of this change.[25] Tulane, Dr. Zadina, and the United States filed a response contesting Cytogel's characterization of the FDA's decision.[26]

On August 19, 2016, the United States and Tulane filed suit against Cytogel for declaratory judgments of ownership and inventorship of the '436 Patent and related

[15] R. Doc. 1 at 12, ¶ 47; R. Doc. 220 at 20, ¶ 55.
[16] R. Doc. 271-4 at 4, ¶ 7; R. Doc. 321-1 at 4, ¶ 7.
[17] R. Doc. 233-1 at 9, ¶ 20; R. Doc. 285 at 7, ¶ 20.
[18] R. Doc. 220 at 23, ¶ 64.
[19] R. Doc. 287-4 at 29, ¶ 81; R. Doc. 371-1 at 36, ¶ 81 (citing R. Doc. 287-20).
[20] R. Doc. 287-4 at 29, ¶ 82; R. Doc. 371-1 at 36–37, ¶ 82 (citing R. Doc. 287-21).
[21] R. Doc. 287-4 at 29, ¶ 83; R. Doc. 371-1 at 37, ¶ 83 (citing R. Doc. 287-22).
[22] R. Doc. 287-4 at 30, ¶ 87; R. Doc. 371-1 at 38, ¶ 87 (citing "Exhibit 18," which was not attached to Tulane and Dr. Zadina's filing).
[23] R. Doc. 403-1 at 1.
[24] *Id.*
[25] R. Doc. 403.
[26] R. Doc. 415.

patent applications.[27] On September 7, 2016, Cytogel filed thirteen counterclaims against Plaintiffs Tulane and the United States, joining Dr. Zadina as Counterclaim-Defendant.[28] 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.[29]

On February 20, 2018, Tulane licensed the '436 Patent compounds to Mirata Pharmaceuticals, LLC ("Mirata").[30]

Dr. Bell prepared an expert report for Cytogel assessing the impact of the alleged actions of Tulane, Dr. Zadina, and the VA on the "commercial value and opportunities of Cytogel."[31] Dr. Bell reports that he estimated the value of the commercial opportunities available to Cytogel in a counterfactual situation in which Cytogel had ownership of the '436 Patent compounds in July 2010.[32] Dr. Bell then estimates the value of the opportunities available to Cytogel in two hypothetical scenarios in which Cytogel is awarded damages at the resolution of the instant case.[33]

Tulane, Dr. Zadina, and the United States filed the instant motion on September 10, 2018.[34] They argue Dr. Bell's opinions are irrelevant, unreliable, and based on speculative and unsupported assumptions.[35] Cytogel opposes.[36]

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[27] R. Doc. 1.
[28] R. Doc. 6.
[29] R. Doc. 220.
[30] R. Doc. 305-61 at 6 (License Agreement between Tulane and Mirata, the authenticity of which the parties do not dispute).
[31] R. Doc. 283-22 at 4, ¶ 4.
[32] *Id.* at 13, ¶ 23; 14 ¶ 26(a). The Provisional Application that led to the '436 Patent was filed in July 2010. R. Doc. 271-4 at 4, ¶ 8; R. Doc. 321-1 at 4, ¶ 8. Dr. Bell states he was instructed to assume this date because "Cytogel could have begun development of the '436 Compounds by July 2010, at the latest." R. Doc. 283-22 at 13, ¶ 23(a).
[33] *Id.* at 13, ¶ 24.
[34] R. Doc. 283.
[35] R. Doc. 283-16.
[36] R. Doc. 309.

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."[37]

The United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[38] provides the analytical framework for determining whether expert testimony is admissible under Rule 702. Under *Daubert*, courts, as "gatekeepers," are tasked with making a preliminary assessment of whether expert testimony is both relevant and reliable.[39] The party offering the expert opinion must show by a preponderance of the evidence that the expert's testimony is reliable and relevant.[40]

The reliability of expert testimony "is determined by assessing whether the reasoning or methodology underlying the testimony is scientifically valid."[41] "The aim is to exclude expert testimony based merely on subjective belief or unsupported speculation."[42] In *Daubert*, the Supreme Court enumerated several non-exclusive factors that courts may consider in evaluating the reliability of expert testimony.[43] "These factors are (1) whether the expert's theory can or has been tested, (2) whether the theory has been subject to peer review and publication, (3) the known or potential rate of error of a

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[37] FED. R. EVID. 702.
[38] 509 U.S. 579 (1993).
[39] *See Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 243–44 (citing *id.* at 592–93).
[40] *Mathis v. Exxon Corp.*, 302 F.3d 448, 459–60 (5th Cir. 2002).
[41] *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 352 (5th Cir. 2007). *See also Burleson v. Texas Dep't of Criminal Justice*, 393 F.3d 577, 584 (5th Cir. 2004); *Bocanegra v. Vicmar Servs., Inc.*, 320 F.3d 581, 584–85 (5th Cir. 2003).
[42] *Burst v. Shell Oil Co.*, 120 F. Supp. 3d 547, 550 (E.D. La. 2015) (internal citations omitted).
[43] *Daubert*, 509 U.S. at 592–96.

technique or theory when applied, (4) the existence and maintenance of standards and controls, and (5) the degree to which the technique or theory has been generally accepted in the scientific community."[44] The Supreme Court cautioned that the reliability analysis must be flexible: the *Daubert* factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[45] Thus, "not every *Daubert* factor will be applicable in every situation . . . and a court has discretion to consider other factors it deems relevant."[46] In sum, the district court is offered broad latitude in making expert testimony determinations.[47]

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.[48] "Unless wholly unreliable, the data on which the expert relies goes to the weight and not the admissibility of the expert opinion."[49] "Vigorous 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."[50]

However, "the expert's testimony must be reliable at each and every step or else it is inadmissible. The reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion, et alia."[51] "[N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only

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[44] *Bocanegra*, 320 F.3d at 584–85 (citing *id.* at 593–94).
[45] *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999).
[46] *Guy v. Crown Equip. Corp.*, 394 F.3d 320, 326 (5th Cir. 2004).
[47] *See, e.g., Kumho Tire*, 526 U.S. at 151–53.
[48] *See Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004).
[49] *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).
[50] *Pipitone*, 288 F.3d at 250 (quoting *Daubert*, 509 U.S. at 596) (internal quotation marks omitted).
[51] *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 355 (5th Cir. 2007) (internal quotation marks and citation omitted).

by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."[52]

"Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known."[53] "[Although] reliable expert testimony often involves estimation and reasonable inferences from a sometimes incomplete record," an expert may not assume facts that "differ[] frequently and substantially from the undisputed record evidence . . . [or] ma[ke] numerous assumptions with no apparent underlying rationale."[54] "An expert's opinion must be preceded by facts in evidence and cannot be the basis of speculation or conjecture."[55]

Under Rule 703 of the Federal Rules of Evidence, expert witnesses may base opinions on facts or data that the expert "has been made aware of or personally observed," including otherwise inadmissible facts or data if "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." A district court is "best placed to evaluate" the reasonableness of an expert's reliance on facts or data.[56] A district court may exclude expert testimony when it is "based on insufficient, erroneous information."[57]

LAW AND ANALYSIS

I. Dr. Bell does not state an adequate basis for his reliance on the statistics in the Lo study.

Dr. Bell relies on probability values in a study published in *Biostatistics* with Dr. Andrew W. Lo as the lead author ("the Lo study").[58] The Lo study estimates the

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[52] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)
[53] *Daubert*, 509 U.S. at 590.
[54] *Moore v. Int'l Paint, L.L.C.*, 547 F. App'x 513, 516 (5th Cir. 2013)
[55] *Lewis v. Par. of Terrebonne*, 894 F.2d 142, 146 (5th Cir. 1990).
[56] *Factory Mut. Ins. Co. v. Alon USA L.P.*, 705 F.3d 518, 526 (5th Cir. 2013).
[57] *Paz v. Brush Engineered Materials, Inc.*, 555 F.3d 383, 389 (5th Cir. 2009)
[58] Chi Heem Wong, Kien Wei Siah, & Andrew W. Lo, *Estimation of Clinical Trial Success Rates and Related Parameters*, BIOSTATISTICS (2018), https://doi.org/10.1093/biostatistics/kxx069 ("the Lo study").

probability of success of clinical trials testing lead indications for central nervous system drugs. The authors of the Lo study estimate the probability of drugs fitting the parameters of their study successfully completing the FDA approval process to be 19.3%.[59] Dr. Bell does not present himself as qualified to express an opinion on the probability that Cyt-1010 and the '436 Patent compounds will succeed at Phase I and Phase II testing and be approved by the FDA, but this probability underlies his entire report. In fact, when asked at deposition whether the figures in the Lo study or the probability figures provided by Dr. Schmidt were "better," Dr. Bell stated that he "form[s] no opinion one way or the other."[60]

A. Dr. Bell does not establish the "fit" between the probability estimates for drugs in the Lo study and Cyt-1010 and the '436 Patent compounds.

Tulane, Dr. Zadina, and the United States argue that "use of the [Lo] study to calculate Cytogel's diminution in value, without knowing more about the nameless drugs analyzed and the facts surrounding the clinical trials, is unreliable."[61] Tulane, Dr. Zadina, and the United States argue the Lo study does not fit this case because the authors of the Lo study state that "any application that was in Phase I for more than 360 days was considered terminated and therefore excluded from further calculations of the probabilities of progressing to Phase II."[62] Tulane, Dr. Zadina, and the United States allege Cyt-1010 "has been in Phase I for roughly 8 years."[63] The Court agrees that the Lo study has not been shown to fit the facts of the case.

In *Daubert*, the Supreme Court held that "[e]xpert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful," labeling this requirement

[59] *Id.*
[60] *Id.* at 9, 28:10–11.
[61] R. Doc. 363 at 10.
[62] R. Doc. 268-14 at 19.
[63] *Id.*

as one of "fit."[64] "'Fit'" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes."[65] In *Gen. Elec. Co. v. Joiner*,[66] the Supreme Court affirmed a district court's finding that several scientific studies "were not a sufficient basis for the experts' opinions" that relied on them.[67] The Court noted district courts need not "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."[68]

At deposition, Dr. Bell testified that the Lo study is peer reviewed, was published in a "fairly high-profile journal," and is "clearly the most comprehensive paper out there on clinical trial success rates."[69] Although these are factors to be considered in determining whether the Lo study is reliable, in general these factors do not establish that the average success rates in the Lo study may be projected onto Cyt-1010 or the '436 Patent compounds.

Dr. Bell provides nothing to establish the results of the Lo study fit the facts of the instant case. In particular, the 360-day time limit on Phase I testing undermines Dr. Bell's reliance on the Lo study. If Cyt-1010 had been included in the Lo study data set, Cyt-1010 would have been considered a failed drug and excluded from the analysis. Dr. Bell has not established that the 19.3% probability of success for all clinical trials of lead indications for central nervous system drugs in the Lo study may reliably be applied to predict the success of Cyt-1010 or the '436 Patent compounds.

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[64] *Daubert*, 509 U.S. at 591 (citation omitted).
[65] *Id.* (citation omitted).
[66] 522 U.S. 136.
[67] *Id.* at 145.
[68] *Id.* at 146.
[69] R. Doc. 283-21 at 8, 23:12–20.

B. Even if the Lo study could reliably be applied to Cyt-1010 or the '436 Patent compounds, the result would not establish liability by a preponderance of the evidence.

Dr. Bell calculates the "probability adjusted" diminution in value of commercial opportunities available to Cytogel. To do this, he multiplies the probability of Cyt-1010 and the '436 Patent being approved by the FDA by his estimate of the value of Cytogel's commercial opportunities.[70] The Court is unaware of, and Cytogel has not provided, any cases establishing that multiplying an expected amount of damages by an estimated probability the event causing the estimated damages will occur is a legitimate, established method for calculating damages.

Furthermore, using the Lo study, Dr. Bell bases his opinions on the probability of success of Cyt-1010 and the '436 Patent compounds being 19.3%.[71] In effect, Dr. Bell's testimony is based on the premise that Cyt-1010 and the '436 Patent compounds will, more likely than not, fail to be approved by the FDA because 19.3%, the probability of success Dr. Bell uses, is lower than 50%. "Under Louisiana law, the plaintiff must prove damages with reasonable certainty," meaning "that the plaintiff must prove damages by a preponderance of the evidence."[72] The Court is not aware of, and Cytogel has not provided, any cases holding an expert's opinion is reliable when the expert expresses his probability of being correct as less than 50%. As a result, Cytogel has failed to establish that Dr. Bell's testimony establishes damages by a preponderance of the evidence.

[70] *See, e.g.*, *id.* at 69 ("Exhibit E-3").
[71] R. Doc. 283-22 at 17, ¶ 32(a)(i).
[72] *Mobil Expl. & Producing U.S., Inc. v. Cajun Const. Servs.*, Inc., 45 F.3d 96, 101–02 (5th Cir. 1995); *see also In re Rushing*, 424 B.R. 747, 753 (Bankr. M.D. La. 2010) ("[Plaintiffs] bear the burden of proving their lost profits by a preponderance of the evidence."); *cf. Huggs, Inc. v. LPC Energy, Inc.*, 889 F.2d 649, 657 (5th Cir. 1989) ("Louisiana courts allow awards of damages for lost profits in oil and gas cases if the plaintiff proves such damage by a preponderance of the evidence.").

II. Dr. Bell's opinions are based on assumptions that are unsupported or are based on facts or data not of the type on which experts reasonably rely.

Dr. Bell assumes:

(1) Cytogel would have continued developing the '436 Compounds and Cyt-1010 "from July 2010 forward";[73]

(2) Cytogel would have achieved a successful Phase II clinical trial result for Cyt-1010 and the '436 Patent compounds and would eventually have launched the products;[74]

(3) Cytogel would have developed Cyt-1010 in "19.8 months for Phase I, 30.3 additional months for Phase II, 30.7 additional months for Phase III, and 16.0 additional months for the FDA's approval";[75]

(4) Cytogel would have incurred costs of $17.3 million associated with Phase I and $13 million associated with Phase II;[76]

(5) "there would be no difference in the value to Cytogel of an out-license of the technology [to a larger pharmaceutical company] or an acquisition of the technology" by a third party;[77]

(6) if Cyt-1010 and the '436 Patent compounds are on the market, sales would be "divided evenly between the products";[78]

[73] R. Doc. 283-22 at 14, ¶ 26(a); 17, ¶ 32(a).
[74] *Id.* at 15, ¶ 27.
[75] *Id.* at 18, ¶ 32(b).
[76] *Id.* at ¶ 32(c).
[77] Dr. Bell proceeds to base his calculations on Cytogel's obtaining a license with royalties. *Id.* at ¶ 32(d).
[78] *Id.*

(7) "both Cyt-1010 and a '436 Compound would be available as an IV formulation," and two years later would become available as an oral formulation";[79]

(8) the relevant market of retail sales of opioids in 2016 is $8.5 billion;[80]

(9) the relevant market for opioids will grow "at an average annual rate of 4.8 percent through 2031";[81]

(10) "once launched, a pharmaceutical product gains share at a rate consistent with estimates in the published literature" until a peak share is reached.[82]

Tulane, Dr. Zadina, and the United States challenge these assumptions, arguing they render Dr. Bell's opinion unreliable and speculative.[83]

A. Dr. Bell's opinions rely on the unsupported assumption that Cytogel has at least an average probability of achieving a successful Phase II trial and obtaining FDA approval (Assumption 2).

Dr. Bell assumes Cytogel would achieve a successful Phase II clinical trial result and eventually obtain FDA approval.[84] Tulane, Dr. Zadina, and the United States argue Dr. Bell's assumption about whether the Cyt-1010 and the '436 Patent compounds would obtain FDA approval is unreasonable because Dr. Bell fails to consider the fact the FDA has put clinical testing of Cyt-1010 on hold for eight years.[85] The Court agrees.

At deposition, Dr. Bell stated he is not a regulatory expert[86] and has "made no opinion" about the likelihood the hold on Cyt-1010 would be lifted.[87] Nowhere in his report or deposition testimony does he indicate he took into account the effect a clinical

[79] *Id.*
[80] *Id.* at 19, ¶ 32(d)(i).
[81] *Id.*
[82] *Id.* at 20, ¶ 32(d)(iii).
[83] R. Doc. 283-16 at 13–19, 24–25.
[84] R. Doc. 283-22 at 15, ¶ 27.
[85] R. Doc. 283-16 at 13–15.
[86] R. Doc. 283-12 at 7, 21: 16–17
[87] *Id.* at 8, 22: 8–9.

hold on testing would have on the likelihood Cyt-1010 would be approved by the FDA or the amount of time required for the approval process. Dr. Bell offers no support for his assumption that clinical holds would have no effect on the amount of time the approval process would take.

The Partial Clinical Hold the FDA issued on November 8, 2010 limited Cytogel's ability to test Cyt-1010, enumerated several steps Cytogel needed to take the resolve the clinical hold deficiency, and identified a response procedure for Cytogel to follow.[88] It took Cytogel until May 2016, over five years after the issuance of the Partial Clinical Hold, to respond.[89] On June 3, 2016, the FDA found Cytogel's response inadequate, placed all studies involving Cyt-1010 on clinical hold, and identified more steps for Cytogel to follow.[90] The FDA did not lift the Full Clinical hold until October 16, 2018, over two years later. [91] Even now, Cyt-1010 is subject to a Partial Clinical Hold.[92]

In *JRL Enterprises, Inc. v. Procorp Assocs., Inc.*,[93] the plaintiff hired an expert to calculate damages. The expert based his calculation on "a list of potential . . . customers, the expected revenues and expenses from potential sales, and the estimated probability of those sales becoming a reality" given to him by the plaintiff, which he did not independently investigate.[94] Relying on these numbers, the expert calculated the potential losses by "subtracting the expected costs from the potential revenue and multiplying that by the probability of the sale."[95] The court excluded the expert testimony, analogizing to another district court case in which the court found a party had "shown no

[88] R. Doc. 283-165 at 1–2.
[89] R. Doc. 287-21.
[90] R. Doc. 287-22.
[91] R. Doc. 403-1 at 1.
[92] *Id.*
[93] No. CIV.A. 01-2893, 2003 WL 21284020 (E.D. La. June 3, 2003) (Fallon, J.).
[94] *Id.* at *5.
[95] *Id.*

evidence that the expert's calculations were 'anything more than an exercise in arithmetic based on inherently unreliable values.'"[96] The *JRL* court noted the expert "performed no independent analysis of the numbers given him . . . [and] failed to show that reasonable accountants would simply and blindly accept such numbers in formulating opinions. His theory [could] not be tested, and the rate of error is not known."[97] Rather, the plaintiff was "presenting its own estimation of damages in the guise of an expert opinion."[98]

Like the expert in *JRL*, Dr. Bell relies on Cytogel's assertions about its ability to get FDA approval for Cyt-1010 and the '436 Patent compounds. His report is an exercise in arithmetic that disguises the fact that it is based on unsupported and unreliable assumptions. For example, Dr. Bell projects Cytogel would have obtained FDA approval for Cyt-1010 and the '436 Patent compounds, launched the product, and reached $169.2 million in sales by 2020.[99] This projection has no basis in the evidence. Because Dr. Bell neither independently analyzes the assumptions Cytogel instructed him to make, nor establishes they are supported by the evidence and reasonable, his reasoning is not scientifically valid.

B. Dr. Bell's opinions are unreliable because Dr. Bell bases his calculations on unsupported information from Cytogel that he does not independently verify (Assumptions 1 and 7).

Dr. Bell assumes Cytogel would have continued developing the '436 Compounds and Cyt-1010 "from July 2010 forward" (Assumption 1),[100] that "both Cyt-1010 and a '436 Compound would be available as an IV formulation," and two years later would become

[96] *Id.* at *7 (citing *Otis v. Doctor's Associates, Inc.*, No. 94 C 4227, 1998 WL 673595 (N.D.Ill. Sept.14, 1998)).
[97] *Id.*
[98] *Id.* at *8; *see also Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 275 (E.D. La. 2014) ("[E]xpert testimony based solely or primarily on the opinions of other experts is inherently unreliable. It is only when the expert undertakes some independent investigation of the underlying opinions that his testimony may be considered reliable.") (citations omitted); *cf. Legier & Matherne, Apac v. Great Plains Software, Inc.*, No. CIV.A. 03-278, 2004 WL 1488597 (E.D. La. June 30, 2004) (Duval, J.) (distinguishing *JRL* in a situation in which an expert independently verified the information upon which he relied).
[99] R. Doc. 283-22 at 59 ("Exhibit D-2").
[100] *Id.* at 14, ¶ 26(a); 17, ¶ 32(a).

available as an oral formulation (Assumption 7),[101] and that "Cytogel's exclusivity with respect to Cyt-1010 will extend until at least 2031" (Assumption 10).[102] These assumptions are based on information provided by Cytogel that Dr. Bell does not verify.

Dr. Bell does not state his basis for assuming Cytogel could have continued developing the '436 Compounds and Cyt-1010 "from July 2010 forward" (Assumption 1).[103] Apparently Dr. Bell relies on the July 9, 2010 date on which the Provisional Application was filed[104] and assumes Cytogel would have been able to test and develop the compounds described in the Provisional Application and submit the application by July 2010. Like the expert in *JRL*, Dr. Bell relies on Cytogel's own assertions, without independently verifying them. This assumption is unsupported.

Dr. Bell also assumes "both Cyt-1010 and a '436 Compound would be available as an IV formulation" and two years later would become available as an oral formulation (Assumption 7).[105] Tulane, Dr. Zadina, and the United States argue this assumption is unreasonable, noting that the Formal Dispute Resolution Request Cytogel filed with the FDA only mentions the Cyt-1010 intravenous solution and not an oral formulation.[106] The only support he provides is a bald assertion that Cytogel "intends to pursue an oral formulation" of Cyt-1010, with a citation to a document not provided to the Court.[107] Dr. Bell relies on assertions from Cytogel about its future plans and the potential for its own drugs without verification or factual support, rendering his opinions unreliable.

[101] *Id.* at 18, ¶ 32(d).
[102] *Id.* at 19, ¶ 32(d)(i).
[103] *Id.* at 14, ¶ 26(a).
[104] R. Doc. 271-4 at 4, ¶ 8; R. Doc. 321-1 at 4, ¶ 8.
[105] R. Doc. 283-22 at 18, ¶ 32(d).
[106] R. Doc. 283-16 at 17.
[107] R. Doc. 283-22 at 10, ¶ 17.

Dr. Bell further assumes Cyt-1010 would be available for the treatment of acute and chronic pain.[108] Tulane, Dr. Zadina, and the United States argue this assumption is unreasonable, noting that Cytogel's Formal Dispute Resolution Request states Cyt-1010 is "intended for acute (not chronic) use."[109] Cytogel responds that it plans initially to obtain approval for acute pain "and then expand into other areas."[110] Based on Dr. Bell's report, the Court cannot ascertain whether Dr. Bell differentiated between acute and chronic pain in his estimation of the size of the opioid market at all. To the extent he did so, the Court finds that Dr. Bell's assumption that Cyt-1010 would be available for acute and chronic pain is based on unsupported assertion by Cytogel about its future plans.

C. Dr. Bell does not establish that the study on which he bases his estimates about the timing and costs associated with Cytogel's products applies to this case (Assumptions 3 and 4).

Citing one scientific study, Dr. Bell estimates Cytogel would need "19.8 months for Phase I, 30.3 additional months for Phase II, 30.7 additional months for Phase III, and 16.0 additional months for the FDA's approval" (Assumption 3).[111] Using the same study, Dr. Bell estimates Cytogel's expected costs associated with Phase I testing to be $17.3 million (Assumption 4).[112] He does not justify his assumption that the estimates in the study can be used to predict the timeline and costs associated with the FDA's approval of Cyt-1010 or the '436 Patent compounds is reasonable. Similar to his failure to establish the applicability of the Lo study, Dr. Bell has not established that the results of the study he cites for his cost and timing estimates fits the instant case.

[108] *Id.* at 6, 7, ¶¶ 8, 10, 11.
[109] R. Doc. 283-16 at 16 (quoting R. Doc. 283-15 at 3).
[110] R. Doc. 309 at 14.
[111] R. Doc. 283-22 at 18, ¶ 32(b) (citing Joseph A. Dimasi *et al.*, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 25 (2016)).
[112] *Id.* at ¶ 32(c).

Based on his assumptions about the timeline of the approval process, Dr. Bell further assumes Cyt-1010 and the '436 Compounds would have been licensed at the end of 2013.[113] Tulane, Dr. Zadina, and the United States argue the FDA's clinical hold would have affected Cytogel's ability to license compounds.[114] Dr. Bell does not indicate in his report that he accounted for the clinical hold when estimating the expected licensing date for Cyt-1010. In light of the reality that the FDA has imposed clinical holds on Cyt-1010 for years, the Court finds unreasonable Dr. Bell's assumption that, had Cytogel owned the '436 Patent in 2010, Cyt-1010 and the '436 Compounds would have been licensed at the end of 2013.

D. Dr. Bell's assumptions about the potential for licensing of Cytogel's products (Assumptions 5 and 6) have no apparent underlying rationale.

Experts may not assume facts "with no apparent underlying rationale."[115] Dr. Bell assumes there would be no difference in the value to Cytogel between licensing Cyt-1010 and the '436 Patent compounds to a larger pharmaceutical company or selling the technology to a third party (Assumption 5).[116] Dr. Bell does not calculate the value of Cytogel's potential for acquisition to support this assumption.[117] Instead, he calculates only the value of Cytogel's licensing opportunities and assumes this calculation is sufficient to estimate the value of Cytogel's commercial opportunities.[118] Dr. Bell provides no basis for his assumption. He merely lists two acquisitions of "new chemical entities in the pain category at Phase II in the development cycle" and the amounts of the upfront

[113] *Id.* at 19, ¶ 33(a).
[114] R. Doc. 283-16 at 20–21. Movants quote the testimony of Cytogel's witness Dean Maglaris, who testified that Phase II data is necessary for a license. *Id.* The exhibit to which Tulane, Dr. Zadina, and the United States cite does not include the quoted portion of the deposition. The quoted portion was filed in the record in connection with a motion for summary judgment. *See* R. Doc. 271-19 at 35, 34:13–14. The Court needs not evaluate the validity of this assertion.
[115] *Moore*, 547 F. App'x at 516.
[116] R. Doc. 283-22 at 15, ¶ 27.
[117] *Id.*
[118] *Id.*

payments and milestone payments associated with the acquisitions.[119] Dr. Bell does not explain how these two applications apply to Cyt-1010 and the '436 Patent compounds. This assumption has no apparent underlying rationale.

Dr. Bell also assumes that, if Cyt-1010 and the '436 Patent compounds are on the market, sales would be "divided evenly between the products."[120] This leads him to assume that, if Cytogel could only license Cyt-1010, it could expect to receive half of the licensing payments it could expect to receive if it also could license both Cyt-1010 and the '436 Patent compounds.[121] Dr. Bell provides no comparison of the sales potential of Cyt-1010 and the '436 Patent compounds and does not assert he would be qualified to provide one. He provides no market studies suggesting that analgesic pharmaceuticals with similar properties launched around the same time split the market evenly. This assumption also has no apparent underlying rationale.

E. Dr. Bell does not establish that his assumptions about the market potential of Cytogel's products (Assumptions 8–10) are based on the type of facts and data on which experts reasonably rely.

Dr. Bell calculates Cytogel could have expected to receive $591,570,001 in total royalties from Cyt-1010 and the '436 Patent compounds.[122] Assumptions 8–10 relate to the calculation of this figure.

Dr. Bell begins with an estimate that the relevant market of retail sales of opioids in 2016 is $8.5 billion (Assumption 8).[123] He does not find this number in a peer-reviewed and generally accepted scientific study. Instead, his estimate is based on an online news article that meets no standard for scientific validity. Further, the author of the article does not distinguish between the markets for drugs meant to treat acute or chronic pain or

[119] *Id.* at 16, ¶ 31.
[120] *Id.* at 18, ¶ 32(d).
[121] *Id.* at 16, ¶ 30.
[122] *Id.* at 69 ("Exhibit E-3").
[123] *Id.* at 19, ¶ 32(d)(i).

between oral or intravenous formulations of drugs, and Dr. Bell has no way to determine whether the estimate of retail sales even fits the facts of this case. [124] In any event, online news articles are not the type of data on which experts may reasonably rely.

Dr. Bell further assumes the United States opioid market will grow "at an average annual rate of 4.8 percent through 2031," citing a market study from which he draws the number (Assumption 9).[125] Dr. Bell offers no evidence that the study he cites is peer-reviewed or meets standards of scientific rigor. He also does not establish that the projected growth rate in the study is applicable to facts in the instant case. The projections in the study extend only until 2025, not 2031.[126] The 4.8% growth rate cited is a projection for the global market, not the United States market.[127] Dr. Bell offers no explanation for why this study may be reliably used to project the growth of the United States opioid market until 2031. He has not shown this is the type of data on which an expert may rely for the projection he makes.

Dr. Bell also assumes that, "once launched, a pharmaceutical product gains share at a rate consistent with estimates in the published literature" (Assumption 10).[128] In support, he cites a two-paragraph online blog post describing a scientific study.[129] The blog post states "the median product follows an S-shaped launch-to-peak penetration curve: achieving 11% of peak sales in Year 1, 31% in Year 2, 58% in Year 3, 76% in Year 4, 89% in Year 5, and 100% (i.e. peak sales) in Year 6."[130] Dr. Bell appears to rely on these

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[124] *Id.* (citing David Crow, *US Seeks a Fix for its Opioid Addiction*, Financial Times (Sept. 11, 2017), https://www.ft.com/content/4bc03acc-915e-11e7-a9e6-11d2f0ebb7f0).
[125] *Id.* (citing GRAND VIEW RESEARCH, OPIOIDS MARKET SIZE, SHARE & TRENDS ANALYSIS REPORT BY PRODUCT, BY APPLICATION (PAIN RELIEF, ANESTHESIA, COUGH SUPPRESSION, DIARRHEA SUPPRESSION, DEADDICTION), BY REGION, AND SEGMENT FORECASTS, 2018 – 2025 (Mar. 2018), https://www.grandviewresearch.com/industry-analysis/opioids-market).
[126] *See* GRAND VIEW RESEARCH, *supra* n.125.
[127] *Id.*
[128] R. Doc. 283-22 at 20, ¶ 32(d)(iii).
[129] Todd Clark, *New Study on Time to Peak Sales for U.S. Pharmaceuticals*, voi Consulting (Jan. 12, 2017), https://voiconsulting.com/blogs/news/new-study-on-time-to-peak-sales-for-us-pharmaceuticals.
[130] *Id.*

figures in calculating Cytogel's expected market share.[131] He does not offer any comparison between Cyt-1010, the '436 Patent compounds, and the drugs referred to in the study the blog post cites or offer any indication he has performed such an analysis. Dr. Bell has not shown this blog post is of the type of data on which an expert would reasonably rely.

III. Dr. Bell does not offer scientific or technical evidence to show his methodology is reliable, and his analysis does not follow any legal test for assessing damages.

Dr. Bell opines on the diminution in value of the commercial opportunities available to Cytogel. Dr. Bell's report does not cite peer-reviewed studies or any sources that validate his methodology in reaching his opinions. Although Dr. Bell cites the Lo study for an average probability of success for central nervous system drugs in the FDA approval process and a study[132] from which he estimates the timing and costs associated with the FDA approval process,[133] he uses these studies merely to obtain inputs for his calculations. Dr. Bell does not cite a single study using the methodology he used. Dr. Bell's methodology has not been subject to peer review and has not been included in any publications, has not been shown to be generally accepted in the scientific community, and has no known or potential rate of error. Dr. Bell's methodology involves comparing convoluted calculations for three hypothetical situations, making the rate of error impossible to ascertain. In the end, Dr. Bell's analysis involves so many hypothetical scenarios and assumptions that it would be impossible to prove or disprove.

Admittedly, calculating lost profits or lost commercial opportunities inherently involves assessing hypothetical scenarios, but there are well-established methods in the

[131] R. Doc. 283-22 at 64 ("Exhibit D-2").
[132] R. Doc. 283-22 at 17, n. 39 (citing Lo study).
[133] *Id*. at 18, n. 40, 41 (citing DiMasi et al., *supra* n.111).

caselaw for estimating damages in similar cases. Under the test first laid out by the Sixth Circuit in *Panduit Corp. v. Stahlin Bros. Fibre Works*,[134] a patent owner seeking damages for lost profits due to patent infringement must prove "(1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made."[135] A patent owner seeking a reasonable royalty for patent infringement may follow the fifteen factors laid out in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*[136] to calculate the amount of a reasonable royalty, which is a permissible measure for calculating damages. Dr. Bell does not follow either of these methods or any other known legal theories for estimating damages. Rather, Dr. Bell offers his own methodology with no scientific or legal support and then states he offers no opinion on whether the calculated diminution in value "equates to damages."[137]

IV. Dr. Bell's report does not comply with the requirements of Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure.

Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, an expert report must contain, among other things, "(i) a complete statement of all opinions the witness will express and the basis and reasons for them [and] (ii) the facts or data considered by the witness in forming them." "The expert report should be 'detailed and complete,' stating the testimony that will be presented during direct examination and the reasons

[134] 575 F.2d 1152 (6th Cir. 1978)
[135] *Id.* at 1156.
[136] 318 F.Supp. 1116 (S.D.N.Y.1970), *aff'd*, 446 F.2d 295 (2d Cir.1971), *cert denied*, 404 U.S. 870 (1971).
Reasonable royalty calculations also apply to trade secret claims. *Taco Cabana Int'l, Inc. v. Two Pesos, Inc.*, 932 F.2d 1113, 1128 (5th Cir. 1991), *aff'd sub nom. Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763 (1992) ("Trade-secret misappropriation damages typically embrace some form of royalty.") (citations omitted); *accord LinkCo, Inc. v. Fujitsu Ltd.*, 232 F. Supp. 2d 182, 186 (S.D.N.Y. 2002) ("Because the plaintiff's loss or the defendant's gain may be very difficult to calculate in intellectual property cases, a reasonable royalty is 'a common form of award in both trade secret and patent cases.'") (citations omitted).
[137] R. Doc. 283-21 at 6, 15:14–16.

therefor."[138] "Expert reports that do not provide the basis and reasons for the stated opinions, or that refer to the basis for the opinions only in vague terms, are insufficient under Rule 26(a)(2)(B)."[139] "The purpose of this requirement is to allow parties to prepare effectively for cross examination of expert witnesses and, if necessary, to arrange for testimony by additional expert witnesses."[140]

Dr. Bell's report does not include a complete statement of all opinions he expresses. Dr. Bell states his opinion that, "as a result of the alleged actions of the Counterclaim-Defendants, there has been a decline in the expected value of the commercial opportunities available to Cytogel as of July 2010."[141] He also states his final estimate of the alleged decline in value. However, the real substance of his opinion—the opinions on Cytogel's probability of achieving a successful product launch and on the royalties Cytogel could expect to received—are only found in the exhibits without an adequate explanation. Instead of fully explaining his calculations, Dr. Bell cursorily states that the "estimates of product sales in each year, assuming approval, are summarized in Exhibit D" [142] and that, "[w]ith respect to the expected value of Cytogel's commercial opportunities had it had the opportunity to begin developing the '436 Compounds as of July 2010, [his] analysis is summarized in Exhibit E."[143] Nowhere in the text of his report does he clearly state his opinions and the reasons therefor. Because Dr. Bell fails to clearly state his opinions, his report fails to comply with the requirements of Rule 26(a)(2)(B).

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[138] *Honey-Love v. United States*, 664 F. App'x 358, 361 (5th Cir. 2016) (citing FED. R. CIV. P. 26 ADVISORY COMMITTEE'S NOTES (1993 Amendments)).
[139] *Broxterman v. State Farm Lloyds*, No. 4:14-CV-661, 2015 WL 11072132, at *2 (E.D. Tex. Oct. 19, 2015) (citing *Sierra Club, Lone Star Chapter v. Cedar Point Oil Co.*, 73 F.3d 546, 571 (5th Cir. 1996)).
[140] *Id.* (citing FED. R. CIV. P. 26 ADVISORY COMMITTEE'S NOTES (1993 Amendments)).
[141] R. Doc. 283-22 at 23, ¶ 36.
[142] *Id.* at 20, ¶ 32(d)(iii).
[143] *Id.* at ¶ 33.

V. The probative value of Dr. Bell's testimony is substantially outweighed by its prejudicial effect and its potential to mislead the jury.

Finally, Rule 403 of the Federal Rules of Evidence provides, "The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needless presenting cumulative evidence."[144] "Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more control over experts than over lay witnesses."[145] "A district court has broad discretion in assessing admissibility under Rule 403."[146]

In the instant case, the Court finds Dr. Bell's testimony is of little probative value. Dr. Bell's testimony has the potential to be misleading to the jury, which would have difficulty evaluating the validity of the assumptions and facts upon which it is based. As a result, the Court finds the probative value of Dr. Bell's testimony is substantially outweighed by the danger of unfair prejudice and by its potential to mislead the jury.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that the Motion in Limine on the Admissibility of the Expert Testimony of Defendant Cytogel Pharma, LLC's expert Dr. Gregory K. Bell, filed by Plaintiffs the United States of America and the Administrators of the Tulane Educational Fund and Counterclaim-Defendant Dr. James E. Zadina, be and hereby is **GRANTED**.[147]

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[144] FED. R. EVID. 403.
[145] *Daubert*, 509 U.S. at 595 (quoting JACK B. WEINSTEIN, *Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991)).
[146] *United States v. Morris*, 79 F.3d 409, 412 (5th Cir. 1996).
[147] R. Doc. 283.

IT IS FURTHER ORDERED that the Motion in Limine on the Admissibility of the Expert Testimony of Defendant Cytogel Pharma, LLC's expert Dr. William K. Schmidt, filed by Plaintiffs the United States of America and the Administrators of the Tulane Educational Fund and Counterclaim-Defendant Dr. James E. Zadina, be and hereby is **DENIED AS MOOT**.[148]

IT IS FURTHER ORDERED that the Motion in Limine on the Admissibility of the Expert Testimony of Cytogel's expert Dr. William A. Clementi, filed by Plaintiffs the United States of America and the Administrators of the Tulane Educational Fund and Counterclaim-Defendant Dr. James E. Zadina, be and hereby is **DENIED AS MOOT**.[149]

New Orleans, Louisiana, this 26th day of November, 2018.

SUSIE MORGAN
UNITED STATES DISTRICT JUDGE

[148] R. Doc. 268.
[149] R. Doc. 281.