

UNITED STATES DISTRICT COURT  
 EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA, ET AL.	*	CIVIL ACTION NO. 16-13987
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	*	SECTION: "E"(1)
VERSUS	*	
	*	JUDGE SUSIE MORGAN
	*	
CYTOGEL PHARMA, LLC	*	MAGISTRATE JUDGE
	*	JANIS VAN MEERVELD
*****	*	

ORDER AND REASONS

Before the Court is the Motion for Leave to File First Amended and Restated Affirmative Defenses and Second Amended and Restated Counterclaims (Rec. Doc. 195). For the following reasons, the Motion is GRANTED.

Background

This lawsuit concerns the ownership of patent rights in certain opioid substitutes. During the relevant period, Dr. Zadina and Dr. Lazlo Hackler<sup>1</sup> (“Dr. Hackler”) were employed jointly by Tulane and the Department of Veterans Affairs (“VA”) and were engaged in developing new compounds that would reduce the side effects associated with opioids. In the 1990s, Dr. Zadina, Dr. Hackler, and Dr. Abba J. Kastin of Tulane University developed a group of cyclic peptide-based opioid compounds (“1<sup>st</sup> Generation Compounds”), for which two patents were ultimately issued (“1<sup>st</sup> Generation Patents”). The 1<sup>st</sup> Generation Patents were assigned to only Tulane because the VA assigned all of its ownership rights to Tulane. In 2003, Cytogel and Tulane entered into a license agreement for the 1<sup>st</sup> Generation Patents. After this agreement was executed, Dr. Zadina advised Cytogel regarding the properties and characteristics of the 1<sup>st</sup> Generation Compounds, at

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<sup>1</sup> Dr. Hackler died in 2013.

first pursuant to an oral agreement, and starting in 2007, pursuant to a written consultancy agreement. This work was performed outside of Dr. Zadina's normal duties for the VA and Tulane. Tulane insists that Dr. Zadina's consultancy never involved work with any opioids other than the 1<sup>st</sup> Generation Compounds.

Tulane alleges that Dr. Zadina and Dr. Hackler continued researching peptide-based opioids for the VA and Tulane and eventually invented certain "2<sup>nd</sup> Generation Compounds," which offered reduced side effects and improved solubility relative to the 1<sup>st</sup> Generation Compounds. Tulane filed a provisional patent application for the 2<sup>nd</sup> Generation Compounds.<sup>2</sup> After Tulane informed Cytogel of the application, Cytogel asserted that it owned the new application. Cytogel alleges that the 2<sup>nd</sup> Generation Compounds were developed by Dr. Zadina using confidential Cytogel information. The dispute continued, and eventually Dr. Zadina terminated his consulting agreement in 2013.

Tulane's provisional application resulted in the issuance of U.S. Patent No. 8,716,436 (the "436 Patent"). There are also three patent applications relating to the 2<sup>nd</sup> Generation Compounds currently pending with the U.S. Patent and Trademark Office ("PTO") U.S. Patent Application No. 14/268,057 (the '057 Application), U.S. Patent Application No. 14/845,813 (the '813 Application), and U.S. Patent Application No. 14/974,249 (the '249 Application and with the '057 Application and the '813 Application, the "Related Applications"). According to Plaintiffs, all have been assigned to, and are co-owned by, the VA and Tulane.

On August 19, 2016, Tulane and the United States filed this lawsuit against Cytogel seeking a declaratory judgment that they are the sole owners of the '436 Patent and the Related

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<sup>2</sup> The VA and Tulane each asserted ownership rights in the eventual '436 Patent, and Drs. Zadina and Hackler then assigned those rights to the VA and Tulane pursuant to their employment agreements. Pursuant to a 2003 agreement, Tulane has the sole right to license patents and patent applications it owns jointly with the VA.

Applications and that Dr. Zadina and Dr. Hackler are the true inventors of the '436 Patent and the Related Applications. Cytogel filed a counterclaim against Tulane, the United States, and Dr. Zadina, alleging that they misappropriated its trade secrets and confidential information. Cytogel seeks a declaratory judgment that it is the owner of the '436 Patent and also asserts claims for breach of contract, infringement of the 1<sup>st</sup> Generation Patents that had been licensed to Cytogel, misappropriation of trade secrets, and other state law claims. Cytogel's amended counterclaim filed on April 11, 2017, stated that "As described in the foregoing paragraphs, the '436 Patent and the '057, '813, and '249 Applications resulted or emerged from materials and information provided to Dr. Zadina by Cytogel, and/or as a result of the consulting process between Dr. Zadina and Cytogel. Therefore, under the Consulting Agreement, Dr. Zadina's interest in the '436 Patent and the '057, '813, and '249 Applications are the property of Cytogel." (Rec. Doc. 68, Para. 78) \

Cytogel now seeks to amend its affirmative defenses and counterclaim. It proposes to add a claim challenging Dr. Hackler's inventorship of the '436 Patent, to assert that Cytogel also owns Dr. Hackler's purported interest in the '436 Patent, to clarify that its claims apply to the Related Applications in addition to the '436 Patent, and to amend its defenses to be consistent with the counterclaims. Cytogel states it did not make these claimsApplications in its original or first amended counterclaim because it lacked sufficient evidence to claim that Dr. Hackler had not invented the '436 Patent or Related Applications and it similarly lacked knowledge of facts sufficient to support a claim challenging any interest Dr. Hackler may have with respect to this intellectual property because his work, like that of Dr. Zadina, emerged from Cytogel's confidential information . Cytogel claims it has since obtained sufficient evidence to make this claim. The Plaintiffs oppose Cytogel's proposed amendment.

## Law and Analysis

### *1. Standard to Amend Pleadings*

Under Federal Rule of Civil Procedure 15(a)(2), when the time period for amending a pleading as a matter of course has passed, a party may amend its pleadings by consent of the parties or by leave of court. “The court should freely give leave when justice so requires.” Fed. R. Civ. Proc. 15(a)(2). Thus, the United States Court of Appeals for the Fifth Circuit instructs that the “district court must possess a ‘substantial reason’ to deny a request for leave to amend.” Smith v. EMC Corp., 393 F.3d 590, 595 (5th Cir. 2004). Nonetheless, “that generous standard is tempered by the necessary power of a district court to manage a case.” Yumilicious Franchise, L.L.C. v. Barrie, 819 F.3d 170, 177 (5th Cir. 2016) (quoting Schiller v. Physicians Res. Grp. Inc., 342 F.3d 563, 566 (5th Cir. 2003)). The court may consider numerous factors when deciding whether to grant a motion for leave to amend, including “undue delay, bad faith or dilatory motive on the part of the movant, repeated failures to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, and futility of the amendment.” Schiller v. Physicians Res. Grp. Inc., 342 F.3d 563, 566 (5th Cir. 2003).

To determine whether a complaint is futile, courts “apply ‘the same standard of legal sufficiency as applies under Rule 12(b)(6).’” Stripling v. Jordan Prod. Co., LLC, 234 F.3d 863, 872–73 (5th Cir. 2000) (quoting Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000)). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In many cases where futility is not clear, courts find the better course is to grant leave to amend and allow the opposing party to respond to

the amended claim with a motion to dismiss or motion for summary judgment. E.g., Tripp v. Pickens, No. 17-CV-0542, 2018 WL 3059614, at \*3 (W.D. La. June 20, 2018) (“The court's ability to decide the viability of the claims at issue will benefit from full briefing within the context of a motion that is devoted to the substantive issues.”)

Where the court ordered deadline for amending pleadings has passed, that schedule “may be modified” to allow for additional amendments “only for good cause and with the judge’s consent.” Fed. R. Civ. Proc. 16(b)(2); see S&W Enterprises, L.L.C. v. SouthTrust Bank of Alabama, NA, 315 F.3d 533, 536 (5th Cir. 2003) (“We take this opportunity to make clear that Rule 16(b) governs amendment of pleadings after a scheduling order deadline has expired.”). When determining whether the movant has shown good cause, the Court considers “(1) the explanation for the failure to [timely move for leave to amend]; (2) the importance of the [amendment]; (3) potential prejudice in allowing the [amendment]; and (4) the availability of a continuance to cure such prejudice.’ ” S&W Enterprises, 315 F.3d at 536 (quoting Reliance Ins. Co. v. Louisiana Land & Expl. Co., 110 F.3d 253, 257 (5th Cir. 1997)) (alterations in original).

## *2. Cytogel’s Explanation for the Failure to Timely Move to Amend*

Trial is set to begin December 3, 2018. The deadline to complete depositions of fact witnesses passed on July 1, 2018, shortly before the present motion was filed on June 25, 2018. The scheduling order provided a deadline to amend pleadings of October 10, 2017, which has passed. Accordingly, the Rule 16 standard applies here.

Cytogel says that its proposed amended pleading could not have been filed earlier because it only recently discovered evidence to seek affirmative relief challenging Dr. Hackler’s inventorship. Cytogel points to an email it received from Tulane in discovery in which Dr. Zadina explained to the Executive Director of Tulane’s Office of Technology Transfer and Business

Development that Dr. Hackler's contribution to the '436 patent was "restricted to chemistry" and that Dr. Hackler "played no role in the non-chem aspects."<sup>3</sup> Cytogel also points to recent testimony of Dr. Zadina, which Cytogel says demonstrates that he had the idea to make the analogs described on the '436 patent and that he instructed Dr. Hackler to conduct the synthesis. Cytogel says this shows that the inventive contributions to the "composition-of-matter" claim were made by Dr. Zadina rather than Dr. Hackler. Cytogel further points to testimony that it says shows that Dr. Hackler's contributions were limited to solving synthesis problems, but Cytogel points out that the '436 Patent does not disclose any novel or inventive method of synthesis. Cytogel also says that through discovery it has determined that Dr. Zadina shared Cytogel's confidential information with Dr. Hackler, which supports its proposed claim that Cytogel owns any interest Dr. Hackler might otherwise have had in the '436 Patent.

Plaintiffs argue that Cytogel has the same knowledge regarding Dr. Hackler's lack of inventorship as it did the day the Complaint was filed. They point out that Plaintiffs alleged that Dr. Hackler and Dr. Zadina were co-inventors of the '436 Patent and the Related Applications. They say that in responding to interrogatories, Cytogel stated that it was unaware of any documentation produced by the Plaintiffs that provides any evidence that Dr. Hackler made a contribution to the conception of the inventions claimed in the '436 Patent. They say this is the same argument Cytogel now makes in support of its counterclaim. The cited discovery responses are dated April 20, 2018. Plaintiffs also point out that Cytogel itself admits in its memorandum that the issue of Dr. Hackler's inventorship has been present since the beginning of the case. Plaintiffs argue that Dr. Zadina's testimony did not reveal anything new. And they argue that Dr.

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<sup>3</sup> Cytogel explains that the '436 Patent contains three types of claims: (1) a "composition-of-matter" claim; (2) a claim based on a "pharmaceutical compound" containing such compounds along with a "pharmaceutically acceptable carrier," (3) and a group of claims for various methods of treating pain with such compounds. Cytogel says the email shows that Dr. Hackler was not involved in the third group of claims.

Hackler's notebook, which was produced to Cytogel in November 2017, contains the first record of the 809 compound of the '436 patent, written in Dr. Hackler's handwriting. They argue this notebook shows when the compound was conceived and made. In reply, Cytogel argues that while the notebook may indicate when compounds were synthesized, it does not indicate who conceived of the invention of the compounds. Thus, they say, the notebook did not provide it with a basis to file its proposed counterclaims.

Plaintiffs also argue that the true reason for Cytogel's belated amendment is the Mirata license agreement. Tulane argues that Cytogel is attempting to interfere with Tulane's ability to license the '436 Patent. In reply, Cytogel denies that the Mirata license has anything to do with the timing of its proposed amendment. The Court finds that even if the Mirata license agreement is part of the motivation for Cytogel's amendment, this does not change the fact that Cytogel only recently discovered evidence to support this amended counterclaim.

Further, the Court finds that Cytogel's delay is excusable. Plaintiffs seem to suggest that Cytogel should have filed its counterclaims regarding Dr. Hackler's inventorship because they had no evidence that Dr. Hackler *did* invent the '436 Patent, even though they had no evidence that he *did not*, (and even though Plaintiffs are seeking a declaratory judgment that Dr. Zadina and Dr. Hackler *are* the true inventors). Through discovery Cytogel now has evidence to affirmatively support its claims that Dr. Hackler did not invent the '436 Patent. This explains why it did not file its proposed amendment earlier. There is no evidence of delay by Cytogel.

### 3. *Importance of the Amendment*

Next Cytogel argues that the amendment is important because it is necessary to afford it complete relief. Tulane does not address this issue. The Court finds Cytogel's amendment is important to the complete resolution of the claims in this lawsuit. The Plaintiffs seek a declaration

that Dr. Zadina and Dr. Hackler are inventors of the '436 Patent and Related Application. The addition of Cytogel's counterclaim that Dr. Hackler is not an inventor and does not have any rights in the patent must be resolved here rather than in separate litigation.

*4. Prejudice and the Possibility of a Continuance*

Cytogel says there will be no unfair prejudice since Dr. Hackler's inventorship has been in dispute since the beginning of this litigation. Cytogel argues there is no reason for additional discovery. Tulane counters that it will be prejudiced. It points out that the discovery deadline (except as to experts) has now passed and that Dr. Zadina has already been deposed. Although their Complaint seeks a declaration that Dr. Zadina and Dr. Hackler are inventors of the '436 Patent and the Related Applications, the Plaintiffs say they did not include Dr. Hackler's status as an inventor as a topic for its discovery. Plaintiffs add that the addition of Cytogel's proposed counterclaims will require them to file another motion to dismiss. They note that they might have to refile the pending motions to dismiss Cytogel's existing counterclaims. They argue that a continuance would not alleviate their burdens because a continuance would allow Cytogel to unfairly delay what Plaintiffs describe as their two straightforward claims.

However, discovery needed as a result of allowing this new claim that Dr. Hackler was not an inventor would seem to be limited. Cytogel has represented that no additional discovery will be needed. Although Tulane complains that Cytogel delayed notice of its motion until after the deposition of Cytogel's witnesses to avoid exposing them to questions regarding inventorship, Tulane fails to explain what information Cytogel's employees might have about Dr. Hackler's involvement with the development of the 2<sup>nd</sup> Generation Compounds. Indeed, it seems that all evidence Tulane needs to support its position that Dr. Hackler was an inventor will be internal to



Tulane. Accordingly, the Court finds that Plaintiffs will not be prejudiced by the addition of Cytogel's claims at this time.

#### 5. *Futility*

Plaintiffs argue that Cytogel's proposed amendment is unsupported by the evidence. The court construes this as an argument that Cytogel's claims are futile. Plaintiffs argue that patent issuance creates a presumption of inventorship, and they argue that individuals who participate in the conception of an invention are the inventors. Cytogel responds in reply that Plaintiffs are seeking to raise summary judgment style arguments, when the futility standard is more akin to a Rule 12(b)(6) standard. The Court finds that Plaintiffs' arguments regarding the viability of Cytogel's claims are better addressed in a motion to dismiss or motion for summary judgment.

Plaintiffs also argue that there is no right of action to challenge inventorship of a pending patent application. The statute for correcting inventorship in pending applications "does not provide a private right of action to challenge inventorship of a pending patent application." HIF Bio, Inc. v. Yung Shin Pharm. Indus. Co., 600 F.3d 1347, 1354 (Fed. Cir. 2010), as amended on reh'g in part (June 14, 2010).<sup>4</sup> Thus Plaintiffs argue it would be futile to add Cytogel's request to correct the inventorship of the Related Applications. In reply, Cytogel points out that it is not seeking an order that the inventor on the pending Related Application be corrected to eliminate Dr. Hackler, but instead that a correction be ordered as to any patents issued from the Related Applications. Similarly to the Court's conclusion above, the Court finds that Plaintiffs' argument

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<sup>4</sup> In HIF Bio, the plaintiffs sought a declaration that they were the true inventors of the disputed invention. They argued they were not contesting patents or patent applications, but were seeking declaratory judgment on the issue of inventorship under state law. But the court found that, "because this dispute involve[d] *pending* patent applications, the plaintiffs' requested relief—a declaration of the 'true' inventor—[was] tantamount to a request for either a modification of inventorship on pending patent applications or an interference proceeding." HIF Bio, 600 F.3d at 1353. The court found that the district court was precluded from granting the plaintiffs' requested relief, and held that the district court should have dismissed the claim because no private right of action exists. Id. at 1354.

that Cytogel has no cause of action to assert ownership in the Related Application is better addressed in a motion to dismiss.


*6. Deferral*

Plaintiffs also argue that ruling on Cytogel's motion for leave to amend should be deferred pending the District Judge's ruling on the pending motions to dismiss Cytogel's existing counterclaims. The Court declines this request as a deferral will only further delay the resolution of the claims in this lawsuit.

Conclusion

Cytogel's proposed counterclaims arise out of recently discovered evidence, yet they relate to issues that have been part of this lawsuit since the beginning. It would serve the interests of judicial economy to have its claims resolved as part of the existing litigation. And, the Court finds there is no prejudice to be suffered by the Plaintiffs because only minimal, if any, additional discovery will need to be performed and trial is not until December 2018. Accordingly, Cytogel's Motion for Leave to File First Amended and Restated Affirmative Defenses and Second Amended and Restated Counterclaims is GRANTED.

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

  
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Janis van Meerveld  
United States Magistrate Judge