

**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 are a Motion to Dismiss Defendant Cytogel Pharma, LLC's ("Cytogel") Second Amended and Restated Counterclaims pursuant to Rule 12(b)(7) of the Federal Rules of Civil Procedure or, in the Alternative, to Dismiss Count 14 of Cytogel's Second Amended and Restated Counterclaims pursuant to Rule 12(b)(6), filed by Plaintiff the Administrators of the Tulane Educational Fund ("Tulane") and Counterclaim-Defendant Dr. James E. Zadina,<sup>1</sup> and a Motion to Dismiss Counts 1, 8, 9, and 14 of Cytogel's Second Amended and Restated Counterclaims, filed by Plaintiff the United States of America.<sup>2</sup> Cytogel opposes these motions.<sup>3</sup> For the reasons that follow, the motions are **DENIED** as to Counts 1–13, and **DENIED WITHOUT PREJUDICE** to the extent they address Count 14. Tulane, Dr. Zadina, and the United States may refile the motions as they pertain to Count 14 at the time of the second trial in this case.

**BACKGROUND**

In the 1990s, Dr. Zadina and his colleagues at Tulane University developed synthetic peptides that stimulate the mu opioid receptor and are related to endomorphins, which are opioid peptides found naturally in the human body.<sup>4</sup> Dr. Zadina

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<sup>1</sup> R. Doc. 235. The Court already has dismissed some of these Counts.

<sup>2</sup> R. Doc. 301. The Court already has ruled on the motion as to some of the Counts.

<sup>3</sup> R. Doc. 252, 346.

<sup>4</sup> R. Doc. 233-1 at 8, ¶ 16; R. Doc. 285 at 6, ¶ 16.

and Plaintiff the Administrators of the Tulane Educational Fund (“Tulane”) obtained two patents, U.S. Patent Nos. 5,885,958 (“the ’958 Patent”) and 6,303,578 (“the ’578 Patent”), claiming synthetic opioid compounds.<sup>5</sup>

On November 1, 2006, Cytogel executed a contract entitled “Consulting Agreement”<sup>6</sup> with Dr. Zadina, an employee of Tulane and the Department of Veterans Affairs (“VA”).<sup>7</sup> In the contract, Dr. Zadina agreed to “provide advice and consultation on topics related to the development of opioid compounds for clinical application.”<sup>8</sup> Cytogel alleges Dr. Zadina, as a consultant to Cytogel, accessed confidential data and information relating to a synthetic opioid compound called Cyt-1010.<sup>9</sup> Cytogel alleges Dr. Zadina used this information to further his own secret work on the development of closely-related opioid compounds that would compete directly with Cyt-1010.<sup>10</sup>

From September 8, 2010 onward, Cytogel “disengaged from” Dr. Zadina.<sup>11</sup> 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.<sup>12</sup> On May 6, 2014, the resulting patent, U.S. Patent No. 8,716,436 B2 (“the ’436 Patent”), issued.<sup>13</sup> 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.”<sup>14</sup>

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<sup>5</sup> R. Doc. 233-1 at 8, ¶ 16; R. Doc. 285 at 6, ¶ 16.

<sup>6</sup> R. Doc. 223-3.

<sup>7</sup> R. Doc. 233-1 at 8, ¶ 15; R. Doc. 285 at 6, ¶ 15.

<sup>8</sup> R. Doc. 223-3 at 2, ¶ 1.

<sup>9</sup> R. Doc. 220 at 13–18.

<sup>10</sup> *Id.* at 22, ¶ 61.

<sup>11</sup> R. Doc. 233-1 at 9, ¶ 19; R. Doc. 285 at 7, ¶ 19.

<sup>12</sup> R. Doc. 1 at 12, ¶ 47; R. Doc. 220 at 20, ¶ 55.

<sup>13</sup> R. Doc. 233-1 at 9, ¶ 20; R. Doc. 285 at 7, ¶ 20.

<sup>14</sup> R. Doc. 220 at 23, ¶ 64.

On August 19, 2016, Tulane and the United States of America filed suit against Cytogel.<sup>15</sup> Plaintiffs allege Cytogel has asserted sole ownership of the '436 Patent and threatened to pursue legal remedies against them.<sup>16</sup> They seek declaratory judgments of ownership and inventorship of the '436 Patent.<sup>17</sup>

On September 7, 2016, Cytogel filed thirteen counterclaims against Plaintiffs Tulane and the United States and Counterclaim-Defendant Dr. Zadina.<sup>18</sup> On April 11, 2017, Cytogel filed its Amended Counterclaims, bringing the same thirteen claims.<sup>19</sup> Neither Cytogel's Counterclaims nor its Amended Counterclaims mention Dr. Hackler. On July 23, 2018, Cytogel filed its Second Amended and Restated Counterclaims, in which it added a fourteenth count for Correction of Inventorship of the '436 Patent and Related Patent Applications.<sup>20</sup> Cytogel's Second Amended and Restated Counterclaims mention Dr. Hackler in passing several times.<sup>21</sup> In the portion of the Second Amended and Restated Counterclaims regarding the newly added fourteenth counterclaim, Cytogel describes Dr. Hackler's role in detail, alleging he "did not significantly contribute" to the invention of the '436 Patent compounds, and requests the Court remove his name as an inventor of the Patent.<sup>22</sup>

On August 13, 2018, Tulane and Dr. Zadina filed the instant Motion to Dismiss all of Cytogel's Second Amended and Restated Counterclaims and First Amended and Restated Affirmative Defenses for failure to join Dr. Hackler's estate, pursuant to Rule

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<sup>15</sup> R. Doc. 1.

<sup>16</sup> *Id.* at 14–16, ¶ 53–62.

<sup>17</sup> *Id.*

<sup>18</sup> R. Doc. 6.

<sup>19</sup> R. Doc. 68.

<sup>20</sup> *Id.* at 28–51.

<sup>21</sup> Dr. Hackler is mentioned in Count 1, describing Dr. Hackler's contributions to the '436 patent; in Count 9, describing Drs. Hackler and Zadina's assignment of the '436 Patent; and in Count 13, mentioning the assignment R. Doc. 220 at 28–29, 39–40, 46–47, ¶¶ 80, 132–33, 164–65.

<sup>22</sup> *Id.* at 47–51.

12(b)(7) of the Federal Rules of Civil Procedure.<sup>23</sup> Alternatively, Tulane and Dr. Zadina seek dismissal of Count 14 of Cytogel's Second Amended and Restated Counterclaims pursuant to Rule 12(b)(6).<sup>24</sup> Cytogel opposes this motion.<sup>25</sup>

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.<sup>26</sup>

On September 21, 2018, the United States filed the instant Motion to Dismiss Counts 1, 8, 9, and 14 of Cytogel's Second Amended and Restated Counterclaims.<sup>27</sup> Cytogel opposes this motion.<sup>28</sup>

### **RULE 12(b)(7) STANDARD**

Rule 12(b)(7) of the Federal Rules of Civil Procedure allows dismissal for "failure to join a party under Rule 19." Deciding whether or not to dismiss a case for failure to join an indispensable party is a two-step inquiry. A court first determines if the party is a required party under Rule 19(a)(1). A party is required if

- (A) in that person's absence, the court cannot accord complete relief among existing parties; or
- (B) that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may:
  - (i) as a practical matter impair or impede the person's ability to protect the interest; or
  - (ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest.<sup>29</sup>

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<sup>23</sup> R. Doc. 235.

<sup>24</sup> *Id.*

<sup>25</sup> R. Doc. 252.

<sup>26</sup> R. Doc. 298.

<sup>27</sup> R. Doc. 301.

<sup>28</sup> R. Doc. 346.

<sup>29</sup> FED. R. CIV. P. 19(a)(1).

Required parties must be joined if feasible.<sup>30</sup> “If a person who is required to be joined if feasible cannot be joined, the court must determine whether, in equity and good conscience,” the action should be dismissed.<sup>31</sup> A court may consider factors including:

- (1) the extent to which a judgment rendered in the person's absence might prejudice that person or the existing parties;
- (2) the extent to which any prejudice could be lessened or avoided by:
  - (A) protective provisions in the judgment;
  - (B) shaping the relief; or
  - (C) other measures;
- (3) whether a judgment rendered in the person's absence would be adequate; and
- (4) whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder.<sup>32</sup>

A district court making a Rule 19 decision must consider the pragmatic, fact-based, and practical effects of joining or declining to join a party.<sup>33</sup>

### **LAW AND ANALYSIS**

Tulane and Dr. Zadina argue that, because Dr. Hackler is a named inventor on the '436 Patent, his estate is entitled to receive royalties from the patent, and he is an indispensable party to an action in which the inventorship of the '436 Patent may be changed.<sup>34</sup> In reality, Tulane and Dr. Zadina's arguments relate only to Count 14 of Cytogel's Second Amended and Restated Counterclaims, but they move the Court to dismiss all of Cytogel's Second Amended and Restated Counterclaims pursuant to Rule 12(b)(7) of the Federal Rules of Civil Procedure.

Counts 1–13 of Cytogel's Second Amended and Restated Counterclaims do not involve Dr. Hackler and were originally pleaded without mentioning him.<sup>35</sup> Because Tulane and Dr. Zadina do not present arguments that Counts 1–13 should be dismissed

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<sup>30</sup> *Id.*

<sup>31</sup> FED. R. CIV. P. 19(b).

<sup>32</sup> *Id.*

<sup>33</sup> See *Pulitzer-Polster v. Pulitzer*, 784 F.2d 1305, 1309 (5th Cir. 1986).

<sup>34</sup> R. Doc. 235-1.

<sup>35</sup> R. Docs. 6, 68.

pursuant to Rule 12(b)(7), the Court finds Dr. Hackler is not a required party for those counts pursuant to Rule 19(a)(1) of the Federal Rules of Civil Procedure. The Court denies Tulane and Dr. Zadina's motion as to these counts.

Count 14 of Cytogel's Second Amended and Restated Counterclaims will be addressed at a separate trial, to be scheduled at a later date.<sup>36</sup> The Court denies without prejudice Tulane and Dr. Zadina's motion to dismiss Count 14 pursuant to Rule 12(b)(7), or, in the alternative, pursuant to Rule 12(b)(6). The Court also denies without prejudice the United States' motion to dismiss Count 14 pursuant to Rule 12(b)(7). Tulane, Dr. Zadina, and the United States may refile the relevant portions of the instant motions in connection with the trial on Count 2 of the Complaint and Count 14 of Cytogel's Second Amended and Restated Counterclaims.

### **CONCLUSION**

For the foregoing reasons, **IT IS ORDERED** that the Motion to Dismiss Defendant Cytogel Pharma, LLC's ("Cytogel") Second Amended and Restated Counterclaims pursuant to Rule 12(b)(7) of the Federal Rules of Civil Procedure or, in the Alternative, to Dismiss Count 14 of Cytogel's Second Amended and Restated Counterclaims pursuant to Rule 12(b)(6), filed by Plaintiff the Administrators of the Tulane Educational Fund ("Tulane") and Counterclaim-Defendant Dr. James E. Zadina<sup>37</sup> be and hereby is **DENIED** as to Counts 1–13, and **DENIED WITHOUT PREJUDICE** as to Count 14. Tulane and Dr. Zadina may refile the motion as it pertains to Count 14 at the time of the second trial in this case.

**IT IS FURTHER ORDERED** that the Motion to Dismiss Counts 1, 8, 9, and 14 of Cytogel's Second Amended and Restated Counterclaims, filed by Plaintiff the United

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<sup>36</sup> R. Doc. 298.

<sup>37</sup> R. Doc. 235.

States of America,<sup>38</sup> be and hereby is **DENIED WITHOUT PREJUDICE** as to Count 14. The United States may refile the motion at the time of the second trial in this case.

**IT IS FURTHER ORDERED** that the Tulane, Dr. Zadina, and the United States file responsive pleadings to Cytogel's Second Amended and Restated Counterclaims by no later than **Monday, November 12, 2018, at 5:00 p.m.**<sup>39</sup>

**New Orleans, Louisiana, this 29th day of October, 2018.**

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**SUSIE MORGAN**  
**UNITED STATES DISTRICT JUDGE**

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<sup>38</sup> R. Doc. 301.

<sup>39</sup> The Court has ruled on all motions to dismiss. Under Rule 12(a)(4) of the Federal Rules of Civil Procedure, if the Court denies a motion to dismiss, “[u]nless the court sets a different time, . . . the responsive pleading must be served within 14 days after notice of the court’s action.”