

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC.,

Plaintiff,

v.

STEFANO FIORUCCI,

Defendant.

Civil Action No. 1:14-cv-01313-RGA

MEMORANDUM OPINION

Thomas C. Grimm, Esq., Jeremy A. Tigan, Esq., MORRIS, NICHOLS, ARSHT & TUNNEL LLP, Wilmington, De, Ellen A. Scordino, Esq., Elizabeth Trafton, Esq., COOLEY LLP, Boston, MA, Ivor Elrifi, Esq., Jonathan Bach, Esq., Scott A. Sukenick, Esq., COOLEY LLP, New York, NY, attorneys for Plaintiff Intercept Pharmaceuticals, Inc.

George Pazuniak, Esq., O'KELLY & ERNST, LLC, Wilmington, DE, Glen M. Diehl, DIEHL LAW LLC, Watchung, NJ, attorneys for Defendant Stephano Fiorucci

September 28, 2017


ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is Plaintiff's Motion for Partial Summary Judgment on the Issue of Inventorship (D.I. 97) and related briefing (D.I. 98, 114, 134), Defendant's Motion for Partial Summary Judgment on the Issue of Ownership (D.I. 100), and Plaintiff's Cross-Motion for Partial Summary Judgment on the Issue of Ownership (D.I. 111) and related briefing (D.I. 101, 112, 132). For the reasons that follow, Plaintiff's Motion for Partial Summary Judgment on the Issue of Inventorship (D.I. 97) and Plaintiff's Cross Motion for Partial Summary Judgment on the Issue of Ownership (D.I. 111) are **GRANTED** and Defendant's Motion for Partial Summary Judgment on the Issue of Ownership (D.I. 100) is **DENIED**.

I. BACKGROUND

Plaintiff, a biopharmaceutical company, develops and commercializes new drugs for treating disease. (D.I. 98 at 3). Plaintiff collaborates with medical research scientists in Italy, including Defendant and Dr. Pellicciari. (*Id.*). Plaintiff, Defendant, and the University where Defendant works collaborated under a series of agreements beginning in 2002. (D.I. 99-1 at Ex. A, Fiorucci Dep. 56:4-9, Nov. 13, 2015). The most recent of these agreements took effect in July 2006. (D.I. 104-1 at Ex. A, Ex. B). Under these agreements, Defendant worked on ligands to bind with the FXR and TGR5 proteins in liver cells. (D.I. 104-1 at Ex. A §1.4).

A. THE PATENTS

When Defendant began his relationship with Plaintiff, Dr. Pellicciari and Defendant worked together on compounds that would treat liver disease through the FXR receptor. (D.I. 44 at ¶ 9). Defendant performed tests to discover the properties and efficacy of the compounds. (*Id.*). Three patents arise out of the research on the FXR ligands: U.S. Patent No. 8,546,365 ("the '365 patent"), U.S. Patent No. 7,932,244 ("the '244 patent"), and U.S. Patent No.

7,858,608 (“the ’608 patent”) (collectively “the FXR patents”). (D.I. 44 at ¶ 9). Both Dr. Pellicciari and Defendant are named as joint inventors, and the patents are assigned to Plaintiff.

In 2003, Dr. Pellicciari started developing chemical compounds to develop a TGR5 agonist, which would bind with the TGR5 receptor to treat metabolic and inflammatory disorders. (D.I. 99-1 at Ex. E, Pruzanski Dep. 39:6-40:8, Apr. 28, 2016). Dr. Pellicciari began working with Plaintiff on the development of these compounds in 2006. (*Id.* at 50:9-16). Defendant was provided with the compounds in 2007 in order to screen the compounds and perform efficacy tests. (*Id.*). Plaintiff filed patents on the TGR5 compounds starting in 2009. (D.I. 44 at ¶ 17). There are five patents arising from the TGR5 research: U.S. Patent No. 8,114,862 (“the ’862 patent”), U.S. Patent No. 8,410,083 (“the ’083 patent”), U.S. Patent No. 8,445,472 (“the ’472 patent”), U.S. Patent No. 8,796,249 (“the ’249 patent”), and U.S. Patent No. 8,999, 964 (“the ’964 patent”) (collectively “the TGR5 patents”). (D.I. 44 at ¶ 17). Dr. Pellicciari is named as the sole inventor on these patents, and all are assigned to Plaintiff.

B. THE AGREEMENTS

There are three agreements at issue: the 2006 Consulting Agreement (“the CA”), the 2006 Sponsored Research Agreement (“the SRA”), and a 2008 final Letter Agreement (“the LA”), which terminated the relationship between the parties. The SRA was executed contemporaneously with the CA. All three Agreements state that Delaware law shall apply. (D.I. 104-1 at Ex. A §7.8, Ex. B §8.13, Ex. D ¶ 11(d)).

The CA was an agreement between Plaintiff and Defendant under which Defendant was hired by Plaintiff to work on ligands to bind to FXR, TGR5, and other proteins. (D.I. 104-1 at Ex. A §1.4). Under the CA, Defendant was to design and implement research plans, lead compound screening efforts, and coordinate patent preparation, among other responsibilities.

(*Id.* Appendix A). Defendant assigned the rights to any inventions created during the term of the agreement to Plaintiff and agreed to execute any documents necessary to complete such assignment. (*Id.* §4.1). In return, Plaintiff was to pay Defendant a quarterly services fee and a yearly intellectual property fee. (*Id.* §§3.1, 3.2).

The SRA was executed between Plaintiff, the University, and Defendant. The SRA defined “Research Parties” as the “University and Principal Investigator [i.e., Defendant] collectively or individually as the context requires.” (D.I. 104-1 at Ex. B §1.4). The SRA repeatedly referred to both the “University,” the “Principal Investigator,” and the “Research Parties.” Under the SRA, Defendant was to investigate ligands for the FXR and TGR5 proteins, in addition to ligands for other proteins. (*Id.* §2.1). Plaintiff, in return, would sponsor the research by paying a fee to the University and providing materials to Defendant. (*Id.* §2.4). The SRA also stated that the Research Parties would assign all rights in the project and all patent rights associated with the project to Plaintiff:

Research Parties hereby assign to Sponsor all rights title and interest in and to all Research Project Patent Rights and Research Project Technology upon creation, each such assignment to be effective as of the date of creation. Research Parties shall cooperate with Sponsor in providing assistance and executing any documentation necessary to perfect such assignment....Each of the Research Parties will cooperate with Sponsor in any such filing, prosecution or maintenance.

(*Id.* §4.2). The Research Project Patent Rights were defined as “any and all patent applications and patents owned or otherwise controlled, in whole or in part, by Research Parties worldwide, covering any invention conceived and/or reduced to practice by Principal Investigator [i.e., Defendant]....” (*Id.* §1.6).

In November 2007, Plaintiff sought to terminate the CA. (D.I. 44 at ¶ 19). Plaintiff made a final payment of €75,000 to Defendant in March 2008. (D.I. 99 at Ex. E, Pruzanski Dep. 69:14-25).

The LA was executed between Plaintiff, the University, and Defendant on April 2, 2008, terminating all previous agreements. (D.I. 104-1 at Ex. D). The Agreement stated that it “constitutes the entire understanding and agreement between the parties...and cancels all previous oral and written negotiations, [and] agreements....” (D.I. 104-1 at Ex. D ¶ 11(e)). The LA provided that the Research Parties would fully release, remise, and discharge Plaintiff and its subsidiaries from any and all claims the Research Parties may have had against them. (*Id.* ¶5). Similarly, Plaintiff and its subsidiaries were to

fully, forever, irrevocably and unconditionally release, remise and discharge [Defendant] ... from any and all Claims that they ever had or now have against [Defendant]; provided, however, that, notwithstanding anything to the contrary in this Agreement, [Defendant is not] released from any of [his] obligations under this letter agreement or related to this letter agreement or from any Claims arising out of this letter agreement.

(*Id.* ¶ 6). Under the LA, it was stipulated that Research Parties did “acknowledge and reaffirm that, except as amended by this letter agreement, their obligations pursuant to [the assignment clause and other clauses of the SRA] remain in full force and effect.” (*Id.* ¶ 8).

Plaintiff filed this suit in the United States District Court for the District of Delaware claiming Defendant breached the CA, SRA, and LA by failing to execute formal assignment documents relating to the FXR and TGR5 patents and seeking a declaratory judgment that Defendant was not an inventor of the TGR5 patents. (D.I. 1 at 12-15).

II. ANALYSIS

A. SUMMARY JUDGMENT STANDARD

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P.56(a). When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party’s favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is “genuine” only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby*, 477 U.S. 242, 247–49 (1986).

B. INVENTORSHIP

For Plaintiff’s Motion for Summary Judgment on the issue of Inventorship (D.I. 97), the issue is whether Defendant is a joint inventor of the TGR5 patents.

When a patent has been issued, there is a presumption that the named inventors are the true and only inventors. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). A party that seeks to be added as an inventor must show that he is an inventor by clear and convincing evidence. *Id.* at 1461. He must demonstrate that he contributed to conception of the invention in a specific way and must provide corroborating evidence, which can include contemporaneous documents prepared by the putative inventor or oral testimony by someone who is not the putative inventor. *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1373 (Fed. Cir. 2003); *Ethicon*, 135 F.3d at 1461; *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). A putative inventor’s testimony “cannot, standing alone, rise to the level of clear and convincing proof.” *Ethicon*, 135 F.3d at 1461 (internal citations omitted).

For conception to be complete, the inventor does not have to know if the invention works, but must have a “specific, settled idea, a particular solution to the problem at hand,” and a clear idea of the form of the invention. *Burroughs Wellcome*, 40 F.3d at 1228. Confirmatory testing or screening of compounds does not constitute a contribution to conception, but is considered reduction to practice. *Id.* at 1229-30; *Applegate v. Scherer*, 332 F.2d 571, 573-74 (C.C.P.A. 1964).

Plaintiff and Defendant do not dispute the following facts: (1) Dr. Pellicciari began researching compounds to bind to the TGR5 protein in 2003 outside of his work for Plaintiff (D.I. 99 at Ex. F 39:6-40:8); (2) Defendant received already existing and newly synthesized compounds for testing from Dr. Pellicciari in 2007 (*id.* at Ex. O 164:23-25); (3) Defendant did not synthesize or create any compounds (*id.* at Ex. O 79:3-80:1); (4) Defendant selected and conducted tests on the compounds sent by Dr. Pellicciari to determine their efficacy (*id.*); and (5) Plaintiff began filing patent applications for the compounds, but only filed on the compounds Defendant determined had good efficacy (D.I. 102 at ¶ 11).

Defendant contends that he suggested that compounds created as ligands for the FXR protein might have efficacy for the TGR5 protein as well, thereby contributing to conception. (D.I. 114 at 5). This fact is supported only by Defendant’s own declaration, and is not corroborated by any other evidence. (D.I. 44 ¶14). Thus, there is insufficient corroborating evidence for Defendant’s statement that he contributed to conception to create a disputed material fact on that issue.

Plaintiff argues that just as Defendant’s alleged suggestion cannot render him an inventor due to a lack of corroborating evidence, Defendant cannot be an inventor of the TGR5 patents by virtue of Defendant’s performance of efficacy testing, because efficacy testing is not a

contribution to conception. (D.I. 98 at 10-11). Plaintiff contends that Defendant's testing merely confirmed that the compounds worked, which is reduction to practice, not conception—even if it eliminates some uncertainty. (*Id.* at 11; D.I. 134 at 7-8). Defendant counters by asserting that he is an inventor of the TGR5 patents because without his testing, Plaintiff would not know which compounds to patent, meaning that conception was not complete until after Defendant performed the efficacy tests. (D.I. 114 at 10). Defendant also argues that *Burroughs Wellcome*, which holds that confirmatory testing or screening of compounds does not constitute a contribution to conception, should be distinguished because the patents in that case were prepared before testing was performed, but in this case, the patents were prepared years later. (*Id.* at 13). This difference in filing time is not material because Defendant's testing was not a contribution to conception given the undisputed facts of this case. When Defendant received the compounds, they had already been created, and Dr. Pellicciari had a clear idea of the form of the compounds. (D.I. 99 at Ex. O 164:23-25). Defendant's testing amounted to screening and confirmation that the compounds worked. That is reduction to practice, not conception.

C. OWNERSHIP

Plaintiff and Defendant dispute ownership of both the FXR and TGR5 patents. Since Defendant is not a joint inventor of the TGR5 patents, he has no ownership claim to them. Only the FXR patents are at issue. Under the contracts, Delaware law applies. (D.I. 104-1 at Ex. D ¶ 11(d)).

The inventor is presumed to be the owner of an invention and its corresponding patent rights. *Teets v. Chromalloy Gasturbine Corp.*, 83 F.3d 403, 407 (Fed. Cir. 1996). Contract law, however, allows the inventor to assign her rights to an invention and its patent to another person or entity. *Id.* Ownership of patent rights is determined by state, not federal law, but whether

patent assignment is automatic is a matter of federal law because it is tied up with the question of standing in patent cases. *Sky Techs. LLC v. SAP AG*, 576 F.3d 1374, 1379 (Fed. Cir. 2009).

When an individual assigns rights in an invention before the invention is created, the assignee is considered to have an expectant interest in the invention. *Filmtec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991). The assignee then holds an equitable title until the invention is created and a patent application is filed, at which point, the assignee has a legal title to the rights. *Id.* Whether such an assignment is automatic upon creation of the invention depends on the language of the contract. *DDB Techs., LLC v. MLB Advanced Media, LP*, 517 F.3d 1284, 1290 (Fed. Cir. 2008). Language like “does hereby grant and assign” rights to future inventions is considered to automatically assign rights upon the creation of the invention. *Id.* An assignment, even one that was automatic, may be declared null and void if there is a forfeiture provision in the contract or if there is a provision of state law to support voiding the assignment. *Jim Arnold Corp v. Hydrotech Sys., Inc.*, 109 F.3d 1567, 1577 (Fed. Cir. 1997).

Plaintiff argues that the assignment provisions in the CA were automatic assignment provisions because the contract stated that “Consultant [i.e., Defendant] hereby assigns to the Company all Inventions and any and all related patents....” (D.I. 104-1 Ex. A §4.1(a)). Defendant does not dispute that the assignment was automatic, but argues that the assignment of the patents should be rescinded for three reasons. First, Defendant argues that payment was a condition upon which assignment was premised. (D.I. 101 at 12-14). Second, Defendant contends that Plaintiff’s failure to pay constituted a failure of consideration. (*Id.*). Third, Defendant argues Plaintiff’s failure to pay was a material breach of the contract. (*Id.*). However, these arguments regarding rescission of the contract are irrelevant due to the later letter agreement.

The LA states, and the parties do not dispute, that

[the LA] contains and constitutes the entire understanding and agreement between the parties hereto with respect to the subject matter hereof (including their funding payments and the settlement claims against the Company) and cancels all previous oral and written negotiations, agreements, commitments, writings in connection therewith. Nothing in this paragraph, however, shall modify, cancel or supersede their obligations set forth in paragraphs 3, 4, 5, 6, 8, 9, or 10 herein.

(*Id.* ¶ 11(e)). As a result, the LA supersedes the earlier CA and SRA. The LA further states that “the Research Parties . . . hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company and its subsidiaries . . . from any and all claims, charges, complaints [etc.] . . . of every kind and nature . . . that they ever had or now have against the Company”

(*Id.* ¶ 5). When “the language of the release is clear, it will be given effect.” *Corp. Prop. Assocs. 6 v. Hallwood Grp. Inc.*, 817 A.2d 777, 779 (Del. 2003). The LA released Plaintiff from any payment obligations and all claims that Defendant may have had under the previous agreements, including the claims that the CA was rescinded. (D.I. 104-1 at Ex. D ¶ 6, D.I. 112 at 8). Whether the CA was rescinded thus becomes irrelevant under the LA.

The LA states that “[t]he Research parties hereby acknowledge and reaffirm that, except as amended by this letter agreement, their obligations pursuant to Articles 2.3, 2.5, 3.2, 4, 5, 7 and 8 of the [SRA] remain in full force and effect.” (*Id.* ¶ 8). Defendant, however, contends that he should not be subject to this clause because he was released from previous obligations, including an obligation to assign his patent rights, in the LA. (D.I. 101 at 15). Paragraph 6 states that Plaintiff and its subsidiaries “hereby fully, forever, irrevocably and unconditionally release, remise and discharge” Defendant from any claims Plaintiff had against Defendant. (D.I. 104-1 at Ex. D ¶ 6). Plaintiff notes that Defendant’s release provides an exception for obligations under the LA, which states “that notwithstanding anything to the contrary in this Agreement, no [Defendant] is released from any of its obligations under this letter agreement or any claims

arising out of this letter agreement.” (D.I. 112 at 12; D.I. 104-1 at Ex. D ¶ 6). In interpreting a contractual release, the court will determine the intent of the parties from the overall language of the release. *Fox v. Rodel, Inc.*, 1999 WL 588293, at *6 (D. Del. Jul. 14, 1999). Just as the clear language of a release must be given effect, when a carve out or exception to a release is unambiguous, it must also be given effect. *Id.* at *7. The language of Defendant’s release under ¶ 6 of the LA is not ambiguous, nor is the exception to it. As a result, Defendant is still subject to obligations under the LA, including the obligations of the SRA that are affirmed.

Defendant argues that he should not be subject to the SRA’s assignment clauses for four reasons.

First, Defendant argues that if he is subject to the assignment clause and other obligations, he is not being unconditionally released, as ¶ 6 of the LA states. (D.I. 101 at 16). Therefore, the reaffirmation of the assignment clause cannot apply to him without conflicting with the plain language of ¶ 6. (*Id.*). As noted above, Defendant’s release in ¶ 6 creates an exception, which must be given effect. Thus, Defendant is still subject to obligations under the LA, including the assignment clause.

Second, Defendant argues that even if his discharge does not release him from obligations under the LA, he is only subject to obligations that are newly created under the LA, not obligations that have been reaffirmed from previous agreements. (D.I. 132 at 9). The LA does not contain language to support this assertion, since the contract states that Defendant is not “released from any of its obligations under this letter agreement or relating to this letter agreement....” (D.I. 104-1 at Ex. D ¶ 6). It does not make any reference that could reasonably be interpreted as drawing a distinction between existing and newly created obligations.

Third, Defendant asserts that the assignment clause of the SRA does not apply to him. (D.I. 101 at 12). The SRA defines Research Parties as the University and Defendant together or individually as the “context” requires. (D.I. 104-1 at Ex. B §1.4). Under Delaware law, when two related contracts are executed contemporaneously, they should be read as a single contract. *Ashall Homes Ltd. V. ROK Entm’t Grp. Inc.*, 992 A.2d 1239, 1250-51, n. 56 (Del. Ch. 2010). Defendant therefore contends that since the CA and SRA were executed simultaneously and refer to the same subject matter, they must be read together. (D.I. 101 at 12). Since his assignment obligations were set forth under the CA, Defendant reasons that the assignment clause of the SRA, which refers to Research Parties, must mean only the University. (*Id.* at 21-22). Thus, when the LA preserves the assignment clause of the SRA, it does not preserve Defendant’s assignment obligations. (*Id.*).

I disagree. Delaware law states that contractual language should be interpreted in a way that gives effect to all terms, “so as not to render any part of the contract mere surplusage.” *Kuhn Constr., Inc. v. Diamond State Port Corp.*, 990 A.2d 393, 397 (Del. 2010). Additionally, the contract must be read as a whole, and contractual provisions must be interpreted in a way that “give[s] effect to every term of the instrument and reconcile[s] all provisions of the instrument.” *Energy Partners, Ltd. v. Stone Energy Corp.*, 2006 WL 2947483, at *13 (Del. Ch. Oct. 11, 2006). Defendant is a separate party to the SRA, and is identified as one of the Research Parties. (D.I. 112 at 11; D.I. 104-1 at Ex. B §1.4). The SRA also states in the assignment clause that “[e]ach of the Research Parties will cooperate with Sponsor,” suggesting that more than one Research Party is subject to the clause. (D.I. 104-1 at Ex. B §4.2). The rights being assigned are the Research Project Patent Rights, which are rights to any inventions created by Defendant. (*Id.* at Ex. B §§1.6, 4.2). In order to give effect to all terms of the assignment clause, reconciling

them with the other terms of the Agreement, and to avoid rendering any term as mere surplusage, the assignment clause must be read as applying to Defendant. Thus, it is not just the University, but also Defendant, who is subject to the assignment clause.

Fourth, Defendant argues that the affirmation of the assignment clause under the LA is subject to an exception. (D.I. 101 at 22). The language of the contract states that the parties reaffirm, except as amended by the LA, certain obligations under the SRA. (D.I. 104-1 at Ex. D ¶ 8). Defendant claims that his release and discharge of obligations is considered an amendment to the obligations, such that he is not subject to the assignment clause. (D.I. 132 at 14).

Although Defendant is correct in stating that the LA anticipates that there may be exceptions to the reaffirmed obligations, Defendant's reading of the language ignores the fact that no exception applies, and he is therefore not released from obligations under the LA. Defendant's reading does not give effect to every term of the contract, and thus, Defendant is required to assign the patents to Plaintiff.

III. CONCLUSION

For the reasons stated herein, Plaintiff's Motion and Cross Motion for Partial Summary Judgment are granted and Defendant's Motion for Partial Summary Judgment is denied.

A separate order will be entered.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC.,

Plaintiff,

v.

STEFANO FIORUCCI,


Defendant.

Civil Action No. 1:14-cv-01313-RGA

ORDER

For the reasons set forth in the accompanying opinion, **IT IS HEREBY ORDERED** that Plaintiff's Motion for Partial Summary Judgment on the Issue of Inventorship (D.I. 97) is **GRANTED**, Plaintiff's Motion for Partial Summary Judgment on the Issue of Ownership (D.I. 111) is **GRANTED**, and Defendant's Motion for Partial Summary Judgment on the Issue of Ownership (D.I. 100) is **DENIED**.

Entered this 28 day of September, 2017.


United States District Judge