IN THEUNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FAMILIES OF SPINAL MUSCULAR ATROPHY,	)	
Plaintiff,	)	No. 16-cv-4262
v.	)	Hon. Amy J. St. Eve
NATIONWIDE CHILDREN'S HOSPITAL and THE RESEARCH INSTITUTE AT NATIONWIDE CHILDREN'S HOSPITAL,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

Defendants Nationwide Children's Hospital and The Research Institute at Nationwide Children's Hospital (collectively, "Defendants") have moved to dismiss Plaintiff Families of Spinal Muscular Atrophy's ("Plaintiff") complaint under Federal Rule of Civil Procedure 12(b)(6). (R. 71.) Additionally, Defendants have moved "to strike from the Amended Complaint pursuant to Rule 12(f) any request for relief by Plaintiff in the form of stock of AveXis, Inc." (*Id.*) For the following reasons, the Court (1) grants in part and denies in part Defendants' motion to dismiss, and (2) denies Defendants' motion to strike to the extent it relates to Plaintiff's remaining claim.

BACKGROUND[1]

I. Factual Allegations

Plaintiff is a nonprofit corporation that funds research related to Spinal Muscular Atrophy ("SMA"), a genetic disease, and Defendants conduct research on various topics, including SMA treatments. (R. 53, Am. Compl., at 1–6, Exs. A–B.) One way Plaintiff raises money to fund additional research "is by including commercialization clauses and provisions in its funding agreements under which it receives royalties and other considerations in the event the funded research and non-financial resource investments made by [Plaintiff] to a research institution lead to commercial licensing of technology associated with the funding agreements." (*Id.* at ¶ 29–31.) This case concerns whether two separate research-funding agreements between the parties entitle Plaintiff to proceeds from a licensing agreement between Defendants and a third party.

A. The Grant Agreement

In September 2009, Defendants applied for a grant for a project entitled "Optimizing Titer and Window of Opportunity for targeting Motor Neurons via an AAV9 vector in Newborn Non-human primates."[2] (*Id.*, Ex. A at 6.) Plaintiff agreed to fund the project, and, in April 2010,

[1] The Court takes the facts presented in the Background from the complaint and presumes them as true for the purpose of resolving the pending motion to dismiss under Rule 12(b)(6). *See Teamsters Local Union No. 705 v. Burlington N. Santa Fe, LLC*, 741 F.3d 819, 823 (7th Cir. 2014); *Alam v. Miller Brewing Co.*, 709 F.3d 662, 665–66 (7th Cir. 2013); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Additionally, although the parties filed numerous documents under seal, the Seventh Circuit has held that "[d]ocuments that affect the disposition of federal litigation are presumptively open to public view, even if the litigants strongly prefer secrecy, unless a statute, rule, or privilege justifies confidentiality." *In re Specht*, 622 F.3d 697, 701 (7th Cir. 2010); *see also United States v. Foster*, 564 F.3d 852, 853 (7th Cir. 2009) (Easterbrook, C.J., in chambers) (sealed documents "that influence or underpin the judicial decision are open to public inspection unless they meet the definition of trade secrets or other categories of bona fide long-term confidentiality.").

[2] The Court presumes familiarity with its prior opinion in this case. (R. 52.) The Court, however, reiterates some background regarding the technology at issue that is helpful to understanding this case. As the Court noted in its previous opinion, Defendants have explained that they created a "therapy technology" that "consists of delivering copies of a gene known as SMN, which is deficient in SMA sufferers, via a proprietary virus known as AAV9 specially modified to carry the SMN gene replacement therapy to the [central nervous system]." (*Id.* at 2 n.3.) According to Defendants, they have developed methods "for both systemic delivery (*i.e.*, intravenously into the blood stream) and intrathecal delivery (*i.e.*, directly into the cerebrospinal fluid)." (*Id.*)

the parties entered into a Grant Agreement (the "GA"). (*Id.* at ¶¶ 58–59, Ex. A at 1.) The GA gave Defendants a $100,000 budget, and Defendants agreed to pay Plaintiff "five percent (5%) of all royalty or other cash income received by the [Defendants] from licenses or sublicenses to all of the Inventions developed from activities under this Agreement." (*Id.* at ¶¶ 61, 66, Ex. A at 1, 3.) The GA defines the term "Inventions" as "any invention (or other intellectual property), whether patentable or unpatentable conceived or first actually reduced to practice as part of the activities under this Agreement." (*Id.* at ¶ 67, Ex. A at 2.)

Plaintiff alleges that, before Defendants' grant application, Defendants' "prior research had shown that systemic treatment with scAAV9 was only successful if administered to *newborn* SMA mice on day 1 after birth." (*Id.* at ¶ 41 (emphasis in original).) If, however, "scAAV9 was delivered 5 days after birth, the therapy was only modestly beneficial, and if administered to mice 10 days after birth, the treatment was unsuccessful." (*Id.*) Thus, according to Plaintiff, Defendants' prior research "provided only a very limited opportunity for practical human clinical trials and treatment and commercialization of systemic SMA treatment with scAAV9." (*Id.* at ¶ 42.) This is the case because, if the results in humans were similar to the results in mice, "treatment of SMA in newborn humans is of limited feasibility and practicality, as SMA in humans is currently diagnosed when a patient is symptomatic and older." (*Id.* at ¶¶ 43–44.)

Plaintiff alleges that Defendants applied for a grant from Plaintiff because they "needed funding . . . to gather critical data and evidence to move to clinical trials and to establish the commercial viability of systemic administration of scAAV9 in humans." (*Id.* at ¶ 47.) In its grant application, Defendants noted that scAAV9 "is able to cross the blood-brain-barrier (BBB) to deliver transgenes via the systemic circulation to the central nervous system (CNS)." (*Id.*, Ex. E at 4.) Defendants explained that they "have noticed a stark age-dependent contrast in the CNS

regions and cell-types transduced"—specifically, in newborn mice, more than half "of motor neurons in the spinal cord appear to be transduced, while in adult animals (60-70 days old), scAAV9-transgenic expression seems strongly limited to non-neuronal (gilal) cells" likely "due to the post-natal development of the BBB." (*Id.* at ¶ 47, Ex. E at 4; *see also id.*, Ex. D-3 at 1972 (explaining that studies in mice showed a "progressive decline in motor neuron transduction" during the first ten days of life).) Defendants reported that their previous studies resulted in "near-complete rescue" after "scAAV9-mediated SMN delivery in newborn mice." (*Id.*, Ex. E at 4.) They said, however, that "[w]hile this is very exciting, we must now translate this method of gene delivery to larger species in order to move to clinical trials." (*Id.*) In furtherance of this ultimate goal, the grant application listed two aims: (1) to "[d]etermine dose of scAAV9 sufficient for neuronal, specifically motor neuron transduction in non-human primates," and (2) to "[a]ssess time-dependent transduction patterning in primates throughout development from 1–180 days after birth." (*Id.*)

According to Plaintiff, the GA research "demonstrated that systemic administration of scAAV9 was successful in non-human primates (*i.e.*, Cynomolgus macaques) at all time points investigated, including in non-newborn primates." (*Id.* at ¶ 73.) Plaintiff alleges that "these results provided confidence for translation to SMA patients by overcoming the potential clinical obstacle for advancing AAV9 gene therapy for SMA by showing that the very limited window of opportunity as suggested by the mice data was not present in non-human primates." (*Id.*) In short, the GA research showed that the window of opportunity for effective administration of scAAV9 was larger in non-human primates than in mice. (*Id.* at ¶¶ 74–78.) Plaintiff contends that "[t]he new information [from the GA project] constitutes an Invention under the grant agreement," because "[t]he technological discovery that systemic administration of scAAV9 is

successful in *non-newborn* non-human primates was first reduced to practice as part of the activities under the [GA]." (*Id.* at ¶¶ 80–81 (emphasis in original).)

B. The Research Collaboration Agreement

Later, in May 2012, the parties entered into a second agreement, the Research Collaboration Agreement (the "RCA"), to conduct a research project entitled "IND Enabling Studies for a CNS Delivered Gene Therapy for Spinal Muscular Atrophy." (*Id.* at ¶¶ 84–110, Ex. B at 1.) Under the RCA, Defendants had a maximum budget of $300,000, (*id.* at ¶ 96, Ex. B at 1, 10), and Defendants agreed to "pay [Plaintiff] five percent (5%) of all royalty[and] other consideration up to a cap of $300,000, received by the [Defendants] from licenses or sublicenses to any of the Inventions solely or jointly owned by [Defendants]," (*id.*, Ex. B at 3.) The RCA defined the term "Inventions" as "any potentially patentable invention conceived in the performance of the Research Project." (*Id.*) The RCA further provided that "the existing inventions and technologies of [Defendants] . . . are their separate property and are not affected by this Agreement, and [Plaintiff] shall not have any claims to or rights in such existing inventions and technologies." (*Id.*) In March 2015, the parties amended the RCA, raising both the maximum budget of the project as well as the cap on "royalty and other consideration" payments Defendants would make to Plaintiff if Defendants licensed any "Inventions." (*Id.* at ¶¶ 112, 117, Ex. B-1 at 1.)

The RCA identified specific "aims" of the research project. One such aim was to "[d]etermine the lowest dosage which yields high motor neuron transduction in nonhuman primates." (*Id.*, Ex. B at 9.; *see also id.*, Ex. B at 8 (noting the aim of "[o]ptimiz[ing] intrathecal dosing in nonhuman primates for most efficient targeting of spinal motor neurons using AAV9").) The criteria for success of this goal was "[t]o complete intrathecal injections in non-

human primates to achieve 70% motor neuron transduction in the spinal cord." (*Id.*, Ex. B at 9.) The purpose of reaching this aim was to take a step toward human clinical trials. (*Id.* ("The lowest dose which yields high motor neuron transduction will determine which doses should be used in the planned first-in-human clinical trial.")

Plaintiff alleges that Defendants encountered obstacles in reaching the goal described in the preceding paragraph. (*Id.* at ¶ 123.) Specifically, they had difficulty "getting high enough motor neuron transduction across spinal cord segments," as there was less than 70% transduction in some regions in the spinal cord. (*Id.* at ¶¶ 122–24) The minutes of a Joint Steering Committee call in May 2013 indicate, that in one test-subject monkey, "58% of cervical MNs were hit, 67% of thoracic MNs, and 78% of MNs in the lumbar spinal cord." (*Id.* at ¶ 128, Ex. O-3 at 2.) The minutes indicate that the lower transduction numbers were "likely due to flow impedance," which "can be improved by optimizing the delivery method." (*Id.*, Ex. O-3 at 2.) Plaintiff alleges that during the May 2013 call, the committee discussed that the "use of tilting techniques in connection with the intrathecal administration of scAAV9, such as the Trendelenburg position, could be useful." (*Id.* at ¶ 129.) Additionally, according to Plaintiff, the committee discussed in November 2013 "that the tilting techniques were providing improvements in motor neuron transductions across spinal segments, using the tilting table delivery method." (*Id.*)

Plaintiff alleges that in August 2014, the committee minute notes indicate that "[i]t was discovered that tilting greatly improves motor neuron transduction." (*Id.* at ¶ 130.) The committee reported that "[t]he best results are seen with 10 minutes of tilting, showing over 50% of cervical MNs were hit, 60% of thoracic MNs, and almost 80% of MNs in the lumbar spinal cord." (*Id.* at O-5 at 2.) Plaintiff claims that "[t]he data from the use of the Trendelenburg

position (tilting table) solved the transduction efficient issues across spinal cord segments." (*Id.* at ¶ 130.) Indeed, Plaintiff alleges that "[b]ased on the tilting experiments reported in August 2014, [the principal investigator for Defendants,] Dr. Kaspar[,] concluded that the monkey studies conducted under the RCA led to a dose that yields higher motor neuron transduction thereby providing an informed dose that should be planned for first-in-human clinical trials in infants." (*Id.* at ¶¶ 60, 131.)

The complaint says that Defendants "filed several patent applications covering research performed under the RCA." (*Id.* at ¶ 132.) One such application—filed July 31, 2013—is International Patent Application No. PCT/US2013/53065 (the "'065 application"), which is entitled "Intrathecal delivery of recombinant adeno-associated virus 9." (*Id.* at ¶¶ 132, 135.) According to Plaintiff, the '065 application "describes the use of a new patient position used during treatment—the Trendelenburg position (tilting position)—and states that using this previously unexplored technique 'results in a two-fold (100%) improvement." (*Id.* at ¶ 137 (quoting *id.* Ex. H at 21).) Additionally, Claim 23 in the patent application "is directed to using the Trendelenburg position in connection with scAAV9." (*Id.* at ¶ 138.)

Plaintiff also refers in the amended complaint to a 2014 article by Dr. Kaspar, which states that "[n]otably, [Defendants were] able to further improve the transduction rate in the brain and brainstem when the nonhuman primates were kept in the Trendelenburg position for 5–10 minutes postinjection." (*Id.* at ¶ 140, Ex. I at 478; *see also id.*, Ex. I at 484 ("Strikingly, the transduction rate with the same dose was drastically improved when subjects were kept in the Trendelenburg position for 10 minutes after vector infusion . . . .").) That article further notes that "[t]ilting tables are regularly used to spread intrathecal delivered anesthetics and drugs in adults and this study is the first one to demonstrate a similar effect on viral vector distribution."

(*Id.*, Ex. I at 484.)

Based on the above, Plaintiff alleges that the technological discovery of using the Trendelenburg position with administration of scAAV9 was first conceived during the performance of the RCA research and therefore constitutes an "Invention" under the RCA. (*Id.* at 143–51.)

C. The AveXis Licensing Agreement

In September 2013, Defendants entered into a license agreement with BioLife Cell Bank, Inc., which is now known as AveXis, Inc. (*Id.* at ¶¶ 159–60, Ex. C; R. 52 at 3.) The agreement gives AveXis an exclusive license to SMN AAV9 delivery technology as represented by various patent applications (including the '065 application) and associated "Technical Information," which includes "research and development information, unpatented inventions, and know-how pertaining to the Licensed Patents." (R. 53 at ¶¶ 162–69, Ex. C at 1–3, 21, 22.) Plaintiff alleges that the inventions it identifies under the GA and RCA "fall within the scope of 'Licensed Technology,' under the AveXis License Agreement." (*Id.* at 170.) In exchange for the technology license, the agreement provides that Defendants would receive over 200,000 shares of AveXis stock. (*Id.* at ¶ 181, Ex. C at 8.) Additionally, the license agreement provides that Defendants will receive payments, subject to certain conditions, at regulatory milestones—specifically, $75,000 for "Approval by the FDA of a Biologics License Application for the scAA V9-SMN gene therapy product for spinal muscular atrophy type 1 for vascular delivery" and $50,000 for "Approval by the FDA of a Biologics License Application for the scAA v9-SMN gene therapy product for intrathecal delivery." (*Id.* at ¶ 180, Ex. C at 8.) Finally, the license agreement entitles Defendants, under certain circumstances, to royalty payments based on "Net Sales of Licensed Products" and sublicenses granted by AveXis. (*Id.*, Ex. C at 8–9.)

Between January 2014 and October 2015, AveXis and Defendants amended the license agreement four times. (*Id.* at ¶ 182, Ex. C-1.) The January 2014 amendment obligates AveXis to make additional payments to Defendants at certain dates and milestones, totaling $50,000. (*Id.* at ¶ 183, Ex. C-1 at 9.)

To date, Plaintiff alleges that Defendants have received a total of $243,163 in cash payments from AveXis. (*Id.* at ¶ 186.) Plaintiff also alleges that, due to license-agreement terms concerning the nondilution of stock, Defendants "currently ha[ve] title to 442,410 shares in AveXis." (*Id.* at ¶ 192.)

Based on these facts, Plaintiff asserts that Defendants breached the GA and the RCA by failing to make payments to Plaintiff after licensing "Inventions" to AveXis. (*Id.* at ¶¶ 210–33.) Plaintiff therefore requests the following relief: judgments that Defendants breached the GA and RCA, "an order that an accounting be held of all cash and consideration received to date by [Defendants] under the [GA and RCA]," and "damages sustained as a result of [Defendants'] breach." (*Id.* at 9). Specifically, Plaintiff seeks "monetary damages of 5% of all cash received by [Defendants] per the [GA and RCA]," "an order that [Defendants] transfer to [Plaintiff] title in 5% of the 442,410[A]veXis shares (22,121 shares) issued to [Defendants]," and "an order that [Defendants] transfer to [Plaintiff] 5% of the proceeds of any sales of shares by [Defendants] per the [GA], and any of those shares transferred to other parties." (*Id.* at 9–10.)

II. Procedural History

Plaintiff filed this lawsuit in April 2016. (R. 1.) In September 2016, the Court granted Defendants' motion to dismiss without prejudice based on Plaintiff's failure to sufficiently allege what "Inventions" arose during the GA and RCA projects. (R. 52.) Plaintiff then filed an amended complaint, (R. 53), and Defendants filed the motion now before the Court, (R. 71).

ANALYSIS

I. Failure to State a Claim

A. Legal Standard

"A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) challenges the viability of a complaint by arguing that it fails to state a claim upon which relief may be granted." *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 736 (7th Cir. 2014). Under Rule 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The short and plain statement under Rule 8(a)(2) must "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). A plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* Put differently, "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 *Twombly*, 550 U.S. at 570). In determining the sufficiency of a complaint under the plausibility standard, courts must "accept all well-pleaded facts as true and draw reasonable inferences in [a plaintiff's] favor." *Roberts v. City of Chicago*, 817 F.3d 561, 564 (7th Cir. 2016).

Some of the facts the Court references come from exhibits attached to the complaint. The Court may properly consider such attachments in ruling on a Rule 12(b)(6) motion to dismiss. *See Phillips v. Prudential Ins. Co. of Am.*, 714 F.3d 1017, 1019–20 (7th Cir. 2013); *McWorthey v. Tech. Ins. Co.*, No. 15-cv-5021, 2016 WL 4398063, at *3 n.3 (N.D. Ill. Aug. 18, 2016). When the exhibits contradict the allegations, "the exhibits trump the allegations." *See Abcarian v. McDonald*, 617 F.3d 931, 933 (7th Cir. 2010); *McWorthey*, 2016 WL 4398063, at *3 n.3.

B. Discussion

The parties agree that Ohio law governs the GA and RCA. (R. 72, Defs.' Mem. Supp. Mot., at 14; R. 77 at 8.) To establish breach of contract under Ohio law, a plaintiff must prove (1) the existence of a contract; (2) the plaintiff performed its contractual obligations; (3) the defendant's breach; and (4) resulting damages. *See V & M Star Steel v. Centimark Corp.*, 678 F.3d 459, 465 (6th Cir. 2012); *Kline v. Mortg. Elec. Sec. Sys.*, 154 F. Supp. 567, 603 (S.D. Ohio 2015); *Villasenor v. Am. Signature, Inc.*, No. 06 C 5493, 2007 WL 2025739, at *7 (N.D. Ill. July 9, 2007) (citing Ohio law). Defendants argue that Plaintiff has failed to adequately plead the third element of breach because Plaintiff does not allege "(1) any Inventions 'conceived or first actually reduced to practice' during the GA Project; or (2) any Inventions 'conceived in the performance of [the RCA Project].'" (R. 72 at 15.) Plaintiff contends that it has adequately alleged one "invention" under the GA—that systemic delivery of AAV9 achieved successful motor neuron targeting in non-newborn primates—and one invention under the RCA—the use of the Trendelenburg position to improve intrathecal delivery of AAV9. (R. 77, Pl.'s Opp.) The Court considers those two putative "inventions" in turn. First, however, the Court explains some of the principles and contract definitions that govern this case.

As the Court described in its previous opinion and as the parties agree, Plaintiff's right to compensation under the GA and RCA turns on whether Defendants licensed any "invention." (R. 52 at 7.) The GA defines the term as "any invention (or other intellectual property), whether patentable or unpatentable conceived or first actually reduced to practice as part of the activities under this Agreement." (R. 53 at ¶ 67, Ex. A at 2.) The RCA defines the term as "any potentially patentable invention conceived in the performance of the [RCA] Project." (*Id.*, Ex. B at 3.)

In interpreting a contract under Ohio law, "courts must give effect to the intent of the parties." *Smith v. Erie Ins. Co.*, No. 2015-1419, 2016 WL 6775837, at *4 (Ohio 2016) (quoting *Granger v. Auto-Owners Ins.*, 40 N.E.3d 1110, 1115 (Ohio 2016)); *see also Hobart Corp. v. Waste Mgmt. of Ohio, Inc.*, 758 F.3d 757, 768 (6th Cir. 2014). Generally, "that intent is presumed to be reflected in the plain and ordinary meaning of the contract language." *Granger*, 40 N.E.3d at 1115. Where another meaning of a term is clear from the face of the instrument, however, courts will ascertain the parties' intent from that meaning. *See Textileather Corp. v. GenCorp. Inc.*, 697 F.3d 378, 382 (6th Cir. 2012). "Technical terms will be given their technical meaning, unless a different intention is clearly expressed." *Foster Wheeler Enviresponse, Inc. v. Franklin Cty. Facilities Auth.*, 678 N.E.2d 519, 526 (Ohio 1997); *see Weaver v. Caldwell Tanks, Inc.*, *Clinch River Capital Ptrs., Inc. v. Elsea, Inc.*, No. 2:11-CV-00400, 2012 WL 5334307, at *4 (S.D. Ohio Oct. 26, 2012).

With good reason, the parties look to patent law to define the terms "conceived" and "reduced to practice." The former version of 35 U.S.C. § 102(g)[3]—which dealt with priority of an invention—provided that "[a] party is a prior inventor if '(1) [she] reduced [her] invention to practice first . . .or (2) [] was the first party to conceive of the invention and then exercised reasonable diligence in reducing that invention to practice." *Bayer Healthcare, LLC v. Zoetis Inc.*, No. 12 C 00630, 2016 WL 4179087, *20 (N.D. Ill. Aug. 8, 2016) (alterations in original). "Conception occurs 'when the inventor has a specific, settled idea, a particular solution to the problem at hand . . . ." *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1383 (Fed. Cir. 2011). In other words, it is "the formation in the mind of the inventor, of a definite

[3] Congress amended § 102 in 2011, moving the patent laws "from a 'first to invent' to a 'first to file' system." *See Bayer Healthcare, LLC v. Zoetis Inc.*, No. 12 C 00630, 2016 WL 4179087, *20 (N.D. Ill. Aug. 8, 2016). This change, however, does not alter the Court's analysis of the terms "conception" and "reduction to practice."

and permanent idea of the complete and operative invention, as it is hereafter applied in practice." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 967 (Fed. Cir. 2014) (quoting *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994)). Reduction to practice requires an inventor to have "(1) constructed an embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose." *Teva*, 661 F.3d at 1383.

As for the definition of an invention—which both the GA and RCA circularly use in defining the term "Invention"— the RCA requires that it be "potentially patentable," thereby incorporating patent-law concepts like nonobviousness. *See* 35 U.S.C. § 103. The GA, on the other hand, indicates that an invention may be "patentable or unpatentable." Therefore, the Court looks to the ordinary understanding of the term—a "discovery" or "finding" according to *Merriam-Webster*, "[t]he action of inventing something, typically a process or device" according to the *Oxford Dictionary*, "something newly designed or created" according to the *Cambridge Dictionary*, or "anything that is created or devised" according to *Black's Law Dictionary*.[4]

1. The GA

Defendants contend that "Plaintiff's own pleading establishes that the SMN AAV9 Delivery Technology was conceived and shown to work for its intended purpose—*i.e.*, transporting gene therapy across the BBB via systemic administration of AAV9 to achieve transduction in the CNS (including in non-human primates), including transmitting SMN and successfully treating SMA—all *before* the GA Project commenced." (R. 72 at 16.) They argue that Plaintiff fails to adequately allege the "conception" or "reduction to practice" of an

[4] *See Invention*, *Merriam-Webster Dictionary*, https://www.merriam-webster.com/dictionary/invention; *Invention*, *Oxford Dictionary*, https://en.oxforddictionaries.com/definition/invention; *Invention*, *Cambridge Dictionary*, http://dictionary.cambridge.org/us/dictionary/english/invention; *Invention*, *Black's Law Dictionary* (10th ed. 2014).

"invention" because Plaintiff "merely asserts that the testing of a preexisting technology, the AAV9 SMN Delivery Technology, on non-human primates—*on which the same preexisting technology was already shown to work*—somehow constitutes a *new* Invention merely because it was shown to also work when applied later after birth." (*Id.* at 17 (emphasis in original) (citations omitted).)

Plaintiff contends that Defendants' research before the GA revealed a key obstacle that stood in the way of systemic AAV9 SMN delivery proving an effective treatment of SMA in humans: Defendants' research on mice demonstrated "a 'stark age-dependent contrast' in the [delivery] Technology's effectiveness" because it worked in newborn but not older mice. (R. 77 at 9.) This result was, according to Plaintiff, a major potential obstacle because "SMA in humans is not diagnosed until a patient is symptomatic and older." (*Id.*) Accordingly, Plaintiff contends that if the systemic administration of AAV9 could not achieve motor neuron transduction in non-newborn humans, it would not effectively treat SMA. In light of these potential roadblocks to effective SMA treatment that the GA research would investigate, Plaintiff alleges that the "invention" resulting from the GA research was "[t]he technological discovery that systemic administration of scAAV9 is successful in *non-newborn* non-human primates was first reduced to practice as part of the activities under the [GA]." (R. 53 at ¶ 81 (emphasis in original); *see* R. 77 at 10.)

Defendants argue that the "incremental window of opportunity data gathered on non-human primates in the GA project" was not *conceived* during the project "since the pleadings establish that [Defendants] presented the concept to Plaintiff in [Defendants'] September 2009 Grant Application." (R. 72 at 17–18.) "An inventor need not know that his invention will work for conception to be complete." *Univ. of Pittsburgh of Commonwealth Sys. of Higher Educ. v.*

Hedrick, 573 F.3d 1290, 1298 (Fed. Cir. 2009); *see also Burroughs*, 40 F.3d at 1228 ("[A]n inventor need not know that his invention will work for conception to be complete."). Instead, "[h]e need only show that he had the complete mental picture and could describe it with particularity; the discovery that the invention actually works is part of its reduction to practice." *Hedrick*, 573 F.3d at 1298. Accordingly, the fact that the GA study bolstered the case for the potential efficacy of using systemic delivery of AAV9 to treat SMA in humans does not mean that Defendants had not conceived of using systemic delivery of AAV9 to treat SMA before the GA project. Indeed, the complaint and its attachments show that Defendants had conceived of such a use before the GA project.[5]

Defendants also argue that Plaintiff's allegations "manifestly defeat, as a matter of law, any finding that the incremental window of opportunity data in non-newborn non-human primates meets the test for reduction to practice. (R. 72 at 20.) The Court agrees.

As noted above, actual reduction to practice requires that the inventor "determine[] that the invention would work for its intended purpose." *Teva*, 661 F.3d at 1383; *see also Intellect Wireless, Inc. v. HTC Corp.*, 910 F. Supp. 2d 1056, 1060 (N.D. Ill. 2012). Reduction to practice does not, however, require that the invention "be in a commercially satisfactory stage of development." *Scott v. Finney*, 34 F.3d 1058, 1061 (Fed. Cir. 1994); *see also Skycam, LLC v.*

[5] To support its argument that an invention was "conceived" during the GA project, Plaintiff cites *Burroughs Wellcome Co. v. Barr Labs.*, 40 F.3d 1223, 1229 (Fed. Cir. 1994), for the proposition that "[a] conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's invention that it is not yet a definite and permanent reflection of the complete idea as it will be used in practice." (R. 77 at 10.) This portion of *Burroughs* does not describe the current case. The passage Plaintiff cites refers to circumstances where "the idea [for the invention] is in constant flux," because such an idea "is not definite and permanent." *Burroughs*, 40 F.3d at 1229. Such a situation arises, for example, when through trial and error, an inventor at last learns the chemical structure of a chemical compound. *Id.* Before learning the chemical structure through experimentation, the inventor has not "conceived" of the chemical substance. *Id.* Here, in contrast, Plaintiff allege that Defendants knew before the GA project how to systemically deliver AAV9 for the purpose of transducing motor neurons. The question remained, however, to what extent this delivery technology would be successful as a potential treatment for SMA. That this question persisted at the time of the GA does not preclude "conception." *See id.* at 1228.

Bennett, 900 F. Supp. 2d 1264, 1278 (N.D. Okla. 2012); *Diodem, LLC v. Lumenis Inc.*, No. CV03-2142 GAF (RCx), 2005 WL 6225364, at *4 (C.D. Cal. Sept. 15, 2005). Moreover, an inventor need not demonstrate successful testing on humans to reduce to practice an invention ultimately intended for human use. *See Scott*, 34 F.3d at 1063 ("The Board erroneously suggested that a showing of reduction to practice requires human testing in actual use circumstances for a period of time."); *see also Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996) (explaining that an inventor showed reduction to practice even though he used a test that did not replicate the conditions of actual use because he used catheters that he knew would be too brittle in humans but could be replaced "by simple substitution of soft, biocompatible material"). Instead, reduction to practice requires "only a reasonable showing that the invention will work to overcome the problem it addresses." *Scott*, 34 F.3d at 1063. An inventor may demonstrate this through testing, which "need not show utility beyond a possibility of failure, but only utility beyond a probability of failure." *Id.* at 1062; *see also Boston Sci. Corp. v. Johnson & Johnson*, 550 F. Supp. 1102, 1112–13 (N.D. Cal. 2008). "The inquiry is not what kind of test was conducted, but whether the test conducted showed that the invention would work as intended in its contemplated use." *Id.* (quoting *E. Rotorcraft Corp. v. United States*, 384 F.2d 429, 431 (Ct. Cl. 1967)); *see also Teva*, 661 F.3d at 1383 (explaining that to establish a reduction to practice, the inventor must determine the invention would work for its intended purpose); *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery*, 514 F. Supp. 2d 351, 359 (D. Conn. 2007) ("[W]hile '[i]t is not necessary for testing to have proceeded to the point where the device is ready for commercialization in order to have an actual reduction to practice, . . . there must be a relationship between the test conditions and the intended functional setting . . . and the tests must prove that the invention will perform satisfactorily in the intended functional setting."

(first, second, and third alterations in original) (quoting *Koval v. Bodenschatz*, 463 F.2d 442, 447 (C.C.P.A. 1972))).[6] The issue of reduction to practice presents a "question[] of law predicated on subsidiary factual findings." *Singh v. Brake*, 317 F.3d 1334, 1340 (Fed. Cir. 2003); *see also Johns Hopkins Univ. v. 454 Life Scis. Corp.*, No. 13-1853-LPS, 2017 WL 382236, at *21 (D. Del. Jan. 26, 2017).

Based on the complaint and its attachments, the Court concludes that the GA-project discovery that systemic delivery of AAV9 achieved motor neuron transduction in non-newborn primates goes to the question of commercial viability of an SMA treatment rather than the question of whether Defendants reduced the technology to practice during the GA. While pre-GA studies showed motor neuron transduction in mice "progressive[ly] decline[d]" during the first ten days of life, they demonstrated extensive neuronal transduction in newborn mice and some transduction in older mice. (R. 53, E-3 at 1972.) Indeed, pre-GA studies resulted in "near-complete rescue" of newborn mice. (*Id.* at ¶ 47.) Moreover, an article attached to the complaint indicates (1) that Type 1 SMA is the most common form of SMA in humans and (2) that the "SMN gene delivery studies were performed in a mouse model that closely resembles type 1 patients and therefore support[] a trial within those patients." (*Id.*, Ex. D-3 at 1976.)[7]

While the pre-GA concerns about the window of opportunity for treatment may have created doubts about the commercial viability of systemic administration of AAV9—as success might require treatment before diagnosis as a prophylactic measure or the use of some sort of

[6] Defendants quote *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996), for the proposition that "[i]n the pharmaceutical arts, [the Federal Circuit] has long held that practical utility may be shown by adequate evidence of any pharmacological activity." (R. 72 at 18.) The *Fujikawa* court, however, made clear that this is true "only when the count does not recite a particular utility." 93 F.3d at 1564 n.4. When a particular utility is at issue, "practical utility requires an adequate showing of the recited utility." *Id.*

[7] The article goes on to say that "because gene delivery to motor neurons can be accomplished at later time points in higher species, it gives hope for later trials in less severe patients" with other types of SMA. (R. 53, Ex. D-3 at 1976.)

SMA screening technology—pre-GA studies established that the systemic administration of AAV9 could achieve motor neuron transduction and rescue newborn mice. Additionally, Plaintiff's attachments to the complaint demonstrate that SMN gene delivery studies in mice supported human trials in type-1 SMA patients. In short, while pre-GA studies did not necessarily show that the systemic treatment technology was full-proof or did not require additional investigation before commercial use in humans, the studies demonstrated the technology's "utility beyond a probability of failure" for motor neuron transduction and SMA treatment. *Scott*, 34 F.3d at 1062. Establishing commercial usefulness is unnecessary—a new data point regarding a pre-existing technology that helps researchers take a step forward on the long road to commercial viability does not constitute a reduction to practice. *See id.* ("Testing for full safety and effectiveness . . . is more properly left to the Food and Drug Administration (FDA)."). The Court therefore dismisses Plaintiff's claim for breach of the GA contract.

2. The RCA

Defendants argue that "Plaintiff's own pleading also defeats its claim that the use of the Trendelenburg position in the RCA Project was 'conceived' in that project." (R. 72 at 22 (citing various attachments from Plaintiff's complaint showing that the Trendelenburg position was conceived long before the RCA)). Plaintiff, however, does not dispute that the Trendelenburg position existed before the RCA project. Instead, Plaintiff claims that the "invention" in question is pairing the Trendelenburg position with the intrathecal administration of AAV9. (R. 77 at 12.)

With respect to this claim, Defendants contend that "[i]t is no answer for Plaintiff to point to the *combination* of such an obvious and well-known technique applicable to intrathecal treatment generally, and the intrathecal administration of the AAV9 SMN Delivery Technology specifically." (R. 72 at 23 (emphasis in original).) Defendants argue that Plaintiff fails to plead

an "invention" because the RCA requires that an "invention" be "potentially patentable," and "[t]he mere application of a known technique to a piece of prior art ready for the improvement' precludes patentability." (*id.* (quoting *Caddy Prods., Inc.*).) To support this argument, Defendants cite two attachments to Plaintiff's complaint that indicate that the Trendelenburg position "is a routine procedure when performing CT myelograms in human subjects," (*id.* at 22 (quoting R. 53, Ex. H at ¶ 0077)), and that the position was "[a] commonly used method to ensure proper spreading of small molecule drugs and anesthetics through the [cerebrospinal fluid]," (*id.* (quoting R. 53, Ex. I at 482)).

Plaintiff responds that the pleadings do not establish that anyone used the Trendelenburg position in conjunction with the intrathecal administration of AAV9, which is neither a small molecule drug nor an anesthetic, but instead a viral vector. (R. 77 at 12.) The question then is whether Defendants are correct that combining the Trendelenburg position with the intrathecal administration of AAV9 is not potentially patentable. The answer to this question comes down to an obviousness inquiry under § 103.

Patent claims are invalid for obviousness "when the differences between the subject matter sought to be patented and the prior art are such that the invention would have been obvious to a person having ordinary skill in the art at the time the invention was made." *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 118 F. Supp. 3d 1022, 1028 (N.D. Ill. 2015) (citing 35 U.S.C. § 103(a) (2006)); *see Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1333 (Fed. Cir. 2015). Obviousness is ultimately a question of law although it is premised on underlying findings of fact, "including the scope and content of the prior art, the differences between the claimed invention and the prior art, and the level of ordinary skill in the pertinent art." *Spectrum*, 802 F.3d at 1333; *see also Bayer*, 2016 WL 4179087, at *14. Secondary

considerations such as commercial success, long felt but unsolved needs, or failure of others are also relevant. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc).

Parties seeking to demonstrate obviousness must show that "a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014). The presence or absence of a motivation to combine prior art references is a factual inquiry, as is the question of the presence or absence of a reasonable expectation of success. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2014). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Instead, when there is an obvious combination of elements that "leads to . . . anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *Id.* at 421.

Here, the pleadings do not establish on their face that "a skilled artisan" would have had (1) reason to combine the Trendelenburg position with intrathecal administration of AAV9, and (2) a reasonable chance of success from such a combination. This issue is a factual matter that the Court cannot resolve at this stage. Moreover, Plaintiff attached the '065 patent application to its Amended Complaint that Defendants filed in which they listed as a claim the intrathecal delivery of AAV9 using the Trendelenburg position. (R. 53, Ex. H at 23.) Accordingly, given the outstanding factual questions that the Court cannot resolve at the motion to dismiss stage as well as Defendants' patent application that appears to claim as nonobvious precisely what they

contend in this litigation is obvious, the Court denies Defendants' motion to dismiss with respect to Plaintiff's claim for breach of the RCA.[8]

II. Motion to Strike

A. Legal Standard

Federal Rule of Civil Procedure 12(f) provides that a district court may strike from a pleading "any redundant, immaterial, impertinent, or scandalous material." Motions to strike are usually disfavored. *Top Tobacco, L.P. v. Good Times USA, LLC*, No.16-cv-4292, 2017 WL 395698, at *2 (N.D. Ill. Jan. 30, 2017) (citing *Heller Fin., Inc. v. Midwhey Powder Co.*, 883 F.2d 1286, 1294 (7th Cir.1989)); *Otero v. Dart*, No. 12 C 3148, 2012 WL 5077727, at *2 (N.D. Ill. Oct. 18, 2012). Motions to strike are appropriate, however, if they serve to streamline the ligiation. *See Heller*, 883 F.2d at 1294; *Top Tobacco*, 2017 WL 395698, at *2; *Otero*, 2012 WL 5077727, at *2, *6 (striking "all references to equitable relief from the Complaint"). Courts may grant a motion to strike where the allegations at issue are "so unrelated to the party's claims as to be devoid of merit and unworthy of any consideration" as well as unduly prejudicial. *See Causay v. Wells Fargo Bank, N.A.*, No. 16-cv-7398, 2016 WL 7188167, at *2 (N.D. Ill. Dec. 12, 2016); *Stop Ill. Health Care Fraud, LLC v. Sayeed*, No. 12 cv 9306, 2016 WL 4479542, at *3 (N.D. Ill. Aug. 26, 2016) *Essex Ins. Co. v. Vill. of Oak Lawn*, 14-cv-04572, 2015 WL 1942937, at *5 (N.D. Ill. Apr. 28, 2015). District courts enjoy considerable discretion in resolving a motion to strike. *See Delta Consulting*, 554 F.3d at 1141; *Essex Ins.*, 2015 WL 1942937, at *5.

[8] Defendants also argue that, because the RCA says that Plaintiff shall have not any claim or right to preexisting inventions, Plaintiff cannot allege breach of contract based on combining the Trendelenburg position with intrathecal administration of the AAV9 SMN delivery technology. (80, Defs.' Reply, at 12–13.) Although the RCA—as well as the nonobviousness requirement built into the contract—precludes Plaintiff from claiming rights to a preexisting invention, it does not prevent Plaintiff from gaining rights to a new invention based on the novel, nonobvious combination of two prior art references. Defendants' argument therefore fails.

The moving party carries the burden to show entitlement to its requested relief. *See Causay*, 2016 WL 7188167, at *2; *Otero*, 2012 WL 5077727, at *2.

B. Discussion

Defendants ask that the Court strike Plaintiff's requested relief in the form of AveXis stock under the GA and RCA. Because the Court has dismissed Plaintiff's GA claims, it need not consider Defendants' motion to strike Plaintiff's request for relief under that contract. With respect to the RCA, the Court denies Defendants' motion to strike.

Under the RCA, Defendants agreed to "pay [Plaintiff] five percent (5%) of all royalty[and] other consideration up to a cap of $300,000, received by the [Defendants] from licenses or sublicenses to any of the Inventions solely or jointly owned by [Defendants],"[9] (R. 53, Ex. B at 3.) Defendants argue that the "cash cap has no meaning unless 'royalty and other consideration' was limited to those paid in cash," and therefore Plaintiff is not entitled to any stock Plaintiff received under the RCA. (R. 72 at 25.) Plaintiff argues that that the term "cash cap" "has an obvious meaning—the dollar value of the non-cash royalty or other consideration." (R. 77 at 15.) While the Court takes no position on whether Plaintiff is indeed correct, the RCA could potentially bear that construction. Striking Plaintiff's requested relief at this stage is unwarranted. *See Ronald McDonald House Charities of Chicagoland & Nw. Ind., Inc. v. Winning Charities Ill., LLC*, No.13 CV 1430, 2014 WL 1480750, at *3 (N.D. Ill. Mar. 24, 2014); *see also Wabash Castings, Inc. v. Fuji Mach. Am. Corp.*, No. 16 C 3629, 2016 WL 6432586, at *3 (N.D. Ill. Oct. 31, 2016) ("Courts are reluctant to construe contracts at the motion to dismiss stage, especially if the contract language is ambiguous.").

[9] The parties later raised the cash cap to $750,000. (R. 53, Ex. B at Ex. B-1.)

CONCLUSION

For the foregoing reasons, the Court (1) grants in part and denies in part Defendants' motion to dismiss, and (2) denies Defendants' motion to strike as it relates to Plaintiff's remaining claim.

Dated: February 13, 2017

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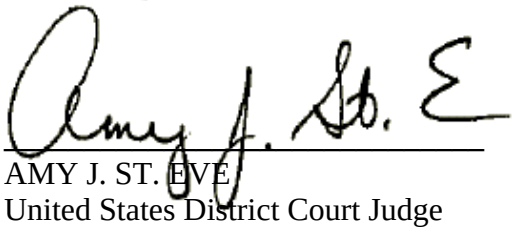

AMY J. ST. EVE
United States District Court Judge