UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SAHEL ONCOLOGY, LLC

Plaintiff,

v.

STA PHARMACEUTICAL HONG KONG LIMITED,

Defendant.

Case No. 23-cv-01458-BAS-DDL

ORDER DENYING PLAINTIFF'S APPLICATION FOR A TEMPORARY RESTRAINING ORDER (ECF No. 5)

Presently before the Court is Plaintiff Sahel Oncology's Application for a Temporary Restraining Order ("TRO"). (TRO Appl., ECF No. 5.) Sahel asks the Court to command Defendant STA Pharmaceutical to produce an experimental cancer drug for a dying seventeen-year-old patient. (*Id.*) STA opposes, arguing the drug's key ingredient is not commercially available, the drug lacks governmental approval, and the requested relief disregards the parties' contract. (Opp'n, ECF No. 8.) The Court heard oral argument.

The Court recognizes the gravity of the situation. It appears that Sahel made promises to its ailing patient that the drug would be ready for use, and STA could have managed expectations better during the negotiation of the parties' contract. Even so, Sahel does not meet the demanding burden for an emergency injunction. Therefore, for the following reasons, the Court denies Sahel's Application for a Temporary Restraining Order.

I. BACKGROUND

Sahel's Drug. Sahel Oncology "specializes in developing and producing cutting edge cancer drug treatments." (Nezami Decl. ¶ 4, ECF No. 5-1.) Sahel's principal is a California-licensed doctor "whose practice includes treating patients with advanced stage four cancer who have failed all other conventional methods." (*Id.* ¶ 2.)

Sahel is developing a cancer treatment that uses quercetin as the drug substance. (Nezami Decl. ¶ 6, ECF No. 5-1.) Quercetin is a "yellow crystalline pigment" sourced from plants.[1] Sahel wants to use this experimental drug "to treat a 17-year-old cancer patient who has failed all standard treatment modalities." (*Id.* ¶ 7.) "The cancer has traveled to his brain, and he recently became blind in one eye." (*Id.* ¶ 28.) Sahel is therefore trying to formulate and obtain its drug as soon as possible. (*See id.*)

Project Agreement. Sahel needs someone to manufacture the drug, which is how STA Pharmaceutical enters the picture. STA offers development and manufacturing services to life science organizations like Sahel. (Faust Decl. ¶¶ 2–3, ECF No. 8-1.) In early June 2023, the parties executed a Project Agreement after negotiating over a four-week period. (Proposal for Sahel Oncology LLC, STA Project ID: SAHEL-20230104.V5 ("Project Agreement"), Faust Decl. ¶ 4, Ex. A, ECF No. 8-5.[2])

The twenty-one-page Project Agreement is filled with timelines, assumptions, and industry terms. Two promises are at issue here. First, STA agrees to "source and purchase the required quantity of [quercetin]" with the necessary safety and quality certifications. (Project Agreement 6–7.) The parties estimated sourcing quercetin would take two months, and Sahel agrees to pay for the substance at "actual cost." (*Id.* 4.) The contract

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[1] *Quercetin*, Merriam-Webster, https://www.merriam-webster.com/dictionary/quercetin (last visited Sept. 14, 2023). It bears emphasizing that Sahel's use of this substance is experimental; the effectiveness of quercetin is an open question. (*See* Nezami Decl. ¶ 6, ECF No. 5-1.) *See* Quercetin, Purported Benefits, Side Effects & More, Memorial Sloan Kettering Cancer Center, https://www.mskcc.org/cancer-care/integrative-medicine/herbs/quercetin (last visited Sept. 14, 2023) ("Presently, considerable laboratory data support the concept of quercetin as an anticancer compound, but it is still unclear from clinical trials whether this effect occurs in the human body.").

[2] The Project Agreement has several sets of page numbers. The Court cites to the imprinted "Ex A" numbers in the center of the agreement's footer.

makes clear, however, that if a material like quercetin "is not commercially available," then Sahel can either supply the material at its expense or amend the agreement "to permit the use of a commercially available substitute." (*Id.* 15.)

As for the second promise, STA agrees to manufacture Sahel's drug in two phases. Initially, STA will produce a toxicology and engineering batch of the drug, which will be "non-GMP" and used for "microbiological test methods verification and defective rate information." (Project Agreement 4.) Hence, there is no suggestion in the contract that this first batch will be used in humans. STA agrees to later produce a "GMP" drug batch after using a "Class C clean room for solution preparation" and taking other precautions. (*Id.* 5, 9.) In contrast to the first batch, this second drug batch will be used for "clinical supplies." (*Id.* 5.)

The Court briefly touches upon the Project Agreement's use of "GMP" and "non-GMP" when describing the manufacturing services. The contract incorporates the Food, Drug, and Cosmetic Act's good manufacturing practices ("GMP") for producing drugs. (*See* Project Agreement 7 (defining GMP to include "current good manufacturing practices and regulations . . . that are promulgated by any competent government authority").) These GMP requirements assure that a drug meets safety criteria "and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B). If a drug is not made under GMP conditions, then the law deems it "adulterated." *Id.* A full discussion of this topic, including any limited exceptions, is beyond the scope of this emergency application, but it is enough to note that a drug manufacturer like STA must be concerned with GMP requirements when it knows a drug will be used in humans. *See, e.g.*, *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 895 (9th Cir. 2017).

Disputes. After executing the Project Agreement, Sahel paid a six-figure sum to start the work, but the parties quickly ran into two complications. First, Sahel wanted STA to make a batch of the drug that could be used on its ailing client as soon as possible, including if that meant skipping the toxicology and engineering run. (*See* Faust Decl. ¶ 13;

see also Nazmi Decl. ¶ 19.) *See Oakland Trib., Inc. v. Chron. Pub. Co.*, 762 F.2d 1374, 1377 (9th Cir. 1985) (providing the court has discretion to assign weight to declarants' statements when considering preliminary relief). Second, STA was unable to find GMP-grade quercetin—that is, quercetin with the necessary purity and compliance certificates to be injected into humans. (Faust Decl. ¶ 18.) *See* 21 U.S.C. § 351(a)(2)(B) (requiring GMP for pharmaceutical drugs and referencing standards recognized in the United States Pharmacopeia ("USP")); *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008) (noting the USP is "an independent compendium of drug standards whose authority is recognized by reference in federal law").

As a workaround, STA believed it could purchase lower, nutraceutical-grade quercetin and purify it inhouse under GMP conditions. (Faust Decl. ¶¶ 18–20.) STA took the position, however, that this work exceeded its obligations under the contract and would necessitate a change order with additional costs for Sahel. (*Id.* ¶ 29, Ex. K.) Sahel disagreed, taking the position that STA is required to conduct this work under the Project Agreement as part of its sourcing obligations. (Nezami Decl. ¶ 21.)

From there, the parties' relationship continued to deteriorate, and no further work has been performed. On August 9, 2023, Sahel filed this action against STA for breach of contract and fraud, claiming STA broke its promises and made fraudulent representations during the contract negotiations. (Compl. ¶¶ 23–38, ECF No. 1.)

II. ANALYSIS

Sahel seeks emergency relief requiring STA to: (1) "immediately take action to source and acquire" the quercetin for producing Sahel's drug; and (2) "manufacture and deliver" enough of the drug "to allow for treatment of Sahel's terminally ill patients." (Proposed TRO, ECF No. 5-3.) Rule 65(b) governs the issuance of a temporary restraining order. Fed. R. Civ. P. 65(b). The standard for a TRO is identical to the standard for a preliminary injunction. *See Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 839 n.7 (9th Cir. 2001). The moving party must show: (1) a likelihood of success on the merits; (2) a likelihood of irreparable harm to the moving party in the absence of

preliminary relief; (3) that the balance of equities tips in favor of the moving party; and (4) that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Generally, a TRO is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* at 22.

Sahel's "burden here is doubly demanding," however, because it is seeking "a mandatory injunction." *See Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) (en banc) (McKeown, J.). Sahel's proposed injunction is mandatory because it requires STA "to take affirmative action"—source the necessary ingredient and manufacture the experimental drug immediately. *See id.*[3] "The district court should deny such relief unless the facts and law clearly favor the moving party. In plain terms, mandatory injunctions should not issue in doubtful cases." *Id.* (cleaned up) (quoting *Anderson*, 612 F.2d at 1114; and *Park Vill. Apartment Tenants Ass'n v. Mortimer Howard Trust*, 636 F.3d 1150, 1160 (9th Cir. 2011)).

A. Success on the Merits

Breach of Contract. To obtain the requested relief on its contract claim, Sahel will have to demonstrate STA breached the Project Agreement and Sahel is entitled to specific performance. *See Darbun Enterprises, Inc. v. San Fernando Cmty. Hosp.*, 239 Cal. App. 4th 399, 409 (2015); *see also Real Est. Analytics, LLC v. Vallas*, 160 Cal. App. 4th 463, 472 (2008) (noting specific performance requires an inadequate legal remedy and

[3] The Court rejects the notion that the injunction is not mandatory because it simply returns the parties to their pre-dispute contractual relationship. *Cf. N.D. ex rel. parents acting as guardians ad litem v. Hawaii Dep't of Educ.*, 600 F.3d 1104, 1112 (9th Cir. 2010) (reasoning that while furlough contracts for educators had been signed when the lawsuit was filed, no furlough days had been taken yet under the contracts, so the status quo was no furlough days). When the dispute arose, STA had not located pharmaceutical-grade quercetin and was not yet obligated to begin manufacturing the experimental drug for use in humans. Ordering STA to do so now would go "well beyond simply maintaining the status quo [p]endente lite" and what was required by the definite terms of the Project Agreement. *See Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 879 (9th Cir. 2009) (alteration in original) (quoting *Anderson v. United States*, 612 F.2d 1112, 1114 (9th Cir. 1980)).

contractual terms that are "sufficiently definite to enable the court to know what it is to enforce").[4]

Given the limited record, there are three hurdles to Sahel's success on this claim. First, the terms of the written contract do not require STA to immediately source the quercetin at all costs. Instead, as mentioned, the Project Agreement provides that if a material like quercetin "is not commercially available," then Sahel can either supply the material at its expense or amend the agreement "to permit the use of a commercially available substitute." (Project Agreement 15.) STA demonstrates there is no commercially available quercetin that satisfies the requirements for manufacturing drugs that will be used to treat patients. Consequently, if the Court ordered specific performance through an injunction, the relief would defy the contract's terms. *See Golden W. Baseball Co. v. City of Anaheim*, 25 Cal. App. 4th 11, 49 (1994) ("[S]pecific performance is a *remedy* for breach of contract, a cause of action which requires proof the contract was breached.").

Along the same lines, the Project Agreement does not require STA to immediately manufacture a drug batch for human injection. The contract includes many prerequisite steps, including a toxicology and engineering batch that must be completed before the GMP batch. (Project Agreement 4.) Plus, although the parties offer competing interpretations of the agreement's timeline, it makes no difference. The contract notes the timeline is "tentative," with this addition:

> Project planning in this timeline is based on resource availability at the time of writing quotation and contingent on timely receipt of the work order and materials to be supplied by Sahel Oncology LLC. A more detailed timeline

[4] The Project Agreement includes a choice-of-law clause opting for Delaware law. (Project Agreement 19.) Both sides, however, cite California law for Sahel's claims. (TRO Appl. 13:14–21, 15:26–5; Opp'n 16:15–18:17.) Further, under the appropriate choice-of-law analysis, the Court declines to apply Delaware law because the Court discerns no substantial relationship between Delaware and the parties or their transaction or any other reasonable basis for applying Delaware law. Sahel is a California limited liability company that is only a citizen of California, and STA is a citizen of Hong Kong, with its principal place of business also in Hong Kong. (Compl. ¶ 4) *See Hatfield v. Halifax PLC*, 564 F.3d 1177, 1182 (9th Cir. 2009) (providing the court applies the choice-of-law rules of the forum state); *Nedlloyd Lines B.V. v. Superior Ct.*, 3 Cal. 4th 459, 465 (1992) (setting forth California's test for enforcing contractual choice-of-law clauses).

> with key dates/milestones will be discussed with Sahel Oncology LLC after acceptance of quotation.

(Project Agreement 12 (emphasis omitted).) Simply put, the plain terms of the contract do not require STA to skip steps or immediately manufacture the drug for human use.[5]

The second hurdle to Sahel's success on its contract claim is that any changes made to the deal after the Project Agreement was signed were not reduced to writing. Sahel contends STA agreed to skip the toxicology and engineering batch and quickly produce a GMP batch during the parties' kick-off meeting. Yet, no amendment to the contract was signed.

It is true that "a contract in writing may be modified by an oral agreement supported by new consideration," but only if the contract does not expressly provide otherwise. Cal. Civ. Code § 1698(c). The Project Agreement contains such an express prohibition: "No modification or waiver of any term of this Agreement or any other form of amendment to this Agreement will be binding unless made expressly in writing and signed by both Parties." (Project Agreement 19.) Hence, Sahel cannot show specific performance based on an oral agreement is appropriate. *See, e.g.*, *Marani v. Jackson*, 183 Cal. App. 3d 695, 704 (1986).[6]

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[5] Sahel relies on *Bionpharma Inc. v. CoreRx, Inc.*, 582 F. Supp. 3d 167 (S.D.N.Y. 2022), a case between a generic drug company and a manufacturer, but that case is readily distinguishable. There, the manufacturer claimed it could not supply the generic drug product, but it did so only after the drug company rebuffed the manufacturer's request for more money. *Id.* at 177–78. Moreover, the manufacturer "refused to provide [the drug company] with a reason for its inability to supply the" drug "in accordance with" the parties' agreement, despite that the [drug company] was the one who had the responsibility for sourcing all active ingredients. *Id.* at 170–172. The parties' Master Manufacturing Supply Agreement also required the manufacturer to "'accept all Firm Orders for a particular calendar month' with few exceptions." *Id.* at 171. Thus, in this case, the Court is confronted with both different contract terms and a different backdrop—the production of an experimental drug instead of a generic one.

[6] A no oral-modification clause is not insurmountable, but Sahel does not show why the clause should not apply. *See, e.g.*, *Biren v. Equal. Emergency Med. Grp., Inc.*, 102 Cal. App. 4th 125, 141 (2002) (reasoning amendment to written approval requirement could be inferred based on past oral actions and where one party's behavior showed an intent to treat the written approval requirement "as if it never existed").

The third hurdle to Sahel's success on the breach of contract claim is California's parol evidence rule. Sahel introduces communications from the parties' negotiations, which suggest that STA agreed to manufacture the drug quickly and would have no issue sourcing the quercetin. The parol evidence rule, however, "provides that when parties enter an integrated written agreement, extrinsic evidence may not be relied upon to alter or add to the terms of the writing." *Riverisland Cold Storage, Inc. v. Fresno-Madera Prod. Credit Assn.*, 55 Cal. 4th 1169, 1174 (2013). The Project Agreement is the "entire agreement between the" parties regarding manufacturing Sahel's drug and "supersedes all previous . . . communications[] and representations" between them. (Project Agreement 19.) Consequently, the writing is an "integrated agreement." *See Alling v. Universal Mfg. Corp.*, 5 Cal. App. 4th 1412, 1433 (1992). And the parol evidence rule prohibits Sahel's attempt to use communications from the parties' negotiations "to alter or add to the terms of the writing." *See Riverisland*, 55 Cal. 4th at 1174. Considering these hurdles, the Court will not order a mandatory injunction based on the breach of contract claim.[7]

Fraud. Sahel's fraud claim alleges STA made false representations while negotiating the Project Agreement, including that STA "had ready access to the [quercetin] necessary to manufacture the new drug" and could obtain the quercetin in "a short amount of time." (Compl. ¶ 31.) Further, Sahel claims it justifiably relied on these representations to enter into the Project Agreement, causing Sahel harm. (*Id.* ¶ 35.)

"An action for promissory fraud may lie where a defendant fraudulently induces the plaintiff to enter into a contract." *Lazar v. Superior Ct.*, 12 Cal. 4th 631, 638 (1996). The elements of promissory fraud include, among other things, "a promise made regarding a material fact without any intention of performing it" and "reasonable reliance by the promisee." *Rossberg v. Bank of Am., N.A.*, 219 Cal. App. 4th 1481, 1498 (2013). Further,

[7] The Court similarly concludes Sahel does not meet its doubly demanding burden to obtain specific performance of any other obligations in the Project Agreement, including provisions concerning project meetings or sharing information about the quercetin sourcing efforts. *See Garcia*, 786 F.3d at 740; *see also Real Est. Analytics*, 160 Cal. App. 4th at 472 (setting forth the requirements for specific performance).

the parol evidence rule cannot "be used as a shield to prevent the proof of fraud." *Riverisland*, 55 Cal. 4th at 1182 (quoting *Ferguson v. Koch*, 204 Cal. 342, 347 (1928)).

The Court finds Sahel's fraud claim does not support a mandatory injunction. Although the Court is not foreclosing any tort liability for STA, the facts in the record do not "clearly favor" Sahel's position. *See Garcia*, 786 F.3d at 740. Sahel produces evidence showing a STA employee stated during negotiations that STA "can target to produce the tox batch [of Sahel's drug] within 2-3M." (Nezami Decl. Ex. 1.) But the same email notes STA's project manager "will work with the team to generate a timetable for [a] deep discussion during the kick-off meeting." (*Id.*) The Project Agreement contains similar, flexible timeline language excerpted above. (Project Agreement 12.) This showing is insufficient to meet the success on the merits requirement for promissory fraud. *See Riverisland*, 55 Cal. 4th at 1183 (emphasizing "that the intent element of promissory fraud entails more than proof of an unkept promise or mere failure of performance" and "promissory fraud, like all forms of fraud, requires a showing of justifiable reliance on the defendant's misrepresentation"); *see also Marlyn Nutraceuticals*, 571 F.3d at 879 (noting mandatory injunctions should not be issued "in doubtful cases").

In short, the Court finds Sahel does not meet its burden to show "that the law and facts clearly favor" Sahel succeeding on its claims for breach of contract and fraud. *See Garcia*, 786 F.3d at 740.

B. Irreparable Harm

Although the success on the merits prong resolves Sahel's request for emergency relief, the Court addresses irreparable harm to remove any uncertainty. Sahel argues it faces irreparable harm for three reasons: (1) its patient could suffer, (2) Sahel's reputation will be damaged, and (3) the Project Agreement limits Sahel's damages. (TRO Appl. 9:8–12:5.)

Sahel's first argument resonates, but Sahel's ailing client is neither the plaintiff seeking preliminary relief nor a party to the contract with STA. (*See* Project Agreement 19 ("The provisions of this Agreement are for the sole benefit for the Parties.").) *See*

Garcia, 786 F.3d at 744 ("The relevant harm is the harm that . . . occurs to the parties' legal interests[.]" (quoting *Salinger v. Colting,* 607 F.3d 68, 81 & n. 9 (2d Cir. 2010))); *see also, e.g.*, *M.R. v. Dreyfus*, 697 F.3d 706, 726–33 (9th Cir. 2012) (reasoning plaintiff patients showed likelihood of irreparable harm where they submitted evidence showing challenged state Medicaid regulation would harm their mental or physical health).

As to Sahel's second point, damage to reputation and goodwill can constitute irreparable harm. *Herb Reed Enterprises, LLC v. Fla. Ent. Mgmt., Inc.*, 736 F.3d 1239, 1250 (9th Cir. 2013). Sahel, though, does not carry its demanding burden. (*See* Nezami Decl. ¶ 14.) The evidence indicates a key ingredient for manufacturing Sahel's experimental drug for human use is not commercially available. Without a stronger showing from Sahel, the Court is unpersuaded that a delay in manufacturing and obtaining the drug in these circumstances is very likely to result in harm to Sahel's reputation and goodwill.

Sahel's final point on irreparable harm concerns the Project Agreement's clause that limits STA's liability. Both parties point to nonbinding authority that could support their respective positions. *See Bennett v. Isagenix Int'l, LLC*, No. CV-23-01061-PHX-DGC, 2023 WL 4562605, at *5 (D. Ariz. July 17, 2023) (collecting cases on this issue, but concluding a likelihood of irreparable harm existed because plaintiffs "appear likely to show that they were required to waive their consequential damages" after receiving the contract terms "on a take-it-or-leave-it basis"); *see also Phibro Biodigester, LLC v. Murphy-Brown, LLC*, No. 4:22-CV-00050-RJS-PK, 2022 WL 17243727, at *10 (D. Utah Nov. 23, 2022) ("It would be antithetical to the freedom of contract if courts worked around the parties' bargained-for limitations to grant extraordinary relief in equity based on those same negotiated limitations."). Given that the outcome on this issue is murky, Sahel does not show the law "clearly favors" its position. *See Garcia*, 786 F.3d at 740.

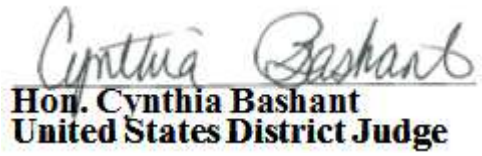
Overall, the Court finds Sahel does not meet its burden on the irreparable harm factor to obtain emergency relief in the form of a mandatory injunction.

III. CONCLUSION

In light of the foregoing, the Court **DENIES** Plaintiff Sahel Oncology's Application for a Temporary Restraining Order (ECF No. 5).

IT IS SO ORDERED.

DATED: September 14, 2023



Hon. Cynthia Bashant
United States District Judge