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MEMORANDUM OPINION AND ORDER

Introduction

The above-entitled matter came before the undersigned United States District Judge on October 25, 2001, pursuant to Defendant Amgen, Inc.'s ("Amgen") Motion for Summary Judgment, Plaintiffs Techne Corporation and Research and Diagnostic Systems, Inc. ("Techne and R&D") Motion for Summary Judgment on Amgen's Counterclaim, and Defendant Amgen's Motion to Strike. By their Complaint, Plaintiffs seek declaratory judgment that they are not obligated to pay any amount due on certain Amgen invoices, and, in addition, Plaintiffs allege Unfair Competition and Breach of Contract. For the reasons set forth below, the Court grants Defendant's Motion for Summary Judgment, denies Plaintiffs' Motion for Summary Judgment on Defendant's Counterclaim, and denies as moot Defendant's Motion to Strike.

Background

Defendant Amgen is a biotechnology company that manufactures EPOGEN®, human erythropoietin ("EPO") produced by recombinant DNA techniques. EPOGEN® has been used successfully to treat anemia in dialysis patients, without the use of blood transfusions. Amgen holds patents for EPOGEN®, the DNA from which EPOGEN was produced, and other EPO inventions.

Prior to receiving the EPO patents and thereafter, Amgen also sold two non-therapeutic forms of EPO in the research market through its Biologicals Business Unit: (1) a highly concentrated form ("Ultrapure EPO") and (2) a less concentrated, tissue culture garde form ("TC EPO"). In or around 1987, Amgen established a Diagnostics Business Unit in Boulder, Colorado, that was responsible for developing and marketing diagnostic test kits used to detect and measure specific proteins in research and diagnostic applications. By 1991, the Diagnostics Business Unit had begun marketing the CLINIGEN® EPO diagnostic kit used to measure levels of EPO. In order to produce the CLINIGEN® EPO kit, the Diagnostic Business Unit used Ultrapure EPO.

Also in 1991, Amgen decided to sell both the Biologicals and Diagnostics Business Units. Plaintiff R&D, another biotechnology corporation and a wholly-owned subsidiary of Plaintiff Techne, submitted a proposal to purchase both Amgen units. Amgen selected R&D to be the purchaser, and the two parties negotiated a purchase and sale agreement. On August 19, 1991, the parties executed two companion agreements-a Purchase and Sale Agreement and a Supply Agreement.

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By the Purchase and Sale Agreement, Amgen agreed to transfer the assets of both business units which included, in part, an inventory of EPO. Amgen lists the acquired inventory as: (1) 149 mg EPO Bulk, i.e., Ultrapure EPO, from the Diagnostics Unit; (2) 3mgs Erythropoietin; and (3) 4.3 mgs TC EPO from the Biologicals Unit, for a total of 156.3 mgs EPO. However, Plaintiffs list the acquired EPO inventory as: (1) 149 mg Ultrapure EPO, from the Diagnostics Unit; and (2) 5.1 mg TC EPO; and (3) 3.1 mg Ultrapure EPO, from the Biologicals Unit, for a total of 152 mg Ultrapure EPO and 5.1 mg TC EPO. Under the terms of the Supply Agreement, Amgen also agreed to sell to R&D, for resale in the research market, six biological reagents, including Ultrapure EPO. The Supply Agreement set the price of \$230,265 per milligram of EPO, a 55% discount from Amgen's 1991 published prices for buyers in the research market. By the Supply Agreement, Amgen agreed to issue an invoice at the contract price, and R&D agreed to make payment at the contract price within 30 days of the invoice date. R&D acquired no rights to independently manufacture EPO. However, R&D intended to profit from the manufacture and sale of the CLINIGEN® EPO kit.

The parties agree that both Agreements are fully integrated and require any modification, amendment, or waiver to be in writing and executed by an officer of the waiving party. ¹ In addition, paragraph 18(e) of the Supply Agreement states that: "[I]n the event that either party shall on any occasion fail to perform any of the terms of this Agreement and the other party shall not enforce that term, the failure to enforce on that occasion shall not prevent enforcement upon any other occasion."

After the business units and the inventory were completely transferred, R&D attempted to set up the necessary purification columns to manufacture the CLINIGEN® EPO kit. To do so, R&D had to use Ultrapure EPO it acquired in the transfer. However, after two attempts, R&D was unsuccessful and requested the assistance of an Amgen representative. The third attempt was equally unsuccessful, and Plaintiffs maintain that the Amgen representative assured R&D that Amgen would replace the EPO lost in the process of setting up the columns, without additional cost to R&D. R&D maintains that it lost 34.7 mgs EPO by its three unsuccessful attempts.

From 1992 through 1999, R&D requested and Amgen sent numerous shipments of EPO. In general, the EPO requests were made by R&D's Dr. Monica Tsang to representatives in Amgen's Clinical Logistics Department, a unit managed by the former manager of the Diagnostics Business Unit. The Clinical Logistics Department was generally responsible for distributing EPO to researchers and doctors performing clinical studies, free of charge, pursuant to negotiated "collaborator contracts." As such, the Clinical Logistics Department did not have a practice of issuing invoices to its collaborators. R&D did not have a "collaborator contract" with Amgen during the relevant time period.

The procedure followed by the Amgen employees responding to R&D EPO requests was quite varied. Some shipments were specifically authorized by an Amgen vice president. The authority for other shipments was verified by contacting the Amgen Legal Department. On such occasions, a paralegal in the Legal Department would consult a contract database to be sure that a relevant contract

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existed, and, on at least one occasion, the actual Purchase Agreement was reviewed. On no occasion, however, did an employee of the Clinical Logistics Department submit an invoice along with the requested shipment of EPO.

The parties substantially agree on the amount and timing of the EPO shipments. However, they disagree as to when Amgen completed its shipments under the Purchase and Sale Agreement and began to make shipments under the Supply Agreement; and it is this disagreement that is central to the current dispute. The parties agree that from October 1991 through August 1996, Amgen made numerous shipments of both Ultrapure and TC EPO-2 in 1991, 3 in 1992, 3 in 1994, and 1 in 1995 through 1999. Amgen contends that the 1991 and 1992 shipments were made pursuant to the Purchase and Sale Agreement and that all subsequent shipments were made upon request by R&D. That said, however, Amgen maintains that its obligations under the Purchase and Sale Agreement and its alleged promise to replace the EPO lost during the recreation of the purification column were not completely satisfied until its last shipment in 1996. Amgen explains that in its review of the shipments to Techne, Amgen discovered that a varying concentration of EPO was sent in the earlier shipments, requiring a recalculation of actual EPO sent and thus adjusting when obligations were met under the Purchase and Sale Agreement and when the Supply Agreement kicked in. Amgen contends that the 1997, 1998, and 1999 shipments were made pursuant to the Supply Agreement, and that while it declines to seek payment for the 1997 shipment, it is entitled to payment for the shipments made in 1998 and 1999. Techne maintains, however, that Amgen completed the inventory transfer under the Purchase and Sale Agreement at the close of 1992, and that all subsequent shipments were made in replacement of the lost EPO or under some other course of performance other than the Supply Agreement. Techne argues that Amgen should not be allowed to recalculate satisfaction of the Purchase and Sale Agreement, when at the time of the early shipments, Amgen operated under the assumption that it was meeting its obligations to transfer EPO inventory.

In 1999, a R&D technical sales representative made three bulk sales of EPO to Alza Corporation, which subsequently merged with Johnson & Johnson, Amgen's largest competitor and licensee of Amgen EPO. R&D provided the EPO to Alza at a purchase price 95% less than retail value. The third sale to Alza was in the exact amount of the most recent shipment received from Amgen.

On April 7, 2000, Alza inquired about pursuing another bulk EPO purchase of 50 to 75 mg. In response to Alza's inquiry, the R&D sales representative wrote in his notes: "[Alza w]as most interested in the turn around time for us getting more material, could we obtain more from Amgen and is it confidential (how many times can we dip from this well)." On April 10, 2000, R&D requested 75 mgs EPO from Amgen. Amgen declined to fill the order.

Also in early April, R&D asked Amgen about the possibility of licensing an additional product. Amgen maintains that pursuant to this request, it reviewed the Purchase and Sale and Supply Agreements already in place and discovered that the 1998 and 1999 EPO shipments had occurred pursuant to the Supply Agreement, and thus payment was now due. On June 26, 2000, Amgen issued

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two invoices covering the 1998 and 1999 shipments in the amounts of \$13,060,630.80 and \$18,872,519.40, respectively. In October 2000, Amgen issued a Credit Memo in the amount of \$3,972,071.25, after determining that a lower concentration of EPO was sent in 1998. To date, R&D has remitted no payment, contending that the Supply Agreement was not in effect due to Amgen's failure to satisfy packaging requirements under the contract and its failure to issue timely invoices. To the contrary, Amgen maintains that the Supply Agreement remains in effect and covers the 1998 and 1999 shipments for which it now seeks the payment of \$27,961,078.95.

By their Complaint, Plaintiffs Techne and R&D seek declaratory judgment that the terms of the Supply Agreement do not apply to the 1998 and 1999 shipments, and further that Amgen is liable for breach of contract and unfair competition. By its Counterclaim, Defendant Amgen seeks the converse declaratory relief and also alleges breach of contract. The current motions before the Court are the Plaintiffs' motion for summary judgment on Defendant's counterclaim and Defendant's motion for summary judgment on the claims against it. Furthermore, Defendant seeks to strike certain exhibits from the affidavit of Plaintiffs' counsel, filed in opposition to Amgen's motion for summary judgment. The Court will address each motion in turn.

Discussion

1. Motion to Strike

Amgen seeks to strike Exhibits 1, 4, 6-11, and 25-27 attached to the Affidavit of Nathan Brenna, Plaintiffs' counsel, filed in support of Plaintiff's Memorandum in Opposition to Amgen's Motion for Summary Judgment, and the respective pages of Plaintiffs' memorandum relying on the contested exhibits. Amgen maintains that they are irrelevant to the ultimate issues before the Court and are highly prejudicial. Having reviewed the exhibits and the related argument in light of the totality of the record and arguments before the Court, the Court finds that the contested exhibits are not determinative, and with or without them, the Court's decisions on the motions for summary judgment would be no different. As such, Defendant's Motion to Strike is denied as moot.

2. Motions for Summary Judgment

a. Standard of Review

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The court must view the evidence and the inferences which may be reasonably drawn from the evidence in the light most favorable to the nonmoving party. Enterprise Bank v. Magna Bank of Missouri, 92 F.3d 743, 747 (8th Cir. 1996). However, as the Supreme Court has stated, "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy, and inexpensive determination of every action.'" Fed.

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R. Civ. P. 1. Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Enterprise Bank, 92 F.3d at 747. The nonmoving party must demonstrate the existence of specific facts in the record which create a genuine issue for trial. Krenik v. County of Le Sueur, 47 F.3d 953, 957 (8th Cir. 1995). A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986); Krenik, 47 F.3d at 957.

b. Defendant's Motion for Summary Judgment and Plaintiffs' Motion for Summary Judgment on Defendant's Counterclaim ²

i. Breach of Contract

Plaintiffs contend that the parties' course of conduct from 1992 through 1999 is evidence that Amgen waived its right to enforce the Supply Agreement, and, as such, the Supply Agreement does not apply to the 1998 and 1999 EPO shipments. To the contrary, however, Defendant argues that the explicit terms of the Supply Agreement, read in conjunction with the terms of the Purchase and Sale Agreement, preclude a waiver of contract rights by a course of performance. Moreover, Defendant maintains that even if a theory of waiver were appropriately invoked in this case, it engaged in no affirmative conduct that could be reasonably construed by Plaintiffs as a waiver of Amgen's contract rights under the Supply Agreement. Defendant concludes that Plaintiffs' failure to pay for the 1998 and 1999 shipments is a breach of the Supply Agreement.

The parties agree that both the Purchase and Sale Agreement and the Supply Agreement call for the application of California law, i.e., California's version of the Uniform Commercial Code ("UCC"), Cal. Com. Code § 2101, et seq. The parties further agree that the relevant agreements are fully integrated and not ambiguous. As set forth in the California civil code, "the language of a contract is to govern its interpretation, if the language is clear and explicit, and does not involve an absurdity." Cal. Civ. Code § 1638. The Court reads the express language of the Agreements in conjunction to contemplate that once the EPO inventory was transferred under the Purchase and Sale Agreement then both parties were agreed and on constructive notice that any further EPO deliveries would occur pursuant to the Supply Agreement. Regardless of when Amgen satisfied its obligation to transfer the EPO under the Purchase and Sale Agreement, the 1998 and 1999 EPO shipments were subsequent to the satisfaction and were thus presumptively subject to the Supply Agreement.

Under California law, courts generally enforce "no oral waiver" contract clauses, like the one in this case. See, e.g., Traumann v. Southland Corp., 842 F. Supp. 386, 391 (N.D. Cal. 1993); Ri-Joyce, Inc. v. New Motor Vehicle Bd., 2 Cal. App. 4th 445, 454 (1992). Indeed, the California commercial code recognizes this practice in section 2209 which states, in relevant part, that: "A signed agreement

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which excludes modification or recission except by a signed writing cannot be otherwise modified or rescinded[.]" ³ Cal. Comm. Code § 2209(2). Plaintiffs urge the Court to look to section 2208 which provides that a course of performance shall be relevant to show modification or waiver of an inconsistent contract term. Cal. Comm. Code § 2208(3). However, even section 2208 cautions that its provisions are subject to those in section 2209 with respect to modification and waiver. Id. Reading sections 2208 and 2209 together, in light of relevant case law, the Court finds the "no oral waiver" clause in this case to be enforceable.

Moreover, even in light of the circumstances Plaintiffs point to as the relevant course of performance, the Court finds insufficient evidence of waiver. "To be valid, a waiver 'must be a clear expression made with full knowledge of the fact[s] and an intent to waive the right." Traumann, 842 F. Supp. at 391 (quoting Spellman v. Dixon, 256 Cal. App. 2d 1 (1967)).

Plaintiffs maintain that the parties never operated pursuant to the terms of the Supply Agreement, and therefore Defendant should be precluded from selectively enforcing the price terms for the 1998 and 1999 shipments. Plaintiffs point to their own failure to meet certain terms of the Supply Agreement and Amgen's corresponding failure to enforce these terms against Plaintiffs as evidence that the Supply Agreement was not in effect. Specifically, Plaintiffs cite their failure: (1) to make each EPO order by written purchase order; (2) to provide 12-month forecasts of anticipated product needs; (3) to provide a copy of any publication in which Techne issues information relating to Supply Agreement products; and (4) to provide quarterly pricing and market share information on Supply Agreement products and their competitors. In addition, Plaintiffs point to Amgen's failure to meet some of its explicit obligations under the Supply Agreement: (1) to ship biological products in "standard Amgen packaging suitable for sales to third parties"; and (2) to bill Techne on a standard Amgen invoice.

The Court does not dispute that a failure to act can often communicate as much or more than an affirmative act. However, the Court does not find that to be the case here. Importantly, paragraph 18(e) of the Supply Agreement provides that: "[I]n the event that either party shall on any occasion fail to perform any of the terms of this Agreement and the other party shall not enforce that term, the failure to enforce on that occasion shall not prevent the enforcement upon any other occasion." The contract terms that the parties failed to enforce or to meet, while apparently significant enough to the parties to become terms of the contract, do not detract from the fact that the 1998 and 1999 deliveries constituted substantial compliance with the contract. Amgen delivered the product for which Techne agreed, by the Supply Agreement, to pay. Moreover, the parties reinforced their intention to comply with the "no oral waiver" provision in 1992 when they executed the only amendment to either agreement, in full compliance with the contract modification provision. The only affirmative acts upon which Plaintiffs rely are those by research and paralegal employees of both corporations, none of whom had authority, pursuant to the agreements, to effectuate modification or waiver.

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There is no requirement in the Supply Agreement that an invoice be sent by Amgen within a certain period of time. While it certainly appears to be a careless oversight by Defendant to let so much time pass before billing for such a substantial amount of product, such an oversight does not excuse Plaintiffs' corresponding obligation to pay for the product it received. It is beyond the Court how Plaintiffs can argue that it should be allowed to receive nearly \$30 million worth of product for free, especially when there is a clear and unequivocal document stating a set price that Plaintiffs agreed to pay. Already, Plaintiffs were receiving a 55% discount, albeit on a very expensive item. To argue that they are somehow now entitled to a 100% discount based on essentially a "gotcha" theory of contract law is absolutely baffling to this Court.

While not necessarily determinative, the Court also finds it worth noting that the EPO shipments at issue were not even used by Techne for research or for maintenance of the CLINIGEN® EPO kit production. Plaintiffs cannot rely on an argument that certain Techne employees may have been operating under the assumption that a "collaborator contract" or some similar relationship existed. Rather, Techne quickly turned the 1998 and 1999 EPO into profit by selling it in bulk in the research market. No such "collaborator contract" existed, and while it may have been better business practice to inform the Techne employees using EPO of the contractual arrangements governing its delivery, Techne cannot rely on the ignorance of a few to mask the awareness of its officers. Significantly, the President and Chairman of R&D and Techne, Tom Oland reiterated this awareness during a November 1996 R&D meeting when he wrote: "*EPO - Amgen has been giving EPO to us & our supplies are low. We don't make it ourselves. The agreement supply contract price is like \$20,000 MG. What do we do?"

In conclusion, the Court finds that neither party modified the agreement by the past course of performance, and Amgen did not waive its right to collect payment for the 1998 and 1999 EPO shipments. Rather, the Court finds that the Supply Agreement was in effect for the 1998 and 1999 deliveries and should be given the effect that the parties originally intended. Accordingly, because the Court finds Amgen's attempt to collect payment on the relevant shipments to fall properly within its contract rights, the Court finds Plaintiffs' claim of unfair business practice to also be without merit.

For the reasons stated, IT IS HEREBY ORDERED THAT:

- 1. Defendant Amgen's Motion for Summary Judgment (Doc. No. 49) is GRANTED;
- 2. Plaintiffs Techne and R&D's Motion for Summary Judgment on Amgen's Counterclaim (Doc. No. 63) is DENIED;
- 3. Defendant Amgen's Motion to Strike (Doc. No. 60) is DENIED AS MOOT;
- 4. Plaintiffs' Complaint (Doc. No. 1) is DISMISSED WITH PREJUDICE; and

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5. Judgment is entered in favor of Defendant Amgen and against Plaintiffs Techne and R&D on Defendant's Counterclaim (Doc. No. 7) in the amount of \$27,961,078.95. However, this judgment shall be stayed for 30 days so that Plaintiffs may submit a letter brief on the issue of why judgment should not be entered by the Court's own motion based on the record before it. Plaintiffs' brief shall be 5 pages or less and submitted within 15 days of the date of this Memorandum Opinion and Order, and Defendant may submit a responsive letter brief of 5 pages or less within 10 days of receipt of Plaintiffs' brief. In submitting the letter briefs, the parties need not follow the local rules to the extent that they require filing of both parties' briefs simultaneously. The Court respectfully requests that the parties submit their letter briefs to the Clerk of Court and two copies to the Court's chambers.

LET JUDGMENT BE ENTERED ACCORDINGLY.

- 1. Both parties note a single written amendment to the Supply Agreement, signed by an appropriate person, as the only written change to either agreement and as irrelevant to the dispute at hand.
- 2. The parties' motions for summary judgment are essentially cross-motions, and as such, the Court's analysis will simultaneously address the merits of each motion, with a separate discussion of Plaintiffs' claim for unfair competition.
- 3. Section 2209 goes on to state that "except as between merchants such a requirement on a form supplied by the merchant must be separately signed by the other party," protecting consumers from becoming unknowingly bound by such a clause.