STATE OF NORTH CAROLINA HENDERSON COUNTY	IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION 21 CVS 2180
INNOVARE, LTD., a Nevada Limited Liability Company, Plaintiff, Counterclaim Defendant, v. SCITECK DIAGNOSTICS, INC., a Delaware Corporation, Defendant, Counterclaim Plaintiff.	**ORDER AND OPINION ON CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS**

THIS MATTER is before the Court on Defendant Sciteck Diagnostics, Inc.'s ("Sciteck") Motion for Judgment on the Pleadings (ECF No. 64), Sciteck's Motion for Partial Summary Judgment, (ECF No. 66), and Plaintiff Innovare, LTD.'s ("Innovare") Motion for Partial Summary Judgment (ECF No. 70) (collectively, "Motions").

THE COURT, having considered the Motions, the briefs of the parties, the arguments of counsel, and all appropriate matters of record, **CONCLUDES** that Sciteck's Motion for Partial Summary Judgment should be **GRANTED in part**, and **DENIED in part**, that Innovare's Motion for Partial Summary Judgment should be **GRANTED in part**, and **DENIED in part**, and that Sciteck's Motion for Judgment on the Pleadings should be **DENIED** as moot.

Smith Debnam Narron Drake Saintsing & Myers, LLP, by Bettie Kelley Sousa, for Plaintiff.

King Law Offices, PLLC, by James Patrick Andrew Twisdale, for Defendant.

Davis, Judge.

INTRODUCTION

1. In its most recent opinion in this case, the Court described the parties as "proverbial ships passing in the night" due to the disparate nature of their respective narratives about the "nature, extent and cessation of their business relationship." *See Innovare, Ltd. v. Sciteck Diagnostics, Inc.*, 2023 NCBC LEXIS 8, at **2 (N.C. Super. Ct. Jan. 19, 2023) ("2023 Opinion"). Now—over a year later and with the benefit of extensive discovery—the parties continue to disagree about virtually every aspect of their relationship to the point that they can hardly be said to be sailing in the same ocean. This case ultimately cries out for resolution by a jury, but the Court must first separate those claims that fail as a matter of law from those claims that require resolution at trial.

FACTUAL AND PROCEDURAL BACKGROUND

2. "The Court does not make findings of fact on motions for summary judgment; rather, the Court summarizes material facts it considers to be uncontested." *McGuire v. Lord Corp.*, 2021 NCBC LEXIS 4, at **1–2 (N.C. Super. Ct. Jan. 19, 2021) (cleaned up).

3. The highly disjointed record complicates the Court's task of explaining the factual background of this case. Nonetheless, what follows is the Court's attempt to summarize the facts—as the Court currently understands them—forming the basis for the issues raised by the Motions and to determine which of those facts are undisputed and which are contested.

4. Sciteck is a corporation that produces biological testing supplies. (*See* Smith (30)(b)(6) Dep., at 19–20, ECF No. 67.1.)

5. Sciteck is organized under Delaware law and is one of several wholly owned subsidiaries of Sciteck, Inc. (Smith (30)(b)(6) Dep., at 1, 17.) Sciteck, Inc. and its subsidiaries are owned by a scientist named Jack Smith. (Smith (30)(b)(6) Dep., at 16–18.) Sciteck leases and operates its only facility in Fletcher, North Carolina. (Smith (30)(b)(6) Dep., at 18–19.)

6. Sciteck develops and manufactures over fifty different biological testing products ranging from "adulteration reagents" for urinalyses to "dry chemistry test strips." (Smith (30)(b)(6) Dep., at 19–20.) Its products are shipped both domestically and internationally through a network of distributors. (Smith (30)(b)(6) Dep., at 21–22, 27, 29.)

7. This lawsuit specifically involves Sciteck's proprietary SARS-CoV-2 ("COVID-19") testing strip called SalivaQuik. Sciteck developed SalivaQuik in response to increased global demand for COVID-19 testing precipitated by the COVID-19 pandemic. SalivaQuik is billed as a "high performance" COVID-19 test that produces a result within three minutes and only requires a small saliva sample. (Smith (30)(b)(6) Dep., at 158, 206, 233; ECF No. 67.9, at 26.)

8. Innovare is a limited liability company that is organized under Nevada law. (Vuono (30)(b)(6) Dep., at 1, ECF No. 67.3.) Innovare provides consulting, software development, and data collection services. (Vuono (30)(b)(6) Dep., at 8, 78.) Ray Vuono and Tamara Caronite serve as Innovare's managing members. (Vuono (30)(b)(6) Dep., at 9.)

9. The relationship between the parties began in 2020 when Sciteck was first introduced to Innovare. (Vuono (30)(b)(6) Dep., at 7.) Around that time,

Innovare sought COVID-19 test processing services from another wholly owned subsidiary of Sciteck, Inc. called "Sciteck Clinical Laboratories" ("Sciteck Clinical"). (Smith (30)(b)(6) Dep., at 17; Vuono (30)(b)(6) Dep., at 8; Caronite Dep., at 12–13, ECF No. 67.4.) Sciteck Clinical is an accredited laboratory that conducts forensic drug testing and other clinical laboratory services. (Smith (30)(b)(6) Dep., at 25.)

10. Initially, the relationship between Sciteck Clinical and Innovare consisted of Innovare purchasing polymerase chain reaction tests for "saliva collection purposes," collecting test samples, and then sending those samples to Sciteck Clinical for processing. When the samples reached Sciteck Clinical, they would be run through a "mechanism to determine whether there [were] any positive or negative findings for [COVID-19]." (Vuono (30)(b)(6) Dep., at 8; Smith (30)(b)(6) Dep., at 30.)

11. At some point between September and November of 2020, Smith learned that Innovare had developed a software called "Access Result," which was designed to help process and deliver COVID-19 test results. (Vuono (30)(b)(6) Dep., at 15, 16, 20–21, 23.) Specifically, Access Result would analyze photos of physical COVID-19 tests that were taken with users' smartphones. (Vuono (30)(b)(6) Dep., at 17.) The readings generated by Access Result could then be used as a type of "pass" to verify or validate users' COVID-19 test results to third parties. (Vuono (30)(b)(6) Dep., at 19.)

12. Innovare contends that after seeing a demonstration of the Access Result software, Smith subsequently expressed interest in working with Innovare to expand the software's capabilities so as to allow Sciteck to provide automatic test

results to SalivaQuik users. (Vuono (30)(b)(6) Dep., at 15, 16, 21, 22.) Smith, conversely, denies that he saw a demonstration of the Access Result software. (Smith (30)(b)(6) Dep., at 32.)

13. Both parties agree that over a period of several weeks and months, they held a series of discussions about the possibility of entering into some sort of formal business relationship. While their recollections about the specific terms of those discussions vary significantly, (*see, e.g.*, Smith (30)(b)(6) Dep., at 33; Vuono (30)(b)(6) Dep., at 15), both parties appear to agree that at least one of the purposes of their prospective business relationship would be to allow Innovare to distribute SalivaQuik tests on Sciteck's behalf. (Vuono 30(b)(6) Dep., at 23; Smith (30)(b)(6) Dep., at 33.)

14. By February 2021, the parties were continuing to discuss the terms of their prospective business relationship. At this point, the relationship was poised to be multi-dimensional, encompassing Innovare's distribution of SalivaQuik on Sciteck's behalf, as well as Innovare's creation of a mobile application that would aid at-home SalivaQuik testing. (ECF No. 71.6, at 7, 9–12.) At one point, Sciteck also asked Innovare to handle overseas distribution of SalivaQuik. (ECF No. 71.6, at 2.)

15. With respect to the software application component of their relationship, Sciteck sent Innovare what appears to be a list of the Food and Drug Administration's ("FDA") requirements for mobile applications and software. (ECF No. 71.6, at 7.) Meanwhile, Innovare created and shared with Sciteck a proposed website that was intended to "support product orders with admin reporting and partner and consumer login." (ECF No. 71.6, at 4.) Additionally, the parties sent each other drafts of an unsigned "Intellectual Property Licensing and Use Agreement" ("IPLUA," ECF No.

71.2, at 7–17), which they would ultimately revise multiple times until they reached a final agreement.

16. On 18 February 2021, both parties signed a "Licensing and Master Distributor Agreement" ("Distributor Agreement"), which had evolved from the various drafts of the IPLUA and served to formalize the terms of the parties' business relationship. (Compl., Ex. A, ECF No. 2.) The Distributor Agreement is the operative agreement between the parties that forms the basis for many of the issues in this lawsuit.

17. As the Court noted in its 2023 Opinion, the Distributor Agreement "is neither a model of specificity nor clarity." *Innovare*, 2023 NCBC LEXIS 8, at **6.[1] That said, its terms remain highly relevant to the issues currently before the Court. Therefore, the Court deems it useful to quote the agreement—which is also notable for its brevity—largely in its entirety.

> This Agreement (this "Agreement") is made and entered into on February 18, 2021 (the "Effective Date") by and between Innovare, Ltd. a Nevada limited liability company ("Innovare") and Sciteck® Diagnostics, Inc., a Delaware corporation ("Sciteck").
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> WHEREAS, Innovare has developed and owns intellectual property and proprietary information (the "IP/Content") to include but not limited to software, websites (e.g. SalivaQuick [sic]), PDA and smart phone software and Sciteck [sic] which has developed and manufactures a rapid diagnostic single use test device technology ("SALIVAQUIK"). The term "SalivaQuik" shall mean and include all rapid test strips produced by Sciteck designed for COVID-19, influenza or any other infectious disease which are part of Sciteck's Chemtest® line of dry chemistry products which "IP/Content" belong to Sciteck.
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> WHEREAS, Sciteck intends to bring the SalivaQuik to market prior, during or after EUA submission(s) or after receipt of the Federal Drug Administration's [sic] (FDA) Emergency Use Authorization ("EUA") for

[1] It also contains a number of typographical errors.

laboratory, non-laboratory and/or at home use approval(s) pursuant to the Instructions For Use. Sciteck principle [sic] operations are the development, manufacturing, and selling products for dry chemistry test strips, biotechnology, urinalysis, clinical chemistry, toxicology, pharmaceuticals, treatment and safety applications and these products wholly belong to Sciteck and are protected under this agreement.

BUSINESS [sic], Sciteck desires to use, as necessary and as permitted hereunder, so much allowed by Innovare to use Innovare's website, software and/or smart phone applications software allowing Innovare to distribute and sell Sciteck's "IP/Content", allowing users of Sciteck's SalivaQuik technology to access the software for use in determining test results and any other functionality that may be available or updated from time to time as needed.

Agreement

NOW, THEREFORE, in consideration of the premises [sic] contained herein and the mutual covenants and restrictions of this Agreement, all of which consideration is hereby deemed and acknowledged as both received and adequate, Innovare and Sciteck agree as follows:

1. **Definitions**. (a) The term "IP/Content" with regards to Innovare includes, but is not limited to the following: all creative designs and concepts, logos, brands, photographs, images, copyrights, trademarks, service marks, illustrations, videos, audio clips and other media, production and operating manuals, associated demonstration and marketing media, printed material, "online" and electronic documentation, applications (sometimes referred to as "SalivaQuick [sic] website"), source codes, object codes, QR codes, software (including the design, application and content thereof and/or therein), narrative and descriptive texts, and all "Innovare", SalivaQuick [sic] related websites (including www.salivaquick.com), applications and all content contained therein regardless of the formatting and presentation thereof and the phrase "Object Code" shall be a computer-executable binary code. The phrase "Source Code" shall mean the human-readable version of a software program that can be compiled into object code, including all accompanying programming notes, programming guides and commentary. The IP/Content shall also include the following QR code, any derivations thereof, and as may be amended or altered from time to time:

   (b) The IP/Content belonging to Sciteck will be its patents pending, patents, intellectual property, proprietary formulations, SalivaQuik test strips, Sciteck technology and trademarks and pending

trademarks to include but not limited to SalivaQuik™, Chemtest®, AdultaCheck®, AutoUA®, Sciteck® and Inventeck®.

2. Grant of Licenses and Restrictions on Use of IP/Content by Sciteck; Payment.

(a) Innovare hereby grants to Sciteck a nonexclusive license (the "Sciteck License"), during the term of this Agreement, so long as Sciteck is not in breach of this Agreement, to use the Innovare Licensed IP/Content for the purposes contemplated in this Agreement and Sciteck is expressly prohibited from using any form of the Innovare Licensed IP/Content for any reason outside the scope and purpose of this Agreement.

(b) Sciteck hereby grants to Innovare a non-exclusive license (the "Sciteck License"), during the term of this Agreement, so long as Innovare is not in breach of this Agreement, to use the Sciteck Licensed IP/Content for the purposes contemplated in this Agreement. Innovare is expressly prohibited from using any form of the Sciteck Licensed IP/Content for any reason outside the scope and purpose of this Agreement.

3. Term. This Agreement will commence on the date of the full execution hereof and will continue for five (5) years, to be automatically renewed thereafter for successive one (1) year periods, unless terminated after year 3 per section 7.

4. Independent Relationship, Warranty and Indemnity.

(a) Innovare and Sciteck will, and throughout the term of this Agreement will be, independent contractors and not employees, partners or agents of the other. Neither Innovare or Sciteck shall have any authority to bind the other to any agreement or contract nor shall it have any authority to represent the other or their respective technologies, intellectual property, business or systems in a fashion other than that expressly set forth herein and Innovare shall not be responsible for any operating expenses, fees, costs or charges, or any income or other tax liabilities of Sciteck. Sciteck shall not be responsible for any operating expenses, fees, costs, or charges, or any income or other tax liabilities of Innovare and Sciteck represents and warrants to Innovare that Sciteck's production, distribution, and sale of the SalivaQuik and Sciteck's use of the Innovare Licensed IP/Content is and will be at all times during the term of this Agreement in full compliance in all respects with all local, state and federal rules, regulations, restrictions, laws, guideline, ordinances and any similar obligation or requirement including, but not limited to, the Federal Drug

Administration's [sic] EUA for the SalivaQuik. Both parties agree and shall fully indemnify each other for any reasons.

4.[2] **Price, Payment Terms.** For Innovare's sell [sic] and distribution of the Sciteck Licensed IP/Content and/or products, Innovare shall receive a royalty to be calculated and paid as follows: On or before the last day of the month following the end of each quarter after the signing of this agreement. [sic] Sciteck shall pay Innovare an amount equal to the number of Strips sold and/or distributed by Innovare multiplied by Thirty Cents ($0.30) for each strip sold (e.g. 30 cents per strip) and the royalties will only be due on Sciteck's receipt of funds for strips sold via Innovare Distributorship and said funds shall have cleared Sciteck's accounts prior to payment of royalties for the quarter paid. The royalty fees shall be inclusive for any and all use of programs, functions, and services provided by Innovare. For clarity, the term "sold" means the strips are no longer the property of Sciteck; the term "produced" means the strips are still the property of Sciteck.

6. **Innovare Distributorship**. All pricings including the wholesale price is [sic] determined and agreed upon by Innovare and Sciteck collectively. Innovare and Sciteck will determine a base cost which will include all costs of production including but not limited to packaging and the Innovare license fee as well as any agreed upon base expenses. Any amount added to the base expenses that will determine the base sale price will be split evenly between Innovare and Sciteck. All sales must be documented in a transaction log that will be maintained by Innovare and may be updated to be an electronic order system when available.

7. **Expressed Authority for Innovare Distributor**. Innovare shall use commercially reasonable efforts to market, distribute and sell the Products in the Territory. Manufacturer, represents and warrants that it has the right and authority to grant the above distribution rights to Distributor. Innovare will be considered the Class A distributor and all other distributors will be under Innovare and listed as Class B Distributors. Sciteck issues expressed [sic] authority to Innovare as Class A Distributor for SalivaQuik marketed products. All Class B distributor sales, appointments and inquiries must be through the Class A distributor. All sales must be documented in a transaction log that will be maintained by Innovare and may be updated to be an electronic order system when available. This Class A designation authority includes all Domestic (USA) and International territories.

8. **Termination**. Either party to this Agreement may terminate this Agreement for the following reasons: (i) a default by the other party

[2] The Distributor Agreement contains two paragraphs labeled as "4" and none labeled as "5."

> hereto after expiration of all applicable notice and cure periods, (ii) a breach of any representation contained herein, or (iii) the failure to satisfy an obligation regarding payment. Either party can terminate at any time with written notice after the 3rd year of the agreement. In case of either Innovare or Sciteck's acquisition the terms of the agreement will not be affected.
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> 9. **Notice and Cure Periods**. Each party has ten (10) business days from the receipt of such notice within to cure such alleged default or provide reasonable proof that such alleged default does not exist. Notice to any party hereunder shall be deemed to have been given (i) when delivered by hand or by Federal Express or a similar overnight courier, or (ii) seven (7) days following the date on which such notice is deposited in the United States Mail as Certified Mail, Return Receipt Requested, First Class Postage.
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> . . .
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> 13. **Innovare Limited Use Authorization for "SalivaQuik"**: Sciteck hereby authorizes Innovare to use the Sciteck SalivaQuik IP solely for the purposes contemplated in this Agreement. Innovare is expressly prohibited from using any form of the Sciteck or SalivaQuik IP for any reason outside the scope and purpose of this Agreement.

(Distributor Agreement, at 1–3.)[3]

18. In order for SalivaQuik to be legally capable of distribution for diagnostic purposes within the United States, it first required "Emergency Use Authorization" ("EUA") from the FDA. (Smith (30)(b)(6) Dep., at 37.)

[3] The parties' arguments in this case suggest that since the beginning of their relationship, they have been operating under different interpretations of several key provisions in the Distributor Agreement. Just as one example, the parties dispute whether—as Innovare contends—the agreement's references to a "nonexclusive license" simultaneously grants Innovare (1) an exclusive license to distribute SalivaQuik; and (2) a non-exclusive license to distribute other Sciteck products, (Vuono (30)(b)(6) Dep., at 58), or whether—as Sciteck contends—Innovare's license is "non-exclusive all the way through and through" and solely encompasses SalivaQuik (as opposed to any other Sciteck products). (Smith (30)(b)(6) Dep., at 59, 74.)

19. In its 2023 Opinion, the Court quoted information contained in Sciteck's counterclaims (that appear to be unchallenged) regarding FDA policies for EUA for products such as SalivaQuik:

> As background information, Sciteck's counterclaims explain how a medical product that has not yet received full regulatory approval may nonetheless be used to "diagnose, treat or prevent serious or life-threatening diseases" under Emergency Use Authorization ("EUA") authority. (Am. Countercls. ¶ 13.) However, certain criteria must be met in order to obtain EUA approval, "including that there are no adequate, approved, and available alternatives." (Am. Countercls. ¶ 13.) The formal process for obtaining EUA approval involves "an application, relevant data and evidence, and a formal request that the FDA [Food and Drug Administration] issue an EUA for the device." (Am. Countercls. ¶ 15.) "[T]he FDA has the authority to require additional data and information on a case-by-case basis to ensure compliance with the statutory criteria for EUA approval of a specific device[,]" and the amount of required data can vary from device to device. (Am. Countercls. ¶ 17.)
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> Generally, a device's sponsor "engage[s] in studies and testing that are compliant with and sufficient for the FDA's EUA approval conditions." (Am. Countercls. ¶ 19.) This necessary testing is called Research Use Only ("RUO") activity, which the FDA strictly regulates, including requiring labeling of all subject devices "for research use only." (Am. Countercls. ¶ 21.) The FDA provides pre-EUA guidelines, "which include[] limiting testing 'to laboratories certified to perform high complexity testing, and at the point-of care when covered by the laboratory's . . . certificate for high complexity testing.' " (Am. Countercls. ¶ 26.)

Innovare, Ltd., 2023 NCBC LEXIS 8, at **2–3.

20. Thus, until such time as it received EUA authorization (or some other specific approval from the FDA), SalivaQuik could only be used for RUO purposes within the United States.[4] (Vuono (30)(b)(6) Dep., at 214.)

[4] To date, SalivaQuik has not received EUA approval from the FDA. (Smith (30)(b)(6) Dep., at 83.)

21. At some point between 2020 and July 2021, Sciteck began soliciting Innovare's assistance with conducting "usability and clinical studies" to supply data for Sciteck's planned application for EUA authorization of SalivaQuik. (Smith (30)(b)(6) Dep., at 252.) The process of conducting such studies required Innovare to distribute SalivaQuik tests to various existing clients, collect and process the completed tests, and report the data to Sciteck. (*See, e.g.*, ECF No. 71.23.)

22. Notably, and as discussed in more detail later in this Opinion, Innovare's assistance with these usability and clinical studies was not listed as one of its contractual obligations in the Distributor Agreement. (Smith (30)(b)(6) Dep., at 283.)

23. One day after the Distributor Agreement was executed, Sciteck forwarded Innovare a series of FDA guidelines regarding the distribution of COVID-19 tests. (ECF No. 71.29.) These FDA guidelines reiterated that the distribution of SalivaQuik for diagnostic purposes could only take place after the product received "premarket clearance, approval, or Emergency Use Authorization (EUA) by the FDA or appropriate notification[] per IV.C of [the Food and Drug Administration's (FDA)] guidance." (ECF No. 71.29, at 2.)

24. Over the next several months, Innovare solicited its existing customers' participation in usability and clinical studies for SalivaQuik. (ECF No. 67.9, at 23.) To that end, Innovare contacted Sciteck on multiple occasions to request shipments of SalivaQuik samples for testing purposes. For example, Innovare requested 650 samples on 25 March 2021 and another 400 samples on 27 April 2021. (ECF No. 71.8; ECF No. 71.23, at 3.) In the course of making these requests, Innovare repeatedly

reassured Sciteck that the SalivaQuik samples would only be used for RUO purposes. (ECF No. 71.23, at 3; ECF No. 71.8, at 2.)

25. On or around 17 August 2021, a Sciteck employee—Kerstin Lanier—received a phone call (the "Alliance Phone Call") from a representative of one of Innovare's customers, a company called "Alliance Title," requesting an instructional video regarding the proper use of SalivaQuik and informing Lanier that SalivaQuik was being used to test Alliance Title employees (ECF No. 67.9, at 1.) After Lanier notified Caronite at Innovare about the Alliance Phone Call, Caronite reassured Lanier that she had separately contacted Alliance Title to explain that "the [SalivaQuik] tests are RUO and not for sale or diagnostic purposes." (ECF No. 67.9, at 1.)

26. In this lawsuit, Sciteck points to the Alliance Phone Call as evidence that Innovare had breached the Distributor Agreement by allowing SalivaQuik to be used for non-RUO purposes in violation of FDA regulations. (Am. Countercls. ¶¶ 60–65, ECF No. 57.) Vuono has testified, however, that Innovare was working with Alliance Title "in order to validate [its] software," that the SalivaQuik tests were being used "for research use only" and not "for diagnostic purposes," and that the tests "weren't being distributed in any way [ ] other than what we already agreed that we were doing."[5] (Vuono 30(b)(6) Dep., at 171, 173.)

[5] As further evidence that Innovare was distributing SalivaQuik for non-RUO purposes, Sciteck also points to a separate phone call that it received from someone at Innovare requesting additional SalivaQuik devices after the "Product Development Activities and Usability and Clinical Studies" had been completed. (Smith (30)(b)(6) Dep., at 255–56.) However, the precise date and time of this call are unclear from the record, as is the date when the usability and clinical studies ceased. (*See* Smith (30)(b)(6) Dep., at 254–56.)

27. Meanwhile, in or around March 2021, Innovare began recruiting third-party companies to serve as "Class B" SalivaQuik distributors pursuant to Section 7 of the Distributor Agreement. (*See, e.g.*, ECF No. 71.9.) As quoted above, Section 7 provided that Innovare was designated a "Class A" distributor of SalivaQuik and that all "Class B distributor sales, appointments and inquiries [had to go] through the Class A distributor." (Distributor Agrmt. § 7.)

28. As part of its recruitment efforts, Innovare reached out to a variety of companies, including Medical Buyers Group LLC ("Medical Buyers"), Owen Test Labs LLC ("Owen Labs"), and Select Medical Systems ("Select Medical"). Medical Buyers expressed interest in purchasing a large volume of SalivaQuik tests at a base price of $10 per test, (ECF No. 71.10, at 2), Owen Labs placed an order for 6,000 SalivaQuik tests, (ECF No. 71.12, at 2), and Select Medical placed an order for 25 SalivaQuik samples.[6] (ECF No. 71.16, at 2.)

29. Throughout the process of recruiting Class B distributors, Innovare kept Sciteck informed about its progress via email. (*See* ECF Nos. 71.9–71.12.) In addition, updated information concerning the Class B distributors was purportedly deposited into an electronic "Partner Portal" that Innovare had created. (Vuono (30)(b)(6) Dep., at 80; Smith (30)(b)(6) Dep., at 111.) Although Sciteck appears to be denying that it actually received information via the portal, Vuono testified that individuals with Sciteck credentials logged into the Partner Portal at various points between April and June of 2021. (Vuono Aff. ¶ 12, ECF No. 72.)

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[6] In a separate email exchange between Caronite and a representative from Select Medical, Myron Myers, Myers stated that "[Smith] requested we connect with you [regarding] Innovare['s] Distribution for AutoUA® and SVT™ product lines." (ECF No. 71.11, at 3.)

30. At some point, Innovare began sending out samples of the SalivaQuik tests to its newly recruited Class B distributors. (Smith (30)(b)(6) Dep., at 136–37.) Innovare initially earned $290 from its deliveries of SalivaQuik tests to Select Medical and Owen Labs. (Vuono (30)(b)(6) Dep., at 88.)

31. As months passed, Innovare continued to expand its network of Class B distributors. In addition to its efforts in that regard within the United States, Innovare also sought to establish Class B distributor relationships with companies in other countries, including India, (ECF No. 71.31, at 2), Cambodia, (ECF No. 87.9, at 2), and Vietnam, (ECF No. 87.6, at 3; ECF No. 87.9.).

32. On 12 September 2021, Innovare agreed to sell six million SalivaQuik tests to a California company called TJ Riley, Inc. ("TJ Riley") at a total cost of $9 million. (ECF No. 71.33, at 17.) The TJ Riley contract stated that the SalivaQuik tests sold thereunder were intended solely for international use and could not be distributed domestically prior to SalivaQuik receiving the appropriate FDA authorization.[7] (TJ Riley Contract, at 17.)[8]

33. As part of its efforts to distribute SalivaQuik overseas, Innovare asked Sciteck to register SalivaQuik on the FDA's Unified Registration and Listing System ("FURLS").[9] (ECF No. 71.32, at 5.) Innovare further suggested that Sciteck's

[7] Although it appears that this proposed sale never actually went through, the record is somewhat muddled as to why.

[8] Sciteck asserts that it was never informed about the TJ Riley contract. (Am. Countercls. ¶ 79.)

[9] FURLS is the FDA's electronic depository for documents and data submitted in connection with products that have already been "cleared" by the FDA. (ECF No. 71.37, at 3; Smith (30)(b)(6) Dep., at 305.)

application be accompanied by a notice that the product was "not being distributed." (ECF No. 71.36, at 2.) Innovare's request was apparently prompted by its belief that the regulatory bodies in other countries would be more likely to approve the importation and distribution of SalivaQuik to their citizens if it was listed on FURLS. (Smith (30)(b)(6) Dep., at 138.)

34. Sciteck ultimately declined to move forward with adding SalivaQuik to FURLS after learning from an alleged "expert in the field of FDA complia[nce]" that registering an unapproved device on FURLS would effectively misrepresent SalivaQuik's approval status with the FDA, leading to the potential for adverse legal consequences. (ECF No. 71.37, at 3; Smith (30)(b)(6) Dep., at 138–39.)[10]

35. Meanwhile, Innovare was continuing to collect data from its usability and clinical studies of SalivaQuik and report this data back to Sciteck. (ECF Nos. 71.24–71.27.) By 12 July 2021, Innovare reported that it had tested over 800 individuals on 25 separate dates as a part of these studies. (ECF No. 71.28, at 2.)

36. During this same time period, Innovare was engaged in ongoing efforts to develop a SalivaQuik mobile application. (*See, e.g.*, ECF No. 71.54.)

37. On 10 August 2021, Sciteck submitted an EUA application to the FDA for SalivaQuik, using the data obtained from Innovare's usability and clinical studies. (ECF No. 67.8, at 5.)

38. On 4 October 2021, the FDA responded to Sciteck's EUA application with a list of concerns about the data contained therein. (ECF No. 67.8, at 5–6.) In

[10] Sciteck contends that Innovare "tried to induce [Sciteck] to commit fraud" by directing it to improperly add certain information on FURLS. (Smith (30)(b)(6) Dep., 137–39.)

this response, the FDA identified several deficiencies and apparently suggested that some of the data was either inaccurate or questionably obtained. (ECF No. 67.8, at 5–8.) Additionally, with respect to the SalivaQuik mobile application, the FDA noted that Sciteck had not "provided sufficient details to understand [its] software design process and architecture." (ECF No. 67.8, at 7.)

39. Soon after learning of the FDA's concerns, a Sciteck employee, Lukas Chaloupka, forwarded excerpts from the FDA's response to Vuono, along with an urgent request for a response within three days. Vuono responded by asking Chaloupka to send him the FDA's response in its entirety, but Sciteck declined to do so. (ECF No. 71.38; Vuono (30)(b)(6) Dep., at 138.)

40. On 5 October 2021, Smith emailed Caronite to express his frustration with what he believed to be Innovare's failure to provide in a timely manner the information requested by the FDA. Smith's 5 October email stated, in relevant part, as follows:

> Let me be perfectly clear, Sciteck Diagnostics is the manufacturer of this product and owns 100% all rights to the product, its production, distribution, etc., and the FDA 100% agrees with this. They do not have any time for nor do they want to talk to any distributors because they, like us, know that distributors have no say in how anything is done or going to be done. The next few days will be interesting, I am already engaging other programmers to look at developing software to replace the current software, and we have so many groups that want to be distributors, it's ridiculous. If Innovare wants to retain any chance to distribute the SalivaQuik and/or provide the software for use with the device, they will provide the information requested when requested.
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> We've already been through this with another distributor recently and they literally got spanked by the FDA for not going through us. We are not having this – you're dreaming if you think we will allow it.
>
> So please respond as quickly as you can to the information Lukas has submitted to you ASAP. If you decide not to do this or are incapable of

> doing it, then Sciteck will decide at a later time if we are to keep you as one of our distributors and/or software providers.

(ECF No. 71.38, at 4.)

41. A few hours later, Caronite replied with an email seeking to reassure Smith that Innovare was preparing the information necessary to respond to the FDA's concerns. (ECF No. 71.38, at 3–4.) Caronite added that "[Innovare wanted] to be constructive" and that the parties' "contract speaks for itself." (ECF No. 71.38, at 3.) Additionally, Caronite stated that Innovare was "interested to move forward and generate sales domestically and internationally upon regulatory approvals." (ECF No. 71.38, at 4.)

42. On 6 October 2021, Smith sent Caronite another email notifying her that Sciteck would need to receive the updated information from Innovare by the following morning in order to respond to the FDA. (ECF No. 71.38, at 2.)

43. On or around 7 October 2021, the FDA denied Sciteck's EUA application for SalivaQuik. (Smith (30)(b)(6) Dep., at 281.)

44. Counsel for Innovare sent a letter to Smith on 22 October 2021 accusing Sciteck of breaching the Distributor Agreement based on Smith's 5 October 2021 email. (ECF No. 71.39.)

45. On 28 October 2021, Smith responded in a letter asserting that it was Innovare (not Sciteck) who had breached the Distributor Agreement by (1) using SalivaQuik in violation of federal law; (2) inducing Sciteck to defraud Vietnamese regulatory authorities by suggesting that Sciteck could add SalivaQuik to FURLS; and (3) failing to properly validate its SalivaQuik mobile application and thus failing

to "provide a portion of Innovare's 'IP/Content' per the [Distributor] Agreement[.]" (ECF No. 71.40.)

46. Counsel for Innovare replied to Smith's accusations by letter dated 5 November 2021, asserting that Sciteck's allegations of breach of contract by Innovare were "unmeritorious" and insisting that Innovare was entitled to payment for "past, present, and future sales, including samples, for all [of Sciteck's] IP-related products." The letter further stated that if Sciteck attempted to "avoid" its obligations under the Distributor Agreement, Innovare would assert contract-related claims against Sciteck that were potentially worth in excess of $1 billion. (ECF No. 71.46.)

47. Beginning in October 2021, Sciteck began contacting other software developers to see whether they would be willing to create a SalivaQuik mobile application, despite the fact that Innovare was apparently continuing its efforts in this regard. (ECF Nos. 71.44–71.45.) Additionally, Sciteck began directly reaching out to solicit other SalivaQuik distributors without Innovare's knowledge. (Smith (30)(b)(6) Dep., at 223–25; ECF Nos. 71.41–71.42.)

48. Sciteck also approached several other entities seeking assistance with new usability and clinical studies. (Smith (30)(b)(6) Dep., at 224–25, 254–55; ECF No. 71.47; ECF No. 71.48)).

49. On 21 December 2021—after this lawsuit had already been filed—the FDA contacted Sciteck regarding concerns about the potential existence of false or misleading claims on Sciteck's website. (Smith (30)(b)(6) Dep., at 213–15.) Specifically, the FDA noted that Sciteck's website listed SalivaQuik as having a pending EUA authorization, even though such authorization had already been

denied. (Smith (30)(b)(6) Dep., at 214.) Because Innovare had created its own website dedicated to SalivaQuik, Sciteck contacted Innovare—through counsel—to demand that Innovare's website also be updated to alleviate the FDA's concerns, which Sciteck contends has still not been done. (Smith (30)(b)(6) Dep., at 214–219.)

50. On 6 December 2021, Innovare initiated the present action by filing a Complaint in Henderson County Superior Court. (Compl., ECF No. 2.) In its Complaint, Innovare asserted claims for breach of contract, breach of the covenant of good faith and fair dealing, unjust enrichment, declaratory judgment, specific performance, and unfair and deceptive trade practices ("UDTP") as well as a claim for injunctive relief. (Compl. ¶¶ 24–60.)

51. This case was designated a complex business case and assigned to the undersigned on 7 December 2021. (ECF No. 1.)

52. Sciteck filed an Answer and Counterclaims on 4 February 2022. (ECF No. 10.)

53. On 19 January 2023, the Court issued its 2023 Opinion dismissing several of Sciteck's counterclaims and striking various affirmative defenses that it had pled. *See Innovare, Ltd.*, 2023 NCBC LEXIS 8, at **43.

54. Sciteck filed an Amended Answer and Counterclaims on 25 January 2023 in which it asserted the following claims against Innovare: (1) violation of the Lanham Act; (2) unfair competition; (2) breach of contract; (3) breach of the covenant of good faith and fair dealing; and (4) UDTP. (Am. Countercls., ¶¶ 121–161, ECF No. 57.)

55. On 28 June 2023, Sciteck filed its Motion for Judgment on the Pleadings, and on 30 June 2023 filed its Motion for Summary Judgment. Innovare also filed its cross-Motion for Summary Judgment on 30 June 2023.[11]

56. A hearing on the Motions took place on 28 March 2024 at which all parties were represented by counsel, and the Motions are now ripe for resolution.

LEGAL STANDARD

57. It is well established that "[s]ummary judgment is proper 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that any party is entitled to a judgment as a matter of law.' " *Morrell v. Hardin Creek, Inc.*, 371 N.C. 672, 680 (2018) (quoting N.C. R. Civ. P. 56(c)). "[A] genuine issue is one which can be maintained by substantial evidence." *Kessing v. Nat'l Mortg. Corp.*, 278 N.C. 523, 534 (1971). "Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion and means more than a scintilla or a permissible inference." *Daughtridge v. Tanager Land, LLC*, 373 N.C. 182, 187 (2019) (cleaned up).

58. On a motion for summary judgment, "[t]he evidence must be considered 'in a light most favorable to the non-moving party.' " *McCutchen v. McCutchen*, 360 N.C. 280, 286 (2006) (quoting *Howerton v. Arai Helmet, Ltd.*, 358 N.C. 440, 470 (2004)). "[T]he party moving for summary judgment ultimately has the burden of

[11] All proceedings in this case following the filing of these Motions were stayed for several months in connection with the withdrawal of Innovare's original attorneys and the substitution of its current counsel.

establishing the lack of any triable issue of fact." *Pembee Mfg. Corp. v. Cape Fear Constr. Co.*, 313 N.C. 488, 491 (1985).

59. The party moving for summary judgment may satisfy its burden by proving that "an essential element of the opposing party's claim does not exist, cannot be proven at trial, or would be barred by an affirmative defense, . . . or by showing through discovery that the opposing party cannot produce evidence to support an essential element of [the] claim[.]" *Dobson v. Harris*, 352 N.C. 77, 83 (2000). "If the moving party satisfies its burden of proof, then the burden shifts to the non-moving party to 'set forth specific facts showing that there is a genuine issue for trial.' " *Lowe v. Bradford*, 305 N.C. 366, 369–70 (1982) (quoting N.C. R. Civ. P. 56(e)). If the nonmoving party does not satisfy its burden, then "summary judgment, if appropriate, shall be entered against [the nonmovant]." *United Cmty. Bank (Ga.) v. Wolfe*, 369 N.C. 555, 558 (2017) (quoting N.C. R. Civ. P. 56(e)).

60. When a party requests offensive summary judgment on its own claims for relief, "a greater burden must be met." *Brooks v. Mt. Airy Rainbow Farms Ctr., Inc.*, 48 N.C. App. 726, 728 (1980). The moving party "must show that there are no genuine issues of fact, that there are no gaps in his proof, that no inferences inconsistent with his recovery arise from the evidence, and that there is no standard that must be applied to the facts by the jury." *Parks Chevrolet, Inc. v. Watkins*, 74 N.C. App. 719, 721 (1985). For that reason, it is "rarely . . . proper to enter summary judgment in favor of the party having the burden of proof." *Blackwell v. Massey*, 69 N.C. App. 240, 243 (1984).

61. "A [Rule 12(c)] motion for judgment on the pleadings is the proper procedure when all the material allegations of fact are admitted in the pleadings and only questions of law remain. When the pleadings do not resolve all the factual issues, judgment on the pleadings is generally inappropriate." *Ragsdale v. Kennedy*, 286 N.C. 130, 137 (1974). "A complaint is fatally deficient in substance, and subject to a motion by the defendant for judgment on the pleadings if it fails to state a good cause of action for plaintiff and against defendant[.]" *Bigelow v. Town of Chapel Hill*, 227 N.C. App. 1, 3 (2013).

62. When deciding a motion under Rule 12(c), the Court may only consider "the pleadings and exhibits which are attached and incorporated into the pleadings." *Davis v. Durham Mental Health/Dev. Disabilities/Substance Abuse Area Auth.*, 165 N.C. App. 100, 104 (2004). The Court must "view the facts and permissible inferences in the light most favorable to the nonmoving party." *Ragsdale*, 286 N.C. at 137. "All well pleaded factual allegations in the nonmoving party's pleadings are taken as true and all contravening assertions in the movant's pleadings are taken as false. All allegations in the non-movant's pleadings, except conclusions of law, legally impossible facts, and matters not admissible in evidence at the trial, are deemed admitted by the movant[.]" *Id.* (internal citations omitted).

ANALYSIS

63. At the outset, it is helpful to note the relief being sought by the parties in the present Motions. Innovare seeks the entry of summary judgment in its favor as to all of Sciteck's counterclaims and as to its own claims for breach of contract and unjust enrichment. Sciteck requests that summary judgment be granted in its favor

as to all claims asserted by Innovare. In addition, Sciteck seeks the entry of judgment on the pleadings in its favor as to Innovare's claims for breach of contract, unjust enrichment, declaratory judgment, specific performance, UDTP, and injunctive relief.

I. Motion for Judgment on the Pleadings

64. It is not entirely clear why Sciteck waited until the close of discovery to file a Rule 12(c) motion—particularly given the fact that it has also filed a summary judgment motion. In any event, the Court concludes that the arguments contained in Sciteck's Motion for Judgment on the Pleadings are substantively subsumed by the arguments contained in its Motion for Summary Judgment. Therefore, the Motion for Judgment on the Pleadings is **DENIED** as moot.

II. Motions for Summary Judgment

A. Claims in Common

65. Both parties have asserted claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and UDTP.

66. The Court deems it appropriate to analyze the parties' respective arguments in support of these claims together.

1. Breach of Contract

67. "The elements of a claim for breach of contract are the existence of a valid contract and a breach of that contract's terms." *JT Russell & Sons, Inc. v. Russell*, 2024 NCBC LEXIS 35, at **9 (N.C. Super. Ct. Feb. 28, 2024).

68. Innovare essentially makes three arguments to support its breach of contract claim. First, it asserts that Sciteck anticipatorily repudiated the Distributor Agreement by improperly threatening to replace Innovare as SalivaQuik's distributor

unless Innovare agreed to provide extra-contractual services in support of Sciteck's EUA submission. (Innovare's Br. Supp. Mot. Part. Summ. J., at 15, ECF No. 73.) Second, Innovare contends that Sciteck breached the Distributor Agreement by engaging with, and continuing to sell its products through, other distributors despite Innovare's status as the sole "Class A" distributor under the Distributor Agreement. (Innovare's Br. Supp. Mot. Part. Summ. J., at 16.) Third, Innovare argues that Sciteck's use of Innovare's IP/Content to contact other distributors and software providers exceeded the scope of use permitted under the Distributor Agreement. (Innovare's Br. Supp. Mot. Part. Summ. J., at 16.)

69. Sciteck's counterclaim for breach of contract incorporates several different theories. First, Sciteck contends that Innovare breached § 4(a) of the Distributor Agreement by "distributing, selling, or providing as a service" SalivaQuik without prior EUA from the FDA. Second, Sciteck asserts that Innovare breached § 2(a) of the Distributor Agreement by not providing software compatible with the SalivaQuik product, thereby failing to "provide a portion of Innovare's 'IP/Content [.]' " Third, Sciteck argues that—unbeknownst to Sciteck—Innovare misrepresented its authority to bind Sciteck to agreements regarding the sale of SalivaQuik tests. Fourth, Sciteck accuses Innovare of establishing a price for the sale of the SalivaQuik tests without input from Sciteck as required under the Distributor Agreement. Finally, Sciteck asserts that Innovare received compensation from selling SalivaQuik tests to third parties without informing Sciteck about these payments or providing Sciteck with its proportionate share. (Am. Countercls. ¶ 146; ECF No. 71.40.)

70. In evaluating the parties' respective breach of contract claims, the Court must first address two threshold issues.

71. The first threshold issue concerns Sciteck's argument that any ambiguities in the Distributor Agreement must be construed against Innovare because Innovare was the primary drafter of the contract. (*See* Sciteck's Br. Supp. Def.'s Mot. Part. Summ. J., at 6–8, ECF No. 67.)

72. It is true that North Carolina courts have previously held that "when an ambiguity is present in a written instrument, the court is to construe the ambiguity against the drafter—the party responsible for choosing the questionable language." *Novacare Orthotics & Prosthetics E., Inc. v. Speelman*, 137 N.C. App. 471, 476 (2000). *See also Loyd v. Griffin*, 2023 NCBC LEXIS 178, at **7 (N.C. Super. Ct. Dec. 29, 2023) ("[A]ny ambiguities are to be resolved against the drafter.").

73. As an initial matter, certain provisions of the Distributor Agreement do, in fact, appear to be ambiguous. For example, it is unclear whether the Distributor Agreement requires Innovare to create new software as part of its obligations thereunder. It is also vague as to whether the Distributor Agreement was intended to encompass other Sciteck products besides SalivaQuik.[12]

74. That said, the Court is unable to agree with Sciteck that any such ambiguities must be construed against Innovare. The record shows that the Distributor Agreement was negotiated between two sophisticated entities with each side proposing various terms for possible inclusion into the final agreement. For this reason, the rule of construction cited by Sciteck is inapplicable on these facts. *See*,

[12] These are only two examples. Other ambiguities appear to exist as well.

e.g., *Joyner v. Adams*, 87 N.C. App. 570, 577 (1987) (holding that the rule that "ambiguity in contract terms must be construed most strongly against the party which drafted the contract" is inappropriate in situations "where the parties were at arm's length and were equally sophisticated . . .").

75. The second threshold issue concerns Innovare's contention that Sciteck anticipatorily repudiated the Distributor Agreement. Innovare argues that Smith's 5 October 2021 email to Caronite constituted such an anticipatory repudiation because it stated Sciteck's intent to no longer be bound by its contractual obligations to Innovare unless Innovare provided information sufficient to satisfy the FDA's stated concerns about SalivaQuik—a condition that was nowhere stated in the Distributor Agreement.

76. North Carolina courts define anticipatory repudiation as follows:

> Repudiation is a positive statement by one party to the other party indicating that he will not or cannot substantially perform his contractual duties. When a party repudiates his obligations under the contract before the time for performance under the terms of the contract, the issue of anticipatory breach or breach by anticipatory repudiation arises. One effect of the anticipatory breach is to discharge the non-repudiating party from his remaining duties to render performance under the contract.

Profile Invs. No. 25, LLC v. Ammons E. Corp., 207 N.C. App. 232, 236 (2010) (quoting *Millis Constr. Co. v. Fairfield Sapphire Valley*, 86 N.C. App. 506 (1987)).

77. Our Court of Appeals has provided further illustration regarding the applicability of this doctrine.

> [T]he refusal to perform must be of the whole contract or of a covenant going to the whole consideration, and must be distinct, unequivocal, and absolute[.] . . . Furthermore, even a distinct, unequivocal, and absolute refusal to perform is not a breach unless it is treated as such by the adverse party. Upon repudiation, the non-repudiating party may at

> once treat it as a breach of the entire contract and bring his action accordingly. . . . Thus, breach by repudiation depends not only upon the statements and actions of the allegedly repudiating party but also upon the response of the non-repudiating party.

Profile Invs. No. 25, LLC, 207 N.C. App. at 237 (citations omitted).

78. In addition, our Court of Appeals has also held that "if a party to the contract states that he cannot perform except on some condition which goes outside the terms of his contract then the statement will constitute a repudiation." *Millis Constr. Co.*, 86 N.C. App. at 511.

79. Here, although admittedly the statements by Smith in his 5 October 2021 email about terminating the agreement appear to be conditioned upon Innovare's provision of extra-contractual services, the threat of termination cannot be properly characterized as "absolute" or "unequivocal." Instead, by its very terms, Smith's email stated that "Sciteck [would] decide *at a later time* if [it would keep Innovare] as one of [its] distributors and/or software providers." (ECF No. 71.38, at 5 (emphasis added).) Moreover, the response email sent by Caronite clearly reflected Innovare's belief that the Distributor Agreement remained in effect and that Innovare desired to preserve its contractual relationship with Sciteck. (ECF No. 71.38, at 3–4.) Finally, Smith's follow-up email on 6 October did not repeat his prior threat to terminate the contract. (ECF No. 71.38, at 2.)

80. Thus, although Innovare's counsel later took the position that Smith's 5 October email constituted an anticipatory repudiation, Innovare's immediate reaction was quite different—stating its desire for the parties' contractual relationship to continue. For these reasons, the Court concludes that no anticipatory repudiation of the Distributor Agreement exists on these facts.

81. Having disposed of these threshold issues, the Court concludes that in all other respects significant questions of fact remain with respect to both parties' claims for breach of contract. Much ink could be spilled detailing the numerous disputed issues that exist between the parties about what the Distributor Agreement actually required and how the opposing party failed to comply with its respective obligations under the agreement. Suffice it to say, however, that these issues must be decided by a jury. Accordingly, both parties' Motions for Summary Judgment as to the breach of contract claims are **DENIED**.

2. Breach of the Implied Covenant of Good Faith and Fair Dealing

82. "Under North Carolina law, every enforceable contract contains an underlying implied covenant of good faith and fair dealing 'that neither party will do anything which injures the right of the other to receive the benefits of the agreement.' " *Kelly v. Nolan*, 2022 NCBC LEXIS 78, at **19 (N.C. Super. Ct. July 19, 2022) (citing *Bicycle Transit Auth., Inc. v. Bell*, 314 N.C. 219, 228 (1985)).

83. The basis for both parties' claims for breach of the implied covenant of good faith and fair dealing largely mirrors the grounds for their respective breach of contract claims.

84. Accordingly, the Court likewise **DENIES** both parties' Motions for Summary Judgment with respect to their claims for breach of the covenant of good faith and fair dealing. *See Woodcock v. Cumberland Cnty. Hosp. Sys.*, 2023 NCBC LEXIS 130, **36 (N.C. Super. Ct. Oct. 18, 2023) (denying motion for summary judgment because "[Plaintiff's] claim for breach of the implied covenant of good faith

and fair dealing [was] based on the same acts as his claim for breach of contract," for which summary judgment was also denied).

3. Unfair and Deceptive Trade Practices

85. "To prevail on a claim of [UDTP] a plaintiff must show (1) an unfair or deceptive act or practice, or an unfair method of competition, (2) in or affecting commerce, (3) which proximately caused actual injury to the plaintiff or to his business." *Stamatakos v. Carolina Urology Partners, PLLC*, 2024 NCBC LEXIS 28, at **25 (N.C. Super. Ct. Feb. 20, 2024) (quoting *Spartan Leasing Inc. v. Pollard*, 101 N.C. App. 450, 460–61 (1991)); *see also* N.C.G.S. § 75-1.1.

86. North Carolina courts have held that "[a]ctions for [UDTP] are distinct from actions for breach of contract, and a mere breach of contract, even if intentional, is not sufficiently unfair or deceptive to sustain an action under N.C.G.S. § 75-1.1." *McDonald v. Bank of N.Y. Mellon Trust Co.*, 259 N.C. App. 582, 589 (2018) (quoting *SunTrust Bank v. Bryant/Sutphin Props., LLC*, 222 N.C. App. 821, 826 (2012)). "When a plaintiff alleges a UDTP violation based upon a breach of contract, the plaintiff 'must show substantial aggravating circumstances attending the breach to recover under [N.C.G.S. § 75-1.1].'" *Dan King Plumbing Heating & Air Conditioning, LLC v. Harrison*, 281 N.C. App. 312, 320 (2022).

87. The Court has carefully considered the parties' respective arguments as to why such aggravating circumstances exist in this case with regard to the opposing party's alleged conduct. The Court ultimately concludes that the evidence upon which each party relies is insufficient to elevate the other side's allegedly breaching conduct into a valid claim for UDTP.

88. However, as discussed below, the Court is denying Innovare's summary judgment motion as to Sciteck's counterclaim for trademark infringement under the Lanham Act.

89. This Court has previously held that a claim for trademark infringement (if proven) can constitute a UDTP. *See JCG & Assocs. LLC v. Disaster Am. USA LLC*, 2022 NCBC LEXIS 156, at **21 (N.C. Super. Ct. Dec. 12, 2022) ("This infringement is also an unfair and deceptive practice that is in or affecting commerce under section 75-1.1."); *Ray Lackey Enters., Inc. v. Vill. Inn Lakeside, Inc.*, 2016 NCBC LEXIS 9, at **37 (N.C. Super. Ct. Jan. 29, 2016) ("Acts of trademark infringement are *per se* unfair and deceptive trade practices.").

90. Accordingly, the Court **GRANTS** Sciteck's Motion for Summary Judgment as to Innovare's UDTP claim but **DENIES** Innovare's Motion for Summary Judgment as to Sciteck's UDTP claim.

B. Innovare's Remaining Claims

91. The remaining claims pled by Innovare in its Complaint are claims for declaratory judgment, specific performance, injunction, and unjust enrichment.

92. In its briefing on the pending Motions, Innovare has stated that it is voluntarily dismissing its claim for declaratory judgment. (Innovare's Br. Opp. Sciteck's Mot. Part. Summ. J., at 11, ECF No. 88.) Therefore, the Court **GRANTS** summary judgment in favor of Sciteck as to that claim.

93. Moreover, at the 28 March hearing, counsel for Innovare was unable to articulate a valid basis for its causes of action for specific performance and injunction.

Therefore, the Court likewise **GRANTS** Sciteck's Motion for Summary Judgment as to these two claims.

94. Accordingly, the only remaining claim by Innovare that the Court must address is Innovare's claim for unjust enrichment.

95. The elements of a claim for unjust enrichment are as follows:

> First, one party must confer a benefit upon the other party. . . . Second, the benefit must not have been conferred officiously, that is it must not be conferred by an interference in the affairs of the other party in a manner that is not justified in the circumstances. . . . Third, the benefit must not be gratuitous. . . . Fourth, the benefit must be measurable. . . . Last, the defendant must have consciously accepted the benefit.

Butler v. Butler, 239 N.C. App. 1, 8 (2015) (quoting *JPMorgan Chase Bank, Nat'l Ass'n v. Browning*, 230 N.C. App. 537, 541–42 (2013)).

96. Innovare's unjust enrichment claim is based upon its contention that it undertook extensive extra-contractual efforts in connection with the usability and clinical studies discussed earlier in this Opinion at Sciteck's request for the purpose of assisting Sciteck in its quest to obtain EUA from the FDA. Specifically, these efforts included "spen[ding] many hours signing up third parties for sample collection events[,] . . . personally travel[ing] around the country to collect such samples[,]" "develop[ing] a survey to use with participants from whom Innovare collected samples[,]" providing the survey results to Sciteck, and ultimately collecting approximately 1,322 samples over 25 separate dates. (Vuono Aff. ¶¶ 16–17, 19.) Innovare further asserts that it undertook these efforts in reliance upon Sciteck's representations that it would pay Innovare for its assistance. (Vuono Aff. ¶ 15–16.) Innovare contends that it has never been compensated by Sciteck for any of the above-referenced efforts. (Vuono Aff. ¶ 17; Vuono (30)(b)(6) Dep., at 212.)

97. Normally, "[i]f there is a contract between the parties[,] the contract governs the claim[,] and the law will not imply a contract." *Booe v. Shadrick*, 322 N.C. 567, 570 (1988). Here, of course, a contract did, in fact, exist between the parties—that is, the Distributor Agreement.

98. However, Innovare is asserting that it is nevertheless entitled to assert an unjust enrichment claim because it provided services for Sciteck that were not required under the contract and for which no compensation was paid. Courts applying North Carolina law have allowed claims for unjust enrichment to proceed under analogous circumstances. *See, e.g.*, *Touchline Video, Inc. v. Intercollegiate Women's Lacrosse Coaches Ass'n*, 2022 U.S. Dist. LEXIS 96280, at *17 (M.D.N.C. May 31, 2022) ("A claim for unjust enrichment for any benefit beyond that required by the [contract at issue] would not be preempted by the presence [of] the contract. At the very least, it is a question of material fact as to whether the benefits . . . conferred . . . were extra-contractual."); *see also Tumlin v. Tuggle Duggins P.A.,* 2018 NCBC LEXIS 217, at *37–38 (N.C. Super. Ct. Dec. 18. 2018) ("While [plaintiff] cannot use an unjust enrichment claim to insulate his potential failure to prove his contract claim, it is not clear at this time whether his evidence presented at trial will include gratuitous extra-contractual services, the value of which [defendant] accepted. Therefore, the Court defers its final consideration of the unjust enrichment claim until the evidentiary record is fully presented at trial.").

99. Here, as the Court has already held in its 19 January 2023 Opinion, the Distributor Agreement imposed responsibility on *Sciteck*—not Innovare—to ensure that regulatory approval was obtained. Therefore, services performed by Innovare at

Sciteck's request to help Sciteck in its efforts to obtain EUA (or any other type of FDA approval) were outside the parties' contractual relationship. However, the Court finds that there is a factual dispute over whether Sciteck actually received a measurable benefit from Innovare's actions. That issue must be decided by a jury.

100. For these reasons, the Court **DENIES** the Motions for Summary Judgment for both Innovare and Sciteck on Innovare's unjust enrichment claim.

C. Sciteck's Remaining Counterclaims

101. Sciteck's remaining counterclaims include a counterclaim under the federal Lanham Act, 15 U.S.C. § 1125, and a claim for unfair competition under North Carolina law.

102. At the 28 March hearing, counsel for Sciteck conceded that it had mistakenly reasserted its unfair competition claim when filing its amended counterclaims after the Court had dismissed that claim in its 19 January 2023 Opinion.

103. Accordingly, summary judgment is **GRANTED** in favor of Innovare as to Sciteck's unfair competition counterclaim. Therefore, the Court need only address Sciteck's Lanham Act counterclaim.

104. The Lanham Act provides, in relevant part, as follows:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> > (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or

> approval of his or her goods, services, or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

105. As the Court explained in its 2023 Opinion, Sciteck's counterclaim under the Lanham Act is based largely upon allegations that Innovare has continued to represent itself as being authorized to sell and distribute SalivaQuik even after its license to do so ended following the termination of the Distributor Agreement. Sciteck further asserts that Innovare has misled consumers into believing that Sciteck distributed SalivaQuik for non-RUO purposes without FDA approval. This conduct, Sciteck contends, has caused the company to suffer reputational harm. (19 Jan. 2023 Op. ¶ 71; Am. Countercls. ¶¶ 121–34.) The Court finds from its examination of the record that a genuine issue of material fact exists on this subject.

106. Sciteck also argues that Innovare continues to maintain a live website featuring references to SalivaQuik.[13] Innovare does not appear to deny this assertion and instead claims that it is still permitted to do so because of the lack of clarity over when, if ever, the Distributor Agreement was actually terminated. Because a factual dispute exists over when the contract between the parties ended, a jury must decide whether Innovare's continued maintenance of its SalivaQuik website (or any other actions it took while representing itself to others as a licensed distributor of

[13] www.salivaquik.com

SalivaQuik) exceeded the scope of its rights under the Distributor Agreement so as to violate the Lanham Act.

107. Finally, Sciteck's Lanham Act claim is also based on its contention that Innovare engaged in a "relabeling" or "repackaging" scheme. This evidence—according to Sciteck—supports the conclusion that "Innovare falsely designated the origin of the SalivaQuik tests and that such false designation was likely to cause consumer confusion." (Sciteck's Br. Opp. Pl.'s Mot. Part. Summ. J., at 18, ECF No. 85; ECF No. 67.1, at 293–99, 302–03.) The Court finds that questions of fact exist on this theory as well.

108. Sciteck's contentions, if proven at trial, would be sufficient for it to show a violation of the Lanham Act. Indeed—as the Court noted in its 2023 Opinion—a number of other courts have recognized the validity of Lanham Act claims premised on analogous theories. *See, e.g., Halo Optical Prods. Inc. v. Liberty Sport, Inc.*, 2017 U.S. Dist. LEXIS 41084, at *27–33 (N.D.N.Y. Mar. 22, 2017) (granting summary judgment for plaintiff distributor on a Lanham Act claim concerning use of a trademark beyond the scope of a licensing agreement); *Ford Motor Co. v. Thermoanalytics, Inc.*, 2015 U.S. Dist. LEXIS 145965, at *9, 13–14 (E.D. Mich. Oct. 28, 2015) (finding trademark infringement when the defendant "exceeded the scope of the [l]icensing [a]greement" and the former licensee created a "likelihood of confusion" by continuing to use the formerly licensed trademark).

109. For these reasons, Innovare's summary judgment motion is **DENIED** with respect to Sciteck's claim under the Lanham Act.

CONCLUSION

THEREFORE, IT IS ORDERED as follows:

1. Sciteck's Motion for Summary Judgment is **GRANTED** as to Innovare's claims for UDTP, declaratory judgment, specific performance, and injunction, and those claims are **DISMISSED** with prejudice. The remainder of Sciteck's Motion for Summary Judgment is **DENIED**.
2. Sciteck's Motion for Judgment on the Pleadings is **DENIED** as moot.
3. Innovare's Motion for Summary Judgment is **GRANTED** as to Sciteck's counterclaim for unfair competition, and that claim is **DISMISSED** with prejudice. The remainder of Innovare's Motion for Summary Judgment is **DENIED**.

SO ORDERED, this the 29th day of May, 2024.

/s/ Mark A. Davis
Mark A. Davis
Special Superior Court Judge
for Complex Business Cases