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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

NOVEX BIOTECH, LLC, a Utah Limited Liability Company. Plaintiff and Counter-claim Defendant, **v.** **CHROMADEX, INC.,** a California Corporation and **DOES 1-10**. Defendant and Counter-claim Plaintiff.	**CHROMADEX, INC.'S MEMORANDUM IN OPPOSITION TO NOVEX BIOTECH, LLC'S MOTION TO DISMISS CHROMADEX'S COUNTERCLAIMS** Case No. 2:19-cv-00271-JNP-PMW The Honorable Judge Jill N. Parrish Magistrate Judge Paul M. Warner **ORAL ARGUMENT REQUESTED**

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INTRODUCTION

ChromaDex is a leading health and wellness company. NIAGEN, ChromaDex's flagship product, is helping improve the way people age by increasing a key cellular resource, nicotinamide adenine dinucleotide (NAD). ChromaDex has *five* robust, published peer reviewed human clinical trials proving that NIAGEN is effective, and dozens of studies showing that NIAGEN is safe. ChromaDex has received two New Dietary Ingredient (NDI) approvals from the U.S. Food and Drug Administration ("FDA") and has successfully filed a dossier with FDA establishing that NIAGEN, as a new ingredient, is "generally recognized as safe" (GRAS). That is the gold standard, far exceeding all legal and regulatory requirements for a dietary supplement.

Novex sells Oxydrene. It makes outlandish claims for this product, including that it is "proprietary" and a "new compound" that "maximizes" "blood oxygenation, muscle recovery and athletic performance" and even that it can make people "run faster," "cut" time off races, and enable "peak aerobic activity." But in reality, Oxydrene contains nothing more than small amounts of commodity household ingredients that provide none of the health benefits claimed. The valid, publicly available scientific research on these well-known ingredients shows that each of Novex's claims is false.

Novex brought baseless claims against ChromaDex for false advertising under the Lanham Act. The premise of its lawsuit was that Oxydrene and NIAGEN compete in the marketplace. ChromaDex had never heard of Novex before. But after reviewing Novex's product and advertising claims (and Novex's allegation of competition), ChromaDex brought counterclaims under the Lanham Act and California state law.

After receiving those counterclaims, Novex has now moved to dismiss on the grounds that NIAGEN and Oxydrene do *not compete*. That argument is contradicted by its own lawsuit. That argument would, of course, doom Novex's own claims too.

Putting the gamesmanship aside, Novex's motion is baseless. The Federal Rules expressly permit the alternative and hypothetical pleading made by ChromaDex. Indeed Federal Rule of Civil Procedure 8 has subsections entitled "Inconsistent Claims or Defenses" and "Alternative Statements of a Claim or Defense."

Novex's other arguments in support of its motion to dismiss fare no better. Novex attempts to re-write the counterclaim into a "lack of substantiation" lawsuit. But ChromaDex's lawsuit brings no such theory. Rather, ChromaDex consistently and repeatedly alleges that the valid scientific evidence shows that each of Novex's claims are false. Novex has no response to this actual falsity theory, because it is unquestionably actionable under both state and federal law.

Finally, Novex makes a variety of arguments that the counterclaim fails to plausibly plead falsity. But again Novex can do so only by ignoring key allegations in the complaint and attempting to reformulate ChromaDex's claims. But at this stage the pleading must be accepted as true and the motion to dismiss should be denied.

FACTUAL AND PROCEDURAL BACKGROUND

I. ChromaDex and NIAGEN

ChromaDex is a leading health and wellness company which markets NIAGEN.[1] NIAGEN contains nicotinamide riboside, which increases nicotinamide adenine dinucleotide (NAD) in the body. NAD is a vital resource for cellular energy and repair. NIAGEN, is backed by five human clinical trials that have been published in peer-reviewed scientific and academic journals. Counterclaims ¶¶ 30-33.

NIAGEN is truly unique. ChromaDex holds rights to patents worldwide for its novel nicotinamide riboside (NR) ingredient. *Id.* ¶ 4. ChromaDex also adheres to the highest regulatory standards. ChromaDex has twice successfully submitted to the Food and Drug Administration safety dossiers establishing that its form of NR is safe in dietary supplement form (known as a New Dietary Ingredient Notification) and has successfully notified FDA a "generally recognized as safe" or GRAS determination by an expert panel of scientists. *Id.* ¶ 2. ChromaDex operates a state-of-the-art quality assurance and research and development laboratory in Longmont, Colorado, staffed by PhDs and other scientists who have developed expertise in the field of NR analytics, production and research. *See id.* ¶¶ 19, 25, 29-33.

II. Novex and Oxydrene

Novex markets an inferior product called Oxydrene. Novex claims that Oxydrene contains a "revolutionary new compound", "powerful functional extract", or "proprietary formula" that it calls "Crenulin-RCC2." Counterclaims ¶¶ 44, 47. Novex advertises that its

[1] For simplicity, this response refers to NIAGEN and TRU NIAGEN collectively as "NIAGEN."

product is essentially a wonder-pill that provides a slew of health benefits including that the product will "increase endurance", "improve aerobic power", "increase VO_2 Max", "optimize Muscle Recuperation Cycle" "maximize the effects of your exercise regimen" and "increase endurance." *Id.* ¶ 45. Novex further claims that Oxydrene will make people run faster, regardless of whether they are just "weekend warriors" or "elite athletes." *Id.* ¶¶ 45, 47. "Oxydrene does not state that these results are merely possible, but rather promises that the results are 'clinically validated' and 'clinically proven' in a 'double-blind placebo controlled clinical trial.'" *Id.* ¶ 48.

III. Procedural History

Novex brought this action against ChromaDex under the Lanham Act on the premise that Oxydrene competes with NIAGEN.[2] Indeed Novex expressly alleges that "ChromaDex sells a product it calls 'Tru Niagen,' which competes with Novex's Oxydrene." Compl. ¶ 13. Novex claims that it has suffered competitive harm as a result of what it alleges are false and misleading advertisements by ChromaDex. It further claims that "ChromaDex's false and misleading statements will divert sales at the expense of Novex's Oxydrene product and/or will lessen the

[2] This is plainly part of its business strategy. On behalf of Novex and its sister companies, this team of lawyers have brought many Lanham Act false advertising lawsuits against other supplement manufacturers in the past few years. *See e.g., Fiber Research Int'l, LLC v. Nutrigold Inc.*, 2:16-cv-01251 (D. Utah), complaint filed Feb. 12, 2016; *Fiber Research Int'l, LLC v. North South Science, LLC*, 2:16-cv-02727 (D. Nev.), complaint filed Nov. 29, 2016; *Novex Biotech, LLC v. Performix LLC*, 2:19-cv-00021 (D. Utah), complaint filed Jan. 15, 2019; *Novex Biotech, LLC v. Herbal Research, Inc.*, 0:17-cv-61863 (S.D. Fl.), complaint filed Sept. 25, 2017; *Sanmedica Int'l, LLC v. Quantum Wellness Botanical Inst., LLC*, 2:16-cv-00191 (D. Utah), complaint filed March 9, 2016; *Sanmedica Int'l, LLC v. LA Nutrition, Inc.* 3:17-cv-000965 (M.D. Tenn.), complaint filed June 21, 2017.

goodwill enjoyed by Oxydrene." *Id.* ¶ 34. Based on information that it has, ChromaDex disputes Novex's claims of competition. Answer ¶¶ 13, 34.

After reviewing Novex's complaint as well as Oxydrene and its claims, ChromaDex determined that Novex was making many false statements in the marketplace. Based on Novex's *own* theory and allegation that the products compete, ChromaDex brought alternative counterclaims under the Lanham Act, 15 U.S.C. § 1125(a)(1), California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq*. and False Advertising Law ("FAL"), Cal. Bus. & Prof. Code § 17500 *et seq*., Counterclaims ¶ 65. In particular, ChromaDex alleges that:

- Novex falsely claims that Oxydrene is new and proprietary, when it is not *id*. ¶ 60;
- Novex falsely claims that Oxydrene is supported by a double blind human clinical trial, *id*. ¶¶ 48, 56-57; and
- Novex falsely claims that Oxydrene provides a number of health benefits, when the science proves that it does not, *id*. ¶¶ 53-55, 58.

Based on Novex's own allegation of competition, ChromaDex pleads in the alternative that: "If Novex and ChromaDex compete—as alleged by Novex—Novex's false claims have harmed ChromaDex in the marketplace, in an amount to be proven at trial. Indeed, by bringing this lawsuit, Novex has asserted that NIAGEN competes with Oxydrene and that the products are comparable." *Id.* ¶ 65. Accordingly, "ChromaDex has been damaged by Novex's conduct in an amount to be proven at trial. Novex's false and misleading advertising claims put ChromaDex at a competitive disadvantage in the dietary supplement market." *Id.* ¶ 86.

LEGAL STANDARD

"A court reviewing the sufficiency of a complaint presumes all of plaintiff's factual allegations are true and construes them in the light most favorable to the plaintiff." *Domo, Inc. v. Grow, Inc.*, No. 2:17-CV-812, 2018 WL 2172937, at *2 (D. Utah May 10, 2018) (quoting *Hall v. Bellmon*, 935 F.2d 1106, 1108 (10th Cir. 1991)). "The court's function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties may present at trial but to 'assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted.'" *Advanced Comfort Tech. Inc., v. London Luxury LLC,* No. 2:17-CV-00497, 2017 WL 6060634, at *4 (D. Utah Dec. 5, 2017) (quoting *Dubbs v. Head Start, Inc*. 336 F.3d 1194, 1201 (10th Cir. 2003)). For claims sounding in fraud, "[t]he purpose of Rule 9(b) is 'to ensure that the complaint provides the minimum degree of detail necessary to begin a competent defense.'" *Northstar Alarm Servs., LLC v. Alder Home Prot.*, No. 2:17-CV-1097, 2018 WL 3611069, at *1 (D. Utah July 27, 2018) (quoting Fulghum v. Embarq Corp., 785 F.3d 395, 416 (10th Cir. 2015)). "Rule 9(b) does not require any particularity in connection with an averment of intent, knowledge or condition of mind, rather it simply refers to only the requirement that a plaintiff identify the circumstances constituting fraud." *RV Horizons, Inc. v. Smith*, No. 1:18-CV-02780-NYW, 2019 WL 1077366, at *14 (D. Colo. Mar. 7, 2019).

ARGUMENT

I. ChromaDex Has Adequately Alleged That NIAGEN Competes With Oxydrene

Novex's primary argument is that ChromaDex has not adequately alleged that Oxydrene and NIAGEN compete because ChromaDex's pleading that the two products compete is (1) inconsistent with its answer, which denies Novex's allegation that the products compete; and (2)

is hypothetical because it uses "if" in its pleading of competition. Motion to Dismiss ("Mot.") at 3.

But, the Federal Rules of Civil Procedure expressly permit both "alternative" pleading (pleading claims that contradict a defense) and also "hypothetical" pleading (pleading claims based upon facts that the other party intends to prove). *See* 5 Wright & Miller, Fed. Prac. & Proc. § 1282 at 724 (3d ed. 2004). The rules are clear:

- Federal Rule 8(d)(3)—which is titled "*Inconsistent Claims or Defenses*"— allows "[a] party [to] state as many separate claims or defenses as it has, *regardless of consistency*." Fed. R. Civ. P. 8(d)(3) (emphasis added).
- Federal Rule 8(d)(2)—which is titled "*Alternative Statements of a Claim or Defense*" allows "[a] party [to] set out 2 or more statements of a claim or defense *alternatively or hypothetically*, either in a single count or defense or in separate ones." Fed. R. Civ. P. 8(d)(2) (emphasis added).

Courts have made clear that under these Rules "counterclaims may be asserted in an alternative or hypothetical manner and need not be consistent with the defenses and *denials raised in the answer*." *Noasha LLC v. Nordic Grp. of Cos., Ltd.*, 630 F. Supp. 2d 544, 550 (E.D. Pa. 2009) (quoting 5 Wright & Miller, Fed. Prac. & Proc. § 1282 at 724 (3d ed. 2004) (emphasis added); *see also Haynes Trane Serv. Agency, Inc. v. Am. Standard, Inc.*, 51 F. App'x 786, 800 (10th Cir. 2002) (reversing district court ruling that party waived counterclaims on the grounds that the rules permit inconsistent pleadings); *Nutraceutical Corp., v. Affordable Naturals, LLC*, No. 2:14-CV-00907, 2017 WL 4564739, at *12 n.9 (D. Utah. Oct. 11, 2017) (Under Rule 8(d)(3) plaintiff could allege counterclaims inconsistent with denials in answer without counterclaims

being converted into judicial admissions); *Mata v. Bd. of Educ. of Las Cruces Pub. Sch.*, No. 12-CV-00136, 2013 WL 12333626, at *2 (D.N.M. Feb. 15, 2013) ("Federal Civil Procedure Rule 8(d)(2) expressly allows alternative statements of a claim, while Rule 8(d)(3) expressly allows a plaintiff to plead mutually inconsistent claims."); *Diamond Triumph Auto Glass, Inc. v. Safelite Glass Corp*., 344 F. Supp. 2d 936, 944 (M.D. Pa. 2004) ("a pleading is not defective simply because it states a claim hypothetically."); 5 Wright & Miller, Fed. Prac. & Proc. § 1282 at 724 (3d ed. 2004).

That is exactly what ChromaDex did here. While ChromaDex does not believe at this time that the two products compete, Novex has alleged that they do and has brought this lawsuit on that basis. Compl. ¶¶ 13, 33-34, 36-37; Mot. at 2 (Novex asserting that "ChromaDex's Tru Niagen directly competes with Novex's Oxedrene [sic] and ChromaDex's false claims give ChromaDex an illegal and unfair advantage over Novex's Oxydrene."). ChromaDex is entitled to deny that allegation, Answer ¶¶ 13, 33-34, 36-37, and plead a counterclaim in the alternative. Counterclaims ¶ 65. If discovery reveals that the products do not compete then both the complaint and the counterclaim would be unmeritorious. If discovery reveals that the products do compete, as Novex affirmatively alleges, then the case could continue to other elements.

It is ironic (and suggests bad faith) that Novex criticizes ChromaDex for this inconsistent hypothetical pleading because that is precisely what Novex is doing in its motion. Novex repeatedly alleged that the products compete. *See* Compl. ¶¶ 13, 33-34, 36-37. But it now wants the Court to dismiss ChromaDex's claims on the grounds that the products do not

compete. If Novex were right about this argument, then its claim would have to be dismissed too. [3]

II. ChromaDex Has Adequately Alleged That Novex's Advertisements are False and Misleading

Novex makes a grab bag of arguments claiming that ChromaDex has failed to plead sufficient facts to plausibly show that Novex's advertisements are false and misleading. These arguments are nothing more than an attempt to recast ChromaDex's counterclaims and argue the evidence and merits of the case which cannot be done at the motion to dismiss stage. Novex does not grapple with the well-pled allegations that are sufficient to state a claim that Novex's advertising statements that (1) Oxydrene is proprietary and new; (2) Novex possesses a clinical trial; and (3) Oxydrene provides a number of health and exercise benefits, are false and misleading.

A. Novex's Advertising Claims That Oxydrene Is New, Proprietary, And Revolutionary Is False And Misleading

ChromaDex has sufficiently alleged that Novex's statement that Oxydrene is "new, proprietary, and revolutionary" is false, misleading, and actionable. Novex appears to concede that Oxydrene is neither "new," nor "proprietary," nor "revolutionary" as it prominently and repeatedly touts in its advertising. Mot. at 8-9. Instead it claims that (1) ChromaDex has failed

[3] Novex's emphasis on ChromaDex's statement that the products are not *comparable*, misstates and misunderstands the point. By bringing this lawsuit Novex seeks to have its inferior product mentioned in the same breath as ChromaDex's. But the products are not *comparable* because NIAGEN is backed by gold standard and voluminous science and meets rigorous FDA standards. Conversely, Novex points to a single purported study, information about which is nowhere to be found, and does not comply with numerous FDA obligations. The products are plainly not comparable, but that has little to do with Novex bringing this lawsuit on the basis that the products allegedly *compete*.

to adequately allege falsity, because even though Oxydrene is made up of old, common ingredients, the combination is allegedly new, and (2) even if ChromaDex had adequately alleged falsity, those claims are mere "puffery," Mot. at 10. These arguments should be rejected.

1. Oxydrene Is Not New, Proprietary, Or Revolutionary

First, Novex argues that its advertising is not literally false because it claims its "formula" is new and proprietary, even though the ingredients in the formula are not. Mot. at 8-9. But this ignores the fact that ChromaDex has pled that Novex's claims are misleading, even if they were technically true. *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997) (Lanham Act prohibits misleading claims); *In re Tobacco II Cases*, 207 P.3d 20, 29 (Cal. 2009) (same for state law causes of action).

For example, ChromaDex plainly alleges that "[w]hile Novex claims that 'Crenulin-RCC2' is 'revolutionary' 'new' and 'proprietary,' it is in reality comprised entirely of garden variety commodity ingredients that have been on the market for years. There is nothing new, revolutionary, or proprietary about it." Counterclaims ¶ 50. ChromaDex further alleges that consumers are misled and deceived as a result of these claims: "[t]he name 'Crenulin-RCC2' is nothing more than a scientific-sounding list of letters and numbers that deceives and misleads consumers into thinking the product contains some special ingredient or process, not just ginkgo biloba extract and rhodiola rosea." *Id.* ¶ 51. *See also id.* ¶¶ 8-10. If Novex wishes to argue that reasonable consumers would understand its claims to be only about a *formula* and not the ingredients, it can make that argument after discovery. However, ChromaDex has alleged to the contrary, and that plausible allegation must be accepted as true at this stage.

But even if Novex could ask this Court to accept its interpretation of the claim at this stage, its motion to dismiss should still be denied. ChromaDex has alleged that Novex's advertising uses "proprietary" and "new" not just in connection with its "formula" but in connection with specific ingredients. For example, Novex advertises that Oxydrene includes a **"revolutionary new *compound,"*** and **"powerful functional *extract."*** Counterclaims ¶¶ 8, 10, 44, 47. Thus, even if Novex were correct that the use of the term "formula" was literally true, it would still be liable for advertising that it has a new compound and extract in its product, as alleged in ChromaDex's counterclaims. [4]

2. Novex's Claims Are Not Puffery

Next, Novex argues that these claims are mere puffery. But only "outrageous generalized statements . . . that are so exaggerated as to preclude reliance by consumers" are "puffery." *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 246 (9th Cir. 1990). "[A]dvertising which merely states in general terms that one product is superior is not actionable" but "misdescriptions of specific or absolute characteristics of a product are actionable." *Brickman v. Fitbit, Inc.*, No. 15-CV-02077, 2016 WL 3844327, at *3 (N.D. Cal. July 15, 2016)). "[T]he determination of whether an advertising statement should be deemed puffery is driven by the context in which the statement is made." *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 495 n.5 (5th Cir. 2000) (quoting *Federal Express Corp. v. United States Postal Service*, 40 F. Supp. 2d 943, 956 (W.D Tenn. 1999)). "Where the context of an

[4] Novex concedes, as it must, that it does not have an NDIN because Crenulin-RCC2 is not, in fact, "new." And as alleged in the Counterclaims, this only underscores the fact that its advertising touting the "proprietary", "new" and unique nature of Oxydrene as a "powerful functional extract" and "revolutionary new compound" are false and misleading to consumers.

advertising statement may lend greater specificity to an otherwise vague representation, the court should not succumb to the temptation to hastily rule a phrase to be unactionable under the Lanham Act." *Id.*

Here, both the *substance* and the *context* of Novex's claims show they are not mere puffery. As to the language itself, courts have regularly found claims that a product is "new" or "proprietary" are not puffery. For example, in *International Franchise Solutions LLC v. BizCard Xpress LLC*, the defendant advertised that its "mapping software" was "sophisticated, unique, and proprietary." No. CV13-0086, 2013 WL 2152549, at *2 (D. Ariz. May 16, 2013). Plaintiff challenged that statement on the grounds that the "Mapping Software was nothing more than a standard, off-the-shelf commercially available software program with no unique or customized features." *Id.* The court held that while "[t]he reference to 'sophisticated' may constitute a subjective characterization [and puffery, . . .], 'unique' and 'proprietary' do not. The latter adjectives provide a description of a product for which the truth or falsity can be precisely determined." *Id.* Similarly in *Torrent v. Yakult U.S.A., Inc.*, the Court held that advertisements that a dietary supplement was "exclusive" and "unique" were not puffery or highly subjective statements. No. SACV 15-00124, 2015 WL 4335076, at *3 (C.D. Cal. July 14, 2015). Indeed, courts in this district have recognized that under the Lanham Act "[t]erms such as 'new and improved' *may be* mere puffing in some circumstances, *but misleading in others*" and have refused to grant summary judgment for defendant on that basis. *digEcor, Inc. v. eDigital Corp*, No. 2:06-CV-437, 2009 WL 928679, at *3 (D. Utah Apr. 2, 2009) (emphasis added).

The Federal Trade Commission, the federal agency charged with consumer protection in advertising, has reached the same conclusion. It has made clear that claims that a product is

"new" can be actionable, including by issuing specific guidance and advisory opinions on when companies can advertise a product as "new." *See* FTC, Advertising FAQ's: A Guide for Small Businesses.[5] The FTC stated "[t]he answer depends on how the ad uses the word 'new'" and "each case must be considered within the context of the ad." *Id.* The FTC has also issued an "advisory opinion [that] has suggested a six-month limit on the use of the word when advertising the introduction of a 'new' product not previously on the market." *Id.* Plainly the FTC does not consider "new" to be unactionable puffery.

This Court should similarly find that Novex's claims that Oxydrene is "new" and "proprietary" are not puffery. Novex claims are not "exaggerated" and are not "generalized." They are specific factual statements subject to (dis)confirmation. A product like this is either proprietary or not and it is either new or not. *S.E.C. v. McCabe*, No. 2:13-CV-161, 2013 WL 6185035, at *4 (D. Utah Nov. 26, 2013) (finding statements that "stock recommendations were supported by research" and claimed to use a "time-tested proprietary investing methodology" were "objectively verifiable assertions" and not puffery).

The context of Novex's claims confirm this conclusion. *See Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1311–12 (11th Cir. 2010). These claims are not made for an ordinary household product. Rather they are made for dietary supplements designed to be ingested to provide certain health benefits. Indeed, Novex actually includes its "proprietary" claim on the FDA required *supplement facts* label on the back of the package. Counterclaims ¶ 44. *See Giles v. Inflatable Store, Inc.*, No. 07-CV-00401, 2009 WL 961469, at *4 (D. Colo. Apr. 6, 2009) (in

[5] *Available at* https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business.

context of a "game involving participants attempting to knock each other to the floor, an equipment seller's representation that its suit was the safest was a statement of value or quality made with the purpose of having it accepted as fact" (quotations and alternations omitted)). ChromaDex is not aware of any court finding that statements on the *legally required* FDA supplement facts panel are mere "puffery," "opinion," or so outrageous, that no consumer could rely on it.

Finally, none of the cases relied on by Novex stands for the proposition that *Novex's* claims are puffery. *See, e.g.*, *Allied Erecting & Dismantling Co. v. Genesis Equip. & Mfg., Inc.*, 649 F. Supp. 2d 702 (N.D. Ohio 2009) (claims were statements of general superiority); *Soilworks LLC v. Midwest Indus. Supply, Inc.*, 575 F. Supp. 2d 1118 (D. Ariz. 2008) (claim of product superiority was vague); *Anunziato v. eMachines, Inc.*, 402 F. Supp. 2d 1133, 1139 (C.D. Cal. 2005) (general statement in user manual that "Each and every eMachines notebook uses the latest technology" was vague and generalized); *In re Virtus Inv. Partners, Inc. Sec. Litig.*, 195 F. Supp. 3d 528, 538 (S.D.N.Y. 2016) (statements were too general that an investor would not have relied on them). Each of those cases turns on the specific context in which the statement was made, and the context is very different from here because here Novex makes specific factual statements subject to test and specifically ties each of the statements to the product's supposed health benefits. It is not simply saying that the product is great.

In any event, and contrary to Novex's assertion (*see* Mot. at n.4), this question cannot be resolved now because the context and consumer interpretation of the claim is crucial to the puffery analysis. For this reason courts routinely defer the issue until after discovery can be completed. As this District has recognized, the "highly factual nature of [the] inquiry" warrants

deferring to a fact finder. *digEcor*, 2009 WL 928679, at *3. And indeed, numerous cases cited by Novex are opinions on motions for summary judgment and even after a full jury trial on the merits. *See Allied Erecting*, 649 F. Supp. 2d 702 (motion for summary judgment); *Soilworks*, 575 F. Supp. 2d 1118 (motion for summary judgement); *Pizza Hut*, 227 F.3d at 493 (jury trial on the merits). The Court should not conclude at this stage that the claims are mere puffery.

B. Novex's Advertising Claims That It Possesses A Clinical Trial On Oxydrene Is False And Misleading

ChromaDex has also plausibly alleged that Novex's statement that it possesses a "double blind placebo controlled trial" in support of Oxydrene is false and misleading. Counterclaims ¶¶ 48, 56. Novex's motion to dismiss makes two arguments in response to this claim. First, Novex argues that ChromaDex did not plausibly plead that the clinical trial statement is false or misleading. Second, Novex asserts that the theory is a non-actionable "lack of substantiation" theory under state and federal law. Both arguments lack merit.

1. ChromaDex Has Pled That Novex's Advertising Statements About Its Clinical Trial Are False

ChromaDex plausibly pleads that Novex's claim that it possesses a clinical trial on Oxydrene is false. ChromaDex's complaint alleges that Novex prominently and repeatedly advertises that it possesses a "double blind placebo controlled trial" in support of its product. Counterclaims ¶¶ 48, 56. In large bright yellow and red font on the front of the bottle, Novex advertises to consumers the product is "[c]linically validated to increase VO2 Max!!!" *Id.* ¶ 43. The phrases "clinically validated" and "clinically proven" are peppered throughout Novex's advertising. *Id.* ¶¶ 47-48. Novex makes these claims prominently throughout its consumer advertising for the product and on its bottle. *Id.*

ChromaDex further alleges that Novex's repeated clinical trial statements are false because Novex has "no scientifically valid human clinical trial on Oxydrene." Counterclaims ¶ 56. ChromaDex makes numerous factual allegations supporting the plausibility of this allegation. First, Novex makes no mention of this purported study on the "science" section of its website (even though it does discuss studies for other products the company sells). Counterclaims ¶ 55. Second, ChromaDex, aided by its team of PhD credentialed scientists, conducted a literature search for Crenulin-RCC2 or the blend of ingredients listed on the supplement facts for the product and found "no studies at all, let alone scientific studies that back its sweeping claims of efficacy."[6] *Id.* ¶ 56. And finally, consumer watchdogs have likewise sought to find this study, and they too have reported that the study does not exist. *Id.* ¶ 57.

These allegations are plausibly plead under *Twobly/Iqbal* that Novex is making an express false statement about its product and having a clinical trial to support it. The allegations also meet the standard under Rule 9(b). Novex's only Rule 9(b) objection is that ChromaDex has pled one paragraph "upon information and belief." But the law in this Circuit is clear that "[a]llegations of fraud may be based on information and belief when the facts in question are peculiarly within the opposing party's knowledge and the complaint sets forth the factual basis for the plaintiff's belief." *Scheidt v. Klein*, 956 F.2d 963, 967 (10th Cir. 1992). ChromaDex has pled detailed factual bases for its belief that no clinical trial exists, and if it does, it would only "peculiarly" within Novex's possession. ChromaDex's pleading therefore satisfies Rule 9(b) too.

[6] Also worth noting, clinicaltrials.gov where human clinical trials are registered, shows no studies registered for Novex, Oxydrene, or Crenulin-RCC2.

2. ChromaDex's Counterclaim Is Not A Lack of Substantiation Claim

Novex's next argument—that this is a mere lack of substantiation theory—fares no better. Courts across the country have made clear that when a company falsely claims that it possesses a clinical trial for a product, that is an actionable false statement under the Lanham Act, and not a mere lack of substantiation issue. *See BASF Corp. v. Old World Trading Co.*, 41 F.3d 1081, 1090 (7th Cir. 1994). For example, in *Riddell, Inc. v. Schutt Sports, Inc.*, the Court held that the plaintiff could state a claim challenging a company's statements about its human "research" study because the claimed study did not exist, rendering the statements "literally false." 724 F. Supp. 2d 963, 976 (W.D. Wis. 2010). Similarly in *Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, the Court explained that the Plaintiff's challenge to advertising statements about a "study" was an actionably falsity theory under the Lanham Act. 348 F. Supp. 2d 165, 181 (S.D.N.Y. 2004); *see also McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991) (Plaintiff "could therefore meet its burden of proof by demonstrating that [claimed] studies did not establish that [the product] provided superior pain relief.").

It is no surprise that courts find that challenges to statements about clinical trials fall outside of the lack of substantiation doctrine. This is because "[w]hen an advertising claim of favorable fact either expressly or impliedly asserts that the fact is testor study-validated, the fact of the validation becomes an integral and critical part of the claim." *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 435 (4th Cir. 1997). As the Seventh Circuit explained the distinction:

> a Lanham Act plaintiff bears the burden of proving literal falsity, but that the proof sufficient to meet this burden will vary depending upon the statement made. If the challenged advertisement makes implicit or explicit references to tests, the plaintiff may satisfy its burden by showing that those tests do not prove the proposition; otherwise, the plaintiff must offer affirmative proof that the advertisement is false.

BASF, 41 F.3d at 1091; *Osmose*, 612 F.3d at 1310. ChromaDex is plainly challenging Novex's false advertising claims *about its clinical trial* itself which is cognizable under the Lanham Act.

ChromaDex's theory is also actionable under state law, as it is not a prohibited lack of substantiation claim under the UCL or FAL. When the "Defendant puts the clinical proof for its product at issue" by including statements about the clinical study on its advertising and plaintiff "allege[s] that no credible scientific evidence supports [Defendant's] representations," it is actionable under the UCL and FAL. *McCrary v. Elations Co.*, No. EDCV 13-0242, 2013 WL 6403073, at *9 (C.D. Cal. July 12, 2013) (denying motion to dismiss UCL and FAL false advertising claim that product contained a "clinically proven combination"); *cf. Cabral v. Supple, LLC*, No. ED 12-00085, 2012 WL 12895824 (C.D. Cal. July 3, 2012) (advertising which stated efficacy was supported by a clinical trial was actionable false advertising where only clinical study cited was on an ingredient not contained in the beverage).[7]

[7] One way to see why ChromaDex is not bringing a lack of substantiation challenge is because even if Novex has scientific evidence to justify its health claims about the benefits of its product (which it does not), it would still be falsely advertising the fact that it possesses a clinical trial for its product. This distinguishes all of the cases Novex cites: there plaintiffs were challenging the substantiation behind the benefit claims, not that the statement about an existence of the study was false. *Kwan v. SanMedica Int'l, LLC*, No. 14-CV-03287, 2015 WL 848868 (N.D. Cal. Feb. 25, 2015) (plaintiff acknowledged that clinical testing had in fact been performed but false advertising claims were based on challenging the adequacy of the study to support the claims), *aff'd*, 854 F.3d 1088 (9th Cir. 2017); *Engel v. Novex Biotech LLC*, No. 14-CV-03457, 2015 WL 846777 (N.D. Cal. Feb. 25, 2015) (same), *aff'd*, 689 F. App'x 510 (9th Cir. 2017); *Racies v.*

When companies make specific false claims about clinical trials or studies, they are responsible for the veracity of *those claims* under state and Federal law. Here, Novex's statements are provably false because there is no such study.

C. Novex's Various Health Benefit Claims Are Proven False By Scientific Evidence

In addition to its advertisements about a clinical trial, ChromaDex also challenges Novex's false statements about the benefits of its product. On this point, Novex recycles the same arguments: (1) that this is a lack of substantiation theory under the UCL and FAL and (2) that if it is not, ChromaDex does not plausibly plead that the health benefit claims are false. Mot. at 11-15. Both arguments lack merit here as well.

1. ChromaDex Challenges Novex's Health Benefit Statements As False, Not Merely Unsubstantiated

ChromaDex is not bringing a lack of substation challenge to the benefit claims. Courts distinguish between complaints that "merely alleg[e] that Defendants' representations were unsubstantiated" (which are not actionable) and those that allege that "Defendants' representations are 'provably false'" by the available scientific evidence (which are actionable). *Vasic v. Patent Health, LLC*, No. 13CV849, 2014 WL 940323, at *7 (S.D. Cal. Mar. 10, 2014). ChromaDex's complaint is in the latter category.

ChromaDex alleged that Oxydrene is "comprised entirely of garden variety commodity ingredients that have been on the market for years." Counterclaims ¶ 50. Rather than supporting

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Quincy Bioscience, LLC, No. 15-CV-00292, 2015 WL 2398268, at *3 (N.D. Cal. May 19, 2015) (alleging that clinical trial claims were unsubstantiated where "abstracts/summaries" of trials on defendant's website "are not competent and reliable scientific 'studies'").

its miracle pill claims, "the available scientific evidence shows that the ingredients in Oxydrene, whether by themselves or in combination, do not provide the promised health benefits." *Id*. ¶ 53. "The ingredients in Oxydrene do not and cannot make people 'run faster.'" *Id*. ¶ 54. "Nor do they 'increase endurance,' 'maximize aerobic power,' 'improve physical performance' or 'optimize muscle recuperation cycle.'" *Id.* "Even if the ingredients could provide some exercise benefits, the dose in the product is entirely too low to see any meaningful benefit." *Id.* "The claims are simply false." *Id*. ¶ 53. ChromaDex's allegations make clear that Novex's "conduct [is] fraudulent and deceptive because the representations and/or omissions made on the Products' packing and within advertisements for the Products can be refuted by reliable scientific data." *Vasic*, 2014 WL 940323, at *4. This is not a lack of substantiation case.

ChromaDex's complaint is in accord with many cases finding that the plaintiff has alleged an actual falsity, rather than lack of substantiation claim, under the UCL and FAL. For example, in *Racies* the plaintiff alleged that defendant's representations that its product "improves memory" are false because the product "cannot work as represented." 2015 WL 2398268, at *4. The scientific evidence shows that "ingestion of [the Product] cannot and does not have any effect on brain function or memory." *Id.* The court held that plaintiff alleged an actionable claim under the UCL based on actual falsity, not just a lack of substantiation. *Id.*; *see also* *In re Clorox Consumer Litig.*, 894 F. Supp. 2d 1224, 1232 (N.D. Cal. 2012) ("[T]he Court cannot conclude that Plaintiffs are merely alleging a lack of substantiation. Rather, the Complaint clearly alleges that the challenged representations are false.").

2. ChromaDex Has Pled Sufficient Facts Showing That Novex's Health Benefit Statements Are False

Novex next argues that the allegations that Oxydrene does not work (and in fact cannot work) are mere conclusions under Rule 8 and 9(b). However, Novex's only argument is to point to paragraphs in its own complaint "by way of contrast" discussing Novex's reading of scientific studies that it believes support *its claims* against ChromaDex. Mot. at 11-12. But Rule 12(b)(6) is not a compare and contrast exercise. And the only reason that Novex was able to cite specific studies is because ChromaDex's product (unlike Novex's) is supported by five human clinical trials (to say nothing of the reams of other types of research) that have all been published in peer reviewed journals. Counterclaims ¶¶ 30-31. Novex's product has none.

In any event, Novex's apparent assertion that ChromaDex needed to cite specific studies in its complaint is legally meritless. Mot. at 12. A plaintiff need not "cite even a solitary study or test" at the pleading stage. *Racies*, 2015 WL 2398268, at *4 (citations omitted). Rather, that "must be left to later stages of the litigation in which the strength of the evidence is an appropriate consideration." *Id.*

Novex is asking this Court "to weigh potential evidence that the parties might present at trial," which is not the proper inquiry on a motion to dismiss. *Advanced Comfort Techs. Inc., v. London Luxury LLC*, No. 2:17-CV-00497, 2017 WL 6060634, at *4 (D. Utah Dec. 6, 2017). ChromaDex "has pled [its] claim with sufficient specificity to give [Novex] notice of the theory of misconduct it must defend against, and no more is required at this stage." *Racies*, 2015 WL 2398268, at *4.

CONCLUSION

Accordingly, ChromaDex respectfully requests that this Court deny Novex's Motion to Dismiss ChromaDex's counterclaims. If the Court is inclined to grant Novex's motion, ChromaDex respectfully requests leave to amend its complaint under Rule 15. *See Procter & Gamble Co. v. Haugen*, 179 F.R.D. 622, 630 (D. Utah 1998), *aff'd in part, rev'd in part*, 222 F.3d 1262 (10th Cir. 2000) (Under Rule 15 "the decision to grant leave to amend a complaint after the permissive period is within the trial court's discretion, and leave is to be freely given when justice so requires."). Each of Novex's concerns can easily be addressed in an amended complaint.

Dated: July 26, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2019, a true and correct copy of the foregoing **CHROMADEX, INC.'S MEMORANDUM IN OPPOSITION TO NOVEX BIOTECH, LLC'S MOTION TO DISMISS CHROMADEX'S COUNTERCLAIMS** was served on the following via CM/ECF notice:

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