United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GUARDANT HEALTH, INC.,

Plaintiff,

v.

NATERA, INC.,

Defendant.

Case No. 21-cv-04062-EMC

PUBLIC/REDACTED VERSION

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION TO DISMISS OR STRIKE AMENDED COUNTERCLAIMS

Docket No. 95

Plaintiff Guardant Health Inc. ("Guardant") filed this action against Defendant Natera, Inc. ("Natera") alleging that Natera launched a "campaign of false and misleading advertising directed at" its new product—"Reveal"—a liquid biopsy cancer assay for early-stage colorectal cancer. *See* Docket No. 1 ("Compl.") ¶ 1. Natera then filed amended counterclaims ("Amended Counterclaims") against Guardant, alleging that Guardant has engaged in a "campaign of false and misleading commercial statements regarding the performance of [Reveal]." *See* Docket No. 90 ("Am. Countercl.") ¶ 3.

Pending before the Court is Guardant's motion to dismiss or strike Natera's Amended Counterclaims. *See* Docket No. 95 ("Mot."). For the following reasons, the Court **DENIES** Guardant's motion to dismiss Natera's Counts I–IV and **GRANTS** its motion to dismiss or strike Natera's Counts V–VIII without prejudice.

I. BACKGROUND

A. Factual History

A detailed factual background of this case can be found in the Court's order denying

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purposes of this motion, the following facts are relevant. The parties offer competing diagnostic tools for colorectal cancer ("CRC")—Guardant's "tumor-naïve" Reveal and Natera's "tumor-dependent" Signatera assay. Am. Countercl. ¶ 28. Guardant bases its contentions that Reveal works on "[p]eer reviewed data published by Parikh, et al., in the journal of Cancer Research" (the "Parikh Study"). Compl. ¶ 20; *see* Aparna R. Parikh et al., *Minimal Residual Disease Detection using a Plasma-Only Circulating Tumor DNA Assay in Colorectal Cancer Patients*, 021 Clinical Cancer Res. OF1, *available at* https://clincancerres.aacrjournals.org/content/early/2021/06/22/1078-0432.CCR-21-0410.full-text.pdf. The senior authors of the study are Dr. Aparna Parikh and Ryan Corcoran who are both faculty at the Harvard Medical School and members of the Department of Medicine, Division of Hematology and Oncology, Massachusetts General Hospital ("MGH") Cancer Center. Docket No. 90-1 (the "Parikh Study" or the "Study") at OF1. 38 of the 43 authors who undertook the study are affiliated with MGH and the remaining five authors are Guardant personnel. *Id.* at OF8.

The Parikh Study evaluated if a plasma-only minimal/molecular residual data ("MRD") assay, *i.e.*, Reveal, can detect circulating tumor DNA ("ctDNA") "with clinically meaningful specificity and sensitivity." *Id.* at OF2. "Specificity" "measures the percentage of negative results that are correctly identified among non-recurring patients." Am. Countercl. ¶ 34. "A test with high specificity is more likely to identify the absence of cancer in a blood sample when no MRD is in fact present, as verified by a clinical 'gold standard' (*e.g.*, the patient remains recurrence-free or progression-free)." *Id.* "Sensitivity" "measures the percentage of positive results that are correctly identified among recurring patients, as verified by a clinical 'gold standard' (*e.g.*, subsequent clinical or radiographic recurrence)." *Id.* ¶ 33. "A test with high sensitivity is more likely to detect the presence of ctDNA in a blood sample in which MRD is actually present." *Id.* The Study allegedly "shows that Reveal offers 91% recurrence sensitivity (i.e., ability to identify which patients will recur based on ctDNA detection) and 100% positive predictive value for recurrence (i.e., all patients Reveal identified as having a 'positive' ctDNA test result later recurred)." Compl. ¶ 20.

The Study utilized the banked blood samples of patients from MGH collected at various

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time points from August 2016 to May 2019. Parikh Study at OF1, OF2, OF7. It presented data at a "landmark" timepoint, "defined as the plasma specimen drawn approximately 1 month after completion of definitive therapy (surgery alone or completion of adjuvant therapy for patients who received adjuvant treatment)." *Id.* at OF2. It assessed data at "longitudinal timepoints," "defined by patients who had subsequent draws after their 'landmark' timepoint." *Id.* And it assessed data from "surveillance" draws, defined as "a draw obtained within 4 months of clinical recurrence." *Id.* The "surveillance" draws were purportedly defined based on methods employed by a separate study, the Reinert study, which evaluated the efficacy of Natera's product, Signatera.[1] *Id.* "Patients without clinical follow-up available were excluded from the study. Analysis was completed for patients with at least 1 year of follow-up and for the overall eligible cohort." *Id.* at OF3.

The Parikh Study reported that, "Landmark recurrence sensitivity and specificity were 55.6% and 100%. Incorporating serial longitudinal and surveillance (drawn within 4 months of recurrence) samples, sensitivity improved to 69% and 91%." *Id.* at OF1. Specifically, of 70 landmark evaluable patients—*i.e.*, patients who had their plasma specimen drawn approximately one month after completion of definitive therapy—17 patients had detectable ctDNA. *Id.* at OF4. Of the 17 patients with detectable ctDNA, 15 patients recurred. *Id.* The Parikh Study reports that landmark recurrence specificity was 100%, however, because the two patients, who had detectable ctDNA but did not recur, had a follow-up of less than one year and the Study only accounted for patients with at least one year of follow-up. *Id.* Therefore, when accounting for patients with at least one year of clinical follow-up, 15 of 15 patients with detectable ctDNA recurred, meaning the landmark recurrence specificity was 100%. *Id.* Additionally, of the 49 patients without detectable landmark ctDNA, 12 patients recurred. *Id.* In other words, of the 27 patients who recurred, Reveal detected ctDNA in 15 of them and therefore the landmark recurrence sensitivity was 55.6% and the specificity was 100%. *Id.*; *see also id.* at OF6, Fig. 3b.

[1] Reinert T., Henricksen TV, Christensen E. et al. study entitled "Analysis of Plasma Cell-Free DNA by Ultradeep Sequencing in Patients with Stages I to III Colorectal Cancer," published in

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Furthermore, after "incorporating serial longitudinal samples" the sensitivity for recurrence prediction improved to 69% and after incorporating "surveillance" samples the sensitivity improved to 91%. *Id.* at OF1. The Parikh Study explains that "sensitivity for recurrence prediction can be improved with longitudinal plasma monitoring." *Id.* Nine of 14 patients "who recurred despite no detectable landmark ctDNA or who lacked landmark draws had at least one evaluable longitudinal specimen at a later timepoint." *Id.* By integrating the longitudinal specimens, the sensitivity improved to 69% because of the 29 patients who recurred, Reveal detected ctDNA in 20 patients. *Id.* at OF6, Fig. 3b. The Parikh Study also "assessed performance in patients with evaluable 'surveillance' draws, defined as a draw within 4 months of clinical occurrence, and observed that sensitivity improved to 91%." *Id.* at OF4. Seven of the 29 patients who recurred did not have a surveillance draw. Of the 22 patients who recurred and had a surveillance draw, Reveal detected ctDNA in 20 out of 22 patients, and therefore the sensitivity improved to approximately 91% under a "surveillance" analysis. *Id.* at OF6, Fig. 3b.

After it was peer-reviewed, the Parikh Study was published in the journal Clinical Cancer Research, which is published by the American Association for Cancer Research. *Id.* at OF1. Guardant has referred to the results of the Parikh Study in its advertisements to doctors, clinicians, and biopharmaceutical companies as well as communications with stakeholders regarding Reveal. *See, e.g.*, Docket No. 90-2 at 18 (conference presentation); Docket No. 90-3 (press release about Reveal's commercial launch).

B. Procedural History

On May 27, 2021, Guardant filed the instant action seeking to enjoin Natera "from continuing to make or disseminate false or misleading statements about the performance of Reveal and Signatera; to require Natera to retract, remove, and correct these false and misleading advertising claims; and to recover damages." Compl. ¶ 4. Guardant raises four causes of action in its Complaint: (1) false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); (2) false advertising in violation of section 17500 of the California Business and Professions Code, Cal. Bus. & Prof. Code §§ 17500–17509; (3) unlawful trade practices in violation of section 17200 of the California Business and Professions Code, Cal. Bus. & Prof. Code §§ 17200–17210;

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and (4) common law unfair competition. *Id.* ¶¶ 56–81.

On June 2, 2021, Guardant filed a motion for a temporary restraining order ("TRO") seeking to enjoin Natera from making derogatory statements about Reveal at the American Society of Clinical Oncology ("ASCO") annual meeting. Docket No. 12 ("First TRO Mot."). By the Court's instruction, the parties filed a joint statement under seal on June 5, 2021, where they agreed not to make any direct head-to-head comparisons of the products until the Court had a chance to rule on Guardant's forthcoming motion for a preliminary injunction. *See* Docket No. 25-3 ("Joint Statement").

On July 20, 2021, Natera filed its own TRO motion, alleging that Guardant is "disseminating false and misleading statements inflating the performance of Reveal . . . as part of a sweeping new 'Product Launch' sales campaign commenced on or around July 15, 2021." *See* Docket No. 62 ("Second TRO Mot.") at 1. Specifically, Natera challenged the veracity of the following statements from a July 15, 2021 advertising email from Guardant's sales team to physicians around the country:

> "Reveal has higher specificity than CEA [carcinoembryonic antigen tests, which are the current standard of care] in the surveillance setting;
>
> Reveal has a 91% sensitivity in the surveillance setting;
>
> Reveal's PPV [positive predictive value] is 100% and can have benefits in patients with stage 2 colorectal cancer, including identifying patients who may benefit most from adjuvant therapy;
>
> and Reveal has a greater lead time for detecting MRD [minimal/molecular residual disease] than current methods."

Id. at 8. It complained that these statements "either lack any support in the Parikh study—the only published study that has ever reported the performance of Reveal in anything approximating a 'surveillance' setting—or severely distort what Parikh actually reported about Reveal," *id.* at 5–8. The Court acknowledged that district courts in the Ninth Circuit have generally issued preliminary injunctions in false advertising and unfair competition cases only when it is clear that the commercial speech at issue is "literally false." PI Order at 8. It denied Natera's motion because it was not clear that Guardant's statements were literally false. *Id.* at 13.

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