UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

| | |
|---|---|
| DNA GENOTEK INC., a Delaware Corporation,<br><br>Plaintiff,<br><br>v.<br><br>SPECTRUM SOLUTIONS L.L.C., a Utah Limited Liability Company, and SPECTRUM DNA, a Utah Limited Liability Company,<br><br>Defendants. | Case No.: 16-CV-1544 JLS (NLS)<br><br>**ORDER DENYING PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**<br><br>(ECF No. 12) |

Presently before the Court is a Motion for Preliminary Injunction filed by Plaintiff DNA Genotek Inc. ("DNAG") in a patent infringement case against Defendants Spectrum Solutions L.L.C. and Spectrum DNA ("Spectrum"). (PI Mot., ECF Nos. 12, 16 (sealed).) Defendants filed a response in opposition to the preliminary injunction motion. (Opp'n PI Mot., ECF Nos. 35, 38 (sealed).) Plaintiff filed a reply in support of its motion for preliminary injunction. (Reply ISO PI Mot., ECF Nos. 50, 51, 53 (sealed).) Defendants filed a sur-reply in opposition to the motion. (Sur-reply Opp'n PI Mot., ECF No. 59.)

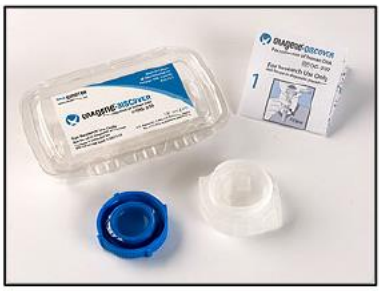
The hearing set for the Motion on September 29, 2016 was vacated, and the matter taken under submission on the papers without oral argument pursuant to Civil Local Rule

7.1.d.1. Having considered the parties' arguments and the law, the Court **DENIES** Plaintiff's Motion for Preliminary Injunction.

## BACKGROUND

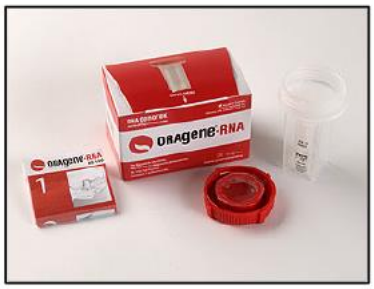
### I. Factual Background

DNAG is a leading provider of biological sample collection products (e.g., saliva collection devices for DNA testing). (PI Mot. 1, ECF No. 12-1) DNAG has several products that it claims are covered by U.S. Patent Number 9,207,164 B2 (the "'164 patent"). (*Id.* at 2.) Representative examples are depicted below:



Oragene•Discover
('164 Pat., Figs. 4-11)

Customized Oragene®
('164 Pat., Figs. 12-21)




OraGene•RNA®
('164 Pat., Figs. 22-24)

(*Id.*) In general, the '164 patent describes a "two compartment" DNA collection container, where one compartment houses a "substance" like a DNA preservative, while the other compartment stores a "sample," like saliva. When used, the DNA preservative mixes with the sample, which preserves the sample and allows testing of the sample at a later date. In at least one of DNAG's products, the preservative is housed in the cap, and, when the user places the cap onto the vial, the "piercing members" of the vial pierce the membrane in the cap, thus releasing the preservative and mixing it with the user's saliva. (*Id.*)

Like DNAG, Spectrum is a company that manufactures saliva collection kits. (Opp'n PI Mot. 5, ECF No. 38.) The accused Spectrum product includes a collection tube, a funnel, and a cap. (*Id.*) The Spectrum product contains the piercing insert inside the cap, not in the vial. (*Id.*)

/ / /

/ / /

## II. Procedural Background

On May 24, 2015, Plaintiff sued Ancestry.com DNA, LLC ("Ancestry") in the District of Delaware ("Delaware litigation") alleging infringement of U.S. Patent Number 8,221,381 (the "'381 patent"). (Opp'n PI Mot. 2, ECF No. 38.) On July 30, 2015, Plaintiff sued Defendants in the same district asserting infringement of the '381 patent. (*Id.*) On August 24, 2015, Plaintiff filed a motion for a preliminary injunction in the Delaware litigation, and on February 24, 2016 the Delaware court denied Plaintiff's motion without prejudice until it addressed personal jurisdiction. (*Id.*)

On October 20, 2015, Ancestry filed a petition seeking IPR of several claims of the '381 patent (the "First '381 Petition"). (*Id.*) On April 8, 2016, the PTAB issued an institution decision finding that Ancestry "ha[d] demonstrated a reasonable likelihood that it would prevail in showing that claims 1, 2, 4, 5, 7, 8, 11, 12, 15-17, 20, 41, 44, and 49 of the '381 patent are unpatentable." (*Id.* at 2–3.) On June 3, 2016, Ancestry filed a new IPR petition (the "Second '381 Petition") seeking review of certain claims of the '381 patent that had not yet been accepted into IPR. (*Id.* at 3.) On July 20, 2016, Ancestry submitted a petition seeking IPR of each asserted claim of the '164 patent at issue in this case. (*Id.*, citing Sanders Decl., Ex. 11.)

On June 20, 2016, Plaintiff DNAG filed the present case alleging that Spectrum infringes the '164 patent and seeking, among other things, injunctive relief. (Compl., ECF No. 1.) The next day Plaintiff filed its Motion for Preliminary Injunction seeking to enjoin Defendants from continuing to infringe the '164 patent through the duration of litigation. Specifically, Plaintiff alleges that Defendants infringe claims 7, 9, 16, 42, and 55 of the '164 patent. (PI Mot. 7–12, ECF No. 12-1.)

## LEGAL STANDARD

"A preliminary injunction is a 'drastic and extraordinary remedy that is not to be routinely granted.'" *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) (quoting *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993)). "A plaintiff seeking a preliminary injunction must establish that he is likely

to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Apple v. Samsung*, 695 F.3d 1370, 1373–74 (Fed. Cir. 2012). In granting or denying a preliminary injunction, a court must "state the findings and conclusions that support its action." Fed. R. Civ. P. 52(a)(2); *see also Murata Mach. USA, Inc. v. Daifuku Co., Ltd.*, 2016 WL 4073320, at *4 (Fed. Cir. 2016). A "'limited analysis may support a trial court's denial of a preliminary injunction' so long as the district court concludes that some of the requisite preliminary injunction factors disfavor the movant." *Murata*, 2016 WL 4073320, at *5 (citations omitted).

## ANALYSIS

With these principles in mind, the Court now considers the factors outlined above as they relate to this case.

### I. Likelihood of Success on the Merits

"With regard to the first factor—establishing a likelihood of success on the merits—the patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). The burdens and presumptions that apply at trial similarly apply at the preliminary injunction stage. *See id.* Plaintiff accuses Defendants of infringing claims 7, 9, 16, 42, and 55 of the '164 patent, while Defendants argue their products are noninfringing. Additionally, Defendants argue that the '164 patent is invalid, a point which Plaintiff obviously contests. Because the Plaintiff is not likely to succeed on the merits with regard to validity, the Court does not consider the parties' infringement arguments.

#### *A. Validity*

At the preliminary injunction stage, the court "does not resolve the validity question, but rather must . . . make an assessment of the persuasiveness of the challenger's evidence, recognizing that it is doing so without all evidence that may come out at trial." *Titan Tire*,

566 F.3d at 1377 (citations omitted). Accordingly, Plaintiff "must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." *Id.* "[I]f the trial court concludes there is a 'substantial question' concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue." *Id.* at 1379 (citations omitted).

Defendants argue that there is a reasonable likelihood that the asserted claims are invalid "as evidenced by the fact that the PTAB has already found a likelihood of success on invalidity with respect to analogous claims of a closely related patent, except for a handful of minor additional elements covered by the pending IPR petitions." (Opp'n PI Mot. 11, ECF No. 38.) Defendants provide comparison charts detailing the similarities and differences between both sets of claims (i.e., the '381 patent claims under *Inter Partes* review and their analogs in the '164 patent). (*See id.* at 11–12, citing Sanders Decl., Exs. 3, 12.) Defendants also cite IPR statistics noting that "an overwhelming percentage of IPR petitions are accepted and result in cancellation or amendment." (*Id.* at 11.) While Plaintiff acknowledges that the PTAB instituted IPR proceedings against claim 1 of the '381 patent—similar in many respects to claim 1 of the '164 patent, on which many of the asserted claims depend—Plaintiff argues that Defendants' IPR argument is irrelevant as to asserted claim 55 because the PTAB "expressly rejected Spectrum's petition to institute IPR proceedings against" similar claims in the '381 patent. (PI Mot. 13, ECF No. 12.)

On balance, the Court is persuaded by Defendants' arguments. Plaintiff has not rebutted Defendants' argument that pending IPR proceedings on claims in a related patent similar to those asserted in this case raise a substantial question about the validity of certain of the asserted claims in this case. While the asserted claims of the '164 patent may not be identical in every respect to those currently under review before the PTAB, the Court finds that the claims are sufficiently similar to those in the related '381 patent currently under IPR to raise serious questions about the validity of the asserted claims in this case. *Cf.*

*Murata Mach. USA, Inc. v. Daifuku Co.*, No. 2:13-CV-866-DAK, 2016 WL 4287040, at *2 (D. Utah Aug. 15, 2016) ("Acceptance of the patents for IPR raises a question about the validity of the patents, which is one of the key considerations in determining whether a plaintiff is able to demonstrate a likelihood of success on the merits. As long as the IPRs are pending before the Patent Trial and Appeals Board, the court concludes that Murata will not be able to demonstrate a likelihood of success on the merits."). Accordingly, at this stage Plaintiff has not shown a likelihood of success on the merits with regard to the validity of asserted claims 7, 16, and 42 of the '164 patent.

However, this reasoning does not currently apply to asserted claims 9 and 55 because neither they nor their related claims in the '381 patent are under review (though Ancestry has recently filed petitions for IPR challenging both claims). Nevertheless, the Court still finds that Plaintiff is unlikely to succeed on the merits with regard to the validity of claims 9 and 55. As discussed, claim 1 of the '164 patent bears close resemblance to claim 1 of the '381 patent, which is currently under review at the PTO. Both claim 9 and claim 55 are dependent on claim 1.

Claim 9 of the '164 patent reads: "The container system of claim 1, wherein said chamber is configured to receive about 1 ml to about 16 ml of said sample." ('164 Patent col. 13 ll. 53-55.) Defendants argue that this is a "minor variation[] disclosed in Genotek's own prior art patent, Birnboim" which, in combination with the O'Donovan reference,[1] would render the claim obvious. (Opp'n PI Mot. 12, ECF No. 38.) In particular, Defendants argue that Birnboim[2] "discloses that the container should be configured to receive ~1-2 milliliters of sample." (*Id.*) Defendants' expert Dr. Terry N. Layton explains that a person of ordinary skill would have been motivated to combine elements from both O'Donovan and Birnboim in order to create an improved container system. (Layton Decl. ¶¶ 104–113.) Alternatively, Dr. Layton explains that it was a "usual practice in medical

[1] U.S. Patent No. 7,645,424 ("O'Donovan).
[2] WO 03/104251 ("Birnboim").

and biomedical industry to collect a few milliliters of blood to run various types of tests," and that O'Donovan discloses using a device to provide a sample such as blood. (*Id.* at ¶ 112.)

Plaintiff argues that the O'Donovan reference "does not meet the limitation in claim 1 of the '164 patent requiring a 'lid configured to removably engage said vial.'" (Reply ISO PI Mot. 6, ECF No. 53.) However, the PTAB was not persuaded by this argument in deciding to institute IPR on claim 1 of the '381 patent, which contains the same 'removably engage' limitation. To the contrary, the PTAB was "persuaded that O'Donovan discloses the 'removably engage' limitation" because the "fact that the cover would ensure that the starter reagent chamber (lid) is *held in place* in the socket of the inspection chamber (vial) implies that the starter reagent chamber is removable from the socket." (*See* Sanders Decl., Ex. 9, at 196 (emphasis in original).) Additionally, neither Plaintiff's reply nor its expert declaration of Dr. John M. Collins appear to address Defendants' contention that claim 9 is obvious over Birnboim in view of O'Donovan. (*See* Sur-reply Opp'n PI Mot. 6, ECF No. 59.) Accordingly, at this juncture Plaintiff has failed to demonstrate that it is likely to succeed on the merits with regard to the validity of claim 9 of the '164 patent.

Claim 55 of the '164 patent reads: "The container system of claim 54, wherein said nucleic acid is DNA or RNA." ('164 Patent col. 16 ll. 26-27.) Claim 55 is dependent on claim 54, which is itself dependent on claim 1.[3] As above, Defendants argue that this claim is obvious by combining Birnboim with the O'Donovan reference. (Opp'n PI Mot. 12, ECF No. 38.) Dr. Layton offers the same motivation to combine as discussed with regard to claim 9. (Layton Decl. ¶ 117.) Regarding the particular limitations of claims 54 and 55, Dr. Layton explains that Birnboim expressly discloses a "device for preserving and/or isolating a nucleic acid obtained from a biological sample" and further teaches that the "nucleic acid to be preserved by the composition can be DNA or RNA." (*Id.* at ¶ 116,

[3] Claim 54 of the '164 patent reads: "the container system of claim 1, wherein said substance is a composition for the stabilization and recovery of a nucleic acid from a biological sample." ('164 Patent col. 16 ll. 23-25.)

citing Birnboim at col. 9 ll. 17-18; col. 6 l. 22.) And as with claim 9, Plaintiff fails to address Defendants' contention that claim 55 is obvious over Birnboim in view of O'Donovan. Accordingly, at this juncture, Plaintiff is unlikely to succeed on the merits with regard to the validity of claim 55 of the '164 patent.

**II. Irreparable Harm**

Plaintiff must also demonstrate that it is likely to suffer irreparable harm as a result of Defendants' patent infringement in the absence of a preliminary injunction. However, the Court declines to address the parties' arguments regarding irreparable harm because the Court concludes that Plaintiff is not likely to succeed on the merits and thus the Court may deny the motion on this finding alone. *See Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994) ("Because, irrespective of relative or public harms, a movant must establish both a likelihood of success on the merits *and* irreparable harm . . . the district court may deny a preliminary injunction based on the movant's failure to establish either of these two crucial factors without making additional findings respecting the other factors."); *see also Murata Mach. USA, Inc. v. Daifuku Co.*, No. 2:13-CV-866-DAK, 2016 WL 4287040, at *2 (D. Utah Aug. 15, 2016) ("Because a movant cannot be granted a preliminary injunction without showing both a likelihood of success on the merits and irreparable harm, the court concludes that its finding that Murata will not be able to demonstrate a likelihood of success on the merits is sufficient, on its own, for the court to deny a preliminary injunction in this case."). Nevertheless, the Court balances the hardships and considers the public interest in the proceeding sections.

**III. Balance of Hardships**

In evaluating Plaintiff's motion for a preliminary injunction, this Court must weigh the harm Plaintiff will likely suffer without an injunction against the harm Defendants will likely suffer if the Court grants an injunction. Plaintiff argues that without an injunction it will be forced to compete against its own patented invention, and that Defendants' lower-cost product might disrupt the market and result in serious and irreparable losses to Plaintiff. (PI Mot. 24, ECF No. 12-1.) Moreover, Plaintiff argues that any hardship

Defendants face "would be the result of its own calculated risk in selling a product with knowledge of [DNAG's] patent," and that such hardship is offset by the fact that Defendants engage "in a wide variety of business ventures." (*Id.* (internal quotations omitted); *see also* Reply ISO PI Mot. 15, ECF No. 53.) Defendants argue that Plaintiff's "calculated risk" argument is inapposite because Defendants' products do not infringe the '164 patent, and that Plaintiff's business diversity argument is disingenuous because Plaintiff is also involved in other business ventures since it is a subsidiary of a larger company. (Opp'n PI Mot. 30, ECF No. 38.) Defendants also argue that granting an injunction "could be devastating" to their business. (*Id.*)

On balance, the Court finds that Defendants would suffer more hardship if the proposed preliminary injunction is granted. While Plaintiff may suffer by having Defendants continue as a market competitor, a complete ban of Defendants' product is much more likely to result in "devastating" harm to Spectrum. *See Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990) ("The hardship on a preliminarily enjoined manufacturer who must withdraw its product from the market before trial can be devastating."). This is especially true where, as here, Defendants vigorously contest infringement and the Court finds that Plaintiff is not likely to succeed on the merits with regard to the validity of the asserted claims. *Contra Illumina, Inc. v. Qiagen, N.V.*, No. C 16-02788 WHA, 2016 WL 4719269, at *11 (N.D. Cal. Sept. 9, 2016) (granting a preliminary injunction where the defendant did not deny that the plaintiff was likely to succeed on the merits with regard to infringement, and noting that while the defendant claimed it might suffer financial hardship if an injunction is granted, "that is the price of its election 'to build a business on a product found to infringe'") (citations omitted). Accordingly, the Court finds that this factor weighs against granting a preliminary injunction.

**IV. Public Interest**

In evaluating Plaintiff's motion for a preliminary injunction, the Court "should pay particular regard for the public consequences in employing the extraordinary remedy of

injunction." *Winter*, 555 U.S. at 24 (citations omitted). Plaintiff argues that an injunction is in the public interest because the patent system encourages innovation and Plaintiff's—and any inventor's—incentive to innovate would be hindered by taking Plaintiff's market benefits and giving them to an accused infringer. (PI Mot. 25, ECF No. 12-1.) Defendants argue that Plaintiff's assertion is generic and unsupported by any analysis. (Opp'n PI Mot. 30, ECF No. 38.) Additionally, Defendants argue that their products are innovative and that some of their sales go to research institutions. (*Id.*)

On balance, the Court finds that the public interest would best be served by denying a preliminary injunction. While Plaintiff is correct that a strong patent system—and its enforcement—is in the public interest, that argument has less force here because there are serious questions regarding the validity of the asserted claims of the '164 patent. In such a case, the public interest would be better served by increased competition between two competitors concerning a product that may not only be found to be noninfringing, but also noninfringing an invalid patent. Accordingly, this factor weighs against granting a preliminary injunction.

## CONCLUSION

Accordingly, the Court **DENIES** Plaintiff's Motion for Preliminary Injunction (ECF No. 12).

**IT IS SO ORDERED.**

Dated: October 6, 2016

Janis L. Sammartino
Hon. Janis L. Sammartino
United States District Judge