United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PRIMUS GROUP, INC.,

Plaintiff,

v.

INSTITUTE FOR ENVIRONMENTAL HEALTH, INC.,

Defendant.

Case No. 18-cv-00005-WHO

ORDER DENYING PRIMUS'S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY; GRANTING INSTITUTE FOR ENVIRONMENTAL HEALTH, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT; MOTIONS TO SEAL

Re: Dkt. Nos. 62, 63, 64, 65, 66, 72, 74, 80

In this action, plaintiff and counter-defendant Primus Group Inc. ("Primus") seeks declaratory judgment of patent invalidity and of patent non-infringement related to two patents owned by defendant and counterclaimant Institute for Environmental Health, Inc. ("IEH"), and IEH asserts a counterclaim contending that Primus infringes on the same two patents. [Dkt. Nos. 23 and 25]. The patents in suit, Patent No. 8,822,143 ('143 Patent) and Patent No. 9,637,771 ('771 Patent), relate to testing for microbial contamination. Now Primus moves for summary judgment to invalidate the patents in suit as being obvious (Primus Motion for Summary Judgment of Invalidity ("Primus MSJ") [Dkt. No. 66]) and IEH seeks partial summary judgment asserting that Primus has infringed on its patents. Defendant Institute for Environmental Health, Inc.'s Notice of Motion and Motion for Partial Summary Judgment ("IEH MSJ") [Dkt. No. 62-4]. Primus's pooled testing method infringes IEH's patented method 99.99% of the time, and IEH does not claim infringement on the other .01%. For the reasons discussed, below Primus's motion for summary judgment is denied and IEH's motion for partial summary judgment is granted.

BACKGROUND

Food Testing

Primus and IEH are competitors in the field of testing for microbial contaminants in the food industry. In order to prevent foodborne illnesses, food is tested for the presence of pathogens such as *E. coli, Salmonella*, and *Listeria*. Declaration of Dr. Bruce Applegate in Support of Institute for Environmental Health, Inc.'s Opposition to Primus Motion for Summary Judgment of Invalidity ("Applegate Decl.") at ¶ 79 [Dkt. No. 74-10]. Notable outbreaks in the past include the 1993 outbreak of *E. coli*, which was traced to hamburgers at Jack-in-the-Box, and the 1996 *E. coli* outbreak traced to Odwalla apple juice. *Id.*[1] According to the Centers for Disease Control, between 1998 and 2002, there were 6,647 reported outbreaks of foodborne disease, causing 128,370 persons to become ill. *Id.* (Michael Lynch, et al., Surveillance for Foodborne-Disease Outbreaks – United States, 1998-2000, CDC (Nov. 10, 2006), https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5510a1.htm).

Traditionally, the food industry approached pathogen testing as if contamination was distributed uniformly through production "lots"; producers maximized the size of their lots to reduce the number of pathogen tests that needed to be performed. *Id.* at ¶ 3. The downside to this approach is that once a pathogen was detected, producers often had to destroy the entire large lot of food. *Id.* But if producers instead used smaller lots, it would drive up costs by requiring additional sampling and assays (tests) of each lot. *Id.* IEH's founder, CEO, and President, Mansour Samadpour, patented a method to test for pathogens that is meant to be faster and more cost effective than testing either large lots or smaller lots individually. *Id.* at ¶ 3.

The Patents at Issue

The patents at issue describe a method for screening test lots for the presence or absence of microorganisms. '143 Patent and '771 Patent attached as Exs. D-F to Declaration of Scott J. Allen

[1] Dr. Applegate cites to Food Safety News, *Jack in the Box E. coli Outbreak – 25th Anniversary* (Dec. 27, 2017), https://www.foodsafetynews.com/2017/12/jack-in-the-box-e-coli-outbreak-25th-anniversary/ and Pam Belluck, *Juice-Poisoning Case Brings Guilty Plea and a Huge Fine*, N.Y. Times (July 24, 1998), https://www.nytimes.com/1998/07/24/us/juice-poisoning-case-brings-guilty-plea-and-a-huge-fine.html).

in Support of Motion for Summary Judgment ("Allen Decl.") [Dkt. No. 66-1]. They are both titled "Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents." *Id.* The invention claimed involves the following steps:

> a) separately collecting multiple independent samples from each of multiple separate lots,[2] wherein each separate lot is separately sampled by taking said multiple independent samples thereof;
>
> b) separately compositing the collected multiple independent samples from each of the separate lots to provide a corresponding set of separate composited lot samples, wherein each of the separate composited lot samples is attributed to a particular corresponding separate lot;
>
> c) enriching each of the separate composited lot samples to provide a set of separate composited lot samples enriched for the target microbe(s);
>
> d) removing portions of each separate enriched composited lot sample, and combining the removed portions to provide a pooled modular composite sample; and
>
> e) testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe(s), wherein when such testing is negative all of said samples that were composited to form the separate composited lot samples are deemed negative for the target microbe(s) and each of the multiple separate lots is validated, and wherein when such testing is positive, each of the individual separate composited lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited lot samples is positive for the target microbe(s), wherein the lots corresponding to any negatively testing composited lot samples are validated.

'771 Patent at 15:30-60; '143 Patent at 15:7-38.

Put more simply, step A involves collecting samples, step B involves combining those samples (pooling/dry compositing), step C involves enriching the pooled samples to allow the targeted bacteria (if present) to grow, step D involves taking portions of each enriched composited sample (pooling again/wet compositing) into a pooled modular composited sample, and step E involves testing that pooled modular composited sample for the presence of the target bacteria. If the test is negative, step E validates all the lots from which the samples were drawn. If the test is

[2] In my Claim Construction Order I construed this claim term as "Collecting multiple samples from different, non-contiguous locations from each of multiple separate lots." [Dkt. No. 50].

positive, step E requires testing of the enriched pooled samples, validating the lots for samples which test negative. Primus characterizes steps A and B together as "dry compositing" and step C as enrichment of the dry composited sample. *Id.* at 2-4. Step D is characterized as wet compositing, with pre-enrichment (after the first of a two-step enrichment process) wet compositing allegedly taught by the USDA and Price references and post-enrichment wet pooling as taught by the Gombas reference. *Id.* at 4-5.

The enriching process described in step C is meant to make contamination easier to detect. Applegate Decl. at ¶ 8. The composite samples are collected into a warm liquid in order to create a condition that encourages bacteria to grow and multiply, akin to how leaving warm food outside the refrigerator causes it to go bad more easily. *Id.* It is easier to detect bacteria in a sample when there is more of it. *Id.* Conversely, pooling dilutes samples and makes contamination harder to detect. *Id.* at ¶ 9. As a result, conventional wisdom taught that dilution should be avoided in testing methods intended to locate small amounts of contaminants. *Id.* The testing method described in the patent is meant to remain accurate despite the pooling, and to make it easier to trace contamination to the correct lot when present.

According to Primus, each of these steps is taught by prior art. Primus MSJ at 2-7.

LEGAL STANDARD

A party is entitled to summary judgment where it "shows that there is no genuine dispute as to any material fact and [it] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is genuine if it could reasonably be resolved in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material where it could affect the outcome of the case. *Id.*

The moving party has the initial burden of informing the court of the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine dispute of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). Once the movant has made this showing, the burden shifts to the nonmoving party to identify specific evidence showing that a material factual issue remains for trial. *Id.* The nonmoving party may not rest on mere allegations or denials from its pleadings, but must "cit[e] to particular parts of materials in the

record" demonstrating the presence of a material factual dispute. Fed. R. Civ. P. 56(c)(1)(A); *see also Liberty Lobby*, 477 U.S. at 248. The nonmoving party need not show that the issue will be conclusively resolved in its favor. *Id.* at 24-49. All that is required is the identification of sufficient evidence to create a genuine dispute of material fact, thereby "requir[ing] a jury or judge to resolve the parties' differing versions of the truth at trial." *Id.* (internal quotation marks omitted). If the nonmoving party cannot produce such evidence, the movant "is entitled to . . . judgment as a matter of law because the nonmoving party has failed to make a sufficient showing on an essential element of her case." *Celotex*, 477 U.S. at 323.

On summary judgment, the court draws all reasonable factual inferences in favor of the nonmoving party. *Liberty Lobby*, 477 U.S. at 255. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Id.* However, conclusory and speculative testimony does not raise a genuine factual dispute and is insufficient to defeat summary judgment. *See Thornhill Publ'g Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738-39 (9th Cir. 1979).

DISCUSSION

I. PRIMUS'S MOTION FOR SUMMARY JUDGMENT

Primus moves for summary judgment that the patents in suit are obvious because they are composed entirely of techniques that were already known and well-understood in the field. Primus MSJ at 1. It argues that IEH's patents' parent only survived re-examination by the USPTO by a thin distinction between the method claimed and prior art. *Id.* That distinction is filled by prior art not considered by the USPTO, according to Primus, and so the elements of the patents would have been obvious to a microbiologist of ordinary skill. *Id.*

A. The Admissibility of Dr. Applegate's Opinions

1. Striking Primus's Counsel's Declaration

IEH's opposition relies heavily on the opinions of its expert, Dr. Bruce Applegate. *See generally* Defendant Institute for Environmental Health, Inc.'s Opposition to Primus's Motion for Summary Judgment of Invalidity ("Primus MSJ Oppo.") [Dkt. No. 74-6]. Primus argues that IEH cannot raise factual disputes based on Dr. Applegate's testimony because he lacks any specialized

expertise in compositing methods or in many of the other topics on which he offers expert opinions. Primus Reply in Support of its Motion for Summary Judgment Invalidity ("Primus MSJ Reply") at 1-2 [Dkt. No. 82]. Because the admissibility of Dr. Applegate's declaration is key to this motion, I will address that issue first.

Preliminarily, Primus attached to its reply a declaration by its attorney, Scott Allen, which is full of legal argument. Scott Allen Declaration in Support of Reply Memorandum, Motion for Summary Judgment ("Allen Reply Decl.") [Dkt 82-1]. IEH objects to portions of it and seeks to have paragraphs 2-14 and Exhibits A-D struck because they contain improper argument and conclusions that amount to a *Daubert* motion to which IEH has not had an opportunity to respond. Defendant Institute for Environmental Health, Inc.'s Objection to Reply Evidence ("IEH Objection") [Dkt. No. 83].

IEH is correct. Under Civil Local Rule 7-5(b), a declaration may only contain facts and must avoid conclusions and argument. Non-compliant declarations may be struck in whole or in part. As IEH argued, Primus attempted to exceed its reply brief page limit by embedding a *Daubert* motion in the Allen Reply Decl. IEH Objection at 1. Its argument should have been in Primus's reply brief, yet its brief provides only a single conclusory statement that Dr. Applegate is not qualified as an expert on a range of topics. *Id.* Otherwise, the reply relies on broad citations to paragraphs 2-14 of the Allen Reply Decl. to provide its actual arguments. *Id.* Argument in a declaration, by Primus's counsel no less, violates Civil Local Rule 7-5(b).

Accordingly, I strike paragraphs 2-14 of the Allen Reply Decl. I will not strike the attachments because they do not contain improper attorney argument.

2. Dr. Applegate's Qualifications

Turning to whether Dr. Applegate's report and declaration should be considered to evaluate Primus's motion for summary judgment, Rule 702 allows a qualified expert to testify "in the form of an opinion or otherwise" where:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;

> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed.R.Evid. 702. Expert testimony is admissible under Rule 702 "if it is both relevant and reliable." *Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007). "[R]elevance means that the evidence will assist the trier of fact to understand or determine a fact in issue." *Id.* Under the reliability requirement, expert testimony must "relate to scientific, technical, or other specialized knowledge, which does not include unsubstantiated speculation and subjective beliefs." *Id.* "Importantly, there must be a recognized body of knowledge, learning, or expertise upon which the witness relies. Where there is no field of expertise, nobody will qualify as an expert witness on the subject." *Perez v. Seafood Peddler of San Rafael, Inc.*, No. 12-cv-00116-WHO, 2014 WL 2810144, at *2 (N.D. Cal. June 20, 2014) (internal quotation marks omitted). The burden is on the proponent of the expert testimony to show, by a preponderance of the evidence, that the admissibility requirements are satisfied. Fed.R.Evid. 702 advisory committee's note.

The relevance of Dr. Applegate's testimony is undisputed, so the question is whether it is reliable. Dr. Applegate is a Professor in the Departments of Food and Biological Sciences at Purdue University and has been associated with the Department of Food Science since 1999. CV of Dr. Bruce M Applegate Ph.D. attached as Exhibit A to Applegate Decl. [Dkt. No. 75-4]. He has knowledge about how beef and lettuce are tested from attending food safety workshops, working with the Agricultural Research Service, and in pursuit of his own research developing methods for the detection of pathogens. Deposition of Bruce Applegate at 17:22-25, 18:1-6, 18:22-19:3, 19:18-21, 20:2-9, 126:13-127:17 attached as Ex. A to Declaration of Jennifer K. Chung in Support of Institute for Environmental Health, Inc.'s Objection to Reply Evidence [Dkt. No. 83-1]. This is sufficient to qualify him as an expert on food testing, despite the testimony identified by Primus that he does not research wet pooling or engage in compositing and noncontiguous sampling specifically. Deposition of Bruce Applegate at 26:11-14, 27:19-24, 34:7-9, 35:8-11 attached as Ex. A to Allen Reply Decl. [Dkt. 82-1].

Dr. Applegate admits that he lacks sufficient independent knowledge to determine whether

or not IEH's invention would meet a long felt but unsatisfied need in the pathogen testing industry in 2004. *See Id.* at 120:8-121:5. His testimony also shows that he is not qualified to provide an analysis of the supply and demand factors in the pathogen testing industry or how those factors might change over time. *Id.* at 192:3-193:12. He may not testify on either of these topics at trial.

B. Obviousness

The crux of Primus's motion is that every step of the patents-in-suit has been taught by prior art and that IEH's patent should in invalidated due to obviousness. 35 U.S.C. § 103(a) prohibits the issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

Obviousness is a question of law based on underlying factual determinations. *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 858 (Fed. Cir. 2015). The underlying factual inquires include: (i) "the scope and the content of the prior art;" (ii) "the level of ordinary skill in the art;" and (iii) "the differences between the claimed invention and the prior art." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). Secondary indicators such as "commercial success, long felt but unsolved needs, [and] failure of others," that can "give light to the circumstances surrounding the origin of the subject matter sought to be patented" should also be considered. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007) (internal citations and quotation marks omitted). Evidence of secondary considerations "may often be the most probative and cogent evidence [of nonobviousness] in the record." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

Each claim in an issued patent is presumed valid. 35 U.S.C. § 282. To invalidate a patent on the basis of obviousness, the moving party must prove obviousness by clear and convincing evidence. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed. Cir. 2003). Summary judgment of obviousness is appropriate if "the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in dispute, and the obviousness of the claim is apparent in light of these factors." *KSR Int'l Co.*, 550 U.S. at 427. A factual dispute as to any

one of the elements will defeat a motion for summary judgment. *See Helifix Ltd. v. Blok–Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

Primus argues that the subject matter of the patents in suit are obvious when considering three academic papers, referred to by the parties as the Davies, Siragusa, and Gombas references, in combination. Primus MSJ at 2-7, 10-11. According to Primus, it is undisputed that the Davies reference teaches steps A (collecting multiple samples from multiple lots), B (dry compositing), and C (enrichment of the dry composites). MSJ at 10; Expert Report of Michael Doyle ("Doyle Report") attached as Exhibit B to Declaration of Michael Doyle, Ph.D. in Support of Motion for Summary Judgment ("Doyle Decl.") at ¶ 37 [Dkt. No. 64-2]. IEH's expert, Dr. Applegate does not dispute that the Davies reference teaches steps A, B, and C.[3] Applegate Decl. at ¶ 27; Applegate Depo at 91:16-92:5, 99:11-25 attached as Ex. Q to Allen Decl. [Dkt. No. 66-1]. In opposition, IEH argues that Primus misrepresents the Gombas reference and that a person of ordinary skill in the art ("POSITA") would not have been motivated to combine dry compositing and enrichment in the Davies reference with the allegedly post-enrichment wet pooling and testing in the Gombas reference. Primus MSJ Oppo. at 8-10.

1. The Scope and Content of Prior Art

a. The Gombas Reference

IEH argues that Primus incorrectly describes the scope and content of the prior art as teaching that combining multiple levels of pooling would be obvious. Primus MSJ Oppo. at 8-12. IEH contends that the Gombas reference does not teach the claimed enrichment process by enriching a non-composite sample. *Id.* at 8. It asserts that this goes to the heart of Primus's obviousness theory. *Id.* It states that to minimize the problematic effects of the dilution inherent in pooling, the Gombas reference teaches two countermeasures: (i) enriching the sample in two stages for a total of 48 hours (instead of the typical 24 hours) and (ii) enriching more of the product by dividing the sample in half and using the first half for pooling and the second half for

[3] The parties somewhat puzzlingly dispute whether the Siragusa, Siliker, Price, and Jarvis references teach steps A, B, and C since it is undisputed that the Davies reference teaches these steps. Primus MSJ Oppo. at 10-12.

follow-up testing. *Id.* at 8-9; Applegate Decl. ¶¶ 75-76 [Dkt. No. 75-4]. But unlike the patents-in-suit, IEH contends that the Gombas reference did not teach enriching non-contiguous samples as its patents require. Applegate Decl. at ¶ 76.

According to Dr. Applegate, this difference exists because a POSITA would have been concerned that enriching small portions of non-contiguous samples would lead to dilution and therefore enriching the largest possible sample would be critical. *Id.* Additionally, Dr. Applegate notes that the Gombas reference involved a two-stage testing process where a portion of the enrichment process served as the first stage. *Id.* at ¶ 77. In the first stage, the Gombas reference used a specialized enrichment medium that made any contamination visible by changing color. *Id.* If the media indicated that the sample might be positive, the Gombas reference would teach that further testing to confirm the presence of contamination should be conducted. *Id.* But if the sample was not presumptively positive, the Gombas reference did not teach conducting any additional testing. *Id.* Dr. Applegate states that although researchers such as the ones in the Gombas reference may skip additional testing to lower costs, a business would not skip additional testing of food that will be released into commerce. *Id.*

IEH has not created a dispute of material fact with regard to whether Primus has misrepresented the scope of the Gombas reference. As Primus argues in reply, the Gombas reference did not involve a two-stage testing process. Instead, it consisted of two separate analyses: screening, where pooling was used, and enumeration, which involved the color changing specialized enrichment medium. Primus MSJ Reply at 3; Gombas at 563-564. There is nothing within the text of the Gombas reference that suggests that any less than all of the enriched samples were subjected to pooled testing during the screening analysis. *Id.* Looking at the reference itself, it does not appear that any additional testing was skipped.[4] Gombas at 563-64.

[4] "After incubation, individual Maryland sample enrichments were swabbed onto two plates of modified lithium chloride-ceftazidime agar (mLCA). . . . Cell growth was collected from one of the plates with a cotton swab for composite screening with Gene-Trak, and the other plate was held for individual screening if needed. For each California sample, 0.1 ml of the demi-Fraser enrichment culture was transferred to 10 ml of morpholinepropanesulfonic acid-*Listeria* enrichment broth and incubated. . . . After the secondary enrichment, 1ml of the broth culture was used for screening with BAX assay as described below." Gombas at 564.

Additionally, that the samples used in the reference were not from non-contiguous samples is not relevant to whether it teaches steps D and E of the patents in suit, because the collection and compositing of non-contiguous samples is not alleged to have been taught by the Gombas reference.

b. The Siragusa Reference

IEH argues that Primus has misrepresented the scope of the Siragusa reference. Primus MSJ Oppo. at 10-11. The Siragusa reference involves a research study that analyzed multiple herds of cows to determine how many herds were contaminated by testing each cow's feces. According to IEH, the reference does not teach sampling, compositing, and enriching the composite because a POSITA would not consider that testing the entire herd was "sampling," which inherently requires testing less than the entire herd. Applegate Decl. at ¶¶ 32-34, 37-40. . Primus counters that IEH is erroneously treating the cows as the samples, rather than the 10 gram portion of their feces. Primus MSJ Reply at 6.

I largely agree with IEH. The purpose of the study was to detect listeria in the cows, not just to study what percentage of cow feces contains listeria. Cow feces are not the product, the cows are. Testing each cow does not teach representative sampling and pooling because it does not allow one to extrapolate something probative about the presence of listeria in one cow to the rest of herd. The method of testing each cow cannot be said teach step A in the patents in suit.

c. The Silliker Reference

IEH and Primus reach opposite conclusions on the scope of the Silliker reference. Primus claims that the reference "conclude[d] that Salmonella could be detected with 'equal facility' in composite samples as individual samples" and this provided a motivation to combine the Gombas reference with either the Siragusa or Davies references. Primus MSJ at 2-3 n.5. Dr. Applegate opines the opposite, stating that the Silliker reference found that compositing samples decreased accuracy and was apt to lead to false negatives. Applegate Decl. at ¶ 121. The parties also disagree if the Silliker reference describes collecting multiple subsamples across multiple lots, or two levels of compositing. Primus MSJ at 3 n.7, 7; Applegate Decl. ¶ 26. Primus notes that the authors of the Silliker reference write that "[a]nalytical results from 26 samples of naturally

contaminated dried foods indicate that Salmonella-positive samples may be detected with equal facility by analyzing sixty 25-g subsamples, fifteen 100-g subsamples, or three 500-g subsamples. Pooling sixty 25-g or fifteen 100-g pre-enrichment cultures into groups of five (wet compositing) followed by selective enrichment of the composites apparently results in the same assurance of detection of positive lots as the analysis of individual samples." Primus MSJ Reply at 5; Silliker 478. But this statement could be interpreted in two ways: as either proof that pooling works or that pooling only works with sufficiently large subsamples to overcome the effects of dilution. Whether a POSITA would interpret it in one way or the other is a disputed issue.

d. The Price and Jarvis References

Primus cites the Price and Jarvis references to support its theory that multiple levels of compositing is obvious, Primus MSJ at 7, 13-14, while IEH counters that Primus's theory is based on an incorrect description of the scope and content of both references. Primus MSJ Oppo. at 12. Dr. Applegate opines that the Price reference does not describe the claimed sampling across lots, the claimed dry compositing across lots, the claimed enrichment of multiple composite samples, the claimed wet compositing, and the claimed validation process. Applegate Decl. ¶¶ 43-50. According to Dr. Applegate, the Price reference teaches pre-enriching individual samples—not composites—and that compositing should be avoided because "if many food samples are pooled at the pre-enrichment stage, the target organism . . . face competition from the flora of all the samples in the pool." Applegate Decl. ¶ 49. He also contends that the reference uses only a single level of pooling and teaches away from adding a second level as claimed by the patents in suit. *Id.* at ¶ 50.

Primus quotes the Price reference in response: "These studies support the conclusion that Salmonella pre-enrichment broths can be pooled for analysis without loss in sensitivity to Salmonella in the individual samples." Primus MSJ at 5-6; Price at 679. It argues that Dr. Applegate's quotation of the Price reference is out of context and merely refers to the superiority of wet compositing over dry compositing. *Id.* The Price reference states: "If, on the other hand, the samples are individually preenriched, the actively growing salmonellae might be expected to compete more favorably with organisms introduced from other samples when pooled at the

enrichment stage." Price at 681. Unlike the reference's unequivocal statements that pooling can be done "without a loss in sensitivity," according to Primus, nothing within the reference's actual text indicates a conclusion on how many "levels" of compositing a method should have. Primus MSJ at 5-6; Price at 681.

As with the Silliker reference, there is a dispute about what the Price reference teaches based on the appropriate level of abstraction. According to IEH, it teaches that one should pool samples after they have been pre-enriched, otherwise it can lead to inaccurate results because the target organism will have less competition. But according to Primus, it teaches that pooling is possible generally if done correctly. This creates a dispute of fact about whether it supports Primus's argument that multiple levels of compositing was obvious.

Similarly, IEH contests Primus's citation to the Jarvis reference as an alternative example of two levels of dilution. Primus MSJ Oppo. at 12. Dr. Applegate opines that it also fails to describe pooling of composites. Applegate Decl. at ¶¶ 51-65. This dispute is also material.

Relatedly, IEH notes that Primus's definition of "enrichment" in its motion differs from their agreed upon definition during claim construction. Primus MSJ Oppo. at 13-14. In the claim construction order, "enrichment" was defined as "incubating a sample under conditions suitable to allow levels of a target agent/organism that is present to reach detectable levels and become uniform or substantially uniform." Claim Construction Order at 4. But in its motion, Primus now states that:

> Enrichment typically involves incubating samples in enrichment media (often a liquid broth) in order to increase the numbers of the target microbe and facilitate detection. Sometimes the enrichment process is conducted in two parts—the first part, referred to as "pre-enrichment," is designed to allow injured bacteria to recover and start to multiply, and the second part, referred to as "secondary enrichment" or "selective enrichment" is then designed to allow bacteria to multiply to detectable levels.

Primus MSJ at 3-4; Doyle Report. at ¶ 28. IEH contends that by expanding the term "enrichment" to include pre-enrichment, Primus is attempting to show that the Silliker and Jarvis references teach step C when both references teach pre-enrichment and not the parties' agreed upon definition of enrichment. Primus MSJ Oppo. at 13-14; Applegate Decl. at ¶¶ 51, 60, 122. IEH

asserts that the Silliker and Jarvis references do not provide a motivation to combine the collection process of the Siragusa or Davies references with the post-enrichment compositing of the Gombas reference. *Id.* Whether a POSITA would learn that the Silliker and Jarvis references teach step C when they involve pre-enrichment rather than enrichment is a disputed issue of fact.

2. Who is a POSITA?

The parties dispute the qualifications of a POSITA in this case. According to Primus's expert, Dr. Michael Doyle, a POSITA would likely have at least a bachelor's degree in the field and either an advanced degree or equivalent professional experience. Doyle Report at ¶ 18. This person would be familiar with a variety of sampling, enrichment, and testing techniques, including the pooling technique discussed in the Gombas reference and the sampling technique discussed in the Davies reference. *Id.*

IEH's expert, Dr. Applegate, asserts that a POSITA would have either an associate's degree and at least one year of experience in the field, or a bachelor's degree in biology (or other closely related subject and some experience in the field). Applegate Decl. at ¶ 10. In support of this position, IEH notes that when Primus hires laboratory technicians it requires some relevant class work, but no degree. *See* Deposition of Gosia Myers at 11:6-12 attached as Ex. D to Declaration of Jennifer K. Chung in Support of Institute for Environmental Health, Inc.'s Opposition to Primus Motion for Summary Judgment of Invalidity ("Chung Decl.") [Dkt. No. 75-3]. When Primus hires microbiologists, it requires no more than a bachelor's degree. *Id.* at 12:3-10.8. IEH also points out that Primus's Director of Microbiology holds a bachelor's degree in microbiology and a master's degree in an unrelated field. *See* Deposition of Adam Hughes at 16:3-17 attached as Ex. C to Chung Decl. [Dkt. No. 75-3].

This conflicting evidence is sufficient to raise a disputed issue of fact regarding the qualifications of a POSITA in this case.

3. Does the Combination of the Davies/Siragusa References and the Gombas Reference Yield Predictable Results?

With the above questions of fact in mind, I must determine if it would be obvious to a POSITA to combine the Davies/Siragusa and Gombas references. "[A] patent composed of several

elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co.*, 550 U.S. at 418. In determining obviousness, a court must avoid hindsight bias and ex-post facto reasoning. *Id.* at 421. "[A] judge must not pick and choose isolated elements from the prior art and combine them so as to yield the invention in question if such a combination would not have been obvious at the time of the invention." *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 810 (1986). In this regard, "knowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to reach the particular claimed method." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373 (Fed. Cir. 2008).

Identifying a motivation to combine is important because "inventions in most, if not all, instances rely upon building blocks since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR In"l Co.*, 550 U.S. at 418-19. When a POSITA is faced with "a finite number of identified, predictable solutions" to a problem and pursues "the known options within his or her technical grasp," the resulting discovery "is likely the product not of innovation but of ordinary skill and common sense." *Id.* at 402-03. But if researchers can only "vary all parameters or try each of numerous possible choices until one possibly arrives at a successful result, where the prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful," then a finding of obviousness is not warranted. *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 997-98 (Fed. Cir. 2009).

Primus argues that the method claimed is obvious because all the steps of the claimed method perform exactly the same functions that they do in the prior art and the patents' combination of steps A-C with steps D-E simply represents application of a known sampling technique to the prior-art pooling method of the Gombas reference. Primus MSJ at 13-14. IEH makes two persuasive arguments to show that the undisputed evidence does not support this factual contention. Primus MSJ at 14-19.

a. The Uncertain Nature of Pathogen Testing

First, IEH argues that a POSITA would not find it obvious to combine the methods

described in the different references to teach every step of the patent-in-suit because the references studied different types of pathogens and products. Primus MSJ Oppo. at 14-16. IEH cites facts that show that different types of foods require different tests in order to determine the presence of pathogens because some food have natural inhibitors, like spices or chocolates, that interfere with the testing method and prevent predictable results when attempting to apply a method of testing one food to another. *Id.*; Deposition of Dr. Michael P. Doyle at 146:1-6, 147:3-12, 148:12-22, 148:23-149:4, 149:6-22 attached as Exhibit A to Chung Decl. [Dkt. No. 74-12].

IEH also refers to two emails from Primus employees to support its argument. The first comes from microbiologist Kenna Smith, who stated:

> Produce is a complicated matrix with many factors to consider (organic residues, pesticides, soil particles, etc) that can cause a test not to function the way it is intended. Many of these challenges are unique to produce, and are not present in the beef or dairy side of the food industry.

Id.; Exhibit L attached to Chung Decl. [Dkt. No. 74-12]. The second is from microbiologist Roberto Guzman, who wrote that "[m]ost of the wet pooled research is made on feces from pigs, turkeys, chicken and carcass but not on fresh produce or matrices more closely similar to the received in our lab." Exhibit M, attached to Chung Decl. [Dkt. No. 74-12]. He also said that "the pool protocol is more viable on meat product." *Id.* This means that a POSITA would not assume that sampling and testing methods used for animal feces or ready-to-eat food would make sense to combine without further expensive and time consuming validation studies and would therefore be nonobvious. *Id.* at 16; Applegate Decl. at ¶ 110.

In reply, Primus argues that that IEH has mischaracterized Dr. Doyle's testimony and that he was actually discussing the reliability of assay methods and not the reliability or predictability compositing techniques.[5] Primus MSJ Reply at 8-10 (to "validate" means to "determine that a particular sample tests negative using the detection assay"). But a close reading of Dr. Doyle's deposition is more ambiguous than Primus suggests. Dr. Doyle is asked why a worker should not select an assay **or a** testing method absent additional data. Doyle Depo. at 145:3-5 attached as Ex.

[5] In the patents-in-suit, the assay is the validation test run to determine the presence of the pathogen after compositing and enrichment. Claim Construction Order at 4.

E to Allen Reply Decl. [Dkt. No. 82-1]. Dr. Doyle responds that:

> Well, when—when a assay is developed that—for example, a shortened assay, and it's done with the idea that you can run this assay in a very short period of time without comparing it to standard protocols where we know it takes longer to detect injured cells, as an example, those comparisons need to be made because if—you miss those, if you have gross contamination, you can likely pick it up. And if the cells aren't injured, you can likely pick it up, and you can make that assay look really good to AOAC, but in real life—in real life, in reality, its very misleading to the—to whoever you are doing the testing for as to the validity of the results.

Doyle Depo. at 145:10-22. The question asked, this response, and its reference to the effects of injured bacterial cells and "real life" conditions, suggests a connection between the method of sampling, dilution, and enrichment to the effect of different assays.

Further, when responding to a question about whether a POSITA would require additional data to confirm that an assay shown to work in one scenario would work in another, Dr. Doyle answered that additional data would be required since "evidence to show that if [the assay] works for one food under certain conditions that are defined by the manufacturer, . . . it may not be translatable to . . . another food. Doyle Depo. at 148:12-22. Dr. Doyle then noted how in the context of *Salmonella* testing, the FDA prescribes different enrichment protocols because certain foods, such as spice and chocolate, have natural inhibitors that require particular enrichment procedures. Doyle Depo. at 148:23-149:4. Dr. Doyle gives a similar answer in response to a question about whether a POSITA could look at an assay or testing methodology and inherently know the different contexts that it would work in. *Id.* at 149:6-22.

I agree with IEH that this is sufficient to create a dispute of material fact over whether a POSITA would find it obvious to combine references related to different foods and pathogens to create the method claimed by the patents in suit. My conclusion is not undermined by Primus's three other counterarguments that (i) the BAM reference teaches that sample collection and dry compositing in the Siragusa/Davies references can be applied to a wide variety of food products, (ii) a POSITA would only need to understand that combining the references might be viable in some scenarios and (iii) that validation is simply part of the scientific process and does not create a shroud of unpredictability. Primus MSJ Reply at 9-10. While those arguments may have some

merit, they speak to the weight of the evidence and do not eliminate the dispute of material fact.

b. Concerns About Dilution

IEH's second argument is that the combination of the method taught by the Davies and Gombas references would add another layer of dilution and multiply the unpredictability of the results, and that a POSITA would understand that there is a cost in terms of accuracy to combining samples and using fewer assays. Primus MSJ Oppo. at 16-17; Applegate Decl. at ¶ 109. IEH notes that numerous references have described the dilution problem that comes with pooling. Primus MSJ Oppo. at 16-17; Applegate Decl. at ¶ 121. Therefore, IEH argues, a POSITA would have known that combining two levels of pooling would yield unpredictable results and would not assume that doing so would be obviously successful. *Id.*; Applegate Decl. at ¶ 109.

Primus responds that IEH fails to explain how its patent solved the dilution problem or improved the accuracy of microbial detection. Primus MSJ Reply at 7-8. Instead, Primus states that "the patents simply claim a combination of dry compositing and wet compositing, with apparent confidence that accuracy will not be compromised." *Id.* It contends that this confidence exists because it is grounded both in the Silliker and Jarvis references.[6] *Id.* But as discussed above, the meaning of those references is disputed and citing to them is not enough to eliminate a material dispute of fact over whether a POSITA would find the results of combining the references predictable in light of fears over dilution. Although the patents-in-suit do not purport to solve the issues presented by dilution, this counter argument does not address whether a POSITA would find the combination obvious.

Because there is a material dispute of fact concerning whether a POSITA would find the combination of prior art obvious, I deny Primus's motion for summary judgment. I need not consider the parties' arguments related to objective indicia of nonobviousness in light of that

[6] Primus also cites to a statement by the USDA in 2008 advising the mead industry that as long as care was taken "to ensure that the enrichment procedure (time and temperature of incubation) is adequate," it "believe[d] that the testing of pooled samples from 5 individual enriched samples can be made without losing sensitivity" Exhibit K to Allen Decl. [Dkt. No. 64-1]. But the patents in suit were continuations of an application filed in 2005 so that statement is not relevant. *See* the '771 Patent and the '143 Patent.

ruling.[7]

II. IEH'S MOTION FOR PARTIAL SUMMARY JUDGMENT

IEH moves for partial summary judgment against Primus for infringing the same patents-in-suit just discussed. IEH MSJ at 1. Primus and IEH compete in the microbiological testing market. Deposition of Adam Hughes ("Hughes Depo.") at 130:21-131:20 attached as Ex. C to Declaration of Benjamin J. Byer in Support of Institute for Environmental Health, Inc.'s Motion for Partial Summary Judgment ("Byer Decl.") [Dkt. No. 63-1]. The parties have won and lost customers from each other and come across each other regularly in the marketplace. *Id.*

Primus had used a pooling testing method in 2007 but stopped in 2008, not restarting it until they were asked to do so by a client.[8] Deposition of Gosia Myers ("Myers Depo") attached as Ex. E to Byer Decl. [Dkt. No. 63-1]. Now it offers pooled testing services to test for four pathogenic bacteria: *Salmonella*; Shigatoxin producing *E. coli* (STEC) serotypes including *E. Coli* O157:H7; *Listeria monocytogenes*; and *Listeria* spp. Declaration of Dr. Bruce Applegate in Support of Institute for Environmental Health, Inc.'s Motion for Partial Summary Judgment ("Applegate MPSJ Decl.") at ¶ 8 [Dkt. No. 62-6].

IEH accuses Primus's pooled testing services of infringing claims 1, 2, 5, 18, 19, 22, 29, 35, and 36 of the '143 patent and claims 1, 2, 4, 6, 22, 23, 26, 36, 37, 38, 47, and 48 of the '771 patent. *See* Applegate MPSJ Decl. ¶ 43; Infringement Table attached as Ex. B. to Applegate MPSJ Decl. [Dkt. No. 62-7]. Using claim 1 of the '143 patent as an example IEH states that:

> ***Method of sampling and testing***: The pooled testing services offered by Primus are a method "of sampling and testing for microbes in multiple separate test lots." [Applegate MPSJ Decl. at] ¶¶ 16-17.
>
> ***Step A***: Primus begins by separately collecting multiple independent samples from multiple separate test lots. Id. ¶¶ 8-9, 18-22. Primus either conducts this step itself or instructs its customers to conduct this step on its behalf. *Id.* ¶ 22; *see Travel Sentry, Inc. v. Tropp*, 877

[7] The evidence here also creates the same issues of material fact with regards to the dependent claims in the patents-in-suit that are more focused on specific industrial applications. Primus MSJ Oppo. at 24-25. Primus's arguments to the contrary are wholly conclusory. Primus MSJ at 2 n.4.

[8] The parties dispute whether this customer provided Primus with the IEH pooling recipe, but it is not material. Myer Depo at 22:22-25; Primus Opposition to IEH's Motion for Partial Summary Judgment ("IEH MSJ Oppo.") at 6-7 [Dkt. No. 73].

> F.3d 1370, 1381 (Fed. Cir. 2017) ("[T]he restrictive view of when the acts of a third party can be attributable to another . . . is no longer the governing law. In other words, [*Akamai V*] 'broaden[ed] the circumstances in which others' acts may be attributed to an accused infringer to support direct-infringement liability for divided infringement . . . .'") (third alteration in original) (citation omitted).
>
> ***Step B***: Primus then separately combines the samples from each of the test lots to create a set of separate composited test lot samples. Applegate Decl. ¶¶ 8-9, 23-29.
>
> ***Step C***: Primus enriches each of the composited test lot samples for the target microbe to create a set of enriched composited test lot samples. Id. ¶¶ 10, 30-31.
>
> ***Step D***: Primus removes portions of each enriched composited test lot sample, and combines the portions together to create a pooled sample. Id. ¶¶ 11, 32-34.
>
> ***Step E***: Primus then uses a suitable detection assay to test the pool for the target microbe. When that test is negative, Primus validates all of the test lots. But when that test is positive, Primus individually tests each of the enriched composite samples to identify those contaminated with the target microbe. At that point, Primus validates the test lots corresponding to any negatively testing composite. See id. ¶¶ 12-13, 35-42.

IEH MSJ at 12-13.

Primus only disputes whether it practices step E. IEH MSJ Oppo. Primus characterizes step E of having two sub-steps: (E1) testing a pooled sample, wherein when the pooled sample tests negative, the individual samples are deemed negative; (E2) when the pooled sample tests positive, testing the individual samples wherein the lots corresponding to any negatively testing composited lot samples are validated. *Id.* at 1-2 (internal quotation marks omitted); '771 Patent. Primus states that its pooled testing protocols do not practice step E2. *Id.* at 2. "Instead, when a pooled sample tests positive, Primus performs testing of the individual samples, wherein negatively testing samples are validated only if at least one other sample in the pool tests positive." *Id.*; Declaration of Adam Hughes in Support of Primus's Opposition to Motion for Partial Summary Judgment ("Hughes Decl.") at ¶ 3 [Dkt. No. 72-5]. If none of the individual samples test positive, all individual samples are deemed presumptively positive and Primus will generally retest the pooled sample using a cultural confirmation assay. Hughes Decl. at ¶ 4. If the cultural confirmation result is negative, the individual samples are then validated, but if the result is positive, under Primus's error protocol the individual samples are deemed positive, despite

having tested negative. *Id.* In other words, according to Primus, under its protocol, one of the following conditions must be met: (i) the pooled sample tests negative; (ii) the individual sample tests negative and at least one of the other samples making up the pooled sample tests positive; or (iii) the pooled sample tests negative upon cultural confirmation. IEH MSJ Oppo.; Hughes Decl. at ¶ 4.

IEH states that Primus's "error protocol" is used exceedingly rarely; according to Primus, this scenario occurs less than .01% of the time. Hughes Depo. at 90:2-22. Dr. Applegate opines that the error protocol is likely only used when something has gone wrong, such as a Primus employee unintentionally contaminating the pool after forming it from uncontaminated samples. Applegate MPSJ Decl. at ¶ 41. IEH is not asserting its patents against instances where Primus follows its error protocol and does not validate lots; therefore, the error protocol should have no relevance to whether Primus infringes the other 99.99% of the time. IEH MSJ at 15.

IEH argues that the patents' claims do not exclude additional testing of the pool or individual samples, so the additional confirmation test in Primus's error protocol does not mean that its standard protocol does not satisfy the validation step in the patents. *Id.* It contends that because the invention claimed is "[a] method of sampling and testing for microbes in multiple separate test lots, comprising" the claim elements, the use of the term "comprising" indicates that it covers methods that include additional steps. *Id.* at 15-16. It also argues that "[u]nder the principles of claim differentiation, the independent claims are presumed to be broader" than a patent's dependent claims. *Id.* (citing *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1376 (Fed. Cir. 2014). It points out that both patents-in-suit include dependent claims requiring additional testing "to enhance confidence in the negative testing results." *Id.*; Claims 28, 38 of the '143 patent; Claims 35 and 40 of the '771 patent. Thus, according to IEH, Primus's additional testing does not affect its infringement. *Id.*

Primus responds that use of the word "comprising" cannot abrogate claim limitations and that the steps must still all be practiced as recited in the claim for a process to infringe. IEH MSJ Oppo. at 3-4 (citing *Dippin'Dots, Inc. v. Mosey*, 476 F. 3d 1337, 1343 (Fed. Cir. 2007); *FlatWorld Interactives LLC v. Apple Inc.*, No. 12-cv-01956-WHO, 2014 WL 31392 (N.D. Cal. Jan. 3, 2014)).

It contends that the claims asserted by IEH do not say that "the lots corresponding to any negatively testing composited lot samples **may be validated**" or that "the lots corresponding to **some** negatively testing composited lot samples are validated"; they say that "the lots corresponding to **any** negatively testing composited lot samples **are** validated." *Id.* at 4 (emphasis in original). Therefore, Primus argues, it does not practice this limitation and its services do not infringe IEH's patents. *Id.*

Primus's argument is unconvincing. As IEH noted in its reply, Primus's assertion is contrary to *FlatWorld* and to the well-understood meaning of "comprising." Reply in Support of Institute for Environmental Health, Inc.'s Motion for Partial Summary Judgment ("IEH MSJ Reply") at 4-7 [Dkt. No. 80-4]. IEH's other dependent claims confirm that step E2 is broad enough to include additional confirmation tests, such as Primus's error protocol, prior to validation. *Id.* at 6.

As the Federal Circuit stated in *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, other claims in a patent can be "valuable sources of enlightenment as to the meaning of a claim term" and that courts should strive to reach a "claim construction that does not render claim language in dependent claims meaningless." 520 F.3d 1358, 1362 (Fed. Cir. 2008) (internal citations and quotation marks omitted). In the '143 Patent, dependent claims 28 and 35 both require testing "to enhance confidence in the negative testing results" and show the patentee intended the independent claims to allow for additional testing. If step E2 did not allow for additional tests prior to validation, these dependent claims would be meaningless. Primus's error protocol does not put its pooled testing services outside of the claims in the Patents-in-Suit.

I also agree with IEH that Primus has misinterpreted *Flatworld*. In that case, Apple and FlatWorld disagreed whether exceeding the threshold velocity was a necessary, as opposed to a sufficient, condition for "throwing" of an image (or removal) to occur. *FlatWorld*, 2014 WL 31392, at *4. I adopted Apple's construction and found that exceeding the threshold velocity was sufficient to cause an image to be removed and that there was no indication in the claims that anything additional was necessary. *Id.* I rejected FlatWorld's argument that "comprising" meant that the "threshold velocity" condition was not, by itself, enough to trigger removal because the

argument made "an unwarranted leap of logic from the proposition that the recited elements are not exclusive to the conclusion that they are insufficient for some previously disclosed result to take place." *Id.* at *5. As IEH argues, here "comprising" means that step E2 does not exclude additional conditions, such as Primus's error protocol, prior to validation. IEH MSJ Reply at 5.

Dippin'Dots also does not support Primus's stance. There, the parties disputed whether the claim was limited to a process that produced beads or if it also included a process that produced beads and irregular particles. 476 F.3d at 1343. The Federal Circuit upheld the district court's refusal to construe "comprising" as including both beads and irregular particles because the patentee had "narrowly defined the claim term it now seeks to have broadened." *Id.* But here, IEH has not narrowly defined step E2, as shown by the dependent claims, to exclude Primus's error protocol.

Primus separately argues that it never performs the validation step as recited in the claims because the error protocol is always a part of its process, even if it is not used in a way that diverges from IEH's patented method 99.99% of the time. IEH MSJ Oppo. at 4-6. Although this argument fails for the reasons discussed above, it also lacks merit for other reasons that I discuss below.

Primus relies heavily on *UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816 (Fed. Cir. 2016), where the patent in suit described a handheld pointing device that could be used to control the cursor on a projected computer screen through measuring its location and orientation relative to the projected image, and use that measurement to determine where on the image to display the cursor. *Id.* at 818-19. UltimatePointer characterized its product as a direct-pointing device where the physical point-of-aim coincides with the item being pointed at. *Id.* This was in contrast to the remote on Nintendo's Wii gaming console, which could control an on-screen cursor through the interaction of the remote and a sensor bar. *Id.* at 820. UltimatePointer sued Nintendo and Wii retailers, alleging that the Wii gaming console infringed several of its patent's claims. *Id.* The court construed UltimatePointer's claims to require a direct pointing device and concluded that the Wii remote was an indirect pointing device because it interacted solely with the sensor and not the screen. *Id.* at 824-25. The court then reasoned that although the rule that "imperfect practice of an

invention does not avoid infringement," and that "an accused device that 'sometimes, but not always, embodies a claim[ ] nonetheless infringes'" was still good law, it was not applicable in that case. *Id.* at 825 (citing *Paper Converting Mach. Co. v. Magna–Graphics Corp.*, 745 F.2d 11, 20 (Fed. Cir. 1984), *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1333 (Fed. Cir. 2013), and *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 622–23 (Fed.Cir.1995)). This was because the Wii remote, in any arrangement, could never infringe on UltimatePointer's patent because it could never act as a direct pointing device. *Id.* It could only perform indirect pointing. *Id.*

This case does not help Primus. Even if I ignore the effect of the dependent claims, Primus's pooled testing method always infringes on the independent claims in the 99.99% of instances where it does not engage in the error protocol. Additionally, as IEH notes "[i]f the condition for performing a contingent step is not satisfied, the performance recited by the step need not be carried out in order for the claimed method to be performed." *Cybersettle, Inc. v. Nat'l Arbitration Forum, Inc.*, 243 F. App'x 603, 607 (Fed. Cir. 2007). Because step E2 is contingent on step E1, Primus infringes the independent claims whenever the pooled sample tests negative and the lots are validated or the pooled sample tests positive and the contamination is traced back to a particular subsample (as occurs 99.99% of the time).

There is a broader absurdity to Primus's argument. According to Primus, anyone could copy a patented method without infringing as long as it introduced some sort of step at the end that is effectively never performed. For a method patent to have any usefulness, this cannot be the case.

For these reasons, I find that there is no dispute of material fact that Primus practices step E of the patents in suit. IEH's motion for partial summary judgment is granted.

III. MOTIONS TO SEAL

The parties filed five motions to seal in conjunction with their motions for summary judgment. [Dkt. Nos. 62, 65, 72, 74, 80]. Courts have long recognized a "general right to inspect and copy public records and documents, including judicial records and documents." *Nixon v. Warner Commc's Inc.*, 435 U.S. 589, 597 (1978). A party seeking to seal judicial records attached

to a dispositive motion must "articulate[ ] compelling reasons supported by specific factual findings that outweigh the general history of access and the public policies favoring disclosure." *Kamakana v. City & Cty. of Honolulu*, 447 F.3d 1172, 1178-79 (9th Cir. 2006) (alteration in original) (internal quotation marks and citations omitted). Examples of compelling reasons include when court records are used for "improper purposes," such as "to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." *Id.* at 1179 (citing *Nixon*, 435 U.S. at 598). Similarly, "sources of business information that might harm a litigant's competitive standing" may also constitute a compelling reason to seal, *see Nixon*, 435 U.S. at 598, as may a company's confidential profit, cost, and pricing information that if publicly disclosed could put the company at a competitive disadvantage, *see Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1225 (Fed. Cir. 2013). The court must balance the competing interests of the public's right of inspection against litigants' need for confidentiality, and "if the court decides to seal certain judicial records, it must base its decision on a compelling reason and articulate the factual basis for its ruling, without relying on hypothesis or conjecture." *Kamakana*, 447 F.3d at 1179.

A. The First Motion to Seal

In the first motion to seal, IEH moves to seal portions of its motion for partial summary judgment and portions of the attached declaration of Dr. Bruce Applegate because Primus has designated certain information confidential under the interim protective order. [Dkt. No. 62]. Primus submits a declaration in support of the motion stating that the redacted portions of exhibit B [Dkt. No. 62-7] contain detailed discussion of the field and laboratory protocols used by Primus based on Dr. Applegate's review of Primus's confidential standard operating procedure documents. [Dkt. No. 68]. Primus argues that if this information were filed publicly, competitors could use it to Primus's disadvantage to develop their own protocols without investing similar time and resources. *Id.* I do not find that Primus's characterization of its methods as confidential to be the equivalent of arguing that they are a trade secret or that its reasons to keep exhibit B under seal outweigh the public's right of inspection. This is particularly true because the specifics of Primus's method are the subject of IEH's motion for summary judgment, which I granted. The motion to seal exhibit B to the declaration of Dr. Applegate is denied.

The redacted portions of exhibits D, G, and J contain internal Primus emails discussing Primus's costs and pricing practices that are not generally known to Primus's customers and competitors. *Id.* If they were filed publicly, Primus claims that competitors could use this information to Primus's disadvantage by adjusting their own pricing to compete more effectively. *Id.* Similarly customers and potential customers could use this information in price negotiations to demand more favorable terms. *Id.* Here, I find Primus's reason to seal to be compelling and I do not use any of the sealed information to decide IEH's motion for summary judgment. The motion to seal as to exhibits D, G, and J is granted.

Finally, exhibits F, G, H, and I contain internal Primus emails revealing the identity of and information about specific customers. *Id.* If filed publicly, competitors could use this information to effectively target their marketing efforts without expending similar time and resources to learn about the product testing needs of particular companies. I find Primus's reasoning compelling here as well, find Primus's redactions to be narrowly tailored, and do not rely on this information in deciding the above motions. The motion to seal exhibits F, G, H, and I is granted.

B. The Second Motion to Seal

In the second motion, Primus seeks to seal portions of its motion for summary judgment and certain exhibits because either IEH marked them confidential under the protective order or because they relate to Primus's sales volumes from 1998-2018. [Dkt. No. 65]. Primus argues that it derives value from the continued confidentiality of this data during its price negotiations with clients and vendors, and disclosure would hurt its competitive standing. *Id.* Primus has not provided compelling reasons to justify sealing the information related to its sales data. Its sales data only states the number and types of tests performed. Primus's conclusory argument that its disclosure would damage its competitive standing is unpersuasive and conclusory. Primus MSJ at 19. This is true of the declaration of Robert Stovicek and the attachments to Stovicek's declaration as well. [Dkt. No. 66-2].

Turning to the arguments in favor of sealing by IEH, Mansour Samadpour submits a declaration in support of Primus's motion to seal stating that IEH seeks to seal documents attached to the declaration of Scott Allen because they contain sensitive and proprietary trade secrets,

including the confidential identities of clients and other confidential client information, IEH's non-public market share, IEH's revenue, details of IEH's business methods, and the technical operation of IEH"s services. [Dkt. No. 69]. As an initial matter, IEH's declaration only identifies and seeks to seal certain portions of each exhibit, constituting 261 out of 497 pages of the Allen declaration. But the entirety of the Allen declaration and the accompanying exhibits have been filed under seal. IEH's request is not narrowly tailored and its sealed filing contains numerous public documents such as the Gombas reference and a PTAB decision.

As for the exhibits identified by IEH, the portions of exhibit A containing Dr. Samadpour's deposition (pages 6-12) and Exhibit N containing a response by Washington Beef, LLC to a FSIS Notice of Intended Enforcement Action (NOIE) dated July 5, 2006 (pages 428-465) contain confidential client information. There is a compelling reason to grant the motion to seal on this information. As to the other exhibits, pages 24-192 contain a slideshow used in the deposition of Dr. Samadpour. IEH argues that it should be sealed because it contains proprietary information about IEH's processes, including trade secret information regarding molecular targets and how IEH applies its proprietary processes over time. Having reviewed the slideshow, I am persuaded that it contains trade secret information beyond the methods taught in IEH's patents or relied upon in my order on Primus's motion for summary judgment. The motion to seal exhibits A and N is granted.

IEH argues that the remaining exhibits contain confidential information pertaining to IEH's business practices, revenue, and business strategy. This includes exhibit B, which contains portions of the deposition of Dr. Mohammad Koohmaraie (pages 207-252); Exhibit C, which contains a selected page from Dr. Applegate's report (page 270); and exhibit P which contains a letter from the Food Safety and Inspection Service (page 485-489). IEH's argument that disclosure of these exhibits would hurt its competitive standing is unpersuasive and does not raise a compelling reason to seal these documents that outweighs the public's right of access. Some of the information IEH seeks to seal is also well known to the public and is not confidential. For example pages 213 to 217 in the attachment to Dr. Koohmaraie deposition describes a well-known *E. coli* outbreak. The motion to seal these exhibits is denied.

Because all the exhibits have been filed under seal together, Dkt. No. 66-1 will remain under seal. IEH is directed to refile exhibits A and N under seal and to also refile unsealed versions of the other exhibits. Primus's unredacted version of its motion for summary judgment [Dkt. No. 66] shall also be unsealed because the redactions relate to exhibits that I have ordered to be unsealed.

C. The Third Motion to Seal

In the third motion to seal, in connection with its opposition to IEH's motion for summary judgment, Primus moves to seal portions of an exhibit that contains confidential communications between Primus and its clients regarding the clients' test results and information marked confidential by IEH. [Dkt. No. 72]. With regards to its own communications, Primus argues that they contain confidential business information concerning Primus's customers and the results of microbiological testing performed for those customers. *Id.* It states that revealing the identity of customers and the specific services provided to them would harm its competitive standing because competitors would more effectively be able to target their marketing efforts without expending the time and resources that it has invested in learning about the product testing needs of these particular companies. *Id.* It also claims that disclosure would provide its competitors and its customers' competitors with valuable insights into the prevalence of particular microbes in particular product categories without conducting similar tests themselves. *Id.* It contends that there is a public interest in sealing these documents because public exposure of test results would undermine food producers' confidence in the confidentiality of such tests and discourage further testing. *Id.* Primus has provided a compelling reason to seal the client emails attached to the declaration of Adam Hughes. [Dkt. No. 72-5].

IEH also submits a declaration in support of Primus's motion stating that exhibit A to the declaration of Gosia Myers contains sensitive and proprietary trade secrets, including confidential identities of clients and other confidential client information, and details of IEH's business methods and the technical operation of IEH's services and that disclosure would hurt IEH's competitive standing. [Dkt. No. 78]. Exhibit A is titled IEH Laboratories Standard Operating Procedure and does not appear to contain any confidential client information. [Dkt. No. 72-6].

Additionally, I am not persuaded by IEH that the methods described differ significantly from the claimed invention such that they constitute a trade secret or that there is otherwise a compelling reason to seal this document. The motion to seal exhibit A to the declaration of Gosia Myers is denied.

D. The Fourth Motion to Seal

The fourth motion to seal is in connection with IEH's opposition to Primus's motion for summary judgment. [Dkt. No. 74]. IEH seeks to seal portions of its opposition, portions of the declaration of Dr. Bruce Applegate filed in support, limited portions of the declaration of Drew E. Voth filed in support, and certain exhibits attached to the declaration of Jennifer K. Chung filed in support because both it and Primus have designated some of the information confidential. *Id.*

With respect to information IEH has designated confidential, it seeks to keep under seal portions of the depositions of Dr. Samadpour and Dr. Koohmaraie attached as Exhibits O and P to the declaration of Jennifer K Chung and [Dkt. No 74-12] and one paragraph of Dr. Applegate's report [Dkt. No. 74-10]. It argues that the portions of those documents should be sealed because they contain sensitive and proprietary trade secrets, including confidential identities of clients and other confidential client information including include IEH's non-public market share, IEH's revenue, and details of IEH's business methods and the technical operation of IEH's services. *Id.* It claims that disclosure of this information would hurt its competitive standing. *Id.* As to the two declarations, I am unable to identify any confidential client information. The other information IEH seeks to seal in the declarations relate to public information about previous outbreaks of food related pathogens and IEH's patented testing method. I am unpersuaded that IEH's allegations of competitive harm here outweigh the public's right of access. I am similarly unpersuaded by IEH's conclusory allegations of harm related to the paragraph in Dr. Applegate's report that describes IEH's sales of its pooled vs. non-pooled pathogen tests between 2008-2018. IEH has not met is burden under the compelling reasons standard and the motion to seal these documents is denied.

Primus also submits a declaration in support of IEH's motion, arguing that the information it has designated as confidential should remain under seal. [Dkt. No. 79]. As an initial matter, Primus does not discuss exhibit A to the Chung declaration, and it shall be unsealed. Primus does

state that exhibits D, E, and G of the Chung declaration, as well as the corresponding redacted portions of its opposition to IEH's motion for summary judgment should remain under seal because they contain emails discussing Primus's costs and pricing practices, which are not generally known to its customers and competitors. It argues that if they were filed publicly, its competitors could use this information to its disadvantage by adjusting their own pricing to compete more effectively. Additionally, Primus claims that this would allow customers and potential customers to disadvantage it in price negotiations by leveraging knowledge of Primus's cost and past pricing practices to demand more favorable terms. These exhibits do not contain any specific information about Primus's costs and pricing practices; the motion to seal them is denied.

Primus next argues that the emails contained in exhibits E, G, H, I, J, L, and M should be sealed because they contain the identity of and information about specific customers. It states that it has invested time and resources developing its knowledge of customers and potential customers of food safety testing services. If filed publicly, Primus contends that its competitors could use this information to its disadvantage by more effectively targeting their marketing efforts without expending similar time or resources. This is not a compelling reason to seal these emails and the motion to seal them is denied. Nothing in these exhibits contains any particularized pricing information as to any particular Primus customer.

Primus seeks to have exhibit M and K remain under seal because they contain emails between Primus and its vendors discussing its confidential laboratory protocols and a confidential study prepared for Primus by its vendor. Primus argues that it has invested time and resources developing the protocols revealed in these exhibits and takes steps to maintain their confidentiality. Primus claims that if its methods were disclosed, competitors could disadvantage it by developing their own protocols without investing similar time and resources. This argument is largely conclusory and the information in exhibit M is relied on in my order. Primus has not shown that there is a compelling reason to seal these exhibits that outweighs the public's right of access.

Finally, Primus seeks to file the declaration of Drew E. Voth under seal because it contains its annual revenue in connection with its pooled sample testing services. It argues that it considers

this data a trade secret and public disclosure would hurt its competitive standing. Specifically, it claims that competitors would be able to use this information about Primus's market share to its disadvantage by more effectively targeting their marketing and business development efforts. This argument is also wholly conclusory and insufficient to justify sealing.

The fourth motion to seal is denied. The sealed exhibits and IEH's unredacted opposition to Primus's motion for summary judgment shall be unsealed.

E. The Fifth Motion to Seal

The fifth motion to seal is filed by IEH in connection with its reply in support of its motion for summary judgment. [Dkt. No. 80]. The motion is based on Primus's confidentiality designations. *Id.* Primus has yet to submit a declaration stating why the portions of IEH's reply and exhibit A to the Declaration of Jennifer K. Chung in Support of Reply in Support of IEH's Motion for Partial Summary Judgment should remain under seal. If Primus does not file a declaration and provide compelling reasons to seal within two weeks of the date of this order, the motion will be denied, and the relevant documents will be unsealed.

CONCLUSION

For the reasons above, Primus's motion for summary judgment is denied. IEH's motion for partial summary judgment is granted. The motions to seal are granted in part and denied in part.

IT IS SO ORDERED.

Dated: August 19, 2019

William H. Orrick
United States District Judge