UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

vs.

BECTON DICKINSON AND COMPANY,

Defendant.

CASE NO. 09cv2319 BEN (NLS)

AMENDED CLAIM CONSTRUCTION ORDER

This matter comes before the Court for claim construction. The parties have filed opening and responsive claim construction briefs and the Court held a claim construction hearing. The parties, Gen-Probe, Inc. ("Gen-Probe") and Becton Dickinson and Company ("BD") seek construction of fifteen terms with regard to the Automation Patents and eight terms with regard to the Cap Patents.[1] Having considered the parties briefing and oral argument, the Court construes the terms as follows.

BACKGROUND[2]

The five Automation Patents[3] at issue in this action result from the development of a single automated instrument to detect a target nucleic acid indicative of the presence of a target pathogen

[1]The parties have paired or grouped some terms for purposes of analysis. Where appropriate, the Court has followed that approach for ease in analyzing the claim terms.

[2]The Court's description of the scientific background is limited to that necessary to provide context for claim construction without outlining in detail every step of the nucleic acid-based diagnostic assay.

[3]U.S. Patent Nos. 7,118,892 (the '892 Patent), 7,560,255 (the '255 Patent), 7,482,143 (the '143 Patent), 7,560,256 (the '256 Patent), and 7,542,652 (the '652 Patent).

within a sample. The two Penetrable Cap Patents,[4] also at issue in this case, describe a specimen collection vessel that allows the contents of the vessel to be sampled by an automated device.

Gen-Probe's automated instrument, TIGRIS® Instrument System, was launched in 2003 for the detection of two viruses and later approved for use in the detection of additional viruses. In this action, Gen-Probe accuses BD of infringing claims of the Automation Patents through the use and sale of the VIPER XTR and BD Max, BD's automated nucleic acid test instruments.

The Automation Patents describe an automated method of nucleic acid-based testing, a method for detecting the presence of a particular pathogen in a sample. Nucleic acid-based testing involves the creation of a complementary nucleotide sequence that a target pathogen will bind to through complementary base pairing. The complementary nucleotide sequence is used as a probe. The probe is introduced to a sample that may contain the target nucleic acid. If the target binds to the probe, it indicates the target nucleic acid is present in the sample.

As explained in the Automation Patents, the performance of this process manually has disadvantages, including human error, carryover contamination, and cross contamination. The Automation Patents automate the steps of this process in a single instrument. Receptacles are moved using transport mechanisms between locations of a processing deck where various steps of the assay are performed. The Cap Patents use a seal or seals on a collection vessel that are penetrated by a fluid transfer device. The seal or seals, in conjunction with the core structure, are intended to prevent the release of aerosols from the sample and limit contamination from fluid on the fluid transfer device after removal.

DISCUSSION

I. Legal Standard

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Courts determine the meaning of disputed claim terms from the perspective of a person of ordinary skill in the art at the time the patent is filed. *Chamberlain Group, Inc. v. Lear Corp.*, 516 F.3d 1331, 1335 (Fed. Cir. 2008). "[T]he

[4]U.S. Patent Nos. 6,893,612 (the '612 Patent) and 7,294,308 (the '308 Patent).

person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Phillips*, 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). Those sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* (citing *Innova*, 381 F.3d at 1116).

Claim terms "are generally given their ordinary and customary meaning." *Phillips*, 415 F.3d at 1312 (internal quotation marks omitted). When construing claim terms, the court should first look to sources in the intrinsic record. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). First, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Second, the claims "must be read in view of the specification, of which they are a part." *Id.* at 1315 (internal quotation marks omitted). The specification is usually "dispositive," as "it is the single best guide to the meaning of a disputed term." *Id.* (internal quotation marks omitted). Third, the court should consider the patent's prosecution history, which is the record of proceedings before the Patent and Trademark Office ("PTO") and includes the prior art cited during the patent examination. *Id.* at 1317. However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

If the intrinsic evidence resolves the ambiguity in the disputed claim terms, then "it is improper to rely on extrinsic evidence." *Vitronics*, 90 F.3d at 1583. If ambiguities in the claim terms remain, however, courts may consider extrinsic evidence. *Id.* at 1584. Extrinsic evidence includes expert testimony, inventor testimony, dictionaries, and scientific treatises. *Phillips*, 415

F.3d at 1317.

II. Automation Patents

The Court notes that the disputed claim terms appear across the five Automation Patents at issue in this case and in numerous claims. However, the parties agree that the disputed terms have common meanings across the different patents and claims. Because the claim terms appear across numerous patents and in multiple claims, the Court incorporates the parties' joint claim construction chart that identifies the specific intrinsic evidence in each of the implicated patents that is relevant to the disputed term rather than reciting each instance of support. The Court's references to particular language in one patent is not intended to be to the exclusion of other intrinsic evidence in additional patents.

Because the disputed claim terms appear across numerous claims and patents, the parties provided exemplary claims in which the disputed terms appear. The Court includes those exemplary claims for each disputed claim term before discussion of each, but does not exclusively rely on the patents from which the exemplary claims are drawn.

A. "process comprising the automated steps" and "process comprising performing the automated steps" and "process comprising performing . . . the . . . automated steps"

> A process for detecting the presence of a target nucleic acid in a sample containing the target nucleic acid, the **process comprising the automated steps** of: ('256 Patent, Claim 1.)
>
> A process for detecting the presence of a target nucleic acid in a sample containing the target nucleic acid, the **process comprising performing the automated steps** of: ('652 Patent, Claim 1.)
>
> A process for preparing and amplifying a target sequence contained within a target nucleic acid present in a fluid sample, the **process comprising performing** in a stand-alone unit **the** ordered and **automated steps** of: ('892 Patent, Claim 1.)

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Gen-Probe proposes that the "process comprising the automated steps" means "the steps of the claimed process are performed by a machine that, once set up and initialized, requires little or no operator intervention." BD proposes that "process comprising the automated steps" means that "each individual step of the claimed process is performed without human intervention, but the claim does not preclude human intervention between steps." Gen-Probe relies primarily on the

specification and BD relies exclusively on the use of the word "comprising." The Court adopts Gen-Probe's construction.

BD argues that because the word "comprising" is an open-ended term, it does not foreclose the addition of elements or steps, including human intervention between steps. However, this construction specifically adds the potential for human intervention between steps, a reading completely contrary to the specification. This is problematic in two respect. First, the language BD proposes, "human intervention between steps," does not originate from the claims, specification, or prosecution history. Rather, it is simply an allowance for inclusion of the opposite of an automated process — human intervention between automated steps. Second, BD's proposed construction contradicts the specification. The specification identifies problems with *manual* performance of the steps of a nucleic-based assay, including practitioner error, pathogen exposure, and cross contamination. ('892 Patent 4:5-9.) The specification then goes on to explain that these problems are addressed by the invention, described as an *automated* clinical analyzer. ('892 Patent 4:30-39, 45-47.) BD's proposed construction is improper because it conflicts with the description of the invention in the specification. *See Phillips*, 415 F.3d at 1313 ("[C]laims must be construed so as to be consistent with the specification.").

Gen-Probe's proposed construction is drawn from language in the specification and is consistent with the purpose described in the specification. Gen-Probe's proposed construction — "the steps of the claimed process are performed by a machine that, once set up and initialized, requires little or no operator intervention" — tracks language from the specification that provides that "once the analyzer . . . is set-up and initialized, it ordinarily requires little or no operator assistance or intervention." ('892 Patent 60:61-61.) Additionally, the portion of the proposed construction that indicates that the process is "performed by a machine" is consistent with the specification language discussed above that describes the invention as an "automated clinical analyzer." ('892 Patent 4:45-47.) Finally, Gen-Probe's proposed construction does not conflict with the use of the word "comprising" in the claim. While "comprising" is an open-ended term allowing for the addition of other elements, *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 502 (Fed. Cir. 2007), Gen-Probe's proposed construction is not closed because it allows for manual set-

up and limited operator intervention as described in the specification. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005) (affirming construction that allowed for manual set up of an automatic process with a claim that used the word "comprising"). Because Gen-Probe's proposed construction is drawn from and consistent with the specification, the Court adopts Gen-Probe's proposed construction. *See Phillips*, 415 F.3d at 1315 ("[T]he specification is always relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.").

B. "stand alone unit" and "self-contained analyzer"

> The process of claim 1, wherein steps a)-f) are performed within a **stand-alone unit**. ('256 Patent, Claim 9.)
>
> (d) detecting the amplification product of step (c) as an indication of the presence of the target nucleic acid in the sample, wherein the steps of the process are performed in a **self-contained analyzer**. ('652 Patent, Claim 1.)

Gen-Probe proposes that "stand alone unit" and "self-contained analyzer" mean "a single unit/analyzer in which all the steps are performed within a shared, open environment." BD proposes that "stand alone unit" and "self-contained analyzer" mean "a single system that integrates and coordinates the operation of various automated stations for performing the steps of a diagnostic assay."[5] Gen-Probe relies on a overall vision of the invention drawn from the specification and file history distinguishing prior art. BD relies on the description of the invention in the summary of the invention section of the specification. The Court adopts the following construction "a single system that integrates and coordinates the operation of various automated stations or modules for performing the steps of a diagnostic assay."

Gen-Probe argues that "stand-alone unit" and "self-contained analyzer" must possess everything within it necessary to perform the assay because the specification describes the automated clinical analyzer as "preferably a self-contained, stand alone unit" with "[a]ssay specimen materials and reaction receptacles, as well as the various solutions, reagents, and other materials used in performing the assay . . . preferably stored within the analyzer." ('892 Patent

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[5]BD initially did not propose to construe either term, but in response to Gen-Probe's proposed construction, BD proposed the above construction.

4:52-58.) But, Gen-Probe goes on to argue that "stand-alone unit" and self-contained analyzer" must also be "a shared, open environment." This language, or even a description similar to "shared, open environment," does not appear anywhere in the specification or file history. Rather, Gen-Probe relies on claims that explain various steps occurring at particular stations or target nucleic acids being transferred from one station to another within something. Gen-Probe suggests these steps must necessarily occur "within a shared, open environment." Additionally, Gen-Probe relies on the file histories, emphasizing that prior art prescribed physical separation of the steps. While the Court agrees that "stand-alone unit" and "self-contained analyzer" describe something that preferably contains all the steps of the assay within itself, there is little support for the vague and ambiguous "shared, open environment" language chosen by Gen-Probe.[6]

BD's proposed construction tracks language in the summary of the invention section of the specification that describes the analyzer. The specification states that the "analyzer integrates and coordinates the operation of various automated stations, or modules, involved in performing one or more assays [and the] analyzer is preferably a self-contained, stand alone unit." ('892 Patent 4:48-52.) BD's proposed construction is more closely aligned with the description of the invention in the specification, although the construction BD offers does not justify using only "automated stations" to the exclusion of "modules." Accordingly, the Court adopts the following construction: "a single system that integrates and coordinates the operation of various automated stations or modules for performing the steps of a diagnostic assay."

C. "the target nucleic acid immobilized in step a)" and "the separated target nucleic acid"

> c) transferring **the target nucleic acid immobilized in step a)** from the first station to a second station using a rotatable transport mechanism ('256 Patent, Claim 1.)
>
> (d) moving a solution comprising **the separated target nucleic acid** to a second station of the analyzer; (d) in an incubator of the second station, subjecting the separated target nucleic acid to an amplification procedure and forming an amplification product ('255 Patent, Claim 1.)

[6]While there is minimal support for this particular language, the language does not conflict with the inventor's description, as advanced by BD. Rather, there is simply no support for adding this vague description of the unit/analyzer.

Gen-Probe proposes that "the target nucleic acid immobilized in step a)" means "at least one target nucleic acid immobilized in step a)" and "the separated target nucleic acid" means "at least one target nucleic acid immobilized in step c)." BD proposes that "the target nucleic acid immobilized in step a)" means "all (or substantially all) of the target nucleic acid immobilized during step a)" and "the separated target nucleic acid" means "all of the separated target nucleic acid that was separated in step c)." Because Gen-Probe's construction follows from the plain language of the claim and BD's construction draws primarily from extrinsic evidence, the Court adopts Gen-Probe's construction. *See Phillips*, 415 F.3d at 1316 ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.").

The parties essentially dispute whether "the" means "at least one" or "all (substantially all)." BD argues that a person of ordinary skill in the art would read "the" to mean an entire group of nucleic acid molecules and encompass all or substantially all of the target nucleic acid. Specifically, with regard to "the separated target nucleic acid," BD argues "the" includes the entirety of the immobilized target nucleic acid present. BD's proposed construction is based on particularizing "the" to a population of target nucleic acids. The Court agrees that "'the' particularizes the subject which it precedes." *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1306 (Fed. Cir. 2005) (quoting *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003)). However, BD's characterization is based on a misinterpretation of extrinsic evidence — Dr. Fred Kramer's deposition testimony — and is not supported by the specification.

Gen-Probe's proposed construction follows from the plain language of the claims and specification because the indefinite article "a" in the preambles for each of the Automation Patents means one or more and that meaning carries through to subsequent uses of the term in the claims with "the" preceding the term. *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1343 (Fed. Cir. 2008); *see also NTP, Inc.*, 418 F.3d at 1306. The claim preambles describe either "a process for preparing and amplifying *a* target sequence contained within *a* target nucleic acid" or "a process for detecting the presence of *a* target nucleic acid in a sample." ('892 Patent, Claim 1, 15, 24; '255 Patent, Claim 1, 18; '143 Patent, Claim 1, 11; '256 Patent, Claim 1, 13; '652 Patent,

Claims 1, 9.) (emphasis added).) The "a" preceding "target nucleic acid" in the preambles means "at least one." *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000) ("Under this conventional rule, the claim limitation 'a,' without more, requires at least one."). The claims go on to refer to "*the* target nucleic acid" and "*the* separated target nucleic acid." ('892 Patent, Claim 1, 15, 24; '255 Patent, Claim 1, 18; '143 Patent, Claim 1, 11; '256 Patent, Claim 1, 13; '652 Patent, Claims 1, 9.) (emphasis added). Gen-Probe's proposed construction results from carrying through the same general plurality from the first use of the term with "a" to the later use of the term with "the." *See Baldwin*, 512 F.3d at 1343. Applying this general rule of construction the Court adopts Gen-Probe's proposed constructions: "the target nucleic acid immobilized in step a)" means "at least one target nucleic acid immobilized in step a)" and "the separated target nucleic acid" means "at least one target nucleic acid immobilized in step c)."

D. "other material"

b) separating **other material** present in the fluid sample from the target nucleic acid immobilized in step a)

Gen-Probe proposes that "other material" means "material not immobilized on the solid support." BD proposes that "other material" means "all (or substantially all) material that is not the target nucleic acid." Gen-Probe primarily relies on the specification, particularly the preferred embodiment, and BD primarily relies on extrinsic evidence from Gen-Probe's expert and a video shown to the Patent Examiner after the specification was filed.

The parties do not dispute that the purpose of this separation step is to remove much of the non-target material and leave behind an immobilized target nucleic acid. However, as Gen-Probe accurately notes, BD's proposed construction, to separate "all (or substantially all) material that is not the target nucleic acid" compels an almost perfect separation that is not required by the claims or the specification. This proposed construction requires not only removing everything that is not the target nucleic acid, but also keeping all the target nucleic acid. The claims and specification simply do not require this. Rather, the claims only require immobilization of the target nucleic acid on a solid support. It does not require immobilization of all the nucleic acid nor does it preclude removal of some of the target nucleic acid.

Moreover, as BD conceded during the claim construction hearing, this very absolute language is not drawn from the claims or specification. BD relies instead on Gen-Probe's expert's deposition testimony and a promotional video shown to the Patent Examiner after the Automation Patent specification was filed with the PTO. Neither is an ideal source of support for BD's proposed construction and neither compels the complete separation BD proposes when the claims and specification do not require it. *See Phillips*, 415 F.3d at 1317-18 (finding extrinsic evidence less significant than the intrinsic record and noting that the prosecution history is less useful than the specification for claim construction purposes). While Dr. Kramer indicates in his deposition that the purpose of the wash step is to remove as much of the non-target nucleic acid as possible, removing as much of the non-target material as possible is not the same as removing "all (or substantially all)" non-target material and leaving all the target nucleic acid. Similarly, the video BD relies on describes the ideal — removal of inhibitors and leaving behind only target nucleic acid — but it does not preclude the removal of some target nucleic acid.

Gen-Probe's proposed construction, "material not immobilized on the solid support," is also more consistent with the claim language and conforms to the specification. In describing the separation step, the specification indicates that "[t]he remaining material within the receptacle vessels should be *substantially* unaffected, thereby isolating the target nucleic acid." ('892 Patent 42:6-8.) The use of "substantially" accounts for some non-target material binding to the solid support. Additionally, the specification provides for repetition of additional wash cycles. ('892 Patent 43:32-38.) The Court adopts Gen-Probe's proposed construction and finds that "other material" means "material not immobilized on the solid support."

E. "receptacle"

> d) amplifying the target sequence in a r**eceptacle** containing the target nucleic acid and amplification reagents provided thereto, the **receptacle** being formed to have an open top end and a closed bottom end ('892 Patent, Claim 1.)

Gen-Probe proposes that "receptacle" means "a vessel formed with a closed end and an open end, for receiving and holding material." BD proposes that "receptacle" means "a vessel capable of receiving and holding material." Gen-Probe primarily relies on the prosecution history in which the PTO allowed deletion of "closed end" without changing the scope of the claims

because it was an inherent feature. BD argues Gen-Probe's inclusion of "closed end and an open end" renders language in Claim 1 of the '892 patent superfluous. The Court adopts Gen-Probe's proposed construction.

The only difference between the parties' proposed constructions is Gen-Probe's addition of the requirement that the receptacle have an open end and a closed end. This construction is supported by the file history and does not render any claim language superfluous. The PTO accepted the deletion of "closed end" from the description of receptacle without limiting the scope of the claim because it was an inherent feature of a receptacle ('255 Patent File History, 10/19/07 Request for Continued Examination at 13.) And it necessarily follows that if it has a closed end, it must have an open end if it is going to receive and hold anything, as the parties agree that it must. Additionally, this construction does not make the language of Claim 1 of the '892 Patent superfluous because there is a difference. Gen-Probe's proposed construction is "a vessel formed with a closed end and an open end . . . ," while Claim 1 of the '892 patent specifies that the receptacle have an "open *top* end and a closed *bottom* end." Because Gen-Probe's proposed construction is supported by the file history and does not render any claim language superfluous, the Court finds that receptacle means "a vessel, formed with a closed end and an open end, for receiving and holding material."

F. "reaction receptacle"

> The process of claim 1, wherein the solution is formed in a **reaction receptacle** ('255 Patent, Claim 6.)

Gen-Probe proposes that "reaction receptacle" means "a receptacle in which a chemical reaction occurs." BD proposes that "reaction receptacle" means "a vessel in which each reaction of the diagnostic assay is performed." Both the proposed constructions are consistent with the specification, but BD's proposed construction limits the claim to the only embodiment described in the specification. Specifically, BD's construction would require the use of a single receptacle in which all the reactions are performed without the sample ever leaving the receptacle. The Court adopts BD's proposed construction.

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Much of the parties' dispute as to this term centers around whether claims can be limited to a single preferred embodiment. The Court is mindful that claims cannot be limited to a preferred embodiment in the specification if the claims are clearly broader than that embodiment. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904, 907 (Fed. Cir. 2004). In *Liebel-Flarsheim v. Medrad,* the Federal Circuit addressed the two competing rules of construction, "twin axioms," that the Court faces in determining if the claims should be limited to the embodiment described in the specification. *Id.* at 904. "On the one hand, claims must be read in view of the specification, of which they are a part. On the other hand, it is improper to read a limitation from the specification into the claims." *Id.* Here, the Court faces "the fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification," with BD advocating the former and Gen-Probe protesting the latter. *Id.* Even when the preferred embodiment is the only embodiment, the claims are not limited to that embodiment. *Id.* at 907 (discussing *Wang Labs., Inc. v. America Online, Inc.,* 197 F.3d 1377, 1388 (Fed. Cir. 1999) and finding that *Wang* "does not stand for the proposition that if a patent specification describes only a particular embodiment, the claims must be limited to that subject matter").

To adopt Gen-Probe's proposed construction, the Court would have to completely ignore the specification that describes a reaction receptacle as the place where the steps of the diagnostic assay occur and disregard claim language consistent with this description. While the claims are not as detailed as the specification, the claims are not clearly broader than the preferred embodiment described in the specification. As BD notes, some steps outlined in the claim suggest the steps of the assay all occur in a reaction receptacle, including "forming a solution comprising the separated target nucleic acid and amplification reagent in a reaction receptacle," "moving the reaction receptacle to a second station," and "amplifying the target sequence in a receptacle." ('255 Patent, Claim 18; '892 Patent, Claims 1 and 24.)

Additionally, the specification supports BD's proposed construction. The summary of the invention section of the specification explains that reaction receptacles are picked up and retrieved by a transport mechanism that "transports the reaction receptacles between the stations of the analyzer." ('892 Patent 4:62-66.) The specification describes the reactions of the assay being

performed by moving a receptacle through the analyzer to the various stations where specimens or reagents are added, the contents of the receptacles are subject to separation, and ascertaining the results of the assay by observing the amount of light emitted from the receptacle. ('892 Patent 5:1-30.) The transport mechanism is described as moving a reaction receptacle between locations on the processing deck "during the performance of an assay within the reaction receptacle." ('256 Patent 12:14-19.) The specification even specifically notes the steps of the assay can be performed on multiple reaction receptacles, suggesting that all the steps are performed in the receptacle. ('892 Patent 4:30-35.) Because the claims are not clearly broader than the embodiment described and the specification supports BD's construction, the Court adopts BD's proposed construction. A "reaction receptacle" means "a vessel in which each reaction of the diagnostic assay is performed."

G. "Amplifying the target sequence in a . . . receptacle containing the target nucleic acid and amplification reagents *provided thereto*"[7]

> d) amplifying the target sequence in a receptacle containing the target nucleic acid and amplification reagents **provided thereto** ('892 Patent, Claim 1.)

Gen-Probe proposes that "Amplifying the target sequence in a . . . receptacle containing the target nucleic acid and amplification reagents provided thereto" means "amplifying the target sequence in a receptacle to which the target nucleic acid and amplification reagents have been provided." BD proposes that "[amplification reagents] provided thereto" means "added to the receptacle in which the target nucleic acid was already present." The parties dispute whether the target nucleic acid and amplification reagents are provided to the receptacle in a particular order. Gen-Probe argues that the target nucleic acid and amplification reagents can be combined in the receptacle in no particular order. BD argues that the amplification reagents must be added to the target nucleic acid in the receptacle. The Court adopts BD's construction because it is consistent with the claim language.

BD's construction is certainly more consistent with the description in the specification, but as discussed above, the Court cannot import limitations from the preferred embodiment into the

[7]Gen-Probe seeks construction of the entire phrase, while BD focuses only on "provided thereto."

claims when the claims themselves are clearly broader. *Kara Tech., Inc. v. Stamps.com, Inc.*, 582 F.3d 1341, 1347 (Fed. Cir. 2009) (a single embodiment "is not enough . . . to limit the patentee's clear broader claims."). However, the claim language itself is not as broad as Gen-Probe suggests and the language of the claims supports BD's proposed construction. *See Phillips*, 415 F.3d at 1313-14 (finding that "the claims themselves provide substantial guidance as to the meaning of particular claim terms" and "the context in which a term is used in the asserted claim can be highly instructive").

The claim language describes a series of steps that can generally be summarized as: immobilizing the target nucleic acid on a solid support; separating other material from the target nucleic acid; and washing the solid support. These steps are followed by "d) amplifying the target sequence in a receptacle containing the target nucleic acid and amplification reagents provided thereto, the receptacle being formed to have an open top end and a closed bottom end . . ." ('892 Patent, Claim 1.) Gen-Probe's assertion that the amplification reagents and target nucleic acid can be combined in the receptacle in any order is not consistent with the claim language because the claim language indicates that the target nucleic acid is already present, having been prepared for amplification through the prior three steps.

Additionally, Gen-Probes's proposed construction essentially reads "provided thereto" out of the claim. Gen-Probe's interpretation would more reasonably follow from the language of the claim without "provided thereto" because it would read, "amplifying the target sequence in a receptacle containing the target nucleic acid and amplification reagents."

Finally, the file history also weighs against Gen-Probe's proposed interpretation because its proposed construction follows from language that was eliminated and replaced by the above claim language during examination. *Bd. of Regents of the Univ. of Tex Sys. v. BENQ America Corp.*, 533 F.3d 1362, 1369 (Fed. Cir. 2008) ("While there are times that the prosecution history lacks the clarity of other intrinsic sources, the prosecution history may be given substantial weight in construing a term where that term was added by amendment."). During examination, the patent examiner suggested and Gen-Probe accepted substituting the above claim language for the phrase, "after step c) combining together in a receptacle the target nucleic acid and reagents under

conditions sufficient to amplify the target sequence." ('892 Patent File History, 08/01/06 Notice of Allowability at 2.) This broader language comes much closer to Gen-Probe's suggestion that the target nucleic acid and amplification reagents can be combined in any order, but that language was eliminated.

As discussed above, the claim language and steps outlined suggest that the target nucleic acid is present, having been the subject of two prior steps, and the amplification reagents are provided to the target nucleic acid for amplification. The Court adopts BD's proposed construction: "provided thereto" means "added to the receptacle in which the target nucleic acid was already present."

H. "station"

> a) at a first **station**, immobilizing the target nucleic acid on a magnetically responsive particle ('256 Patent, Claim 1.)

Gen-Probe proposes that "station" means "a location integrated and coordinated with one or more other locations within a shared, open environment to perform one or more assays." BD proposes that "station" means "a separately housed module capable of receiving a reaction receptacle." Gen-Probe relies on the use of the term in the claims, specification, and prosecution history in arguing that stations are merely locations within the automated clinical analyzer and draws part of its proposed construction language from the description in the summary of the invention section of the specification. BD also relies on the specification and argues that the term is always used to refer to a separately housed physical module that receives a reaction receptacle. The Court adopts the following construction: "a location integrated and coordinated with one or more other locations to perform one or more assays."

BD's proposed construction is based primarily on the uses of term in the specification to describe separately housed modules on the processing deck and the interchangeability of the terms station and module, justifying defining a station as a module. The Court agrees that station is used throughout the specification to describe locations that are often covered by a separate housing and capable of receiving a reaction receptacle. But, adopting BD's proposed construction *requires* that every station described in the specification be a separately housed module that is capable of

receiving a reaction receptacle. That is not the case. As Gen-Probe notes, there are at least two places in the specification where BD's proposed construction of station conflicts with the description of a station in the specification. The "tip wash/disposal *station*" is not separately housed and not capable of receiving a reaction receptacle and the "specimen transfer *station*" is not separately housed. ('892 Patent 11:45-54; 27:63-67.) This is problematic because a "construction that excludes a preferred embodiment . . . 'is rarely, if ever correct,'" *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1285 (Fed. Cir. 2005) (quoting *Vitronics*, 90 F.3d at 1583), and the term is not defined by implication because it is not used consistently throughout the specification. *Cf. AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1052 (Fed. Cir. 2010) (finding that a term is defined by implication if it used "throughout the entire patent specification, in a manner consistent with only a single meaning").

Additionally, the Court finds that the terms "station" and "module" are not interchangeable. BD argues that the terms are interchangeable because the summary of the invention section states that "the automated clinical analyzer integrates and coordinates the operation of various automated *stations, or modules*, ..." ('892 Patent 4:47-49 (emphasis added).) BD does not cite, and the Court is not aware of, any authority finding that terms are interchangeable simply because they are connected by "or" in one place in the specification. But, even if the Court assumes this use suggests the terms are interchangeable, the use of them distinctly in the specification suggests that the terms are not interchangeable. The specification discusses diagnostic assays "which require the use of one or more of the stations, components, and modules described herein" and goes on to explain that the particular assay described is "merely for the purpose of illustrating the operation and interaction of the various stations, components, and modules of the analyzer. ('892 Patent 15:20-26.) BD's proposed construction of "station" conflicts with the use of the term in the specification and improperly construes "station" as module.

Gen-Probe's proposed construction, "a location integrated and coordinated with one or more other locations within a shared, open, environment to perform one or more assays" is partially drawn directly from the description of the invention in the specification. ('892 Patent 4:47-50 ("the clinical analyzer integrates and coordinates the operation of various automated

stations, or modules, involved in performing one or more assays . . .").) Gen-Probe's use of location to describe a station is broad, but consistent with use of the term "station" throughout the entire specification. However, as previously discussed in addressing "stand alone unit" and "self contained analyzer," Gen-Probe's insertion of "shared, open environment" is not supported by the claims or specification. Accordingly, the Court adopts Gen-Probe's proposed construction, without this unsupported language, "a location integrated and coordinated with one or more other locations to perform one or more assays."

I. "housing"

> The process of claim 8, wherein the first and second stations and the transport mechanism are contained within a **housing** of the stand-alone unit. ('256 Patent, Claim 9.)

Gen-Probe proposes that "housing" means "a covering for an interior open environment." BD proposes that "housing" means "a covering." The parties agree that a housing is a covering, but Gen-Probe argues that it must be a covering for an interior open environment. The Court adopts BD's construction.

Gen-Probe emphasizes three uses of housing within the specification: (1) "Analyzer includes a housing built over an internal frame structure . . . ;" (2) "An extension portion 102 . . . extends above the top portion of housing 60 so as to provide vertical clearance for moving components within the housing 60;" and (3) "The processing deck . . . separates the interior of the housing . . ." However, none of these references require or describe an "interior open environment" covered by the housing. Like Gen-Probe's attempts to import an "open, shared environment" into other claim terms, this also lacks sufficient support in the intrinsic record and would only serve to add ambiguity to a simple term. The Court adopts BD's proposed construction for housing. A "housing" means a "covering."

J. "transport mechanism"

> c) transferring the target nucleic acid immobilized in step a) from the first station to a second station using a rotatable **transport mechanism**; ('256 Patent, Claim 1.)

Gen-Probe proposes that "transport mechanism" means "a device that moves a material." BD proposes that "transport mechanism" means "a device that can carry a reaction receptacle."

Gen-Probe provides no explanation for its proposed construction except to assert that it is the most logical and legally sound in light of the claims and specification. However, Gen-Probe essentially asks the Court to completely ignore the specification, including the specific description of a transport mechanism in the specification, as only a preferred embodiment. BD relies on the definition of transport mechanism in the specification and numerous other descriptions of its function in the specification. The Court adopts BD's proposed construction.

As previously discussed in construing the term "reaction receptacle," the claims cannot be limited to a preferred embodiment in the specification, even when that preferred embodiment is the only embodiment, if the claims are clearly broader than that embodiment. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d at 904, 907. But, the claims are not clearly broader than the specification. *See Kara Tech.,* 582 F.3d at 1347. Additionally, the specification defines a transport mechanism and describes it throughout as a mechanism for transporting a reaction receptacle. *See Phillips*, 415 F.3d at 1315 (finding that the specification is "the single best guide to the meaning of a disputed term" and usually dispositive of the term's meaning).

Claim 27 of the '255 Patent describes the reaction receptacle being moved between the first and second station with a transport mechanism that includes a receptacle carrier assembly. ('255 Patent, Claim 27.) This claim language indicates that the transport mechanism is "a device that can carry a reaction receptacle," as proposed by BD, rather than just a "device that moves a material," as proposed by Gen-Probe. Additionally, reading the claims "in view of the specification, of which they are a part," *Phillips*, 415 F.3d at 1315 (citing *Markman,* 52 F.3d at 979), the Court finds that transport mechanism means "a device that can carry a reaction receptacle." The transport mechanism is described as "automatically transport[ing] the reaction receptacles between the stations of the analyzer." ('892 Patent 4:65-67.) It is also more specifically defined as "engag[ing] and manipultat[ing] a reaction receptacle and mov[ing] it from one location on the processing deck to another as the reaction receptacle is sequentially moved from one station to another during the performance of an assay within the reaction receptacle" and including a receptacle carrier assembly. ('256 Patent 12:7-19; '255 Patent 11:67-12:1 (describing the transport mechanism as having a receptacle carrier assembly).) Figure 14 of the '892 Patent

also depicts the transport mechanism engaged with a reaction receptacle. ('892 Patent 6:10-15.) Descriptions of other component and the transport mechanism also support BD's proposed construction. ('892 Patent 5:30-31 ("Reaction receptacles can be independently transported between stations by the transport mechanism"); '255 Patent 11:67-12:65-67 (explaining that reaction receptacles are placed into or removed from the temperature ramping station by the transport mechanism); '255 Patent 12:40-44 (describing an incubator as having an opening through which a transport mechanism can insert and retrieve a reaction receptacle)).

The Court adopts BD's proposed construction. "Transport mechanism" means "a device that can carry a reaction receptacle."

K. aspirating non-immobilized components of the sample" and "aspirating . . . other material present in the fluid sample"

> b) subjecting the magnetically responsive particle to a magnetic field and **aspirating non-immobilized components of the sample**; ('256 Patent, Claim 1.)
>
> The process of claim 6, wherein the separating step comprises subjecting the solid support to a magnetic field and **aspirating** the **other material present in the fluid sample**

Gen-Probe proposes that "aspirating non-immobilized components of the sample" and "aspirating . . . other material present in the fluid sample" means "removing non-immobilized components of the sample/other material present in the fluid sample through contact with a suctioning device." BD proposes that "aspirating non-immobilized components of the sample" means "removing, by suction, non-immobilized components of the sample" and "aspirating . . . other material present in the fluid sample" means "removing by suction all material present in the fluid sample that is not the target nucleic acid." The parties agree that aspirating means suction, but dispute whether aspirating means removal by suction or removing with a suctioning device. Additionally, BD again attempts to require the removal of "*all* material present in the fluid sample that is not target nucleic acid." The Court has already rejected this construction in construing "other material" and also rejects it here because it is not supported by the claims or specification.

Gen-Probe argues that aspirating requires the use of a suctioning (aspirating) device based on the specification's explanation of the manual process being automated and a dictionary

definition. BD argues that there is no basis in the claims, specification, or prosecution history for a structural requirement for a suctioning device. The Court adopts the following constructions: "aspirating non-immobilized components of the sample" means "removing non-immobilized components of the sample by suction" and "aspirating . . . other material present in the fluid sample" means "removing other material present in the fluid sample by suction."

The only suggestion of a suctioning device is in the portion of the background section of the specification that discusses the problems with the manual performance of a nucleic acid-based assay. ('892 Patent 4:5-29.) As Gen-Probe notes, this portion of the specification mentions the use of an aspirator device and performance of aspirating with hand-held non-fixed instruments. ('892 Patent 4:11-12, 16-17.) However, this portion of the specification is not describing the invention, it is laying the groundwork for the next portion of the background section that explains how the proposed invention solves the problems associated with the manual process. Accordingly, the aspirator device mentioned in the specification is not describing the claimed process, it is actually distinguishing it.

The dictionary definitions relied on by Gen-Probe are equally unpersuasive in requiring the use of a suctioning device. The first definition cited supports BD's proposed construction because it defines "aspirate" as "to remove by aspiration." STEDMAN'S MEDICAL DICTIONARY 156 (27th ed. 2000). This is consistent with removal by suctioning. Gen-Probe attempts to rely on definitions for "aspirator," but this is not appropriate because there is no mention of an aspirator or any other device in the claims or description of the claimed invention to aspirate. There is simply no support for incorporation of a suctioning device into the claims.

As noted above, the Court also rejects BD's proposed construction of "aspirating . . . other material present in the fluid sample" because it improperly attempts to incorporate the removal of all non-target nucleic acid. Accordingly, the Court adopts the following constructions that do not import any requirements that lack support in the claims and specification: "aspirating non-immobilized components of the sample" means "removing non-immobilized components of the sample by suction" and "aspirating . . . other material present in the fluid sample" means "removing other material present in the fluid sample by suction."

III. Penetrable Cap Patents

As with the Automation Patents discussed above, the disputed claim terms appear across the two Cap Patents at issue in this case and in numerous claims. However, the parties agree that the disputed terms have common meanings across the different patents and claims.

The following exemplary claim is provided for all Penetrable Cap Patents disputed claim terms unless otherwise noted:

> A cap comprising: a **core structure** comprising a closed side wall adapted to grip an open-ended vessel and having an opening formed therein; and axially aligned first and second **frangible seals affixed to** the core structure, the first **frangible seal** being situated beneath the second **frangible seal** in a spaced-apart relationship and covering the opening in the core structure so as to provide a fluid barrier, wherein the first and second **frangible seals** are constructed and arranged to remain **affixed to** the core structure when **penetrated by** a fluid transfer. ('308 Patent, Claim 1.)

A. "frangible seal" or "frangible" and "seal"

In addition to their dispute about the meaning of the terms, the parties also dispute what the relevant claim term is. Gen-Probe believes the relevant claim term is "frangible seal" because the words always appear together as "frangible seal" in the patent claims, but BD argues for two separate terms "frangible," and "seal" to obtain a separate construction of the term seal. As to the term "frangible seal" Gen-Probe proposes that "frangible seal" means "a breakable seal that irreparably tears or fractures when penetrated by the fluid transfer device." BD proposes that "frangible" means "penetrable and does not require either tearing or leaving a hole," and that "seal" means "material that covers the opening in the core structure."[8] As to the proposed constructions, Gen-Probe primarily relies on the descriptions in the specification which explain that the frangible seal should tear or fracture resulting in the creation of air passageways. BD relies on the preference in the specification for tearing or fracturing to argue that it is not required because it is preferable. The Court adopts Gen-Probe's proposed construction of "frangible seal."

BD has not provided the Court with any authority for dissecting a term, "frangible seal," into two separate terms for purposes of construction when the term consistently appears only as "frangible

[8]BD initially argued that "seal" meant "covers the opening in the core structure and forms a substantially leak-proof barrier," but BD has now agreed with the construction Gen-Probe proposed if the Court decided to separate the term into "frangible" and "seal."

seal" throughout multiple claims of multiple patents. Accordingly, the Court will construe the term "frangible seal" as it always appears throughout the claims. Additionally, BD's proposed construction is not consistent with dictionary definitions of "frangible." As to "frangible seal," Gen-Probe's proposed construction is not only supported by the specification, but also by the definition of "frangible."

As previously noted, the Court must construe the claim terms in light of the specification, as the specification is the primary basis for construing a disputed term. *Phillips*, 415 F.3d at 1315. Here, the specification repeatedly describes tearing of the frangible seal by a fluid transfer device to create air passageways that allow the venting of air from within the collection device. ('612 Patent 4:62-66 ("When the cap is penetrated by the pipette tip, air passageways are formed between the pipette tip and the frangible seal or seals of the cap, thereby facilitating the venting of air from within the vessel."); '612 Patent 9:43-50 ("In order to facilitate the venting of air from within a collection device 10, the frangible seal 32 is preferably constructed so that it tears when the seal is penetrated by a fluid transfer device, thereby forming air passageways 70 between the seal and the fluid transfer device."); '612 Patent 13:52-66 ("When a cap 30A-E of the present invention is pierced by a fluid transfer device . . . one or more tears are preferably formed in the frangible seal 32 . . . . . As Figure 18 illustrates, these tears in the frangible seal form air passageways 70 which facilitate the venting of air displaced from within a collection device.")

Additionally, multiple dictionaries, particularly a technical dictionary definition of "frangible" support Gen-Probe's proposed construction. The Court can rely on dictionaries in claim construction and technical dictionaries are particularly helpful because they provide guidance on commonly accepted definitions in the various fields of science and technology. *Phillips*, 415 F.3d at 1318 (noting the usefulness of dictionaries in claim construction and explaining that technical dictionaries are particularly helpful because they "collect accepted meanings of terms used in various fields of science and technology"). Something that is "frangible" is defined as "breakable, fragile, or brittle." MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 849 (6th ed. 2003); *see also* THE NEW OXFORD AMERICAN DICTIONARY 672 (2001) (defining "frangible" as "fragile; brittle"). These definitions are consistent with a "frangible seal" being "a breakable seal that irreparably tears or

fractures when penetrated by the fluid transfer device."

"Frangible seal" means "a breakable seal that irreparably tears or fractures when penetrated by the fluid transfer device."

B. "affixed to"

Gen-Probe proposes that "affixed to" means "physically attached or fastened to and not integral with." BD proposes that "affixed to" means "connected with the core structure and may be, but need not be, integral with the core structure." The parties' dispute whether the frangible seal, "affixed to" the core structure, is or is not an integral component of the core structure. The parties agree that "affixed to" is most commonly used in the claims to describe a frangible seal being affixed to a surface ledge, including the surface ledge of the core structure. However, the parties disagree about whether "affixed to" means the frangible seal is or is not integral with the core structure.

The claims describe the frangible seal being affixed to a surface ledge, the core structure, and the top surface of the closed side wall. ('612 Patent, Claims 1 and 6; '308 Patent, Claims 1 and 11.) The specification describes the frangible seal being affixed to the core structure *after* the core structure is created from injection molding and being sufficiently cured. ('612 Patent 8:38-44 (emphasis added).) The specification also outlines in detail the components of the integrally molded core structure and it does not include the frangible seal. ('612 Patent 7:12-23.) These descriptions conflict with the frangible seal being integral with the core structure, as proposed by BD, and support Gen-Probe's assertion that a frangible seal is not integral with the core structure. Additionally, the specification goes on to explain that "[t]he frangible seal is preferably not an integral component of the core cap." ('612 Patent 9:7-9.) Construing the claim terms in light of the specification, as the Court must, the Court adopts Gen-Probe's proposed construction. *See Phillips*, 415 F.3d at 1315. The term "affixed to" means "physically attached or fastened to and not integral with."

C. "filter"

> The cap of claim 1 further comprising a **filter** interposed between the first and second frangible seals. ('308 Patent, Claim 14.)

Gen-Probe proposes that "filter" means:

> a material which *(1)* performs *either* a wiping function to remove fluids present on the outside of a fluid transfer device *or* an absorbing function to hold or otherwise sequester fluids removed from the outside of a fluid transfer device *(or both)*, and (2) has pores or *small or narrow spaces or crevices between its parts* which admit the passage of a gas

BD proposes that "filter" means:

> *any* material that *both (1)* performs a wiping function to remove fluids present on the outside of a fluid transfer device and/or performs an absorbing function to hold or otherwise sequester fluids removed from the outside of a fluid transfer device, and (2) has pores or interstices which admit the passage of gas.

When the patentee gives a claim term a special definition, "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). The parties agree that the specification provides a special definition for filter. According to the specification, a filter is:

> a material which performs a wiping function to remove fluids present on the outside of a fluid transfer device and/or an absorbing function to hold or otherwise sequester fluids removed from the outside of a fluid transfer device. For reasons discussed below, the filters 33 of the present invention are composed of a material or combination of materials having pores or interstices which admit the passage of gas.

('612 Patent 10: 29-37.)

Gen-Probe asks the Court to substitute "small or narrow spaces or crevices between its parts" for interstices because the word interstices may be unknown to a jury. BD objects to this alteration because the special definition in the specification should control. The Court agrees that the special definition in the specification controls the meaning of the term "filter" and adopts the following construction. "Filter" means:

> a material which (1) performs a wiping function to remove fluids present on the outside of a fluid transfer device and/or absorbing function to hold or otherwise sequester fluids removed from the outside of a fluid transfer device and (2) has pores or interstices which admit the passage of gas

D. "penetrated by" or "penetrated" and "penetrating"

> wherein the first and second frangible seals are constructed and arranged to remain affixed to the core structure when **penetrated by** a fluid transfer. ('308 Patent, Claim 1.)

> A method for removing a fluid substance from the closed system of claim 17, the method comprising the steps of: (1) **penetrating** the first and second frangible seals with a fluid transfer device; ('308 Patent, Claim 18.)

Gen-Probe identified "penetrated by" as the relevant claim term in the Joint Claim Construction Chart. However, Gen-Probe's briefing addresses BD's proposed constructions. BD proposes that "penetrated" means "to have passed through and does not require either tearing or leaving a hole" and "penetrating" means "passing through and does not require either tearing or leaving a hole." Gen-Probe argues that no construction is necessary, but if the Court construes it, the terms should mean "passed through by."

The Court has already rejected BD's attempt to import "does not require either tearing or leaving a hole" in construing "frangible seal" and finds that the Court need not construe the terms. The terms "penetrated by," "penetrated," and "penetrating" are common terms that need no clarification. *See Netflix, Inc. v. Blockbuster, Inc.*, 477 F. Supp. 2d 1063, 1068 (N.D. 2007). "A district court need not construe every single disputed word." *Id.* (citing *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997)).

E. "core structure"

BD proposes that "core structure" in all claims of the '308 Patent, except Claim 2,[9] means "the cap need not be a unitary piece; it need not be plastic; and it need not have a generally cylindrical shape." Gen-Probe argues that no construction is necessary, but if the Court construes it, "core structure" means "principal structure" or "basic structure" and "must have an opening formed in it and be designed to grip an open-ended vessel." BD does not dispute these characteristics of the core structure, but argues that the Court must construe "core structure" as not being a number of things — unitary piece, plastic, and generally cylindrical shaped — based on claim differentiation.

"Differences among claims can . . . be a useful guide in understanding the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. As the *Phillips* Court explained, "a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1315 (citing *Liebel-Flarsheim*, 358 F.3d at 910). Claim 1 of the '308 Patent

[9]BD concedes in briefing that the proposed construction could not apply to the term "core structure" in Claim 2 of the '308 Patent because the basis for BD's proposed construction is claim differentiation from the Claim 2 limitation.

describes the core structure. Claim 1 does not include any limitations regarding a unitary piece of plastic piece or having a generally cylindrical shape. Dependent Claim 2 claims "[t]he cap of claim 1, where the core structure is a unitary plastic piece having a generally cylindrical shape." Because dependent Claim 2 of the '308 Patent "adds a particular limitation," *id.* at 1315 — "a unitary plastic piece having a generally cylindrical shape," ('308 Patent, Claim 2) — the "limitation gives rise to a presumption that [this] limitation . . . is not present in the independent claim," Claim 1. *See Phillips*, 415 F.3d at 1315. Accordingly, the Court construes "core structure" in independent Claim 1 as "need not be a unitary plastic piece having a generally cylindrical shape."

CONCLUSION

The Court construes the disputed claim terms as discussed above.

IT IS SO ORDERED.

DATED: November 21, 2011

Hon. Roger T. Benitez
United States District Judge