IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

EPPENDORF AG, EPPENDORF ARRAY	:	CIVIL ACTION
TECHNOLOGIES SA, EPPENDORF NORTH	:	
AMERICA INC.,	:	NO. 09-0504
	:	
Plaintiffs,	:	
	:	
V.	:	
	:	
NANOSPHERE INC.	;	
	:	
Defendant.	:	

MEMORANDUM ON CLAIM CONSTRUCTION

Baylson, J.

July 12, 2010

I. <u>Introduction</u>

Plaintiffs Eppendorf AG, Eppendorf Array Technologies SA, and Eppendorf North America Inc. (collectively, "Eppendorf"), allege, <u>inter alia</u>, that Defendant Nanosphere, Inc., infringed upon their patent, United States Patent Number 7,321,829 (filed May 19, 2000) ("829 Patent"), which describes a "[m]ethod for the identification and/or the quantification of a target compound obtained for a biological sample upon chips." '829 Patent, col. 1, II. 1–4. Specifically, at the claim construction hearing, Eppendorf described the '829 Patent as providing an efficient and cost–effective method of testing a human tissue sample (e.g. blood, urine) to determine whether a person has a particular antigen (c.g. DNA). (Markman Hr'g Tr. 8:22–10:16, June 10, 2010, ECF No. 90.) Eppendorf further explained that the '829 Patent functions, <u>inter</u> <u>alia</u>, by putting capture molecules on an array of solid support (e.g. a glass slide) to "snag" the substance that the test is looking for ("target compound"), which is in a liquid solution, to cause hybridization or binding between the capture molecules and the target compound; then, because such hybridized molecules are not yet visible, the '829 Patent causes additional particles (e.g. gold), and then precipitate (e.g. silver) to attach to the target molecule so that the target molecules' presence can be quickly discerned using light and a scanner. (Markman Hr'g Tr. 11:20–30:17.)¹

Presently before the Court are the parties' briefs on claim construction pursuant to <u>Markman v. Westview Instruments, Inc.</u>, 52 F.3d 967 (Fed. Cir.1995) (en banc), <u>affd 517 U.S.</u> 370. (Docket Nos. 60, 63, & 73–74.) On June 10, 2010, the Court heard oral argument on claim construction and offered tentative constructions on the disputed claim terms. (Docket No. 90.) On June 21, 2010, after the parties indicated that they were amenable to the Court's tentative constructions, and proposed alternate constructions for one term that they continued to dispute, the Court entered an Order providing constructions of the disputed terms in the '829 Patent. (Docket No. 92).² The following Memorandum explains the Court's reasoning for each construction.

II. Legal Standards

Generally, a claim term is given its "ordinary and customary meaning," that being the definition given by "a person of ordinary skill in the art in question at the time of the invention." <u>Phillips v. AWH Corp.</u>, 415 F.3d 1303, 1313 (Fed. Cir . 2005) (en banc). The Federal Circuit has explained that the claim construction inquiry begins by looking at the intrinsic evidence: the language of the claims, the specification, and the prosecution history.

"[T]he claims themselves"-that is "the use of a term within the claim," "[o]ther claims

¹Nanosphere does not dispute Eppendorf's brief explanation of the '829 Patent. (Markman Hr'g Tr. 33:13.)

²Prior to the filing of this Memorandum, Nanosphere filed a Motion for Reargument (Docket No. 96) seeking to reargue and disputing the construction of two of the claim terms at issue. Nanosphere has not yet submitted a substantive Memorandum explaining why it disputes the construction of those terms.

of the patent in question, both asserted and asserted," and "[d]ifferences among claims"—"provide substantial guidance as to the meaning of particular claim terms." Id. at 1314. "[1]t is [also] appropriate for a court . . . to rely heavily" on the specification, the patentce's written description, for guidance as to the meaning of the claims." Id. at 1314. In fact, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Id. at 1315 (quoting <u>Vitrionics Corp. v. Conceptronic, Inc.</u>, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Additionally, the court "should also consider the patent's prosecution history, if it is in evidence." <u>Markman</u>, 52 F.3d at 980. Though "less useful" and "often lack[ing] the clarity of the specification," "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim's scope narrower than it would otherwise be." <u>Phillips</u>, 415 F.3d at 1317.

Apart from intrinsic evidence, the court is also authorized to rely on extrinsic evidence, that being "evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." <u>Id.</u> (quoting <u>Markman</u>, 52 F.3d at 980). Such evidence, through "shed[ding] useful light on the relevant art," is "less significant than the intrinsic record in determining the legally operative meaning of claim language," and "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." <u>Id.</u> at 1317, 1319 (internal quotation marks omitted).

III. <u>Discussion</u>

In their Markman briefs, the parties disputed the construction of several terms relating to

the following: (A) "discrete region(s)," (B) "fixed upon a solid support according to an array comprising discrete regions," (C) "determining the possible presence and quantification of precipitate(s) in said discrete region(s)," (D) "correlating the presence and quantification of the precipitate(s) at the discrete region(s) with the identification and/or quantification of said target compound, (E) "colloidal gold particles coupled to the bound target compound," (F) "wherein the possible presence and quantification of a precipitate is obtained by reflection, absorption or diffusion of a light beam upon said precipitate," (G) "wherein binding of said target compound to one or more of said multiple species of capture molecules leads to a catalytic reduction of a metal present in solution, and a formation of a metallic precipitate in one or more of said region(s)," and (H) "wherein said computer is programmed to detect and/or quantitate said target compounds."³

At the June 10, 2010 hearing, the Court proposed tentative constructions for the disputed terms. The parties, although reserving their "right to challenge the Court's Markman ruling defining the claim terms," were "amenable to the Court's proposed claim definition(s)," with the exception of the construction of the fourth term, "correlating the presence and quantification of the precipitate(s) at the discrete region(s) with the identification and/or quantification of said target compound." (Supp. Markman Letter 2–3, Docket No. 91.) For this term, the parties continued to disagree as to its construction, and submitted alternative proposed constructions. (Supp. Markman Letter 2.)

The Court will explain briefly its reasons for arriving at each claim construction.

³In addition, the parties initially disputed, but subsequently agreed upon, constructions of the following claim terms: "target compound," "one species of capture molecule(s)," and "a particle associated with said target compound." (Pls.' Resp. 1 n. 1, Docket No. 74.)

A. "Discrete Region(s)"

Claim Term	Eppendorf's Construction	Nanosphere's Construction
"discrete region(s)"	finite areas containing molecules such as capture molecules separated from each other such that the finite areas do not overlap	regions that are separate and distinct

Claims 1 and 16 of the '829 Patent describe the precipitate as being located in "discrete region(s)." '829 Patent, col. 11, ll. 53, 57, 59, & 61; col. 12, ll. 59, 60, & 66-67. Despite offering different constructions of the term "discrete region(s)," both Eppendorf and Nanosphere argued that the term describes areas that are unconnected and contained (Pls.' Opening 13, Docket No. 60; Def.'s Opening 18, Docket No. 63), and conceded that their proposed constructions are "similar" (Pls.' Resp. 5, Docket No. 74; see also Def.'s Resp. 24, Docket No. 73 (noting that the parties are "for the most part," "in agreement")).

The Court has concluded that the simplest and most appropriate construction of "discrete region(s)" is "finite areas that do not overlap." This definition is supported by the specification, which describes the discrete areas as being unconnected: "These locations or spots have preferably a diameter comprised between 10 and 500 µm and are <u>separated by distance of similar</u> order of magnitude " "829 Patent, col. 3, II. 36–39 (emphasis added). The words "finite" and "do not overlap," which appear in Eppendorf's proposed construction, are marginally more effective at conveying the unconnected nature of the regions in question, than the words "separate and distinct," which Nanosphere has proposed. Moreover, the remaining portion of Eppendorf's proposed construction relating to the content of the discrete areas, namely "capture molecules," is unnecessary and redundant, because both of the claims in which the term "discrete

region(s)" appears already describe such contents: Claim 1 reads "each of said discrete regions being fixed with one species of capture molecule," <u>id.</u> col. 11, ll. 53–54, and Claim 16 reads, "each of said discrete regions being fixed with one species of capture molecule which recognizes a target compound," <u>id.</u> col. 12, ll. 60–61.

В.	"Fixed upon a Solid Support According to an Array Comprising Discrete
	Regions"

Claim Term	Eppendorf's Construction	Nanosphere's Construction
"fixed upon a solid support according to an array comprising discrete regions"	attached or linked to a surface of a solid support in a linear or two-dimensional spatial layout of discrete regions according to a specific pattern	directly or indirectly attached to any kind of surface that allows the formation of an "array" of capture molecules, including glasses, filters, electronic device, polymeric, or metallic materials, etc.
"array"	[no separate definition provided]	a plurality of discrete regions of capture molecules, which may or may not be in specific locations or presented according to a specific pattern

Claim 1 also describes the capture molecule in the '829 Patent as being "fixed upon a solid support according to an array comprising discrete regions." '829 Patent, col. 1, ll. 50–52. Each of the parties' proposed constructions is lengthy and composed of multiple parts, which must be addressed in turn.

First, insofar as the parties seek to explain the words "fixed upon," their constructions do not differ greatly. They agree that these words refer to the capture molecule's attachment to a solid support "surface," but Nanosphere also seeks to describe such attachment as being either "direct[] or indirect[]," whereas Eppendorf describes the capture molecule as being "attached or linked" to a solid support surface. However, the parties have neither provided intrinsic or extrinsic support for their word choices, nor expressly disagreed with one another's proposed language, and the patent itself does not use the words "direct," "indirect," "link," or "attach" to describe the relationship between the capture molecule and the solid support surface. After considering both parties' proposed language concerning "fixed upon," the Court has determined that "attached or linked" actively describes the relationship between the capture molecule and the solid support surface, whereas "direct[] or indirect[]" attachment is ambiguous, given that it is unclear what either of those types of attachment entails.

As for "solid support," the parties, after submitting their Markman briefs, agreed that the words should be construed to mean "any kind of solid support that allow [sic] the formation of arrays of capture molecules (specific pattern) upon one or more of its surfaces. Said solid support can be made of glasses, filters, electronic device, polymeric or metallic materials, etc." (Supp. Markman Letter, App'x at 1.) In light of this agreed–upon definition, "fixed upon a solid support according to an array comprising discrete regions" need not reiterate the lengthy "solid support" definition included in Nanosphere's proposed construction.

Turning next to "array," although the parties agree that the word is composed of "discrete regions," Eppendorf contends that it also has a "linear or two-dimensional spatial layout . . . according to a specific pattern," whereas Nanosphere avers that the array "may or may not be in specific locations or presented according to a specific pattern." The only part of the '829 Patent that uses the words "specific pattern" is the following excerpt from the "Summary of the Invention" section of the specification:

The "hybridisation chips" according to the invention are any kind of solid support that allow the formation of arrays of capture molecules (specific pattern) upon one or more of its surfaces.... Preferably said arrays contain specific locations (advantageously presented according to a specific pattern), each of them containing normally only one species of capture molecule.

'829 Patent, col. 2, II. 62–65, 67–col. 3, I. 3 (emphases added). This quoted language at no point explains what a "specific pattern" entails, and only provides that the arrays arc "[p]referably" "presented according to a specific pattern." Id. col. 3, I. 1. Because the Federal Circuit in Phillips made clear that the construction of a claim term should not be restricted to the patent's preferred embodiments, thereby reading in unnecessary and unintended limitations, 415 F.3d at 1323, this Court is not persuaded that the capture molecule arrays described in the '829 Patent must be presented "according to a specific pattern." In any event, the Court does not find any language concerning "specific pattern" to be helpful in explaining how the arrays should be organized, and in particular, Nanosphere's proposed language of "may or may not be in specific locations or presented according to a specific pattern," adds unnecessary confusion.

As for whether the array encompasses three-dimensional layouts, as Nanosphere contends (Def.'s Resp. 15–21), or solely "linear or two dimensional layouts," as Eppendorf avers (Pls.' Resp. 6–7), the Court is not persuaded that the arrays described in the '829 Patent are limited to "linear or two-dimensional layouts." Although Nanosphere has provided numerous references to three-dimensional "solid support[s]," for example disclosing the arrays of capture molecules can form "upon <u>one or more</u> of [a solid support's] surfaces," '829 Patent, col. 2, 11. 64–65 (see also Def.'s Resp. 15–21), such language does not indicate that the arrays themselves, rather than solid supports, can be three-dimensional. Neither, however, does the '829 Patent indicate that an array must be limited to "a linear or two-dimensional array." The Court declines to include any language regarding the possible dimensions encompassed by the '829 Patent's arrays, because "a court, under the rubric of claim construction, may [not] give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," <u>PPG Indus. v. Guardian Indus. Corp.</u>, 156 F.3d 1351, 1355 (Fed. Cir.

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1998).

Given the reasons detailed above, the Court has construed "fixed upon a solid support according to an array comprising discrete regions" to mean "attached or linked to a surface of a solid support." The parties did not oppose this construction either at the Markman hearing or in their subsequent letter to the Court.

C. "Determining the Possible Presence and Quantification of Precipitate(s) in Said Discrete Region(s)"

Claim Term	Eppendorf's Construction	Nanosphere's Construction
"determining the possible presence and quantification of precipitate(s) in said discrete region(s)"	acquiring one or more special representation(s) of the array comprising one or more sets of pixel data, and processing and/or filtering the pixel data (i) to determine the location(s) of the discrete region(s) having	determining the possible presence of the metallic precipitate(s) and determining, by comparison to reference standards, the specific amount of the volume of metallic precipitate(s)
region(s)"	precipitate(s), and (ii) to determine one or more values related to the amount of precipitate(s) in the discrete region(s)	detecting and determining, by comparison to reference standards, the specific amount of the volume of metallic precipitate in said discrete region

Claims 1 and 16 specify that the method described in the '829 Patent comprises "determining," and "detecting and quantifying" the "precipitate in said discrete region(s)." '829 Patent, col. 11, ll. 58–59; col. 13, ll. 1–2. Eppendorf's proposed construction describes the precipitate determination process as "comprising one or more sets of pixel data," and Nanosphere's proposed constructions largely recite the words in the disputed claim terms in question, but specify that the method described in the '829 Patent determines the "volume" of precipitate, "by comparison to reference standards."

Turning first to the appropriate measure of precipitate, Eppendorf has conceded that "obtaining the three-dimensional volume of the precipitate is undeniably an embodiment disclosed and claimed in the '829 Patent," but insists that the invention, as presently used by the parties, comprises "obtaining a two dimensional scan of the array and assigning pixel values based on the intensity readings." (Pls.' Resp. 8.) Both parties rely upon numerous extrinsic sources such as expert declarations to support their proposed constructions (Pls.' Resp. 7–15; Def.'s Resp. 3–12), but have not provided the Court with reasons compelling the inclusion of the appropriate measure for determining precipitate in the construction of the disputed terms. Not only is this Court reluctant to adopt a construction that imports "additional precision or specificity" not present in the patent itself, <u>PPG Indus.</u>, 156 F.3d at 1355, but also, the Federal Circuit does not require "mathematical precision" in a patentee's definition of his invention. <u>Oakley, Inc. v. Sunglass Hut Int'l</u>, 316 F.3d 1331, 1340-41 (Fed. Cir, 2003).

As for Nanosphere's recommendation that the construction include "by comparison to reference standards," the Court finds such language imprecise and unhelpful, given that Nanosphere's proposed construction does not explain what the appropriate reference standards are, and how the quantification of the precipitate can be compared to any such standard. The Court, therefore, will not construc the precipitate quantification process as involving either pixel data or comparisons to reference standards.

With the exception of the reference to "pixel data," Eppendorf's proposed construction, unlike Nanosphere's, does not largely recite the words in the disputed claim terms, and instead explains that the process of detecting and quantifying precipitate involves acquiring "spatial representation(s)" and determining "values related to the amount of precipitate(s)." Accordingly, the Court has construed the disputed terms regarding quantifying the precipitate to mean "acquiring one or more spatial representation(s) of the array (i) to determine the location(s) of the discrete region(s) having precipitate(s), and (ii) to determine one or more values related to the amount of precipitate(s) in the discrete region(s)."

D. "Correlating the Presence and Quantification of the Precipitate(s) at the

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<u> </u>	Eppendorf's Construction	Nanosphere's Construction
Initial Proposed Constructions (Markman Briefs)		
"correlating the presence and quantification of the precipitate(s) at the discrete region(s) with the identification and/or quantification of said target compound"	associating a species of capture molecule with the presence of precipitate(s) in one or more discrete regions of the test array and performing mathematical comparison(s) of the value(s) determined by the quantification of precipitate(s) in the aforementioned discrete region(s) to one or more reference(s) or standard(s) to determine if the target compound is present and/or to determine the amount of target	correlating both the presence and specific amount of the metallic precipitate(s) with the presence and/or amount of target compound using a standard concentration curve that plots the specific amount of metallic precipitate versus the amount of "target compound"
Alternate Propos	ed Constructions (Supplemental	Markman Letter
	associating a species of capture molecule with the presence of precipitate(s) in one or more discrete regions of the test array and comparing the quantification of the precipitate(s) with the identification and/or quantification of the target compound	associating the presence and specific amount of the precipitate in one or more discrete regions of the test array with the identification and/or quantification of the target compound

Discrete Region(s) with the Identification and/or Quantification of Said Target Compound"⁴

Claims 1 and 31 include in their description of the '829 Patent's method, "correlating the presence and quantification" of the precipitate(s) at the "discrete region(s) with the identification and/or the quantification" of the "target compound." '829 Patent, col. 11, ll. 59–62; col. 14, ll. 25–27. Eppendorf's initial proposed construction described "performing mathematical comparison(s)" determined by "one or more reference(s) or standard(s)" to determine the "amount of target compound in the sample." Nanosphere, however, initially defined the disputed claim term as involving the use of a "standard concentration curve."

⁴This is the sole disputed claim term for which the parties were not "amenable" to the Court's tentative construction, and for which they subsequently submitted alternative constructions. (See Supp. Markman Letter 1–2.)

The Court has determined that both initial constructions improperly seek to "give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," <u>PPG Indus.</u>, 156 F.3d at 1355, and are also overly wordy and cumbersome. The patent does not use the words "mathematical comparison(s)," but the specification does explain that quantification "allow[s] a statistical comparative analysis" to be performed," '829 Patent, col. 8, 11. 29–30, and that "[u]nexpectedly . . . a concentration curve could be obtained" for a gold–labelled nucleotide sequence, <u>id.</u> col. 5, 11. 8–11. Similar to preferred embodiments, <u>see Phillips</u>, 415 F.3d at 1323, a permissive measurement should not be used be restrict, or impose an unintended limitation upon, the construction of a disputed claim term.

As between the parties' alternative proposed constructions, the Court finds Eppendorf's to be more comprehensible and supported by the intrinsic evidence. Eppendorf's alternative proposal explains not only that the precipitate is associated with the target compound, but that "a species of capture molecule" is associated with "precipitate(s)," which in turn is compared with the target compound. Such a definition is helpful at explaining the relationships among the capture molecule, precipitate, and target compound, because the method described by the '829 Patent involves "putting into contact the target compound with a capture molecule," and a "reaction leading to a precipitate formed at the location of the binding," '829 Patent Abstract, without clarifying how the precipitate relates to the binding between the target compound and the capture molecule. Accordingly, the Court has adopted Eppendorf's straightforward alternate proposed construction.

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E. "Colloidal Gold Particles Coupled to the Bound Target Compound"

<u> </u>	Eppendorf's Construction	Nanosphere's Construction
"colloidal gold particles coupled to the bound target compound"	one or more gold nanoparticles directly or indirectly linked to the target compound bound to the capture molecule	colloidal gold particles directly attached by a chemical bond to a bound "target compound"

Claim 4 of the '829 Patent describes the method of identifying and quantifying a target compound as involving the chemical reduction of silver in the presence of "colloidal gold particles coupled to the bound target compound." '829 Patent, col. 12, ll. 3–4. The Court has determined that Eppendorf's proposed language is consistent with the intrinsic evidence, and is the appropriate construction.

First of all, the parties have agreed that "colloidal gold particles" means "gold nanoparticles or 'nanogold." (Supp. Markman Letter, App'x at 1.) As for the "coupl[ing]" of those particles to the target compound, the "preferred embodiment" of the '829 Patent illustrates that this can be accomplished either directly or indirectly:

Direct labelling of the target molecules with gold is possible by using gold-labelled antigens, antibodies or nucleotides.

An alternative is to avoid any labelling of the target molecule, and then a second nucleotide sequence is used which is labelled. They then formed a sandwich hybridisation or a sandwich reaction with the capture molecule fixing the target and the labelled nucleotide sequence . . .

<u>Id.</u> at col. 4, II. 55–63. Because the specification provides examples in which colloidal gold particles can be "coupled to the bound target compound" directly or indirectly, restrictively construing "coupled" to include only "directly attached," "the term 'coupled to' is entitled a broader scope" which encompasses indirect linking. <u>Bradford Co. v. Conteyor N. Am., Inc., 603</u> F.3d 1262, 1271 (Fed. Cir. 2010); <u>see also id.</u> at 1270–71 (construing "coupled to" to allow for both direct and indirect attachments in a collapsible shipping containers patent, because the claim

terms provided examples of indirect attachments).

Turning next to "bound target molecule," Nanosphere again repeats the words themselves in its proposed construction, without explaining what "bound target molecule" means. Eppendorf's definition, in contrast, provides context for the words, by providing that a "bound target molecule" is "the target compound bound to the capture molecule." This definition is consistent with the "Summary of the Invention" section of the specification, and claim 1, which explain that the method described in the '829 Patent "put[s] into contact the target compound with a capture molecule in order to allow a specific binding between said target compound with a (corresponding) capture molecule," '829 Patent, col. 2, II. 44–48; col. 11, II. 47–49; <u>see also id.</u> col. 12, II. 5–7, 9–11, & 13–15 (describing the "binding between the target compound and its corresponding capture molecule"). Thus, Eppendorf's construction of "colloidal gold particles coupled to the bound target compound" has been adopted.

Claim Term	Eppendorf's Construction	Nanosphere's Construction
"wherein the possible presence	determining the presence of a	[No need to construe "possible
and quantification of a	precipitate and quantifying a	presence and quantification of a
precipitate is obtained by	precipitate using light that is	precipitate"]
reflection, absorption or	reflected, absorbed or	
diffusion of a light beam upon	diffused/scattered by the	
said precipitate"	precipitates on the array	
"reflection of a light beam	[None provided]	using a beam of light which
upon said precipitate"		leaves a precipitate at the same
		as the angle as it strikes the
		precipitate
"absorption of a light beam		attenuation of a beam of light
upon said precipitate"		passing through a substance
"diffusion of a light beam		reflection of light by a rough
upon said precipitate"		reflecting surface, multiple
		scattering of a photons entering
		a substance, or the transmission
		of light through a translucent
		material

F. "The Possible Presence and Quantification of a Precipitate Is Obtained by Reflection, Absorption or Diffusion of a Light Beam upon Said Precipitate"

In the '829 Patent, Claim 8 then describes the invention as follows: "wherein the possible presence and quantification of a precipitate is obtained by reflection, absorption or diffusion of a light beam upon said precipitate." '829 Patent, col. 12, ll. 17–20. Nanosphere contends that "the possible presence and quantification of a precipitate" has already been defined, and need not be redefined, and then provides very detailed definitions for "reflection," "absorption," and "diffusion" of a "light beam upon said precipitate." (Def.'s Opening 22–23.)

The Court has concluded that Eppendorf's proposed construction is consistent with the intrinsic evidence, and appropriately defines the disputed claim term. Although "possible presence and quantification of a precipitate" has already been construed, the Court declines to construe only the remainder of the disputed claim term, because providing a construction of the full claim term will help a jury understand the relationship between the precipitate quantification process and the use of the light beam. As for "reflection," "aborption," and "diffusion," these words need not be separately defined because they are scientific terms with commonly accepted meanings that lay persons understand and that the parties do not greatly dispute.

G. "Binding of Said Target Compound to ... Capture Molecules Leads to a Catalytic Reduction of a Metal Present in Solution, and a Formation of a Metallic Precipitate"

Claim Term	Eppendorf's Construction	Nanosphare's Construction
"wherein binding of said target compound to one or more of said multiple species of capture molecules leads to a catalytic reduction of a metal present in solution, and a formation of a metallic precipitate in one or more of said discrete region(s)"	the binding of the target compound to one or more species of capture moleculc(s) is a necessary condition for the formation of a metallic precipitate, which is formed by the catalytic reduction of a metal present in solution, in one or more of said discrete regions containing these capture molecules	binding of the target compound to one or more of the species of capture molecules results in a catalytic reduction of a metal present in solution and formation of a "metallic precipitate" in one or more of the "discrete regions"

Claim 16 of the '829 Patent explains that the diagnostic and/or quantification apparatus that the invention can be described as follows: "wherein binding of said target compound to one or more of said multiple species of capture molecules leads to a catalytic reduction of a metal present in solution, and a formation of a metallic precipitate in one or more of said discrete region(s)." '829 Patent, col. 12, ll. 62–67. The parties offer similar proposed constructions, but dispute whether by stating that the binding of the target compound and capture molecules "leads to" a catalytic reduction of metal and formation of precipitate, the disputed claim term provides that the initial binding "is a necessary condition for" forming the precipitate, which is formed by the catalytic reduction, as Eppendorf asserts, or whether the initial binding "results in" the eatalytic reduction and precipitate formation, as Nanosphere contends.

The "Summary of the Invention" section of the specification teaches that the initial binding of the target compound to the capture molecule(s) <u>results in</u> the formation of metallic precipitate:

[1]he present invention is related to a method for identification and/or quantification of at least one target compound present in a biological sample by its binding upon a capture molecule fixed upon arrays of a solid support . . . , the binding of said target compound its corresponding capture molecule <u>resulting in</u> the formation of a metal precipitate at the location of said capture molecule.

Id. col. 2, 11. 35–42 (emphasis added). This understanding is supported further by the common understanding of the verb "to lead" as "to tend toward or to have a result." Merriam- Webster Collegiate Dictionary 659 (10th ed. 1995). Accordingly, the Court has construed the disputed claim term to mean "binding of the target compound to one or more of the species of capture molecules results in a catalytic reduction of a metal present in solution and formation of a metallic precipitate in one or more of the discrete regions."

<u>Claim</u> Term	Eppendorf's Construction	Nanosphere's Construction
"wherein said computer is programmed to detect and/or quantitate said target compounds"	performing mathematical comparison(s) of the quantity of precipitate associated with the discrete region(s) to one or more references or standards to detect (e.g., determine if the target is present) and/or quantify (e.g., determine the concentration of target in the sample	detect and determine the specific amount of the target compounds

H.	"Said Computer is Programmed to Detect and/o	or Quantitate Said Target Target
	Compounds"	0 0

Claim 30 describes the invention's apparatus as follows: "wherein said computer is programmed to detect and/or quantitate said target compounds." '829 Patent, col. 14, ll. 18-20. The parties agree that "detect and/or quantitate" means to detect and determine the amount of target compounds; however, Eppendorf also seeks to add that language specifying that the computer apparatus "perform[s] mathematical comparison(s) of the quantity of precipitate associated with the discrete region(s) to one or more references or standards." As explained above, the Court will not construe claim terms by referring generally to "references and standards," which provides no guidance to the jury as to how the patent functions. As for the language concerning mathematical comparisons, Eppendorf only relies upon extrinsic evidence, namely Eppendorf expert Dr. Steven M. Blair's declaration, for support. Neither Eppendorf nor Dr. Blair provides any intrinsic evidence indicating that the computer apparatus in fact performs mathematical comparisons in order to detect and/or quantitate the target compounds, and instead make state in conclusory fashion that the patent's claim language, specification, and prosecution history support Eppendorf's proposed definition. Accordingly, the Court has construed "wherein said computer is programmed to detect and/or quantitate said target compounds," to be "detect

and/or determine the specific amount of the target compounds."

IV. Conclusion

The Court has construed the terms in the '829 Patent consistent with the above analysis. An appropriate Order (Docket No. 92) setting forth the claim constructions has already been entered.

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BY THE COURT:

1 Au _____ Michael M. Baylson, U.S.D.J.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

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EPPENDORF AG, et al.

CIVIL ACTION

v.

NANOSPHERE INC.

NO. 09-504

<u>ORDER</u>

Following the hearing on Markman issues on June 10, 2010, and the parties' subsequent

letter to the Court dated June 17, 2010, which will be docketed, the Court concludes as follows:

1. The parties have agreed upon the following claim term definitions:

Agreed-Upon Definitions

CLAIM TERM	AGREED DEFINITION
"target compound"	a molecular species of interest obtained from a sample
"one species of capture molecules"	a type of molecule intended to selectively bind to a specific target compound
"wherein said metallic precipitate is formed on the surface of a particle associated with said target compound"	the metallic precipitate is formed on the surface of a particle with which the target compound is either directly or indirectly labelled with the particle
"solid support"	"Any kind of solid support that allow the formation of arrays of capture molecules (specific pattern) upon one or more of its surfaces. Said solid support can be made of glasses, filters, electronic device, polymeric or metallic materials, etc." "829 Patent, 2:63-67
"precipitate"	A solid or solid phase separated from a solution
"colloidal gold particles"	Gold nanoparticles or "nanogold"
"catalytic reduction"	A reduction assisted by a catalyst.
	"Reduction" is a chemical reaction in which a
	chemical species gains electrons.

2. As to disputed claim terms 1-8, the parties, either at the hearing or in the

subsequent letter will, following the Court's ruling, adhere to the Court's definition of claim

terms 1-3 and 5-8. After considering the discussion at the hearing and in the letter of June 17,

2010, the Court will adopt the alternative proposal by Plaintiffs as to claim term 4.

, 	CLAIM TERM	COURT'S RULING
1	"discrete region(s)"	finite areas that do not overlap
2	"fixed upon a solid support according to an array comprising discrete regions"	attached or linked to a surface of a solid support
3	"determining the possible presence and quantification of precipitate(s) in said discrete region(s)"	acquiring one or more spatial representation(s) of the array (i) to determine the location(s) of the discrete region(s) having precipitate(s), and (ii) to determine one or more values related to the amount of precipitate(s) in the discrete region(s)
4	"correlating the presence and quantification of the precipitate(s) at the discrete region(s) with the identification and/or quantification of said target compound"	Associating a species of capture molecule with the presence of precipitate(s) in one or more discrete regions of the test array and comparing the quantifications of the precipitate(s) with the identification and/or quantification of the target compound
5	"colloidal gold particles coupled to the bound target compound"	one or more gold nanoparticles directly or indirectly linked to the target compound bound to the capture molecule
6	"wherein the possible presence and quantification of a precipitate is obtained by reflection, absorption or diffusion of a light beam upon said precipitate"	determining the presence of a precipitate and quantifying a precipitate using light that is reflected, absorbed or diffused/scattered by the precipitates on the array

Disputed Definitions

	CLAIM TERM	COURT'S RULING
7	"wherein binding of said target compound to one or more of said multiple species of capture molecules leads to a catalytic reduction of a metal present in solution, and a formation of a metallic precipitate in one or more of said discrete region(s);"	Binding of a target compound to one or more of the species of capture molecules results in a catalytic reduction of a metal present in solution and formation of a metallic precipitate in one or more of the discrete regions
8	"wherein said computer is programmed to detect and/or quantitate said target compounds"	Detect and/or determine the specific amount of the target compounds

3. The Court will issue a summary Memorandum shortly; however, the parties may

proceed with the balance of the Pretrial Order based on this Order on claim construction.

6/18/10 Date: _

BY THE COURT

Michael M. Beylson, U.S.D.J.

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