IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GE HEALTHCARE UK LIMITED, Plaintiff/Counterdefendant, v. BECKMAN COULTER, INC. AND BECKMAN COULTER GENOMICS, INC., Defendants/Counterclaimants.	§ § § § § § § § § § §	C.A. No. 09-974-RK **JURY TRIAL DEMANDED**

GE'S OPENING CLAIM CONSTRUCTION BRIEF

OF COUNSEL:
Nicholas Groombridge
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153-0119
(212) 310-8242

David J. Ball, Jr.
Azra Hadzimehmedovic
Rachelle H. Thompson
Annaka Nava
WEIL, GOTSHAL & MANGES LLP
1300 Eye Street, NW, Suite 900
Washington, DC 20005
(202) 682-7000

Frederick L. Cottrell, III (#2555)
Anne Shea Gaza (#4093)
Stephen M. Ferguson (#5167)
Richards, Layton & Finger
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700
cottrell@rlf.com
gaza@rlf.com
ferguson@rlf.com
Attorneys for Plaintiffs

Dated: August 6, 2010

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS 1

II. SUMMARY OF ARGUMENT AND GOVERNING LEGAL PRINCIPLES 1

III. STATEMENT OF FACTS 2

IV. ARGUMENT 5

A. "Beads Which Do Not Specifically Bind The Nucleic Acid" ('231 Patent, Claim 1; '946 Patent, Claim 1) 5

1. GE's Proposed Construction Provides The Ordinary Meaning Of "Specific Binding" In Nontechnical Terms 6

2. Beckman's Proposed Construction Reads "Specifically" Out Of The Claims And Is Inconsistent With The Intrinsic Record 7

B. "Becomes Aggregated With And Entraps The Beads" ('231 Patent, Claim 1) 10

1. "Becomes Aggregated With And Entraps" Is Already Understandable To Nonscientists And Need Not Be Construed 11

2. If "Becomes Aggregated With And Entraps The Beads" Is Construed, It Should Be Given Its Ordinary Meaning Of "Clusters With And Traps The Beads" 11

3. Beckman's Attempts To Import Additional Requirements Into The Claim Should Be Rejected 12

C. "Becomes Non-Specifically Associated With The Beads" ('946 Patent, Claim 1) 13

1. GE's Proposed Construction Explains In Nontechnical Terms What It Means For Association To Be "Non-Specific" 14

2. "Becomes Non-Specifically Associated With The Beads" Is Not Indefinite 14

3. This Term Should Not Be Given The Same Construction As "Becomes Aggregated With And Entraps" 17

D. "Suspended" And "Re-Suspend The Beads" ('231 Patent, Claim 1; '946 Patent, Claim 1) 18

TABLE OF CONTENTS
(continued)

Page

V. CONCLUSION 20

TABLE OF AUTHORITIES

Page(s)

Cases

Baldwin Graphic Sys., Inc. v. Siebert, Inc.,
512 F.3d 1338 (Fed. Cir. 2008).....17

Chef America, Inc. v. Lamb-Weston, Inc.,
358 F.3d 1371 (Fed. Cir. 2004).....11

Datamize, LLC v. Plumtree Software, Inc.,
417 F.3d 1342 (Fed. Cir. 2005).....14, 15, 19

Halliburton Energy Servs., Inc. v. M-I LLC,
514 F.3d 1244 (Fed. Cir. 2008) 14, 16

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005).....1, 2

Primos, Inc. v. Hunter's Specialties, Inc.,
451 F.3d 841 (Fed. Cir. 2006).....7

Vitronics Corp. v. Conceptronic, Inc.,
90 F.3d 1576 (Fed. Cir. 1996) 2, 8

Other Authorities

Manual of Patent Examining Procedure § 1302.14 (8th ed. Rev. 9, July 2010) 15

Rules

35 U.S.C. § 112 14

I.

STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

GE Healthcare UK Limited ("GE") has sued defendants Beckman Coulter, Inc. and Beckman Coulter Genomics, Inc. ("Beckman") for willful infringement of U.S. Patents Nos. 5,523,231 ("the '231 patent") and 5,681,946 ("the '946 patent").[1] The '231 and '946 patents issued in 1996 and 1997, respectively. GE offered to provide Beckman with a license to the patents. Beckman refused and instead sought two successive reexaminations of each patent on the ground that they were allegedly invalid. The Patent Office consistently rejected Beckman's arguments and confirmed the patentability of the '231 and '946 patent claims. GE subsequently filed this lawsuit.

The claim construction hearing is scheduled for September 8, 2010.

II.

SUMMARY OF ARGUMENT AND GOVERNING LEGAL PRINCIPLES

1. The leading decision on claim construction is *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). *Phillips* explains that the purpose of claim construction is to determine how the claim terms would have been understood by a person of ordinary skill at the time when the original patent application leading to the patents at issue was filed – which in this case was in 1990. *Id*. at 1313.

2. The primary resource in construing the claims is the intrinsic record, consisting of the patent itself and its prosecution history. *Phillips*, 415 F.3d at

[1] The '231 and '946 Patents are attached as Exhibits 1 and 2 to the Declaration of Rachelle Thompson being filed contemporaneously with this brief. All citations to "Exh. ___" in this brief refer to the Exhibits to the Thompson Declaration. The '231 and '946 Patents are related and have a common specification with only minor and immaterial differences. When this brief refers to the specification, it provides column and line numbers for the '231 Patent. Corresponding citations to the '946 Patent may be found in GE's portion of the Joint Claim Construction Statement.

1317. The specification is the "single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). But it is improper to import limitations into the claims from examples in the specification. *See Phillips*, 415 F.3d at 1323 ("although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments").

3. Extrinsic evidence such as dictionary definitions and expert and inventor testimony may also be considered during claim construction, but it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (citation omitted). Extrinsic evidence may not be used to contradict the intrinsic record. *Vitronics*, 90 F.3d at 1584.

4. There are five disputed terms in this case. GE's proposed constructions convey their meanings in nontechnical terms. Beckman's proposed constructions, by contrast, seek to import limitations into the claims and are inconsistent with the intrinsic record.

III.

STATEMENT OF FACTS

The '231 and '946 Patents claim methods that can be used to isolate nucleic acids. Nucleic acids such as DNA are the genetic material contained in all living organisms. Kool Decl. ¶ 14.[2] It is desirable to have a way to separate nucleic acids from other compounds in a solution so that they can be used in a purified form. This can be done by "precipitating" the nucleic acids out of the solution while leaving behind the

[2] The declaration of Dr. Eric T. Kool, Ph.D. is being filed contemporaneously herewith. Dr. Kool is a Professor of Chemistry at Stanford University and GE's expert.

other compounds. The precipitated nucleic acids are called the "precipitate," and once they are brought to the bottom or side of the container, the remaining solution is called the "supernatant." The supernatant solution can be discarded, leaving the nucleic acid precipitate. *Id.*

Before the invention of the '231 and '946 Patents, this precipitation process required time-consuming and expensive steps like centrifugation. *E.g.*, Exh. 1, '231 Patent at 1:38-41, 4:45-57. Centrifugation techniques spin nucleic acid samples extremely rapidly to cause the nucleic acids to pellet or settle out of the solution. Kool Decl. ¶ 15. The spinning process takes time, and centrifuge instruments can handle only a limited number of samples at a time. *Id.*

Dr. Reeve invented a better way to isolate nucleic acids through precipitation using magnetic beads. Kool Decl. ¶¶ 14, 26. Dr. Reeve discovered that when nucleic acids are precipitated out of a solution in the presence of suspended magnetic beads, the nucleic acid precipitate "becomes aggregated with and entraps the beads" as stated in claim 1 of the '231 Patent, and "becomes non-specifically associated with the beads" as stated in claim 1 of the '946 Patent. Exh. 1, '231 Patent at 12:25-28; Exh. 2, '946 Patent at 12:24-27. As a result, using a magnet not only pulls down the magnetic beads, but also pulls down the nucleic acids clustered with them, and does so more quickly than centrifugation and in a way that is better suited to automation. Exh. 1, '231 Patent at 4:49-57; Kool Decl. ¶ 26.

The claim terms to be construed appear in claim 1 of the '231 Patent and claim 1 of the '946 Patent. Claim 1 of the '231 Patent provides:

> 1. A method of making a product solution containing a nucleic acid by treating a starting solution containing the nucleic acid by the use of

> *suspended* magnetically attractable *beads which do not specifically bind the nucleic acid*, comprising the steps of:
>
> precipitating the nucleic acid out of the starting solution in the presence of the *suspended* magnetically attractable beads whereby a nucleic acid precipitate *becomes aggregated with and entraps the beads*,
>
> applying a magnetic field to draw down the precipitate of the nucleic acid and the entrapped beads and to form a first supernatant liquid,
>
> separating the precipitate and the entrapped beads from the first supernatant liquid,
>
> adding a liquid to the precipitate and the entrapped beads to re-dissolve the nucleic acid and *re-suspend the beads*,
>
> applying a magnetic field to draw down the beads and to form a second supernatant liquid, and
>
> separating from the beads the second supernatant liquid as said product solution containing the nucleic acid.

Exh. 1, '231 Patent at 12:20-41 (emphasis added to show disputed terms). Claim 1 of the '946 Patent is similar, but the first step in that claim provides: "precipitating the nucleic acid out of the starting solution in the presence of the suspended magnetically attractable beads whereby a nucleic acid precipitate *becomes non-specifically associated with the beads*." Exh. 2, '946 Patent at 12:19-40 (emphasis added to show disputed term).

The invention of the '231 and '946 Patents is important. For example, there are many instances where having inexpensive and rapid automated purification of not just one but many biological samples is invaluable. Kool Decl. ¶ 16. This was important to the Human Genome Project that mapped human DNA, and it remains important today for research into the genetic causes of diseases, genetic engineering, and other applications. *Id.* ¶¶ 16-20. Twenty years after the Reeve invention, isolation of

nucleic acids using magnetic beads and precipitation is still one of the best methods for automated purification of nucleic acids. *Id.* ¶ 21.

IV.

ARGUMENT

A. "Beads Which Do Not Specifically Bind The Nucleic Acid" ('231 Patent, Claim 1; '946 Patent, Claim 1)

Term	GE's Construction	Beckman's Construction
"beads which do not specifically bind the nucleic acid"[3]	Beads that do not attach to the nucleic acid in a way that is governed by the particular structure of that particular nucleic acid	Particles that are inert or do not have an affinity for nucleic acids

This term distinguishes the claimed invention from methods using magnetic beads that "specifically" bind nucleic acids. As explained below, "specific binding" is a term that is well-understood by persons of ordinary skill in the art to mean binding governed by the particular structure of the particular substance involved, and is used in this fashion in the '231 and '946 Patents. GE's proposed construction conveys this ordinary meaning in more jury-friendly nontechnical terms.

Beckman's proposed construction uses words like "inert" and "affinity" that will have to be explained to the jury if they are adopted. Beckman's proposed construction also is not accurate, because it improperly suggests that the beads do not bind at all. The claims do not say the beads "do not bind"; the claims say the beads do not "specifically" bind. Beckman's proposal would read "specifically" out of the claims.

[3] This claim term appears in the preamble, which the parties agree is limiting.

1. GE's Proposed Construction Provides The Ordinary Meaning Of "Specific Binding" In Nontechnical Terms

The term "specific binding" was well known in biochemistry and molecular biology when Dr. Reeve filed his first patent application in 1990. Specific binding refers to binding that is governed by the particular structure of the particular substances being bound. Kool Decl. ¶ 32. Likewise, non-specific binding refers to binding that is ***not*** governed by that particular structure. *Id*. An example of specific binding is binding between a compound called "EcoRI" and DNA. *Id.* ¶ 37. EcoRI binds only to DNA having a particular structure. *See id.* An example of non-specific binding is the binding between single stranded binding proteins ("SSB") and single stranded DNA. SSBs do not need a particular structure in the DNA to bind to it. *Id.* ¶ 42.

This distinction between specific and non-specific is confirmed by the patents Beckman relies upon to support its invalidity and noninfringement contentions:

- The Vorpahl patent, which was filed in 1989 and which Beckman argues is prior art, defines specific binding as "the specific recognition of one of two different molecules for the other to the exclusion of other molecules," and non-specific binding as "relatively independent of specific surface structures." Exh. 3, U.S. Patent No. 5,279,936 ("Vorpahl") at 14:15-33.

- The Hawkins patent, which is not prior art but which Beckman asserts describes and covers the method used in Beckman's accused products and services, defines "non-specific DNA binding" as "binding of different DNA molecules with approximately the same affinity to magnetic microparticles despite differences in the nucleic acid sequence or size of the different DNA molecules." Exh. 4, U.S. Patent No. 5,705,628 ("Hawkins") at 4:18-21.

The '231 and '946 Patents use "specific binding" in its ordinary sense. The patents teach that the absence of specific binding to a particular substance distinguishes the claimed invention from prior art:

> It is a feature of the invention that the magnetic beads *do not specifically bind* the polymer. By this feature, the

> present invention *is distinguished* from many prior art techniques which involve providing a coating on the surface of magnetic beads designed to *specifically bind* the substance to be drawn down out of solution.

Exh. 1, '231 Patent at 3:27-32 (emphasis added). Echoing this, the Patent Examiner stated that the '231 Patent should be issued because "[t]he magnetic particles of the present invention do not specifically associate with the precipitated biopolymer by antibody/antigen attachment or by any covalent bonding, as in the prior art." Exh. 5, Notice of Allowance at 2 (Oct. 2, 1995). The examples the Examiner provided – antibody/antigen and covalent bonding – are the same examples of specific binding that are listed in the Vorpahl patent that Beckman cites. Exh. 3, Vorpahl Patent at 14:15-33.

The remaining question is the construction of "bind." A person of ordinary skill would have understood "bind" and "attach" to be synonymous in this context. Kool Decl. ¶ 44. When substances, like the beads and nucleic acids disclosed in the patents, bind each other, they function as one unit attached to each other. *Id.*

2. Beckman's Proposed Construction Reads "Specifically" Out Of The Claims And Is Inconsistent With The Intrinsic Record

a. The Term "Specifically" Is Important

Every word in a patent claim is presumed to be important and given meaning wherever possible in claim construction. *See Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 848 (Fed. Cir. 2006). "Specifically" is particularly important. The use of beads that do not "specifically" bind is a feature by which the invention "is distinguished from many prior techniques." Exh. 1, '231 Patent at 3:27-35. The Abstract states that the patent describes "[a] method of recovering a biopolymer from solution [that] involves the use of magnetically attractable beads which do not specifically bind the polymer." The '231 Patent is even titled "Method to Isolate

Macromolecules Using Magnetically Attractable Beads Which Do Not Specifically Bind The Macromolecules."[4]

b. "Do Not Specifically Bind" Does Not Mean No Binding At All

As explained above, there is a particular type of chemical interaction called non-specific binding. The '231 and '946 Patents recognize that non-specific binding occurs, stating that the nucleic acid precipitate "becomes non-specifically associated with the beads." Exh. 1, '231 Patent at Abstract, 2:47, 3:32-38. Moreover, when the patents want to say there is no association at all, they do so expressly. The common specification states that "when in solution, the polymer does not become associated with the beads," but once precipitated, the polymer "becomes non-specifically associated with the beads." Exh. 1, '231 Patent at 3:32-38.

Beckman offers extrinsic evidence to support a "no binding at all" requirement, but extrinsic evidence cannot be used to contradict the intrinsic record. *See, e.g., Vitronics*, 90 F.3d at 1584. And the extrinsic evidence does not support Beckman's position. Beckman's cited Vorpahl and Hawkins Patents, discussed above, show that non-specific binding is actual binding. Exh. 3, Vorpahl Patent at 14:23-33; Exh. 4, Hawkins Patent at 1:24-28. The product literature Beckman cites, for a commercial embodiment of the '231 and '946 Patents called "FMP" or Fast Magnetic Purification, also does not exclude binding. While the literature states that FMP magnetic beads "do

[4] The prosecution history further confirms the importance of "specifically." The statement of Reasons For Allowance for the '231 Patent discusses the lack of "anything on their [the magnetic beads'] surface designed to specifically bind." The Reexamination Patent Examiner likewise stated that this claim term "requires that the magnetically attractable beads do not have anything on their surface designed to specifically bind." Exh. 6, Office Action at 5 (Nov. 7, 2008).

not interact or bind," the same paragraph states that "they are pretreated to reduce" – not eliminate – "permanent binding"; and that they "have been specifically designed to ensure minimum" – not zero – "non-specific binding." Exh. 7, L. Eccleston et al., *A Magnetic Attraction*, 41 LAB PRACT., 1992 at 9, 10. Even this FMP example, which is an embodiment and not the entire invention, did not rule out any binding at all.

c. Beckman's Proposed Construction, If Adopted, Would Confuse The Jury By Suggesting A Complete Absence Of Binding Is Required

Beckman proposes to construe "beads which do not specifically bind the nucleic acid" as particles that are inert or do not have an affinity for nucleic acids. This is inconsistent with the claimed invention. "Inert" implies "chemically inactive," with no interaction at all. Kool Decl. ¶ 46. "Do not have an affinity" implies lacking any tendency to bind. Kool Decl. ¶ 51.

Beckman's proposal is inconsistent with the intrinsic record, which does not use the word "affinity." As for "inert," the specification states that one type of magnetic beads that might be used are "completely encapsulated in inert polymer." Exh. 1, '231 Patent at 3:2-5. But it also teaches that "the organic polymer may be omitted." *Id.* at 2:58. The specification also teaches that the beads may also be coated with phosphate groups, *id.*, which are chemically active and non-inert. Kool Decl. ¶¶ 50, 52.[5] Beckman's proposal would improperly exclude this preferred embodiment from being covered by the claims.

[5] Although during prosecution of the '231 Patent, the applicant discussed "inert non-binding magnetic particles," the applicant also stressed that "the method of the present invention" includes "the separate step of precipitating the polymer out of solution, whereby it becomes non-specifically associated with the beads." Exh. 8, Response To Office Action at 6, 8 (Oct. 20, 1993). This, like the specification, shows that the applicant did not intend to require that the beads be capable of no binding at all.

d. Beckman's Proposed Construction Substitutes "Particles" For "Beads"

Beckman's proposed construction of "beads which do not specifically bind the nucleic acid" refers to "particles" instead of "beads." GE has no objection, but the term "beads" appears several places in the claims, and if it is going to be replaced with "particles" in one of those places, it needs to be replaced in them all.

B. "Becomes Aggregated With And Entraps The Beads" ('231 Patent, Claim 1)

Term	GE's Construction	Beckman's Construction
"becomes aggregated with and entraps the beads"	Clusters with and traps the beads *GE believes this term need not be construed, but should the Court determine that construction is required, GE proposes the construction stated above.*	Clusters together and surrounds the beads such that the beads are passively enmeshed in the precipitate

The words in this claim term are used in the '231 Patent with their ordinary meaning, which is understandable to nonscientists as stated and does not need to be construed. If it is construed, the parties agree that "becomes aggregated" can be construed as "clusters." However, the parties disagree regarding the word "entraps." Beckman's proposal would go beyond the concept of trapping to read three additional unnecessary limitations into the claim: (1) not just trapping, but "surround[ing]" the beads; (2) doing so in a way that requires the beads to be "enmeshed in the precipitate"; and (3) requiring that any such enmeshment be "passive[ ]." Each of these additional limitations is inconsistent with the intrinsic evidence and should be rejected.

1. "Becomes Aggregated With And Entraps" Is Already Understandable To Nonscientists And Need Not Be Construed

Ordinary words do not require construction when their meaning is plain. *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372 (Fed. Cir. 2004). The two operative words here are "aggregated" and "entraps." "Aggregated" is a word that is used in the same way by scientists and non-scientists alike. Kool Decl. ¶¶ 54-55. The technical dictionaries cited by both sides rely on the ordinary meaning of "aggregate." *Id.* "Entraps" likewise would be understood by a person of ordinary skill in the art and the layperson juror as having its usual everyday meaning. Kool Decl. ¶ 56. There is nothing in the '231 specification to suggest that any special meaning was intended when the terms "aggregated" and "entraps" were used. *Id.*[6]

2. If "Becomes Aggregated With And Entraps The Beads" Is Construed, It Should Be Given Its Ordinary Meaning Of "Clusters With And Traps The Beads"

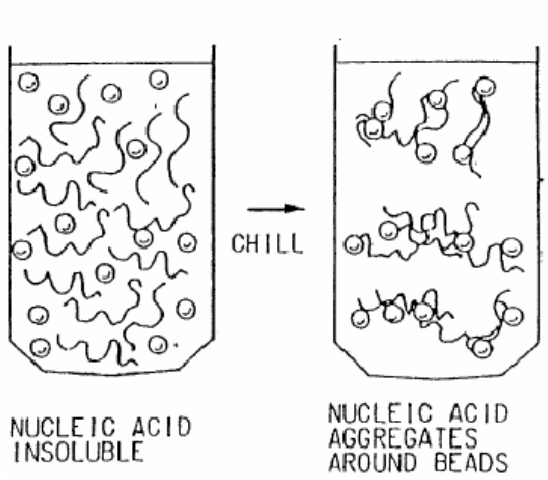
The parties agree that "aggregated with" can be construed as "clusters." The disputed term is "entraps," but here again, Beckman does not appear to seriously dispute that this term should be understood in its ordinary sense of trapping the beads. Beckman offers no intrinsic evidence to suggest that "entraps" means something different from "traps," and even Beckman's extrinsic evidence agrees that the term has this meaning. Beckman cites a technical paper from 1992 which discusses the International Patent Application that preceded the '231 patent. Exh. 9, Alderton, *Magnetic Bead Purification of M13 DNA Sequencing Templates*, 201 ANAL. BIOCHEM, 166, 166 (1992).

[6] Beckman's proposal to construe "entraps" is also inconsistent with Beckman's treatment of variants of that term elsewhere in the same claim. Claim 1 of the '231 Patent refers to "entrapped beads" three times. Exh. 1, '231 Patent at 12:30-35. But Beckman does not seek to construe "entrapped beads," reflecting that entrapment is a familiar and understandable concept that does not require explanation to the jury.

It states: "the principle of our approach" in the application "consists of trapping magnetic beads within the specifically induced aggregation of any particle or molecule of interest and thereby making it applicable to selective, magnetic separation." *Id*.

3. Beckman's Attempts To Import Additional Requirements Into The Claim Should Be Rejected

Beckman seeks to import a requirement that the precipitated nucleic acid "surrounds" the beads. The intrinsic record does not refer to "surrounding" the beads. The specification only states that the precipitated nucleic acid aggregates "around" the beads. *See, e.g.*, Exh. 1, '231 Patent, Figure 1a. Figure 1a shows that in that preferred embodiment, the beads are entrapped without being surrounded:



The drawing on the right, labeled "Nucleic Acid Aggregates Around Beads," shows the nucleic acids, represented by squiggly lines, and the beads represented by circles. The nucleic acids do not surround the beads by completely encircling them on all sides.[7] A

[7] The word "surrounds" has connotations of complete encirclement on all sides of the beads. *See* Exh. 10, *Webster's Third New Int'l Dictionary* (Philip B. Gove ed., Merriam-Webster Inc. 1986) (defining "surround" as "2: to be situated or found around, about, or in a ring around: as . . . f: to form a ring around: extend around or about the edge of: constitute a curving or circular boundary for: lie adjacent to all around or in most directions: ENCIRCLE"; and "3: to cause to be encompassed, encircled, or enclosed with something"); *see also* Kool Decl. ¶ 60.

person of ordinary skill in the art would not interpret this figure to mean that the nucleic acids must fully encircle or surround the beads. Kool Decl. ¶ 60.

Second, Beckman's proposal to add "enmeshed in the precipitate" to the construction is also flawed. While "enmeshed" is not a technical term, it also is not a word often used by the typical juror. Beckman provides no guidance on what it intends by the use of "enmeshed" in the context of this claim language, and including the term would threaten to require the Court to engage in a construction within a construction analysis to simplify it for the factfinder. If Beckman's intent with "enmeshed" is merely to convey the concept of entrapment, there is a simpler word that does the job with less potential for jury confusion: "traps." If Beckman's intent is to require something more than entrapment, then it presents the same problem as the proposed addition of "surrounds": it would require more than the claim provides. *See* Kool Decl. ¶ 61.

Third, Beckman seeks to import a requirement that the beads be "passively" enmeshed in the nucleic acid precipitate. The word "passively" and its variants do not appear in the intrinsic record. And like the term "inert," discussed above, "passively" has connotations of an absence of interactions between the nucleic acid and magnetic beads. Kool Decl. ¶ 62. The claimed invention includes no such requirement.

C. "Becomes Non-Specifically Associated With The Beads" ('946 Patent, Claim 1)

Term	GE's Construction	Beckman's Construction
"becomes non-specifically associated with the beads"	Interacts with the beads in a way that is not governed by the particular structure of that particular nucleic acid	1. Indefinite 2. Clusters together and surrounds the beads such that the beads are passively enmeshed in the precipitate

This is similar to the term "beads which do not specifically bind the nucleic acid" discussed in Part A. above. Thus, GE proposes a similar construction.

Beckman argues that the present claim term either is "indefinite" and therefore incapable of construction; or that it should be given the same construction that Beckman proposes for the claim term "becomes aggregated with and entraps the beads."

1. GE's Proposed Construction Explains In Nontechnical Terms What It Means For Association To Be "Non-Specific"

As explained in Part A. above, the term "non-specific" had a well-understood meaning to persons of ordinary skill in the art in 1990. A "non-specific" association is an interaction that is not governed by the particular structure of the particular substance being interacted with. Kool Decl. ¶¶ 30-43. GE's proposed construction tracks this ordinary meaning and should be adopted.

2. "Becomes Non-Specifically Associated With The Beads" Is Not Indefinite

Beckman attempts to invalidate claim 1 of the '946 patent by arguing that this claim term is "indefinite" and therefore fails the statutory requirements for patentability set forth in 35 U.S.C. § 112. To prove indefiniteness, Beckman must prove that "a person of ordinary skill in the art could not determine the bounds of the claims, *i.e.*, the claims were insolubly ambiguous." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Beckman must show by "clear and convincing evidence" – the standard to invalidate a patent – "that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Id.* at 1249-50.

"[C]laims are not indefinite merely because they present a difficult task of claim construction." *Halliburton*, 514 F.3d at 1249. Claims can be found indefinite "only if reasonable efforts at claim construction prove futile." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). "If the meaning of the

claim is discernable, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Id.* (citation omitted).

The prosecution history does not support indefiniteness. It is true that the '231 Patent Examiner recommended changes to "improve claim definiteness," and one of the changes the applicant made in response was to replace the claim term now at issue – "becomes non-specifically associated with the beads" – with the term "becomes aggregated with and entraps the beads" discussed in Part B. above. But Beckman ignores the same Examiner's statement of "Reasons for Allowance":

> The magnetic particles of the present invention do not specifically associate with the precipitated biopolymer by antibody/antigen attachment or by any covalent bonding, as in the prior art.

Exh. 5, Notice of Allowance at 2 (Oct. 2, 1995). The phrase "magnetic particles … do not specifically associate with," is the inverse of the claim term "becomes non-specifically associated with the beads." The Examiner would not have used this phrase if he thought it was indefinite, because the entire point of issuing Reasons for Allowance is to "clearly reflect, as much as is reasonably possible, the reasons why the application was allowed." Manual of Patent Examining Procedure § 1302.14 (8th ed. Rev. 9, July 2010). One week later, on September 26, 1995, the Examiner made the statement about "improv[ing] definiteness" that led the applicant to amend the claims. But the Examiner did not change his Reasons for Allowance; instead, on October 2, 1995, he issued them as written along with the rest of the Notice of Allowance package.[8] *See* Exh. 5.

[8] Moreover, a comment regarding "improv[ing] definiteness" does not mean that the claims were fatally indefinite. The '231 Examiner never entered a claim rejection on the ground that "becomes non-specifically associated with the beads" was indefinite. And

As for the ’946 patent, the ’946 Examiner allowed claim 1 to issue with the phrase “becomes non-specifically associated with the beads” intact. Beckman tries to explain this away by asserting that the applicant hoodwinked the ’946 Examiner. But the applicant had told the ’231 Examiner that the applicant was going to refile another patent application using this phrase, out of concern that “becomes aggregated with and entraps the beads” had a different scope. Exh. 11, Third Supp. Response at 7 (Sept. 27, 1995). The applicant also included specific reference to the ’231 prosecution history, including the name of the ’231 Examiner, in the application papers for the ’946 patent, giving the new Examiner notice of the ’231 Examiner’s actions. Exh. 12, Divisional-Continuation Program Application Transmittal Form, at 1-2 (Apr. 3, 1996).

The ultimate question for indefiniteness is whether a person of ordinary skill in the art would have understood what it means to “become[ ] non-specifically associated with the beads.” *See Halliburton*, 514 F.3d at 1249. The words “specifically” and “non-specifically” on which this claim term is built have a common and well-understood meaning. Kool Decl. ¶¶ 30-43, 65-66. Moreover, this meaning is shared by the Hawkins patent, which Beckman has stated covers Beckman’s own accused technology. Defs.’ Am. Answer ¶¶ 8 & 19, D.I. 54. The Hawkins patent uses “non-specific” to refer to binding in a way that is not governed by the particular structure of the particular DNA molecules involved, just as it is recognized in the art and as GE proposes.

---

the Examiner never objected to the use of this phrase in several places in the specification. *See* Exh. 1, ’231 Patent at Abstract, 2:46, 3:34-35.

See Exh. 4, Hawkins Patent at 4:18-21. Hawkins understood "non-specific," and it is not indefinite.[9]

3. This Term Should Not Be Given The Same Construction As "Becomes Aggregated With And Entraps"

Beckman further confuses the picture by arguing for identical constructions for the very different claim terms addressed here and in Part B. above, while Beckman argues for different constructions for the very similar claim terms addressed here and in Part A. above. Fidelity to the actual claim language calls for similar terms to be construed similarly. *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1346 (Fed. Cir. 2008) ("[a]n ordinarily skilled artisan would simply not construe similar terminology so differently from one usage to another."). GE does this by providing fully consistent constructions for similar terms.

The intrinsic record shows, once again, that Beckman's proposed construction should be rejected as seeking to import additional limitations into the claims. As explained in Part B. above, there is nothing in the specification or prosecution history to suggest that the beads must be "surround[ed]" or "enmeshed in the precipitate." Kool Decl. ¶¶ 59-61, 67. And there is no place for such language, which Beckman offered as an (incorrect) construction of "becomes aggregated with and entraps the beads," in the construction of the present claim term which instead refers to non-specific association. Kool Decl. ¶ 67. The word "passively" is even less appropriate here. Non-specific

[9] Beckman's arguments also are internally inconsistent. As explained in Part A. above, Beckman has proposed a construction for the related claim term "beads which do not specifically bind the nucleic acid." Beckman does not assert that the use of "specifically" in that claim term is indefinite. But if that claim term can be construed, then so can "becomes non-specifically associated with the beads."

association can involve chemical interactions or binding, Kool Decl. ¶ 68, and thus to require no binding would be incorrect.

D. "Suspended" And "Re-Suspend The Beads" ('231 Patent, Claim 1; '946 Patent, Claim 1)

Term	GE's Construction	Beckman's Construction
"suspended"	Dispersed	Thoroughly dispersed throughout the solution in the absence of a magnetic field
"re-suspend the beads"	Re-disperse the beads	Thoroughly re-disperse the magnetic beads throughout the solution in the absence of a magnetic field

Beckman has proposed that "disperse" is an acceptable construction of "suspend" and GE is willing to agree to this proposal. However, Beckman once again goes further to inject additional limitations into the claims that are inconsistent with the intrinsic evidence.

First, Beckman proposes that the beads not only be required to be dispersed, but that they must be "thoroughly" dispersed "throughout the solution." This is unnecessary. The claims use "suspended" to refer to the "suspended magnetically attractable beads" in the presence of which the nucleic acid is precipitated, and the claims use "re-suspend the beads" as part of the step of re-dissolving the precipitated nucleic acid. *E.g.*, Exh. 1, '231 Patent at 12:25-28, 35-37. None of the examples in the specification state that the beads need to be dispersed "thoroughly" or "throughout the solution" during either of these steps. For instance, Example 1 merely states to "mix" the magnetic beads into the starting solution, not to mix "thoroughly" or "throughout the solution." *Id.* at 8:65-9:3.[10]

[10] Moreover, the specification teaches that it is desirable that the inventive method be performed quickly by automation equipment. *E.g.*, Exh. 1, '231 Patent at 4:53-56. A

The specification also describes the use of beads of different sizes in terms showing that such "thorough" suspension "throughout the solution" is not required or even possible, particularly with regard to larger beads that are heavier and fall to the bottom. "[E]ven the larger beads remain in suspension at least for the duration of the precipitation step; their subsequent tendency to settle out assists the magnetic field in drawing down the precipitate." Exh. 1, '231 Patent at 2:59-64. A person of ordinary skill in the art in 1990 would have understood that such larger beads would have begun to fall to the bottom immediately upon being added to the solution. The specification's use of "suspension" to refer to this scenario shows that the suspension need not be "thorough" and "throughout the solution." Kool Decl. ¶ 75.

Second, Beckman proposes that to be "suspended," the beads must be added "in the absence of a magnetic field." But the claim term must be considered in the context of the claims as a whole. *Datamize*, 417 F.3d at 1348. And the claims as a whole show that when the applicant wanted to refer to a magnetic field, he did so expressly. In each patent, claim 1 refers twice to "applying a magnetic field." Exh. 1, '231 Patent at 12:29, 38; Exh. 2, '946 Patent at 12:28, 37. But there is no reference to a magnetic field in connection with the term "suspended" or "re-suspend the beads." If removing the magnetic field were necessary it would have been stated in the claims.[11]

---

person of ordinary skill in the art would have understood that there is a trade-off between performing the method faster and achieving more thorough suspension, with greater speed meaning less thorough mixing. Kool Decl. ¶ 75.

[11] Likewise, examples in the specification refer to performing certain other steps in the absence of a magnetic field, but when it comes to the step of re-dissolving the precipitated nucleic acid and re-suspending the beads, the examples merely state: "redissolve magnetic bead pellet in the required volume of TE buffer." *E.g.*, Exh. 1, '231 Patent at 9:9-10. Other parts of the specification refer to re-dissolving the precipitate in the absence of a magnetic field, *e.g.*, *id.* at 4:34-36, but these examples do not.

V.

CONCLUSION

For the foregoing reasons, GE's proposed constructions should be adopted.

/s/ Stephen M. Ferguson

Frederick L. Cottrell, III (#2555)
Anne Shea Gaza (#4093)
Stephen M. Ferguson (#5167)
Richards, Layton & Finger
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700
cottrell@rlf.com
gaza@rlf.com
ferguson@rlf.com
Attorneys for Plaintiffs

OF COUNSEL:
Nicholas Groombridge
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153-0119
(212) 310-8242

David J. Ball, Jr.
Azra Hadzimehmedovic
Rachelle H. Thompson
Annaka Nava
WEIL, GOTSHAL & MANGES LLP
1300 Eye Street, NW, Suite 900
Washington, DC 20005
(202) 682-7000

Dated: August 6, 2010

Moreover, a person of ordinary skill would understand that some degree of suspension for some period of time can be achieved even when a magnetic field is present, depending on its strength and the force applied through vortexing, pipetting, or otherwise. Kool Decl. ¶ 77.

CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2010, I caused to be served by **hand delivery and electronic mail** copies of the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Steven J. Balick
Lauren E. Maguire
Caroline Hong
Ashby & Geddes
500 Delaware Avenue
Wilmington, DE 19801
sbalick@ashby-geddes.com
lmaguire@ashby-geddes.com
chong@ashby-geddes.com

I further certify that on August 6, 2010, I caused to be served by **electronic mail** copies of the foregoing document upon the following counsel of record:

James G. Gilliland, Jr.
Townsend and Townsend and Crew LLP
Two Embarcadero Center, 8th Floor
San Francisco, CA 9411
jggilliland@townsend.com

Susan M. Spaeth
Anne M. Rogaski
Robert J. Artuz
Townsend and Townsend and Crew LLP
379 Lytton Avenue
Palo Alto, CA 94301
smspaeth@townsend.com
amrogaski@townsend.com
rjartuz@townsend.com

/s/ Stephen M. Ferguson
Stephen M. Ferguson (#5167)
ferguson@rlf.com