United States District Court,
D. Nebraska.

STRECK, INC., a Nebraska Corporation,
Plaintiff/Counterdefendant.
v.
RESEARCH & DIAGNOSTIC SYSTEMS, INC., a Minnesota Corporation, and Techne Corporation, a Minnesota Corporation,
Defendants/Counterclaimants.

No. 8:06CV458

Nov. 12, 2008.

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MEMORANDUM OPINION

JOSEPH F. BATAILLON**, Chief District Judge.**

This matter is before the court for resolution of issues of claim construction after a hearing pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996), on June 5, 2008. FN1 This is an action for patent infringement. Streck alleges that defendants/counterclaimants R & D Research & Diagnostic Systems, Inc ., and Techne, Corp. have made, sold or offered for sale certain products, specifically, the "CBC-XE" and the "CBC-4K Plus Retics" integrated hematology control products in violation of Streck's patent rights under three of its patents: 1) United States Patent No. 6,200,500, ("the '500 patent"); 2) United States Patent No. 6,221,668 ("the '668 patent"), and 3) United States Patent No. 6,399,388 ("the '388 patent") (collectively, "the Streck patents"). Filing No. 1, Complaint, Exhibits ("Exs.") A-C. All three patents involve a "Hematology Control and System for Multi-Parameter Hematology Measurements." Id. Defendants deny infringement, assert the defense of invalidity, and counterclaim for a declaratory judgment of noninfringement and invalidity. *See* Filing No. 14, Answer and Counterclaim. The language in the dispute appears in Claims 28 and 29 of the 500 patent, Claims 1, 4, 5, 15 and 26 of the ' 668 patent, and Claim 13 of the ' 388 patent.

FN1. At the hearing, the court overruled Streck's motion to exclude certain evidence propounded by defendants, Filing No. *95*. *See* Filing No. *121,* Transcript at 56. The court has considered the evidence to the extent that it is relevant, but finds the evidence of little value to its determination.

I. Background

Streck manufactures and sells hematology control products for various hematology instruments. These control products are used to test the proficiency of hematology instruments that measure certain properties of blood. A hematology control product is a substance that mimics blood to the instrument and can be used to determine whether or not the instrument is working correctly. The three patents at issue in this case involve control compositions for use with a multi-parameter automated hematology instrument capable of analyzing the various constituents of a single sample of blood without requiring the use of a separate instrument to measure each separate constituent. FN2 The ' 668 patent is a continuation in part of the ' 500 patent and the ' 388 patent is a continuation of the ' 668 patent. The later patents claim the benefit of the filing date of the ' 500 patent, August 20, 1999. Filing No. 1, Complaint, Ex. B (the ' 668 patent), col. 1, ll. 5-13; Ex. C (the '338 patent), col. 1, ll. 5-11. In addition, several other patents are incorporated by reference into the patents at issue. FN3

FN2. As examples of such commercially available multi-parameter instruments, the '500 patent lists the Beckman-Coulter STKS or Gen S Systems, the Abbott Cell-Dyn 4000 Hematology System, Bayer ADVIA System, the Sysmex XE2100 System, or the like. Ex. A, col. 1, ll. 26-29. The patent notes that these improved automated instruments can measure one or more of: 1) reticulocytes, 2) red blood cells, 3) nucleated red blood cells, 4) platelets, 5) reticulated platelets, 6) white blood cells, including lymphocytes, monocytes, neutrophils, eosinophils, basophil and 7) white blood cells with all phenotypes. Id., col. 1, ll. 29-36.

FN3. These include U.S. Pat. No. 5,262,327 ("the '327 patent") for the diluent SUPERTRATE, U.S. Pat. No. 5,529,933 ("the "3 patent) for suspension media for alligator and avian red blood cells as analogs for white blood cells, U.S. Pat. No. 5,432,089 ("the '089 patent") for preparation of the reticulocyte component, U.S. Pat. No. 5,459,073 for fixed white blood cells for flow cytometry. *See, e.g.,* Filing No. *1,* Complaint, Ex. A (the '500 patent), col. 1, ll. 49-50; col. 4, ll. 62-64.

The Streck patents at issue are all entitled "Hematology Control and System for Multi-parameter Hematology Measurements" and the patents describe the material and process for making integrated control compositions that "comprise a reticulocyte component, a white blood cell component, a red blood cell component, a nucleated red blood cell component, a platelet component, and a reticulated platelet component" that "are particularly useful as a control for multi-parameter automated instrument systems." *See, e.g.,* Filing No. 1, Complaint, Ex. A (the'500 patent) at 1, Abstract. The control composition provides values for various constituents of blood that a multi-parameter instrument is capable of measuring. Id., column ("col.") 1, lines ("ll.") 64-66. The claims of the patents presently at issue, broadly speaking, involve a control that has a five-differential white blood cell component and a reticulocyte component.

The "background" section of the '500 patent provides that in the preferred embodiment, the control composition includes "a liquid suspension of particulates that has characteristics like whole blood" and "includes one or more blood cell components (i.e., components treated to simulate such a component as found in whole blood), or their analogs, that may or may not be fixed, stabilized, or prepared by other treatment prior to final suspension ." Id., Ex. A (the '500 patent), column 1, ll. 38-46. The "components of the control preferably are suspended in a suitable suspension medium that permits the control to be

processed through the automated instrument." Ex. A., col. 2, ll. 16-22.; col. 3, ll. 21-23; *see also* Ex. B., '668 patent, col. ll. 6-9.

The '500 patent further provides that the "blood cell components or analog materials may be derived from a source that will exhibit the size, shape or other characteristics of human, animal, or other whole blood," incorporating other patents involving these types of blood cell components or analogs. Id., col. 1, lines 46 to 53. The hematology control composition claimed in the '500 patent "comprises components for simulating reticulocyte, white blood cell, red blood cell, nucleated red blood cell, platelet or reticulated platelet constituents of whole blood." Id., col. 2, ll. 1-4. The '388 patent contemplates a control composition that has components that simulate the readouts on an instrument and "exhibit similar light scattering, conductivity, impedence, optical (including fluorescence), photometric, or other property responses detected by the instrument in operation, as would the corresponding components of whole blood." Id., Ex. C (the '388 patent), col. 2, ll. 51-60.

A. The Parties' Proposed Constructions

For purposes of this litigation, the parties have agreed to the construction of the term "component" as "an element forming a measurable part of the whole." Filing No. 87, Joint Statement, Ex. A at 2. Additionally, the parties agree that the term "control composition" should be construed as "a preparation of one or more blood components, including naturally occurring blood components, or analogs thereof, which sufficiently simulate the relevant characteristics of whole blood when measured by the hematology instrument." Id. The parties also agree that the phrase "fixed and stabilized white blood cells" means "white blood cells or analogs thereof that have been preserved to stabilize the cell morphology analyzed by the hematology instrument." Id.

Both parties request construction of the term "isotonic suspension medium." The defendants propose: "a solution containing electrolytes with a measured osmolarity equivalent to human blood." Id. at 3. Streck proposes: "a solution that permits the control to be properly processed through the automated instrument having an osmolarity sufficient to maintain the stability and size of the components in the control." Id. The defendants request that the court construe the term "corresponds substantially with that of human whole blood" to mean "the values of the components are approximately within the range of possible values for human blood." Id. Streck contends that no construction of that term is necessary, but proposes that, if construed, the phrase should mean "largely, but not necessarily wholly, agrees with the relevant characteristics of whole human blood for which the instrument tests." Id. at 3.

Defendants next request construction of the terms "reticulocyte," "reticulocyte component," "stabilized reticulocyte component," and "reticulocyte analog" (collectively referred to as "the reticulocyte terms"). The defendants propose that reticulocyte means "naturally occurring immature anucleate red blood cells containing some ribonucleic acid that are isolated from blood," whereas Streck contends that "reticulocyte" is defined in its patents and means: "immature, anucleate red blood cells containing some ribonucleic acid." Id. at 4. Defendants propose that the phrase "reticulocyte component" should be construed to mean "naturally occurring reticulocytes isolated from blood, or reticulocyte analogs made from a source other than naturally occurring reticulocytes isolated from blood." Id. Streck proposes that "reticulocyte component" should be construed to mean "a component that appears to the instrument as reticulocytes that naturally occur in the whole blood for which the instrument is intended." Id. Defendants argue that "stabilized reticulocyte component" should be construed as "naturally occurring reticulocytes isolated from blood, or reticulocyte analogs made from a source other than naturally occurring reticulocytes isolated from blood,

containing some ribonucleic acid whose measured value remains substantially constant over a useful period of time." Id. at 3. Streck proposes that "stabilized reticulocyte component" should be construed as "a component that appears to the instrument as immature, anucleate red blood cells containing a detectable amount of ribonucleic acid, and that has been treated so as to inhibit undue diminishment of its utility as a component of a hematology control." Id. Defendants propose that a "reticulocyte analog" be construed as a "reticulocyte component made from a source other than naturally occurring reticulocytes isolated from blood." Id. at 4.

Streck seeks construction of the phrase "reticulated platelet component," contending that the term should be interpreted to mean: "a component that appears to the instrument as platelet cells containing some ribonucleic acid enclosed within the membrane." Id. at 3. Defendants contend that the term means: "a platelet containing some ribonucleic acid, or an analog thereof." Id. Streck also requests that the court construe the phrase "white blood cells for cellular types," and "white blood cells for all phenotypes," both of which appear in claim 5 of the '668 patent. Id. at 4. Streck's proposed construction for "white blood cells for cellular types" is "white blood cells that simulate the relevant characteristics of two or more of the following: lymphocytes, monocytes, neutrophils, eosinophils or basophil," and for "white blood cells for all phenotypes," Streck submits "white blood cells in which antigenic sites have been preserved for a useful period of time" for "white blood cells for all phenotypes." Id. Defendants, on the other hand, contend that "white blood cells for cellular types" means "lymphocytes, monocytes, neutrophils, eosinophils and basophil" and "white blood cells for all phenotypes" means "all subtypes of white blood cells ." Id.

In support of its position, Streck submits the patents at issue and excerpts from dictionaries and scientific articles. *See* Filing Nos. *89* and *94,* Indices of Evidence. The defendants submit other dictionary definitions and declarations, exhibits and motions submitted in the *Johnson v. Ryan Interference, No. 105,522,* an interference action presently pending before the Patent Board. *See* Filing Nos. *91* and *98,* Indices of Evidence.

II. DISCUSSION

A. The Law

The claims of a patent define the scope of the patent. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (en banc). The claims of a patent are of primary importance in determining what is patentable and the function and purpose of a claim is to "delimit the right to exclude." Id. at 1312. The purpose of claim construction is to "determin[e] the meaning and scope of the patent claims asserted to be infringed." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), aff'd, 517 U.S. 370 (1996). The construction of the terms in a patent is a matter of law reserved entirely for the court. Markman, 517 U.S. at 372. A claim construction order will dictate how the court will instruct the jury regarding a claim's scope. O2 Micro Int'l Ltd. v. Beyond Innovation Technology Co., Ltd., 521 F.3d 1351, 1359 (Fed.Cir.2008). "A district court is not obligated to construe terms with ordinary meanings, lest trial courts be inundated with requests to parse the meaning of every word in the asserted claims." *Id.* However, when the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute. *Id.* at 1360. The words of a claim are generally given their ordinary and customary meaning, which is the meaning a term would have to a person of ordinary skill in the art in question at the time of the invention. Phillips, 415 F.3d at 1313. The inquiry into how a person of ordinary skill in the art understands a term provides an objective baseline for which to begin claim interpretation. *Id.* Importantly, a 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 claim appears, but in the context of the entire patent, including

the specification. *Id*. (noting that a court does not look to the ordinary meaning of the term in a vacuum; it must look at the ordinary meaning in the context of the written description and the prosecution history). Absent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis. DSW, Inc. v. Shoe Pavilion, Inc., 537 F.3d 1342, 1347 (Fed.Cir.2008).

"In some cases, the ordinary meaning of claim language ... may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314. However, in many cases, the meaning of a claim term as understood by persons of skill in the art is not readily apparent. *Id*. In cases that involve "little more than the application of the widely accepted meanings of commonly understood words," general purpose dictionaries may be helpful, but in many cases, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art and the court "must look to those sources that are available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." *Id*. at 1314. "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*. *(quoting* Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1116 (Fed.Cir.2004)).

The claims themselves provide substantial guidance as to the meaning of particular claim terms, quite apart from the written description and the prosecution history. Phillips, 415 F.3d at 1314. The context in which a term is used is highly instructive-other claims of the patent in question can also be "valuable sources of enlightenment as to the meaning of a claim term," as can differences among claims. *Id*. (also noting that the usage of term in one claim can often illuminate the meaning of the same term in other claims).

Because the claims do not stand alone, but are part of a fully integrated written instrument, the specification is usually the best guide to the meaning of a disputed term. *Id*. The specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess; in such cases, the inventor's lexicography governs. *Id*. The patent's prosecution history, if it is in evidence, should also be considered, second in importance to the patent's specification. *Id*. at 1317 (noting, however, that because it represents an ongoing negotiation, the prosecution history "often lacks the clarity of the specification and is thus less useful for claim construction purposes").

When looking at a specification in the patent, the court adheres to two axioms. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 904 (Fed.Cir.2004). "On the one hand, claims 'must be read in view of the specification, of which they are a part.' " *Id*. *(quoting* Markman, 52 F.3d at 976, aff'd, 517 U.S. 370 (1996). On the other hand, a court may not read a limitation from the specification into the claims. Innovad Inc. v. Microsoft Corp., 260 F.3d 1326, 1332 (Fed.Cir.2001) (noting that the "interpretative process forbids importing limitations from the specification into the defining language of the claims."). The distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be difficult to apply in practice. *Phillips,* 415 F.3d 1323. The purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so and "[o]ne of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case." *Id*. On reading the specification in that context, it will often become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the

claims and the embodiments in the specification to be strictly coextensive. *Id*. (noting also that "there will still remain some cases in which it will be hard to determine whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature.")

Although intrinsic evidence is preferred, courts are also authorized to rely on extrinsic evidence "which consists of all evidence external to the patent and prosecution history including expert and inventor testimony, dictionaries and learned treatises." *Id*. (noting that "extrinsic evidence is less significant than the intrinsic record in determining the 'legally operative meaning of claim language.' ").

The court is guided in its endeavor by several "canons of construction' " or guideposts. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed.Cir.2001). Under the doctrine of claim differentiation, a dependent claim has a narrower scope than the claim form which it depends and an independent claim has a broader scope than the claim that depends from it. Free Motion Fitness, Inc. v. Cybex Int'l, Inc., 423 F.3d 1343, 1351 (Fed.Cir.2005). Also, ordinarily, claims are not limited to the preferred embodiments disclosed in the specification. Phillips, 415 F.3d at 1323. Different words in a patent have different meanings and the same words have the same meaning. Innova/Pure Water, Inc., 381 F.3d at 1119-20. Use of the open-ended term of art, "comprising," allows the addition of other elements so long as the named elements, which are essential, are included. *See* Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed.Cir.1997); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271 (Fed.Cir.1986) (noting that "comprising" opens a method claim to the inclusion of additional steps, but does not affect the scope of the structure recited within the steps). If possible, claims should be construed so as to preserve the claim's validity, but that maxim is limited "to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.' " Phillips, 415 F.3d at 1327 (*quoting* Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed.Cir.2004)). When a document is "incorporated by reference" into a host document, such as a patent, the referenced document becomes effectively part of the host document as if it were explicitly contained therein. Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1329 (Fed.Cir.2001).

B. Claim Construction

The court has carefully reviewed the patents at issue and the intrinsic evidence. The court's claim construction is generally guided by the language of the claims, in the context of the other claims of the patents, the specifications, and the other patents incorporated therein. Because the intrinsic evidence of record provided a sufficient foundation for the court's claim construction, the court need not resort to extrinsic evidence. Although the court reviewed submissions in the related interference action, it found the evidence of limited value, in view of the sufficiency of the claims and specifications of the patents.

1. "Isotonic Suspension Medium"

Streck argues that "isotonic suspension medium" should be described to the jury as a solution that permits the control to be properly processed through the automated instrument having osmolarity sufficient to maintain the stability and size of the components of the control. The defendants argue that Claims 28 and 29 of the '500 patent use the term isotonic suspension medium in connection with human blood so a proper claim construction should take the human blood element into consideration. FN4 Arguing that there is nothing in the specifications of the '500 and the ' 668 patents to contradict their proposed construction, they then argue that "isotonic suspension medium" should be construed to include the osmolarity of human blood.

FN4. The defendants ignore the important distinction that the patents' cited reference to human blood is preceded by the modifying phrase "to yield a readout" that corresponds substantially with human blood. *See* Ex. A (the '500 patent), col 10, line ("l.") 36. Subparagraph (e) of claim 28 and claim 29 of the '500 Patent reads:
"an isotonic suspension medium, wherein each of said components (a)-(d) is present in sufficient amounts to be measurable with an automated hematology instrument and *to yield a readout* that corresponds substantially with that of human whole blood."

Filing No. *1*, Complaint, Ex. A, col. 10, ll. 32-37, 43-48 (emphasis added).
The court finds no support for the defendants' proposed construction. Merely because a proposed construction may not be contradicted by language in a specification does not mean that the proposed construction is proper. Importantly, the patents' specifications provide several combinations of buffers and additives as examples of possible embodiments of the suspension medium. *See* Ex. A, col. 3, ll. 23-29; Ex. B., col. 11, ll. 6-17. Among the possible embodiments of the invention, the patent provides that the isotonic suspension medium can consist of a buffer, antioxidant, protein or a mixture thereof, or, in the preferred embodiment of a suspension medium for white blood cells with a five-point differential, the '500 patent incorporates the patented diluent SUPERTRATE. Id., col. 4, ll. 12-15 (referring to U.S. Pat. No. 5,262,327 ("the 327 patent").

The court finds that no construction of the term "isotonic suspension solution" is necessary and that the meaning of the term is relatively clear in the context of the patents as a whole. It is clear from the patents' descriptions that the function of the isotonic suspension media is to maintain stability and to allow the control to be processed through the relevant hematology instrument. The patents' specifications include several examples of suspension media, each specific to the component that the designated instrument measures. Given the open, broad, and expansive meaning afforded to use of the term "comprise" in a patent's language, the court finds the defendants' proposed construction would limit the claim to a specified osmolarity, a limitation that is not supported by the claim language or the specifications.

2. "Corresponds Substantially with that of Whole Blood"

Defendants contend that in order for the measured values to "correspond substantially with that of whole blood" in the patents' claims, the values must be approximately within the range of possible values for human blood. Again, defendants ignore the modifying phrase, "yields a readout." In the context of the specifications, a readout could be either a stain or a scattergram. In order to function as a "control" for the instrument, the control should approximate the result of an actual sample. This means it would produce a readout that is similar, but not identical, to a readout produced by the actual sample. Logically, the similarity should be to the relevant characteristics of the blood constituent that the instrument tests. The relevant characteristics that the patent controls are designed to simulate are shown in readouts exhibiting test results in the form of light scatter or scattergrams, cell-population counts, conductivity, impedence, optical, photometric, or other property responses that can be detected by the instrument. There is no support for the contention that the control's values would have to match the measured values that the instrument would produce for an actual sample. Importantly, it is the operation of the machine that the control is testing, not the measured values that the instrument would produce in testing actual blood.

The court again finds it unnecessary to construe this phrase. A jury can be expected to understand that the

word "substantially" does not mean "fully" or "totally." Further explanation or elaboration would be a matter for expert testimony or argument to the jury.

3. The Reticulocyte Terms

a. "Reticulocyte"

The patents at issue provide a definition for reticulocyte. Ex. A (the '500 patent), col. 2, ll. 33-34; Ex. B (the '668 patent), col. 3, ll. 14-16; and Ex. C ('338 patent), col. 3, ll. 11-14. Streck's proposed construction matches the patents' definition. The patents all describe "reticulocytes" parenthetically as "immature anucleate red blood cells containing some ribonucleic acid." Id. Under the canons of construction, the definition provided in the patent governs.

Defendants' proposed construction would add the antecedent phrase "naturally occurring" to the patents' definition and further modify the definition to provide that the reticulocytes "are isolated from blood." Importantly, the claims of the patents make it clear that the reticulocyte component of the control composition can be either a reticulocyte or an analog of a reticulocyte. *See, e.g.,* Ex. A (the'500 patent), col. 8, l. 24. The specifications further support the use of analogs for blood cell components. *See, e.g.,* id., col. 3, ll. 41-46. The specification of the '500 patent mentions "true mammalian reticulocytes" prepared by red blood cell encapsulation or isolation from whole blood. Id., col. 2, 37-41. It also incorporates U.S. Pat. No. 5,432,089, as an example of suitable preparation of the reticulocyte component. Id., Col. 2, ll. 36-37. The '668 patent provides that "it is possible to obtain suitable reticulocytes by obtaining blood from an anemic animal (e.g., a pig, goat, rabbit or the like)." Ex. B (the '668 patent), col. 3, 23-25.

The doctrine of claim differentiation also supports the patents' definition. Claim 4 of the '668 patent is a dependent claim wherein the reticulocyte "comprises reticulocytes prepared by isolation from whole blood." Ex. B., col. 16, ll. 53-55. Under the doctrine of claim differentiation, if a dependent claim is narrower than the independent claim from which it depends, the court presumes that the limitation is not present in the independent claim. Accordingly, the court will adopt Streck's proposed construction (which is identical to the patents' definition) for the term "reticulocyte."

b. "Reticulocyte Component"

Reticulocyte is defined in the patent and the parties have agreed to the meaning of component. It should not be a difficult task for the jury to understand the meaning of the two words in combination. The court finds no separate construction is warranted.

c. "Stabilized Reticulocyte Component"

Defendants urge that the court first adopt their construction of "reticulocyte component," together with a construction of "stabilized" as a reticulocyte component "whose measured value remains substantially constant over a useful period of time." Streck proposes that the "stabilized" reticulocyte component "has been treated so as to inhibit undue diminishment of its utility as a component of a hematology control," and adds the qualifier that the component "appear to the instrument" as a reticulocyte, as defined in the patent. The claims and specifications of the patents, as well as the parties' agreed-upon definitions of "control composition" and "fixed and stabilized white blood cell component" show that the overall function of a control composition component is to "simulate" or "resemble" various blood constituents and thus to "appear to the instrument" as the blood constituent for which it substitutes.

There is only a slight semantic difference between the two proposals with respect to the reticulocyte components' usefulness or stability over time. Because the meaning of terms in a patent should align with the purpose of the patent, the court finds Streck's proposed construction is proper. In the context of the patents as a whole, the term "stabilized" means that the control composition would be useful for the purpose for which it was intended for some reasonable length of time. The defendant's proposed interpretation of this "stability" or "shelf life" factor as requiring that "a measured value [remain] substantially constant over a useful period of time" would confuse the jury. The court finds that Streck's proposed characterization of the "stability" time factor ("treated to inhibit undue diminishment of its utility") is marginally more understandable and would benefit the jury. Thus, the court will adopt Streck's proposed construction of this term.

d. "Reticulocyte Analogs"

The term reticulocyte is defined in the patents. In the patent specification, the reticulocyte component of the control can be a reticulocyte "or an analog thereof." Ex. A, '500 patent, col. 2, l. 34. Defendants submit a proposed construction that would define "analog" as a reticulocyte "made from other than naturally occurring reticulocytes isolated from blood," whereas Streck proposes "particles made from a source other than naturally occurring reticulocytes, such particles appearing to the instrument as reticulocytes that naturally occur in whole blood for which the instrument is intended."

Analog is commonly understood to mean something that is analogous to or similar to something else. *See, e.g., Webster's II New Riverside University Dictionary* 104 (1984). The jury can be expected to know the widely accepted meaning of this commonly understood word. Several examples of analogs for various blood constituents are described in the '500 patent specification, such as avian red blood cells for nucleated red blood cells, encapsulated human red blood cells for reticulocytes, stabilized human platelets or platelets simulated from goat, bovine or porcine blood cells for reticulated platelets and suitable or treated red blood cells for white blood cells. *See, e.g.,* Ex. A ('500 patent), col. 2. ll. 66-67 to col. 3, ll. 1-2; col. 8, ll. 26-29; col. 3, ll. 5-8; col. 5, ll. 60-61; col. 6, ll. 4-6; col. 6, ll. 49-51; col. 5, ll. 4-6. From the context of the patent as a whole, together with the other patents referred to and incorporated in the patents at issue, it is clear that an analog is something other than a reticulocyte that appears to the relevant instrument as a reticulocyte. An analog of any component is something that is not the component, but appears to the instrument to be the component. A commonsense interpretation of "analog" should correspond to the meaning of the term in connection with the other blood components described in the patents.

The court finds it unnecessary to provide any further interpretation of the two words in combination-one is defined in the patent and the other is commonly understood. Both of the parties' proposed constructions either read limitations into the claims or are superfluous to information that can be gleaned from the language of the claims and specifications as a whole. As noted above, that the component "appear to the instrument" as a blood constituent is apparent from the function and utility of the patented controls.

4. The White Blood Cell Terms

a. "White Blood Cells for Cellular Types"

The court finds that Streck's proposed construction of "white blood cells for cellular types" as "white blood cells that simulate the relevant characteristics of two or more of the following: lymphocytes, monocytes, neutrophils, eosinophils or basophils" is proper. The requirement of "two or more" is consistent with the

specification example that the "white blood cells for cellular types" component comprises one or more of the five white blood cell subpopulations. Use of the term "comprises" allows additional terms as long as the essential element is included. The defendants' proposed construction would add a limitation that would require all five subclasses to be represented in the white blood cell component. The patents require only that the fixed and stabilized white blood cell component be capable of exhibiting a five-part differential, not that it always exhibit a five-part differential. The defendants' proposed construction is not supported by the specifications of the patents and ignores the function of the control, which is to simulate or resemble the cells to the instrument.

The doctrine of claim differentiation supports Streck's proposed construction. Dependent claim 19 of the '668 patent is limited to a control containing all five subclasses, meaning that the independent claims are not so limited. In the context of the patents' specifications, the phrase relates to the component of the control composition that corresponds to the relevant characteristics for which the instrument is testing, which could be fewer than all five cellular types, and the component would "simulate" the characteristics exhibited by the cellular types being tested by the relevant instrument. Accordingly, the court will adopt Streck's proposed construction of this term.

b. "White Blood Cells for All Phenotypes"

Streck's proposed construction of this term is premised on the Streck's U.S. Pat. No. 5,459,073 (the '073 patent"). The '500 patent discusses the use of white blood cells that have been fixed under the disclosure of U.S. Pat. No. 5,459,073 ("the '073 patent") for use in flow cytometry for phenotyping. Ex. A (the '500 patent), col. 4, ll. 62-65. The '073 patent discloses the fixative and discusses the use of the fixative to preserve antigens present on cells. Filing No. *89,* Index of Evid, Ex. I (the '073 patent), col. 1, ll. 36-42. It describes a method for preserving the antigenic sites on cells so that they can be phenotyped. Id. at 5, Fig. 5. The court finds Streck's proposed construction is supported by the patents' specifications and would aid the jury. The result of an adoption of the defendants' proposed construction would eliminate the distinction between "white blood cells for cellular types" and "white blood cells for all phenotypes" and would violate the canons of construction.

5. "Reticulated Platelet Components"

In the context of the specification and the agreed-upon construction of terms, a "reticulated platelet component" would include actual reticulated platelets and analogs thereof. Both parties' proposed constructions agree that a reticulated platelet component could be either an actual reticulated platelet or an analog. Both parties' constructions also provide that the cell contain some ribonucleic acid ("RNA"). The only apparent points of distinction are RNA presence within the membrane of the platelet and that the component appear to the instrument as platelet cells containing RNA enclosed within the membrane. As noted above, the patents' functionality makes it clear that the component must appear to the instrument as the blood cell that it is intended to simulate. The "enclosed within the membrane" qualifier is supported by the patents' specification of an example of "reticulated platelet component" as goat red blood cells with encapsulated nucleic acids. Although the court finds little difference between the two proposed constructions, the court finds that Streck's proposal is supported by the patents' specifications and would aid the jury. Accordingly,

IT IS ORDERED that the court adopts the following claim constructions:

Control composition: a preparation of one or more blood components, including naturally occurring blood

components, or analogs thereof, which sufficiently simulate the relevant characteristics of whole blood when measured by the hematology instrument.

Component: an element forming measurable part of the whole.

A fixed and stabilized white blood cell component: White blood cells or analogs thereof that have been preserved to stabilize the cell morphology analyzed by the hematology instrument.

Reticulocyte*:* immature anucleate red blood cells containing some ribonucleic acid.

Stabilized reticulocyte *component:* a component that appears to the instrument as immature, anucleate red blood cells containing a detectable amount of ribonucleic acid, and that has been treated so as to inhibit undue diminishment of its utility as a component of a hematology control.

Reticulated platelet *component:* a component that appears to the instrument as platelet cells containing some ribonucleic acid enclosed within the membrane.

White blood cells for cellular types: white blood cells that simulate the relevant characteristics of the following: lymphocytes, monocytes, neutrophils, eosinophils or basophils.

White blood cells for all phenotypes: white blood cells in which antigenic sites have been preserved for a useful period of time.

Reticulocyte *analogs:* "particles made from a source other than naturally occurring reticulocytes, such particles appearing to the instrument as reticulocytes that naturally occur in the whole blood for which the instrument is intended"

D.Neb.,2008.
Streck, Inc. v. Research & Diagnostic Systems, Inc.

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