IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

STRECK, INC., a Nebraska Corporation, Plaintiff/ Counter-defendant, v. RESEARCH & DIAGNOSTIC SYSTEMS, INC., a Minnesota Corporation, and TECHNE CORPORATION, a Minnesota Corporation, Defendants/ Counter-claimants.	8:06CV458 MEMORANDUM OPINION

This matter is before the court on the following motions: 1) plaintiff Streck, Inc.'s ("Streck's") motion for partial summary judgment that certain claims of the patents-in-suit are not invalid under the written description requirement of 35 U.S.C. § 112, Filing No. 160; defendants Research & Diagnostic Systems, Inc., and Techne Corporation's (collectively "R&D's") motion for summary judgment seeking a declaratory judgment in its favor on the issue of willfulness and a declaration that certain claims of the patents at issue are invalid under 35 U.S.C. § 112, Filing No. 161; Streck's motion for a partial summary judgment of infringement, Filing No. 166; Streck's motion for partial summary judgment that its patents-in-suit are not invalid by reason of novelty under 35 U.S.C. §§ 102(a)-(e) or obviousness under 35 U.S.C. § 103, Filing No. 168.

This is an action for patent infringement. In this action, Streck alleges that R&D has made, sold or offered for sale certain products, specifically, the "CBC-XE," the "CBC-4K Plus Retics," and the "CBC-5D Plus Retics" integrated hematology control products ("the

accused 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. Streck asserts that the accused products infringe claims 28 and 29 of the '500 patent, claims 1, 4, 5, 6, 8, 9, and 13 of the '668 patent and claim 13 of the '388 patent. R&D asserts invalidity and priority of invention as defenses and has counterclaimed for a declaratory judgment of noninfringement and invalidity.

The following undisputed facts are gleaned primarily form the parties' various statements of undisputed facts. See Filing Nos. 162, 167, 169, 183, 191, 202, 203, 207, 209, 210, 212, and 214, briefs. Streck is a corporation organized under the laws of Nebraska having a principal place of business at 7002 S. 109th St., La Vista, Nebraska. Defendant R&D is a corporation organized under the laws of Minnesota, having a principal place of business at 614 McKinley Place, Minneapolis, Minnesota. Defendant Techne Corporation is the parent corporation of Techne and is a corporation organized under the laws of Minnesota, having a principal place of business at 614 McKinley Place, Minneapolis, Minnesota.[1] Both Streck and R&D manufacture and sell hematology control products.

The accused products are integrated reticulocyte controls. The first accused product R&D sold commercially was called CBC-XE. With respect to the sale of CBC-XE, an R&D internal memorandum stated: "[t]he release of this product (our first 5 part

[1]Defendant R & D's corporate disclosure statement under Fed. R. Civ. P. 7.1 shows that defendant Techne is the parent corporation of defendant R&D. Filing No. 15.

differential control with addition of reticulocytes) may also trigger a legal action by Streck." R&D admits that it has no written opinion of counsel regarding the validity of Streck's patents-in-suit or their infringement by R&D's accused products.

Dr. Wayne Ryan is the majority owner and Chief Executive Officer of Streck. John Scholl is a research and development manager at Streck. Dr. Ryan is the named inventor on the 500' patent, and Dr. Ryan and Scholl are named as co-inventors on the '668 and '388 patents. Dr. Ryan filed his application for the '500 patent related to integrated hematology control technology on August 20, 1999. The '500 patent issued on March 13, 2001. *Id.* The '668 patent, issued April 24, 2001, is a continuation of the '500 patent, and the '388 patent, issued June 4, 2002, is a continuation of the '668 patent. Dr. Ryan and Scholl assigned the '500, '668, and '388 patents to Streck. The reticulocyte component of Streck's commercial integrated reticulocyte controls is made using human red blood cell encapsulation.

Dr. Johnson is a senior scientist in R&D Systems' Hematology Division. Dr. Johnson of R&D Systems filed a patent application for integrated hematology control technology on October 18, 1999 (the "'991 application"), resulting in U.S. Patent No. 6,444,471, issued on September 2, 2002. Dr. Johnson admitted he was aware of Streck's patents-in-suit shortly after they were issued in 2001 and 2002, which was before R&D released their accused products starting in 2004. Dr. Johnson assigned his '991 application to his employer, R&D Systems, prior to the issuance of the '471 patent. R&D's Patent Application entitled "Reticulocyte Containing Complete Blood Control" claims priority to October 18, 1999, which is after the priority date of Streck's patents-in-suit.

An "interference" is a proceeding that the United States Patent and Trademark Office ("PTO") conducts to determine questions of priority (i.e., who was first to invent common subject matter claimed in an issued patent or patent application) and validity. Dr. Johnson filed the '995 application in an attempt to provoke an interference proceeding between the '995 application and the patents relating to integrated reticulocyte controls that Dr. Ryan assigned to Streck, including the patents-in-suit. On June 12, 2003, after the '388 patent issued, Dr. Johnson further amended the claims of the '995 application and formally requested that the PTO declare an interference between the '995 application and Streck's patents. R&D released the first two of its accused products while its request for an interference was pending. The PTO did not declare the interference until March 21, 2007. The PTO has not yet ruled on the interference action.

On December 14, 2006, the parties agreed to be bound in this case by Rules 3-1, 3-2, 3-3, 3-4, 3-7 and 3-8 of the Patent Local Rules of the United States District Court for the Northern District of California regarding required disclosures of asserted claims and infringement and invalidity contentions. Additionally, the parties agreed to a modified version of Rule 3-6.[2] The Patent Rules of the Northern District of California require

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[2]That rule provides:

> Amendment of the Infringement Contentions or the Invalidity Contentions may be made only by order of the Court upon a timely showing of good cause. Nonexhaustive examples of circumstances that may, absent undue prejudice to the nonmoving party, support a finding of good cause include: (a) a claim construction by the Court different from that proposed by the party seeking amendment; (b) recent discovery of material, prior art despite earlier diligent search; and (c) recent discovery of nonpublic information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contentions. The duty to supplement discovery responses does not excuse the need to obtain leave of court to amend contentions.

Patent L.R. 3-6 (N.D. Ca. 2008).

defendants to serve Preliminary Invalidity Contentions 45 days after the plaintiff's infringement contentions. The Patent Rules further require that defendants identify specific prior art references that invalidate the patents-in-suit and provide "[a] chart identifying where specifically in each alleged item of prior art each element of each asserted claim is found." The court's progression order required that the parties' final invalidity contentions, if filed, were due 50 days after the claim construction ruling was issued. Filing No. 134. Pursuant to the agreed Patent Rule 3-7, the supplementation of invalidity contentions was allowed only by order of court on a showing of good cause. Streck informed R&D on December 16, 2008, that it only asserted infringement of claims 28 and 29 of the '500 patent; claims 1, 4, 5, 6, 8, 9, and 13 of the '668 patent; and claim 13 of the '388 patent.

On January 19, 2007, R&D served its Preliminary Invalidity Contentions. Its contentions asserted invalidity under 35 U.S.C.§ 102(g) based upon R&D's alleged prior invention. Invalidity under 35 U.S.C. § 102(a)-(e) or 35 U.S.C. § 103 was not asserted. No specific prior art references were identified by R&D. On March 27, 2007, R&D served Amended Preliminary Invalidity Contentions that asserted invalidity under 35 U.S.C. § 102(g) (prior invention) and § 112, ¶¶1-2 (written description requirement). Again, R&D based no contentions on 35 U.S.C. §§ 102(a)-(e) or 35 U.S.C. § 103. On January 2, 2009, R&D served its Final Invalidity Contentions that assert invalidity under 35 U.S.C. §§ 102(g) and 112, ¶¶1-2, and not 35 U.S.C. §§ 102(a)-(e) or 103. R&D did not provide any invalidity analysis or charts for §§ 102(a)-(e) or 103, but stated that it reserved the right to demonstrate that the Johnson inventions render Streck's claims obvious.

R&D provided an expert report of Dr. Elkin Simson on December 22, 2008, on the issue of invalidity. In the report, Dr. Simson provided invalidity analyses for written

description (§ 112), enablement (§ 112), indefiniteness (§ 112), and priority of invention (§ 102(g)). Dr. Simson did not address invalidity of Streck's patents-in-suit under 35 U.S.C. §§ 102(a)-(e) or 103 in his expert report.[3]

Streck informed R&D on December 16, 2008, that its allegations of infringement were limited to claims 28 and 29 of the '500 patent; claims 1, 4, 5, 6, 8, 9, and 13 of the '668 patent; and claim 13 of the '388 patent.[4] The reticulocyte component of Streck's commercial integrated reticulocyte controls is made using human red blood cell encapsulation.

For purposes of Streck's motion for summary judgment in the issue of infringement, Streck agreed to adopt R&D's description of the experience required for someone to be a "person of ordinary skill in the art," as set forth by R&D's expert, Dr. Elkin Simson, as follows:

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[3]Subsection (a) -(e) of 35 U.S.C. § 102 provide that a person is entitled to a patent unless--

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
> (c) he has abandoned the invention, or
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent. . . .

35 U.S.C. § 102 (a)-(e). There is no dispute that subsections (a)-(d) are not relevant herein.

[4]Streck has not moved for summary judgment with respect to infringement of claim 4 and claim 9 of the '668 patent.

> A person of ordinary skill in the art would typically have an advanced degree, such as a Masters, Ph.D. or equivalent degree, in biological sciences with 5-10 years of post-graduate experience working in the field of laboratory hematology, assays for determining the number or presence of the formed elements of blood, control compositions used in performing such assays, and processes for preparing, and methods for using such controls; or a bachelors of science or equivalent degree with 15-20 years of post-graduate experience working in the field.

Filing No. 170, Affidavit of Merrit Westcott at 5.

DISCUSSION

A. Law

Summary judgment is appropriate when, viewing the facts and inferences in the light most favorable to the nonmoving party, "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Harder v. ACANDS, Inc.*, 179 F.3d 609, 611 (8th Cir. 1999). The burden of establishing the nonexistence of any genuine issue of material fact is on the moving party. Fed. R. Civ. P. 56(c); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). Therefore, if the moving party does not meet its initial burden with respect to an issue, summary judgment must be denied notwithstanding the absence of opposing affidavits or other evidence. *Adickes*, 398 U.S. at 159-60; *Cambee's Furniture, Inc. v. Doughboy Recreational Inc.*, 825 F.2d 167, 174 (8th Cir. 1987). If the moving party meets the initial burden of establishing the nonexistence of a genuine issue, the burden then shifts to the opposing party to produce evidence of the existence of a genuine issue for trial. *Johnson v. Crooks*, 326 F.3d 995, 1006 (8th Cir. 2003); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 325, (1986) (stating that while the burden rests on the party moving for summary judgment to show "that there

is an absence of evidence to support the non-moving party's case," the nonmoving party must affirmatively demonstrate by specific factual allegations that a genuine issue of material fact exists for trial). Mere denials or conclusory statements are insufficient; rather, "[t]he party opposing the [summary judgment] motion must point to an evidentiary conflict created on the record at least by a counter statement of a fact or facts set forth in detail in an affidavit by a knowledgeable affiant." *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 836 (Fed. Cir. 1984).

A "genuine" issue of material fact exists "when there is sufficient evidence favoring the party opposing the motion for a jury to return a verdict for that party." *Johnson v. Crooks*, 326 F.3d at 1006. In determining whether a genuine issue of material fact exists, the evidence is to be taken in the light most favorable to the nonmoving party. *Id.* "In ruling on a motion for summary judgment, a court must not weigh evidence or make credibility determinations." *Kenney v. Swift Transp., Inc.*, 347 F.3d 1041, 1044 (8th Cir. 2003). "Where the unresolved issues are primarily legal rather than factual, summary judgment is particularly appropriate." *Koehn v. Indian Hills Cmty. Coll.*, 371 F.3d 394, 396 (8th Cir. 2004).

The patentee has the burden of proving infringement by a preponderance of the evidence. *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004). A patent is presumed valid. 35 U.S.C. § 282. The burden is on the party challenging the validity of a patent to show invalidity by clear and convincing evidence. *Impax Labs., Inc. v. Aventis Pharma., Inc.*, 545 F.3d 1312, 1314 (Fed. Cir.2008) (stating that "[b]ecause issued patents enjoy a presumption of validity, obviousness and anticipation must be proven by clear and convincing evidence."). Patent infringement and invalidity are two

separate issues. *See* *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983) (stating that "[t]hough an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity.").

Invalidity can be based on a contention that the patented invention is not novel or new. 35 U.S.C. § 102(g)(2) (providing that a patent is invalid if "before such person's invention thereof, the invention was made in this country by another inventor. . . ."). If the prior art "anticipates" the claimed invention, the anticipated claims are invalid. *See, e.g.*, *Z4 Technologies, Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007). Section 102(g) has been interpreted "to provide that 'priority of invention goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice.'" *Id.* (*quoting* *Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1362 (Fed. Cir. 2001). Under 35 U.S.C. § 103, the patented subject matter must be nonobvious. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007) (noting that the objective reach of the claim matters and "[i]f the claim extends to what is obvious, it is invalid under § 103.") Novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103 are separate conditions of patentability and therefore separate defenses available in an infringement action. *Cohesive Technologies, Inc. v. Waters Corp.*, 543 F.3d 1351, 1363-64 (Fed. Cor. 2008); *Jones v. Hardy*, 727 F.2d 1524, 1529 (Fed. Cir. 1984) (noting that they are separate and distinct concepts). The tests for anticipation and obviousness are different. *Id.* at 1364. Obviousness can be proven by combining existing prior art references, while anticipation requires all elements of a claim to be disclosed

within a single reference. *Id.* Anticipation is a question of fact and obviousness is a question of law based on underlying facts. *Medical Instrumentation and Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1220 (Fed. Cir. 2003).

The determination of infringement is a two-step process: first, the court construes the asserted claims as a matter of law to determine their meaning, and second, the trier of fact compares the properly construed claims to the accused product to determine whether it contains each limitation of the claims, either literally or under the doctrine of equivalents. *Ferguson Beauregard/Logic Controls, Div. of Dover Resources, Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003). Application of the claim to the accused device is a question of fact. *Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F.3d 1336, 1345 (Fed. Cir. 2001). The infringement inquiry remains focused at all times on the claim language, as illuminated by the written description and the prosecution history. *Id.* at 1345-46.

To show a patent claim is literally infringed, the patentee must show that the accused device includes elements corresponding to each and every limitation recited in the patent claim. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). Patent infringement under the Doctrine of Equivalents is established on limitation-by-limitation basis; thus, to establish infringement under the Doctrine of Equivalents, an accused device must be shown to include an equivalent for each literally absent claim limitation. *See Dawn Equip. Co. v. Kentucky Farms*, 140 F.3d 1009, 1015 (Fed. Cir. 1998). An accused device infringes the patent under the Doctrine of Equivalents if there are only "insubstantial differences" between the accused device and the claimed invention. If an accused device does not literally contain each claim element, a finding of

infringement is nevertheless proper where the device contains only insubstantially different components for the claim elements not literally present. *Ethicon Endo Surgery v. United States Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998). To determine whether "insubstantial differences" are present, the court may consider whether the accused device performs substantially the same function in substantially the same way to achieve substantially the same result as the patented invention. *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1364 (Fed. Cir. 2007). If the accused device performs substantially the same function in substantially the same way with substantially the same result as each nonliterally infringed claim of the patented product, then the accused device infringes the patent. *Id.*

Although it has not stated a *per se* rule, the Federal Circuit has noted that "relevant expert testimony regarding matters beyond the comprehension of laypersons is sometimes essential" to the infringement inquiry. *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1369-70 (Fed. Cir. 2004) (holding that a patentee could not withstand summary judgment on the issue of literal infringement in a case involving complex technology in the absence of expert testimony). "'[T]ypically expert testimony will be necessary in cases involving complex technology." *Id.* at 1370. Additionally, "when the patent holder relies on the doctrine of equivalents . . . the difficulties and complexity of the doctrine require that evidence be presented to the jury or other fact-finder through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert, who (on a limitation-by-limitation basis) describes the claim limitations and establishes that those skilled in the art would recognize the equivalents." *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1329 (Fed. Cir. 2007).

Under 35 U.S.C. § 112, the specification is required to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112. The written description must clearly allow persons of ordinary skill in the art to recognize that the applicant invented what is claimed. *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). Compliance with the written description requirement is a question of fact. *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993). The claims as filed are part of the specification, and may provide or contribute to compliance with § 112. *Id.* Minutiae of descriptions or procedures perfectly obvious to one of ordinary skill in the art, yet unfamiliar to laymen need not be set forth. *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998). The written description must include the limitations of the count with sufficient clarity and specificity that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations. *Id.* at 1355. Thus, missing subject matter in a description can be shown to be part of the prior art that would be understood as part of the description of the subject matter of the count. *Id.* at 1353.

There is no question that a case or controversy is a jurisdictional predicate for declaratory judgment under 28 U.S.C. § 2201. *Grain Processing Corp. v. American Maize-Products Co.*, 840 F.2d 902, 906 (Fed. Cir. 1988). "[A]n actual controversy must be extant at all stages of review, not merely at the time the complaint is filed." *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1360 (Fed. Cir. 2008). The burden is on the party seeking a declaratory judgment to establish that jurisdiction over its declaratory judgment action existed at, and has

continued since, the time the complaint was filed. *International Med. Prosthetics Research Assoc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed. Cir.1986). The actual controversy requirement precludes a declaration about the validity of claims unless the defendant objectively has a "reasonable apprehension that it will face an infringement suit" on those claims. *Id.* The Federal Circuit has established a two-part test to determine if a party is in reasonable apprehension of being sued by a patent holder on a particular claim: (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity. *BP Chems, Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). The required reasonable apprehension must be an objective, not purely subjective, apprehension. *International Med. Prosthetics Research Ass., Inc. v. Gore*, 787 F.2d at 575.

To establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. *In re Seagate Technology, LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer. *Id.* The willfulness inquiry is one of fact and "is determined from the totality of the circumstances." *ACCO Brands, Inc. v. ABA Locks Mfrs.*, 501 F.3d 1307, 1312 (Fed. Cir. 2007).

B. **Analysis**

1. Streck's motion for partial summary judgment - § 112 (written description)

Streck seeks a declaration that asserted claims 28 and 29 of the '500 patent, claims 1, 5, 6, and 13 of the '668 patent, and claim 13 of the '388 patent are not invalid by reason of failure to satisfy the written description requirement of 35 U.S.C. § 112. In support of that contention, Streck submits the testimony of defendants' expert, Dr. Elkin Simson, who has admitted (1) that the level of skill in the art of hematology controls is high; (2) that naturally occurring reticulocytes are well known to those of skill in the art; (3) that the specification (including the originally filed claims) objectively evidenced an intent to encompass controls employing naturally occurring reticulocytes as reticulocyte components; and (4) that a minor stenographic error in the specification would readily have been recognized as such by those of skill in the art.

In opposition, R&D contends that the '500 patent specification does not sufficiently describe an integrated reticulocyte control with true reticulocytes or the procedure for preparing "reticulocytes" or "reticulocytes prepared by isolation from whole blood." It argues the inventor, Dr. Wayne Ryan, testified at length regarding the difficulties associated with the preparation and use of true reticulocytes and explained why Streck did not pursue using true reticulocytes in an integrated reticulocyte control.

The court finds that uncontroverted evidence establishes as a matter of law that the claims and specifications of the patents-in-suit are sufficient to satisfy the written description requirement. Defendants' arguments to the contrary relate mainly to the enablement prong of § 112, which is not at issue in Streck's motion. Further, R&D's

arguments relate primarily to claims that are not asserted to have been infringed, most specifically, claim 3. The uncontroverted evidence shows that the term reticulocyte was understood by persons of skill in the art at the time of the invention to mean an immature anucleate containing some ribonucleic acid, as set out in the court's claim construction order. R&D's arguments that the patent specification does not describe "naturally occurring" reticulocytes runs counter to the court's claim construction ruling and is contradicted by the express disclosure in claim 4 of the '500 patent of a control composition "wherein the reticulocyte component comprises reticulocytes prepared by isolation form whole blood." Filing No. 1, Complaint, Ex. A, '500 patent at col. 8, ll. 29-31. The '668 and '388 patents contain additional disclosure of the use of reticulocytes isolated from the blood of anemic animals. *Id.*, Ex. B, '668 patent at col. 4, ll. 23-25; Ex. C, '388 patent at col. 3, ll. 21-24. The court finds Dr. Ryan's statements with respect to the "difficulty" of using true reticulocytes relates to the commercial practicalities of use of true reticulocytes on a large scale and not to the feasibility or viability of true reticulocytes in a control.

2. R&D's motion for summary judgment

a. Section 112

R&D seeks a summary judgment of invalidity on claims 1-32 of the '500 patent, claims 1-31 of the '668 patent, and claims 1-19 of the '388 patent for failure to satisfy the written description requirement and the enablement requirement under 35 U.S.C. § 112,

¶ 1.[5] It also contends that claim 3 of the '500 patent and claim 3 of the 668 patent are invalid as indefinite under 35 U.S.C. § 112, ¶ 2, inoperative under 35 U.S.C. § 101, or not enabled under 35 U.S.C. § 112, ¶ 1. Further, it contends the '388 is invalid for misjoinder under 35 U.S.C. § 102(f).

As noted above in connection with Streck's motion, the evidence establishes that the language of the claims satisfies the written description requirement. R&D has not produced clear and convincing evidence that establishes, as a matter of law, that the asserted claims of the patents are invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1. The evidence presented in support of and opposition to the motion shows that there is a genuine issue of material fact with respect to the enablement issue.

With respect to R&D's contentions regarding claim 3 of the '500 and '668 patents, Streck does not assert infringement of those claims. R&D has no "reasonable apprehension" it will face an infringement suit on any claims other than those that Streck asserts it has infringed in this action. There is also nothing in the record to suggest any intent to sue on the nonasserted claims. The harm that creates a justiciable controversy and gives rise to declaratory judgment jurisdiction is not present with respect to the unasserted claims. Accordingly, the court will not address R&D's contentions with respect to claim 3. Also, to the extent that the '388 patent could be found invalid for misjoinder, the court notes that 35 U.S.C. § 102(f) was not raised by R&D in its final invalidity contentions. Moreover, Mr. Scholl testified that his contribution to the '388 patent was to claim 1 of the

[5]Defendant do not seek invalidation of claim 20 of the '388 patent on written description grounds because they contend claim 20 is directed solely to a composition containing reticulocyte analogs and does not encompass true reticulocytes.

patent, a claim that is not alleged to have been infringed. R&D has not presented clear and convincing evidence that inventorship is incorrect with respect to the claim of the '388 patent that is alleged to have been infringed, claim 13. In any event, absent deceptive intent, incorrect inventorship is a technical defect that can be corrected. *See* 35 U.S.C. § 256.

b. Willfulness

R&D argues that Streck's claim of willful infringement fails as a matter of law under *Seagate* because no reasonable jury could find that R&D acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. The court finds that there is evidence from which a jury could find willfulness under the *Seagate* standard. The issue of willfulness is a question of fact for the jury. Accordingly, R&D's motion for summary judgment in its favor on its counterclaim for declaratory relief will be denied.

3. Streck's motion for partial summary judgment of infringement

Streck contends that undisputed evidence shows that 1) R&D's accused product, the "CBC-4K Plus Retics," infringes claims 29 of Streck's '500 Patent; claims 1, 5, 6, 8 and 13 of Streck's '668 Patent; and claim 13 of Streck's '388 Patent; 2) R&D's "CBC-XE" product infringes claim 29 of Streck's '500 Patent; claims 1, 5, 8 and 13 of Streck's '668 Patent; and claim 13 of Streck's '388 Patent; and 3) R&D's "CBC-5D Plus Retics" product infringes claims 28 and 29 of Streck's '500 Patent; claims 1, 5, 6, 8 and 13 of Streck's '668 Patent; and claim 13 of Streck's '388 Patent. Streck has submitted voluminous evidence in support of its motion. The court has reviewed that evidence and finds that Streck has presented evidence that establishes as a matter of law that it is entitled to judgment on the issue of infringement.

Streck has shown that the accused products include elements corresponding to the limitations recited in the asserted patent claims. The court has considered the materials presented in support of and in opposition to the motion and finds that there is no genuine issue of material fact with respect to the question of whether the accused products meet all of the limitations of, and thus literally infringe, Streck's asserted claims. R&D does not seriously controvert the contention that its accused products contain the red blood cell, white blood cell, reticulocyte, and platelet components as they are construed in the asserted claims of Streck's patents.

R&D has not presented expert evidence on the issue of infringement to refute Streck's expert testimony. The issues in this case involve complex technology. This is not the type of patent question that the fact finder can determine without the assistance of expert testimony. In this case, according to R&D's own expert, a person skilled in the art of control compositions would be a person with an advanced degree, such as a Masters degree, a Ph. D., or equivalent, in biological sciences with 5-10 years of post-graduate experience working in the field, or a Bachelor of Science or equivalent degree with 15 to 20 years of experience working in the field.

R&D essentially relies on its invalidity defense in opposition to Streck's infringement claim. R&D's challenge to Streck's infringement accusation is reliance on the assertion that the accused products are not "control compositions" because it alleges that Streck has not presented scattergram evidence that "sufficiently simulate[s] the relevant characteristics of whole blood when measured by a hematology instrument." The court finds that R&D's argument in this regard is lacking in merit. The evidence, including R&D's admissions, its marketing and advertising materials, as well as product information,

manufacturing procedures and assay sheets, shows that R&D knowingly sold and marketed the accused products as "controls" or "control compositions." It is clear that its products were sold for the purpose of sufficiently simulating the relevant characteristics of whole blood as measured by the hematology instruments. R&D's arguments with respect to evidence of "reduction to practice" properly relate to a prior invention defense, not to issues of infringement.

The court has considered the materials presented in support of and in opposition to the motion and finds that there is no genuine issue of material fact that the accused products meet all of the limitations of, and thus literally infringe the patent claims at issue. The court finds that R&D's sale of the CBC-4K Plus Retics literally infringes claim 29 of the '500 Patent; claims 1, 5, 6, 8 and 13 of the '668 Patent; and claim 13 of the '388 Patent. R&D's sale of the CBC-XE literally infringes claim 29 of the '500 Patent; claims 1, 5, 8 and 13 of the '668 Patent; and claim 13 of the'388 Patent. R&D's sale of the CBC-5D Plus Retics literally infringes claims 28 and 29 of the '500 Patent; 1, 5, 6, 8 and 13 of the '668 Patent; and claim 13 of the '388 Patent.[6]

4. **Streck's motion for partial summary judgment that its patents-in-suit are not invalid under 35 U.S.C. §§102(a)-(e) or 103**

Streck argues that R&D has failed to present evidence that creates a genuine issue of material fact with respect to the issue of whether the patents are invalid under 35 U.S.C. § 102 (a)-(e) or 35 U.S.C. § 103. R&D concedes that it does not assert invalidity under 35 U.S.C. § 102 (a) -(e). With respect to the defense of obviousness under 35 U.S.C. § 103,

[6]Alternatively, the claim phrase "isotonic suspension medium" as found in claims 28 and 29 of Streck's '500 Patent would also be found to infringe under the doctrine of equivalents. Notably, R&D did not present expert testimony on the issue.

Streck relies on R&D's failure to include obviousness under § 103 in its final invalidity contentions to support Streck's position that it is entitled to judgment on this issue. R&D argues that its § 103 obviousness defense involves the same evidence as its § 102(g) prior invention defense and contends that it has presented sufficient evidence that Streck's asserted claims would be obvious over Dr. Johnson's work if that work is found to be a prior invention under 35 U.S.C. § 102(g). R&D concedes, however, that it has not presented evidence of any prior art other than Dr. Johnson's alleged work that would render Streck's asserted claims obvious.

The court finds that R&D's failure to include an obviousness defense in its final validity contentions is fatal to R&D's belated assertion of the § 103 defense. Although R&D "reserved the right" to add such contentions, the fact remains that it has not done so. Discovery is now closed. The court will not entertain the addition of new contentions or theories at this late date. Moreover, if it were to allow an obviousness defense, the court would find, as a matter of law, that R&D has not shown it is entitled to the defense. Accordingly, for the reasons set forth above.

IT IS ORDERED:

1. Streck's motion for partial summary judgment that certain claims of the patents-in-suit are not invalid under the written description requirement of 35 U.S.C. § 112 (Filing No. 160) is granted.

2. Research & Diagnostic Systems, Inc., and Techne Corporation's motion for summary judgment seeking a declaratory judgment in its favor on the issue of willfulness and a declaration that certain claims of the patents at issue are invalid under 35 U.S.C. § 112 (Filing No. 161) is denied.

3. Streck's motion for a partial summary judgment of infringement (Filing No. 166) is granted.

4. Streck's motion for partial summary judgment that its patents-in-suit are not invalid under 35 U.S.C. §§102(a)-(e) or 35 U.S.C. § 103 (Filing No. 168) is granted.

DATED this 9th day of September, 2009.

BY THE COURT:

s/Joseph F. Bataillon
CHIEF DISTRICT JUDGE

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